Declaration of conflicts

- According to the Labour Progression study, LaPS
- I have no conflicts of interest to declare



The Labour Progression Study, LaPS

A Multi Centre Cluster Randomized Trial, Investigating the Effect of the WHO Partograph and the Zhang Guideline for Assessing Labour Progression on Intrapartum Caesarean Section THE LANCET





Stine Bernitz, RN, RM, PhD



Associate professor/researcher

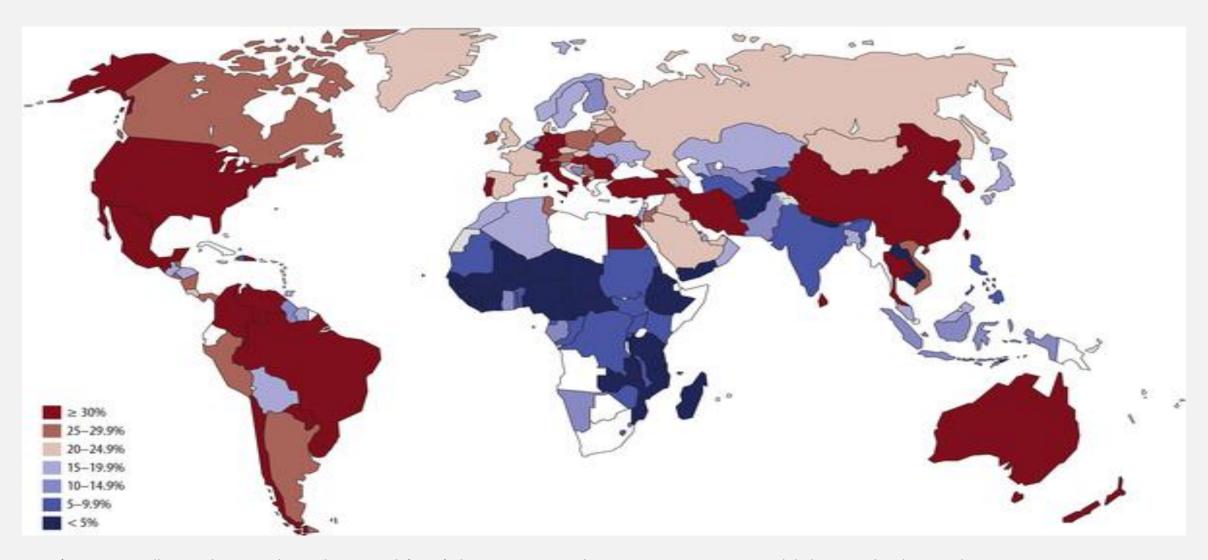
their resistance to a calamitous



Oslo Metropolitan University, Norway/Østfold Hospital Trust, Norway



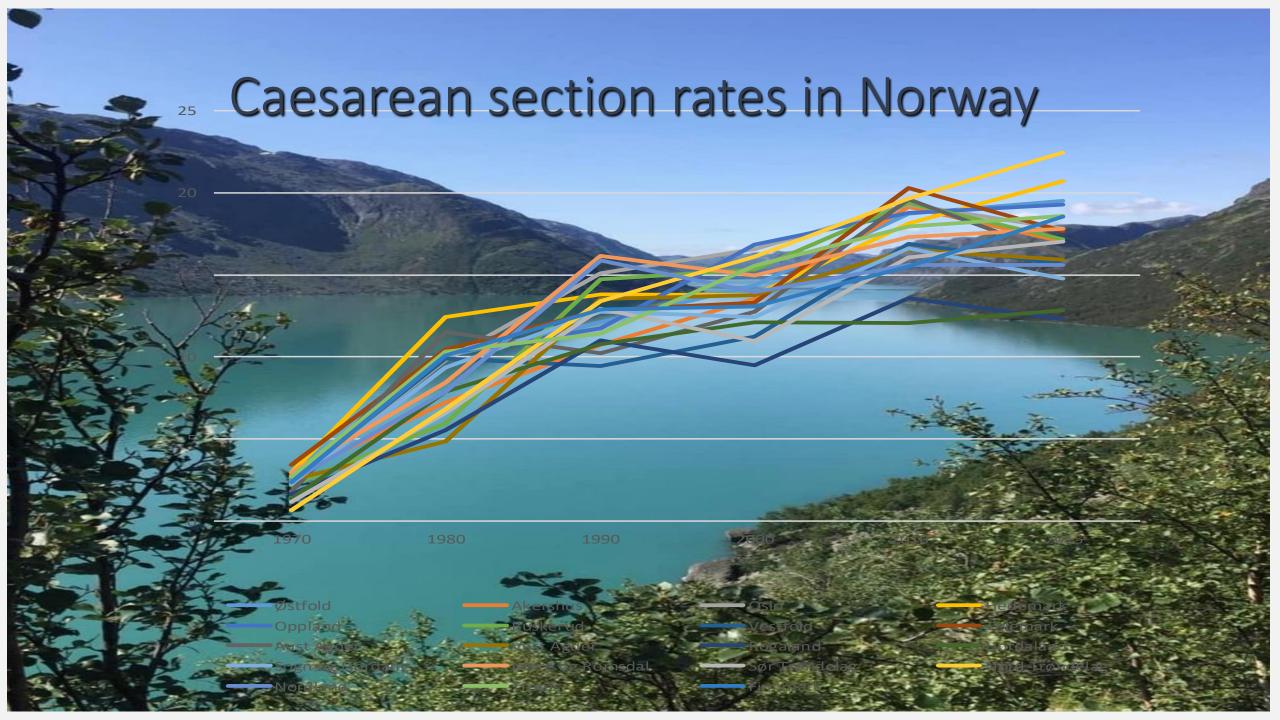
Latest available data on caesarean section rates by country (not earlier than 2005).



Betrán AP, Ye J, Moller AB, Zhang J, Gülmezoglu AM, et al. (2016) The Increasing Trend in Caesarean Section Rates: Global, Regional and National Estimates: 1990-2014. PLOS ONE 11(2): e0148343. https://doi.org/10.1371/journal.pone.0148343

https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148343





Challenges

 Most common indication for intrapartum caesarean sections: slow progress of labour (labour dystocia)

 There is no consensus on duration of labour; hence no consesus on when labour dystocia should be diagnosed

 Increasing use of synthetic oxytocin, even in cases with no labour dystocia

Assessing labour progression

- The partograph is used in many countries world-wide to enable early detection of complications so that referral, action or closer observations can ensue
- The partograph receives global support, still there are concerns that it has not reached its full potential in improving clinical outcomes. This has resulted in several variations of the tool and a plethora of studies that aim to explore the benefits and the optimum design
- The advantages and disadvantages of the partograph are being discussed and investigated, both if it should be used and if so, which is the preferred design



The WHO partograph vs Zhang's guideline





Static guideline



Dynamic guideline

Cervical dilation (cm)	10 7 9 - 8 - 7 - 6 - 5 -			P2+//	P1	/	P0	
	3 1	1	2	3 Time (4 (hours)	5	6	7

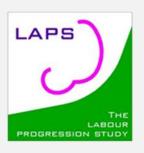
Cervical Dilation (cm)	Parity 0 (n=25,624)	Parity 1 (n=16,755)	Parity 2+ (n=16,219)
3-4	1.8 (8.1)	_	_
4-5	1.3 (6.4)	1.4 (7.3)	1.4 (7.0)
5-6	0.8 (3.2)	0.8 (3.4)	0.8 (3.4)
6-7	0.6 (2.2)	0.5 (1.9)	0.5 (1.8)
7-8	0.5 (1.6)	0.4 (1.3)	0.4(1.2)
8_9	0.5 (1.4)	0.3 (1.0)	0.3 (0.9)
9-10	0.5 (1.8)	0.3 (0.9)	0.3 (0.8)
Second stage with epidural analgesia	1.1 (3.6)	0.4 (2.0)	0.3 (1.6)
Second stage without epidural analgesia	0.6 (2.8)	0.2 (1.3)	0.1 (1.1)

Objective of the LaPS

To investigate whether the rate of intrapartum cesarean section differ when adhering to Zhang's guideline for labor progression compared to the WHO partograph for nulliparous women who had a singleton fetus, cephalic presentation and spontaneous onset of active labour at term

Hypotesis

Intrapartum caesarean section rate can be reduced by 25 % by adhering to Zhang's guideline compared to the WHO partograph



Study design

Multicentre cluster randomised design (Power: 80 %, significans level: 95 %: 14 clusters/birth care units and 6582 participants)



Invited clusters: 20

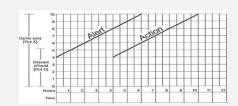
Abstained participation: 6

Parity 0

Parity 1 Parity 2+

Randomised birth care units: 14

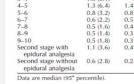
Stratified for size and prior ICS rate



Control group: 7



Intervention group: 7





Women assessed for eligibility (n=5421)

Not included in the analysis

- Abstained participation (n=16)
- Signed consent not available (n=2100)



Women assessed for eligibility (n=6194)

Not included in the analysis

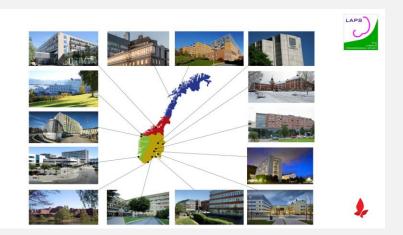
- Abstained participation (n=41)
- Signed consent not available (n=2181)



Available for analysis (n=3305)



Available for analysis (n=3972)



Baseline characteristics

	Zhang group	WHO group
	Participants	Participants
	(n=3972)	(n=3305)
Hospital characteristics		
Deliveries per year		
<3000, 6 hospitals in each group, n (%)	2688 (36.9)	2233 (30.7)
≥3000, 1 hospital in each group, n (%)	1284 (17.6)	1072 (14.7)
Characteristics related to the mother		
Maternal age in year at delivery, mean (SD)	28.4 (4.6)	28.5 (4.5)
Civil status (cohabitant or married), n (%)	3741/3946** (94.8)	3137/3271** (95.9)
Higher education >12 years, n (%)	2412 (60.7)	2017 (61.0)
Smoking during first trimester, n (%)	230/3963** (5.8)	210/3247** (6.5)
Pre-pregnant body mass index†, mean (SD)	23.6/3966** (4.3)	23.8/3287** (4.3)
Gestational age at onset of active labour	281 (7.0)	281 (8.0)
(days), mean (SD)		
Characteristics related to the newborn		
Birth weight (gram), mean (SD)	3528 (427)	3518 (414)
Head circumference (cm), mean (SD)	35.0 (1.4)	35.0 (1.4)

Main outcome: intraparum cesarean sections



	WHO partograph (control) group		Zhang's guideline (intervention) group		
	n (%)	Number assessed	n (%)	Number assessed	
Primary endpoint					
Intrapartum caesarean sections*	196 (5.9%)	3305	271 (6.8%)	3972	
Descriptive endpoints					
Intrapartum caesarean sections for labour dystocia	132 (67·3%)	196	178 (65.7%)	271	
Intrapartum caesarean sections for labour dystocia at a cervical dilatation of less than 6 cm	28 (21-2%)	132	25 (14.0%)	178	
Labour dystocia, according to the allocated guideline	1512 (45.7%)	3305	1882 (47·4%)	3972	
Labour dystocia, according to the allocated guideline, diagnosed at a cervical dilatation of less than 6 cm	214 (14-2%)	1512	222 (11-8%)	1882	
Initiation of synthetic oxytocin during labour at a cervical dilatation of less than 6 cm	289 (18.5%)	1561	244 (14·7%)	1658	
Duration of active phase of labour, hours†	6.05 (3.38–9.50)	NA	6.59 (3.55-10.53)	NA	

NA=not applicable. *Adjusted relative risk is $1\cdot17$ (95% CI $0\cdot98-1\cdot40$; p= $0\cdot08$), giving an adjusted risk difference of $1\cdot0\%$ (95% CI $-0\cdot1$ to $2\cdot1$), and an intraclass correlation coefficient (estimated within centres) of $3\cdot4\times10^{-34}$; the number needed to treat with the WHO guideline to avoid one intrapartum caesarean section was therefore 100. †Data are median (IQR).

Table 2: Intrapartum caesarean sections and labour dystocia

Secondary outcomes

	WHO partograph (control) group (n=3305)	Zhang's guideline (intervention) group (n=3972)	Adjusted relative risk (95% CI)	Adjusted risk difference (95% CI)	pvalue	Intraclass correlation coefficient, assessed within centres (95% CI)
Clinical interventions during labour						
Operative vaginal delivery	581 (17-6%)	839 (21.1%)	1.06 (0.84-1.34)	1·1% (-3·3 to 5·5)	0.62	0.02 (0.01-0.06)
Artificial rupture of the membranes	1223 (37-0%)	1396 (35·1%)	0.92 (0.79-1.06)	-3·2% (-8·4 to 2·0)	0.23	0.01 (0.01-0.03)
Augmentation with oxytocin during labour	1561 (47.2%)	1658 (41.7%)	0.98 (0.84-1.15)	-0.8% (-7.8 to 6.1)	0.81	0.02 (0.01-0.05)
Epidural analgesia	1653 (50-0%)	1913 (48-2%)	0.96 (0.81-1.15)	-1·9% (-10·5 to 6·8)	0.67	0.03 (0.01-0.07)
Perineal surgical incision in women delivering vaginally	881 (28-3%)*	1151 (31-1%)†	0.91 (0.68–1.20)	-2·9% (-11·3 to 5·5)	0.50	0-04 (0-02-0-09)
Other secondary outcomes						
Obstetric anal sphincter injuries in women delivering vaginally	79 (2·5%)*	112 (3.0%)†	1-14 (0-86-1-52)	0·4% (-0·4 to 1·2)	0.36	1·9×10 ⁻³⁴ (NE)
Blood transfusion administered	82 (2.5%)	115 (2.9%)	1.16 (0.79-1.69)	0.4% (-0.6 to 1.4)	0.45	0-02 (0-01-0-11)
Apgar score of less than 7 after 5 min	36 (1.1%)	49 (1.2%)	1.14 (0.74-1.75)	0.2% (-0.3 to 0.7)	0.55	1.7 × 10 ⁻³⁵ (NE)
Neonates with an umbilical cord artery pH of less than 7-0‡	19 (0-6%)	22 (0-6%)	0.99 (0.46-2.15)	0 (-0·4 to 0·4)	0.98	0.04 (0.01-0.46)

Data are n (%). NE=not estimable. *Out of 3109 participants assessed. †Out of 3701 participants assessed. ‡Missing values (33%) were imputed with best outcome.

Table 3: Secondary outcomes



The use of oxytocin

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ORIGINAL RESEARCH ARTICLE



The Labor Progression Study: The use of oxytocin augmentation during labor following Zhang's guideline and the WHO partograph in a cluster randomized trial

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Torbjørn Moe Eggebø^{5,6} | Daniella Rozsa⁶ | Kathrine Frey Frøslie⁷ | Pål Øian⁸ |
Ellen Blix²

	Intervention group (n = 3972)	Control group (n = 3305)	Estimated difference (95% CI)	P-value
Oxytocin augmentation during labor, n (%)	1658 (41.7)	1561 (47.2)	ARR: 0.98 (0.84 to 1.15) ARD: -0.8% (-7.8 to 6.1)	0.8
Duration of oxytocin augmentation (minutes), ^a median (IQR)	134 (57-270)	115 (50-250)	AMD: 17.9 (2.7 to 33.1)	0.021
Maximum dose of oxytocin augmentation (mL/h), ^a median (IQR)	75 (45-120)	90 (60-120)	AMD: -0.1 (-13.5 to 13.3)	0.99
Dose of oxytocin when initiating augmentation (mL/h) ^a median (IQR)	30 (30-30)	30 (15-30)	AMD: -0.4 (-3.6 to 2.9)	0.82
Discontinuation of oxytocin, ^a n (%) ^b	74 (4.5%)	54/1554 (3.5%)		
Cervical dilatation when initiating oxytocin (cm	n), ^a n (%) ^c			
4 cm	101 (6.1)	128 (8.2)	ARR: 0.73 (0.55 to 0.98) ARD: -2.2 (-4.2 to -0.1)	0.04
5 cm	244 (14.7)	289 (18.5)	ARR: 0.79 (0.66 to 0.95) ARD: -3.9 (-6.9 to -0.9)	0.01
6 cm	399 (24.1)	443 (28.4)	ARR: 0.84 (0.75 to 0.94) ARD: -4.6 (-7.6 to -1.6)	0.003
7 cm	552 (33.3)	565 (36.2)	ARR: 0.92 (0.83 to 1.01) ARD: -3.0 (-6.3 to 0.2)	0.07
8 cm	712 (42.9)	692 (44.3)	ARR: 0.96 (0.88 to 1.05) ARD: -1.7 (-5.7 to 2.3)	0.40
9 cm	914 (55.1)	835 (53.5)	ARR: 1.01 (0.93 to 1.11) ARD: 0.8 (-4.1 to 5.7)	8.0
10 cm	1658 (100)	1561 (100)	ARR: 0.98 (0.88 to 1.09) ARD: -0.8 (-5.7 to 4.1)	0.8

Abbreviations: AMD, adjusted mean difference; ARD, adjusted risk difference; ARR, adjusted relative risk; IQR, interquartile range.

^aInclude women with oxytocin augmentation during labor.

^bTotal numbers are presented due to missing values.

^cNumbers in % are cumulative.

Duration of labour

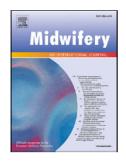
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The Labour Progression Study (LaPS): Duration of labour following Zhang's guideline and the WHO partograph – A cluster randomised trial



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Duration of stages and phases and in active labour.

	Zhang group $n = 3972$ Unadjusted median (5th, 95th percentile)	Adjusted estimated median (95% CI)	WHO group $n = 3305$ Unadjusted median (5th, 95th percentile)	Adjusted estimated median (95% CI)	Accelerated delivery time factor (95% CI)		p-value
Duration of labour (≥4 cm to delivery)† (hours)	6.6 (1.4, 16.0)	7.0 (6.5–7.5)	6.1 (1.3, 13.8)	6.2 (5.7-6.6)	1.14 (1.0-1.2)	0.84 (0.2–1.5)	0.008
Duration of 1st stage (4 cm to 10 cm) †.* (hours)	5.0 (0.5, 15.0)	5.6 (5.2–6.0)	4.5 (0.5, 12.5)	4.9 (4.5–5.4)	1.13 (1.0- 1.3)	0.66 (0.1–1.2)	0.023
Duration of 2nd stage (10 cm to delivery) [‡] (min)	76 (17, 242)	88 (83.2–92.7)	75 (16, 204)	77 (72.4–81.4)	1.14 (1.1–1.2)	0.18 (0.1-0.3)	0.000

CI: Confidence interval.

Analysed with Weibull regression, adjusted for annual ICS rates and number of deliveries, maternal age, body-mass index, civil status, educational level, cervical dilatation at first registration and birthweight and head circumference of the neonate.

[†] Full Analysis Set (FAS)

^{*} Censoring; ICS.

[‡] Women with ICS in the first stage of labour were left censored at the time of ICS and not included in the analysis.

Childbirth Experience

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ORIGINAL RESEARCH ARTICLE



The effect of Zhang's guideline versus the WHO partograph on childbirth experience measured by the Childbirth Experience Questionnaire in the Labor Progression Study (LaPS): A cluster randomized trial



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