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Effect of a multifaceted intervention with audit and feedback on low-risk childbirth practice: a multicentre prospective study

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Abstract

Background Care for low-risk childbirths constitutes a large proportion of deliveries and is highly influenced by factors such as region, birthing facilities, and health care providers. Audit and feedback as a quality indicator (QI) intervention alone have limited effectiveness. Multidisciplinary approaches, including QI and organizational development, are reportedly effective; however, the impact on low-risk childbirth care remains unclear. We aimed to assess the impact of multifaceted intervention, including audit and feedback, on improving care for low-risk childbirths using QIs.

Methods We conducted a 1-year pre–post comparison targeting healthy pregnant women in four obstetric wards in Japan. The intervention included audit and feedback combined with multifaceted approaches, improvement efforts by a multidisciplinary team, and educational training on health care quality and organizational culture. The outcomes were 12 QIs.

The main analysis used interrupted time-series analysis over 6 months pre- and post-intervention. We compared the 9 months pre-intervention with 3 months post-intervention in secondary analysis to assess delayed effects.

Results We included 288 women pre-intervention and 167 women post-intervention. "The spontaneous vaginal delivery indicator showed a significant increase in slope (risk ratio [RR] 1·08, 95% confidence interval [CI]: 1·00–1·16, $p < 0·05$), indicating a trend-based improvement rather than an immediate change per month in the main analysis. Secondary analysis showed a significant increase in the administration of uterotonic agents during the third stage of labour (RR 1·19, 95% CI: 1·01–1·41, $p < 0·05$).

Conclusion The improvement effects of multifaceted interventions, including audit and feedback, using QIs for low-risk childbirths were limited. However, some indicators may improve over time, suggesting a potential delayed effect.

Trial registration Not applicable.

Keywords Audit and feedback, Quality improvement, Quality of health care, Quality indicators, Obstetric delivery, Midwifery

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Background

Childbirth is one of the most important life events for women, with considerable effects on the health of both the mother and newborn. Therefore, ensuring the quality and safety of medical care during childbirth is crucial. Low-risk childbirth, which involves no known medical risks to the mother or foetus, makes up the largest proportion of all deliveries. Even in these cases, poor quality of care can negatively affect maternal and neonatal health. Studies focusing on low-risk pregnancies have shown that the type of health care provider and the birth setting (hospital vs. non-hospital birthing centre) can lead to differences in the proportions of caesarean delivery, vaginal delivery, induced labour, episiotomy, postpartum haemorrhage, neonatal hospitalization, and breastfeeding initiation [1–5]. In obstetric care, evidence from randomised controlled trials reveals medical disparity in processes and outcomes [6–9], including unnecessary medical interventions during caesarean and vaginal deliveries [10–12], the need to promote early breastfeeding [13], and differences in outcomes between hospitals and midwifery-led birthing centres [14]. However, effective context-specific intervention methods remain unclear [14–18]. Studies focusing on the impact of improving interventions for low-risk pregnancies are limited.

Although several studies have examined quality indicators (QIs) for low-risk childbirth, evaluation of their practical use and validity has not been reported. Our group developed QIs using a modified Delphi method based on multiple clinical practice guidelines and existing QIs [19]. The modified Delphi method used in this study is a consensus development method based on the RAND/UCLA Appropriateness Method [20] and is widely used for developing quality indicators [21, 22]. This method comprises two main steps: a systematic review of the literature followed by a structured face-to-face meeting with an interdisciplinary expert panel. This enables the integration of scientific evidence and expert clinical opinion. For the present study, our panel included obstetricians, paediatricians, midwives, nurses, mothers with childbirth and parenting experience, and epidemiologists, who evaluated the appropriateness of candidate QIs. This consensus process ensured that the resulting indicators were suitable for obstetric care settings in Japan. We have been updating [23] and verifying the applicability of these QIs [24]. This effort is aimed at providing new insights to improve the quality of childbirth care and optimise maternal and neonatal health outcomes.

Implementation and evaluation of quality improvement interventions using QIs for low-risk childbirth, including those developed by the authors, remain an important challenge. Quality improvement interventions are strategic approaches to enhancing care processes and outcomes. Audit and feedback are widely used methods [25–30], but unidirectional reporting of QI measurement results alone is insufficient. Effective quality improvement requires multifaceted practices, including audit and feedback, multidisciplinary collaboration, and organizational efforts led by health care opinion leaders; however, interventions specifically for low-risk childbirth are extremely limited [17, 31].

In Japan, approximately 99% of births occur in hospitals or clinics [32]. For women with low-risk pregnancies, midwives typically provide continuous care, and obstetricians oversee the process and perform medical interventions when necessary. However, under Japanese law, midwives are not authorized to independently perform certain medical procedures such as episiotomy, administration of epidural anaesthesia or oxytocin, or instrumental delivery.

Care for low-risk pregnancies and childbirth is not covered by the public health insurance system and is therefore not captured in national health insurance claims (receipt data). Consequently, the quality and content of this type of care are not systematically monitored or evaluated at the administrative level. To address this gap and support quality improvement in clinical practice, we used clinical data extracted from medical records, which offer important insights into care processes not reflected in insurance databases.

Therefore, the study aimed to assess the impact of multifaceted interventions, including audit and feedback, on medical care for low-risk childbirth using QIs.

Methods

Design

This was a multicentre prospective study conducted over 1 year. In the participating facilities, a multifaceted intervention including audit and feedback using QIs was implemented over 6 months, and its impact was evaluated.

Setting

The criteria for selecting from participating facilities in the study were established as follows:

- the facility showed a desire to improve the quality of their health care services,
- the facility was willing to collaborate with researchers in providing care for low-risk childbirths in an obstetric ward
- the facility handled approximately 100 to 1,000 deliveries annually in its obstetric unit,
- the facility was capable of using feedback from QI measurements to set goals and implement quality

improvement actions at both the ward and individual levels,
- the facility had the ability to develop quality improvement programs in collaboration with other facilities or research organizations.

Based on these criteria and expert feasibility assessments, four facilities agreed to participate.

The participating facilities included two tertiary care facilities (i.e., advanced perinatal centres in Japan) with approximately 1000 and 800 annual births, one general hospital with approximately 200 annual births and one clinic with approximately 500 annual births, for a total of four facilities. One facility provided in-hospital midwifery-led care for low-risk pregnancies. Another had previously offered such care but, at the time of the study, primarily handled high-risk pregnancies and operated under a collaborative care model involving both midwives and obstetricians. The remaining two facilities also used a mixed care model, in which midwives and obstetricians worked together to manage low-risk deliveries.

Although the degree of continuous midwifery-led care varied across the facilities, all demonstrated a strong commitment to quality improvement. Before selecting the above facilities, we confirmed that each had a system in place to incorporate feedback into clinical practice. On this basis, we determined that all four facilities were appropriate for inclusion in the study.

The study was conducted from August 2020 to January 2022 in four obstetric wards in Japan (Fig. 1). The study lasted for 12 months, divided into two phases: 6 months before the intervention (Phases 1–2) and 6 months after the intervention (Phases 3–4). This study adheres to the SQUIRE 2.0 standards (Standards for Quality Improvement Reporting Excellence) [33].

Participants

Inclusion criteria

We included women diagnosed with a low-risk pregnancy in late pregnancy, defined as those without complications or risk factors that would categorise them as high-risk, with an expectation of a normal delivery.

Exclusion criteria

We excluded women with elective caesarean delivery (requested by the pregnant woman before the onset of labour), those who did not receive prenatal care and had not reserved a delivery, women with stillbirth before admission for delivery, those who refused to participate in the study, and cases where follow-up was impossible owing to transfer before delivery (including returning to the woman's hometown for childbirth).

Interventions

In this study, we implemented an intervention involving a multifaceted strategy including audit and feedback, efforts for improvement by a multidisciplinary team, and educational training focused on health care quality and organizational culture (Fig. 2). Details about the intervention are provided in Supplemental file 1 (Supplementary Materials).

Intervention procedures

The intervention, which combined audit and feedback with multifaceted efforts, was conducted over 6 months (Fig. 2, Supplemental file 1 in Supplementary Materials).

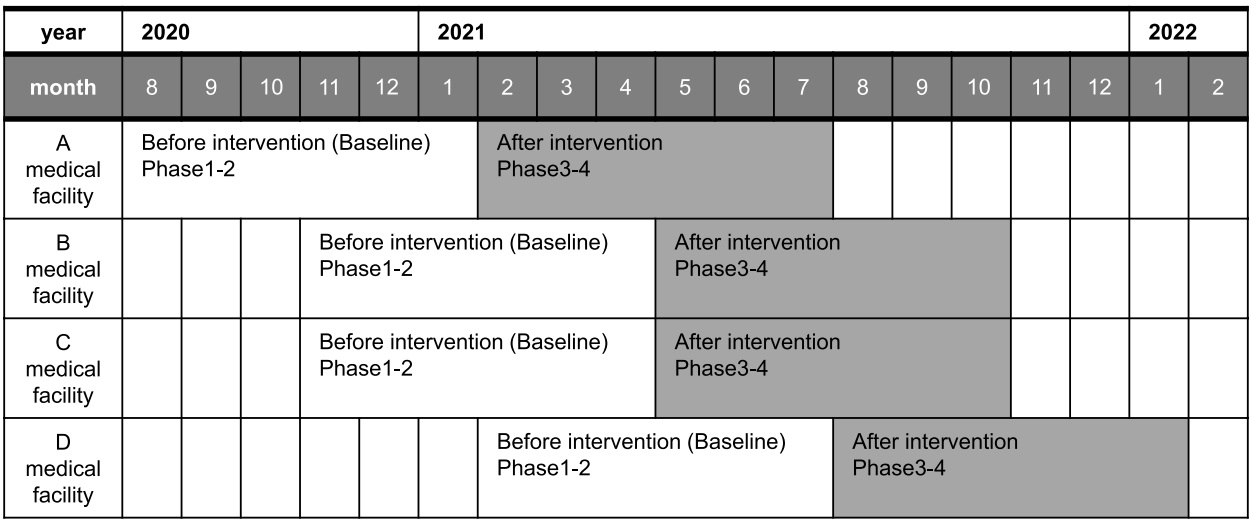

Fig. 1 Study timeline

Fig. 2 Overview of intervention procedure QI: Quality Indicator

The roles within the health care improvement team were determined in consultation with the administrators of each participating facility. These roles included Champion, Opinion Leader, and Formally Appointed Internal Implementation Leader [34, 35]. The quality improvement teams from each facility, along with the research team, formed a multidisciplinary team. The multifaceted intervention involved collaboration between the participating facilities' QI teams and the research team to conduct health care improvement efforts, as well as educational training on health care quality and organizational culture.

Theoretical framework

The theoretical framework for the intervention was based on the Consolidated Framework for Implementation Research to systematically identify barriers to and facilitators of implementation and adaptation of the multifaceted intervention to the field [34]. Additionally, the Clinical Performance Feedback Intervention Theory was used to integrate factors influencing the implementation of audit and feedback into the intervention planning [36], making it easier to reflect on the intervention itself. The Clinical Performance Feedback Intervention Theory is a comprehensive feedback theory specifically developed for health care based on 30 existing theories related to audit and feedback [36]. It posits that effective feedback functions as a continuous process cycle. Furthermore, the Plan-Do-Study-Act) cycle and Goal Setting Theory, which are often used in clinical settings in Japan to improve health care processes, were applied. The study was designed in advance by the research team and implemented in the participating facilities to achieve greater feasibility.

Measures

We considered 35 QIs, developed and validated by the authors, as potential outcome indicators for health care improvement. Because these QIs were initially designed for in-hospital midwifery, additional indicators were necessary for low-risk childbirth care in obstetric hospitals. Twenty-four indicators were extracted by the researchers from the Core Outcome Set Studies related to pregnancy and childbirth outcomes (registered as

of June 2020), predicting these could be measured via chart review. After excluding 12 indicators that overlapped with QIs and nine indicators that were difficult to measure, three additional candidate indicators were added. When data were collected up to approximately 6 months into the study, the applicability of the 35 QIs and three candidate indicators was evaluated. Two criteria were used for applicability assessment [24]: low potential for improvement (indicator measurement value ≥ 90% or ≤ 10%) and low feasibility (missing data rate > 25%). Indicators meeting both criteria were selected. As a result, 11 QIs and the episiotomy indicator were adopted, resulting in 12 indicators being used as outcomes in this study.

The 12 indicators aimed at improvement directions were as follows.

Indicators where higher values are better:

- Spontaneous vaginal birth
- No perineal tear and no perineorrhaphy
- Use of uterotonics preventing postpartum haemorrhage
- Exclusive breastfeeding at the time of discharge
- Exclusive breastfeeding during the 1-month health examination

Indicators where lower values are better:

- Labor induction
- Second-degree perineal laceration
- Postpartum haemorrhage exceeding 500 g within 2 h of birth
- Admission to the paediatrics department within a week post-birth
- Formula supplementation without medical rationale during hospitalization
- Women transitioning to care primarily provided by an obstetrician
- Episiotomy

Data collection

Data were collected and entered by participating staff during delivery, at discharge postpartum, and at 1 month postpartum. To ensure data quality, each ward team implemented measures to address data omissions. During the 6-month pre-intervention period, staff were trained in data collection methods via videos and pamphlets, and the research team flagged any data entry errors or omissions to minimise mistakes and missing data. All data collection and registration were managed using the REDCap data management system.

Sample size

Owing to the lack of prior studies, assuming 500 annual deliveries per facility, with 40% being low-risk and 50% consent and follow-up rates, each facility was expected to contribute approximately 100 cases. With four facilities participating, the estimated sample size was approximately 400 cases.

Primary analysis

Background information was compiled by summarizing the characteristics of participating facilities and pregnant women. To identify differences before and after the intervention, we applied the Wilcoxon rank-sum test for continuous variables and the Pearson's chi-square test for binary variables.

For each of the 12 indicators, results from the four hospitals were combined and calculated as the overall outcome for all hospitals. Interrupted time-series analysis was performed on the monthly proportions [37–39]. The main analysis compared the 6-month pre-intervention and post-intervention periods using interrupted time-series analysis to assess changes in levels and slopes [38]. This statistical approach adopted a log-linear model for binary outcomes, incorporating level, slope, and time change as explanatory variables. Levels were interpreted as the immediate effect of the intervention, and slopes indicated the gradual impact over time. The intervention's effect was presumed to occur immediately after implementation, excluding any time lag in the analysis. The analysis results, including post-intervention changes in levels and slopes, were presented as risk ratios and their 95% confidence intervals (CIs). All analyses were performed using SAS version 9.4 (SAS Institute, Cary, NC, USA), with significance set at a two-sided p-value of less than 0·05.

Secondary analysis

Assuming a time lag for the intervention effect, a 3-month lag was set, and interrupted time-series analysis was conducted comparing the pre-intervention period (9 months) with the post-intervention period (3 months) [25, 38]. The analysis model used in the secondary analysis was the same as that used in the main analysis.

Ethics

This study received approval from the Ethics Committee of Kyoto University Graduate School Faculty of Medicine (Nos. R2342, R2344) on June 4, 2020. This study was conducted in accordance with the current Ethical Guidelines for Medical and Health Research Involving Human Subjects in Japan and the Declaration of Helsinki.

All participating facilities agreed to collaborate on health care improvement efforts in the wards as part of the research and confirmed that no other competing studies would be conducted during the study period. Written explanations of the study were provided to health care staff (midwives, nurses, obstetricians) at each participating facility, and their consent to participate was obtained.

The information used to evaluate the intervention includes data on women admitted for childbirth at the participating facilities. Therefore, each woman admitted for childbirth was individually informed of the study's purpose and consented to participate. All participants were assured of their right to refuse or withdraw from the study at any time.

The study was registered in the University Hospital Medical Information Network Clinical Trials Registry (UMIN000050285, first registered date: 4th June 2020).

Results

Of the 457 pregnant women who consented to participate in the study, 455 were eligible for data analysis, after excluding two women who were lost to follow-up owing to transfer before delivery. Among them, 288 women were in the pre-intervention group and 167 in the post-intervention group. The characteristics of participating facilities, women, and infants are summarised in Table 1. The four facilities included two perinatal medical centres, one general hospital, and one clinic. The two groups were similar in terms of maternal age, primiparity, body mass index, birth weight, and infant sex, with no significant differences observed in Table 2. Multifaceted intervention involving audit and feedback was implemented for 146 midwives, 16 nurses, and 31 physicians who provided care to women hospitalised for low-risk childbirth. The denominators for each indicator used in the analysis varied owing to differences in the inclusion and exclusion criteria.

Comparing the periods 6 months before and after the intervention, the indicator for "spontaneous vaginal childbirth" showed a significant increase in slope (p<0·05) (Table 3). After the intervention, the rate of spontaneous vaginal delivery increased by a risk ratio of 1·08 (95% CI: 1·00–1·16) per month. However, the level change was 0·87 (95% CI: 0·65–1·02) per month, with no significant difference observed. No significant changes were found in the level or slope of the other indicators. In the secondary analysis, the indicator for uterotonic administration during the third stage of labour showed a significant increase in slope (p=0·035) (Supplemental file 2 Table S2, Supplemental file 3 Figure S3 in Supplementary Materials). After the intervention, the use of uterotonic agents during the third stage of labour increased by a risk ratio of 1·19 (95% CI: 1·01–1·41) per month. The level change was 0·70 (95% CI: 0·45–1·10) per month, with no significant difference observed. No significant changes were found in the level or slope of the other indicators.

Figure 3 shows the observed time series for each indicator, along with the fitted trends before and after the intervention. The model's fit using interrupted time-series analysis was deemed adequate.

Discussion

Principal findings

This study showed that a multifaceted intervention that includes audit and feedback with QIs for low-risk

Table 1 Characteristics of the study facilities

Characteristics			
Medical facilities	**Facilities (*N* = 4)**		**Women (*N* = 455)**
Type of facility			
Tertiary care	2		246
General hospital	1		94
Clinic	1		115
Mean number of medical health care providers per facility	Obstetrician–gynaecologist	Midwife	Nurse
Tertiary care	12	56	1
General hospital	4	24	7
Clinic	3	10	7
Means number of beds per facility	Obstetrics ward	MFICU	NICU/GCU
Tertiary care	35	6	50
General hospital	12	0	0
Clinic	9	0	0

MFICU: Maternal–foetal intensive care unit, *NICU*: Neonatal intensive care unit, *GCU*: Growing care unit

Table 2 Characteristics of participating women and infants

	Before intervention (baseline) (*N*=288)		After intervention (*N*=167)		*p*-value
Women					
Age, years	30·9	±4·7[a]	30·6	±4·5[a]	0·597
Nulliparous women, *n* (%)	140	(48·6)	78	(47)	0·739
Gestational age at delivery, weeks	39	±1[a]	39	±1·1[a]	0·604
Body mass index before pregnancy, kg/m^2	21·1	±2·5[a]	21·1	±3[a]	0·512
Body mass index at delivery, kg/m^2	24·8	±2·6[a]	24·8	±2·9[a]	0·481
Woman's height, cm	159	±5·3[a]	158	±4·8[a]	0·534
Total blood loss at delivery, mL	362	±262[a]	348	±220[a]	0·770
Smoking or passive smoking, *n* (%)	21	(7·39)	11	(6·63)	0·760
Cesarean delivery, *n* (%)	12	(4·17)	13	(7·78)	0·134
Maternal death, *n* (%)	0	(0)	0	(0)	
Infants					
Birth weight, g	3110	±331[a]	3116	±371[a]	0·921
Cord blood arterial acidity, pH	7·30	±0·08[a]	7·30	±0·08[a]	0·541
Female infant, *n* (%)	149	(52·1)	85	(51·2)	0·855
Foetal or neonatal death, *n* (%)	0	(0)	0	(0)	

Continuous variables tested using the Wilcoxon rank–sum test, categorical variables tested using Pearson's chi-square test

[a] Mean±standard deviation

childbirth led to an increase in spontaneous vaginal deliveries over the 6-month period before and after intervention. Additionally, comparing the 9 months before the intervention with the 3 months post intervention, there was an increase in uterotonic administration during the third stage of labour to prevent postpartum haemorrhage. However, no significant improvements were observed in other indicators. Whereas the overall impact of the intervention was limited, these findings suggest that some indicators may improve over time following the intervention.

Interpretation of primary analysis results

The primary analysis showed a significant increase in the rate of spontaneous vaginal deliveries, with a monthly rise of 1·08 times (95% CI: 1·00–1·16) after the intervention.

Although the change in level was not statistically significant, the steady increase in spontaneous vaginal deliveries may suggest a clinically meaningful improvement. This pattern implies that the effects of the intervention developed gradually over time, rather than having an immediate impact. This It may reflect a slow shift in clinical practices among health care providers. Given the constraints of the COVID-19 pandemic [39], such as limited resources and changes in care delivery, the effect of the quality improvement efforts might have been delayed or diminished, potentially explaining this gradual change. Spontaneous vaginal delivery is generally considered to consume fewer medical resources compared with caesarean delivery because it reduces the use of operating rooms and the involvement of staff. However, during the COVID-19 pandemic, spontaneous vaginal delivery may have placed a different kind of burden on health care providers. Because spontaneous vaginal delivery requires continuous monitoring and hands-on support throughout labour, the combination of infection prevention protocols and staff shortages may have considerably increased the workload for midwives and nurses. Indeed, during the study period, many midwives at the participating facilities expressed a strong desire to support spontaneous delivery as much as possible for women who did not require induction or caesarean delivery. Although this type of care is undoubtedly a core part of the midwifery role, it demands substantial time and personnel resources, and the associated workload during the pandemic was likely greater than under normal conditions. Additionally, changes in hospital policy, such as restrictions on the use of delivery and operating rooms, increased promotion of scheduled deliveries, and the reassignment of obstetric staff to COVID-19-related duties may have significantly altered the delivery care environment. These contextual factors may have influenced both the implementation of the intervention and how it was perceived by health care providers. Thus, although the increase in spontaneous vaginal deliveries may be interpreted as a favourable clinical outcome, it should be considered within the context of the substantial

Table 3 Results of interrupted time-series analysis evaluating differences between groups for 11 quality indicators and one clinical outcome (perineal incision) before and after multifaceted audit and feedback intervention

Primary Outcome	Risk Ratio (95%CI)	*P* value
Indicator 1 - Spontaneous vaginal birth		
Preintervention slope (per month)	0.97 (0.93 to 1.02)	0.212
Change in level after intervention	0.87 (0.65 to 1.02)	0.366
Change in slope (per month) after intervention	1.08 (1.00 to 1.16)	0.037[a]
Indicator 2 - Labour induction		
Preintervention slope (per month)	1.02 (0.85 to 1.22)	0.864
Change in level after intervention	2.01 (0.81 to 4.94)	0.131
Change in slope (per month) after intervention	0.82 (0.62 to 1.08)	0.158
Indicator 3 – No perineal tear and no perineorrhaphy		
Preintervention slope (per month)	1.09 (0.95 to 1.25)	0.225
Change in level after intervention	0.65 (0.30 to 1.40)	0.272
Change in slope (per month) after intervention	1.00 (0.82 to 1.23)	0.974
Indicator 4 - Second degree perineal laceration		
Preintervention slope (per month)	1.01 (0.96 to 1.07)	0.574
Change in level after intervention	1.01 (0.77 to 1.33)	0.919
Change in slope (per month) after intervention	0.98 (0.90 to 1.06)	0.549
Indicator 5 - Postpartum haemorrhage more than 500 grams within 2 hours of birth		
Preintervention slope (per month)	0.95 (0.82 to 1.01)	0.475
Change in level after intervention	1.13 (0.47 to 2.73)	0.784
Change in slope (per month) after intervention	1.01 (0.79 to 1.28)	0.965
Indicator 6 - Uterotonics for the prevention of postpartum haemorrhage		
Preintervention slope (per month)	1.01 (0.97 to 1.04)	0.629
Change in level after intervention	0.86 (0.67 to 1.10)	0.225
Change in slope (per month) after intervention	1.00 (0.94 to 1.07)	0.902
Indicator 7 - Admission to paediatrics department within a week after birth		
Preintervention slope (per month)	0.90 (0.78 to 1.05)	0.175
Change in level after intervention	0.92 (0.36 to 2.34)	0.859
Change in slope (per month) after intervention	1.13 (0.86 to 1.44)	0.329
Indicator 8 - Feeding only breast milk at the time of discharge from the hospital		
Preintervention slope (per month)	1.01 (0.92 to 1.11)	0.818
Change in level after intervention	1.02 (0.58 to 1.79)	0.951
Change in slope (per month) after intervention	0.97 (0.83 to 1.13)	0.699
Indicator 9 - Formula supplementation without medical rationale during hospitalization		
Preintervention slope (per month)	1.01 (0.85 to 1.19)	0.911
Change in level after intervention	0.89 (0.34 to 2.29)	0.802
Change in slope (per month) after intervention	1.07 (0.84 to 1.36)	0.586
Indicator 10 - Women switched to receive care provided primarily by obstetricians		
Preintervention slope (per month)	1.10 (0.95 to 1.26)	0.203
Change in level after intervention	0.90 (0.36 to 2.28)	0.831
Change in slope (per month) after intervention	0.80 (0.62 to 1.04)	0.096
Indicator 11 - Feeding only breast milk at the time of the health examination for children of 1 month of age		
Preintervention slope (per month)	1.03 (0.96 to 1.11)	0.383
Change in level after intervention	1.14 (0.79 to 1.64)	0.479
Change in slope (per month) after intervention	0.93 (0.83 to 1.03)	0.159
Indicator 12 - Perineal incision		
Preintervention slope (per month)	1.09 (0.95 to 1.25)	0.229
Change in level after intervention	0.69 (0.29 to 1.64)	0.404
Change in slope (per month) after intervention	0.92 (0.71 to 1.19)	0.533

[a] *p*-value <0.05

operational pressures faced by health care systems during the pandemic.

In contrast, induced labour showed a decreasing trend, with a monthly slope of 0·82 times (95% CI: 0·62–1·08). The study was conducted during a period when concerns about the spread of COVID-19 were heightened in Japan, leading to the reinforcement of preventive measures in all hospitals across the country. Many facilities may have promoted induced labour to shorten delivery times and reduce contact between medical staff and pregnant women. Although we do not have data from other facilities with which to compare, it is possible that induced labour rates increased elsewhere. However, in the participating facilities, there was no increase in induced labour, suggesting that the intervention may have helped limit this trend. The observed increase in spontaneous vaginal deliveries, despite conditions that could have reduced them, implies that without the COVID-19 pandemic, the intervention might have led to even greater increases in spontaneous vaginal deliveries.

Interpretation of secondary analysis results

The secondary analysis showed a significant increase in the use of uterotonic agents during the third stage of labour, aimed at preventing postpartum haemorrhage, with a monthly increase of 1·19 times (95% CI: 1·01–1·41) after the intervention. This desirable change was observed later in the intervention period rather than early on. Oxytocin is the first-choice drug for preventing postpartum haemorrhage and has long been recommended in countries like the United Kingdom, Australia, New Zealand, and Canada [40]. Oxytocin was recommended in the United States in 2017 [41] and in Japan in 2020 [42]. Although Japan was somewhat behind, the promotion of oxytocin for postpartum haemorrhage prevention became more strongly recommended in 2023 [43]. It is possible that awareness of oxytocin use increased during the study period. However, in Japan, midwives (who primarily manage low-risk deliveries) are not legally allowed to administer medications independently. Therefore, the deeply rooted culture of minimizing medication use may have delayed the widespread adoption of preventive oxytocin administration. This same tendency is likely to have been observed in the facilities that participated in this study. A cluster randomised controlled trial by Althabe et al. [8] found that promoting oxytocin use for postpartum haemorrhage prevention requires 1·5 years before a significant increase in prescriptions is seen, suggesting that changes in prescribing behaviour may take time. The increase in uterotonic use during the intervention period may have been influenced by external promotion, but the delay suggests it took time for this practice to become more widely accepted.

Lack of change in most indicators

Of the 12 indicators measured, 10 showed no significant change following the intervention (Table 3, Supplemental file 2 Table S2 in Supplementary Materials). The study was conducted during the COVID-19 pandemic, which caused global disruptions in health care and created a challenging environment for quality improvement efforts. Despite this, none of the indicators deteriorated, suggesting that the participating facilities made extra effort to maintain or improve the quality of care under adverse conditions. For example, three indicators related to breastfeeding were included: exclusive breastfeeding during hospitalization, the absence of formula feeding without a medical reason during hospitalization, and exclusive breastfeeding at 1 month postpartum. Initiating and sustaining breastfeeding requires close support. However, during the COVID-19 pandemic, efforts to reduce contact between midwives and postpartum mothers likely resulted in shorter hospital stays and fewer opportunities for in-person support. Despite these challenges, the three breastfeeding indicators showed no significant change, suggesting that the intervention may have had a positive impact, potentially promoting breastfeeding if the pandemic had not occurred. Additionally, although there was potential for increased episiotomy rates owing to efforts to shorten contact and delivery times, no increase was observed during the study period. Besides the impact of COVID-19, the lack of change in 10 of the 12 indicators might also be because the participating facilities already maintained a relatively high standard of care for low-risk deliveries, leaving little room for improvement. Therefore, the lack of significant changes in these indicators should not be seen as a limitation of the audit and feedback approach and organizational efforts, but rather as an indication that these indicators may still have the potential to improve with continued intervention.

Change in participant characteristics: rates of caesarean delivery

Upon re-examining participant characteristics, we found an increase in the rate of caesarean delivery from 4.2% to 7.8% after the intervention (see Table 2). When analysed by facility, this increase was observed at only one site (Unit 4), where the rate rose from 2 out of 47 cases (4.3%) to 8 out of 47 cases (17.0%). There were no significant differences between the pre- and post-intervention groups in maternal age, parity, gestational age at delivery, body mass index, or smoking history. This increase was not expected. By contrast, the other three facilities did not exhibit any notable change in caesarean delivery rates.

A detailed review of the clinical records from Unit 4 revealed that the most frequently documented indication

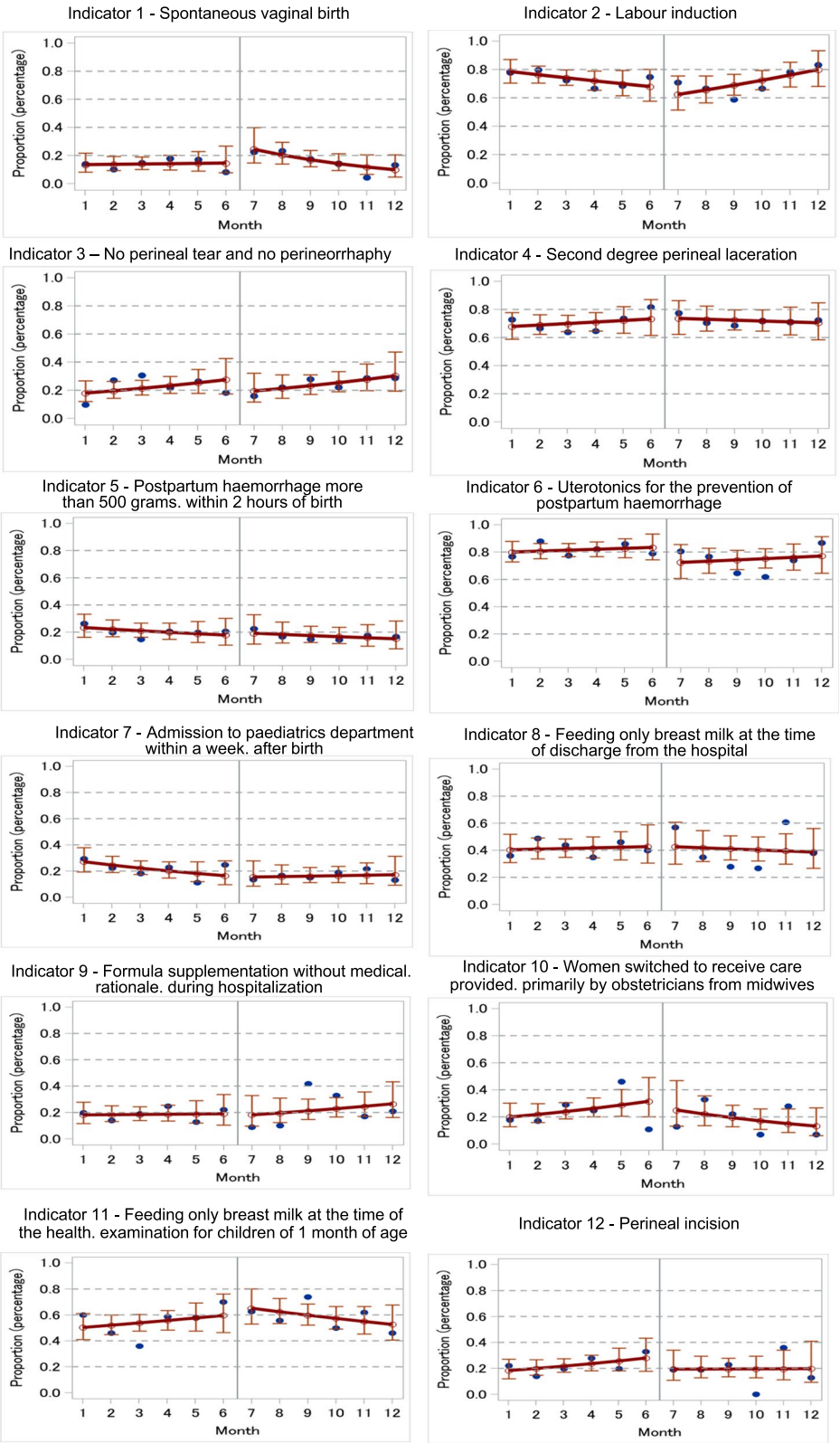

Fig. 3 Main analyses for the effect of multifaceted audit and feedback intervention for low-risk childbirth care Blue dots: observed data (measured values); red circles: predicted values; red line: regression line

for caesarean delivery was suspected foetal distress. In addition, none of the caesarean deliveries at Unit 4 involved known perinatal risk factors—such as preterm birth or hypertensive disorders of pregnancy—that are commonly associated with adverse outcomes during the pandemic [39].

Therefore, regarding the reason why the increase in caesarean deliveries occurred only at Unit 4 after the intervention, we note that the intervention program itself did not include any elements that would promote caesarean delivery. Moreover, no contextual factors specific to Unit 4 were identified that would reasonably explain the observed increase. Thus, at present, it is difficult to provide a sufficient explanation other than unexpected intrapartum events related to maternal or foetal conditions.

Limitations

First, as previously mentioned, the COVID-19 pandemic likely had a negative impact on the quality of care, potentially masking improvements that could have been achieved by the intervention. Some indicators may reflect a decline in care quality owing to the pandemic. Second, in Japan, health care staff often undergo internal transfers, rotational hiring, retirement and resignations, as well as leadership changes in March and April each year, which could have influenced the intervention's effectiveness. However, no significant changes in outcome indicators were observed during this period in our study.

Third, testing multiple outcomes (12 indicators) introduces the risk of Type I error owing to multiple testing.

Fourth, the changes observed during the study period may have been influenced by the Hawthorne effect, where increased awareness among care providers leads to temporary behaviour changes, potentially overestimating the effect of intervention. The ultimate goal of quality improvement initiatives is to establish a culture and environment where continuous improvement is embedded in care practices. Understanding the long-term impact of these changes after the observation period remains an important challenge.

Fifth, the COVID-19 pandemic led to changes in the delivery of perinatal care in Japan. For example, many facilities reduced contact time between health care providers and patients, shortened postpartum hospital stays, and reallocated staff to COVID-related duties. These changes may have affected both the implementation of the intervention and its impact on maternal and neonatal care [44]. However, as our study because we did not collect quantitative data on contextual factors such as staffing levels or midwife–patient contact time, we were unable to evaluate the specific influence of these pandemic-related changes.

Finally, the present study involved hospitals that were more conscious of improving the quality of care for low-risk deliveries than the average obstetric hospital in Japan; therefore, caution is needed when generalizing the findings to other facilities.

Conclusions

In this study, we found a limited impact of a multifaceted intervention including audit and feedback based on QIs for low-risk childbirth, with no major changes observed. However, some indicators showed potential for improvement over time. Because this study was conducted during the COVID-19 pandemic, the effect of the intervention may have been underestimated.

Abbreviations

QI Quality Indicator
CIs Confidence intervals

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12884-025-07681-2.

Supplementary Material 1: Detail of the intervention procedure. Supplemental file 2: Table S2. Secondary analysis: pre-intervention, 9 months; intervention 3 months Results of interrupted time-series analysis evaluating the difference between groups in 11 quality indicators and one clinical outcome with multifaceted audit and feedback intervention. Supplemental file 3: Figure S3. Secondary analyses evaluating the effect of multifaceted audit and feedback intervention for low-risk childbirth care.

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Authors' contributions

KU, MT, YT, HS, and TN conceptualized and designed the study. KU, MT, YT, HS, and TN managed the study and performed the intervention. KU and MT contributed to data collection and data management. KU, MT, YT, NO, and TN contributed to data analysis and drafting the tables, the figures, and the supplemental files. KU drafted the manuscript. All authors contributed to the revision of the manuscript and approved the final version.

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Data availability

The datasets generated and/or analyzed during the current study are not publicly available due to ethical concerns, as consent was not obtained from the participants to publicly disclose the raw data or to share it for secondary use at the time of publishing the study results. However, the datasets are available

from the corresponding author upon reasonable request. Researchers interested in accessing the data must contact Dr. Kayo Ueda (moriyasukayo@gmail.com). Requests will be considered on a case-by-case basis, in compliance with ethical guidelines.

Declarations

Ethics approval and consent to participate

We obtained informed consent from all panel members. This study received approval from the Ethics Committee of University Graduate School Faculty of Medicine (Nos. R2342, R2344) on June 4, 2020.

Consent for publication

Not applicable.

Competing interests

The authors declare no competing interests.

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