APPROPRIATE USE OF CAESAREAN SECTION THROUGH QUALITY DECISION-MAKING BY WOMEN AND PROVIDERS

GRANT AGREEMENT NUMBER 847567 QUALI-DEC

DELIVERABLE 1.2 (WP 1)

Title:	POPD Requirement No. 2
Work package:	1
Due date of deliverable:	June 2020
Actual submission date:	10 June 2020
Start date of project:	1st January 2020
Duration:	60 months
Organisation name:	IRD
Author (s):	Alexandre Dumont
Nature:	Confidential

Project co-funded by the European Commission within the Horizon 2020 Programme (2014-2020)		
Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	**X**

Description :

1) The beneficiary must check if special derogations pertaining to the rights of data subjects or the processing of genetic, biometric and/or health data have been established under the national legislation of the country where the research takes place and submit a declaration of compliance with respective national legal framework(s).

2) The host institution must confirm that it has appointed a Data Protection Officer (DPO) and the contact details of the DPO are made available to all data subjects involved in the research. For host institutions not required to appoint a DPO under the GDPR a detailed data protection policy for the project must be kept on file.

3) The beneficiary must explain how all of the data they intend to process is relevant and limited to the purposes of the research project (in accordance with the 'data minimisation 'principle). This must be submitted as a deliverable.

4) A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants must be submitted as a deliverable.

5) A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing must be submitted as a deliverable.

6) Description of the anonymisation/pseudonymisation techniques that will be implemented must be submitted as a deliverable.

7) In case of further processing of previously collected personal data, an explicit confirmation that the beneficiary has lawful basis for the data processing and that the appropriate technical and organisational measures are in place to safeguard the rights of the data subjects must be submitted as a deliverable.

Specific derogations

Thare are no specific derogations in participating countries (see ethical approvals)

Data Protection Officer (DPO)

The DPO at the host Institution (IRD) is Pierre Bos
E-mail: pierre.bos@ird.fr
Adress: 44 bd de Dunkerque, CS 90009 13572 Marseille Cedex 02, France
Tél. 04 91 99 95 08
Contact details of the DPO are made available in each informed consent forms

Data minimization principle

The specific research objectives of QUALI-DEC project are : 1) tailoring the QUALI-DEC strategy to each study context (objective 1), evaluating the strategy at the health system and provider levels (objective 2), evaluating the strategy at the woman level (objective 3),

assessing the effectiveness of the strategy on caesarean practice at the hospital level (objective 4), and enhancing the utilisation of project findings (objective 5)

In accordance with the GDPR's "data minimization" principle, only data directly relevant to the stated aims of the QUALI-DEC project will be collected, including information on practices relating to delivery care in study hospitals (relevant and limited to the purposes of objective 4), information on women and providers' decision-making process regarding mode of delivery (objectives 2 and 3), out-of-pocket expenditure (objective 4), institutional and societal context affecting decision-making and practices (objectives 1). Health data including women's reproductive and demographic information, pregnancy risk factors and care during delivery are necessary to collect in order to understand the appropriateness of the decision to perform a caesarean (objective 2). Data collected will also include information on socio-economic status and ethnicity in order to assess the extent of inequalities in care received during childbirth and the impact of the intervention on these inequalities (objective 3).

Organization to safeguard the rights and freedoms of the data subjects/research participants

As presented in each Informed Consent Template (see D1.1), the participation of subject is voluntary, the information collected will remain confidential and each participant has the right to refuse or withdraw. Here are excerpts from the Informed consent tempate that guarantee women's rights and freedoms, for example :

Voluntary Participation

« Your participation in this research is entirely voluntary. It is your choice whether to participate or not. If you choose not to participate, it will have no bearing on the type of care you receive throughout your pregnancy and childbirth. You may change your mind later and stop participating even if you agreed earlier."

Procedures

"I am asking you to help us learn more about care during pregnancy and childbirth, including caesarean section. I am inviting you to take part in this research project. If you accept, I will ask you to participate in an interview with myself. During the interview, I will sit down with you in a private, comfortable place. If you do not wish to answer any of the questions during the interview, you may say so and I will move on to the next question. No one else but me will be present, unless you would like someone else to be there. The information recorded is confidential, and no one else except me will have access to the information documented during your interview. The entire interview will be tape-recorded, but no-one will be identified by name on the tape. The tape will be stored on my computer. The information recorded is confidential, and no one else except me will have access to the tapes. The tapes will be destroyed after four weeks."

Confidentiality

« The research being done may draw attention from other people in your local community and if you participate you may be asked questions by other people in the community. We will not be sharing information about you to anyone outside of the research team. The information that we collect from this research project will be kept private. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone. »

Sharing the Results

« Nothing that you tell us today will be shared with anybody outside the research team, and nothing will be attributed to you by name. The knowledge that we get from this research will be shared with you and your community before it is made widely available to the public. There will also be meetings in the community and these will be announced. Following the meetings, we will publish the results so that other interested people may learn from the research. »

Right to Refuse or Withdraw

« You do not have to take part in this research if you do not wish to do so, and choosing to participate will not affect the care you receive during post-partum in any way. You may stop participating in the interview at any time that you wish without your care being affected. I will give you an opportunity at the end of the interview to review your remarks, and you can ask to modify or remove portions of those, if you do not agree with my notes or if I did not understand you correctly. »

Security measures to prevent unauthorised access to personal data

Specific provisions are in place for quantitative and qualitative data security. Data will be safely stored in certified repositories for long term preservation and curation.

Provisions in place for data security

Quantitative data

Quantitative data collected from participants and study hospitals will be entered onto a digital database in the study countries by the study coordinator in each participating hospital, and uploaded to REDCap (https://www.project-REDCap.org/), a secure online application hosted in Karolinska Institute (KI) via a secure weblink, accessible only to members of the research team. REDCap allows for different users to have different access privileges according to their particular role and site, which will ensure standards for safety of data transfer are respected. Participating hospitals will be able to view other participating hospitals' monthly statistics on the REDCap online platform, however no individual-level information on women will be accessible to study team members from other hospitals.

Security measures will be implemented to prevent unauthorised access to personal data or computers used for analysis, including storing study computers requiring "strong" passwords changed every 6 months, requiring password entry after a period of inactivity, and a limited number of study team members having access to identifiable personal data.

Qualitative data

Throughout the project, all other data collected and generated will be stored on a secure, password-protected server accessible only to the study team, restricted according to work package.

We will use Sharedocs platform to store and share data during the project between members. ShareDocs is a French collaborative workspace developed by the Very Large Research Infrastructure Huma-Num for the scientific community (https://www.huma-num.fr/about-us). It allows to store research data in a secure space, to synchronize them and to exchange them easily with its research team. ShareDocs is accessible from a web interface and hosted by Huma-Num on its own file server (NAS) and in cooperation with CNRS (French National Center for Scientific Reasearch).

Personal data on study participants, including provider surveys and in-depth interview transcripts, will be stored in accordance with EU-GDPR principles. The study protocol, documentation, data and all other information generated will be held in strict confidence. No information concerning the study or identifiable data will be released to any unauthorised third party, without prior written approval of the Sponsor.

Certified repositories for long term preservation and curation

Data deposited in the Zenodo repository, stored in the CERN data centre, is safely stored for long term preservation and curation. Data files and metadata are stored in multiple independent online replicas.

Description of the anonymisation/pseudonymisation techniques

Monthly hospital summary statistics for Robson classification will be directly entered into RedCap by each hospital every month. Data collectors will directly capture aggregated data, thus no patient identifying variables will be available. Each hospital will only be able to compare itself with anonymized facilities in the four study countries.

Questionnaire to post-partum women will be collected in hard copy forms, with a study participant number determined by the investigator. We will implement an auxiliary form called SNL (Subject Form Register - used in several previous WHO studies) from which data collectors can obtain the corresponding consecutive number per hospital to be used as women identifier variable (key variable). This auxiliary form will also allow the Data manager to link the questionnaires to post-partum women with medical records (in case a data discrepancy requires review) and to contact the participant (if needed).

This auxiliary form will not be entered in RedCap or any electronic system to prevent violation of anonymity. The medical record number and the contact information will be used carefully. This auxiliary form will be confidential and not to be taken from site.

Concerning qualitative data (in-depth interviews with women, companions and providers), an anonymization process will be done during transcription to ensure that identifiable variables are not available during data sharing. Directly identifiable variables include - but

are not limited to - national ID number, name, phone number, ZIP-code, e-mail address, address, geographical coordinates (at a resolution that risks identification).

Processing of previously collected data

Processing of previously collected data will consist in analysis of participating hospital records for monthly hospital statistics, and will be conducted in accordance with GDPR principles and laws in the study countries. Permission to use the hospital data sets will be obtained from hospital managers. No identifying information on women will be collected for the aggregate monthly hospital statistics; personal data from hospital records on women recruited for the post-partum survey will be pseudonymized in the same way as newly collected data (as described above).