The cost-effectiveness of foetal monitoring with ST analysis

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ABSTRACT

How to allocate resources in the health care sector is academically dealt with within the subject of health economics. Economic evaluations are within this area used to compare the costs and effects of medical interventions with the purpose to help decision makers decide how to allocate resources.

Oxygen deficiency in the foetus during birth can lead to severe life long injuries in the child. In high-risk deliveries, there is therefore considered necessary to use foetal surveillance with a scalp electrode and the choice is between surveillance with internal cardiotocography (CTG) and surveillance with ST analysis. The standard procedure is in most hospitals currently CTG, which records the foetal heart rate and the uterine contractions. The second strategy, in this thesis referred to as ST analysis, complements CTG with foetal electrocardiography (ECG) and ST analysis.

The objective of this report is to from a societal perspective determine the cost-effectiveness of using ST analysis in complicated deliveries, compared to the use of CTG alone. A cost-utility analysis was performed based on a probabilistic decision model incorporating the relevant strategies and outcomes. The costs and effects of the two different treatment strategies were compared in a decision tree. Discounted costs and quality-adjusted life-years (QALYs) were measured and simulated over a life-time perspective.

The analysis resulted in an incremental effect of 0.005 QALYs for the ST analysis strategy, when compared to the CTG strategy. ST analysis was also associated with a €30 lower cost. Thus, CTG is dominated by the ST analysis strategy. The probability that ST analysis is the cost-effective alternative is high for all values of willingness-to-pay for a QALY, which means that a decision to implement the ST analysis strategy based on the results of this thesis would be surrounded by a low degree of uncertainty.

Keywords: ST analysis, cardiotocography, CTG, cerebral palsy, cost-effectiveness, cost-utility, decision model, foetal monitoring.
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1. INTRODUCTION

The subject of health economics deals with the allocation of resources within the health care sector. Collectively funded health care systems have limited budgets and decision makers within these systems need to prioritize when deciding what health-care interventions should be made available to the society [1]. Economic evaluations are tools used by health economists when comparing alternative treatment strategies. Leading literature within the subject of health economics, defines the ultimate purpose of economic evaluation in health care as to inform decision makers about the efficient allocation of health care resources [2]. In Sweden, the cost-effectiveness principle was legislated in 1997, with the purpose to reach a reasonable relation between costs and effects when deciding on what treatment strategy to use [3]. The perspective of cost-effectiveness contributes to a better use of resources and, as a consequence, the resources can be used by a greater amount of patients.

Oxygen deficiency in the foetus during birth may result in neurological damage and in 0.06% of all births the deficiency is of such severity that it leads to cerebral palsy or death. To be able to take appropriate actions in order to prevent such injuries, foetal surveillance with a scalp electrode is used in high risk deliveries. Currently, the most common method of such foetal surveillance is internal cardiotocography (CTG). This method of surveillance has however been shown to have several weaknesses and must often be coupled with blood sampling to achieve sufficient specificity. To overcome some of these weaknesses and enhance the detection of foetuses at risk of oxygen deficiency, a new method of combining CTG with ST analysis of the foetal electrocardiography (ECG) has been developed. This method provides an automatic analysis of the ST interval and when compared to CTG alone, it is thought to rely less on subjective interpretations made by the personnel.[4]

Several randomised controlled trials (RCTs) comparing CTG with ST analysis have been published [5-7] and a Cochrane review concluded that there is a reduction in cases of metabolic acidosis¹ and operative deliveries associated with ST analysis, when compared to CTG[8]. Whether the decrease in cases of metabolic acidosis also leads to a reduction in cases of cerebral palsy, is still not investigated. Nevertheless, the severe human, social and economic implications associated with cerebral palsy makes the connection to cerebral palsy important to consider when evaluating the outcome of ST analysis.

Even though the direct health outcome associated with ST analysis appears to be positive, when choosing between the two methods, it is important to compare

¹ A sign of oxygen deficiency.
the health effects with the additional costs of adding ST analysis to the labour surveillance. The ST analysis equipment costs approximately twice as much as the CTG equipment [4]. To assess the cost-effectiveness of ST analysis, an economic evaluation will be performed in this report, taking into account the relevant effects and costs. Until now, no other studies assessing the cost-effectiveness of ST analysis have been done. A Dutch cost-effectiveness study is at the moment in progress and is expected to be finished in 2009[9].

1.1 Purpose

The purpose of this report is to from a societal perspective assess the cost-effectiveness of CTG complemented with foetal ECG and ST analysis, compared to surveillance with CTG alone. It will be presented both as a paper in CMT Discussion Series and as a Master Thesis at Linköping University.

1.2 Methods

By the performance of a cost-utility analysis, two forms of internal foetal monitoring were compared. The comparison was between current standard procedure with internal CTG alone and the alternative of CTG complemented with ECG and ST analysis (henceforth referred to as ST analysis). Because of the severe implications of cerebral palsy, a decision was made to include an extrapolation from the treatment effect in cases of metabolic acidosis to cases of cerebral palsy and death.

A decision tree was developed to model the long-term costs and effects of each strategy. In order to find relevant connections to the construction of the tree, a literature search in Pubmed was performed. To analyse the results, the expected costs and outcomes of each intervention were calculated. The expected cost was found by summing up the cost of the intervention itself with the therapy-specific costs of the different pathways in the tree, each weighted by the probability that the patient will follow them. The same was done with the effect of the intervention even though there was no initial effect to take into account. The expected effect outcome for each intervention is the sum of each pathway’s expected effect outcome, consisting of each pathway’s probability multiplied with its effect.[2]

Discounted costs and quality-adjusted life-years (QALYs) were calculated over a life-time perspective in a probabilistic model. To reflect the uncertainty in the model, the parameters in the model were defined in probability distributions. A cohort of hypothetical individuals was run through the model as the parameters
were drawn randomly from the defined probability distributions. This procedure was repeated 5000 times which means that the costs and QALYs in the model were calculated the same amount of times. The mean costs and mean effects of these drawings are the result of the model. The model was programmed and analysed in Microsoft® Excel (Microsoft Corporation, Redmond, Washington, USA).

The methods will be more explicitly explained when I further on in the report explain my choices concerning the analysis and the decision model.

### 1.3 Limitations and criticism of the sources

When possible, data in the analysis has been estimated according to Swedish circumstances and include effects in both the infant and the mother. In my search of literature I have, for the purpose of this study, excluded articles from developing countries. As a consequence of performing the study according to Swedish circumstances, I have not been able to use cost studies performed in other countries. I have also excluded articles presented in other languages than Swedish, English and Spanish. This has resulted in that it sometimes has been difficult to find estimates.

I have in some cases chosen to not include some of the costs concerning complications in the child and the mother as consequences of the mode of delivery. This is because finding these estimates would take an important quantity of time and are not thought to change the results of my analysis in a considerable way. A further discussion about excluded costs can be found in the discussion in chapter six. I have also limited the costs of complications in the mother as a consequence of mode of delivery to only include direct treatment costs and when calculating the costs in the model, it was assumed that every delivery only results in the birth of one child. The results of the study are only valid for term deliveries.

### 1.4 Disposition

This report describes the construction of an economic model, the findings of necessary inputs and the results of running the model. It begins with a chapter about the two intervention strategies. The CTG and the ST analysis strategies will both be presented to give the reader an understanding of the difference between the two methods. Secondly, the most common forms of economic evaluations, their relationship to theories of decision making and the basics of decision models will be presented. The choice of economic evaluation and
decision model for this study will also be motivated. In the following chapter, there will be an illustration of the structure of my model and a description of the data I have used. Further, the results of the analysis will be presented in a base-case analysis and various sensitivity scenarios. In the penultimate chapter, issues of importance to the interpretation of the results will be discussed and finally I will present my conclusions. I find it important to clarify that theories, methods and empirical data will all be mixed throughout the report. The reason for this is that I have found the analysis more accessible to the reader explaining methods and theories in association to their practical use instead of giving them their own chapter. As the report is directed to students of Economics who are not expected to be familiar with the medical terms, a glossary can be found in the appendix explaining the most common medical expressions in this report.
2. FOETAL SURVEILLANCE

Foetal surveillance is used with the purpose to detect foetuses with insufficient oxygen supply during labour. Approximately 20% of all deliveries require the use of foetal monitoring with a scalp electrode attached to the foetal head [4]. In this chapter, the differences between the two available methods of internal monitoring of the foetus, CTG and the ST analysis, will be described. Foetal blood sampling was optional in both strategies [8].

2.1 The CTG strategy

CTG is today standard procedure in most hospitals. It has been used since the 1970’s and is an electronic device which registers the foetal heart rate and the contractions of the matrix[4]. It can be used externally by using an ultrasound transducer attached to the mother’s abdomen and internally by using a scalp electrode applied to the foetal head. The scalp electrode can only be used after membrane rupture, and generally provides more accurate information. In this analysis, the CTG strategy consists of internal CTG. In general, CTG has a low specificity and many foetuses show “abnormal” CTG at least once during labour even though they are not suffering from lack of oxygen. The changes in the foetal heart rate are not always associated with lack of oxygen and the method has a reputation of being difficult to interpret, leading to unnecessary operative interventions and ignorance of significant changes[10]. Abnormal CTG is often complemented with a scalp blood sample, a method that has been criticised for only giving an instantaneous image of the health state of the foetus and can sometimes be technically difficult to perform[4].

2.2 The ST analysis strategy

To obtain more information on the condition of the foetus than CTG can provide, it is possible to use foetal ECG. The ST analysis strategy is used on the same indications as internal CTG but combines CTG with foetal ECG and performs an analysis of the ST waveform. The ST analysis has its focus on the ST interval and the T wave in the ECG complex.

One ECG complex consists of the representation of one heartbeat (Figure J)[11]. The T wave is the ultimate part of the ECG-complex and represents the preparation for the next beat. When the child suffers from oxygen deficiency, the height of the T wave is increased as a consequence of liberation of adrenaline and energy production without oxygen. The QRS complex, which lies before the T wave, does not change when the foetus suffers from oxygen
deficiency, and can therefore be used to measure the increase in the height of the T wave. The height of the T wave is divided by the height of the QRS complex and the quota is printed parallel to the CTG registration. The quota is marked with a cross and when there are changes this is marked by the numbers 1, 2, 3 or the word ST event. When CTG is normal no attention should be given to abnormalities in the ST analysis. If CTG is abnormal or pathological, the severity of the ST event decides what intervention is the most adequate. For a preterminal CTG, immediate delivery is the recommended intervention.[4]

Figure 1. The ECG complex.

The ECG complex begins with the P wave in which the electrical impulses are spread over the atria (the upper chambers in the heart). The QRS complex represents the contraction of the ventricles and finally the T wave represents the preparation for the next heart beat[11].

Even though most children show the described reaction when exposed to oxygen deficiency, there are deviations. Malformations of the heart and infections can affect the form of the ST interval even though the foetus is not suffering from oxygen deficiency. In addition, the maturity of the foetus has significance for the reaction of the foetus. Growth inhibited foetuses cannot react in the same way as a healthy foetus. A possible disadvantage of the ST analysis strategy is that the staff relies too much on the results of ST analysis and therefore does not intervene even though there are other signs of that the foetus is suffering from oxygen deficiency.[4]
3. ECONOMIC EVALUATIONS AND DECISION MAKING

In this chapter, the differences between alternative forms of economic evaluation and their relationship to decision making within the health care sector will be explained. At the end of the chapter, decision-analytic modelling will be introduced. The choice of evaluation and type of model for this study will also be motivated.

3.1 Choice of analysis

The purpose of this part of the report is to clarify the terms cost-effectiveness analysis (CEA), cost-utility analysis (CUA) and cost-benefit analysis (CBA).

A CUA was determined to be the most adequate form of evaluation for this report but to motivate this choice and make it understandable to the reader it was found necessary to first explain the basics of all three forms of analysis. Some authors do not distinguish between CEA and CUA when writing about them and treat the CUA as a particular case of CEA[2]. To be able to separate them when writing about them in this report, the term CEA will only be used when referring to the most basic form of CEA. However, when discussing the concept of cost-effectiveness further on in this report it is important to remember that despite their names all three forms of analysis discussed in this chapter are used with the purpose to determine the cost-effectiveness of treatment strategies.

3.1.1 Cost-effectiveness, cost-utility or cost-benefit?

All three sorts of evaluation are in most cases identical on the cost side, but differ on the side of the effect outcome. In the CEA, the health effects are measured in natural units as life years gained, cases found or cases of disease avoided. Most commonly, the results are presented as a cost per unit of effect.[2] If having chosen to build this report on a CEA, the most important effect results would have been presented as a number of avoided cases of metabolic acidosis (the effect outcome in the RCTs on CTG and ST analysis). Metabolic acidosis is an intermediate outcome which means that it is not a final diagnosis. If having chosen metabolic acidosis to be the central effect outcome in this report, the long-term effects of oxygen deficiency at birth would have been lost.

The main difference between the most basic CEA and a CUA is that the CUA requires that the effect outcome can be converted into an outcome measure like QALYs gained [2]. The use of a standard outcome measure like QALYs makes...
it possible to make comparisons between treatments in different disease areas, without having to involve monetary units [12]. In order to capture the larger panorama of health and well-being, QALY is the recommended outcome in economic evaluations of health care interventions [2] and was so also chosen to be the outcome in this report. This implied that it was necessary to establish a link from the intermediate outcome metabolic acidosis to the final outcome cerebral palsy. The QALY concept will be explained more in detail in the next chapter.

If instead having chosen a CBA as the appropriate form of evaluation, I would have taken a step even further and measured the effect outcome in monetary units [2]. Because of expressing both effects and costs in monetary units the results of a CBA is easier to interpret and use in decision making. Yet, it is not a common method in health economics. The reason for this is that valuing health outcomes as changes in pain, suffering, functional status and mortality in monetary units is not easy and not many people is comfortable with doing it. In addition, the way of obtaining the monetary measurement by estimating individuals’ willingness to pay for improvements of their health is criticised for favouring the wealthy over the poor [13] as wealthy people are thought to be willing to pay more for improvements of their health and therefore, value health effects higher.

3.1.2 Quality-adjusted life-years (QALYs)

The major advantage of using QALYs is that they combine the effect in morbidity with the effect in mortality. The mortality is shown by the change in life years and the morbidity by the change in the size of the quality weights.[2]

\[
QALY = w \times Y
\]

\( w = \) QALY weight for a particular health state

\( Y = \) number of years spent in that health state

When using QALYs in an evaluation, one needs to find the quality weights which are to be used for the possible health states in the analysis. These weights are also called utilities and to satisfy the QALY concept they should comply with three criterions. The utilities have to be based on preferences, anchored on perfect health and death and be measured on an interval scale. Utilities are preference weights for given health states, with the number zero representing death and one representing perfect health. As these two states both will occur in treatment programmes evaluated with QALYs, they are set as the two anchor or reference points of the interval scale for the quality weights. The weights demonstrate people’s preferences for different health states and the more preferred health state receives a greater weight.[2]
In Figure 2, the area between the two curves represents the QALYs gained by a person when using an intervention instead of another. This example shows QALYs for a person being exposed to two different interventions. A person that is being treated with the first intervention follows the path for intervention 1. If the same person instead is treated with the second treatment, it follows the path for intervention 2. The y-axis represents the quality weights on a scale from 0 to 1 and the x-axis is the representation of the years an individual lives after the use of the intervention. With intervention one, death will occur at Death 1 but with intervention two, death will instead occur at Death 2. From the beginning of treatment until death, the quality of life is always higher for a person that is being treated with intervention 2. It can be seen in the figure that the quality of life in both health states decreases until it reaches 0, the state of death.[13]

**Figure 2. Quality-adjusted life-years (QALYs).**

There are two different methods to calculate utilities; empirical investigation or preference-based quality of life questionnaires. The first method is based on an interview with the patient. The patient is asked to rate scenarios concerning his or her health and the treatment he or she is receiving. The values that results from this method are then used to rate the quality of life benefits of treatment. There are different techniques to be used when performing the interview with the patient. The Standard Gamble (SG) method lets the patient choose between two alternatives varying the probability in one of them. The Time Trade-off
(TTO) method asks the patient to decide at what time with full health followed by death he or she would be indifferent to an intermediate health state for the time followed by death. Using Visual Analogue Scales, the patient is asked to decide where on a line between the best and worst thinkable health states he or she would value a pre-defined intermediate health state. Another alternative approach is to ask professionals on the subject to valuate the different health states and treatments. In the second method, instruments like SF-36, EQ-5D and HUI are used. They are all questionnaires with a predefined set of scores associated to them and can therefore be used to directly calculate QALYs.[12]

3.2 When does the society benefit from an intervention?

The theories regarding economic evaluations have their roots in welfare economics. According to Gold et al. cost-effectiveness analysis is not necessarily based on the principles of welfare economics and all principles of welfare economics do not apply to the practice of cost-effectiveness analysis. However, also Gold et al. have, when writing about cost-effectiveness, chosen to depart from the theory of welfare economics because of its ability to answer methodological questions concerning how the society should value resource costs. Gold et al. defines this cost-effective analysis as a normative analysis because of its purpose of being a practical tool to achieve goals of the society.[13]

In welfare economic theory, there are different ways to look at if the society has benefited from an intervention. The Pareto criterion, says that the society has benefited from an intervention if the use of this intervention leads to an improvement in welfare for some individual without letting any other individual worse off [14]. A disadvantage of this criterion is that not many interventions benefit everyone implying that very few treatment strategies would pass this criterion [13]. A more common approach is therefore the criterion of Kaldor-Hicks, also called the potential Pareto criterion. It is developed from the Pareto criterion and says that the society as a whole has benefited from an intervention if those who benefit from the intervention can compensate the losers of it and still be better off than before. The theory does not say that the compensation really has to be carried through, only that the losers should be able to get compensation from those who benefit from it. The Kaldor-Hicks criterion is criticized for only taking into account the net benefit and not the distribution of the benefits and losses.[14]

If the health outcome is measured in monetary units, the Kaldor-Hicks criterion is fulfilled when the value of the health effects of an intervention is higher than
the subsequent costs. When working with other forms of health outcome it is however, not that simple. How do we know if there is a gain to the society when the outcome in effect and in costs are not in the same unit and therefore cannot be compared? Neither the CEA nor the CUA present the health effects and costs in the same units. A comparison of the two outcomes is therefore not possible. Decision makers are in these analyses interested in the lowest cost per health outcome when comparing intervention strategies. When deciding if an intervention should be implemented, decision-makers compare the gain in effect and the cost of achieving that gain with their maximum willingness-to-pay for the health outcome.[13]

The different forms of analysis do all contribute with valuable information but are not the only factor that needs to be taken into account in decision making. When presenting their results, concepts of fairness and justice are captured neither in the effect outcome nor in the costs. Economic evaluations are not used with the purpose to decide what decision should be made, they should be seen more as a way of developing recommendations that the decision makers can either choose to follow or ignore.[13]

3.3 Decision-analytic modelling

Decisions about the use of health care interventions often have to be made even if the evidence available is weak. Decision analytic models offer the possibility to make these decisions on an analytical basis relying on explicit methods and assumptions. The theoretical foundations of this form of model can be found in statistical analysis and expected utility theory. The most popular structures are the decision tree and the Markov model. Both structures are used to represent the path of an individual after having been exposed to one of the treatment strategies under evaluation.[2] When evaluating the cost-effectiveness of medical technology in which different events occur at given probabilities at a relatively short time-period, the recommended decision model is a decision tree[12]. The decision tree models the possible prognoses of an individual by letting them be represented by a series of pathways, also called branches. The Markov model, on the other hand, has its basis on a series of states, occupied by the patient at a given point in time. The probability of the transition of a patient to a given state is assessed over cycles. In each health state there is a probability that the patient moves to any of the other health states. The use of a decision model makes it possible to combine different sources of evidence. It also provides the possibility to extrapolate to a longer time frame than clinical trials and test different assumptions about risk, costs and effectiveness.[2]
In this report, a decision tree was constructed. It was structured to represent the costs and effects within the trial periods earlier reported but, first and foremost it was developed to extrapolate the costs and effects to a life-time perspective taking into account the probability of developing cerebral palsy. This was done by searching relevant connections in the literature and connecting branches with the different possible outcomes to the chance nodes in the model.[2]
4. MODEL STRUCTURE AND INPUT DATA

In the previous chapter, the theories underlying the choice of analysis in this report were presented. In this chapter, the structure of the model will be illustrated. The origin of the data used in the model will also be presented.

4.1 Illustration of the model structure

The simplified model structure is shown in Figure 3. The structure of the decision tree is identical for both treatment strategies, with only the probabilities of mode of delivery and metabolic acidosis varying between the two. The long term extrapolation from metabolic acidosis to cerebral palsy is equal with regards to structure and probabilities for both alternatives.

A foetus being delivered in the model is facing a treatment-specific probability of being born through spontaneous vaginal, instrumental vaginal or caesarean delivery with the alternative methods of delivery resulting in different degrees of complications in the mother. After birth, the child can show signs of metabolic acidosis or not at a rate dependent on the treatment strategy. No published evidence of a direct correlation between metabolic acidosis and cerebral palsy, known to the author, is available. However, it is known that on its way from an intrapartum hypoxic-ischemic injury causing cerebral palsy, the child progresses through newborn encephalopathy [15]. To utilize this connection, the transition from signs of metabolic acidosis to cerebral palsy was therefore modelled through levels of encephalopathy, via the children’s level of base deficit. The children were classified as having no, minor, moderate or severe encephalopathy [16]. Children with moderate or severe encephalopathy face an elevated risk of dying or developing cerebral palsy but can also follow a development without complications. Those classified as having no or minor encephalopathy, were assumed to develop without any complications due to oxygen deficiency but still face a risk of developing cerebral palsy due to other causes. The risk of cerebral palsy increases with the severity of encephalopathy [17]. When defining the different grades of cerebral palsy the following classification was used: minimal cerebral palsy is defined as motor signs present but no functional impairment, mild cerebral palsy as symptoms resulting in some functional impairment, moderate cerebral palsy as between mild and severe, e.g. ambulant with walking frame and severe cerebral palsy as “little purposeful voluntary action, though function may be acquired, IQ permitting”[18].
Different modes of delivery are modelled as consequences of CTG and ST analysis. Irrespective of the method of delivery there is a probability that the child shows metabolic acidosis after birth. This probability differs between the two intervention strategies. The probability that the child develops different grades of newborn encephalopathy depends on whether the child shows metabolic acidosis or not. Moderate or severe encephalopathy could lead to cerebral palsy of different severity but can also lead to death or a development without complications. Children with no or mild encephalopathy face a risk of developing cerebral palsy due to other causes than oxygen deficiency. CTG = cardiotocography, ST analysis = cardiotocography complemented with foetal ECG and ST analysis.
4.2 Input data

In the previous chapter, the structure of the model was shown in a decision tree. In this chapter, the data used when running the model is presented. The data in the model is drawn from RCTs comparing CTG and ST analysis or clinical studies of the different health outcomes. A computerized literature search in Medline and the Cochrane Library was done to find the necessary data. Costs and QALYs were discounted by 3 % per annum according to recent guidelines[2].

4.2.1 Probabilities

The probabilities used in the model are shown in Table 1. Two RCTs have shown that the use of ST analysis results in a reduction of cases of metabolic acidosis and operative deliveries [5, 6]. On the other hand, a trial by Ojala et al. has shown both an increase in cases of metabolic acidosis and operative deliveries associated with the use of ST analysis [7]. This trial has been criticised for using an inappropriate method of measuring metabolic acidosis [19]. The probabilities of metabolic acidosis, operative deliveries and foetal blood sampling, used in the base case analysis, are drawn from the Cochrane review [8] taking the study by Ojala et al. into account. However, a sensitivity scenario was performed where the effect of excluding the third trial was investigated [20]. The RCT by Amer-Wåhlin et al. has been criticised for not having included all cases of metabolic acidosis in the ST analysis arm [21]. This critique has been answered by the research group arguing that there are no errors in 11 of the 13 cases mentioned in the critique [22]. The other two cases are currently being investigated. These two cases under investigation were included in a sensitivity scenario.

In the Cochrane review used in the analysis, metabolic acidosis was defined as a cord-artery blood pH of less than 7.05 and a base deficit of more than 12.0 mmol/L[8]. Enabling transition from metabolic acidosis to encephalopathy in the model, estimates from a trial investigating the relation between base deficit and encephalopathy were used [16]. In this trial, the distribution of different stages of encephalopathy was presented in four different groups of children. The four groups were differentiated by their values of base deficit in the children’s cord artery; children with a base deficit of 4-8 mmol/L, 8-12 mmol/L, 12-16 mmol/L and finally children with a base deficit of more than 16 mmol/L. Based on the definition of metabolic acidosis of an base deficit of more then 12.0 mmol/L, this allowed us to create a connection between metabolic acidosis and encephalopathy. To incorporate the distribution of base deficit levels in children
born in Sweden, base excess\(^2\) data from Vrinnevi Hospital in Norrköping was used (base excess data for 4939 of 5984 children born 2004-2006) [23]. Children having a base deficit of less than four mmol/L were not included in the study by Low. For this group it was assumed that there were no cases of moderate or severe encephalopathy, due to the level of base deficit.

The probability of children being diagnosed with cerebral palsy depends on the presence and severity of newborn encephalopathy. The estimates in the model are based on a trial by Badawi et al [17]. The same trial was used for the probability of the different degrees of cerebral palsy. The probability of death the two first years as a consequence of moderate or severe encephalopathy however, was retrieved from a meta-analysis [24] on the long-term adverse outcome of newborns. The meta-analysis included studies following the children for a time period up to between 18 months and three and a half year.

\(^2\) Base excess = negative base deficit
### Table 1. Parameter estimates used in the model.

<table>
<thead>
<tr>
<th>Event</th>
<th>Probability</th>
<th>Distribution</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maternal mortality after caesarean section</td>
<td>$0.18 \times 10^{-3}$</td>
<td>Beta</td>
<td>[25]</td>
</tr>
<tr>
<td>Maternal mortality after spontaneous and instrumental vaginal delivery</td>
<td>$0.21 \times 10^{-4}$</td>
<td>Beta</td>
<td>[25]</td>
</tr>
<tr>
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<td>$0.51 \times 10^{-3}$</td>
<td>Beta</td>
<td>[26]</td>
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<td>Deep vein thrombosis after caesarean section</td>
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<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Cerebral thrombosis after caesarean section</td>
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<td>[26]</td>
</tr>
<tr>
<td>Pulmonary embolism after spontaneous and instrumental vaginal delivery</td>
<td>$0.11 \times 10^{-3}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Deep vein thrombosis after spontaneous and instrumental vaginal delivery</td>
<td>$0.28 \times 10^{-3}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Cerebral thrombosis after spontaneous and instrumental vaginal delivery</td>
<td>$0.91 \times 10^{-4}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Blood transfusions after caesarean section</td>
<td>$0.46 \times 10^{-2}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Blood transfusions after instrumental vaginal delivery</td>
<td>$0.40 \times 10^{-2}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Blood transfusions after spontaneous vaginal delivery</td>
<td>$0.13 \times 10^{-2}$</td>
<td>Beta</td>
<td>[26]</td>
</tr>
<tr>
<td>Sepsis after caesarean section</td>
<td>$0.15 \times 10^{-2}$</td>
<td>Beta</td>
<td>[27]</td>
</tr>
<tr>
<td>Sepsis after spontaneous and instrumental vaginal delivery</td>
<td>$0.48 \times 10^{-3}$</td>
<td>Beta</td>
<td>[27]</td>
</tr>
<tr>
<td>Metabolic acidosis after CTG</td>
<td>0.01</td>
<td>Beta</td>
<td>[8]</td>
</tr>
<tr>
<td>RR metabolic acidosis after ST analysis</td>
<td>0.64</td>
<td>Gamma</td>
<td>[8]</td>
</tr>
<tr>
<td>Caesarean section after CTG</td>
<td>0.09</td>
<td>Dirichlet</td>
<td>[8]</td>
</tr>
<tr>
<td>Instrumental vaginal delivery after CTG</td>
<td>0.14</td>
<td>Dirichlet</td>
<td>[8]</td>
</tr>
<tr>
<td>Spontaneous vaginal delivery after CTG</td>
<td>0.77</td>
<td>Dirichlet</td>
<td>[8]</td>
</tr>
<tr>
<td>RR caesarean section after ST analysis</td>
<td>0.97</td>
<td>Gamma</td>
<td>[8]</td>
</tr>
<tr>
<td>RR instrumental delivery after ST analysis</td>
<td>0.87</td>
<td>Gamma</td>
<td>[8]</td>
</tr>
<tr>
<td>Foetal blood sampling after CTG</td>
<td>0.11</td>
<td>Beta</td>
<td>[8]</td>
</tr>
<tr>
<td>RR Foetal blood sampling after ST analysis</td>
<td>0.76</td>
<td>Gamma</td>
<td>[8]</td>
</tr>
<tr>
<td>BD of &gt;16 mmol/L in the metabolic acidosis group</td>
<td>0.28</td>
<td>Beta</td>
<td>[23]</td>
</tr>
<tr>
<td>BD of 8–12 mmol/L in the no metabolic acidosis group</td>
<td>0.08</td>
<td>Dirichlet</td>
<td>[23]</td>
</tr>
<tr>
<td>BD of 4–8 mmol/L in the no metabolic acidosis group</td>
<td>0.29</td>
<td>Dirichlet</td>
<td>[23]</td>
</tr>
<tr>
<td>BD of &lt;4 mmol/L in the no metabolic acidosis group</td>
<td>0.63</td>
<td>Dirichlet</td>
<td>[23]</td>
</tr>
<tr>
<td>No encephalopathy when BD &gt;16 mmol/L</td>
<td>0.39</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Minor encephalopathy when BD &gt;16 mmol/L</td>
<td>0.20</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Moderate encephalopathy when BD &gt;16 mmol/L</td>
<td>0.29</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Severe encephalopathy when BD &gt;16 mmol/L</td>
<td>0.12</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Condition</td>
<td>Probability</td>
<td>Distribution</td>
<td>Reference</td>
</tr>
<tr>
<td>---------------------------------</td>
<td>-------------</td>
<td>--------------</td>
<td>-----------</td>
</tr>
<tr>
<td>No encephalopathy when BD is 12–16 mmol/L</td>
<td>0.72</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
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<td>Minor encephalopathy when BD is 12–16 mmol/L</td>
<td>0.19</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
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<td>Moderate encephalopathy when BD is 12–16 mmol/L</td>
<td>0.07</td>
<td>Dirichlet</td>
<td>[16]</td>
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<tr>
<td>Severe encephalopathy when BD is 12–16 mmol/L</td>
<td>0.02</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>No encephalopathy when BD is 8–12 mmol/L</td>
<td>0.83</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Minor encephalopathy when BD is 8–12 mmol/L</td>
<td>0.17</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Moderate encephalopathy when BD is 8–12 mmol/L</td>
<td>0.16 x 10^{-3}</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Severe encephalopathy when BD is 8–12 mmol/L</td>
<td>0.22 x 10^{-3}</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>No encephalopathy when BD is 4–8 mmol/L</td>
<td>0.95</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Minor encephalopathy when BD is 4–8 mmol/L</td>
<td>0.18 x 10^{-1}</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Moderate encephalopathy when BD is 4–8 mmol/L</td>
<td>0.36 x 10^{-1}</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Severe encephalopathy when BD is 4–8 mmol/L</td>
<td>0.15 x 10^{-3}</td>
<td>Dirichlet</td>
<td>[16]</td>
</tr>
<tr>
<td>Cerebral palsy after moderate encephalopathy</td>
<td>0.84 x 10^{-1}</td>
<td>Beta</td>
<td>[17]</td>
</tr>
<tr>
<td>Mortality in first two years after moderate encephalopathy</td>
<td>0.62 x 10^{-1}</td>
<td>Beta</td>
<td>[24]</td>
</tr>
<tr>
<td>Cerebral palsy after severe encephalopathy</td>
<td>0.23</td>
<td>Beta</td>
<td>[17]</td>
</tr>
<tr>
<td>Mortality in first two years after severe encephalopathy</td>
<td>0.67</td>
<td>Beta</td>
<td>[24]</td>
</tr>
<tr>
<td>Proportion of severe cerebral palsy in children diagnosed with moderate or severe encephalopathy</td>
<td>0.46</td>
<td>Dirichlet</td>
<td>[17]</td>
</tr>
<tr>
<td>Proportion of moderate cerebral palsy in children diagnosed with moderate or severe encephalopathy</td>
<td>0.19</td>
<td>Dirichlet</td>
<td>[17]</td>
</tr>
<tr>
<td>Proportion of mild cerebral palsy in children diagnosed with moderate or severe encephalopathy</td>
<td>0.16</td>
<td>Dirichlet</td>
<td>[17]</td>
</tr>
<tr>
<td>Proportion of minimal cerebral palsy in children diagnosed with moderate or severe encephalopathy</td>
<td>0.19</td>
<td>Dirichlet</td>
<td>[17]</td>
</tr>
<tr>
<td>Cerebral palsy in children with no or mild encephalopathy</td>
<td>0.12 x 10^{-2}</td>
<td>Beta</td>
<td>[17]</td>
</tr>
<tr>
<td>Proportion of severe cerebral palsy in children diagnosed with no or mild encephalopathy</td>
<td>0.25</td>
<td>Dirichlet</td>
<td>[17]</td>
</tr>
</tbody>
</table>
Proportion of moderate cerebral palsy in children diagnosed with no or mild encephalopathy
0.30 Dirichlet [17]

Proportion of mild cerebral palsy in children diagnosed with no or mild encephalopathy
0.32 Dirichlet [17]

Proportion of minimal cerebral palsy in children diagnosed with no or mild encephalopathy
0.12 Dirichlet [17]

\( RR = \text{relative risk}, \ BD = \text{base deficit}, \ CTG = \text{cardiotocography}, \ ST \text{ analysis} = \text{CTG complemented with foetal electrocardiography and ST analysis.} \)

### 4.2.2 Costs

The cost parameters used in the model can be found in Table 2. The costs of experiencing caesarean section, instrumental vaginal delivery and spontaneous vaginal delivery included costs for the mode of delivery plus costs for potential complications. To calculate the cost per delivery of utilizing either ST analysis or CTG, data from Linköping University Hospital, Sweden, was used. The costs for the four devices used at this hospital were divided with the time of depreciation (seven years) and the amount of deliveries per year at which ST analysis has been used (approximately in 20% of 2523 deliveries)[28]. The cost of the ST analysis equipment was €29 800 (SEK 280 000) and the cost of the CTG equipment €14 900 (SEK 140 000) [4]. Added to the costs of the equipment were the costs of the scalp electrodes. The costs of educating the staff in the use of CTG and ST analysis were excluded from the cost per delivery as they were not thought to differ between the two strategies.

The costs of the first eight years for children with severe cerebral palsy were drawn from a study where the costs as a consequence of erroneous management at child delivery were investigated [29]. In this particular study five of nine children had some degree of invalidity, one of the degree of 50-70% and four of the degree of 71-100%. As the primary diagnose associated with severe injuries caused by erroneous management during child delivery has been shown elsewhere to be cerebral palsy[30], these costs are in the model employed for patients with severe cerebral palsy. For individuals with cerebral palsy older than eight years, figures from an American cost-of-illness study were used as weights to extrapolate the costs to a life-time perspective [31]. Children with severe cerebral palsy were assumed not to be able to work. Annual costs for productivity losses were drawn from official data collected by Statistics Sweden[32]. The average age for achieving a first job was assumed to be 20 years and production losses were included for the ages 20-64. The effect of including these production losses was tested in a sensitivity analysis.
However, there are various costs that are not included in this model although they are thought to vary with the use of CTG or ST analysis. Complications in the mother that are excluded because of lack of data or uncommonness are the following: hysterectomy, wound infections, wound ruptures, reoperations, uterus ruptures at following deliveries, urine- and anal incontinence. Costs associated with complications in the child after delivery but which are excluded because they are considered rare and not thought to affect the result of the model significantly are: brachial plexus injury, cephalhaematoma, skin lacerations, intracranial haemorrhage, facial nerve palsy and scalp injuries. Included in the cost of a scalp blood sample was the cost for the use of the device ABL-5 (Radiometer, Copenhagen, Denmark), the necessary time of a doctor, a midwife and an assistant nurse, two clinitubes and a blood-gas syringe [33].

Costs are expressed in euros (€) at 2006 price level and have been adjusted to 2006 price level according to the Swedish Consumer Price Index[34].

Table 2. Cost parameters in the model.

<table>
<thead>
<tr>
<th>Cost estimates</th>
<th>Mean cost (euros)</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caesarean section (per delivery)</td>
<td>4170</td>
<td>[35]</td>
</tr>
<tr>
<td>Instrumental delivery (per delivery)</td>
<td>1990</td>
<td>[35]</td>
</tr>
<tr>
<td>Spontaneous vaginal delivery (per delivery)</td>
<td>1470</td>
<td>[35]</td>
</tr>
<tr>
<td>Use of ST analysis (per delivery)</td>
<td>56</td>
<td>[4, 28]</td>
</tr>
<tr>
<td>Use of CTG (per delivery)</td>
<td>39</td>
<td>[4, 28]</td>
</tr>
<tr>
<td>Fetal scalp blood sampling (per sample)</td>
<td>28</td>
<td>[28, 33]</td>
</tr>
<tr>
<td>Pulmonary embolism (per woman)</td>
<td>3200</td>
<td>[36]</td>
</tr>
<tr>
<td>Deep vein thrombosis (per woman)</td>
<td>2720</td>
<td>[37]</td>
</tr>
<tr>
<td>Cerebral thrombosis (per woman)</td>
<td>4040</td>
<td>[38]</td>
</tr>
<tr>
<td>Blood transfusion (per woman)</td>
<td>230</td>
<td>[35]</td>
</tr>
<tr>
<td>Sepsis (per woman)</td>
<td>4370</td>
<td>[36]</td>
</tr>
<tr>
<td>CP 0–1 years (per year)</td>
<td>58 820</td>
<td>[29, 31]</td>
</tr>
<tr>
<td>CP 2–4 years (per year)</td>
<td>35 680</td>
<td>[29, 31]</td>
</tr>
<tr>
<td>CP 5–17 years (per year)</td>
<td>41 480</td>
<td>[29, 31]</td>
</tr>
<tr>
<td>CP 18+ years (per year)</td>
<td>70 100</td>
<td>[29, 31]</td>
</tr>
<tr>
<td>Production losses for individuals with severe cerebral palsy, after 20 years of age (per year)</td>
<td>35 790</td>
<td>[32]</td>
</tr>
</tbody>
</table>

CP = Cerebral palsy, CTG = cardiotocography ST analysis = cardiotocography complemented with foetal ECG and ST analysis. Costs are in euros.
4.2.3 Life expectancy and QALY weights

To the author’s knowledge, no complete age-specific standard mortality statistics are available for the definitions of cerebral palsy used in the model. However, evidence of survival time for the definitions of cerebral palsy used in the model does exist for a time period of 25-40 years of age [18]. The findings from this study were incorporated into the model by employing a parametric time-to-event survival model with a Weibull distribution [39]. The results of the Weibull regression indicated a decreasing hazard of death with respect to age as the ancillary gamma parameter was below one (-0.2 [SE 0.08]). The constant in the regression was -3.51 (SE 0.21). Applying appropriate formulas the fitted hazard function was transformed to yearly probabilities of death. The nature of the Weibull regression will lead to an ongoing decrease in probability of death not accounting for the natural increase later in life. The probability of death was therefore only based on the regression as long as it was above the standard mortality [40]. The probability of dying during the first two years was for the children with moderate or severe encephalopathy already included in the model. Therefore, the two first years of the survival curves for these individuals were excluded to not double count the death risk.

The QALY weights used in the model are shown in Table 3. The definition of cerebral palsy has been agreed on internationally as “an umbrella term covering a group of non-progressive, but often changing, motor impairment syndromes secondary lesions or anomalies of the brain arising in the early stages of development”[41]. Based on the term non-progressive, an assumption was made that the decrements of quality of life for individuals with cerebral palsy do not vary during their life time. Relative to the QALY weights found in the general population[42], the QALY weights used in the model for individuals diagnosed with mild, moderate and severe cerebral palsy were incorporated as decrements based on quality of life measures in adolescents[43] classified by the Gross Motor Function Classification System (GMFCS). As the severity of cerebral palsy in this model, is not based on the GMFCS levels, an assumption was made that the values for level I, level II and III, and level IV and V correspond to the definitions by Blair et al.[18] of mild, moderate and severe cerebral palsy.[44]
<table>
<thead>
<tr>
<th></th>
<th>QALY weights</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Severe CP</td>
<td>0.04</td>
<td>[43, 44]</td>
</tr>
<tr>
<td>Moderate CP</td>
<td>0.45</td>
<td>[43, 44]</td>
</tr>
<tr>
<td>Mild CP</td>
<td>0.84</td>
<td>[43, 44]</td>
</tr>
<tr>
<td>General population &lt; 30</td>
<td>0.90</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 30</td>
<td>0.88</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 40</td>
<td>0.87</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 50</td>
<td>0.85</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 60</td>
<td>0.82</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 70</td>
<td>0.78</td>
<td>[42]</td>
</tr>
<tr>
<td>General population 80+</td>
<td>0.69</td>
<td>[42]</td>
</tr>
</tbody>
</table>

*CP = cerebral palsy, QALY = quality-adjusted life-year.*
5. RESULTS

Until now, the methods and assumptions used in the model have been described. The structure of the model has been illustrated and the necessary data and its origin have been presented. In this chapter, the results of running the model are presented. The chapter begins with the base-case analysis in which the costs and effects are based on the average values of the model. The results are also shown in a cost-effectiveness plane and a cost-acceptability curve. Various sensitivity scenarios were performed with the purpose to show how the results of the model changed when varying some of the parameters in the model.

5.1 Base-case analysis

The probability of developing cerebral palsy was in this model 0.002151 in the ST analysis arm and 0.002198 in the CTG arm. The results of the base-case analysis are shown in Table 4. The costs are average costs of each intervention and include the cost of the equipments and the average costs associated with the outcomes and treatments following the use of the intervention. The second column in Table 4 shows the average cost per delivery associated with each method of surveillance. The third column shows the difference in average costs between the two methods. The negative number in this column has the significance that the ST analysis strategy saves money compared to CTG. The cost associated with the use of ST analysis is €30 lower than the cost associated with the use of CTG. The fourth column shows the effectiveness of ST analysis and CTG. The fifth column shows the incremental gain in effectiveness. The incremental gain for ST analysis is 0.005 QALYs. As the ST analysis strategy is both more effective and saves money it is the dominating strategy.

Table 4. Comparison of costs and effects.

<table>
<thead>
<tr>
<th>Method</th>
<th>Costs</th>
<th>Incremental costs</th>
<th>Effectiveness (QALYs)</th>
<th>Incremental effectiveness</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST analysis</td>
<td>2977</td>
<td>27.1641</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>−30</td>
<td></td>
<td>0.0054</td>
<td>Dominating</td>
</tr>
<tr>
<td>CTG</td>
<td>3008</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CTG = cardiotocography, ST analysis = CTG complemented with foetal ECG and ST analysis. Costs are in euros.
The cost-effectiveness plane (Figure 4) is used with the purpose to compare the additional effects that results from an intervention with the additional costs it imposes over the other intervention and is found by determining the incremental cost-effectiveness ratio, also called ICER. A dot in the plane shows the difference in costs between the two interventions on one axis and the difference in effect on the other. Most interventions, when evaluated, fall into the left higher quadrant. They cost more but are also more effective. The 5000 dots in this cost-effectiveness plane represent the different values of the 5000 drawings in the model. The fact that the majority of the dots fall into the right lower quadrant has the significance that ST analysis, in most drawings, is both more effective and less costly than CTG alone.[2]

Figure 4. Cost-effectiveness plane.

The x-axis shows the incremental effect in QALYs associated to the ST analysis strategy when compared to CTG. The y-axis shows the incremental cost of using the ST analysis strategy instead of CTG.

Based on the dots in the effectiveness plane, the cost-effectiveness acceptability curve (CEAC) demonstrates the probability that an intervention is cost-effective when compared to other interventions. In Figure 5 the probability that ST analysis or CTG are the cost-effective alternative is shown for different values of health outcomes. As there is no single true willingness-to-pay for a QALY, the probability can be presented for a range of values, making it possible for the
decision maker to establish the willingness-to-pay in a specific application and then assess the probability that the treatment strategy is cost-effective [45]. The curve is derived from the joint uncertainty in costs and effects and shows the probability that it is a correct decision to fund or reimburse the intervention evaluated[2]. From Figure 5, it can be seen that the probability of ST analysis being cost-effective is high for all willingness-to-pay values.

Figure 5. Cost-effectiveness acceptability curve.

CTG = cardiotocography, ST analysis = CTG complemented with foetal ECG and ST analysis, QALY = quality-adjusted life-year.

5.2 Sensitivity scenarios

When there is uncertainty surrounding a variable in the analysis, one way to handle this is to make assumptions about the clinical evidence and compensate for the uncertainty by doing some kind of sensitivity analysis. If the final result does not change too much with changes in the estimate, it can be considered not worthy to put extra time and effort in finding a better estimate.[2]

The results of the sensitivity analyses are shown in Table 5. Neither of them changes the conclusion that ST analysis is dominating CTG.
Table 5. Results of the sensitivity scenarios.

<table>
<thead>
<tr>
<th>Method</th>
<th>Costs</th>
<th>Incremental costs</th>
<th>Effectiveness (QALYs)</th>
<th>Incremental Effectiveness</th>
<th>ICER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Excluding the trial by Ojala et al.</td>
<td>ST analysis 2954</td>
<td>−61</td>
<td>27.1665</td>
<td>0.0092</td>
<td>Dominating</td>
</tr>
<tr>
<td></td>
<td>CTG 3015</td>
<td></td>
<td>27.1573</td>
<td></td>
<td></td>
</tr>
<tr>
<td>25-year time horizon</td>
<td>ST analysis 2440</td>
<td>−16</td>
<td>16.4674</td>
<td>0.0033</td>
<td>Dominating</td>
</tr>
<tr>
<td></td>
<td>CTG 2457</td>
<td></td>
<td>16.4641</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Including two extra cases of metabolic acidosis in the ST analysis arm</td>
<td>ST analysis 2981</td>
<td>−27</td>
<td>27.1635</td>
<td>0.0048</td>
<td>Dominating</td>
</tr>
<tr>
<td></td>
<td>CTG 3008</td>
<td></td>
<td>27.1588</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Excluding production losses for individuals with cerebral palsy</td>
<td>ST analysis 2754</td>
<td>−24</td>
<td>27.1641</td>
<td>0.0054</td>
<td>Dominating</td>
</tr>
<tr>
<td></td>
<td>CTG 2778</td>
<td></td>
<td>27.1588</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

CTG = cardiotocography, ST analysis = CTG complemented with foetal ECG and ST analysis. Costs are in euros.

According to the results of the base-case analysis (Table 4) the utilization of ST analysis results in a gain in QALYs at a lower cost, and is therefore dominating CTG. The lower cost of the ST analysis strategy despite the higher initial costs of ST analysis, are primarily due to avoidance of costs related to cerebral palsy. However, even in the time perspective up until just after delivery, the two strategies were seen to be cost neutral, due to the lower rate of complicated deliveries (Table 6). This sensitivity scenario is presented in a separate table as the effect outcome is in another type of unit.
Table 6. Comparison of costs and effects when excluding the extrapolation to cerebral palsy.

<table>
<thead>
<tr>
<th>Method</th>
<th>Costs</th>
<th>Incremental costs</th>
<th>Effectiveness (in cases of metabolic acidosis)</th>
<th>Incremental effectiveness (in avoided cases of metabolic acidosis)</th>
<th>ICER (costs per avoided case of metabolic acidosis)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ST analysis</td>
<td>1824.96</td>
<td>0.00781</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CTG</td>
<td>1825.06</td>
<td>-0.10</td>
<td>0.0122</td>
<td>0.00439</td>
<td>cost neutral</td>
</tr>
</tbody>
</table>

CTG = cardiotocography, ST analysis = CTG complemented with foetal ECG and ST analysis. Costs are in euros.
6. DISCUSSION

The purpose of this report was to from a societal perspective assess the cost-effectiveness of the ST analysis strategy compared to CTG alone. The study has shown that ST analysis is cost-effective when compared to the current standard practice CTG. Including treatment costs for complications as a consequence of the chosen method of delivery and the lifetime costs for individuals with cerebral palsy, ST analysis is a cost-saving method when compared to CTG. A Cochrane review [8] showed that ST analysis, compared to CTG alone, contributed to a gain in avoided cases of metabolic acidosis. This study showed that the use of ST analysis also results in a gain in QALYs when taking into account the effects of cerebral palsy and death. By being the first study assessing the cost-effectiveness of ST analysis, this study contributes with valuable information to decision makers within the area.

There has been criticism directed towards the sensitivity of the ST analysis method and the content of the method’s clinical guidelines [21]. This criticism has mainly concerned the uncertainty regarding how to act when the ST analysis does not warn even though the child is suffering from oxygen deficiency and CTG shows a pathological or preterminal pattern. New guidelines have recently been developed and published with the aim to overcome user errors and to reduce ambiguity and the risk of adverse outcome [46]. In this context, it is important to clarify that the results of this study are valid only under the particular circumstances of the RCTs included in the Cochrane review [8].

In two of the included RCTs, the result has been questioned [19, 21]. The criticism towards the trial by Ojala et al. [7] concerned the method of measuring metabolic acidosis. The inclusion of this trial in the base-case analysis reduced the difference between the two strategies in cases of metabolic acidosis and operative deliveries. However, ST analysis was still the dominant intervention and when excluding this trial in a sensitivity scenario, the use of ST analysis resulted in even higher gains of QALYs at lower costs. On the other hand, the trial by Amer-Wåhlin et al.[5] has been criticized for having excluded cases of metabolic acidosis from the ST analysis arm. When in a sensitivity scenario including the cases of metabolic acidosis that are still under investigation, the differences in QALYs and costs between the two strategies were slightly reduced but the ST analysis strategy was still dominant.

To model the path followed by a child affected by oxygen deficiency severe enough to cause cerebral palsy, a link between metabolic acidosis and cerebral palsy was established by using previous research on this relationship. The concept of extrapolating costs and outcomes by modelling a longer time period than for which available trial data exists might seem doubtful from a clinical
point of view. When evaluating cost-effectiveness, however, the appropriate time horizon should be the time over which the costs and effects of the alternatives might differ. The time the patients remain alive is often the only relevant time horizon even if the patients never are followed for that period in trials. In this study, evaluating different methods of foetal surveillance, the gap of information between what has been observed in clinical trials and what could be expected future effects on health and costs is literally consisting of a whole lifetime.

To see how the results would change if not taking the long-term consequences into account, the extrapolation was excluded in a sensitivity scenario. It was seen that the ST analysis strategy and the CTG strategy were cost neutral when only including treatment costs associated with the mode of delivery. This means that the additional cost of using the ST analysis equipment instead of CTG is outweighed by the costs saved by avoiding caesarean sections and instrumental vaginal deliveries.

It is common to validate the model by comparing the probabilities in the model with other models or clinical studies. In this model, the extrapolation to cerebral palsy and death was performed in two steps and involved various sources. It was, therefore, considered appropriate to make a comparison of the probability of developing cerebral palsy in this model with outcomes in clinical studies on the subject. Himmelmann et al. concluded that the mean prevalence of cerebral palsy was 11.1 per 10 000 live births [47]. The prevalence of cerebral palsy in my model was higher, 21.51 and 21.98 per 10 000 in the ST analysis and CTG arm respectively. The difference could perhaps be explained by the use of Australian and Canadian studies when determining the probabilities of encephalopathy and cerebral palsy (the overall rate of term cerebral palsy in the Australian study was 15.8 per 10 000). Another explanatory factor could be a higher prevalence of metabolic acidosis in our model than in the population of Himmelmann et al.

To avoid over estimation of the effects of ST analysis, a conservative approach to the analysis has been applied, i.e. when determining what assumptions to make and what data to use, the least favourable option to the cost-effectiveness of ST analysis was when possible chosen. Some relevant costs were not available and therefore not included in the model. Most of these costs would if included benefit the ST analysis strategy. There were no available data for costs of care in neonatal intensive care unit, as a consequence of metabolic acidosis and encephalopathy. Neither were there cost data for children with mild and moderate cerebral palsy. An inclusion of these costs would have affected the cost-effectiveness of ST analysis in a positive direction as there, according to this model, are fewer cases of metabolic acidosis, encephalopathy and cerebral
palsy after the use of ST analysis than after the use of CTG alone. Production losses were included both for the relatives to the children with cerebral palsy and the children themselves as adults [29, 32]. The sensitivity scenario, excluding the costs of production losses for the children with cerebral palsy, did not yield results changing the conclusion that ST analysis should be considered cost-effective. If included, anal incontinence in the mother would probably have made ST analysis more cost-effective since it is a costly complication more likely to occur after instrumental vaginal deliveries than after spontaneous vaginal deliveries [48, 49]. Urine incontinence is more common after vaginal deliveries than after caesarean sections and may reduce the cost-effectiveness of ST analysis [49, 50]. If including the fact that there are sometimes multiple births, the cost per delivery would augment. As this increase in costs would occur in both strategies this is not thought to affect our results considerably.

In this model, the age related decrements of the QALY weights used for cerebral palsy do not differ from the general population. Cerebral palsy is defined as a non-progressive impairment and the physical state was therefore assumed not to change with age because of the disease. However, it is not known how the individual’s perception of having cerebral palsy changes as he or she grows older. The difference in mobility, between a person with cerebral palsy and a person without cerebral palsy, is thought to increment with age during childhood and adolescence. At the same time, the individual might adapt and accept the disease with time. The weights used in this study were, however, the most relevant found in the literature.

By using a probabilistic model, uncertainties in the parameter estimates were considered in the model and the uncertainty of the results was illustrated in an acceptability curve. It can be seen in the analysis that the probability of ST analysis being cost-effective was high for all values of the willingness to pay for a health outcome. Relating the results of this study to the criterions in decision-making, earlier presented, ST analysis should be the recommended strategy. It is not only the most effective strategy in this evaluation; it is also the less costly. As there are no extra costs (the cost is negative) generated by ST analysis to achieve the gain in QALYs, it is not necessary to compare the ICER to how much decision makers are willing to pay for a QALY.
7. CONCLUSIONS

According to the results of the base-case analysis, ST analysis is the cost-effective alternative in comparison to CTG alone when used in high-risk term deliveries. The average costs for ST analysis has been shown to be lower and there is a gain in QALYs associated with ST analysis. Thus, the ST analysis strategy is dominating the CTG strategy. By using a probabilistic model, uncertainties in parameter estimates were considered in the model and the uncertainties were illustrated in an acceptability curve. In this curve, it was seen that the probability of ST analysis being cost-effective was high for all values of the willingness to pay for a health outcome. ST analysis is the recommended strategy.
APPENDIX

LIST OF ABBREVIATIONS

CEAC  Cost Effectiveness Acceptability Curve
CTG   Cardiotocography
ECG   Electrocardiography
ICER  Incremental Cost-Effectiveness Ratio
QALY  Quality-Adjusted Life-Year
RCT   Randomised Controlled Trial

GLOSSARY

Asphyxia  Suffocation or condition where someone is prevented from breathing and therefore cannot take oxygen into the bloodstream [51].
Caesarean section  Surgical operation to deliver a baby by cutting through the abdominal wall into the uterus [51].
Cerebral palsy  Disorder of the brain mainly due to brain damage occurring before birth, or due to lack of oxygen during birth [51].
Encephalopathy  Disease of the brain [51].
Ischaemic  Lacking in blood [51].
Metabolic acidosis  Cord pH less than 7.05 and base deficit greater than 12 mmol/L [8].
Umbilical cord  Cord containing two arteries and one vein which links the foetus inside the womb to the placenta [51].
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