NATIONAL HEALTH MISSION
राष्ट्रीय स्वास्थ्य मिशन

सत्यमेव जयते

Operational Guidelines

Use of Gentamicin by ANMs for management of sepsis in young infants under specific situations

Ministry of Health and Family Welfare
Government of India

February 2014

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Foreword

Janani Suraksha Yojana (JSY) and Janani Shishu Suraksha Karyakram (JSSK) under the National Rural Health Mission (NRHM) have brought millions of mothers and newborns nearer to public health facilities and free entitlements. By implementing Facility Based Newborn Care (FBNC) and Home Based Newborn Care (HBNC) programmes, States are ensuring the continuum of care to newborns at community and facility levels.

Addressing the challenge of timely care and reaching out to those living in the remote and inaccessible areas would still require empowerment of the frontline health workers for delivery of appropriate care and management of sick newborns. Use of injection Gentamicin by ANM is a significant leap towards achieving increased availability and accessibility of health care.

NRHM has a major role in strengthening health facilities by expanding the pool of human resources, increasing availability of equipment and essential supplies and promoting demand through community level processes.

I am confident that the guidelines would complement several other newborn care initiatives made under NRHM for ensuring long term benefits to young infants.

(Keshav Desiraju)

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Preface

"A Strategic Approach to Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCH+A)" in India has brought a paradigm shift in the approach to health services. However, neonatal mortality still remains a crucial challenge. While, there has been acceleration in the decline of the infant mortality rate in the last five years, reduction in neonatal mortality rate has been slow. Amongst the three major killers of newborns, neonatal sepsis accounts for 16% of neonatal deaths.

Early diagnosis and referral to an appropriate facility is crucial for the survival of the sick newborn. To address this, a decision to equip the Auxiliary Midwives (ANMs) with appropriate knowledge and skills to treat young infants with sepsis with injectable and oral antibiotics has been taken and "Guidelines on use of Injection Gentamicin by ANMs for the management of Sepsis in Young Infants under specific situations" are being disseminated. The guidelines will provide program officers a stepwise approach to initiate and implement these guidelines effectively in the state and equip ANM to carry out the important task of managing sepsis in young infant under specific conditions.

I urge upon the states to disseminate and implement these guidelines with focus on the high priority districts.

(Anuradha Gupta)

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Prologue

Neonatal sepsis is associated with increased mortality and morbidity including neuro-developmental impairment and prolongation of hospital stay. Clinical features of sepsis are non-specific in neonates and a high index of suspicion is required for timely diagnosis and treatment with effective antibiotics.

Effective Newborn care is a crucial challenge that is faced by every health care setting dealing in child health. A key component is to equip the staff with appropriate knowledge and skill to get the best care possible at the right time and in the right place.

However, given the existing reality of the high mortality from sepsis and limited access to health facilities in many areas, the health workers need to be empowered to manage sepsis in young infants appropriately. The decision to implement this intervention all across the country was taken by Government of India in consultation with team of technical experts which enables the ANMs to use Injection Gentamicin and other oral drugs for managing sepsis in young infants (upto 2 months of age) under specific conditions.

This historic decision has a potential to avert large number of neonatal deaths due to sepsis alone. The initiative urges maximum benefits to the remote and tribal populations.

I wish success and extend unstinting support towards implementation of this initiative.

(Dr. Rakesh Kumar)

Acronyms

ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
AWW	Anganwadi Worker
CHW	Community Health Workers
IMNCI	Integrated Management of Neonatal and Childhood Illnesses
JSSK	Janani Shishu Suraksha Karyakaram
MCTS	Mother and Child Tracking System
MO	Medical Officer
MoHFW	Ministry of Health and Family Welfare
NRHM	National Rural Health Mission
PSBI	Possible Serious Bacterial Infection
RCH	Reproductive and Child Health
RMNCH+A	Reproductive, Maternal, Newborn, Child and Adolescent Health
VHND	Village Health and Nutrition day
WHO	World Health Organization

Contents

Background and rationale

India's commitment to Millennium Development Goal-4 is reflected in a plethora of maternal and child health initiatives under the National Rural Health Mission (NRHM) that have led to a steady reduction in child mortality in recent years. As per the Sample Registration Survey 2012, neonatal mortality is a big challenge as it now accounts for 69% of the total infant deaths and 56% of the total under-5 deaths in the country. Nearly 27% of the global burden of newborn deaths takes place in India, and the neonatal mortality rates are higher in rural areas than in urban areas. Bacterial infections are a leading cause of neonatal mortality. According to the Lancet 2012 estimates, neonatal infections or sepsis contribute to 33% of the neonatal deaths (Figure 1). In the second month of life, pneumonia is the leading cause of death. Thus it is evident that improved survival of young infants [0 – 2 months] depends greatly on the prevention, detection and treatment of systemic infections [sepsis and pneumonia].

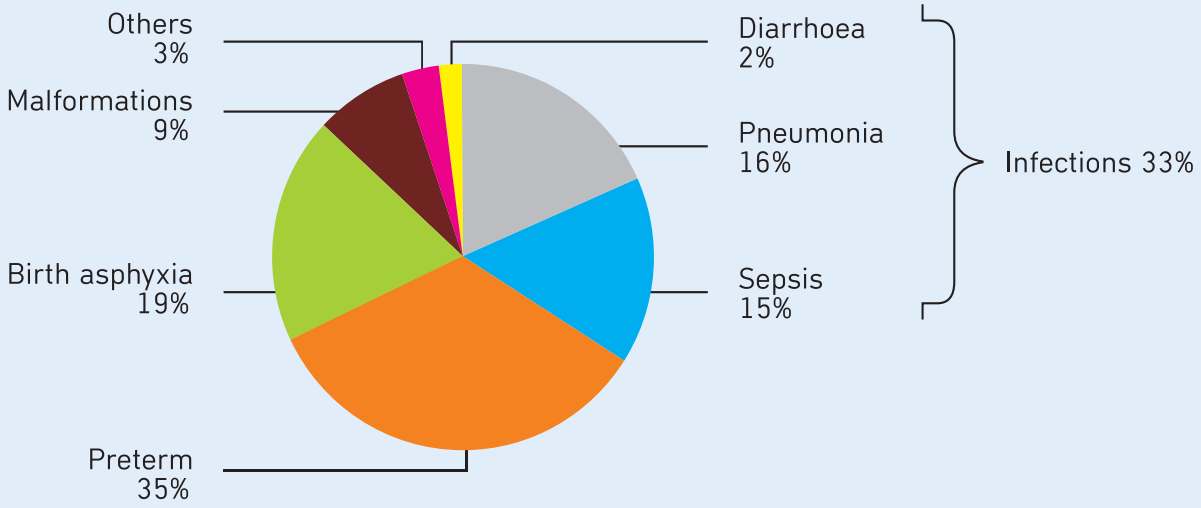


Figure 1: Causes of neonatal deaths in India*

For the management of systemic infection in a young infant [0 — 2 months], the Integrated Management of Neonatal and Childhood Illness (IMNCI) guideline recommends inpatient admission in a health facility and treatment with injectable antibiotics and supportive care. However there are challenges in the care-seeking, referral and management of such cases at the health facilities which leads to inappropriate or delay in care. These challenges include:

Delay in care seeking - Inability or delay in recognition of sickness by the mother or the caregiver leads to delay in care-seeking.

Limited or no access to health facilities - Long distance and/or lack of financial resources to reach facilities.

Long duration of treatment - Effective treatment requiring indoor admission and stay at the health facility for 7 days limits the completion of the treatment regimen.

Gender inequity in care-seeking - The girl child is at a further disadvantage because of the gender bias in care-seeking.

**Source of Figure 1*

Global, regional, and national causes of child mortality: an updated systematic analysis for 2010 with time trends since 2000. Liu et al. Lancet 2012; 379 (9832): 2151-2161.

Role of ANM

Provision of injectable antibiotic is crucial in the management of systemic infections in young infants who fail to reach facilities despite best effort. Empowering Auxiliary Nurse Midwives (ANMs) to use injectable Gentamicin is vital towards the management of sick newborn.

Under the public health system, ANMs interact directly with the community and are the key front line health functionaries responsible for the delivery of Reproductive and Child Health Programme. They are well-versed with administering injections and in injection safety practices as they have been regularly giving injectable vaccines to infants, and emergency injectable medications (intramuscular injection magnesium sulphate, injection oxytocin, intravenous fluids, etc.) to mothers, Moreover they have been trained under the IMNCI programme to detect young infants with Possible Serious Bacterial Infection (PSBI) or suspected sepsis using the features listed in Box 1.

Box 1

ANM assesses for the presence of following features (signs and symptoms) of PSBI using the Health Workers module of IMNCI

- Not able to feed / no breast attachment at all / not suckling at all
- Less than normal movements
- Lethargic or unconscious
- Convulsions
- Fast breathing [60 breaths per minute or more]
- Severe chest in drawing
- Nasal flaring
- Grunting
- 10 or more skin pustules or a big boil
- Axillary temperature 37.5 C or above (or feels hot to touch) or temperature less than 35.5 C (or feels cold to touch)
- Blood in the stool

Antibiotic treatment of sepsis in young infants

Experiences from India have confirmed the safety and efficacy of home or out patient-based treatment of neonatal sepsis where referral was not possible. These studies have shown that the Community Health Workers (CHWs) can be trained to identify newborn infants with probable sepsis and administer Injection Gentamicin safely and effectively in combination with other antibiotics (oral or injectable).

In case of sepsis in a young infant, a combination of Ampicillin plus Gentamicin administered in injectable form is the standard first line antibiotic therapy in health facilities. Oral Amoxicillin is generally accepted as an effective switch over antibiotic to injectable Ampicillin when the child becomes better Amoxicillin has similar antimicrobial profile as Ampicillin and is affordable, well tolerated and safe for use in young infants.

Recommendation

A combination of Injection Gentamicin with oral Amoxicillin is an appropriate choice of treatment for young infants with sepsis in a community setting where referral is not possible or is refused.

Use of Injection Gentamicin by ANM under specific situations

Under IMNCI, ANMs are well trained to recognize signs of suspected sepsis or PSBI in young infants and provide pre-referral treatment. Hence under the circumstances where referral is not possible or is refused, ANMs are best placed to be trained to administer appropriate antibiotic treatment to young infants with sepsis.

ANMs should administer Injection Gentamicin along with oral Amoxicillin to young infants [0 – 2 months] suspected with sepsis under the following situations;

- **Pre-referral dose -** The ANM will give the first dose of each antibiotic before referral to a health facility.
- **Completion of antibiotic treatment -** If the infant has not completed a course of either of the antibiotic following discharge from a health facility, the ANM will complete the course of the treatment as prescribed by the Medical Officer
- **Referral not possible or refused -** Under this special situation where referral is not possible or is refused, the ANM will continue to give treatment for 7 days (Refer Table 1).

Dosage & administration

Injection Gentamicin

- **Dosage:** 5 mg/kg body weight once a day.
- **Route of administration:** intramuscular
- **Site of Injection:** Antero-lateral aspect of the thigh
- **Preparation:** Injection Gentamicin is available in two preparations – 20 mg/2 ml and 80 mg/2 ml. It is recommended that only 80 mg/2 ml preparation is used in young infants. This provides 40 mg Gentamicin per 1 ml. This preparation ensures that the volume of injection Gentamicin fluid for young infants does not exceed the safe limit of 1 ml.
- **Storage:** Gentamicin is a heat stable drug and can be maintained at room temperature. There is no need for refrigerator/cold chain maintenance for the storage of the drug.
- **Syringe and needle:** 1 ml disposable syringe with 23 Gauge needle should be used. Alternatively Insulin syringe could be used. Auto disposable syringes provided for immunization should not be used because of varying dosage marking.
- **Duration of treatment:** Total duration of treatment is 7 days. In cases of follow up treatment, the ANM may follow the advice as per the discharge ticket/ doctor's prescription.

Syrup Amoxicillin

- **Dosage:** 15-25 mg/kg per dose given 12 hourly.
- **Route of administration:** Orally
- **Preparations:** Amoxicillin is available as Syrup [powder based/ ready to use] formulation and Dispersible tablets for pedeatric use. Syrup formulations are available as 125 mg/5 ml [1 ml contains 25 mg].
- **Duration of treatment:** The treatment is to be given for a period of 7 days.

About Gentamicin

Gentamicin is an aminoglycoside with excellent antimicrobial spectrum against Gram-negative bacteria. It is also active against Staphylococcus aureus when given in combination with one of the Penicillins.

Figure 3: Vial of Injection Gentamicin with 40 mg per ml concentration

Figure 2: Showing 1 ml syringes with markings of 0.1 ml

About Amoxicillin

Amoxicillin is an antibiotic of penicillin group active against Gram positive bacteria (such as Staphylococci) that cause sepsis in young infants. The antimicrobial profile is similar to that of Ampicillin.

Table 1: Summary of antibiotic treatment for sepsis in a young infant

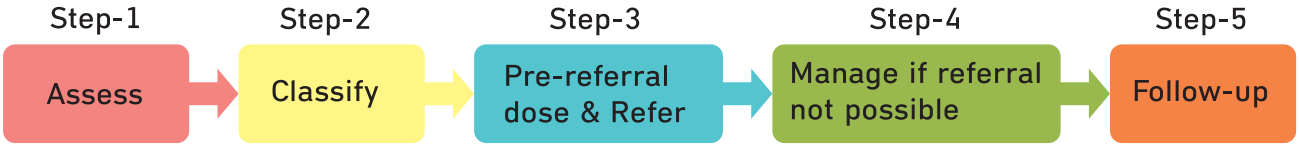
Young infant's weight	Amount of Gentamicin to be given intramuscularly as Injection (contains 80 mg in 2 ml vial)	Amount of Amoxicillin to be given per-orally as Syrup (contains 125mg / 5 ml)
Less than 1.5 Kg	To be referred to higher facility	
Above 1.5 kg - upto 2.0 Kg	0.2 ml	2 ml
Above 2.0 kg - upto 3.0 Kg	0.3 ml	2.5 ml
Above 3.0 kg - upto 4.0 Kg	0.4 ml	3 ml
Above 4.0 kg - upto 5.0 Kg	0.5 ml	4 ml
Route of administration	Intramuscular	Oral
Dosage	5 mg/kg/dose * Once a day	25 mg/kg/dose** Twice a day

*Precaution: If the treatment is to be continued same vial can be reused for the entire course of 7days, provided it is stored properly and its contents do not change colour or have turbidity. In case of any doubt it is better to use a new vial

**The ANM will instruct the mother how to reconstitute the syrup if it is in powder form

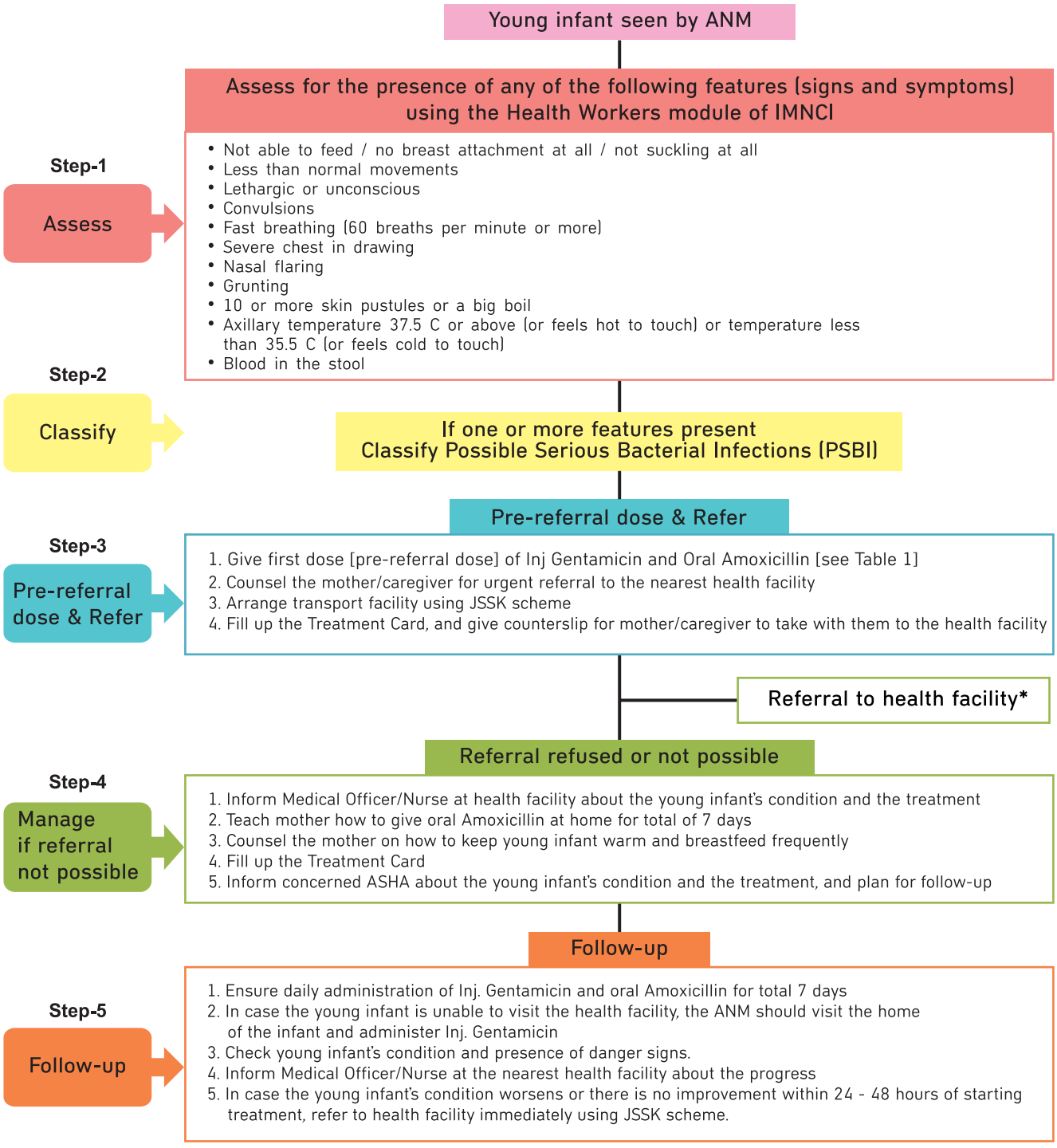
Steps for management of sepsis in young infants by the ANM

The ANM should follow the following five (5) steps for diagnosing and treating sepsis in young infants



The ANM must make every possible effort to refer young infants with sepsis to a health facility for providing standard antibiotic treatment and supportive care. However if referral is not possible, she should start treatment for sepsis in this specific situation and make all efforts to communicate with the Medical Officer or Staff Nurse of nearest health facility on a daily basis. The Flow Chart (on next page) outlines the five steps in detail.

Flow Chart: Management of sepsis in young infants by the ANM



***Steps to be taken by the ANM before and during referral to health facility**

1. Warm the young infant by skin to skin contact with mother/care giver if temperature less than 35.5 (or feels cold to touch) while arranging referral and during transport.
2. Treat to prevent low blood sugar using Health Workers module of IMNCI

- **If the child is able to breastfeed:** Ask the mother to breastfeed the child.
- **If the child is not able to breastfeed but is able to swallow:** Give 20-50 ml (10 ml/kg) expressed breastmilk or locally appropriate animal milk (with added sugar) before departure. If neither of these is available, give 20-50 ml (10 ml/kg) sugar water.
- **To make sugar water:** Dissolve 4 level teaspoons of sugar (20 grams) in a 200-ml cup of clean water.

Operationalization at state level

- The states should prioritize implementation of these Guidelines particularly in the High Priority districts, and in districts with home delivery rates above 20%. Efforts should be made to plan separately for the urban areas and link with the Urban RCH programme.
- The states should ensure that all the ANMs are IMNCI trained and well versed with safe injection practices.
- The State Child Health Officer should oversee the implementation and monitoring of the programme.
- Meetings should be organized with the District health officials including RCH/Child Health officers to orient them for these Guidelines.
- The district health officials should ensure dissemination of information to all the Block Medical Officers (MOs).
- The Block MOs should orient the ANMs in these Guidelines including the use of the Flow chart.
- The Treatment Card provided in the guidelines should be used at the block level as a tool for record keeping and reporting. The counter slips in the Treatment Card are to be collected by the Block MO and submitted at the district level and then state level on a monthly basis.
- The district and state officials should ensure regular procurement and availability of Injection Gentamicin and Syrup Amoxicillin at Sub-centres as well as all health facilities.

Orientation

- ANMs should be oriented towards these Guidelines by the Block MO at the block level meetings held every week.
- During orientation, the MO should ensure that the ANMs are able to diagnose sepsis and follow steps of sepsis treatment using the IMNCI Guidelines and the Flow Chart given in this guideline. Emphasis should be given on when to start antibiotics and correct dosages according to young infants weight.
- The key messages of the guideline should be reinforced regularly during block level meetings and during supervisory visits.
- The MO should ensure that the ANMs practice filling up of the Treatment Card correctly and the card is used for record keeping and reporting.
- Safe injection practices should be re-emphasized during the orientation. The practices for biomedical waste disposal of needles and syringes should also be emphasized.
- During meetings, feedback should be taken on the progress of this new activity and proper reporting.

Supervision

- The state should regularly supervise this new activity during the routine supervisory visits.
- The supervisory visits should be used as an opportunity to provide onsite training.
- During the visits, the supervisor should check for the availability of Injection Gentamicin, Syrup Amoxicillin, disposable syringes (1ml), disposable needles [23 gauge], poster of the Flow Chart, and the Treatment Card.
- He or she should check whether the ANMs are able to diagnose sepsis, follow the steps of sepsis treatment as explained during the orientation meeting, and use correct dosages according to young infants weight.
- Record keeping and reporting by the ANM including her ability to fill up the Treatment Card correctly should also be supervised.

Logistics

Following supplies would be made available at the Sub-centers

Inj Gentamicin vials **80 mg/2 ml;** i.e. 40 mg/ml

Syrup Amoxicillin 125 mg/5ml,

Disposable syringes 1 ml size with 0.1 ml markings and

Disposable hypodermic needles 23 Gauge

How to calculate logistics at the Sub-centre level

- In a population of 5000 covered by an ANM, 108 neonates would be born each year [assuming Crude Birth Rate of 21.6 per 1000 population]
- About 15% of them [16 in number] would develop suspected sepsis/pneumonia in the first 2 months of life
- Assuming referral would be refused by half of them, the ANM would treat 8 young infants for sepsis each year
- Therefore 8 vials of Injection Gentamicin, and about 60 syringes of 1 ml with equal number of 23 gauge needles (for 7 days treatment) would be required each year
- Likewise a total of 8 bottles of Syrup Amoxicillin (each bottle containing 60 ml or more) would be required each year
- The wastage factor may be added up later depending on the antibiotic use rate

Instructions to ANMs

- This guideline allows the ANM to use Injection Gentamicin and Syrup Amoxicillin for the treatment of sepsis in young infants under specific situations.
- Wherever possible, ANM should make all efforts to ensure that a young infant with sepsis is referred to the nearest health facility for appropriate treatment after giving the first dose/pre-referral doses of Injection Gentamicin and Syrup Amoxicillin.
- Before and during referral, the ANM should advise the mother/caretaker on how to keep the young infant warm, and to continue breastfeeding during referral if the young infant is able to suck.
- The IMNCI guidelines should be adhered to and over-use and misuse of antibiotics should be avoided.
- The ANM is expected to ensure the completion of the antibiotic treatment for the specified period. In case the mother/caretaker or the parents are unable to access the sub—center or the ANM goes for field visit, then the ANM must visit the young infant's home to ensure the scheduled dose of Injectable Gentamicin is not missed.
- In case the ANM has to provide the full course of antibiotic treatment (for 7 days), she should inform the MO/Nurse at the health facility about the young infant's condition and the treatment.
- She should also inform the concerned ASHA about the young infant's condition and ensure regular follow-up visits.
- The ANM should register all the young infants diagnosed with sepsis and fill up the Treatment Card. The daily treatment details should be entered in the Card to ensure record keeping and reporting.
- The ANMs should utilize all possible windows of opportunity for community contact including home visits by ASHAs (HBNC programme), Village Health and Nutrition Day (VHND), and Anganwadi Workers (AWW), to raise awareness about the need for early care seeking and appropriate treatment of young infants with suspected sepsis.
- During home visits, the ASHAs should identify young infants with danger signs and refer them to the ANM or the nearest health facility. She should support the ANM in ensuring treatment compliance and data collection.

Record keeping and Reporting

Records of young infants with sepsis and their antibiotic treatment should be maintained by the ANM using the Treatment Card provided by the Block MO. Counter slips of the Treatment Card [Section A] should be collected by the ANM and compiled at each block level. This key information should be then transferred from the compiled records to the existing Mother and Child Tracking System (MCTS).

Block level information should be compiled at the district level on a monthly basis. Further, states should compile data from each district and monitor key indicators (given below) on a quarterly basis. This quarterly information should be shared at the national level after being reviewed.

Key Indicators

1. **Proportion of young infants diagnosed with sepsis by the ANM and given pre-referral dose of Injection Gentamicin and Syrup Amoxicillin** = Number of young infants given pre-referral dose/Number of young infants diagnosed with sepsis by the ANM.
2. **Proportion of young infants who completed 7-day antibiotic treatment** = Number of young infants who completed 7-day antibiotic treatment/Number of young infants diagnosed with sepsis by the ANM.
3. **Proportion of young infants who were treated by the ANM and survived** = Number of young infants who were treated by the ANM and survived/Number of young infants diagnosed with sepsis by the ANM.

Use of Treatment Card (Annexure 1)

Treatment Card is an instrument to be used for monitoring the intervention and support collect data. The card should be filled by the ANM. Section A is to be kept at the health facility by the ANM so that follow-up is ensured while Section B (main card) should be given to the mother/family before referral. If a referral is refused, ANM should provide daily antibiotic treatment including Injection Gentamicin to the young infant for a total of 7 days, and record daily treatment and progress in the Treatment Card. In case 7 - day treatment is not completed, the reason for incomplete treatment should be provided in the Remarks column.

The card contains details about the symptoms, diagnosis, treatment and duration of treatment. The counter slips (Section A) should be used for record keeping and reporting. These counter slips should be compiled at the block level. In addition, ANMs can record the details of the young infant in their register for reference.

Annexure 1: Treatment Card

Treatment Card: Management of sepsis in young infants

Section-A: This part is to filled by ANM, preserved and complied at health facility

District _____ Block _____

Village _____ Sub-Centre _____

Young Infant"s Name _____ Age of the baby (days/months) _____

_____ Sex of baby Male/ Female

Weight (in kg) _____ Address with contact Number _____

Father/Mother's Name _____ _____
Caregiver's name if no Father/Mother

Features of Sepsis

Not able to feed or no breast attachment at all or not sucking at all	Y/N
Less than normal movements	Y/N
Lethargic or unconscious	Y/N
Convulsions	Y/N
Fast breathing (60 breaths per minute or more)	Y/N
Severe chest in drawing	Y/N
Nasal flaring	Y/N
Grunting	Y/N
10 or more skin pustules or a big boil	Y/N
Axillary temperature 37.5 °C or above (or feels hot to touch) or temperature less than 35.5 (or feels cold to touch)	Y/N
Blood in the stool	

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Action taken by the ANM (Check all that apply)

Advice on referral to nearest HF and care during referral	Y/N
Pre-referral doses of antibiotics given	Y/N
Inform young infant's condition to MO/SN	Y/N
Patient refuses referral	Y/N
Completion of 7 - days of treatment	Y/N
Outcome after treatment	Survive / Dead
Remarks	

Treatment Card: Management of sepsis in young infants

Section-B: This part is to filled by ANM, preserved and complied at health facility

District _____ Block _____

Village _____ Sub-Centre _____

Young Infant"s Name _____ Age of the baby (days/months) _____

_____ Sex of baby Male/ Female

Weight (in kg) _____ Address with contact Number _____

Father/Mother's Name _____ _____
Caregiver's name if no Father/Mother

Features of Sepsis

Not able to feed or no breast attachment at all or not sucking at all	Y/N
Less than normal movements	Y/N
Lethargic or unconscious	Y/N
Convulsions	Y/N
Fast breathing (60 breaths per minute or more)	Y/N
Severe chest in drawing	Y/N
Nasal flaring	Y/N
Grunting	Y/N
10 or more skin pustules or a big boil	Y/N
Axillary temperature 37.5 °C or above (or feels hot to touch) or temperature less than 35.5 (or feels cold to touch)	Y/N
Blood in the stool	Y/N

Treatment Given

Date	Day of treatement	Inj. Gentamicin Dose : ..... ml. once a day (Check when given)	Syrup Amoxicillin Dose : ..... ml. twice a day (Check when given) Mor.	Eve.	Remarks or Sign.
..../.../.....	Day 1				
..../.../.....	Day 2				
..../.../.....	Day 3				
..../.../.....	Day 4				
..../.../.....	Day 5				
..../.../.....	Day 6				
..../.../.....	Day 7				
Outcome after treatment		Survive / Dead			

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