Non-clinical interventions for reducing unnecessary caesarean section

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1. INTRODUCTION

Unnecessary caesarean sections are those which are done without there being a medical indication. Consequences of unnecessary caesarean sections are of two types: (i) iatrogenic maternal and neonatal morbidity and mortality; and (ii) increased costs for the health system and for the household in settings where there is no social protection. The latter is of particular importance in middle- and low-income countries where catastrophic expenditures can occur following a caesarean section. In high-income countries, where a maternal death is a rare event, the relative risk of a mother dying from caesarean section compared with death during vaginal delivery was 2.8 [95% CI, 1.9?4.4] in United Kingdom, as reported in the 2000?2003 Report of Confidential Enquiries into Maternal Deaths (1). In a multi-country facility-based survey (WHO Global Survey on Maternal and Perinatal Health), which used a stratified multistage cluster sampling design to obtain a sample of countries and health institutions worldwide, Souza et al. showed that, compared with spontaneous vaginal delivery, all other modes of delivery were associated with an increased risk of death, admission to intensive care unit, blood transfusion and hysterectomy, including antepartum caesarean section without medical indications [adjusted odds ratio (Adj OR) 5.93, 95% confidence interval (CI) 3.88?9.05] and intrapartum caesarean section without medical indications (Adj OR 14.29 [95% CI, 10.91?18.72]. In addition, this association was stronger in Africa, compared with Asia and Latin America (2). Clearly, caesarean deliveries, even in mothers with no underlying medical issues, can be life-threatening (3). The present Cochrane review (4) aimed to evaluate the effectiveness and safety of non-clinical interventions for reducing unnecessary caesarean sections.

2. METHODS OF THE REVIEW

The reviewers considered non-clinical interventions as policy-related interventions and sought to evaluate interventions targeting three main groups: (i) pregnant women and their families; (ii) health-care providers who work with expectant mothers; and (iii) communities and advocacy groups. The review authors grouped
non-clinical interventions applied to eligible participants aimed at reducing unnecessary caesarean section rates as follows: (i) patient-directed interventions; (ii) professionals, including education, audit and feedback, practice guidelines; (iii) organizational (e.g. quality improvement strategies); (iv) financial (e.g. incentives for certain procedures); and (v) regulatory (e.g. mandatory second opinions).

The division between non-clinical and clinical interventions made by the authors is debatable. For instance prenatal classes by a midwife is classified in this review as non-clinical while continuous support during labour by a midwife or a lay person is considered as a clinical intervention. But both have the same objective: supporting the mother to reduce stress (by answering to her questions, giving tips on how to breath, how to move during labour pain, etc.). The cut-off point between the two are not so obvious. Internal peer review and mandatory secondary opinion are also considered as non-clinical strategies by the authors, but a secondary opinion is one step in the clinical decision to perform a caesarean or not. Hence, the theoretical categorizations made in this review do not seem to be optimal.

The reviewers' selection criteria included randomized controlled trials (RCTs), quasi-experimental studies, controlled clinical trials (CCTs), controlled before-and-after studies (CBAs) with at least two intervention sites and two control sites, and interrupted time series analyses (ITS) in which the intervention time was clearly defined and there were at least three data points before and three after the intervention.

Two primary outcomes were measured: the rate of caesarean section and the rate of unnecessary caesarean section. Three types of secondary outcome were analysed: (i) maternal and fetal or neonatal complications; (ii) costs and financial benefits noted from the change in procedures rates; and (iii) patient and provider satisfaction. Studies that reported only secondary or “other” outcomes, but not the primary outcomes, were excluded.

The reviewers searched the Cochrane Effective Practice and Organisation of Care (EPOC) Group Specialised Register, the Cochrane Pregnancy and Childbirth Group Specialised Register, the Cochrane Central Register of Controlled Trials, Medline (1950 to March 2010), EMBASE (1947 to March 2010) and CINAHL (1982 to March 2010).

Three review authors independently assessed the quality and abstracted data of all eligible studies using a standardized data extraction form and contacted study authors for additional information. Discrepancies were resolved by discussion between two review authors.

The main results were reported in natural units from the text and tables presented in the articles. When there were insufficient data to calculate effect size, reviewers presented results of studies in the form reported in the original papers. For studies reporting dichotomous outcomes, they calculated a standard effect size. If baseline levels were available they reported absolute adjusted risk differences (Adj RD). In studies without baseline data, they calculated absolute differences (between intervention and control). For continuous outcomes, they calculated post-intervention raw mean differences. For Interrupted Time Series (ITS) studies, they analysed the results either with a regression adjusted for autocorrelation and any periodic change or ARIMA analysis. The review authors presented the effects after six months as the difference between the fitted value for the sixth month post-intervention data point minus the predicted outcome six months after the intervention based on the pre-intervention slope only and similarly after one year, two year, etc. In case the ITS design papers did not provide an appropriate analysis of reporting results, the authors re-analysed data using the methods described in Ramsay 2003 (5). If the original study performed multivariate adjustment, they did not re-analyse the study from the summary graph because of uncertainty about the direction and magnitude of the standard error of the effect sizes. For controlled before-and-after studies, they reported only relative effects. For dichotomous outcomes they reported on the risk ratio adjusted for baseline differences in the outcome measures. Finally, for continuous variables they reported on the relative change, adjusted for baseline differences in the outcome measures.
3. RESULTS OF THE REVIEW

A total of 16 studies were included in the review consisting of five cluster-RCTs, six RCTs and five ITS. According to the intervention target, six studies included interventions designed to affect pregnant women’s behaviour and 10 included interventions designed to effect clinician behaviour (among which six targeted the individual physician, one public health nurses and three the hospital or department). The number of participants is not systematically mentioned by the review authors and varied between 110 and 366,246 pregnant women. In only one study targeting care providers the number of subjects (76 physicians) was mentioned. The quality of the studies reviewed was unequal: three of the five cluster-RCTs had unit of analysis errors and could not be re-analysed; the five ITS had significant methodological concerns, but four of the five ITS were re-analysed. As there were wide differences in the nature of the interventions and the context of each study site, the review authors decided not to pool data for any outcomes.

Only two of the six interventions targeting pregnant women were effective in reducing caesarean section rates: one was relaxation education and the second birth class preparation (6). However the evidence from those two small studies is limited because they were conducted in middle-income countries with a pre-existing high level of caesarean section rates.

Three interventions targeting health-care professionals were effective in reducing caesarean section rates: guidelines with mandatory second opinion (Adj RD ?1.9; 95% CI ?3.8 to ?0.1) (7); guidelines with the support of opinion leaders (vaginal birth after previous C-section: absolute difference between audit with feedback group and local opinion leader education = 13.5%) (8); internal peer review and mandatory second opinion (for repeat caesarean section, change in level at 48 months was ?6.4%; 95% CI ?9.7% to ?3.1%) (9). However, the two last studies had an interrupted time series design in which the review authors identified significant methodological problems.

4. DISCUSSION

Limited data suggests that guidelines requiring mandatory second opinion, support of opinion leaders (for repeat caesarean section), and internal peer review and mandatory second opinion help to reduce caesarean section rates. Increasing fees for doctors, proving information to pregnant women with decision-aids, clinical guidelines alone, external peer reviews alone, audit and feedback alone, and childbirth education classes for primary care nurses seem to be ineffective non-clinical interventions for reducing caesarean section rates.

4.1. Applicability of the findings

None of the selected studies were done in Africa and Asia. The two interventions targeting women that showed positive results in decreasing caesarean rates (relaxation sessions and birth preparedness classes) were done in the Islamic Republic of Iran. The results of these two small studies are not sufficient to say that birth preparedness will be effective in decreasing caesarean rates in other countries and contexts with high caesarean rates, such as in Brazil. These interventions aimed at mothers can have an impact on caesarean rate only if the providers and the health services are willing to reduce unnecessary caesarean sections. Alone, it may not work.

Guidelines with mandatory second opinion, guidelines with the support of opinion leaders, internal peer review feedback at department meetings can be applicable in hospital settings in low-income countries, although evidence of success of these interventions comes from Taiwan, USA, and Latin America. These interventions do not need a lot of financial resources for application; it is more a question of leadership and health-care organization.

This review does not address the context of the health system and characteristics of care providers – possibly the most influential factors – in reducing caesarean section rates. The influence of factors such as differences
in practice between public and private structures, medico-legal context (fear to litigation), patient capacity to pay, experience and age of the obstetrician have been reported to impact caesarean section rates (10, 11).

### 4.2. Implementation of the intervention

We recommend mandatory second opinion and peer review feedback in middle- and low-income countries to reduce unnecessary caesarean. Based on common sense it may be suggested that patient-centred care and anxiety release interventions for the mother should also be implemented, even there is no form evidence from RCTs.

Birth preparedness is more problematic to implement as it represents a cost for the mothers and only economically better-off mothers can actually follow them in countries without social protection. This birth preparedness should be proposed for free to allow regular attendance but, as said earlier, any intervention aimed at mothers during pregnancy cannot work if programme managers and care providers are not sensitized and agree to reduce unnecessary caesarean.

### 4.3. Implications for research

RCTs may not be the best design for studies when health services organizations and providers’ attitude and characteristics are important determinants of the intervention effectiveness: mechanisms and contexts matter in studying such determinants. Sociological and anthropological research to understand these logics could be more useful for proposing solutions to decrease unnecessary caesarean sections.

### References

- Victora CG, Barros FC. Beware: unnecessary caesarean sections may be hazardous. The Lancet 2006;367(9525):1796-1797.