Patient information leaflet

Belgian Obstetric Surveillance System

sponsored by the College of Mother and Child

Dear Madam, dear Sir,

Your obstetrician gave you this information leaflet, because you recently experienced a serious complication during your pregnancy or childbirth.

Currently this serious complication is under investigation by the Belgian Obstetric Surveillance System (B.OSS). The aim of this B.OSS study is to better understand this complication, which only occurs very rarely. By improving our knowledge, we want to provide better information and better care to future expectant mothers in Belgium.

Therefore, including the details of your specific case in this B.OSS investigation is extremely important. You will find detailed information on the study in this information leaflet. For more information you can further visit the website www.b-oss.be.

Background and purpose of the study

In our Western world, most women have a happy and successful pregnancy without any problems. Only a small number of women will develop a minor complication during pregnancy or childbirth. And even more rarely a woman will suffer a serious complication, that requires an emergency intervention to save her and / or her baby's life.

These serious complications are so rare, making them difficult to investigate. As a result, we have no hard evidence on how frequent they occur, on strategies to prevent them or the best way to manage these complications. By registering all cases of this complication that occurred in a larger region – Belgium in this case - and by analysing the details of these cases, we can improve our knowledge. Better knowledge in turn will improve the information we can provide to our mothers and will further improve our quality of care. The United Kingdom was a pioneer in this area with the United Kingdom Obstetric Surveillance System (UKOSS) started up in 2005 and they demonstrated that UKOSS-studies contributed efficaciously to improved care for pregnant women and their babies.

The Belgian Obstetric Surveillance System (B.OSS) was launched in 2011 with the support of the College of Physicians for Mother and Newborn of the Federal Public Service Public Health.

With the data retrieved by B.OSS, we are able to compare the obstetric care in Belgium with the care in our neighboring countries, hence develop and improve Belgian guidelines.

Which data are collected?

B.OSS investigates serious complications that occur during pregnancy or childbirth and that put the life of the mother and/or the unborn child at risk. These are rare complications that affect less than one out of 2,000 women.

Every serious complication is studied over a given period of about 2 to 4 years.

By sending a monthly email to the B.OSS-investigator in every Belgian maternity unit, we determine how frequent this complication occurs in our country.

Further, we analyse every reported case based on the information provided by the obstetrician. Therefore, the obstetrician needs to complete a questionnaire, requesting the following details:

- general data on age, weight and height, ethnic origin, occupation, smoking status
- medical and surgical history
- relevant family history
- the course of previous pregnancies
- the course of this pregnancy
- the circumstances and the course of the complication
- the management of the complication
- the outcome for the mother
- the outcome for the baby

This questionnaire is filled out based on the data available in the medical notes. All data recorded and provided to B.OSS is **anonymous:** B.OSS does not receive any identifiable information related to your person: no name, no date of birth, no place of residence, no file number.

Ethical considerations

The B.OSS study is approved by the Ethics Committee of the University of Ghent as a central ethics committee (EC UZG 2015/1470, B670201526875). Further, the study is approved by the local ethics committee of the hospital where you were admitted.

Permission

If you agree to include the data of your pregnancy and childbirth in this B.OSS study, you can simply confirm this to your obstetrician. In some hospitals, it is required to sign a consent form, which you can find attached to this leaflet.

Likewise, in case you would prefer your data not to be included in the B.OSS study, you simply notify your wish to your obstetrician. This will not affect in any way your further treatment, the follow-up or the relationship with your obstetrician or other health care providers.

What happens to the data?

The anonymous data are collected in a secured database. At the end of the registration period the data will be processed and analysed by the B.OSS research team. When the data analysis is completed and the relevant results made public, the database will be kept for 20 years on the secured server of the University of Ghent.

Because we can learn more out of international comparisons, B.OSS is part of the International Network of Obstetric Survey System (INOSS). The INOSS network enables the realisation of international studies. It is possible that the B.OSS - data are transferred to another research team within INOSS to contribute to an international comparative study.

Questions?

If you have further questions regarding this study, please don't hesitate to discuss them with your obstetrician.

You can also contact the B.OSS research team via B.OSSVlaanderen@gmail.com or perinatalite@cepip.be.

Many thanks for your time to read this information leaflet and for your contribution to B.OSS.

We wish you all the best and a quick and full recovery.

Warm regards,

The B.OSS research team

Consent form

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I received sufficient information regarding the B.OSS - study from my obstetrician and through the information leaflet. I agree on a voluntary basis to participate in the study of rare and serious complications of pregnancy and allow my obstetrician to provide the relevant details of my medical record to the B.OSS - study.

Date: _ _ / _ _ / 20 _ _

Name:

Signature: