RESEARCH PROJECT REPORT

EVALUATION OF MATERNAL AND FETAL OUTCOMES AFTER IMPLEMENTATION OF OXYTOCIN CHECKLIST IN RWANDA

A DISSERTATION TO BE SUBMITTED IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF DEGREE OF MASTER OF MEDICINE IN OBSTETRICS AND GYNECOLOGY OF THE UNIVERSITY OF RWANDA.

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Abstract

Objective

The study aimed at comparing neonatal and maternal outcomes based on using a pre established oxytocin checklist for labor augmentation and usual standard of care in low to middle income country.

Method

From April 2015 to October 2015, we conducted serial chart review of 158 patients who delivered after augmentation of labor using oxytocin based on local standard of care and retrieved data on neonatal and maternal outcomes. From November 2015 to January 2016, we used an oxytocin checklist for 150 mothers who were augmented and the same outcomes were collected and compared.

Results

The demographic characteristics were similar in both groups. After the use of checklist, the total amount of oxytocin used (in drops per minute) reduced significantly (24 vs. 16, p=0.0021), the amount of time on oxytocin was decreased (148 vs. 120 min p=0.011) and the time from oxytocin administration to delivery was shortened (180 vs. 155 min p=0.0099). Neonatal outcomes were improved with fewer APGAR scores of <7 at the first minute (12.7% to 6%) after the use of checklist (p=0.046.) The number of newborns admitted to NICU significantly dropped from 26 (16.7%) to 11 (7.4%) after using checklist (p=0.013). Our study failed to demonstrate a significant impact of the checklist on cesarean section rates (before checklist 24.7% compared to 16% after checklist. (P=0.059).

Conclusion

In a low resource setting, using the oxytocin checklist for augmentation of labor reduced the amount of oxytocin used, shortened time on oxytocin and shortened interval from infusion to delivery with improved neonatal outcomes.

Key words: Oxytocin, oxytocin checklist, cesarean section, limited resources.

Introduction

High maternal morbidity and mortality are among the most important and most difficult health challenges faced by sub-Saharan Africa. The maternal mortality ratio, defined as the death of a woman while pregnant or within 42 days of the end of a pregnancy, is as high as 1200/100livebirths in some sub-Saharan African countries, and nearly 50 times higher than the United States(1). In Rwanda, the WHO's most recent estimate of maternal mortality has improved, but it is still extremely high at 540/100,000 with young girls having an adult lifetime risk of maternal death of 1 in 35(1). The large discrepancies seen indicate that known methods of medical care can be implemented to address the preventable and treatable causes of maternal morbidity and mortality. The top 5 major causes of maternal mortality across the world are obstetrical hemorrhage, infection, pre-eclampsia/eclampsia, obstructed labor, and unsafe abortion(2). In Africa, hemorrhage is the leading case of maternal deaths and accounts for 34% of cases. The second leading cause of maternal death is "indirect causes," which mainly include complications encountered during interventions such as surgery (i.e. cesarean section) and during induction of anesthesia. These "indirect causes" account for 17% of maternal deaths in Africa. Preeclampsia/eclampsia, the 4th leading cause of maternal death, accounts for approximately 9% (3). Proper medical attention during delivery can reduce the risk of complications and infections that may lead to morbidity and mortality for the mother and baby(4). However, resources for safe drug delivery and monitoring are often lacking in areas with limited resources and some drugs, such as intravenous oxytocin, may be administered without close attention. In Rwanda maternal mortality has decreased over the last 15 years from 1071 deaths in 2000 to 210 deaths/100 000 live births in 2015(5). Yet maternal mortality is still high and many efforts are still needed to reduce this large number of maternal deaths. It is estimated that between 44,000 and 98,000 deaths are caused by medical error each year in the United States(6). There is

no data in Rwanda on the contribution of medical error to maternal mortality and morbidity.

Factors that increase human error, stress and fatigue(7), are far too common in medicine and are markedly increased in high intensity fields such as Obstetrics. One strategy being advocated to reduce the amount of error is the use of checklists. Checklists are typically designed to ensure key components of patient care are addressed and recognized by the user.

Ideally they consist of a short list of items reflecting the current standard of care for a given clinical situation that the user either checks as present or absent.

The utility of checklists in medicine first became widely recognized with the work by Pronovost et al (6), which showed that infection rates fell dramatically after implementation of checklists for insertion of central venous catheters in an intensive care unit setting(8). Its applicability on a global scale was evidenced when the World Health Organization's Patient Safety Programme, "Safe Surgery Saves Lives," designed a checklist for surgical safety. This WHO Surgical Safety Checklist was implemented in eight hospitals in eight economically diverse cities across the world. Results showed the rate of death fell from 1.5% to 0.8% and the rate of inpatient complications fell from 11% to 7% after implementation of the checklist⁴.

Checklists have a long and proven history in the aviation industry, a safety-conscious field where even the smallest of mistakes can cost thousands of lives. Recently, checklists are being promoted by many for use in the complex, high-intensity and high-stress medical fields to aid in reducing human error and improving patient safety(9)(10). Obstetrics is one such field where emergencies occur almost daily and where protocols and checklists can save lives. Research has shown, for example, that implementation of an oxytocin-checklist on a labor ward may result in decreased cesarean deliveries and improved neonatal outcomes,(11) and that surgical checklists can reduce the rate of post-operative complications and death(12).

In low and middle income countries, where resources are poor, evidence shows that checklists can be of immense benefit as well(12). To date, however, there are no studies examining the role and utility of obstetrical checklists in such settings. We carried out a study to implement and evaluate the effectiveness of oxytocin checklist on the maternity ward of Muhima District Hospital, one of the busiest maternity wards in the country with more than 7200 deliveries per year (Muhima Hospital Annual Report) with a total of 20 midwives working in labor and

delivery in different shifts. Our goal was to determine the impact on maternal and neonatal outcomes of the implementation of the oxytocin safety checklist at Muhima District Hospital. Specifically we sought to examine whether the implementation of an oxytocin safety checklist would decrease the rate of cesarean delivery and improve neonatal outcomes.

Methods

We conducted a cohort study to evaluate the impact on patient outcomes of the implementation of oxytocin safety checklist on the maternity ward at Muhima District hospital in Kigali, Rwanda. The checklist used is found in Appendix A. There are no electronic medical records at Muhima District Hospital. Therefore, a comprehensive review of all admissions to the maternity ward was undertaken to identify all pertinent cases for the checklist. Chart review was conducted by University of Rwanda faculty and Muhima District Hospital staff to identify cases of oxytocin utilization managed by current standards on the maternity ward prior to checklist implementation. Charts for the most recent 158 cases were reviewed. Sociodemographic data, basic medical and surgical history, and number of prenatal visits were abstracted from the charts. Maternal and neonatal outcomes were abstracted from the charts.

Based on our primary outcome, which was a reduction in cesarean section rate (25%), we calculated that 150 patients of implementation of the oxytocin checklist would give our analysis an 80% power to have a 50% reduction of cesarean sections with an Alpha error of 0.05 by using the following formula, $n = (Z_{\alpha/2}+Z_{\beta})^2 * (p_1(1-p_1)+p_2(1-p_2)) / (p_1-p_2)^2$.

The head of the maternity ward carried out training on utilization of the checklist for all nurses and midwives on the ward. Under their supervision, the checklists were completed by the midwives. The first successive 150 cases of oxytocin utilization were reviewed after implementation of the checklist and the same maternal and neonatal outcomes were collected by chart review. No single patient refused to participate in the study.

Maternal morbidity were categorized as yes or no, with yes being defined as any one of the following: blood transfusion, cesarean delivery, hysterectomy, stroke, surgical site infection, wound separation, fascial dehiscence, sepsis, or cardiac arrest.

Neonatal morbidity was categorized as yes or no, with yes being defined as any one of the following: birth weight less than 2500g, respiratory distress, low APGAR Score (less than 7) or newborn intensive care admission. Table 1 illustrates the maternal and neonatal outcome data collected.

The main predictor variable was the correct utilization of the checklist. In addition, potential confounding factors include maternal co-morbidities such as but not limited to malaria, hypertension, HIV-infection, prematurity and anemia (hemoglobin<10 g/dL).

All pregnant women admitted to Muhima District Hospital's maternity ward were eligible for this study. All women with indications for oxytocin utilization as determined by local standards of care were eligible for the study. The checklist was administered by ancillary staff, therefore did not impact management or delivery of care.

Statistical analyses:

The retrospective data collected from the checklist implementation were analyzed using parametric and non-parametric tests as appropriate. Specifically, associations of baseline sociodemographic and clinical characteristics were assessed using Pearson chi-square and Fisher's exact tests for all categorical variables.

Analyses of variance were used for assessing associations between categorical variables and continuous variables with normal distributions within the defined categories. Student's *t*-tests was used for assessing associations between dichotomous variables and continuous variables with Normal distributions. All statistical analyses were done using STATA software, version 12. Two-sided tests were used, with statistical significance defined as having P<0.05.

Ethical considerations

All data obtained or acquired from Muhima Hospital were kept confidential. No identity was made available. Our research did not interfere at any point with the management of the patient since the checklist was filled with an ancillary person not involved in the management of the patient directly.

Kigali University Teaching Hospital Institution Review Board (IRB) and MUHIMA/IRB approvals have been obtained prior to the beginning of the study. Informed consent was obtained from patient who was eligible and it was translated in Kinyarwanda and there was no patient who was excluded to participate due to language barrier.

Results

There were 4477 patients delivered (vaginal deliveries and cesarean sections) at Muhima District Hospital from April 1st to October 31st 2015. The implementation of oxytocin checklist started from October 1st 2015 to January 31st 2016 and during this period 150 were enrolled. All mothers with inclusion criteria were eligible for this study and were analyzed. Successive patients were reviewed but not all files were available.

Table 2 outlines the baseline characteristics of the population before and after the implementation of the checklist. There were no major differences in the groups in terms of age, parity, prior cesarean section and antenatal consultation. A statistically significant difference was observed in the category of term pregnancy, 107(71.3%) during implementation of the checklist compared to 74(46.8%) before checklist (P <0.001). Before the checklist, the majority of women were post term 82 (51.9%) as compared to 37 (24.7%) after the use of the checklist (P<0.001). This difference may be attributable to the systematic use of ultrasound when using the checklist as only 28(17.7%) of patients received ultrasounds at admission prior to initiation of the checklist vs. 99(66.0%) after the protocol was implemented (p<0.001). Antenatal consultations were done in both groups and there was no statistically significant difference in pre checklist and post checklist groups.

Table 3 summarizes maternal outcomes prechecklist and post checklist. Analysis showed that there was no statistical difference before and after oxytocin checklist in terms of maternal complications with dichotomous categories (yes/no) (P=0.064). There was a trend in decreasing the rate of cesarean section after the checklist with a 24.7% vs 16% cesarean rate in the groups (p= 0.059.) The total time of oxytocin infusion fell significantly from 148 minutes [IQR: 480-30=450] before checklist to 120 minutes [IQR: 180-90=90] after checklist implementation (p=0.011). The time from oxytocin initiation to delivery also decreased from 180 minutes [IQR:

275-110=165] before the checklist to 155 minutes [IQR: 210-100=110] after implementation of the checklist (p = 0.0099). The method of infusing intravenous oxytocin at the study hospital consists of diluting 5 IU of oxytocin in 500cc of normal saline and then administering the infusion in drops per minute. This was analyzed and found that the median of drops per minute decreased from 24 [IQR: 32-16=16] and 16 [IQR: 24-12=12] after checklist (P value of 0.0021). Analysis showed that the total time of oxytocin infusion and the time from initiation to delivery decreased with a statistically significance difference after the use of oxytocin checklist. Analysis of neonatal outcomes (Table 4) showed that the APGAR score of <7 at the first minute improved significantly from 20(12.7%) newborns before the checklist to 9(6%) after the checklist and APGAR score >=7 increased from 138 (87.3%) to 141 (94%) respectively (P= 0.046). The analysis of the APGAR score of <7 and APGAR score >=7 at the fifth minute failed to show any significant difference before and after oxytocin checklist implementation with a P value of 0.921.

NICU admissions improved significantly after implementation of oxytocin checklist, from 26(16.7%) before checklist to 11 (7.4%) post checklist (p= 0.013).

The number of days of admission in NICU did not differ in both groups with a Median of 4 [IQR: 6-3=3] pre checklist and 3 [IQR: 5-2=3] post checklist. There was no statistical significant difference in newborn birthweight.

Discussion

To date there are no published studies on oxytocin checklists based in low resource settings. A study performed in the U.S. by Clark et al(11) demonstrated improved maternal and neonatal outcomes, Our study demonstrated that there was significant reduction in the amount of oxytocin used with use of the oxytocin checklist, which is consistent with findings from the Clark et al. study (11) The method of oxytocin is administration in Rwanda varies among practitioners and from one institution to another. Many components of oxytocin administration in a low resource setting is challenging, as automated intravenous infusion pumps are not available. Calculating the number of drops of oxytocin can be subjective and the flow of the perfusion may depend on the position of catheter insertion, and can change considerably from time of insertion to delivery. This can significantly affect medication delivery. It is clear that Rwandan institutions need to have a standard means of administering oxytocin since electric syringes are lacking in most institutions and in this study.

However despite limited resources our study shows that a simple standardized oxytocin checklist which takes 5-10 minutes to fill can significantly reduce the amount of oxytocin delivered without an increase in the cesarean section rate. We also showed that time from oxytocin administration to delivery and the total time on oxytocin infusion decreased significantly in the checklist group. In contrast, Clark et al. (11) failed to demonstrate any clinically significant difference in time of oxytocin to delivery and total time on oxytocin.

In our analysis, though there was a trend in decreasing cesarean rate, we did not find a significant difference in mode of delivery and these findings were consistent with the study by Clark et. al(11). A larger sample size may be necessary to demonstrate a difference. Another American study, Hayes et al. (13), showed that using a standardized oxytocin protocol reduced the

complications arising from oxytocin use such as hyperstimulation and unnecessary cesarean section. Wei et al. (14) found that using a high oxytocin dose was associated with advantages such as reduction in cesarean section rate and a small increase in vaginal delivery.

We evaluated maternal complications and found that implementation of the oxytocin checklist did not significantly affect maternal complications. These included operative vaginal delivery, cesarean delivery, cesarean delivery for fetal heart rate abnormalities, cesarean delivery for labor arrest, uterine hyperstimulation (>5 contractions in 10 minutes), uterine rupture, fetal heart rate abnormalities, postpartum hemorrhage, surgical site infection, and wound dehiscence. These findings were consistent with those from Clark et al.

In evaluating fetal outcomes, we found the APGAR scores at the first minute statistically improved with use of the oxytocin checklist. However, the APGAR score at five minutes after birth was not affected by the checklist. These findings were similar in the Clark et al study. NICU admission improved significantly after implementation of oxytocin checklist but the number of days of hospitalization in NICU did not change. Clark et al. did not show any improvement in terms of admission to NICU nor the length of stay to NICU for those who were admitted with use of the checklist. We failed to demonstrate any difference in birthweight before and after oxytocin checklist implementation, but Clark et al. showed an increase in birth weight with P= 0.017.

In a low resource setting such as Rwanda, with limited resources in labor and delivery and variability in protocols on administration of oxytocin, the use of an oxytocin based checklist to augment labor should be considered. Our study showed a reduction in the maximum amount of oxytocin used, reduction in total time on oxytocin and a shortened time from initiation to delivery with the use of such a checklist. We failed to demonstrate an improvement in maternal outcomes or a decrease in cesarean section rate due to checklist use but a larger sample size may be needed to demonstrate this. Neonatal outcomes were improved with significant improvement of APGAR scores at the first minute and a decrease in the number of NICU admissions after the use of checklist. We recommend that a randomized trial should be conducted in low resource

settings to evaluate the benefit of an oxytocin checklist based protocol where resources are limited, to make the use of oxytocin in labor augmentation safe and beneficial for the mother and the newborn. The benefits of a standardized protocol for labor augmentation have been demonstrated in developed countries and could make a significant impact on the health of mothers and infants worldwide.

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Results tables

Table 1

Checklist Topic	Maternal Outcomes	Neonatal Outcomes
Oxytocin utilization	• Time of oxytocin initiation to	• Birth weight
	delivery	• APGAR scores
	• Total time of oxytocin infusion	• Respiratory
	• Operative vaginal delivery	distress
	Cesarean delivery	• Antibiotic
	• Cesarean delivery for fetal heart	administration
	rate abnormalities	• Newborn intensive
	• Cesarean delivery for labor	care admission
	arrest	• Perinatal mortality
	• Uterine hyperstimulation (>5	(neonatal death)
	contractions in 10 minutes)	
	• Uterine rupture	
	• Fetal heart rate abnormalities	

	Before oxytocin checklist	After oxytocin checklist	
Variables	Frequency (%)	Frequency (%)	P-value
Age			
<20 years	19 (12.0)	11 (7.3)	0.165
20-35 years	130 (82.3)	120 (80.0)	0.609
>35 years	9 (5.7)	19 (12.7)	0.03
Parity			
Nullipara (0)	101 (63.9)	90 (60.0)	0.478
Term pregnancy (>=1)	57 (36.1)	60 (40.0)	0.478
Prior cesarean			
Yes	10 (6.3)	8 (5.3)	0.710
No	148 (93.7)	142 (94.7)	0.710
Gestational age			
<37 weeks	2 (1.3)	6 (4.0)	0.132
37-42 weeks	74 (46.8)	107 (71.3)	< 0.001
>42 weeks	82 (51.9)	37 (24.7)	< 0.001
Antenatal consultation			
0	2 (1.3)	3 (2)	0.610

 Table 2: Baseline demographic characteristics of the population study before and after oxytocin safety checklist

1	60 (38)	71 (47.3)	0.097
>1	96 (60.7)	76 (50.7)	0.075
Use of ultrasound			< 0.001
Yes	28(17.7)	99 (66.0)	
No	130(82.3)	51 (34.0)	
Table 2. Catagorical variables	chaming motornal aut	annea hafara and afta	n orretoo

 Table 3: Categorical variables showing maternal outcomes before and after oxytocin

 checklist

Variable	Before oxytocin checklist	After oxytocin checklist	P-value
	Frequency (%)	Frequency (%)	
Maternal complications			0.694
Yes	9 (5.7)	7 (4.7)	
No	149 (94.3)	142 (95.3)	
Mode of delivery			0.059
Vaginal	119 (75.3)	126 (84.0)	
Cesarean	39 (24.7)	24 (16.0)	
The usage of oxytocin			
	Median [IQR]*	Median [IQR]*	
Time of oxytocin infusion (in minutes)	148 [IQR: 480- 30=450]	120 [IQR: 180- 90=90]	0.0110
Time from oxytocin initiation to delivery (in minutes)	180 [IQR: 275- 110=165]	155 [IQR: 210- 100=110]	0.0099

Maximum oxytocin dose	24 [IQR: 32-16=16]	16 [IQR: 24-12=12]	0.0021
(Drops per minute)			
IQR*: Interquartile range			
Table 4: Variables showing neo	onatal outcomes befor	e and after oxytocin c	hecklist.
Variables	Before oxytocin checklist	After oxytocin checklist	P-value
	Frequency (%)	Frequency (%)	
APGAR score in 1 minute of delivery			0.046
<7	20 (12.7)	9 (6.0)	
>=7	138 (87.3)	141 (94.0)	
APGAR score in 5 minutes of delivery			0.921
<7	7 (4.4)	7 (4.7)	
>=7	151 (95.6)	143 (95.3)	
NICU Admission			0.013
Yes	26 (16.7)	11 (7.4)	
No	130 (83.3)	138 (92.6)	
DAYS IN NICU Median [IQR]	4 [IQR: 6-3=3]	3 [IQR: 5-2=3]	0.1676

Dinthwoight (in grome)	3280 [IQR: 3500-	0.2272	
Dirtiiweight (in grams)	3000=500]	3000=500]	

<u>Appendix</u>

PRE - OXYTOCIN CHECKLIST

To be completed before beginning oxytocin

DOCTOR	Name	Date/Time	
Indication:			
□ Induction of	f labor: Post term / Oligohydra	mnios / Pre-eclampsia / Eclampsia/ Feta	l demise
Rupture of Augmentati	membranes on of labor: # contractions per	10 minute period:	/10minutes
 Last cer Perform Perform Presenta Verify p Examin Pubic ar Ischial S Sacral F Sacrum Final as 	vical examination: Time Dilation: Effacemer cervical examination now: Tin Dilation: Effacemer Fetal caput / Fetal moulding / Fluid: Meconium / Clear / B ation: Cephalic / Breech / Tra presentation by: Exam / Ultra e maternal pelvis (circle one for rch: Narrow / Average / Wi Spines: Converging (narrow) / Promontory: Palpable / Not p /Posterior outlet: Deep / Shal sessment: Adequate pelvis / S	ht:Station: meStation: ht:Station: V Neither bloody insverse sound r each dimension): de Straight / Diverging (wide) palpable low Small pelvis	
Estimate	e fetal weight:	_g	Page 18
\square Verify I	FHR \geq 110 over 20 minute perio	od	
⊔ Verifv I	HR is not <110 immediately a	tter a contraction	

<u>NURSE</u>	Name	Date/Time
□ Materr □ Estima	al admission history and physical e ted gestational age and weight of fe	xamination completed in chart tus is documented in the chart.
□ Partog	raph has been completed and update	ed within the last 15 minutes including:
	Current FHR (taken immediately a \Box FHR > 110 (unless fetal de	tter a contraction if patient is contracting) mise)
	Current contraction pattern over a	ten minute time period
	Current cervical exam	
	Current maternal vital signs	
Physic hospita	ian capable of performing cesarean l.	delivery is aware of patient and present in the
□ Physic	ian evaluation of patient and labor of	ourse written by physician in chart
D Physic	ian documented his/her physical ex	am in chart including:
	Presence of an adequate pelvis	
	Cervical exam	
	Fetal presenting part	
□ Physic	ian order for oxytocin written by ph	ysician in chart

ALL OF THE ABOVE ARE NOT COMPLETE, DO NOT BEGIN OXYTOCIN

Pitocin Checklist

Complete every 30 minutes

If you circle No for any of the items below, stop the infusion immediately

	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	
Time:						
						#drops per minute ?
	Y / N	Y / N	Y / N	Y / N	Y / N	FHR > 110 (taken immediately after a contraction)
	Y / N	Y / N	Y / N	Y / N	Y / N	Are there <i>less than</i> 5 contractions in 10 minutes (evaluate over 30 minutes)?
	Y / N	Y / N	Y / N	Y / N	Y / N	Do all contractions last <i>less than</i> 60 seconds?
	Y / N	Y / N	Y / N	Y / N	Y / N	Is the uterus soft between contractions ?
	Y / N	Y / N	Y / N	Y / N	Y / N	Has a cervical examination been performed every 2 hours in active labor?
						Nurse initials/signature

Doctor called if there is no progress in two hours during active labor:
 Time_____Name_____

	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	
Time:						
						#drops per minute ?
	Y / N	Y / N	Y / N	Y / N	Y / N	FHR > 110 (taken immediately after a

					contraction)
Y / N	Y / N	Y / N	Y / N	Y / N	Are there <i>less than</i> 5 contractions in 10 minutes (evaluate over 30 minutes)?
Y / N	Y / N	Y / N	Y / N	Y / N	Do all contractions last <i>less than</i> 60 seconds?
Y / N	Y / N	Y / N	Y / N	Y / N	Is the uterus soft between contractions ?
Y / N	Y / N	Y / N	Y / N	Y / N	Has a cervical examination been performed every 2 hours in active labor?
					Nurse initials/signature

Doctor called if there is no progress in two hours during active labor: Time______
Name______

	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	<u>30min</u>	
Time:						
						#drops per minute ?
	Y / N	Y / N	Y / N	Y / N	Y / N	FHR > 110 (taken immediately after a contraction)
	Y / N	Y / N	Y / N	Y / N	Y / N	Are there <i>less than</i> 5 contractions in 10 minutes (evaluate over 30 minutes)?
	Y / N	Y / N	Y / N	Y / N	Y / N	Do all contractions last <i>less than</i> 60 seconds?
	Y / N	Y / N	Y / N	Y / N	Y / N	Is the uterus soft between contractions ?
	Y / N	Y / N	Y / N	Y / N	Y / N	Has a cervical examination been performed every 2 hours in active labor?
						Nurse initials/signature