

Guidance Note on Use of Uterotonics during labour





September 2015

Maternal Health Division

Ministry of Health & Family Welfare Government of India, Nirman Bhawan, New Delhi-110011



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Preface

Maternal Mortality and morbidity and perinatal mortality have been identified as major public health problems in India. It has long been recognized that the majority of perinatal deaths have an intrapartum origin and are a consequence of interventions carried out around the time of delivery.

A range of practices is used to manage labor, delivery and the new-born with the aim of improving health outcomes for the mother and new-borns. Evidence based research has resulted in perceptible change in modern labor and delivery care. It is now known that many interventions previously considered to be effective are not beneficial and infact can even be harmful; conversely some other interventions which had not been routinely practiced have a major role in preventing maternal deaths and perinatal mortality.

One such intervention is augmentation of labor with use of utetrotonics. Various studies and research have shown that augmentation of labour is associated with many adverse effects both for the foetus and the mother. There is high risk of foetal distress and perinatal mortality with the labour augmented with uterotonics such as Oxytocin.

The guidance note prepared by the Maternal Health Division of this Ministry clearly brings out when and how to use uterotonics by the front line health care worker, the medical officer and program managers.

I am confident this will help the health care worker, particularly the medical officers and staff nurses posted at the maternity ward, to judiciously make use of uterotonics for augmentation of labor subject to valid indications so as to provide high quality of services to the mothers and newborn across the country.

(C.K Mishra)



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Foreword

Improving maternal and child health and ensuring survival of the new-born are central to the achievement of national health goals under the National Health Mission (NHM) as well as the Millennium Development Goals (MDG) 4 and 5. In the recent years, India has made significant progress in its quest to improve maternal health in the country. Despite this, the desired level of reduction in maternal and child mortality has not been achieved due to lack of quality intra and post-partum care.

Various studies and surveys have shown that induction and augmentation of labour are conducted frequently, often unnecessarily, and many a time in absence of the appropriate indications. This is a serious issue that is adversely affecting quality of care and therefore needs immediate redressal.

The Maternal Health Division of the Ministry of Health & Family Welfare has drafted a guidance note which clearly defines the correct use of uterotonics during labour in health institutions.

The Guidance Note articulates the operational and technical aspect of the use of uterotonics for use by the frontline health care worker, the medical officer and program managers.

I commend the efforts put in by the Maternal Health Division and the contributing experts for developing this Guidance Note. I am fully confident that this will successfully help the health care worker in providing high quality of services to the mothers and newborn in the country.

(Dr. Rakesh Kumar)

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Program Officer's Message

Government of India is committed to reducing the burden of high maternal and infant mortality both under MDGs and National Health Mission (NHM). Quality of services during and after child birth heavily influences the rate of reduction in maternal and infant mortality rate.

Various studies and surveys from India have shown that induction and augmentation of labour is conducted in the absence of appropriate indications quite often. This adversely affects the quality of care and needs immediate attention. While appropriate use of uterotonic agents is lifesaving, their use with inadequate clinical understanding may lead to severe complications like fetal distress (leading to neonatal asphyxia), uterine hyper stimulation, and uterine rupture.

In order to address this issue of serious concern, the Maternal Health Division, MoHFW, has come out with a concise and user friendly Guidance Note with technical inputs from various experts.

I am grateful to Shri. C.K Mishra, AS&MD for providing constant support and guidance during preparation of this note. I am also indebted to Dr. Rakesh Kumar, Joint Secretary (RMNCH+A) for his able and extraordinary leadership in taking the process forward.

The concerted efforts of Dr. Bulbul Sood, Dr. Somesh, Dr. Vikas Yadav, JHPIEGO need special mention. I would like to thank my colleague Dr Veena Dhawan, AC-MH; Dr. Tarun, Dr. Rajeev, Dr. Pushkar and Ms. Jenita, consultants with the Division for their valuable inputs and support.

(Dr Dinesh Baswal)

Healthy Village, Healthy Nation



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Guidance Note on Use of Uterotonics during labour

Background

Uterotonics are chemical compounds that increase the tone and contraction of the smooth muscles of the uterus. These agents intensify uterine muscle contractions during labour, and during the postpartum period. During the labour process, natural uterotonic is released in the body that causes uterine contraction and facilitates progression of labour. Oxytocin, a hormone produced by the posterior pituitary gland, is a natural uterotonic.

Uterotonic drugs are also used during the process of labour for various indications to induce and/or augment uterine contractions. Additionally, the uterotonics are also used after delivery to prevent and control postpartum haemorrhage (PPH) due to uterine atony. While appropriate use of uterotonic agents is lifesaving, their use with inadequate clinical understanding of mechanisms of their action may lead to severe complications like foetal distress (leading to neonatal asphyxia), uterine hyper stimulation, and uterine rupture.

Various studies and surveys from India have shown that Induction and Augmentation of labour is conducted very frequently, unnecessarily, and in absence of appropriate indications. This is a big issue adversely affecting quality of care and needs immediate redressal. It is important to note that a large proportion of neonatal asphyxia can be prevented by minimizing the unnecessary induction and augmentation of labour and injudicious use of uterotonic drugs.

The following guidelines are intended to clearly define the correct use of uterotonics during labour in institutions.

Types of uterotonics

- Most commonly used uterotonic agents are Oxytocin, Misoprostol,
 Methergine and other Prostaglandins.
- Oxytocin is a synthetic version of the natural hormone produced in the posterior pituitary gland. It can be used intramuscularly or intravenously.
- Methergine is a semi-synthetic ergot alkaloid that can be used intramuscularly or orally.
- Misoprostol is a synthetic prostaglandin E1 analogue that is available in 200 mcg or 600 mcg oral preparations. It can be used orally, sublingually, vaginally or rectally.
- Carboprost or 15 methyl PGF2 alpha is generally recommended for treatment of PPH secondary to uterine atony not responsive to first line uterotonics, i.e., oxytocin, misoprostol, or methergine.

Use of Uterotonics at Sub-centres, Additional PHCs (APHCs) & PHCs where cold storage facilities (for Oxytocin) are not available

Out of 4 Uterotonics mentioned above **only Tablet Misoprostol** is permitted for use at these facilities for following indications only:

- Active Management of Third Stage of Labour (AMTSL) for prevention of PPH in all deliveries
- ✓ For treatment of PPH (only initial management with Misoprostol is recommended for these centres)
- ✓ Use of uterotonics for induction or augmentation of labour is not recommended at these centres

Uterotonics for AMTSL

Uterotonics should be used in all deliveries as a part of the AMTSL. This helps in expulsion of placenta, reduces blood loss, and reduces the duration of third stage of labour. Overall it helps in prevention of PPH.

- Uterotonics are to be given immediately after the delivery of baby after duly ruling out the presence of another baby in the uterus.
- Misoprostol 600 mcg should be given orally for AMTSL.

Uterotonics for Management of Postpartum Haemorrhage (PPH)

PPH is a major cause of death among mothers in India. Majority of cases of PPH occur due to uterine atony. Uterotonics are the first line drugs for management of atonic PPH. Immediate use of uterotonics in cases of PPH (even when uterotonic was given as a part of AMTSL) can be a life-saving intervention.

- 800 mcg Misoprostol should be given sublingually to a woman with PPH immediately upon the diagnosis.
- The woman should be referred to a higher centre (after giving Misoprostol) as soon as possible, with intravenous (IV) fluid administration, if available.

Use of uterotonics at PHCs and CHCs where cold storage facilities (for Oxytocin) are available but caesarean section facilities are not available

In these centres, uterotonics can be used for the following:

- ✓ AMTSL for prevention of PPH in all deliveries
- ✓ For treatment of PPH
- Use of uterotonics for induction or augmentation of labour is not recommended at these centres

Uterotonics for AMTSL

Uterotonics should be used in all deliveries as a part of the AMTSL. This helps in expulsion of placenta, reduces blood loss, and reduces the duration of third stage of labour. Overall it helps in prevention of PPH.

- Uterotonics are to be given immediately after the delivery of baby after duly ruling out the presence of another baby in the uterus.
- Oxytocin 10 IU (International Unit) intramuscularly is the uterotonic of choice for AMTSL. Oxytocin should not be given as IV bolus.
- In case oxytocin is not available, misoprostol 600 mcg orally should be given for AMTSL.
- Intramuscular Methergine should be used for AMTSL only if Oxytocin
 or Misoprostol are not available at the facility. However, Methergine
 is contraindicated in cases of pre-eclampsia/ eclampsia or
 hypertension. If Methergine has been given for AMTSL, controlled
 cord traction should be performed to prevent retained placenta.

Uterotonics for Management of PPH

PPH is a major cause of death among mothers in India. Majority of cases of PPH occur due to uterine atony. Uterotonics are the first line drugs for management of atonic PPH. Immediate use of uterotonics in cases of PPH (even when uterotonic was given as a part of AMTSL) can be a life-saving intervention.

- Use of Oxytocin for management of PPH:
 - o Initial Dose: Infuse 20 IU in 1 L NS/RL at 60 drops per minute
 - Continuing dose: Infuse 20 IU in 1 L NS/RL at 40 drops per minute
 - Maximum Dose: Not more than 3 L of IV fluids containing oxytocin
- If IV oxytocin is not available sublingual misoprostol (800mcg) should be used.
- If bleeding is not controlled after use of oxytocin, it is recommended to switch over to next uterotonic IV methergine, fixed dose or sublingual misoprostol 800 mcg.

Use of Uterotonics at First Referral Unit (FRU)/District Hospital (DH)/Women's Hospital (WH) Level (where Caesarean Section facilities are available)

In these centres, uterotonics can be used for the following:

- ✓ AMTSL for prevention of PPH in all deliveries
- For treatment of PPH
- For induction or augmentation of labour (only in select cases with specific indications)

Uterotonics for AMTSL

Uterotonics should be used in all deliveries as a part of the AMTSL. This helps in expulsion of placenta, reduces blood loss, and reduces the duration of third stage of labour. Overall it helps in prevention of PPH.

- Uterotonics are to be given immediately after the delivery of baby after duly ruling out the presence of another baby in the uterus.
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- If IV oxytocin is not available, sublingual misoprostol (800 mcg) should be used.

If bleeding is not controlled after use of oxytocin, it is recommended to switch over to next uterotonic IV methergine, fixed dose or sublingual misoprostol 800 mcg.

Uterotonics for Induction of Labour

Uterotonics, when given before delivery, facilitate the contraction of uterus and dilatation of cervix, and can help induce delivery. WHO recommends use of uterotonics for induction of labour in limited, specific clinical conditions. Induction of labour should be done very cautiously as unnecessary induction using uterotonics may lead to complications in mother and baby such as hyperstimulation of uterus and foetal distress. Wherever possible, Induction of labour should be carried out only in facilities where caesarean section can be performed. Outpatient induction of labour should never be performed. Women receiving uterotoincs (oxytocin, misoprostol, or other prostaglandins) should never be left unattended.

Indications for induction of labour

- Induction of labour can be performed in pregnant women only when they are known with certainty to have reached 41 weeks (> 40 weeks + 7 days) of gestation. In settings or cases where true estimation of gestational age is not possible, this recommendation is not applicable. Induction of labour should not be performed in uncomplicated pregnancies <41 weeks.
- Induction of labour should be done in cases of:
 - pre-labour rupture of membranes at term pregnancies (prelabour rupture of membrane means watery vaginal discharge

- that can be sudden gush or intermittent leaking of fluid, with no contractions within 1 hour)
- women in third trimester, with a dead fetus
- foetal growth retardation showing signs of foetal jeopardy
- pregnancies with chorioamnionitis
- o eclampsia/ severe preeclampsia/ placental abruption
- Induction of labour at term is not recommended in normal pregnancies, pregnancies presenting only with gestational diabetes or suspected fetal macrosomia.

Guidance for use of uterotonics for induction of labour

 Oral and low-dose vaginal misoprostol is recommended for induction of labour in cases with indications.

Dosage of Misoprostol for Induction of labour

- Recommended oral dose of Misoprostol for induction of labour is 25 mcg, 2-hourly. Vaginal low dose (25 mcg, 6-hourly) misoprostol can also be used for induction of labour. However, oral route of misoprostol is found to be better than vaginal in terms of outcomes.
- If there is no response after two doses of 25 mcg, increase to 50 mcg every six hours. Do not use more than 50 mcg at a time and do not exceed four doses (total 200 mcg).
- Misoprostol is not recommended for induction of labour in women with previous caesarean section
- If prostaglandins are not available, intravenous oxytocin alone should be used for induction of labour.

Dosage of Oxytocin for induction of labour:

 Infuse oxytocin 2.5 IU in 500 mL of dextrose (or normal saline) at 10 drops per minute. This is approximately 2.5 mIU per minute.
 Increase the infusion rate by 10 drops per minute every 30 minutes until a good contraction pattern is established (three contractions in 10 minutes, each lasting more than 40 seconds) (refer to Annexure III B). Maintain this rate until delivery is completed.

Record the following on Partograph every 30 minutes:

- Rate of infusion of Oxytocin
- Monitor uterine contractions (frequency and duration)
- Foetal Heart Rate (FHR)
- If a good contraction pattern has not been established with the infusion rate at 60 drops per minute,
 - Increase the oxytocin concentration to 5 IU in 500 mL of normal saline/dextrose and adjust the infusion rate to 30 drops per minute (15 mIU per minute);
 - Increase the infusion rate by 10 drops per minute every 30 minutes until a good contraction pattern is established or the maximum rate of 60 drops per minute is reached.
- If a good contraction pattern still has not been established using the higher concentration (5 IU in 500 mL of normal saline/dextrose) of oxytocin:
 - In multigravida and in women with previous caesarean scars, induction has failed; deliver by caesarean section.
 - In primigravida: infuse oxytocin at the higher concentration (10 IU in 500 mL).
- If good contractions are still not established at the maximum dose, deliver by caesarean section.
- If hyper stimulation occurs (any contraction lasts longer than 60 seconds) or if there are more than four contractions in 10 minutes, stop the infusion and relax the uterus using tocolytics:
 - Terbutaline 250 mcg IV slowly over five minutes OR
 - Salbutamol 10 mg in 1 L IV fluids (normal saline or ringer's lactate) at 10 drops per minute.
- Amniotomy alone is not recommended for induction of labour.
- Uterine contraction and foetal heart rate should be continually monitored during induction.

- In woman with previous caesarean section, procedure with low risk
 of uterine hyperstimulation (such as balloon catheter) should be
 used in case where induction of labour is indicated. Misoprostol is
 not recommended for induction of labour in cases of previous
 caesarean sections.
- The combination of balloon catheter plus oxytocin is recommended as an alternative method of induction of labour when prostaglandins (including misoprostol) are not available or are contraindicated.
- In women with a dead or anomalous fetus, oral or vaginal misoprostol are recommended for induction of labour.

Uterotonics for augmentation of labour

Similar to the use of uterotonics for induction of labour, use of uterotonics for augmentation of labour should be done very cautiously. Unnecessary interventions during delivery using uterotonics may lead to complications in mother and baby such as uterine hyperstimulation of uterus, fetal distress and in some instances, uterine rupture. Augmentation of labour is recommended in very limited specific conditions where inadequate uterine activity is suspected during $\mathbf{1}^{\text{st}}$ or $\mathbf{2}^{\text{nd}}$ stage of labour. Augmentation of labour should be carried out only at facilities where caesarean section can be performed.

Recommendations for augmentation of labour

- Augmentation of labour should be performed only:
 - When there is a clear medical indication and the expected benefits outweigh the potential harms.
 - After carefully ruling out the presence of cephalopelvic disproportion (CPD), or any other reasons with a potential for obstruction of labour such as malpresentations or malpositions, or presence of a scarred uterus. Augmentation of labour in multiparous women with CPD can lead to uterine rupture.
 - Only in cases with confirmed delay in labour (prolonged labour) due to inadequate uterine activity, after ruling out CPD, malpresentations and malpositions, and foetal distress.

9

- In cases with suspected CPD, malpresentations or malpositions, and foetal distress, caesarean sections should be performed.
- Prolonged active phase means that cervical dilation has crossed alert line on the partograph and is approaching action line.
- Interventions such as augmentation or caesarean section should be done in active labour when the action line on the partograph is crossed. Preparations for referral etc. should be started when alert line is crossed.
- Inadequate uterine activity means less than 3 contractions in 10 minutes, each lasting less than 40 seconds during active phase.
 Augmentation of labour can be done only when inadequate uterine activity is leading to prolonged labour. Prolonged labour in cases of good uterine contractions is generally due to obstruction, and augmentation of labour is not recommended in such cases as it may lead to complications.

Guidance for uterotonic use for augmentation of labour

- Uterotonics should be used very cautiously for augmentation of labour and should be done only under expert medical advice. Uterotonics should be used only after the confirmation of delay in labour.
- Measures such as continuous companionship, adoption of mobility and an upright position by pregnant woman help in reducing the duration of 1st stage of labour and should be used in all cases. Oral fluids and food use by pregnant woman is also recommended.
- Use of oxytocin alone is recommended for treatment of delay in labour. Oxytocin should be initiated in low doses and should be gradually escalated. Uterine contraction and foetal distress should be monitored regularly when oxytocin is given. Augmentation should be done using intravenous oxytocin infusion.
- Dosage of Oxytocin for augmentation: Infuse oxytocin as described for induction of labour (see above).
- Oxytocin with amniotomy can be used for augmentation of labour.
 However, amniotomy alone is not recommended for augmentation of labour. Amniotomy should not be performed in HIV cases.
- Misoprostol should not be used for augmentation of labour.

Annexure I: Summary of recommended and non-recommended practices for augmentation of labour

Prevention

Treatment

Recommended

Active phase partograph with a four hour action line to monitor labour progress Parting assessments with digital Active phase partograph with a light and active progress. Parting assessments with digital Active phase partograph with a light and active phase partograph with a light active phase partograph with a light active phase partograph with a four hours action line to monitor labour progress. Active phase partograph with a four hours action line to monitor labour progress. Active phase partograph with a four hours action line to monitor labour progress.

- Routine assessments with digital vaginal exams at 4-hour intervals
- Encouraging mobility and upright position
- · Continuous companionship
- The use of oxytocin alone for treatment of delay in labour
- The use of amniotomy and oxytocin for treatment of confirmed delay in labour

Not Recommended

- The use of a package of care for prevention of delay in labour
- · Administration of an enema
- The use of early amniotomy with early oxytocin augmentation
- The use of oxytocin in women receiving epidural analgesia
- The use of amniotomy alone
- · Pain relief for preventing delay
- Restricting fluid and food intake for women at low risk
- The use of intravenous fluids to shorten labour

- Augmentation with intravenous oxytocin prior to confirmation of delay in labour
- High starting and increment dosage regimen of oxytocin
- · The use of oral misoprostol
- · The use of amniotomy alone
 - The use of internal tocodynamometry (compared with external tocodynamometry)

Annexure II: Do's and Don'ts for Uterotonic Use

DO's

FRU/DH

- Use oxytocin as a part of AMTSL for all cases just after delivery
- Use oxytocin as a first line of management of PPH
- Use misoprostol for AMTSL (600 mcg orally) and PPH management (800 mcg sublingually) if oxytocin is not available
- Always store oxytocin with appropriate temperature management and save misoprostol from moisture
- Induce labour only in cases of confirmed post term pregnancy (reached 41 weeks), pre-labour rupture of membranes at term, dead/anomalous foetus, eclampsia/severe preeclampsia, placental abruption
- Use oxytocin only (IV infusion gradual dose increase) for induction of labour in case prostaglandins are not available
- Use oral or low dose misoprostol for induction of labour only in indicated cases
- Augment labour only in cases where there is a clear medical indication and the expected benefits outweigh the potential harms

SC/PHC

- Use oxytocin (10 IU IM injection)as a part of AMTSL for all cases just after delivery in facilities where it can be used under cold chain
- Use Misoprostol (600 mcg orally) for AMTSL in all cases in case Oxytocin is not available or cold chain can't be maintained
- Use oxytocin as a first line of management of PPH if available and IV line facility is available
- Use misoprostol for PPH management (800 mcg sublingually) if oxytocin is not available
- Always store oxytocin with appropriate temperature management and save misoprostol from moisture

DON'Ts

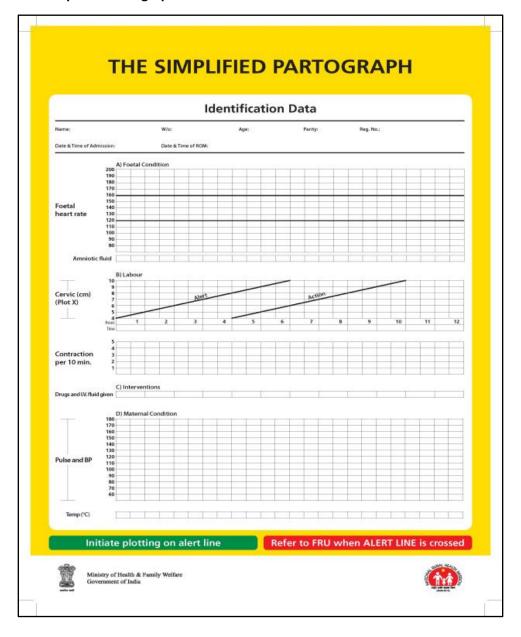
FRU/DH

- Do not use methyl ergometrin in cases of pre-eclampsia/ eclampsia or hypertension
- Do not use Oxytocin as IV bolus
- Do not use uterotonics for induction of labour in normal pregnancies at term
- Do not use misoprostol for induction of labour in cases of previous caesarean sections
- Do not augment labour in absence of prolonged labour and cases where uterine contractions are good
- Do not augment labour using uterotonics in cephalopelvic disproportion, or any other reasons with a potential for obstruction of labour such as malpresentations or malpositions, or presence of a scarred uterus
- Do not use uterotonics for augmentation of labour in health centres where caesarean section facilities are not available
- Do not use misoprostol for augmentation of labour

SC/PHC

- Do not use methyl ergometrin in cases of pre-eclampsia/ eclampsia or hypertension
- Do not use Oxytocin as IV bolus
- Do not use uterotonics for induction of labour in normal pregnancies at term
- Do not attempt induction or augmentation of labour, refer such cases to FRU/District Hospitals

Annexure III: Monitoring the Progress of Labor through Partograph III A) The Simplified Partograph



III B) Plotting and Interpretation of Partograph

Identification data- is filled in the respective columns of:

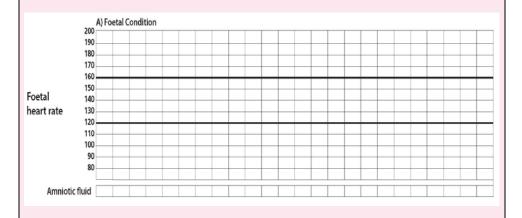
- Name
- Age
- Parity
- Date and time of admission
- Registration number
- Date and Time of rupture of membranes (ROM)

Identification Data						
Name:	W/o:	Age:	Parity:	Reg. No.:		
Date & Time of Admission: Date & Time of ROM:						

Fetal Condition- Denoted by Fetal Heart Rate (FHR) and Amniotic Fluid Color

FHR is plotted by a dot on the time axis every half an hour:

- Count fetal heart rate every 30 minutes
- Count for one full minute, immediately following a uterine contraction
- Plot half hourly readings by marking dots and join them
- The two dark lines at 120 and 160 signify the normal FHR which should be between 120-160 per minute
- Any deviation above or below these two lines, i.e. FHR <120 beats/minute or >160 beats/minute shows Fetal Distress and requires immediate action



Record status of membranes and amniotic fluid color every half hour as follows:

- Membranes intact (mark 'l')
- Blood stained (mark 'B')
- Clear liquor (mark 'C')
- Meconium stained liquor (mark 'M')

Labor- the progress of labor is denoted by Cervical Dilatation (in cms) and Contractions (per 10 minutes)

Cervical Dilatation (in cms)

- Begin plotting in active labor, i.e. when Cervical dilatation > = 4 cm
- Always plot initial finding at alert line (marked as a X) and note the time
- Repeat P/V after 4 hours and plot the cervical dilatation and join with the previous marking(s)
- The two dark lines signify the Alert and Action line
- In active phase cervical dilatation should be 1 or more than 1 cm/ hour,
 i.e. cervical dilatation line runs along or is on the left of alert line
- If the line with cervical dilatation marking shifts to the right of alert linedenotes abnormal labor (prolong/obstructed) and provider needs to prepare for intervention (referral/arrangement for necessary action)
- While referring, send partograph with patient
- Crossing of the Action line (the plotting moves to the right of the Action line) indicates the need for intervention
- By the time the action line is crossed the woman should ideally have reached the FRU for the appropriate intervention to take place

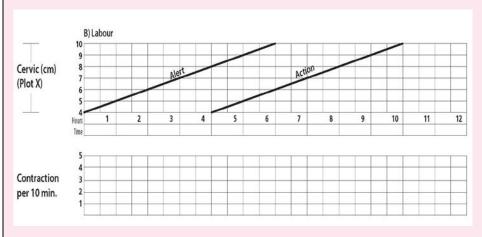


Chart the contractions every half an hour:

- Plot the number of contractions in 10 minutes
- Count the duration of each contraction in seconds, and shade the plotted blocks as:

Less than 20 seconds (mild contraction)

Between 20-40 seconds (20 and 40 included) (moderate contraction)



More than 40 seconds (strong contraction)



Interventions

Mention dose, route and time of administration of any drug and IV fluid given before delivery

	C) Interven	itions					
Drugs and I.V. fluid given							

Maternal Condition

- Record maternal pulse every half hour and mark with a dot
- Record maternal BP every 4 hours using a vertical arrow, with upper end signifying systolic BP and lower end diastolic BP
- Record the temperature every 4 hours and note on temperature graph



Indications for Referral/Specialist Care

- FHR is <120 beats / min or >160 beats / min
- Meconium and /or blood stained amniotic fluid
- When cervical dilatation plotting crosses the alert line (moves towards the right side of the alert line)
- Contractions not increasing in duration, intensity and frequency e.g. 2 or less contractions lasting for <20 sec in 10 min

