NORWELG
The Norwegian WHO Labour Care Guide Trial

DEN NORSKE WHO LABOUR CARE GUIDE STUDIEN

SYKEHUSET ØSTFOLD

INFORMATION ABOUT A RESEARCH PROJECT FOR EXPECTANT MOTHERS INTENDING TO GIVE BIRTH AT ØSTFOLD HOSPITAL

AIM OF THE STUDY

During childbirth, Norwegian hospitals use a template to assess the progress of labor called the WHO - Partogram. In 2020, the World Health Organization (WHO) introduced a new template which is now recommended, the Labour Care Guide. The Labour Care Guide is based on updated research about the progress of childbirth, including the fact that cervical dilation varies among women. The Labour Care Guide also focuses on the woman`s right to shared decision-making, including during labor. In Norway, we have not yet introduced the Labour Care Guide as of 2024. The aim of this study is to examine the effect of the template through a research project before it is potentially introduced nationwide, in order to deliver research-based and tailored care to all women in Norway. Østfold Hospital is one of ten hospitals taking part in this research project, where the Labour Care Guide will be introduced during the period 2025-2026. The timing of the transition by the various hospitals from the WHO partograph to the Labour Care Guide will be determined by an electronic system, without any influence from the researchers. All births will be monitored using the new template once the hospitals have implemented it. Until then, all births will be monitored using the old template.

WHAT DOES THE PROJECT ENTAIL FOR YOU?

Your birth will be monitored based on both your own needs and those of your child using the same template to assess progress in childbirth which the hospital uses when you give birth, regardless of whether or not you participate in the project. The study involves no disadvantages for you or your child.

The information we wish to collect for the research project is the same information that is routinely entered in each new mother’s birth record. This information includes age, gestational age, labor duration, interventions and actions during childbirth, and information entered in your record about the newborn child.

If you would like to contribute your information from this childbirth to this research project, you do not need to sign or send us this form.

You will be asked to respond to a questionnaire about your childbirth experience. A text message will be sent to you about four weeks after you have given birth with a link to information and a questionnaire. This questionnaire will take about 20 minutes to complete. It is entirely voluntary whether you wish to answer the questionnaire. If you do answer the questionnaire, you consent to us including information from your questionnaire in the research project.

After the birth, we will also ask a random sample of women to take part in a focus group interview about their birth experience. We will contact some participants via text message and the interview will take place in groups at the hospital and will last about an hour. It is entirely voluntary whether you wish to participate. If you agree to participate in the focus group interview, you will be asked to sign a separate consent form so that we can include information from the interview in the research project. The results may be included in publications related to the study in anonymized form, but it will not be possible to identify you.

WHAT WILL HAPPEN TO YOUR INFORMATION?

All information about you and your child will be treated confidentially and de-identified before being analyzed. This means that the information will be processed without your name and social security number, or any other directly recognizable information. The code linking you to your information will be stored in secure data systems in accordance with applicable guidelines and laws concerning the storage of research data. Only the researchers and project coordinator will have access to the codes and it will not be possible to identify individuals when the data is published. Once the research project has been concluded, the research data will be stored for five years for control purposes. You will have the right to view the information that has been

registered about you and have any errors in the registered information corrected. You will also have the right to be informed of the security measures being followed in the processing of the information. You can complain about the handling of your information to the Data Protection Authority (Datatilsynet) and the institution's data protection officer.

APPROVALS

The Regional Committee for Medical and Health Research Ethics has conducted a research ethics assessment and approved the project (#603063). The study has been approved by the management at the Women's Clinic at Østfold Hospital and a recommendation has been given by the data protection officer at Østfold Hospital. Østfold Hospital and project leaders Rebecka Dalbye and Stine Bernitz are responsible for the project. Participation in the project is based on passive consent, in that patients who do not actively opt out are considered to consent to participation under Section 13 of the Health Research Act. The information provided in this document is considered to meet the requirements for co-determination, transparency and predictability. The legal basis for the processing of personal and health information in the research project is the General Data Protection Regulation – Article 6(1)(e) (processing for purposes in the public interest) and Article 9(2)(j) (processing for scientific research purposes). There is also an additional basis in Sections 8 and 9 of the Personal Data Act.

CONTACT DETAILS

If you have any questions about the project, you are welcome to contact the project leaders. If you have any question about privacy in the project, you should contact the Østfold Hospital's data protection officer: personvernombudet@so-hf.no.

Kind regards, the project leaders.

Rebecka Dalbye, midwife, PhD, rebdal@so-hf.no
Associate professor, Faculty of Health Sciences, OsloMet
Researcher, Women`s Clinic, Østfold Hospital.

Stine Bernitz, midwife, PhD, stiber@so-hf.no
Professor, Faculty of Health Sciences, OsloMet
Researcher, Women`s Clinic, Østfold Hospital.

RIGHT TO OPT OUT

You have the right to opt out of having information from your childbirth used in the study. It will not have any negative consequences for you or your treatment if you decide not to permit us to use your information in the research project.

If you would like information concerning your childbirth to be used as described, you should NOT sign this form.

TO EXPECTANT MOTHERS WHO DO NOT WISH THEIR INFORMATION TO BE USED IN THE RESEARCH PROJECT

If you do not wish your birth data to be used for research purposes, you should sign this form and hand it to your midwife or doctor in the ward, who will register your wishes.

I **do not** wish my information to be used in the research project ☐

Place and date _____ Signature, first and last name_____

Print first and last name_____

For more information about the project or information about the project in the following languages: English, Espanol, Français, Polski, اردو (urdu), عربي (arabisk), Soomaali, українська (ukrainsk), Türkçe, ትግርኛ (tigrinja) and دری (dari) go to the web page https://uni.oslomet.no/norwelcg/