

Participatory Women's Groups Linked to Improved Neonatal Outcomes in India, but Not Bangladesh

Women's groups that meet monthly to discuss, identify and address factors that contribute to poor maternal and neonatal health may improve birth outcomes in rural, low-resource settings—at least in some circumstances. A pair of randomized trials conducted in India and Bangladesh that examined the potential benefits of establishing such groups yielded mixed results.^{1,2} In the Indian study, the odds of neonatal mortality were lower in areas with participatory women's groups than in control areas without groups (odds ratio, 0.68), particularly during the final two years of the three-year study (0.55). No decrease in maternal depression—an outcome assessed only in the Indian trial—occurred for the study as a whole, although the odds of moderate depression were reduced in the women's group areas during the final year (0.43). In the Bangladeshi trial, however, no improvements in neonatal or maternal outcomes occurred in areas with women's groups, a finding that may reflect the lower density of groups in the Bangladeshi program.

The trials were inspired by an earlier study in which a women's group intervention in rural Nepal produced neonatal mortality rates 30% lower than those in comparison areas. To examine whether this approach could be replicated in other low-resource settings, one follow-up trial was organized in three contiguous districts of Bangladesh (Bogra, Faridpur and Moulavibazar), and another in two Indian states (Jharkhand and Orissa). The trials, which were launched in 2005 and lasted about three years, were broadly similar in format. In each country, the study areas were divided into clusters, half of which were randomly chosen to serve as intervention areas. In Bangladesh, researchers met with leaders of 451 villages to obtain permission to establish women's groups in the intervention areas, and trained facilitators visited every 10th household to invite married women of reproductive age to join; in India, 172 existing women's groups (involved in savings and credit activities) were invited to participate in the intervention, and 72 addi-

tional groups were established. In both countries, groups met monthly and began by discussing the reasons for neonatal and maternal deaths and the problems that women face before, during and after delivery; at subsequent meetings, strategies for addressing these problems were discussed and, if possible, implemented. Groups used a variety of approaches, both in discussing problems (storytelling and role playing were frequently used) and in implementing solutions. Participatory group meetings were not held in the control clusters, although in these areas (as in the intervention areas) efforts were made to improve medical referral systems and to refresh providers' knowledge of neonatal and maternal care.

The studies' primary outcomes were neonatal mortality (death of a live-born infant within 28 days of birth) and, in the Indian trial, maternal depression; secondary outcomes included early and late neonatal mortality (deaths occurring within 1–6 and 7–28 days of birth, respectively), stillbirths, maternal mortality (pregnancy-related deaths within 42 days of the end of pregnancy) and home-care practices during and after delivery. To monitor outcomes and collect demographic information, trained informants (generally traditional birth attendants) identified all births, neonatal deaths and maternal deaths in the region, and women or family members were interviewed about six weeks after delivery; supervisors conducted “verbal autopsies” with mothers in cases of neonatal death and with family members in cases of maternal death. In India, maternal depression was assessed using a 10-item screening scale and classified as mild, moderate or severe. Analyses were by intention-to-treat.

Baseline surveys in the intervention and control areas of Bangladeshi women who had given birth in the year before the study revealed that most were Muslim (81–88%), aged 20–29 (60–65%) and had no more than a primary school education (76–82%). Fewer than half had use of a sanitary latrine (32–46%). Only 34–36% of the women had

received any formal antenatal care during their last pregnancy, and relatively small proportions of deliveries had occurred in a medical facility (7–9%) or been supervised by a trained birth attendant (15–18% of home deliveries). The Indian study areas were impoverished as well: About three-quarters of women who had had births in the past year belonged to scheduled castes or scheduled tribes (73–78%), and similar proportions were illiterate (70–78%). Most women had obtained some prenatal care during their pregnancy (59–69%), but the majority of the deliveries had occurred at home (83–86%), generally without a birth attendant (61–63%).

During the ensuing three years, data were collected on 18,775 births in India and 36,113 births in Bangladesh. Because pregnant women in Bangladesh often travel to their mother's home for the delivery, more than 10% of the interviewed women in that country were temporary residents of the relevant districts; they were included in the mortality analyses but not the analyses of secondary outcomes, which were restricted to the 30,952 births to permanent residents.

In India, the neonatal mortality rate was lower in intervention areas than in control areas (42 vs. 59 per 1,000 live births). After adjustment for clustering and baseline differences between regions, the odds of neonatal death were lower in the areas with women's groups than in the control areas (odds ratio, 0.68), especially during the last two years of the study (0.55). Similar reductions were apparent in early neonatal mortality (0.62) and perinatal mortality (0.79), but not in late neonatal mortality or stillbirth.

Overall, women in the intervention and control areas did not differ in rates of postpartum depression. However, during the third year—by which time more than half of the mothers had joined a women's group—the proportion of mothers with moderate depression was lower in the intervention areas than in the comparison areas (5% vs. 10%; odds ratio, 0.43). Rates of mild and severe de-

pression did not differ between areas.

Finally, the researchers found changes in rates of beneficial home care practices. During the study's final two years, several such practices—including use of soap by the birth attendant, use of a safe delivery kit and use of a boiled thread to tie the umbilical cord—were utilized more often in intervention areas than in control areas (odds ratios, 2.3–4.3).

Unfortunately, the results were not as encouraging in Bangladesh, where only 9% of women aged 15–44 were group members by 2007. The neonatal mortality rate was lower than in India (34–38 per 1,000 live births), but it did not differ between the intervention and control areas, even in the later stages of the trial. Moreover, no differences were apparent in other neonatal outcomes, and maternal mortality was elevated in the intervention areas—a result the researchers suspect was a chance finding, in part because none of the deceased women had belonged to a women's group.

The authors of the Indian study suspect that the reduction in neonatal mortality in the intervention areas was due to the higher rates of hygienic practices in those regions; forthcoming analyses of the verbal autopsies may yield a more definitive explanation. Social support and group problem-solving may have led to the reduction in moderate maternal depression seen in intervention areas toward the

end of the study. Overall, women's groups such as the ones in this study “have the potential to create improved capability in communities to deal with the health and developmental difficulties arising from poverty and social inequalities,” the researchers state.

In the Bangladeshi trial, on the other hand, the intensity of the intervention may have been too low to provide benefits: One women's group was established for every 1,414 residents, compared with one per 468 residents in the Indian trial and one per 756 residents in the earlier Nepalese trial. Moreover, group facilitators in Bangladesh had more groups to supervise than did their counterparts in the other two trials. The researchers note that future studies should shed light on the factors, including population coverage, that influence the effectiveness of using women's groups to influence maternal and neonatal outcomes; in fact, an “intensive scale-up” of the intervention is under way in Bangladesh.—*P. Doskoch*

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Household Wealth, Travel Associated with Having Multiple Partners Among Sub-Saharan African Men

The likelihood that a man will have multiple sex partners—a key factor promoting the spread of HIV—may be mediated by his financial resources and his exposure to social control mechanisms, such as monitoring by village elders and family members.¹ In many of the 15 Sub-Saharan African countries included in a recent study, the odds of having had multiple partners in the previous 12 months were elevated among men with greater household wealth and those with nonagricultural occupations. In addition, the odds of having had multiple partners were frequently elevated among men who were relatively free from social control because they lived alone or traveled away from home; for example, Ethiopian men who had taken six or more long trips in the past year, including at least one that lasted a month, were far more likely than nontravel-

ers to have had multiple partners (odds ratio, 8.1).

The researcher used self-reported data on men aged 15–49 from Demographic and Health Surveys conducted in Burkina Faso, Cameroon, Côte d'Ivoire, Ethiopia, Ghana, Guinea, Kenya, Lesotho, Malawi, Mali, Niger, Rwanda, Senegal, Tanzania and Zambia. He excluded men in polygynous marriages, who accounted for 1% (in Rwanda) to 15% (in Guinea) of men in that age range. Respondents reported their marital status, their age at first sex and the number of sex partners they had had in the 12 months prior to the interview. The key socioeconomic variables included in the study were household wealth (categorized in quintiles), education (none, some primary, completed primary, some secondary or completed secondary) and em-

ployment status (student, unemployed or employed in one of seven broad occupational categories). In addition, the researcher used three indicators of social control mechanisms that might affect men's sexual behavior: rural or urban residence (because social control mechanisms are presumably weaker in urban regions), travel away from home in the past 12 months, and social position in the household, determined by whether the man lived alone, headed a two-person household, headed a larger household, was the son or grandson of the head of the household, or was in another position. Logistic regression was used to elucidate any relationships among men's characteristics, social control variables and having had multiple partnerships.

The proportion of respondents who were currently married ranged from 27% in Côte d'Ivoire to 59% in Malawi. Those with no education accounted for between 5% (in Kenya and Zambia) and 64% (in Niger) of respondents; men living in rural areas accounted for 40% (in Cameroon) to 84% (in Ethiopia) of respondents. The proportion of men who reported having had two or more sex partners in the previous 12 months ranged from 1% in Ethiopia to 28% in Cameroon, and exceeded 10% in nine countries.

A relationship between marital status and having had multiple sex partners was evident in 11 of the 15 countries. The odds of having had multiple partners were lower among monogamously married men than among never-married men in five countries (odds ratios, 0.2–0.6 in Burkina Faso, Côte d'Ivoire, Guinea, Mali and Niger)—a finding that runs counter to the common assumption that men's marital authority over their wives facilitates their having multiple partners. Tanzania was the only country in which married men were more likely than never-married men to have had more than one partner in the past 12 months (1.4). The odds of having had multiple partners were elevated among unmarried cohabiting men in Côte d'Ivoire, Rwanda and Senegal (1.5–4.0) and formerly married men in Cameroon, Kenya, Tanzania and Zambia (1.5–3.6).

In about half of the 13 countries for which relevant data were available, wealth was related to having had multiple partners. In three (Cameroon, Côte d'Ivoire and Ghana), the risk of men having had more than one partner in the past year generally increased with greater household wealth. For example, in Cameroon, the odds that men had had multiple partners

rose as household wealth increased from the poorest quintile (the reference group) to the second poorest quintile (odds ratio, 1.7), the middle and second-richest quintiles (2.2 each) and the richest quintile (3.1). Multiple partnerships were more prevalent among only the wealthiest men in Burkina Faso, Kenya, Niger and Senegal (1.7–7.5), while in most of the remaining countries wealth was not consistently related to men's partnerships.

In nine countries (Burkina Faso, Côte d'Ivoire, Ghana, Kenya, Lesotho, Mali, Rwanda, Senegal and Zambia), the odds of having had multiple partners were higher among men in one or more nonagricultural occupations than among agricultural workers (odds ratios ranged from 1.5 among unskilled manual laborers in Kenya to 3.6 among professional, technical and managerial workers in Mali). Compared with agricultural workers, men who were unemployed had lower odds of having had multiple partners in Tanzania (0.5), but higher odds in Cameroon, Côte d'Ivoire, Ghana and Mali (1.7–2.2)—possibly because some unemployed men “use sex with multiple partners as a way of reasserting their masculinity,” the author suggests. Students were generally less likely than agricultural workers to have had multiple partnerships.

In eight of the 15 countries, men living in urban areas had elevated odds of having had multiple sex partners (odds ratios, 1.6–4.3). In 11, men living alone—who presumably were the most free from familial monitoring—were more likely than heads of large households to have had more than one partner (1.8–4.0). Finally, in all 11 countries for which travel data were available, men who had been

away from home in the previous 12 months—and who thus had experienced freedom from social control—were generally more likely than those who had not traveled to have had multiple partners. For example, in Côte d'Ivoire, men who had taken at least one trip lasting a month were more likely than non-travelers to have had more than one partner (3.0–4.0). The odds of having had multiple partners were highest among Ethiopian men who had taken six or more trips, including at least one that had lasted a month (8.1).

The researcher asserts that given the diversity among Sub-Saharan countries in the prevalence of men's multiple sexual partnerships, generalizations about the region should be avoided. Nonetheless, he argues that evidence connecting men's escape from social strictures and their control of financial resources with their increased risk of having multiple partners could help shape strategies for addressing HIV risk. Meanwhile, he points out that there was little evidence that their authority over their wives—commonly thought to facilitate extramarital sex and the spread of HIV—contributes to men's having had multiple sex partners. He concludes that “programs intended to reduce the spread of HIV and other sexually transmitted infections through behavior change may be able to build upon, enhance the effectiveness of, or operate synergistically with” the formal and informal social control mechanisms delineated above.—*H. Ball*

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round. The vast majority of respondents remained in the study during the subsequent six rounds: The attrition rate between the first and last rounds was 15%. Survey rounds were irregularly spaced, but most intervals were 7–10 months.

In each round, women were asked, “Would you like to have a(nother) child with your husband/partner, or would you prefer not to have any more children with him?” Women who wanted a child in the future were asked about their preferred timing; on the basis of their answers, they were classified as wanting a child soon (within two years), wanting a child later, wanting no more children, undecided or infecund. To assess women's ideal family size, the researchers asked women at study entry, “If you could go back to the time when you did not have any children and could choose exactly the number of children to have in your whole life, how many would that be?” Respondents also provided information on their marital status, contraceptive use, pregnancies and demographic characteristics.

The researchers conducted two analyses. They first examined, for each woman, changes in fertility preference categories between consecutive survey rounds; thus, information was available for up to seven survey intervals per respondent. The second analysis, ideally, would have examined the preference patterns of individual women across the study's eight rounds, but doing so posed statistical challenges because of the high number of possible patterns. Instead, the researchers performed a latent class analysis using data from rounds 2, 4, 6 and 7. In this approach, which simplified the statistical analysis and provided intersurvey intervals of about one year, fecund women whose preference patterns were broadly similar were grouped into classes.

Overall, 1,428 women participated in the study. Mean age at study entry was 31, and about four-fifths of the women were married. More than a third (35%) had never attended school, and another one-fourth (24%) had no more than an elementary school education. Most women were Christian (60%) or Muslim (21%). During the course of the study, the mean lifetime number of births among study participants increased from 3.5 to 4.2, and the mean number of live children rose from 2.8 to 3.5. At baseline, mean ideal family size was 4.4.

Between rounds one and eight, the proportion of women who wanted no more chil-

In the Short Term, Childbearing Desires Remain Relatively Stable Among Women in Ghana

Ghanaian women's fertility preferences are generally stable in the short term, according to a study that repeatedly assessed such preferences over a five-year period.¹ Among fecund women, 81% of those who said in a given survey round that they did not want any more children reported the same preference in the next round, typically 7–10 months later; similarly, 79% of those who did want a child in the future felt the same at the subsequent survey. However, the stability of women's preferences varied according to whether they had attained their ideal family size.

Data on fertility preferences are used for such purposes as estimating unmet need, and these preferences are often assumed to be stable. However, recent work suggests that fertility desires may be influenced by temporary factors, such as economic conditions. To examine the extent to which preferences fluctuate, researchers asked women in southern Ghana about their fertility preferences up to eight times from 1998 to 2003. A total of 1,219 women aged 15–50 were interviewed in the study's first round, and an additional 209 were added to the sample in the second

dren increased from 30% to 36%, and the proportion who reported being infecund rose from 2% to 9%. Conversely, decreases occurred in the proportions of women who wanted a child within two years (from 28% to 22%) or later (from 34% to 22%). Consistency of fertility preferences between consecutive survey rounds was highest for women who wanted no more children (76%) and lowest for women who were undecided (38%); stability of preferences was intermediate among women who wanted a child soon (55%) or later (62%).

In analyses that omitted infecund respondents, 81% of women who wanted no more children in a given round expressed the same preference in the next round; the proportion was greater among those who had attained their ideal family size than among those who had not (86% vs. 75%). However, only 58% of women who reported in any of the first seven rounds that they wanted no more children expressed the same preference in the final round.

Preferences were also generally stable among women who wanted more children: Seventy-nine percent reported in the next round that they wanted a child in the future. Here, consistency was greater if women had not yet reached their ideal family size. For example, among women who wanted a pregnancy soon, nearly two-thirds (64%) of those who had not attained their ideal family size reported at the next survey that they wanted a pregnancy within two years, compared with only 39% of those who had attained their ideal family size.

The latent class analysis revealed five broad groups of women. The largest, comprising 31% of respondents, consistently reported wanting a child, but not in the next two years. These women were generally young (mean age at baseline, 24) and hence relatively early in their reproductive careers; they had an average of one birth during the study. A similar proportion of women (29%) tended to report not wanting to have a child in the future; these women were typically nearing the end of their reproductive years. The third largest group, representing 16% of women, typically first reported wanting a child after two years but then switched to wanting no more children. The fourth group was generally characterized by women who repeatedly said they wanted a child soon, though most did not in fact give birth during the study, while women in the fifth and smallest group tended to be

undecided about their childbearing preferences, in part because they were less likely than their peers to be married.

Overall, the findings show that “approximately one in five women changes her mind about whether to have an additional child within the next several months,” indicating that “considerable regularity and stability exist in stated fertility preferences over time,” according to the researchers. The results suggest “that most women’s preferences are reasonably strongly held and are not likely to be driven by everyday circumstantial factors.” In a separate analysis, the researchers found that most women who wanted no more children said their partner felt otherwise. Because perceived spousal disagreement about family size is a substantial barrier to adoption of modern contraceptives, the authors emphasize that “empowering women to exercise control over their fertility is clearly central to the achievement of their fertility preferences,” and family planning policies should “promote contraceptive methods suitable to [women’s] familial and social contexts.”—*P. Doskoch*

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STI Levels Decline Among Sex Workers in India After Program Implementation

Levels of HIV and other STIs declined, and condom use increased, among female sex workers in southern India in the three years following the initiation of a large-scale HIV-prevention program.¹ Compared with female sex workers surveyed 7–19 months after the start of the program, those surveyed 28–37 months after the intervention began were less likely to test positive for HIV (odds ratio, 0.8), high-titer syphilis (0.5) and either chlamydia or gonorrhea (0.7). They were also more likely to report having not engaged in any unprotected sex acts with clients in the past month (2.4) and having used condoms the last time they had sex with a repeat client (2.0). Longer durations of exposure to the program were generally associated with higher levels of condom use.

The program, implemented by the Karnataka Health Promotion Trust in January

2004–April 2005, serves 60,000 female sex workers in Karnataka state; it provides sexual health services, promotes condom use through peer outreach, mobilizes communities around HIV prevention and empowers the sex work community. Seven to 19 months after implementation, the researchers interviewed a probability-based sample of 2,312 female sex workers in five districts (Bangalore Urban, Belgaum, Bellary, Mysore and Shimoga). The sample included street-based sex workers, as well as those who worked at home, brothels or other sites. A follow-up survey was conducted with 2,400 women 28–37 months after the program started; about 17% of respondents in the first survey also took part in the follow-up survey. In both surveys, the researchers collected data on women’s social and demographic characteristics, age at sexual debut, age at initiation of sex work, primary place of solicitation, earnings from sex work, number of clients per week and condom use with clients and regular partners. They also asked women to report their exposure to five program components: having been visited by a peer educator, having visited a drop-in center, having visited the program’s sexual health clinic, having received a pack for treating chlamydia and gonorrhea, and having witnessed a condom demonstration. In addition, respondents were tested for HIV, syphilis, chlamydia, gonorrhea and (in Mysore only) trichomonas at the time of the survey.

Respondents had a median age of 30; on average, they had been 15 years old when they first had sex and 25 when they began sex work. Some 33–46% of women from the initial and follow-up surveys were married, and 36–44% were separated, divorced, widowed or abandoned. Two-thirds were illiterate. The majority (54–55%) solicited customers in public places. The proportion earning more than 1,500 rupees per week (roughly US\$30) from sex work increased from 31% to 52% between surveys.

At the time of the first survey, 20% of respondents tested positive for HIV, with prevalence ranging from 10% in Shimoga to 34% in Belgaum. Brothel-based sex workers were more likely than home- or street-based workers to be infected with HIV (33% vs. 14–21%) or either chlamydia or gonorrhea (12% vs. 6–10%), while those who solicited clients in public places were more likely than other workers to have high-titer syphilis (9% vs. 2–3%).

Between the first and follow-up surveys, ex-

posure to most program components increased; for example, the proportion of respondents who had ever been visited by a peer educator rose from 83% to 95%, and increases occurred for visits to the drop-in center (from 32% to 77%) and sexual health clinic (from 68% to 85%). In some instances, changes in exposure varied by women's place of solicitation; for example, receipt of the chlamydia and gonorrhea treatment pack increased among home-based respondents, declined among brothel-based sex workers and did not change among street-based workers. Moreover, by the follow-up survey, brothel-based workers were less likely than others to have visited the drop-in center (62% vs. 74–81%) or the sexual health clinic (75% vs. 85–87%), or to have received a treatment pack (55% vs. 59–68%).

Condom use at last sex with a repeat client was reported by 66% of respondents at the initial survey and 84% at follow-up, a significant increase between surveys (odds ratio, 2.0). The odds of having had no unprotected sex acts in the past month also increased over time (2.4). Increases in condom use at last sex with an occasional client and with a regular partner were smaller and were not significant after adjustment for demographic and other variables. However, the odds of condom use with occasional clients, repeat clients and regular partners were all positively associated with greater duration of exposure to the program. Condom breakage was reported by significantly fewer women at follow-up than at the first survey (14% vs. 17%; odds ratio, 0.8).

Finally, STI prevalence was generally lower at follow-up than at the initial survey. The proportion of respondents who tested positive for HIV fell from 20% to 16% (odds ratio,

0.8); the proportion with high-titer syphilis decreased from 6% to 3% (0.5); and the proportion with either chlamydia or gonorrhea declined from 9% to 7% (0.7). In Mysore, the prevalence of trichomonas infection dropped from 33% to 14% (0.3). The proportion of sex workers infected with either chlamydia or gonorrhea was negatively associated with length of program exposure—it ranged from 13% among women who had not been exposed to the program to 3% among those exposed for more than 33 months—but there was no correlation between length of exposure and infection with other STIs.

The declines in STI prevalence among female sex workers in Karnataka suggest that “sexual health promotion programmes and services are now starting to reach this population, and safer sex practices are being adopted,” the researchers conclude. They attribute the lack of gains in condom use between surveys to the high levels of use achieved in the months between program initiation and the first survey, and posit that community mobilization and the creation of a less hostile environment may have contributed to improvements in sex workers' sexual health practices and outcomes. However, because some sex workers (e.g., those based in brothels) received fewer program services and experienced higher levels of certain STIs than other workers did, the researchers stress that “concerted efforts that target the most vulnerable women must continue and be strengthened.”—*H. Ball*.

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the resources it requires might be better used to increase access to ART. For this reason, researchers sought to determine whether routine monitoring of ART efficacy and toxicity has meaningful benefits for patients' long-term clinical outcomes.

Between January 2003 and October 2004, symptomatic HIV-positive adults aged 18 or older who had not begun ART and who had CD4 cell counts of less than 200 per microliter were enrolled from three centers in Uganda and one in Zimbabwe; participants were followed until December 2008. Patients were excluded if they were considered unlikely or unable to follow an ART regimen or attend follow-up sessions, were undergoing chemotherapy or the intensive phase of antituberculosis therapy, had an acute infection or laboratory results that precluded initiation of ART, or were pregnant or breast-feeding. The final sample of 3,316 participants was randomized into two groups, one that received clinically driven monitoring (i.e., the need to switch medications or test for toxicity was determined by the clinician's assessment) and one that received both clinical monitoring and routine laboratory testing for toxicity and efficacy.

All participants received triple-drug ART. At screening, as well as at four weeks, 12 weeks and every 12 weeks thereafter, participants from both study groups met with a doctor and had routine blood tests. Results for participants in the routine testing group were given to their clinicians, while those for patients in the clinically driven monitoring group were provided only if requested for clinical reasons or if the tests revealed potentially life-threatening toxicity. In both groups, clinicians were free to perform additional tests and treat new diagnoses as needed. Patients who developed severe HIV-related conditions—specifically, those classified as stage 4 conditions by the World Health Organization, such as recurrent severe pneumonia or Kaposi's sarcoma—were switched to a different (second-line) ART regimen; in the routine monitoring group, the patients were also switched if their CD4 cell counts fell below 100 per microliter. A nurse used a standard symptom checklist to review the status of all participants every four weeks.

The trial examined rates of two primary patient outcomes. The first was either death or the occurrence of a new stage 4 HIV-related condition; the second was the occurrence of a serious adverse event, which referred to

Benefits of Routine Laboratory Testing for HIV Patients Receiving Antiretroviral Therapy May Be “Small”

Patients receiving antiretroviral therapy (ART) for HIV typically undergo routine blood tests to ensure that the drugs are working and not causing toxic side effects. However, according to a randomized trial conducted in two Sub-Saharan African countries, ART can be dispensed safely without routine testing for toxicity.¹ On the other hand, the trial also found that routine lab testing may provide a small improvement in the efficacy of treatment by alerting clinicians that the patient's regimen is

losing its effectiveness and that a switch of drugs is warranted. Twenty-one percent of patients assigned to routine laboratory monitoring either died or developed a serious HIV-related condition during five years of ART, compared with 28% of those whose physicians relied on clinical assessments to make therapeutic decisions.

Routine laboratory testing of patients receiving ART is often cost-prohibitive in developing nations; even if such testing is available,

only to HIV-related conditions but to any serious medical condition that was life-threatening or fatal, caused disability or required a hospital admission. The study was a noninferiority trial, which meant that the researchers aimed to show that a new treatment (here, clinically driven monitoring) was not worse than a standard treatment (routine monitoring) by a prespecified, clinically meaningful degree; they determined that the upper 95% confidence limit of the hazard ratio for the measure encompassing death and new stage 4 conditions could not exceed 1.18. Kaplan-Meier plots, log-rank tests and proportional hazard models were used to compare outcomes between groups.

At baseline, characteristics of the two study groups were similar: Some 64–66% of participants were women, their median age was 36 and 99% reported having been infected with HIV through heterosexual contact. Median follow-up was 4.9 years, during which time both groups attended 98% of nurse visits and 99% of doctor visits.

The proportion of participants reporting one or more serious side effects from therapy did not differ between the two groups (16–17%). Although the blood test results were available upon request to the clinicians of patients in the clinical monitoring group, fewer than 4% of these results were requested.

By the end of the trial, the proportion of patients who had been switched to a second-line ART regimen was higher in the routine monitoring group than in the clinically driven monitoring group (22% vs. 19%). Twenty-eight percent of patients receiving clinically driven monitoring, but only 21% of those receiving routine monitoring, had died or developed a new stage 4 condition, indicating that one death or stage 4 condition was prevented for every 59 patients receiving routine monitoring for one year. This translates to a hazard ratio of 1.31 (95% confidence interval, 1.14–1.51), which means that the two treatment strategies can not be considered equivalent.

A prespecified subgroup analysis showed that outcomes for the two groups were generally similar for the first two years of treatment. However, from the third year on, deaths and stage 4 conditions were roughly twice as frequent among patients receiving clinically driven monitoring as among those receiving routine monitoring. Thirteen percent of patients in the clinically driven monitoring group and 10% of those in the routine monitoring group died, a difference equivalent to one death prevented

annually for every 130 patients who received routine instead of clinically driven monitoring.

The authors conclude that although routine laboratory monitoring offers a “small” benefit in reducing disease progression, “good ART outcomes with low mortality can be attained without” such monitoring. They suggest that “a greater public health effect would be gained from widening access to ART for untreated patients with low CD4 cell counts who are at high risk of mortality rather than providing routine laboratory monitoring for people already receiving ART.” In light of this, the authors suggest that “funding...be focused on drug procurement, strengthening of diagnostic laboratory services, and training and supervision for health care workers to foster quality clinical monitoring, [in order] to support scale-up of ART rollout to rural Africa where 60% of the HIV-infected population live.”

—L. Melhado

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In Asia, Cesarean Section Associated with Increased Risk of Neonatal Mortality

In Asia, women who give birth via cesarean section may be at an increased risk for negative health consequences.¹ According to an observational study conducted by the World Health Organization (WHO) in nine Asian countries, women who undergo an unplanned cesarean section before or during labor or who have an assisted (operative) vaginal delivery are more likely than those who have a spontaneous vaginal delivery to experience morbidity. Furthermore, infants born by assisted vaginal delivery or a medically indicated cesarean section have about twice the odds of dying during delivery, spending at least seven days in intensive care or both than do those born without surgical aid (odds ratios, 1.9–2.1). Women who have elective cesarean deliveries before going into labor are more likely than those with spontaneous vaginal deliveries to require admission to the intensive care unit (9.9). For infants with a breech presentation, however, cesarean delivery is associated with reduced neonatal mortality.

Cesarean section is often perceived to be safer than vaginal delivery for mothers and

their infants, and thus has become increasingly common around the globe. However, research shows that the procedure may actually be detrimental to maternal and infant health, while consuming valuable resources, especially in poorer countries.

In the current analysis—part of WHO’s global study examining maternal and perinatal care—the researchers used stratified multi-stage cluster sampling and random selection to choose 128 health facilities in Cambodia, China, India, Japan, Nepal, the Philippines, Sri Lanka, Thailand and Vietnam for assessment. To be included in the study, facilities had to offer cesarean section and manage more than 1,000 deliveries annually; they also had to be located in each country’s capital city or in one of the two provinces that were randomly selected for each country. Six facilities declined to participate, leaving a total of 122 sites. From October 2007 to May 2008, data were collected over a two-month period from facilities that anticipated more than 6,000 deliveries yearly, and over a three-month period from those that expected 6,000 or fewer deliveries. At each facility, staff provided data on all deliveries, including information on women’s demographic characteristics, pregnancy-related risk factors, delivery type, and maternal and neonatal complications. For mothers, the outcomes of interest were death, blood transfusion, admission to the intensive care unit, hysterectomy and surgery to control pelvic arterial bleeding; for infants, the key outcomes were death or receiving at least seven days of neonatal intensive care. The researchers conducted univariate and multivariate analyses to assess associations between study variables and maternal and neonatal outcomes.

The final sample consisted of 107,950 deliveries, half of which were in India, China or Sri Lanka. About nine in 10 women were married (94%) and a similar proportion (90%) were aged 17–34; for 43%, the pregnancy was their first. One in five (19%) had come to the hospital because of pregnancy or delivery complications. The overall cesarean rate was 27%; rates were highest in China (46%), Vietnam (36%) and Thailand (34%). Women who underwent a medically necessary cesarean section most often did so because they had had a previous cesarean delivery (24%). Other common reasons included fetal distress (21%) and breech or other abnormal presentation (13%). Almost two-thirds of facilities offered doctors a financial incentive for performing a cesarean section.

In multivariate analyses, the researchers found that the odds of maternal death among women who had had an assisted vaginal delivery were three times those among women who had had a spontaneous vaginal delivery (odds ratio, 3.1). Women who had had an assisted vaginal delivery also had an elevated likelihood of being admitted to intensive care (2.4), as did women who had had an elective antepartum cesarean delivery (9.9) or a medically necessary cesarean delivery (42.8–55.7).

The odds of receiving a blood transfusion were greater among women who had had an assisted vaginal delivery, who had undergone a medically necessary cesarean section before labor or who had had an elective cesarean delivery during labor (odds ratios, 2.1–4.7) than among women who had had a spontaneous vaginal birth. The odds of having had a hysterectomy were elevated only for women who had had a medically necessary cesarean section (5.8–6.9). Overall, the odds of either dying, being admitted to the intensive care unit, or having a transfusion, a hysterectomy or pelvic arterial ligation surgery were elevated among women with a surgical vaginal delivery (2.1), an elective antepartum cesarean delivery (2.7) or a medically necessary cesarean section (10.6–14.5).

In analyses that took into account fetal presentation (e.g., breech or other non-headfirst positions), the odds of fetal death were lower for infants delivered by cesarean section prior to labor than for those with a spontaneous vaginal birth (odds ratio, 0.6). Infants born via assisted vaginal delivery or medically necessary intrapartum cesarean section were more likely than those born spontaneously to die during delivery (1.6 and 1.5, respectively) or before leaving the hospital (2.5 and 2.6, respectively); infants delivered by a medically necessary antepartum cesarean section also had elevated odds of dying before discharge (1.7). Compared with spontaneously delivered infants, those whose mother required surgical assistance to deliver had about double the odds of receiving neonatal intensive care for at least seven days (1.9–2.4) or of either needing this type of care or dying during delivery (1.9–2.1).

In a subgroup analysis focusing on infants who were in a breech or other abnormal presentation prior to labor, the odds of neonatal death before or during delivery were lower for cesarean deliveries than for spontaneous vaginal deliveries (odds ratios, 0.1–0.6). However, infants born during medically necessary surgical deliveries had increased odds of

needing seven or more days of intensive care (1.7–2.1). Death before hospital discharge was reduced only among infants delivered by medically indicated antepartum cesarean section (0.4).

Despite the large scale of this study, the investigators caution that these findings cannot be applied to each country as a whole or to smaller hospitals, and that, among other limitations, they may not have been able to fully segregate women's and infants' risk factors from the risks of surgical intervention. Noting that in this study, as in other research, cesarean delivery was associated with poorer health outcomes for women but with improved neonatal outcomes in cases of abnormal fetal presentation, the researchers suggest that cesarean section be performed only when medically necessary. They urge "women who choose to have caesarean section, and the doctors who recommend the operation with no medical indication...to make that decision with the understanding of the increased risks."

–S. Ramashwar

REFERENCE

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