

MEDICAL AND OBSTETRICAL QUESTIONNAIRE (FIRST TRIMESTER)

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1. PURPOSE AND APPLICABILITY

The purpose of this SOP is to describe the procedure of filling in the medical and obstetrical questionnaire (i.e. current and past medical and obstetrical conditions and medication) in the first trimester of pregnancy.

Past medical and obstetrical history and the ongoing medical and obstetrical procedures or conditions may have an important impact on the conclusions obtained from the study and should be considered in the analysis. Therefore, we agreed to register every participant detail on past and current medical and obstetrical history filling written questionnaires. In the same recruitment visit in the first trimester, the questionnaire will record both the past medical and obstetrical history and the current situation. In the second and third trimesters, it will record the current situation. This SOP corresponds to the first trimester.

2. RESPONSIBILITIES AND USERS

1. The BISC steering committee is responsible for final review and approval of this SOP.
2. The BISC obstetricians/gynecologists and nurses are responsible for ensuring that new versions of this SOP are available for the relevant members of the project team and its instructions are properly implemented.
3. This SOP will be principally applied by BISC nurses and obstetricians/gynecologists in the first trimester.
4. If the procedures of this SOP are changed, the change has to be documented according to instructions and it has to be communicated to the SOP coordinator and BISC steering committee. The changed SOP is subject to review and approval by the BISC steering committee.
5. The users of the SOP are obliged to work according to this SOP. All potential deviations in implementing this SOP have to be carefully documented (who changed, when, why, what changes, possible impacts) and reported.

3. DEFINITIONS AND ABBREVIATIONS

SOP: Standard Operating Procedure

Participant: A pregnant woman participating in the BISC study as a study subject

4. EQUIPMENT AND MATERIALS

4.1. Equipment

- Medical consultation
- Computer with internet connection
- Hospital Data Software (SAP) (for digital hospital records)

4.2. Materials

- *Online Clinapsis questionnaire on medical/obstetrical history*
- *Written Hospital Data (for paper hospital records)*
- *Inter-hospital database for clinical history*

5. PROCEDURES

5.1. Obtaining records

Questionnaires on past medical and obstetrical history and current medical and obstetrical conditions will be filled in by BISC nurses at the 12-week pregnancy visit in the agreed consultations, after informed consent has been signed. Questions will be in Catalan and Spanish as we believe they are the most common languages in our cohort.

5.2. Data questionnaires

All questions have been previously agreed and organized by BISC principal investigators as shown in the attachments. Answers will be noted down in the Clinapsis online database by the nurses.

5.3. Hospital records

In case patients are not able to answer completely about previous or ongoing medical or obstetrical conditions, BISC nurses and obstetricians/gyneacologists will search on hospital's past medical data to fill in the correct answer. This data may be found either in paper or digital forms. There may also be the need for online inter-hospital shared database consultation to complete past medical history. Details on year of diagnosis of past illnesses, time of duration and procedures required, as well as medication administration or hospital stay in case of need will be noted down. If the patient has undergone previous surgery, data and hospital stay will also be noted down.

The same database will be also used, if needed, to complete information on previous or ongoing medication (doses and time of exposure).

In addition to BiSC assessments, routine fetal ultrasounds and blood analytics will be also recorded. These procedures are performed with routine hospital protocols.

6. QUALITY CONTROL

Questionnaires will be filled in by trained personnel (nurses). To avoid missing information, the online Clinapsis platform for questionnaires will not appear as completed until all fields are filled in. Moreover, the participants' answers to the questionnaires will be checked periodically against the hospital records to evaluate the consistency of the two records.

7. REFERENCES

Section not applicable

8. ANNEXES

The current version of the questionnaires can be checked in:

- a. Past medical/obstetrics:
bisc(B:)/Questionnaires/BISC QUESTIONNAIRES/1st trimester 12w/2-Medical History MIDWIFE
- b. Current pregnancy medical information:
bisc(B:)/Questionnaires/Routine_Medical_Data_Pregnancy/372_Hosp1visit.pdf
 - Questions asked by nurses:
 - page 1, visit information and symptoms
 - page 7-8: pregnancy perception
 - Questions from hospital records: rest (routine examinations)