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

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<th>Definition</th>
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<tbody>
<tr>
<td>ACNM</td>
<td>American College of Nurse-Midwives</td>
</tr>
<tr>
<td>ACS</td>
<td>Antenatal corticosteroids</td>
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<tr>
<td>ACT</td>
<td>Antenatal Corticosteroids Trial</td>
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<tr>
<td>AMTSL</td>
<td>Active management of the third stage of labour</td>
</tr>
<tr>
<td>ANC</td>
<td>Antenatal care</td>
</tr>
<tr>
<td>BEmONC</td>
<td>Basic Emergency Obstetric and Newborn Care</td>
</tr>
<tr>
<td>BMI</td>
<td>Body mass index</td>
</tr>
<tr>
<td>CEmONC</td>
<td>Comprehensive Emergency Obstetric and Newborn Care</td>
</tr>
<tr>
<td>CPAP</td>
<td>Continuous positive airway pressure</td>
</tr>
<tr>
<td>DHS</td>
<td>Demographic and Health Survey</td>
</tr>
<tr>
<td>DRC</td>
<td>Democratic Republic of the Congo</td>
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<tr>
<td>EML</td>
<td>Essential medicines list</td>
</tr>
<tr>
<td>EmONC</td>
<td>Emergency Obstetric and Newborn Care</td>
</tr>
<tr>
<td>ENAP</td>
<td>Every Newborn Action Plan</td>
</tr>
<tr>
<td>ENC</td>
<td>Essential newborn care</td>
</tr>
<tr>
<td>EWEC</td>
<td>Every Woman Every Child</td>
</tr>
<tr>
<td>FMOH</td>
<td>Federal Ministry of Health</td>
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<tr>
<td>GA</td>
<td>Gestational age</td>
</tr>
<tr>
<td>GAPPS</td>
<td>Global Alliance to Prevent Prematurity and Stillbirth</td>
</tr>
<tr>
<td>HBB</td>
<td>Helping Babies Breathe</td>
</tr>
<tr>
<td>HMIS</td>
<td>Health management information system</td>
</tr>
<tr>
<td>IMNCI</td>
<td>Integrated Management of Neonatal and Childhood Illness</td>
</tr>
<tr>
<td>KMC</td>
<td>Kangaroo mother care</td>
</tr>
<tr>
<td>LBW</td>
<td>Low birth weight</td>
</tr>
<tr>
<td>LMIS</td>
<td>Logistics management information system</td>
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<tr>
<td>LMP</td>
<td>Last menstrual period</td>
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<tr>
<td>MCH</td>
<td>Maternal and child health</td>
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<tr>
<td>MCSP</td>
<td>Maternal and Child Survival Program</td>
</tr>
<tr>
<td>MICS</td>
<td>Multiple Indicator Cluster Surveys</td>
</tr>
<tr>
<td>MNH</td>
<td>Maternal and newborn health</td>
</tr>
<tr>
<td>MOH</td>
<td>Ministry of Health</td>
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<tr>
<td>NG</td>
<td>Nasogastric</td>
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<tr>
<td>NGO</td>
<td>Non-governmental organization</td>
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<tr>
<td>NICU</td>
<td>Neonatal intensive care unit</td>
</tr>
<tr>
<td>PCI</td>
<td>Project Concern International</td>
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<tr>
<td>pPROM</td>
<td>Preterm premature rupture of membranes</td>
</tr>
<tr>
<td>PROM</td>
<td>Premature rupture of membranes</td>
</tr>
<tr>
<td>PTB</td>
<td>Preterm birth</td>
</tr>
<tr>
<td>RMNCH</td>
<td>Reproductive maternal and newborn health</td>
</tr>
<tr>
<td>SBA</td>
<td>Skilled birth attendant</td>
</tr>
<tr>
<td>SPA</td>
<td>Service Provision Assessments</td>
</tr>
<tr>
<td>STG</td>
<td>Standard treatment guidelines</td>
</tr>
<tr>
<td>TRT</td>
<td>Technical Resource Team</td>
</tr>
<tr>
<td>TWG</td>
<td>Technical Working Group</td>
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<tr>
<td>UNCoLSC</td>
<td>United Nations Commission on Life-Saving Commodities for Women and Children’s Health</td>
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<td>USAID</td>
<td>United States Agency for International Development</td>
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<td>WHO</td>
<td>World Health Organization</td>
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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.

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. 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 www.everypreemie.org/countryprofiles).

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.

1 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 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.2

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).

2 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.

![Table 1. UNCoLSC Life-Saving Commodities and Indicated Use](image)

<table>
<thead>
<tr>
<th>COMMODITY BY LIFE STAGE</th>
<th>INDICATED USE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Maternal Health Commodities</strong></td>
<td></td>
</tr>
<tr>
<td>1. Oxytocin</td>
<td>Postpartum hemorrhage</td>
</tr>
<tr>
<td>2. Misoprostol</td>
<td>Postpartum hemorrhage</td>
</tr>
<tr>
<td>3. Magnesium sulfate</td>
<td>Eclampsia and severe pre-eclampsia</td>
</tr>
<tr>
<td><strong>Newborn Health Commodities</strong></td>
<td></td>
</tr>
<tr>
<td>4. Injectable antibiotics</td>
<td>Newborn sepsis</td>
</tr>
<tr>
<td>5. Antenatal corticosteroids</td>
<td>Preterm respiratory distress syndrome</td>
</tr>
<tr>
<td>6. Chlorhexidine</td>
<td>Newborn cord care</td>
</tr>
<tr>
<td>7. Resuscitation devices</td>
<td>Newborn asphyxia</td>
</tr>
<tr>
<td><strong>Child Health Commodities</strong></td>
<td></td>
</tr>
<tr>
<td>8. Amoxicillin</td>
<td>Pneumonia</td>
</tr>
<tr>
<td>9. Oral rehydration salts</td>
<td>Diarrhoea</td>
</tr>
<tr>
<td>10. Zinc</td>
<td>Diarrhoea</td>
</tr>
<tr>
<td><strong>Reproductive Health Commodities</strong></td>
<td></td>
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<tr>
<td>11. Female condoms</td>
<td>Sexually transmitted infections</td>
</tr>
<tr>
<td>12. Contraceptive implants</td>
<td>Family planning/contraception</td>
</tr>
<tr>
<td>13. Emergency contraception</td>
<td>Family planning/contraception</td>
</tr>
</tbody>
</table>

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

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3 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”4. 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 sub-recommendations for ACS use and outlined the overall parameters for its safe and effective use in the following statement.

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**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).


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**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.

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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 www.everypreemie.org/country-profiles).

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

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

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\(^5\), the UN Commission on Life Saving Commodities report\(^6\), and relevant journal articles were also reviewed\(^7,8\). 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\(^9\). 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.

\(^5\) *Countdown to 2015: A Decade of Tracking Progress for Maternal, Newborn and Child Survival The 2015 Report.*


\(^7\) *Antenatal corticosteroids for management of preterm birth: a multi-country analysis of health system bottlenecks and potential solutions, BMC 2015.*

\(^8\) *Basic Newborn Care Bottle Neck Analysis, BMC 2015.*

\(^9\) 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)\(^\text{10}\).

Table 3: ACS Guidelines and ACS Implementation by Country

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>APPROVED LEVEL OF CARE FOR ACS USE</th>
<th>WHERE ACS ACTUALLY IN USE</th>
<th>INDICATIONS FOR USE</th>
<th>PRE-REFERRAL DOSE ALLOWED</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRC</td>
<td>Tertiary and Maternity Hospitals</td>
<td>Tertiary and maternity hospital in capital city only</td>
<td>pPROM, eclampsia, preterm labour</td>
<td>No</td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Referral, General, Primary Hospitals, and Health Centers</td>
<td>Tertiary and Secondary hospitals</td>
<td>Preterm labour</td>
<td>Yes</td>
</tr>
<tr>
<td>Malawi</td>
<td>Central and District Hospitals</td>
<td>Central and District Hospitals</td>
<td>Preterm labour</td>
<td>No</td>
</tr>
<tr>
<td>Nigeria</td>
<td>Tertiary Hospitals</td>
<td>Tertiary hospitals</td>
<td>Preterm labour</td>
<td>No</td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>Tertiary Hospitals including District Referral Hospitals</td>
<td>Tertiary and District Referral Hospitals</td>
<td>None</td>
<td>No</td>
</tr>
<tr>
<td>Tanzania</td>
<td>Hospitals, Health Centers</td>
<td>Hospitals</td>
<td>Preterm labour</td>
<td>Yes</td>
</tr>
<tr>
<td>Uganda</td>
<td>Hospitals, Health Centers IV, III, and II</td>
<td>Hospitals, Health Center IV</td>
<td>pPROM and “risk of preterm delivery”</td>
<td>Yes</td>
</tr>
</tbody>
</table>

\(^{10}\) 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\(^\text{11}\) 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

<table>
<thead>
<tr>
<th>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:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Condition</td>
</tr>
<tr>
<td>DRC</td>
</tr>
<tr>
<td>Ethiopia</td>
</tr>
<tr>
<td>Malawi</td>
</tr>
<tr>
<td>Nigeria</td>
</tr>
<tr>
<td>Sierra Leone</td>
</tr>
<tr>
<td>Tanzania</td>
</tr>
<tr>
<td>Uganda</td>
</tr>
</tbody>
</table>

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

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11 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

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

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

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>RESUSCITATION</th>
<th>THERMAL CARE</th>
<th>INFECTION PREVENTION AND TREATMENT</th>
<th>FEEDING SUPPORT</th>
<th>SAFE OXYGEN USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRC</td>
<td>Bag &amp; mask</td>
<td>Skin-to-skin</td>
<td>Handwashing</td>
<td>Nasogastric (NG) tubes</td>
<td>Oxygen mixers</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators (not prevalent)</td>
<td></td>
<td>Daily weight monitoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Kangaroo Mother Care (KMC)</td>
<td></td>
<td>Daily intake monitoring</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators (some available)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hand wash</td>
<td>Antibiotics</td>
<td>Exclusive breastfeeding</td>
<td>Oxygen concentrators</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Sterilization of equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Handwashing</td>
<td></td>
</tr>
<tr>
<td>Ethiopia</td>
<td>Bag &amp; mask</td>
<td>Drying, cleaning, wrapping</td>
<td>Antibiotics</td>
<td>Express exclusive breastfeeding</td>
<td>Oxygen titration</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin-to-skin</td>
<td></td>
<td>Sterilization of equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>KMC</td>
<td></td>
<td>Handwashing</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Radiant warmers/ incubators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hand wash</td>
<td>Antibiotics</td>
<td>Express milk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Separate ward with babies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td>Bag &amp; mask</td>
<td>Skin-to-skin</td>
<td>Antibiotics</td>
<td>Expression milk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators (some available)</td>
<td></td>
<td>Sterilization of equipment</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hand wash</td>
<td></td>
<td>Handwash</td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nigeria</td>
<td>Bag &amp; mask</td>
<td>KMC</td>
<td>Antibiotics</td>
<td>NG tube</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators (at general hospitals)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Separate ward with babies</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sierra Leone</td>
<td>Bag &amp; mask</td>
<td>Dry, warm, stimulate</td>
<td>Antibiotics</td>
<td>NG tube (general and teaching hospitals)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Breastfeeding and all feeding alternatives</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>KMC</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td>Bag &amp; mask</td>
<td>Skin-to-skin</td>
<td>Handwash</td>
<td>NG tube</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Expression milk</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Uganda</td>
<td>Bag &amp; mask</td>
<td>Skin-to-skin</td>
<td>Handwash</td>
<td>NG tube</td>
<td>Oxygen mixer</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Incubators (limited supply and irregular power supply)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Expression milk</td>
<td></td>
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</tbody>
</table>

**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 in-service 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. 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 skin-to-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 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.

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12 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

<table>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “ACS on EML for obstetric use”</td>
<td>• “MOH involvement and ownership”</td>
</tr>
<tr>
<td>• “Intervention needs to be cost effective”</td>
<td>• “Guidelines, policies exist for most countries”</td>
</tr>
<tr>
<td>• “Need comprehensive package not just guidelines”</td>
<td>• “Strong political will and partner support for this intervention”</td>
</tr>
<tr>
<td>• “Including BEmONC facilities would expand reach of ACS”</td>
<td></td>
</tr>
<tr>
<td>• “Policies, guidelines, pre-service education, in-service education, regulatory bodies all need alignment”</td>
<td></td>
</tr>
<tr>
<td>• “Need increased community awareness of PTB”</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “Expand standards and guidelines to include assessment (i.e. how to determine who should receive ACS)”</td>
<td>• “Inadequate training and capacity building”</td>
</tr>
<tr>
<td>• “Need studies of ACS impact at scale”</td>
<td>• “Inadequate information available to safely scale up in low income countries”</td>
</tr>
<tr>
<td>• “Partner commitment, political will”</td>
<td>• “Delay in diagnosis of preterm labour”</td>
</tr>
<tr>
<td>• “Strengthen quality of ANC”</td>
<td>• “ACS not in pre-service training”</td>
</tr>
<tr>
<td>• “Increase community awareness to reduce delay in diagnosis”</td>
<td>• “Poor supply chain”</td>
</tr>
<tr>
<td>• “Partner commitment, political will”</td>
<td>• “Lack trained health care workers”</td>
</tr>
<tr>
<td>• “Strengthen quality of ANC”</td>
<td>• “No specific implementation guidelines for new WHO recommendations”</td>
</tr>
<tr>
<td>• “Increase community awareness to reduce delay in diagnosis”</td>
<td>• “Lack of diagnostics such as ultrasound for GA”</td>
</tr>
<tr>
<td>• “Partner commitment, political will”</td>
<td>• “Many deliveries are occurring at lower level facilities where it is not appropriate to provide ACS”</td>
</tr>
</tbody>
</table>

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
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

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

Corticosteroids on the Essential Medicines List

Gestational age at which ACS is prescribed in country
- Minimum gestational age (weeks) 28
- Maximum gestational age (weeks) 34

How to determine gestational age (GA) when giving ACS

National level guidance or criteria:
- Indicates that ACS is contraindicated in the presence of infection.
- How to determine gestational age (GA) when giving ACS

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%

METRICS

ACS use captured in HMIS: No data

ACS USE

Facilities authorized to provide ACS
Facilities authorized to provide a pre-referral first dose of ACS: No data

TRAINING

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

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

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

Newborn interventions reportedly available at facilities that give full course ACS:
- Resuscitation
- Thermal care
- Infection prevention/treatment
- 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.

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

<table>
<thead>
<tr>
<th>Recommandations au niveau national ou critères:</th>
<th>Âge gestationnel auquel les ACS sont prescrits dans le pays</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indique que l’administration d’ACS est contre-indiquée en cas d’infection</td>
<td>Âge gestationnel minimal (en semaines)</td>
</tr>
<tr>
<td>Détermination de l’âge gestationnel lors de l’administration d’ACS</td>
<td>Âge gestationnel maximal (en semaines)</td>
</tr>
</tbody>
</table>

Corticostéroïdes dans la liste des médicaments essentiels
- Contenus dans la liste
- Indiqués pour les soins obstétriques et de maternité

Recommandations au niveau national ou critères pour déterminer si une femme présente un risque imminent d’accouchement prématuré

<table>
<thead>
<tr>
<th>Recommandations au niveau national ou critères:</th>
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</thead>
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</tr>
<tr>
<td>Détermination de l’âge gestationnel lors de l’administration d’ACS</td>
<td>Âge gestationnel maximal (en semaines)</td>
</tr>
</tbody>
</table>

SOINS CLINIQUES DE LA MÈRE ET DU NOUVEAU-NÉ

Établissements habilités à fournir un traitement ACS complet
- Hôpitaux de référence en maternité et hôpitaux tertiaires à Kinshasa
- Aucune donnée

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

Établissements habilités à administrer une première dose d’ACS pré-transfert
- Membres du personnel soignant autorisés à prescrire et administrer un traitement complet aux ACS sous supervision clinique
  - Médécins
  - Sages-femmes
  - Infirmières
- Membres du personnel soignant autorisés à administrer une première dose pré-transfert sous supervision clinique
  - Aucune donnée

Défis principaux à la mise en œuvre des interventions
- Les formations importantes et des renforcements de capacité sont nécessaires à tous les niveaux des soins de santé.
- Informations insuffisantes pour étendre l’utilisation sécurisée d’ACS.
- 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 interventions
- Le Ministère de la Santé a supervisé le programme des ACS, notamment la rédaction et l’application des normes et recommandations liées à l’usage des ACS.
- Les ACS font partie des matières incluses dans les formations continues.
- Administrer des ACS est simple.

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, 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:


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, 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.

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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:

<table>
<thead>
<tr>
<th>Condition</th>
<th>Documentation</th>
<th>Adequate childbirth care is available</th>
<th>Adequate preterm newborn care is available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age can be accurately undertaken</td>
<td>National Standard Treatment Guidelines do not provide specific information or direction on accurately assessing GA.</td>
<td>The national clinical standards state that the use of ACS in the presence of infection is contraindicated.</td>
<td>NICUs are present in tertiary and maternity reference hospitals where ACS is provided.</td>
</tr>
<tr>
<td>Preterm birth is considered imminent</td>
<td>National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.</td>
<td>Tertiary and maternity reference hospitals where ACS is provided are CEmONC facilities.</td>
<td></td>
</tr>
<tr>
<td>No clinical evidence of maternal infection</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate childbirth care is available</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate preterm newborn care is available</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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 DRC

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Dystocia (Salbutamol)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Eclampsia and severe pre-eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>pPROM (Ampicillin, alternatives Amoxicillin and Erythromycin)</td>
</tr>
</tbody>
</table>

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

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

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 15.

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 HMIS16 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

<table>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Dexamethasone is on the national list of essential medicines and is indicated</td>
<td>“The Ministry of Health has oversight of the ACS program including the</td>
<td>“Expand the standards and guidelines for ACS”</td>
<td>“Significant training and capacity building needed at all levels of health</td>
</tr>
<tr>
<td>for fetal lung maturation”</td>
<td>design and use of standards and guidelines related to ACS use”</td>
<td></td>
<td>care”</td>
</tr>
<tr>
<td>“Dexamethasone is produced locally”</td>
<td>“ACS is included in the training materials for on-the-job training”</td>
<td></td>
<td>“Insufficient information to expand the safe use of ACS”</td>
</tr>
<tr>
<td>“ACS is not used on a large scale”</td>
<td>“ACS administration is easy”</td>
<td></td>
<td>“There is a long delay in the diagnosis of preterm labour, making</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>interventions difficult”</td>
</tr>
</tbody>
</table>

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;

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15 Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries. 2015.
16 September 2015. World Health Organization, Department of Essential Medicines and Health Products.
17 MCSP HMIS indicator data
• 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.
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 for how to determine if a woman is at risk of imminent preterm birth
- FMOH Standard Treatment Guidelines for Primary Hospital 2014
- FMOH Standard Treatment Guidelines for General Hospital 2014
- FMOH Standard Treatment Guidelines for Health Centers, 2014

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%

Preterm births and deaths metrics:
- ACS use captured in HMIS
- In-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth
- Pre-service curricula reportedly include provision of ACS for women at risk of imminent preterm birth

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

TRAINING
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

MATERNAL AND NEWBORN CLINICAL CARE

Key Services Related to the Safe and Effective Use of ACS

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:
- Nurses
- Midwives

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

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

Newborn interventions reportedly available at facilities that give full course ACS:
- Resuscitation
- Thermal care
- Infection prevention/treatment
- Feeding support
- Safe oxygen use

Implementable 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.


¹ 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\textsuperscript{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.

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\textsuperscript{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\textsuperscript{20} 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\textsuperscript{21}, 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.

\textsuperscript{18} General Hospital: Shall mean a health facility at secondary level of healthcare which provides promotive, preventive, curative, and rehabilitative services 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)

\textsuperscript{19} 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).


\textsuperscript{21} 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:

<table>
<thead>
<tr>
<th>Causes of Preterm Labour:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiple gestation</td>
</tr>
<tr>
<td>• Infection like urinary tract infection, febrile illness, abdominal surgery</td>
</tr>
<tr>
<td>• Uterine anomalies, antepartum hemorrhage (placenta previa and abruptio placentae)</td>
</tr>
<tr>
<td>• pPROM</td>
</tr>
<tr>
<td>• Low socioeconomic status</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Clinical Features:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• 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</td>
</tr>
<tr>
<td>• Cervical dilatation greater than 1cm</td>
</tr>
<tr>
<td>• Cervical effacement of 80 percent or greater</td>
</tr>
</tbody>
</table>

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>
<thead>
<tr>
<th>Table 12. Standards and Services to Support the Provision of ACS as per the WHO Recommendations in Ethiopia</th>
</tr>
</thead>
<tbody>
<tr>
<td>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:</td>
</tr>
<tr>
<td>Gestational age can be accurately undertaken</td>
</tr>
<tr>
<td>National Standard Treatment Guidelines do not provide specific information or direction on accurately assessing GA.</td>
</tr>
</tbody>
</table>

Comprehensive/Basic Emergency Obstetric Care
In Ethiopia, regular health centers are expected to be BEmONC facilities, while A-Type health centers22, 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:

• 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

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Preterm labour (nifedipine)</td>
</tr>
<tr>
<td></td>
<td>Eclampsia (methyldopa, alternative nifedipine)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Preterm premature rupture of membranes (pPROM)</td>
</tr>
<tr>
<td></td>
<td>(ampicillin, alternative erythromycin)</td>
</tr>
</tbody>
</table>

**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

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>REPORTED BY KEY INFORMANT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation</td>
<td>• Provided at all facility levels: using guidelines from Helping Babies Breathe (HBB).</td>
</tr>
<tr>
<td></td>
<td>o 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.</td>
</tr>
<tr>
<td></td>
<td>• The STGs for Primary Hospitals also have a Neonatal Resuscitation Plan.</td>
</tr>
<tr>
<td>Thermal Care</td>
<td>• All facilities implement drying, cleaning and wrapping</td>
</tr>
<tr>
<td></td>
<td>• Skin-to-skin is encouraged for all babies for 1+ hour and for preterm babies KMC is encouraged</td>
</tr>
<tr>
<td></td>
<td>• Radiant warmers and incubators have been sent to 178 of the 264 hospitals</td>
</tr>
<tr>
<td></td>
<td>• KMC is included in the STGs for Primary Hospitals and the Newborn Training Manual for care of low birthweight infants</td>
</tr>
<tr>
<td>Infection Prevention and Treatment</td>
<td>• Part of B/CEmONC services, provided at health center and higher levels of care</td>
</tr>
<tr>
<td></td>
<td>o Amoxicillin or ampicillin are provided for free by the MOH</td>
</tr>
<tr>
<td></td>
<td>• As part of labour and delivery services: infection prevention, sterilization, hand washing, using sterile cord cutter, cleaning with clean towels</td>
</tr>
<tr>
<td>Feeding Support</td>
<td>• Exclusive breast feeding is encouraged</td>
</tr>
<tr>
<td></td>
<td>• Very preterm and sick babies are supported with expressed milk and tube feeding24</td>
</tr>
<tr>
<td></td>
<td>• Standardized MOH NICU guidelines call for daily weight monitoring</td>
</tr>
<tr>
<td></td>
<td>• The STGs for Primary Hospitals include Feeding Problems: Feeding of a preterm, small for date and infants of diabetic mothers.</td>
</tr>
<tr>
<td>Safe Oxygen</td>
<td>• 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.</td>
</tr>
<tr>
<td></td>
<td>• Oxygen concentrators are used, oxygen mixers are not available.</td>
</tr>
<tr>
<td></td>
<td>• There is no standardized Safe Oxygen Protocol available for facilities.</td>
</tr>
</tbody>
</table>

---

23 National Standard Treatment Guidelines for Primary Hospitals
24 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)\(^25\).

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\(^26\) on BEmONC, while data from the secondary analysis indicated only obstetricians and pediatricians are provided pre-service training\(^27\). 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\(^28\). 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)
  - 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).

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.

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\(^25\) 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.

\(^26\) Ibid.


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

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

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”.

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## HEALTH SECTOR READINESS

ACS in clinical guidelines for preterm birth

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

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

### ACS USE

- Facilities authorized to provide ACS
- Central Hospitals and District Hospitals
- Facilities authorized to provide a pre-referral first dose of ACS

### 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
  - No 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
- Newborn interventions reportedly available at facilities that give full course ACS:
  - Resuscitation
  - Thermal care
  - Infection prevention/treatment
  - 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.

### METRICS

- ACS use captured in HMIS
- 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
- Yes
- No

### TRAINING

- 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

### 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
- Births at health facility: 91%

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

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.

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\textsuperscript{30} 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.

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; and
- The Participants Manual in Integrated Maternal and Neonatal Care (IMNC) indicate ACS for 24 to 37 weeks.

\textsuperscript{30} See page 12 for more information on the ACT findings.
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

<table>
<thead>
<tr>
<th>Gestational age can be accurately undertaken</th>
<th>Preterm birth is considered imminent</th>
<th>No clinical evidence of maternal infection</th>
<th>Adequate childbirth care is available</th>
<th>Adequate preterm newborn care is available</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Standard Treatment Guidelines do not provide specific information or direction on accurately assessing GA</td>
<td>National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.</td>
<td>The National Standard Treatment Guidelines do not state that the use of ACS in the presence of infection is contraindicated.</td>
<td>District and central hospitals where ACS is provided are CEmONC facilities.</td>
<td>NICUs are present in district and central hospitals where ACS is provided.</td>
</tr>
</tbody>
</table>

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\(^{32}\) 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\(^{33}\)

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Pregnancy Induced Hypertension (MgSO4, Methyldopa, Nifedipine)</td>
</tr>
<tr>
<td></td>
<td>Pre-eclampsia (Methyldopa, Hydralazine, alternative Nifedipine)</td>
</tr>
<tr>
<td></td>
<td>Severe pre-eclampsia (Magnesium Sulfate)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Pre-eclampsia, Eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>Prelabour/PROM</td>
</tr>
<tr>
<td></td>
<td>(Health Center: Erythromycin, Metronidazole)</td>
</tr>
<tr>
<td></td>
<td>Hospital: Ampicillin, Erythromycin, alternative Benzylencillin)</td>
</tr>
</tbody>
</table>

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.

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\(^{31}\) Guidance for determining GA is implied and not explicitly stated.


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

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

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.³⁴

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 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 2015.³⁵ 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”.

MALAWI

The Participants Manual on IMNC 2015 targets midwives and other skilled birth attendants in the provision of ACS for 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 ACS³⁶
  - Baseline: to be determined
  - 2020 Coverage Target: 60%
  - 2025 Coverage Target: 65%
  - 2030 Coverage Target: 70%
  - 2035 Coverage Target: 75%.

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**:
  - 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>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>“Staff orientation is key to adoption of new interventions”</td>
<td>“Partner commitment supported the nationwide orientation of ACS use”</td>
<td>“Partner commitment”</td>
<td>“Women report to facilities too late when they have signs of preterm labour, as such they do not benefit from ACS”</td>
</tr>
<tr>
<td>“BEmONC facilities need to be included if more women are to be reached”</td>
<td>“All secondary and tertiary level facilities are providing ACS”</td>
<td>“Very strong political will”</td>
<td>“Lack of adequate resources, i.e. ultrasounds, to safely use ACS”</td>
</tr>
<tr>
<td>“Supportive supervision is key to ensure adherence to prescribed standards”</td>
<td>“Inclusion of ACS in obstetric protocols”</td>
<td>“Regulating bodies and health care workers are willing to support ACS use for preterm labour”</td>
<td>“Most deliveries occur at primary level facilities not authorized to provide ACS”</td>
</tr>
</tbody>
</table>

### 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

**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**

Births at health facility: **36%**

**TRAINING**

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

- Yes

- No

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: Tertiary Hospitals

- Facilities authorized to provide a pre-referral first dose of ACS: No data

**ACSM USE**

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

- Consultant Obstetricians

- Senior Residents in Obstetrics

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

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

**MATERIAL AND NEWBORN CLINICAL CARE**

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

- Resuscitation

- Thermal care

- Infection prevention/treatment

- 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.

Strengthes 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.

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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.

Building on this initiative, the Government of Nigeria, based on the recommendations of the UNCoLSC, developed an implementation plan\(^37\) 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\(^38\) 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

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

Information from secondary research\(^39\) 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.

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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

<table>
<thead>
<tr>
<th>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:</th>
<th>Adequate childbirth care is available</th>
<th>Adequate preterm newborn care is available</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age can be accurately undertaken</td>
<td>Preterm birth is considered imminent</td>
<td>National Standard Treatment Guidelines do not provide specific information or direction on accurately assessing GA.</td>
</tr>
<tr>
<td>National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.</td>
<td>National Standard Treatment Guidelines do not provide detail on determining if preterm birth is imminent.</td>
<td>National Standard Treatment Guidelines do not state that the use of ACS in the presence of infection is contra-indicated.</td>
</tr>
<tr>
<td>Tertiary hospitals where ACS is provided are CEmONC facilities, but not all general hospitals are CEmONC.</td>
<td>Tertiary hospitals where ACS is provided are CEmONC facilities, but not all general hospitals are CEmONC.</td>
<td>NICUs are present at tertiary hospitals where ACS is provided.</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Eclampsia (Hydralazine or Labetalol)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>No information on PROM or pPROM in STGs</td>
</tr>
</tbody>
</table>

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.

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40 2008 National Standard Treatment Guidelines
Table 22. Summary of Preterm Newborn Care Interventions per WHO Recommendations Reported by Key Informants in Nigeria

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>Details</th>
</tr>
</thead>
</table>
| 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 and Treatment | • Aseptic technique  
• 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 and is widely used for other indications, especially allergies, it is not listed in the 2010 Essential Medicines List, 5th 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.

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. 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.

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41 Regulation and procurement of life-saving commodities for women and children in Every Woman Every Child (EWEC) countries. September 2015. World Health Organization, Department of Essential Medicines and Health Products.
42 ibid.
Table 23. ACS Implementation: Lessons Learned, Strengths, Opportunities, and Challenges Reported by Key Informant in Nigeria

<table>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>• “There is a need for proper documentation and information sharing by the few tertiary centers that are presently providing ACS”</td>
<td>• “There is a consensus by stakeholders, including medical providers, on the use of ACS for management of imminent preterm birth”</td>
<td>• “ACS is included in the training package”</td>
<td>• “No national ACS guidelines in place”</td>
</tr>
<tr>
<td>• “Ongoing implementation at tertiary health facilities”</td>
<td>• “ACS has very recently been added to the EML for management of imminent preterm birth at tertiary health facilities”43</td>
<td>• “Newborns are a priority of the government”</td>
<td>• “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)”</td>
</tr>
<tr>
<td>• “Finalizing Nigeria’s Every Newborn Action Plan”</td>
<td></td>
<td>• “Development of the Nigeria Every Newborn Action Plan”</td>
<td>• “Lack of basic equipment (i.e. incubators, CPAP) and commodities”</td>
</tr>
</tbody>
</table>

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.

43 This could not be validated.
### 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

<table>
<thead>
<tr>
<th>National level guidance or criteria:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicates that ACS is contraindicated in the presence of infection</td>
</tr>
<tr>
<td>How to determine gestational age (GA) when giving ACS</td>
</tr>
</tbody>
</table>

**Gestational age at which ACS is prescribed in country**
- Minimum gestational age (weeks): 28
- Maximum gestational age (weeks): 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%

### ACS USE

**Facilities authorized to provide ACS**

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

### TRAINING

**Tertiary Hospitals including District Referral Hospitals**

**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**
- 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

### 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

**Newborn interventions reportedly available at facilities that give full course ACS:**
- Resuscitation
- Thermal care
- Infection prevention/treatment
- 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
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: |
|----------------------------------|---------------------------------|---------------------------------|---------------------------------|---------------------------------|
| 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 |
| 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\textsuperscript{44} components to meet EmONC compliance;
- Map the distribution of EmONC services to determine geographical equity;

\textsuperscript{44} 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

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

### 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

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Resuscitation</td>
<td>• Bag and mask</td>
</tr>
<tr>
<td>Thermal Care</td>
<td>• Baby is dried and covered in Vaseline, then wrapped in clothes, blankets, and a hat.</td>
</tr>
<tr>
<td></td>
<td>• KMC is practiced</td>
</tr>
<tr>
<td>Infection Prevention and Treatment</td>
<td>• Antibiotics are available (ampicillin, gentamycin)</td>
</tr>
<tr>
<td>Feeding Support</td>
<td>• 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</td>
</tr>
<tr>
<td></td>
<td>• Nasogastric tubes</td>
</tr>
<tr>
<td></td>
<td>• Daily weighing and calculating</td>
</tr>
<tr>
<td>Safe Oxygen</td>
<td>• O2 mixer at 5L per minute, give babies 1L per minute</td>
</tr>
<tr>
<td></td>
<td>• Pulse oximeter</td>
</tr>
<tr>
<td></td>
<td>• Protocol available</td>
</tr>
</tbody>
</table>

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

The UNCoLSC report 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.

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45 MOH Basic Package of Essential Health Services (BPEHS) for Sierra Leone 2015-2020.
46 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.
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

<table>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
</tr>
</thead>
<tbody>
<tr>
<td>None reported</td>
<td>Provided on behalf of the GLOAG Foundation – Freetown hospital: • &quot;Trained midwives and doctors, and availability of ultrasound to determine GA at Freetown hospital&quot; • &quot;Available drugs and equipment&quot; • &quot;Guidelines in place for care of the low birth weight babies&quot;</td>
<td>• “Identification of women at risk, including effective antenatal screening for pre-eclampsia as an important cause of preterm delivery” • “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 pre-eclampsia” • “Staff are trained in the use of the drug and have training, and protocols in place (under supervision)”</td>
<td>• “Lack of clinical guidelines for ACS use” • “Lack of skilled workforce, especially midwives (and supervision of midwives)” • “Lack of diagnostics, such as ultrasound use” • “Lack of transport, money for women at risk of preterm labour” • “Lack of capacity, and training in ACS provision”</td>
</tr>
</tbody>
</table>

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.

47 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.
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**

**Gestational age at which ACS is prescribed in country**
- Minimum gestational age (weeks): 28
- Maximum gestational age (weeks): 34

**Corticosteroids on the Essential Medicines List**
- Included on list
- Indicated for obstetrics/maternal health

**Facilities authorized to provide ACS**
- Hospital Level
- Health Center Dispensary

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

**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%

**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**

**ACU USE**
- Yes
- No
- Please see corresponding annex of this report for data sources

**METRICS**
- ACS use captured in HMIS

**TRAINING**
- Hospital Level
- Health Center Dispensary

**ACU 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
- Comprehensive emergency obstetric and newborn care (CEmONC) services

**Newborn interventions reportedly available at facilities that give full course ACS:**
- Resuscitation
- Thermal care
- Infection prevention/treatment
- 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 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.
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:

<table>
<thead>
<tr>
<th>Gestational age can be accurately undertaken</th>
<th>Preterm birth is considered imminent</th>
<th>No clinical evidence of maternal infection</th>
<th>Adequate childbirth care is available</th>
<th>Preterm newborns receive adequate care</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Standard Treatment Guidelines/ACS Guidelines do not provide specific information or direction on accurately assessing GA.</td>
<td>National Standard Treatment Guidelines/ACS Guidelines do not provide detail on determining if preterm birth is imminent.</td>
<td>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.</td>
<td>Hospitals and health centers where ACS is provided are CEmONC facilities.</td>
<td>NICUs are not available in the majority of facilities where ACS is provided.</td>
</tr>
</tbody>
</table>

Comprehensive/Basic Emergency Obstetric Care
The key informant reported that all facilities offering ACS, both hospitals and health centers providing pre-referral 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.

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.

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

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Pre-eclampsia (Methyldopa OR Nifedipine) Severe pre-eclampsia (Nifedipine, Hydralazine, plus Magnesium Sulfate)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Severe pre-eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>pPROM no infection: Amoxycillin OR Erythromycin pPROM with Infection: Ampicillin OR Ceftriaxone OR Benzyl Penicillin</td>
</tr>
</tbody>
</table>

Table 29. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Tanzania

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Indication</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Pre-eclampsia (Methyldopa OR Nifedipine) Severe pre-eclampsia (Nifedipine, Hydralazine, plus Magnesium Sulfate)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Severe pre-eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>pPROM no infection: Amoxycillin OR Erythromycin pPROM with Infection: Ampicillin OR Ceftriaxone OR Benzyl Penicillin</td>
</tr>
</tbody>
</table>

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

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

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 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

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

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 Commodities

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

<table>
<thead>
<tr>
<th>National level guidance or criteria:</th>
<th>Gestational age at which ACS is prescribed in country</th>
</tr>
</thead>
<tbody>
<tr>
<td>Indicates that ACS is contraindicated in the presence of infection</td>
<td>Minimum gestational age (weeks)</td>
</tr>
<tr>
<td>How to determine gestational age (GA) when giving ACS</td>
<td>Maximum gestational age (weeks)</td>
</tr>
</tbody>
</table>

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%

**METRICS**

ACS use captured in HMIS

**TRAINING**

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

**PRETERM BIRTHS AND DEATHS**

Preterm birth rate (babies born <37 weeks): 14%
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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%

**MATERNAL AND NEWBORN CLINICAL CARE**

Key Services Related to the Safe and Effective Use of ACS

- Basic emergency obstetric and newborn care (BEmONC) services only
- Comprehensive emergency obstetric and newborn care (CEmONC) services

Newborn interventions reportedly available at facilities that give full course ACS:
- Resuscitation
- Thermal care
- Infection prevention/treatment
- 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. This commitment was followed by revision of 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.

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.

49 A Promise Renewed: Reproductive Maternal, Newborn, and Child Health Sharpened Plan for Uganda, November 2013
50 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

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age can be accurately undertaken</td>
</tr>
<tr>
<td>Preterm birth is considered imminent</td>
</tr>
<tr>
<td>No clinical evidence of maternal infection</td>
</tr>
<tr>
<td>Adequate childbirth care is available</td>
</tr>
<tr>
<td>Adequate preterm newborn care is available</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Clinical Guidelines do not provide specific information or direction on accurately assessing GA.</td>
</tr>
<tr>
<td>National Clinical Guidelines provide limited detail on determining if preterm birth is imminent.</td>
</tr>
<tr>
<td>The National Clinical Guidelines do state that the use of ACS in the presence of infection is contraindicated</td>
</tr>
<tr>
<td>Hospitals and health centers where ACS is provided are CEmONC facilities.</td>
</tr>
<tr>
<td>NICUs are not available in the majority of facilities where ACS is provided.</td>
</tr>
</tbody>
</table>

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.

Table 33. Maternal Health Interventions for Improved Preterm Birth Outcomes and Indications in Uganda

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>INDICATION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tocolytics</td>
<td>Eclampsia (Hydralazine, alternative Nifedipine)</td>
</tr>
<tr>
<td>Magnesium Sulfate</td>
<td>Eclampsia</td>
</tr>
<tr>
<td></td>
<td>Severe pre-eclampsia</td>
</tr>
<tr>
<td>Antibiotics</td>
<td>PROM</td>
</tr>
<tr>
<td></td>
<td>With infection (Ampicillin and Gentamicin)</td>
</tr>
<tr>
<td></td>
<td>No infection (Erythromycin and Amoxicillin)</td>
</tr>
</tbody>
</table>

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.

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51 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

<table>
<thead>
<tr>
<th>INTERVENTION</th>
<th>Details</th>
</tr>
</thead>
</table>
| 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 and Treatment | • Hand washing  
• 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\(^{52}\) 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.

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.

\(^{52}\) 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
  - 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

<table>
<thead>
<tr>
<th>LESSONS LEARNED</th>
<th>STRENGTHS</th>
<th>OPPORTUNITIES</th>
<th>CHALLENGES</th>
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<tr>
<td>• “Local contexts (policies and practices) including health professional bodies and regulations need to be in harmony with available evidence”</td>
<td>• “The introduction of ACS has been integrated in the roll-out of the essential newborn care package”</td>
<td>• “There is an integrated Helping Babies Breathe Plus package for in-service training that includes ACS use”</td>
<td>• “There is no clear policy guidance available for frontline health workers on GA estimation, ascertaining active and premature labour, and corresponding preterm baby management”</td>
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<td>• “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”</td>
<td>• “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”</td>
<td>• “Government willingness to introduce use of ACS and available partner support”</td>
<td>• “Professional bodies (e.g. Obstetricians and Gynecologists) have concern for the safety and capacity of other cadres administering ACS”</td>
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<td>• “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”</td>
<td>• “The process was systematic starting with a pilot study to understand the drivers and barriers to effective ACS use in the country”</td>
<td>• “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”</td>
<td>• “Overall weak health system not allowing for availability of appropriate newborn care at Basic and Emergency Health facilities in the country”</td>
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<td>• “ACS use should be introduced along with other newborn care aspects since the preterm baby is even more prone to newborn complications of infection, asphyxia, and hypothermia”</td>
<td>• “Quality improvement indicators developed and in use, offering the opportunity to add ACS metrics”</td>
<td>• “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”</td>
<td>• “Pharmacists not included in ACS training and guideline dissemination”</td>
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<td></td>
<td></td>
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<td>• “Shifting positions on available evidence”</td>
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<td></td>
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<td></td>
<td>• “Limiting regulations in terms of cadres that can and cannot administer ACS for lung maturation”</td>
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<td>Additional Support Needed</td>
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<td>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:</td>
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<td>• 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</td>
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<td>• 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.</td>
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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 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 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