

MEDICAL AND OBSTETRICAL QUESTIONNAIRE (SECOND 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 medical and obstetrical conditions and medication) in the second 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 this information in 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 second trimester.

2. RESPONSIBILITIES AND USERS

1. The BISC steering committee is responsible for final review and approval of this SOP.
2. The BISC nurses/obstetricians 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/obstetricians in the second 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

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

4.2. Materials

- *Online Clinapsis questionnaire of Visit 2nd trimester*
- *Written Hospital Data (for paper hospital records)*
- *Inter-hospital database for clinical history*

5. PROCEDURES

5.1. Obtaining records

The questionnaires on ongoing medical and obstetrical conditions will be filled in by BISC nurses/obstetricians at the second trimester (20 weeks of pregnancy). Questions will be available 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 attached form. Answers will be noted down in the Clinapsis online database by the nurses/obstetricians. Because there is no BISC visit at the second trimester, all the information for the second trimester will be collected from hospital records.

5.3. Hospital records

BISC nurses/obstetricians will search on hospital's records to obtain the medical and obstetrical data collected from the routine hospital visit of the second trimester, including clinical examination, fetal ultrasounds and blood analytics (that do not belong to the BISC assessment) and medication data. This data may be found either in paper or digital forms. There may also be the need for online inter-hospital shared database consultation.

6. QUALITY CONTROL

Questionnaires will be done by trained personnel (nurses). To avoid missing information, the online Clinapsis platform for questionnaires will not appear as completed until all fields are filled. 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 questionnaire can be found in:

- a. Current pregnancy medical information:
bisc(B:)/Questionnaires/Routine_Medical_Data_Pregnancy/372_Hosp2visit