Selecting and predicting cost-effective policy options to improve the health of women during labour, delivery and the postpartum in Argentina: From effectiveness to cost-effectiveness

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Abstract

The aim of the research was to select an intervention likely to prove an efficient option for the improvement of the health of women during labour, delivery and the post-partum, in Argentina and to provide an indication of the cost-effectiveness of the new policy option compared with current practice. The process of estimation was as important as the final results as the Global Forum for Health Research was interested in methods for estimating cost-effectiveness of a range of health interventions in different settings. After identifying all relevant systematic reviews held on the Cochrane database, this paper begins by justifying the selection of the study intervention: routine versus restrictive episiotomy.

A decision tree was constructed, based on alternative probabilistic outcomes per patient obtained from the largest trial within the systematic review set in Argentina, and used for modelling incremental cost-effectiveness ratios, from a provider perspective. Only those outcomes, which differed significantly between trial arms, were included. Three alternative methods to identifying resource use and costs were considered. Few resource use or cost data were found within the studies in the review and it was difficult to obtain additional data from the authors themselves. Consequently, interviews with obstetricians were essential to ascertain patient management. Local epidemiological and cost data were also obtained.

The model includes probabilistic sensitivity analysis, providing ranges for the cost-effectiveness ratios. Our results suggest that a restrictive practice of episiotomy could reduce economic costs by between $12 and $20 per pregnancy. We discuss the impact of different information on results; what potential there is for this research approach to aid the construction of a database on the cost-effectiveness of health interventions; and its application in other countries.

Keywords: cost; effectiveness; episiotomy; Argentina; decision-tree; Cochrane

Introduction

This research was compiled for the Global Forum for Health Research (GFHR) to "support the building of an extensive database on the cost-effectiveness of health interventions through an international collaboration based on the use of a standard methodology" (GFHR, 1999). Given the paucity of information available on the cost-effectiveness of health interventions in developing countries and the potential expense of undertaking large numbers of randomised controlled studies, our research considers an alternative approach to generating knowledge about the cost-effectiveness of health interventions in settings where such information is limited.

The existing knowledge base on cost-effectiveness of interventions during the labour, delivery and post-partum (LDP) period is particularly sparse. To address this gap, and to contribute to the objectives of the GFHR, we contemplate here the implications of predicting cost-effectiveness from a Cochrane review of effectiveness, for an intervention during the LDP period, and apply these predictions to two settings in Argentina.

A review from the Cochrane database was the basis for calculating costs and cost-effectiveness, as the approach taken to searching published and grey literature is systematic and conclusions are based on randomised controlled trials (RCTs), 'generally accepted as the most powerful tool for assessing the effectiveness of interventions, medications or procedures'[1]. An intervention: restrictive versus routine episiotomy, was selected on the grounds of its relevance to Argentina. Argentina was selected due to the wide range of

[1] (Gold et al, 1996)

disease burdens and health care settings within the country, enabling the consideration of cost-effectiveness ratios in diverse settings. We consider two provinces: Santa Fe and Salta. Within Salta province a greater proportion of the population live in rural areas and average income levels are lower than in Santa Fe (PAHO, 1998). In terms of health care there is a greater number of physicians and health facilities per 10,000 population in Santa Fe compared to Salta (ibid)[2] and maternal mortality rates in Santa Fe are almost 50% lower at 53/100,000 compared to 104/100,000 in Salta province (Timaeus et al., 1996).

Against this background, the main objectives were to:

- Identify all the reviews held on the Cochrane data base relevant to the LDP period;
- Develop a rationale for selecting an intervention;
- Extract resource use and cost data from the papers in the selected Cochrane review;
- Contact and follow-up authors of these papers to obtain additional data;
- Develop a decision tree to model cost effectiveness in two provinces of Argentina;
- Develop a model based on probabilistic sensitivity analysis to account for the effects of uncertainty;
- Examine the impact of alternative assumptions of the model and raise hypotheses about causes of variation in cost-effectiveness;
- Consider the benefits and disadvantages of this approach to predicting cost-effectiveness, particularly with respect to its application to other interventions in other countries.

[2] 19 physicians and 0.5 health facilities per 10,000 population in Salta compared to 28 physicians and 1.3 health facilities per 10,000 population in Santa Fe.

Selection of an Intervention from the Cochrane Database

Materials and Methods

The majority of reviews relevant to interventions during pregnancy and childbirth are co-ordinated by the Cochrane Pregnancy and Childbirth Group. These reviews were first identified then a more exhaustive search of the Cochrane database was conducted for terms in the title of reviews and mesh terms[3]. Following a discussion with two of the authors of this study: Carroli (MD) and Bergel (epidemiologist), a two-stage selection process was developed and judgements were made for each criterion, about the inclusion / exclusion of each of the reviews.

Firstly, the following general inclusion criteria were derived. The intervention had to accord with the following:

- A beneficial form of care recommended by the Cochrane reviewers for routine clinical practice;
- Leads to a statistically significant improvement in clinically important maternal or newborn outcomes;
- Is independent of other reviews.

Interventions which satisfied these general criteria were then ranked in order of their relevance to Argentina: Argentina specific criteria (ranking of interventions is presented in Appendix 1):

- A significant reduction of the burden of a disorder or disease that is prevalent in Argentina such that the Population-based numbers needed to treat (PB-NNT[4])<100;
- The intervention is not widely practised in Argentina. Less than 75% of eligible patients are estimated to receive the intervention;
- The intervention would lead to a modification of current clinical practice;
- The intervention is likely to be affordable (ranked: yes/no);
- The intervention is likely to be feasible (ranked: yes / no);
- Relevant published or unpublished trial data is available from Argentina or other Latin American countries.

Results

The outcome of the selection process is presented in Figure 1 below.

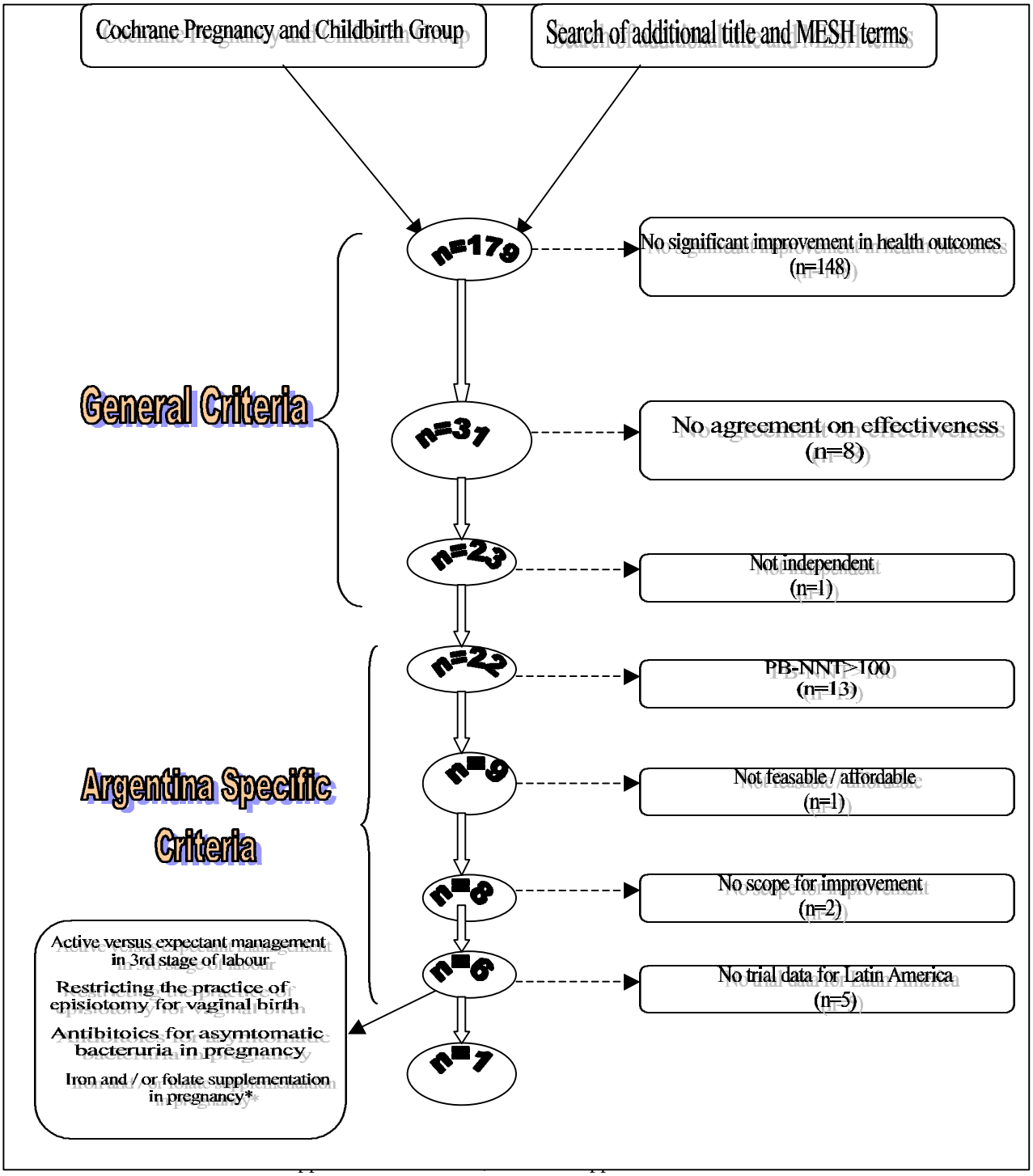
FIGURE 1 Selection of Cochrane Review

[3] Search terms: pregnan*, newborn, neonatal, fetal, foetal, eclampsia, pre-eclampsia, labor, labour, delivery, birth, caesarean, cesarean, episiotomy, intrapartum, antenatal, prenatal, maternal, mother. **NOT ("Cochrane pregnancy and childbirth group")**.

[4] The PB-NNT takes into account the effectiveness of the intervention (expressed by the risk ratio), the baseline incidence of the condition/disorder and the proportion of all pregnant women who are eligible for the intervention. The formula is as follows:

$$\text{PB - NNT} = \frac{1}{(1 - \text{RR}) \times (\text{baseline risk}) \times (\text{proportion of women elegible for the intervention})}$$

with RR = Relative Risk (risk in the intervention group / risk in the control group).



supplementation considered here as a combined intervention: iron and / or folate supplementation.

Although each of the six candidates depicted in the final list were considered to be good candidates, restrictive versus routine episiotomy was the only intervention with trial data available for Argentina[5]. This large, multi-centre study included hospitals in three provinces in Argentina, enabling comparisons to be made between different geographical areas. Furthermore, estimates of money savings, from a policy of selective episiotomy had been carried out in two Latin American countries, providing an estimate of potential savings, in

[5] (Argentine Episiotomy Trial Collaborative Group, 1993)

suture materials, of between USD 6.50 and 12.50 for every vaginal birth without episiotomy in the public sector.

Predicting the cost-effectiveness of restrictive versus routine episiotomy

Materials and Methods

Health Outcomes

Following a brief definition of episiotomy and the intervention's target population, the first issue we consider is how to select health outcomes for inclusion in the cost-effectiveness analysis. Therefore, we begin by presenting and justifying the selection of the health outcomes included in the model in order to facilitate the understanding of the methods used and assumptions made. We also discuss the difficulties of using pooled effectiveness data for this review.

Episiotomy is the surgical enlargement of the vaginal orifice by an incision of the perineum during the last part of the second stage of labour or delivery. This procedure is done with scissors or a scalpel and requires repair by suturing (Carroli et al., 1999). The intervention targets women in uncomplicated labour with expected spontaneous vaginal delivery. Women undergoing a caesarean section were excluded from the trials. Assisted deliveries occur in a small (<3%) proportion of cases and were not considered here due to the very different associated resource use (ibid).

Six studies were included in the Cochrane review[6]. Evidence on effectiveness was taken from the Cochrane review and based on those maternal and neo-natal outcomes which differed significantly (Peto odds ratio) between trial arms, as presented in Table 1[7]. There were no significant differences in outcome between arms, except for perineal pain, healing complications and wound dehiscence. Restrictive episiotomy was found to be more effective in improving these measures of outcome (Carroli et al., 1999). It can be seen that the adverse events are derived uniquely from the Argentine Episiotomy Trial Collaborative Group (1993). Suturing rates and rates of anterior trauma in each of the trial arms are very similar between the Argentine Episiotomy Trial Collaborative Group (1993) and the pooled average from the review. However, the Argentine Episiotomy Trial Collaborative Group (1993) does not provide information regarding the rates of posterior perineal trauma.

[6] Argentine Episiotomy Trial Collaborative Group (1993), Harrison et al (1984), House et al (1986), Klein et al (1992), Sleep et al (1984) and Eltorkey et al (1994).

[7] This approach is supported in an analysis of the costs of intrapartum care in a midwife-managed delivery unit and a consultant-led labour ward (Hundely VA, et al, 1995).

TABLE 1: Measures of Outcome

Outcome (number of studies from review)	**Source of data**	**Estimated % of women**		**Odds ratio**	**95% CI**	
		Routine	**Restrictive**		**Low**	**High**
Number of episiotomies (n=6)	Pooled	72.73	27.57	0.15	0.14	0.17
	Argentina	80.59	29.97	0.13	0.11	0.15
Any anterior perineal trauma (n=4)	Pooled	11.06	19.82	1.97	1.67	2.32
	Argentina	8.10	19.21	2.58	2.05	3.26
Any posterior perineal trauma (n=4)	Pooled	81.63	71.61	0.56	0.46	0.69
	Argentina					
Need for suturing (n=5)	Pooled	86.12	63.80	0.31	0.27	0.35
	Argentina	88.15	63.04	0.26	0.21	0.31
Adverse events						
Perineal Wound dehiscence at 7 days (n=1)	Pooled	9.45	4.49	0.47	0.29	0.74
	Argentina	9.45	4.49	0.47	0.29	0.74
Healing complication at 7 days (n=1)	Pooled	29.79	20.54	0.61	0.47	0.80
	Argentina	29.79	20.54	0.61	0.47	0.80
Any perineal pain at discharge (n=1)[8]	Pooled	42.47	30.74	0.60	0.51	0.71
	Argentina	42.27	30.74	0.60	0.51	0.71

NOTE TO TABLE: Shaded area indicates outcomes for which no data where available.

A review of definitions of restrictive and routine episiotomy highlighted much heterogeneity, as shown in the right hand section of Table 2. Furthermore, one author (Klein et al., 1992) considered midline rather than mediolateral episiotomy, which has been found to increase the risk for third and fourth-degree lacerations (Myers-Helfgott MG et al., 1999; Zetterstrom J et al., 1999; Helwig JT et al., 1993) and increase blood loss (Myers-Helfgott MG, 1999). The differing definitions are also represented partly by differing rates of episiotomy as seen the left hand section of Table 2.

TABLE 2: Episiotomy rates in each arm of the trial and corresponding definitions of restrictive and routine practice.

	Restrictive	**Routine**	**Restrictive**	**Routine**
	Episiotomy rate		**Definitions**	
Argentine Episiotomy Trial Collaborative Group, 1993	30%	81%	Foetal indications or to avoid a severe perineal tear	Comply with traditional hospital practice
Eltorkey et al., 1994	53%	83%		Conduct episiotomy unless absolutely unnecessary
Harrison et al., 1984	8%	100%	If there would be greater damage without an episiotomy	Comply with traditional hospital practice
House et al., 1986	18%	69%		Foetal distress or to shorten the 2nd stage of labour
Klein et al., 1992	44%	65%	Try to avoid an episiotomy	Use liberally to try to prevent a tear
Sleep et al., 1984	10%	51%	Foetal indications or to avoid severe perineal tear	
Total Pooled	28%	73%		

[8] There was no significant difference between arms for moderate/severe perineal pain at 10 days or any perineal pain at 3 months within each arm of the trial (Sleep et al., 1984). House et al., 1986 found that there was no significant difference between arms for moderate /severe perineal pain at 3 days.

In the face of such disparities, it is not recommended to use a pooled estimate of effectiveness (Saint et al., 1999). Consequently, we chose to consider the effectiveness data from the largest trial in the review (Argentine Episiotomy Trial Collaborative Group, 1993).

Resource Use, Costs and Modelling Cost-Effectiveness

Costs were evaluated from a provider perspective: the Municipalities of Rosario City (Santa Fe) and Salta city (Salta). Women's preferences and costs, although an important issue (Kitzinger S et al, 1981a & 1981b; Klein M 1988:19-25), are not considered here. Resource use and costs were considered only up to 1 month after delivery, based on the duration of adverse events figuring in Table 1 (Carroli et al 1999).

To identify resource use associated with each practice, three methods were used. The first involved reviewing each paper included in the systematic review of effectiveness with a common set of questions to identify: who carried out the intervention at each stage; what was done, and how the intervention was carried out; the target population (the number of women in each arm); the study / trial time period; where the intervention was carried out and which resources were used at each stage of the intervention.

The second approach involved contacting the authors of the studies to clarify the types of and quantities of resources used. Where possible, the authors were contacted first by phone explaining the purpose of the study and information needed. If they agreed to help, a questionnaire was sent for completion[9].

The third method involved contacting obstetricians. An obstetrician in the UK helped identify the standard treatment path and resources used for women during and following an episiotomy. Subsequently, a questionnaire was developed and distributed to a sample of seven obstetricians to identify differences in practice between Santa Fe and Salta (see Appendix 3)[10]. Obstetricians were interviewed in a large maternity hospital of similar capacity in Santa Fe and Salta. Treatment patterns in each province were entirely determined by the questionnaire results.

Costs of equipment, utilities and overheads were extracted from a cost analysis of maternal health services in Rosario, Argentina (Borghi et al, 2000), costs of drugs and medical materials were derived from the national pharmacy price list. Capital costs were annualised using a linear discount rate of zero and estimates of life expectancy. All costs are presented in 1999 US$ (assuming a nominal exchange rate of $1 = 1 Peso), where necessary costs were inflated to 1999 prices using the inflation rates: 1997-1999[11]. The majority of input prices were set nationally (drug, medical materials and staff) and therefore one price was used for both provinces: Santa Fe and Salta. Data relating to throughput for maternity hospitals in Salta province were unavailable, therefore, overhead costs were assumed to be the same for both provinces.

To structure the problem, a decision tree was constructed and a number of assumptions were formulated based on the questionnaire findings:

[9] See Appendix 2.
[10] Due to the logistical difficulties in selecting obstetricians in Argentina from the UK, obstetricians chosen to participate in the study were collaborating with CREP.
[11] Source: www.worldbank.org

- The outcome 'need for suturing perineal trauma', measured during the trial, is considered to avoid differentiating between anterior and posterior trauma. Perineal trauma does not always require suturing, so the 'need for suturing' variable enables the measurement of resource use in terms of suture material.
- All women having undergone an episiotomy are assumed to require suturing.
- Women experiencing adverse events can suffer from either[12]:
    1. Perineal pain alone
    2. Perineal pain and healing complications
    3. Perineal pain and wound dehiscence
    4. Perineal pain and healing complications and wound dehiscence
    5. Healing complications alone
    6. Healing complications and wound dehiscence
    7. Wound dehiscence alone
- Women suffering from perineal pain alone after discharge do not require re-admission to hospital.
- 1% of women suffering from wound dehiscence and or healing complications will be re-admitted to hospital for between 2-7 days.
- 1% of women suffering from wound dehiscence and or healing complications will require re-suturing.
- The intervention does not affect length of stay.
- The subjective probabilities for each of the branches were derived from the Argentinean trial.
- For a woman suffering from healing complications and wound dehiscence, we consider only the cost of managing wound dehiscence. As the treatment paths are similar, this avoids double counting.
- Absorbable suture material is used to carry out suturing and, therefore, the costs associated with the removal of suture material are not considered.
- In Salta province:
    - no epidural anaesthetic is administered for normal vaginal delivery (only local anaesthetic);
    - no treatment is provided to patients suffering from perineal pain alone;
    - wound dehiscence and healing complications are managed in the same way.

Handling Uncertainty

To account for uncertainty regarding many of the cost and effectiveness variables, a probabilistic sensitivity analysis, whereby probability distributions are assigned to the model inputs, was used to provide information regarding the range of likely values within which the cost-effectiveness ratio may fall. Where data showed a peaked distribution (or it was felt that a peaked distribution was likely), a triangular distribution was used. Data on the mean values and confidence intervals were unavailable and consequently a normal distribution could not be constructed. The model was iterated according to a Monte Carlo sampling type with standard recalculation of expected value, until convergence was reached (all output percentages change less than 1.5%). Palisade @RISK software (version 3.5) was used to carry out the simulation. The cost-effectiveness-ratio outputs were expressed as probability distributions rather than as

[12] While the outcomes themselves were identified from the Cochrane review as explained previously, the questionnaire enabled us to justify this classification.

single point estimates. The mean and range in which 90% of the cost-effectiveness ratios fell (Goodman et al., 1999), were used as summary indicators.

Sensitivity analyses were also carried out to test the impact of varying point estimate variables, for which a probability distribution could not be estimated, on final results. We also considered the impact on results of varying episiotomy rates in the routine and restrictive groups. Finally, a hypothetical notion of 'need' was added into the decision tree and true/false negative/positive cost-effectiveness ratios were calculated. In each case, the simulations were re-run using these new values to indicate the impact on the cost-effectiveness ratio ranges.

Results

Resources were classified as staff, medical materials, drugs, equipment and building. There was overall consensus within the studies regarding those responsible for the deliveries and for conducting the episiotomy and suturing. 3/6 gave some information regarding drug use. 2/6 provided information regarding medical materials used and 1/6 referred to equipment used, namely the instrument used to carry out the episiotomy. All studies referred to where the intervention was carried out. . The findings and gaps are presented in Table 3 below.

TABLE 3: Resource Use Findings from Studies Included in the Review

	Staff	**Drugs**	**Medical materials**	**Equipment**	**Overhead (location)**
During delivery					
Episiotomy	Midwife, obstetrician, person in charge of delivery (n=6)	Analgesics (n=1)		Scissors (n=1)	Delivery room (n=5)
Suturing	Midwife, obstetrician, person in charge of delivery (n=5)		Catgut (n=2) Tapercut needle (n=2)		
Anaesthetic		Local anaesthetics (n=2)			
After delivery, before discharge					
Adverse events		Oral analgesics (n=1)			
Removal of stitches					
After discharge from hospital					
Removal of stitches					
Re-suturing					
Continuation of adverse events					

NOTE TO TABLE: Shaded areas illustrate the gaps where no information was available.

It can be seen from Table 3 that there were a number of gaps in the data including:

- *During hospital stay:* the use of medical materials for episiotomy; equipment for suturing, staff and materials for the administration of anaesthetics; the management of adverse events during hospitalisation; removal of stitches; and the length of inpatient stay
- *After discharge from hospital:* management of adverse events, removal of stitches and re-suturing and the re-admission procedure
- No information regarding the duration (number of days of prescribed medication, minutes / hours of staff time) or quantity (drug dosage) of resource use. Both are needed to calculate total costs

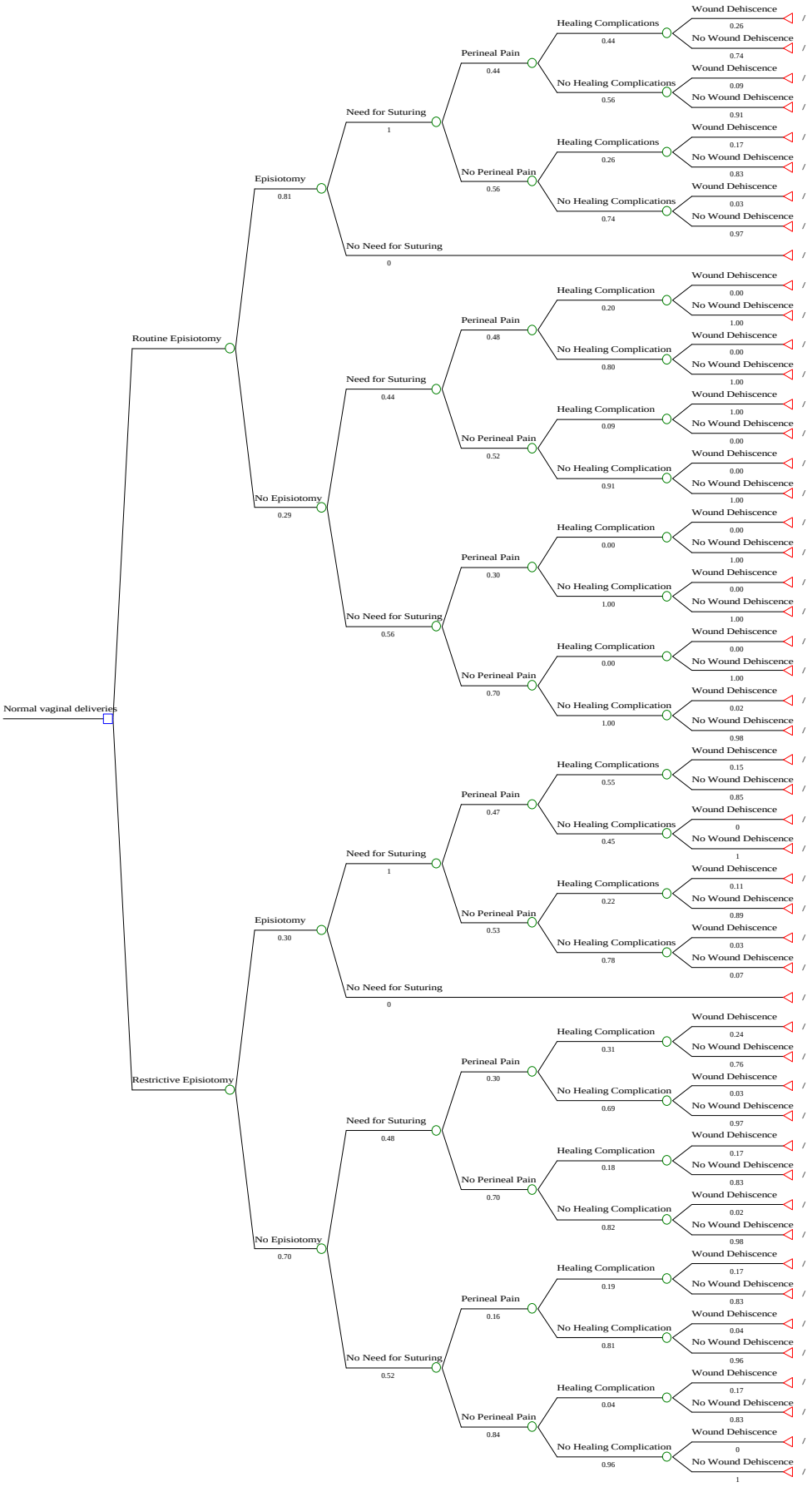
- An absence of data on unit costs.

Although a response was obtained from three out of four of the authors (Argentine Episiotomy Trial Collaborative Group 1993; Sleep et al., 1984; Harrison et al., 1984, and House et al., 1986) to whom the questionnaire was sent[13] for two of these authors, the study had taken place so long ago (>15 years) that the relevant information was no longer accessible. However, some of the members of the Argentine Episiotomy Trial Collaborative Group were able to provide data relating to the management of side effects, in particular, the use of antibiotics for perineal infection and the use of analgesics for perineal pain within the trial. From the completed questionnaires to obstetricians, resource use and unit costs could be identified for each element of the intervention: episiotomy, suturing (with and without episiotomy), adverse events: perineal pain, healing complications and wound dehiscence, for both Santa Fe and Salta provinces.

Figure 2 shows the decision tree model. Attached to each of the branches are a probability and a cost. The probabilities figure above the branches of the tree and are conditional on the events occurring in the previous branches. The tables (A2-A6) in Appendix 4 show the values and the probability distributions around each of the variables which were fed into the model.

[13] We were unable to trace two authors (Eltorkey et al., 1994) and (Klein et al., 1992).

FIGURE 2 Decision Tree



The unit costs of each activity: episiotomy, suturing, anaesthetic, management of adverse events are applied to relevant branches and figure in Table 4. Each includes the costs of staff, medical materials, drugs, equipment and overheads as indicated in the Tables A2-6. Table 4 shows that the costs associated with the management of adverse events resulting from the practice of episiotomy are the most substantial in both provinces.

TABLE 4: Breakdown of Costs associated with Episiotomy in US$ 1999[14]

Event	Santa Fe Province	Salta Province
Episiotomy (incl. anaesthetic)	2.60	0.73
Suturing with no episiotomy (incl. anaesthetic)	5.78	3.90
Suturing with episiotomy (no anaesthetic)	3.64	3.64
Management of perineal pain	7.04	0.00
Management of healing complications	22.70	13.86
Management of wound dehiscence	24.39	

Table 5 indicates that for each woman having a normal vaginal delivery, there is a potential reduction in cost of $20.21 ($21.09-$19.36) with a restrictive policy of episiotomy in Santa Fe and a reduction of $11.63 ($10.89-$12.42) in Salta. Both reductions are statistically significant at 95% level.

TABLE 5: Differences in total cost and total effect between arms

	Routine Practice (C)	Restrictive Practice (I)	Difference (I-C)
Total cost (US$ 1999)			
Santa Fe Province	64.88 (62.19; 67.67)*	44.66 (42.79; 46.62)*	-20.21 (-21.09; -19.36)*
Salta Province	36.06 (33.90; 38.51)*	24.42 (22.92; 26.14)*	-11.63 (-10.89; -12.42)*
Probability of perineal pain^	0.42 (0.40; 0.45)	0.31 (0.28; 0.33)	0.12 (0.10; 0.14)*
Probability of healing complications^	0.30 (0.26; 0.34)	0.21 (0.17; 0.24)	0.09 (0.07; 0.12)*
Probability of wound dehiscence^	0.09 (0.07; 0.12)	0.04 (0.03; 0.06)	0.14 (0.12; 0.16)*

* 90% ranges in which the parameters fell. Other ranges are 95% confidence intervals, assuming normal distribution of effectiveness results. ^ Taken from the Cochrane Review (Carroli et al., 1999).

This confirms that a restrictive episiotomy policy is a dominant strategy over routine episiotomy: it is less costly and more effective. The results show this is the case in both provinces, although more strongly so in Santa Fe. Given this result of strong dominance, neither the provision of incremental cost-effectiveness ratios or the translation of effectiveness to utility (in this case DALYs) adds any more information to the results (Drummond et al, 1997: 142 & 248).

If the opportunity costs of staff time are not included in the model for Santa Fe, the results are robust in both Santa Fe and Salta provinves. When prices of drugs and medical materials are reduced by 50%, the total cost in the routine group in Santa Fe falls to $38.53 ($36.25; $40.98) compared to $26.12 ($24.55; $27.87) in the restrictive group (a reduction of $12.41). Under the same change in prices for Salta, the difference in cost between each arm falls to $8.12 ($8.91; $7.35).

[14] These are the costs applied to the tree at each branch.

The impact of assumptions about the episiotomy rates under routine and restrictive policies was also examined. In Santa Fe, if routine practice were characterised by episiotomy rates as low as 51%, compared to 44% for the restrictive practice[15], the total cost in the routine group would fall to $53.13 ($50.99; $55.39) compared to $50.33 ($48.19; $52.61) in the restrictive group: the difference reduces to $2.80 ($2.96; $2.64). Using the same rates in Salta, policy options are now almost equal, with a difference of only $0.57 ($0.49; $0.67).

If episiotomy rates were to fall to 8% in the restrictive group (rates remaining constant in the routine group), our model suggests this policy option would become even more cost-effective, implying that cost-effectiveness would be at an episiotomy rate of zero. However, this implication should be handled with much caution as it results simply from the inability to capture 'need' within the model. Consequently, a conceptual notion of 'need' was incorporated into the decision-tree and the expected cost-effectiveness ratios re-estimated (see Appendix 5). It can be seen from Table 6 that by reducing / increasing the episiotomy rate below / above that which is actually 'needed' the rate of true negatives / of false positives and associated adverse events will increase. The costs of managing these adverse events will weigh against such an option, making it less cost-effective. However, until the level of need is known, a conclusion cannot be reached about the optimal level of episiotomy.

TABLE 6: Cost per correctly treated case in US$ 1999 (assuming level of need: 30%)

	Santa Fe		Salta	
	Routine	Restrictive	Routine	Restrictive
Cost per false positive	47.41	6.56	26.90	3.68
Cost per false negative	1.2	15.97	0.55	8.51
Cost per true positive	47.41	6.56	26.90	3.68
Cost per true negative	1.2	6.56	0.55	8.51

[15] The most extreme cases from the Cochrane review, implying a reduction in episiotomy rates of only 7%.

Discussion and Conclusions

Is a policy of selective episiotomy more cost-effective than routine episiotomy?

This research showed that the more effective restrictive episiotomy policy at 30% compared with routine episiotomy policy at 81% was also less costly. It is a policy option which dominates existing practice in Argentina. The results were robust and consistent in two provinces with differing population characteristics in terms of income and maternal mortality (Santa Fe and Salta) in Argentina. However, we are unable to accurately estimate the impact, in terms of cost-effectiveness, of a restrictive policy of less than 30% due to the absence of information regarding need. Indeed, from a decision makers perspective, the fundamental question is to know whether 30% is the optimal episiotomy rate for a specific population in terms of meeting the 'need' of that population for an episiotomy. Whilst episiotomy rates of 5% may reduce costs further, they may also result in detrimental foetal and neonatal outcomes for those cases where an episiotomy was clearly indicated, but not carried out. However, we do not know how the various outcomes change (increase / decrease rate) as episiotomy rates fall / rise. Failure to consider need alongside costs and effects could potentially result in reducing practice to harmful levels.

How generalisable are these results?

It is important to note how the costs associated with episiotomy varied by treatment practice. Indeed, costs related to episiotomy were substantially lower in Salta province where epidural anaesthetic is not usually administered to women during vaginal birth, and where perineal pain is not treated (although would be treated if it was a symptom of healing complications / wound dehiscence). Similarly the drug treatment is less costly for other adverse events in Salta than Santa Fe province. Given that the routine rate of episiotomy is substantially higher than 51% in all provinces[16], it would therefore seem appropriate to suggest that the effectiveness results can be generalised for the whole of Argentina and that costs will reduce, whilst the size of the cost reduction may vary by province. Applicability of results to other countries will depend on how closely the rates, costs and need for episiotomy match the assumptions of this model. Indeed, an episiotomy rate, which defines the most cost-effective restrictive practice in one country, may be of a very differing level elsewhere.

We are conscious that our model does not distinguish between alternative risk factors related to the 'need' for an episiotomy. Parity may be such a risk factor with nulli and primiparous women being at higher risk than multiparous women (Carroli et al., 1999). Consequently, we would expect a higher episiotomy rate in this former group, and hence higher costs in countries with higher birth rates.

The development of more generalised assessments rather than contextualised analyses is being encouraged (Murray CJL et al., 2000). Indeed, the consideration of average cost-effectiveness ratios: the comparison of an intervention with respect to 'the null set', has been encouraged to enable comparisons to be made between different interventions, and to 'enhance the allocative efficiency of many health systems' (ibid). In this way it is felt that each

[16] These figures were extracted from the large database (Perinatal Information System) developed from the content of data collection forms designed by The Latin American Centre for Perinatal Research (CLAP). For this study all the records from Argentina were extracted and only hospitals that collected data on episiotomy were considered. The analyses include only vaginal births. Abortions and stillbirths are excluded.

study will contribute to the existing body of knowledge of cost-effectiveness of different interventions. In order to estimate the average cost-effectiveness we would need to consider the intervention: normal vaginal birth with restrictive compared to routine episiotomy. This requires the estimations of the cost of the delivery process as a whole (our study considered only the costs of managing women who did or didn't have an episiotomy), and of the management of all adverse events (including those which weren't significantly different between arms). Additionally, we would be required to compare the cost-effectiveness of vaginal birth with routine and restrictive episiotomy to the case of vaginal birth with 'no episiotomy' (termed 'the null set' (ibid)). As we have discussed we do not know the underlying level of 'need' required for this estimation. Furthermore, Murray et al. point out that the development of 'natural history models' are necessary for an accurate estimation of the null set, along with clear guidelines and standards (ibid). Such developments should facilitate this kind of research. It is also important to quantify the additional research time required for the collection of a wider realm of cost data required for this type of analysis. Indeed, Murray et al., acknowledge that 'there is a trade off between making CEA information precisely relevant to a given context and the time and resources required for that contextualisation' (ibid).

What potential is there for our research approach to aid the construction of a database on the cost-effectiveness of health interventions?

Use of the Cochrane Review

The availability of the reviews published under the Cochrane Pregnancy and Childbirth Group was a real strength. Nevertheless there are two issues which are worth considering: the criteria used in selecting the review and the definition of effectiveness and relevant outcomes.

With hindsight, we believe that more objective criteria could be set up for selecting the intervention. For example, in terms of defining feasibility, all equipment required to carry out the intervention should be specified and, potentially, a survey carried out to evaluate its availability within a selected sample of hospitals. To determine affordability, the purchase price and maintenance cost of such equipment could be compared to the general or specific hospital budget. More consideration could be given to who makes the decisions regarding hospital practice (for example, by random sampling of relevant health providers, hospital managers or possibly accountants). Consideration should also be given to the institutional settings of the obstetricians questioned i.e. a large urban maternity hospital versus a small maternity ward in a rural-based general hospital.

Two 'objective' selection criteria were used, one of which was the PB-NNT. However, the PB-NNT criterion does not weight the outcomes in terms of their importance (national priority or preferences). For example, due to the small number of women who will suffer from eclampsia, the PB-NNT for magnesium sulphate is very high (>100) and, therefore, is not included for further analysis. However, it may be that people attach more weight to reducing the risk of such a disabling disorder, rather than a less disabling disorder which can be effectively treated retrospectively. An alternative criterion would have been the disability adjusted life year (DALY). The DALY is a measure of health outcome which incorporates premature death, years of life lost (YLLs) and morbidity and disability from a given

disease/disorder, years of life lived with a disability (YLDs). In this case those interventions targetting a disease / disorder with the greatest number of associated DALYs for Argentina, would have been chosen. However, the data requirements would be susbtantial and for many of the outcomes such as, for example, caesarean section rates, still birth, perineal trauma, the data is, to the best of our knowledge, unavailable.

Whilst the Cochrane review certainly did provide a good basis of evidence there were also three associated problems. First it was apparent that very different definitions of episiotomy were used in the trials reviewed. Their different implications for resource use made it difficult to use the pooled results. So, the decision model was built around the effectiveness results of the largest trial, which was fortunately set in Argentina. However, had we focussed on another country for the same issue, this may not have been relevant.

Secondly, we only included those outcomes that had statistically significant differences in outcomes. It is possible that outcomes for which there were not statistically significant differences in effectiveness do have a statistically significant impact on costs, although we are not aware of any clear conclusions about how to handle this. It certainly would have increased the level of detail needed for costing, which would be difficult in the absence of good secondary data.

Thirdly, basing the effectiveness side purely on the Cochrane review meant that we lacked information in certain key areas. Although the Cochrane review provided information on the proportion of multi- and primiparas who have an episiotomy in each arm, we were unable to tell how parity affects other important outcomes such as perineal pain, healing complications and wound dehiscence. Consequently, we were unable to integrate these or other risk factors into the model, which would be essential to defining the optimal restrictive practice in different groups of women. This suggests that the Cochrane database is a useful starting point, but that much additional data is needed to work alongside the analysis.

Identifying resource use and cost data

We used three approaches to collecting data on of resource use and it is useful to reflect on the value of the different approaches in the light of future work. While all studies included in the review gave information as to who was responsible for conducting the episiotomy and suturing and where this took place within the hospital, there was no information regarding the nature of the staff involved in the administration of anaesthetics or the management of adverse events. Information on drug use and medical materials was limited and there were some important gaps regarding the quantification of resource use in terms of the number of units, the duration of use and unit costs.

Overall, contacting the authors of the papers was not a successful means of identifying resource use and cost data. In this case, an inhibiting factor was the problem of recall and access to data due to the important time lapse since the year of publication. Had data been accessible, it is questionable whether it would have still been relevant to practice today. We were very fortunate that one of our collaborators was also one of the authors of the Argentinean trial paper (Carroli G) and this proved helpful in accessing some relevant data. We were also helped by the fact that the trial had taken place relatively recently. Probabilities

were derived from the Argentinean trial data and enabled the construction of the decision tree. However, there were still little or no data available regarding resource use and duration of hospital stay, requiring a number of assumptions to be made.

It would appear that, given the absence of key resource data in the review papers, contacting relevant medical personnel involved in the provision of services is essential to getting the full picture of how patients are managed and which resources are used and how.

With respect to ascertaining cost data, we were particularly fortunate that a recent study of hospital costs had been conducted in Rosario, Santa Fe. We drew extensively on this data, without which it would have been almost impossible to estimate the costs of services. Therefore, the creation of a database on cost-effectiveness is likely to be more forthcoming in those environments where cost analyses have been conducted to date and are available as either published papers or unpublished reports.

How appropriate is this research approach for application in other countries?

We are continuing with one of our original aims of research, which was to seek further funding to replicate this research approach in Bangladesh, and are doing so in the light of the findings from this research. We are planning to modify our research approach in light of the above conclusions. However, for Bangladesh, there is a particular concern in basing results on the Cochrane review: the majority of reviews focus on hospital based interventions. In a country where only 3.5% of pregnant women give birth in a health facility and only 9.5% receive delivery care from a medically trained person, it is possible that this approach will not select the most efficient approach to improving health of women during labour, delivery and the post-partum (Stewart et al., 1997). Therefore we are considering two further options; broadening the inclusion of systematic reviews to include observational and quasi-experimental studies; and involving a third research approach based on the development of consensus amongst health professionals and decision-makers based in Bangladesh.

Recommendations for research

Additional trials are needed in order to understand the relationship between certain risk factors (the baseline level of need), the rates of episiotomy and the outcomes of the model. This would enable the construction of a dynamic model which could address the essential question of: what is the optimal episiotomy practice, such that all women who need an episiotomy actually have one? It will, therefore, be necessary to ascertain whether and how the need for an episiotomy affects outcomes (in terms of an increased number of true negatives and false positives) and how to identify those who need episiotomy and the associated risk factors.

Better quality data on cost-effectiveness of health interventions is likely to emanate where: Cochrane reviews of effectiveness exist; recent large scale trials of effectiveness have been conducted; economic evaluators can visit the location and be involved in selecting an intervention from Cochrane reviews and ensure consensus around the key inputs and assumptions into the decision; health economics units already exist (hence increasing the likelihood that desegregated cost analyses for disease groups exist in the health sector).

Further research is required to investigate the impact of excluding outcomes which are not significantly different between arms from costing and cost-effectiveness analyses.

APPENDIX 1: TABLE A1 SELECTION OF INTERVENTION FOR PREDICTION OF COST-EFFECTIVENESS

Intervention	Target Population	Evidence of Effectiveness in improving direct health outcomes (Cochrane reviews). Relative risk	Prevalence of disorder in target / control population	PB-NNT	Extent of practice of intervention in Argentina	Affordability	Feasibility	Generalisability	Trial data available
Active versus expectant management in the third stage of labour	All women with normal vaginal deliveries: 80-85%*of total	PPH (>500ml) 0.35(0.28-0.42)	25%*	7.5	Low	Yes	Yes	Yes	No
Antibiotic prophylaxis for Cesarean section	All women undergoing emergency or elective c-section: 15-20%* of total	Serious maternal infection/death 0.44(0.32 to 0.68) maternal urinary infection 0.55(0.47 to 0.66) endometritis 0.37(0.33-0.42) wound infection 0.40(0.33-0.47)	2.6% 9.3% 20.7% 9.4%	392.5 136.5 43.8 101.3	High	Yes	Yes	Yes	No
Antibiotics for asymptomatic bacteriuria in pregnancy	Women with asymptomatic bacteriuria. 10%*	Pyelonephritis 0.25(0.19-0.34) preterm or low birth weight 0.64(0.50-0.82)	19.0% 14.4%	70.2 192.9	Low	Yes	Yes	Yes	No

Balanced protein/energy supplementation in pregnancy	All women with first antenatal care visit before 28 weeks gestation: 79.5%* of total.	Stillbirth 0.52(0.31 to 0.86) neonatal death 0.62(0.40,0.95) SGA 0.71 (0.60-0.84) birthweight(mean) 32.1(3.5;60.7)	 1.07%* 0.92%* 10.1%*	238.2 367.8 42.9	Low	No	No	Yes	No
Caregiver support for women during childbirth	All women: 100%	Neonatal sepsis 0.45(0.21 to 0.96)	0.9%	202.0	Low	Yes			No
Episiotomy for vaginal birth	All women with normal vaginal deliveries: 80-85%* of total	Need for suturing perineal trauma 0.74 (0.71 to 0.77)	88.1%	5.3	Low	Yes	Yes	Yes	Yes
Interventions aimed at decreasing the risk of mother-to-child transmission of HIV infection	All women HIV (+): 1%** of total	Stillbirth 0.31 (0.11-0.90) HIV (+) newborn 0.53 (0.41-0.68) Child mortality 0.46 (0.24-0.90)	 2.5% 24.5% 6.4%	5797.1 868.4 2893.5	High	Yes	Yes	Yes	Yes
Routine induction of labour after 41 weeks gestation	All women reaching 41 weeks or more gestation: 13.7%* of total	Perinatal mortality 0.41(0.13 to 0.99)	0.4%*	3092.9	High	Yes	Yes	Yes	No
Interventions for promoting smoking cessation during pregnancy	All women smoking during pregnancy: 12%*	lbw 0.82(0.69-0.97) preterm 0.83(0.68-0.99)	 11%* 12.5%*	420.9 392.2	Low	Yes	Yes	Yes	No
Intrapartum antibiotics for Group B streptococcal colonisation	Women with Group B streptococcal colonization: 15-20% ***	Infant sepsis 0.12(0.03 to 0.44)	5.5%	118.1	Low	Yes			No
Folate supplementation in pregnancy	All women with first antenatal care visit before 28 weeks gestation: 79.5%* of total	Anaemia 0.73 (0.66-0.80)	13%*	35.8	Low	Yes	Yes	Yes	No

Iron and folate supplementation in pregnancy	All women with first antenatal care visit before 28 weeks gestation: 79.5%* of total	Anaemia 0.22 (0.15–0.33)	 13%*	12.4	Low	Yes	Yes	Yes	No
Iron supplementation in pregnancy	All women with first antenatal care visit before 28 weeks gestation: 79.5% *of total	Anaemia 0.21 (0.16-0.26)	 13%*	12.2	Low	Yes	Yes	Yes	No
Magnesium sulphate versus diazepam for eclampsia	All women with eclampsia: 0.14%* of total	Recurrence of convulsions 0.50 (0.38; 0.65)	 27%	5291.0	High	Yes	Yes	Yes	No
Magnesium sulphate versus phenytoin for eclampsia	All women with eclampsia: 0.14% *of total	Recurrence of convulsions 0.332 (0.20; 0.49) Pneumonia 0.44 (0.24; 0.79) Death or in SCBU>7 days 0.77 (0.63; 0.95)	 18% 8.8% 43.0%	5922.8 14494.4 7222.3	High	Yes	Yes	Yes	No
Maternal iodine supplements in areas of deficiency	All women attending antenatal care, and living in areas with iodine deficiency: ≈0%**	Childhood mortality 0.71 (0.56; 0.90) Cretinism (10-16) 0.17 (0.05; 0.58)	 18.9% 6.5%	18244845.8 18535681.2	Very low	Yes	No	Yes	No
Oxytocin for prelabour rupture of membranes at or near term	Women with spontaneous rupture of membranes before labour or at or after 34 weeks pregnancy: 1%*	Chorioamnionitis 0.63 (0.51; 0.78) Endometiritis 0.72 (0.52; 1.00) Neonatal infection 0.65 (0.45; 0.95)	 7.2% 3.1% 2.4%	 3753.8 11520.7 11904.8	High	Yes	Yes	Yes	No
Prostaglandins for prelabour rupture of membranes at or near term	Women with spontaneous rupture of membranes before labour or at or after 34 weeks pregnancy: 1%*	Chorioamnionitis 0.78 (0.63; 0.98)	 8.3%	5476.5	High	Yes	Yes	Yes	No

Prophylactic corticosteroids for preterm birth	Women expected to deliver preterm: 11%*	RDS 0.64 (0.56; 0.72) Neonatal death 0.63 (0.51; 0.77) Intraventricular haemorrhage 0.30 (0.14; 0.66)	23.7% 11.7% 5.5%	30.2 210.0 236.1	High	Yes	Yes	Yes	No
Amnioinfusion for umbilical cord compression in labour	Women whose babies were considered to be at increased risk of, or had fetal heart rate patterns suggestive of, umbilical cord compression; women considered at risk of or with evidence of intrauterine infection: 3%**	Caesarean Section rate 0.56(0.42; 0.75) Postpartum endometritis 0.45 (0.25; 0.81)	16 % 11%	473.48 550.96	Low				No
External cephalic version for breech presentation at term	Women with breech presentation at term and no contraindications to external cephalic version: 3%**	Caesarean Section rate 0.52 (0.39; 0.71)	30%	231	Low	Yes	Yes	Yes	No
Prevention versus treatment for malaria in pregnant women	Women with malaria: ≈ 0%**	Placental malaria 0.19 (0.21; 0.31) LBW (only primigravidae) 0.59 (0.41; 0.85)	18.6% 20.7%	6637461.8 11782726.5	Very low	No	No	Yes	No

NOTE TO TABLE: *Data from Argentina: from WHO antenatal care trial; **Data from Argentina: personal communication E Abalos); ***Data from the Cochrane reviews.
Shaded areas: did not meet specific criteria.

APPENDIX 2 QUESTIONNAIRE TO AUTHORS OF COCHRANE REVIEW PAPERS

QUESTIONNAIRE TO IDENTIFY THE RESOURCE USE ASSOCIATED WITH THE PRACTICE OF ROUTINE VERSUS RESTRICTIVE EPISIOTOMY

In order to attach costs to each of the inputs associated with episiotomy, we need to quantify the intensity of resource use and the types of resources used. We would be grateful for any help you could give in filling the tables below.

Staff

Staff time: How long did suturing take on average (minutes)	
Did time vary significantly with type of tear and whether or not episiotomy has been conducted?	

Drugs

What proportion of patients received local anaesthetics during labour in each group?	
What did they receive?	

Were analgesics given to all routinely or just to patients who asked for them?	

For the analgesics administered ***during labour***, on average, what dosage was given, what were the quantity and the duration of treatment?	***DRUG***	***DOSAGE***	***QUANTITY***	***DURATION (days)***

For analgesics given ***after delivery*** and any other treatment given, what was the time of administration and the indications for treatment?	DRUG	INDICATION	TIME (hours after delivery)	DOSAGE	QNTY	DURATION (days)

If not already covered above: How were patients treated if suffered:		***DRUG***	***DOSAGE***	***QNTY***	***DURATION (days)***
	Perineal pain at discharge				
	Wound dehiscence at 7 days				
	Healing complication at 7 days				

Medical Materials

Which materials were used to carry out suturing?	
Did this vary depending on whether was suturing for an episiotomy or a tear?	

Equipment

How was the episiotomy conducted (scissors, scalpal, other?)	

Length of hospital stay

Was there a statistically significant difference in hospital length of stay between the trial arms (if so, by how much?)	

APPENDIX 3 QUESTIONNAIRE TO ESTIMATE THE RESOURCE USE AND COST ASSOCIATED WITH THE PRACTICE OF EPISIOTOMY

1. What proportion of women (on average) have an epidural anesthetic during labour and what drugs / medical materials are necessary? Who administers the anaesthetic?

2. For a woman who had not undergone an epidural anaesthetic who required an episiotomy and/or suturing due to perineal tear, which local anaesthetic would be given?

3. In order to give a local anaesthetic to a woman who has not undergone an epidural anaesthetic what materials would be used?
   - Gloves?
   - Syringe?
   - What else?

4. What proportion of women received analgesics during labour and which drugs are usually prescribed (brand name, dosage and quantity)?

6. How would patients be treated if suffering from:

	Drugs prescribed			Number of extra days of stay in hospital	Other forms of treatment explain…	Probability of re-admission to hospital	Medical Staff responsible
	Dosage	Name	Quantity				
Any perineal pain at discharge							
Moderate / severe perineal pain at 10 days							
Healing complication at 7 days							

Episiotomy

7. Who carries out the episiotomy?

8. On average how many scissors for episiotomy are held per hospital?

- Are they only used for episiotomy or for other indications? If they are used for other things, please estimate what is the % use for episiotomy

9. Is it reasonable to suggest that if a staff member is spending more time with a patient due to an episiotomy, they would have less time to deal with other patients? Or are there sufficient quantities of staff available for this not to be a problem?

10. For women experiencing blood loss after an episiotomy, what proportion, would you estimate, would need a blood transfusion?

Suturing

11. Who carries out the suturing?

12. What materials are necessary to conduct the suturing ?

13. Please can you describe how you would practice suturing:

- Collect suture package and other materials: yes/no.
- If yes, would the person carrying out the delivery collect the materials or would an additional person do this (if so: who?). Duration in minutes
- Clean patient: yes/no
- Start stitching: duration in minutes
- How does this duration vary for 1st....., second ……and third degree tear……minutes.
- Clean patient and surrounding area: yes/no. Duration in minutes
- Other: yes/no. Specify……. Duration in minutes.
- Total staff time in minutes

14. Would any of the following equipment / materials be used during episiotomy or suturing (please specify: episiotomy, suturing or both):

- Sterilisation pack: yes/no. If yes, would this be in the standard delivery kit already?
- Cleaning solution for woman: yes/no. If yes, what would this be?
- Bowel for cleaning solution: yes/no. If yes, how often would this be washed/sterilised? (after how many episiotomies?)
- Tray for suture set: yes/no. If yes, how often would this be washed/sterilised?
- Sterile sheets: yes/no. If yes, how many?
- Surgical swabs: yes/no. If yes, how many?
- Gloves: yes/no
- Would any of the above be used only for episiotomy (or are they all used also for delivery without episiotomy)?

15. Where is suturing carried out? Delivery room yes/no

16. Who would remove the suture material?

17. How long would it take to remove stitches (minutes)?

18. What proportion of women having had suturing, would require suture material to be removed?

19. In general, what proportion of women would require re-suturing? Which physical conditions might lead a woman to be re-sutured?…….Would this require re-admission to hospital and if so for how long (hours/days)?

Length of stay

21. If a patient had severe perineal infection, on average how long would they be admitted for (days) (your best estimate).

22. If need to be re-sutured due to healing complication, how many extra days in hospital would be necessary?

23. What is the average length of stay in hospital (hours /days) for patients having undergone an episiotomy

    24. With any posterior perineal trauma
    25. With any anterior trauma
    26. With severe vaginal / perineal trauma
    27. With severe perineal trauma
    28. With no perineal trauma

24. What is the average length of stay in hospital (hours /days) for patients NOT having undergone an episiotomy

    25. With perineum intact?
    26. With any posterior perineal trauma
    27. With any anterior trauma
    28. With severe vaginal / perineal trauma
    29. With severe perineal trauma

Cost data

25. Hourly wage of obstetrician, anaesthetist and of the person who carries out suturing if not midwife or obstetrician

APPENDIX 4 INPUTS INTO PROBABILISTIC SENSIVITY ANALYSIS

TABLE A2: Model variables for practice of episiotomy alone (costs in US$ 1999)

Model Variables	**Probability Distribution**	**Distribution Parameters**
STAFF		
Probability obstetrician Probability resident	Triangular 1-(probability obstetrician)	Mode: 0.50, Minimum 0.3, Maximum 0.7
Salary obstetrician/minute	Point estimate	$0.08
Salary resident/minute	Point estimate	$0.05
DRUGS AND MEDICAL MATERIALS		
Probability of an Epidural anaesthetic	Triangular	Mode: 0.07, Minimum 0.06, Maximum: 0.1
Lidocaine 2%[17]	Point estimate	$0.12
Bupivicaina 0.5%*	Point estimate	$18.10
Fentanilo citrate*	Point estimate	$2.20
Needle	Point estimate	$0.07
Syringe	Point estimate	$0.08
Catheter*	Point estimate	$1.78
Trocar*	Point estimate	$0.03
Self adhesive cloth*	Point estimate	$0.29
CAPITAL ITEMS		
Equipment: scissors[18]	Triangular	Mode: 0.14, Minimum: $4.28.10^{-6}, Maximum: $0.24
Overhead costs[19] (building and utilities (per minute)	Triangular	Mode: 0.01, Minimum: $0.007, Maximum: $0.012
Duration of procedure (minutes)	Triangular	Mode: 3.89, Minimum: 2, Maximum: 7

NOTE TO TABLE: * Used for epidural anaesthetic alone

[17] Epidural and local anaesthetic. Probability of use is 1.00

[18] The distribution around cost reflects two alternative methods of costing considered here. Scissors are used only for episiotomy (no other intervention) and are cleaned at the end of each delivery by sterilisation. The first costing method consists in evaluating the scissors by means of the value of the sterilisation pack used to sterilsie the scissors prior to the next delivery (data obtained from ANC costing). The second method consists in using the annualised value of the scissors (assuming a linear discount rate and an expected length of life of 10 years).

[19] Obtained from Borghi et al. (2000). The minimum and maximum values represent costs in a delivery room of a genrealist hospital with a maernity ward and a large maternity hospital in Rosario, respectively.

TABLE A3: Model Variables for practice of Suturing alone (costs in US$ 1999).

Model Variables	Probability Distribution	**Distribution Parameters**
STAFF		
Probability obstetrician Probability resident	Triangular 1-(probability obstetrician)	Mode: 0.50, Minimum 0.3, Maximum 0.7
Salary obstetrician/minute	Point estimate	$0.08
Salary resident/minute	Point estimate	$0.05
DRUGS AND MEDICAL MATERIALS		
Iodine Solution 10ml	Point estimate	$0.36
Needle for suturing	Point estimate	$0.24
Surgical catgut No 0	Point estimate	$1.60
Surgical Swabs (x1)	Point estimate	$0.04
Tray for suture set	Point estimate	$0.07
Needle holder	Point estimate	$0.07
Forceps for dissection	Point estimate	$0.24
CAPITAL ITEMS		
Overhead costs (building and utilities (per minute)	Triangular	Mode: 0.01, Minimum: $0.007, Maximum: $0.012
Duration of procedure (minutes)	Triangular	Mode: 8.06, Minimum: 5, Maximum: 25

TABLE A4: Model variables for treatment of adverse events: perineal pain (costs in US$ 1999)

Model Variables	**Probability Distribution**	**Distribution Parameters**
Perineal pain		
DRUGS AND MEDICAL MATERIALS		
Paracetamol 500mg*	Point estimate	$0.09
Ibuprofen 200mg*	Point estimate	$0.15
Naproxeno 250mg*	Point estimate	$0.19
Quantity paracetamol/ibuprofen (tablets)	Triangular	Mode: 31.92, Minimum: 30, Maximum: 40
Quantity naproxen (tablets)	Point estimate	40
Probability paracetamol/ibuprofen	Point estimate	0.08
Probability naproxen	Point estimate	0.84

NOTE TO TABLE: * Obtained from LEM

TABLE A5: Model variables for treatment of adverse events: healing complications and wound dehiscence (costs in US$ 1999).

Model Variables	**Probability Distribution**	**Distribution Parameters**
DRUGS AND MEDICAL MATERIALS		
Cefalexine 500mg	Point estimate	$0.15
Iodine Solution 10ml	Point estimate	$0.36
Cotton	Point estimate	$0.04
Quantity cefalexine tablets	Triangular	Mode: 31.46, Minimum28, Maximum40
Quantity iodine solution/cotton	Triangular	Mode: 32.10, Minimum: 30, Maximum:40
Probability cefalexine	Point estimate	0.67
Probability Iodine and Cotton	Point estimate	1
Probability re-admission/re-suturing	Triangular	Mode: 0.01, Minimum: 0, Maximum: 0.02
Duration of stay (days)	Triangular	Mode:3.97, Minimum:2, Maximum: 7
Cost re-suturing	Triangular	Mode: $4.51, Minimum: $42.9, Maximum: $5.23
Cost inpatient ward/day	Triangular	Mode: $94.28, Minimum: $85.59, Maximum: $144.84
Wound Dehiscence alone		
Cefalexine 1000mg	Point estimate	$0.29
Probability cefalexine 1000mg	Point estimate	0.17

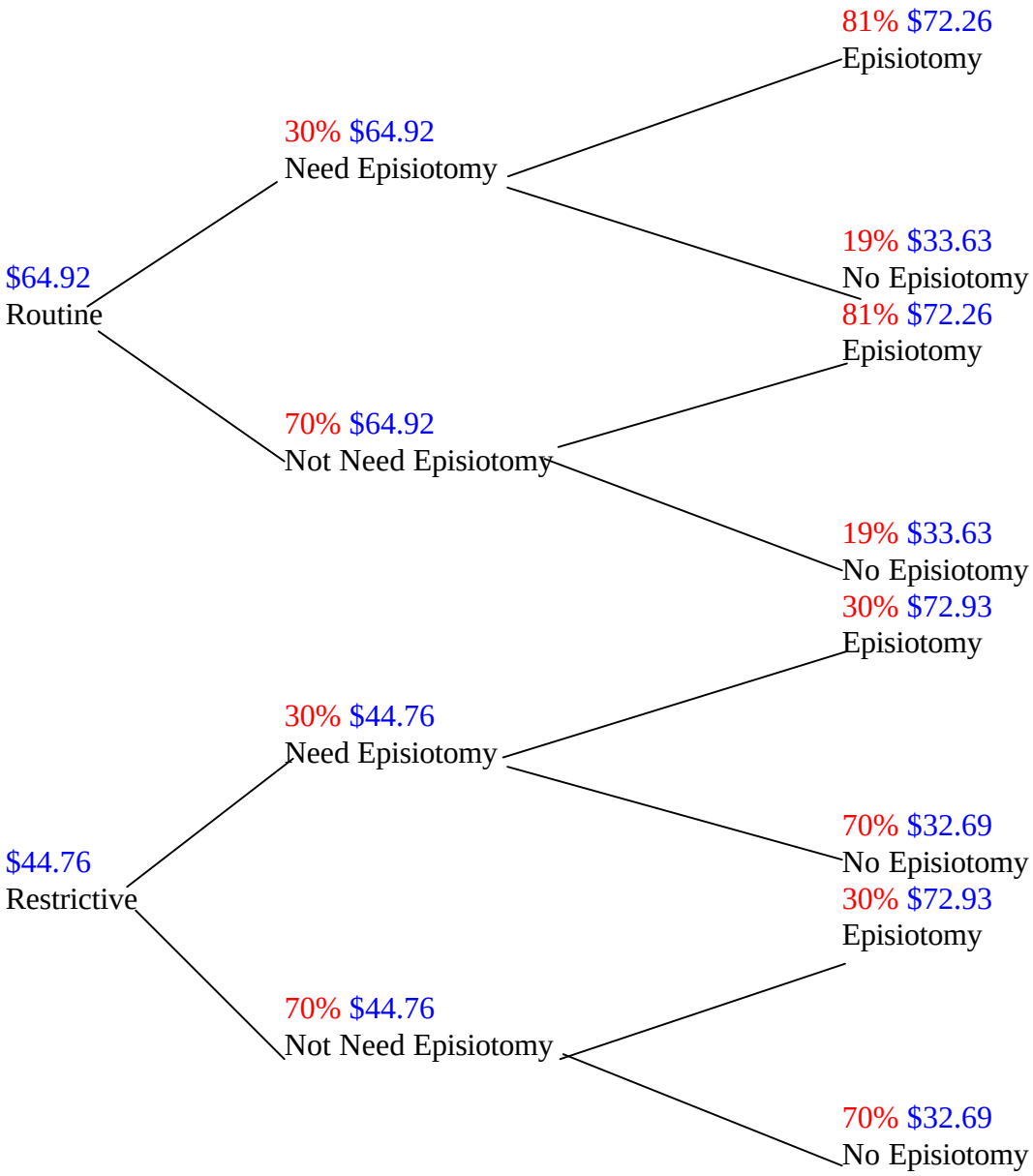
TABLE A6: Model Variables for Effectiveness Measures (Santa Fe and Salta)

Model Variables	**Probability Distribution**	**Distribution Parameters**
Probability of Perineal pain at discharge ROUTINE GROUP	Triangular	Mode: 0.41, Minimum:0.40, Maximum: 0.45
Probability of perineal pain at discharge RESTRICTIVE GROUP	Triangular	Mode: 0.29, Minimum: 0.28, Maximum:0.33
Probability of healing complications at 7 days ROUTINE GROUP	Triangular	Mode: 0.27, Minimum: 0.26, Maximum:0.34
Probability of healing complications at 7 days RESTRICTIVE GROUP	Triangular	Mode: 0.20, Minimum: 0.17, Maximum: 0.24
Probability of wound dehiscence at 7 days ROUTINE GROUP	Triangular	Mode: 0.08, Minimum: 0.07, Maximum:0.12
Probability of wound dehiscence at 7 days RESTRICTIVE GROUP	Triangular	Mode: 0.04, Minimum: 0.03, Maximum: 0.06
Probability of maternal sepsis with wound dehiscence/healing complications	Triangular	Mode: $9.09.10^{-6,}$ Minimum: $6.67.10^{-6,}$ Maximum: $1.33.10^{-5}$

Salta Province Results:

- An analgesic (Klosidol): $0.09/tablet
- Amoxiclavonic 125 mg: $0.14/tablet
- Quantity (tablets): (triangular distribution): minimum: 15. Maximum: 28, mode: 22.57
- Antiseptic and cotton (as above)
- Quantity (antiseptic/cotton units): triangular, minimum: 5 maximum: 7; mode: 5.93

APPENDIX 5 INCORPORATING NEED INTO THE MODEL: REVISED DECISION TREE



Within the simplified tree above, we have assumed a 30% baseline level of need (ie. The restrictive practice offers an episiotomy to all those women who need one). The figure simply illustrates the incapacity of the model to assess the impact of changes in episiotomy rates with regard to underlying need. As indicated, variations in the levels of need will have no impact on cost as we have no data regarding the impact on adverse events (of an increased rate of false positives/negatives) which we have had to assume remain constant due to a lack of information.

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