A HealthTech Report

Oxytocin in Uniject:
Market Landscape Analysis

June 2011

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Oxytocin in Uniject: Market Landscape Analysis

Background

In December 2010, the US Agency for International Development (USAID) asked PATH to fund an external analysis of the viability of supporting oxytocin in the Uniject™ injection system (OiU) as a niche product in both the public and private sectors. A major component of this analysis was to conduct separate market analyses in a subset of countries identified by USAID as priority countries for maternal health interventions.

In consultation with USAID, PATH tasked a market analyst consultant in February 2011 to conduct an initial market landscape analysis across USAID's 30 priority countries using readily available data. The scope of the work included:

- A high-level analysis of potential and relative need for OiU.
- The estimated potential demand for OiU under different scenarios.
- The development of a country opportunity assessment tool to score countries based on the relative market opportunity for OiU.

USAID's 30 maternal-health priority countries account for a disproportionately high number of maternal deaths. Between 343,000 and 358,000 maternal deaths occurred worldwide in 2008, with approximately 75 percent of those deaths occurring in the 30 priority countries.[1,2] Maternal death is defined as the death of a woman while pregnant or within 42 days of the termination of pregnancy from any cause related to or aggravated by the pregnancy or its management.[3] Obstetric hemorrhage is the leading cause of maternal death and accounts for 35 percent of maternal deaths globally.[4]

Oxytocin is a drug that causes the uterus to contract, reducing the risk of death from hemorrhage during childbirth. The use of oxytocin in the Uniject™ injection system could expand access to the drug in low-resource settings where many women do not give birth in health facilities. OiU could enable midwives, village health workers, and others with lower levels of training to provide oxytocin in an easy-to-use, injection-ready format.

This narrative report summarizes the results of the analysis. More detail is contained in the presentation slides attached as Appendix 1.

Analysis

Maternal mortality and birth care statistics

Multiple data sources were identified for 27 of the 30 priority countries; Afghanistan, Sudan, and Tajikistan were excluded from the analysis due to data constraints. The maternal mortality ratio (MMR), or the number of maternal deaths per 100,000 live births, was compared across the remaining 27 countries. The MMR ranged from a low of 38 in Azerbaijan to 990 in Liberia[2]—a 25-fold difference between the lowest and highest MMRs. The largest numbers of annual maternal deaths were in India (62,000), Nigeria (51,000), Democratic Republic of Congo (19,000), and Ethiopia (15,000) (Figure 1).

The analysis also evaluated the percentage of births using skilled birth attendants (SBAs) or traditional birth attendants (TBAs) in each of the 27 countries. SBAs are accredited doctors, nurses, or midwives trained in providing lifesaving obstetric care. The availability of SBAs outside health care facilities is particularly important in countries where a large proportion of the population lives in rural areas and cannot easily travel to health care facilities to give birth. In some countries, the proportion of births using SBAs exceeds the proportion of in-facility births, suggesting that SBAs are available outside health care facilities in these countries.

TBAs are nonaccredited health care providers who typically perform birthing services outside health care facilities. Training levels likely vary significantly across the 27 countries in this analysis, though data are not routinely collected. The percentage of births using TBAs ranges from 2 percent in Rwanda to 73 percent in Bangladesh (Figure 2). In some countries, a high proportion of births are attended by family members or friends, or the woman gives birth alone. In Ethiopia and Nepal, 66 percent and 56 percent of births, respectively, are attended by family members or friends, or by the mother alone.

The density of health care providers in each country (the number of doctors, nurses, and midwives per 10,000 people) was also examined. The World Health Organization (WHO) recommends 23 health care providers per 10,000 people to deliver essential health care services. Only three of the 27 countries analyzed (Azerbaijan, Bolivia, and the Philippines) met the WHO recommendation. Ten countries fell significantly below the WHO recommendation with five or fewer health care providers per 10,000 people.

The country opportunity assessment tool

Public health need, market size, and other enabling factors were considered in identifying the relative OiU market opportunity among the 27 priority countries. Need indicators were used to identify countries that are more vulnerable to maternal deaths. Market size indicators estimated the number of women who could be reached with OiU based on WHO guidelines for use of uterotonics. Enabling factor indicators were used to assess government health care financing and other factors that may impact the opportunity to introduce OiU. Indicators were selected based on the ability to compare recent relevant data across most countries in the analysis.

Need

Both facility and community birth data were analyzed to assess need. Facility need was deemed to be higher in countries with a relatively high MMR, a high proportion of births occurring in facilities, and an inadequate number of health care providers (based on the WHO recommendation).

Facilities with a shortage of SBAs are more likely to be vulnerable to conditions that lead to maternal death and could potentially benefit from a novel uterotonic delivery system such as OiU that is designed to make injections safe and easy to administer. OiU also has been shown to save health care workers time, an important factor when a single health care provider must attend to the needs of both mothers and newborns. It is important to note that PATH is not advocating for replacement of oxytocin in ampoules with OiU in all uses, but

rather in those scenarios where the higher cost of OiU may be justified by its ability to increase proper and timely use for prevention of PPH.

International and country-level policies often favor increasing facility births rather than improving the health outcomes of community births. In many countries, however, the majority of births occur in the community, not in health facilities. In 20 countries in the analysis, more than half of births occur in the community. Community need was evaluated by identifying countries with a relatively high MMR combined with a high proportion of births occurring in the community and a high rural population. In these circumstances, OiU may expand prophylactic uterotonic coverage to women who would not otherwise receive this important intervention.

Market size

Potential market size was calculated for both community births and facility births. Data on community market size include both the annual number of community births using SBAs and the annual number of births using TBAs but did not include births attended only by family members or friends. Data on facility market size are derived from the annual number of births in a facility.

The potential market size estimates are based on WHO recommendations for prevention of postpartum hemorrhage.[6] WHO recommends that skilled attendants offer oxytocin to all women for prevention of postpartum hemorrhage. If a skilled attendant is not available, WHO recommends that an uterotonic drug, preferably oxytocin, be offered by a health care worker trained in its use. Births attended by family members, friends, or the mother alone were not included in market size calculations.

Other enabling factors

Three additional factors also were evaluated. First, health expenditure as a percentage of gross domestic product was examined. Countries that invest more in health care and have relatively high health expenditures as a percentage of gross domestic product were viewed favorably. Additionally, USAID Global Health Initiative Plus countries were ranked higher. These countries receive additional technical and management resources in maternal and child health that may help increase OiU access. Lastly, countries where OiU pilots have been conducted were also viewed favorably because governments in these countries already have some exposure to and interest in evaluating the potential benefits of OiU.

Results

Countries were scored and ranked on each variable relative to the other countries in the dataset, with the goal of identifying a subset of countries that scored higher for need, market size, and enabling factors. Table 1 below summarizes all variables for each scenario. Detailed data can be found in Appendix 1.

The country opportunity assessment tool identified 11 high-scoring countries: Bangladesh, Benin, Cambodia, Democratic Republic of Congo, Ethiopia, Ghana, India, Kenya, Malawi, Nigeria, and Uganda.

These countries represent a theoretical maximum annual demand for OiU of:

- 17.6 million births in facilities.
- 2.6 million births outside facilities with SBAs.
- 16.6 million births outside facilities with TBAs.*

To create annual demand estimates more reflective of OiU's potential use as a niche product, PATH applied a factor to reduce the theoretical maximum demand results. In past OiU market sizing work, PATH has used estimates of 30% of facility births and 20% of community births to calculate potential niche demand. In that case, the estimated annual niche demand in these 11 countries would be:

- 5.3 million births in facilities. (17.6 million x 30%).
- 0.5 million births outside facilities with SBAs. (2.6 million x 20%).
- 3.3 million births outside facilities with TBAs. (16.6 million x 20%).

Next steps

With the initial market landscape assessment now complete, PATH is using existing HealthTech funding to undertake a review of relevant policies in the 11 high-scoring countries. Where possible, this will include a more in-depth search for secondary data sources, discussions with country experts, including PATH offices in those countries, and discussions with other programs. Results will be reported by the close of the HealthTech agreement in September, 2011.

The next logical step would be in-depth, in-country market analysis of OiU's potential niche and viability in a small number of countries. While undertaking this is not feasible under the current HealthTech funding or timeline, we would like to plan for a more detailed country-level market and stakeholder analysis by:

- Identifying two to three candidate countries for in-depth market analysis through the policy review and USAID consultation.
- Establishing the process for an in-depth analysis of market niche and viability.
- Preparing to implement the plan if funds become available in the future.

* PATH recognizes that TBA-attended births may not be reached with OiU due to reluctance on the part of many Ministries of Health to work with TBAs. Thus, it may be more feasible to reach a higher percentage of SBA-attended births outside of facilities.

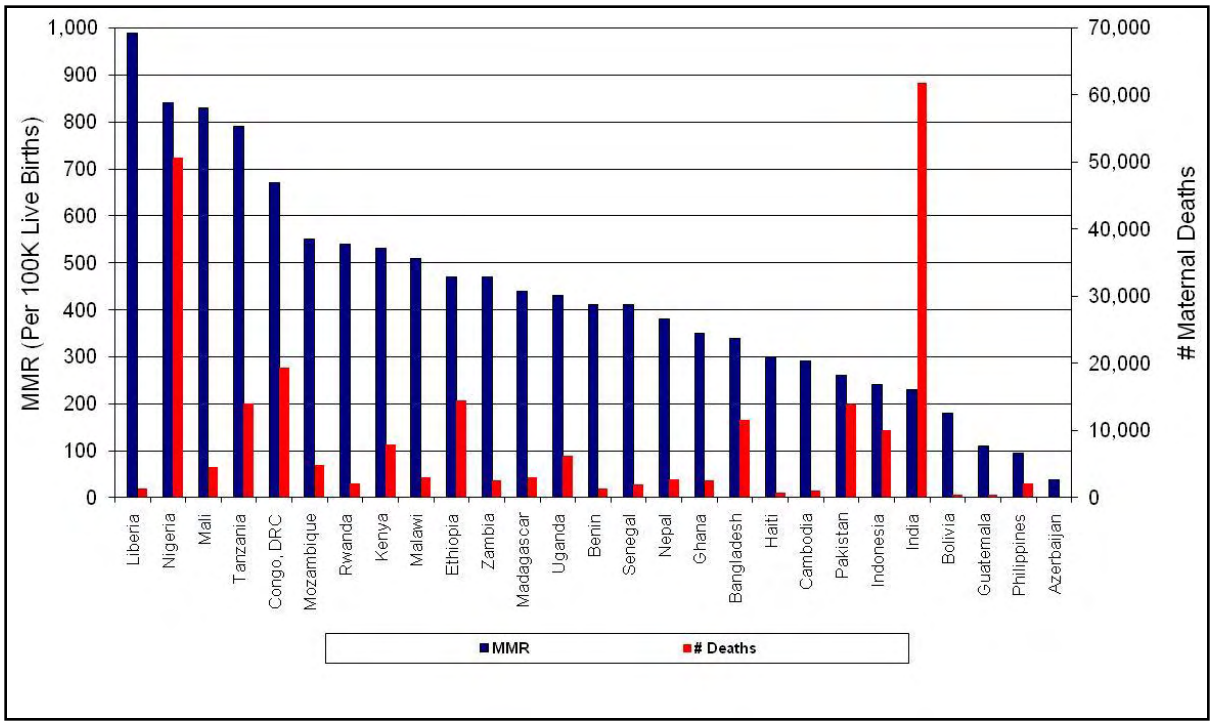

Figure 1. The maternal mortality rate (MMR) and total number of maternal deaths across 27 USAID priority countries.

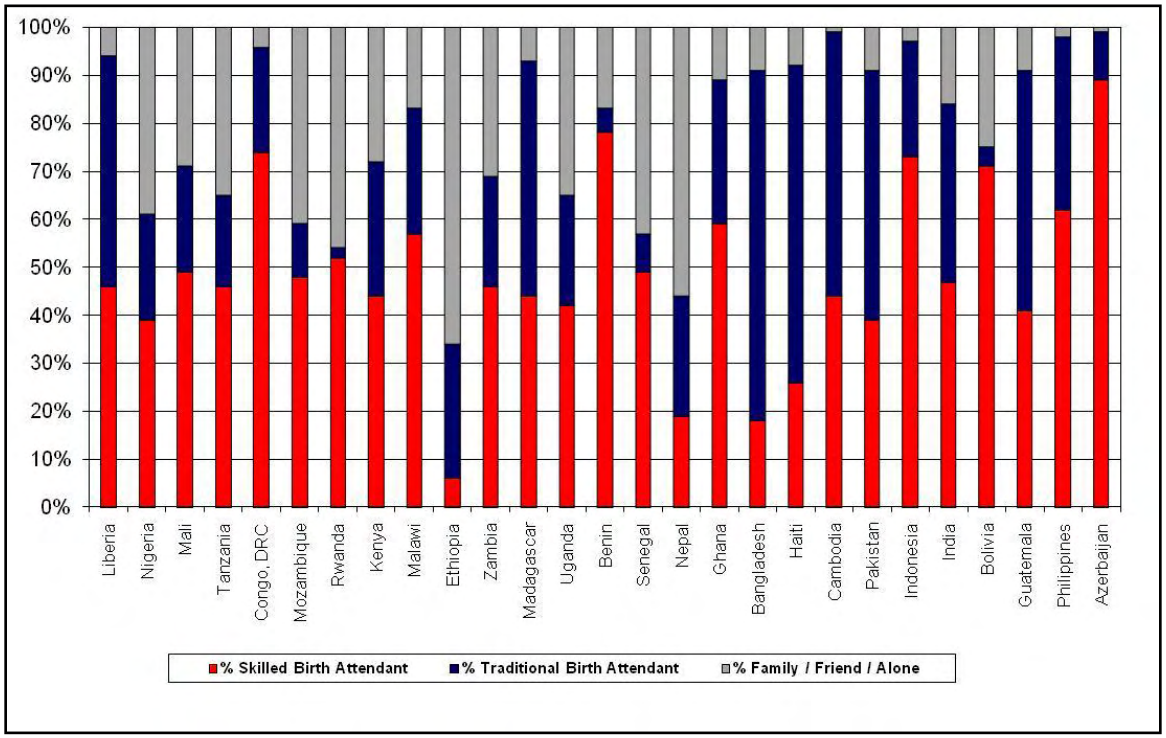

Figure 2. The percentage of births using a skilled attendant, a traditional birth attendant, or attended by family, friends, or the mother alone across 27 USAID priority countries.

	Need	Uterotonic Market Size	Enabling Factors
Facility (Constrained Birth Attendant Workforce)	• High MMR • High % of births occur in the facility • Inadequate number of skilled attendants	• Number of facility births with a skilled attendant	• OiU pilot work • Health expenditure (% GDP) • USAID GHI Plus Countries
Community (High Proportion Births in the Community)	• High MMR • High % of births occur in the community • High % of the population lives in rural areas	• Number of community births with a skilled attendant • Number of community births with a TBA	• OiU pilot work • Health expenditure (% GDP) • USAID GHI Plus Countries

Table 1. Variables used to score and rank countries on need, market size, and other enabling factors.

Acknowledgement

This project is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the HealthTech program, Cooperative Agreement #GPH-A-00-01-00005-00. The contents are the responsibility of PATH and do not necessarily reflect the views of USAID or the United States Government.

Appendix 1. Market Landscape Analysis Consultant Presentation with Introduction by PATH

Oxytocin in Uniject:
Market Landscape Analysis

PATH Introduction and Key Findings Summary

June 2011

USAID Request to PATH (Dec 2010)

- Fund an external analysis (through HealthTech agreement) to ascertain the viability of supporting oxytocin in the Uniject injection system (OiU) as a niche product in both the public and private sector. This analysis would include:

  a. Reviewing existing market analyses (overall and country specific) that were conducted prior to production and product registration

  b. Conducting market analyses in a subset of USAID's priority countries to ascertain the viability of OiU as a niche product that is part of a comprehensive PPH prevention and treatment strategy

  c. Approaching partners (e.g. UNFPA, WHO, Bill and Melinda Gates Foundation) to see whether they would be willing to subsidize the cost of OiU in any potential partnership efforts

  d. Exploring whether a Public Private Partnership would be of interest to producers (e.g. BIOL, Gland Pharma) and partners (e.g. UNFPA, WHO, Bill and Melinda Gates Foundation, others)

PATH Comments on USAID Request (Dec 2010- Jan 2011)

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  d. Exploring whether a Public Private Partnership would be of interest to producers (e.g. BIOL, Gland Pharma) and partners (e.g. UNFPA, WHO, Bill and Melinda Gates Foundation, others)

PATH noted that the OiU producers have done very little independent market analysis

PATH Comments on USAID Request (Dec 2010- Jan 2011)

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  d. Exploring whether a Public Private Partnership would be of interest to producers (e.g. BIOL, Gland Pharma) and partners (e.g. UNFPA, WHO, Bill and Melinda Gates Foundation, others)

PATH identified a consultant to work on market analysis component

PATH Comments on USAID Request (Dec 2010- Jan 2011)

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  d. Exploring whether a Public Private Partnership would be of interest to producers (e.g. BIOL, Gland Pharma) and partners (e.g. UNFPA, WHO, Bill and Melinda Gates Foundation, others)

PATH suggested these steps better done by PATH and USAID rather than a consultant

Overall Market Analysis Process

Overview of Market Analysis Process and Outcomes	
Activity	Process and Outcomes
Step 1 – Market Landscape Assessment (Completed)	**PROCESS:** • Using existing secondary data, conduct a high-level assessment of 30 USAID priority countries in the areas of market size, public health need and other enabling factors. **OUTCOMES:** • Contribute to understanding of market size and conditions in each of these countries • Based on broad criteria and readily available data, identify a subset of countries that may be optimal candidates for more detailed market analysis
Step 2 – Country-level policy review (in progress)	**PROCESS:** • Within this subset of countries, conduct a high-level survey of the policy environment surrounding delivery of uterotonic drugs, such as: o Which cadres are allowed to give injections? o What are policies around use of misoprostol and oxytocin for PPH prevention? o Are there any efforts underway that support increasing access to AMTSL and/or uterotonic drugs at the community level? **OUTCOMES:** • Provide additional context and understanding of opportunities within a subset of USAID priority countries • Contribute to identification of optimal settings for in-depth market analysis
Step 3 – Conduct in-depth market analysis in a subset of USAID priority countries (to be determined)	**PROCESS:** • Conduct in-depth market analysis in a subset USAID priority countries (2 or 3), as identified in the previous work and in consultation with USAID. **OUTCOMES:** • Provide primary, robust market data and analysis regarding the market niche for OiU in high opportunity USAID priority countries. • Establish evidence and local support for potential follow-on demonstration projects or research studies

Background

- Consultant, Tara Herrick, CV and Scope of Work vetted with USAID January 2011

- Summary of Market Landscape Analysis Scope of Work:

  Using available secondary data, undertake a market landscape analysis across USAID's 30 priority MCHN countries

  - High level analysis of potential (and relative) need for OiU
  - Estimate potential demand for OiU under different scenarios
  - Gain insight into commercial feasibility across the countries
  - Develop country opportunity assessment tool and score countries

- Herrick commenced work February 2011, target completion early April 2011.

- Herrick worked closely with PATH throughout (weekly meetings, extensive in-progress review from wide range of PATH staff)

Country Opportunity Assessment Tool

- Country Opportunity Assessment Tool developed—sorts countries into groups of relative opportunity for OiU by scoring available indicators of
  - OiU public health need
  - OiU potential market size
  - Factors that might further enable OiU uptake

- Country Opportunity Assessment Tool also separates country markets into
  - Births in facilities
  - Births outside facilities attended by skilled birth attendant (SBA)
  - Births outside facilities attended by trained birth attendant (TBA)

- Tool certainly has limitations (policy and sales data not readily available across all countries, choice of enabling factors subjective and incomplete, scoring system subjective)

Key Findings

Notable Country Opportunity Assessment Results:

- 11 out of the 30 countries scored “High” in the Opportunity Assessment: Bangladesh, Benin, Cambodia, Congo-DRC, Ethiopia, Ghana, India, Kenya, Malawi, Nigeria, Uganda
- “High” means more theoretical relative OiU opportunity compared to the other countries (based on available secondary data)
- OiU could still find markets (and serve needs) in other countries (tool is imperfect, many additional factors influence market uptake)

Key Findings (continued)

Notable OiU Demand Estimate Results:

- The 11 countries represent a theoretical maximum annual demand for OIU of
  - 17.6 million births in facilities
  - 2.6 million births outside facilities with SBA attendance
  - 16.6 million births outside facilities with TBA attendance
- If OiU's niche is in 30% of births in facilities and 20% of births outside facilities (estimates PATH has used in other OiU market analyses), the estimated annual demand in these 11 countries would be
  - 5.3 million births in facilities
  - .5 million births outside facilities with SBA attendance
  - 3.3 million births outside facilities with TBA attendance
- PATH recognizes that TBA births may not be reached with OiU due to MOH reluctance to work with TBA's (may be more feasible to reach a higher % of SBA births outside facilities and a lower % of TBA births)

Next Steps

- We are moving forward with step 2 in market analysis process:
  - Gather more detail on policy issues in the 11 countries, as feasible
    - Secondary sources, discussions with country experts, input from PATH offices if in those countries, discussion with other programs
    - Not doing extensive in-country primary data gathering
    - We can complete this within existing HealthTech budget for OiU

- We want to prepare and plan for step 3 – more in-depth detailed country level market and stakeholder analysis
  - Identify lead candidate countries (through above process and USAID consultation)
  - Scope process (will include significant time for local consultant or PATH office in each chosen country)
  - Be ready to implement if funds become available in next few months, or in future

Oxytocin in Uniject:
Market Landscape Analysis

Completed by Tara Herrick, PATH Consultant

April 2011

Objectives and Resources

- **Analysis objectives:**
  - Better understand the market landscape for oxytocin in Uniject (OiU) in 30 USAID maternal health priority countries using secondary data
  - Create a country opportunity assessment tool to sort countries into groups of relative OiU opportunity by scoring indicators of need, market size and enabling factors
  - Use tool to identify countries that would warrant more in-depth analysis

- **Resources:**
  - Most recent demographic health survey data
  - WHO Global Health Observatory
  - WHO Recommendations for the Prevention of Postpartum Hemorrhage (PPH)
  - UNICEF statistics
  - Select publications related to PPH
  - PATH generated resources and knowledge

- **Limitations:**
  - Uterotonic use and sales data is not easily available across all 30 countries
  - Policy analysis has not been conducted (planned as next step)
  - Afghanistan, Sudan and Tajikistan are not included due to data constraints

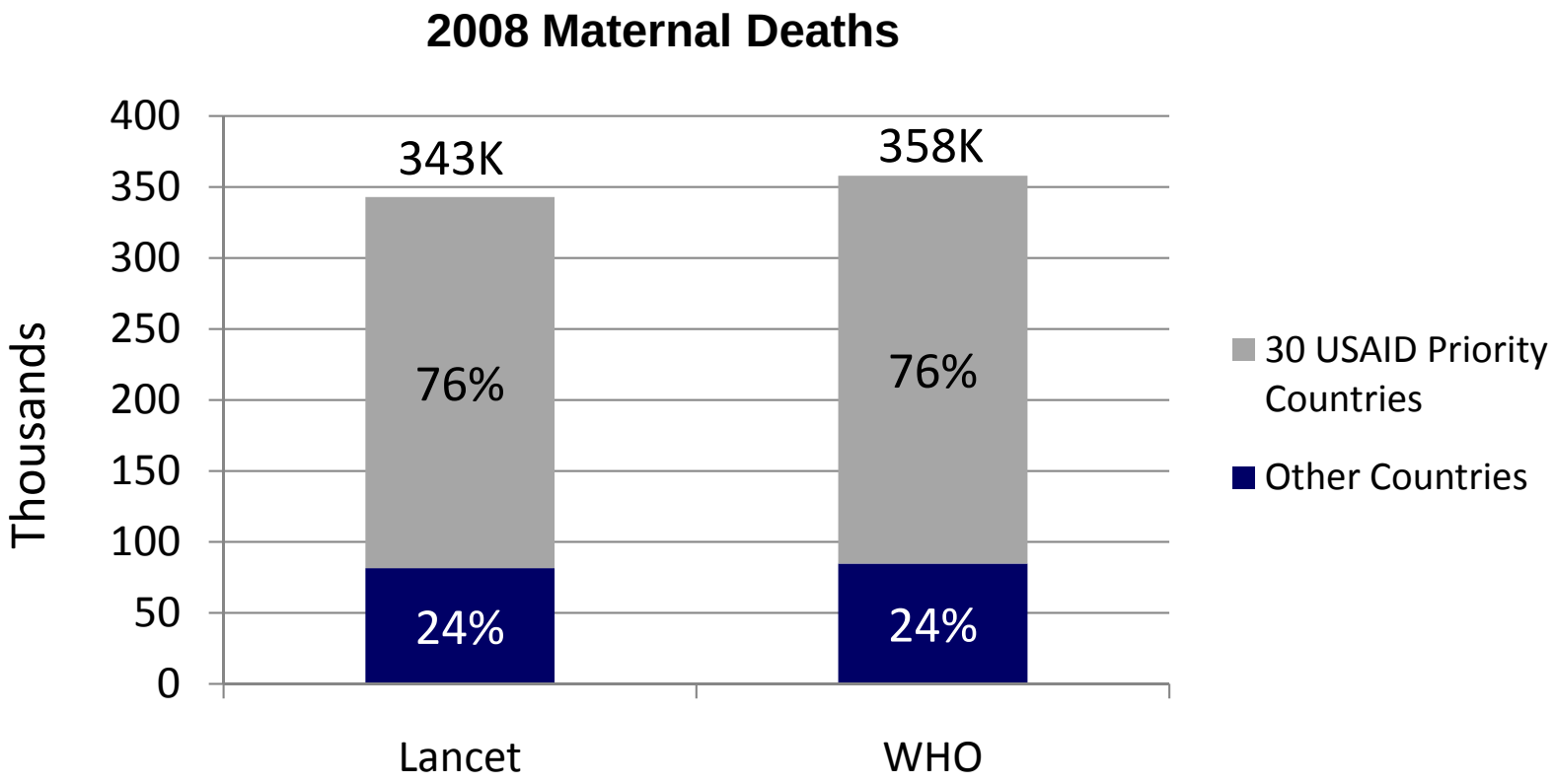
Contents

- Background on maternal mortality
- Summary statistics for 27* USAID priority countries including:
  - Maternal mortality rate (MMR)
  - Number of maternal deaths
  - Percent births with skilled attendant(s)
  - Percent births with a traditional birth attendant(s) (TBA)
  - Percent births relative(s)/friend(s) or alone
  - Density of healthcare providers
  - Percent births in a facility
- Summary of OiU value proposition
- Draft country opportunity assessment methodology and results
- Conclusions and next steps

*Afghanistan, Sudan and Tajikistan excluded due to data constraints

Maternal Mortality Background

- Maternal mortality remains a significant challenge to health systems globally
  - An estimated 343K to 358K maternal deaths worldwide in 2008
  - Approximately 75% of deaths are in the USAID maternal health priority countries
  - Maternal mortality is defined as the death of a women during pregnancy childbirth or in the 42 days after delivery



Sources: Maternal mortality for 181 countries, 1980-2008: a systematic analysis of progress towards Millennium Development Goal 5. Lancet 2010; 375: 1609-23, WHO Global Health Observatory, UNICEF
http://www.unicef.org/statistics/index_24183.html (2008 birth cohort), see notes for additional information

Notes: Slide 15

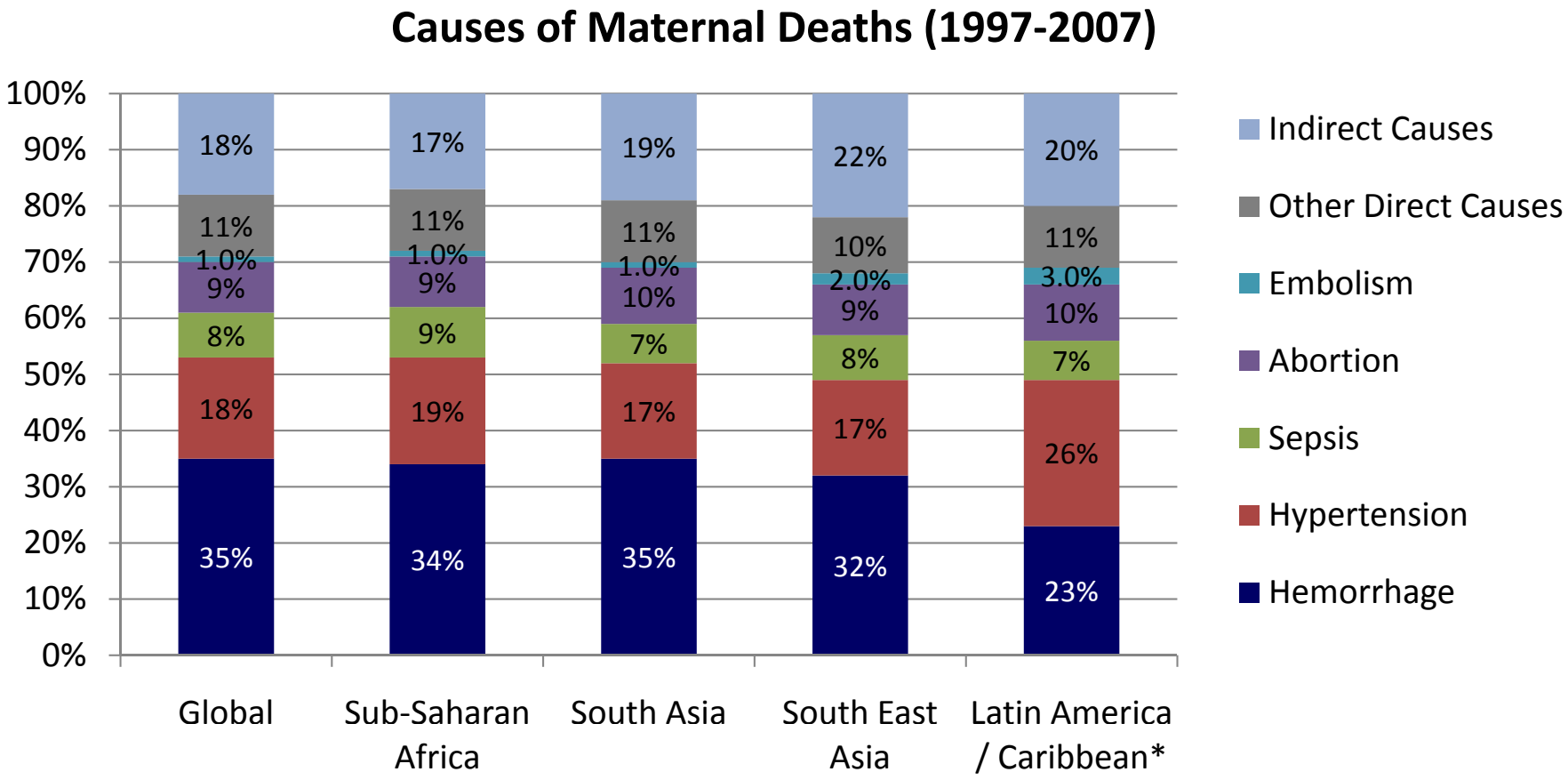
Calculation:

(2008 MMR Estimate / 100,000)*2008 birth cohort

WHO data was utilized for the presentation due to the process of interacting with countries to give them the opportunity to review the estimates, data sources and methods. Both studies were published in 2008.

Obstetric Hemorrhage is the Leading Cause of Maternal Death Globally

- Obstetric hemorrhage, hypertension and indirect causes are responsible for the majority of deaths
- Obstetric hemorrhage alone accounts for approximately 1/3 of maternal deaths
  - PPH is the most common type of obstetric hemorrhage
- Indirect causes account for approximately 20% of the deaths
  - Includes deaths due to malaria, HIV/AIDS and cardiac diseases



* Only 3 of the 30 countries under analysis are in Latin America / Caribbean

Sources: http://www.countdown2015mnch.org/reports-publications/2010-report/2010-report-downloads, http://www.who.int/making_pregnancy_safer/publications/newsletter/mps_newsletter_issue4.pdf

Notes: Slide 16

The most recent assessment of maternal mortality, which was jointly sponsored by WHO, UNICEF, UNFPA, and the World Bank,

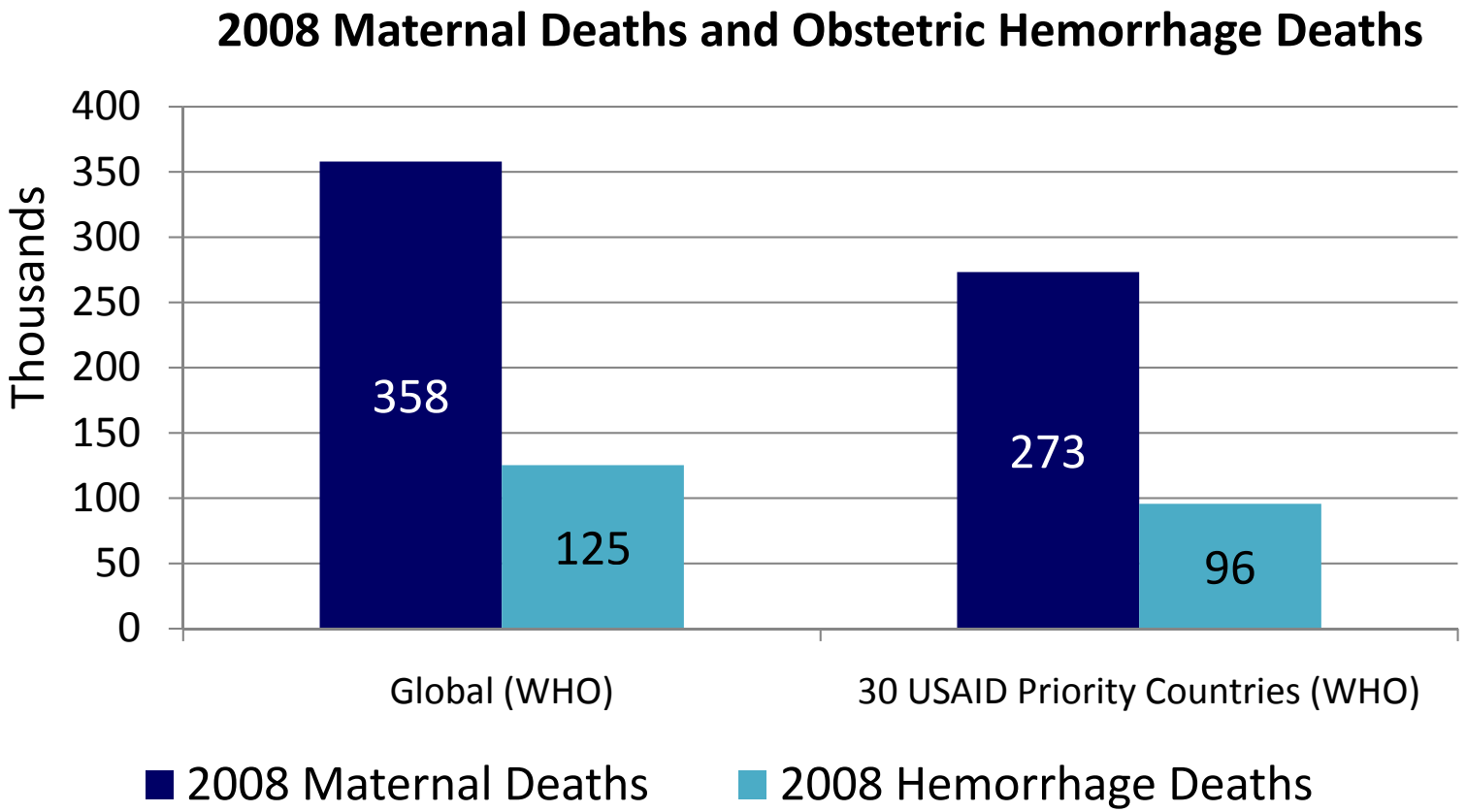
reported 576 300 maternal deaths globally in 1990, and 535 900 maternal deaths in 2005—a 0・48% yearly rate of decline.

Recent developments provide an opportunity for substantially improved estimates of maternal mortality.

First, the Global Burden of Disease (GBD) study28 has undertaken a detailed analysis of vital registration data to identify misclassifi ed deaths from causes such as maternal mortality. Second, methodological advances allow for the correction of known biases in survey sibling history data, including whether sibling deaths are from maternal causes.29 Third, population-based verbal autopsy studies have been done that measure maternal mortality both nationally and subnationally. Fourth, a systematic assessment of data sources for adult female mortality has provided estimates of mortality for women of reproductive age (15–49 years) from 1970 to 2010.30 Finally, methodological developments in other areas have provided improved methods for estimation. In this study, we used all available data to assess levels and trends in maternal mortality from 1980 to 2008 for 181 countries.

Nearly 100K Obstetric Hemorrhage Annual Deaths in USAID Maternal Health Priority Countries (2008)

- About 35% of maternal deaths are caused by obstetric hemorrhage in the regions under analysis
  - PPH is the most common type of obstetric hemorrhage
- WHO MMR data is utilized for this analysis
  - 2008 global estimates are similar for Lancet and WHO (see earlier slide)
  - WHO study consulted countries to gain feedback on MMR methodology



Sources: Countdown to 2015 Maternal, Newborn and Child Survival WHO and UNICEF
http://www.countdown2015mnch.org/reports-publications/2010-report/2010-report-downloads (see previous slides)

Notes: Slide 17

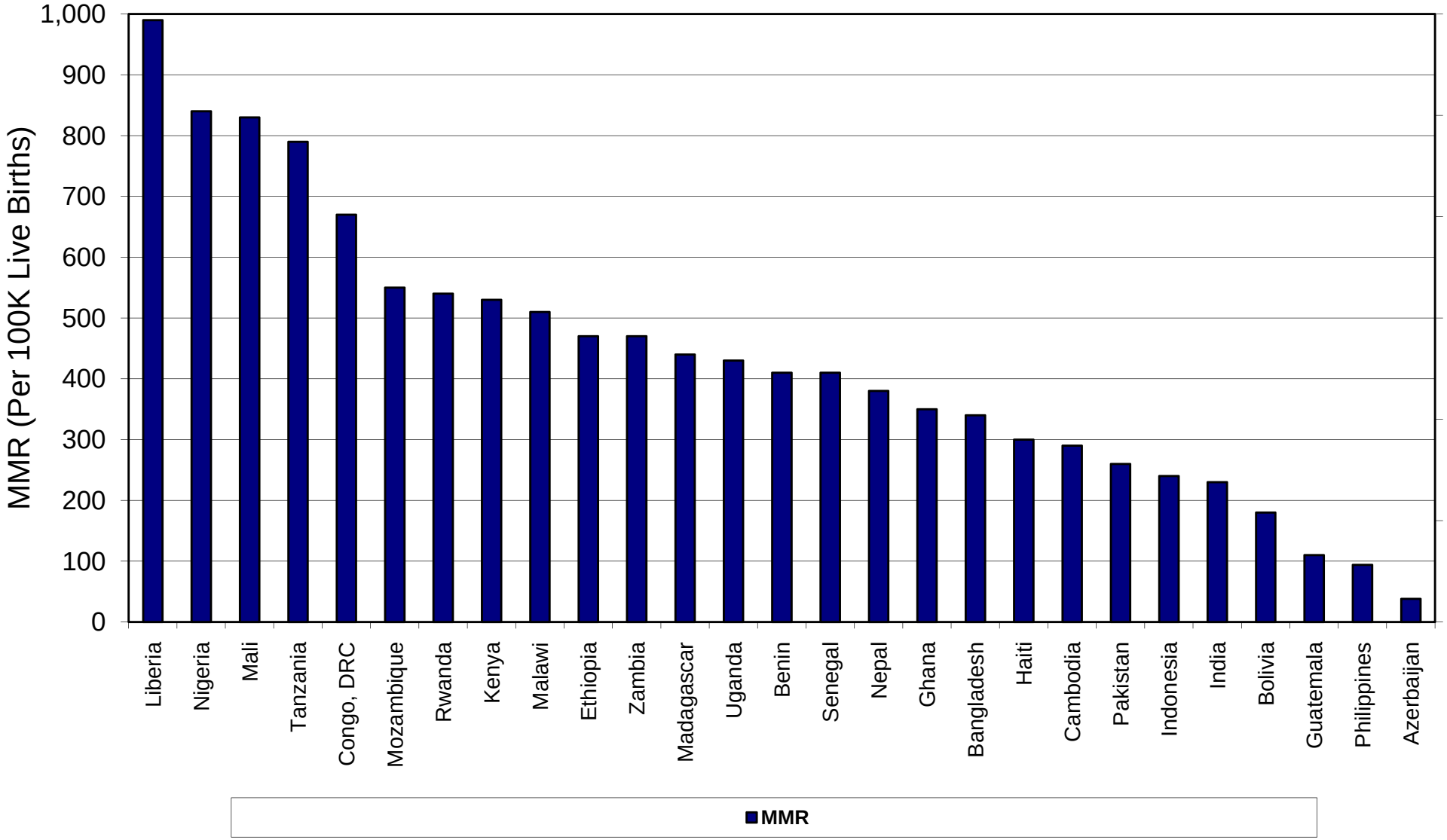
Assume 35% of deaths are due to obstetric hemorrhage

Notes: Slide 19

Maternal Deaths Calculation

(2008 MMR/100,000)*# total births in 2008

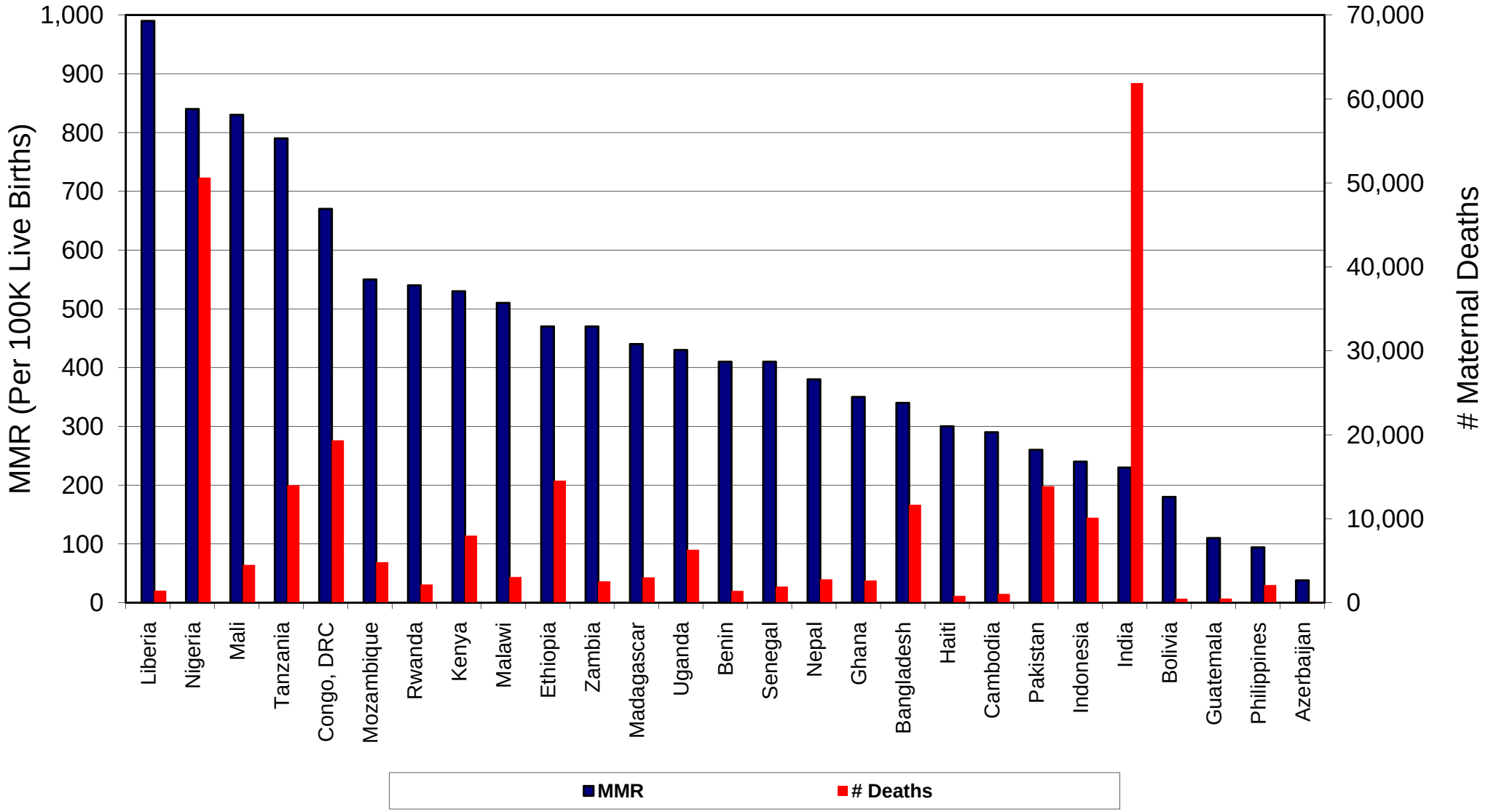
2008 Maternal Mortality Rate (MMR) Per 100K Live Births: USAID Priority Countries



MMR is death of a women during pregnancy, childbirth, or in 42 days after delivery

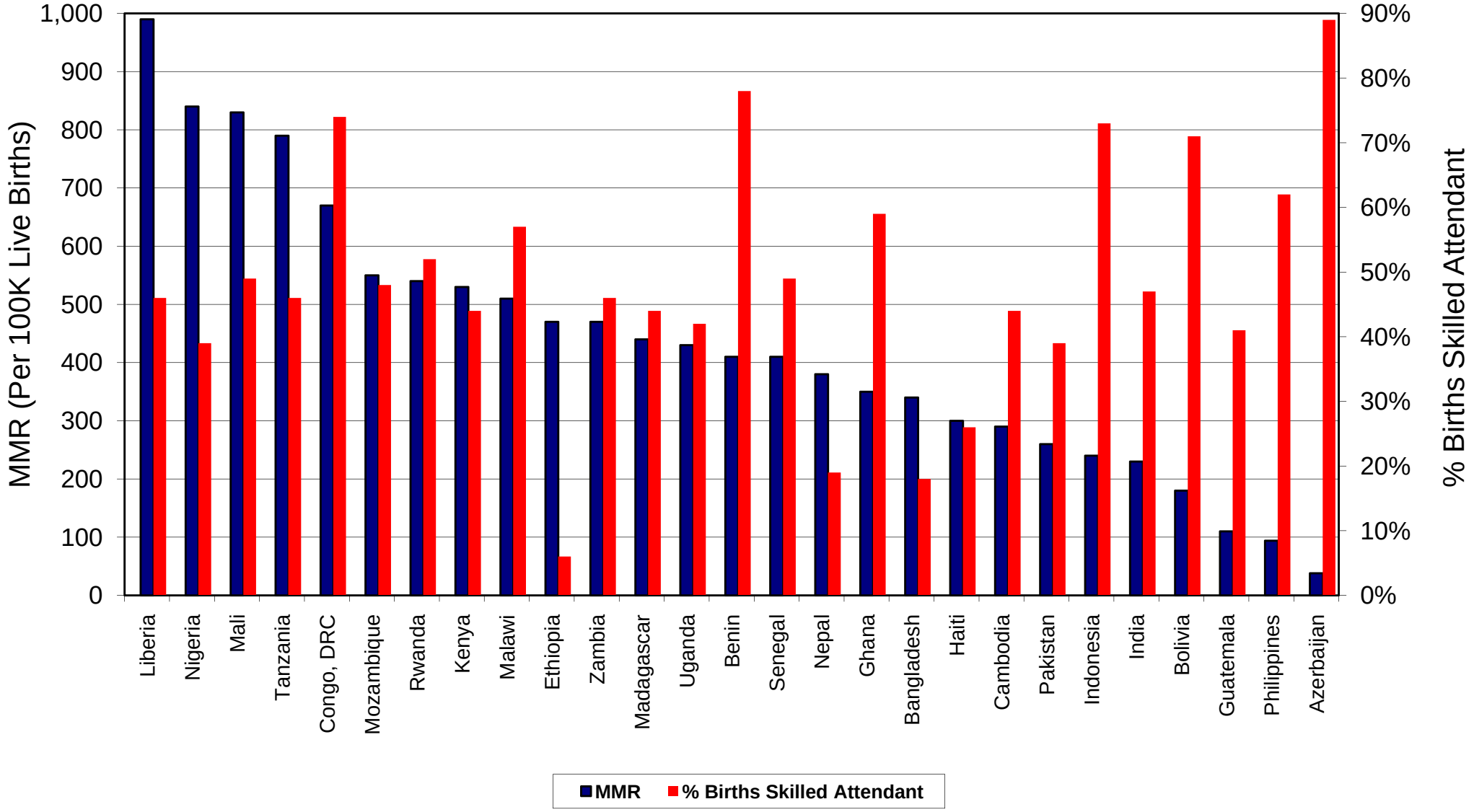
Source: WHO Trends in Maternal Mortality 2010 http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf

Maternal Mortality Rate Compared to Number of Maternal Deaths



Source: WHO Trends in Maternal Mortality 2010 http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf, UNICEF http://www.unicef.org/statistics/index_24183.html (2008 birth cohort), see notes calculation

Weak Correlation Between MMR and the Percent of Births Using a Skilled Attendant



Skilled Attendant Definition: accredited doctors, nurses or midwives trained in providing life saving obstetric care (see notes)

Source: WHO Trends in Maternal Mortality 2010 http://whqlibdoc.who.int/publications/2010/9789241500265_eng.pdf (MMR), Demographic Health Surveys (Skilled Attendant Births)

Notes: Slide 20

WHO global health observatory data for % of births with a skilled attendant was compared to DHS data. The difference between these sources was typically less than 5%. One exception to note is Madagascar (WHO has 51% and DHS has 44%). Data excludes traditional birth attendants.

WHO definitions

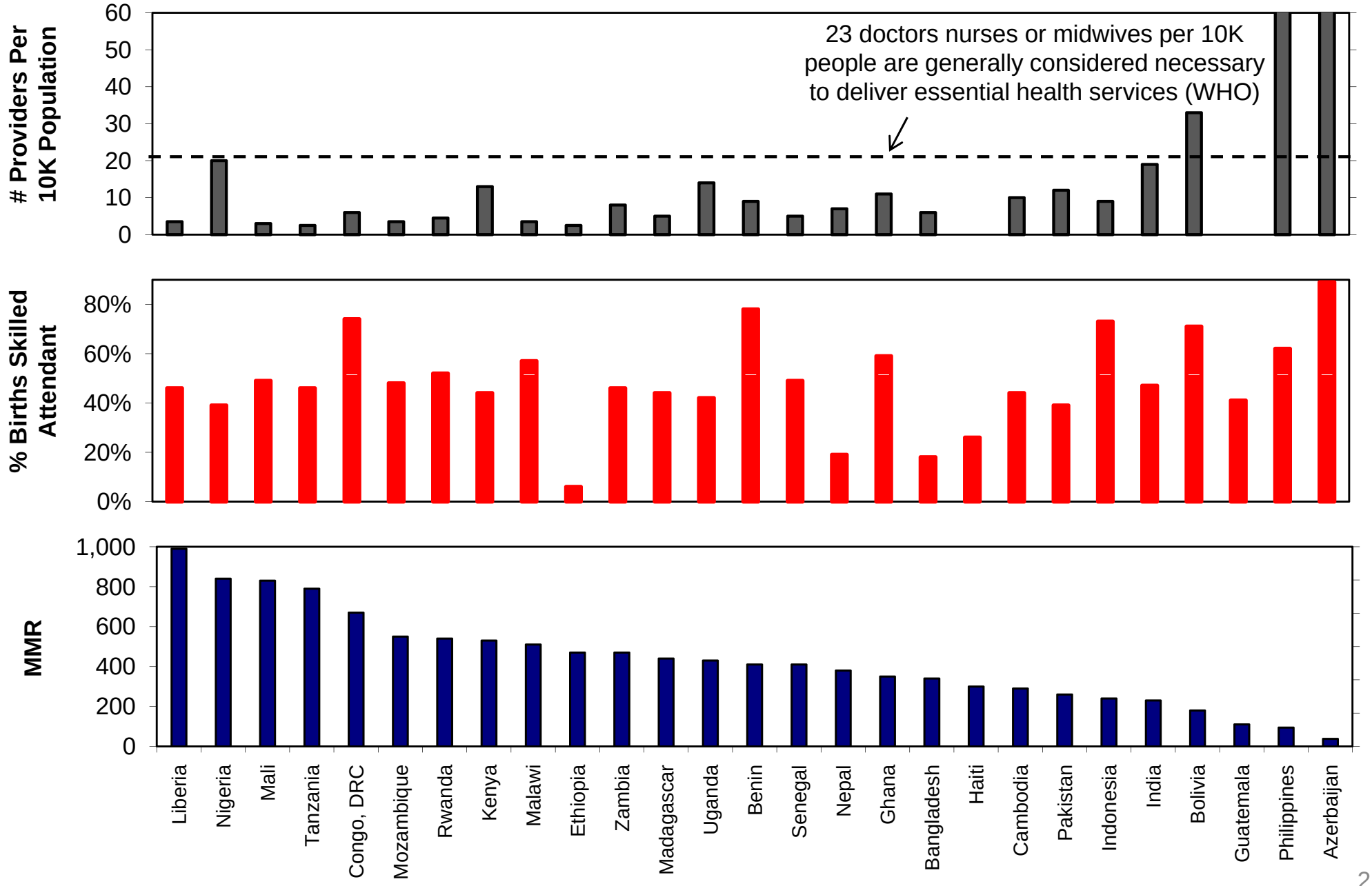
Numerator:
The number of births attended by skilled health personnel (doctors, nurses or midwives) trained in providing life saving obstetric care, including giving the necessary supervision, care and advice to women during pregnancy, childbirth and the post-partum period; to conduct deliveries on their own; and to care for newborns.

Denominator:
The total number of live births in the same period.

Coverage estimates for service delivery contacts—such as antenatal care, skilled attendant at birth and postnatal visits for the mother—do not address the quality of that contact or whether it provided needed interventions such as active management of the third stage of labour or counselling on family planning. Quality assessments of such services are an essential part of sound programme management.

Skilled birth personnel (WHO definition): An accredited health professional—such as a midwife, doctor or nurse—who has been educated and trained to proficiency in the skills needed to manage normal (uncomplicated) pregnancies, childbirth and the immediate postnatal period, and in the identification, management and referral of complications in women and newborns. Traditional birth attendants (TBA), trained or not, are excluded from the category of skilled attendant at delivery.

Density of Healthcare Providers May Impact Effectiveness of Maternal Care During Childbirth



Note: Demographic Health Surveys and WHO Global Health Observatory, http://www.who.int/whosis/whostat/2010/en/ (see notes)

Notes: Slide 21

WHO Health Workforce

http://www.who.int/hrh/workforce_mdgs/en/index.html

Most recent data is utilized for all statistics

Providers is physicians, nurses or midwives per 10K population and MMR are from the WHO Global Health Observatory

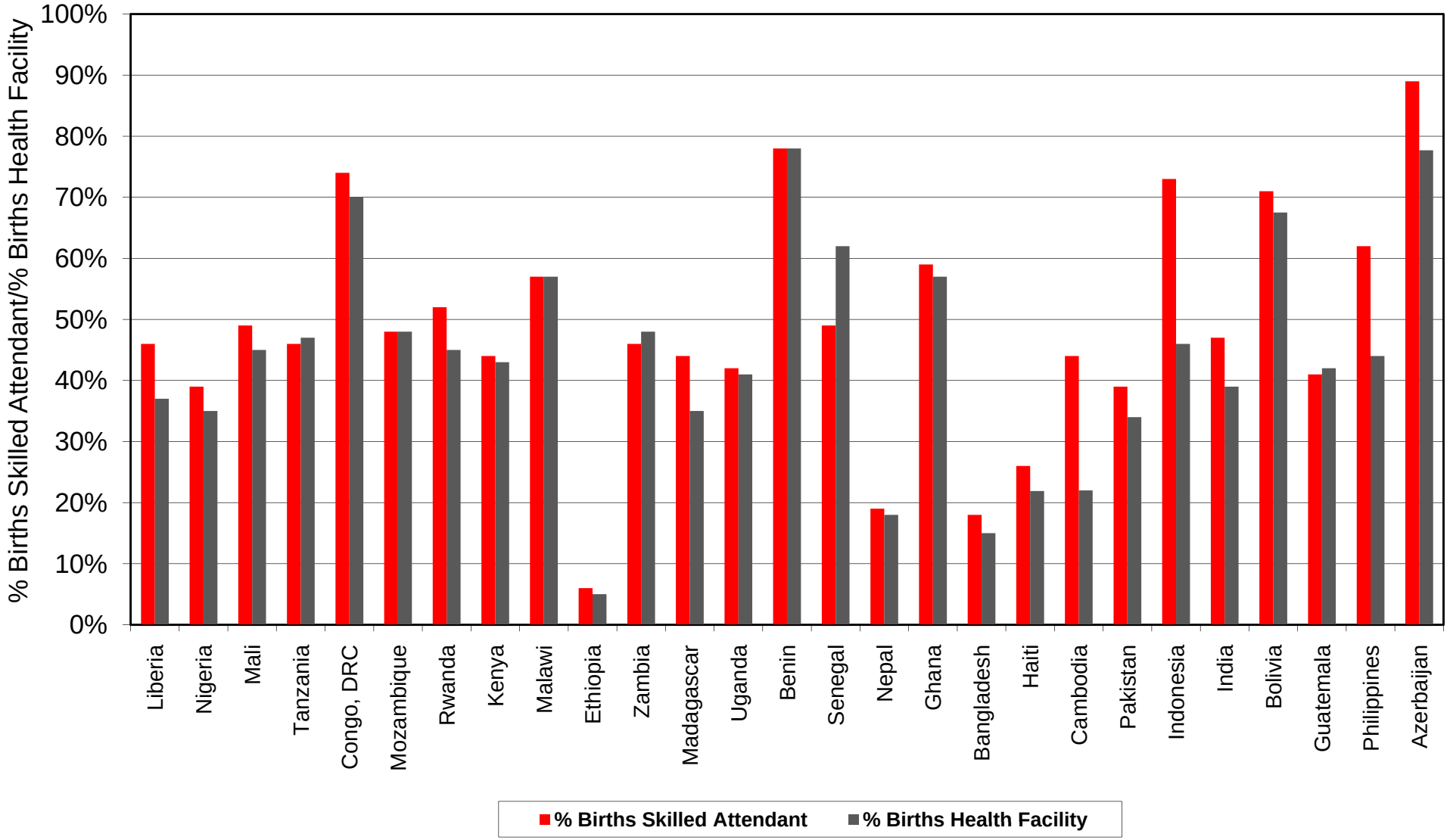
Skilled attendant births is from the most recent DHS

Publication dates for the data were compared for the number of providers per 10K population and the percent of births with a skilled attendant. In all cases, the DHS publication and WHO publications dates were within 4 years except: Bolivia, Cambodia, Kenya and the Philippines (5-7 year gap between publications). Over 70% of the countries publication dates were within 3 years or less.

Providers Per 10K Population for the Philippines = 73 and Azerbaijan = 122

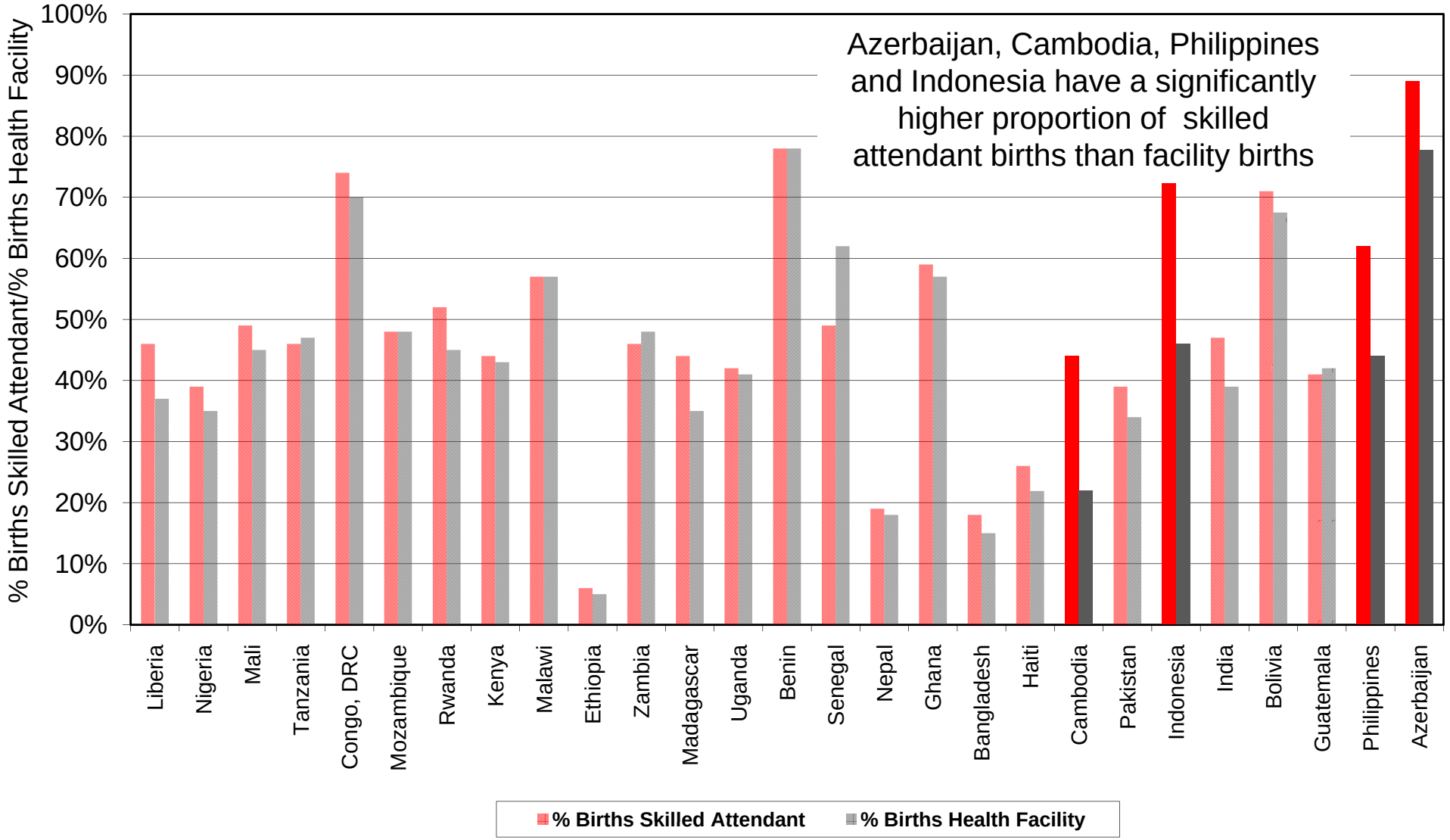
Data for number of providers is not available for Haiti or Guatemala

Data Suggests That Skilled Attendants Are Available Outside Healthcare Facilities in Some Countries



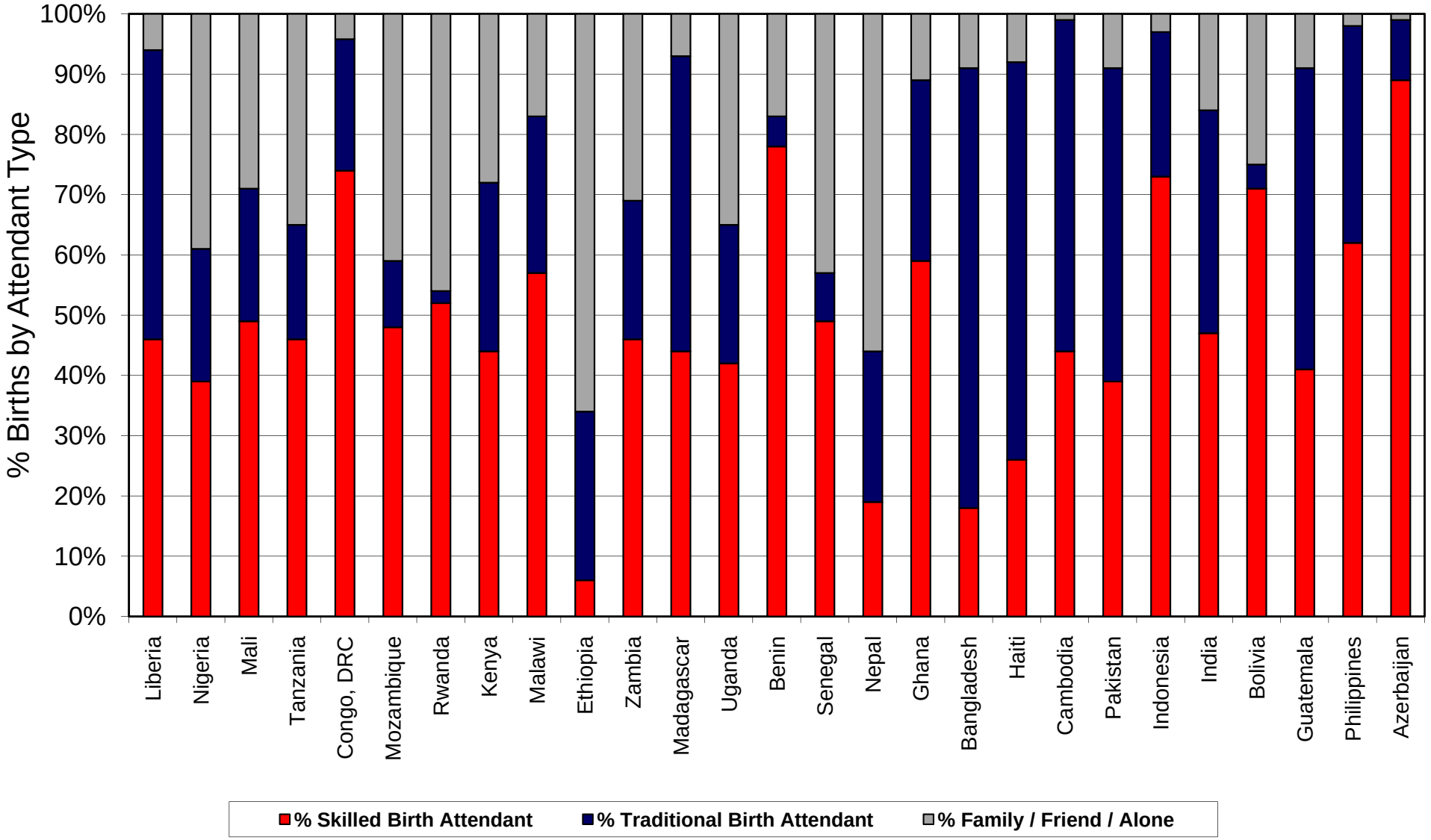
Source: Demographic Health Surveys

Data Suggests That Skilled Attendants Are Available Outside Healthcare Facilities in Some Countries



Source: Demographic Health Surveys

Traditional Birth Attendants (TBA) Are Common in Many Countries



TBA's are unlicensed trained or untrained healthcare providers/midwives that perform birthing services (data includes all types)

Sources: Demographic Health Surveys (% family, friend or alone is calculated – see notes)

Notes: Slide 24

TBA data and skilled attendant data is from the most recent DHS survey and other category is calculated (skilled birth attendants + TBA + Other = 100%). If the respondent mentioned more than one health care provider, only the most qualified is reported.

TBA's were sometimes referred to as traditional midwives

TBA's include all types (level of training was not specified in the majority of countries)

Notes: Slide 30

http://whqlibdoc.who.int/hq/2007/WHO_MPS_07.06_eng.pdf

If skilled attendant births exceed facility births, they are assumed to take place in the community. All TBA births are assumed to be in the community.

Notes: Slide 35

Nepal was excluded from high priority because it failed to score well in all three categories

Overview of Value Proposition of Oxytocin in Uniject

Ease of Use / Simplicity

- Potential for administration by a less skilled healthcare provider
- High acceptability / user preference
- Saves healthcare worker time, which can be critical when one healthcare worker attends the needs of both the mother and baby
- Eliminates difficulties in breaking ampoules
- Allows for easy, rapid initial treatment of PPH (where treatment protocols allow)

Auto Disabled

- Eliminates the possibility of needle reuse

Pre-filled and Measured

- Assures accuracy of dosing

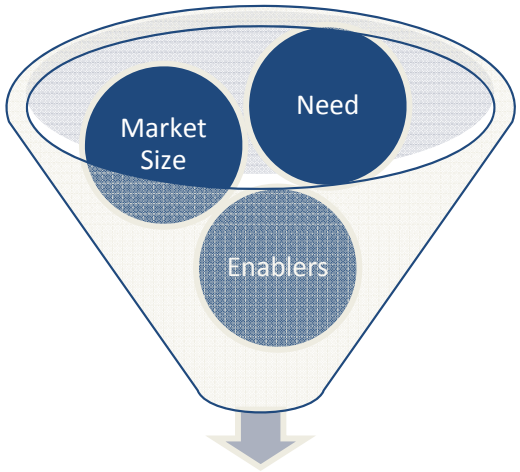
Quality Assurance

- OiU comes with a Time Temperature Indicator (TTI) that assures quality

Assessing Opportunities for OiU

- A country opportunity assessment tool was developed to sort countries into groups of relative OiU opportunity by scoring indicators of public health need, market size and enabling factors
  - Need indicators attempted to identify countries that are more vulnerable to maternal death from hemorrhage
  - Market size indicators analyzed how many women could be reached with OiU based on WHO guidelines
  - Enabling factors include government healthcare financing and other resources that may positively impact OiU uptake
- Indicators were chosen based on the ability to compare recent relevant data across most countries
- Given limited resources, high scoring countries should be prioritized for deeper analysis
- The other countries may still offer opportunity for OIU—all 27 countries need MCH improvement

27 Countries*

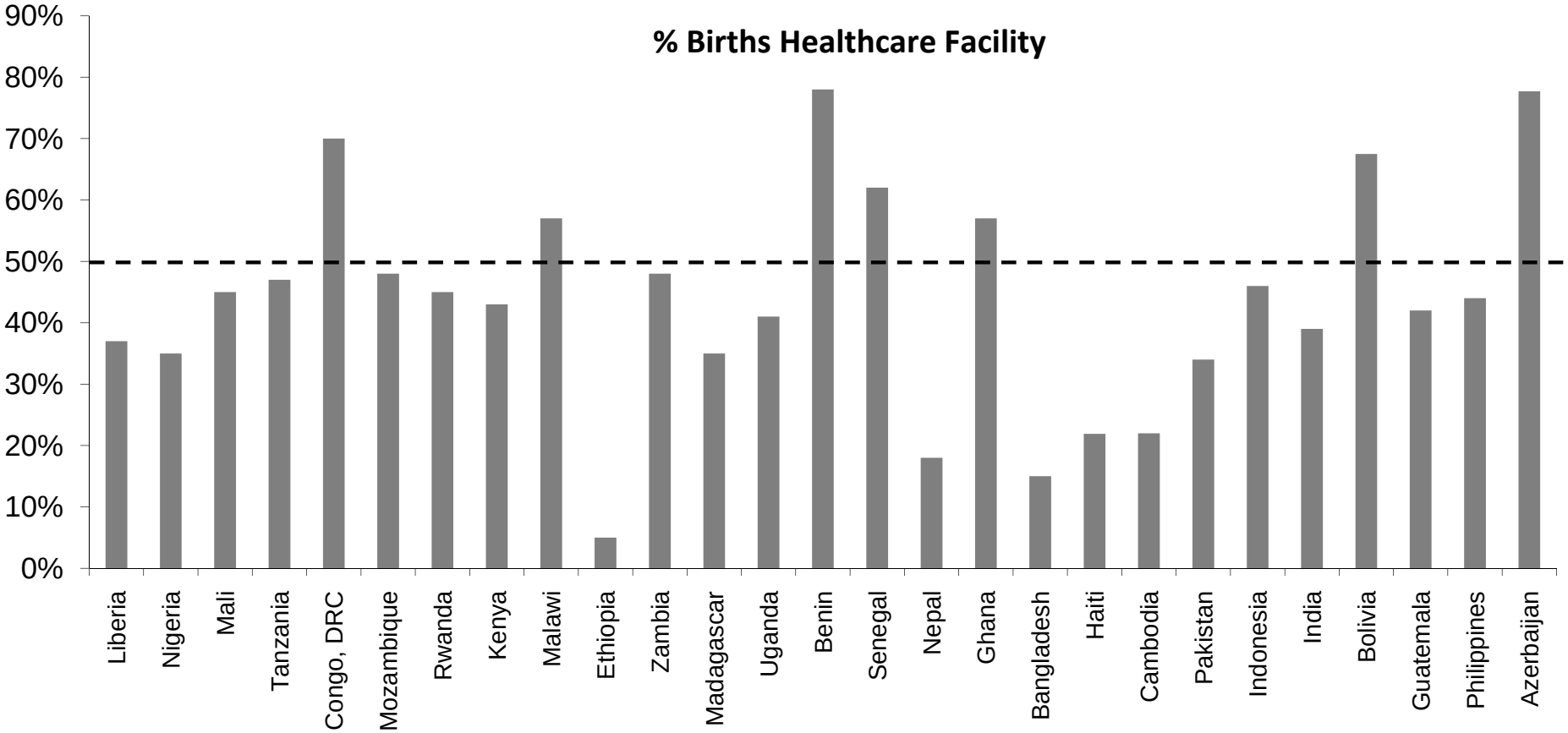


11 High Scoring Countries

*USAID maternal health priority countries (Afghanistan, Sudan and Tajikistan were excluded due to data limitations)

Facility and Community Birth Scenarios Considered

- Scenario analysis by healthcare setting is beneficial for the following reasons:
  - Provides insight on how to reach those in need (community distribution, facility distribution or both)
  - Allows the prioritization tool indicators to be defined differently for community and facility births
  - Takes into consideration where the majority of births occur (see graph below)



Opportunity Assessment Methodology Summary

- Countries were scored high, medium or low for each indicator
- Scoring: high = 2 points, medium = 1 point and low = 0 points
- Scores were tallied for need, market size and enabling factors separately
- Need, market size and enabling factors categories received equal weights
- A country can not get an overall high score if it had a low score in any of the three categories

	Need	Uterotonic Market Size	Enabling Factors
Facility Scenario (Constrained Birth Attendant Workforce)	• High MMR • High % of births occur in the facility • Inadequate number of skilled attendants	• Number of facility births with a skilled attendant	• OiU pilot work • Health expenditure (% GDP) • USAID GHI Plus Countries
Community Scenario (High Proportion Births in the Community)	• High MMR • High % of births occur in the community • High % of the population lives in rural areas	• Number of community births with a skilled attendant • Number of community births with a TBA	• OiU pilot work • Health expenditure (% GDP) • USAID GHI Plus Countries

Opportunity Assessment: Need Based Indicators—Additional Detail

- Prioritization tool analyzed need by health care setting for 27 countries
- Countries that met the criteria for a greater number of indicators were ranked higher

Facility Need: Constrained Birth Attendant Workforce

- **Variables utilized:**
  - High MMR
  - High proportion of births occur in the facility
  - Inadequate number (less than 23 per 10K people) of providers*
- **Rationale:** countries with a constrained workforce may benefit from a more simple uterotonic device
  - OiU is designed to make injections safe and easy to administer (see OiU value proposition)
  - Not seeking to replace oxytocin in ampoules but find scenarios where the added cost may be justified

Community Need: High Proportion of Community Births

- **Variables utilized:**
  - High MMR
  - High proportion of births occur in the community
  - High proportion of the population lives in rural areas
- **Rationale:** birth resources are more limited in community settings
  - OiU has potential to expand coverage to minimally trained healthcare workers

*Providers include: physicians, nurses or midwives
*23 doctors, nurses and midwives per 10,000 people generally considered necessary to deliver essential health services
Sources: Definitions from WHO Global Health Observatory, http://www.who.int/whosis/whostat/2010/en/)

Opportunity Assessment: Uterotonic Market Size—Additional Detail

- Prioritization tool analyzed market size by health care setting for 27 countries
- Market size is based on WHO recommendations for uterotonic use
- Market size for facility and community scenarios are calculated separately
- Countries with a larger market size receive higher score

Facility Market Size

- **Calculation:**
  - Number of births with a skilled attendant in a facility
- **Rationale:**
  - WHO recommends that all women should receive active management of third stage labor (AMTSL) by skilled attendants
  - Skilled attendants should offer oxytocin to all women for PPH prevention
  - Oxytocin is the preferred uterotonic

Community Market Size

- **Calculation:**
  - Number of births with a skilled attendant in the community (see notes)
  - Number of births with a traditional birth attendant (TBA)*
- **Rationale:**
  - WHO recommends that in the absence of AMTSL, a utertonic drug be offered by a healthcare worker that is trained in its use
  - Oxytocin is the preferred uterotonic
  - Training of TBA for proper administration is needed
  - Births delivered by family, friends or alone are excluded

*TBA are not accredited; level of training is variable (includes all types)
Sources: World Health Organization Recommendations for the Prevention of PPH (see notes)

Opportunity Assessment: Enabling Factors—Additional Detail

The team felt the following additional variables were likely relevant in an overall assessment of country opportunity for OiU, these were then added in the third Enabling Factors category:

- Countries where OiU pilots have been conducted
  - Indicates a government that is interested in evaluating the potential benefits of OiU
  - Countries where OiU pilots have not been conducted may also be interested in the product
- Relatively high health expenditure as a % of GDP
  - Highlights countries that invest more in healthcare
- USAID Global Health Initiative (GHI) Plus countries
  - GHI Plus countries will receive additional technical and management resources in maternal and child health and other areas

Note: These are the same for both scenarios—no difference in facility use or community use. The team recognizes the choice of the enabling factors was quite subjective.

Sources: USAID Dolphn (Health Expenditure % GDP), PATH website, USAID Press Release (provided by PATH – Brooke)

Opportunity Assessment: Scoring System--Additional Detail

High Medium Low

	Facility Need				Facility Market Size		Enabling Factors				
Country	MMR	% Births Facility	Provider Density	Subtotal (Score)	# Facility SA Births	Subtotal (Score)	Health Expen. % GDP	USAID GHI Plus	OiU Pilots	Subtotal (Score)	Total Score
Azerbaijan	38	78%	122	2 (0)	128,982	0 (0)	3.6			0 (0)	0 Low
Bangladesh	340	15%	6	3 (1)	514,500	1 (1)	3.4	X		2 (1)	3 Medium
Benin	410	78%	9	5 (2)	266,760	1 (1)	4.4			1 (1)	4 High

1. **Country data for each indicator was sorted into groups (high, medium, low) and assigned points.**
   - Break-points were chosen to reflect apparent groups to the extent possible.
   - Groups are indicated by shading: High by dark green, Medium by light green and Low by grey.
   - Point values: High (dark green) = 2 points, Medium (light green) = 1 point , Low (grey) = 0 points.
   - For graphic simplicity, points are not shown in each indicator cell.
2. **Points for each country were subtotaled within each category of Need, Market Size, and Enabling Factors.**
   - This country category subtotal is shown as the unbracketed number in the Subtotal (Score) column.
3. **Country category subtotals were again sorted into groups (high, medium, low) and assigned points. These points are the category score for each country.**
   - Break-points were chosen to reflect apparent groups to the extent possible.
   - Point values: High (dark green) = 2 points, Medium (light green) = 1 point , Low (grey) = 0 points.
   - The country category score is the bracketed number in the Subtotal (Score) column.
6. **The country category scores were totaled to create the Total Score.**
7. **Total Score was then sorted into three final groups (high, medium, low).**
   - Break-points were chosen to reflect apparent groups to the extent possible.
   - High = 4-6 total score, medium = 3 total score, low = 0-2 total score.

Opportunity Assessment Results

Facility Scenario Scoring Results

High Medium Low

	Facility Need				Facility Market Size		Enabling Factors				
Country	MMR	% Births Facility	Provider Density	Subtotal (Score)	# Facility SA Births	Subtotal (Score)	Health % GDP	USAID GHI Plus	OiU Pilots	Subtotal (Score)	Total Score
Azerbaijan	38	78%	122	2 (0)	128,982	0 (0)	3.6			0 (0)	0 Low
Bangladesh	340	15%	6	3 (1)	514,500	1 (1)	3.4	X		2 (1)	3 Medium
Benin	410	78%	9	5 (2)	266,760	1 (1)	4.4			1 (1)	4 High
Bolivia	180	67%	33	2 (0)	177,525	0 (0)	6.7			2 (1)	1 Low
Cambodia	290	22%	10	2 (0)	79,420	0 (0)	10.9			2 (1)	1 Low
Congo, DRC	670	70%	6	6 (2)	2,020,200	2 (2)	4.0			1 (1)	5 High
Ethiopia	470	5%	2.5	4 (1)	154,650	0 (0)	5.9	X		4 (2)	3 Medium
Ghana	350	57%	11	3 (1)	431,490	1 (1)	4.5		X	3 (2)	4 High
Guatemala	110	42%	N/A	0 (0)	185,730	0 (0)	5.4	X	X	5 (2)	2 Low
Haiti	300	22%	N/A	1 (0)	59,787	0 (0)	7.5			2 (1)	2 Low
India	230	39%	19	2 (0)	10,496,070	2 (2)	4.8			1 (1)	3 Medium
Indonesia	240	46%	9	2 (0)	1,941,200	2 (2)	3.1		X	2 (1)	3 Medium
Kenya	530	43%	13	3 (1)	647,580	1 (1)	4.3	X		3 (2)	4 High
Liberia	990	37%	3.5	4 (1)	53,650	0 (0)	4.7			1 (1)	2 Low
Madagascar	440	35%	5	4 (1)	240,450	0 (0)	2.7			0 (0)	1 Low
Malawi	510	57%	3.5	5 (2)	341,430	1 (1)	9.3	X		4 (2)	5 High
Mali	830	45%	3	4 (1)	243,900	0 (0)	4.8	X	X	5 (2)	3 Medium
Mozambique	550	48%	3.5	4 (1)	420,480	1 (1)	4.7			1 (1)	3 Medium
Nepal	380	18%	7	2 (0)	131,760	0 (0)	5.3	X		3 (2)	2 Low
Nigeria	840	35%	20	3(1)	2,109,800	2 (2)	5.0			1 (1)	4 High
Pakistan	260	34%	12	2 (0)	1,814,580	2 (2)	2.4			0 (0)	2 Low
Philippines	94	44%	73	0 (0)	983,840	2 (2)	3.2			0 (0)	2 Low
Rwanda	540	45%	4.5	4 (1)	181,350	0 (0)	3.7	X		2 (1)	2 Low
Senegal	410	62%	5	6 (2)	230,300	0 (0)	5.1			1 (1)	3 Medium
Tanzania	790	47%	2.5	4 (1)	814,660	1 (1)	4.3			1 (1)	3 Medium
Uganda	430	41%	14	3 (1)	601,060	1 (1)	7.3			2 (1)	3 Medium
Zambia	470	48%	8	3 (1)	249,320	1 (1)	5.4			1 (1)	3 Medium

Community Scenario Scoring Results

High Medium Low

	Community Need				Community Market Size			Enabling Factors				
Country	MMR	% Births Community	% Rural	Subtotal (Score)	# Community SA Births	# Community TBA Births	Subtotal (Score)	Health % GDP	USAID GHI Plus	OiU Pilots	Subtotal (Score)	Total Score
Azerbaijan	38	22%	50%	0 (0)	18,758	16,600	0 (0)	3.6			0 (0)	0 Low
Bangladesh	340	85%	75%	4 (1)	102,900	2,503,900	3 (2)	3.4	X		2 (1)	4 High
Benin	410	22%	55%	3 (1)	0	17,100	0 (0)	4.4			1 (1)	2 Low
Bolivia	180	33%	36%	0 (0)	9,205	10,520	0 (0)	6.7			2 (1)	1 Low
Cambodia	290	78%	81%	5 (2)	79,420	198,550	2 (1)	10.9			2 (1)	4 High
Congo, DRC	670	30%	68%	3 (1)	115,440	629,148	2 (1)	4.0			1 (1)	3 Medium
Ethiopia	470	95%	84%	6 (2)	30,930	866,040	2 (1)	5.9	X		4 (2)	5 High
Ghana	350	43%	54%	1 (0)	15,140	227,100	1 (1)	4.5		X	3 (2)	3 Medium
Guatemala	110	58%	53%	1 (0)	0	226,500	1 (1)	5.4	X	X	5 (2)	3 Medium
Haiti	300	78%	62%	4 (1)	11,193	180,180	0 (0)	7.5			2 (1)	2 Low
India	230	61%	71%	4 (1)	2,153,040	9,957,810	4 (2)	4.8			1 (1)	4 High
Indonesia	240	54%	53%	2 (0)	1,139,400	1,012,800	4 (2)	3.1		X	2 (1)	3 Medium
Kenya	530	57%	60%	4 (1)	15,060	421,680	1 (1)	4.3	X		3 (2)	4 High
Liberia	990	63%	53%	4 (1)	13,050	69,600	0 (0)	4.7			1 (1)	2 Low
Madagascar	440	65%	73%	5 (2)	61,830	336,630	1 (1)	2.7			0 (0)	3 Medium
Malawi	510	43%	83%	4 (1)	0	155,740	0 (0)	9.3	X		4 (2)	3 Medium
Mali	830	55%	67%	4 (1)	21,680	119,240	0 (0)	4.8	X	X	5 (2)	3 Medium
Mozambique	550	52%	63%	4 (1)	0	96,360	0 (0)	4.7			1 (1)	Low
Nepal	380	82%	85%	5 (2)	7,320	183,000	0 (0)	5.3	X		3 (2)	*4 Medium**
Nigeria	840	65%	53%	4 (1)	241,120	1,326,160	3 (2)	5.0			1 (1)	4 High
Pakistan	260	66%	66%	4 (1)	266,850	2,775,240	3 (2)	2.4			0 (0)	3 Medium
Philippines	94	56%	38%	1 (0)	402,480	804,960	4 (2)	3.2			0 (0)	2 Low
Rwanda	540	55%	80%	5 (2)	28,210	8,060	0 (0)	3.7	X		2 (1)	3 Medium
Senegal	410	38%	50%	2 (0)	0	37,600	0 (0)	5.1			1 (1)	1 Low
Tanzania	790	53%	64%	4 (1)	0	336,490	1 (1)	4.3			1 (1)	3 Medium
Uganda	430	59%	88%	5 (2)	14,660	337,180	1 (1)	7.3			2 (1)	4 High
Zambia	470	52%	64%	4 (1)	0	124,660	0 (0)	5.4			1 (1)	2 Low

Summary: 11 Countries with High Score

Country	% Births Facility	Facility Score	Community Score
Azerbaijan	78%	Low	Low
Bangladesh	15%	Medium	High
Benin	78%	High	Low
Bolivia	67%	Low	Low
Cambodia	22%	Low	High
Congo, DRC	70%	High	Medium
Ethiopia	5%	Medium	High
Ghana	57%	High	Medium
Guatemala	42%	Low	Medium
Haiti	22%	Low	Low
India	39%	Medium	High
Indonesia	46%	Medium	Medium
Kenya	43%	High	High
Liberia	37%	Low	Low
Madagascar	35%	Low	Medium
Malawi	57%	High	Medium
Mali	45%	Medium	Medium
Mozambique	48%	Medium	Low
Nepal	18%	Low	Medium
Nigeria	35%	High	High
Pakistan	34%	Low	Medium
Philippines	44%	Low	Low
Rwanda	45%	Low	Medium
Senegal	62%	Medium	Low
Tanzania	47%	Medium	Medium
Uganda	41%	Medium	High
Zambia	48%	Medium	Low

Summary: 12 Countries with Medium Score

Country	% Births Facility	Facility Score	Community Score
Azerbaijan	78%	Low	Low
Bangladesh	15%	Medium	High
Benin	78%	High	Low
Bolivia	67%	Low	Low
Cambodia	22%	Low	High
Congo, DRC	70%	High	Medium
Ethiopia	5%	Medium	High
Ghana	57%	High	Medium
Guatemala	42%	Low	Medium
Haiti	22%	Low	Low
India	39%	Medium	High
Indonesia	46%	Medium	Medium
Kenya	43%	High	High
Liberia	37%	Low	Low
Madagascar	35%	Low	Medium
Malawi	57%	High	Medium
Mali	45%	Medium	Medium
Mozambique	48%	Medium	Low
Nepal	18%	Low	Medium
Nigeria	35%	High	High
Pakistan	34%	Low	Medium
Philippines	44%	Low	Low
Rwanda	45%	Low	Medium
Senegal	62%	Medium	Low
Tanzania	47%	Medium	Medium
Uganda	41%	Medium	High
Zambia	48%	Medium	Low

Summary: 5 Countries with Low Score

Country	% Births Facility	Facility Score	Community Score
Azerbaijan	78%	Low	Low
Bangladesh	15%	Medium	High
Benin	78%	High	Low
Bolivia	67%	Low	Low
Cambodia	22%	Low	High
Congo, DRC	70%	High	Medium
Ethiopia	5%	Medium	High
Ghana	57%	High	Medium
Guatemala	42%	Low	Medium
Haiti	22%	Low	Low
India	39%	Medium	High
Indonesia	46%	Medium	Medium
Kenya	43%	High	High
Liberia	37%	Low	Low
Madagascar	35%	Low	Medium
Malawi	57%	High	Medium
Mali	45%	Medium	Medium
Mozambique	48%	Medium	Low
Nepal	18%	Low	Medium
Nigeria	35%	High	High
Pakistan	34%	Low	Medium
Philippines	44%	Low	Low
Rwanda	45%	Low	Medium
Senegal	62%	Medium	Low
Tanzania	47%	Medium	Medium
Uganda	41%	Medium	High
Zambia	48%	Medium	Low

Conclusions

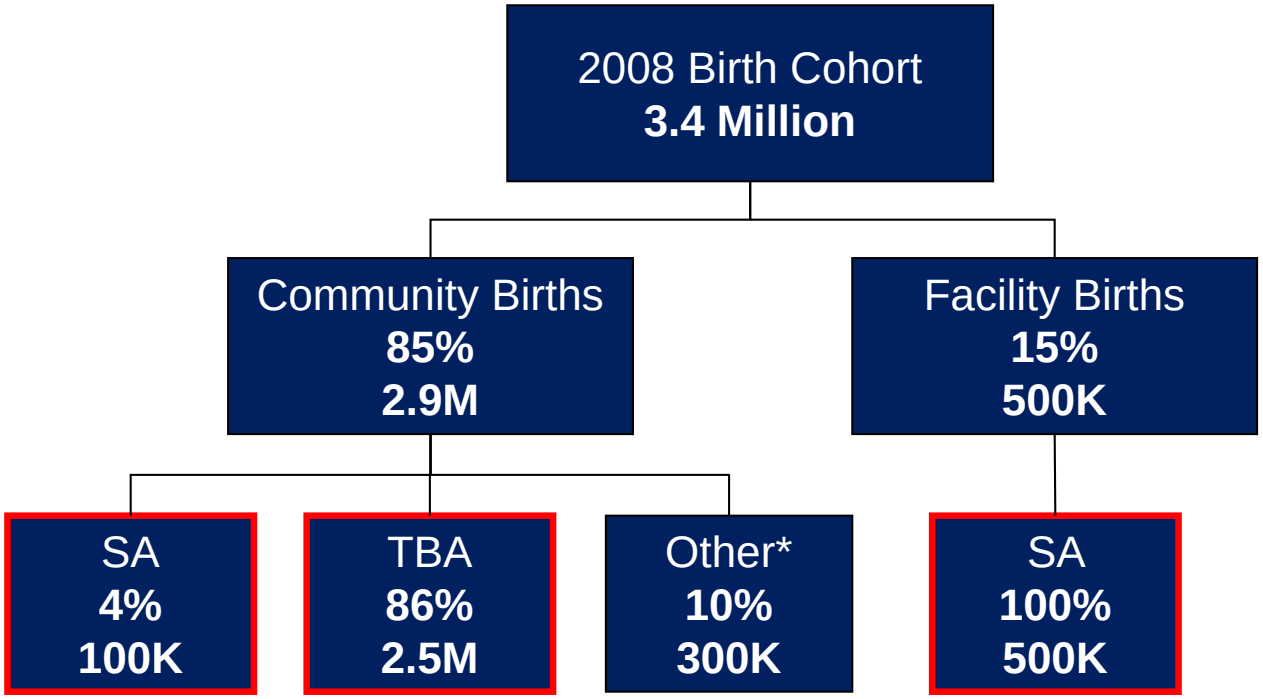
- Using a country opportunity assessment tool, 11 countries were identified that have relatively high need, market size and enabling factors
  - Majority (9/11) of the countries would benefit from a community or community/facility distribution approach
- OiU opportunity assessment tool has limitations on the extent to which it can measure enabling factors
  - Exclusively utilizes secondary data that can be compared across a large number of countries
  - Government policy and potential for PATH partnerships were not evaluated and are vital to the product's success
- Lower priority countries could still have opportunity
  - All countries evaluated are on the USAID maternal health priority list
  - Need to consider the goals and interests of all stakeholders
- Country specific issues that do not fit in to the tool will be considered on a case-by-case basis

Potential Next Steps

- Additional due diligence is recommended on the high priority targets including:
  - In country stakeholder analysis
  - Government policies including:
    - Who is authorized to administer uterotonic products and in what settings
    - Current initiatives on community based birthing strategies or willingness to develop community based birthing strategies
  - Availability of uterotonic products (including misoprostol)
  - Expressed interest in OiU by buyers

High Scoring Country Summary Slides

Bangladesh Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

- Community distribution approach is needed to reach the majority of women
- Large proportion of community births are attended by TBAs
- Misoprostol is registered but use is unknown
- Nearly 12K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (6)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	340
# Deaths	11,662

See notes for sources, calculations and assumptions

Notes: Slides 42-43

% other: Remainder

Registration data is from Venture Strategies Innovation: Getting products to people: the case of misoprostol and PATH (OiU)

If skilled attendant births exceed facility births they are assumed to occur in the community

Total number of community skilled attendant births / total number of community births = % of community births with a skilled attendant

All TBA births are assumed to occur in the community

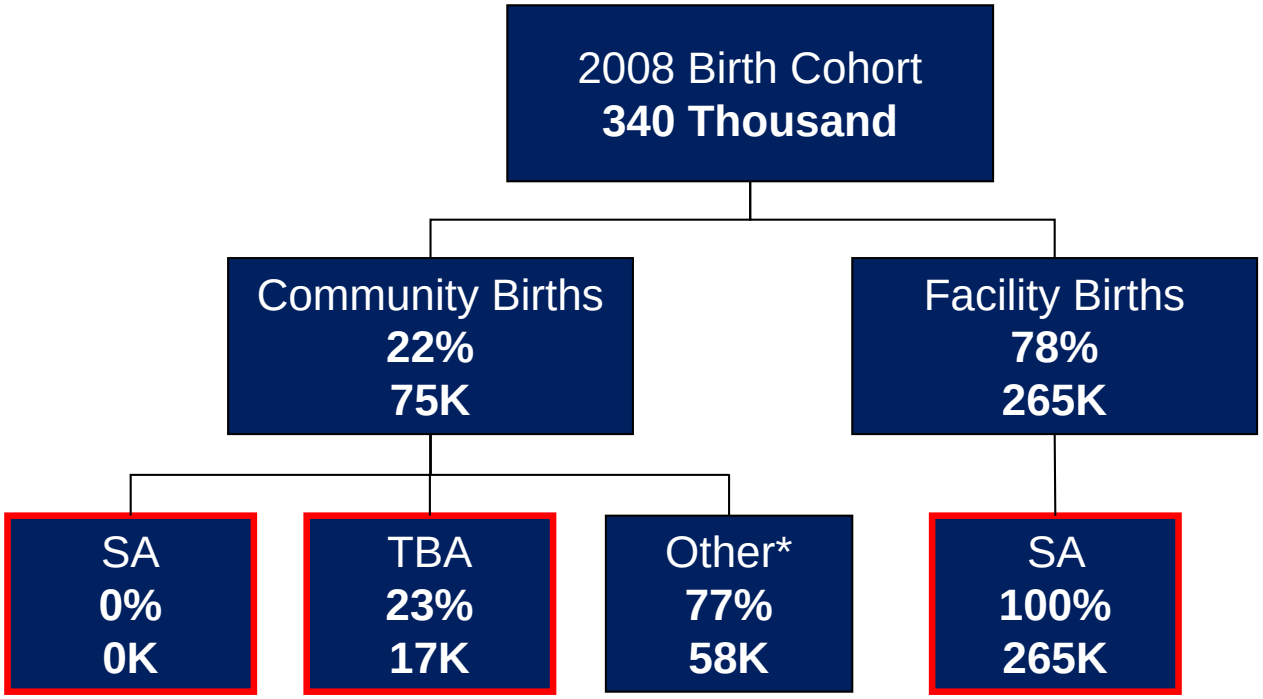
Total number of TBA births / total number of community births = % of community births with a TBA

All other births are assumed to occur in the community

Total number of other births / total number of community births = % of community births with a family, friend or alone

Note: % births skilled attendant, TBA and other in DHS are reported for the total number of births (not by community or facility)

Benin Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

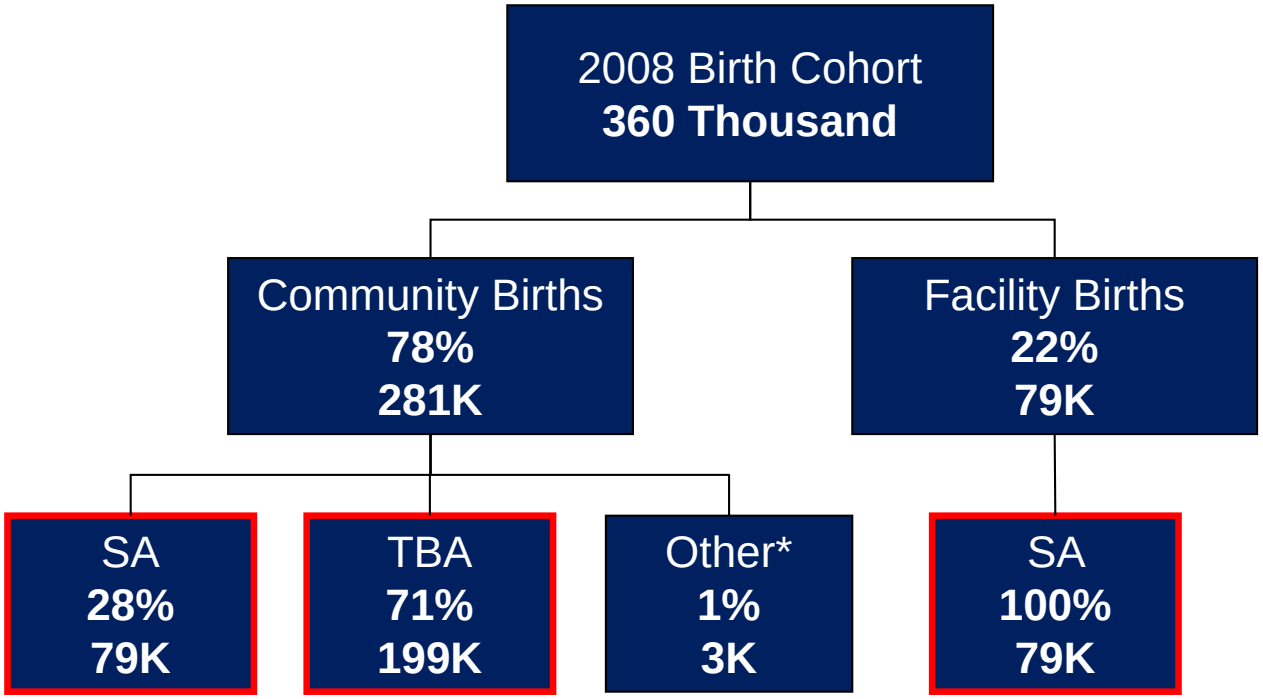
- Facility distribution approach is needed to reach the majority of women
- Majority of community births occur without any healthcare assistance
- Misoprostol and OiU are currently not registered
- More than1.4K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (9)

Product Registration for PPH Prevention	
Misoprostol	-
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	410
# Deaths	1,402

See notes for sources, calculations and assumptions

Cambodia Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

- Community distribution approach is needed to reach the majority of women
- Data suggests that skilled attendants are available outside the healthcare facility
- Large proportion of community births utilize a TBA
- Misoprostol and OiU are currently not registered
- Over 1000 annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (10)

Product Registration for PPH Prevention	
Misoprostol	-
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	290
# Deaths	1,047

See notes for sources, calculations and assumptions

Notes: Slide 44

Birth cohort: UNICEF statistics http://www.unicef.org/statistics/index_24183.html

% births facility / community: DHS

% Skilled attendant births: DHS

% TBA births: DHS

% other: Remainder

Registration data is from Venture Strategies Innovation: Getting products to people: the case of misoprostol and PATH (OiU)

If skilled attendant births exceed facility births they are assumed to occur in the community

Total number of community skilled attendant births / total number of community births = % of community births with a skilled attendant

All TBA births are assumed to occur in the community

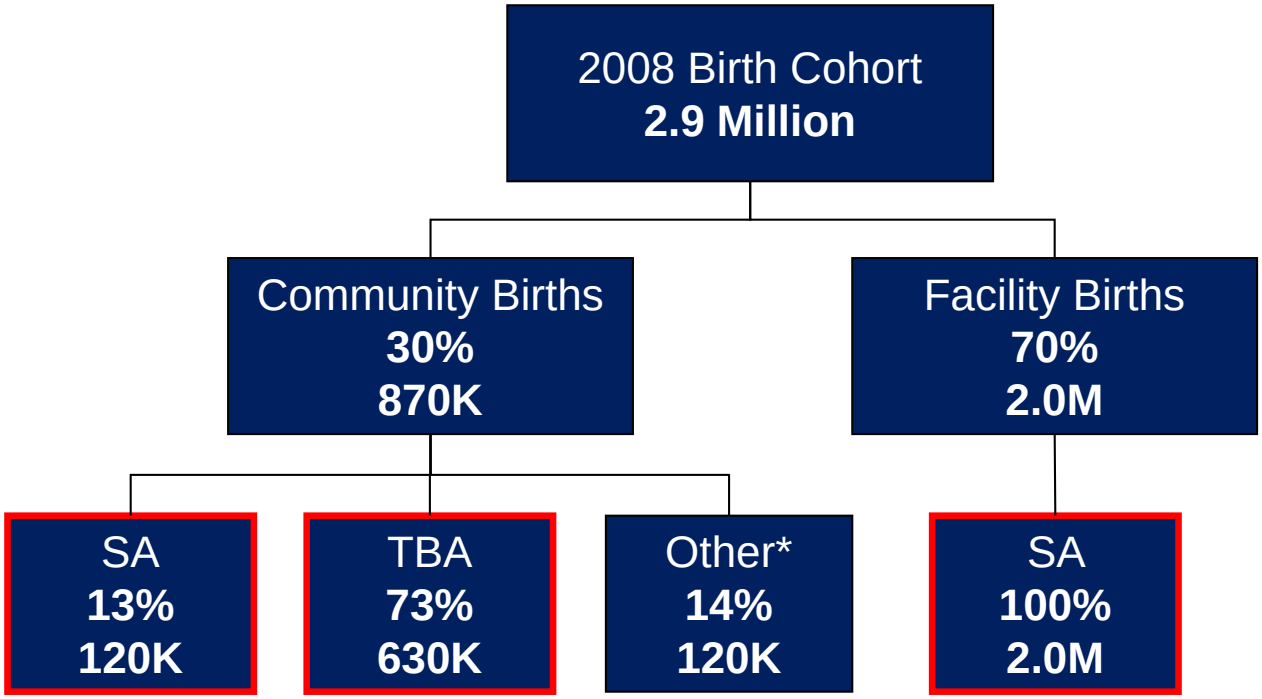
Total number of TBA births / total number of community births = % of community births with a TBA

All other births are assumed to occur in the community

Total number of other births / total number of community births = % of community births with a family, friend or alone

Note: % births skilled attendant, TBA and other in DHS are reported for the total number of births (not by community or facility)

Congo, DRC Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

- Facility distribution approach is needed to reach the majority of women
- Majority of community births occur with a TBA
- Misoprostol and OiU are currently not registered for PPH
- More than19K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (6)

Product Registration for PPH Prevention	
Misoprostol	-
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	670
# Deaths	19,336

See notes for sources, calculations and assumptions

Notes: Slides 45-52

% other: Remainder

Registration data is from Venture Strategies Innovation: Getting products to people: the case of misoprostol and PATH (OiU)

If skilled attendant births exceed facility births they are assumed to occur in the community

Total number of community skilled attendant births / total number of community births = % of community births with a skilled attendant

All TBA births are assumed to occur in the community

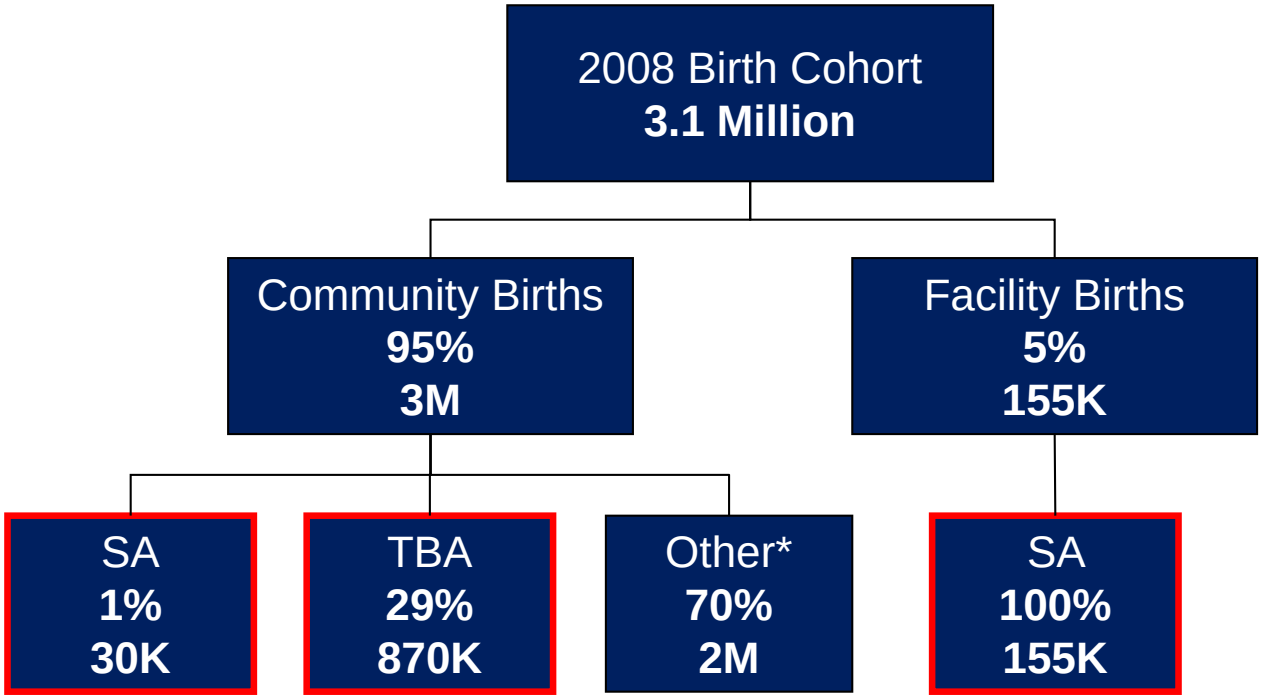
Total number of TBA births / total number of community births = % of community births with a TBA

All other births are assumed to occur in the community

Total number of other births / total number of community births = % of community births with a family, friend or alone

Note: % births skilled attendant, TBA and other in DHS are reported for the total number of births (not by community or facility)

Ethiopia Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

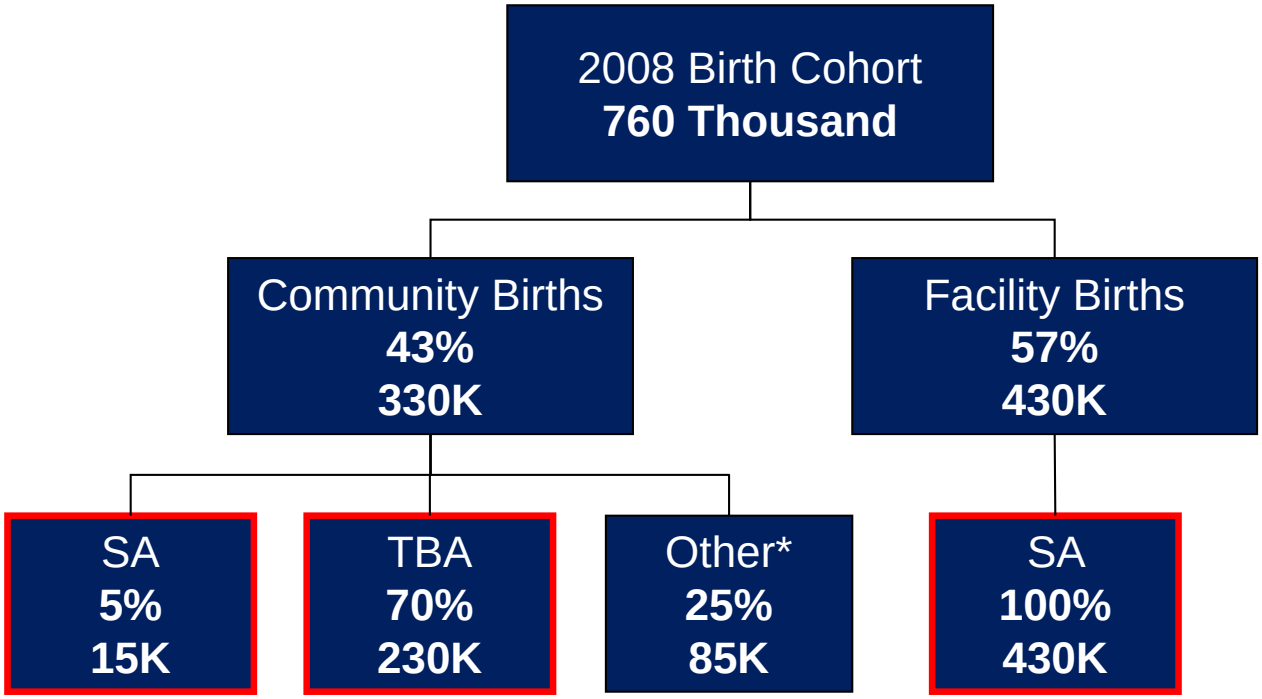
- Community distribution approach is needed to reach the vast majority of women
- Large proportion of community births are attended by family, friends or alone
- TBAs are also used in 30% of community births
- Misoprostol is registered but use is unknown
- Nearly15K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (2.5)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	470
# Deaths	14,537

See notes for sources, calculations and assumptions

Ghana Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

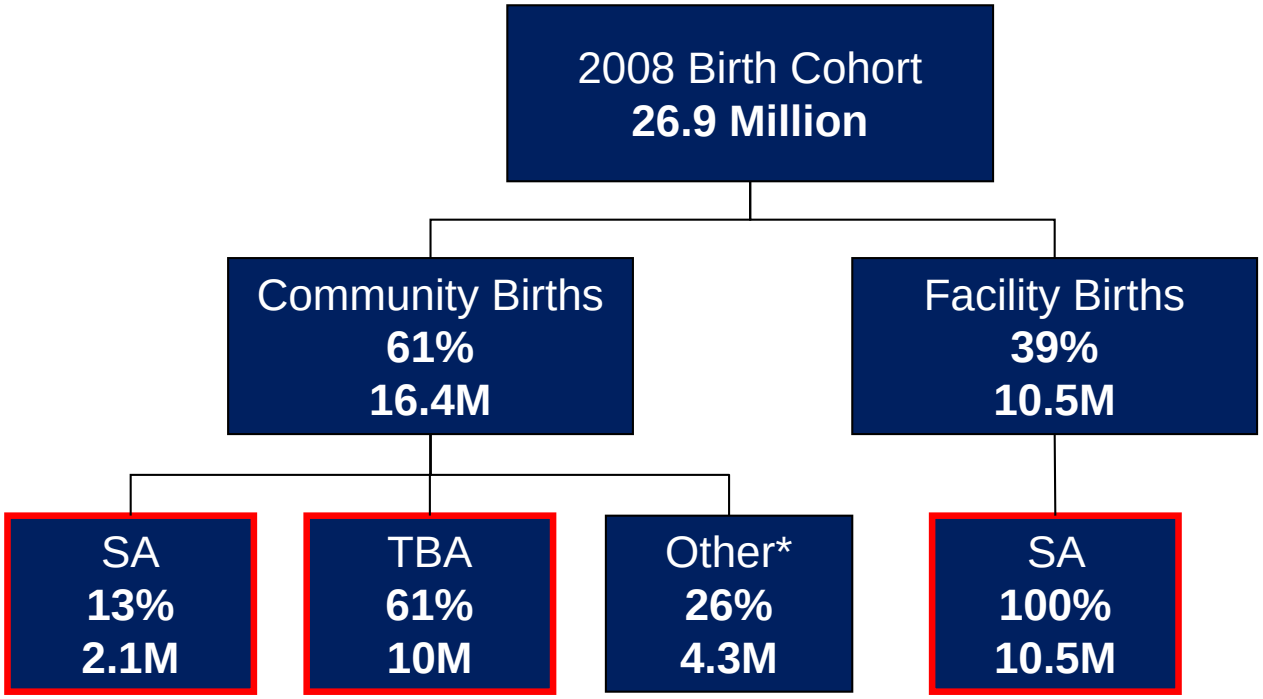
- Facility and community distribution approaches may be beneficial
- Majority of community births occur with a TBA
- Misoprostol is registered but use is unknown
- More than 2.6K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (11)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	350
# Deaths	2,650

See notes for sources, calculations and assumptions

India Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

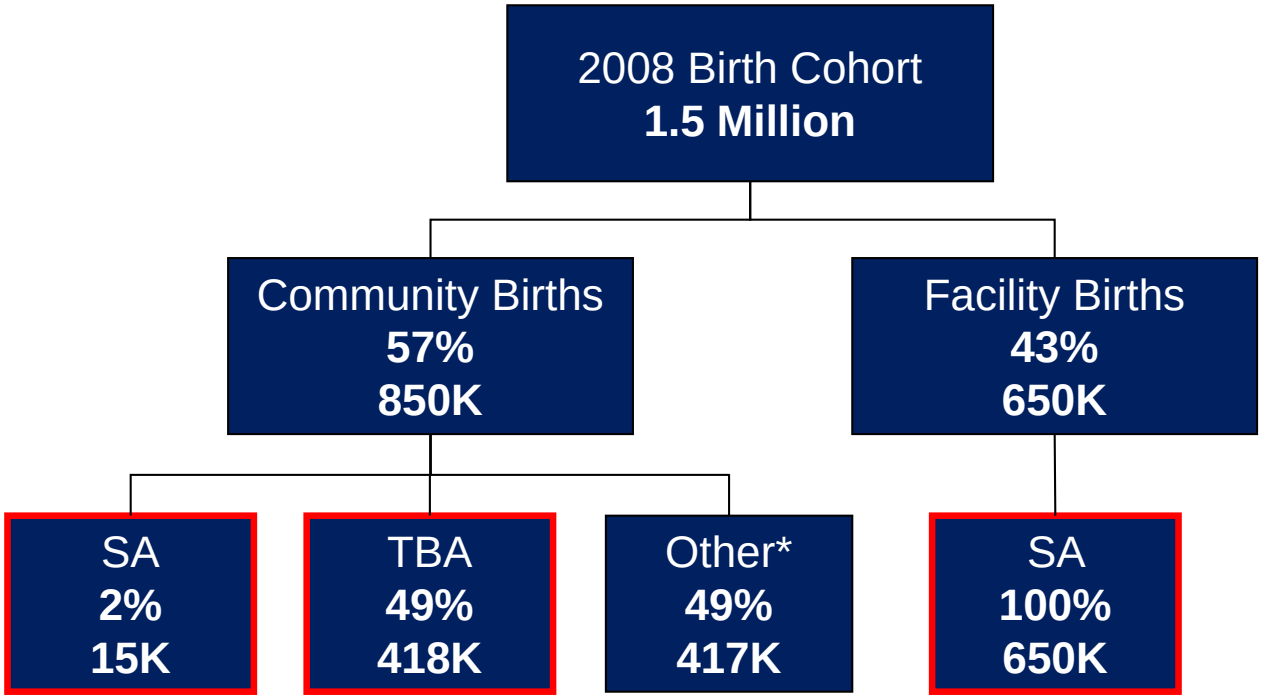
- Community distribution approaches will reach the majority of women
- Data suggests that skilled attendants are available outside the healthcare facility
- Majority of community births occur with a TBA
- Misoprostol is registered but use is unknown
- More than 60K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (19)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	Yes

Maternal Mortality (2008)	
MMR (deaths per 100K births)	230
# Deaths	61,900

See notes for sources, calculations and assumptions

Kenya Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

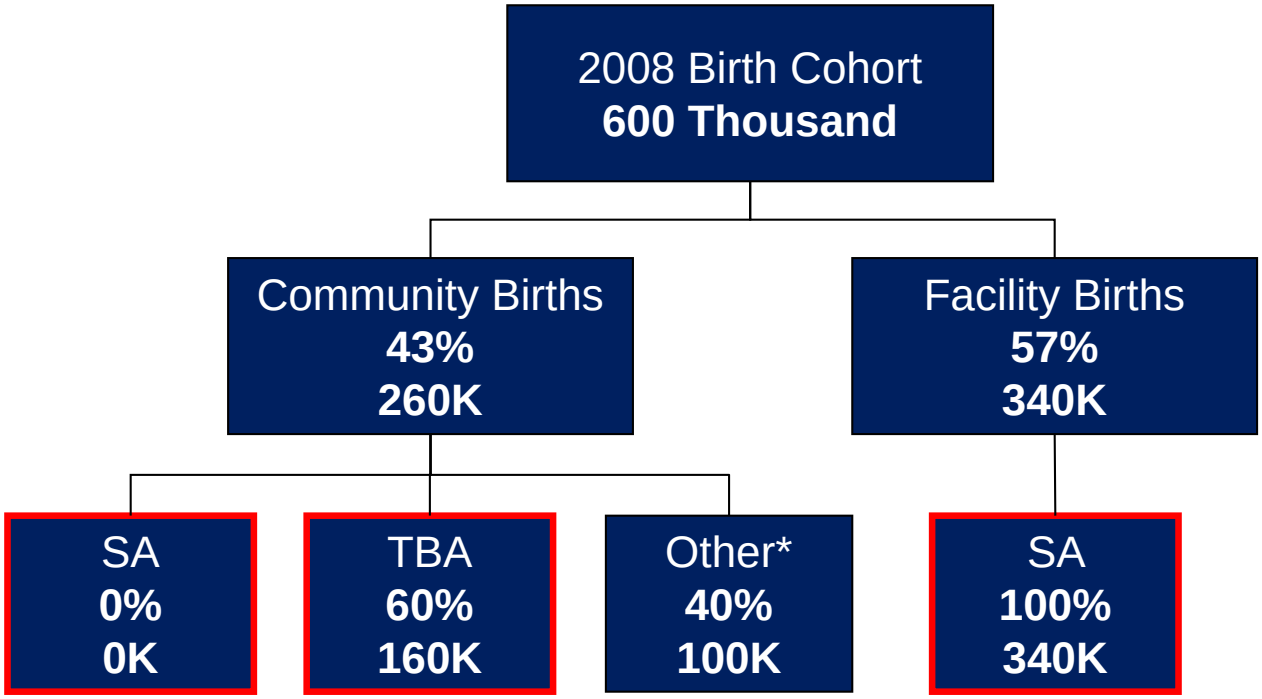
- Facility and community distribution approaches may be beneficial
- Many community births occur with either TBAs or with family members, friends or alone
- Misoprostol is registered but use is unknown
- Nearly 8K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (13)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	530
# Deaths	7,982

See notes for sources, calculations and assumptions

Malawi Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

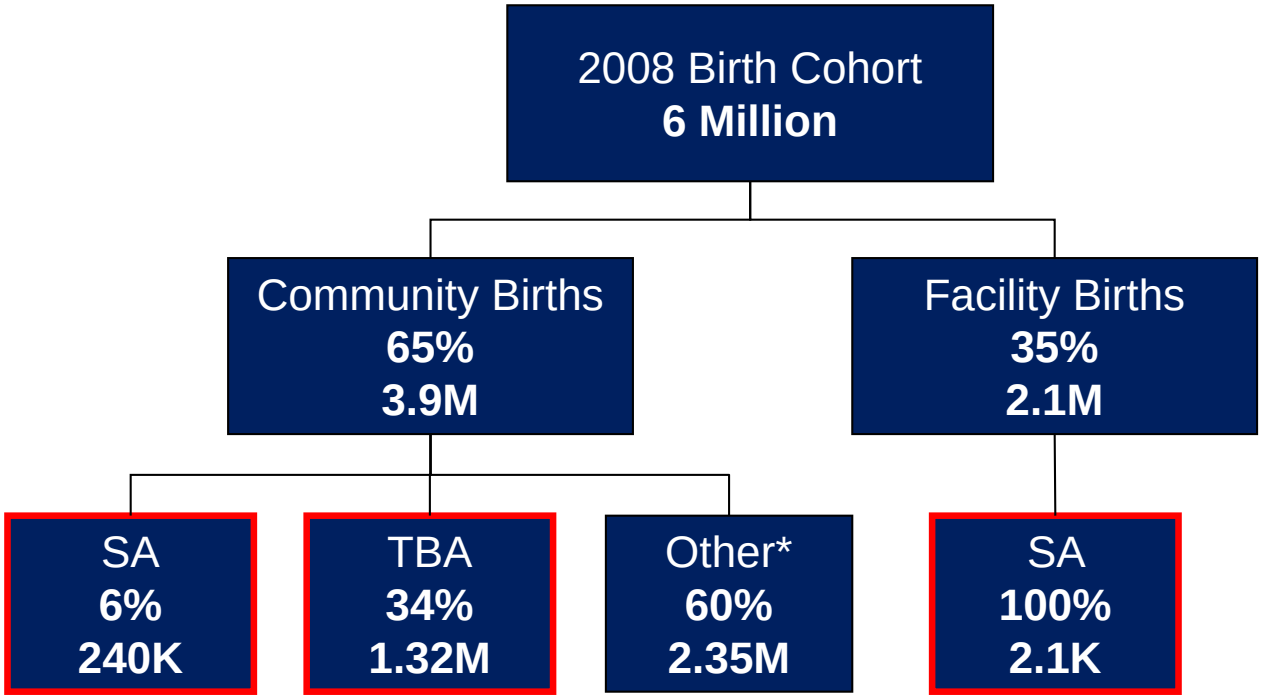
- Facility and community distribution approaches may be beneficial
- Many community births occur with TBAs
- Misoprostol is registered but use is unknown
- Over 3K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (3.5)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	510
# Deaths	3,055

See notes for sources, calculations and assumptions

Nigeria Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

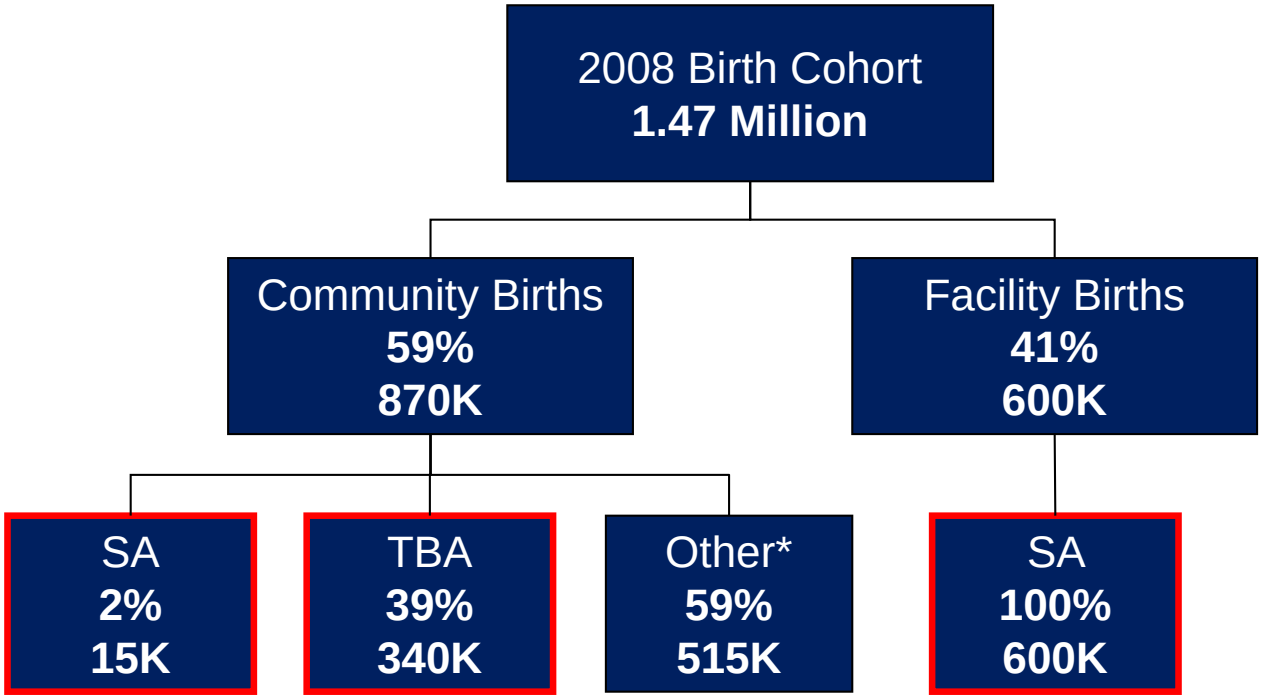
- Community distribution approaches will reach the majority of women
- Large proportion of community births occur with family, friends or alone
- TBAs are also used in 34% of community births
- Misoprostol is registered but use is unknown
- Over 50K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (20)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	840
# Deaths	50,635

See notes for sources, calculations and assumptions

Uganda Key Statistics



Red indicates potential uterotonic market size
***Other is family, friend or alone**

Key Takeaways:

- Facility and community distribution approaches may be beneficial
- Many community births occur with either a TBA or family/friend/alone
- Misoprostol is registered but use is unknown
- Over 6K annual maternal deaths in 2008
- Density of healthcare providers per 10K people does not meet WHO recommendations (14)

Product Registration for PPH Prevention	
Misoprostol	Yes
OiU	-

Maternal Mortality (2008)	
MMR (deaths per 100K births)	430
# Deaths	6,304

See notes for sources, calculations and assumptions