

# Reducing Infections Among Women Undergoing Cesarean Section in Colombia by Means of Continuous Quality Improvement Methods

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**Background:** Improving obstetric care in resource-limited countries is a major international health priority.

**Objective:** To reduce infection rates after cesarean section by optimizing systems of obstetric care for low-income women in Colombia by means of quality improvement methods.

**Methods:** Multidisciplinary teams in 2 hospitals used simple methods to improve their systems for prescribing and administering perioperative antibiotic prophylaxis. Process indicators were the percentage of women in whom prophylaxis was administered and the percentage of these women in whom it was administered in a timely fashion. The outcome indicator was the surgical site infection rate.

**Results:** Before improvement, prophylaxis was administered to 71% of women in hospital A; 24% received prophylaxis in a timely fashion. Corresponding figures in

hospital B were 36% and 50%. Systems improvements included implementing protocols to administer prophylaxis to all women and increasing the availability of the antibiotic in the operating room. These improvements were associated with increases in overall and timely administration of prophylaxis ( $P < .001$ ) in both hospitals by time series analysis, with adjustment for volume and case mix. After improvement, overall and timely administration of prophylaxis was 95% and 96% in hospital A and 89% and 96% in hospital B. In hospital A, the surgical site infection rate decreased immediately after the improvements ( $P < .001$ ). In hospital B, the infection rate began a downward trend before the improvements that continued after their implementation ( $P = .04$ ).

**Conclusion:** Simple quality improvement methods can be used to optimize obstetric services and improve outcomes of care in resource-limited settings.

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**C**OMPLICATIONS of pregnancy and childbirth are the leading cause of death and disability among women of childbearing age in low- and middle-income countries.<sup>1</sup> The majority of complications are caused by infection, preeclampsia, hemorrhage, and obstructed labor, all of which can be treated in facilities providing emergency obstetric services.<sup>2</sup> Improving the availability, utilization, and quality of these services is a major international public health priority.<sup>3-5</sup>

A number of publications have provided practical tools for evaluating obstetric services and identifying areas for improvement.<sup>6-8</sup> However, these publications offer limited guidance in how to actually improve care. Clinicians need guidance in the process of improvement because systems of patient care are often complex and require multidisciplinary problem solving to achieve meaningful improvement.<sup>9</sup>

There is growing experience in the use of continuous quality improvement (CQI) methods to evaluate and improve systems of patient care in North America and Europe, although conclusive evidence that use of CQI methods has led to improved patient outcomes is limited.<sup>10,11</sup> Nonetheless, the rationale for applying this approach in resource-limited settings is compelling, since it offers the potential to improve systems of patient care and outcomes in the context of existing resources.<sup>12</sup>

This program was conducted in 2 non-profit hospitals providing obstetric care for low-income pregnant women in Bogotá, Colombia. The objective was to reduce the incidence of infection after cesarean section by optimizing systems of care for women by means of CQI methods. The program focused on this objective for several reasons: (1) previous experience in both hospitals indicated that infections after cesarean section (including infections of the surgical incision and endometritis) ac-

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## METHODS

### PARTICIPATING HOSPITALS

The program was conducted in 2 nonprofit hospitals in Bogotá, Colombia, during 1996 to 1998. These hospitals are among the 5 regional obstetric referral hospitals for low-income women in Bogotá and were the first and only hospitals approached for participation in the study for logistic reasons. Both hospitals are university-affiliated, teaching hospitals. Hospital B also serves as a tertiary-care obstetric referral center for women with high-risk pregnancies for the entire metropolitan area and surrounding regions. The study leader was the chief of obstetrics and gynecology in hospital A and the assistant hospital director (who was also a senior obstetrician) in hospital B. The hospital administrations, clinical research committees, and obstetric departments of each hospital approved the program.

### STUDY DESIGN

The study design was a segmented time series analysis of the effect of improvements in systems of care on quantitative process and outcome indicators. Process indicators were defined during the course of the program by means of CQI methods (see "CQI Methods" section below). The outcome indicator was the rate of surgical site infection after cesarean section.

### SURVEILLANCE OF SURGICAL SITE INFECTIONS AFTER CESAREAN SECTION

Surgical site infection after cesarean section was defined according to criteria published by the Centers for Disease Control and Prevention.<sup>15</sup> This definition divides surgical site infections into incisional infections, which are subclassified as superficial or deep incisional infections, and organ/space infections. Endometritis and endomyometritis after cesarean section are included in this definition as organ/space infections.<sup>15</sup>

Active, prospective surveillance of surgical site infections was performed at both hospitals. At hospital A, the obstetrical head nurse and 2 obstetrical residents identified infections during twice-a-day bedside rounds and chart review. The program leader performed an independent validation survey during a 1-month period in 1997 and did not identify any additional infections or any falsely identified infections. At hospital B, 2 infection control nurses identified infections by every-other-day bedside rounds and chart review. This surveillance was performed under the supervision of the infection control head nurse. An obstetrician who was a subspecialist in obstetric infections confirmed the presence of infection in all cases identified by the surveillance nurses and consulted on any questionable cases. Women who were readmitted for complications during the postpartum period were surveyed for infection in both hospitals. Postdischarge surveillance was not performed in either hospital.

Rates of infection were expressed as the number of infections per 100 cesarean sections. Infection rates were presented to clinicians during departmental meetings at least every quarter in both hospitals. At hospital B, surgeon-specific infection rates were also reported confidentially to individual obstetricians and residents.

### OTHER DATA COLLECTION

The number of deliveries per month was obtained from administrative sources. The number of cesarean sections per month was determined by active surveillance. Other data recorded during active surveillance of women undergoing cesarean section were as follows: elective (presence of neither labor nor rupture of membranes) vs nonelective cesarean section (presence of either labor or rupture of membranes), the date and time of delivery, and the use and time of administration of perioperative antibiotic prophylaxis.

### MULTIDISCIPLINARY TEAMS AND CQI TRAINING

The program was supported by the hospital leadership as a demonstration project and was the first organized, interdepartmental CQI project in either hospital. No one in either hospital had previous formal CQI training or experience. Hospital personnel formed multidisciplinary CQI teams containing at least 1 of each of the following personnel: an attending obstetrician, a resident, an obstetric and/or operating room nurse, a pharmacist, and an administrator. The leader of each team was the senior obstetrician. Facilitators with previous training and experience in CQI methods provided training in CQI principles during a 2-day workshop conducted during the second month of the program and "just-in-time" training in the use of CQI tools during the teams' work sessions.

### REVIEW OF THE LITERATURE

Teams reviewed authoritative texts and published reports to identify risk factors for surgical site infections and effective prevention strategies.<sup>13,14,16-27</sup> Electronic literature searches were performed by means of the MEDLINE database (MeSH terms: cesarean section, endometritis, surgical wound infection, cross infection, and infection control). Several team members summarized the literature during the 2-day workshop.

### CQI METHODS

The teams followed the Model for Improvement developed by Nolan and colleagues and applied extensively to health care quality improvement initiatives in the United States.<sup>28-31</sup> The model poses 3 questions. The first question (What are we trying to accomplish?) emphasizes that the team must define a consensus goal for improvement. The second question (How will we know that a change is an improvement?) requires the team to measure outcome indicators (eg, surgical site infection rates) and/or process indicators (eg, the use and timing of perioperative antibiotic prophylaxis). These indicators enable teams to analyze the existing performance of a system of care and to determine whether a change in the system results in performance improvement. The third question (What changes can we make that will result in improvement?) and the accompanying Plan-Do-Study-Act (PDSA) cycle emphasize that the team must design and test changes in systems of care: a change is planned (Plan), it is implemented on a small scale (Do), its effect is evaluated (Study), and, depending on the result, the change is accepted, modified and tested again, or abandoned (Act).

The teams used standard CQI tools to apply this model.<sup>30,32</sup> First, they identified causes of post-cesarean

section infection during a brainstorming session. Then they organized these causes into a cause-and-effect diagram (ie, fishbone or Ishikawa diagram)<sup>32</sup> with 5 major groupings: preexisting host and antenatal factors; complications or adverse events during labor; inappropriate use of perioperative prophylaxis; improper preparation of the skin at the incision site; and surgical risk factors. Teams then used a priority matrix to focus their improvement efforts on causes that were both important and amenable to improvement. Using a semiquantitative scale (1, least; 4, most), they evaluated the importance of each cause and their capacity to address this cause effectively. They also assessed the time frame required for change (short, weeks to several months; medium, several months to 1 or more years; long, several years). The cost of improvement was not ranked separately, but team members considered available resources in determining their rankings.

Using these tools, the teams decided that their consensus goals were to evaluate and optimize the systems for preparing the skin at the incision site and prescribing and administering perioperative antibiotic prophylaxis. Their decisions were based on the importance of these systems in preventing infection and their capacity to improve the systems within a relatively short time with available resources.

In both hospitals, the procedures for preparing the skin were reviewed. No changes were made in hospital A. Hospital B modified its procedure to shave women only as necessary immediately before surgery.

Because their respective systems for prescribing and administering perioperative antimicrobial prophylaxis were more complex, involving multiple steps and different individuals, teams used flow diagrams to describe these systems of care qualitatively (hospital A, **Figure 1**; hospital B, **Figure 2**). They also defined process indicators to evaluate the performance of these systems quantitatively. The process indicators were the percentage of women who received prophylaxis (utilization indicator) and the percentage of women receiving prophylaxis in whom the antibiotic was administered within 1 hour after delivery (timing indicator). Women who received an antibiotic for a suspected or confirmed infection before the cesarean section were excluded from these indicators. The timing indicator was defined as such because most experts and published guidelines recommend administration of the antibiotic after delivery to avoid transfer of antibiotic to the infant via the placenta.<sup>26,27,33</sup> One hour after delivery was used as a practical approximation, although it was recognized that the antibiotic should be administered immediately after umbilical cord clamping.

Teams used these flowcharts to design and test changes in their systems, monitoring the effect of these changes on the process indicators.

#### DATA AND STATISTICAL ANALYSIS

Surveillance data were recorded and analyzed using Epi-Info (version 6.02; USD Inc, Stone Mountain, Ga). In hospital B, the surveillance system was interrupted for 2 months (months 15 and 16) because of a maternity leave. Data from these 2 months are missing from the analysis. Data collection procedures before and after this period were maintained as described previously.

The program was initiated at the same time in both hospitals. The entire program was divided into 3 periods:

the preintervention period (period 1), the first intervention period (period 2), and the second intervention period (period 3). Period 1 was 3 months long in each hospital. The length of periods 2 and 3 were different in the 2 hospitals because the start of each period was defined by the date when major improvements in the system for prescribing and administering antibiotic prophylaxis were undertaken. Period 2 was 7 months long in hospital A and 9 months long in hospital B. Period 3 was 5 months long in hospital A and 12 months long in hospital B.

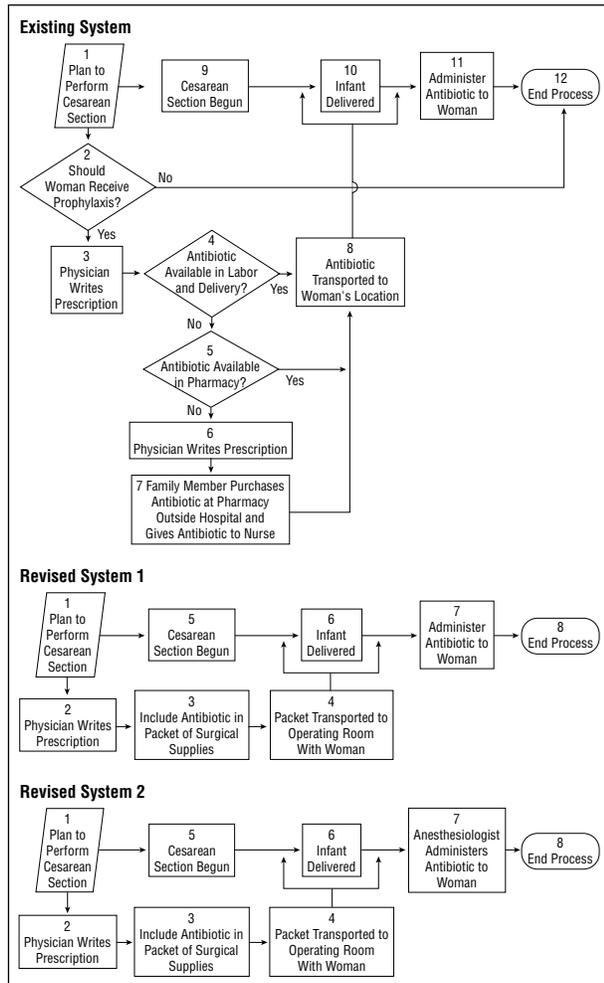
Each delivery was regarded as an independent event because only a small number of women delivered twice during the program.

Time series analysis was performed to determine the effect of the program on monthly process indicator data and surgical site infection rates, adjusting for the effects of time trends in the preintervention period and several covariates.<sup>34,35</sup> Segmented linear regression models were constructed by means of the PROC AUTOREG procedure in the SAS System for Windows (release 6.12; SAS Institute Inc, Cary, NC).

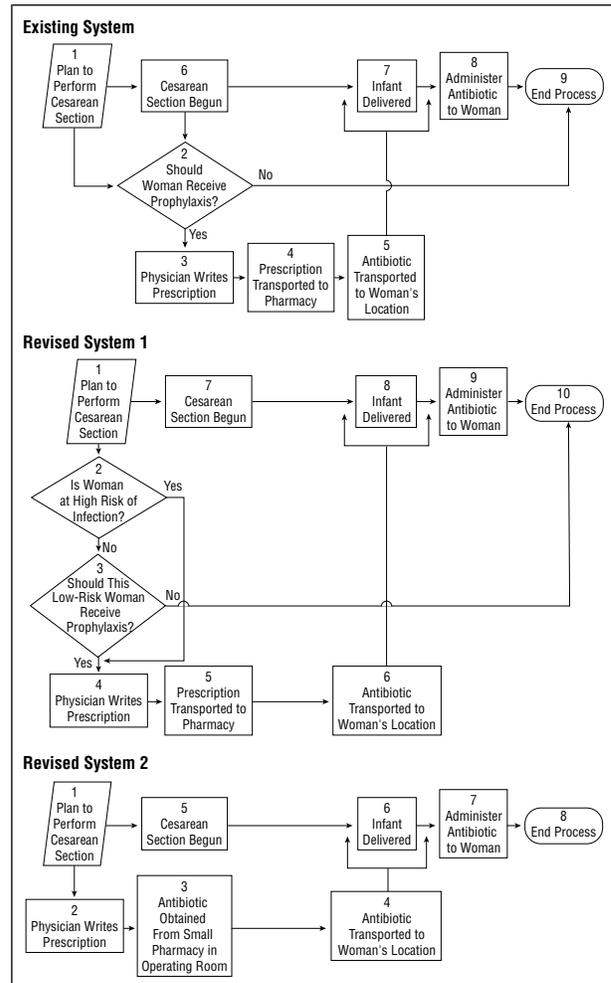
Models contained 3 segments, 1 for each of the program periods. Each segment was described by 2 independent variables (total of 6 variables for the 3 segments). One variable represented the level of the segment (ie, the y-intercept for the first segment and the join points of successive segments) and the second represented the trend (ie, slope) of the segment. A change in the level variable represented an immediate change at the beginning of the period; a change in the trend variable represented a change over time during the period. For example, implementation of a new protocol at the beginning of an intervention period might have an immediate effect on a process indicator (level change), and reinforcement of the protocol through additional staff education may have a progressive effect during the intervention period (trend change).

First-, second-, and third-order autoregressive terms were tested and, if significant, were included in the models to control for autocorrelation. A volume covariate (the total number of deliveries) and two case-mix covariates (the percentage of deliveries by cesarean section and the percentage of cesarean sections that were nonelective) were included in each model. These covariates were included for several reasons. First, the participating hospitals are understaffed and have limited material resources; therefore, large changes in the volume of deliveries could affect care despite improvements in hospital systems. Second, both changes in the characteristics of women presenting for delivery and changes in antepartum care practices that affect the frequency of cesarean section would be reflected in the case-mix covariates. Third, the percentage of cesarean sections that were nonelective is an important covariate in the analysis of surgical site infections to adjust for the presence of labor and rupture of membranes.<sup>14</sup>

Nonsignificant level and trend variables ( $P > .05$ ) were excluded from the models by stepwise backward elimination. Autocorrelation was assessed by means of the Durbin-Watson statistic.<sup>36</sup> The adequacy of each model was tested by standard methods of residual analysis.<sup>37</sup> Models using proportions of dependent and independent variables were compared with models using counts of these variables. Because the 2 approaches yielded nearly identical results and because models using proportions are more easily interpretable, only the latter models are presented.



**Figure 1.** Flow diagram of the existing and revised systems for prescribing and administering perioperative antibiotic prophylaxis at hospital A. The parallelogram is the initiating step in the system, and the rounded rectangle is the end of the system. Diamonds represent decision points; rectangles, actions.



**Figure 2.** Flow diagram of the existing and revised systems for prescribing and administering perioperative antibiotic prophylaxis at hospital B. The parallelogram is the initiating step in the system, and the rounded rectangle is the end of the system. Diamonds represent decision points; rectangles, actions.

counted for the vast majority of postpartum infections; (2) there is a large base of evidence regarding modifiable risk factors and strategies for prevention of these infections<sup>13,14</sup>; and (3) risk-reduction strategies can be implemented effectively by hospital-based programs.

## RESULTS

### VOLUME AND CASE MIX OF DELIVERIES

The volume and case mix of deliveries at hospitals A and B are summarized in **Table 1**. In hospital A, the number of deliveries per month decreased during the program. There was no change in the percentage of deliveries by cesarean section, but the percentage of cesarean sections that were nonelective increased. In hospital B, the number of deliveries per month increased during period 2, then decreased during period 3. The percentage of deliveries by cesarean section increased and the percentage of cesarean sections that were nonelective decreased. Hospital B had a higher percentage

of delivery by cesarean section than did hospital A, probably as a result of its status as a tertiary care obstetrics hospital.

### IMPROVING SYSTEMS FOR PRESCRIBING AND ADMINISTERING PERIOPERATIVE ANTIMICROBIAL PROPHYLAXIS

Monthly data for the process indicators and surgical site infection rates are displayed in **Figure 3** (hospital A) and **Figure 4** (hospital B). Lines in these figures represent the predicted values from the time series models (**Table 2**).

#### Hospital A

In the existing system (Figure 1), each obstetrician made a decision whether to prescribe prophylaxis and which antibiotic to use. Because of problems with the availability of the antibiotic in the labor and delivery unit and the pharmacy, family members were often required to purchase the antibiotic outside the hospital.

**Table 1. Volume and Case Mix of Deliveries in Hospitals A and B**

Period*	Volume of Deliveries		Case Mix of Deliveries	
	Total	Median No./mo	% of Deliveries by Cesarean Section	% of Cesarean Sections That Were Nonelective
<b>Hospital A</b>				
1	920	308	26	74
2	1892	272	23	84
3	1210	217	27	88
<b>Hospital B</b>				
1	1157	396	42	64
2	8236	1026	40	52
3	9474	709	44	47

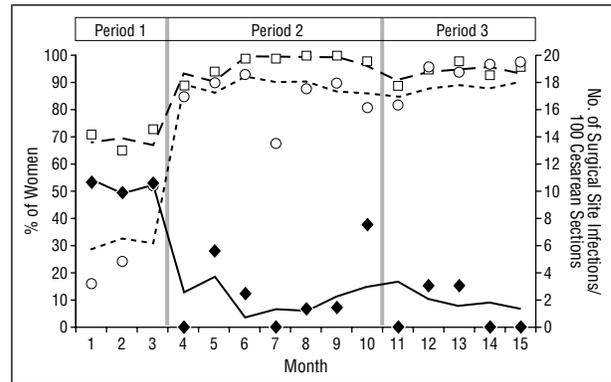
\*In hospital A, periods corresponded to the following program months: 1, months 1 to 3; 2, months 4 to 10; and 3, months 11 to 15. In hospital B, periods corresponded to the following program months: 1, months 1 to 3; 2, months 4 to 12; and 3, months 13 to 24.

During period 1 (Figure 3), the median utilization and timing indicators were 71% (range, 65%-73%) and 24% (range, 16%-52%), respectively. There was an upward trend in the timing indicator during period 1, but this change was not significant (Table 2). Antibiotics prescribed for prophylaxis were cephalothin sodium (67% of regimens), penicillin G potassium (23%), ampicillin sodium (9%), and penicillin and gentamicin sulfate (1%).

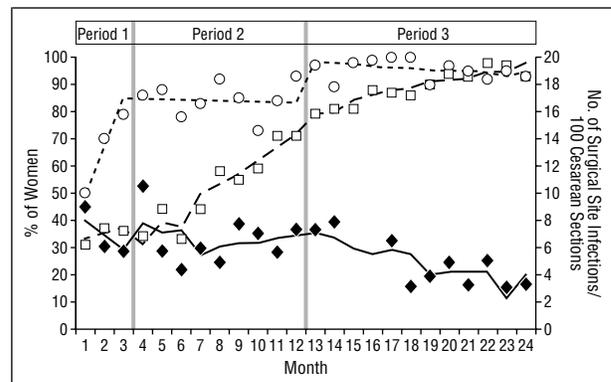
At the beginning of period 2, the department implemented a protocol to routinely administer prophylaxis to all women undergoing cesarean section (Figure 1, revised system 1), on the basis of evidence of the efficacy of perioperative antibiotic prophylaxis presented during the workshop.<sup>26,27</sup> A first-generation cephalosporin was the antibiotic of choice. To improve the availability of the antibiotic, the pharmacy director ensured that an adequate supply of the antibiotic would be maintained on the labor and delivery unit. The head nurse began including a vial of the antibiotic in the package of surgical supplies that was transported with the woman to the operating room.

These changes coincided with immediate increases in the utilization (+31.6;  $P < .001$ ) and timing (+62.2;  $P < .001$ ) indicators (Table 2, Figure 3). Because the timing of antibiotic administration was still suboptimal during period 2, the team reviewed the system again and determined that the responsibility for administering prophylaxis had not been assigned specifically. At the beginning of period 3, the protocol was revised to specify that the anesthesiologist was responsible for administering the antibiotic immediately after umbilical cord clamping (Figure 3, revised system 2). The timing indicator increased during period 3, but this change was not significant. The utilization indicator degraded slightly (-4.9;  $P < .001$ ; Table 2) at the beginning of period 3.

During period 3 (Figure 3), the median utilization and timing indicators were 95% (range, 89%-98%) and 96% (range, 82%-98%), respectively. Antibiotics prescribed for prophylaxis during periods 2 and 3 were cephalothin (98% of regimens), ampicillin (1%), and penicillin (<1%). The median time of administration was 5 minutes after delivery (interquartile range, 0-23 minutes).



**Figure 3.** Utilization and timing of perioperative antibiotic prophylaxis and surgical site infection rates after cesarean section at hospital A. Open squares represent the utilization indicator (percentage of women undergoing cesarean section who received perioperative antibiotic prophylaxis) and are plotted on the left y-axis. Open circles represent the timing indicator (percentage of women receiving prophylaxis in whom the antibiotic was administered within 1 hour of delivery) and are plotted on the left y-axis. Solid diamonds represent the surgical site infection rate after cesarean section and are plotted on the right y-axis. The hatched, dashed, and solid lines represent the predicted values for the utilization indicator, the timing indicator, and the surgical site infection rate after cesarean section, respectively, as determined by the segmented linear regression models (Table 2). Period 1 was a baseline period. Periods 2 and 3 were successive intervention periods (see the "CQI Methods" subsection of the "Methods" section for a description of the interventions).



**Figure 4.** Utilization and timing of perioperative antibiotic prophylaxis and surgical site infection rates after cesarean section at hospital B. Open squares represent the utilization indicator (percentage of women undergoing cesarean section who received perioperative antibiotic prophylaxis) and are plotted on the left y-axis. Open circles represent the timing indicator (percentage of women receiving prophylaxis in whom the antibiotic was administered within 1 hour of delivery) and are plotted on the left y-axis. Solid diamonds represent the surgical site infection rate after cesarean section and are plotted on the right y-axis. The hatched, dashed, and solid lines represent the predicted values for the utilization indicator, the timing indicator, and the surgical site infection rate after cesarean section, respectively, as determined by the segmented linear regression models (Table 2). Period 1 was a baseline period. Periods 2 and 3 were successive intervention periods (see the "CQI Methods" subsection of the "Methods" section for a description of the interventions).

### Hospital B

As in hospital A, in the existing system each obstetrician made a decision about whether to prescribe prophylaxis and which antibiotic to use (Figure 4). This decision was made in the operating room immediately before, during, or after the procedure. Because a written prescription was required, administration of the antibiotic was delayed if the decision to prescribe prophylaxis

**Table 2. Segmented Linear Regression Models of Process Indicators for Perioperative Antibiotic Prophylaxis and Surgical Site Infection Rates After Cesarean Section in Hospitals A and B**

Variables*	Hospital A			Hospital B		
	Process Indicators		Surgical Site Infection Rate§	Process Indicators		Surgical Site Infection Rate§
	Utilization†	Timing‡		Utilization†	Timing‡	
Period 1 variables						
Level (intercept)	47.5 ± 9.6	32.5 ± 67.2	13.9 ± 13.3	5.1 ± 14.3	30.8 ± 16.2	17.8 ± 5.8
Trend	NS	NS	NS	NS	18.4 ± 2.8 ( <i>P</i> < .001)	-0.1 ± 0.1 ( <i>P</i> = .042)
Period 2 variables						
Change in level vs period 1	31.6 ± 1.3 ( <i>P</i> < .001)	62.2 ± 10.6 ( <i>P</i> < .001)	-9.8 ± 2.1 ( <i>P</i> < .001)	NS	NS	NS
Change in trend vs period 1	NS¶	NS	NS	5.4 ± 0.7 ( <i>P</i> < .001)	-18.7 ± 2.8 ( <i>P</i> < .001)	NS
Period 3 variables						
Change in level vs period 2	-4.9 ± 0.9 ( <i>P</i> < .001)	NS	NS	7.1 ± 3.3 ( <i>P</i> = .047)	15.2 ± 3.1 ( <i>P</i> < .001)	NS
Change in trend vs period 2	NS	NS	NS	-4.1 ± 1.1 ( <i>P</i> = .001)	NS	NS

\*Variables listed were included in each model along with first-, second-, and third-order autoregressive terms and the following covariates: the number of deliveries, the percentage of deliveries by cesarean section, and the percentage of cesarean sections that were nonelective. Nonsignificant level and trend variables (*P* > .05) were excluded by backward elimination. Parameter estimates plus or minus their SEs are displayed for level and trend variables remaining in the final model (parameter estimates for covariates not shown).

†Percentage of women undergoing cesarean section who received prophylaxis.

‡Percentage of women receiving prophylaxis in whom it was administered within 1 hour of delivery.

§Number of surgical site infections per 100 cesarean sections.

||In hospital A, periods corresponded to the following program months: 1, months 1 to 3; 2, months 4 to 10; and 3, months 11 to 15. In hospital B, periods corresponded to the following program months: 1, months 1 to 3; 2, months 4 to 12; and 3, months 13 to 24.

¶NS indicates not significant.

was made during or after the procedure. Further delays were incurred if transport of the prescription to the pharmacy or transport of the antibiotic back to the operating room was slow.

During period 1 (Figure 4), the median utilization and timing indicators were 36% (range, 31%-37%) and 70% (range, 50%-79%), respectively. The timing indicator had a significant upward trend during period 1 (Table 2). Antibiotics prescribed for prophylaxis were cephalothin (71% of regimens), ampicillin (27%), clindamycin plus gentamicin (1%), and penicillin plus metronidazole (1%). More than 1 dose of antibiotic was prescribed in 41% of regimens.

At the beginning of period 2, the department developed a prophylaxis protocol (Figure 2, revised system 1) requiring use of prophylaxis for high-risk women only (women undergoing a nonelective cesarean section or women with diabetes, preeclampsia, or other medical conditions). It encouraged use of prophylaxis for low-risk women, but allowed obstetricians to make their own decisions in this regard. A first-generation cephalothin or ampicillin was the antibiotic of choice. The protocol specified that the prescription should be written at the time of the decision to perform a cesarean section to allow sufficient time to obtain the antibiotic from the pharmacy.

The utilization indicator for all women increased gradually during period 2 (+5.4 per month; *P* < .001; Table 2, Figure 4). This rate of increase was nearly identical among high-risk and low-risk women (data not shown), and further review of the data showed that one third of high-risk women undergoing cesarean section had not received prophylaxis. The experiences of teams at both hospitals were discussed at a joint meeting, where hospital A presented

its protocol for prophylaxis of all women and its preliminary data suggesting that infection rates had decreased during period 2 (Figure 3). The upward trend in the timing indicator that began during period 1 in hospital B was not sustained during period 2 (Figure 4, Table 2).

At the beginning of period 3, hospital B revised its protocol to require use of prophylaxis for all women (Figure 4, revised system 2). In addition, a small pharmacy was established in the operating room to dispense medications for patients undergoing surgical procedures, including cesarean section.

These changes coincided with immediate increases in the utilization (+7.1; *P* = .047) and timing (+15.2; *P* < .001) indicators (Table 2, Figure 4). The upward trend in the utilization indicator continued during period 3, although at a lesser slope.

During period 3 (Figure 4), the median utilization and timing indicators were 89% (range, 79%-98%) and 96% (range, 89%-100%), respectively. Antibiotics prescribed for prophylaxis were ampicillin (67% of regimens), cephalothin (31%), clindamycin (2%), and others (<1%). One dose of antibiotic was prescribed in 93% of the regimens. The median time of administration was 5 minutes after delivery (interquartile range, 0-10 minutes).

#### REDUCTIONS IN SURGICAL SITE INFECTION RATES

In hospital A (Figure 3), the median surgical site infection rate was 10.5 per 100 cesarean sections (range, 9.9-10.7) during period 1, 1.4 (range, 0-7.6) during period 2, and 0 (range, 0-3.0) during period 3. There was a large

immediate decrease at the beginning of period 2 (−9.8 infections per 100 cesarean sections;  $P < .001$ ; Table 2). In hospital B (Figure 4), the median surgical site infection rate was 6.1 per 100 cesarean sections (range, 5.7–9.9) during period 1, 5.9 (range, 4.3–10.6) during period 2, and 4.4 (range, 3.1–7.9) during period 3. A downward trend began during period 1 and continued through periods 2 and 3 (−0.1 infection per 100 cesarean sections per month;  $P = .042$ ; Table 2).

## COMMENT

This study demonstrates that multidisciplinary hospital quality improvement teams can improve patient care systems and clinical outcomes for women undergoing childbirth in resource-limited settings.

The significance of this work extends beyond optimizing perioperative antibiotic prophylaxis for women undergoing cesarean section. Guidelines for the evaluation of obstetric services in low- and middle-income countries have been distributed widely,<sup>6–8</sup> yet examples of how these guidelines have been used to improve obstetric care are limited.<sup>38,39</sup> Moreover, there is little information about the actual process of improvement that clinicians should use in optimizing care in their own hospitals or clinics. This program illustrates how a general method for multidisciplinary teamwork and systems analysis can be used to translate evidence-based guidelines into improved patient care.

The key to the teams' success was their ability to analyze and improve systems of care. This focus on systems has been termed "the key organizing concept for an effective approach to improvement."<sup>40</sup> While problems with the existing systems in each hospital seemed idiosyncratic, they are representative of systems problems in all health care settings. According to the schema of the Institute of Medicine's National Roundtable on Health Care Quality,<sup>41</sup> these problems included underuse (eg, prophylaxis was underutilized), misuse (eg, less effective antibiotics were used and the administration of the antibiotic was delayed), and overuse (eg, too many doses of antibiotic prophylaxis were used). These problems are often seen in systems that are complex and that involve multiple individuals and a series of interdependent steps occurring over time in different locations. As was seen in this program, improving these systems requires qualitative and quantitative analysis, multidisciplinary problem solving, and often several rounds of changes before improvement goals are met. In this program, the active leadership of physicians and the opportunity for the teams to share their experiences also likely contributed to their success.<sup>42,43</sup>

It was not the purpose of the study to compare the effectiveness of specific changes in systems of care, nor was this appropriate given the study design. Indeed, Berwick<sup>44</sup> has argued against such an approach, instead advocating use of rapid-cycle tests of small-scale changes (ie, the PDSA cycle) and evaluating these changes in terms of their contribution toward reaching an overall goal. Nonetheless, a few interinstitutional comparisons are relevant. Improvement in the utilization of prophylaxis was rapid in hospital A, where a protocol requiring use of prophylaxis for all women undergoing cesarean section was

implemented immediately. In contrast, improvement occurred more slowly in hospital B, where a protocol was implemented initially that required each obstetrician to decide whether a woman was at high risk or low risk for infection and mandated prophylaxis only for high-risk women. Hospital B ultimately implemented a protocol for universal prophylaxis, because antibiotic utilization remained suboptimal with the initial approach and the knowledge that the universal prophylaxis approach in hospital A appeared to be lowering its infection rate. Both approaches were defensible by means of the literature available at the time,<sup>26,27,45</sup> although a recent meta-analysis supports universal prophylaxis.<sup>46</sup> Systems improvements designed to increase the efficiency of antibiotic administration also differed in each hospital, although both had a positive effect. However, one could argue that the establishment of a small pharmacy in the operating suite of hospital B was a more permanent change that will also benefit patients undergoing other surgical procedures. Although their specific paths to improvement differed, the fact that both hospitals achieved their goals is a powerful example of the benefits of collaborative organizational learning and improvement advocated by quality improvement experts.<sup>40,43,47</sup>

To guide their work, the teams used a CQI model, commonly referred to as the Model for Improvement developed by Nolan and colleagues. Several CQI models have been used to improve clinical practice,<sup>28,48</sup> but the Model has gained widespread acceptance in the United States, in part because of its use by the Institute for Healthcare Improvement in its Breakthrough Series.<sup>31,40,49</sup> The Model is appealing because it helps teams focus on an important, achievable goal; use valid data to gauge improvement; and design, implement, and evaluate rapid-cycle tests of changes in systems, a process akin to the scientific method of experimentation. The Breakthrough Series has used this model to assist groups of hospitals to optimally apply evidence-based interventions by enabling them to exchange information and learn from each other's successes and failures.<sup>31,40,49</sup> The teams applied the Model and a collaborative learning approach in hospitals where personnel had no previous formal training in CQI principles or methods, demonstrating that broad-based training programs in CQI "culture" are not a prerequisite for meaningful improvement. Instead, just-in-time training, use of simple CQI tools, and facilitation by experienced individuals enabled the teams to complete their work. While this approach was sufficient for this demonstration project, more complex CQI initiatives involving chronic multisystem diseases, collaboration among many departments, or diverse care settings may require a greater up-front investment in the infrastructure and support for CQI.

Other international projects are using CQI methods to improve the quality of health care in low-resource settings.<sup>50–54</sup> To our knowledge, this is the first report that has linked the use of well-defined CQI methods with improvements in care practices and patient outcomes in resource-limited settings.

The resource requirements of the program were modest. Surveillance of infections, collection of other data, and data entry and analysis were performed by hospital personnel largely during the course of routine nosocomial in-

fection surveillance mandated by existing hospital policies and governmental regulations. Multidisciplinary team meetings were usually held as a part of previously scheduled departmental meetings. With support from a modest extramural grant, individuals with CQI experience provided training and guidance in CQI methods to team members. The cost-effectiveness of the perioperative antibiotic prophylaxis for cesarean section has been documented extensively,<sup>45,55</sup> and the actual antibiotics used (cephalothin and ampicillin) are relatively inexpensive (approximately \$1.50 for each 1-g dose).

The study had several limitations. First, there was no control group to evaluate whether changes that were independent of the teams' activities affected care practices or infection rates. Given the program's focus on improving hospital systems, it was impossible to identify a suitable control group within the same hospital. For logistical and ethical reasons, it was difficult to use control hospitals in which process indicators and surgical site infection rates were measured but no systems improvements were implemented. Nonetheless, our analysis controlled for important threats to internal validity, such as the effects of time trends in the preintervention period and changes in important covariates. No effort was made during the program to change the management of labor or prolonged rupture of membranes, and surgical techniques and obstetrician characteristics (eg, number and responsibilities of staff and resident obstetricians) remained constant. Consequently, these factors are not likely to have affected our results substantially.

Second, feedback of process and outcome data to physicians and nurses in the obstetrics departments was an integral part of the program and may have had an effect independent of the systems changes implemented by the teams (ie, a Hawthorne effect). In addition, the 2-day workshop was held in the latter part of the preintervention period (period 1) and may have affected the practices of some participants, even though changes in systems of care had not yet occurred.

Third, the relatively small number of observations during the preintervention period may have overestimated or underestimated preexisting trends in the process indicator and surgical site infection data. While it would have been helpful to have a longer preintervention period, it was not possible to collect data retrospectively, because relevant data were not recorded reliably in patient medical charts. A longer preintervention period would have also increased the likelihood of contamination of the preintervention period as described above. Nonetheless, in this case, the short preintervention period appears to have biased our estimates of effects of the systems improvements toward the null.

Finally, postdischarge surveillance of infections was not performed, although women readmitted to the hospital during the postpartum period were surveyed for evidence of infection. The number of infections occurring after discharge that did not require readmission was likely to be relatively constant, because there was little variation in the length of stay after cesarean section in either hospital during the course of the program.

Although a recent meta-analysis concluded that a first-generation cephalosporin or ampicillin is an adequate pro-

phylactic agent,<sup>56</sup> the increasing prevalence of antimicrobial resistance among bacteria causing surgical site infections may lead some to question whether these antibiotics are still adequate for prophylaxis. In addition, wider use of prophylaxis may conceivably increase the prevalence of antimicrobial resistance. Although these are legitimate concerns, they are unsubstantiated at present.

Childbirth is a leading reason for hospitalization in most low- and middle-income countries,<sup>57</sup> so programs to improve the quality of obstetric care have broad-based importance. Although this program focused on the prevention of surgical site infection after cesarean section, its methods could be used to improve other critical aspects of obstetric care, such as the management of obstructed labor, identification and management of preeclampsia, and prevention and management of postpartum hemorrhage. Data from the Centers for Disease Control and Prevention indicate that 73% of women undergoing cesarean section in the United States from 1994 to 1999 received perioperative antibiotic prophylaxis (Teresa C. Horan, MPH, written communication, July 24, 2001). Use of these methods could also increase the use of antibiotic prophylaxis and potentially lower infection rates after cesarean section in the United States.

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