

"Pregnant and new mum in Horten and Tønsberg – are vulnerable women identified and how does their care work for them"?

## Purpose of the study

The midwives and community health nurses continually work with evaluating and where possible improve their care. The past few years several new initiatives have been taken to increase the quality of care through individualizing it. Some pregnant women are in a situation where they need extra care. These women can be called vulnerable. Factors that make a woman vulnerable include physical complication in pregnancy, such as diabetes; psychological challenges such as depression, other factors such as unemployment, newly immigrated to Norway, addiction problems or a tough situation at home. The purpose of this study is to find out if women who need extra care are being identified and given this care. Midwifery master students will be included in this project at a later stage to write their thesis on the collected data. It is also possible that a doctoral student will be connected to this project.

#### Who is responsible for this project?

The University of South-Eastern Norway (USN) is responsible for the project. Horten and Tønsberg Kommune have approved the project.

## Who will receive an invitation to participate?

For a period of approximately 1,5 years all pregnant women receiving antenatal care in Horten and Tønsberg will be invited.

#### What does participation mean?

Participation involves filling out 2 questionnaires during pregnancy, one just before the first visit and one at around 34 weeks and one questionnaire when the baby will be about 3 months old. It will take about half an hour or less to complete each questionnaire. The questions are about wellbeing during pregnancy as well as some questions about general and mental health. It is also possible to respond with free text if there are issues not covered by the questions.

For all participants we will collect the following information from the electronic patient notes: number of visits to the midwife, pre-pregnancy body mass index, referrals to other services, home-visits by the midwife, information from the discharge note from the hospital such as the child's birth weight and condition. If the midwife registers results from their new initiative, for example the answers to a set of specific on depression, these will be collected.

A small number of pregnant women (approximately 12) will be invited to an interview. The interview is to find out how the care during pregnancy is experienced. These interviews are recorded and some notes are taken.

#### **Participation is voluntary**

It is voluntary to participate. Consent can be retracted at any time without having to give a reason. If a person opts out of the study all the information will be removed. Opting out will not have any negative effect. Non-participation will not affect the care received from services in Horten and Tønsberg.

### How do we store and use data – the protection of personal information

We will use the data we collect for the purpose we have given in this information. We will treat information confidentially in agreement with the regulations for this. Data will be stored at the research-server of USN. Professor Lukasse can access data. Students or other researcher will only be able to have access if Lukasse gives it to them. Name and contact details well be replaced by a code which will be kept separately from your data at Horten and Tønsberg Kommune. Data from the medical notes will be registered in a separate form with the code and transferred in encrypted form to the research server at USN. Nettskjema.no will be used for data-collection. Information from the study will not be registered in medical notes. Master students will receive access to anonymized data only. Transcription of interviews will be stored at the same location on the research server and only be available for 3 – 4 persons responsible for analysis (2 students, main supervisor and co-supervisor). Participants will not be recognizable in the scientific publications/thesis.

# What happens with the data when the study is finished?

Data will be anonymized when the project is finished which we plan for by the end of 2025.

### What gives us the right to use personal data?

We use your data on the basis of your informed consent.

On behalf of USN has NSD – Norwegian Center for Data from research AS considered if the way personal data will be used and stored is in agreement with the regulations for this. The study has be also been considered by the Regional Ethics Committee (REC). The study has been approved by NSD nr. 36907 and REC nr. 29206

## **Personal rights**

As long as the data can be identified it is possible to:

- Receive information about which data we are using and receive a copy of them
- Correct information about which appears wrong or misleading
- Have information removed
- Send a complaint to NSD about the way the data is being used

If questions about the study, or wish to know more, or wish to use peronal rights, please contact:

- University of South-Eastern Norway (USN) with Professor Mirjam Lukasse,
  Mirjam.Lukasse@usn.no Mobil: 95 77 18 64
- Project leader Horten Kommune: Helene Samnøy, <u>Helene.Samnoy@horten.kommune.no</u>
- Project coordinator Horten Kommune: Kristin Forsberg, <u>Kristin.Forsberg@horten.kommune.no</u>
  and Tønsberg Kommune Nina Schütt <u>Nina.Schutt@tonsberg.kommune.no</u>
- USN dataprotection responsible: Paal Are Solberg, USN, personvernombud@usn.no

If questions to NSD in relation to the approval of the study, contact them at:

NSD – Norwegian Center for Research data AS, email: <a href="mailto:personverntjenester@nsd.no">personverntjenester@nsd.no</a> or phone: 55 58 21 17.

Yours sincerely, Mirjam Lukasse Professor