

Prevalence of Female Genital Cutting Declines In Senegalese Villages Following Educational Program

Knowledge of female genital cutting and its adverse consequences increased, and adherence to the practice declined, after implementation of an educational program aimed at empowering women and promoting health in southern Senegal.¹ In intervention villages, the proportion of women who approved of female genital cutting declined from 72% at baseline to 16% among program participants, whereas a much smaller decline occurred in comparison areas (from 89% to 60%). Moreover, the proportion of daughters aged 5–10 who had not been cut increased from 21% to 49% among program participants, but did not change in comparison areas.

The program, developed by the Senegalese nongovernmental organization Tostan, consisted of three two-hour classes per week for six months; it discussed the negative aspects of female genital cutting as part of a broader curriculum that covered human rights, women's health and basic hygiene. In each village, roughly 30 women and up to 10 men took part; to facilitate dissemination of the material, participants were encouraged to regularly share the information they learned with a close friend or relative.

The researchers evaluated the intervention using a quasi-experimental, longitudinal approach, conducting surveys at baseline (December 2000), in the postintervention period (January 2002) and at endline (January 2003). Twenty villages were randomly selected to represent the 90 villages participating in the program and were surveyed at all three timepoints. Twenty villages that did not participate in the intervention and that were distant enough from the participating villages to have not been "contaminated" by the intervention were selected to serve as a comparison group; these villages, which were similar to the intervention villages in population size and ethnic makeup, were surveyed at baseline and endline.

At baseline, the researchers surveyed 576 women and 373 men from the intervention area. Because of attrition, and because some of the individuals surveyed at baseline did not

actually attend any classes, the researchers were able to interview only 333–350 female program participants and 82–85 male participants (approximately 17 women and 4 men per village) at the two follow-up surveys, as well as roughly 200 nonparticipating women and 200 nonparticipating men from the same villages. Finally, they surveyed approximately 200 women and 200 men from the comparison villages at baseline and endline.

Most study participants in both the intervention and comparison groups were Muslim, married and from the Pulaar ethnic group. Some 97–100% of women reported having experienced genital cutting. At baseline, women in the intervention group were less likely than those in the comparison group to report that their daughters aged five and older had been cut. (In Senegal, genital cutting is typically performed around age 4.)

The proportion of women reporting that they had received information from any source about female genital cutting rose among all groups between baseline and endline, though the increase was greater among residents of intervention villages than among those of the comparison area; 87% of program participants and one-quarter of nonparticipants in the same villages identified Tostan as their main source for this information. No increases were apparent in the proportion of men who had received information about female genital cutting. However, the proportion of program participants who knew at least two consequences of genital cutting increased among program participants of both genders (from 7% to 83% among women and from 11% to 80% among men). Roughly half of nonparticipants in the intervention villages were able to cite at least two consequences, perhaps because of information sharing: At endline, 92% of female program participants had shared information about cutting with nonparticipants, and more than 90% had participated in a public discussion of the issue after the program's end.

The proportion of respondents who supported female genital cutting declined among

all groups, but the decreases were greater among residents of intervention villages, and especially among program participants, than among residents of comparison villages. Among women, approval of the practice dropped from 72% in intervention villages at baseline to 16% among program participants and 28% among nonparticipants; among women in the comparison area, the proportion declined from 89% to 60%. The vast majority (85%) of female program participants who disapproved of female genital cutting at endline attributed their attitude to their participation in the Tostan program. In intervention villages, 70% of women initially believed female genital cutting to be a social necessity; by endline, this proportion had declined to 15% among program participants and to 29% among nonparticipants. In the comparison group, the decrease was again much smaller: Eighty-eight percent of women espoused this belief at baseline and 61% did so at endline. Similarly, the proportion of women who reported that they intended to have their daughters cut declined from 71% in intervention villages to 12% among participants and 23% among nonparticipants, and from 89% to 54% among women in the comparison group. Among men, intentions to have their daughters cut in the future declined more among program participants than among their peers in comparison villages; at endline, men's preference for women who had been cut was lower and their willingness to help end the practice was greater among program participants than among men in comparison villages.

Finally, the prevalence of female genital cutting declined significantly in intervention villages. For example, the proportion of girls aged 0–4 who had not been cut increased from 68% at baseline in the intervention area to 78% among program participants and 83% among nonparticipants in the same villages. The proportion aged 5–10 who had not been cut increased from 21% to 49% and 44%, respectively. No such changes occurred in comparison villages.

The researchers conclude that the Tostan program changed attitudes about female genital cutting and helped reduce the practice in participating villages. Further, the findings suggest that the effectiveness of the program was magnified through successful dissemination of information through social networks in intervention villages. In fact, according to the researchers, the attitudinal and behavioral changes achieved as a result of the program contributed to a mass public declaration against female genital cutting in 2002. They posit that “education, when appropriately organized and presented within a wider process of social mobilization, can be a powerful and effective means for facilitating rapid change in long-standing harmful traditional behaviors.”—*H. Ball*

REFERENCE

I. Diop NJ and Askew I, The effectiveness of a community-based education program on abandoning female genital mutilation/cutting in Senegal, *Studies in Family Planning*, 2009, 40(4):307–318.

Ugandan Trial Suggests Home-Based HIV Care Is Effective and Reduces Costs

For Ugandans whose access to HIV care is compromised by poverty or lack of transportation, receiving HIV treatment at home may be a viable alternative to visiting a facility for services.¹ In a four-year trial conducted in southeastern Uganda, the mortality rate among patients who received home-based care was the same as that among patients who received standard clinic care (14%), and about two-thirds of patients in each group had undetectable plasma viral loads at the end of the trial. Moreover, home-based care resulted in lower costs for patients (mostly due to reduced transportation and child-care costs) and for the health service.

Because the number of qualified medical staff in Uganda and some other parts of Africa is insufficient to serve the HIV-positive population, especially in poor areas, and because previously studied off-site care programs relied on nurses or clinic staff, researchers conducted a trial comparing an HIV clinic’s services with a home-based treatment program that used fieldworkers who underwent a month of training in providing antiretroviral therapy. The researchers divided the area served by the clinic into nine strata and 44

clusters according to HIV prevalence, proportion of urban residents and distance from the clinic, and in each stratum the clusters were randomly assigned to home-based care or clinic-based care.

Patients were eligible for the trial if they were 18 or older, had stage 3 or 4 HIV (according to World Health Organization criteria) or a CD4 cell count below 200 cells per ml (the threshold for an AIDS diagnosis) and had started antiretroviral treatment at the clinic between February 2005 and December 2006. Eligible patients who declined to participate, or who withdrew after the trial started, received facility-based care. The final sample consisted of 594 persons with HIV in the clinic-based care group and 859 in the home-based treatment group. In both groups, the majority of patients were women (68–73%) and nearly two-thirds were widowed, divorced or separated (62–64%). Almost all were at an advanced clinical stage (the median baseline CD4 count was about 100 cells per ml) and needed transportation to visit the clinic (95–96%).

Each month, field officers brought medication to patients in the home-care group and used checklists to assess their condition; nurses saw patients in the clinic-care group when they came for medication. In both groups, patients received antiretroviral therapy and were referred to a clinic doctor as needed; all patients could visit the clinic any time they felt ill or after they missed a home visit or clinic appointment. In addition, two months after the start of therapy and at least once every six months thereafter, patients visited the clinic for a medical evaluation, including CD4 cell count, and were interviewed about their adherence to their medication. The trial ended in January 2009.

Patient outcomes for the two treatment programs were essentially equivalent. For example, among patients with undetectable viral loads at six months who remained in the trial beyond a year, the proportion who had an elevated plasma viral RNA load (more than 500 copies per ml) was statistically identical in the two groups (16–17%), as were the proportions who died (14%) or were admitted to a hospital at least once (11–13%) by the end of the trial; 11% of patients in each group died within the first year. At their final follow-up, eight in 10 patients had CD4 cell counts above 200 cells per ml and 63–66% had undetectable plasma viral loads. Adherence to assigned treatment programs was high in

both groups: At scheduled follow-up visits, 91–94% of patients said they had followed their medication regimen completely during the past month.

The investigators used clinic records and patient questionnaires to assess the costs of treatment (in 2008 US\$) to patients (including transportation fees, lost work time and child-care costs) and the health service (including staff time, transportation, lab fees, medication and administrative overhead). The home-based care program saved the clinic \$45 per patient annually: The average cost was \$793, compared with \$838 for clinic-based care. Patients had similar savings: The average annual cost of home-based care was \$18, compared with \$54 for clinic-based care.

Overall, the findings attest to the efficacy of home-based treatment, the researchers conclude, noting that mortality and virological failure rates in both treatment groups were comparable to those in similar studies conducted elsewhere in Africa. Moreover, they suggest that in addition to saving considerable time and money, home-based care programs “could enable improved and equitable access to HIV treatment” by increasing continuity of care, reducing HIV stigma and establishing “trust ... between patients and the community.”

—*S. Ramashwar*

REFERENCE

I. Jaffar S et al., Rates of virological failure in patients treated in a home-based versus a facility-based HIV-care model in Jinja, southeast Uganda: a cluster-randomised equivalence trial, *Lancet*, 2009, 374(9707):2080–2089.

Intimate Partner Violence Against Mothers Associated With Child Death in India

Mortality is elevated among infants and young children of mothers who have experienced intimate partner violence, according to a study conducted in India.¹ Mothers’ experiences of physical intimate partner violence were associated with an increased risk of mortality among children aged 60 months or younger (risk ratio, 1.2), including both infants younger than 12 months (1.2) and children aged 12–60 months (1.3). In addition, sexual and psychological abuse by an intimate partner were each associated with death among infants (1.4 and 1.3, respectively).

The data came from the 2005–2006 Indian National Family Health Survey, a national-

ly representative household-based study. The researchers analyzed survey responses from married women aged 15–49 who had had a singleton live birth in the past 60 months. Women were asked about a wide range of social, demographic and other characteristics, including their age, employment, wealth, caste, religion, age at delivery and degree of autonomy (whether they participated in decisions about obtaining health care, making household purchases, making large purchases and visiting relatives). They were also asked about their children's characteristics, including age, gender, birth order and age at death (if applicable). In addition, respondents reported their experiences with three types of abuse by intimate partners. Physical violence was defined as having ever been pushed, shaken, slapped, punched, hit with a fist or object, kicked, dragged, choked, burned, or threatened or attacked with a knife or gun, or having had one's arm or hair pulled by one's husband. Sexual violence was defined as having ever been forced by a spouse to have sex or perform unwanted sexual acts. Psychological abuse was defined as having ever been insulted, humiliated or threatened with harm by one's husband. The researchers conducted regression analyses to examine the relationship between women's experiences of intimate partner violence and infant and child mortality, with children (rather than mothers) serving as the unit of analysis.

The final sample consisted of 39,096 children, of whom 7,153 were infants (i.e., were aged 0–12 months), 30,466 were aged 12–60 months and 2,069 had died. Most were their mothers' first- or second-born child (30% and 28%, respectively), and about two in five (39%) had been born when their mothers were aged 20–24.

Most of the children's mothers were Hindu (69%) and did not have a paying job (64%); their mean age was 29. Forty-two percent had no formal education and another 30% had had no more than eight years of schooling. However, a substantial proportion (41%) reported a high level of autonomous decision making (i.e., they participated in decision making in all four realms).

Thirty-eight percent of the children's mothers reported having experienced some form of intimate partner abuse; 33% had experienced physical violence, 14% psychological abuse and 9% sexual violence. Some 15% had experienced multiple types of abuse, and

12% had been injured as a result of physical violence. The children who had died represented 5.3% of all children sampled and 6.4% of those whose mothers had been abused by an intimate partner.

Among children whose mothers had experienced any type of intimate partner violence, mortality rates were elevated for all those aged 0–60 months, as well as for infants (risk ratios, 1.2 for both). Having a mother whose partner had physically abused her was associated with an increased risk of death among all children aged 0–60 months, including both infants and children aged 12–60 months (1.2, 1.2 and 1.3, respectively); sexual violence was associated with death only among infants (1.4). Having a mother who had been psychologically abused was a risk factor for death among all children (1.1) and infants (1.3). Infants also had an increased risk of death if their mothers had experienced multiple types of abuse (1.5).

Several child and maternal characteristics were also associated with childhood mortality. Among all children aged 0–60 months, mortality was higher among those whose mother had autonomy in at least two of the four domains (1.1–1.3) than among those whose mother had autonomy in none of the domains; higher among those whose mother had a manual (1.4), nonmanual (1.5) or agricultural (1.3) job than among those whose mother did not work; and higher among those whose mother had up to 12 years of education (1.5–2.4) than among those whose mother had at least 13 years of schooling. Infants were at increased risk if their mother had an agricultural or manual job (1.6 and 1.7, respectively). For children aged 12–60 months, the risk of mortality was greater among third- and higher-order children (risk ratios, 1.8–2.5) than among first-born children. A child's gender had no bearing on his or her risk of death.

The direct causes of children's deaths were not determined by the study, but the researchers postulate that intimate partner violence may harm children through "physical or psychological maternal health outcomes that prevent proper care of the child, psychological stress resulting from observation of [intimate partner violence], or direct physical injury incurred by the child." The researchers propose that increased efforts by the medical, public health, public policy and public security fields to eliminate intimate partner violence could "improve health outcomes

and...reduce social health disparities" among children.—H. Ball

REFERENCE

1. Ackerson LK and Subramanian SV, Intimate partner violence and death among infants and children in India, *Pediatrics*, 2009, 124(5):e878–e889.

Option of Covert Use Is An "Important" Advantage Of the Diaphragm in Africa

One in 11 women who used a diaphragm as part of an HIV prevention trial conducted in South Africa and Zimbabwe never told their partner that they were using the method, and 41% said that covert use was a "very important" advantage of the diaphragm.¹ Focus group discussions conducted with trial participants revealed that disclosure of diaphragm use occurred along a continuum: While some women told their partner about their diaphragm use immediately, others did so only after using the method for a period, and others reported occasional covert use, particularly when their partner refused to use a condom.

The findings come from the Methods for Improving Reproductive Health in Africa study, a randomized controlled trial that examined whether the combination of the diaphragm (used with a lubricant gel) and condoms was more effective than condoms alone for preventing HIV. The trial, which included 5,039 women, was conducted in 2003–2007 at five clinics—two near Durban, South Africa; one in Johannesburg, South Africa; and two near Harare, Zimbabwe. Participants were randomized to one of the two groups and followed quarterly for 12–24 months; analyses showed that the incidence of HIV infection did not differ between the two groups.

In a secondary analysis, the investigators explored disclosure of diaphragm use among the 2,316 women in the intervention group who had been 49 or younger at baseline, had completed a survey on diaphragm acceptability at their last follow-up visit and had responded to a question about whether they had told their primary partner that they were using the diaphragm. The researchers used logistic regression to examine relationships among women's covert diaphragm use and demographic characteristics, STI risk factors, experiences of domestic abuse, fertility and partner characteristics.

In addition, the researchers conducted focus groups with a systematically selected sample of trial participants and their male partners. For this analysis, they examined transcripts from 14 focus groups involving 105 women from the intervention group and seven focus groups involving 31 male partners. Because the focus group participation rate was much lower for male partners than for female study participants (14% vs. 60%), the researchers also conducted in-depth interviews with 10 men. Focus group and interview participants were asked in detail about their experiences with the trial and their perceptions and use of the diaphragm, gel and condoms.

Women who took part in the trial were aged 28 at baseline, on average, and their mean length of participation was 21 months. Eighty-eight percent of women revealed their diaphragm use to their primary partner during the first three months of the trial; only 9%, or one in 11 women, concealed their use for the entire trial.

Among respondents who did not disclose their diaphragm use, the most common reason for concealment was that the woman thought her partner would disapprove of or be upset about her diaphragm use (60%); smaller proportions said that their partner would insist on not using the method (18%), believed that the matter was not their partner's business (15%) or gave other reasons (7%). Even though the vast majority of women told their partner that they were using the diaphragm, the ability to conceal its use was widely considered an important advantage of the method: Eighty-eight percent of participants agreed or strongly agreed that women like the diaphragm because they can use it without their partner's knowledge, and 41% said that they themselves considered it "very important" that the method could be used covertly.

In logistic regression analyses, study site was the factor most strongly associated with concealment: Women in South Africa were much more likely than their counterparts in Zimbabwe to report covert use (odds ratios, 8.8 and 12.4 for Durban and Johannesburg, respectively). In addition, women aged 35–49 at baseline were more likely than 18–24-year-olds to report covert use (1.7), and the odds of concealment were also elevated among women who were not living with their primary partner (1.6), had used male condoms during the study (4.1) or knew, suspected or weren't sure whether their regular partner had

had other partners in the past three months (1.7–1.8). In addition, women who had had sex 1–3 times per week were less likely than those who had had sex at least four times a week to conceal their diaphragm use (0.6).

In focus group discussions and interviews, most women and their partners said that diaphragm use should be a joint decision, and that covert use, if discovered, would likely result in "serious fights" between husband and wife and possibly lead to violence or divorce. However, findings also suggested that disclosure of diaphragm use occurred along a continuum that, while bookended by full disclosure and complete concealment, included several intermediate approaches. For example, some women initially hid their diaphragm use to test whether their partner could feel the device. Others did not tell their partner for a long time; used the diaphragm covertly when their partner did not want to use a condom; or adopted a "don't ask, don't tell" approach in which they mentioned the diaphragm once but did not discuss it again. Covert use was higher in South Africa than in Zimbabwe, interview results suggested, because women placed greater emphasis on individual rights in the former country and had greater fear about the consequences of being caught in the latter.

The researchers suggest that the rate of covert use among study participants may have been lower than would occur under real-world conditions, because the frequent clinic visits required for the trial made it difficult for women to conceal their participation. Nonetheless, the qualitative findings suggest that "occasional and circumstantial covert use was strategically important for many women." The issue may be particularly relevant for disempowered women, who lack the ability to request or insist that their partner use a condom; for these women, the investigators note, the decision to use a diaphragm covertly involves weighing the risk of becoming infected with HIV (if they don't use the method) against the risk of being beaten or divorced (if their covert use is discovered). They add that research on the relationship between gender dynamics and disclosure of diaphragm use should shed light on "the need and preference for covert use across different populations."—*P. Daskoch*

REFERENCE

1. Sahin-Hodoglugil NN et al., Degrees of disclosure: a study of women's covert use of the diaphragm in an HIV prevention trial in Sub-Saharan Africa, *Social Science & Medicine*, 2009, 69(10):1547–1555.

In Malawi, the Desire To Have a Child Falls After a Positive HIV Test

After learning that they had tested positive for HIV, Malawian men and women reported a substantially reduced desire to have a child in the future, according to a longitudinal study.¹ The proportion of respondents who said they wanted another child declined from 60% to 19% among those who had learned that they were HIV-positive, while it dropped to a much smaller degree—from 51% to 30%—among those who had not received a positive result. In interviews, the dominant concern of HIV-positive women who wanted to stop childbearing was fear that having a child would undermine their health, whereas HIV-positive men who wanted to stop having children believed that they would not live long enough to provide for those children or benefit from having them.

The relationship between HIV status and fertility preferences is receiving increased attention from researchers, but the pathways linking infection and childbearing remain poorly understood. This study examined how the fertility preferences of men and women in Malawi were affected after they learned that they had the virus. Because both its fertility rate and its HIV prevalence are high, Malawi is well-suited for such a study. Furthermore, HIV testing and counseling became widely available in 2004 in district hospitals and subsequently in rural hospitals and clinics. Data were from the Malawi Diffusion and Ideational Change Project (MDICP), in which 1,521 ever-married women and their husbands were randomly selected from 120 villages across the country and were surveyed in 2001, 2004 and 2006. Respondents did not know their HIV status prior to the 2004 survey, when the project offered participants HIV testing and counseling; they reported their fertility preferences in the 2001 and 2006 surveys. Data were analyzed using difference-in-differences logistic regression models, both with and without propensity score matching of respondents; the difference-in-differences approach allowed for comparison of changes in fertility preferences between respondents who had received positive HIV test results and those who had not received their results, had tested negative or had not been tested, while propensity matching ensured that the demographic and

sexual history characteristics of HIV-positive respondents were similar to those of other participants. In addition, the researchers analyzed qualitative data collected from 23 in-depth interviews with HIV-positive men and women who either were MDICP participants or had attended a clinic for the prevention of mother-to-child transmission of HIV.

In 2001, the mean ages of surveyed women and men were 32 and 40, respectively, and respondents had an average of four living children. One in five women had at least a primary education, as did two in five men; nearly all respondents were married. By 2006, 5.5% of women and 2.5% of men had tested positive for HIV and received their test result. Compared with respondents who had not received a positive HIV test result by 2006, those who had were more likely to be female or unmarried and to suspect that their spouse had had an extramarital relationship; in addition, they had fewer living children and had been married a greater number of times. However, following propensity score matching, these differences were no longer statistically significant; similarly, no differences were apparent when the sample was divided by gender.

Between 2001 and 2006, the proportion of women who said they wanted to have a child in the future declined from 53% to 28%, while the proportion of men who wanted a child fell from 50% to 31%. The proportion who said they wanted a child declined by 41 percentage points (from 60% to 19%) among respondents who had received a positive HIV test result, but by only 21 percentage points (from 51% to 30%) among those who had not received a positive result.

In the multivariate regression analyses, which controlled for gender, age, education, marital status, number of living children and region, respondents who had received a positive HIV test result were less likely than those who had not received such a result to report that they wanted to have a child in the future (odds ratio, 0.3); among men, the odds were even lower (0.1). The findings were similar when propensity score matching was included in the regression models: In both the combined and men-only models, the odds of wanting a child were reduced among respondents who had received a positive HIV test result (0.4 and 0.2, respectively). The women-only models found no differences in the likelihood of wanting to have children.

Qualitative data largely supported the regression findings. In general, both men and

women who had received a positive HIV test result said they did not want a child, but their motivations differed. Most of the interviewed women wanted to stop childbearing because of concerns for their own health, while some also feared for the health of a future child; a small minority said they wanted to continue having children because they believed that doing so would allow them to live a “normal” life until they became ill. Men’s motivations for not wanting children were considerably different from women’s: They believed that because they would not live long enough to provide for these children or to benefit from them (e.g., as a source of pride or future financial support), there was little reason to have them. Men also believed that these children were likely to die within a few years.

This study was unique in examining change in fertility preferences over time and in assessing both quantitative and qualitative data. Yet the researchers noted several limitations of the study. First, the MDICP sample was not nationally representative; female respondents were older and nearer to the end of their child-

bearing years than the typical Malawian woman of reproductive age. Second, in the five-year period between the 2001 and 2006 surveys, a variety of factors may have influenced respondents’ fertility desires, although propensity score matching should have limited the effect of any possible bias. Third, the attrition rate was higher among respondents who had tested positive than among those who had tested negative; however, among the former, attrition was higher among those who had not received their results than among those who had. Nonetheless, the study found that when Malawians learn that they are HIV-positive, many “may plan to have fewer children or decide to stop childbearing altogether,” and the researchers note that “in the high-fertility, high-HIV-prevalence context of rural Sub-Saharan Africa...this shift will have large demographic, epidemiological, and reproductive health implications.”—*J. Thomas*

REFERENCE

1. Yeatman S, HIV infection and fertility preferences in rural Malawi, *Studies in Family Planning*, 2009, 40(4): 261–276.

Intravaginal Washes with Chlorhexidine May Not Reduce Neonatal Sepsis in Low-Resource Settings

The use of chlorhexidine wipes during labor does not prevent early-onset neonatal sepsis or vertical transmission of group B streptococcus, according to a randomized, controlled trial conducted in South Africa.¹ No differences in the rates of neonatal sepsis (3–4%) or mother-to-child transmission of group B streptococcus colonization (54–55%) were observed between the intervention and control groups. These results contrast with those of earlier African studies in which the use of chlorhexidine was associated with significant reductions in neonatal and maternal sepsis and neonatal mortality. In a comment on the study, Mullany and Biggar suggest that contextual differences between the current study and the earlier ones may account for the conflicting results, and that this simple, low-cost intervention should not be abandoned because of the new findings.²

Intravaginal washes with chlorhexidine have been thought to reduce sepsis by preventing newborns from acquiring vaginal bacteria during childbirth. Although nonrandomized studies have found intravaginal chlorhexidine washes efficacious in the re-

duction of sepsis-associated morbidity and mortality, the lack of demonstrated results from a randomized, controlled trial has hindered worldwide acceptance of the approach. If effective, such a cheap and accessible intervention would be a particular boon to developing nations, where the intrapartum antibiotic prophylaxis that has greatly reduced early-onset group B streptococcal disease in developed nations is typically unavailable.

Between 2004 and 2007, pregnant women presenting at the Chris Hani-Baragwanath Hospital, an urban public facility in Soweto that provides free maternal and pediatric care to low- to middle-income patients, were screened for eligibility to participate in the trial. Women were excluded if they planned to have a caesarean section, had genital warts or ulcers, had had antepartum hemorrhage or an intrauterine death, had a known allergy to chlorhexidine, were fully dilated, were younger than 15, or were carrying a fetus that had a severe congenital malformation or was presenting face first. In all, 8,011 women (and 8,129 newborns) were randomly assigned to either the chlorhexidine group or the control group.

During labor, the cervix, vaginal walls and external genitalia of women in the intervention group were wiped with cotton pads soaked in 0.5% chlorhexidine gluconate solution; for women in the control group, external genitalia were wiped with autoclaved tap water. After they had been bathed, newborns assigned to the intervention were wiped with the chlorhexidine solution from head to toe (excluding the face and ears); newborns in the control group received a chlorhexidine foot wipe. In addition, for a subset of both groups, swabs were taken from mothers and newborns to determine if vertical transmission of group B streptococcus had occurred. Vertical transmission was defined as the isolation of the same bacteria from both the mother and child, and early-onset sepsis was defined as sepsis occurring within the first three days of life. Analysis was by intention to treat; in the intervention group, all of the mothers and 99% of infants were wiped with chlorhexidine.

Participant characteristics were similar across study groups: The women had a mean age of 26 years, 10% received intrapartum antibiotics and 26% were HIV-positive; the median gestational age of the infants was 39

weeks. Early-onset sepsis occurred in 3% of newborns in the intervention group and 4% of those in the control group. Among infants born to women with group B streptococcus, vertical transmission was found in 54% of those in the chlorhexidine group and 55% of those in the control group. Neither difference was statistically significant. The neonatal mortality rate was lower in the intervention group than in the control group (8.3 per 1,000 births vs. 12.8 per 1,000); however, most of the difference was due to deaths that occurred soon after delivery and hence were probably not related to sepsis.

On the basis of their results, the authors conclude that “chlorhexidine is unlikely to prevent vertically acquired neonatal infections in any setting or population.” The lack of an effect on vertical transmission, they add, provides further evidence that the difference between groups in the infant mortality rate was unrelated to the intervention.

In their comment, Mullany and Biggar suggest that the authors of earlier chlorhexidine studies in Malawi and Egypt may have been mistaken when they attributed the reductions in sepsis in those studies to the prevention of vertical transmission; instead, chlorhexidine

may have reduced morbidity and mortality by preventing environmental or hospital-acquired infections. The authors of the South African study seem to support this view, noting that the “results of a review of pathogens associated with neonatal sepsis in developing countries suggest that many neonatal infections might be acquired environmentally.” Unlike the earlier studies, the current study took place in a hospital “in which professional care and facilities were superior, antibiotic use was extensive, aseptic conditions were maintained and overall rates of mortality and sepsis were low”; Mullany and Biggar note that the lack of such conditions in previous studies “might explain why chlorhexidine antiseptics was reported as efficacious.” Given this possibility, “further studies of the role of chlorhexidine use in low-resource delivery rooms and community settings” continue to be warranted.—*L. Melhado*

REFERENCES

1. Cutland CL et al., Chlorhexidine maternal-vaginal and neonate body wipes in sepsis and vertical transmission of pathogenic bacteria in South Africa: a randomized, controlled trial, *Lancet*, 2009, 374(9705): 1909–1916.
2. Mullany LC and Biggar RJ, Vaginal and neonatal skin cleansing with chlorhexidine, *Lancet*, 2009, 374(9705): 1873–1875.