Towards improved, individualized labor care with the WHO next-generation partograph: the PICRINO trial

Purpose and aims

More than one-third of maternal deaths, one-half of stillbirths, and one-quarter of neonatal deaths result from complications that occur during labor and childbirth. Monitoring of labor and childbirth and the early identification and treatment of complications are critical for preventing adverse birth outcomes. In contrast, overuse of interventions during labor has not been proven to improve further birth outcomes. The way in which we currently monitor childbirth in Sweden, and how we define what is considered normal and when interventions are needed, is based on research conducted by Friedman in the 1950s, with minor adjustments made in the 1990s. The World Health Organization (WHO) has recently synthesized the research spanning the last decade into a novel recommendation, the Labour Care Guide (LCG). The degree of safety associated with implementing this recommendation within a high-income setting, and its potential to enhance birth outcomes remain undetermined.

This stepped-wedge cluster, randomized controlled trial aims to evaluate the implementation and impacts of using two different guidelines for monitoring labor with respect to neonatal and maternal outcomes (the LCG and the currently used standard care guideline). The core hypothesis is that use of the novel LCG will reduce the number of adverse neonatal outcomes and decrease the number of intrapartum Cesarean sections, as compared with the standard care.

Survey of the field

In 2018, the WHO published updated recommendations on intrapartum care for a positive childbirth experience.(1) The recommendations included updated definitions and durations for the first and second stages of labor, based on evidence from systematic reviews.(2,3) To facilitate implementation of the recommendations, the WHO in 2020 published the LCG, a next-generation partograph to monitor women in active labor.(4) A partograph is a graphical record to monitor the progress of labor and the well-being of the mother and the fetus during childbirth. The LCG promotes women-centered care, includes evidence-based definitions of onset and progress of labor, and emphasizes the monitoring of supportive care. However, to date there have been no randomized controlled studies comparing the LCG with standard care with regards to safety (neonatal outcomes) and other key outcomes of labor in high-income countries. The differences between LCG and standard care in Sweden are listed in Table 1.

Table 1. Differences between the Labour Care Guide (LCG) and standard care.

LCG	Standard care
Active phase of labor: 5 to 10 cm of cervical dilatation	Active phase of labor: 3 to 10 cm of cervical dilatation
Evidence-based time limits, at each centimeter of cervical dilatation, for normal labor progress	Fixed 1 cm cervical dilation per hour. Unrealistically fast for some women, and inaccurate at identifying women at risk of adverse birth outcomes
Meticulous monitoring of the second stage of labor	Local initiatives but no uniform recommendations
Explicit recording of supportive care on a continuous basis	Local initiatives but no uniform recommendations
Shared decision-making (woman and provider) is highlighted, and has its own section for documentation	Stated in the Swedish law: Patientlagen (2014:821) but not fully implemented
All deviations are highlighted, and a corresponding plan is required from the provider	No system available to highlight deviations

The LCG has been developed for low- and middle-income country settings, mainly for women with low-risk pregnancies, although the WHO recommends use of the LCG for all pregnancies and in all formal healthcare settings. The usability, feasibility, and acceptability of the LCG have been tested in six health facilities in South America, Asia, and Africa.(5) Practitioners, who participated in that study described the LCG as supporting precise and meticulous monitoring during labor, encouraging critical thinking as part of labor management, and improving the provision of woman-centered care. Importantly, the LCG has not been tested in high-income settings such as Sweden, and the WHO has acknowledged that application of the

LCG is not finalized, since evidence is lacking regarding its safety, usability, and effectiveness within a high-resource setting. In addition, knowledge as to how the LCG can be embedded in routine care in high-income countries is needed, considering the complexity of guideline implementation.(6) However, so far, few studies have explicitly investigated the question regarding implementation, e.g., What are the key determinants for successful implementation? and To what extent is the LCG used (fidelity)? The addition of implementation information to the LCG literature will be valuable in terms of understanding the impact of the LCG in a real-world setting, and this has been proposed as a top priority by the WHO LCG Research Prioritization Group.(7)

The obstetric care provided in Sweden is acknowledged with respect to its high level of safety and low perinatal mortality rate. Nevertheless, there is growing concern among women and providers regarding escalating medicalization, characterized by an increased proportion of interventions, such as labor augmentation and Cesarean section. More than half (58.9%) of all primiparous women in Sweden receive oxytocin augmentation due to slow labor progress, in line with the current guidelines. Nevertheless, oxytocin use during labor is associated with uterine hyperstimulation with an increased risk of neonatal acidemia at birth.(8) Compared with other countries, the frequency of term, intrapartum Cesarean sections is low in Sweden (10%), albeit with prominent differences seen between maternity wards (range, 6.1%-13.5%). Labor protraction or arrest is the most common reason for Cesarean section. Recently, a randomized controlled trial (RCT) conducted in India that included 271 women showed a significant lower rate of Cesarean sections in the LCG group compared with the control group (1.5% vs 17.8%).(9) Furthermore, in 2022, only 61% of Swedish women giving birth rated their childbirth experience as positive, highlighting another area that needs improvement.

Introducing the LCG in Sweden as a RCT will contribute with fundamental knowledge of how the LCG will affect different key outcomes of labor in a high-resource setting. This will subsequently ensure that the high standards of quality and safety are maintained within the Swedish maternity health-care system when the currently used partograph and guideline are replaced by the LCG and the new WHO guidelines.
The main direct clinical benefit of introducing the LCG in Sweden is expected to be a reduction in the number of adverse neonatal outcomes, reduction of unnecessary interventions in birthing women, improved support to women during labor, a larger proportion of women with a positive birth experience. In order to conduct the PICRINO trial, a Swedish version of the LCG needs to be developed and customized to the context in which it will be used.

Study design
This study comprises a national, multicenter, stepped-wedge cluster, randomized trial that includes 24 maternity wards randomized to six clusters. Outcome data will be extracted from: (i) the Swedish Pregnancy Register (SPR), which is a national quality register that contains prospectively collected data from early pregnancy to 2 months after birth; (ii) the Swedish Neonatal Quality Register (SNQ), which includes data on neonatal outcomes for all infants admitted to a neonatal unit; and (iii) the Swedish National Patient Register (NPR), which contains diagnoses from inpatient care and outpatient specialist care settings. Secondary outcomes will be collected through questionnaires based on validated instruments, as well as through interviews.

Study design according to the PICO model
Population: Women in active labor at 24 participating maternity wards in Sweden in the period of November 2023 through September 2025.
Intervention: Use of the LCG for women who are in active labor.
Control: Use of standard partograph and labor guidelines.
Outcome: Primary: 1) a composite neonatal outcome set; and 2) the rate of intrapartum Cesarean section. Secondary: other neonatal and maternal outcomes (see below), women's and partners' experiences of childbirth, obstetric staff experiences of the LCG, health economics

evaluation. In addition, both determinants for implementation as well as implementation outcomes will be investigated.

Research questions

Primary research question

How does the use of the LCG affect the neonatal outcome (composite outcome) and the rate of intrapartum Cesarean sections compared to standard care?

Secondary research questions

How does the use of the LCG impact maternal and neonatal outcomes compared to standard care?

How do women and their partners experience the LCG?

How do healthcare staff experience the LCG?

Is the LCG cost-effective compared to standard care?

The secondary research questions concerning the implementation process are described in Table 3.

Variables and measures

Primary outcomes:

1) The core neonatal outcome set comprises any of the following: *perinatal and neonatal mortality, 5-minute Apgar score <7, occurrence of hypoxic ischemic encephalopathy II-III, and admission to a neonatal unit*. The primary outcome variables are all dichotomous (yes/no) and will be extracted from the SPR and the SNQ. The incidence of any adverse neonatal outcome.

2) The rate of intrapartum Cesarean section (%).

The number of Cesarean sections performed is available in the SPR.

The rationale for having two primary outcomes is that if an intervention (LCG) improves one outcome (neonatal outcome) at the expense of an increased frequency of interventions (Cesarean section), one should critically appraise whether the LCG should be introduced.

All primary outcome variables in the present trial are included in the proposed Swedish Perinatal Core Outcome Set for the management of labor at or near term (SPeCOS).(10)

Secondary outcomes:

Table 2. Overview of secondary outcomes, populations, and data sources.

Secondary and exploratory outcomes	Subgroup	Data source
Neonatal and obstetric variables	All	SPR, SNQ, LCG
Women´s experiences of childbirth	All All N≈2000 N≈25	SPR (Numeric Rating Scale before discharge) SPR (Patient Reported Experience Measures) Childbirth Experience Questionnaire (CEQ2) Individual interviews
Partner´s experiences of childbirth	N≈25	Individual interviews
Staff experiences of the LCG	N≈40 N≈3400	Focus group interviews Questionnaire
Cost and need for providers and premises	All	NPR

Neonatal variables

The variables that form the primary composite neonatal outcome will also be studied individually as in secondary exploratory analyses. Further secondary exploratory neonatal outcomes: Intracranial hemorrhage, Seizures, Meconium aspiration syndrome, 5-minute Apgar score <4, Respiratory disorders, Infection, Hypoglycemia, Jaundice, Shoulder dystocia, Obstetric brachial plexus injury.

Obstetric variables

Secondary exploratory obstetric outcomes: Spontaneous vaginal delivery, Instrumental delivery, Artificial rupture of membranes, Oxytocin use as augmentation, Epidural use, Postpartum hemorrhage >1,000 ml, Perineal laceration (grades II-IV), Cervical dilation at onset of augmentation, Time estimates of the active phase of labor and the 2nd stage of labor.

Childbirth Experience Questionnaire version 2 (CEQ2)

The validated CEQ2 (11) comprises 22 items aggregated into 4 domains, i.e., Own capacity, Professional support, Perceived safety, and Participation. Most of the items in the four subscales of the CEQ2 are rated on a 4-point Likert scale. A web-based form of the CEQ2 will be sent out 1 month (standard) after birth to the intervention and control groups.

Individual interviews

The interviews will be conducted 2-3 months postpartum in-person, via a digital meeting (audio only) or by phone depending on the preference of the participant. An interview guide, including open-ended questions to explore perceptions and experiences of childbirth, will be used. Inductive content analysis (12) will be used in the data analysis.

Cost and need for providers and premises

Data on healthcare utilization (diagnosis and intervention), diagnosis-related group (DRG), and cost per patient (KPP) will be obtained from each region's patient register. As the LCG may affect the childbirth process, data regarding childbirth duration, occupancy rate, staff density (midwife per patient), and facilities available and used will be extracted from each participating maternity ward. A cost-effectiveness analysis will be performed, and the result will be presented as an incremental cost-effectiveness ratio (ICER) (13).

Material: patient selection – population, sample

All 44 maternity wards in Sweden received a first invitation to participate in PICRINO in June 2022, followed by more-detailed information in October 2022. Between October and December of 2022, online meetings with interested wards took place in which staff members, lead obstetricians and lead midwives at each maternity ward participated. The recruitment process was stopped in December 2022 when 24 maternity wards had been contracted for participation in the full trial. Four additional wards are currently on a waiting list, to provide cover for potential dropouts. Participating maternity wards exhibit a range of sizes and encompass University Hospitals, County Hospitals and District Hospitals. The geographic distribution of participating maternity wards in Sweden is shown in Figure 1.

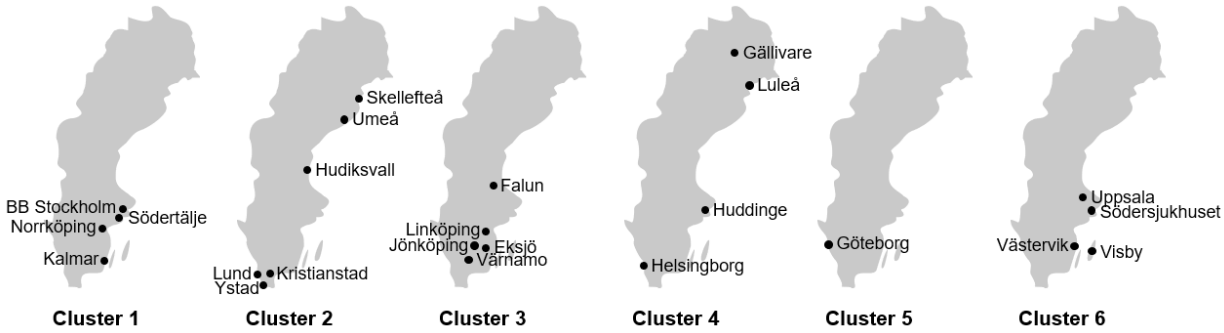

Figure 1. Participating maternity wards randomized to the indicated clusters.

The stepped-wedge cluster, randomized design is chosen because it reduces the risk of selection bias (such as the exclusion of immigrants due to language barrier), while increasing the inclusion rate, feasibility, and generalizability of the results. The proposed primary outcome occurs seldomly (in 6%-7% of cases), necessitating a large study population, which it will be possible to recruit in a reasonable time with the chosen design. The stepped-wedge approach, whereby each center contributes with both cases and controls, can also bridge the differences in clinical routines, as well as the differences in the proportions of high-risk pregnancies between participating sites.

The intervention involving the LCG will be introduced over a 22-month period in 2024-2025 (Figure 2).

	Births/year	Births/month	Wards	Controls	23-11	23-12	24-1	24-2	24-3	24-4	24-5	24-6	24-7	24-8	24-9	24-10	24-11	24-12	25-1	25-2	25-3	25-4	25-5	25-6	25-7	25-8	25-9	Cases
Cluster 1	10591	882	4	2646	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	882	15876
Cluster 2	10350	862	6	5172	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	862	12930
Cluster 3	9628	802	5	7218	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	802	9624
Cluster 4	10427	869	4	10428	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	869	7821
Cluster 5	10320	860	1	12900	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	860	7821
Cluster 6	13059	1088	4	19584	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	1088	3264
		5363	24	57948																								57336

Figure 2. Clipboard from the cluster randomization timeline (year and month) of the 24 participating maternity wards.

Data collected during the 'intervention phase' after the introduction of the LCG intervention (blue shading in Figure 2) will be compared with data acquired during the 'control phase', i.e., the period during which standard care is followed, from the trial start to the time of introduction of the intervention (yellow shading in Figure 2). A transition period (pink shading in Figure 2) of 2 months between the introduction of the intervention and data outcome collection will be used.

Patient selection – population, sample in the sub-studies concerning experiences (Table 2)

Randomly selected women giving birth at 3 to 4 hospitals included in the PICRINO trial will be invited to participate in the questionnaire (CEQ2)-based study. Women younger than 18 years will be excluded. For the individual interviews, a purposive sampling strategy will be used to recruit a broad range of women based on age, parity, number of previous births, geographic location, and socioeconomic status. Women register their interest to participate by contacting the contact person for the study (as specified in the invitation and information letter). Informed consent will be obtained verbally prior to each interview. For the partners, the recruitment strategy, eligible criteria, data collection and analysis methods will follow the same procedures as the interviews with the women. The intended sample sizes in the sub-studies are presented in Table 2.

Estimated sample size and power

Power analyses have been performed considering the number of time periods, number of clusters, the number of observations per time-period, the before-trial incidence of outcome, the between-units variation coefficient, and the anticipated risk reduction. The incidence of any adverse neonatal outcome (defined as *perinatal or neonatal death, Apgar score <7 at 5 minutes, occurrence of hypoxic ischemic encephalopathy grades II-III, or admission to neonatal unit)* was estimated using data from the SPR and the SNQ 2017-2021.

Number of time periods: All deliveries during a period of 2 years divided into seven time periods. Number of clusters: Half of the 44 Swedish delivery units will participate in the trial (thus, 22 units). Number of observations per time period: The total number of births that met the inclusion criteria during the 5 observed years was 466,615, giving a yearly estimate of 93,300 births that meet the inclusion criteria. Based on the number of deliveries during 2021, the 22 recruited units will together have approximatively 100,000 observations during a 2-year period, which corresponds to approximately 14,000 observations per time unit. Pre-trial mean incidence of composite outcome: 6.73%. Between-unit coefficient of variation: 0.46 (variance between units / overall mean). Anticipated risk reduction: 20% Risk reduction (corresponding to a Risk Ratio of 0.8). Power: With significance level of 0.05, the power to detect the anticipated risk reduction would be >0.999 given the settings listed above.

The mean rate of intrapartum Cesarean section for term pregnancies in Sweden between 2017 and 2021 was 9.1% (range, 5.6%-1.8%). No power analysis was performed explicitly for intrapartum Cesarean section (due to the higher occurrence of intrapartum Cesarean section compared to the incidence of the composite neonatal outcome). If adjusting for multiple comparison, considering that the setting has two primary outcomes (thus instead of using alpha=0.05, using alpha=0.05/2 with corresponding Za=2.24), the power to detect the anticipated risk reduction would still be satisfactory (0.993).

Interim analysis

Two interim analyses will be performed one-third and two-thirds of the way through the trial. The interim analyses are focused on safety and will be performed by comparing the primary core outcome set (*perinatal and neonatal mortality, 5-minute Apgar score <7, occurrence of hypoxic ischemic encephalopathy grades II–III, and admission to a neonatal unit*) in the control group (standard care) and the intervention group (LCG) by a statistician who is not involved in the PICRINO trial. Neonatal outcomes will be extracted from the SPR and SNQ. A Security Board that includes the external statistician and an experienced obstetrician, as well as a neonatologist will interpret the data. These individuals will all be independent of the PICRINO Steering Committee. Furthermore, the PICRINO Steering Committee will be kept blinded to the results unless a 'stop' recommendation is made by this independent Security Board based on a statistically significant clinically worse outcome ($p<0.05$) in the intervention group. The study will not be interrupted due to a significantly better clinical outcome in the intervention group compared with the control group since the new guidelines could not be implemented faster than via the PICRINO trial protocol.

Statistical methods

Generalized Estimating Equations (GEE) will be used to analyze the effect of the intervention, considering the individual-level binary outcomes. An exchangeable correlation structure will be assumed. The intervention effect will be expressed as relative risk, the after versus before intervention (=control) period. GEE analyses have been chosen because they have been shown to be more robust to mis-specification of the variance than Linear Mixed Models or General Linear Mixed Models. GEE has been shown to inflate type 1 errors if the numbers of clusters or time periods are low. This will not be an issue with the setting in the current trial. The high number of clusters and time intervals will suit the asymptotic-based GEE. All analyses will be 2-sided, using a 5% significance level. A strict intention-to-treat policy will be applied, and all results will be reported according to the randomization scheme. Analyses will be made using the SPSS (version 29), and R (version 4.2.2) software packages. A complete statistical analysis plan is available. Responsible statistician: Karin Källén (Professor of Clinical Epidemiology, University of Lund).

Feasibility

A Steering Committee with clear roles and competencies leads this project. Marie Blomberg (MB), who is Professor of Obstetrics and Gynecology at Linköping University, and Project Leader, has long experience as a lead obstetrician who empowers vaginal birth. MB has received national awards for successful and sustainable improvements in Swedish maternity care. The share of her time that she allocated as Project Leader of PICRINO during 2022-2023 was 20%, which worked out well in relation to preparations for the PICRINO trial and other clinical and research undertakings. MB has the formal competence concerning the regulatory frameworks and has an established contact with Forum Östergötland, Clinical Studies Sweden. The Steering Committee members have specific competencies and experiences that cover all aspects of the PICRINO trial, the user perspective, leadership of nationwide clinical studies in clinical therapy research, deep knowledge of WHO-LCG, neonatology and core competencies in epidemiology and statistics (for details, see *National collaboration*). The PICRINO trial was approved by the Swedish Ethical Review Authority on November 9, 2022, (Dnr. 2022-04868-01) and an amendment was approved on July 19, 2023 (Dnr. 2023-04264-02). The trial was registered at www.clinicaltrials.gov (NCT05560802) on September 29, 2022. Furthermore, the PICRINO trial is supported by the Swedish Network for National Clinical Studies in Obstetrics and Gynecology (SNAKS, https://www.snaks.se/) since December 12, 2022.

Outcome data will be extracted through linkage of the SPR, SNQ, and NPR, to be performed by the National Board of Health and Welfare, and a pseudonymized dataset will be forwarded to the research team. All questionnaires will be distributed, and incoming information will be collected using RedCap, taking the GDPR into consideration.

During 2022, a systematic preparation and evaluation of the LCG-SE (Swedish version of the LCG) has been performed by the PICRINO Group, consisting of 14 physicians, midwives, assistant nurses, and a care administrator, all of whom are working clinically in the maternity ward in Linköping. This work was made possible by the main applicant's grant from the Swedish Research Council (VR 2021-06573) for planning of clinical studies in therapy research. To summarize, a series of workshops was held in the labor ward in Linköping, where multi-professional end-users could deliver feedback on the LCG regarding translation, layout and modifications required for a high-income setting. Once a blueprint of the LCG-SE was produced, both local and national expert clinicians tested it through case discussions, and minor adjustments were made. In October 2022, the adapted LCG-SE was pilot-tested in a clinical setting. About 30 obstetricians, midwives and assistant nurses used a paper version of the LCG-SE in daily clinical practice for 4 weeks at two labor wards. Shortly after the test period, seven explorative, qualitative, multi-professional focus group interviews were conducted to explore the perceived acceptability, feasibility, appropriateness, and usability of the LCG-SE. Preliminary findings were that LCG-SE is easy to learn and use, highlights supportive care, provides a more comprehensive picture of the labor than the current partograph and emphasizes the importance of shared decision-making.
Furthermore, group members in collaboration with CSAM MedSciNet AB (the same digital platform as the SPR and SNQ) have during spring 2023 developed a digitized version of the LCG-SE, which is currently being beta-tested. Furthermore, the PICRINO group is finalizing all parts of the implementation process, including the education package´s content and scope, in anticipation of implementing the LCG-SE and the new guidelines at the participating maternity wards.

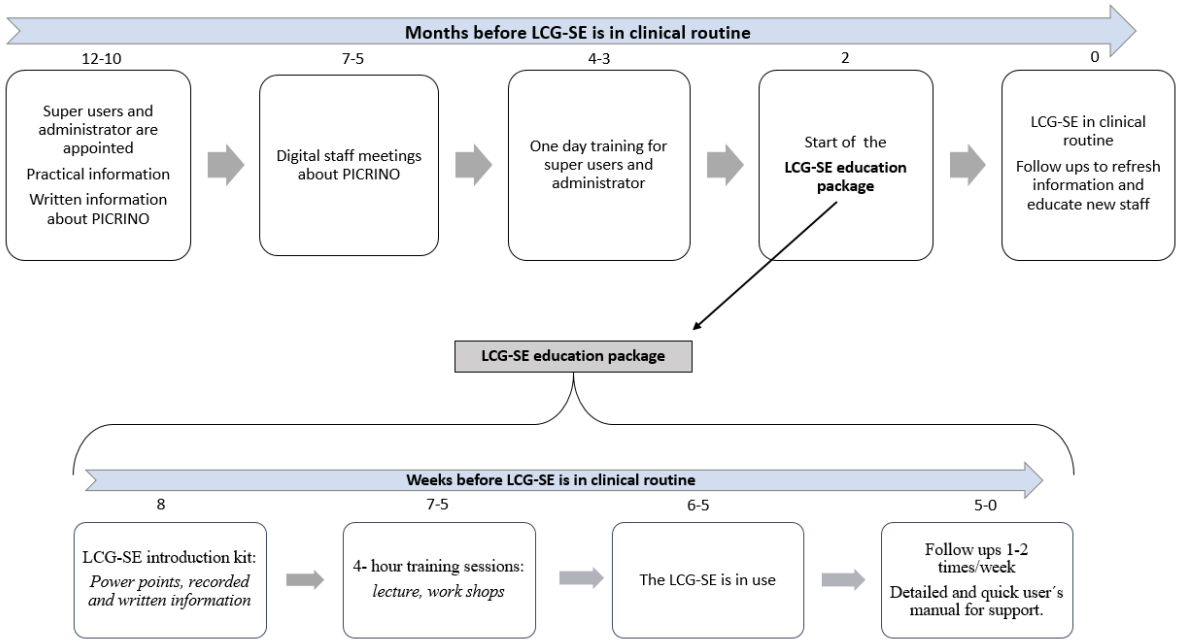

Figure 3. The proposed implementation process for LCG-SE.

Implementation process

All included sites will undergo a structured implementation process with the LCG-SE (Figure 3), which will be provided by the PICRINO Group. Each site will have 2–6 selected local superusers (midwives and/or obstetricians) who will be in regular contact (phone calls, e-mails, online meetings) with the PICRINO Group. Each site will also have a locally appointed administrative staff to facilitate the administrative work that the implementation entails. About 10–12 months before the LCG-SE is in clinical routine, the site, is informed about the practical things needed for the trial (appointed superusers and administrator, planning of the digital information sessions, information about specific dates to be reserved and confirmed). The site also obtains information about the LCG-SE and PICRINO in a PowerPoint slide presentation

that can be forwarded to the staff members for information. About 5–7 months prior to the start, digital staff meetings will be held at each site to give short information and answer questions about PICRINO. Furthermore, 4–5 months before the start, superusers and administrators will be invited to a one-day training in Linköping to acquire deeper knowledge of the LCG-SE and to get the information that they will need in their roles as supporters of PICRINO at their sites. All sites will receive an education package, which will start at each site when the transition period (according to the time schedule for the trial) starts. The education package includes several steps. First, all providers working at the labor ward (assistant nurses, midwives and physicians) will receive an LCG-SE introduction kit that includes PowerPoint slides, recorded information materials and written information about the LCG, the background of the evidence and instructions regarding documentation in the digital tool of the LCG-SE. About 1–3 weeks later, all providers will undergo a scheduled 4-hour training session that includes a lecture about LCG-SE, followed by workshops with pre-designed case descriptions where providers will practice the LCG guidelines and learn how to document in the LCG-SE protocol. This training will be held at the local sites by members of the PICRINO Group. The number of sessions depends on the size of the clinic and number of employees. Furthermore, 1–2 times/week the providers will have the opportunity for follow-ups, in which they can ask questions and practice the LCG-SE protocol by case-based learning with real-world cases. The providers will have a detailed user's manual to help them during the learning phase and a quick user´s manual as a support throughout the trial. In addition, regular follow-up meetings will be held during the trial period to refresh the information and, together with the superusers, educate new staff.

Implementation evaluation

Both the determinants for implementation and the implementation outcomes will be investigated using qualitative and quantitative approaches (Table 3).

Table 3. Planned and ongoing studies of determinants for implementation of the LCG-SE and implementation outcomes. Informants are health-care professionals (midwives, assistant nurses, and obstetricians).

Aim	Data source
To investigate perceptions of organizational readiness for implementing LCG-SE and fidelity linked to using the tool.	Questionnaire
To explore the conditions for using the LCG-SE for monitoring women in active labor. Completed in 2022.	Focus group interviews
To evaluate the LCG-SE and its implementation process in terms of perceived acceptability, feasibility, and appropriateness.	Focus group interviews
To evaluate the satisfaction of each section of the LCG-SE and perceived usability.	Questionnaire
To investigate the degree of fidelity to the new definition of labor dystocia presented in the LCG-SE.	LCG-SE, SPR

Implementation determinants in terms of perceived ***acceptability, feasibility and appropriateness*** of the LCG-SE and guidelines will be explored in mixed focus groups that contain midwives, assistant nurses and obstetricians, using a semi-structured guide. Purposive and maximum variation sampling will be employed to obtain as information-rich material as possible. Various health-care professions from different study sites including urban and rural locations, will be recruited. Interviews will be audio-recorded and transcribed verbatim. Inductive content analysis according to Elo and Kyngäs (13) will be used, including recommended steps, such as open coding, coding sheets, grouping, categorization and abstraction. Based on the recruitment strategy and analysis, we estimate that 4-6 focus groups with about six informants per group will be sufficient. To evaluate quantitatively the usability and satisfaction with the LCG-SE, a digital questionnaire, developed and used by Vogel et al (5) in low- and middle-income countries, will be sent to 3,400 providers about 4 months after the ward has switched from standard care to LCG-SE. In addition, implementation determinants in terms of ***organizational readiness*** for using the LCG-SE and guidelines will be investigated at 10

intervention wards from Clusters 1 and 2 (n=1,500) using an instrument that has been validated for the Swedish healthcare context.(14) Organizational readiness is the perceived shared capability and willingness at the wards to implement the LCG-SE and guidelines. Questionnaire data regarding readiness will be collected during the transition period after the respondents have received training on the LCG-SE but before actual implementation has commenced, thereby following the recommended protocols for measuring readiness for change. Finally, implementation outcomes ***fidelity (adherence)*** (15) will be investigated in terms of fidelity to the new guidelines (definition of labor dystocia) and completing the LSG-SE tool. A representative sample of the study sites will be included in the analysis based on, for example, geographic location, size, and staff density. Registry data will include information as to which point during labor the distribution of intravenous oxytocin starts in relation to cervical dilation and labor progress as a whole. This will enable determination of whether the timing of augmentation in women with spontaneous labor onset is consistent with the new guidelines. In addition, a comparison will be made between women for whom the guidelines have been followed (high fidelity) and women who are treated with oxytocin intravenously outside of the recommended guidelines in the LCG-SE (low fidelity), concerning the characteristics and outcomes.

GANTT chart: Timeline for the project

Activity (The main trial in **bold letters**)	**2024**				**2025**			**2026**		**2027**	
	Q1	**Q2**	**Q3**	**Q4**	**Q1**	**Q2**	**Q3-Q4**	**Q1-Q2**	**Q3-Q4**	**Q1-Q2**	**Q3-Q4**
Evaluation of organizational readiness for implementing LCG-SE	x	x									
Implementation of the LCG-SE, Cluster number	**1**	**2**	**3**	**4**	**5**	**6**					
Safety analysis (interim analysis)			**x**		**x**						
Childbirth experience, questionnaire			x				x				
Womens' and partners´ experiences of childbirth, qualitative interviews, and analysis of data				x	x						
Perceived acceptability, feasibility, and appropriateness of the LCG-SE and its implementation process		x	x	x							
Satisfaction and perceived usability of the LCG-SE		x	x	x	x	x					
Extraction of data for primary and secondary outcomes								**x**	**x**		
Analysis of data for primary and secondary outcomes									**x**	**x**	**x**
Degree of fidelity to the LCG-SE									x	x	
Health economics evaluation									x	x	x
Presentation of results at national and international conferences										x	x
Preparation and publishing of the results in peer-reviewed scientific journals										x	x
Dissemination of results to expectant mothers, maternity wards, and policymakers										x	x

The expected major findings of this trial are a reduction in the number of adverse neonatal outcomes and reduced numbers of unnecessary interventions (intrapartum Cesarean section and oxytocin use for augmentation of labor) associated with using the LCG compared with standard care guidelines. This is expected to be attributable to the broader limits for normal labor progression and improved continuous support for women giving birth offered by the LCG intervention. In addition, we expect a higher degree of birth satisfaction among women and partners and to have staff who are more satisfied with their work situation.

As the PICRINO trial includes more than half of eligible women in active labor in Sweden, the results could be generalized to women giving birth in similar settings, both nationally and internationally. If the results are in favor of the LCG, the implementation process will be well-documented, thoroughly evaluated, and readily available for replication at any maternity ward.

Risk mitigation

The necessary approvals are ready, the recruitment process for the participating maternity wards is finished, including coverage for potential dropouts, and a data management plan has been arranged. To mitigate the risk that several centers decide to terminate their participation or that the primary outcome is lower than previously observed, the trial is purposely somewhat overpowered. There are aspects with the trial that can imply higher financial costs for the caregivers; the new guidelines might entail a longer stay at the labor ward for the birthing woman since the guidelines according to the LCG, compared with standard care, allows a slower progression during labor before actions are needed to speed up the labor process. In the light of an anticipated improved child outcome and a reduced number of costly interventions, this potential increase in costs is negligible.

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Equipment

Equipment and staff are in place within the healthcare system. No trial-specific equipment is needed.

Need for research infrastructure

A collaboration with Clinical Studies Sweden, Forum Östergötland has been established, including infrastructure for the creation of the databases for the questionnaires.