Annex A. ACS Technical Working Group Meeting Participant List, June 14, 2016

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*via web-conference

Annex B. Framework for ACS Policy and Implementation Landscape Analysis

Part I (secondary data): Desk review

1. **Basic outcome and coverage**
    a. # babies born preterm (<37 weeks gestation/year)
    b. # of babies born extremely preterm (<28 weeks gestation/year)
    c. Preterm birth rate
    d. Stillbirths per 1000 total births
    e. Neonatal mortality per 1000 live births
    f. # under 5 deaths due to direct cause of preterm birth complications
    g. 4 or more antenatal care visits during pregnancy (%)
    h. First antenatal care (ANC) visit <20 weeks (%)
    i. Births attended by skilled attendant (%)
    j. Births by Cesarean Section (%)
    k. Postnatal Care within two days (mothers) (%)
    l. ACS in stock in hospitals

2. **Basic newborn care**
    a. Early initiation of breastfeeding (%)
    b. Exclusive breastfeeding <6 months (%)
    c. Postnatal care within 2 days (newborn) (%)
    d. Bag and mask in stock
    e. Space designated for kangaroo mother care (KMC)
    f. Infants weighed at birth (%)

3. **National Policy**
    a. ACS in national policy for use in women at imminent risk of preterm birth
    b. KMC in national health policy
    c. Safe oxygen use and Continuous Positive Airway Pressure (CPAP) in national health policy

4. **National Standard Treatment Guidelines**
    a. ACS included in national clinical standards of care for use at the hospital level in women at imminent risk of preterm birth
    b. Level of health care facility for which ACS use is approved
    c. Health care cadre authorized to give ACS
    d. Pre-referral dose prior to transfer to higher level of care. Level of facility and cadre allowed to give pre-referral dose
    e. Pregnancy complications for which ACS is indicated
    f. Essential newborn care guidelines
    g. Preterm/low birth weight standard treatment guidelines

5. **WHO preconditions for ACS use – will obtain a list of indicators by country from the United States Agency for International Development (USAID) Maternal and Child Survival Project (MCSP) database that are related measures for the WHO preconditions for ACS use**

6. **Commodities, logistics & supply chain**
    a. ACS on Essential Medicines List (EML)/Essential Drug List (EDL)
        i. Type of corticosteroid (dexamethasone or betamethasone)
    b. ACS on EML/EDL for obstetric indication in management of PTB

Part II (primary data): Key informant questionnaire on national level implementation of ACS

1. **Alignment with WHO recommendations for Preterm Birth (PTB)**

a. Aware of national level discussion about the newly released *WHO recommendations on interventions to improve preterm birth outcomes 2015?*
b. Are the country's preterm birth policies aligned with the *WHO recommendations on interventions to improve PTB outcomes 2015*? If no, is there a plan to update the policies?
c. Are the country's preterm birth clinical guidelines aligned with the *WHO recommendations on interventions to improve preterm birth outcomes 2015*? If no, is there a plan to update the clinical guidelines?

2. National program for ACS implementation

a. Current ACS policy and clinical standards in country
    i. Is ACS in national policy or clinical guidelines for PTB?
b. Clinical care of women at risk of imminent preterm birth
    i. Are facilities currently providing ACS to women at risk of imminent PTB?
    ii. Any facilities authorized to provide a pre-referral first dose of ACS?
    iii. Is there national level guidance or criteria for how to determine if a woman is at risk of imminent PTB?
    iv. Are facilities authorized to provide full course ACS also required to provide BEmONC services?
    v. Are facilities authorized to provide full course ACS required to provide CemONC services?
    vi. Is there national level guidance or criteria to determine if a woman has an infection when giving ACS?
    vii. Is there national level guidance or criteria for determining gestational age when giving ACS?
    viii. What is the maximum gestational age at which ACS is prescribed in your country?
    ix. What is the minimum gestational age at which ACS is prescribed in your country?
c. Clinical care for preterm newborns
    i. Are Neonatal Intensive Care Units or Special Care Wards required at facilities giving full course ACS to women at risk of imminent PTB?
    ii. Which of the below preterm newborn interventions are required to be available at facilities that give full course ACS to women at risk of imminent PTB?
        1. Resuscitation
        2. Thermal Care
        3. Infection prevention and treatment
        4. Feeding support
        5. Safe oxygen use
d. Human Resources
    i. Which health care worker cadres are authorized to administer full course ACS with clinical supervision?
    ii. If pre-referral dose is allowed, which health care worker cadres are authorized to administer a pre-referral first dose with clinical supervision?
    iii. Which health care worker cadres are authorized to independently prescribe and administer a full course of ACS?
e. Education
    i. Does pre-service curricula for any cadre include provision of ACS for women at risk of imminent preterm birth?
    ii. For cadres that provide ACS, do the relevant in-service curricula include provision of ACS for women at risk of imminent preterm birth?
f. Metrics
    i. Are there indicators related to ACS use in the HMIS?
    ii. Are there plans to add an indicator related to ACS use?

3. Learning from ACS implementation

a. Support for safe and effective implementation
    i. Are there any other ways, not yet mentioned, that the MOH is supporting the safe and effective implementation of ACS?
b. Challenges/barriers

   i. What are the top three key challenges or barriers to the implementation of ACS use in your country?
   ii. Do concerns around safe use of ACS hinder uptake and coverage of ACS in your country?

c. Opportunities/strengths
   i. What are the 3 most important strengths of your country's ACS implementation process?
   ii. What are the 3 most important opportunities to improve safe and appropriate use of ACS in your country?

d. Lessons learned
   i. What are the 3 most important lessons learned from your country's experience implementing ACS?

e. Support needed for ACS implementation
   i. What (additional) support, if any, is needed to implement ACS in your country?

Annex C. Key Informant Questionnaire

INTRODUCTION SCRIPT

Thank you for taking the time to speak with me today. My name is (fill in blank) and I am from the Every Preemie SCALE program. As you may be aware, our program works globally to catalyze the uptake and coverage of evidence-based preterm birth interventions. We are interviewing key informants in the 8 UN Commission on Life Saving Commodities pathfinder countries of Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Senegal, Tanzania, Uganda.

The purpose of this activity is to better understand the actual implementation of Antenatal Corticosteroids (ACS) in your country. Your input will be used to inform the important dialogue at the global level and in your country around ACS implementation as a preterm birth intervention.

I anticipate our interview will take approximately 30-45 minutes. I will be recording your responses on my computer. Is that ok with you? YES/NO

Your participation is purely voluntary. Please answer the questions to the best of your ability. If you feel that you cannot answer a question please let me know and we will move on. If at any time you would like to end the interview, please let me know.

We appreciate your time today.

First, I would like to confirm your position and organization:

Date:
Interviewer:
Interviewee Name:
Country:
Position/title:
Affiliation/organization:
Email:
Tel:

National program for ACS implementation		
Current ACS policy and clinical standards in country		
Script: Now I'd like to ask you a question about ACS policy and clinical guidelines.		
Question	**Response**	**Interview Guide**
1. Is ACS in the national policy or clinical guidelines for preterm birth? If yes, a. What are the titles of the clinical guidelines and/or policy documents that most closely pertain to ACS use?	**YES** **NO** **DON'T KNOW**	Response type: Yes/no/don't know/ comment

b. Could you share electronically your country's clinical guidelines and/or policy for preterm birth? c. If not, how might we obtain a hard copy?		
Clinical care for women at risk of imminent preterm birth		
Script: Thank you. The following questions are about clinical care for women at risk of imminent preterm birth.		
Question	**Response**	**Interview Guide**
2. Are facilities currently providing ACS to women at risk of imminent preterm birth? If yes, • What levels of care facilities are currently authorized to provide a **full course** of ACS?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know/ comment *Instructions for interviewer: Can prompt interviewee by listing the levels of facility care in their country* *FOR INTERVIEWER REFERENCE:* *A full course of ACS is 2 doses 12mg betamethasone IM 24hr apart OR 4 doses of 6mg dexamethasone IM 12hr apart*
3. Are any facilities authorized to provide a **pre-referral first dose** of ACS? If yes, a. Which levels of care facilities are currently authorized to provide a **pre-referral first dose** of ACS facility? If no, SKIP QUESTION #14	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know/ comment *Instructions for interviewer: Can prompt interviewee by listing the levels of facility care in their country* *FOR INTERVIEWER REFERENCE:* *Pre-referral first dose of ACS pertains to facilities that are not authorized to provide full course treatment with ACS, but can diagnose and treat a woman with first dose of ACS prior to transfer to higher level of care.*
4. Is there national level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth? If yes, a. What is the title of the document that contains this? b. Could you share with us electronically the document that contains this guidance / criteria?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know/ comment
5. Are facilities authorized to provide **full course ACS** also required to provide all basic emergency obstetric and newborn care (BEmONC) services? Probe: If unsure, a. Would you like me to define the components of BEmONC?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know/ comment *Instruction for interviewer: If needed, provide BemONC definition below* *FOR INTERVIEWER REFERENCE:* *BEmONC includes:* • *Parenteral antibiotics for maternal infection* • *Parenteral magnesium sulfate for pre-eclampsia* • *Parenteral oxytocic drugs for hemorrhage* • *Manual removal of placenta for retained placenta* • *Removal of retained products of conception*

		• *Assisted vaginal delivery (vacuum or forceps)* • *Resuscitation with bag and mask of non-breathing neonate*
6. Are facilities that are authorized to provide **full course ACS** required to provide <u>comprehensive emergency obstetric and newborn care (CemONC)</u> services? Probe: If unsure, a. Would you like me to define the components of CemONC?	**YES** **NO** **DON'T KNOW** **UNSURE**	Response type: yes/no/don't know response. *Instruction for interviewer: If needed, provide CemONC definition* *FOR INTERVIEWER REFERENCE:* *CemONC includes:* • *BEmONC as above AND* • *Surgery (cesarean) with anesthesia* • *Blood transfusion*
7. Is there national level guidance or criteria to <u>determine if a woman has an infection</u> when giving ACS? Probe: If yes, a. What is the title of the document that contains this? b. Could you share with us electronically the document that contains this guidance? criteria?	**YES** **NO** **DON'T KNOW** **UNSURE**	Response type: yes/no/don't know response.
8. Is there national level guidance or criteria for <u>determining gestational age</u> (GA) when giving ACS? If yes, a. What is the title of the document that contains this? b. Could you share with us electronically the document that contains this guidance / criteria?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know response. *FOR INTERVIEWER REFERENCE:* *GA calculated by* • *Known Last Menstrual Period (LMP)* • *1st trimester (0-12 weeks) ultrasound (least available, most costly, but most accurate). And reasonably accurate for GA up to 18 weeks.* • *Known date of conception* • *Fundal height (measurement from top of uterus to pubic bone correlates with gestational age) (least reliable)* • *Reported date of quickening (least reliable)*
9. What is the **maximum** gestational age (in weeks) at which ACS is prescribed in your country?	**RESPONSE:** **DON'T KNOW**	Response type: # weeks or don't know *Instructions for interviewer: Clarify the number of weeks gestation. (Example: If s/he says "34 weeks" reply "can you clarify, do you mean the start of 34 weeks or the end of 34 weeks?")*
10. What is the **minimum** gestational age (in weeks) at which ACS is prescribed in your country?	**RESPONSE:** **DON'T KNOW**	Response type: # weeks or don't know *Instructions for interviewer: Clarify the number of weeks gestation. (Example: If s/he says "24 weeks" reply "can you clarify, do you mean the start of 24 weeks or the end of 24 weeks?")*
Clinical care for preterm newborns		
Script: Thank you. The next questions are about clinical care of the preterm newborn.		

Question	Response	Interview Guide
11. Are Neonatal Intensive care Units (NICUs) or Special Care Wards required at facilities giving **full course** ACS to women at risk of imminent preterm birth?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/ don't know
12. I am going to list some preterm baby interventions. Please tell me which of these interventions are required to be available at facilities that give **full course** ACS to women at risk of imminent preterm birth. a. Resuscitation including: bag and mask? b. Thermal care including: Continuous skin-to-skin care for small babies? Incubator? c. Infection prevention and treatment including: hand washing? intravenous antibiotics? Separate ward for sick babies? d. Feeding support including: nasogastric tube? Expressed breast milk? Daily weight monitoring? e. Safe oxygen use including: oxygen mixer? Pulse oximetry? Oxygen titration guidelines? Protocol for oxygen use during resuscitation?		Response type: yes/no/ don't know/ comment *FOR INTERVIEWER REFERENCE:* • *KMC or Kangaroo Mother Care is an approach to the care of small/preterm babies that includes continuous skin-to-skin care, exclusive breastfeeding, and early discharge from the hospital. Other times, it means a package of care for small babies, and still other times is used to mean only thermal care. So please avoid use of this term, or if informant uses this term, then clarify what the term means for them.* • *Pay attention to (e): the respondent may want to say YES to "safe oxygen use". IF the respondent says YES, then please probe across all variables.* • *Oxygen mixer is defined as device that blends oxygen and room air to adjust concentration for baby's needs* • *Pulse oximetry is defined as device to measure % oxygenated blood through skin* • *Oxygen titration guidelines refers to how to adjust oxygen % for baby's needs*
Human Resources		
Script: Thank you. The next 3 questions are about authorization of ACS use.		
Question	**Response**	**Interview Guide**
13. Which health care worker cadres are authorized to administer **full course** ACS with clinical supervision? Probe: a. Are there any other cadres?	**RESPONSE:** **DON'T KNOW**	Response type: Open-ended *FOR INTERVIEWER REFERENCE: clinical supervision means the health care worker must seek and receive approval from a higher level provider i.e. a doctor before administering*
14. Since your country allows pre-referral first dose, which health care worker cadres are authorized to administer a **pre-referral first dose** with clinical supervision?	**RESPONSE:** **DON'T KNOW**	Response type: Open-ended *Instructions for interviewer: SKIP IF ANSWERED NO TO #3* *FOR INTERVIEWER REFERENCE: clinical supervision means the health care worker must seek and receive approval from a higher level provider i.e. a doctor before administering*
15. Which health care worker cadres are authorized to independently prescribe and administer a **full course** of ACS? Probe: a. Are there any other cadres?	**RESPONSE:** **DON'T KNOW**	Response type: Open-ended *FOR INTERVIEWER REFERENCE: independently prescribe and administer means the health care worker does not need to seek approval from anyone else and is empowered to prescribe and administer medication him/herself*

Education		
Script: Thank you. Now I will ask you about education.		
Question	**Response**	**Interview Guide**
16. Do pre-service curricula for any cadre include provision of ACS for women at risk of imminent preterm birth? If yes, a. For which cadres is ACS included?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/ don't know *FOR INTERVIEWER REFERENCE: pre-service is the education/training provided to health care worker students before they practice officially as a professional.*
17. For cadres that provide ACS, do the relevant in-service curricula include provision of ACS for women at risk of imminent preterm birth?	**YES** **NO** **DON'T KNOW**	Response type: Open-ended *FOR INTERVIEWER REFERENCE: in-service is additional training given to a health care worker professional during their career to update skills and practice.*
Metrics		
Script: Thanks, I'd like to ask you about metrics for ACS		
Question	**Response**	**Interview Guide**
18. Are there indicator/s related to ACS use in the HMIS? If yes, a. What is/are the indicator(s)? b. Is there an electronic version of a document that defines the/se indicator(s)?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/ don't know/ comment
19. Are there plans to add an indicator/s related to ACS use? If yes, a. Do you know what the proposed indicator is?	**YES** **NO** **DON'T KNOW**	Response type: yes/no/ don't know/ comment
Alignment with WHO recommendations for PTB		
Script: I would like to ask you a few questions about your country's ACS policy and guidelines and the new *WHO recommendations on interventions to improve preterm birth outcomes*, released in August 2015.		
Question	**Response**	**Interview Guide**
20. First, are you aware of the 2015 WHO recommendations? If no, SKIP TO # 23 If yes or unsure, a. We emailed you a link to the WHO recommendations document and the 5 conditions required for ACS use prior to today. Is it okay if I read the 5 conditions required for ACS use? If yes, *WHO recommendations state that 5 conditions should be met for safe and effective use of ACS:*	**YES** **NO** **DON'T KNOW**	Response type: yes/no/don't know *Instruction for interviewer: If needed, provide WHO recommendations below* *FOR INTERVIEWER REFERENCE:* http://apps.who.int/iris/bitstream/10665/183055/1/WHO_RHR_15.16_eng.pdf?ua=1 http://www.who.int/reproductivehealth/publications/maternal_perinatal_health/preterm-birth-highlights/

• *Gestational age can be accurately undertaken* • *Preterm birth is considered imminent* • *There is no clinical evidence of maternal infection* • *Adequate childbirth care is available (including the capacity to manage preterm labor and birth)* • *Preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection prevention and treatment, and safe oxygen use)* If yes or unsure, b. Are you aware of any discussions nationally regarding these new WHO recommendations?		
21. Although the WHO recommendations are new, have there been any discussions about updating the clinical guidelines to reflect the new WHO recommendations? If yes, a. What are the gaps in the clinical guidelines compared to the new WHO recommendations? If no, b. Is there a plan to update the national clinical guidelines to reflect the new WHO recommendations?	**YES** **NO** **DON'T KNOW**	Response type: Open-ended yes/no/don't know
Script: Now I'd like to ask you the same question about national policy.		
22. Although the WHO recommendations are new, have there been any discussions about updating national policies to reflect the new WHO recommendations? If yes, a. What are the gaps in the national policy compared to the new WHO recommendations? If no, b. Is there a plan to update national policies?	**YES** **NO** **DON'T KNOW**	Response type: Open-ended yes/no/don't know
Learning from ACS implementation		
Script: These last questions pertain to what can be learned from your country's implementation of ACS.		
Support for safe and effective implementation		
Question	**Response**	**Interview Guide**
23. Are there any other ways, not yet mentioned, that the MOH is supporting	**YES** **NO**	Response type: Open-ended yes/no/don't know

the safe and effective implementation of ACS? If yes, a. What other measures has the MOH taken?	**DON'T KNOW**	
Challenges/barriers		
Question	**Response**	**Interview Guide**
24. What are the top three key challenges or barriers to the implementation of ACS use in your country? Probe: a. That was one (or two), is there a third challenge or barrier?		Response type: Open-ended *Instructions for interviewer: If relevant, can mention you are aware their country participated in ENAP bottleneck analysis data collection in 2013.*
25. Do concerns around safe use of ACS hinder uptake and coverage of ACS in your country? If yes, • What are the specific concerns in your country?	**YES** **NO** **DON'T KNOW**	Response type: Open-ended yes/no/don't know
Opportunities/strengths		
Question	**Response**	**Interview Guide**
26. What are the 3 most important strengths of your country's ACS implementation process?		Response type: Open-ended *Instructions for interviewer: Skip if NOT implementing ACS*
27. What are the 3 most important opportunities to improve safe and appropriate use of ACS in your country?		Response type: Open-ended *Instructions for interviewer: Skip if NOT implementing ACS* *FOR INTERVIEWER REFERENCE for probing: Opportunities could mean areas need more attention or work.*
Lessons learned		
Question	**Response**	**Interview Guide**
28. What are the 3 most important lessons learned from your country's experience implementing ACS?		Response type: Open-ended *Instructions for interviewer: Skip if NOT implementing ACS*
Support needed for ACS implementation		
Question	**Response**	**Interview Guide**
29. What (additional) support, if any, is needed to implement ACS in your country? If needed, a. What type of support is needed?		Response type: Open-ended *Instructions for interviewer: Prompt informant to be as specific as possible when describing the needed support.* *FOR INTERVIEWER REFERENCE, type of support could be political, policy, funding, research, training materials, etc*

CLOSING SCRIPT:
This concludes the interview questions. Thank you for your time and the information you provided. Do you have any final comments or questions before we end this call/meeting? (Record comments)

Comment:

Can you recommend someone else in the MOH or from a professional association with whom I should do this interview?

Name: Email: Phone:

I would like to email you a summary document based on our interview today and our review of your country's documents in a few days. Would you mind reviewing that document for accuracy?

Yes/No

Should you have any questions later, please feel free to email me (provide interviewer's email).
Is it okay if I contact you should there be any follow up questions from our interview today?

Yes / No If Yes, best times and contact info.

I will also email you the contact information for the primary contacts* for this activity at Every Preemie.
**CONTACT NAMES AND EMAIL ADDRESSES. Judith McCord: jmccord@pciglobal.org* and *Jim Litch: jlitch@yahoo.com*

Annex D. Country-Level Key Informants

Country	Name	Title	Organization
DRC	Dr. Laetitia Mavinga	Pediatrician, Neonatology Unit	Cliniques Universitaires, Kinshasa University
DRC	Dr. Muyila Delphin	Pediatrician, Chief of the Neonatology Unit, in Charge of Preterm Babies	Provincial Referral Hospital of Kinshasa
Ethiopia	Dr. Lisanu Taddesse Gebremariam	Newborn and Child Health Technical Advisor	Federal Ministry of Health
Malawi	Edward Moses	Head of Programs	MaiKhanda Trust
Malawi	Eneles Kachule	MOH Desk Officer for Care of Low Birth Weight and Premature Babies	Ministry of Health
Nigeria	Dr. Bose Adeniran	Head of the Child Health Division	Federal Ministry of Health
Sierra Leone	Dr. Alimamy Philip Koroma	Senior Obstetrician/Gynecologist, Director	Princess Christian Maternity Hospital, Freetown – Cottage Hospital
Sierra Leone	Olivia Hill	Clinical Director (nurse/midwife)	Aberdeen Women's Centre GLOAG Foundation – Freetown hospital (charity supported MOH facility)
Sierra Leone	Dr. Jeredine George	National Doctor	Aberdeen Women's Centre GLOAG Foundation – Freetown hospital (charity supported MOH facility)
Sierra Leone	Dr. Mariatu Tamimu	National Doctor	Aberdeen Women's Centre GLOAG Foundation – Freetown hospital (charity supported MOH facility)
Sierra Leone	Dr. Lilly Varghese	Gynecologist (Supervisor of Doctors)	Aberdeen Women's Centre GLOAG Foundation – Freetown hospital (charity supported MOH facility)
Tanzania	Dr. Hussein Lesio Kidanto	Consultant Obstetrician and Gynecologist, Reproductive, Maternal and Newborn Health Section	Ministry of Health
Uganda	Dr. Jesca Sabiiti	Assistant Commissioner Health Services, Child and Newborn Health	Ministry of Health

Annex E. Individuals Who Supported the Implementation of the ACS Landscape Analysis

Country	Name	Organization	Title
DRC	Lina Piripiri	USAID/DRC	Maternal & Child Health (MCH) Program Management Specialist
Tanzania	Dr. John E. Varallo	Maternal and Child Survival Program (MCSP)/Jhpiego	Senior Technical Advisor – Maternal Health
Tanzania	Ráz Stevenson	USAID/Tanzania	Senior Maternal Child Health Advisor
Malawi	Dr. Fannie Kachale	Ministry of Health, Malawi	Director, Reproductive Health Department
Nigeria	Abimbola Williams	Save the Children	Head of Health and Child Survival
Uganda	Patrick Aliganyira	Samasha	Senior RMNCH Technical Advisor
Sierra Leone	Emma Warwick	Irish Aid	Head of Development, Sierra Leone and Liberia
	Lisa Hedman	WHO	Group Lead, Supply and Access to Medicines, Essential Medicines and Health Product/ Policy Access and Use
	Blerta Maliqi	WHO	Department of Maternal Newborn Child and Adolescent Health (MCA) and RMNCH Strategy and Coordination Team (SCT)
	Barbara Rawlins	MCSP/Jhpiego	Monitoring and Evaluation Team Leader
	Emma Williams	MCSP/Jhpiego	Monitoring, Evaluation and Research Advisor
	Scott Merritt	MCSP/Jhpiego	Informatics Advisor
	Jillian Rossman	MCSP/Jhpiego	Administrative Coordinator
	Bennett Nemser	UNICEF	Senior Monitoring and Evaluation Officer RMNCH Strategy and Coordination Team, UNICEF
	Jane Briggs	Management Sciences for Health	Principal Technical Advisor, Systems for Improved Access to Pharmaceuticals and Services (SIAPS), Pharmaceuticals and Health Technologies Group
	Rachel Taylor	MCSP/Save the Children	Director, Country Support
	Dr. Steve Hodgins	Saving Newborn Lives/ Save the Children	Senior Technical Advisor
	Gerard Visser	University Medical Center Utrecht	Chair, FIGO Committee Safe Motherhood Newborn Health
	Lily Kak	USAID/BGH/HIDN/ MCH	Senior Advisor for Global Partnerships and Newborn Health
	Deborah Armbruster	USAID/BGH/HIDN/ MCH	Senior Maternal and Newborn Health Advisor
	Donna Vivio	USAID/BGH/HIDN/ MCH	Senior Newborn Health Advisor
	Lindsey Grenier	MCSP/Jhpiego	Maternal Health Advisor
	Kate Kerber	Consultant	Health Consultant

Annex F. MCSP HMIS Survey Indicators Related to WHO Preconditions for ACS Use

Compendium of MCSP HMIS indicators available as proxy indicators for verification of services recommended as pre-conditions for safe use of ACS from all USAID priority MCH countries (source: MCSP 2015).

1. **Gestational age assessment can be accurately undertake**
    a. ANC 4+ visits
    b. ANC Gestational Age (in weeks)

2. **Preterm birth is considered imminent**
    a. ANC Maternal complication diagnosed: Pre-eclampsia/ Eclampsia
    b. L&D Maternal complication diagnosed: Preterm premature rupture of membranes (PPROM)
    c. L&D Maternal complication diagnosed: Antepartum hemorrhage

3. **There is no clinical evidence of maternal infection**
    a. L&D Maternal complication diagnosed: Sepsis

4. **Adequate childbirth care is available (including the core functions of emergency obstetric care and essential newborn care)**
    a. L&D ACS for preterm delivery
    b. L&D AMTSL
    c. L&D Maternal complication – treatment: Blood transfusion
    d. Method of delivery: C-section
    e. PNC: Maternal complication treatment: Sepsis

5. **The preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection prevention and treatment, and safe oxygen use)**
    a. L&D Gestational age in weeks (newborn)
    b. L&D Newborn complication diagnosed: Preterm
    c. L&D Newborn complication referred
    d. L&D Newborn resuscitation
    e. L&D Essential newborn care: breastfeeding within 1 hour
    f. L&D Essential newborn care: Delayed cord clamping
    g. L&D Essential newborn care: Immediate drying
    h. L&D essential newborn care: Immediate skin-to-skin
    i. PNC Newborn complication referred: KMC
    j. PNC Newborn complication treatment: Sepsis
    k. PNC Day 2

Annex G. Indicators by WHO Precondition for the Safe and Effective Use of ACS by Country (derived from MCSP HMIS Indicator Survey, 2015)

MCSP HMIS Survey: Indicators by WHO Preconditions for the Safe and Effective Use of ACS						
PRECONDITION 1: Gestational age assessment can be accurately undertaken						
	DRC	**ETHIOPIA**	**MALAWI**	**NIGERIA**	**TANZANIA**	**UGANDA**
• ANC 4+ Visits	√	√	√	√	√	√
• ANC Gestational Age (in weeks)	√	√	√		√	√
PRECONDITION 2: Preterm birth is considered imminent						
	DRC	**ETHIOPIA**	**MALAWI**	**NIGERIA**	**TANZANIA**	**UGANDA**
• ANC Maternal complication diagnosed: Pre-eclampsia/ Eclampsia			√			
• L&D Maternal complication diagnosed: Preterm premature rupture of membranes (PPROM)						
• L&D Maternal complication diagnosed: Antepartum hemorrhage		√	√		√	
PRECONDITION 3: There is no clinical evidence of maternal infection						
	DRC	**ETHIOPIA**	**MALAWI**	**NIGERIA**	**TANZANIA**	**UGANDA**
• L&D maternal complication diagnosed: Sepsis			√			
PRECONDITION 4: Adequate childbirth care is available (including the core functions of EmOC and ENC)						
	DRC	**ETHIOPIA**	**MALAWI**	**NIGERIA**	**TANZANIA**	**UGANDA**
• L&D ACS for preterm delivery						
• L&D AMTSL	√					
• L&D Maternal complication – treatment: Blood transfusion			√		√	
• Method of delivery: C-section						
• PNC: Maternal complication treatment: Sepsis			√			
• L&D ACS for preterm delivery						
• L&D ACS for preterm delivery						
PRECONDITION 5: The preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection prevention and treatment, and safe oxygen use)						
	DRC	**ETHIOPIA**	**MALAWI**	**NIGERIA**	**TANZANIA**	**UGANDA**
• L&D Gestational age in weeks (newborn)						√
• L&D Newborn complication diagnosed: preterm	√	√	√	√		
• L&D Newborn complication referred		√				
• L&D Newborn resuscitation	√	√	√		√	
• L&D Essential newborn care: breastfeeding within 1 hour	√	√	√		√	√
• L&D Essential newborn care: Delayed cord clamping						
• L&D Essential newborn care: Immediate drying						
• L&D essential newborn care: Immediate skin-to-skin						√
• PNC Newborn complication referred: KMC				√		
• PNC Newborn complication treatment: Sepsis					√	
• PNC Day 2						

Annex H. Democratic Republic of the Congo: Clinical Guides and Related Preterm Birth Interventions

<table>
<tr><th colspan="2">DEMOCRATIC REPUBLIC OF THE CONGO</th></tr>
<tr><th>National Document</th><th>Indication</th></tr>
<tr><td>Maternal, Newborn, and Child Standards of Health User Manual, April 2015</td><td>Preterm Labour</td></tr>
<tr><td colspan="2">Summary of Document Chapter 4 Dexamethasone
• General Information
○ Presentation: form and dosage: Solution for injection of 4 mg/ml, 1-ml ampoule
○ Therapeutic indications: Fetal lung maturity in case of threat of premature delivery before 34 weeks of gestation and in case of medical decision to prematurely terminate a pregnancy before 34 completed weeks
▪ Note: for this indication betamethasone may also be included
○ Dosage and administration: Fetal lung maturation for the mother: 6mg by IM every 12 hours for 48 hours (total dose 24mg)
○ Contra indications: Systemic infection untreated by antibiotics
• Procedures
○ For fetal lung maturation in case of preterm labour up to 34 weeks of gestation, dexamethasone 4mg/ml is administered as follows:
▪ Universal precautions for infection prevention
• Wash hands with soap or ash
• Disinfect hands with alcohol or other antiseptic/ disinfectant
• Wear sterile gloves
▪ Administration guidelines
• Prepare the injection solution by sucking 4mg or 6mg in a 5ml syringe
• Aspirate to verify that it is not in a blood vessel
• Administer dexamethasone with one of the following:
○ 6mg administered every 4 hours for 24 hours IM (total dose 24mg)
○ 6mg by IM, every 12 hours for 48 hours (total dose 24 mg)
○ 12 mg administered every 12 hours IM for 24 hours (total dose 24mg)</td></tr>
<tr><td>Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012</td><td>PROM</td></tr>
<tr><td colspan="2">Summary of Document:
• Guidelines for the management of premature rupture of membranes
• PROM clinical features, diagnosis, signs of severity
○ Gestational age 28-34 weeks
○ Infection prevention measures
○ Initiate antibiotic treatment
▪ Ampicillin or Amoxicillin
○ Refer to the General Reference Hospital
• At the General Reference Hospital
○ Administer corticosteroids to accelerate fetal lung maturation
▪ IM dexamethasone 12 mg x 2 in a day, or Betamethasone 24 mg IM
▪ Unless there are signs of infection</td></tr>
<tr><td>Obstetric Care Training and Neonatal Emergency Facilitators Guide, May 2012</td><td>Eclampsia and Pre-Eclampsia</td></tr>
<tr><td colspan="2">“Explain that it would be necessary to give some medications that accelerate lung maturation in the fetus; to prevent respiratory complications at birth (corticosteroids are generally administered, if indicated, in pregnant women less than 34 weeks)”</td></tr>
</table>

Annex I. Ethiopia: Clinical Guides and Related Preterm Birth Interventions

ETHIOPIA	
National Document	**Indication**
FMOH STGs for Primary Hospitals, 2014	**Preterm Labour**

Summary of Information in Preterm Labour Section

- Preterm labour can be defined as regular uterine contractions that cause progressive dilatation of the cervix after 28th weeks of gestation and before 37 completed weeks. Approximately 8-10% of all pregnancies end in preterm labour. Prematurity is one of the major causes of perinatal mortality and morbidity.
- Causes: The etiology of preterm labour is multi-factorial that includes:
    - Multiple gestation
    - Infection like urinary tract infection, febrile illness, abdominal surgery
    - Uterine anomalies, antepartum hemorrhage (placenta previa and abruptio placentae)
    - PROM
    - Low socio economic status
- Clinical features:
    - Pushing down sensation in the mother and if the clinician detects regular rhythmic uterine contraction of four in 20 minutes or eight in 60 minutes that leads to progressive cervical dilatation and effacement
    - Cervical dilatation greater than 1cm
    - Cervical effacement of 80 percent or greater
- Investigations:
    - Complete Blood Count
    - Fasting Blood Sugar
    - Trans vaginal ultrasound can show cervical dilatation and effacement
- Treatment: When the diagnosis of preterm labour is made, the medical team should attempt to determine the cause and whether further continuation of the pregnancy will be beneficial or harmful to the mother and fetus. The choice of treatment depends on the answer to these questions and maturity of the fetus. Once fetal maturity is assured there is no benefit by conservative management and pregnancy should be terminated through the safest route. But if the fetus is premature, conservative management should be attempted.
- Objectives:
    - Prevent or early detect intrauterine infection
    - Prolonged pregnancy until fetal maturity is achieved
    - Promote fetal lung maturity by administering corticosteroids
    - Treat any underlying cause e.g. urinary tract infection, malaria, pyelonephritis etc
- Nonpharmacologic:
    - Bed rest
    - Oral hydration, especially with nutritive calories, such as fruits juices, milk etc.
- Pharmacologic: Use of a tocolytic drugs is not associated with a clear reduction in perinatal or neonatal mortality or neonatal morbidity. The main effect of tocolytic drugs when used for women in preterm labour is to reduce the numbers who deliver within 48 hours or within 7 days after the drug administration. Data on long-term outcome are sparse. It remains plausible that, for selected women, such as those who require transfer for neonatal care or time to complete a course of corticosteroids, there may be benefit associated with tocolysis. However, this benefit has not been formally evaluated in randomized trials.
- NB: There is no benefit from maintenance tocolytic therapy.
    - Nifedipine, initial 20mg orally, followed by 10-20mg three to four times daily, adjusted according to uterine activity for up to 48 hours, a total dose of 60mg/day appears to associated with 3-4 fold in adverse events such as headache and hypotension.
    - ADRs: Flushing, oedema of ankle, headache, gingival hypertrophy
    - C/Is: Unstable angina, hypotension
    - D/Is: Cimetidine may enhance its anti-hypertensive effect Dosage forms: Tablet, 10 mg, 20 mg; capsule, 5 mg, 10 mg, 20 mg PLUS
    - Steroid therapy for stimulation of surfactant production to be given 28-34weeks of gestation

(For dosage regimens, ADRs, C/Is and dosage forms, see specific steroids)

- First line: Bethamethasone, two doses of 12mg 24 hours apart. At 48 hours following the first dose, the full effect on maturing the surfactant has been obtained. If patient does not deliver within one week, the treatment should be repeated if the fetus is less than 34 weeks of gestation.
    - ADRs: Hyperglycemia, psychiatric reactions, gastrointestinal disturbance, infections, osteoporosis, central obesity, hirstusim
    - C/Is: Herpes simplex infection of the eye, epilepsy, peptic ulcer, psychic instability, thromboembolic disorders
    - P/C: In hypertension, diabetis mellitus, liver cirrhosis, epilepsy, osteoporosis Dosage forms: Tablet, 0.5mg Alternative Dexamethasone; 6mg PO for two doses six hours apart for two doses. (ADRs, C/Is, and P/C are same as those of bethametasone)
    - Dosage forms: Injection, 4mg/ml, 25mg/ml, 50mg/ml; Tablet, 0.5mg, 0.75mg, 1mg, 2mg
- Alternative: Dexamethasone; 6mg PO for two doses six hours apart for two doses.
    - (ADRs, C/Is, and P/C are same as those of bethametasone)
    - Dosage forms: Injection, 4mg/ml, 25mg/ml, 50mg/ml; Tablet, 0.5mg, 0.75mg, 1mg, 2mg
- N.B.: Use of corticosteroids in the presence of infection is contraindicated
- Sympathomimetics: Ritodrine and salbutamol are associated with significant; potentially life threatening maternal side effects (particularly if given in combination with corticosteroids) which include fluid overload, pulmonary edema, myocardial ischemia, hyper of hypoglycemia, hence, these combinations should be abandoned totally in the management of preterm labour.
- Refer: Patients who develop preterm labour should be referred to nearby general hospital for better neonatal care.

FMOH STGs for General Hospitals, 2014	**Preterm Labour**

Same as above, with the following exceptions:

- Inclusion of an additional investigation: Fibronectin in vaginal secretion
- Inclusion of additional non-pharmacologic activity: Cervical cerclage
- Does not include a reference to refer.

FMOH STGs for Health Centers	**Preterm Labour**

Same as STGs for Primary Hospitals, with the following exceptions:

- Does not include ultrasound as an investigation
- Refer: Patient with preterm labour should be treated in a center where there is neonatal Intensive Care Unit (ICU) and should be referred as early as possible.

FMOH Management Protocol on Selected Obstetrics Topics for Health Centers	**Preterm Labour pPROM**

Summary of Information in Preterm Labour Section

- Introduction: Preterm labour refers to the onset of labour before the 37 completed weeks of gestational age. Preterm labour complicates up to 10% of all pregnancies. It is by far most common cause of prematurity which is one of the three most important causes of neonatal morbidity and mortality. Preterm labour also leads to considerable maternal morbidity. The risk of maternal and neonatal morbidity and mortality from preterm labour is higher the earlier the gestational age at which labour ensues.
- Etiology of Preterm Labour: The etiology of preterm labour is often unknown. However, preterm labour is known to be more common in pregnancies with certain obstetric risk factors and conditions. These include:
    - Multiple pregnancies
    - Prior history of preterm delivery
    - Polyhydramnios
    - Malpresentation
    - Hypertensive disorders of pregnancy
    - Antepartum hemorrhage
    - History of smoking and drug abuse
    - Preterm PROM
    - Abdominal trauma during pregnancy
    - Diabetes mellitus during pregnancy
    - Maternal anemia
- Complications of Preterm Labour: Preterm labour can lead to minor as well as serious and, at times,

fatal complications on the mother as well as the fetus/neonate. These include:
  - Maternal complications
    - Increased operative delivery
    - Increased risk of birth trauma
  - Fetal/Neonatal Complications
    - Preterm birth and prematurity
    - Birth Injury
    - Perinatal/neonatal asphyxia
- Diagnosis
  - History
    - Onset of regular, rhythmic and painful uterine contractions before 37 complete weeks of gestational age.
  - Physical examination
    - Abdominal examination At least two uterine contractions palpated within ten minutes occurring rhythmically and continuously
  - Pelvic examination
    - Cervical dilatation of > 2 centimeters and/or > 80% effacement
    - Progressive cervical effacement and dilatation noted during follow up ward
- Diagnostic criteria for preterm labour
  - Gestational Age < 37 completed weeks plus
  - At least 2 regular rhythmic contractions lasting more than 30 seconds every 10 minutes plus
  - Cervical dilatation of > 2 cms and/or > 80% effacement OR
  - Progressive effacement and dilatation of the cervix noted during follow up (if mother has been
  - admitted to the labour ward and cervical status was progressively followed
- Management:
  - Management for preterm labour requires hospital care. Once you make diagnosis of preterm labour ascertain gestational age (for GA less than 34 weeks administer initial dose of corticosteroid to the mother to improve fetal lung maturity (dexamethasone 6mg IM or Bethamethasone 12 mg IM).
  - Then transfer mother to hospital care as soon as possible for further management of preterm labour and delivery such as tocolysis and management of the premature neonate (NICU). During the course of referral (explain to the client and family the need for referral, call in advance to the referral end, escort the client in order to provide support in route (IV infusion for hydration, fetal monitoring, make sure you have resuscitation equipment for the newborn in case of delivery on the way to hospital and avoid hypothermia).
  - Notes:
    - In the case of imminent delivery attend the labour and provide essential care for the newborn and keep him/her warm.
    - Undertake immediate referral for babies who are very low birth weight and very premature (<1500kg and GA <32 weeks), make sure the baby is transferred with the mother to hospital for better care.

Preterm PROM:
  - Ascertain gestational age
  - Avoid digital pelvic examination
  - Assess for complications
  - If chorioamnionitis is present (fever, abdominal tenderness, fetal tachycardia)- initiate broad spectrum antibiotics
  - Administer corticosteroid to the mother to improve fatal lung maturity when gestational age is less than 34 weeks (administer initial dose of Dexamethasone 6mg IM or Bethamethasone 12 mg IM)
  - Refer mother for hospital care as soon as possible (explain to client family, advance call, escort providing support in route like fluids, analgesia)

FMOH Basic Emergency Obstetric and Newborn Care Training Manual	**PROM**
Summary of Information in PROM Section	

- Confirm accuracy of calculated gestational age, if possible.
- If there are no signs of infection and the pregnancy is less than 37 weeks (when fetal lungs are more likely to be immature):
    - Give antibiotics to reduce maternal and neonatal infective morbidity and to delay delivery:
        - erythromycin base 250 mg by mouth three times per day for 7 days
        - PLUS amoxicillin 500 mg by mouth three times per day for 7 days
    - Give corticosteroids to the mother to improve fetal lung maturity:
        - betamethasone 12 mg IM, two doses 12 hours apart
        - OR dexamethasone 6 mg IM, four doses 6 hours apart.
    - Note: Corticosteroids should not be used in the presence of frank infection.

Annex J. Malawi: Clinical Guides and Related Preterm Birth Interventions

MALAWI	
National Document	**Indication**
Malawi STGs Incorporating Malawi EML, 2015	**Preterm Labour, Eclampsia, PROM**

Summary of Hypertensive Disorders in Pregnancy:

- Severe Pre-Eclampsia:
  - If <34 weeks gestation:
    - Inform clinician
    - Assess fetal well-being using ultrasound or cardiotocograph
    - Give Dexamethasone 6mg every twelve hours i/m for 4 doses; Alternatively, Betamethasone 12mg i/m once daily for a total of 2 doses
- Pre-labour/Premature rupture of membranes
  - Definition, signs, and symptoms
  - Management if gestation less than 34 weeks
    - If at Health Center: Give corticosteroids if <34 weeks. Refer immediately.
    - If at Hospital: If signs of intrauterine infection or fetal distress. Inform the most senior person available, and plan urgent delivery regardless of gestational age.

Malawi National Reproductive Health Service Delivery Guidelines, 2014–2019	**Preterm Labour, PROM, pPROM**

Summary of Management of Preterm Labour:

- Definition, management options
  - Overview of antenatal corticosteroids (ACS) for preterm labour:
    - Corticosteroids are recommended for all women between 28 and 34 weeks of pregnancy who are at risk for preterm delivery.
    - Patients eligible for therapy with Beta-agonists (tocolytic agents) are also eligible for treatment with antenatal corticosteroids.
    - Tocolytic agents should be used to delay delivery for 24–48 hours in order to administer corticosteroids to promote fetal lung maturity.
    - When the risk of preterm delivery persists or recurs following initial treatment, decisions to repeat treatment should be made on an individual basis.
    - Corticosteroids may be used in patients with severe preeclampsia/hypertension. However, they need to be closely monitored.
    - Impaired glucose tolerance may occur if repeated doses of corticosteroids are given, especially in conjunction with Beta-agonist therapy
  - Mechanism of Action
    - Give dexamethasone 6 mg IM every 12 hours for 4 doses. Dexamethasone is the preferred ACS based on current evidence, as noted below. It is also preferred because the generic form is widely available (alternatively, give betamethasone 12 mg IM every 12 hours for 2 doses).
    - Give the first dose immediately upon determining that the woman has a condition that increases her chance of preterm birth within the next 7 days. The maximum benefit of medication is achieved after 48 hours. Because the precise time of delivery cannot be predicted, the medication should be initiated immediately when a condition leading to preterm birth is identified.
    - Note: There is no additional benefit of rapid administration (less than 48 hours) of all doses prior to an imminent birth.
    - Note: Administering provider: The decision to give ACS is typically made by a skilled birth attendant (SBA). The injection can be administered by personnel trained to give injections, according to local county policy.
  - Steps to Administer ACS
    - Follow these steps for proper administration of ACS:
    - Once a woman who presents with threatened preterm birth has been evaluated and a condition increasing of preterm birth is identified, ACS are indicated. Determine if ACS can be administered at the facility or if referral is needed.

- All facilities that provide MNH services should be able to initiate a course of ACS by administering the first dose prior to transfer. If referral is needed, follow facility protocol for immediate referral.
    - If able to administer ACS, follow these steps:
    - Explain to the woman what will be done.
    - Wash and dry hands and put on clean gloves.
    - Prepare the IM injection site (either the upper arm, buttock, or thigh). Clean the skin with cotton and alcohol or spirits.
    - Using a small sterile syringe and needle, draw up 4 mg (1 ml) of dexamethasone from the first ampoule. Maintain sterile technique and draw up 2 mg (0.5 ml) of dexamethasone from the second ampoule. Discard both ampoules and remaining drugs.
    - Explain to the woman what will be done and give the injection.
    - Properly dispose of the needle and syringe in an appropriate sharps container.
    - Properly remove gloves and discard appropriately.
    - Wash and dry hands
    - Document medication, dose, site of administration, and time it was given in the patient record. Document the time when the next dose should be administered.
    - Advise the woman of the timing of the next dose.
- Considerations
    - There are no absolute contra-indications for ACS. However, in women with diabetes, blood sugar should be closely monitored and an increased insulin requirement should be anticipated. Women on chronic steroids can receive ACS according to the protocol and may also need a stress dose of their steroids at the time of delivery.
- Contraindications to Inhibition of Preterm Labour
- In the following situations where delivery is imminent or when other obstetric factors dictate that delivery should not be delayed, inhibition of preterm labour may be withheld:
    - Fulminating pre-eclampsia
    - Severe abruptio placentae
    - Fetal distress
    - Severe chorioamnionitis in the presence of ruptured membranes
    - Fetal demise or lethal fetal anomaly
    - Development of serious side effects during the use of Beta-agonists
- Delivery of the Preterm Fetus
    - Delivery of the preterm fetus should take place in an obstetric unit with neonatal care facilities.
    - Fetal monitoring during labour is important to ensure fetal well-being.
    - In the absence of obstetric risk factors or complications that would otherwise preclude a vaginal delivery, a preterm fetus with a vertex presentation may be delivered vaginally.
    - However, if the presentation is not vertex, delivery by Caesarean section may be considered.

Participants Manual in Integrated Maternal and Neonatal Care, January 2015	**Preterm Labour**

Summary of Module 7: Management of Preterm Labour

- Same information as in the Malawi National Reproductive Health Service Delivery Guidelines, with the following exceptions:
- Inclusion of causes/pre-disposing factors, signs and symptoms, management
- Corticosteroid Therapy
    - Corticosteroids are recommended for all women between 24 and 37 weeks of pregnancy who are at risk for preterm delivery.
- Steps to Administer Antenatal Corticosteroids (ACS)
    - Considerations
    - Contraindications to Inhibition of Preterm Labour
- Delivery of the Preterm Fetus
- Management of Preterm Membrane Rupture

Reproductive Health Unit Obstetric Management Protocols District/Central Hospital	Preterm Labour

Infections Protocol:

- Definition: Rupture of the membranes before labour has begun (before, at or after 37 weeks gestation)
- Diagnosis: Watery vaginal discharge
- Management
    - Gestation less than 34 weeks:
        - No digital vaginal examination should be done
        - When in doubt, perform speculum examination
        - Check temperature 4 hourly, inspect liquor daily, assess foetal heart rate
        - Give prophylactic antibiotics: Erythromycin 250 mg by mouth 3 times per day for 7 days PLUS Metronidazole 400 mg by mouth tds for 7 days
        - Give Corticosteroids: Betamethasone 12 mg IM, 2 doses 12 hours apart; OR Dexamethasone 6 mg IM, 4 doses 6 hours apart
        - Do ultrasound scan
        - If signs of intra-uterine infection develop (temperature 37.5º C or more, purulent or offensive liquor, foetal tachycardia), inform the most senior person available, who should plan urgent delivery
        - Deliver at 34 weeks

Annex K. Nigeria: Clinical Guides and Related Preterm Birth Interventions

NIGERIA	
National Document	Indication
Report of Expert Consensus Panel on the use of ACS, October 2014	**Preterm Labour**
Summary: Generally, after having examined the ACT study and listened the focal presentation including review of other reference documents and discussed the attendant practices around ACS in Nigeria with key stakeholders input. The panel had affirmed that the current cautionary approach to use of ACS in the country was in tandem with the evolving evidence. It therefore listed the following consensus that was reached. These itemized areas are to serve as suggested guidance to the Federal Ministry of Health on interim decision, pending when a formal WHO guidance is received. The panel chair therefore listed the key areas as follows: • ACS should only be used at the tertiary facilities upon recommendation of senior personnel. • All other lower level facilities should adopt referrals for such cases. • Before the use of the ACS, the Gestational Age must be accurately established. • Level 2 NICU as a minimum • This decision should be written out as an Expert Panel Report and passed to all relevant professional bodies for their study and assent.	
FMOH National Strategic Health Development Plan (NSHDP) 2010-2015	**Preterm Labour**
Summary: • Essential Package of Care, Individual/Clinical Oriented Services includes: o Antenatal steroids for preterm labor o BEmONC, CEmONC o Resuscitation o Antibiotics for PROM o Universal emergency neonatal care (asphyxia aftercare, management of serious infections, management of VLBW infant)	
"Saving One Million Lives" Accelerating improvements in Nigeria's Health Outcomes through a new approach to basic services delivery	**Respiratory Distress Syndrome for Newborns**
Summary: • Program Component 1: Improving Maternal, Newborn and Child Health (MNCH)" o Newborn Health - ACS - Respiratory Distress Syndrome for Newborns	

Annex L. Sierra Leone: Clinical Guides and Related Preterm Birth Interventions

SIERRA LEONE	
National Document	**Indication**
Maternity Africa: Policies and Guidelines for Intrapartum Postnatal and Neonatal Care	**pPROM, Preterm Labour**

Summary of Information in pPROM section:

- Definition, Aetiology, Major complications, differential diagnosis,
- Management and therapy
    - General rules:
        - DON'T PERFORM A VAGINAL EXAMINATION UNLESS THE PATIENT IS IN LABOUR (this increases the risk of Chorioamnioitis)
        - Patients in labour, regardless of gestational age, with cervix more than 4cm dilated, should be allowed to deliver.
        - Tocolysis is indicated if:
            - Gestation between 24 and 34 weeks
            - Cervix Less than 4 cm dilated
            - No overt suggestion of Chorioamnioitis
    - Less than 36 weeks gestation
        - Prophylactic antibiotic therapy should be started immediately when the gestation is under 36 completed weeks - Erythromycin 250mg orally 6 hourly until delivery
        - Note: Do not use Augmentin as it increases risk of Necrotising Entrocolitis in the neonate
        - Patient with PPROM has to be closely monitored, 4hrly Temp, pulse and FHR and check the pad, especially for any signs of infection. Deliver immediately if signs of infection
        - In a situation with clinical chorioamnionitis the principles are to deliver regardless of gestational age and to administer higher doses of IV antibiotics, e.g. Ampicillin 2g IV every 6 hrs for at least 48hrs then review. Maintain Antibiotic therapy for at least 5-7 days either IV or oral.
        - Severe cases with threatening septicemia are given Gentamycin 160mg IV daily and Metronidazole 500mg IV TDS as well.
- Considerations for management of PPROM at different gestational ages:
    - The undelivered patient is exposed to the risk of infection.
    - In the case of a fetus of a gestational age below 34 weeks, prematurity poses a higher risk of perinatal mortality than complications from infections, therefore treat the mother with antibiotics and give steroids and review after 48 hrs.
- PPROM when the gestation is between 28 and 36 weeks:
    - Always give Steroids Dexamethasone 8mg IM 12 hourly x 4 doses for fetal lung maturation.
    - If necessary Tocolysis should be given for the 48 hours of fetal lung maturation.
    - As long as leakage is significant or the presenting part of the fetus is mobile above the pelvis, the patient should be kept in supine position or even with slightly elevated pelvis.
    - After 48 hours for lung ripening (Dexamethasone 8mg 12 hourly for 4 doses) has elapsed, labour may be induced in patients with a high risk of infection, e.g. with vaginitis or cervical dilatation.
    - In the absence of signs of infection (like maternal temperature above 38°C, maternal and/or fetal tachycardia, preterm labour, tenderness of the uterus, malodorous or purulent discharge) an expectant management with prophylactic antibiotics (erythromycin 250mg 6hrly until delivered) is required.

Summary of Information in Preterm Labour section:

- Definition: Preterm labour is the presence of regular painful contractions before 37 weeks gestation.
- Exclude any infection as that is the most common cause of Preterm Labour. UTI, Vaginal discharge, Malaria or Typhoid.

- Always make a thorough assessment to ensure that it is true preterm labour:
  - observe contractions for 10 minutes and review
  - vaginal examination
  - USS for cervical length if possible
  - Check urine for UTI and exclude any other infection
- Tocolysis if:
  - Gestation < 35+6 weeks
  - Cervix < 3cm dilated, always do a vaginal examination prior to giving tocolysis
  - No chorioamnionitis, pre-eclampsia or bleeding
  - No fetal distress
  - An alive fetus
- If true labour, i.e. cervical change with painful contractions, is suspected after 28 weeks gestation and before 35+6 weeks, steroids should be given.
  - Dexamethasone 8mg IM stat
  - 2nd dose of dexamethasone IM 12 hours later. To give a total of 4 doses. It has been shown the most effective intervention to improve newborn outcomes for women in preterm labour is the administration of corticosteroids.
- If contractions but no cervical change then:
  - Admit and observe
  - Exclude any infection and treat if present.
- Note: Steroids should not be given in the presence of frank infection
- Management
  - The use of calcium channel blockers, when compared with any other tocolytic agent, showed a statistically significant decrease in the number of women giving birth within seven days of initiation of the treatment.
  - 1st line treatment: 20mg oral Nifedipine if after 20 min still contracting repeat the dose, and if still contracting 30 min later give a 3rd dose of 20mg Nifedipine.
  - Closely monitor the mother's blood pressure, contractions and fetal heart beat while on this medication.
  - Consider giving 50 -100mg Pethidine IMI to assist tocolytics if woman is very uncomfortable
  - 2nd Line treatment: Salbutamol can be given intravenously, 4mg in 500ml of 5% dextrose solution started at 10 drops per minute. The dose was increased at interval of 15-20 minutes until the contractions stopped or the maternal pulse increased to 140 beats per minutes or above, then it was maintained on oral salbutamol 4mg twice a day for further 5 days.
    - Do not give tocolytic drugs for longer than 48hrs
    - Maintenance dose of 20mg Nifedipine TDS/QID as required
    - Can stop Nifedipine 24hrs after 2nd dose of steroids given
    - Membranes should be left intact.
    - If labour continues at gestation<37 weeks give 2g Ampicillin 6hrly in labour.
    - Anticipate resuscitation of preterm infant, as well as possible transfer to a higher care centre.
    - Post delivery review to see if IV antibiotics must be continued or if you can change to oral medication to complete the course.

MSF, Essential Obstetric and Newborn Care, 2015	**Preterm Delivery**

Summary of Information in threatened preterm delivery section:

- Regular uterine contractions and cervical changes before 37 weeks LMP.
- Causative Factors
  - PROM
  - Infection, fever
  - Pregnancy related disorder: pre-eclampsia, polyhydramnios, placenta praevia
  - Malnutrition
  - Multiple pregnancy
  - Cervical incompetence, immature uterus in the young primipara
- Management
- Always look for malaria (rapid test) and urinary tract infection (dipstick test); treat the apparent causes.

- Let the woman deliver:
  - If she is >34 weeks LMP and her waters have been broken.
  - If labour is too advanced to be stopped (cervix effaced, 4cm dilation), no matter what gestational age.
  - If the mother's life is threatened (very poor general condition, pre-eclampsia, eclampsia, abruptio placentae, etc.), no matter what gestational age.
  - If fetal death is confirmed (no fetal movements and no fetal heart tone at several checks or ultrasound confirmation of fetal death).
- Otherwise, try to stop the contractions:
  - bed rest
  - Tocyolytic therapy: The main objective is to postpone delivery in order to administer corticosteroids for accelerating fetal lung maturation
    - Nifedipine PO: 10mg to be repeated every 15 minutes if uterine contractions persist (maximum 4 doses or 40 mg), then 20mg every 6 hours. OR
    - Salbutamol IV infusion
  - Duration of treatment is 48 hours, regardless of which drug is used.
  - Do not combine nifedipine and salbutamol.
- Prepare the fetus for preterm birth:
  - After 26 weeks LMP and before 34 weeks LMP, help lung maturation with dexamethasone IM: 6mg every 12 hours for 48 hours. In case of severe maternal infection, start antibiotic therapy prior to dexamethasone.

Annex M. Tanzania: Clinical Guides and Related Preterm Birth Interventions

TANZANIA	
National Document	**Indication**
Administration of Antenatal Corticosteroids in Pre-Term Labour, July 2015 Guidelines	**Preterm Labour**

Summary of Guidelines:

- Risks/ causes of preterm labour/birth
- Complications of preterm delivery
- Antenatal Corticosteroids
    - Level of care to use antenatal corticosteroids
        - In Tanzania, antenatal corticosteroids may be safely used at a hospital level. If a woman with premature labour presents in a health facility other than a hospital such as dispensary or health centre, she should be given a first dose of ACS and then be referred to the hospital.
    - Type of corticosteroids to be used
        - The antenatal corticosteroid of choice is intramuscular dexamethasone. However, if available, intramuscular betamethasone may also be used.
    - Who should receive antenatal corticosteroids?
        - ACS shall be given to all women at risk of preterm birth from any cause from 28 to 34 weeks of gestation. However, by a specialist opinion in a well-equipped health facility, ACS may be given at a gestation age as low as 24 weeks.
    - Dose for antenatal corticosteroids:
        - Dexamethasone 6 mg intramuscularly every 12 hourly to a total of 4-doses.
        - Betamethasone 12mg injection given every 24 hours (once a day) to a total of 2 doses
    - Precautions when administering antenatal corticosteroids:
        - Antenatal corticosteroids are immunosuppressive medicines. For this reason these medicines need to specially manage in situation of:
            - Any form of obstetric sepsis such as chorioamnionitis.
            - In existence of systemic infections such as TB and others.
            - In diabetes mellitus where adjustment of insulin dose vs administration of ACS is required.

Standard Treatment Guidelines and Essential Medicines List, Fourth Edition, 2013	**Respiratory Distress Syndrome, Preterm Labour**

Summary of Section:

- Respiratory Distress Syndrome in newborn
    - Clinical features:
        - Respiratory Distress Syndrome may occur in newborn and in premature labour before 36 weeks gestation. The following steroids can be used to prevent this.
- Medicine of choice Hydrocortisone (IV) 250 mg repeat after 24 hours
- Second choice Dexamethasone (IV) 12 mg, two doses at an interval of 12 hours
- NOTE: If no delivery the course can be repeated after one week
- CAUTION: Anaemic patients under Beta stimulants and steroids are inclined to congestive cardiac failure

Annex N. Uganda: Clinical Guides and Related Preterm Birth Interventions

UGANDA	
National Document	**Indication**
MOH Uganda Guidelines 2012, National Guidelines for Management of Common Conditions	**PROM**

Summary of Guidelines:

- Premature Rupture of Membranes
- PROM is a rupture of membranes before the start of labour and can occur either when foetus is immature (preterm or <37weeks) or mature (term).
- Investigation
    - The typical odor of amniotic fluid is diagnostic.
    - If membrane rupture is not recent or leakage is gradual, confirming the diagnosis may be difficult
        - Place a vaginal pad over the vulva and examine visually and by smell after 1 hour
        - Use a high-level disinfected speculum for vaginal examination
            - Fluid may be seen coming from the cervix or forming a pool in the posterior fornix
            - Ask patient to cough; this may cause a gush of fluid
            - Do not do digital vaginal examination - it does not help diagnosis and may cause infection
        - If available, do tests:
            - Nitrazine test (may get false positive due to blood and some vaginal infections)
            - Ferning test (false negative common)
- Management
    - If vaginal bleeding with abdominal pain (intermittent or constant)
        - Suspect and treat as abruptio placentae (see 16.3016.30)
    - If signs of infection (fever, foul-smelling vaginal discharge)
        - Give antibiotics as for Amnionitis
    - If no signs of infection and pregnancy <37 weeks (foetal lungs more likely to be immature)
        - Give 7-day course of antibiotics to reduce maternal and neonatal infective morbidity and to delay delivery
            - Erythromycin 250mg every 8 hours
            - Plus amoxicillin 500mg every 8 hours
        - Consider referral for special care of the newborn
        - Give corticosteroids to the mother to improve foetal lung maturity: dexamethasone 6mg IM every 6 hours for a total of 4 doses
            - Do not use steroids in presence of infection
            - Deliver at 37 weeks
        - If palpable contractions and blood- stained mucus
            - Suspect preterm labour

MOH Uganda Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving Commodities.	**PROM and Risk of Preterm Delivrey**

Summary of Guidelines:

Note: Dexamethasone injection is indicated for women at risk of Pre-term delivery even when membranes have not ruptured.

An initial dose should be given to women at risk and then referred to higher centers for further management. HC2

- Rupture of membranes before start of labour can occur either when foetus is immature (preterm or <37weeks) or mature/term (37 weeks or more)
- Confirming the diagnosis
    - The typical odour of amniotic fluid is diagnostic.

- If membrane rupture is not recent or leakage is gradual, confirming the diagnosis may be difficult:
  - Place a vaginal pad over the vulva and examine visually and by smell after 1 hour
  - Use a high-level disinfected speculum for vaginal examination:
  - Fluid may be seen coming from the cervix or forming a pool in the posterior fornix
  - Ask patient to cough; this may cause a gush of fluid
- Do not do digital vaginal examination - it does not help diagnosis and may cause infection
- If available, do tests:
  - Nitrazine test (may get false positive due to blood and some vaginal infections)
  - Ferning test (false negative common)

- Management
  - If there is vaginal bleeding with abdominal pain (intermittent or constant):
    - Suspect and treat as abruptio placenta
  - If there are signs of infection (fever, foul- smelling vaginal discharge):
    - Give antibiotics as for amnionitis
  - If there are no signs of infection and pregnancy <37 weeks (foetal lungs more likely to be immature):
    - Give 7-day course of antibiotics to reduce maternal and neonatal infective morbidity and to delay delivery: Erythromycin 500mg every 8 hours plus Amoxicillin 500mg every 8 hours
  - Consider referral for special care of the newborn
  - Give Corticosteroids to the mother to improve foetal lung maturity:
  - Dexamethasone 6mg IM start and refer immediately HC2
  - Dexamethasone 6 mg IM every 6 hours for a total of 4 doses HC3
    - Do not use in presence of infection
  - Deliver at 37 weeks
- If there are palpable contractions and blood-stained mucus: suspect preterm labour