

# ANTENATAL CORTICOSTEROIDS FOR WOMEN AT RISK OF IMMINENT PRETERM BIRTH IN THE DEMOCRATIC REPUBLIC OF THE CONGO, ETHIOPIA, MALAWI, NIGERIA, SIERRA LEONE, TANZANIA AND UGANDA

	A	<b>Policy</b>	and Im	plementatio	n Landsca	pe Anal	vsis
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Suggested Citation: McCord, JR, Litch JA, Greensides D, Noriega A. Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in the Democratic Republic of the Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda - A Policy and Implementation Landscape Analysis; Washington DC: UNCoLSC and Every Preemie - SCALE; June 2016. Report PDF available at <a href="http://www.everypreemie.org/resources/">http://www.everypreemie.org/resources/</a>

Direct download link: <a href="http://www.everypreemie.org/wp-content/uploads/2016/06/ACS-Policy-and-Implementation-Landscape-Analysis-June-2016.pdf">http://www.everypreemie.org/wp-content/uploads/2016/06/ACS-Policy-and-Implementation-Landscape-Analysis-June-2016.pdf</a>

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### **Acronyms**

ACNM American College of Nurse-Midwives

ACS Antenatal corticosteroids
ACT Antenatal Corticosteroids Trial

AMTSL Active management of the third stage of labour

ANC Antenatal care

BEMONC Basic Emergency Obstetric and Newborn Care

BMI Body mass index

CEMONC Comprehensive Emergency Obstetric and Newborn Care

CPAP Continuous positive airway pressure
DHS Demographic and Health Survey
DRC Democratic Republic of the Congo

EML Essential medicines list

EmONC Emergency Obstetric and Newborn Care

ENAP Every Newborn Action Plan ENC Essential newborn care EWEC Every Woman Every Child FMOH Federal Ministry of Health

GA Gestational age

GAPPS Global Alliance to Prevent Prematurity and Stillbirth

HBB Helping Babies Breathe

HMIS Health management information system

IMNCI Integrated Management of Neonatal and Childhood Illness

KMC Kangaroo mother care LBW Low birth weight

LMIS Logistics management information system

LMP Last menstrual period MCH Maternal and child health

MCSP Maternal and Child Survival Program
MICS Multiple Indicator Cluster Surveys
MNH Maternal and newborn health

MOH Ministry of Health NG Nasogastric

NGO Non-governmental organization
NICU Neonatal intensive care unit
PCI Project Concern International

pPROM Preterm premature rupture of membranes

PROM Premature rupture of membranes

PTB Preterm birth

RMNCH Reproductive maternal and newborn health

SBA Skilled birth attendant

SPA Service Provision Assessments
STG Standard treatment guidelines
TRT Technical Resource Team
TWG Technical Working Group

UNCoLSC United Nations Commission on Life-Saving Commodities for Women and Children's Health

USAID United States Agency for International Development

WHO World Health Organization

### **Acknowledgements**

The Every Preemie—SCALE Project, a consortium of Project Concern International, the Global Alliance to Prevent Prematurity and Stillbirth, and the American College of Nurse-Midwives, gratefully acknowledge the contributions that many individuals and organizations have made to the development of this landscape analysis. Judith Robb-McCord, Director, Every Preemie—SCALE / Project Concern International, James A. Litch, Evidence, Research and Learning Lead, Every Preemie—SCALE / Global Alliance to Prevent Prematurity and Stillbirth, Dawn Greensides, Health Consultant, and Angeline Noriega, Maternal Health Consultant were responsible for the study framework, protocol, and analysis, and authored the report. The team would also like to recognize the valuable contributions of Chelsea Dunning and Rebecca Freeman both with Every Preemie—SCALE / Project Concern International, Kate Kerber, Health Consultant, and Ian Stanley, Graphic Design consultant.

We are particularly grateful to those who supported the landscape analysis in the seven UNCoLSC Pathfinder countries. Participation in the key informant interviews and at the ACS Technical Working Group meeting in Washington, DC demonstrate national commitment to the preterm birth agenda and the implementation of critical, life-saving interventions. We would especially like to thank (in alphabetical order) Dr. Bose Adeniran, Head of Child Health Division, Nigeria Federal Ministry of Health; Dr. Hussein Kidanto, Consultant Obstetrician & Gynecologist, Reproductive, Maternal and Newborn Health Section, Tanzania Ministry of Health; Dr. Delphin Muyila Ikie-Ikie, Pediatrician, Chief of the Neonatology Unit, Provincial Referral Hospital of Kinshasa, Democratic Republic of the Congo; Eneles Kachule, MOH Desk Officer for Care of Low Birth Weight and Premature Babies, Reproductive Health Division, Malawi Ministry of Health; Dr. Alimamy Philip Koroma, Senior Obstetrician/Gynaecologist; Director, Princess Christian Maternity Hospital, Freetown - Cottage Hospital, Sierra Leone: Olivia Hill. Clinical Director-Nurse-Midwife. Aberdeen Women's Centre GLOAG Foundation - Freetown Hospital; Dr. Jeredine George, National Doctor, Aberdeen Women's Centre GLOAG Foundation – Freetown Hospital; Dr. Mariatu Tamimu, National Doctor, Aberdeen Women's Centre GLOAG Foundation - Freetown Hospital; Dr. Lily Varghese, Gynaecologist/Supervisor of Doctors, Aberdeen Women's Centre GLOAG Foundation - Freetown Hospital; Dr. Lisanu Taddesse Gebremariam, Newborn and Child Health Technical Advisor, Ethiopia Federal Ministry of Health; Dr. Laetitia Mavinga, Pediatrician, Neonatology Unit at the Cliniques Universitaires, Kinshasa University, Democratic Republic of the Congo; Dr. Edward Moses, Head of Programs, Maikhanda Trust, Malawi and; Dr. Jesca Sabiiti, Assistant Commissioner Health Services, Child and Newborn Health, Uganda Ministry of Health.

This landscape analysis benefited from the participation of many other partners including representatives from Irish Aid in Sierra Leone, Jhpiego, Management Sciences for Health, Save the Children, Samasha/Uganda, UNICEF, the United States Agency for International Development (USAID), the University Medical Center Utrecht, and the World Health Organization (WHO). The Monitoring and Evaluation team at USAID's flagship Maternal and Child Survival Program deserve a particular note of thanks for sharing the data set from their 2015 Health Management Information System Maternal and Newborn Health (MNH) Indicator Survey conducted across the 23 USAID priority maternal and child survival countries. The survey data provide valuable insights into indicators countries are measuring across the five WHO preconditions for the safe and effective use of antenatal corticosteroids.

The United Nations Commission on Life-Saving Commodities and USAID provided financial support for this work. The views of the funding bodies have not influenced the content of this report.

We would like to acknowledge the diversity of partners in the maternal and newborn health arena and recognize the commitment to innovation and shared learning that informs and drives much of our work. It is our firm hope that the findings from this exercise will be used to further the global dialogue around preterm birth and to inform and strengthen country-level programming to benefit our most important stakeholders—preterm newborns.

### **Executive Summary**

Interventions to prevent preterm birth and promote improved preterm birth outcomes span a woman's reproductive life from pre-pregnancy, through pregnancy, labour and delivery and the postpartum period. In addition to prevention measures and specialized preterm newborn care, there is a growing body of evidence around specific maternal health interventions that can be used to improve preterm birth outcomes in low-income countries. These include tocolytics, magnesium sulfate, antibiotics for preterm premature rupture of membranes, a reduction in routine, early cesarean section and antenatal corticosteroids (ACS).

ACS is one of thirteen critical commodities identified by the United Nations Commission on Life Saving Commodities for Women and Children (UNCoLSC) and is one of ten interventions in the WHO *Recommendations for interventions to improve preterm birth outcomes, 2015.* In early-2016, the USAID-funded Every Preemie—SCALE project was asked by the UNCoLSC Newborn Health Technical Resource Team to conduct a policy and implementation landscape analysis of ACS use for women at risk of imminent preterm birth.

ACS use for fetal lung maturation in pregnant women 24 to 34 weeks gestational age who are at imminent risk of preterm labour is widely acknowledged as an effective, evidence-based intervention for improved preterm birth outcomes.

The landscape analysis was framed around the parameters for the safe and effective use of ACS as outlined in the WHO *Recommendations* and was conducted in seven of the eight UNCoLSC Pathfinder countries—the Democratic Republic of the Congo (DRC), Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda<sup>1</sup>. Data for the landscape analysis were gathered via key informant interviews in each of the seven countries, and via the review of publically available national government documents including national maternal and newborn health strategies and standard treatment guidelines. Data were furthered supplemented by USAID's Maternal and Child Survival Program's 2015 HMIS MNH Indicator Survey conducted in the 23 USAID priority maternal and child health countries. A fourth component involved inclusion of demographic data from the *Every Preemie—SCALE Country Profiles for Preterm and Low Birth Weight Prevention and Care* published in 2015 (see <a href="www.everypreemie.org/countryprofiles">www.everypreemie.org/countryprofiles</a>).

Findings highlight the use of ACS in each of the seven countries and emphasize elements of health sector readiness, the level of care where ACS is being used, providers who are authorized to prescribe and/or administer ACS, health provider training, and the availability of critical maternal and newborn health care services. Key informants also offered further insights into opportunities for and challenges to expanded ACS implementation. While the analysis did not allow scrutiny into the actual *scale* or *quality* of implementation, it does provide valuable information regarding the framework for implementation in these seven countries. Given the dramatic contribution of preterm birth complications to newborn and under-five mortality and the evidence around ACS use, countries are moving forward with its implementation.

Each country with the exception of Nigeria and Sierra Leone have either a national ACS policy and/or guidelines with indicated ACS use ranging from preterm labour alone to threatened preterm birth including eclampsia, and preterm premature rupture of membranes. ACS is approved for use at CEmONC facilities with neonatal intensive care services in the DRC, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda; and a pre-referral dose is approved at the health center level in Ethiopia, Tanzania and Uganda prior to patient transfer to a higher level facility. However, key informant data from those three countries indicate that a pre-referral first dose is not actually being implemented at that level.

In the DRC, Ethiopia, Nigeria, Tanzania, and Uganda only high-level clinical practitioners such as doctors, including obstetrician-gynecologists, are nationally authorized to prescribe ACS. In addition to doctors, Malawi reportedly has mid-level providers including medical or clinical officers prescribing ACS, while Ethiopia has a Masters in Emergency Surgery and Obstetrics cadre also reportedly able to prescribe ACS. Nurses and midwives are allowed to administer ACS with clinical oversight but not prescribe ACS in the DRC, Ethiopia, Malawi, Tanzania, and Uganda. Sierra Leone does not have national guidance for ACS prescriptive authority or administration but it was reported that resident doctors and obstetrician-gynecologists have prescriptive authority while clinical health officers, medical officers, and midwives can administer ACS with clinical oversight.

<sup>&</sup>lt;sup>1</sup> Senegal was excluded from the survey as outreach to potential key informants was unsuccessful.

The WHO *Recommendations* provide guidance for the safe and effective use of ACS when five conditions are met: (1) accurate gestational age calculation, (2) PTB is imminent, (3) no clinical evidence of maternal infection, (4) adequate childbirth care is available, and (5) adequate preterm newborn care is available. There is variability on the inclusion of these conditions in clinical protocols and standard treatment guidelines among the countries. The national level guidance for gestational age criteria varies between countries ranging from 24-37 weeks, 28-34 weeks, and less than 34 weeks with no minimum gestational age required. Importantly, of the seven countries included in this analysis, Malawi, Sierra Leone and Uganda have national level guidance for gestational age criteria that exceeds the 34 week threshold. Nigeria is in the process of revising their standard treatment guidelines and reportedly plans to include how to assess gestational age and how to determine if there is clinical evidence of infection. No other country includes language on how to actually assess gestational age although Ethiopia includes language on postpartum gestational age assessment.

Ethiopia is the only country to include language in its standard treatment guidelines on *how* to determine if a woman is at risk of imminent preterm birth. Only the clinical standards and guidelines in the DRC, Ethiopia and Uganda indicate that ACS use is contraindicated in the presence of maternal infection

The WHO *Recommendations* recommend ACS use when adequate childbirth and newborn care is available. The majority of countries include language in their clinical protocols or standard treatment guidelines emphasizing the availability of adequate childbirth care, while the DRC, Ethiopia, Malawi, Nigeria and Uganda also emphasize the importance of preterm newborn care when using ACS. The majority of countries reported that facilities providing ACS meet comprehensive emergency obstetric and newborn care standards and all countries reported the availability of some form of special newborn care or the availability of Neonatal Intensive Care Units.

Metrics for maternal and newborn care are an essential component of informed programming. The landscape analysis found that none of the seven countries currently have an indicator measuring the use of ACS although Ethiopia, Malawi, Nigeria, Tanzania, and Uganda have each proposed a national indicator for ACS use to be integrated into their health management information systems. Based on analysis of the Maternal and Child Survival Program's 2015 HMIS MNH Indicator Survey, six of the seven Pathfinder countries capture data on a range of proxy indicators related to the five WHO preconditions for the safe and effective use of ACS. The DRC, Ethiopia, Malawi and Nigeria each have an indicator on the diagnosis of preterm birth as a newborn complication in labour and delivery. Other indicators that are captured in two or more countries include four or more antenatal care visits, birthweight, the diagnosis of antepartum hemorrhage in labour and delivery, cesarean section as a method of delivery, resuscitation, and breastfeeding within one hour of birth.

Discussions with country representatives highlighted that while all countries have ACS and other maternal and newborn health interventions available, ACS implementation is fairly nascent. Participants noted that there is great variability in implementation and there are many gaps in consistent coverage, quality, and safe use of ACS and other maternal and newborn health services and interventions. In Sierra Leone, the Ebola outbreak has had a particularly devastating impact on their health system and the delivery of other health care services. Country representatives emphasized that the pace of the global conversation is outpacing the ability of countries to keep implementation current and that countries need time to institutionalize new global recommendations and to harmonize policies, guidelines, and materials.

Future efforts can be directed at more in-depth, field-based surveys to validate the quality of care for the provision of critical aspects of ACS implementation as outlined under the WHO *Recommendations*. The implementation experience and innovative programming at the country level should be captured and shared broadly. This landscape analysis provides a starting point for further enquiry and ideally, will be used to continue meaningful conversations at the global and national levels regarding the safe expansion of ACS for improved preterm birth outcomes.

#### Introduction

This report presents the findings of a recent policy and implementation landscape analysis on the use of antenatal corticosteroids (ACS) for women at risk of preterm birth. The landscape analysis was requested by the United Nations Commission on Life-Saving Commodities for Women and Children's Health (UNCoLSC) Newborn Health Technical Resource Team (TRT). It was designed and conducted by the USAID/Washington-funded Every Preemie—SCALE project. The analysis covered seven of the eight UNCoLSC Pathfinder

Every Preemie—SCALE (Scaling, Catalyzing, Advocating, Learning, Evidence-Driven) was awarded by the United States Agency for International Development (USAID) in 2015. The project is designed to support practical, catalytic, and scalable approaches to expand the uptake of preterm birth (PTB) and low birth weight (LBW) interventions in 23 USAID priority countries mainly in Asia and Africa\*. Every Preemie is implemented by a consortium of partners comprised of Project Concern International (PCI), the Global Alliance to Prevent Prematurity and Stillbirth (GAPPS), and the American College of Nurse-Midwives (ACNM).

\*Afghanistan, Bangladesh, Democratic Republic of the Congo, Ethiopia, Ghana, Haiti, India, Indonesia, Kenya, Liberia, Madagascar, Malawi, Mali, Mozambique, Nepal, Nigeria, Pakistan, Rwanda, Senegal, South Sudan, Tanzania, Uganda, Zambia

countries—the Democratic Republic of the Congo (DRC), Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania, and Uganda. These countries plus Senegal were established as Pathfinder countries via engagement with the UNCoLSC in 2013.

ACS is one of thirteen life-saving commodities identified for maternal, newborn, and child health by the UNCoLSC in 2012, and is included in the World Health Organization (WHO) Recommendations on interventions to improve preterm birth outcomes, 2015. To gather data and information about ACS use in the Pathfinder countries, during April/May 2016, the Every Preemie team used both primary data from key informant interviews, and secondary data gathered from publically available sources, including national standard treatment guidelines, in all countries with the exception of Senegal<sup>2</sup>.

Points of query for this analysis included whether or not ACS is in use and at what level of care, and

the availability of clinical guidelines to determine: if a woman is at risk of imminent preterm birth, the presence of maternal infection, gestational age (GA) parameters, and how to establish accurate measures for GA. The analysis also looked at the availability of comprehensive emergency obstetric care services, and special newborn care services. Key contacts were queried on the strengths of implementation as well as existing challenges and barriers.

Representatives from the DRC, Ethiopia, Malawi, Nigeria, Sierra Leone and Uganda traveled to Washington, DC in mid-June 2016 to participate in the final ACS Technical Working Group (TWG) as formed by the UNCoLSC. The Tanzanian representative was unable to travel. Findings were presented to TWG members including participants from a range of international non-governmental organizations (NGOs), professional associations, and USAID (see Annex A for the ACS TWG Meeting Participants List, June 14, 2016).

### **Background**

#### Preterm Birth—A Public Health Crisis

Every year approximately fifteen million babies are born prematurely (before 37 weeks gestation) and more than one million babies die due to complications of preterm birth. Prematurity is the leading cause of newborn deaths in the first four weeks of life and the leading cause of death among children under five around the world. Preterm birth is also a prominent cause of disability and ill health later in life.

An effective health services response to preterm birth includes its prevention, management of preterm labour, and care for the preterm newborn across two continuums:

- 1. From the household/community to the health center and hospital; and
- 2. From pre-pregnancy and pregnancy through labour and delivery, care of the preterm newborn, and postpartum care for the mother (including family planning for birth spacing).

<sup>&</sup>lt;sup>2</sup> Key informants were unavailable in Senegal.

The vast majority of preterm babies are born between 32 and 37 weeks gestation. Essential newborn care (handwashing, drying, skin-to-skin contact, hygienic cord care, immediate and exclusive breastfeeding) as well as continuous thermal support, adequate feeding, support for breathing difficulties, the prevention and management of infections, and careful monitoring can mean the difference between life and death for these vulnerable newborns.

At the same time, there is a body of evidence around specific maternal health interventions that can be used to improve preterm birth outcomes. These include tocolytics, magnesium sulfate, antibiotics for preterm labour, and a reduction in routine, early cesarean sections. ACS use for fetal lung maturation in select pregnant women who are at imminent risk of preterm labour is also widely acknowledged as an effective, evidence-based intervention for improved preterm birth outcomes.

#### **Thirteen Life-Saving Commodities**

The UNCoLSC was formed in 2012 by the UN Secretary-General as part of the global Every Woman Every Child (EWEC) movement. EWEC challenges the global community to increase access to and appropriate use of essential medicines, medical devices, and health supplies that effectively address the leading preventable causes of death during pregnancy, childbirth, and childhood. The UNCoLSC identified ACS as one of thirteen life-saving commodities within their maternal, newborn, and child health commodities framework (see Table 1). Projections indicated that the potential benefits from investing in these commodities over a five-year period while also promoting health systems strengthening for improved access to and use of these commodities, could save the lives of an estimated six million women and children by 2017<sup>3</sup>.

Table 1. UNCoLSC Life-Saving Commodities and Indicated Use

Table 1. UNCOLSC Life-Saving Commodities and indicated Use					
COMMODITY BY LIFE STAGE INDICATED USE					
Maternal Health Commodities					
1. Oxytocin	Postpartum hemorrhage				
2. Misoprostol	Postpartum hemorrhage				
Magnesium sulfate	Eclampsia and severe pre-eclampsia				
Newborn Health Commodities					
4. Injectable antibiotics	Newborn sepsis				
5. Antenatal corticosteroids	Preterm respiratory distress syndrome				
6. Chlorhexidine	Newborn cord care				
<ol><li>Resuscitation devices</li></ol>	Newborn asphyxia				
Child Health Commodities					
8. Amoxicillin	Pneumonia				
Oral rehydration salts	Diarrhoea				
10. Zinc	Diarrhoea				
Reproductive Health Commodities					
11. Female condoms	Sexually transmitted infections				
12. Contraceptive implants	Family planning/contraception				
13. Emergency contraception	Family planning/contraception				

The UNCoLSC proposed ten recommended actions to advance this important agenda. Recommendations ranged from shaping global and local delivery markets, to innovative financing, quality strengthening for product manufacturing and marketing, improved awareness and utilization, and product innovation.

To move the recommendations to action, eight Pathfinder countries were engaged for focused action and expert groups or TRTs were established. TRTs included Family Planning, Maternal Health, Newborn Health, and Advocacy. The TRTs created technical working groups, spanning the thirteen commodities and ten recommendations, in order to focus on specific aspects of their agendas. The TRTs and related TWGs have been working to advance the UNCoLSC's recommended actions for the past three to four years and are drawing to a close in June 2016.

Since 2013, under the auspices of the Newborn Health TRT, the ACS TWG has convened a range of experts from UN organizations, universities, donors, research, and scientific organizations and NGOs. Members include ACNM, the American College of Obstetrics and Gynecology, the Bill & Melinda Gates Foundation, Cincinnati

<sup>&</sup>lt;sup>3</sup> Every Woman, Every Child. *UN Commission on Life-Saving Commodities for Women and Children Commissioner's Report.* 31 August 2012.

Children's Hospital, GAPPS, Instituto de Efectividad Clinica y Sanitaria, the Maternal and Child Survival Program (MCSP), Save the Children, the US National Institutes of Health, USAID, and WHO. To improve the uptake of ACS in low-income countries the ACS TWG developed a plan to aggregate known data and gather new data related to ACS use and barriers to use, share evidence, and systematically address barriers to ACS use.

In addition, the ACS TWG led the effort to have dexamethasone added to WHO's Essential Medicines List for fetal indications for the specific use of accelerating lung maturity in preterm babies. The ACS TWG also supported the development of the WHO *Recommendations on interventions to improve preterm birth outcomes, 2015.* 

#### WHO Recommendations on interventions to improve preterm birth outcomes

The design of the WHO recommendations was based on the premise that in addition to newborn care interventions, "the most beneficial set of maternal interventions are those that could improve survival chances and health outcomes of preterm infants when preterm birth is inevitable". ACS to improve preterm birth outcomes is among five evidence-based maternal health interventions listed in the WHO *Recommendations*.

The WHO Technical Consultation team that developed the recommendations established ten subrecommendations for ACS use and outlined the overall parameters for its safe and effective use in the following statement.

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:

- Gestational age assessment 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 recognize and safely manage preterm labour and birth); and
- The preterm newborn can receive adequate care if needed (including resuscitation, thermal care, feeding support, infection prevention and treatment and safe oxygen use).

Source: WHO Recommendations on interventions to improve preterm birth outcomes, 2015.

#### **Country-Level Implementation of ACS**

Despite the positive evidence around ACS use, there remain significant challenges and barriers to broaden uptake in low-income countries. In many settings, maternal and newborn health care services remain inconsistent and inadequate, thus compromising the safe use and effectiveness of ACS. A careful interplay of health interventions and available care services is critical to ensure the use of ACS has the intended effect. Prescribing ACS in the absence of, for example, accurate gestational age measures, adequate preterm newborn care, and the ability to identify maternal infections can actually cause harm to the mother and preterm newborn.

Given the dramatic contribution of preterm birth complications to newborn and under-five mortality and the evidence around ACS use, low-resourced countries are moving forward with its implementation. This ACS policy and implementation landscape analysis provides insights into various aspects of programming in seven of the UNCoLSC Pathfinder countries. While the analysis did not allow scrutiny into the actual *quality* of implementation, it does provide valuable information regarding the framework for implementation in these seven countries.

<sup>&</sup>lt;sup>4</sup> World Health Organization. *Recommendations on interventions to improve preterm birth outcomes*. 2015.

### **Design and Implementation**

#### Methodology

The collection and analysis of ACS data across the seven Pathfinder countries was conducted via key informant interviews and a desk review of publically available documents. Data were furthered supplemented by MCSP's 2015 HMIS MNH Indicator Survey conducted in the 23 USAID priority maternal and child health countries. A fourth component involved inclusion of demographic data from the *Every Preemie—SCALE Country Profiles for Preterm and Low Birth Weight Prevention and Care* published in 2015 (see <a href="www.everypreemie.org/country-profiles">www.everypreemie.org/country-profiles</a>).

#### **Key Informant Interviews**

Every Preemie—SCALE developed a semi-structured questionnaire focusing on national-level ACS policy and implementation. The questionnaire was derived from a framework that laid out the overall objectives of the landscape analysis and key points of query. The framework was shared with members of the ACS TWG for their review and input. The framework and questionnaire can be found in Annex B and C, respectively.

Key informants in the study were identified by a variety of in-country and international stakeholders, including USAID/Washington, USAID Mission representatives, implementing partners and via Every Preemie in-country contacts. One key informant was identified for each of the eight Pathfinder countries originally, and additional informants were added as needed to complete the questionnaire. A full list of key informants by country can be found in Annex D. Once key informants in each of the Pathfinder countries were identified, emails were sent explaining the objectives of the landscape analysis, and requesting participation in the country-level interviews. Upon acceptance of participation, an additional email was sent to key informants that provided information on the interview process and included a copy of the WHO Recommendations on interventions to improve preterm birth outcomes, 2015. Despite several attempts to reach suggested key informants in Senegal, efforts were unsuccessful. Senegal was therefore omitted from the exercise.

When possible, the key informant interviews were conducted over the phone or in-person during a four-week period between April 6 and May 6, 2016. Due to language or telephone connection issues, three participants were provided an electronic copy of the questionnaire to record their written responses. The questionnaire was also professionally translated into French for key informants from the DRC who preferred to provide written responses in French. See Table 2 for the number of key informants and method of interview by country.

Table 2. Number of Key Informants and Method of Interview by Country

COUNTRY NUMBER OF KEY INFORMANTS METHOD OF INTERVIEW		METHOD OF INTERVIEW
DRC	2	Phone interview with one informant and provision of French questionnaire to both informants for written responses
Ethiopia	1	Phone interview
Malawi	2	In-person interviews
Nigeria	1	Phone interview
Sierra Leone	4	Phone interview and provision of questionnaire to finalize answers due to poor connection
Tanzania	1	Written responses
Uganda	1	In-person interview

#### **Desk Review**

A desk review and analysis of secondary information on ACS policy and use was completed during March and April 2016 to complement the information gathered via the key informant interviews. Publically available documents, including: national standard treatment guidelines, essential medicines lists, drug formularies, national strategies and plans, national roadmaps, programmatic reports, and intrapartum protocols were collected and reviewed for each country. A full list of documents reviewed for each country can be found in Annexes H through N. Relevant information on the use of ACS in the country was abstracted and used to validate information provided via the key informants. Updated information and national documents were provided by Ethiopia, Malawi, Nigeria and Sierra Leone at the June TWG meeting.

Global-level documents, including the *Countdown to 2015* report<sup>5</sup>, the UN Commission on Life Saving Commodities report<sup>6</sup>, and relevant journal articles were also reviewed<sup>7,8</sup>. Other global sources that were reviewed included:

- Countdown 2014 health systems and policy survey dataset collected by WHO from December 2013 to June 2014;
- Regulatory and procurement survey collected between August 2013 and March 2014 by the WHO
  Essential Medicines and Health Products Department, using two modules from the Landscape
  Synthesis of Reproductive, Maternal, Newborn and Child Health and Life-Saving Commodities (RMNCH
  Landscape Synthesis) from the UNCoLSC; and
- Landscape Synthesis of Reproductive, Maternal, Newborn and Child Health and Life-Saving Commodities (RMNCH Landscape Synthesis) from the UNCoLSC 2014 for Nigeria and 2013 to complete other data points from other countries.

See Annex E for a list of individuals who supported the implementation of the landscape analysis.

#### **Analysis of the HMIS MNH Indicator Survey**

Questions regarding the inclusion of ACS indicators in national health management information systems (HMIS) were included in the key informant interview questionnaire. To supplement this information, the landscape analysis team reached out to USAID's MCSP team on their 2015 HMIS survey conducted in the 23 USAID priority maternal and child health (MCH) countries. The team reviewed the full indicator list captured by the MCSP HMIS MNH Indicator Survey and prioritized indicators that could be used as proxy indicators against the five WHO preconditions for the safe and effective use of ACS (see Annex F). MCSP searched their database and provided a list of these indicators across six of the Pathfinder countries: the DRC, Ethiopia, Malawi, Nigeria, Tanzania and Uganda<sup>9</sup>. Specific indicators are highlighted within each country summary. While these indicators do not provide any information regarding the actual delivery of services, they do provide a sense of where countries are with respect to monitoring critical maternal and neonatal health care services and interventions.

#### **Every Preemie Preterm Birth/Low Birth Weight Country Profiles**

Demographic data from the *Every Preemie—SCALE Preterm Birth Country Profiles* published in 2015 were used to inform the country-level demographics illustrated in the country infographics for this report. Demographic data presented in the Every Preemie country profiles were derived from secondary data sources including population-based surveys such as the Demographic and Health Survey (DHS), Multiple Indicator Cluster Surveys (MICS) and Service Provision Assessments (SPA), where available.

#### **Challenges and Limitations**

Due to the limited time available for this study, interviews were held with one to four key informants in each country. Representatives from each country had relevant experience and information regarding the use of ACS for women at imminent risk of preterm labour and were able to provide valuable insights. The key informants were nominated by knowledgeable local and global experts, providing a purposeful sample. However, interviews may not be representative of all views, or even the dominant view.

In every case possible, verification of the key informant interview data was obtained using country-level documentation obtained in the desk review. However, verification of key informant data was not possible for care practices or the quality of those practices such as adequate preterm newborn care and childbirth care. For Sierra Leone, the national level standard treatment guidelines and the updated Essential Medicines List were unavailable.

<sup>&</sup>lt;sup>5</sup> Countdown to 2015: A Decade of Tracking Progress for Maternal, Newborn and Child Survival *The 2015 Report.* 

<sup>&</sup>lt;sup>6</sup> Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries 2015. September 2015. World Health Organization, Department of Essential Medicines and Health Products.

<sup>&</sup>lt;sup>7</sup> Antenatal corticosteroids for management of preterm birth: a multi-country analysis of health system bottlenecks and potential solutions, BMC 2015.

<sup>&</sup>lt;sup>8</sup> Basic Newborn Care Bottle Neck Analysis, BMC 2015.

<sup>9</sup> Sierra Leone is not a priority USAID MCH country, therefore, the MCSP HMIS survey did not capture this information for Sierra Leone.

This landscape analysis focused on public sector services and does not reflect the implementation of ACS in private sector health facilities.

There were inconsistencies between the raw data provided from the Countdown, WHO, and UNCoLSC reports, and the secondary data obtained through the landscape analysis desk review. The landscape analysis team attempted to gain information on how the raw data were gathered and validated, but was unable to gain clarification on the protocols used by the other surveys.

Every effort was made to identify all of the available secondary information for review and analysis in each country. Although it is possible that documents were missed or that a more up-to-date version was not identified, the team used multiple sources to identify relevant materials to mitigate this risk.

### **Overview of Findings**

#### **ACS Guidelines and Implementation**

National-level policies and guidelines are a critical foundation when adopting a new intervention and all countries interviewed have either a national ACS policy and/or guidelines with indicated ACS use ranging from preterm labour alone to threatened preterm birth including eclampsia, and preterm premature rupture of membranes (pPROM).

ACS is approved for use at tertiary facilities in the DRC, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda; and a pre-referral dose is approved in Ethiopia, Tanzania and Uganda prior to patient transfer to a higher level facility. Interestingly, while ACS is approved for use at facilities below tertiary levels of the health care system in Ethiopia, Tanzania and Uganda, key informant data indicate that ACS is not actually being implemented at those levels. See Table 3 for a list of countries and approved level of care for ACS use and actual level of use. Reported reasons for not implementing ACS at all levels where it is approved included: inadequate newborn care at lower levels of care, ACS is not available, guidelines for ACS are not available at lower levels of care, staff at lower level facilities are not adequately trained to provide ACS safely and implementation is on hold due to outcomes of the Antenatal Corticosteroids Trial (ACT)<sup>10</sup>.

Table 3: ACS Guidelines and ACS Implementation by Country

Table 3: ACS Guidelines and ACS implementation by Country				
COUNTRY	APPROVED LEVEL OF CARE FOR ACS USE	WHERE ACS ACTUALLY IN USE	INDICATIONS FOR USE	PRE-REFERRAL DOSE ALLOWED
DRC	Tertiary and Maternity Hospitals	Tertiary and maternity hospital in capital city only	pPROM, eclampsia, preterm labour	No
Ethiopia	Referral, General, Primary Hospitals, and Health Centers	Tertiary and Secondary hospitals	Preterm labour	Yes
Malawi	Central and District Hospitals	Central and District Hospitals	Preterm labour	No
Nigeria	Tertiary Hospitals	Tertiary hospitals	Preterm labour	No
Sierra Leone	Tertiary Hospitals including District Referral Hospitals	Tertiary and District Referral Hospitals	None	No
Tanzania	Hospitals, Health Centers	Hospitals	Preterm labour	Yes
Uganda	Hospitals, Health Centers IV, III, and II	Hospitals, Health Center IV	pPROM and "risk of preterm delivery"	Yes

<sup>&</sup>lt;sup>10</sup> ACT was a population-based, multifaceted strategy to implement an ACS intervention package for women up to 36 weeks gestation age versus standard care for the reduction of neonatal mortality due to preterm birth in low-income and middle-income countries. Since the study was not designed to reliably determine gestational age for all participants, the proxy outcome used was mortality among those born below the 5th percentile for birth weight. Study outcomes included an increase in neonatal deaths in the intervention group and the risk of maternal infections seemed to have increased for women exposed to ACS as an intervention. The full body of evidence to date including ACT suggests that ACS should only be used for gestational age between 24 and 34 weeks and only when a specific set of conditions can be met.

#### **Provision of ACS**

In the DRC, Ethiopia, Nigeria, Tanzania, and Uganda only high-level clinical practitioners such as doctors, including obstetrician-gynecologists, are nationally authorized to prescribe ACS. In addition to doctors, Malawi reportedly has mid-level providers including medical or clinical officers prescribing ACS, while Ethiopia has a Masters in Emergency Surgery and Obstetrics cadre also reportedly able to prescribe ACS. Nurses and midwives are allowed to administer with clinical oversight<sup>11</sup> but not prescribe ACS in the DRC, Ethiopia, Malawi, Tanzania, and Uganda. Also, in Ethiopia nurses and midwives at the health center level are authorized to prescribe and administer a pre-referral first dose of ACS. Sierra Leone does not have national guidance for ACS prescriptive authority or administration but one key informant reported resident doctors and obstetrician-gynecologists have prescriptive authority while clinical health officers, medical officers, and midwives can administer ACS with clinical oversight. The key informant from Uganda reported that restricting ACS prescriptive authority to only high-level providers significantly limits accessibility of ACS since labour wards are often staffed with nurses and midwives rather than high-level practitioners.

#### **Clinical Standards**

The WHO *Recommendations* provide guidance for the safe and effective use of ACS when five conditions are met: (1) accurate gestational age calculation, (2) PTB is imminent, (3) no clinical evidence of maternal infection, (4) adequate childbirth care is available, and (5) adequate preterm newborn care is available. Based on a review of the most currently-available clinical protocols and/or standard treatment guidelines in each of the seven countries, there is variability on the inclusion of these conditions in these documents among the countries. Ethiopia is the only country to include language in its standard treatment guidelines (STGs) on how to determine if a woman is at risk of imminent preterm birth. Only the clinical standards and guidelines in the DRC, Ethiopia and Uganda indicate that ACS use is contraindicated in the presence of maternal infection. Nigeria is in the process of revising their STGs and reportedly plans to include how to assess GA and how to determine if there is clinical evidence of infection. The majority of countries, however, include language in their clinical protocols or STGs emphasizing the availability of adequate childbirth care, while the DRC, Ethiopia, Malawi, Nigeria and Uganda also emphasize the importance of newborn care when using ACS. See Table 4 for a summary of the WHO sub-recommendations and their inclusion in national clinical protocols and/or STGs.

Table 4. National-Level Clinical Standards and Guidelines that Support the Provision of ACS by Country as per the WHO Recommendations

Antenatal corticosteroid therapy is recommended for women at imminent risk of preterm birth from 24 weeks to 34 weeks of gestation when the following criteria are met:					
Condition	Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Adequate preterm newborn care is available
DRC	No	No	Yes	Yes	Yes
Ethiopia	No	Yes	Yes	Yes	Yes
Malawi	No	No	No	Yes	Yes
Nigeria	No	No	No	Yes	Yes
Sierra Leone	No info	No info	No info	No info	No info
Tanzania	No	No	No	Yes	No
Uganda	No	Yes	Yes	Yes	Yes

One of the more challenging aspects of ACS use is the accurate determination of GA for women at risk of imminent preterm birth. Given too early or too late in a pregnancy, ACS can have a negative impact on the health of the preterm newborn. A GA range of at least 24 weeks and not more than 34 weeks of pregnancy is an important clinical standard to guide the decision making process for the use of ACS. Five of the seven countries—DRC, Ethiopia, Malawi, Tanzania, and Uganda—have national-level criteria for GA appropriate to the

<sup>&</sup>lt;sup>11</sup> Clinical oversight refers to physical or non-physical supervision by a provider with prescriptive and administrative authority over a provider who has administrative authority only.

safe use of ACS. Only Sierra Leone does not have a nationally standardized GA range, but the key informant reported a commonly accepted GA of 28-35 weeks. Nigeria is reportedly in the process of revising the STGs to include a GA of 30-34 weeks, however current STGs do not yet reflect this update. The national-level guidance for GA criteria varied between countries ranging from 24-37 weeks, 28-34 weeks, and less than 34 weeks with no minimum gestational age required. Importantly, Malawi, Sierra Leone and Uganda have national level guidance for GA criteria that exceeds the 34 week threshold. See Table 5 for GA range by country.

While four of the seven countries have national criteria for the GA range appropriate to receive ACS, none of the countries currently have national level guidance on how to calculate GA relevant to preterm labour. In the Ethiopian *Management Protocol on Selected Obstetric Topics for Health Centers, March 2014*, there is a detail on how to determine GA, but it is found only in the Post Term Pregnancy Section.

Table 5. National-Level Criteria and Reported Criteria for Gestational Age Parameters for ACS Use by Country

COUNTRY	GA CRITERIA	ADDITIONAL INFORMATION
DRC	28-34 weeks	
Ethiopia	28-34 weeks	
Malawi	<34 weeks 28-34 weeks 24-37 weeks	GA criteria varies between national documents available for review.
Nigeria	30 – 34 weeks	No national level criteria, GA reported by key informant
Sierra Leone	28-35 weeks	No national level criteria, GA reported by key informant
Tanzania	28-34 weeks	As low as 24 weeks if birth is at a well-equipped facility with a specialist available to manage the premature newborn.
Uganda	32-37 weeks	

#### **Comprehensive and Basic Emergency Obstetric and Newborn Care**

According to the WHO *Recommendations*, ACS is recommended when adequate childbirth care is available. Facilities meeting comprehensive emergency obstetric and newborn care (CEmONC) standards are the most well-equipped and staffed to handle higher risk labour and complications related to preterm delivery. The DRC, Ethiopia, Malawi, Sierra Leone, Tanzania, and Uganda reported that facilities providing ACS meet CEmONC standards. Nigeria stated some but not all tertiary facilities providing ACS meet CEmONC standards. Malawi reported facilities authorized to provide pre-referral first dose ACS at lower levels of the health care system meet basic emergency obstetric and newborn care (BEmONC) standards.

#### **Special Newborn Care and Neonatal Intensive Care**

The safe and effective use of ACS includes the provision of comprehensive preterm newborn care. All countries reported the availability of some form of special newborn care or the availability of Neonatal Intensive Care Units (NICUs). Wide variation exists among countries regarding the availability of NICUs where ACS is given. Only DRC and Tanzania require a NICU to be in place in order to give ACS; however, Tanzania also reported that NICUs are often not available in facilities providing ACS. The DRC and Nigeria reported that NICUs are always present in facilities providing ACS, while Ethiopia, Malawi, and Uganda reported that NICUs are reportedly available in facilities that most often provide ACS. Sierra Leone's key informants reported that NICUs are not available in private facilities providing ACS. It was further clarified at the June ACS TWG meeting that NICU care is only available at one hospital in Freetown, Sierra Leone and is limited in terms of quality of care.

The WHO *Recommendations* specify ACS use only when adequate preterm newborn care is available including resuscitation, thermal care, infection prevention and treatment, feeding support, and safe oxygen use. All countries reported that these preterm newborn care interventions are available at facilities providing ACS, although they were not specifically stated as *required* to be in place to provide ACS. Key informant data also indicated that because these interventions are not currently required nor defined by the MOH, the availability, content and quality of the preterm newborn care interventions varies widely across facilities and countries. See Table 6 below highlighting which preterm newborn care interventions are reportedly available by country.

Table 6. Preterm Newborn Care Interventions by Country per WHO Recommendations Reported by Key Informants

COUNTRY	RESUSCITA- TION	THERMAL CARE	INFECTION PREVENTION AND TREATMENT	FEEDING SUPPORT	SAFE OXYGEN USE
DRC	Bag & mask	<ul> <li>Skin-to-skin</li> <li>Incubators (not prevalent)</li> <li>Kangaroo Mother Care (KMC)</li> </ul>	<ul><li>Handwashing</li><li>Antibiotics</li><li>Separate unit for sick babies</li></ul>	<ul> <li>Nasogastric (NG) tubes</li> <li>Daily weight monitoring</li> <li>Daily intake monitoring</li> </ul>	<ul><li>Oxygen mixers</li><li>Oxygen titration</li><li>Pulse oximetry</li></ul>
Ethiopia	Bag & mask	<ul> <li>Drying, cleaning, wrapping</li> <li>Skin-to-skin</li> <li>KMC</li> <li>Radiant warmers/ incubators</li> </ul>	<ul><li>Antibiotics</li><li>Sterilization of equipment</li><li>Handwashing</li></ul>	<ul> <li>Exclusive breastfeeding</li> <li>Expressed milk</li> <li>Tube feeding</li> <li>Daily weight monitoring</li> </ul>	<ul><li>Titrate oxygen</li><li>Oxygen concentrators</li></ul>
Malawi	Bag & mask	Skin-to-skin     Incubators     (some available)	Hand washing     Antibiotics     Separate ward sick babies	NG tube     Expressed     breast milk     Daily weight     monitoring	Oxygen mixer     Pulse oximetry     Oxygen titration
Nigeria	Bag & mask	KMC     Incubators (at general hospitals)	Aseptic technique     Antibiotics     Separate wards for sick babies	NG tube     (general and teaching hospitals)     Breastfeeding and all feeding alternatives	Pulse oximetry
Sierra Leone	Bag & mask	Dry, warm, stimulate     KMC	Antibiotics	<ul> <li>Expressed breast milk</li> <li>Formula</li> <li>NG tube</li> <li>Daily weight monitoring</li> </ul>	Oxygen mixer     Pulse oximetry
Tanzania	Bag & mask	Skin-to-skin     Incubators	<ul><li>Handwashing</li><li>Antibiotics</li><li>Separate ward for sick babies</li></ul>	<ul><li>NG tube</li><li>Expressed breast milk</li><li>Daily weight monitoring</li></ul>	<ul><li>Oxygen mixer</li><li>Pulse oximetry</li><li>Oxygen titration</li></ul>
Uganda	Bag & mask	Skin-to-skin     Incubators     (limited supply     and irregular     power supply)	Handwashing     Antibiotics     Separate ward     for sick babies	NG tube     Expressed breast milk     Daily weight monitoring	Oxygen mixer/ concentrator (limited use due to irregular power supply)

#### **National Essential Medicines List (EML)**

Corticosteroids are on the EML for all countries, however, they are not listed for obstetric indications in any of the seven countries. Key informant data from Nigeria reported that ACS is indicated for obstetric purposes in the revised EML to be released later in 2016.

#### **Human Resources Training and Capacity Building**

There was limited secondary data elaborating on the inclusion of ACS in pre-service and in-service training. Key informants in Ethiopia, Nigeria and Uganda reported that ACS is in their pre-service clinical training materials. In addition, the DRC, Ethiopia, Malawi, Sierra Leone, Tanzania, and Uganda reported having ACS in their inservice clinical training materials. All countries listed training and capacity building for health care providers on ACS as an area of identified need for their programs. No information was collected on the content or comprehensiveness of either pre-service or in-service training for ACS implementation.

#### **Metrics for ACS**

None of the countries in the landscape analysis have an existing indicator for ACS use in their HMIS. However, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda have each proposed a national indicator for ACS to be integrated into the HMIS. Ethiopia, Malawi, and Tanzania have a nationally proposed indicator for ACS specifying "women less than 34 weeks receiving ACS." Other proposed indicators mentioned include: stock out of ACS in the past month, hospitals providing ACS, women receiving steroids with delivery between 24-27 weeks gestation, women receiving steroids with delivery between 28-34 weeks gestation and women in preterm labour receiving at least one dose of ACS before delivery.

Analysis of MCSP's 2015 HMIS MNH Indicator Survey revealed that six of the seven Pathfinder countries (the DRC, Ethiopia, Malawi, Nigeria, Tanzania, and Uganda) captured data on a range of proxy indicators related to the five WHO preconditions for the safe and effective use of ACS<sup>12</sup>. These include number of ANC visits (4 or more); maternal complications (pre-eclampsia/eclampsia) diagnosed in antenatal care (ANC); preterm birth as a complication diagnosed in labour and delivery; maternal complications diagnosed in labour and delivery (pPROM and antepartum hemorrhage); maternal gestational age measured in labour and delivery; maternal blood transfusion; essential newborn care including breastfeeding within one hour of birth and immediate skinto-skin contact; and newborn resuscitation in labour and delivery.

Each of the six countries is capturing ANC (4+ visits) and all but Nigeria are capturing GA (in weeks) in ANC. Malawi has an indicator for the diagnosis of pre-eclampsia/eclampsia in ANC while Ethiopia, Malawi and

Tanzania have indicators for the diagnosis of antepartum hemorrhage in labour and delivery. The DRC is the only country with an indicator for the active management of the third stage of labour, and both Malawi and Tanzania have indicators for cesarean section as a method of delivery. All countries but Nigeria have an indicator for breastfeeding within one hour of birth and only Uganda has an indicator for immediate skin-to-skin contact as part of essential newborn care. Nigeria is the only country with an indicator for referral to KMC for postnatal care as part of managing

The DRC, Ethiopia, Malawi and Nigeria each have an indicator on the diagnosis of preterm birth as a newborn complication in labour and delivery.

newborn complications. See Annex G for a full list of indicators by WHO precondition for the safe and effective use of ACS across all countries but Sierra Leone.

#### ACS Implementation: Lessons Learned, Strengths, Opportunities, Challenges

Key informants shared their country-specific views on lessons learned, strengths, opportunities, and challenges regarding the implementation of ACS in their countries. Strengths for implementation include "strong political will and partner support for this intervention", and the recognition that "guidelines, policies exist for most countries". Key informants also see ACS implementation as an opportunity to "strengthen quality of ANC", and "increase community awareness to reduce delay in diagnosis (of preterm labour)".

Reported reasons for not implementing ACS at all levels of care where it is approved in the seven Pathfinder countries include "inadequate newborn care at lower levels of care", "ACS is not available", "guidelines for ACS are not available at lower levels of care", "staff at lower level facilities are not adequately trained to provide ACS safely", and safety concerns due to outcomes of the Antenatal Corticosteroid Trial (Ethiopia, Tanzania and Uganda) published in 2014. Other challenges as reported by key informants include "inadequate provider training and capacity building", "the lack of specific implementation guidelines for the new WHO *Recommendations*", "the lack of diagnostics such as ultrasound for gestational age assessment" and "the prevalence of births in facilities where ACS use is not approved".

Key informants expressed a wide range of areas needing additional support to ensure the safe use of ACS including "the need to align policies, guidelines, and pre-service and in-service clinical training with the most up-to-date information on ACS use", "improved supply chain management", "research on the practicalities and safe use of ACS in low-income countries", "the authorization of facilities providing basic emergency obstetric and newborn care facilities to provide ACS", and "the need to authorize midwives and nurses to prescribe ACS". See Table 7 for a complete list of lessons learned, strengths, opportunities and challenges highlighted by key informants.

<sup>&</sup>lt;sup>12</sup> As previously mentioned, Sierra Leone is not a USAID priority MCH country and therefore was not included in MCSP's HMIS survey.

Table 7. Compiled List of ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges

Reported by Key Informants

Reported by Key Informants	
LESSONS LEARNED	<ul> <li>"ACS on EML for obstetric use"</li> <li>"Intervention needs to be cost effective"</li> <li>"Need comprehensive package not just guidelines"</li> <li>"Including BEmONC facilities would expand reach of ACS"</li> <li>"Stakeholders need to be informed of new WHO recommendations"</li> <li>"Policies, guidelines, pre-service education, in-service education, regulatory bodies all need alignment"</li> </ul>
	"Need increased community awareness of PTB"
STRENGTHS	<ul> <li>"MOH involvement and ownership"</li> <li>"Guidelines, policies exist for most countries"</li> <li>"Strong political will and partner support for this intervention"</li> </ul>
OPPORTUNITIES	<ul> <li>"Expand standards and guidelines to include assessment (i.e. how to determine who should receive ACS)"</li> <li>"Need studies of ACS impact at scale"</li> <li>"Partner commitment, political will"</li> <li>"Strengthen quality of ANC"</li> <li>"Increase community awareness to reduce delay in diagnosis"</li> </ul>
CHALLENGES	<ul> <li>"Inadequate training and capacity building"</li> <li>"Inadequate information available to safely scale up in low income countries"</li> <li>"Delay in diagnosis of preterm labour"</li> <li>"ACS not in pre-service training"</li> <li>"Poor supply chain"</li> <li>"Lack trained health care workers"</li> <li>"No specific implementation guidelines for new WHO recommendations"</li> <li>"Lack of diagnostics such as ultrasound for GA"</li> <li>"Many deliveries are occurring at lower level facilities where it is not appropriate to provide ACS"</li> </ul>

#### **Additional Support Needed**

Key informants reported a wide range of areas needing additional support to ensure the safe use of ACS for women at risk of imminent preterm birth. Suggestions for additional support included:

- "Increase training of healthcare workers in ACS including financial support";
- "Authorize nurses and midwives to prescribe ACS":
- "Provide supportive supervision for ACS program";
- "Integrate ACS into pre-service";
- "Development of a HMIS indicator for ACS use";
- "Include ACS across all policy, guidelines, pre-service, in-service training, and regulatory practices and harmonize these documents and services";
- "More research on practicalities and safety of ACS use in low income countries"; and
- "Improve supply chain management".

### **Country Summaries**

Democratic Republic of the Congo Ethiopia Malawi Nigeria Sierra Leone Tanzania Uganda



# DEMOCRATIC REPUBLIC OF THE CONGO



ACS POLICY AND IMPLEMENTATION LANDSCAPE ANALYSIS FOR WOMEN AT RISK OF IMMINENT PRETERM BIRTH

### **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



Integrated Maternal, Newborn, and Child Standards for Health, Volume 2 - Obstetric Emergency Care, April 2012

Maternal, Newborn, and Child Standards for Health, User Manual, April 2015

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection.

How to determine gestational age (GA) when giving ACS



is prescribed in country Minimum gestational age

Maximum gestational age

Gestational age at which ACS



Included on list



Corticosteroids on the

**Essential Medicines List** 

### PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 12% Low birth weight rate (babies born <2,500g): 10%

> Babies born preterm per year: 382,000 Ratio of boys to girls born preterm: 1.17

Babies born per year <28 weeks: 17,200 Impaired preterm survivors per year: 8,300 Direct preterm child deaths per year: 40,600

Births at health facility: 80%

See http://www.everypreemie.org/country-profiles/ for data sources.



### **ACS USE**

Facilities authorized to provide ACS

**Tertiary and Maternity Reference** Hospitals in Kinshasa

Facilities authorized to provide a pre-referral first dose of ACS

No data



Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth

In-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth



### **ベツ METRICS**

ACS use captured in HMIS

No data

Yes





### **ACS PRESCRIPTION AND ADMINISTRATION**

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Medical Doctors
- Obstetricians/Gynecologists

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Residents of Obstetrics & Gynecology
- Midwives
- Nurses

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

No data



sources



### MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Comprehensive emergency obstetric and newborn care (CEmONC) services

Resuscitation

Thermal care

Infection prevention/treatment



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS





### IMPLEMENTATION CHALLENGES AND STRENGTHS

Challenges to the implementation of ACS use in country:

- 1. Significant training and capacity building needed at all levels of health care.
- 2. Insufficient information to expand the safe use of ACS.
- 3. There is a long delay in the diagnosis of preterm labour, making interventions difficult.

Strengths of country's ACS implementation process:

- 1. The Ministry of Health has oversight of the ACS program including the design and use of standards and guidelines related to ACS use.
- 2. ACS is included in training materials for on-the-job training.
- 3. The administration of ACS is easy.

Source: McCord, JR, Litch JA, Greensides D, Noriega A. Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in the Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda - A Policy and Implementation Landscape Analysis; Washington DC: UNCoLSC and Every Preemie - SCALE; June 2016.



## RÉPUBLIQUE DÉMOCRATIQUE DU CONGO



ADMINISTRATION PRÉNATALE DE CORTICOSTÉROÏDES (CI-APRÈS ACS) CHEZ LA FEMME PRÉSENTANT UN RISQUE IMMINENT D'ACCOUCHEMENT PRÉMATURÉ

### NIVEAU DE PRÉPARATION DU SECTEUR MÉDICAL

Les ACS dans les recommandations cliniques en cas de naissance prématurée



- Normes de santé intégrée pour la mère, le nouveau-né et l'enfant, Tome 2 – Soins d'urgence obstétrique, Avril 2012

 Normes de santé pour la mère, le nouveau-né et l'enfant, Mode d'emploi, Avril 2015 Recommandations au niveau national ou critères pour déterminer si une femme présente un risque imminent d'accouchement prématuré



Recommandations au niveau national ou critères:

Indique que l'administration d'ACS est contre-indiquée en cas d'infection





Âge gestationnel maximal (en semaines)

Âge gestationnel minimal

(en semaines)

Âge gestationnel auquel les

ACS sont prescrits dans le pays



(28

Corticostéroïdes dans la liste des médicaments essentiels

Contenus dans la liste





### NAISSANCES PRÉMATURÉES ET DÉCÈS

Taux de naissances prématurées (bébés nés avant 37 semaines):12%

Taux de faible poids de naissance (bébés nés avec un poids inférieur à 2 500 g): 10%

Bébés nés prématurés par an: 382,000

Rapport du nombre de garçons au nombre de filles nés prématurés: 1.17

Bébés nés avant 28 semaines par an: 17,200

Nombre annuel de prématurés survivants présentant des

Décès d'enfants liés directement à la naissance prématurée par an: 40,600

Naissances dans l'établissement de santé (pourcentage): 80%



### **USAGE DES ACS**

Établissements habilités à fournir des ACS

Établissements habilités à administrer une première dose d'ACS pré-transfert

Hôpitaux de référence en maternité et hôpitaux tertiaires à Kinshasa

Aucune donnée



### **FORMATION**

Selon certaines sources, les curriculums pré-service incluent l'administration d'ACS chez la femme présentant un risque imminent d'accouchement prématuré

Selon certaines sources, les curriculums en service incluent l'administration d'ACS chez la femme présentant un risque imminent d'accouchement prématuré



### **INDICATEURS**

déficiences: 8,300

Usage des ACS mesuré par le système HMIS (système de gestion médicale informatique)

Aucune donnée



### PRESCRIPTION ET ADMINISTRATION D'ACS

Membres du personnel soignant autorisés à prescrire et administrer de manière indépendante un traitement complet aux ACS

- Médecins
- Gynécologues et obstétriciens

Membres du personnel soignant autorisés à prescrire et administrer un traitement complet aux ACS sous supervision clinique

- Sages-femmes
- Infirmières

Membres du personnel soignant autorisés à administrer une première dose pré-transfert sous supervision clinique

Aucune donnée



Oui

Non

Veuillez vous reporter à l'annexe correspondante de ce rapport pour consulter les sources d'informations.



### SOINS CLINIQUES DE LA MÈRE ET DU NOUVEAU-NÉ

Services principaux liés à un usage sûr et efficace des ACS

Établissements habilités à fournir un traitement ACS complet fournissent aussi, selon certaines sources:

Services de base en soin néonatal et obstétrique d'urgence (BEmONC)

Services complets en soin néonatal et obstétrique d'urgence (CEmONC)



 $\bigotimes$ 

Interventions néonatales disponibles, selon certaines sources, dans les établissements administrant un traitement complet aux ACS:

Réanimation

Traitement thermique

Prévention et traitement des infections



Accompagnement de l'allaitement



Utilisation sûre de l'oxygène



Des unités de soins intensifs néonatals ou de soins spécialisés sont disponibles, selon certaines sources, dans les établissements administrant un traitement complet aux ACS



### DÉFIS À LA MISE EN ŒUVRE ET SOLUTIONS

Défis principaux à la mise en œuvre de l'usage des ACS dans le pays:

- 1. Des formations importantes et des renforcements de capacité sont nécessaires a tous les niveaux des soins de sante.
- 2. Informations insuffisantes pour étendre l'utilisation sécurisée d'ACS.
- 3. Le grand retard dans le diagnostic des accouchements prématurés explique les difficultés dans les interventions.

Points forts du pays dans le processus de mise en œuvre des ACS dans le pays:

- Le Ministère de la Santé a supervisé le programme des ACS, notamment la rédaction et l'application des normes et recomman dations liées à l'usage des ACS.
- 2. Les ACS font partie des matières incluses dans les formations continues.
- 3. Administrer des ACS est simple.

La source de données: McCord, JR, Litch JA, Greensides D, Noriega A. Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in the Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda - A Policy and Implementation Landscape Analysis; Washington DC: UNCoLSC and Every Preemie - SCALE; June 2016.

#### **Democratic Republic of the Congo**

#### **ACS Guidelines and Implementation**

Key informants in the DRC reported that ACS is provided at tertiary and maternity reference hospitals in Kinshasa, but there was no knowledge about whether or not ACS is being used outside the capital for women at risk of preterm labour. Provision of ACS for obstetric indications at hospitals in Kinshasa, including preterm labour, premature rupture of membranes (PROM), and eclampsia, is consistent with the *Maternal, Newborn*,

#### **DRC**

ACS is indicated for preterm labour, PROM, and eclampsia in tertiary and maternity hospitals in the DRC.

Sources: Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012, and Maternal, Newborn, and Child Standards for Health, User Manual, April 2015 and Child Standards for Health, User Manual, April 2015 (Normes de la Zone de Sante Relatives Aux Interventions Intégrées de Sante de la Mère, Du Nouveau-Né et De L'Enfant en République Démocratique du Congo, Guide D'Utilisation. Avril 2015), and the Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012 (Normes de la Zone de Sante Relatives Aux Interventions Intégrées de Sante de la Mère, Du Nouveau-Né et De L'Enfant en République Démocratique Du Congo: Volume 2. Soins Obstétricaux D'Urgence, Avril 2012). There was no indication in any of the national documents that a pre-referral dose from a lower level facility was authorized, and this was confirmed via the key informant interviews.

Other national guidelines or documents that include ACS for obstetric indications include:

 Obstetric Care Training and Neonatal Emergency Facilitators Guide, May 2012 (Formation en Soins Obstétricaux et Néonatals d'Urgence, Guide du Facilitateur, Mai 2012).

For detailed information contained in relevant national documents, see Annex H. Democratic Republic of the Congo: Clinical Guides and Related Preterm Birth Interventions.

Although the national standards do not specifically indicate who is authorized to prescribe or administer ACS for preterm labour, key informants stated that medical doctors and obstetrician-gynecologists are allowed to prescribe and administer ACS, while residents of obstetrics-gynecology, nurses, and midwives are allowed to administer ACS with clinical oversight.

#### **Clinical Standards**

The DRC national clinical standards indicate that the provision of ACS is indicated between 28 and 34 weeks GA, but they do not provide specific information or direction on how to accurately assess GA. Key informants stated that medical practitioners use the following methods: last menstrual period (LMP), fundal height measurement, and ultrasound. The national standards do not provide specific information on how to determine if preterm birth is imminent but do provide detailed information on how to diagnose PROM and eclampsia <sup>13</sup>, which can lead to preterm birth. The national standards do clarify that ACS is not indicated when maternal infection is present. However, there is no guidance for how to determine if a pregnant woman has an infection.

See Table 8 below for highlights of standards and services that are in place in the DRC to support the provision of ACS as per the WHO *Recommendations*.

<sup>&</sup>lt;sup>13</sup> Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012. DRC Ministry of Health, Secretariat General.

Table 8: Standards and Services to Support the Provision of ACS as per the WHO Recommendations in the DRC

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:					
Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Adequate preterm newborn care is available	
National Standard Treatment Guidelines do <i>not</i> provide specific information or direction on accurately assessing	National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.	The national clinical standards state that the use of ACS in the presence of infection is contraindicated.	Tertiary and maternity reference hospitals where ACS is provided are CEMONC facilities.	NICUs are present in tertiary and maternity reference hospitals where ACS is provided.	

#### Comprehensive/Basic Emergency Obstetric Care

Key informants reported that all facilities providing ACS for obstetric indications in the DRC are required to provide CEmONC services. However, secondary data to confirm this information were unavailable.

It is suggested in the secondary data analysis that these services are strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 9 for these maternal health interventions.

Table 9. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in the DRC14

Table of Maternal Health III	corventions for improved recommendation of decoming and indications in the Brita
INTERVENTION	INDICATION
Tocolytics	Dystocia (Salbutamol)
Magnesium Sulfate	Eclampsia and severe pre-eclampsia
Antibiotics	pPROM (Ampicillin, alternatives Amoxicillin and Erythromycin)

#### **Neonatal Intensive Care/Special Newborn Care**

Key informants reported that NICUs are present and required in facilities providing ACS. Other newborn care interventions are *not* nationally required at facilities providing ACS, however, there are a range of newborn care services that are reportedly available. See Table 10 for a summary of the services or interventions reported by the key informants.

Table 10. Summary of Preterm Newborn Care Interventions per WHO *Recommendations* Reported by Key Informants in the DRC

Informants in the DRC	
INTERVENTION	
Resuscitation	Bag and masks are available
	The larger hospitals and university have the necessary equipment for resuscitation. If a
	facility does not have the equipment they will refer the patient.
	Surfactant is not available in Kinshasa, only oxygen is used.
Thermal Care	Skin to skin is encouraged if the baby is stable
	Incubators (however, not prevalent)
	Kangaroo Mother Care
Infection Prevention	Handwashing
and Treatment	Antibiotics
	Sick babies kept in separate unit
Feeding Support	Nasogastric tube
	Daily weighing
	Daily intake
Safe Oxygen	Oxygen mixers and pulse oximeters are used
	<ul> <li>If oximetry &lt;90%, 0.5L oxygen given to preterm baby for three hours</li> </ul>

<sup>14</sup> Integrated Maternal, Newborn, and Child Standards for Health, Volume 2: Obstetric Emergency Care, April 2012 (Normes de la Zone de Sante Relatives Aux Interventions Intégrées de Sante de la Mère, Du Nouveau-Né et De L'Enfant en République Démocratique Du Congo: Volume 2. Soins Obstétricaux D'Urgence, Avril 2012).

#### **National Essential Medicines List**

It is important to note that while ACS, specifically dexamethasone, is indicated within the national standards for preterm labour and pPROM, dexamethasone is not listed under an obstetric indication on the 2014 National Essential Medicines List (Liste Nationale des Médicaments Essentiels Révision, Juin 2014). In addition, while betamethasone is listed as an alternative treatment, only dexamethasone is listed on the EML or is available in country<sup>15</sup>.

#### **DRC**

Dexamethasone and betamethasone are indicated for preterm labour in the national standards, but they are not found with an obstetric indication on the national Essential Medicines List.

#### Human Resources Training and Capacity Building

Key informants stated that both pre-service and in-service training on ACS provision for women at risk of imminent preterm birth are available, however, detailed information about the training was not available. The 2012 Obstetric Care Training and Neonatal Emergency Facilitators Guide does not provide detail on how to provide ACS. It only contains the following statement within a case study of eclampsia: "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)".

#### **Metrics for ACS**

There are no ACS indicators in the DRC HMIS<sup>16</sup> and key informants were unaware of any discussions at the national level with respect to updating the HMIS. ACS-related indicators that were listed in the HMIS MNH Indicator Survey include the following obstetric information:

- Number of antenatal care visits;
- Obstetric complications: hemorrhage, eclampsia/pre-eclampsia, and PROM;
- Labour and delivery: active management of the third stage of labour (AMTSL), cesarean section, postpartum infection; and
- Newborn care: prematurity, early initiation of breastfeeding, and KMC.

#### **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of DRC's experience with ACS implementation.

Table 11. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informants in the DRC

informatics in the BNC					
LES	SSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES	
•	"Dexamethasone is on the national list of essential medicines and is indicated for fetal lung maturation <sup>17</sup> " "Dexamethasone is produced locally" "ACS is not used on a large scale"	<ul> <li>"The Ministry of Health has oversight of the ACS program including the design and use of standards and guidelines related to ACS use"</li> <li>"ACS is included in the training materials for on-the-job training"</li> <li>"ACS administration is easy"</li> </ul>	<ul> <li>"Expand the standards and guidelines for ACS"</li> <li>"Some pharmaceutical companies have agreed to supply dexamethasone to health facilities"</li> <li>"Should conduct studies to understand the impact of ACS use on preterm outcomes on a larger scale"</li> </ul>	<ul> <li>"Significant training and capacity building needed at all levels of health care"</li> <li>"Insufficient information to expand the safe use of ACS"</li> <li>"There is a long delay in the diagnosis of preterm labour, making interventions difficult"</li> </ul>	

#### **Additional Support Needed**

The key informants reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- Regular training for health care providers;
- Advocacy to empower midwives and nurses to prescribe ACS for women in preterm labour;

<sup>&</sup>lt;sup>15</sup> Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries.2015. September 2015. World Health Organization, Department of Essential Medicines and Health Products.

<sup>&</sup>lt;sup>16</sup> MCSP HMIS indicator data

<sup>&</sup>lt;sup>17</sup> Inconsistent with 2014 EML.

- Financial support to formalize continued training to ensure provider competence and ensure support for other programmatic inputs; and ACS drugs need to be more readily available for use in hospitals.





FMOH Standard Treatment Guidelines

FMOH Standard Treatment Guidelines

FMOH Standard Treatment Guidelines for Health Centers 2014

Corticosteroids on the

**Essential Medicines List** 

National level guidance or criteria for how to determine if a woman is at risk of

for Primary Hospital 2014

for General Hospital 2014



### **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



- FMOH Standard Treatment Guidelines for Primary Hospital 2014
- FMOH Standard Treatment Guidelines for General Hospital 2014
- Management Protocol on Selected Obstetric Topics for Health Centers, 2014

#### National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection.





Gestational age at which ACS is prescribed in country Minimum gestational age

Maximum gestational age



imminent preterm birth



obstetrics/maternal health

### PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 10% Low birth weight rate (babies born <2,500g): 20%

> Babies born preterm per year: 320,000 Ratio of boys to girls born preterm: 1.17

Babies born per year <28 weeks: 15,700 Impaired preterm survivors per year: 7,900 Direct preterm child deaths per year: 24,400

Births at health facility1: 10%

See http://www.everypreemie.org/country-profiles/ for data sources.



### **ACS USE**

Facilities authorized to provide ACS Referral Hospital, General Hospital, and Primary Hospitals

Facilities authorized to provide a pre-referral first dose of ACS

**Health Centers** 



### **RAINING**

Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth

In-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth



### **METRICS**

ACS use captured in HMIS





### **ACS PRESCRIPTION AND ADMINISTRATION**

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Obstetricians/Gynecologists
- General Practitioners
- Masters in Emergency Surgery and Obstetrics

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Nurses
- Midwives

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

- Health Officers
- Midwives
- Nurses



corresponding annex of this report for data sources



### MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Comprehensive emergency obstetric and newborn care (CEmONC) services



Resuscitation

Thermal care

Infection prevention/treatment

Newborn interventions reportedly available at facilities that give full course ACS: Feeding support

Safe oxygen use





Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS



### IMPLEMENTATION CHALLENGES AND STRENGTHS

Challenges to the implementation of ACS use in country:

- 1. Lack of detailed guidelines including criteria to determine gestational age for facilities providing ACS in developing country settings.
- 2. Practitioners and programmatic people are reluctant to accept new interventions.
- 3. Significant training and skill building is needed.
- 4. Academia and program people should work closely so challenges are brought up and discussed at the program level.
- 5. Lack of continuous availability of ACS and confidence of professionals to prescribe ACS.

Strengths of country's ACS implementation process:

- 1. Acceptance of ACS as a very important and effective intervention by FMOH and MCH programs.
- 2. FMOH has put ACS in the guidelines for preterm labour.
- 3. The FMOH has rolled out ACS to secondary and tertiary hospitals.
- 4. Presence of reimbursement protocol for the use of ACS in authorized facilities.

<sup>1</sup> Health and Health Related Indicators for the Ethiopian Fiscal Year 2014/15 reports facility births at 61%. While this information is not derived from a population-based survey, the FMOH political commitment for facility births, utilization of the Health Development Army, and several initiatives have contributed to this reported increase in facility-based births.

#### **Ethiopia**

#### **ACS Guidelines and Implementation**

Prior to the release of the WHO *Recommendations*, the Ethiopian Federal Ministry of Health (FMOH) initiated the provision of ACS for preterm labour at the secondary and tertiary hospital levels (general and specialized hospitals, respectively). Provision of ACS at these hospitals began in 2014 and is consistent with the 2014 National Standard Treatment Guidelines for General Hospitals 18. The Management Protocol of Selected Obstetric Topics, 2010 has been used as an implementation protocol for ACS use in tertiary hospitals since 2010 although ACS implementation was not part of a large scale national program prior to 2014.

#### **ETHIOPIA**

ACS is indicated for preterm labour at the primary level (primary hospitals and upgraded A-type health centers) secondary (general hospitals) and tertiary (specialized hospitals) levels in Ethiopia.

Sources: 2014 National Standard Treatment Guidelines for General Hospitals, 2014 National Standard Treatment Guidelines for Primary Hospitals, Key informant

ACS provision is also indicated for preterm labour at primary hospitals and in health centers in the 2014 National Standard Treatment Guidelines for Primary Hospitals 19 as well as in the 2014 National Standard Treatment Guidelines for Health Centers and the 2014 FMOH Management Protocol on Selected Obstetrics Topics for Health Centers, yet the key informant reported that these facilities are not providing ACS at this time.

The key informant stated that the supply chain of ACS to the primary hospital and health center levels is not fully functional. In addition, although the primary hospitals provide CEmONC and health centers are providing BEmONC services, the staff at these facilities do not have the clinical training or experience required to safely provide ACS.

In addition to the documents listed above, other national guidelines or documents that include ACS for preterm labour include:

- The November 2015 Federal Ministry of Health (FMOH) Minimum Newborn Care Package Intervention Guide; and
- The 2013 FMOH Basic Emergency Obstetric and Newborn Care (BEmONC) Training Manual.

For detailed information contained in relevant national documents, see Annex I. Ethiopia: Clinical Guides and Related Preterm Birth Interventions.

Although the national STGs do not specifically indicate who is authorized to prescribe or administer ACS for women at risk of imminent preterm birth, information from secondary research<sup>20</sup> and the key informant interview indicate that medical doctors, including obstetrician-gynecologists, general practitioners, and masters in emergency surgery and obstetrics are allowed to prescribe and administer ACS. Key informant data revealed midwives and nurses are allowed to administer ACS with clinical oversight. In addition, the BEmONC Training Manual<sup>21</sup>, which specifically addresses midwives and any cadre such as nurses and health officers working in labour and delivery at the health center and district hospital level, asserts that those cadres are allowed to provide ACS as a pre-referral dose prior to referral to the most appropriate level of care for the newborn.

<sup>&</sup>lt;sup>18</sup> General Hospital: Shall mean a health facility at secondary level of healthcare which provides promotive, preventive, curative, and rehabilitative service that requires diagnostic facilities and therapeutic interventions with a minimum capacity of 50 beds and at least shall provide gynecology and obstetrics, pediatrics, internal medicine, surgery, psychiatry, and emergency services. In addition, it shall provide laboratory, imaging and pharmacy services, and other related services stated under this standard. (Ethiopian Standard: General Hospital - Requirements, ES3614:2012, 1st edition)

<sup>&</sup>lt;sup>19</sup> Primary Hospital: Shall mean a health facility at primary level of healthcare which provides promotive, preventive, curative, and rehabilitative services with a minimum capacity of 35 beds and provides at least 24 hour emergency services, general medical services, treatment of basic acute and chronic medical problems, basic emergency surgical intervention, and Comprehensive Emergency Obstetric Care (CEOC) including laboratory, imaging and pharmacy services, and other related services stated under this standard (Ethiopian Standard: Primary Hospital - Requirements, ES3617:2012, 1st edition).

<sup>&</sup>lt;sup>20</sup> Molla, Yordanos, et al. Rapid Assessment of national documents and policy environments to use ACS for premature birth. Maternal and Child Survival Integrated Program and Saving Newborn Lives, 2011.

<sup>&</sup>lt;sup>21</sup> This training manual is a component of the Basic Emergency Obstetric and Newborn Care learning resource package (LRP) prepared for use in Ethiopia for in-service training of doctors, midwives, health officers and/or nurses with midwifery skills who, as team members, will provide BEmONC at health centers and district hospitals to avert maternal and newborn mortality and morbidity. Although the LRP is developed primarily for use in district hospitals and health centers, it can also be used by the same mid-level health care providers in higher level facilities to provide initial care and until consultation.

#### **Clinical Standards**

The Ethiopian national-level STGs for both the primary and general hospitals as well as health centers indicate that the provision of ACS is indicated between 28 and 34 weeks gestational age, but does not provide specific information or direction on how to accurately assess gestational age. Yet, the STGs do provide this important clarification:

"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.**"

In addition, in the FMOH *Management Protocol on Selected Obstetric Topics for Health Centers, March 2014*, there is a detail on how to determine GA in the Post Term Pregnancy Section.

The STGs also provide the following detail to help the practitioner determine if preterm birth is imminent:

#### **Causes of Preterm Labour:**

- Multiple gestation
- Infection like urinary tract infection, febrile illness, abdominal surgery
- Uterine anomalies, antepartum hemorrhage (placenta previa and abruptio placentae)
- pPROM
- Low socioeconomic 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

The STGs, as well as the BEmONC Training Manual, specifically state that the use of corticosteroids in the presence of maternal infection is contraindicated.

See Table 12 for highlights of standards and services that are in place in Ethiopia to support the provision of ACS as per the WHO *Recommendations*.

Table 12. Standards and Services to Support the Provision of ACS as per the WHO Recommendations in Ethiopia

Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Adequate preterm newborn care is available
National Standard Treatment Guidelines do <i>not</i> provide specific information or direction on accurately assessing GA.	National Standard Treatment Guidelines do provide detail on determining if preterm birth is imminent.	The National Standard Treatment Guidelines and BEMONC Training Manual state that the use of ACS in the presence of infection is contraindicated.	General and specialized hospitals where ACS is provided are CEMONC facilities.	NICUs are present in general and specialized hospitals where ACS is provided.

#### Comprehensive/Basic Emergency Obstetric Care

In Ethiopia, regular health centers are expected to be BEmONC facilities, while A-Type health centers<sup>22</sup>, Primary Hospitals, and above, are CEmONC facilities. This is an outcome of the *FMOH National Reproductive Health Strategy* 2005-2015, which provided the following targets:

<sup>&</sup>lt;sup>22</sup> Ethiopia FMOH National Reproductive Health Strategy 2005 – 2015.

- Equip one health post per 5,000 population to provide essential obstetric and newborn care;
- Equip one health center per 25,000 population to provide basic emergency obstetric and newborn care;
   and
- Equip one A-Type health center or primary hospital (100,000 population coverage) to provide comprehensive emergency obstetric care.

These services are strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 13 for other maternal health interventions related to improved preterm birth outcomes.

Table 13. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Ethiopia<sup>23</sup>

INTERVENTION	INDICATION
Tocolytics	Preterm labour (nifedipine) Eclampsia (methyldopa, alternative nifedipine)
Magnesium Sulfate Eclampsia	
Antibiotics	Preterm premature rupture of membranes (pPROM) (ampicillin, alternative erythromycin)

#### **Neonatal Intensive Care/Special Newborn Care**

The key informant reported that NICUs are present in general and specialized hospitals, but are only found in approximately one third of primary hospitals in the country. The presence of a NICU is not a national requirement for the provision of ACS. As discussed above, at this time only general and specialized hospitals are providing ACS in Ethiopia, and therefore, specialized newborn care is only available to preterm neonates in these facilities. When ACS is rolled out to the primary hospital level, the level of NICU care may vary.

See Table 14 for a summary of newborn health care interventions that are reportedly available but not required in facilities providing ACS.

Table 14. Summary of Preterm Newborn Care Interventions per WHO *Recommendations* Reported by Key Informant in Ethiopia

in Ethiopia	
INTERVENTION	
Resuscitation	<ul> <li>Provided at all facility levels: using guidelines from Helping Babies Breathe (HBB).</li> <li>All midwives, at the primary level, are being trained in bag and mask resuscitation through the BEmONC and newborn trainings. Coverage and distribution of trained nurses and midwives is increasing. Currently providers in 2000 of the 3500 health centers have been trained.</li> <li>The STGs for Primary Hospitals also have a Neonatal Resuscitation Plan.</li> </ul>
Thermal Care	<ul> <li>All facilities implement drying, cleaning and wrapping</li> <li>Skin-to-skin is encouraged for all babies for 1+ hour and for preterm babies KMC is encouraged</li> </ul>
	<ul> <li>Radiant warmers and incubators have been sent to 178 of the 264 hospitals</li> <li>KMC is included in the STGs for Primary Hospitals and the Newborn Training Manual for care of low birthweight infants</li> </ul>
Infection Prevention and Treatment	<ul> <li>Part of B/CEmONC services, provided at health center and higher levels of care         <ul> <li>Amoxicillin or ampicillin are provided for free by the MOH</li> </ul> </li> <li>As part of labour and delivery services: infection prevention, sterilization, hand washing, using sterile cord cutter, cleaning with clean towels</li> </ul>
Feeding Support	<ul> <li>Exclusive breast feeding is encouraged</li> <li>Very preterm and sick babies are supported with expressed milk and tube feeding<sup>24</sup></li> <li>Standardized MOH NICU guidelines call for daily weight monitoring</li> <li>The STGs for Primary Hospitals include Feeding Problems: Feeding of a preterm, small for date and infants of diabetic mothers.</li> </ul>
Safe Oxygen	<ul> <li>Hospitals have been using safe oxygen, i.e. not giving 100% as part of preterm treatment.         Recently the MOH has expressed concerns on safe oxygen use and is trying to improve its use.</li> <li>Oxygen concentrators are used, oxygen mixers are not available.</li> <li>There is no standardized Safe Oxygen Protocol available for facilities.</li> </ul>

<sup>&</sup>lt;sup>23</sup> 2014 National Standard Treatment Guidelines for Primary Hospitals

<sup>&</sup>lt;sup>24</sup> Key Informant: The nurses feed the neonates, it is the parents' responsibility to bring formula if the mother does not have milk production or if she is sick.

Additional national-level information on support for preterm or low birthweight babies can be found in the *FMOH Newborn Care Training Participants Manual* December 2014 and the *FMOH Minimum Newborn Care Package Intervention Guide* November 2015.

#### **National Essential Medicines List**

It is important to note that while ACS is indicated within the national documents for preterm labour, dexamethasone and betamethasone are not listed for obstetric indication on the 2010 FMOH EML, or the Ethiopian Medicines Formulary (2nd edition 2013). In addition, while betamethasone is listed as the first line treatment for women in preterm labour in the STGs, only dexamethasone is available in country, included on the national tender, or tracked by the national logistics management information system (LMIS)<sup>25</sup>.

### ETHIOPIA

Betamethasone and dexamethasone are indicated for preterm labour in Ethiopia's national STGs, however, they are not listed for any obstetric indications on the national EML or Drug Formulary.

#### **Human Resources Training and Capacity Building**

In-service training on ACS provision for women at risk of imminent preterm birth is available, however, it was difficult to determine where the in-service training is actually offered. The key informant stated that, outside of medical curricula, there was minimal pre-service training on ACS currently offered in the country. However, the FMOH BEMONC Training Manual specifically states that the training package is meant to serve as a standard guide and resource both for pre-service and in-service trainings of health professionals<sup>26</sup> on BEMONC, while data from the secondary analysis indicated only obstetricians and pediatricians are provided pre-service training<sup>27</sup>. Training in newborn, integrated management of neonatal and childhood illnesses (IMNCI), pediatric AIDS care, and emergency obstetric care is planned to be integrated into the pre-service training curriculum of all medical and paramedical training institutions<sup>28</sup>. Therefore, inconsistencies exist with respect to the levels of pre-service training on ACS that are available and provided in Ethiopia.

#### **Metrics for ACS**

It was reported that there are currently no ACS indicators in the Ethiopia HMIS. Because the country does recognize ACS as a significant life-saving and cost effective intervention, there are plans to include ACS indicators in the HMIS at the 2017/18 review.

Indicators that have been proposed within national level documents include:

- Percentage of women with preterm labour (<34 weeks of gestation) received steroid (FMOH National Strategy for Newborn and Child Survival in Ethiopia 2015/16 - 2019/20, June 2015)
  - o Baseline: Not available
  - 2020 target 90% (yearly, data from HMIS and surveys); and
- All women giving birth in facility who are <34 completed weeks and received one dose of ACS for being
  at risk of preterm birth (including stillbirths, macerated and fresh) / Per number of live births in facility by
  gestation age in weeks (FMOH Minimum Newborn Care Package Intervention Guide Nov 2015).</li>

ACS-related indicators that were listed in the HMIS MNH Indicator Survey include:

- Number of ANC visits (4+);
- Gestational age in weeks measured during ANC;
- Maternal complication diagnosed in ANC;
- Newborn complication diagnosed in labour and delivery; and
- Newborn resuscitation provided in labour and delivery.

Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries.2015.
September 2015. World Health Organization, Department of Essential Medicines and Health Products.

<sup>&</sup>lt;sup>27</sup> Molla, Yordanos, et al. Rapid Assessment of national documents and policy environments to use ACS for premature birth. Maternal and Child Survival Integrated Program and Saving Newborn Lives, 2011.

<sup>&</sup>lt;sup>28</sup> National Strategy for Newborn and Child Survival in Ethiopia. 2015/16 – 2019/20. Maternal and Child Health Directorate, Federal Ministry of Health. June 2015.

#### **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Ethiopia's experience with ACS implementation.

Table 15. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informant in Ethiopia

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
<ul> <li>"Cost effective interventions are important"</li> <li>"Formal guidelines are not all that is needed to bring change to lower level facilities"</li> <li>"Partners need to play a role in supporting the Ministry of Health (MOH), creating momentum, and supporting change"</li> </ul>	The MOH and Maternal Child Health (MCH) programs have accepted ACS as a very important and effective intervention"  The FMOH has included ACS in the guidelines for preterm labour"  The FMOH has rolled out ACS to secondary and tertiary hospitals"  "Presence of reimbursement protocol for the use of ACS in authorized facilities"	"Utilize the maternity waiting homes as sites to address preterm labour"     "Commitment on making facility delivery as an agenda for development"     "Reimbursement protocol, and provision of services for ANC, delivery, and PNC care is an important opportunity for scale up"	<ul> <li>"Lack of a detailed guideline including criteria to determine gestational age, for facilities providing ACS in developing country setting"</li> <li>"Practitioners and programmatic people are reluctant to accept new interventions"</li> <li>"Significant training and skill building is needed"</li> <li>"Academia and program people should work closely so challenges are brought up and discussed at the program level"</li> <li>"Lack of continuous availability of ACS and confidence of professionals to prescribe ACS"</li> </ul>

#### **Additional Support Needed**

Prior to the release of the WHO *Recommendations*, the FMOH held discussions on the need for further clarification and consolidation of the country-level recommendations for ACS provision. The decision on certain health system strengthening challenges; what expertise and capacity is required to provide ACS (i.e. ability to determine gestational age); and what specific components need to be expanded and clarified (i.e. when to repeat a dose of ACS) remain to be addressed. The FMOH recognizes this need and there are plans in place to begin discussions with the appropriate stakeholders.

The key informant reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- "Support expanding and integrating the guidelines for ACS use";
- "Expansion of ACS use at facility, regional, and central levels"; and
- "Clinical mentorship to improve the quality of ACS use and related services/interventions".

<sup>&</sup>lt;sup>29</sup> Molla, Yordanos, et al. Rapid Assessment of national documents and policy environments to use ACS for premature birth. Maternal and Child Survival Integrated Program and Saving Newborn Lives, 2011.



PRETERM BIRTHS

AND DEATHS

Preterm birth rate (babies born <37 weeks): 18%

Low birth weight rate (babies born <2,500g): 13%

Babies born preterm per year: 120,000 Ratio of boys to girls born preterm: 1.17

Babies born per year <28 weeks: 5,900

Impaired preterm survivors per year: 3,100

Direct preterm child deaths per year: 4,800

## ACS POLICY AND IMPLEMENTATION LANDSCAPE ANALYSIS FOR WOMEN AT RISK OF IMMINENT PRETERM BIRTH

### **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



Standard Treatment Guidelines incorporating Essential Medicines List 2015 (for all levels of

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection.





is prescribed in country Minimum gestational age

Maximum gestational age

Gestational age at which ACS



34

Included on list



Corticosteroids on the **Essential Medicines List** 



obstetrics/maternal health

See http://www.everypreemie.org/country-profiles/ for data sources.

### **ベツ METRICS**

ACS use captured in HMIS



**ACS USE** 

Facilities authorized to provide ACS

Central Hospitals and District Hospitals

Facilities authorized to provide a pre-referral first dose of ACS





### RAINING

Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth

In-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth





Births at health facility: 91%





### ACS PRESCRIPTION AND ADMINISTRATION

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Doctors
- **Clinical Officers**
- Doctors of Obstetrics

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Nurse Midwives

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision



Please see corresponding annex of this report for data sources



### MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Thermal care

Infection prevention/treatment

Resuscitation



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS





### **IMPLEMENTATION CHALLENGES AND STRENGTHS**

Challenges to the implementation of ACS use in country:

- 1. Late reporting of women to facilities when they have signs of preterm labour.
- 2. Lack of resources, i.e. ultrasounds.
- 3. Most deliveries occur at primary level facilities not authorized to provide ACS.

Strengths of country's ACS implementation process:

- 1. Partner commitment supported the nationwide orientation of ACS use.
- 2. All secondary and tertiary level facilities are providing ACS.
- 3. Inclusion of ACS in obstetric protocols.
- 4. No reported stock outs of ACS.
- 5. Regulating bodies and health care workers are willing to support ACS use for preterm labour.

Source: McCord, JR, Litch JA, Greensides D, Noriega A. Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in the Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda - A Policy and Implementation Landscape Analysis; Washington DC: UNCoLSC and Every Preemie - SCALE; June 2016.

#### Malawi

#### **ACS Guidelines and Implementation**

In July 2015 Malawi launched their Malawi National Every Newborn Action Plan (ENAP) detailing the plan of action to reduce neonatal mortality from 29 per 1,000 live births to 23 per 1,000 live births by 2020, and 15 per 1,000 live births by 2035. In coordination with this launch, the *Malawi Standard Treatment Guidelines Incorporating Malawi Essential Medicines List 2015* were updated to include ACS for preterm labour. In line with these updated guidelines, key informants reported that ACS is provided for preterm labour at the district and central level hospitals.

#### MALAWI

ACS is indicated in the national guidelines for preterm labour at health centers, and at district and central level hospitals.

**Source:** Malawi Standard Treatment Guidelines Incorporating Malawi Essential Medicines List 2015

The 2015 Malawi STGs also include ACS provision for preterm labour and pPROM at a health center with an immediate referral, but it was reported by the key informants that health center facilities are not currently providing ACS. Across the national documents there is inconsistency and a lack of information detailing what is required at the facility to determine if the patient is provided a pre-referral dose or a full course of ACS. One key informant stated that it was initially planned that BEmONC facilities (health centers) would provide pre-referral first dose, but this was halted when the results from ACT<sup>30</sup> were published.

Other national level documents that include ACS for preterm labour include:

- The Malawi National Reproductive Health Service Delivery Guidelines, 2014–2019;
- The Participants Manual in Integrated Maternal and Neonatal Care, Edited January 2015; and
- The Malawi National Every Newborn Action Plan 2015.

For detailed information contained in relevant national documents, see Annex J. Malawi: Clinical Guides and Related Preterm Birth Interventions.

Although the national STGs do not specifically indicate who is authorized to prescribe or administer ACS for women at risk of imminent preterm birth, key informants state that medical doctors, doctors of obstetrics, and clinical officers are allowed to prescribe and administer ACS, while nurses and midwives are allowed to administer ACS with clinical oversight. Within both the *National Malawi National Reproductive Health Service Delivery Guidelines* and the *Participants Manual in Integrated Maternal and Neonatal Care* it states "the decision to give ACS is typically made by a skilled birth attendant (SBA)".

#### **Clinical Standards**

The Malawi STGs indicate that provision of ACS is indicated at GA less than 34 weeks, but neither the STGs, nor the other national level documents, provide specific information or direction on how to accurately assess GA. Key informants reported that a mixed method of calculating from the LMP, fundal height, or ultrasound are commonly used, although many women do not know their LMP. There is also some inconsistency on the GA that ACS can be provided across the national documents:

- The 2015 STGs indicate ACS for less than 34 weeks with no minimal gestational age indicated;
- The Malawi National Reproductive Health Service Delivery Guidelines indicate ACS for 28 to 34 weeks;
- The Participants Manual in Integrated Maternal and Neonatal Care (IMNC) indicate ACS for 24 to 37 weeks.

<sup>&</sup>lt;sup>30</sup> See page 12 for more information on the ACT findings.

#### Participants Manual on IMNC - Management of Preterm Labour

#### Causes/Predisposing Factors

- Obstetric complications, including hypertension in pregnancy, antepartum
- hemorrhage, infection, polyhydramnios, fetal abnormalities
- Malaria
- Premature rupture of membranes
- Young age of mother less than 16 years of age OR > 35 years
- Lower socioeconomic class
- Reduced body mass index (BMI) BMI less than 19.0
- Cigarette smoking
- Previous preterm delivery
- Multiple pregnancy
- Cervical incompetence
- Uterine abnormalities
- Excessive alcohol intake
- More than 50% of women who deliver prematurely, however, have no known antecedent risk factors.

#### **Signs and Symptoms**

- Bleeding, trickle, or gush of fluid from vagina
- Lower abdominal pain and backache / pressure
- A feeling that the baby is pushing down
- Fever, chills, dizziness, vomiting, or a severe headache
- Blurred vision
- Sudden or severe swelling of the feet, hands, or face
- A significant change in the fetal movements
- A sudden increase in the amount of vaginal discharge
- Some women may just feel that "something is not right".

Neither the STGs, the *National Reproductive Health Service Delivery Guidelines*, nor the *Participants Manual in IMNC*, indicate that ACS are contraindicated in the presence of maternal infection. In fact, this statement is included in the *National Reproductive Health Service Delivery Guidelines* and the *Participants Manual in IMNC*:

"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."

The STGs do not provide detail to help the practitioner determine if preterm birth is imminent, although they do provide signs and symptoms of pre-eclampsia, severe pre-eclampsia, eclampsia, and PROM. The *Participants Manual on IMNC* is the only national document reviewed that provides detailed information on causes, predisposing factors, signs and symptoms of preterm labour.

See Table 16 for highlights of standards and services that are in place in Malawi to support the provision of ACS as per the WHO *Recommendations*.

Table 16. Standards and Services to Support the Provision of ACS as per the WHO Recommendations in Malawi

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:				
Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Adequate preterm newborn care is available
National Standard Treatment Guidelines do <i>not</i> provide specific information or direction on accurately assessing GA <sup>31</sup>	National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.	The National Standard Treatment Guidelines do not state that the use of ACS in the presence of infection is contraindicated.	District and central hospitals where ACS is provided are CEMONC facilities.	NICUs are present in district and central hospitals where ACS is provided.

#### Comprehensive/Basic Emergency Obstetric Care

Key informants reported that all facilities offering a full course of ACS are required to be CEmONC facilities, while health centers, which were originally intended to provide a pre-referral dose of ACS, are BEmONC facilities. A 2014 needs assessment<sup>32</sup> stated:

"UN guidelines recommend at least five 5 Emergency Obstetric and Newborn Care (EmONC) facilities (including at least one comprehensive facility) for every 500,000 people. Applying these standards to Malawi's 2014 projected population of 15,805,239, there should be 158 EmONC facilities: 126 basic EmONC facilities and at least 32 comprehensive EmONC facilities. In this assessment, 64 fully functioning EmONC facilities were found: 45 comprehensive and 19 basic EmONC facilities. While there is a deficit of 107 basic EmONC facilities, the minimum number of comprehensive EmONC facilities is exceeded by 13."

These services are strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 17 for other maternal health interventions related to improved preterm birth outcomes.

Table 17. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Malawi<sup>33</sup>

The state of the s				
INTERVENTION	INDICATION			
Tocolytics  Pregnancy Induced Hypertension (MgSO4, Methyldopa, Nifedipin Pre-eclampsia (Methyldopa, Hydralazine, alternative Nifedipine) Severe pre-eclampsia (Magnesium Sulfate)				
Magnesium Sulfate	Pre-eclampsia, Eclampsia			
Antibiotics	Prelabour/PROM (Health Center: Erythromycin, Metronidazole Hospital: Ampicillin, Erythromycin, alternative Benzylenicillin)			

#### **Neonatal Intensive Care/Special Newborn Care**

Key informants reported that neonatal nursery units are present in facilities providing a full course of ACS, although that for some, the unit is very basic and not very specialized. The presence of a neonatal nursery unit (i.e. NICU) is not a national requirement for the provision of ACS. Hospitals are providing ACS in Malawi, and newborn care is available to preterm neonates at varying levels of quality and consistency in these facilities. See Table 18 for a summary of newborn care interventions that are reportedly available but not nationally required at facilities providing ACS.

<sup>&</sup>lt;sup>31</sup> Guidance for determining GA is implied and not explicitly stated.

<sup>&</sup>lt;sup>32</sup> Malawi Emergency Obstetric and Newborn Care Needs Assessment, 2014. Malawi MOH, USAID, UNFPA, UNICEF, CHAI, Save the Children.

<sup>&</sup>lt;sup>33</sup> Malawi Standard Treatment Guidelines Incorporating Malawi Essential Medicines List 2015.

Table 18. Summary of Preterm Newborn Care Interventions per WHO *Recommendations* Reported by Key Informants in Malawi

INTERVENTION	
Resuscitation	Bag and mask
	The national STGs include neonatal resuscitation with care flow chart
Thermal Care	Skin to skin is encouraged
	The national STGs include prevention of hypothermia within the Neonatal section
	The Malawi National Guidelines for Kangaroo Mother Care, revised 2009
	Incubators are used when available
Infection Prevention	Hand washing
and Treatment	Intravenous antibiotics
	Separate ward for sick babies
	The national STGs include prevention of neonatal infections
Feeding Support	Nasogastric tube
	Expressed breast milk
	Daily weight monitoring
	The national STGs include hypoglycemia and feeding section within the Neonatal section
Safe Oxygen	Oxygen mixers, pulse oximetry, and oxygen titration is available
	The national STGs include Respiratory Distress Syndrome, which includes Continuous
	Positive Airway Pressure (CPAP)

Additional national-level information on support for preterm or low birthweight babies can be found in the *National STGs*.

#### **National Essential Medicines List**

Within the *Malawi Standard Treatment Guidelines Incorporating Malawi Essential Medicines List 2015* both dexamethasone and betamethasone are listed under specific medicines for neonatal care: medicines administered to the mother. Dexamethasone is considered a vital medication, it is routinely procured, and its use is authorized from the district hospital up. Betamethasone is considered essential and is allowed for use in central hospitals, but is not routinely procured<sup>34</sup>.

#### **MALAWI**

Dexamethasone is only indicated for use at district level hospitals and above. The national STGs state a pre-referral dose of corticosteroids can be provided at the health center level. The specific type of corticosteroid is not specified.

**Source:** Malawi Standard Treatment Guidelines Incorporating Malawi Essential Medicines List 2015

#### **Human Resources Training and Capacity Building**

In-service training on ACS provision for women at risk of imminent preterm birth does occur and the *Participants* 

#### **MALAWI**

The Participants Manual on IMNC 2015 targets midwives and other skilled birth attendants in the provision of ACS for preterm labour.

Manual on Integrated Maternal and Neonatal Care was updated in January 2015. Health care workers were trained and ACS for preterm labour was introduced throughout district level hospitals in 2015<sup>35</sup>. This manual also provides detailed information on the management of preterm labour with the goal to "equip the midwife and other skilled birth attendants with knowledge, skills and attitudes during admission and management of preterm labour".

#### **Metrics for ACS**

It was reported that there are currently no ACS indicators in the Malawi HMIS, but that there are currently plans to introduce them. Indicators that have been proposed within national level documents include:

- Percentage of women with preterm labour (gestation <34 weeks) receive at least one dose of ACS<sup>36</sup>
  - o Baseline: to be determined
  - o 2020 Coverage Target: 60%
  - o 2025 Coverage Target: 65%
  - o 2030 Coverage Target: 70%
  - 2035 Coverage Target: 75%.

<sup>&</sup>lt;sup>34</sup> Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries 2015. September 2015. World Health Organization, Department of Essential Medicines and Health Products.

<sup>&</sup>lt;sup>35</sup> Malawi National Every Newborn Action Plan 2015. Ministry of Health.

<sup>&</sup>lt;sup>36</sup> Malawi National Every Newborn Action Plan 2015. Ministry of Health.

ACS-related indicators reported in the MCSP HMIS MNH Indicator Survey include:

- ANC: Four or more ANC visits; gestational age; pre-eclampsia/eclampsia diagnosed;
- Labour and Delivery:
  - o Maternal: Complication diagnosed: antepartum hemorrhage, postpartum hemorrhage; sepsis
  - Newborn: Birthweight, blood transfusion; newborn complication diagnosed; breastfeeding within one hour of birth; newborn resuscitation; and
- Postnatal Care: Maternal complications—treatment; maternal complication treatment—sepsis.

#### **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Malawi's experience with ACS implementation.

Table 19. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informants in Malawi

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
<ul> <li>"Staff orientation is key to adoption of new interventions"</li> <li>"BEMONC facilities need to be included if more women are to be reached"</li> <li>"Supportive supervision is key to ensure adherence to prescribed standards"</li> </ul>	"Partner commitment supported the nationwide orientation of ACS use"     "All secondary and tertiary level facilities are providing ACS"     "Inclusion of ACS in obstetric protocols"     "There are no reported stock outs of ACS"     "Regulating bodies and health care workers are willing to support ACS use for preterm labour"	"Partner commitment"     "Very strong political will"	"Women report to facilities too late when they have signs of preterm labour, as such they do not benefit from ACS"     "Lack of adequate resources, i.e. ultrasounds, to safely use ACS"     "Most deliveries occur at primary level facilities not authorized to provide ACS"

#### **Additional Support Needed**

The key informants reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- Supply chain management support to make sure that the country does not experience stock outs of ACS:
- Extend provision of ACS to BEMONC facilities to increase reach;
- ACS should be included in the pre-service training as part of the management of preterm labour;
- Support for the inclusion of ACS indicators into the HMIS; and
- Update the registers to capture ACS use for preterm labour.







## **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



In development, reported by key informant

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



In development, reported by key informant

National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection.





is prescribed in country

Minimum gestational age

Gestational age at which ACS



Maximum gestational age



Corticosteroids on the Essential Medicines List

Included on list





# PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 12%

Low birth weight rate (babies born <2,500g): 15%

Babies born preterm per year: 871,000

Ratio of boys to girls born preterm: 1.21

Babies born per year <28 weeks: 43,800

Impaired preterm survivors per year: 21,300 Direct preterm child deaths per year: 98,300

in HMIS

Births at health facility: 36%

**METRICS** 

See http://www.everypreemie.org/country-profiles/ for data sources.



## **ACS USE**

Facilities authorized to provide ACS Tertiary Hospitals

Facilities authorized to provide a pre-referral first dose of ACS





Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth





ACS use captured







## **ACS PRESCRIPTION AND ADMINISTRATION**

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Consultant Obstetricians

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Senior Residents in Obstetrics

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

No data



Yes



sources

Please see corresponding annex of this report for data



## MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Comprehensive emergency obstetric and newborn care (CEmONC) services

Thermal care

Resuscitation

Infection prevention/treatment



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS





## **IMPLEMENTATION CHALLENGES AND STRENGTHS**

Challenges to the implementation of ACS use in country:

- 1. No national guidelines in place for ACS.
- 2. Inadequate human resources and capacity to manage newborns at general hospitals.
- 3. Lack of basic equipment and commodities.
- <sup>1</sup> Key informant reported the EML will be updated in 2016 to include indication for obstetrics/maternal health

Strengths of country's ACS implementation process:

- 1. There is consensus by stakeholders, including medical professionals, on the use of ACS for imminent preterm birth.
- 2. Ongoing implementation at tertiary health facilities.
- 3. ACS was recently added to the Essential Medicines List for management of imminent preterm birth at tertiary health facilities.
- 4. Nigeria's Every Newborn Action Plan is being finalized.

## **Nigeria**

## **ACS Guidelines and Implementation**

In October 2012, Nigeria's President launched the government's *Saving One Million Lives Initiative* which provides a framework that sets clear, ambitious targets to strengthen basic health services and maternal, newborn, and child health goals before 2015. The initiative called for the upgrading of health facilities, training, and equipping facility staff to resuscitate babies and practice thermal care, expanding the use of chlorhexidine gel for cord care, accelerating the practice of KMC to manage preterm and low birth weight babies, and improving management of neonatal jaundice.

NIGERIA
The key informant for Nigeria
reported that tertiary hospitals are
authorized to prescribe ACS. The
upcoming ACS guidelines are
expected to include this
authorization.

Building on this initiative, the Government of Nigeria, based on the recommendations of the UNCoLSC, developed an implementation plan<sup>37</sup> in 2013 to provide a roadmap for activities and targets that will ensure the availability and use of prioritized life-saving commodities for women and children, including the use of ACS. In 2014, an expert consensus panel of experts and stakeholders on ACS was included in the National Newborn Health Conference to discuss the pros and cons of expanding access to ACS and to establish Nigeria's position on the use of ACS based on recent peer-reviewed evidence and implementation realities in the country.

The panel affirmed that the current cautionary approach to the use of ACS in the country was in tandem with the evolving evidence and suggested the following guidance for the FMOH, pending formal WHO guidance:

- ACS should only be used at tertiary facilities upon recommendation of senior personnel;
- All other lower level facilities should adopt referrals for such cases:
- Before the use of ACS, GA must be accurately established;
- Level 2 NICU must be in place in facilities providing ACS, as a minimum; and
- This decision should be written out as an Expert Panel Report<sup>38</sup> and passed to all relevant professional bodies for their study and assent.

Although ACS provision is not included in the 2008 National Standard Treatment Guidelines, the following national documents do mention ACS provision:

- The FMOH National Strategic Health Development Plan 2010-2015, November 2010;
- The "Saving One Million Lives" Accelerating improvements in Nigeria's Health Outcomes through a new approach to basic services delivery. Program Document, August 2012;
- The Country Implementation Plan for United Nations Commission on Life-Saving Commodities for Women and Children, August 2013; and
- The FMOH Saving Newborn Lives in Nigeria: Situation Analysis and Action Plan for Newborn health in the context of the Integrated Maternal, Newborn and Child Health Strategy, 2009.

For detailed information contained in relevant national documents, see Annex K. Nigeria: Clinical Guides and Related Preterm Birth Interventions.

Information from secondary research<sup>39</sup> and the key informant interview indicate that consultant obstetricians and senior doctors are allowed to prescribe and administer ACS for women at risk of imminent preterm birth while Residents of Obstetrics are allowed to administer ACS with clinical oversight. The secondary research also indicates that obstetricians, pediatricians, and other doctors prescribe regardless of authorization.

<sup>&</sup>lt;sup>37</sup> Federal Republic of Nigeria. Country Implementation Plan for United Nations Commission on Life-Saving Commodities for Women and Children, August 2013.

<sup>&</sup>lt;sup>38</sup> Report of Expert Consensus Panel on the Use of Antenatal Corticosteroids, 23 October 2014. Nigeria.

<sup>&</sup>lt;sup>39</sup> Molla, Yordanos, et al. Rapid Assessment of national documents and policy environments to use ACS for premature birth. Maternal and Child Survival Integrated Program and Saving Newborn Lives, 2011.

### **Clinical Standards**

There is currently no national level guidance provided to facilities on how to determine imminent preterm birth, how to determine correct GA, or that ACS is contraindicated in the presence of infection. The outputs of the 2014 stakeholder discussion determined the level at which ACS provision would be approved. Detailed criteria for the provision of ACS were not discussed. At this meeting, it was decided that the country would await further guidance from the WHO before any additional decisions on ACS provision in the country would be made. See Table 20 for highlights of standards and services that are in place in the Nigeria to support the provision of ACS as per the WHO *Recommendations*.

Table 20. Standards and Services to Support the Provision of ACS as per the WHO Recommendations in Nigeria

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:				
Gestational age can be accurately	Preterm birth is considered	No clinical evidence of maternal	Adequate childbirth care is available	Adequate preterm newborn care is
undertaken	imminent	infection		available
National Standard	National Standard	National Standard	Tertiary hospitals	NICUs are present at
Treatment Guidelines	Treatment Guidelines	Treatment Guidelines	where ACS is	tertiary hospitals
do <i>not</i> provide	do <i>not</i> provide detail	do not state that the	provided are	where ACS is
specific information or	on determining if	use of ACS in the	CEmONC facilities,	provided.
direction on	preterm birth is	presence of infection	but not all general	
accurately assessing	imminent.	is contra-indicated.	hospitals are	
GA.			CEMONC.	

## Comprehensive/Basic Emergency Obstetric Care

As reported by the key informant, all general and tertiary level hospitals are supposed to provide CEmONC services, while all health centers should provide BEmONC. At this time, this is not fully realized, as some general hospitals do not have CEmONC services, and many health facilities do not have BEmONC services.

Based on the 2009 Saving Newborn Lives in Nigeria: Newborn Health in the Context of the Integrated Maternal, Newborn, and Child Health Strategy, 33 percent of the nation's private facilities meet B/CEmONC standards, while only five percent of public health facilities meet the criteria – most in wealthier, urban areas. According to the Harmonized Country Plan of Priority Interventions for 2014-2015, the government and its development partners have stepped up initiatives to increase the availability of BEmONC intervention projects across the country, and the key informant reports that there is a plan in place over the next two years to link primary health centers to general hospitals providing CEmONC services.

These services can be strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 21 for other maternal health interventions related to improved preterm birth outcomes.

Table 21. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Nigeria<sup>40</sup>

INTERVENTION	INDICATION	
Tocolytics	Eclampsia (Hydralazine or Labetalol)	
Magnesium Sulfate	Eclampsia	
Antibiotics	No information on PROM or pPROM in STGs	

### **Neonatal Intensive Care/Special Newborn Care**

The key informant reports that NICUs are present in tertiary hospitals, and the teaching hospitals have NICUs with two levels: "in" newborn care units for those born within the hospital, and "out" newborn care units for those born outside the hospital and referred to the hospital after birth.

Table 22 provides a summary of newborn care interventions that are reportedly available but not nationally required at facilities providing ACS.

<sup>&</sup>lt;sup>40</sup> 2008 National Standard Treatment Guidelines

Table 22. Summary of Preterm Newborn Care Interventions per WHO Recommendations Reported by Key

Informants in Nigeria

INTERVENTION	
Resuscitation	Bag and mask present
	Primary health care workers trained in resuscitation
	Helping babies breathe interventions included in new training package
	MCSP wants to promote CPAP in two states and will supply equipment to general hospitals
Thermal Care	• KMC
	Incubators at teaching and general hospitals
Infection Prevention	Aseptic technique
and Treatment	Antibiotics
	UNCoLSC antibiotics – Benzylpenicillin, gentamycin, amoxicillin
	Separate wards
Feeding Support	Breastfeeding and all feeding alternatives
	Nasogastric tube used at general and teaching hospitals
Safe Oxygen	At general and teaching hospitals promoting pulse oximeter

### **National Essential Medicines List**

Although dexamethasone is available in country<sup>41</sup> and is widely used for other indications, especially allergies, it is not listed in the 2010 Essential Medicines List, 5<sup>th</sup> Revision for use in preterm labour. In the 2014 FMOH document, Nigeria's Call to Action to Save Newborn Lives, there is an indication that the EML has been reviewed and updated to appropriately reflect neonatal commodities including the use of dexamethasone for obstetric indications, but a copy of that revision was unavailable for review.

### **NIGERIA**

Dexamethasone is not indicated for use in preterm labour in the current EML, but the EML has reportedly been updated to include dexamethasone for obstetric indications.

## **Human Resources Training and Capacity Building**

The key informant reported that pre-service training on ACS provision for women at risk of imminent preterm birth was provided during undergraduate training of medical doctors, which is in line with secondary research<sup>42</sup>. The key informant reported that there is a proposed addendum to the essential newborn care training package for obstetricians and pediatricians, which will include ACS, and that the curriculum of the community health workers has been reviewed and strengthened to include skin-to-skin care of the newborn, resuscitation, and breastfeeding. There is also a plan to improve the curriculum for nurse midwives and doctors, but no indication of the timeline was given. Currently ACS is not included in in-service training.

### **Metrics for ACS**

It was reported that the national HMIS is currently under review and indicators on ACS and KMC will be incorporated, including:

Stock out of ACS in the past one month.

ACS-related indicators reported by the MCSP HMIS MNH Indicator Survey for Nigeria include:

- Four or more ANC visits:
- Preterm newborn diagnosed in labour and delivery; and
- Postnatal care referral of preterm newborns to KMC.

## **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Nigeria's experience with ACS implementation.

<sup>&</sup>lt;sup>41</sup> Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries.2015. September 2015. World Health Organization, Department of Essential Medicines and Health Products.
<sup>42</sup> ibid.

Table 23. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key

Informant in Nigeria

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
"There is a need for proper documentation and information sharing by the few tertiary centers that are presently providing ACS"	<ul> <li>"There is a consensus by stakeholders, including medical providers, on the use of ACS for management of imminent preterm birth"</li> <li>"Ongoing implementation at tertiary health facilities"</li> <li>"ACS has very recently been added to the EML for management of imminent preterm birth at tertiary health facilities"<sup>43</sup></li> <li>"Finalizing Nigeria's Every Newborn Action Plan"</li> </ul>	<ul> <li>"ACS is included in the training package"</li> <li>"Newborns are a priority of the government"</li> <li>"Development of the Nigeria Every Newborn Action Plan"</li> </ul>	<ul> <li>"No national ACS guidelines in place"</li> <li>"Inadequate human resources and capacity to manage newborns at general hospitals (training for general hospital providers has been done with 6 master trainers on ENC in the 36 states)"</li> <li>"Lack of basic equipment (i.e. incubators, CPAP) and commodities"</li> </ul>

## **Additional Support Needed**

The key informant reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- Development of National Clinical Guidelines, inclusion in the Essential Newborn Care training package, and Nigeria Every Newborn Action Plan; and
- Assistance from stakeholders to lead the development of the National Guidelines.

<sup>&</sup>lt;sup>43</sup> This could not be validated.

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ACS POLICY AND IMPLEMENTATION LANDSCAPE ANALYS
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## **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



In development, reported by key informant

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



In development, reported by key informant

National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection



How to determine gestational age (GA) when giving ACS



Minimum gestational age Maximum gestational age

28 35

Corticosteroids on the **Essential Medicines List** 

Included on list

Indicated for obstetrics/maternal health



## PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 10%

Low birth weight rate (babies born <2,500g): 11%

Babies born preterm per year: 22,900

Ratio of boys to girls born preterm: 1.12

Babies born per year <28 weeks: 1,100

Impaired preterm survivors per year: 500

Direct preterm child deaths per year: 3,300

Births at health facility: 54%

See http://www.everypreemie.org/country-profiles/ for data sources.



## **ACS USE**

Facilities authorized to provide ACS

**Tertiary Hospitals including District Referral Hospitals** 

Facilities authorized to provide a pre-referral first dose of ACS





Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth

In-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth



## ベン METRICS

ACS use captured in HMIS

No data



# ACS PRESCRIPTION AND ADMINISTRATION

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- **Resident Doctors**
- Obstetricians/Gynecologists

Health care worker cadres authorized to administer full course ACS with clinical oversight

- **Clinical Health Officers**
- **Medical Officers**
- Midwives

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

No data



Yes

corresponding annex of this report for data sources



## MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Comprehensive emergency obstetric and newborn care (CEmONC) services

Resuscitation

Thermal care

Infection prevention/treatment



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS



## IMPLEMENTATION CHALLENGES AND STRENGTHS

Challenges to the implementation of ACS use in country:

- 1. Lack of clinical guidelines for ACS use.
- 2. Lack of skilled workforce, especially midwives.
- 3. Lack of diagnostics, such as ultrasound use.
- 4. Lack of transport and money for women at risk of preterm labour.
- 5. Lack of capacity and training of health care providers.

Strengths of country's ACS implementation process:

- 1. Trained midwives and doctors, and availability of ultrasound to determine GA at Freetown Hospital.
- 2. Drugs and equipment available at Freetown Hospital.
- 3. Guidelines in place for care of low birth weight babies at Freetown Hospital.

Source: McCord. JR. Litch JA. Greensides D. Noriega A. Antenatal Corticosteroids for Women at Risk of Imminent Preterm Birth in the Democratic Republic of Congo, Ethiopia, Malawi, Nigeria, Sierra Leone, Tanzania and Uganda - A Policy and Implementation Landscape Analysis; Washington DC: UNCoLSC and Every Preemie - SCALE; June 2016.

### Sierra Leone

## **ACS Guidelines and Implementation**

Key informants in Sierra Leone reported that ACS is being provided at tertiary and district level referral hospitals, for which there are only two facilities in the entire country. However, they also stated that there are no defined national policies or guidelines on ACS use. It was reported that the hospitals using ACS for preterm labour define their own guidelines. The GLOAG Foundation – Freetown hospital (charity-supported MOH facility—the key informant facility) outlined the use of ACS using the *Policies and Guidelines for Intrapartum Postnatal and Neonatal Care, Maternity Africa, November 2015* and *Essential Obstetric and Newborn Care: Practical guide for midwives, doctors with obstetric training, and health care personnel who deal with obstetric emergencies, Médecines sans Frontières (MSF), 2015 Edition.* 

Relevant documents for Sierra Leone including STGs were unavailable. The *Ministry of Health Reproductive, Newborn, and Child Health Strategy 2011-2015* (available online) mentions ACS but with no significant detail.

For detailed information contained in the relevant documents being used at the GLOAG Foundation – Freetown hospital, see Annex L. Sierra Leone: Clinical Guides and Related Preterm Birth Interventions.

Key informants reported resident doctors and obstetrician-gynecologists are prescribing and administering ACS independently. The Sierra Leone representative in attendance at the June TWG meeting added that midwives, clinical health officers, and medical officers are allowed to administer ACS with clinical oversight.

### **Clinical Standards**

As mentioned above, clinical guidelines for Sierra Leone and other national documents describing how ACS are provided in the country were unavailable. Key informants reported that at their facility, provision of ACS is indicated between 28 and 34 weeks (sometimes 35 weeks if the medical professional deems it appropriate). It was reported that there is no national guidance on how to accurately determine GA. The methods used at their facility for GA assessment are LMP, ultrasound, fundal height, and "guessing". Ultrasound is reported to be expensive (and women must pay for it), and in the northern part of the country ultrasound is not available.

Key informants also reported that there is no national guidance to help the practitioner determine if preterm birth is imminent, nor any information that ACS is contraindicated in the presence of maternal infection. The key informants reported that they do uterine testing but did not describe the process or procedure for uterine testing. Key informants explained that if chorioamnionitis is suspected, ACS is not provided. ACS and antibiotics are provided for PROM. Table 24 illustrates the lack of information available in Sierra Leone for the safe and effective use of ACS across the five WHO *Recommendations*.

Table 24. Standards and Services to Support the Provision of ACS as per the WHO *Recommendations* in Sierra Leone

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:					
3	Preterm birth is No clinical evidence   Adequate childbirth   Adequate preterm				
be accurately	considered	of maternal	care is available	newborn care is	
undertaken imminent infection available					
No information	No information	No information	No information	No information	

## Comprehensive/Basic Emergency Obstetric Care

Key informants reported that the two facilities in Freetown providing ACS are CEmONC facilities. The *Reproductive, Newborn, and Child Health Strategy 2011-2015* promotes the delivery of and access to basic and comprehensive emergency obstetric care, with the following key activities highlighted:

- Strengthen community health centers and hospitals in all ENABLER<sup>44</sup> components to meet EmONC compliance:
- Map the distribution of EmONC services to determine geographical equity;

<sup>&</sup>lt;sup>44</sup> Facilities are scored on seven standards which need to be met in order to achieve the relevant status. These became known as enablers. These enablers are: Water and sanitation; Electricity; Referrals; Equipment for special procedures; Blood storage and laboratory; Staffing; and Drugs and supplies.

- Scale up task-shifting protocols and undertake training in essential services, e.g. performance of caesarean section and anesthetics; and
- Develop a district referral plan that ensures there is an integrated communication and transportation system.

The MOH Basic Package of Essential Health Services (BPEHS) for Sierra Leone 2015-2020 states that the community health centers are BEmONC facilities and the District Hospitals and Regional Hospitals are CEmONC facilities. See Table 25 for other maternal health interventions related to improved preterm birth outcomes.

Table 25. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Sierra Leone<sup>45</sup>

Intervention	Indication
Tocolytics	The BPEHS 2010-2015: Lists the following with no reference to indication: Salbutamol 2mgTablets Salbutamol 4mgTablets Salbutamol 0.5mg/ml Amp Oxytocin/Ergometrine (Syntometrine) 5units/500mcg /ml injection
Magnesium Sulfate  The BPEHS 2010-2015: Anticonvulsants and Antiepileptic Magnesium Sulphate 50%	
Antibiotics	No information found through desk review

## **Neonatal Intensive Care/Special Newborn Care**

The key informants reported that there is only one NICU in the country. The NICU is in Freetown at Cottage Hospital and has 28 beds, phototherapy machines, incubators, and oxygen concentrators, but no CPAP.

See Table 26 for a summary of newborn health care interventions that are reportedly available at the key informants' facility, the GLOAG Foundation Hospital in Freetown, but not required in facilities providing ACS.

Table 26. Summary of Preterm Newborn Care Interventions per WHO Recommendations Reported by Key Informants in Sierra Leone

INTERVENTION	
Resuscitation	Bag and mask
Thermal Care	<ul> <li>Baby is dried and covered in Vaseline, then wrapped in clothes, blankets, and a hat.</li> <li>KMC is practiced</li> </ul>
Infection Prevention and Treatment	Antibiotics are available (ampicillin, gentamycin)
Feeding Support	<ul> <li>If a mother finds it difficult to express milk, babies are start on 10% formula based on weight for 48 hours until mother can express milk</li> <li>Nasogastric tubes</li> </ul>
Safe Oxygen	<ul> <li>Daily weighing and calculating</li> <li>O2 mixer at 5L per minute, give babies 1L per minute</li> </ul>
Sale Oxygen	Pulse oximeter     Protocol available

### **National Essential Medicines List**

Key informants reported that dexamethasone is indicated on the EML for preterm birth. The MOH Basic Package of Essential Health Services for Sierra Leone 2015-2020 also lists dexamethasone injection 4mg/ml as an essential SIERRA LEONE
Dexamethasone is indicated on the EML for preterm birth according to key informants.

medicine at secondary level hospitals, but it does not provide any information on the indication for its use.

The UNCoLSC report<sup>46</sup> states the registration for dexamethasone injection has expired, yet it is included on the EML, in the national policy/guideline for preterm labour, and on the national tender. The UNCoLSC further reported that ACS use is tracked by the LMIS and is supplied free of charge in the public sector, and is used outside the public sector. The team was unable to verify any of this information.

<sup>&</sup>lt;sup>45</sup> MOH Basic Package of Essential Health Services (BPEHS) for Sierra Leone 2015-2020.

<sup>&</sup>lt;sup>46</sup> Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries.2015. September 2015. World Health Organization, Department of Essential Medicines and Health Products.

## **Human Resources Training and Capacity Building**

The key informants reported that there is no known pre-service training on ACS provision for women at risk of imminent preterm birth. In-service training is available, but very minimally, as there is no full curriculum but a two-page protocol on management of preterm deliveries.

### **Metrics for ACS**

The key informants did not believe there were any ACS indicators in Sierra Leone's HMIS. The *Ministry of Health Reproductive, Newborn, and Child Health Strategy 2011-2015* had the following indicators for support services listed:

- % of target community health centers fully functional as BEmONC: Baseline: 0, 2011: 26%, 2012: 50%, 2013: 70%:
- % of hospitals strengthened as CEmONC level facilities and meet the 'green' standards: Baseline 0, 2011: 100%; and
- % of community health centers strengthened as CEmONC level facilities and meet the 'green' standards: Baseline 0, 2011: 100%.

## **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Sierra Leone's (key informants') experience with ACS implementation.

Table 27. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informants in Sierra Leone

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
None reported	Provided on behalf of the GLOAG Foundation — Freetown hospital:  • "Trained midwives and doctors, and availability of ultrasound to determine GA at Freetown hospital"  • "Available drugs and equipment"  • "Guidelines in place for care of the low birth weight babies"	<ul> <li>"Identification of women at risk, including effective antenatal screening for pre-eclampsia as an important cause of preterm delivery"</li> <li>"Providing information to pregnant women, as there is a general lack of health education. Focus on early reporting to a health facility at the first signs of pregnancy complications such as preterm uterine contractions, PROM, and symptoms of preeclampsia"</li> <li>"Staff are trained in the use of the drug and have training, and protocols in place (under supervision)"</li> </ul>	<ul> <li>"Lack of clinical guidelines for ACS use"</li> <li>"Lack of skilled workforce, especially midwives (and supervision of midwives)"</li> <li>"Lack of diagnostics, such as ultrasound use"</li> <li>"Lack of transport, money for women at risk of preterm labour"</li> <li>"Lack of capacity, and training in ACS provision"</li> </ul>

### **Additional Support Needed**

The key informants reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- Training and supervision of midwives at the primary health care level; and
- There are very few neonatal health-care facilities and access to expensive interventions such as surfactant therapy. All district hospitals in the provinces need these types of services.

<sup>&</sup>lt;sup>47</sup> All enablers in all facilities should eventually be "green" as this represents their ability to deliver ALL signal functions as a BEMONC or CEMONC and in addition, meet the minimum requirements as identified in the Basic Package of Essential Health Services (BPEHS). The green code is allocated when all criteria under a particular enabler have been met, with yellow, amber and red depicting failure to achieve all criteria for each enabler. The community health centres (CHC) should be equipped to provide BEMONC services while all government hospitals should be equipped to provide CEMONC services.





S POLICY AND IMPLEMENTATION LANDSCAPE ANALYSIS FOR WOMEN AT RISK OF IMMINENT PRETERM BIRTH

## **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth



Administration of Antenatal Corticosteroids in Pre-Term Labour, July 2015

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



28

National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection





Minimum gestational age

is prescribed in country

Maximum gestational age

Gestational age at which ACS

Included on list



Corticosteroids on the **Essential Medicines List** 



## PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 11% Low birth weight rate (babies born <2,500g): 8%

Babies born preterm per year: 236,900

Ratio of boys to girls born preterm: 1.18

Babies born per year <28 weeks: 11,100 Impaired preterm survivors per year: 5,700

Direct preterm child deaths per year: 10,800

Births at health facility: 50%

See http://www.everypreemie.org/country-profiles/ for data sources.



## **ACS USE**

Facilities authorized to provide ACS Hospital Level

Facilities authorized to provide a pre-referral first dose of ACS

**Health Center Dispensary** 



## RAINING

Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth







ACS use captured in HMIS





## ACS PRESCRIPTION AND ADMINISTRATION

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Medical Officers
- Assistant Medical Officers

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Nurses
- Midwives

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

- Nurses
- Nurse Midwives
- Clinical Officers









## MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only





and newborn care (CEmONC) services



Resuscitation

Thermal care

Infection prevention/treatment



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS



## IMPLEMENTATION CHALLENGES AND STRENGTHS

Challenges to the implementation of ACS use in country:

- 1. Poor commodity supply chains, hence ACS is not available in many facilities.
- 2. Only dexamethasone is available.
- 3. Lack of training for health care providers due to inadequate funds.

Strengths of country's ACS implementation process:

- 1. ACS guidelines are in place.
- 2. Dexamethasone has been included on the Essential Drugs List by the MOH.

### **Tanzania**

## **ACS Guidelines and Implementation**

In July 2015, the Ministry of Health and Social Welfare in Tanzania released the *Administration of Antenatal Corticosteroids in Pre-Term Labour* Guidelines (2015 ACS Guidelines), which indicate the provision of a full course of ACS for women in premature labour at the hospital level and a pre-referral dose of ACS at the health

### **TANZANIA**

ACS is indicated for preterm labour at hospital level as well as a pre-referral dose at health centers in Tanzania.

**Source:** Administration of Antenatal Corticosteroids in Pre-Term Labour Guidelines (2015 ACS Guidelines)

center level. These guidelines followed the *National Road Map Strategic Plan to Accelerate Reduction of Maternal, Newborn, and Child Deaths in Tanzania; Sharpened One Plan, April 2014,* which included the following as an intervention to increase access to safe delivery: "Lay the foundation for introduction of ACS as part of preterm birth management. This work will involve establishment of policy and guidelines, as well as quantification to ensure ACS are available".

Although the 2015 ACS Guidelines state there were no prior national policies or guidelines, the 2013 Tanzania Standard Treatment Guidelines and Essential Medicines List, Fourth Edition, do include the provision of ACS for women in premature labour under the section on newborn respiratory distress syndrome.

For detailed information contained in relevant national documents, see Annex M. Tanzania: Clinical Guides and Related Preterm Birth Interventions.

While the 2015 ACS Guidelines do not provide detailed guidance on who is authorized to prescribe and administer ACS they do state: "Guideline may be used by doctors, clinical officers, nurses, and other health professionals responsible for providing care at the dispensary, health centre, and hospital to help them to make appropriate decision". The key informant reported that medical officers and assistant medical officers are authorized to prescribe and administer ACS, while nurses and midwives are authorized to administer under clinical oversight and provide the pre-referral dose.

### **Clinical Standards**

The 2015 ACS Guidelines state that the provision of ACS is indicated at GA between 28 to 34 weeks with the addition that a specialist in a well-equipped facility can give ACS at GA as low as 24 weeks. Yet, neither the 2015 ACS Guidelines nor the STGs provide specific information or direction on how to accurately assess GA, or how to determine if a woman is at risk of preterm birth. While the 2015 ACS Guidelines do not specifically state that the use of ACS is contraindicated in the presence of maternal infection, the guidelines do emphasize that antenatal corticosteroids are immunosuppressive medicines and for this reason need to be specially managed in the following situations:

- Any form of obstetric sepsis such as chorioamnionitis;
- In existence of systemic infections such as TB and others; and
- In diabetes mellitus where adjustment of insulin dose vs administration of ACS is required.

See Table 28 for highlights of standards and services that are in place in Tanzania to support the provision of ACS as per the WHO *Recommendations*.

Table 28. Standards and Services to Support the Provision of ACS as per the WHO Recommendations in Tanzania

Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of gestation when the following conditions are met:				
Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Preterm newborns receive adequate care
National Standard Treatment Guidelines/ ACS Guidelines do not provide specific information or direction on accurately assessing GA.	National Standard Treatment Guidelines/ ACS Guidelines do not provide detail on determining if preterm birth is imminent.	The National Standard Treatment Guidelines do not state that the use of ACS in the presence of infection is contraindicated, but the ACS guidelines state that ACS must be specially managed in the presence of infection.	Hospitals and health centers where ACS is provided are CEMONC facilities.	NICUs are not available in the majority of facilities where ACS is provided.

## Comprehensive/Basic Emergency Obstetric Care

The key informant reported that all facilities offering ACS, both hospitals and health centers providing prereferral doses, are required to be CEmONC facilities. This is in line with the *Ministry of Health and Social Welfare Health Sector Strategic Plan July 2015 - June 2020 (HSSP IV)*, which states:

"The health sector will continue to expand the provision of quality services during pregnancy, childbirth and the post-natal period. Emphasis will be on the provision of Basic Emergency Obstetric and Newborn Care (BEmONC), and Comprehensive Emergency Obstetric and Newborn Care (CEmONC), starting in strategically located areas (along the lines of "Big Results Now" BRN), to address the needs of larger populations, and in facilities with high burden of reproductive, maternal, newborn, child and adolescent health (RMNCAH) problems. By 2020, 70% of primary health facilities will provide BEmONC; 50% of health centres and 100% of hospitals will provide CEmONC."

These services are strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 29 for other maternal health interventions related to improved preterm birth outcomes.

Table 29. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Tanzania<sup>48</sup>

Intervention	Indication	
Tocolytics	Pre-eclampsia (Methyldopa OR Nifedipine) Severe pre-eclampsia (Nifedipine, Hydralazine, plus Magnesium Sulfate)	
Magnesium Sulfate	Severe pre-eclampsia	
Antibiotics	pPROM no infection: Amoxycillin OR Erythromycin pPROM with Infection: Ampicillin OR Ceftriaxone OR Benzyl Penicillin	

### **Neonatal Intensive Care/Special Newborn Care**

The key informant reported that neonatal nursery units are required in facilities providing ACS, but that they are not available in the majority of facilities.

See Table 30 for a summary of newborn care interventions that are reportedly available but not nationally required at facilities providing ACS.

<sup>&</sup>lt;sup>48</sup> 2013 Tanzania Standard Treatment Guidelines and Essential Medicines List, Fourth Edition

Table 30. Summary of Preterm Newborn Care Interventions per WHO Recommendations Reported by Key Informants in Tanzania

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INTERVENTION	
Resuscitation	<ul> <li>Bag and mask</li> <li>The MOHSW Essential Newborn Care Trainee Manual, July 2013, provides a full session on how to perform resuscitation on a newborn.</li> </ul>
Thermal Care	<ul> <li>Continuous skin-to-skin care for small babies</li> <li>Incubator</li> <li>The MOHSW Essential Newborn Care Trainee Manual, July 2013, provides a session on how to keep the baby warm after delivery</li> </ul>
Infection Prevention and Treatment	<ul> <li>Hand washing</li> <li>Intravenous antibiotics</li> <li>Separate ward for sick babies</li> <li>The MOHSW Essential Newborn Care Trainee Manual, July 2013, provides a session on routine care of newborn baby - infection prevention and control</li> <li>The 2013 STGs also provide information on neonate treatment for a variety of illnesses</li> </ul>
Feeding Support	<ul> <li>Nasogastric tube</li> <li>Expressed breast milk</li> <li>Daily weight monitoring</li> <li>The MOHSW National Integrated Community Maternal, Newborn and Child</li> <li>Health Guidelines 2012 provides a section on support for feeding of preterm, low birth weight, and sick babies</li> </ul>
Safe Oxygen	<ul> <li>Oxygen mixer</li> <li>Pulse oximetry</li> <li>Oxygen titration guidelines</li> <li>Protocol for oxygen use during resuscitation</li> </ul>

Additional national level information on support for preterm or low birthweight babies can be found in the MOHSW Essential Newborn Care Trainee Manual, July 2013.

### **National Essential Medicines List**

Within the 2015 ACS Guidelines dexamethasone is indicated as the first line treatment, with betamethasone as the alternative for use in preterm labour. However, in the 2007 and updated 2013 STGs and EML, hydrocortisone is the first line treatment for preterm labour with dexamethasone as the alternative. Of note, in the same 2013 STGs and EML, the EML does not indicate either of these steroids

TANZANIA
The 2015 ACS Guidelines indicate dexamethasone and betamethasone for use in preterm labour.

with an obstetric indication; instead corticosteroids are listed under "Adrenal Hormones and Synthetic Substitutes." In addition, the *2013 STGs* and *EML* lists hydrocortisone as indicated for use in health centers, and dexamethasone is indicated for use in regional and referral hospitals.

### **Human Resources Training and Capacity Building**

The key informant reported that while in-service training on ACS provision for women at risk of imminent preterm birth does occur, there is no pre-service training. The 2015 ACS Guidelines state: "The book (guidelines) may also be used for both pre- and in-service training".

## **Metrics for ACS**

The key informant reported that there are currently no ACS indicators in the Tanzania HMIS, but that they are present in the electronic LMIS. The *2015 ACS Guidelines* provide the following indicators applicable at the council, regional, and national levels:

- Proportion (%) of hospitals providing ACS;
- Proportion (%) of women with premature birth who received ACS at 28 and 34 weeks gestation; and
- Proportion (%) of pregnant women who delivered at 24-27 weeks who received ACS.

The MCSP HMIS MNH Indicator Survey identified a range of indicators that are relevant to ACS use. These include:

ANC: Four plus visits; gestational age (in weeks);

- Labour and delivery: birthweight; blood transfusion; essential newborn care (breastfeeding within one hour, resuscitation); maternal complications diagnosed (antepartum hemorrhage, postpartum hemorrhage); and
- Postnatal care: Newborn complications referred (sepsis, meningitis, tetanus).

## **Lessons Learned from ACS Implementation**

The following table summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Tanzania's experience with ACS implementation.

Table 31. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informant in Tanzania

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
"Stakeholders need to be trained on the country guidelines and the new WHO Recommendations"	"ACS guidelines are in place"     "Dexamethasone has been included on the essential drug list by the MOH"	"Currently three sites are collecting data on ACS use and perinatal outcome, results of which will be used during scale-up"	"Poor commodity supply chains, hence ACS is not available in many facilities. Only dexamethasone is available"  "Lack of training of health care providers due to inadequate funds"

## **Additional Support Needed**

The key informant reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- · Funding for training and training materials;
- Funding for research; and
- Political and policy support.







## **HEALTH SECTOR READINESS**

ACS in clinical guidelines for preterm birth

- Clinical Guidelines 2012



- Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving

National level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth



National level guidance or criteria:

Indicates that ACS is contraindicated in the presence of infection





Gestational age at which ACS is prescribed in country

Minimum gestational age



Maximum gestational age



Corticosteroids on the **Essential Medicines List** 

Included on list



Indicated for obstetrics/maternal health



## PRETERM BIRTHS AND DEATHS

Preterm birth rate (babies born <37 weeks): 14% Low birth weight rate (babies born <2,500g): 12%

Babies born preterm per year: 226,000

Ratio of boys to girls born preterm: 1.17

Babies born per year <28 weeks: 11,000 Impaired preterm survivors per year: 5,700

Direct preterm child deaths per year: 12,500

Births at health facility: 57%

See http://www.everypreemie.org/country-profiles/ for data sources.



## **ACS USE**

Facilities authorized to provide ACS Hospitals, Health Center IV

Facilities authorized to provide a pre-referral first dose of ACS

Health Center level III, Health Center level II



## RAINING

Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth





## ベン METRICS

ACS use captured in HMIS





## **ACS PRESCRIPTION AND ADMINISTRATION**

Health care worker cadres authorized to independently prescribe and administer full course of ACS

- Obstetricians/Gynecologists
- **Experienced General Doctors in Maternity Units**

Health care worker cadres authorized to administer full course ACS with clinical oversight

- Clinical Officers working in Maternity Units
- Nurses working in Maternity Units
- Junior Medical Officers (General Practitioners) - Midwives (Enrolled and Registered Midwives)

Health care worker cadres authorized to administer a pre-referral first dose with clinical supervision

- Enrolled Comprehensive Nurses



Yes

corresponding annex of this report for data sources



## MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

Facilities authorized to provide full course ACS also reportedly provide:

Basic emergency obstetric and newborn care (BEmONC) services only



Comprehensive emergency obstetric

Thermal care

Resuscitation

Infection prevention/treatment



Newborn interventions reportedly available at facilities that give full course ACS:

Feeding support

Safe oxygen use



Neonatal Intensive Care Units (NICUs) or Special Care Wards are reportedly available at facilities giving full course ACS





## IMPLEMENTATION CHALLENGES AND STRENGTHS

Challenges to the implementation of ACS use in country:

- 1. No clear policy guidance available on GA estimation, ascertaining active and premature labour, or preterm baby management.
- 2. Professional bodies (obstetricians and gynecologists) have concerns for the safety and capacity of other cadres administering ACS.
- 3. A weak health system causes inadequate newborn care at BEmONC and CEMONC facilities.
- 4. Pharmacists not included in ACS training and guideline dissemination.

Strengths of country's ACS implementation process:

- 1. Introduction of ACS has been integrated in the roll-out of the essential newborn care package.
- 2. Growing attention to newborn health, from policy to implementation, led by a National Newborn Steering Committee and supported by MOH and partners.
- 3. ACS implementation has been systematic, starting with a pilot study of the drivers and barriers to effective ACS use in the country.
- 4. Quality improvement indicators are designed and in use, offering the opportunity to add ACS metrics.

## Uganda

## **ACS Guidelines and Implementation**

On World Prematurity Day in November 2012, the Government of Uganda committed to a new goal to reduce deaths due to complications of preterm birth between 2010 and 2025. Specifically, to incorporate targets for preterm care into the national policies and plans, increase the pace of scale-up of high impact interventions to reduce deaths due to prematurity, especially management of women in preterm labour using antenatal corticosteroids, and to promote Kangaroo Mother Care services<sup>49</sup>. This commitment was followed by revision of

### **UGANDA**

ACS is indicated for PROM and risk of premature delivery at the Health Center IV and Hospital levels as well as a pre-referral dose at the Health Center II and III levels.

Source: MOH Uganda Guidelines 2012, National Guidelines for Management of Common Conditions, and the MOH Uganda Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving the MOH Uganda Guidelines 2012, National Guidelines for Management of Common Conditions, and the MOH Uganda Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving Commodities. The national guidelines indicate the provision of a full course of ACS for women with PROM and at risk of premature delivery at Health Center IV and hospital levels, while the addendum includes the provision for a pre-referral dose at Health Center II and III levels<sup>50</sup>.

Uganda was among the first countries to undertake a pilot study on ACS with stewardship from the MOH and Government of Uganda. This was a systematic effort to introduce and scale up effective and safe use of ACS, but these efforts were derailed by the ACT findings in 2014.

The key informant recognized that while the *Addendum to the National Guidelines* allows for a pre-referral dose, the standard of care at authorized facilities is inadequate. There is current discussion at the national level to revise the guidelines to be more in line with the WHO *Recommendations*.

For detailed information contained in relevant national documents, see Annex N. Uganda: Clinical Guides and Related Preterm Birth Interventions.

While the 2012 National Clinical Guidelines and Addendum 2 do not provide detailed guidance on who is authorized to prescribe and administer ACS, the key informant reported that obstetricians-gynecologists and experienced general doctors in maternity care are authorized to prescribe and administer ACS, while midwives (enrolled and registered), clinical officers and nurses working in maternity units, and junior medical officers (general practitioners) are authorized to administer ACS with clinical oversight.

## **Clinical Standards**

The 2012 Uganda Clinical Guidelines and Addendum 2 indicate ACS provision if gestational age is less than 37 weeks. However, they do not state a minimum gestational age nor do they provide any indication of how to accurately assess gestational age. The key informant reported that the current practice is not standardized but ACS is used among pregnant women with threatened preterm labour starting at 32 weeks of gestation and that practitioners are using conventional estimated due date and LMP methods to determine gestational age.

While there is no specific information or direction on how to accurately determine if a woman is at risk of preterm birth, both the 2012 Uganda Clinical Guidelines and Addendum 2 state "If there are palpable contractions and blood- stained mucus: suspect preterm labour". The Guidelines and Addendum both state to not use ACS in the presence of maternal infection. In addition, the key informant reported that the national clinical guidelines also provide guidance on the assessment and management of maternal sepsis. See Table 32 for highlights of standards and services that are in place in Tanzania to support the provision of ACS as per the WHO Recommendations.

<sup>&</sup>lt;sup>49</sup> A Promise Renewed: Reproductive Maternal, Newborn, and Child Health Sharpened Plan for Uganda, November 2013

<sup>&</sup>lt;sup>50</sup> Uganda Health system levels include HC I – community level/community health worker; HC II – at Parish level, only outpatient care with an Enrolled Comprehensive Nurse; HC III – first BEmONC facility level, and a Clinical Officer; HC IV – first CEmONC facility level and Medical Officer; and Hospitals – district, regional, and national levels (Information from the Essential Medicines and Health Supplies List for Uganda 2012 and the key informant).

Table 32. Standards and Services to Support the Provision of ACS as per the WHO *Recommendations* in Uganda Antenatal corticosteroid therapy is recommended for women at risk of preterm birth from 24 weeks to 34 weeks of

gestation when the following conditions are met:						
Gestational age can be accurately undertaken	Preterm birth is considered imminent	No clinical evidence of maternal infection	Adequate childbirth care is available	Adequate preterm newborn care is available		
National Clinical Guidelines do not provide specific information or direction on accurately assessing GA.	National Clinical Guidelines provide limited detail on determining if preterm birth is imminent.	The National Clinical Guidelines do state that the use of ACS in the presence of infection is contraindicated	Hospitals and health centers where ACS is provided are CEMONC facilities.	NICUs are not available in the majority of facilities where ACS is provided.		

## Comprehensive/Basic Emergency Obstetric Care

The key informant reported that all facilities offering ACS are expected to be equipped with the equipment and workforce to provide care for the preterm newborn and that the Health Center IV is the first level where CEmONC services are provided. The *National Guidelines: Addendum 2*, indicates a pre-referral dose of ACS provision at the Health Center II and III levels.

These services are strengthened by the inclusion of additional obstetric interventions within the STGs. See Table 33 for other maternal health interventions related to improved preterm birth outcomes.

Health Center IV and hospitals provide CEmONC services, and Health Center II and III provide prereferral doses of ACS.

Source: MOH Uganda Guidelines 2012, National Guidelines for Management of Common Conditions, and the MOH Uganda Clinical Guidelines and Essential Medicines and Health Supplies List for Uganda, 2012, Addendum 2: RMNCH Lifesaving Commodities.

Table 33. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Uganda<sup>51</sup>

INTERVENTION	INDICATION		
Tocolytics	Eclampsia (Hydralazine, alternative Nifedipine)		
Magnesium Sulfate	Eclampsia Severe pre-eclampsia		
Antibiotics	PROM With infection (Ampicillin and Gentamicin) No infection (Erythromycin and Amoxicillin)		

## **Neonatal Intensive Care/Special Newborn Care**

The key informant reported that neonatal care corners (at a minimum) are present in Health Center IV and hospitals; and that NICUs are present at regional and national referral hospitals. See Table 34 for a summary of newborn care interventions that are reportedly available at facilities providing ACS.

<sup>&</sup>lt;sup>51</sup> MOH Uganda Guidelines 2012, National Guidelines for Management of Common Conditions

Table 34. Summary of Preterm Newborn Care Interventions per WHO *Recommendations* Reported by Key Informants in Uganda

informants in Oganda				
INTERVENTION				
Resuscitation	Bag and mask			
	The 2012 National Clinical Guidelines include a section on Newborn Resuscitation			
Thermal Care	Continuous skin-to-skin care for small babies			
	Incubators are few and limited by irregular or no power supply			
	The National Newborn Health BSS/Advocacy Strategy 2014-2018 provides the message that			
	extra effort should be taken to ensure premature and low birth weight babies are kept warm			
	by wrapping them in cloth with skin-to-skin contact between the mother and the newborn			
	both at night and during the day			
Infection Prevention	Hand washing			
and Treatment	Intravenous antibiotics			
	Separate wards for sick babies are provided in some postnatal wards, pediatric wards, and			
	NICUs			
	The 2012 National Clinical Guidelines include newborn hygiene care and the assessment for			
	special treatment needs for infection			
	The MOH Standards for Newborn Health Care Services, April 2010 includes a section on			
	infection prevention			
Feeding Support	Nasogastric tube			
	Expressed breast milk			
	Daily weight monitoring			
	The 2012 National Clinical Guidelines includes extra care of small babies/twins in first days of			
	life, which includes exclusive breastfeeding, and teaching mother alternative feeding			
	methods			
	The National Newborn Health BSS/Advocacy Strategy 2014-2018 also provides information			
	on alternative feeding methods			
Safe Oxygen	Oxygen mixer/concentrators available but limited use due to irregular or no power supply			

Additional national level information on support for preterm or low birthweight babies can be found in the 2012 National Clinical Guidelines and MOH Standards for Newborn Health Care Services, April 2010.

### **National Essential Medicines List**

Within the MOH Essential Medicines and Health Supplies List for Uganda 2012, dexamethasone is listed as an essential<sup>52</sup> drug for use at the Health Center IV level or higher, but it is not indicated for an obstetric use. The 2012 National Clinical Guidelines Addendum 2 indicates dexamethasone as vital for women in preterm labour and is for use at Health Center II level and above.

## **UGANDA**

Dexamethasone is indicated for PROM and for preterm labour in the clinical guidelines, but not listed on the EML for any obstetric indication in Uganda.

### **Human Resources Training and Capacity Building**

The key informant reported that pre-service training on the use of ACS for women at risk of imminent preterm birth is available for medical doctors and midwives, but they may provide ACS only under the supervision of an obstetrician-gynecologist. This is consistent with the *Roadmap for Accelerating the Reduction of Maternal and Neonatal Mortality and Morbidity in Uganda 2007-2015,* which included:

- Build the capacity of training institutions and service providers for key maternal and newborn health issues;
- Review and revise a competency-based professional training curriculum to ensure BEmONC is compulsory in the pre-service training for nurses/midwives and clinical officers;
- Implement an in-service program on quality essential obstetric and neonatal care with focus on BEmONC and resuscitation of the newborn;
- Equip institutions with teaching and learning materials to provide competency-based training in BEmONC and emergency newborn care;
- Implement an in-service program on family planning technology updates; and
- Train health service providers on newborn resuscitation skills, Life Saving Skills and post abortion care.

<sup>&</sup>lt;sup>52</sup> Vital medicines are procured first, essential medicines are procured if budget allows.

### **Metrics for ACS**

The key informant reported that the HMIS does not currently contain any indicators related to ACS provision, but does provide for collection of data on prematurity as a condition at the out-patient level. However, these data are not summarized on a monthly basis for reporting at the district and national levels. Additionally, the key informant stated that there is a scheduled review of the HMIS tools which will provide an opportunity to include indicators for ACS use.

The secondary analysis found the following indicators listed in the 2013 A Promise Renewed: Reproductive Maternal, Newborn, and Child Health Sharpened Plan for Uganda:

- Illustrative Planning Matrix Provision of ACS at all levels where delivery occurs. Baseline: 5 percent, 2017: 60 percent; and
- Illustrative Indicators for a District level Scorecard: Women in preterm labour receive at least one dose of dexamethasone.

There are a number of ACS-related indicators listed in the MCSP HMIS MNH Indicator Survey. These include:

- ANC: Four or more visits; gestational age (in weeks); maternal complications diagnosed; and
- Labour and delivery:
  - Newborn: birthweight; essential care (breastfeeding within one hour; immediate skin-to-skin; resuscitation
  - o Maternal: gestational age (in weeks); maternal complication diagnosed
  - Postnatal care: maternal complication referred; newborn complication referred.

## **Lessons Learned from ACS Implementation**

Table 35 summarizes key informant interview data on lessons learned, strengths, opportunities, and challenges of Uganda's experience with ACS implementation.

Table 35. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informant in Uganda

LESSONS LEARNED	STRENGTHS	OPPORTUNITIES	CHALLENGES
"Local contexts (policies and practices) including health professional bodies and regulations need to be in harmony with available evidence"     "Identifying local barriers and drivers to effective use of ACS at facility level is a critical step to driving effective use through implementation of quality improvement practices"     "One of the most limiting factors to use is lack of knowledge and skills amongst health workers to use ACS for preterm labour management. This should go along with clear guidance and protocols available to all frontline health workers managing labour and newborns"     "ACS use should be introduced along with	The introduction of ACS has been integrated in the roll-out of the essential newborn care package"  "There is growing attention to newborn health, crossing from policy to implementation, with stewardship of a nationally recognized technical support committee (National Newborn Steering Committee) and supported by MOH and partners"  "The process was systematic starting with a pilot study to understand the drivers and barriers to effective ACS use in the country"  "Quality improvement indicators developed and in use, offering the opportunity to add ACS metrics"	"There is an integrated Helping Babies Breathe Plus package for inservice training that includes ACS use"     "Government willingness to introduce use of ACS and available partner support"     "Uganda is a pathfinder country for Global Financing Facility funding and is benefiting from the second wave of funding following the recently developed investment case"     "The national hospital and basic standards for newborn care that are currently being revised, provide for provision of ACS to all mothers with preterm labour/ previous history of prematurity starting at HC III as a standard"	<ul> <li>CHALLENGES</li> <li>"There is no clear policy guidance available for frontline health workers on GA estimation, ascertaining active and premature labour, and corresponding preterm baby management"</li> <li>"Professional bodies (e.g. Obstetricians and Gynecologists) have concern for the safety and capacity of other cadres administering ACS"</li> <li>"Overall weak health system not allowing for availability of appropriate newborn care at Basic and Emergency Health facilities in the country"</li> <li>"Pharmacists not included in ACS training and guideline dissemination"</li> <li>"Shifting positions on available evidence"</li> <li>"Limiting regulations in terms of cadres that</li> </ul>
all frontline health workers managing labour and newborns"  "ACS use should be	indicators developed and in use, offering the opportunity to add ACS	previous history of prematurity starting at	dissemination"  • "Shifting positions on available evidence"  • "Limiting regulations in

## **Additional Support Needed**

The key informant reported that the country needs the following additional support to ensure the safe use of ACS for women at risk of imminent preterm birth:

- Technical assistance to expand/scale up the use of ACS, to ensure that all practice and policy
  guidelines are harmonized, implementation is carefully monitored and documented, and health
  systems supports are in place including appropriate supervision and mentoring tools, quantification
  and forecasting guidance; and
- Broaden research evidence especially implementation, impact, and cost effectiveness research, in particular, studies done in low-income countries and in the context of more integrated interventions.

## **Conclusions and Recommendations**

There are nearly 2.2 million preterm births and approximately 195,000 direct preterm child deaths annually across the seven Pathfinder countries highlighted in this analysis. Countries are responding to preterm birth as a public health priority and are moving to implement evidence-based interventions within national maternal and newborn health programs. ACS is one intervention for improved preterm birth outcomes and represents the continuum of care from its provision during preterm labour to the need for high quality childbirth and preterm newborn care to realize its positive impact on newborn survival while limiting the risk of resultant maternal and newborn complications.

The WHO *Recommendations* provide a necessary framework for the safe and effective implementation of ACS in low-income settings when five conditions are met: (1) accurate gestational age calculation, (2) PTB is imminent, (3) no clinical evidence of maternal infection, (4) adequate childbirth care is available, and (5) adequate preterm newborn care is available. Each of the seven Pathfinder countries is implementing ACS for women at risk of preterm birth and the majority of countries include language in their clinical protocols or standard treatment guidelines regarding the use of ACS; although, none of the countries include language on how to accurately measure gestational age, and there are gaps in national-level guidance or criteria for how to determine if a woman is at risk of imminent preterm birth. At the same time, only a few include guidance that indicates ACS is contraindicated in the presence of infection. Existing standard treatment guidelines do, however, emphasize the need for adequate childbirth care and preterm newborn care when using ACS.

There is general agreement among the Pathfinder countries that ACS should be provided within a comprehensive package of maternal and newborn care for preterm birth that includes newborn intensive care that is consistently available. The majority of countries reported that facilities providing ACS meet comprehensive emergency obstetric and newborn care standards and all countries reported the availability of some form of special newborn care or the availability of Neonatal Intensive Care Units. However, countries further reported that there is great variability in the quality and availability of these services across their health systems. Specific newborn care interventions listed as conditions for ACS use in the WHO *Recommendations* are resuscitation, thermal care, infection prevention and treatment, feeding support, and safe oxygen use.

Access to the appropriate level of care for the safe provision of ACS remains a challenge. According to population-based survey data, births at health facilities range from a low of 10 percent in Ethiopia to a high of 91 percent in Malawi with an unweighted average of 31 percent across the seven countries—leaving great room for improvement.

HMIS indicators measuring the use of ACS are lacking in the Pathfinder countries, though most countries have proposed a national indicator for ACS use to be integrated into their health management information systems. There are currently no suitable proxy indicators related to the five WHO preconditions for the safe and effective use of ACS.

Countries are building the foundations necessary for expanded implementation and recognize that challenges remain in terms of consistent and quality maternal and newborn care to safely and effectively provide ACS. Each country identified specific areas to improve ACS implementation including, for example, re-establishing GA guidelines in Malawi and Uganda to meet international recommendations; expanding the type of providers who can prescribe and administer ACS in Ethiopia; the design and release of new STGs in Nigeria and Sierra Leone to direct ACS implementation; and developing an e-learning curricula for ACS in Uganda.

Country representatives recommended continued support for several implementation components including clinical guidelines, inclusion of obstetric indications for dexamethasone and betamethasone in Essential Medicine Lists, provider capacity building to safely use ACS, measuring and collecting ACS-related data, and attention to the quality of childbirth care and preterm newborn care. Participants thought it would be useful to have in-depth quality of care surveys conducted to more comprehensively evaluate the safe and effective implementation of MNH services including ACS use. Emphasis was also placed on ways to address gestational age including: making pregnancy test kits available in ANC to confirm pregnancy before palpation is possible; ensuring the availability of ultrasound equipment in ANC; training ANC providers to use ultrasound technology to estimate GA; and improving ANC provider skills to do abdominal palpations and to measure fundal height. Country representatives look forward to the dissemination of the Threatened Preterm Birth learning module

(developed by the Helping Babies Survive partnership) and welcome support for up-to-date training material and educational tools.

The ultimate goal for ACS as an intervention within national MNH programs is to improve health outcomes related to preterm birth. Ensuring consistently available quality MNH services and interventions is essential to the realization of this goal. This analysis has identified crucial needs within health care systems that must be addressed by the international community as well as by national and local stakeholders. Ideally, the information provided here and ensuing conversations will meaningfully add to the global and national exchange regarding the safe expansion of ACS and, ultimately, inform comprehensive programming for improved preterm birth outcomes.

## **Annexes**

- Annex A. ACS Technical Working Group Meeting Participant List, June 14, 2016
- Annex B. Framework for ACS Policy and Implementation Landscape Analysis
- Annex C. Key Informant Questionnaire
- Annex D. Country-Level Key Informants
- Annex E. Individuals Who Supported the Implementation of the ACS Landscape Analysis
- Annex F. MCSP HMIS Survey Indicators Related to WHO Preconditions for ACS Use
- Annex G. Indicators by WHO Precondition for the Safe and Effective Use of ACS by Country (derived from MCSP HMIS Indicator Survey, 2015)
- Annex H. Democratic Republic of the Congo: Clinical Guides and Related Preterm Birth Interventions
- Annex I. Ethiopia: Clinical Guides and Related Preterm Birth Interventions
- Annex J. Malawi: Clinical Guides and Related Preterm Birth Interventions
- Annex K. Nigeria: Clinical Guides and Related Preterm Birth Interventions
- Annex L. Sierra Leone: Clinical Guides and Related Preterm Birth Interventions
- Annex M. Tanzania: Clinical Guides and Related Preterm Birth Interventions
- Annex N. Uganda: Clinical Guides and Related Preterm Birth Interventions