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Long-term effects of the nine-item list intervention on obstetric and neonatal outcomes in Robson group 1 – A time series study

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Abstract

Introduction: The nine-item list, with organizational and cultural changes, was implemented at the delivery unit in Linköping, Sweden between 2007 and 2010, aiming at improving the quality of care by offering more women a safe and attractive vaginal delivery. The target group for the intervention was nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1). The aim of this study was to evaluate pregnancy outcomes before, during, early post and late post introduction of the nine-item list.

Material and methods: Robson group 1 births (n = 12763) from 2004 to 2018 were divided into four time periods; before the nine-item list (2004-2006), during introduction of the nine-item list (2007-2010), early post introduction of the nine-item list (2011-2014) and late post introduction of the nine-item list (2015-2018). The nine-item list consists of monitoring of obstetric results, midwife coordinator, risk classification of women, three midwife-competence levels, teamwork—the midwife, obstetrician and nurse working as a team with the common goal of a normal delivery, obstetric morning round, fetal monitoring skills and obstetric skills training. Perinatal outcomes before, during, early post and late post introduction were compared using a Student's t test for numerical variables and a Pearson chi-squared test for categorical variables.

Results: Apgar score <7 at 5 minutes, Apgar score <4 at 5 minutes and umbilical cord arterial pH <7 did not differ significantly between the four time periods. Between before introduction and early post introduction, instrumental vaginal delivery decreased from 19.8% to 12.2% and cesarean section from 9.6% to 4.5%. The late post introduction period showed a maintained effect with 10.7% instrumental deliveries and 3.9% cesarean sections. Obstetric anal sphincter injury grade III decreased instantly during the introduction of the nine-item list from 7.8% to 5.1% and thereafter remained unchanged.

Conclusions: Implementation of the nine-item list increased the proportion of spontaneous vaginal deliveries by reducing the number of instrumental deliveries and cesarean sections without affecting the neonatal outcomes in nulliparous women

Abbreviations: CS. cesarean section: HIE. hypoxic ischemic encephalopathy: NICU, neonatal intensive care unit: OASI, obstetric anal sphincter injury.

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with spontaneous onset of labor. The nine-item list intervention seems to provide long-term sustainable results.

KEYWORDS

cesarean section, intervention, neonatal outcome, nine-item list, Robson group 1

1 | INTRODUCTION

There seems to be consensus worldwide that in many countries and regions cesarean section (CS) rates are too high. However, the number of studies presenting clinical interventions that actually decreased the CS rate are not correspondingly high and when it comes to long-term effects or sustainable results of performed interventions, information is sparse.

Some studies have shown benefits of using The Ten Group Classification System,²⁻⁴ first to categorize data and further to analyze them in clinical audit cycles aimed at reducing CS rates.⁵⁻⁸ The longest follow-up time after introducing audit cycles in these studies was 3 years.

Other interventions aiming to reduce CS rates have recently been described at both hospital and regional levels. A weekly retrospective review conference where all CSs were discussed was introduced in a single institution in the USA. Measurement was performed of CS rates before and after implementation of this conference and significant reductions were found overall and in nulliparous women. A two-stage intervention package including health education, skills training and capacity building was implemented by the municipal government in a Chinese region. The CS rate fell from 42% before the intervention to 35% in Stage 2.

Two studies present long-term data and detailed descriptions of the interventions performed, both leading to an increased number of vaginal deliveries without increasing adverse neonatal outcomes. One quality improvement initiative was carried out in a high CS rate context, ¹¹ and the other one, the nine-item list, in a low CS rate setting. ¹² The effects of the nine-item list on organizational and cultural changes were presented in the total population of women giving birth.

The primary aim of the present study was to evaluate neonatal outcomes in the target group, nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1), before, during, early post and late post introduction of the nine-item list. The secondary aim was to assess the short-term and long-term effects of the nine-item list on obstetric outcome in Robson group 1.

2 | MATERIAL AND METHODS

Data from all births in Robson group 1 between 1 January 2004 and 31 August 2018 (n = 12 763) at the University Hospital in Linköping were extracted from electronic medical records. The births were further divided into four time periods: before the nine-item list (2004-2006), during the introduction of the nine-item list (2007-2010), early post introduction of the nine-item list

Key message

Implementation of the nine-item list decreased the proportion of cesarean sections without affecting the neonatal outcomes in nulliparous women with spontaneous onset of labor. The nine-item list intervention seems to provide long-term and sustainable results in this group.

(2011-2014) and late post introduction of the nine-item list (2015 1 January-2018 31 August). The reason for not including the year 2003 was a lack of reliable and consistent data, because a peripheral hospital was closed down and women were referred for child-birth to Linköping University hospital.

All four groups (time periods) were compared concerning primary outcomes: Apgar <7 at 5 minutes, Apgar <4 at 5 minutes, umbilical cord arterial pH <7, the occurrence of hypoxic ischemic encephalopathy (HIE) grade 1-3, cooling yes/no (HIE grade 2-3), days at neonatal intensive care unit (NICU) (HIE grade 2-3), stillbirth (including intrapartum fetal death) and early neonatal death. Secondary outcomes compared between the groups were: mode of delivery, postpartum hemorrhage and obstetric anal sphincter injury (OASI).

Hypoxic ischemic encephalopathy grades 1-3 was defined as both International Classification of Diseases –10th revision diagnosis of P910A-C (withdrawn 31 December 2008) and International Classification of Diseases –10th revision diagnosis of P916A-C. Data on maternal age, smoking, maternal height and weight in early pregnancy, cohabitation with partner and whether the woman had a history of mental illness, were also extracted from the women's electronic medical records.

2.1 | Intervention: the nine-item list

The nine-item list, earlier described in detail, consists of organizational and cultural changes performed at a single institution (Figure 1).¹² The nine-items include:

- Monitoring of obstetric results: The results are presented regularly to the staff at the delivery unit and further used for benchmarking with other units, so that goals can be set based on the "best units" results of each measured variable.
- 2. A midwife coordinator: A midwife coordinator leads the work on every shift. A coordinator needs to have excellent obstetric skills, as well as leadership abilities.

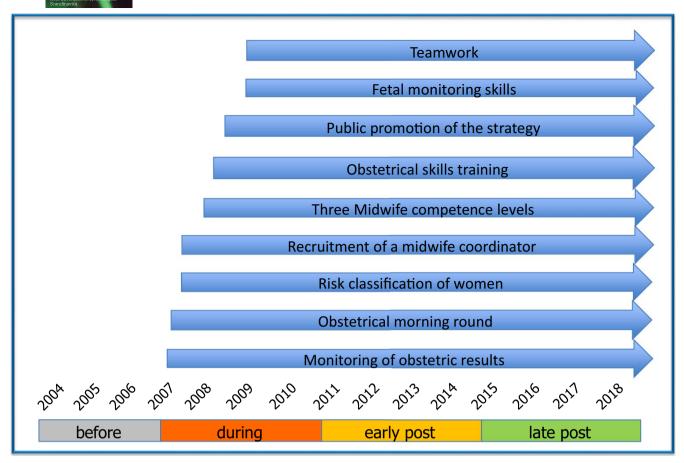


FIGURE 1 Time frame of introduction and continuation of the nine-item list interventions

- 3. Risk classification of women: Every pregnant woman attending the unit is classified according to a traffic-light model.
- 4. Three midwife competence levels: Midwives are classified into competence levels. The level of midwife competence is combined with the risk assessment of women in labor.
- Teamwork: The midwife, obstetrician and nurse in the delivery unit work as a team with the common goal of a normal delivery in both low-risk and high-risk pregnancies.
- 6. Obstetric morning round: A non-traditional morning round where all attendants are important and expected to contribute to discussions concerning both the care of the women at the unit on that particular day as well as case audits.
- 7. Fetal monitoring skills
- 8. Obstetric skills training 13,14
- 9. Public promotion of the strategy

2.2 | A summary of the labor ward processes at the University Hospital in Linköping

Until 2015, onset of active labor was defined as cervix dilatation of ≥ 3 cm in women with painful regular uterine contractions. This definition was based on a state-of-the-art document by the

Swedish National Board of Health and Welfare published in 2001. For the definition of active spontaneous onset of labor, from 2015 and onwards, at least two out of three of the following criteria had to be fulfilled: spontaneous rupture of the membrane, regular painful contractions (2-3 contractions/10 minutes) and cervix dilated 4 cm or cervix effaced and dilated >1 cm. Labor arrest during the active phase in the first stage of labor from 2011 was defined as progress delayed by 3 hours (previously 2 hours) from the expected 1 cm/h cervical dilatation. During the second stage, labor arrest was defined as no descent of the presenting fetal part for 1 hour. Rupturing of membranes and oxytocin infusion were indicated when labor arrest was diagnosed. The standard solution for infusion of oxytocin for augmentation of labor had a concentration of 10 mU/mL. The infusion started with 3.3 mU/min and the infusion rate increased every 20 minutes by 3.3 mU/min until 4-5 contractions/10 min were achieved and/or normal progress of labor occurred. During oxytocin treatment the fetus should be continuously monitored with cardiotocography and the fetal scalp blood should be sampled when indicated. A maximum pace of 30 mU/min is recommended by national Swedish guidelines, 15 but could in some women be exceeded after staff team time out and overall assessment of maternal characteristics, number of contractions and the fetus's well-being according to cardiotocography. The attitude at the unit toward epidural use was generous.

2.3 | Statistical analyses

Data were analyzed using IBM SPSS Statistics for Windows, Version 24.0. (IBM Corp.). Descriptive statistics were presented as mean score, standard deviation, and absolute and relative frequency. Neonatal and obstetric outcomes were evaluated using chi-squared tests for categorical variables and t tests for numerical variables. All analyses were two-sided, and *P*-values <.05 were considered as statistically significant. Tests were adjusted for pairwise comparisons using Bonferroni correction.

2.4 | Ethical approval

The study was approved by the Ethical Review Board on 15 August 2018 (Dnr 2018/336-31).

3 | RESULTS

In order to fully interpret outcomes in Robson group 1, the target group for the nine-item list intervention, proportions of CSs in Robson group 1 and Robson group 2 together as well as a subdivision of Robson group 2 into Robson group 2a (inductions of labor) and Robson group 2b (pre-labor CS) are presented in Figure 2. Robson group 2 includes nulliparous women with single cephalic pregnancy, ≥ 37 weeks of gestation who either had labor induced or who were delivered by CS before labor. A decreasing trend of CS was seen in Robson group 1+2, 2 and 2a with the most pronounced change during the introduction of the nine-item list. The proportion of CSs in Robson group 2b remained fairly unchanged over the time periods.

The final study population of Robson group 1 included 12 763 women. Maternal characteristics over the four time periods are shown in Table 1. Smoking was more common in the before the nineitem list group in comparison with the late post introduction group, which is in accordance with the general trend in the pregnant population. In contrast, a history of mental illness increased substantially over time. The mean maternal age at birth (28 years) was stable over the time periods. Despite that, the proportion of obese women increased from 7.8% in the before the nine-item list group to 11.2% in the late post introduction group.

Neonatal outcome was analyzed in the four time periods in three different modalities, Apgar score <7 at 5 minutes, Apgar score <4 at 5 minutes and umbilical cord arterial pH <7 (Table 2). No significant differences were found in any of the pairwise comparisons between the four time periods. Cases with a diagnosis of HIE grade 1-3, stillbirths and early neonatal deaths were very few and, therefore, only presented as absolute numbers. Furthermore, cooling and days in the NICU for infants with HIE grade 2-3 are presented in Table 2. Cooling was introduced at our NICU in May 2008.

Before the nine-item list, spontaneous vaginal delivery occurred in 70.5% of all births, instrumental delivery in 19.8% and CS in 9.6% (Table 3). During introduction of the nine-item list spontaneous vaginal delivery occurred in 81.1% of all births, instrumental delivery in 13.1% and CS in 5.7%. From 2011 to 2014, representing the early post introduction of the nine-item list, the corresponding results were 83.4%, 12.2% and 4.5%, respectively. During the late post introduction of the nine-item list group spontaneous vaginal delivery occurred in 85.4% of all births, instrumental delivery in 10.7% and CS in 3.9%.

The occurrence of OASI grade III decreased from 7.8% before introduction of the nine-item list to 4.7% during late post

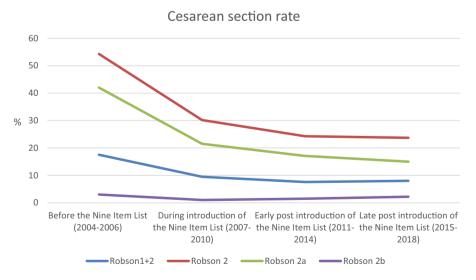


FIGURE 2 Proportions of cesarean section (CS) in four time periods in nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1) and nulliparous women with single cephalic pregnancy, ≥37 weeks of gestation who either had labor induced or were delivered by CS before labor (Robson group 2). Proportions of CSs are also shown in the subgroups Robson group 2a (induction of labor) and Robson group 2b (pre-labor CS). The denominator in the proportion of CS in Robson group 2b is all nulliparous women at term with cephalic presentation



TABLE 1 Maternal characteristics of nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1) according to study period (N = 12 763)

Study periods	2004-2006 Before the nine- item list (N = 2509)	2007-2010 During introduction of the nine-item list (N = 3574)	2011-2014 Early post introduction of the nine-item list (N = 3576)	2015-2018 Late post introduction of the nine-item list (N = 3105)
Age (years), mean [SD]	28.4 [4.5]	28.1 [4.8]	28.2 [4.8]	28.3 [4.7]
Smoking	149 (7.4)	228 (6.6)	198 (5.7)	105 (3.4)
BMI (kg/m²), mean [SD]	24.0 [4.1]	24.2 [4.4]	24.5 [4.6]	24.3 [4.4]
BMI (kg/m²), n (%)				
<18.5	51 (2.6)	114 (3.4)	107 (3.1)	86 (2.8)
18.5-24.9	1322 (66.8)	2141 (63.1)	2188 (62.9)	1898 (62.2)
25-29.9	452 (22.9)	827 (24.4)	817 (23.5)	726 (23.8)
30-34.9	105 (5.3)	218 (6.4)	270 (7.8)	241(7.9)
35-39.9	35 (1.8)	76 (2.2)	73 (2.1)	66(2.2)
≥40	13 (0.7)	18 (0.5)	26 (0.7)	33(1.1)
Cohabitation with partner, n (%)	1886 (75.2)	3217 (90.0)	3182 (89.0)	2869 (92.4)
History of mental illness, n (%)	178 (8.9)	320 (9.3)	386 (11.1)	428 (13.7)

Data are presented as mean \pm SDs or as n and %.

Abbreviations: BMI, body mass index.

TABLE 2 Neonatal outcome in nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1) according to study period

Study periods	2004-2006 Before the nine-item list (N = 2509)	2007-2010 During introduction of the nine-item list (N = 3574)	2011-2014 Early post introduction of the nine-item list (N = 3576)	2015-2018 Late post introduction of the nine-item list (N = 3105)	
Apgar <7 at 5 min, n (%)	31 (1.2)	68 (1.9)	62 (1.7)	56 (1.8)	NS
Apgar <4 at 5 min, n (%)	4 (0.2)	10 (0.3)	13 (0.4)	9 (0.3)	NS
Umbilical cord arterial pH <7, n (%)	11 (0.7)	14 (0.5)	15 (0.5)	22 (1.0)	NS
Missing values on arterial pH, n (%)	958 (38.2)	647 (18.1)	775 (21.7)	830 (26.7)	
HIE grade 1, ^a n	1	7	3	4	
HIE grade 2, ^a n	2	4	5	2	
HIE grade 3, ^a n	1	1	0	0	
Cooling ^{b,c}	0	1	4	1	
Days at NICU ^c	15-22	3-17	13-20	8-15	
Stillbirth ^a	0	2	0	3	
Early neonatal death, ^a n	0	1 ^d	1	0	

Groups were compared using chi-squared tests for categorical variables. All analyses were two-sided, and *P*-values <.05 were considered as statistically significant. Tests were adjusted for pairwise comparisons using Bonferroni correction.

Abbreviations: HIE, hypoxic is chemic encephalopathy; NICU, neonatal intensive care unit; NS, non significant.

introduction, whereas OASI grade IV remained constant. Overall postpartum hemorrhage decreased significantly from 506 to 459 mL, postpartum hemorrhage after vaginal delivery decreased from 490 to 450 mL, whereas hemorrhage at cesarean delivery remained constant during the total study period.

4 | DISCUSSION

In this data set of 12 763 Robson 1 deliveries from 2004 to 2018, organizational and cultural changes representing the nine-item list increased the proportion of spontaneous vaginal deliveries from

^aHIE, stillbirths and early neonatal deaths are presented as absolute numbers only.

^bAvailable since May 2008.

^cHIE grade 2-3.

^dThis infant is also marked for HIE grade 3 in the table.

TABLE 3 Obstetric outcome in nulliparous women at term with spontaneous onset of labor and cephalic presentation (Robson group 1) according to study period

Study periods	2004-2006 Before the nine-item list (N = 2509)	2007-2010 During introduction of the nine-item list (N = 3574)	2011-2014 Early post introduction of the nine-item list (N = 3576)	2015-2018 Late post introduction of the nine-item list (N = 3105)	
Mode of delivery, n (%)					
Spontaneous vaginal delivery	1766 (70.5)	2900 (81.1)	2981 (83.4)	2653 (85.4)	P < .05 Before vs all others $P < .05$ During vs Late post
Instrumental delivery	498 (19.8)	469 (13.1)	435 (12.2)	331 (10.7)	P < .05 Before vs all others $P < .05$ During vs Late post
Cesarean section/ emergency	241 (9.6)	205 (5.7)	160 (4.5)	121 (3.9)	P < .05 Before vs all others $P < .05$ During vs Late post
Postpartum hemorrhage (mL), mean [SD]	506 [325.9]	509 [389.0]	477 [315.0]	459 [332.9]	P < .05 Before vs Early and Late P < .05 During vs Early and Late
Postpartum hemorrhage: cesarean section (mL), mean [SD]	677 [397.0]	689 [302.3]	706 [385.6]	703 [398.5]	NS
Postpartum hemorrhage: vaginal delivery (mL), mean [SD]	490 [311.0]	499 [391.0]	467 [307.7]	450 [326.7]	P < .05 Before vs Late P < .05 During vs Early and Late
OASI grade III, n (%)	196 (7.8)	181 (5.1)	203 (5.7)	145 (4.7)	P < .05 Before vs all others
OASI grade IV, n (%)	22 (0.9)	29 (0.8)	19 (0.5)	14 (0.5)	NS

Groups were compared using chi-squared tests for categorical variables and t tests for numerical variables. All analyses were two-sided, and *P*-values <.05 were considered as statistically significant. Tests were adjusted for pairwise comparisons using Bonferroni correction.

Abbreviations: NS, non significant; OASI, obstetric anal sphincter injury.

71% before implementation of the nine-item list to 85% in the late post introduction period without affecting the neonatal outcomes. A post implementation follow-up time of 8 years indicates long-term and sustainable effects on perinatal outcomes.

A meta-analysis by Chaillet et al concluded in 2007 that it is possible to reduce CS safely with interventions that involve health workers in analyzing and modifying their practice. Among the included studies the strongest effect on reducing CS rate was observed in studies where audit and feedback were used in a multifaceted strategy, leading to a 27% reduction. The multifaceted intervention involved two or more interventions targeting several barriers to change, such as guideline education, audit and feedback, hospital payment and malpractice reform, and identification of barriers to change.

More recently, Boatin et al identified six studies that used the Robson classification to evaluate interventions aimed at reducing CS rates. ⁵ All six studies reported a reduction or maintenance in CS rates without an increase in neonatal morbidity. Again, multifaceted strategies were found to be effective in reducing the CS rate. The nine-item list intervention evaluated in the present study was classified in that systematic review as multifaceted.

Although a significant reduction of CS rates was described, a shortcoming was the lack of long-term follow-up and evidence of

sustainable change. Vadnais et al presented an example of continuous multi-strategic quality improvements in a tertiary-care academic medical center leading to a reduction in CSs. ¹¹ The intervention included provider education, feedback and new policies. The CS rate decreased from 35% to 21% in the group of nulliparous women at term with singleton pregnancies, vertex presentation and cesarean deliveries, without affecting the Apgar score <5 at 5 minutes, or the incidence of NICU admissions and shoulder dystocia. This study reports yearly results from 2005 to 2015. The same time-series approach was used in an earlier study from Linköping where it seemed that the nine-item list of specific and persistent multidisciplinary activity reduced CS rates without increasing the risk of neonatal complications in the total population of laboring women. ¹²

Although a CS has specific indications during pregnancy and childbirth and seems necessary to reduce maternal or fetal morbidity, it has been difficult to show benefits for the child concerning cerebral palsy. Indeed in the meta-analysis by O'Callaghan, elective CS delivery did not reduce the overall risk for cerebral palsy. Emergency CS seemed to increase the risk for cerebral palsy, but the result was probably affected by indication bias. Moreover, CSs can also lead to both short-term and long-term effects for the mother and the child. In a series of articles in the *Lancet* about optimizing

the CS rate, the increased risk on maternal mortality, severe acute morbidity and higher risk in a subsequent pregnancy related to abnormal placentation, uterine rupture, stillbirth and preterm birth are stated. 19 Children born by CS are exposed to more short-term risks related to a different hormonal, bacterial and medical exposure that might affect immune development, allergy, asthma and the microbiome in the gut in comparison with vaginally born infants. In the same series of articles, Betrán et al concluded that interventions are needed to reduce unnecessary CSs in healthy women and babies. 20 There are many factors affecting the CS rate in a particular clinic, such as professional health worker level, education and training, convenience of CS birth, dysfunctional teamwork and beliefs about vaginal birth after CS.

The absolute rates of obstetric interventions and perinatal complications rendered by the implementation of the nine-item list might be unique in its specific context. In the late post introduction group the CS rate was 3.9%. That is much lower than in the most recent publications on CS rates in Robson group 1, for example in Lithuania 11.6%, ²¹ La Ribera University Hospital, Spain, 11.5%, ²² Islamabad, Pakistan 22.2%, ²³ Canada 18.4% ²⁴ and Tosamaganga Hospital, Tanzania, 27.4%. ²⁵ The reason for such enormous variations is certainly multifactorial and highlights the lack of evidence of a fixed CS rate that is optimal everywhere. Interestingly, the Tanzanian study reports a percentage of 2.1% of infants born with Apgar <7 at 5 minutes, which is just slightly higher than in the present study. We strongly encourage more reports on obstetric and neonatal outcomes in all groups of the Robson classification, ² as this would enable comparisons and benchmarking.

This study has certain strengths and limitations. A strength is the long follow-up period after the implementation of the nine-item list, making it possible to show a sustainable CS rate, indicating that the nine-item list interventions have lasting effects. Definition, documentation and classification of both the study group (Robson 1) and the perinatal variables were consistent throughout the whole study period, minimizing the risk of misclassification bias.

A limitation is that the before the nine-item list group only covered a 3-year period due to reorganization of the obstetric care in the region, where two delivery units were merged together and unfortunately data were unavailable from one of the units for the year 2003. Another limitation is that adverse neonatal outcomes in the study population are rare, despite including more than 12 000 deliveries, which makes comparisons between the periods difficult, so the results must be interpreted with caution. We regularly perform audits of infants born with severe asphyxia, intrapartum fetal deaths and early neonatal deaths. Besides the clinical routine, for the purpose of this study, all maternal and neonatal medical records in cases of adverse neonatal outcomes were scrutinized. It was not possible to present all details, or to draw any conclusions on changes in obstetric management over time, from these anecdotal cases. Ethical approval only included permission for evaluation of unidentified data at a group level, and these rare cases might, with a detailed description on obstetric interventions and neonatal status, be possible to identify in our small unit and with short time periods.

Another shortcoming is the lack of consistent data concerning women's experience of childbirth. We only have valid data for the late post introduction of the nine-item list group, making comparisons over time impossible. Two recent studies showed that emergency CS was significantly related to dissatisfaction with childbirth, so one might hypothesize that reducing CS rate would improve women's experience of childbirth. ^{26,27}

This study was performed at a single institution and the findings might only be generalizable to populations and settings with similar characteristics. Causality between the intervention (nine-item list) and the outcome could not be determined, although no other obvious organizational changes affecting the rate of spontaneous vaginal delivery were made during the study period. The number of OASIs grade III decreased instantly during the introduction of the nine-item list, and the rate was thereafter almost unchanged, indicating that later national interventions focused on reducing perineal lacerations could not have affected the result. Between the study periods, the number of smokers decreased and the number of women with a history of mental illness increased. This was not taken into account, although it is unlikely that these factors could explain the pronounced changes in mode of delivery rates.

5 | CONCLUSION

Implementation of the nine-item list increased the proportion of spontaneous vaginal deliveries by reducing the number of instrumental deliveries and CSs without affecting the neonatal outcomes in nulliparous women with spontaneous onset of labor. Furthermore, the nine-item list instantly decreased the number of OASIs grade III, and in a dose-dependent pattern, postpartum hemorrhage after vaginal delivery. These findings indicate that structured, high-quality work, organization and culture focusing on the Robson group 1 such as the nine-item list can reduce the CS rate substantially without increasing neonatal complications. The composite of the nine-item list with monitoring of the results, team-based work focusing on spontaneous vaginal delivery, in combination with training in obstetric skills and interpretation of cardiotocography probably made this possible. The nine-item list intervention seemed to lead to long-term and sustainable obstetric outcomes. Minimizing unnecessary CSs has potential for reducing complications following the surgery, for both mother and the child.

CONFLICT OF INTEREST

None.

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