Mandatory second opinion to reduce rates of unnecessary caesarean sections in Latin America: a cluster randomised controlled trial

Fernando Althabe, José M Belizán, José Villar, Sophie Alexander, Eduardo Bergel, Silvina Ramos, Mariana Romero, Allan Donner, Gunilla Lindmark, Ana Langer, Ubaldo Farnot, José G Cecatti, Guillermo Carroli, Edgar Kestler, for the Latin American Caesarean Section Study Group

Summary

Background Latin America has a high rate of caesarean sections. We tested the hypothesis that a hospital policy of mandatory second opinion, based on the best existing scientific evidence, reduces the hospital caesarean section rate by 25%, without increasing maternal and perinatal morbidity and mortality.

Methods 36 hospitals in Argentina (18), Brazil (eight), Cuba (four), Guatemala (two), and Mexico (four), were randomly assigned to intervention or control in a matched pair design. All physicians in the intervention hospitals deciding a non-emergency caesarean section had to follow a policy of mandatory second opinion. The primary outcome was the overall caesarean section rate in the hospitals after a 6-month implementation period. We also assessed women's satisfaction with labour and delivery care and physicians' acceptance of the second opinion policy.

Findings A total of 34 hospitals attending 149 276 deliveries were randomised and completed the protocol. The mandatory second opinion policy was associated with a small but significant reduction in rates of caesarean section (relative rate reduction 7·3%; 95% CI 0·2–14·5), mostly in intrapartum sections (12·6%; 0·6–24·7). Other maternal and neonatal outcomes and women's perceptions and satisfaction with the process of care were similarly distributed between the groups.

Interpretation In hospitals applying this policy of second opinion, 22 intrapartum caesarean sections could be prevented per 1000 deliveries, without affecting maternal or perinatal morbidity, and without affecting mothers' satisfaction with the care process.

Lancet 2004; **363:** 1934–40
See Commentary page 1921

Latin American Center for Perinatology, Pan American Health Organization, WHO, Montevideo, Uruguay (F Althabe MD, J M Belizán MD, E Bergel MSc)**; UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development, and Research Training in Human Reproduction, Department of Reproductive Health and Research, WHO, Geneva, Switzerland** (J Villar MD)**; Ecole de Santé Publique, Université Libre de Bruxelles, Brussels, Belgium** (S Alexander MD)**; Center for the Study of State and Society, Buenos Aires, Argentina** (S Ramos PhD, M Romero MD)**; Department of Epidemiology and Biostatistics. University of Western Ontario, London, Canada** (A Donner PhD)**; Department of Obstetrics and Gynaecology, University of Uppsala, Sweden** (G Lindmark MD)**; Population Council, Regional Office for Latin America and the Caribbean, Mexico City, Mexico** (A Langer MD)**; Hospital Gineco-Obstétrico "América Arias", Havana, Cuba** (U Farnot MD)**; Center of Studies in Maternal and Child Health of Campinas, University of Campinas, Brazil** (J G Cecatti MD)**; Centro Rosarino de Estudios Perinatales (CREP), Rosario, Argentina** (G Carroli MD)**; and Epidemiological Research Center in Reproductive and Sexual Health, Guatemala City, Guatemala** (E Kestler MD)

Correspondence to: Dr Fernando Althabe, Latin American Center for Perinatology, Hospital de Clínicas, Av Italia s/n Casilla de Correos 627, Montevideo 11000, Uruguay
(e-mail: althabef@clap.ops-oms.org)

Introduction

Over the past 30 years, a rise in the incidence of caesarean section has been noted.[1–6] Latin America is probably the region with the highest caesarean section rate—25–30% of all deliveries.[7] Although strategies to reduce caesarean section rates have been proposed[8,9] very few have been assessed through randomised controlled trials, and none have been done in Latin America.

A mandatory second opinion given to the attending obstetrician at the moment of the indication of non-emergency caesarean section could potentially reduce the rate of unnecessary operations. This strategy has been shown to be effective in two non-randomised intervention studies, in Chicago, USA, more than a decade ago,[10] and in one hospital in Quito, Ecuador, in 1996.[11] Such a policy could influence a physician's decision to perform a caesarean section through different mechanisms: case discussion, provision of support and reassurance by a peer, perception of being audited, and incorporation of evidence-based pregnancy and delivery care through a clinical guidelines component. An intervention based on similar rationale, a joint consultation between physicians in the context of general practice, has been proven effective to reduce referrals and diagnostic procedures, and to modify treatments.[12,13]

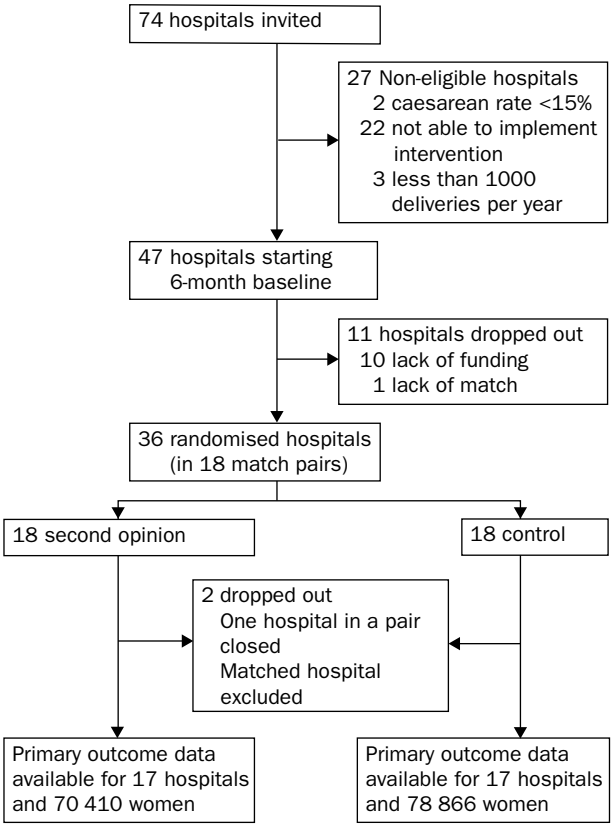
We present the results of a cluster randomised trial to test the hypothesis that a mandatory second opinion for non-emergency caesarean sections given by another obstetrician who has the same or higher clinical status than the attending physician, following protocols based on the best existing scientific evidence, reduces caesarean section rates by 25% without increasing perinatal morbidity and mortality.

Methods

Trial design and participants

The study was a multicentre cluster randomised controlled trial. Hospitals were eligible if they had a baseline caesarean section rate of 15% or greater, more than 1000 deliveries per year, and were able to implement the protocol clinical guidelines. Of the 74 hospitals contacted, 47 met the inclusion criteria and began a 6-month period of baseline data collection. 36 of these hospitals completed the baseline period (18 in Argentina, eight in Brazil, four in Cuba, two in Guatemala, and four in Mexico) and were randomised (figure). Hospitals were matched by country, type of hospital (public, private or social security), and baseline caesarean section rate (15–20%, 21–35%, or

For personal use. Only reproduce with permission from The Lancet.



Trial profile

>35%), and the paired units were randomly assigned to intervention or control. The matching of the hospitals and their randomisation were independently done in the statistical unit of the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction, WHO in Geneva, Switzerland, with SAS statistical software.[15]

All decisions to undertake caesarean sections (either elective or intrapartum) in intervention hospitals were eligible for a mandatory second opinion, except if the woman specifically refused to be seen by a second doctor or the situation was an extreme emergency such as maternal haemorrhage, cord prolapse, suspected uterine rupture, or any situation where the attending physician judged that a delay would constitute malpractice.

The trial was implemented between October, 1998, and June, 2000, and co-ordinated by the Latin American Center for Perinatology in Montevideo, Uruguay, together with the Rosario Center for Perinatal Studies in Rosario, Argentina. The component in which physicians' and women's opinions were assessed was co-ordinated by the Center for the Study of State and Society in Buenos Aires, Argentina.

There were three study periods: first, 6 months for baseline data collection and trial preparation, immediately followed by randomisation; a second period of 1 month for training the staff at hospitals randomised as intervention units; and a third period of 6 months during which the second opinion policy was implemented and assessed.

To ensure that all hospitals had the same baseline knowledge about, and access to, evidence-based information on pregnancy and delivery care, a formal seminar was carried out before randomisation in the selected hospitals using the WHO Reproductive Health Library[14] as a source of evidence-based interventions for pregnancy and delivery care.

To determine the appropriate sample size, we did a survey before the trial in 23 Latin American hospitals to obtain data about caesarean section (mean rate 18·9%, SD 5·1; unpublished data). On the basis of these data we assumed an average caesarean section rate in the control group of 20% with estimated SD 5·1. Standard sample size calculations show that a total of 17 hospitals in each group would provide 80% power for detecting a reduction from a mean rate of 20% to 15% at the two-sided 5% level. Since we judged that it would be difficult to assess the expected effect of matching in advance, the matching was ignored in these calculations.[16] This is a conservative approach that ignores the gain in precision likely to be achieved from matching.

The protocol was approved by the scientific and ethical review group of the UNDP/UNFPA/WHO/World Bank Special Programme on Research, Development, and Research Training in Human Reproduction, the WHO Committee for Research into Human Subjects, and the institutional review boards or corresponding authorities of the 36 participating centres. No informed consent was sought from individuals, because the intervention was a policy change at the hospital level, control hospitals would not alter their usual practices, and no individual data were to be obtained. The hospital directors acted as ethical guarantors of the trial.[17] Information for patients about the trial was given only at the intervention hospitals in the form of informative posters explaining how caesarean sections were decided at the hospital during the trial period. In Cuba, for a trial of labour in women with a previous caesarean section (which was included in the present study), signed consent was required. Women and professionals were asked to give informed consent for the women's and physicians' survey.

Procedures

The intervention consisted of the implementation of a policy of mandatory second opinion at the hospitals assigned to the intervention group. Second opinion was to be sought by the attending physician systematically before caesarean section. The attending physician had professional status to fully act independently at the hospital, therefore residents were not considered as attending physicians for this trial. The physician providing the second opinion had to be a person with clinical qualifications equal to or higher than those of the attending physician, working at the same hospital, selected by the obstetrics department for this trial, and who had agreed to follow the clinical guidelines. A physician could have the role of attending physician on some days and consultant on others.

To assess the clinical case, the consultant followed guidelines prepared as decision flowcharts, for six primary indications for caesarean section. Each guideline had suggestions about how to deal with the problem that originated the indication. Both physicians discussed the case in relation to the guidelines. After this process, the attending physician made the final decision. The guidelines were made available for all physicians at intervention hospitals.

We developed the evidence-based guidelines for reviewing caesarean section indications. Guidelines for dystocia, intrapartum fetal distress, previous caesarean section, and breech presentation had the format of decision-making flowcharts. For other maternal and fetal indications we provided general recommendations. A seventh guideline for "other indications" was also developed for causes not included in the main six (ie, maternal request).

For personal use. Only reproduce with permission from The Lancet.

	Intervention hospitals (n=18)	Control hospitals (n=18)
Country*		
Argentina	9 (1287 [537–3656])	9 (1312 [633–5894])
Brazil	4 (2667 [1291–3011])	4 (1772 [674–2745])
Cuba	2 (2399 [1934–2863])	2 (1471 [999–1943])
Guatemala	1 (6551)	1 (2736)
Mexico	2 (3718 [3123–4313])	2 (3741 [3413–4068])
Type of hospital		
Public or non-profit	16	16
Social security	2	2
Residency programmes	15	15
Resources available		
Cardiotocograph	12	11
Fetal scalp blood pH determination	0	0

Data are number of hospitals. *Median (range) number of deliveries during 6-month baseline period stated in parentheses.

Table 1: **Baseline characteristics of randomised hospitals**

We were interested in assessing whether the mandatory second opinion policy was effective under routine obstetrical practice conditions; therefore, strategies to improve compliance with the intervention were left to the decision of each hospital co-ordinator.[18] We did not formally assess compliance with the second opinion. Some indication of compliance was obtained by noting the proportion of non-emergency sections that went through a second opinion process.

During the 13 months, clinical outcomes were recorded and individual second opinion forms were collected. A simple data collection system was elaborated, using routine data from the hospital logbooks, a method that has shown low levels of errors.[19] On a daily and monthly basis, a summary of deliveries was noted on an aggregate data form, which was sent to the co-ordinating centre. Data quality was checked by random comparisons of the trial forms corresponding to 50 deliveries with photocopies of the logbooks.

The primary outcome was caesarean section rate, defined as the number of caesarean sections divided by the total number of deliveries. The rate of elective and intrapartum caesarean sections as well as the rate of caesarean sections by cause were secondary outcomes. Other maternal outcomes were maternal admission to intensive care unit, maternal stay in hospital for more than 3 days, and maternal mortality. Perinatal outcomes were perinatal mortality, and neonatal admission to intensive care unit for more than 1 day.

The number of second opinions in the intervention group and the number of second opinions in which the consultant disagreed with the attending physician were the main process outcomes. Among those second opinions in which disagreement existed, we also recorded the number of cases in which the attending physician changed the initial decision to undertake a caesarean section.

	Intervention group (17 hospitals, 34 735 women)	Control group (17 hospitals, 39 175 women)
Primiparous women	37·8 (8·6)	33·5 (8·4)
Previous caesarean section	13·5 (5·5)	13·8 (5·0)
Caesarean section		
Total	26·3 (9·4)	24·6 (7·6)
Elective	8·9 (4·4)	9·1 (5·4)
Intrapartum	17·4 (9·2)	15·4 (7·2)
Low birthweight	10·7 (4·5)	10·5 (4·4)
Macrosomic infants	5·9 (2·3)	3·5 (2·5)
Stillbirths	1·6 (0·8)	1·6 (0·9)
Neonatal mortality	1·1 (0·6)	1·1 (1·1)
Neonatal admission to ICU for more than 1 day	8·4 (4·4)	3·1 6·7)

Data are mean (SD) of rates for all hospitals in group (n=17).

Table 2: **Baseline characteristics of mothers and neonates during 6 months before randomisation**

At the end of the study, we did a survey to assess women's satisfaction with the quality of care and acceptability of the process, and the acceptability of the second opinion strategy among the physicians and their opinion about the feasibility of its application in public and private hospitals. We surveyed women at hospitals in both trial arms; women at intervention hospitals who, having been prescribed a caesarean section, received a second opinion, regardless of the type of delivery they finally had; and women at control hospitals, whose pregnancies ended in a non-emergency caesarean section. A semi-structured questionnaire was used by a specially trained interviewer during postpartum hospital stay, to interview all consecutive eligible women who gave birth during the fifth month of the intervention period and agreed to participate with signed informed consent.

The physicians' survey was self-administered, and was distributed after the end of the trial to all physicians who worked in the intervention arm.

Statistical analysis

The primary outcome was expressed as the mean rate difference between groups (with 95% CI). This value was measured as the difference between matched hospitals (intervention hospital minus control hospital) in caesarean section rate change (caesarean section rate in the intervention period minus caesarean section rate in the baseline period). Negative percentages indicate lower rates of caesarean section in the intervention group, adjusted for baseline rates. A one-sample two sided *t* test was used to assess whether the mean rate difference between groups was statistically different from zero. A nonparametric permutation test[16] was also used with an exact p value computed using the R statistical package.[20] Since the *t* test and the permutation test provided very similar results, only the results for the *t* test are reported. Finally, we investigated the consistency of the intervention effect over the 17 pairs with a sign test. For secondary outcomes we followed the same approach. To adjust the mean rate difference in caesarean sections between groups for variables that showed some residual imbalance after pair-matching, a multiple linear regression model was used, with the rate difference between matched hospitals as the dependent variable and variables with baseline differences between groups as the independent variables. Adjusted inferences for the effect of the intervention were estimated by calculating the intercept of the resulting regression equation and comparing it to its estimated standard error.[21] A secondary analysis prespecified in the protocol was used to test whether the effect of the intervention increased according to increasing baseline caesarean rates. A linear regression model with the effect size as the dependent variable and the average baseline caesarean rate for each pair as the independent variable was fitted to test whether the effect size increased with increasing baseline caesarean rate.

For the women's survey, the main outcome was the mean rate of responses of all women interviewed in both groups of hospitals. For the physicians' survey, we report the rate of positive answers in the intervention group.

Role of the funding source

The funding sources had no involvement in the study design, collection, analysis, and interpretation of data, in the writing of the report, or in the decision to submit the paper for publication, except for the participation of the WHO staff.

For personal use. Only reproduce with permission from The Lancet.

	Intervention hospitals (17 hospitals)			Control hospitals (17 hospitals)			Difference between matched hospitals		
	Mean baseline rate (34 735 women)	Mean follow-up rate (35 675 women)	Mean rate change*	Mean baseline rate (39 175 women)	Mean follow-up rate (39 638 women)	Mean rate change*	Mean difference in rate change (95% CI)†	Relative rate reduction‡	p
All	26·3	24·7	–1·6	24·6	24·9	0·3	–1·9 (–3·8 to –0·1)	7·3	0·044
Elective	8·9	9·1	0·1	9·1	9·0	–0·1	0·2 (–1·4 to 1·8)	–2·1	0·808
Intrapartum	17·4	15·6	–1·8	15·4	15·9	0·4	–2·2 (–4·3 to –0·1)	12·6	0·041
By indication									
Dystocia	6·3	5·1	–1·3	4·9	4·9	0·0	–1·3 (–2·0 to –0·5)	20·2	0·002
Fetal distress§	4·3	3·4	–1·0	3·1	3·1	0·0	–0·9 (–1·9 to –0·0)	21·6	0·048
Previous caesarean section	7·0	7·1	0·1	7·8	7·7	–0·1	0·2 (0·7 to 1·2)	–3·0	0·636
Breech	2·4	2·3	–0·1	2·5	2·3	–0·2	0·2 (–0·2 to 0·5)	–6·8	0·376
Maternal indication	2·3	2·2	–0·1	1·8	2·4	0·7	–0·7 (–1·4 to –0·1)	28·8	0·034
Emergencies	1·2	1·3	0·1	1·2	1·3	0·1	0·0 (–0·5 to 0·4)	0·5	0·977
Other	2·9	3·4	0·5	3·3	3·2	–0·1	0·6 (–0·5 to 1·8)	–21·8	0·274

*Follow-up rate–baseline rate. †Rate change in intervention group–rate change in control. ‡(Mean follow-up rate intervention/mean follow-up rate control)/(mean baseline rate intervention/mean basline rate control). §Intrapartum fetal distress.

Table 3: **Effect of second opinion policy on caesarean section rates**

Results

36 hospitals initiated the trial. One hospital closed after randomisation and therefore the hospital with which it was matched was also excluded. 34 hospitals and 149 276 women completed the study. Baseline characteristics were mostly similar between hospitals in the two groups (table 1). However, at baseline the proportion of primiparous women and the intrapartum caesarean section rate were higher in the intervention group than in the control group (table 2).

The second opinion policy was associated with a small but significant reduction in rates of caesarean section (mean difference in caesarean section rate change between groups: –1·9%; 95% CI –3·8 to –0·1; p=0·044; relative rate reduction [RRR] 7·3%; 0·2 to 14·5). Among the 17 pairs of hospitals, a reduced caesarean section rate was observed in 13 pairs (sign test p value=0·049).

Secondary analysis by elective and intrapartum sections, defined a priori, showed that the effect of the second opinion policy on reduction of caesarean rates was concentrated in intrapartum sections. There was a –2·2% difference in intrapartum caesarean section rates, compared with no change in elective caesarean section rates (table 3). This value represents an RRR of 12·6% (95% CI 0·6–24·7). When stratified by indication, the effect was concentrated among intrapartum dystocia and intrapartum fetal distress (table 3). There was some residual group imbalance after pair-matching with respect to the proportion of primiparous women and the proportion of women with operative vaginal deliveries and macrosomic infants. Adjustment for these differences resulted in an increase in the estimated effect size (adjusted absolute rate reduction –2·9; 95% CI –5·8 to 0·1, p=0·054).

The intervention and control groups were similar in terms of maternal and perinatal mortality and indicators of morbidity (table 4). There was no trend in the effect of the intervention according to the baseline caesarean rate of the hospitals pairs (test for trend p=0·86).

Data validations comparing the caesarean section rates from trial forms with those from hospital logbooks for the follow-up period resulted in a median error rate of 0 (IQR –1·2 to 0·2) at intervention hospitals, and 0 (–0·05 to 2·1) at control hospitals.

During the intervention period, in the intervention group there were a total of 9019 caesarean sections, from which 8583 were non-emergency caesarean sections, eligible for a second opinion. Table 5 shows the number of second opinions during the intervention period, according to the indication for caesarean sections. There were 7518 second opinions; thus, the second opinion process was implemented in 88% of the non-emergency caesarean sections. Most (96%) of the consultants agreed with the attending physician, and only 117 (1·5%) second opinions led to the initial decision for a caesarean section being changed (table 5). None of the control hospitals adopted a mandatory policy of second opinion during the study period.

From the 36 hospitals that initiated the trial, two did not participate in the women's survey. One hospital closed and a second declined participation, and therefore their pairs were excluded from this analysis. A total of 3497

	Intervention hospitals (17 hospitals)			Control hospitals (17 hospitals)			Difference between matched hospitals		
	Mean baseline rate (34 735 women)	Mean follow-up rate (35 675 women)	Mean rate change*	Mean baseline rate (39 175 women)	Mean follow-up rate (39 638 women)	Mean rate change*	Mean difference in rate change (95% CI)†	Relative rate reduction‡	p
Newborn									
Stillbirths	1·6	1·7	0·1	1·6	1·9	0·3	–0·1 (–0·6 to 0·3)	7·2	0·513
Neonatal mortality	1·1	0·9	–0·2	1·1	1·0	–0·1	–0·1 (–0·4 to 0·3)	6·5	0·756
Perinatal mortality	2·6	2·4	–0·2	2·8	2·9	0·2	–0·3 (–1·0 to 0·3)	11·8	0·273
Neonatal admission to ICU for more than 1 day	8·4	8·0	–0·5	8·1	8·3	0·2	–0·7 (–2·1 to 0·8)	8·0	0·340
Maternal									
Operative vaginal deliveries	4·4	4·9	0·5	2·8	3·4	0·6	–0·1 (–1·4 to 1·2)	7·9	0·850
Maternal postpartum admission to ICU or referral	0·7	0·9	0·2	0·4	0·6	0·2	0·0 (–0·4 to 0·4)	11·3	0·979
Maternal death§	3·2	4·3		5·9	7·5				

ICU=intensive care unit. *Follow-up rate–baseline rate. †Rate change in intervention group–rate change in control. ‡Mean follow-up rate intervention/mean follow-up rate control)/mean baseline rate control. §Rate per 10 000 livebirths.

Table 4: **Effect of second opinion policy on maternal and perinatal outcomes**

For personal use. Only reproduce with permission from The Lancet.

	n (%)
Number of second opinions	
Total	8583
Missing data	758
Total with valid data	7518 (100%)
By type of guideline	
Dystocia	1113 (14·8%)
Intrapartum fetal distress	825 (11·0%)
Previous caesarean section	2335 (31·1%)
Breech presentation	732 (9·7%)
Maternal indications	881 (11·7%)
Fetal indications	722 (9·6%)
Other indications	916 (12·2%)
Attitudes of consultants and consulting physicians	
Did the consultant agree or disagree with the initial indication of caesarean section made by the consulting physician?	
Agreed	7218 (96·0%)
Disagreed	300 (4·0%)
If the consultant disagreed, did the consulting physician change his initial indication of caesarean section for another intervention?	
Yes	117 (1·5%)
No	183 (2·4%)

Table 5: **Second opinion process**

women in 32 hospitals were invited and agreed to answer the questionnaire (1512 in intervention group and 1975 in the control group). Women in the intervention and control groups were similar with respect to their age (mean age 25·3 years, 26·4 years, respectively), years of education (mean 8·0 years, 8·0 years), and parity (proportion of primiparous women 38·1%, 37·3%). The effect of the intervention on women's perceptions and satisfaction with the process of care is shown in table 6. More women in the second opinion group than in the control group were told or had seen that their cases had been consulted with another physician (58·6% *vs* 47·8%), but the difference was not statistically significant. About 90% of women in each group felt favourable towards the fact that their physician discussed their case with another professional. Most women in both groups said that they would return to the same hospital to deliver another baby (87·9% *vs* 87·0%) or would recommend the hospital to other pregnant women (91·2% *vs* 93·2%).

The questionnaire for assessing physicians' acceptability of the second opinion was answered by 339 physicians at the intervention hospitals, from a total eligible population of 367 physicians. 188 (54%) physicians judged that the second opinion was "effective" or "very effective" in reducing caesarean sections, before the results were available; 294 (87%) thought that the second opinion was a feasible strategy to apply in public hospitals, and 140 (41%) thought it feasible to apply in private hospitals. Finally, 307 (91%) of the physicians said that they would recommend use of the second opinion in public hospitals, and 219 (65%) said they would recommend use of the strategy in private hospitals.

Discussion

We have shown that a policy of mandatory second opinion before a caesarean section is associated with a small overall reduction in rates of caesarean section. For every 1000 deliveries in a hospital applying this second opinion policy, 20 caesarean sections were prevented, without affecting maternal or perinatal morbidity, or the mothers' satisfaction with the care process. A strength of the pragmatic approach used in this trial is that the results are probably very close to those that could be observed in Latin American public hospitals under routine conditions.

The second opinion intervention did not achieve the 25% reduction in caesarean section rates judged clinically important in our hypothesis. One probable explanation is that the intervention was not powerful enough to change physicians' attitudes towards indications for caesarean section. The high agreement between attending physicians and consultants (96%), and the fact that only 1·5% of the second opinions led to changes in the initial indication of caesarean section lend support to this conclusion.

Another possible explanation is that the intervention was not correctly implemented. Although the estimated compliance was high (88% of the non-emergency caesarean sections went through a second opinion process), some of the consultants might have implemented the intervention superficially as an administrative process rather than as a careful assessment of the caesarean section indications. Because of the pragmatic approach we adopted in the trial we do not have a detailed assessment of the second opinion process to better explain the observed results.

Although the observed effect was less than that postulated, we noted a significant relative reduction of 7·3% in the rate of caesarean section at the intervention hospitals. This effect was concentrated in intrapartum caesarean sections, in which caesarean sections for dystocia and fetal distress presented a relative reduction of 20·2% and 21·6%, respectively. A probable explanation for these exploratory findings is that the guidelines for dystocia and fetal distress indications to be followed in the second opinion process included two kinds of steps: first, confirmation or re-definition of the diagnosis of the entity; and, second, alternatives for management in case the diagnosis was confirmed. Thus, the reduction in caesarean sections for dystocia and fetal distress could have been achieved through either a change in the diagnosis or in the treatment of both entities. The guidelines for the other

	Mean rate		Mean rate difference (95% CI)*	p
	Intervention hospitals (16 hospitals, 1512 women)	Control hospitals (16 hospitals, 1975 women)		
Text of questions				
(A) Did someone tell you that he was going to consult with another physician to decide if a caesarean section was indicated in your case? (B) Have you seen your physician consulting your case with someone else? (proportion of women answering "Yes" to questions [A] or [B])	58·6	47·8	10·8 (–4·3 to 25·9)	0·15
(C) How did you feel about the fact that your physician discussed your case with another professional? (proportions of women answering "Better")*†	90·1	89·9	0·3 (–7·1 to 7·6)	0·94
(D) If in the future you became pregnant again, would you attend this hospital? (proportion of women answering "Yes")	87·9	87·0	0·9 (–2·9 to 4·7)	0·63
(E) Would you recommend this hospital to other pregnant women? (proportions of women answering "Yes")	91·2	93·2	–2·0 (–7·8 to 3·8)	0·46

*Two hospital pairs had missing values for all participants (279 women in control group and 272 women in intervention group). †This question was asked only if questions (A) or (B) were answered "Yes".

Table 6: **Effect of the second opinion policy on women's preferences and satisfaction with care process**

For personal use. Only reproduce with permission from The Lancet.

caesarean section indications included mainly alternatives for treatment, since most of the diagnoses are straightforward and do not involve the use of technology or subjective interpretations (ie, previous caesarean section, breech presentation, preterm birth, pre-eclampsia). Changing treatments for some specific conditions (ie, caesarean section for fetal distress) is usually more difficult than changing their diagnosis; treatments are frequently supported by explicit guidelines, whereas the diagnosis of some conditions rely on subjective assessments of the attendants (ie, fetal distress or dystocia).

The intervention most probably worked by reducing the diagnosis of dystocia and fetal distress, more than changing the indication of caesarean section for confirmed entities. We think that the reduction in the diagnosis was achieved mainly through changes in the behaviour of attending physicians, who indicated fewer sections for dystocia and fetal distress, than by changes on caesarean section indications after a second opinion process. This assumption is supported by the high rate of agreement noted between attending physicians and consultants. In view of the absence of effect on overall elective caesarean section, we think that at least part of the observed reduction in caesarean section for maternal indications could be a change in the indication to other categories (ie, other indications category), rather than a true reduction.

The intervention was well accepted by both women and physicians. More women in the second opinion group than controls realised that their situation was consulted with another physician, although we cannot exclude chance as an explanation. Most women felt better with the idea of a second opinion, and no differences were observed between the study groups. 91% of the physicians on the intervention hospitals would recommend the mandatory second opinion to be used in public institutions, if it was proven effective at the expected level. We do not know the physicians' reactions to the observed magnitude of effect.

The observed small relative reduction in caesarean section rates in hospitals with baseline rates lower than 21% was similar to that in hospitals with baseline rates greater than 35%, suggesting that the intervention could be implemented with similar results in different settings, irrespective of the physicians' attitudes towards caesarean section. Only public hospitals participated in the trial, but the effect of the intervention might be larger or at least similar in private hospitals, assuming a similar rate of compliance, since doctors work alone more frequently in private settings and may be more in need of support and reassurance by peers. Furthermore, a higher agreement rate between attending physicians and consultants than that observed in public hospitals is unlikely.

The implementation of a mandatory second opinion policy in public hospitals on an indication of intrapartum caesarean section could prevent 22 caesarean sections for every 1000 women in labour without harmful effects on the baby or the mother. Moreover, this intervention is well accepted by pregnant women and attending physicians. Hospital staff and policy makers should judge whether the magnitude of the effect justifies the efforts and financial implications of implementing such a policy, and make recommendations on the basis of this analysis. To reduce unnecessary elective caesarean sections, stronger strategies have to be identified and assessed in other randomised controlled trials. The definition of which caesarean sections are unnecessary and should be prevented is still under debate in the obstetric community.

The Latin American caesarean section study group
Steering committee—J Belizán, S Alexander, J Villar, F Althabe, G Lindmark, A Donner, G Breart, P Buekens (until 1998).
Trial co-ordinating unit—J Belizán (principal investigator), S Alexander (co-principal investigator) F Althabe (trial coordinator), J Chaure (data manager), P Taillades (trial administrator), M Amespiel (administrative assistant), M Loubriat (administrative assistant).
Statistical support—E Bergel, A Donner, G Piaggio.
Guidelines development group—F Althabe, S Alexander, G Lindmark, M Boulvain, G Tomasso, C Sosa, J C Iglesias (graph designer).
Countries' co-ordinating teams—Argentina: G Carroli (country co-ordinator), O Althabe (regional co-ordinator), A Blake (regional co-ordinator), M A Casares (regional co-ordinator), A M Bonotti (data supervisor), J C Belmonte (data supervisor), M Belizán (data supervisor); *Brazil:* A Faundes (country co-ordinator), J G Cecatti (regional co-ordinator and data supervisor); *Cuba:* U Farnot (country co-ordinator), J Vázquez (regional co-ordinator), J C Vázquez (regional co-ordinator), E Díaz (data supervisor); *Guatemala:* E Kestler (country co-ordinator), L Ramírez (data supervisor); *Mexico:* A Langer (country co-ordinator), P Sanhueza (assistant co-ordinator), M E Reyes (data supervisor), S Reynoso (data supervisor).
Participating hospitals and staff—Argentina: M C Frers Campos, G Finkelstein, E Tcherskanski, S D Silvia Cenci, R Scrigmar, G Rey, M Zarlenga, S L Zellez, S De Vincenci, M Suárez, G Bruno, I Chajnik, S Méndez Arriondo, D Espeche, J Azar, F Soriano, M Bentancour, L Otegui, G Willnecker, V Villaverde, M Cristeff (Hospital Bocalandro); M Pesaresi, A Karolinski, J C Nassif, E Balbi, L Campos, S Hermosid, J M Baier, I Stasi, R Garfagnini, R Aberazturiz, E Kupman, P Gimenez, A Albarracín, A Figueroa, A Umana, C Tabusso, M L Sueldo, R Zlatkes, H Rozenblum, T Di Pietro (Hospital Durand); A Casavilla, S Lipovesky, M C Vazquez, R Fernández, V H Pichel, L Azzarini, V Sivo, M Murolo, A Spat, N Martínez, M E Brey, E S Milano (Hospital Equiza); M A Albanesse, J Arellano, J Rodríguez Kisner, C Colombo, G Gorbeña, N Güerini, E Cattaneo, M Plana, P Pelegrin, D De la Cruz, H Picone, A Giurgiovich, R Ibáñez, L Martínez, R Mendez, C Catalano, C Magnoni (Hospital Evita Pueblo); F Casavilla (h), R Beltrame, J O Azar, A M Andreis, A Barbitta, C Berra, J C Castillo, O De Luca, J Ferrari, M A Ferro, G Gasquet, R Martínez Viademonte, C Mastrogiovanni, C Miracca, JC Moreno, V Torres Cristina, T Torres Mendoza, M Sitzer, A Villar, E Zanardi (Hospital Germani); G Manetti, M E Afonso, M Katez, E Kreimer, V Caligiuri, O Aizpeolea, F Mezzattesta, A S Capaldo (Hospital Belgrano); M Palermo, J A Ferreiros, D Montes Varela, M G Beroiz, A Monaco, F Franze, S Trillo, M Damiano, C Girollet, J Salatino, M Gentile, A Pereyra, M Esteban, J Mignolo, A Lachter, C Colasurdo, M Quinones, G Martínez, S Wizenberg, M Melis, M Censori, M Rosmino, P Leonino, M Trabuco, C Siamarella, A Gradia, F Arrizurieta, D Alfonzo, M Turconi, S Lucero, S Medina, M Contrera, M Etchegaray, V Pantano, R Casale, E Lijdens, S Gamarino, C Ramos, M Salvo, C Frias (Hospital Posadas); J L Castaldi, J M Boughen, S Ranielli, M C Monti, D Listingart, S Mendoza, A Terrizi, M E Sánchez Bejarano, L Schulman, M Bajo, R Esterkin, N Romero, H Nardi, A Espinosa, M Scenna, C Labrousse, M Bertin, G Rodríguez, E Boiza, A M Zyla, G Scabuzzo, J Boccia, D Cachiarelli, J Straguadagno, S Gasparini, Y Partida, E Ayala, M I Carballo, S A Perelló (Hospital Penna); C Taboada, C Donatti, C Gregoris, S Pirillo, P Gourdin, J Seoane, J Campos Cossio, M Rodríguez, H Cabeza Jerez, S Zambrini, O Desbouts, C A Pérez, S M Romero (Hospital Virgen del Carmen); J Anton, J E Dos Santos Lopez, W Choclin, G Lopez Rendón, S Cirelli, F Sarchi, A De Mattia, G Lioy, P Ponssa, M De Diego, A Miersejewsky, J L Mousatche, C Vittori, A Chait, M Chmielewski, M Maffi, V Selva, U Menechian, M Laboski, L Pedotti, C Bridgiotti (Hospital Heroes de Malvinas); S Amenabar, M F Reina, M A Brizuela, C Brito, M B Miranda, J D Martín, C Sosa Piñero, V Cagna, F Zelada Zurita, P Alcorta, J Nuñez, A Ahumada, S Bernedo Lopez, N Capua, A Bunader, E Cárdenas Carpio, H Ciaravino, R Carrapizo, R Chahla, A Cocimano, E Franco, E Fonio, C Majul, V Guzmán, M Perez Gorena, L Jalil, P Rojas Tomás, G Martinez Ribó, C Sancho Miñano, M Ríos, J Rodriguez, M Romano, L Roqué, M A Raya, M Valdez, M Mazzamuto, S Forneris, S Ortega Ancasi, N Cioccolani, J Charubi, P Sabeh, N Rossi, A Diaz Montivero, A Montes, M Diaz Montivero, E Soria, M Marenchino, R Carrizo, E Esquivel, S Nieto, A Agote, J E Mecle, S Khozameh, A Gonzalez, J C Medina, S Patton, E Hurtado, N Papa, R Gutierrez, C Valdez, M G Castro, M Gonzalez (Maternidad Nuestra Señora de las Mercedes); W Barbato, S Busquets, M Cabral, F Candio, R Di Mónaco, A Dimarco, J Garro, C Maciel, H Martínez, P Perfumo, G Renzi, O Schmück, J C Singeresky, M Torres (Hospital Centenario); G J Baccifava, M V Baraldi, A C Ceballos, C G Cevallos, S Dayub, E De la Mata, R Feldman, F Fernández Ramos, L García, W F García, P Giommarini, G Guerschanick, J E Klingler, O M López, E C Ludmer, A M Nasazzi, M Osta, M R Raffagnini, C Solís, N Tisera, M E Ventura, A H Veraldi, S Zanuttini (Hospital R Saenz Peña); E Abalos, M C Abello, I Alcácer, D Barrera, N F Burgueño, N Cabrejas, C Cañavate, S Carbognani, A Carrizo, G Carroli, H Constanti, G Covián, D Crosta, E Di Orio, J Elder, A Golatto, R Gorina, E Guzmán, A Leroux, G Lombarte, J Malamud, M Marchetti, K Martínez, M Meneghini, C Nardin, J C Nardin, C Páez, V Pantoja, S Parfait, G Paz, F Pérez Machado, M Perotti, J L Rivas, L Sáenz de Vicuña, G Sinópoli, C Vigetti, D Villeco, C Zaffora, E Zanuttini, A Golatto, F Burgueño (Maternidad Martin); M A Casares, S Paco Leaños (Maternidad Provincial de Salta); M V Martínez de Riquelme, J Muñoz (Maternidad de Jujuy); E M Morales, J D Aguirre, L E Ayala, J G Acosta (Hospital Vidal);

For personal use. Only reproduce with permission from The Lancet.

S Elizalde Cremonte †, M A Elizalde Cremonte, S Elizalde Cremonte, M Miranda (Hospital Llanos). *Brazil:* M A Parpinelli, J L Pinto e Silva, J G Cecatti, J C Gama da Silva, R Passini Jr, B G Pereira, H M B Milanez, A Bacha, E Amaral, R Knobel, F G C Surita, E C Couto, H Sabatino, R Zaccaria, M L Nomura (Maternidade CAISM-UNICAMP); C Mariani Neto, M M A Aquino, R E F Cury (Hospital e Maternidade Leonor Mendes de Barros); G L Acácio, G Baggio (Hospital Universitário de Taubaté); I M P Calderón, M Rudge, J C Peraçoli, J Abade, R A A Costa, V T M Borges, I Maestá, M Consoni (Hospital da Faculdade de Medicina de Botucatu); L C Santos, E Campelo (Instituto Materno Infantil de Pernambuco); F J Galvão Neto, M C C Batista, A M L Souza, C H Nascimento, C J Fonseca, C A L Beltrão, C N B Albuquerque, C F Araújo, C M R Ferreira, D C Araújo, D L Campos, D M M Silva, E A Gomes, F B Borba, H C F Rosenthal, H M V Brito, I G O Magalhães, I Cavalcanti, J Sother Filho, L A França, M C M Soares, M F Borba, M F S Nascimento, M C M Paula, M S S Ribas, M I P Tenório, M I A Dubeux, M L D Souza, M L O Barros, M L Lima, M M A Widmer, M M V Pinto, M S C Almeida, M Carvalho, N N S Souza, N B Cavalcanti, O N P Batista, R M F Castro, R S L Pessoa, R B Almeida, R M Silva, R H C Lima, S F N Marques, T Correia Jr, V M M Sena, W P Freire (Hospital Barão de Lucena); S Freire, C B Santos (Hospital das Clínicas da Universidade Federal de Pernambuco); F Rebelo, M Vanderlei (Hospital Barros Lima). *Cuba*: S Candelario, M Llanes, J Requena, A Rodríguez, R Pérez, C Peñate, L Román, G Hernández, A Martínez, G Valle, J Piñera, S Valdés, N Cendán (Hospital América Arias); V Saez, A. Rodríguez, J Cabrera, A Peseira, M Figueroa, L Ortuzar, C Ortiz, J Pérez, E Castro, N Pérez, C Guzmán, N Pérez, T Gutiérrez (Hospital Clodomira Acosta); M P García, L Fernández, J García (Hospital Maternidad 10 de octubre); N Sánchez, S Porto, A Méndez (Hospital Gozález Coro). *Guatemala:* H I Vanegas, N O Pelaez, S Bonilla, J A López, M J Aguirre, J E De León (Hospital Dr. Juan José Arévalo Bermejo); M Lobos, L H Araujo, A H Dardón (Hospital de Gineco Obstetricia). *Mexico:* R Gutiérrez Vega, J E Motta Martínez, G Rojo Herrera, G Oropeza Rechy, S Romero Hernández, M T Méndez Gómez, A Velasquillo Hernández, F Zarama Márquez, J Otañez Rodríguez (Hospital General de Mexico); S Fuentes Aguirre, E E Cuervo Vite, M A Flores Salinas, Dr César Sosa Perea, M Escalante Rovina, M Chong Rodríguez, A Chávez Reyes, J M Flores Gómez, R Ruiz Salinas, O Pérez Hernández, A Reyes Cansino, J Areno Hernández, P Valdespino Soria, M Casillas Barrera, A Valle Rodríguez, J Ríos Tapia, LV Morelos Vizcaya, I Romero Gamiz, J Chávez Brambila, H Jiménez Guillén, R Sánchez Téllez, G Ortega González, J M Hilton Cáceres, M A Padilla Franco, J Rodríguez de Santiago, D Martínez Becerra, P Aragón Sulik, J H Morales Serrato, F González Martínez, L Corona Neri, H Morales Pacheco, R Rodríguez Guerrero, J T Morales Ferreto, M Landeta García, J J Bautista García (Hospital Materno Infantil Inguarán); R A Real Gómez, E J Parra Pelcastre, A Ortíz Vázquez, L M Bedia Sánchez, M E Martínez Azuela, R Pineda Lara, S Fuentes Esquinca, L F Chaires Vela, C Mejía Villarreal, E Pérez Figueroa, E Ortíz Campos, N Jiménez Martínez, E Yescas Gómez, O R García Sánchez, J M Flores Gómez, P Robledo Rodríguez, J J Martínez Rodríguez, J Carpinteyro Astorga, J M Buxade y Pérez, R Macías Belmon, C Sosa Perea, M J Hernández Fierro, H López Gutiérrez, S Jiménez Arana, C F Ramírez González, N Lechuga Villegas, A Rivera Serrano, S Zavala Ramírez, R Ruiz Salinas, P Franco Coops, D Delgadillo Vera, A Beltrán Oseguera (Hospital Magdalena de las Salinas); A T Medina, R Martínez Aguirre Dr Eduardo Navarro Oviedo, S Gutiérrez Jaimes, J González Bracamontes, D Hernández Arcos, F Hernández Alemán, G García Gaytán, B Escalona Almazán, R Marín López, A Rosey Reyes, M C Enríquez Miranda, JA Ramírez Calvo, V Espíndola Núñez, M I García Argueta, R Flores Morales, A Alaniz Sánchez, M G Pérez Ramírez, H Guillén Soldevilla, M Arzate Delgado, F Álvarez Sánchez, A Hernández Mendoza, R Marín López, G Ortega Rojas, E González Mejía (Hospital Tlatelolco).

Women's and physicians' assessment group—S Ramos (principal investigator), M Romero (associate researcher), L Acosta (statistician), E A Pantelides (consultant).

Argentina: M Romero (country co-ordinator), D Szulik (assistant researcher), M Belizán (field co-ordinator, Rosario), E Ayala, C Pérez, C Frías, M Cristeff, E Zanardi, E Milano, C Bringiotti, A Francesconi, N Candia, L Pedotti, E G Chilali, N L Ramírez, G Ramírez, M Brizuela, G Romeo (interviewers). *Brazil:* M J Osis (country co-ordinator), E Pontual Santos, G Alves Duarte, K Simonia de Pádua, R H Pedrosa Monteiro, T Rodrigues de Souza (field co-ordinators), C Barros Santos, E Pontual Santos, E Bertanha Consonni, F da Costa Ribeiro, I M Rodrigues, L H Xavier de Lima, L Alves Moreira, M C Furtado Lancia, M de Melo Leoni, N Satie Toyofuku, R H Pedrosa Monteiro, T T Scudeller Prevedel, V Serra de Moraes (interviewers). *Cuba:* G Rojas (country co-ordinator and interviewer), Y Puiseaux Himely, C Pérez Cárdenas, E Fuentes Pérez, M Quintana Suárez (interviewers). *Guatemala:* S Saenz de Tejada (country co-ordinator and interviewer), G García, M de Castillo (interviewers). *Mexico:* A Castro (country co-ordinator), A M Martínez Barajas, A E Quiróz Almaraz, J Santiesteban García, M L Cano, S Valdez Velazco, M G Sanchez Antillón, A Heimburger (interviewers).

Contributors

J Belizán and J Villar had the original idea and designed the first protocol. S Alexander and F Althabe, wrote the final protocol in collaboration with J Belizán and J Villar. F Althabe prepared manuals and guidelines, in collaboration with S Alexander, G Lindmark, A Langer, U Farnot, J G Cecatti, G Carroli, and E Kestler. F Althabe, with the support of J Belizán, J Villar, and S Alexander, co-ordinated the overall execution of the study. A Langer, U Farnot, J G Cecatti, G Carroli, and E Kestler co-ordinated the implementation of the study at country level. E Bergel wrote the plan of analysis in collaboration with A Donner, and did the statistical analysis in collaboration with A Donner and F Althabe. F Althabe, J Belizán, Eduardo Bergel, S Alexander, and J Villar wrote the paper with input from all authors, especially A Donner. S Ramos and M Romero, in collaboration with F Althabe, J Belizán, and J Villar, wrote the protocol for the women's and physicians' assessment, and did the corresponding analysis.

Conflict of interest statement

None declared.

Acknowledgments

We thank all midwives and nurses working at the participating hospitals, all women and babies who attended those hospitals, and R Mercer for the support to the trial in Argentina. The clinical trial was funded by the European Union, the Pan American Health Organization (PAHO/WHO), and by the UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction of WHO, which also funded the women's and physicians' assessment component. This component was also supported by the Research Support Fund of São Paulo State, Brazil. Additional funding was provided by the Maternal and Infant Programme, Buenos Aires, Argentina; the Population Council—Regional Office for Latin America and the Caribbean; the Epidemiological Research Center in Reproductive and Sexual Health, Guatemala; and the Center of Studies in Maternal and Child Health of Campinas, Brazil.

References

1 Wolfe S. Unnecessary caesarean sections: curing a national epidemic. *Public Citizen Health Research Group* 1994; **10:** 1–7.
2 Faúndes A, Cecatti JG. Which policy for caesarian sections in Brazil? An analysis of trends and consequences. *Health Policy Plan* 1993; **8:** 33–42.
3 Barros FC, Vaughan JP, Victora CG, Huttly SRA. Epidemic of caesarean sections in Brazil. *Lancet* 1991; **338:** 167–69.
4 Murray SF, Serani Pradenas F. Caesarean birth trends in Chile, 1986 to 1994. *Birth* 1997; **24:** 258–63.
5 Notzon FC, Cnattingius S, Bergsjö P, et al. Caesarean section delivery in the 1980s: international comparison by indication. *Am J Obstet Gynecol* 1994; **170:** 495–504.
6 Ballacci F, Medda E, Pinnelli A, Spinelli A. Caesarean delivery in Italy: a European record. *Epidemiol Prev* 1996; **20:** 105–06.
7 Belizán JM, Althabe F, Barros FC, Alexander S. Rates and implications of caesarean section in Latin America: ecological study. *BMJ* 1999; **319:** 1397–400.
8 Kristensen MO, Hedegaard M, Secher NJ. Can the use of caesarean section be regulated? A review of methods and results. *Acta Obstet Gynecol Scand* 1998; **77:** 951–60.
9 Walker R, Turnbull, D, Wilkinson C. Strategies to address global caesarean section rates: a review of the evidence. *Birth* 2002; **29:** 28–39.
10 Myers SA, Gleicher N. A successful program to lower caesarean-section rates. *N Engl J Med* 1988; **319:** 1511–16.
11 Sloan NL, Pinto E, Calle A, Langer A, Winikoff B, Fassihian G. Reduction of the caesarean delivery rate in Ecuador. *Int J Gynaecol Obstet* 2000; **69:** 229–36.
12 Vierhout WP, Knottnerus JA, van OOij A, et al. Effectiveness of joint consultation sessions of general practitioners and orthopaedic surgeons for locomotor-system disorders. *Lancet* 1995; **346:** 990–94.
13 Vlek JF, Vierhout WP, Knottnerus JA, et al. A randomised controlled trial of joint consultations with general practitioners and cardiologists in primary care. *Br J Gen Pract* 2003; **53:** 108–12.
14 WHO. Department of Reproductive Health and Research, UNDP/UNFPA/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction. The WHO Reproductive Health Library No 1. Geneva: World Health Organization, 1998.
15 SAS Institute, SAS Release 6, Cary, North Carolina, 1997.
16 Sprent P. Applied nonparametric statistical methods. 2nd edn. London: Chapman and Hall, 1993.
17 Edwards SJL, Braunholtz DA, Lilford RJ, Stevens AJ. Ethical issues in the design and conduct of cluster randomised controlled trials. *BMJ* 1999; **318:** 1407–09.
18 Ross S, Counsell CE, Gillespie WJ, et al. Factors that limit the number, progress, and quality of randomised controlled trials: a systematic review. In: Stevens A, Abrams K, Brazier J, Fitzpatrick R, Lilford R, eds. The advanced handbook of methods in evidence based healthcare. London: SAGE Publications, 2001; 38–55.
19 Chez RA, Hill VS, Lowry LW. Logbook data as a source of birth information. Are they valid? *J Reprod Med* 1997; **42:** 658–62.
20 R Development Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing, Vienna, Austria, 2003. http://www.R-project.org (accessed Feb 16, 2004).
21 Donner A, Klar N. Design and analysis of cluster randomization trials in health research. London: Arnold Pub Co, 2000.

For personal use. Only reproduce with permission from The Lancet.