



Operational Guidelines and Reference Manual for Advance Distribution of Misoprostol to Prevent Postpartum Haemorrhage during Home Births

October 2013

Maternal Health Division
Ministry of Health and Family Welfare
Government of India





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FOREWORD

The Department of Health and Family Welfare, Government of India has a commitment to universal ante-natal, intra-natal and post-natal quality obstetric care. Since the launch of the National Rural Health Mission, the demand for services in the public sector has gone up substantially which is reflected in the surge in OPD and IPD attendance and institutional deliveries. Availability of drugs, diet and transport has increased manifold. The contribution made by various initiatives taken up under NRHM, especially Janani Suraksha Yojana and Janani Shishu Suraksha Karayakram in generating demand and providing quality obstetric care at health facilities is enormous.

However, for a variety of reasons, a significant number of women, particularly those in remote, inaccessible areas of the country are still not able to access public health facilities for care during pregnancy and child birth and continue to deliver at home, exposing themselves to the risk of dying from complications of pregnancy and child birth, the major one being postpartum hemorrhage.

It is the endeavor of the Department of Health and Family Welfare, GOI to provide skilled care at birth and other evidence based interventions to these women at the time of home delivery for preventing deaths due to such complications. With the objective of preventing disability and death due to postpartum hemorrhage in women delivering at home, the Department of Health and Family Welfare has taken a decision to permit ASHAs and ANMs to undertake community based distribution of Misoprostol tablets to these women during the later stages of pregnancy for consuming immediately after delivery.

With this in view, a set of operational guidelines and reference manual for training for the prevention of postpartum hemorrhage through community based distribution of Misoprostol, have been prepared by the Maternal Health Division of the Department of Health and Family Welfare. I hope these would be useful for providing guidance to programme managers, service providers and frontline workers, ASHAs and ANMs on the modalities of distribution of Misoprostol to prevent postpartum hemorrhage in women who deliver at home and would be taken up for implementation in the right earnest.

(Keshav Desiraju)



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PREFACE

Reduction of Maternal Mortality Ratio is a key goal that we have set ourselves under the National Rural Health Mission. This requires a multipronged strategy for improving access to evidence based interventions for ante-natal, intra-natal and post-natal care. While increasing access to quality obstetric care at health facilities remains the cornerstone of any strategy to reduce the Maternal Mortality Ratio, other complementary strategies and interventions, particularly for women in remote and inaccessible areas, who for a variety of reasons still deliver at home, are equally important. These women are unable to access institutions for obstetric care and therefore, need contextualized interventions as an exception to the general policy.

We have, therefore, been urging States to identify villages where for justifiable reasons, Institutional Deliveries cannot take place and incentivize S B A trained ANM to attend to women delivering at home. It must, however, be kept in mind that it is a special dispensation for a small numbers of select villages and emphasis on promoting Institutional Deliveries must not get diluted in any manner.

To further increase accessibility to evidence based interventions for women in select villages, we have taken a decision to allow ASHAs and ANMs to undertake community based distribution of tablet Misoprostol in the later stages of pregnancy to prevent postpartum haemorrhage in women who deliver at home.

This decision has been taken in the light of the growing body of international evidence and programme experiences on advance distribution of Misoprostol for prevention of PPH in settings where home deliveries still account for a significant proportion of all births. This is not only an evidence based intervention to reduce Maternal Mortality, it also assumes special significance in this country, by virtue of its potential in preventing death and disability due to postpartum haemorrhage in the most vulnerable and marginalized women from underserved, remote and inaccessible areas who are unable for some reason to access institutional care during and after pregnancy and child birth.

These operational guidelines and reference manual for training for prevention of postpartum haemorrhage through community based distribution of Misoprostol have been prepared with the purpose of orienting programmes managers, service providers and frontline workers i.e. ASHAs and ANMs on the processes and mechanisms for implementing this intervention in identified areas of their States. I am confident that these guidelines and manual will be valuable in providing direction to public health managers in the country in rolling out this new initiative.


(ANURADHA GUPTA)



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ACKNOWLEDGEMENT

Operational Guidelines and Reference Manual for Training for the prevention of postpartum hemorrhage through community based distribution of Misoprostol have been meticulously developed by the Maternal Health Division of MoHFW through a consultative process within a group of Experts.

The constant encouragement provided by Shri Keshav Desiraju, Secretary, Ministry of Health and Family Welfare and the vision and guidance of Ms. Anuradha Gupta, Additional Secretary and Mission Director, Ministry of Health and Family Welfare have enabled us to bring out these guidelines.

I would like to acknowledge the contribution of all members of the Expert Group in developing the content of these guidelines and training manual. I would especially like to appreciate the concerted efforts made by Dr. Manisha Malhotra and Dr. H. Bhushan Deputy Commissioners, Maternal Health, Dr. Bulbul Sood, Jhpiego, Dr. Somesh Kumar, Jhpiego, and Dr. Rajani Ved, NHSRC in the preparation, review and revision of the content of these guidelines.

The contribution of Dr. Dinesh Baswal, Deputy Commissioner, Maternal Health and the Consultants of MH Division, especially Dr. Ravinder Kaur deserves a special mention.

These guidelines and reference manual for training are designed to provide guidance to programme managers, service providers and frontline workers i.e. ASHAs and ANMs for operationalising this new initiative and taking it to the doorstep of women who deliver at home.

RKC
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PROGRAMME OFFICER'S MESSAGE

The Maternal Health Division of the Ministry of Health and Family Welfare has made endeavours to develop a number of guidelines and tools to help programme managers and service providers in delivering quality care to women during pregnancy and childbirth; as also to provide services for improving the reproductive health of women e.g. safe abortion care and managing reproductive tract and sexually transmitted infections. The MH Division has also taken the lead in developing guidelines on cross cutting areas like Quality Assurance and setting up Skill Labs for training.

This new initiative of developing “Operational Guidelines and Reference Manual for Training, for prevention of Post Partum Haemorrhage through Community based distribution of Misoprostol” has been taken with the intention of enhancing the access of women continuing to deliver at home in remote and underserved geographical areas, to interventions designed to prevent the morbidity and mortality associated with postpartum haemorrhage.

These guidelines and manual are the product of the collective efforts of the Programme Officers and Consultants of the Maternal Health Division, experts from Jhpiego and NHRSC and others in the core group. It is hoped that these would be optimally utilised by the State programme managers to build the requisite skills of ANMs and ASHAs and enable them to successfully implement this new initiative and thus save many women’s lives.

(DR. MANISHA MALHOTRA)

Healthy Village, Healthy Nation



एड्स - जानकारी ही बचाव है
Talking about AIDS is taking care of each other

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ABBREVIATIONS

ANM	Auxiliary Nurse Midwife
ASHA	Accredited Social Health Activist
CHW	Community Health Worker
EDD	Expected Date of Delivery
JSY	Janani Suraksha Yojana
JSSK	Janani Shishu Suraksha Karyakram
LMP	Last Menstrual Period
MNH	Maternal and Newborn Health
PHC	Primary Health Centre
PPH	Postpartum Hemorrhage
SBA	Skilled Birth Attendant
VHND	Village Health and Nutrition Day
WHO	World Health Organization

Operational Guidelines for Advance Distribution of Misoprostol to Prevent Postpartum Hemorrhage During Home Births

I) Rationale

The Ministry of Health and Family Welfare, Government of India (MoHFW, GoI) is committed to provide free of cost quality institutional care to mothers and their newborns during and just after childbirth under the Janani Suraksha Yojana and the Janani Shishu Suraksha Karyakram. However, there remain a number of pockets in the country where the coverage of institutional deliveries is still sub-optimal due to a variety of reasons like remoteness and inaccessibility. In these circumstances, where some of the women are not able to access institutional care and deliver at home, the ANMs are expected to provide quality intra- and immediate postpartum care to women and their newborns.

It is a well-known fact that hemorrhage is the largest contributor to maternal mortality in India and is responsible for almost 40% of the maternal deaths in the country, the major part of these deaths being due to Postpartum Hemorrhage (PPH). Various high-impact medical interventions effectively prevent postpartum hemorrhage. Active management of the third stage of labor, using Injection oxytocin as the uterotonic of choice, is being used at health facilities for prevention of PPH. In the event of Injection oxytocin not being available due to constraints of optimal storage conditions or other logistical barriers, Misoprostol is recommended to be given for prevention of PPH. GoI has authorized the ANMs to administer Misoprostol for prevention of PPH during home deliveries. However, administration of uterotronics currently requires the assistance of a skilled birth attendant (SBA), and therefore is not available to women experiencing unattended home births.

Misoprostol an oral prostaglandin E1 analogue that, can be administered immediately following delivery, offers an important alternative for PPH prevention in resource constrained settings and during home births, where Injection oxytocin is not available or where its use is not feasible. Oral Misoprostol does not require provider skills of administering injections or the consumables for injections or refrigeration and can therefore be stored and used easily. These factors enable programs using misoprostol for the prevention of PPH to potentially achieve high coverage and use, particularly by women who live in the remote and more inaccessible areas where a health facility may be located at a prohibitively long distance.

Existing evidence demonstrates that misoprostol is both safe and effective in the prevention of PPH. This body of evidence led the World Health Organization (WHO) to amend its model list of essential medicines in March 2011 to include misoprostol for the prevention of PPH in settings “where oxytocin is not available or cannot be safely used”. The WHO Guidelines on “Optimizing HW Roles for MNH Interventions through Task Shifting” have also given a positive recommendation for the use of Misoprostol by a “Lay Worker” for home births, for the prevention of PPH. Recently published studies have additionally concluded that the drug can be safely used at the community level through either administration by health providers or distribution by Community Health Workers (CHWs) directly to pregnant women for self-administration at home.

As the ANMs may not be available to attend to the woman at the time of home delivery in a significant number of cases due to various factors, due consideration was given to the fact that ASHAs are available in the community who could give Misoprostol to women in late pregnancy, to prevent

PPH. This was supported by the available body of global evidence on the effectiveness, feasibility and safety of advance distribution of Misoprostol to pregnant women for prevention of PPH. The overarching objective of introducing community-based distribution of Misoprostol to pregnant women by ANMs and ASHAs is to increase the accessibility of this life saving commodity by bringing it to the doorstep of pregnant women who are likely to deliver at their homes.

Policy Decision: In the light of the rationale as explained above, the MoHFW, GoI has taken a policy decision to permit ASHAs to undertake advance distribution of Misoprostol to pregnant women who are likely to deliver at home, for prevention of PPH.

In India, Misoprostol, a Schedule “H” drug, has been permitted by the Drug Controller General of India for manufacture for use in postpartum haemorrhage. However, by virtue of the drug being authorized for use in the public health system, it is categorized as a schedule K drug and is exempt from the restrictions imposed on the schedule H drugs. Hence the drug is permitted for distribution by frontline health workers including Community Health Volunteers through the Government Health System.

II) Conditionalities for Advance Distribution of Misoprostol for Prevention of Postpartum Hemorrhage (PPH)

Advance distribution of Misoprostol: Key considerations

All pregnant women should be counseled to deliver at the nearest health facility that can provide appropriate care for the mother and the newborn.

- In cases where, for some reason, the woman is unable to access the health facility at the time of delivery and home delivery is imminent, this should be attended by the ANM or any other skilled birth attendant.
 - For notified hilly and other remote and inaccessible areas with poor road connectivity, GoI has recommended incentives for ANMs to attend to home births.
- a) ***Criteria for selection of areas for implementation:*** In the exceptional scenario where a pregnant woman is not likely to access a health facility for delivery and the ANM is also unlikely to attend to her during delivery at home, advance distribution of Misoprostol for prevention of PPH should be considered.

There are two additional special scenarios where Misoprostol may be given for self-administration or administration by ASHAs, for the prevention of PPH:

- Those women who intended to deliver at institutions but delivered at home instead.
- Those women who intended to deliver at institutions but delivered in transit to the health facility.

This policy decision will be applicable only to pre-identified areas of the country including remote and inaccessible areas which have low institutional delivery rates. The following areas have been identified for advance community based distribution of Misoprostol by ANMs and ASHAs:

- All districts of the HF states of Bihar, Uttar Pradesh, Madhya Pradesh, Jharkhand, Uttarakhand, Rajasthan, Chhattisgarh, Orissa, Assam, Himachal Pradesh, Jammu and Kashmir where home delivery rate is more than 20%.
- All 184 High Priority Districts.
- Hilly and tribal districts.
- Based on the experience of implementation of the intervention of allowing community based distribution of Misoprostol in the high focus states/districts as mentioned above, this can be scaled up to all those districts of the other states of the country where home delivery rates are more than 20%.
- In districts where institutional delivery rate is more than 80 % (i.e. home delivery rate is less than 20%), states can identify additional blocks/areas which are hard to reach/ remote/inaccessible throughout the year or for some parts of the year due to snow, floods, water logging etc. for implementation of this strategy.

b) ***Steps for identification of pregnant women for community-based advance distribution of Misoprostol:***

- The ANMs and ASHAs are expected to enlist all the pregnant women in their respective catchment areas at any point of time. They (ANMs and ASHAs) are then supposed to counsel and follow-up these women for undertaking timely ANC visits and encouraging them for delivering at the nearest appropriate level of health facility.
- This enlisting of the pregnant women and follow-up through their pregnancy will allow the ANMs and ASHAs to understand which pregnant women are likely to deliver at home.
- Additionally, ANMs and ASHAs can use the pre-identified criteria given below to identify women who are likely to deliver at home, for advance distribution of Misoprostol for prevention of PPH. This enlisting should be done for all women who are currently pregnant and who have completed 6 months of pregnancy.

Criteria to identify the pregnant women who are likely to deliver at home:

- Past history of one or more home deliveries in the house-hold.
- Families where women customarily deliver at home due to social/religious/cultural/ economic reasons.
- Number of ANCs: If the pregnant woman has undertaken less than two ANC visits by the end of the 6th month of the current pregnancy.
- No other care giver at home: Women who do not have anyone at home to take care of her other children/family if she goes to the facility for delivery.

- Choice of the woman/family: Cases where the woman/ her family has indicated that she may/would deliver at home, despite best counseling and advocacy for institutional delivery by the ANM and ASHAs.
 - Women with disabled children, or from families where there is no other support from an adult.
 - Women which, due to the location of their homes in the following hard to reach areas, are likely to deliver at home:
 - Remote villages/hamlets which do not have motorable road connectivity.
 - Remote villages/hamlets villages on hilltops or in the fields, or in the areas which are cut off from mainland.
 - Snow bound/waterlogged areas/villages for the period the area/villages cut-off from the mainland for >1 month.
 - Any other circumstances where the ANM and ASHA are convinced of the probability that the woman might deliver at home.
- c) ***Responsibility for advance distribution:*** The ANM is the chosen health functionary for advance distribution of Misoprostol for prevention of PPH. However in the instances where the ANM is not able to distribute the Misoprostol tablets to the targeted women during the 8th month of pregnancy, the ASHA is the appropriate functionary to give these tablets to the pregnant women through home visits.

Excluding multiple pregnancy: For all pregnancies where Misoprostol is to be distributed to pregnant women for prevention of PPH, it is mandatory that the ASHAs take these women to the ANM at the nearest sub-center or 24 X 7 PHC by the 8th month to rule out the presence of multiple pregnancy. In case multiple pregnancy is diagnosed, the pregnant woman should be referred to the appropriate level of facility for further care.

- d) ***Process of distribution:***
- **Time of distribution:** Advance distribution of Misoprostol tablets would be made to those women who have been identified as likely to deliver at home and **have reached the 8th month of their pregnancy**. This is to ensure that the woman remembers the instructions for taking Misoprostol for PPH prevention.
 - **Counseling:** Such identified women need to be counseled by the ANM and ASHA at least twice at one week's interval with detailed instructions on the self- administration of Misoprostol tablets.
 - **Dosage:** As per the GoI's SBA guidelines, the recommended dose of Misoprostol for PPH prevention i.e. three tablets of 200 mcg each (total of 600 mcg) will be adhered to for the advance distribution of Misoprostol for prevention of PPH.
 - **Site of distribution:** Advance distribution of Misoprostol for prevention of PPH, should preferably be done **through home visits** by the ANMs or ASHAs. As a woman in labor may

not be in a position to take the Misoprostol tablet herself during the third stage, a female family member with whom she is living should be given the appropriate instructions for administration of the tablet.

- **Special Cases:** In cases where the ASHA is accompanying the woman to the facility for childbirth and the woman happens to deliver in transit, and in cases where women intended to deliver at a health facility but delivered at home, the ASHA/family member accompanying the woman should give 600 mcg of Misoprostol to the woman just after delivery of the baby.
- e) **Adverse events:** Though adverse events following administration of Misoprostol are minor and rarely serious, the ANM and ASHA should record and report all cases of adverse events due to the intake of Misoprostol.

IMPORTANT MESSAGES

Caution:

1. The pregnant women with the following conditions should be referred for delivering at health facilities.
 - Previous Cesarean Section
 - Myomectomy
 - Malpresentation e.g. breech or transverse lie
 - Severe PIH/severe anemia
 - Cardiac disease or any other medical complications
2. Misoprostol should not be taken during pregnancy/before delivery as it increases uterine tone and induces contractions which may cause partial or complete abortion and pre-term labour. If taken during labour before delivery, there is a risk of rupture uterus. Its use in pregnancy has also been associated with birth defects.

Side/Adverse Effects of Misoprostol:

- Fever/chills and rigors
- Nausea/Vomiting
- Abdominal cramps
- Diarrhea or constipation
- Headache
- Severe allergic reaction (rare)

III. Supply and Storage of Misoprostol Tablets:

Misoprostol will be distributed to the ASHAs by the ANMs and it will be the responsibility of the ANMs to ensure that the ASHAs have an adequate stock of Misoprostol tablets with them.

The calculation for doses of Misoprostol to be given to ASHAs by the ANMs should be based on the number of pregnant women enlisted as likely to deliver at home.

The ANM should ensure that, at any point of time, the ASHA should have the required number of doses of Misoprostol to cover all enlisted women expected to deliver at home, plus one/two additional doses to meet any other eventuality eg. an unexpected delivery at home or for emergency administration of Misoprostol to women who deliver during transportation to the facility.

$$\text{Number of doses of Misoprostol to be kept with ASHAs at any point of time} = \text{Number of women enlisted (women expected to deliver at home)} + \text{one or two emergency doses}$$

IV. Training:

The ANMs and ASHAs will be given a one day joint training in the advance distribution of Misoprostol for prevention of PPH. This training will build on the modules 6 and 7 for the training of ASHAs. This training may be given to the ASHAs and ANMs at an appropriate location at the block level. The trainers can be identified from among the medical officer or LHV of the respective block. These trainers from the block level will be trained by a TOT at the state or district level. The logistics and stationary required for the training will include Flip chart, Marker Pens, AV Screen, Handouts etc. The main components of the one day training will be as follows:

- Calculation of the expected date of delivery.
- Birth preparedness and complication readiness
- Counseling on the importance of health institutions as the preferred place of delivery.
- Instructions for taking the identified pregnant women, who are likely to deliver at home, to the ANM at the nearest sub-center or to the 24 X 7 PHC by the 8th month to rule out the presence of multiple pregnancy. In case multiple pregnancy is diagnosed, the woman should be referred to the appropriate level of facility for further care.
- Directions on the appropriate timing of advance distribution of the Misoprostol tablets to the pregnant women (8th month of pregnancy or at the time of delivery).
- Instructions for the pregnant women/ female family member for taking Misoprostol in case of a delivery at home, focusing on when to take Misoprostol (just after delivery), how to take Misoprostol (oral), how many (3 tablets of 200 mcg) , when not to take Misoprostol (before child-birth) etc.
- Contra-indications, and common side/adverse effects of Misoprostol and their management
- How to identify postpartum hemorrhage
- Proper storage of Misoprostol tablets
- Recording and reporting

The details of the training curriculum, job-aids and service delivery tools are annexed to the document. In addition to the trainings, the ANMs and ASHAs will be given job-aids for easy reference during the advance distribution of Misoprostol for prevention of PPH.

V. Recording and Reporting:

The stock of Misoprostol will be distributed to the ANM by the pharmacist of the PHC preferably in the presence of the MO-PHC. The ANMs will, in turn, give the Misoprostol tablets to the ASHAs who will be responsible for distribution of the tablets in the community.

Recording and reporting will be an essential component of this initiative. The pharmacist will be expected to maintain the records of all Misoprostol tablets distributed to ANMs, along with the batch number, expiry date of the product and date of distribution. ANMs will be expected to maintain a record of the doses distributed to the ASHAs, along with the batch number, expiry date of the product and the date of distribution. The ASHAs will be expected to maintain a record of the doses distributed to the pregnant women. The ASHAs will submit a consolidated report every month to the ANMs, who will then submit a consolidated report to the Block PHC/CHC. All these formats will be filled up and submitted to the respective functionaries on a monthly basis.

Though adverse events following administration of Misoprostol are minor and rarely serious, the ANM and ASHA will record and report all cases of adverse events. In the event of reporting of any adverse event after the administration of Misoprostol, the ASHA will inform the ANM immediately and the case will be referred to the nearest health facility, following which the respective ANM will visit the woman who was affected by the adverse event and record the adverse event on the designated format.

Reporting formats are annexed to the training reference manual document.

VI. Incentives:

If all the conditionalities listed above have been fulfilled and certified by the ANM, the ASHAs will be suitably incentivized for each case where she has distributed a dose of Misoprostol for prevention of PPH. The conditionalities for distribution of incentives to ASHAs will include pre-identification of pregnant women likely to deliver at home, certification of ruling out multiple pregnancy or other contraindications by the ANM on the MCP card and proper instructions to the woman on the mode and dosage of administration of Misoprostol for prevention of PPH.

Reference Manual

Session Outline

One day training on Community based distribution of Misoprostol for prevention of Postpartum Haemorrhage

Time	Session/Topic	Contents (Training Activities)	Resource Materials
09:30 am - 10:30 am	Introductory Session	<ul style="list-style-type: none"> ▪ Goals and Objectives of the training ▪ Background on the initiative for advance distribution of Misoprostol for prevention of PPH <ul style="list-style-type: none"> ✓ Contribution of postpartum haemorrhage to maternal mortality ✓ Use of Uterotonics of prevention of PPH ✓ Rationale for advance distribution of Misoprostol for prevention of PPH ✓ Basic information about Misoprostol 	<ul style="list-style-type: none"> ▪ Hand-outs on Goals and Objectives ▪ Hand-outs on background for the initiative for advance distribution of Misoprostol
10:00 am - 10:30 am	Instructions for advance distribution of Misoprostol for prevention of PPH	<ul style="list-style-type: none"> ▪ Whom to give: Enlisting women likely to deliver at home ▪ When to give: During 8th month of pregnancy ▪ How much to give (Dosage): 3 tablets of 200 mcg each ▪ Where to give (site of distribution): Home of the client, Village Health and Nutrition Day 	<ul style="list-style-type: none"> ▪ Hand-outs on the conditionalities for advance distribution of Misoprostol ▪ Flip Chart, Marker Pens
10:30 am - 11:00 am	Enlisting women likely to deliver at home	<ul style="list-style-type: none"> ▪ Calculation of estimated number of pregnancy in a given area (Exercises) ▪ Criteria for identification of women likely to deliver at home ▪ Calculation of EDD (Exercises) ▪ Establish date of tablet distribution (Exercises) 	<ul style="list-style-type: none"> ▪ Flip chart ▪ Marker pens ▪ Exercises ▪ Registration format
11:00 am - 11:20 am	Tea-break		
11:20 am - 12:20 pm	Counselling of women at the time of and after advance distribution of Misoprostol	<ul style="list-style-type: none"> ▪ Instructions on the self-administration of Misoprostol at home deliveries focusing on <ul style="list-style-type: none"> ○ when to take Misoprostol (just after delivery and after ruling out any other fetus in uterus) ○ how to take Misoprostol (oral) ○ how many (3 tablets of 200 mcg) ○ when not to take Misoprostol(before child-birth) ○ potential adverse effects ○ storage of Misoprostol tablets 	<ul style="list-style-type: none"> ▪ Power point slides/hand-outs ▪ Pictorial job-aid ▪ Flip Chart, Marker pens for exercise

Time	Session/Topic	Contents (Training Activities)	Resource Materials
12:20 pm - 12:50 pm	Role play on counselling of women during and after advance distribution of Misoprostol	<ul style="list-style-type: none"> ▪ Three role plays from participants on simulation of a counselling session of woman at the time of and after advance distribution of Misoprostol 	<ul style="list-style-type: none"> ▪ Facilitated role play
12:50 pm - 1:30 pm	Instructions on Precautions for advance distribution	<ul style="list-style-type: none"> ▪ Precautions for advance distribution 	<ul style="list-style-type: none"> ▪ Hand-outs
1:30 pm - 2:15 pm	Lunch		
2:15 pm - 2:45 pm	Recognition of danger signs requiring referral to health facility	<ul style="list-style-type: none"> ▪ Instructions on recognition of danger signs during and after childbirth, including recognition of signs and symptoms of postpartum haemorrhage 	<ul style="list-style-type: none"> ▪ Hand-outs ▪ Pictorial job-aid
2:45 pm - 3:00 pm	Supply and storage of Misoprostol tablets	<ul style="list-style-type: none"> ▪ Mechanism for ensuring uninterrupted supply of Misoprostol tablets ▪ Conditions for storage of Misoprostol tablets 	<ul style="list-style-type: none"> ▪ Hand-outs
3:00 pm - 3:30 pm	Recording and Reporting	<ul style="list-style-type: none"> ▪ Tools/Formats for recording and reporting of Misoprostol Tablet distribution ▪ Adverse event reporting formats 	<ul style="list-style-type: none"> ▪ Flip chart, Marker Pens ▪ Recording and reporting formats
3:30 pm - 3:45 pm	Closing Session	<ul style="list-style-type: none"> ▪ Evaluation of participation knowledge ▪ Closing remarks and next steps 	<ul style="list-style-type: none"> ▪ Reference Manual

Community Based Distribution of Misoprostol for Prevention of Postpartum Haemorrhage

Objectives of the training

By the end of this session, the ANMs and ASHAs will be able to:

- Enlist the conditionalities for advance distribution of Misoprostol for prevention of PPH.
- Explain key instructions for the women on the use of Misoprostol for prevention of PPH during home delivery.
- Specify Do's and Don'ts for use of tablet misoprostol during home birth to women and their family.
- Enlist the conditions where advance distribution of Misoprostol is not recommended.
- Demonstrate the maintenance of formats for recording and reporting of Misoprostol distribution.

Background for Decision on Community Based Distribution of Misoprostol for Prevention of PPH

- All efforts should be made by ANMs and ASHAs to encourage all pregnant women to go to health facilities for safe and quality care during labour and delivery.
- However, due to a variety of reasons, many women in our country still deliver at home. In these cases where the delivery happens at home, the ANMs are supposed to attend these deliveries and administer injection Oxytocin or tablets Misoprostol orally after childbirth, for prevention of PPH.

In cases where even the ANMs are unable to attend to deliveries at home, the MoHFW, GoI has taken a policy decision to permit ASHAs to undertake advance distribution of Misoprostol to pregnant women in the 8th month of pregnancy, for self-administration just after childbirth, for prevention of PPH.

Facts about Postpartum Haemorrhage and its Prevention

- Postpartum haemorrhage contributes to the maximum number of maternal deaths in India.
- Immediate postpartum haemorrhage is defined as more than 500ml bleeding within 24 hours of childbirth.
- PPH can be identified if there is soaking of one or more average size pad with blood in 5 minutes or a continuous slow trickle of blood after childbirth.
- The bleeding after birth is mainly due to the failure of the uterus to contract after child birth, injury to the birth canal, or failure of the placenta or part of the placenta to come out.

- It can be prevented if delivery is conducted with assistance from a skilled birth attendant like a doctor or a nurse/ANM at a health facility or at home.
- In case of institutional delivery or home delivery, PPH can be prevented by administration of injection Oxytocin/Tablet Misoprostol just after childbirth.
 - PPH is the most common cause of death of women during childbirth in India.
 - A woman with PPH can die within 2 hours after the onset of bleeding if she does not receive treatment.
 - PPH can be prevented by administration of injection Oxytocin or tablet Misoprostol during institutional deliveries and home deliveries, after childbirth.
 - In home deliveries where ANMs cannot attend to the women, ASHAs have been allowed to undertake advance distribution of Misoprostol to pregnant women in the 8th month of pregnancy, for self-administration just after childbirth, for prevention of PPH.

Pre-requisites for Deciding on Advance Distribution of Misoprostol for Prevention of PPH

- The ANMs and ASHAs are expected to enlist all the pregnant women in their respective catchment areas at any point of time.
- This enlisting should be done for all women who are pregnant at a given point of time.
- All pregnant women should be counseled to deliver at the nearest health facility that can provide appropriate care for the mother and the new-born.
- The cases, where for some reason, the woman is not able to access the health facility at the time of delivery and home delivery is imminent, should be attended by the ANM or any other skilled birth attendant.
- In the exceptional scenario where a pregnant woman is not likely to access a health facility for delivery and the ANM is also not likely to attend to her during delivery at home, advance distribution of Misoprostol for prevention of PPH should be considered.

Criteria for identifying women who are likely to deliver at home

Based on certain pre-defined criteria, ASHAs, in consultation with ANMs, will identify the pregnant women in their area who are likely to deliver at home, for advance distribution of Misoprostol for prevention of PPH. This enlisting should be done for all women who are currently pregnant and who have completed 6 months of pregnancy. The following criteria may be used to identify the pregnant women who are likely to deliver at home:

- Past history of one or more home deliveries in the house-hold.
- Families where women customarily deliver at home due to social/religious/cultural/economic reasons.

- Number of ANCs: If the pregnant woman has undertaken less than two ANC visits by the end of the 6th month of the current pregnancy.
- No other care giver at home: Women who do not have anyone at home to take care of her other children/family if she goes to the facility for delivery.
- Choice of the woman/family: Cases where the woman/ her family has indicated that she may/would deliver at home, despite the best counselling and advocacy for institutional delivery by the ANM and ASHAs.
- Women with disabled children, or from families where there is no other support from an adult.
- Women which, due to location of their homes in the following hard to reach areas, are likely to deliver at home:
 - Remote villages/hamlets which do not have motorable road connectivity
 - Remote villages/hamlets villages on hilltops or in the fields, or in the areas which are cut off from mainland
 - Snow bound/waterlogged areas/villages for the period the area/village is cut-off from the mainland for >1 month
- Any other circumstances where the ANM and ASHA are convinced of the probability that the woman might deliver at home.

Process of Advance Distribution of Misoprostol for Prevention of PPH

- Once a pregnant woman is identified in consultation with ANM to be most likely to deliver at home as per the criteria given above, ANM is the chosen health functionary for advance distribution of Misoprostol for prevention of PPH.
- However in those instances where the ANM is not able to distribute the Misoprostol tablets to the targeted women, **the ASHA is the appropriate functionary to give these tablets to the pregnant woman through home visits.**
- Advance distribution of Misoprostol tablets would be made only to those pregnant women who have been identified as likely to deliver at home and **have reached the 8th month of their pregnancy.**
- **Site of distribution:** Advance distribution of Misoprostol for prevention of PPH, to pregnant women who are likely to deliver at home, should preferably be done **through home visits** by the ANMs or ASHAs.
- Village Health and Nutrition Day (VHND) can also be utilized for advance distribution of Misoprostol to pregnant women who are expected to deliver at home, but this should not be the preferred platform, as it may influence other beneficiaries to opt for home delivery.
- Identified pregnant women need to be counseled in the presence of family members by the ANM and ASHA at least twice at one week's interval, during and after distribution of tablets Misoprostol, with detailed instructions on the self- administration of Misoprostol tablets. As a woman in labor may not be in a position to take the Misoprostol tablet herself during the third

stage, it is important to give appropriate instructions for administration of the tablet to a female family member with whom she is living.

- **Dosage:** Three tablets of 200 mcg each (total of 600 mcg) of Misoprostol should be given by ANMs/ASHAs to the pregnant women during the 8th month of pregnancy.
- The ASHA is also expected to give a follow up home visit close to the date of delivery, and reinforce the instructions for taking Misoprostol tablet to the women.
- **Special Cases:** In cases where the ASHA is accompanying the woman to the facility for childbirth and the woman happens to deliver in transit, and in cases where women who intended to deliver at a health facility but delivered at home, the ASHA/family member accompanying the woman to health facility should give 600 mcg of Misoprostol to the woman just after delivery of the baby.

Use of Misoprostol for Prevention of PPH

- Misoprostol is a drug which, after the birth of the baby, helps the uterus to contract, expels the placenta, and reduces the risk of excessive bleeding after childbirth.
- It comes in the form of a small tablet which is taken orally with water.
- One tablet contains 200 micrograms of misoprostol.
- The woman has to take 3 tablets of misoprostol (200 microgram each = total 600 micrograms) by mouth with water within one minute or soon after the delivery of the baby and before the placenta comes out. This leads to very low risk of bleeding after birth.
- The woman must take the tablets even if the placenta comes out soon after the baby is born.
- These tablets are to be taken **ONLY ONCE**.
- When taken orally, it may have some side effects such as nausea, headache, diarrhoea, fever and chills. These side effects are not harmful. They do not need any medication as they usually disappear after a short time.
- **Tablet Misoprostol should be administered after childbirth only after ruling out another baby in uterus.**
- **Misoprostol should NEVER be taken when the baby is in the uterus.** The tablets will make the uterus contract and the baby may die in the uterus or the mother and baby may die as her uterus may rupture. This is a very important message for the woman and her family. It should ONLY be taken after the birth of the last baby and before the placenta is out.
- **Excluding multiple pregnancies:** For all pregnancies where Misoprostol is to be distributed to mothers for prevention of PPH, it is mandatory that the ASHAs take these women to the ANM at the nearest sub-center or a 24 X 7 PHC by the 8th month to rule out the presence of multiple pregnancies. In case multiple pregnancies are diagnosed, the woman should be referred to the appropriate level of facility for further care.

Counselling and key instructions for use of tablet misoprostol to women who plan to or have home delivery:

Tips for being an effective counsellor:

BEFORE HOME VISIT:

- Be prepared with the instructions for a woman planning a home birth before starting to work on it in the community
- Always carry along the record forms and misoprostol tablets
- Ensure that the woman has time and has family members, preferably female members, to join the counselling session

DURING HOME VISIT:

- Always ask for permission before entering the house
- Always be respectful
- Speak slowly and in the local language
- Provide the instructions regarding the use of tablets misoprostol along with the do's and don'ts as mentioned earlier in this manual
- Answer questions and ask questions to ensure understanding
- Listen actively to what the woman and her family members have to say
- Give the woman 3 tablets of misoprostol if she is in the 8th month of pregnancy or more and instruct her and the family again on how and when to use them during home birth
- Plan for the next visit if she is not ready to talk this time for any reason as the attention and receptivity of the woman and her family to your instructions for the use of misoprostol are critical
- Thank the woman and her family for their time

AFTER HOME VISIT:

- Ensure that you have completed the record and reporting formats as suggested in Module 6 and the additional information regarding the use of tablet misoprostol.
- Note down the number of tablets given to the woman with her contact details in your records. (You will need to check after her birth whether she took the tablets as recommended or forgot to take them. In both the cases, make a note of it in your records and if she has not taken the tablets, take them back, note it in the records. Inform the ANM regarding your stock record and misoprostol use in the community and the resultant prevented heavy bleeding or need for health facility visits for excessive bleeding or any other complications).

Key messages for Counselling:

- A woman should always prefer delivering at health facilities as unforeseen complications can be best managed at health facilities.
- The woman should keep the tablets in a safe place and should let other members of her family know where they are stored. The tablets should be kept out of reach of children.
- Some side effects may occur which are harmless and do not need medication.
- **Need for Referral:** Even after taking the tablets, if the woman has bleeding which soaks more than one average size pad in five minutes, feels weak or faint, is sweating or looks pale, or expels clotted blood, she should be **transferred immediately** to the hospital/ FRU.

IMPORTANT MESSAGES

Caution:

1. The pregnant women with the following conditions should be referred to a health facility for delivery:
 - Previous Cesarean Section
 - Myomectomy
 - Malpresentation e.g. breech or transverse lie
 - Severe PIH
 - Severe anemia
 - Cardiac disease or any other medical complications
2. Misoprostol should not be taken during pregnancy/before delivery as it increases uterine tone and induces contractions resulting in partial or complete abortion and pre-term labour. If taken during labour before delivery, there is a risk of rupture uterus. Its use in pregnancy has also been associated with birth defects.

Side/ Adverse Effects:

- Fever/ chills and rigors
- Nausea/ Vomiting
- Abdominal cramps
- Diarrhea or constipation
- Headache
- Severe allergic reaction (rare)

Do's and Don'ts for tablet misoprostol use at homebirth

Do's	Don'ts
Remind the woman and her family during home visit for ANC, and also before or when labour starts, regarding the key instructions on how and when to take the tablets.	Do not take the tablets if the baby is still in the uterus. It will make the uterus contract and the baby may die. The mother may also die as the contractions with the baby in the uterus may cause it to rupture and there will be excessive bleeding. This is an EMERGENCY and should be avoided.
Keep the tablets in a cool dry place, away from moisture, heat and children.	Do not keep the tablets in a place where children can access them.
Take the tablet after the birth of the last baby. After one baby is born, the attendant should check for an undiagnosed twin or another baby by putting her hand on the abdomen of the woman and feeling for baby parts. If there is no other baby, give the tablets to the woman.	
Give the three tablets one by one or together with drinking water to the woman after the birth of the baby and before the placenta is out. If the placenta comes out quickly the tablets can still be given to prevent excessive bleeding.	
Ensure that the woman and her family member who is to attend to her during birth is aware of the place of storage of the tablet at home so that it is easily available at the time of administration.	
Remind the woman and family about side effects and that they are harmless and will subside on their own.	
Keep arrangement for money and transport to take to an FRU in case of any emergency.	
If the woman has to be transported to a health facility for a complication before the birth of the baby, she can carry the misoprostol tablets with her and inform the doctor/SBA attending her to give them after the baby is born.	

Calculating the 8th month of pregnancy

In Module 6 of ASHA training manual, you have learned about how to calculate LMP and EDD. As you are required to provide tablets misoprostol to the pregnant women in their 8th month, it will be good to practice calculating the 8th month of pregnancy.

For example:

To calculate EDD

If the first day of the LMP is:	10 th December 2012
Nine months later will be:	10 th September 2013
Adding seven days is:	17 th September 2013
Therefore the EDD is:	17 th September 2013

To calculate the 8th month:

Add eight months to the LMP: 10th August 2013

Misoprostol can be distributed: During the eighth month of pregnancy

Supply and Storage for Tablet Misoprostol:

- The stock of Misoprostol will be distributed to the ANM by the pharmacist of the PHC, preferably in the presence of the MO-PHC, who will keep a record of the batch number and other details of the drug.
- Misoprostol will be distributed to the ASHAs by the ANMs and it will be the responsibility of the ANMs to ensure that the ASHAs have an adequate stock of Misoprostol tablets with them.
- The calculation for doses of Misoprostol to be given to ASHAs by the ANMs will be based on the number of pregnant women enlisted as likely to deliver at home.
- The ANM will ensure that at any point of time, the ASHA at any point of time, should have the number of doses of Misoprostol to cover all enlisted women expected to deliver at home, plus one/two additional doses to meet any other eventuality eg. an unexpected delivery at home or for emergency administration of Misoprostol to women who deliver during transportation to the facility.

Number of doses of Misoprostol to be kept with ASHAs at any point of time = Number of women enlisted (women expected to deliver at home) + one or two emergency doses

- ASHAs will need to be very careful about the women to whom they are giving the tablets, the time of distribution, expected time of administration, and follow up to see if they were consumed or not.
- Misoprostol will not be left with the woman or family if it is contraindicated or not likely to be used during childbirth.

- In all cases the ASHAs will make a note of the use of each tablet of Misoprostol distributed and take back the unused tablets from the woman and enter in their records, which they will share with the ANM for her information and for replenishing the stock of misoprostol for other women in their community.
- It will be the overall responsibility of the ANMs to ensure that their respective ASHAs are providing correct information to the women and her family for appropriate use of the tablets misoprostol, is distributing them correctly, and is maintaining an updated record.
- ANMs will check the records of their respective ASHAs on a monthly basis and provide the stock of tablet misoprostol @ 3 tablets per woman likely to deliver at home, plus for two women extra in case they are not able to go to the facility during labour. They will ensure that ASHAs collect the tablets from the woman if she has not consumed them after childbirth due to any reason.
- The ANMs will conduct home visits with their respective ASHAs to these women during pregnancy and reinforce the instructions and do's and don'ts of misoprostol use to the woman and her family. She should also counsel the woman /her family on the benefits of institutional delivery and encourage them for visiting a facility for birth.

Recording and Reporting:

Recording and reporting will be an essential component of this initiative. The pharmacist will be expected to maintain the records of all Misoprostol tablets distributed to ANMs, along with the batch number, expiry date of the product and date of distribution. ANMs will be expected to maintain a record of each and every dose distributed to the ASHAs, along with the batch number, expiry date of the product and date of distribution. The ASHAs will be expected to maintain a record of each and every dose distributed to the pregnant women. The ASHAs will submit a consolidated report every month to the ANMs, who will then submit a consolidated report to the Block PHC/CHC. All these formats will be filled up and submitted to the respective functionaries on a monthly basis.

Though adverse events following administration of Misoprostol are infrequent, minor and rarely serious, the ANM and ASHA will record and report all cases of adverse events. In the event of reporting of any adverse event after the administration of Misoprostol, the ASHA will inform the ANM immediately and the case will be referred to the nearest health facility, following which the respective ANM will visit the woman who was affected by the adverse event and record the adverse event on the designated format.

Recording register for advance distribution of tablet Misoprostol for ASHAs (To be filled on a monthly basis)

Name of ASHA..... Name of ANM.....

Name of Village..... Name of Sub-centre.....

Name of PHC..... Name of District.....

Name of State..... Month/year of record.....

SN	Name of client	Village/mohalla	Husband's Name	MCTS no.	No of tablets given	Date of distribution	Date of delivery	Status of use ✓/X	No. of tablets recovered if not used at delivery
1.									
2.									
3.									
4.									
'n'									

Stock Register for ASHAs for tablet Misoprostol (to be filled on a monthly basis)

Month/Year	Total no. of tablets in stock at the start of month	Total no. of tablets distributed this month	Total no. of tablets recovered this month	No. of tablets received this month	Date of Receipt of tablets	Batch no. of received tablets	Total no. of tablets at end of month

Recording register for ANMs, for distribution of tablet Misoprostol to ASHAs (To be filled on a monthly Basis)

Name of ANM..... Name of Sub-centre.....

Name of PHC..... Name of District.....

Name of State..... Month/year of record.....

SN	Name of ASHA	No of tablets given	Batch number	Date of expiry	Date of distribution	No. of tablets recovered from ASHAs
1.						
2.						
3.						
4.						
'n'						

Stock Register for ANMs for tablet Misoprostol (to be filled on a monthly basis)

Month/ Year	Total no. of tablets in stock at the start of month	Total no. of tablets distributed this month	Total no. of tablets recovered this month	No. of tablets received this month	Date of Receipt of tablets	Batch no. of received tablets	Total no. of tablets at end of month

Recording register for PHC pharmacist/distributing authority, for distribution of tablet Misoprostol to ANMs (To be filled on a monthly Basis)

Name of PHC..... Name of District.....

Name of State..... Month/year of record.....

SN	Name of ANM	No of tablets given	Batch number	Date of expiry	Date of distribution	No. of tablets recovered from ANMs
1.						
2.						
3.						
4.						
'n'						

Stock Register for PHC pharmacist/distributing authority for tablet Misoprostol (to be filled on a monthly basis)

Month/ Year	Total no. of tablets in stock at the start of month	Total no. of tablets distributed this month	Total no. of tablets recovered this month	No. of tablets received this month	Date of Receipt of tablets	Batch no. of received tablets	Total no. of tablets at end of month

Post Training Knowledge Assessment

Q1. How many tablets of misoprostol does a woman have to take to prevent bleeding after child birth?

Ans. **Three tablets of 200 mcg each (total of 600 mcg)**

Q2. How does misoprostol prevent bleeding after childbirth?

Ans. **By contracting the uterus which helps the placenta to come out.**

Q3. At what time during the child birth should a woman take misoprostol tablets?

Ans. **After the last baby is born and before the placenta comes out.**

Q4. What should the attendant do if the placenta comes out before the woman could take the tablets?

Ans. **Still take the three tablets as recommended. It helps.**

Q5. How many doses of tablet misoprostol should a woman take?

Ans. **Only ONE dose, which is of 3 tablets.**

Q6. How should the woman take the tablets?

Ans. **By mouth, with drinking water.**

Q7. What are the side effects of misoprostol?

Ans. **Nausea, diarrhoea, fever and chills.**

Q8. Where should the woman store the tablets?

Ans. **In a cool, dry place, away from the reach of children. She should inform other family members of the location.**

Q9. When should the woman NOT take misoprostol?

Ans. **Before the baby is born.**

Q10. How much does Tablet misoprostol cost?

Ans. **Nothing, it is free through government supply.**

Records to be kept by ASHA and ANM have to be separated, and instructions given accordingly to the reference manual

**Maternal Health Division
Ministry of Health and Family Welfare
Government of India**

