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# Phase I Report

## WASH for Neonatal and Maternal Sepsis Reduction Study

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The Maternal and Child Survival Program (MCSP), is a global, US Agency for International Development (USAID) Cooperative Agreement to introduce and support high-impact health interventions in 24 priority countries with the ultimate goal of ending preventable child and maternal deaths within a generation. MCSP supports programming in maternal, newborn and child health, immunization, family planning and reproductive health, nutrition, health systems strengthening, water/sanitation/hygiene, malaria, prevention of mother-to-child transmission of HIV, and pediatric HIV care and treatment. MCSP will tackle these issues through approaches that also focus on health systems strengthening, household and community mobilization, gender integration, and eHealth, among others. Visit [www.mcsprogram.org](http://www.mcsprogram.org) to learn more.

This study is made possible by the generous support of the American people through the United States Agency for International Development (USAID) under the terms of the Cooperative Agreement AID-OAA-A-14-00028. The contents are the responsibility of the Maternal and Child Survival Program and do not necessarily reflect the views of USAID or the United States Government.

We would like to thank the following institutions and individuals for their participation and support: Nigeria Federal Ministry of Health, Nigeria Federal of Water Resources, Kogi and Ebonyi State Ministries of Health, the Paediatric Association of Nigeria, the Nigerian Society of Neonatal Medicine, as well as other development partners. The staff and management of participating health facilities for generously providing request information. A very special thanks to the Save the Children Nigeria team for coordinating the study, and the special contributions of Dr. Abimbola Williams, Mr. Israel Ayegbusi and Mr. Patrick Ezeani and the Maternal and Child Survival Program (MCSP) teams in Nigeria and the USA for their technical contributions and support to the overall planning specifically, Dr. Adetiloye Oniyire, Dr. Chibugo Okoli, Dr. Emmanuel Ugwa, Dr. Gabriel Aloo, Dr. Gladys Olisaekee, Mr. Ian Moise, Dr. Joseph de Graft-Johnson, Dr. Obianuju Igbokwe, Dr. Olayinka Umar-Farouk and Dr. Soyannwo Tolulope.

May 2017

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# Abbreviations

<b>aOR</b>	Adjusted Odds Ratio
<b>CHX</b>	Chlorhexidine
<b>CI</b>	Confidence Interval
<b>HCAI</b>	Health Care-Associated Infection
<b>HCF</b>	Health Care Facility
<b>HHC</b>	Hand Hygiene Compliance
<b>IPC</b>	Infection Prevention and Control
<b>IQR</b>	Interquartile Range
<b>KII</b>	Key Informant Interview
<b>LMIC</b>	Low- and Middle-Income Countries
<b>MCSP</b>	Maternal and Child Survival Program
<b>MNCH</b>	Maternal, Newborn, and Child Health
<b>NNM</b>	Neonatal Mortality
<b>PHC</b>	Primary Health Center
<b>RR</b>	Relative Risk
<b>USAID</b>	United States Agency for International Development
<b>WASH</b>	Water, Sanitation, and Hygiene
<b>WHO</b>	World Health Organization

# Background

An estimated 3 million babies die during the neonatal period—the first 28 days of life—annually (Liu et al. 2015). Around 75% of neonatal deaths occur in the first week of life, and the majority of these transpire within 48 hours of birth (Lawn et al. 2005). This is also the highest-risk period for maternal deaths (Li et al. 1996). Infections account for approximately 15% of all neonatal deaths globally (Blencowe et al. 2011), and, in populations with very high neonatal mortality, such as Nigeria, it is estimated that up to half of all neonatal deaths may be caused by infections (Leach et al. 1999). Newborns delivered in health care facilities (HCFs) in low-income countries are estimated to be at between three to 20 times greater risk of health care-associated infections (HCAIs) as compared to babies delivered in facilities in high-income countries (Zaidi et al. 2005). Similarly, pregnant women are at risk of acquiring an infection—the global maternal mortality estimates found a 9.7% prevalence of sepsis-related deaths, independent of the place of birth (Kassebaum et al. 2014).

Childbirth and the days immediately after are considered a particularly vulnerable time for mothers and their newborns. It has been estimated that between 30% and 40% of infections resulting in neonatal sepsis deaths are transmitted at the time of childbirth (Ganatra et al. 2010). In low-income settings, approximately 25% of all neonatal deaths that occur during days one to six after birth are caused by sepsis and pneumonia (Baqui et al. 2006). For mothers, bacterial infections around the time of childbirth account for about one-tenth of maternal deaths globally (Say et al. 2014). The unhealed umbilical cord is considered an important route of transmission for neonates during this period (Blencowe et al. 2011). However, far less is understood about other potential transmission routes for mothers and newborns, especially for births that occur in contaminated environments.

Recently, there has been growing concern about hygiene and sanitation conditions during labor, delivery, and postnatal care in HCFs (Campbell et al. 2015; Graham et al. 2016; Velleman et al. 2014). One approach to improving hygienic conditions at the time of birth is birth kits, which were originally aimed at improving standards of cleanliness during home deliveries (WHO 1994). Linked to these kits has been the recommendation of the “six cleans” at the time of birth: a clean surface for delivery (e.g., a plastic sheet), clean hands of the birth attendant, clean cutting of the umbilical cord, clean perineum, clean cord tying, and clean cord care (WHO 1994; WHO 1998). The six cleans are considered fundamental practices for both facility and home births.

Adequate water quantity and quality, facilities for safely managing excreta and health care waste, and the application of hygienic practices, such as hand hygiene and environmental cleaning, are essential for the delivery of most infection prevention and control (IPC) practices, and are important for improving quality of care (WHO 2009a). Despite this, water, sanitation, and hygiene (WASH) coverage in HCFs in low- and middle-income countries (LMIC) is very low. A recent assessment in 54 LMIC found that 38% of HCFs lack an improved water source, 19% lack improved sanitation, and 35% lack soap for handwashing (WHO 2015b). A recent review of Service Provision Assessment data from four East African countries that accounted for water supply in labor rooms suggest that coverage rates are below 30% (Gon et al. 2016), a finding that mirrored similar previous estimates for Tanzania (Benova, Cumming, Gordon et al. 2014) and for India and Bangladesh (Velleman et al. 2014). In various countries, studies have also identified significant gaps in the hygiene practices in institutional (Bazzano, Taub et al. 2016; Ith et al. 2012; Rhee et al. 2008) and community settings (Greenland et al. 2013; Kamm et al. 2016) that are linked to significant risk of neonatal (Mullany et al. 2007) and maternal infection and subsequent mortality.

To investigate the current hygiene practices of health care staff, mothers, and other caregivers from the onset of labor through the first two days of life, the USAID-funded Maternal and Child Survival Program (MCSP) has commissioned the Improved Hygiene for Maternal and Newborn Sepsis Reduction Study. This study, is part of a larger 4-phased activity MCSP is conducting in Eboni and Kogi States, Nigeria. As part of the first phase of this study, the research team has reviewed the literature, interviewed global and national key informants, and undertaken a scoping visit to the two MCSP program states in Nigeria. This report provides details of the methods used, key findings, and synthesis of insights, which will be used to update the study

protocol (Phase II) and inform potential avenues for future interventions to improve hygiene practices at the time of birth which will be designed and implemented in MCSP program supported facilities in Kogi and Ebonyi States in Nigeria as part of Phase III and IV of the activity

# Methods

## Literature Review

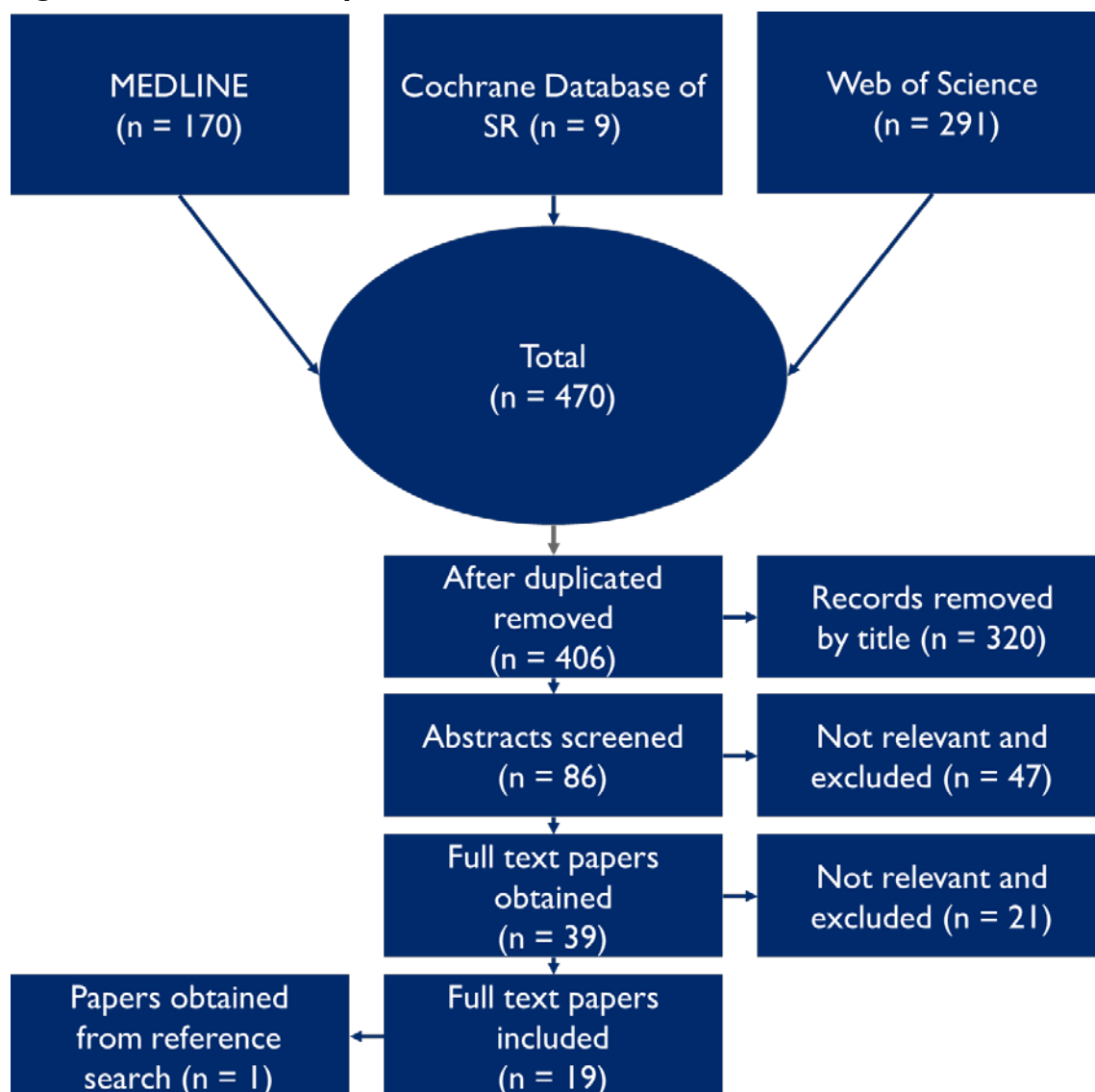
This literature review was implemented in two stages. The first stage focused on the existing systematic reviews and meta-analysis evaluating the effectiveness of interventions aimed at improving hygiene practices by health care staff, mothers, and other caregivers from the onset of labor through the first two days of life. To identify relevant systematic reviews, the authors searched PubMed, Web of Science, and the Cochrane Library for studies published between January 2000 and February 2017.

In the second stage of the review, a broader search strategy was implemented to identify qualitative or quantitative studies that describe psychological, social, and environmental drivers of hygiene behaviors of mothers or health care workers at the time of birth. To identify relevant papers at this stage, the authors searched PubMed and the Web of Science between January 2000 and February 2017. The search strategies developed used keywords and Medical Subject Heading terms that aligned closely with the six cleans. Grey literature was also searched to identify global reference documents and Nigerian national policies relevant to maternal and neonatal hygiene at the time of birth.

Predefined inclusion and exclusion criteria were used to further identify the most relevant publications. Reviews of interventions or studies of behavioral determinants outside the labor, delivery, and postnatal/neonatal periods were excluded. Papers in languages other than English and those presenting studies on disease outbreaks or interventions delivered in specialty areas, such as neonatal intensive care units, were excluded, as they were considered beyond the scope of this project.

A total of 470 papers were retrieved from the Stage 1 search, 64 of which were duplicates. Title screening for relevance removed an additional 320 publications. The abstracts of 86 papers were then reviewed and a further 47 removed. Full-text papers were obtained for 39 papers, and a further 21 were deemed not relevant to the aims of this study. Ultimately, 18 papers were included for analysis, and one additional paper was retrieved from the references. Of the 19 papers, the majority discussed hand hygiene, and five were solely focused on cord care at birth. Stage 2 was significantly wider in scope, retrieving over 4,932 articles, of which 1,225 were duplicates. After reviewing records by title, the study team deemed only 361 papers were deemed relevant to this study (41 papers on chlorhexidine [CHX] and 12 systematic reviews already captured in Stage 1 were removed at this point). Of the final 361, papers presenting research carried out in Nigeria or other West African countries were prioritized. Section 6 of this report presents findings from the literature review under a series of thematic areas.

**Figure I. Assessment of systematic reviews**



## Key Informant Interviews and Scoping Visit

The purpose of the scoping visit was to engage with MCSP partners and gather contextual information pertinent to the development of the observational study (Phase II). It included site visits to seven HCFs in the states of Ebonyi and Kogi, and time with the MCSP team in Abuja. Interviews with national and global key informants gathered contextual information and ascertained important information about global priorities, ongoing studies looking at hygiene practices at the time of birth, and critical evidence gaps. In partnership with the MCSP team, 41 people were identified for interviews. Key informant interviews (KIIs) included staff from primary, secondary, and tertiary HCFs in Kogi and Ebonyi; academic institutes; UN agencies and nongovernmental organizations; the government of Nigeria; and a pharmaceutical company. Three requested interviews have not yet been scheduled, but attempts will be made to interview these key informants before Phase II begins. Pertinent notes were taken for all KIIs and consolidated into prominent thematic areas, described in Section 5 below.



# Literature Review

## Newborn and Maternal Health Outcomes

While there is consensus on the importance of good hygiene at birth for the prevention of maternal and neonatal mortality, estimating the size of effect has been more challenging (Benova, Cumming, and Campbell 2014; Blencowe et al. 2011). A meta-analysis of the best available studies suggests women in households with poor sanitation have 3.1 times the odds of dying during the maternal period compared to women with better sanitation, and women with poor water supply have roughly 1.8 times the odds of maternal mortality compared to those with adequate water (Benova, Cumming, and Campbell 2014), after adjustment for various potential confounders. However, most studies in this field are of low methodological quality, and there are very few intervention studies. The absence of good evidence combined with high biological plausibility resulted in Blencowe et al. (2011) using a Delphi expert opinion process to estimate the importance of clean birth practices in the reduction of neonatal sepsis deaths. Through this process, 30 experts reached consensus regarding the risk reduction of neonatal sepsis deaths by clean birth practices at home (15% [IQR (interquartile range) 10–20]) or in a facility (27% [IQR 24–36]), and by clean postnatal care practices (40% [IQR 25–50]). The panel also estimated that neonatal tetanus mortality was reduced by clean birth practices at home (30% [IQR 20–30]) or in a facility (38% [IQR 34–40]), and by clean postnatal care practices (40% [IQR 30–50]) (Blencowe et al. 2011). Estimates on the impact of hygienic behaviors at the time of birth on key outcomes are detailed in Figure 1.

**Figure 2. Impact of various exposures on key outcome measures. 1 (Blencowe et al. 2011), 2 (Imdad, Mullany et al. 2013), 3 (Shariff et al. 2016), 4 (Benova, Cumming, and Campbell 2014), \*low-quality evidence, ^Delphi estimate**

Outcome	Exposure	Impact
Neonatal Mortality	Handwashing (mother)	44% reduction (95% CI: 18–62%) <sup>1,*</sup>
	Chlorhexidine cord care	23% reduction (95 % CI: 0.63, 0.94) (home-based births) <sup>2</sup> 20% reduction (95% CI: 0.6–1.0) (all births) <sup>3</sup>
	Handwashing (birth attendant)	19% reduction (95% CI: 1–34%) <sup>1,*</sup>
Maternal Mortality	Poor sanitation	3.07 higher odds (95% CI 1.72–5.49) <sup>4</sup>
	Poor water	1.50 higher odds (95% CI 1.10–2.10) <sup>4,*</sup>
Neonatal Sepsis Mortality	Clean birth practices	15% reduction (IQR 10–20) (home-based births) <sup>1,^</sup> 27% reduction (IQR 24–36) (facility-based births) <sup>1,^</sup> 40% reduction (IQR 25–50) (postnatal care) <sup>1,^</sup>
Neonatal Tetanus Mortality	Clean birth practices	30% reduction (IQR 20–30) (home-based births) <sup>1,^</sup> 38% reduction (IQR 34–40) (facility-based births) <sup>1,^</sup> 40% reduction (IQR 30–50) (postnatal care) <sup>1,^</sup>
	Clean birth surface	93% reduction (95% CI: 77–100%) <sup>1,*</sup>
Omphalitis	Handwashing (mother)	24% reduction (95% CI: 5–40%) <sup>1,*</sup>
	Chlorhexidine cord care	54% reduction (95 % CI: 0.32–0.66) (home-based births) <sup>2</sup>

### Clean Cord Care

In 2015, hygienic cord care was named as one of six interventions that are clearly effective for reducing neonatal, infant, and child mortality (Lassi and Bhutta 2015). In 2016, a systematic review and meta-analysis concluded that trials on the topical application of CHX on the newborn umbilical cord stump significantly reduced the incidence of all-cause neonatal mortality (NNM) (pooled relative risk [RR] 0.8; 95% confidence interval [CI]: 0.6–1.0; P=0.04) and omphalitis (infection of the umbilical cord stump) (pooled RR 0.4; 95%

CI: 0.3–0.7;  $P < 0.001$ ) (Shariff et al. 2016). Estimates in the reduction of all-cause NNM as a result of the use of CHX range from 23% to 28% for low-birthweight infants and 34% when applied in the first 24 hours (Blencowe et al. 2011; Lassi et al. 2015; Salam et al. 2014). The reduction in the incidence of omphalitis range from 27% to 54% (Imdad, Bautista et al. 2013).

Earlier reviews, primarily from high-income countries, found evidence for the use of CHX for cord care in community settings but not for hospital settings (Imdad, Bautista et al. 2013; Sinha et al. 2015; Zupan et al. 2004). However, Shariff et al. (2016) found that when trials are stratified by the obstetric settings (hospital or community), the incidence of NNM did not significantly differ between CHX intervention and control groups, likely due to the fact that the vast majority of facility-born babies in LMIC are discharged into the same environment as those born at home.

The frequency of CHX application was not found to be studied extensively, but a pooled analysis of three studies found no difference in mortality reduction between single versus multiple applications. However, multiple applications were found to be beneficial for the reduction of omphalitis (Imdad, Bautista et al. 2013). It was also suggested that the most prominent protective effects of CHX use occurs in the first week of life, but CHX use remains significant throughout the neonatal period (Imdad, Mullany et al. 2013).

This growing body of evidence prompted the World Health Organization (WHO) to add 7.1% CHX digluconate to the 2013 List of Essential Medicines for Children, specifically for umbilical cord care. In January 2014, it also issued new recommendations, described in Figure 2, for umbilical cord care as part of its updated recommendations in Postnatal Care of the Mother and Newborn (WHO 2013). In Nigeria, the use of CHX for umbilical cord cleaning was introduced in 2015, and in 2016, the Federal Ministry of Health developed the National Strategy for Scale-Up of Chlorhexidine in Nigeria, detailing the supply and demand approaches needed for scale.

While best practice guidelines have been established, less is known about the drivers and barriers to this important practice. Supply is one potentially important factor. In a recent study of birth kits, no kits included CHX despite WHO recommendations (Hundley et al. 2012). A structured questionnaire given to 497 women from a university teaching hospital in Nigeria found factors most associated with beneficial cord care practices to be maternal level of education and the infant's sex—male babies were more likely to receive the recommended care compared to their female counterparts (odds ratio: 1.724,  $P=0.013$ ) (Abhulimhen-Iyoha and Ibadin 2012). The study also found choices of cord care practices were influenced mainly by nurses, followed by the participants' mothers (Abhulimhen-Iyoha and Ibadin 2012). The influence of nurses was most dominant among those who practiced hygienic cord care. A household study carried out in Bangladesh found that the willingness or ability to pay for CHX was another important factor (Coffey et al. 2013). This suggests that even if supply is sufficient and adequate demand exists, price may still inhibit use, especially among poor households.

### **Figure 3. World Health Organization (WHO) recommendations for umbilical cord care**

“Daily Chlorhexidine (7.1% chlorhexidine digluconate aqueous solution or gel, delivering 4% chlorhexidine) application to the umbilical cord stump during the first week of life is recommended for newborns who are born at home in settings with high neonatal mortality (30 or more neonatal deaths per 1,00 live births). Clean, dry cord care is recommended for newborns born in health facilities and at home in low neonatal mortality settings.” (WHO 2014)

## **Hand Hygiene**

The link between handwashing and infection during childbirth was established over 200 years ago. The purpose of handwashing in labor, delivery, and postnatal periods is to prevent the spread of pathogens through physical contact. A recent estimate suggests that handwashing of birth attendants reduces all-cause NNM (19% [95% CI 1–34%]), cord infection (30% [95% CI 20–39%]), and neonatal tetanus (49% [95% CI 35–62%]) (Blencowe et al. 2011). Similarly, a study of maternal handwashing during the postnatal period

found a reduction in all-cause NNM (44% [95% CI 18–62%]) and cord infection (24% [95% CI 5–40%]) (Blencowe et al. 2011).

Two identified systematic reviews focused on the effectiveness of interventions (or packages of interventions) in improving hand hygiene compliance (HHC) (Cherry et al. 2012; Shlomai et al. 2015). All interventions reviewed were packages of or multimodal interventions, rather than a single intervention. They included a mix of educational campaigns with and without demonstrations, performance feedback, videos, provision of products (alcohol-based gels), and self-study modules. Both reviews found consistent benefits across a variety of different strategies to improving HHC, patient outcomes, or both (Cherry et al. 2012; Shlomai et al. 2015). In the hospital setting, rates of compliance post-intervention were between 60% and 70%. There was a large range of compliance rates pre-intervention—the lowest was reported at 4.5% (Cherry et al. 2012). Although improvements were seen, a ceiling effect was found, after which improvement in HHC become very difficult (Cherry et al. 2012). Generally, post-intervention infection rates dropped and HHC rates improved. These benefits were seen across different strategies, contexts (low- and high-income settings), and time periods (1991 to 2013).

Although the effect of single interventions could not be isolated, a number of important factors for enhancing HHC were reported. First, multimodal interventions were found to be better than single interventions in terms of prompting and sustaining behavior change, and continuous interventions had more of an impact than one-off interventions in sustaining impact (Cherry et al. 2012). Without these measures, studies found a “washout” effect, where HHC declined to baseline levels post-intervention (Cherry et al. 2012). The delivery of performance feedback, alongside other measures, also improved HHC noticeably (OR 2.81; 95% CI 1.32–5.96) (Shlomai et al. 2015). Methods included individual feedback from supervisors to health care workers, group feedback in the form of discussions, and ultraviolet light technology. Qualitative studies from a number of countries, including Nigeria, provide more insights on the potential drivers of this critical behavior. A cross-sectional, hospital-based interventional study from Nigeria found that, despite an overall increase in compliance, the highest compliance rates were “after-body fluid exposure” (75.3%) and “after touching a patient” (73.6%), and the lowest compliance rate was recorded “before touching a patient” (58%) (Uneke, Ndukwe, Oyibo et al. 2014). A study in Ghana revealed compliance was higher when risk was perceived to be higher (e.g., in the emergency and wound-dressing/treatment rooms and labor wards) (Yawson and Hesse 2013).

For caretakers, HHC during the neonatal period has also been shown to be extremely low. One study from Nepal revealed that only 13.3% of the caretakers always washed their hands before caring for their infant (Karas et al. 2012). In a study from rural Egypt, nearly half (43%) of mothers reported that they did not wash their hands before neonatal care, and only 7% washed hands after diaper changes (Darmstadt et al. 2007). All papers retrieved looked at compliance (moments for handwashing) rather than competence (method of handwashing), which is likely to be another important measure.

Neither systematic review on the topic reported formally on the placement or availability of handwashing products, such as soap or alcohol-based gels, although a number of included studies reported the provision of alcohol-based gels as a component of their multimodal interventions. A systematic review included in the review by Shlomai et al. (2015) found the introduction of alcohol-based hand rub or gel to be one of the most important factors influencing HHC. This suggests that the availability and location of hand hygiene products can have a positive influence on compliance. On the other hand, factors associated with noncompliance include inadequate supply of water, soap, and towels; lack of awareness; inadequate human resources; absence of guidelines on hand hygiene and disinfection practices; unreported consequences of noncompliance (Bazzano, Oberhelman et al. 2015; Friday et al. 2012; Uneke, Ndukwe, Nwakpu et al. 2014; Yawson and Hesse 2013). In a number of studies, knowledge was reported to be high but inconsistent with current practice (Aluko et al. 2016; Friday et al. 2012).

To promote hand hygiene practices among health care workers at a global level, WHO initiated the Clean Care Is Safer Care program in 2005. Per its guidelines, when working with patients, staff should perform hand hygiene at five key moments, preferably by using an alcohol-based rub or by handwashing with soap

and water if the hands are visibly dirty (WHO 2009b). The five moments for hand hygiene are before touching a patient, before clean and aseptic procedures (e.g., catheter insertion), after contact with body fluids, after touching a patient, and after touching patient surroundings.

## Clean Delivery Surface

Contaminated surfaces at the time of delivery are one accepted mechanism through which maternal or newborn infection can occur (Benova, Cumming, and Campbell 2014). However, despite the likely importance of a clean surface at the time of delivery, the review retrieved limited information on the topic. Blencowe et al. (2011) found low-quality evidence to suggest a clean birth surface supports a reduction in neonatal tetanus mortality (93% [95% CI 77%–100%]) but concluded that data currently available are inadequate to evaluate the effect of clean birth surface on mortality from neonatal sepsis. A needs assessment by Cross et al. (2016) in seven maternity units in India and Bangladesh found that *Staphylococcus aureus*, a pathogen commonly linked to health facility-associated, antimicrobial-resistant infections, was present on delivery room door handles and maternity ward beds at the approximate location of patients' hands and feet.

Birth kits regularly include plastic mats for women to lie on during delivery. However, Hundley et al. (2012) found that of two studies that included clean delivery surfaces as an outcome measure, one had a statistically significant relationship between use of a birth kit and use of a clean delivery surface, but the other study did not. Interestingly, in the second study, the inclusion of a commodity did not guarantee its use. Reasons for it not being used were poorly understood, but the authors suggest it might include lack of understanding of the rationale for that item and cultural beliefs.

## Clean Perineum

WHO recommends that the perineum be washed with soap and water prior to delivery (WHO 1994). Despite this recommendation, the review retrieved limited evidence on its effectiveness in improving neonatal and maternal outcomes. Blencowe et al. (2011) found two case control studies, which reported no association, after adjustment, between cleaning the perineum with soap and water, and reduction in the incidence of neonatal tetanus; they concluded that data currently available are low quality and inadequate to evaluate the size of the effect of perineum cleaning on neonatal tetanus, sepsis, or infection. Two further systematic reviews were retrieved on vaginal cleansing with CHX during labor: one looking specifically at the prevention of early-onset group B  $\beta$ -hemolytic *Streptococcus* (Ohlsson et al. 2014), and the second looking more generally at neonatal and maternal infections (Lumbiganon et al. 2004). Both reviews found no evidence to support the use of vaginal CHX during labor (Lumbiganon et al. 2004; Ohlsson et al. 2014), and, as a result, it is not currently recommended by WHO for the prevention and treatment of maternal peripartum infections (WHO 2015c). In terms of practice, birth kits were found to be significantly associated with the mother's perineum having been washed during facility-based births where specific items to facilitate this were included (Hundley et al. 2012).

## Clean Cord Cutting and Tying

No systematic reviews were retrieved on clean cord cutting or clean cord tying, but a number of authors included these practices as part of their wider reviews (Blencowe et al. 2011; Hundley et al. 2012; Soubeiga et al. 2014). Similar to perineum cleaning, Blencowe et al. (2011) concluded that existing studies were of low quality and inadequate to evaluate the size of the effect of a clean cord-cutting implement and clean cord tying on mortality from neonatal sepsis. However, their review found two case control studies and one cohort study that reported strong evidence of lower neonatal tetanus mortality associated with use of clean cord-cutting tools adjusted odds ratio (aOR)=0.3 (95% CI 0.13–0.62), aOR=0.4 (95% CI 0.24–0.66), and aOR=0.25 (95% CI 0.08–0.75) (Blencowe et al. 2011). Only one study, using hospital-based cases, reported an aOR of 0.1 (95% CI 0.01–1.1) for clean cord-tie use and neonatal tetanus incidence or mortality (Blencowe et al. 2011).

In terms of promoting clean cord cutting and tying, the Birth Preparedness and Complication Readiness interventions\* were associated with an increased likelihood of clean cutting of the umbilical cord (relative risk [RR]=1.33, 95% CI: 1.14–1.55) for home deliveries (Soubeiga et al. 2014). Similarly, there was some evidence to suggest that birth kit use can help increase clean delivery practices in home and health facilities, but the use of cord-cutting and cord-tying items was not reported on despite products to facilitate these practices being included in every kit (Hundley et al. 2012). Community education and birth attendant training were also associated with cutting the cord with a clean blade and tying the cord with a clean tie (Blencowe et al. 2011).

## Infrastructure, Supplies, Guidelines, and Training

A wide range of studies have reported insufficient infrastructure as a critical determinant of hygiene practices at the time of birth, both in HCFs and at home (Bazzano, Oberhelman et al. 2015; Friday et al. 2012; Hancart-Petit et al. 2011; Uneke, Ndukwe, Oyibo et al. 2014; Yawson and Hesse 2013). A recent assessment in 54 LMIC found that 38% of HCFs lacked an improved water source and 19% lacked improved sanitation (WHO 2015b). Assessments carried out in two MCSP states in Nigeria suggest that facility infrastructure, including supply of water and sanitation, is poor (Health Finance and Governance Project 2016a, 2016b). In Ebonyi, only 47% of the facilities assessed had a source of water supply and only 30% of delivery rooms had functioning handwashing stations (Health Finance and Governance Project 2016a). Coverage figures decline even further for primary HCFs. In Kogi, water supply was considerably worse. Most of the primary health center (PHC) facilities did not have water available for patient and staff use, nor did they have water available in the delivery room (Health Finance and Governance Project 2016b). To address these challenges, the government of Nigeria, with development partners, recently published the Technical Guide for Water, Sanitation and Hygiene (WASH) in Primary HCFs in Nigeria (UNICEF 2016). The guide aims, for the first time, to set standards for the design, construction, operation, and maintenance of WASH facilities in HCFs.

Reports also suggest essential products are in short supply, including disinfectants for cleaning, soap and alcohol-based gel for handwashing, gloves, and facilities for washing linen. In Cambodia, insufficient supplies resulted in health care workers implementing “ego-protective” practices (e.g., wearing the same pair of gloves throughout the day to protect themselves from the potentially dangerous environment) (Hancart-Petit et al. 2011). Lack of supplies may also be impeding routine cleaning practices (Cross et al. 2016; Hancart-Petit et al. 2011). Cross et al. (2016) found *Staphylococcus aureus* on delivery room door handles and maternity ward beds at the approximate location of patients’ hands and feet. *Klebsiella* and *Pseudomonas* were found, as well as nonpathogenic organisms, such as *Bacillus subtilis*, all suggestive of poor cleaning practices (Cross et al. 2016). In a prospective study in a university teaching hospital in Nigeria, *Staphylococcus aureus* was also found, accounting for 45.5% of neonatal sepsis cases (Ojukwu et al. 2006). It is unsurprising that Hancart-Petit et al. (2011) found cleaning to be done sparingly and in random locations throughout a facility, never observing systematic and complete cleaning as per guidelines.

Similarly, training on IPC was reported to be considerably lacking (Bazzano, Oberhelman et al. 2015; Cross et al. 2016; Friday et al. 2012). One study from Nigeria found only 33% of facilities sampled to have an ongoing training program on IPC (Friday et al. 2012). In Asia, studies have found levels of staff training on IPC practices to be very unequal among different caregivers. When training occurs, it is mainly given verbally during the first days on the job (Cross et al. 2016; Hancart-Petit et al. 2011). Most cleaners, who are at the bottom of hospital hierarchy, do not receive proper IPC training, despite being responsible for cleaning, sterilization, and waste management (Cross et al. 2016; Hancart-Petit et al. 2011). IPC guidelines and monitoring were also reported to be lacking or inconsistent with best practices (Cross et al. 2016; Friday et al. 2012; Uneke, Ndukwe, Nwakpu, et al. 2014).

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\* Includes counseling for women and their families to 1) encourage them to make decisions before the onset of labor, 2) inform them about the signs of complications, 3) inform them about the locations of emergency services to make the care-seeking process more efficient, and 4) encourage them to save the money needed to pay for services and to plan their transportation to a health facility during labor and in case of emergency.

# Key Informant Interviews and Scoping Visit

## Hygiene Practices at the Time of Birth

Standard delivery kits, purchased by patients, seem to be frequently used in facility-based births in the two study states. Most equipment required for a clean delivery is contained in these kits, including CHX when it is available. It was also reported that the perineum is often cleaned with an antiseptic cream containing cetrimide and CHX gluconate, but some key informants were unclear on the evidence to support this practice. Women's abdomens are also reported to be cleaned routinely, as this is where the baby is placed immediately after delivery. CHX was widely used in Kogi facilities. In Ebonyi, however, few facilities used CHX gel. The tertiary-level facility in Ebonyi reported that only 11 out of 133 neonates received CHX gel in January 2017. Facility staff in Ebonyi said that they recommend CHX gel to patients and wanted it to be included in delivery kits. However, the gel was not commonly available in health facility pharmacies, precluding its use. Key informants from health facilities generally attributed procurement barriers to cost, while some were not aware of the supply chain processes and simply reported that CHX was unavailable. A key informant from Drugfield Pharmaceuticals asserted that it has sufficient supply to meet all demand within Nigeria, and it is focusing its efforts on community, facility, and government demand creation. In one facility, nursing staff in the neonatal unit reported that they continue to apply methylated spirits to the cord every two hours in addition to CHX (applied once every four hours) because they are not satisfied with the "wet" appearance of the cord with just CHX gel, suggesting there may be some issues around its acceptability in some contexts. In relation to cord cutting and cord tying, it was noted that different types of blades are regularly used, although there is a preference for single-use blades. Some blades are reported to be quite small and exposed to the health care workers' hands during use. Cord ties or clamps are often not available, resulting in patients improvising with string sterilized in alcohol.

In relation to handwashing, researchers working on another hygiene-at-birth study in Tanzania highlighted that delivery is chaotic and the WHO five moments of hand hygiene might not be easily adhered to during this event. They remarked that, at the time of delivery, there is often one continuous moment of contact with the mother and the baby, with no opportunity for handwashing. They also noted that early studies have indicated that visibly clean surfaces are not necessarily microbiologically clean (as detailed in the findings from the literature review).

## IPC Protocols and Training

Few facilities had written guidelines or standard operating procedures on labor and neonatal IPC protocols. Nearly all facility-level informants referenced and applauded MCSP training on essential newborn care and IPC standards. Health facility staff appreciated MCSP trainings and noted that trainings included IPC information. Several informants spoke about the importance of understanding the connection between hygiene behaviors and their impact on IPC. This impact appeared to be a strong motivator to adhere to standard hygiene processes. Other than the MCSP training, nurses and doctors noted that there are few if any trainings to stay up to date on new clinical standards, expressing a desire for more frequent training. Of three health facility cleaners interviewed, only one had received formal training on hygiene processes and IPC. Cleaners' responsibilities include sterilizing equipment, cleaning delivery and neonatal beds and incubators, and more general cleaning of the labor and neonatal wards. Often considered the lowest-ranking health workers in the labor ward, and the facility as a whole, cleaners may not have supportive supervision, may not feel motivated to adhere to hygiene protocols, and may lack knowledge of the potential for infection transmission. Global key informants noted that IPC guidelines often already exist, and it will be important to make sure WASH elements are accurately reflected and that there is consistency across policies, guidelines, and procedures.

## Infrastructure and Supplies

It was frequently reported that lack of facility infrastructure and supplies often prevented staff from following standard protocols, particularly at the PHC level, where access to source water onsite is uncommon. Many

facilities, particularly PHCs, reported inconsistent availability of hygiene consumables, such as gloves, masks, hair caps, boots, liquid soap, and alcohol-based hand sanitizer. Phase II should attempt to capture some of the variability in infrastructure and supplies between and within HCFs. It should include obtaining a clear understanding on the availability of critical infrastructure, such as water supply and basins for handwashing, especially in different areas of the facility (e.g., labor wards, delivery rooms, and postnatal care areas).

## Human Resources

Nearly all key informants discussed the shortage in staff. National-level officials reported that some PHCs are staffed by just one community health extension worker. Inadequate human resources is frequently the reason that facilities cannot remain open 24 hours a day. Health workers in facilities that are open 24 hours a day emphasized the potential differences in quality of care during the daytime versus nighttime, when staff are spread very thin. Many PHCs are only open eight hours per day, which means that women who go into labor outside these hours would need to deliver at home or travel to an alternative facility. Although it was reported that cleaners do not interact with patients on a clinical basis, they were often requested to assist health workers in bringing them equipment or transporting a baby from the neonatal unit to its mother, possibly doing work that is outside of their responsibilities due to staff shortages.

## Hygiene Information/Education

The degree to which patients are provided with educational information on discharge varied among, and at times within, facilities. While all facilities reported providing some type of hygiene education information on discharge, none had official protocols in place. One tertiary facility had begun developing a maternal/neonatal patient discharge protocol but stopped due to limited funding. Some facilities reported that the degree of educational discharge information was dependent on the health worker who happened to be completing the discharge—if a more senior health worker discharged the patient, it was more likely that he or she would provide educational information. More comprehensive discharge might include information on handwashing, cleaning the nipple prior to breastfeeding, CHX use and cord care, and general personal and environmental hygiene. Only one facility provided a pamphlet for the mother to take home. Although clients may not be able to read, picture-based materials would most likely serve as helpful aids to promoting hygiene and IPC as the mother transitions her neonate home. During the study, it will be important to understand what hygiene information is provided to patients throughout their stay, not just at discharge.

## Research Priorities and Potential Interventions

Key informants at the global level provided some insights into research priorities and potential areas where this study could contribute. A number of key informants reported the importance of enhancing understanding of exposures and transmission routes of newborn infections, and what WASH interventions, beyond cord care, are needed to prevent the transmission of infections. Understanding motivations, barriers, and drivers of handwashing and other hygiene practices, especially in poor-resource settings, is critical, as is understanding the hygiene practices of caretakers and newborn exposures at home in the immediate days after birth. Delivery was also highlighted as a chaotic time for health care workers but also a critical time for mothers and their newborns, in terms of infection transmission. Greater understanding of how health care workers can maintain hygiene and clean hands in this window was proposed as a priority. Other potentially important areas for new research include bed spacing, layout, and crowding—it is believed that nothing is known about this at present. In terms of potential interventions, one key informant flagged the Safe Birth Checklist as a relatively successful intervention to improve quality of care that might be worth looking into.

## Other Important Considerations for the Study Protocol and Future Interventions

Key informants flagged a number of other issues to be considered during Phase II and Phase III of this study. For the observational study, it was recommended that the team purposefully select facilities with at least 70 deliveries per month to ensure a sufficient number of observations can be carried out. Accordingly, it was suggested that the best approach might be to focus on the district (secondary)-level facilities to capture the breadth of care, which would also be pragmatic for the intervention, as there would be capacity to change

behavior. If possible, it will be important for the observational study to continue through the night to observe the natural progression of labor, delivery, and postpartum care, and any potential variations in the standard of care. To achieve this, three enumerators or teams of enumerators could work over three shifts covering a full 24-hour period. Where possible, these shifts should align with those of the health care facility. When developing the observational tools, it was considered important to identify early who or what would be observed (e.g., the practices of the midwife or moments for improved hygiene). Similarly, as women navigate through the facility in the course of admission, labor, delivery, and postpartum care, they may be transferred to various rooms and interact with many health workers. It will be important for observers to take note of this, paying particular attention to health worker-client interactions and any hygiene information regarding hygiene within the facility or home care shared in these interactions. Key informants put a strong emphasis on pilot-testing tools thoroughly and revising tools as needed based on field experience.

## Synthesis

### Contextual Factors

In 2015, Nigeria's maternal mortality ratio (number of maternal deaths during a given time period per 100,000 live births during the same time period) was 560 per 100,000 live births (WHO 2015a). Mortality during the critical neonatal period is also persistently high, estimated at 34 deaths per 1,000 live births (UNICEF 2015). Hygiene standards in HCFs are also concerning. These contextual factors provide significant room for improvement and motivation, but they may also be very demotivating. During Phase III, consideration should be given to how these factors can be used advantageously (e.g., quick feedback loops to show rates of HHC and hopefully decreasing infection rates).

Training on IPC seems to be limited for most staff, especially cleaners, who are ultimately responsible for routine cleaning of the facilities and equipment. The desire for training was noted by facility staff during the KIIs.

While not a focus of this review, two studies from Nigeria found poor sanitary conditions of HCFs to be a major cause of dissatisfaction for patients, potentially influencing care-seeking behavior during the pre- and postnatal periods (Adekanye et al. 2013; Oyo-Ita et al. 2007).

### Social Factors

A number of important social factors will need to be considered for Phase II and Phase III of this study. First and foremost, HHC is likely to be very low for both health care workers and new mothers. Multimodal interventions, including feedback activities, should be considered to enhance handwashing during labor, delivery, and postnatal care. However, to design an effective intervention, more needs to be understood about the motivators for handwashing, especially handwashing before touching a mother/newborn, which is often the least-adhered-to moment for both health care workers and new mothers. Health care workers' perceived risk to themselves but not their patients should be examined.

For health care workers, including cleaners, it seems imperative that they have a clear understanding of the rationale for practicing the various hygienic behaviors. For routine cleaning, this might require the use of microbiological swabbing to highlight that visibly clean surfaces are not always safe, helping to reinforce the importance of regular, systematic cleaning.

Nurses and other health care workers play a potentially important role in influencing the hygiene practices of new mothers, identifying opportunities or moments for health care workers to provide new mothers with accurate and digestible hygiene information (e.g., about cord care or handwashing) should be considered.

### Technological Factors: Infrastructure and Supplies

Insufficient infrastructure and supplies are likely to be some of the major barriers to health care workers and new mothers practicing hygienic behaviors. The literature review, KIIs, and scoping visit all suggest that



HCFs, especially lower-level facilities, do not have an adequate and consistent supply of products needed for staff to effectively carry out their job. Understanding and addressing the bottlenecks related to this issue is likely a necessary starting point.

In most instances, the provision of goods, coupled with education, correlates with increased use, but this is not always the case. Understanding the purpose of certain products (e.g., CHX) that are acceptable in various contexts will be important. New products or technologies may also be worth exploring (e.g., the provision of alcohol-based gels in areas where there is frequent contact between the health care worker and mother/newborn). Any new products or technologies that are identified could be delivered as part of existing and established quality of care initiatives, such as delivery kits or the Safe Birth Checklist. For products targeted at households, consideration will need to be given to cost to ensure they are not beyond the reach of the poorest.

## Conclusions

There is consensus about the importance of good hygiene practices at the time of birth and the hours and days immediately after. Handwashing and IPC procedures are considered standard practice in HCFs across the world. Despite this, the impact of improved hygiene on neonatal and maternal health in LMIC has been difficult to quantify. Nevertheless, there is clear evidence that improvements in hygiene practices at the time of birth need to be made. Findings from the literature review, KIIs, and scoping visits suggest priority should be given to the following areas: ensuring clean cord care, especially the provision and use of CHX on the cord stump; improving HHC among health care workers and mothers; ensuring staff have sufficient infrastructure, such as running water, and continued access to essential supplies, such as soap; and exposing staff to regular IPC training. Several larger challenges were also identified, especially for primary HCFs, which are beyond the scope of this study and MCSP, such as inadequate staffing and onsite water supply.

## Limitations

Due to security restrictions, travel outside the capital city of Kogi was not permitted during the scoping visit. This precluded the team from seeing and speaking with individuals from a more diverse set of facilities in this state. Similarly, most health facilities visited and KIIs were in urban areas, so rural-urban differences could not be reflected in the findings.

The literature review was deliberately wide in scope to capture evidence on the effectiveness of multiple hygiene behaviors as well as insights into motivators and barriers to practicing these potentially important behaviors. The breadth of the review restricted the depth of information gathered on certain topics. Specifically, limited information was gathered on the hygiene practices of mothers and other caretakers, as a large majority of papers that were retrieved studied health care worker practices.

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