

ObsteCare's AFL®-method for measuring lactate concentration in arrested labor

- A cost analysis

Lars Bernfort, Lars-Åke Levin

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Preface

Dystocia or failure-to-progress is a commonly occurring problem in childbirth, especially among primiparas. Arrested labor poses an increased risk of protracted labor, which in turn increases the risk of complications and the need for emergency (acute) caesarean section and instrumental delivery. Besides the suffering and risks posed to mothers and infants, complications also entail increased healthcare costs.

The standard strategy in arrested labor has been to treat women in labor with an infusion of oxytocin to stimulate the uterine muscle. However, in some cases, oxytocin augmentation causes overstimulation and an excessively elevated concentration of lactate (lactic acid). In the presence of high lactate levels, oxytocin has the opposite effect and prolongs time-to-delivery. It is thus of great value to be able to determine lactate levels prior to any decision to administer oxytocin, or not in the presence of a pre-existing high concentration.

By means of a method devised by ObsteCare, lactate levels can now simply and reliably be measured in amniotic fluid (reflecting the lactate concentration in the myometrium). In this study, a cost analysis was performed of this measurement method compared with non-measurement among primiparas affected by dystocia. The analysis was restricted to the healthcare episode in which delivery was accomplished.

The analysis demonstrates that measurement of lactate levels may be assumed to reduce the number of acute caesarean sections by approximately 30% and instrumental deliveries by approximately 12%. For primiparas affected by dystocia, the healthcare costs are calculated as being reduced by an average of SEK 1,662 per delivery, including the costs of lactate measurement.

According to available evidence it would thus be cost-saving for the health service to adopt this means of measuring lactate levels in arrested labor. Equally, all logic indicates that this strategy is also of benefit to mothers and infants. All factors considered, the recommendation is for lactate measurement in the presence of dystocia to be introduced widely.

Lars Bernfort

PhD, Associate Professor

Center for Medical Technology Assessment (CMT)

Linköping University

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Abstract

A commonly occurring problem in childbirth, not least among first-time-mothers-to-be (primiparas) is arrested labor and the risk of delayed delivery. Dystocia arising from deficient uterine contractions increases the risk of instrumental delivery or acute caesarean section, which in turn increases the risk of complications (e.g. hemorrhage).

The established treatment for dystocia is to administer oxytocin, which, however, carries the risk of overstimulating the uterine muscle and, instead of prolonging labor. ObsteCare has devised a flexible, reliable and non-invasive method of measuring lactate levels in amniotic fluid. Such measurements support well-informed decisions on whether or not to administer oxytocin in the presence of dystocia. Avoiding the infusion of oxytocin in the presence of pre-existing high lactate levels would result in a reduction in needlessly protracted labor and fewer acute (emergency) caesarean sections and instrumental deliveries.

In order to examine whether the cost of using ObsteCare lactate measurement is merited by cost-savings achieved as a result of changes in delivery outcomes, a health economics (cost) analysis was conducted of employing this method for primiparas compared with non-use of this method. The analysis is limited to the care episode in which delivery occurs and to costs.

The most prominent result of the analysis was the reduction in the number of acute caesarean sections of approx. 30% and of instrumental vaginal deliveries by approx. 12%. The healthcare cost reduction is estimated at SEK 1,662 (-4%) per delivery in the presence of arrested labor (including the cost of lactate measurement).

The result of this analysis indicates that measurement of lactate levels in the presence of arrested labor in primiparas reduces costs. The available evidence indicates that this strategy should be introduced in Swedish healthcare.

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1 Introduction

A commonly occurring problem in the delivery room is arrested labor, also known as failure-to-progress or labor dystocia. Studies indicate that 20% of all deliveries globally are “dysfunctional”. [1-3] Dystocia due to inadequate uterine contractions causes protracted labor with the entailed risk of various complications and adverse maternal experiences [4]. Protracted labor ends not uncommonly in “unnatural” delivery by acute caesarean section or instrumental vaginal delivery (e.g. ventouse or forceps). Besides the health risks posed to both the mothers and the infants, such interventions also result in increased healthcare costs.

The established treatment for arrested labor is to administer synthetic oxytocin in order to stimulate the myometrium to resume adequate regular contractions [5, 6]. In many cases, this has been an effective means of shortening the time spent in labor and for achieving “natural” (vaginal) births. However, in certain cases, oxytocin fails to have the intended effect. The explanation for this is assumed to be that oxytocin augmentation can result in over-exertion of the uterine muscles and hence excessively elevated levels of lactic acid (lactate). Uterine lactate levels are reflected in amniotic fluid lactate (AFL®) [4, 7]. In the absence of information about the cause of labor dystocia, there is a high probability that oxytocin augmentation will be continued in order to induce contractions. Elevated AFL® levels and continued oxytocin augmentation causes muscle fatigue which carries a risk of even more protracted and difficult deliveries – again, with the increased risk of acute caesarean section or assisted vaginal delivery (forceps/ventouse) [7].

On the premise that in the presence of elevated lactate levels the muscles involved should be allowed rest and restitution as opposed to being stimulated, a method was devised for measuring the AFL® concentration. Certain knowledge of the AFL® level would in turn provide an indication of how a delivery may best be managed. In the presence of low or normal levels of AFL®, oxytocin-augmentation of contractions should be continued, and in the presence of high AFL® levels, further oxytocin administration should be deferred and halted if necessary. Similarly, the AFL® level can be measured at the first signs of arrested labor and prior to the decision to administer oxytocin. For low or normal AFL® levels, oxytocin should be administered, and for high levels should be deferred.

The object of this analysis was to evaluate the use of AFL® measurement in arrested labor among primiparas. Comparison (control) was achieved by refraining from measuring AFL® levels, and outcomes of interest were the probabilities of different delivery outcomes together with the health service costs incurred during the healthcare episode in which delivery was accomplished.

2 The relationship between lactate levels and delivery outcomes

The relationship between lactate levels and delivery outcomes has been investigated by a number of studies in recent years. The principal findings of some of these studies are summarized briefly below.

Wiberg-Itzel et al. [8] found that high lactate levels (> 10.1 mmol/l) in two consecutive samples collected during labor (60 minutes apart) correlated strongly with dystocia. The authors found that for deliveries preceded by two consecutive samples showing high AFL® concentrations (> 10.1 mmol/l), 25/29 resulted in dystocic deliveries and only 4/29 in spontaneous vaginal deliveries. Deliveries without two consecutive samples of high AFL® concentration resulted in 6 cases out of 25 of dystocia, while 19/25 ended in spontaneous vaginal deliveries. The practice proposed is thus to measure AFL® as decision-support to guide continued management.

In a study of 825 women in active labor, Wiberg-Itzel et al.[3] investigated the value of AFL® concentration as a predictor of delivery outcomes. AFL® values in addition to a partogram were compared with partogram-only as a predictor of dystocia and operative delivery. The conclusion was that the addition of AFL® measurement provided a more reliable outcome prediction. High AFL® concentrations in labor dystocia were associated with an increased risk of operative delivery, while low AFL® concentrations improved the likelihood of vaginal delivery. The final conclusion was that AFL® measurement increases the likelihood of appropriate management and hence a higher proportion of uncomplicated deliveries.

Wiberg-Itzel et al. [9] analyzed AFL® concentration in relation to oxytocin use and "undesirable" (operative) deliveries. More specifically, the study investigated the extent to which the incidence of operative delivery correlates with lactate level and oxytocin use. The study included 74 women in active labor. The lactate level was sampled continuously (at 30 minute intervals) and the women were assigned to one of two groups; one with and one without oxytocin. Ten of the 74 (13.5%) deliveries were completed operatively. The lactate levels increased as labor progressed, and more markedly so if oxytocin was administered. In the operative deliveries, the AFL® concentrations were significantly higher. In those cases where infusion of oxytocin was paused (due to overstimulation), the outcome was normal delivery with no operative intervention needed. These results indicate that in the interests of optimized obstetric care, it is important to monitor AFL® levels.

Murphy et al. [10] assessed whether elevated AFL® levels were predictive of labor dystocia and acute caesarean section in primiparas (nulliparas) at term. This study included 905 women in spontaneous labor, and the standard procedure was to administer oxytocin for arrested labor. High AFL® levels were associated with higher oxytocin dosing, dystocia and acute caesarean section. It was found that an AFL® ≥ 10.0 mmol/l was a significant independent predictor of acute caesarean section. For women with AFL® < 10 mmol/l, oxytocin may be used, and the dose adjusted to achieve the desired result.

Wiberg-Itzel et al. [11] also studied primiparas and the extent to which AFL® concentration in arrested labor (when oxytocin was deemed warranted) is a predictor of delivery outcome. Their prospective multicenter study included 3,000 women with spontaneous onset of labor (dilated by ≥ 3 cm on arrest of labor). They concluded that AFL®, analyzed at least 30 minutes before oxytocin augmentation, serves as a predictor of delivery outcome. Prediction accuracy, i.e. of outcome in the form of caesarean section or not based on data on high (≥ 10.1 mmol/l) or low (< 10.1 mmol/l) AFL®, was 83.7% when AFL® sampling was performed. High AFL® levels also correlated with labor duration (> 12 hours) and with post-partum fever and hemorrhage.

2.1 Deliveries in Stockholm, Sweden, 2019 (unpublished figures)¹

A review of deliveries in Stockholm, Sweden in 2019 revealed as follows:

A total of 28,730 women were delivered (greater number of infants as some women gave birth to more than one infant) and the following details are notable:

- 3,492 women (12%) were diagnosed with dystocia according to the definition that the expected normal progression during the active phase of labor is delayed by three hours
- 11,586 received oxytocin augmentation (40%)
- 111 of the women with dystocia were never given oxytocin
- 8,094 of the women on oxytocin were not diagnosed with dystocia (meaning that 70% of those infused had not been diagnosed with dystocia)
- In total, 5,992 caesarean sections were performed (20.9%)
- Of these, 2,709 were performed as emergencies (approximately 45% acute and 55% planned). Acute caesarian sections accounted for 9.4% of deliveries.

This means that a large number of women received unwarranted augmentation (without the diagnosis of dystocia), which is indicative of the need for AFL® measurement.

2.2 ObsteCare – AFL® measurement

A practical, reliable and non-invasive method of measuring amniotic fluid lactate has been developed by the Swedish company ObsteCare. By means of a device and single-use supplies in the form of a test probe and syringe, the lactate concentration can be measured easily and rapidly. This provides support for great flexibility and individualized on-the-spot delivery management. The method provides rapid feedback on lactate concentration to inform decisions to increase/reduce/defer oxytocin augmentation in each individual case. As described in the foregoing, this information makes it possible to prevent unwarranted protracted labor with undesirable outcomes and increases the probability of achieving as many natural (vaginal) deliveries as possible. This reduces the risk of complications for both mother and infant and reduces both suffering and costs.

¹ Personal communication, Eva Wiberg-Iltzel.

3 Health economics analysis of ObsteCare AFL® measurements

A traditional health economics analysis compares two or more strategies for the treatment of a medical condition, or, as in this case, the management of a healthcare procedure. The analysis entails comparing costs and effects/impacts of the alternative strategies with each other in an incremental study. An analysis of two alternative strategies, A and B, produces an incremental cost-effectiveness ratio:

$$(\text{Costs}_A - \text{Costs}_B) / (\text{Benefits}_A - \text{Benefits}_B)$$

For the analysis to be meaningful, it is crucial that the intervention to be assessed is compared with a relevant alternative. In this case, AFL® measurement (in arrested labor) is compared with “conventional management”, i.e. how the situation would have been managed in the absence of access to AFL® measurement.

The most appropriate timeframe for use in an analysis depends on the health technology analyzed and the period of time in which applicable costs and benefits of treatment/management may be assumed to be incurred. In this case, we lack knowledge of what transpires after the health care episode in which delivery is accomplished. The timeframe for the analysis is consequently limited to a relatively short period of time. In further studies, it would naturally be of value to assess the more long-term impacts of different delivery outcomes with respect to factors such as infant health, maternal health and fear of childbirth etc.

Analysis is typically performed from a socioeconomic perspective in that costs and effects ensuing from treatment/management should be addressed regardless of who they harm or benefit. In certain cases, it is more appropriate to operate with a healthcare perspective entailing that costs incurred by the health system are the principal interest (in parallel with patient health/quality of life). As hinted at above, evidence is lacking as to what transpires after the initial care episode and outside of the healthcare system. The present analysis was thus performed from a healthcare perspective.

The benefits in health economics assessments are typically expressed in terms of Quality-Adjusted Life-Years (QALYS) according to which quality of life and time are aggregated in a combined metric. The health and wellbeing of mothers during labor was not established, and their quality of life was not measured in any viable manner. Moreover, the analyzed timeframe is very short, which means that any benefits for maternal quality of life (in QALYS terms) can be assumed to be negligible. Consequently, the present analysis solely addresses costs.

The analysis is based around the probabilities for the different deliver outcomes: “vaginal delivery”, “instrumental delivery” and “acute caesarean section”. Figure 1 below presents a simple model of the initial proposal for how the decision-making issue (AFL® measurement or not?) might be assessed.

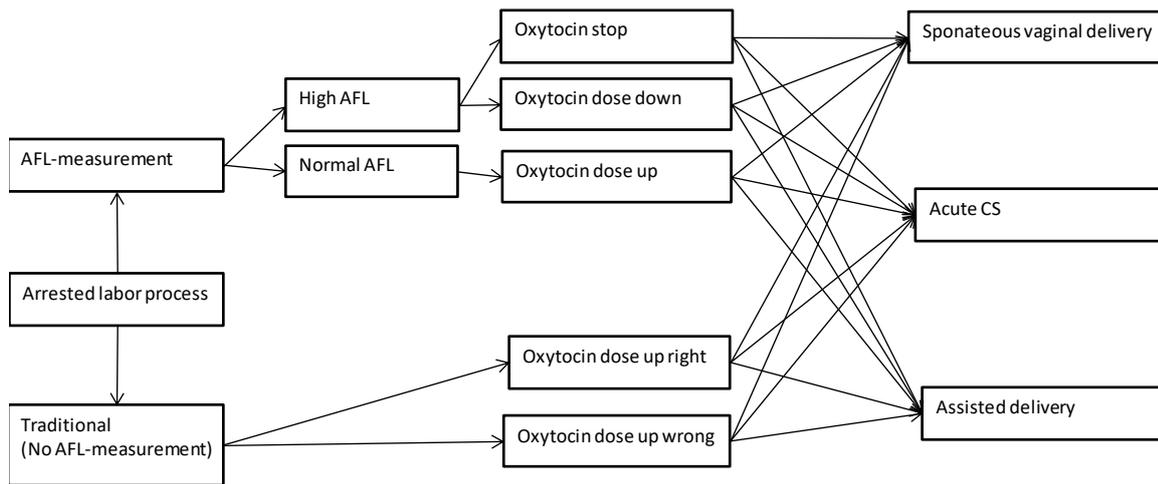


Figure 1. Structure of proposed Markov Model.

The idea of using a Markov Model was abandoned in view of the short timeframe covered by the analysis. A more precise and more relevant method to serve the present objective was to create a decision tree indicating clearly how “patients” progress through the model.

The tree structure set up for the questions: 1) whether oxytocin should initially be administered for arrested labor or 2) whether ongoing oxytocin infusion should be continued (or increased) or suspended is shown in Figure 2.

The analysis compares (access to and) use of AFL® measurement with not measuring AFL® in arrested labor. If AFL® is measured, the lactate concentration will be either “normal” (< 10.1 mmol/l) or increased (≥ 10.1 mmol/l; alternatively broken down into measurably increased (10.1-12.0 mmol/l) or heavily increased (>12 mmol/l)). For normal AFL® concentrations, oxytocin is used as standard with a dose increase if deemed warranted. For measurably increased AFL® concentrations, a “wait-and-see” approach can be employed, with measurement repeated after 30-60 minutes and then deciding if oxytocin augmentation is to be continued. For heavily increased AFL® concentrations, oxytocin administration should be suspended. Without AFL® measurement, lactate concentrations remain unknown, and arrested labor is assumed by initial infusion of oxytocin or dose increase. Without being able to establish AFL® concentrations, the oxytocin augmentation/dose increase may prove appropriate or inappropriate (“oxytocin up right” or “oxytocin up wrong”). All the alternative branches through the decision tree result in differing probabilities in any of the three delivery outcomes: “spontaneous vaginal delivery”, “acute caesarean section” or “assisted delivery”.

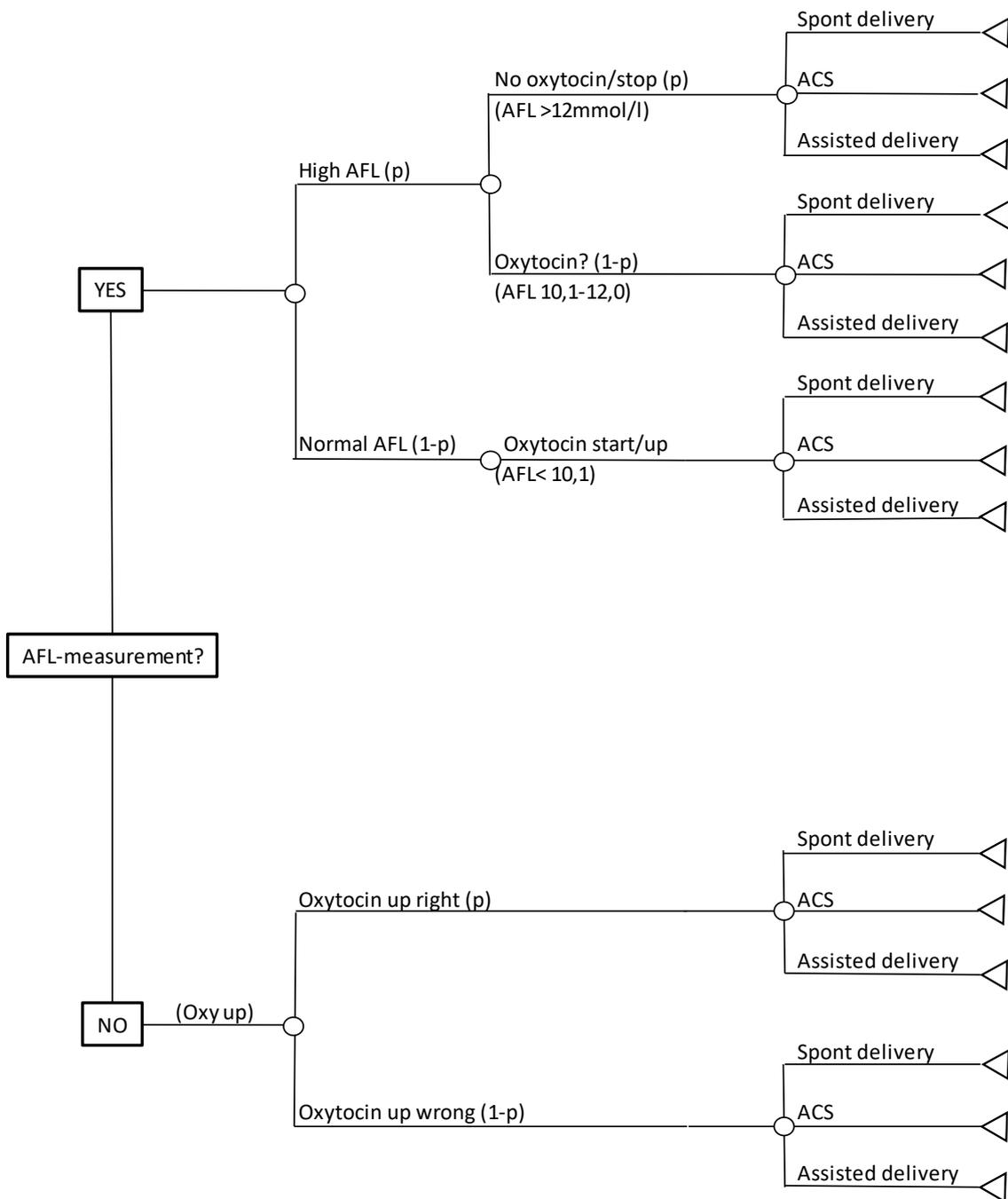


Figure 2. Decision tree, initial infusion or dose increase of oxytocin or not.

The difficulty of analyzing the process of repeated measurements (for increased AFL® concentrations as measured) in terms of the number of measurements, outcomes etc. meant that the analysis had to be simplified by the assumption that AFL® concentrations are either normal (< 10.1 mmol/l) or high (≥ 10.1 mmol/l). The analysis is thus based on the simplification of measuring AFL® and then either administering or increasing the dose (normal concentrations) or refraining from administering or suspending (increased concentrations). This simplified tree structure is shown in Figure 3.

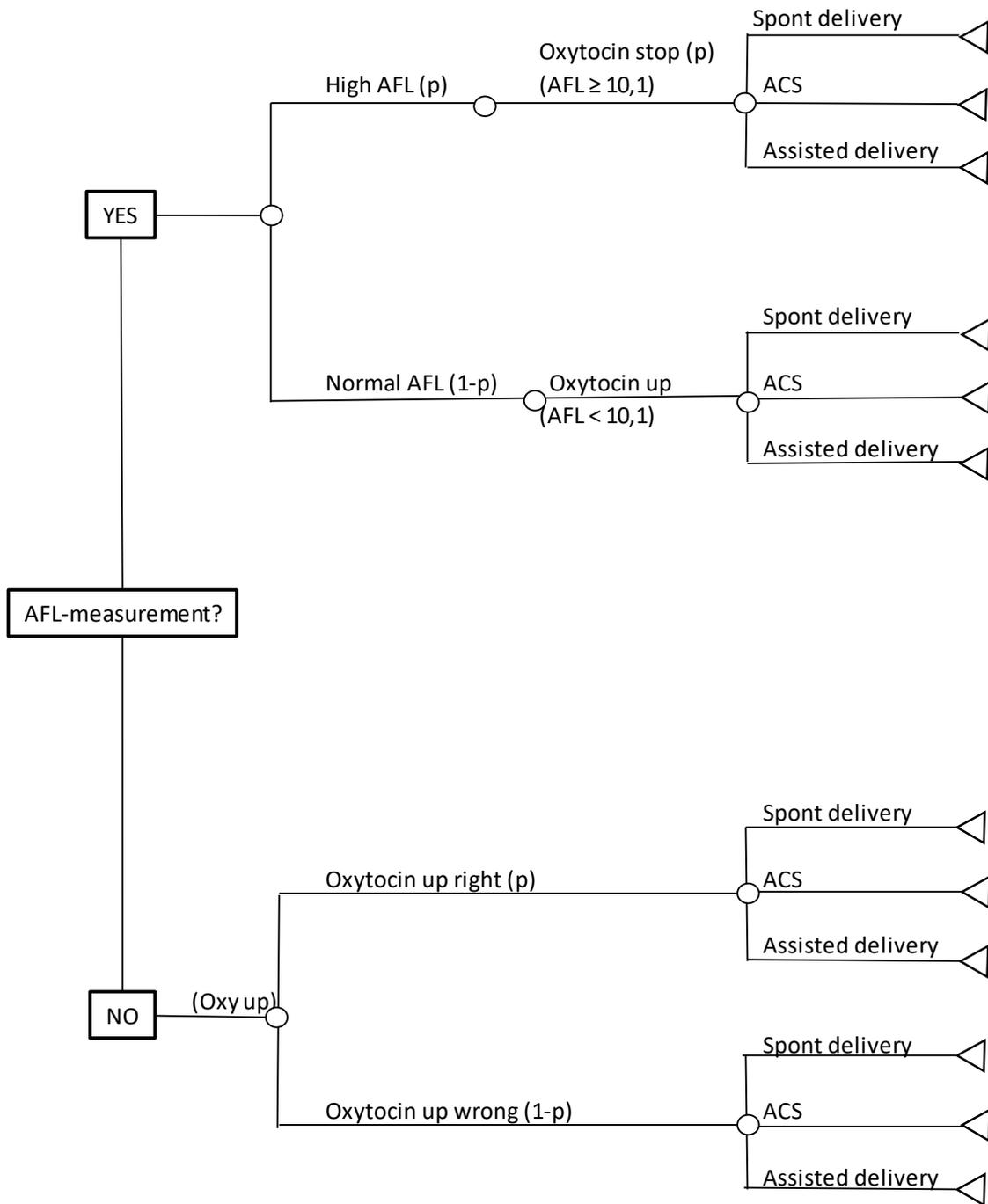


Figure 3. Simplified decision tree, initial infusion or dose increase of oxytocin or not.

3.2 Probabilities

In order to analyze the tree structure in line with Figure 3 and the outcomes of measuring lactate concentrations versus not doing so, several possible branches (transitions) through the tree structure were created with reference to probabilities based both on previous studies and registry data. Probabilities employed for the analysis are set out in Table 1.

Table 1. Probabilities for various branches through the decision tree.

Transition (alt. choices)	Probability	Description	Source
AFL® measurement	0/1	Choice, either or	
No AFL® measurement	0/1	Choice, either or	
Meas., high AFL®	0.135		[11]
Meas., normal AFL®	0.865		[11]
High AFL®, oxy susp.	1	Oxytocin suspended	Assumed
Normal AFL®, oxy up	1	Oxytocin dose increased	Assumed
Not measured, oxy up right	0.865	Oxytocin increased appropriately	[11]
No meas., oxy up wrong	0.135	Oxytocin inappropriately high	[11]
Oxy susp., vaginal	0.82	Outcomes where oxytocin was suspended. Assumptions based on reporting in the Swedish Pregnancy Register's Annual Report 2018 and unpublished figures, Stockholm, Sweden, 2019.	[12]
Oxy susp., unpl. C-section	0.08		[12]
Oxy susp., assisted	0.1		[12]
Oxy up, vaginal	0.746	Outcomes where oxytocin dose was increased (with measurement)	[12]
Oxy up, unpl. C-section	0.091		[12]
Oxy up, assisted	0.163		[12]
Oxy up right, vaginal	0.746	Outcomes where oxytocin dose was increased appropriately (no measurement)	[11]
Oxy up right, unpl. C-section	0.091		[11]
Oxy up right, assist.	0.163		[11]
Oxy up wrong, vaginal	0.36	Outcomes where oxytocin dose was increased inappropriately (not measured)	[11]
Oxy up wrong, unpl. C-section	0.373		[11]
Oxy up wrong, assist.	0.267		[11]

3.3 Costs

Costs used in the analysis include the costs of measuring AFL® concentrations (the device and single-use supplies), and, notably, all the costs associated with the different delivery outcomes. The hypothesis is that if AFL® measurement can help us in certain cases to prevent the protracted and complicated deliveries that often end in acute caesarean section or assisted delivery, then there are healthcare cost savings to be made (quite apart from the obvious benefits for the mothers, which are beyond the remit of this analysis).

Dystocia of labor and complicated deliveries (acute caesarean sections or instrumental deliveries) carry increased costs (as compared with spontaneous vaginal deliveries) depending on factors such as time-to-delivery, postpartum hemorrhage and other complications. The present analysis uses DRG (Diagnosis-related Group) classification for the different delivery outcomes (Swedish Association of Local Authorities and Regions (SALAR) costs database, 2018) In the SALAR database, diagnostic designations for the different delivery outcomes are classified by degree of complication and healthcare contacts broken down into cost “inliers” and “outliers”. For the purposes of this analysis, the SALAR database of inpatient and outpatient care was used. The classifications of the three different degrees of complication (highly complicated, complicated, uncomplicated) and of inliers (“I”) and outliers (“O”) are used in calculating the average cost of the different delivery outcomes: “spontaneous vaginal delivery”, “assisted delivery” and “acute caesarean section”, as adopted below.

3.3.1 Vaginal delivery and assisted delivery

For vaginal deliveries, the costs were as shown in Table 2.

Table 2. DRG costs, vaginal deliveries.

DRG code	Volume	Cost (SEK)	Av. cost (SEK) per diagnosis and case
P05A, highly complicated, I	597	71,975	
P05A, highly complicated, O	22	287,195	79,624
P05C, complicated, I	24,545	42,304	
P05C, complicated, O	774	133,523	45,093
P05E, uncomplicated, I	66,632	28,944	
P05E, uncomplicated, O	1,383	89,974	30,185

I = Inlier, O = Outlier

The distribution between different delivery outcomes (based on the Swedish Pregnancy Register’s Annual Report, 2018 and unpublished figures on deliveries in Stockholm, Sweden, 2019) was assumed to break down into 82% vaginal deliveries, 10% instrumental deliveries and 8% acute caesarean sections. The total number of deliveries in 2018 was approximately 115,000, which means that assisted deliveries should amount to approximately 11,500 and these are assumed to represent a case mix of P05A (619 cases) and P05C (10,900 cases). Similarly, vaginal deliveries are assumed to be made up of a case mix of P05E (68,015 cases) and P05C (14,419 cases).

The average cost of vaginal and assisted delivery, respectively, is thus calculated as follows:

Vaginal delivery: $(68,015 / (68,015 + 14,419)) * 30,185 + (14,419 / (68,015 + 14,419)) * 45,093 = \text{SEK } 32,793.$

Assisted delivery: $(619 / (619 + 10,900)) * 79,624 + (10,900 / (619 + 10,900)) * 45,093 = \text{SEK } 46,949.$

3.3.2 Acute caesarean sections

Only inpatient acute caesarean sections were within the remit of this analysis. These broke down as shown in Table 3.

Table 3. DRG costs of caesarean section, acute, inpatient care.

DRG code	Volume	Cost (SEK)	Av. cost (SEK) per diagnosis and case
P01, inlier	12,622	68,824	
P01, outlier	631	203,046	75,215

Thus, SEK 75,215 was adopted as the average cost per acute caesarean section.

3.3.3 Measurement of AFL®

The measurement of AFL® entails costs relating both to the device to be purchased and to the single-use supplies required for each individual measurement instance. The purchase price of the device is SEK 120,000, and the assumption is that one device will be required per delivery-room complex (46 in Sweden as at the start of 2017). The inventory depreciation time for this device was assumed to be eight years. Approximately 115,000 deliveries in Sweden in 2018, of which 20% were dysfunctional, i.e. approximately 23,000 deliveries in which AFL® measurement would be of value. This amounts to approximately 500 (23,000/46) deliveries per device and year, or 4,000 deliveries per device in total (over eight years).

This means that the cost of each device is to be spread over approx. 4,000 deliveries:

$$120,000/4,000 = \text{SEK } 30 \text{ per delivery.}$$

The requisite single-use supplies consist of a measurement probe (SEK 300 each) and syringe (SEK 5 each). The assumption is that two samples are needed on average per primipara in arrested labor. The total cost of AFL® measurement per delivery (in the presence of arrested labor) is thus an average of $30 + 2*(300+5) = \text{SEK } 640$.

4 Result

The result, in terms of different delivery outcomes, of measuring AFL® or, respectively, of not doing so was as follows:

Table 4. *Different delivery outcomes from different strategies.*

Strategy	Vaginal delivery	Instrumental delivery	Acute caesarean section
AFL® measurement	75.6%	15.5%	9.0%
No AFL® measurement	69.4%	17.7%	12.9%

The average costs for both alternative strategies total:

AFL® measurement: SEK 38,941

No AFL® measurement: SEK 40,775

According to this analysis, AFL® measurement will thus be a cost-saving. For each primipara in arrested labor, the Swedish health service would save SEK 1,662 from using ObsteCare AFL® measurement.

In 2018, 114,728 deliveries were completed in Sweden [12]. According to “unpublished figures from Stockholm, Sweden, 2019”, 40% of women in labor underwent oxytocin augmentation, despite the fact that the proportion of those diagnosed as being in arrested labor was only 12%. Based on these figures, this means that AFL® measurement will be of value in approximately 46,000 deliveries annually in Sweden. This would result in a total annual saving for the health service of approximately SEK 76 million.

In addition, we may assume that this would have beneficial effects for women in labor and their newborns; benefits which were beyond the remit of the present analysis.

5 Discussion

This analysis indicates that the use of AFL® measurement in arrested labor (dystocia) among primiparas would save costs. Improved management and delivery outcomes also improve maternal and infant health, which again, could not be addressed within the remit of this analysis.

With lactate measurement, complications can be prevented, and consequently the number of acute caesarean sections and instrumental deliveries can be reduced. Moreover, by adopting this strategy, it is possible to identify the group with normal lactate levels for which oxytocin augmentation is warranted. In other words, lactate measurement facilitates accurate identification of those women in active labor who stand to benefit from oxytocin, and those who do not.

The implication of this result should be the widescale introduction of AFL® measurement (as offered by ObsteCare). Recently published findings [13] indicate that measurement of, and hence knowledge of, lactate concentration can be used to inform decisions of whether to treat with bicarbonate, which lowers the lactate concentration, thereby aiding delivery. The benefits of AFL® measurement should thus be even greater than those demonstrated by the results of the present analysis if measurement is also used to support decisions to treat with bicarbonate.

Weaknesses/failings

The weaknesses of the present analysis are that information/assumptions concerning certain probabilities are uncertain. Furthermore, we were only able to analyze a very short timeframe, and the analysis is somewhat biased in that it solely addresses direct healthcare costs and not the value of benefits for health/quality of life.

Bearing this in mind, further research should aim to provide better knowledge/evidence regarding the probabilities of different (delivery) outcomes, and the long-term consequences in terms of both costs and health/quality of life.

The final conclusion in this respect is thus that in the interests of cost-saving and health promotion, healthcare systems would be well-advised to take advantage of this health technology for measuring lactate levels in the presence of labor dystocia. This analysis concerns primiparas, but the findings should also be applicable to multiparas.

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Mail address: CMT, Department of Medical and Health Sciences (IMH), Linköping University, SE-585 83, Linköping, Sweden

Street address: Building 511-001, entrance 76, level 13, Campus US, Linköping, Sweden