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

GRANT AGREEMENT NUMBER 847567 QUALI-DEC

DELIVERABLE D2.3 (WP 2)

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Dissemination Level		
PU	Public	**X**
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)	

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Acronym list

C-sections : Caesarean section

CC BY 4.0 : Creative Commons Attribution 4.0

CDM : Country Data Manager

CERN : European Organization for Nuclear Research

CNRS : French National Center for Scientific Reasearch

DAT : Decision-Analysis Tool

DMCI : Dublin Core Metadata Initiative

DOI : Digital Object Identifiers

DPO : Data Protection Officer

EU-GDPR : European Union General Data Protection Regulation

GCP : Good Clinical Practice

ICH : International Conference on Harmonization

IDI : In-Depth Interviews

IRD : French National Research Institute for Sustainable Development

KI : Karolinska Institute

NIDA : National Drug Abuse Treatment

PDM : Principal Data Manager

REDCap : Research Electronic Data Capture

SOP : Standard Operating Procedures

TGCS : Ten Groups Classification System

Introduction

The overall aim of the project is to design and evaluate a strategy, named Quality Decision-Making by women and clinicians (QUALI-DEC), to implement non-clinical interventions targeted simultaneously at clinicians, women and health organisations to reduce unnecessary C-sections in Argentina, Burkina Faso, Thailand and Vietnam. The QUALI-DEC strategy is designed to combine four key active ingredients: (1) opinion leaders to implement evidence-based clinical guidelines; (2) caesarean audits and feedback to help providers identify potentially avoidable C-sections, (3) a Decision-Analysis Tool (DAT) to help women make an informed decision on mode of delivery; and (4) implementation of WHO recommendations on companionship during labour to support women during vaginal birth.

A pragmatic hybrid effectiveness-implementation mixed methods study design will be used, which focuses on testing the implementation strategy while gathering data on the impact the intervention has on relevant clinical outcomes. The study consists of a 6 months pre-intervention or baseline period to assess the context and tailor the design of the four components of the QUALI-DEC strategy (formative research), a 2-year intervention period to assess its implementation and scalability, and a two 2.5-year post-intervention period, when the relevant outcomes will be assessed and the results will be exploited. We will use a formative research design to assess the context in baseline period. Cross-section surveys among post-partum women will be carried out at two time points: before the intervention period and after the intervention period. These surveys will allow us to assess changes in maternal and perinatal outcomes, birth experience and costs. We will use a qualitative approach during and at the end of the intervention for scalability and process evaluation. A longitudinal study will assess changes in caesarean section rates at hospital level, using the Robson classification.

This document is the first version of the QUALI-DEC data management plan (DMP) and constitutes the deliverable 2.3. of the project. The purpose of this DMP is to describe how research data during the QUALI-DEC lifetime will be collected/generated, processed, disseminated/made accessible, protected and stored.

The QUALI-DEC DMP follows the structure of the Horizon 2020 DMP template. Each part contains a set of questions (provided in the H2020 template) and the proposed answers. These responses will be clarified/updated throughout the project in case of significant changes during the periodic evaluation of the project.

The QUALI-DEC DMP describes:

- the type of data that will be collected, processed, or gathered
- the processing of research data during and after the project
- what methodologies and standards will be applied
- how the data will be made FAIR (Findable, Accessible, Interoperable and Re-usable)
- what resources (financial and human) will be required to manage QUALI-DEC data
- how the data will be stored and preserved during and after the project
- how data will be shared and stored safely
- ethical aspects related to data

1. Data summary

1.1. What is the purpose of the data collection/generation and its relation to the objectives of the project?

Data collected under the QUALI-DEC project will serve to address its objectives of tailoring the QUALI-DEC strategy to each study context (WP3), assessing the effectiveness of the strategy on caesarean practice at the hospital level (WP4), evaluating the strategy at the woman level (WP5), evaluating the strategy at the health system and provider levels (WP6), and enhancing the utilisation of project findings (WP7). Table 1 details for each data what is the associated objective.

1.2. What types and formats of data will the project generate/collect?

Data collection and data generated in this project can be categorised into six categories (see table 1 for details):

- Aggregated quantitative data
- Individual-level quantitative data
- Qualitative data
- Existing documents
- Additional developped documents
- Dissemination materials

REDCap (Research Electronic Data Capture), a secure web application for building and managing online surveys and databases (see 4.1.), will be used to collect aggregate and individual quantitative data (https://www.project-REDCap.org/). These numeric data will be available in Stata. DTA format as well as .CSV format, for importing into a wide range of statistical software. Qualitative data and the diverse documents will stored in open readable formats (plain text, .PDF or .DOCX) on the ShareDocs platform (see 4.1.). Further, additional developed documents could be available in format such as application .PPTX, AVI, or MP4**.**

1.3. Will you re-use any existing data and how?

Every month, summary statistics will be collected from hospitals birth registers by a data collector in each hospital for the Robson Ten Groups Classification System (TGCS). Only aggregated data will be entered into RedCap. Researchers will use existing policy documents at a national and local level to gain a better understanding of the clinical context in which providers practice in different settings. Policy makers and hospital directors will use existing documents and clinical guidelines to compare guidelines for the management of work-related and pre-work caesarean sections, and adapt their own guidelines. No other existing data will be used in the QUALI-DEC project.

1.4. What is the origin of the data?

Quantitative and qualitative data will be collected in the 32 hospitals of the project (see table 1). The quantitative data are composed of monthly hospital summary statistics, questionnaires to post partum women and caesarean audit and feedback reports. Monthly hospital summary statistics and audit reports will be entered onto the REDCap application in the study countries by the study coordinator in each participating hospital. Postpartum questionnaire on women's surveys on birth experience and out-of-pocket costs will be collected among women at the hospital by the research team of each country and entered onto the REDCap application.

The qualitative data include providers and women and partners in-depth interviews (IDI) will be realised in hospitals by research team and retranscription will be done using Microsoft Word

software. Retranscriptions will be stored on Sharedocs to be shared with QUALI-DEC researchers and analysed in a collaborative way.

Existing documents such as clinical guidelines and protocols on caesarean sections and policy documents come from international institution or national policy available in each country. Additional documents and dissemination material (videos, policy briefs, scientific reports and articles) will be developed following analysis of the quantitative and qualitative data. All these materials will be available on QUALI-DEC website to be accessible and re-used by a large public.

See table 1 for detailed information on each data and material.

1.5. What is the expected size of the data? (if known)

The shared repository, Zenodo (see 2.2.5.), that we will use to compil data will be hosted at the CERN (European Organization for Nuclear Research) data center. Some data may also be hosted at any partner institution in the consortium. The data repository size is estimated at 10 TB, which includes all raw data (database and in-depth interview retranscription) as well as processed and structured data (documents, data analysis, results).

1.6. To whom might it be useful ('data utility')?

A key proposal of our plan is to use an online platform accessible (REDCap) to study liaisons in each hospital to contribute their data. Ease of data entry will be optimised by providing each hospital liaison with a unique identifier linked to hospital information, and by creating an online form for entering a limited number of fields (number of vaginal and caesarean deliveries across the Robson TGCS). Once entered, the data will be used to automatically generate a maternity dashboard showing the distribution of women across Robson groups, the caesarean rate in each group and the contribution of each group to the overall caesarean rate. These indicators will be added to month-by-month graphs of process and outcome indicators for the hospital, and will enable convenient tracking of trends over time and comparison with anonymised facilities in the four study countries. Pospartum questionnaire to women data will collected on paper forms will be entered into REDCap, as well as audit report.

A free online comparator software of monthly hospital summary statistics for Robson classification will be developped. It will be accessible on the QUALI-DEC website to people outside of the study team during and after the end of the project (for at least 5 years), with interactive graphs allowing for filtering according to geographic area, time or facility type. Health facility managers of hospitals not participating to QUALI-DEC project will further be able to voluntarily enter their data from their facilities into the comparator sofware. They will re-use aggregate quantitative data from QUALI-DEC hospital to compare their own hospital-based statistics to QUALI-DEC's results. The interactive software will calculate overall caesarean rate, distribution of women and caesarean rate across Robson groups, and compare the statistics to those collected in QUALI-DEC hospitals in the same country. Health facility managers and policy-makers will be able to easily compare their facilities to others in the same geographical area or facility level

Quantitative data from cross-sectional post-partum surveys will be used by QUALI-DEC researchers to assess safety and effectiveness outcomes of the QUALI-DEC intervention. Researchers outside the study team will be able to re-use anonymised, cleaned individual-level datasets to conduct new analyses on risk factors for C-section, maternal and perinatal morbidity, maternal, unstatisfatory birth experience, out-of-pocket cost. Survey instruments will also be made available.

We also aim to create an online repository of clinical guidelines relating to caesarean section decision-making (including protocols, algorithms and decision analysis tool) at country and facility level, for both participating and non-participating countries and facilities. There are no standardised,

agreed upon clinical guidelines for decision-making on caesarean sections before or during labour, and existing protocols have not been collated. Policy-makers and facility managers outside of the project will be able to compare protocols across different settings and view the Decision-Analysis Tool (DAT) for women adapted for each study country, stimulating innovation and cross-fertilisation for improving care at birth.

New deliverables will also be generated during the project, including newly developed clinical guidelines, training materials, films and animations, as well as dissemination outputs such as policy briefs and peer-reviewed articles. These new materials will be re-use by a large public including researchers and policy makers and will be available on QUALI-DEC website, manage by a web designer. The materials will be available in English, Spanish and French.

Curated datasets and documents will come out of this project and will be deposited at the project website (www.qualidec.com) and an open access data repository, Zenodo (see 2.2.5.).

Potential users and uses of each type of data are summarised in the table 1 below.

Table 1. Description of data collected and generated in QUALI-DEC project and potential users and uses

	Type of data collected or generated [WP]	Description	Data collection and generation				Potential users and uses	Potential for exploitation
			Source/ Origin	When?	Who?	Used tools and formats		
Aggregated quantitative data	**Monthly hospital summary statistics** including Ten Groups Classification System (TGCS) (per facility/month) [WP4]	Proportion of vaginal and caesarean deliveries across the 10 Robson groups	Hospital registers and medical records	Every month from month 1 to month 60	Data collectors in each hospital	Data will be collected in each hospital using REDCap	**Health facility managers** can compare their monthly statistics to other facilities as a support for evaluating and changing their practice, using interactive graph displays to restrict according to facility characteristics and location. They will also be able to contribute their monthly summary statistics using the online contribution form. **Researchers** can use monthly statistics to conduct novel analyses. **Policy-makers** can use data to better understand facilities in their geographic area.	≈ 1500 health institutions identified during the WHO global survey on maternal and perinatal health in Africa, Latin America and Asia

Individual-level quantitative data	**Questionnaires to post-partum women** [WP5]	Cross-section surveys among post-partum women will be carried out to assess maternal and perinatal outcomes, birth experience and costs.	Medical records and interviews	At baseline and at the end of the intervention period (month 6 and month 30)	Local research team (two data collectors per country)	Interview responses will be recorded on paper by the data collector and entered into REDCap	**Researchers** will be able to use anonymised, cleaned individual-level datasets to conduct novel analyses on risk factors for fear of childbirth, decision conflict on mode of delivery and postnatal satisfaction. Survey instruments will also be made available.	
	Caesarean audits and feedback [WP4 and WP6]	Indications of C-sections and caesarean practice among lower-risk women (Robson groups 1-4) are audited by a local committee, with timely feedback to all health-care professionals.	Medical records	During the 2-year intervention period (month 7 to month 30)	Multidisciplinary local audit committees (doctors, midwifes and/or nurses and representative of the hospital administration)	Information generated during caesarean audit and feedback will be entered into REDCap	**Health facility managers and policy-makers** will be able to examine individual data on caesareans reviewed during the audits to gain a better understanding of which women receive unnecessary caesareans and the contextual factors at play.	≈ 1500 health institutions
Qualitative data	**IDIs with health professionals** [WP3 and WP6]	Semi-structured interviews guide to investigate aspects of professional preferences, views	Face-to-face interviews with health professionals	At baseline and at the end of the intervention period (month 6	Local research team (one data collector per country)	Interview responses will be recorded on paper by the researcher	**Researchers** will be able to use anonymised interview and focus group transcripts to	Researchers at academic and non-governmental

		on C-sections and vaginal births, and views on the role of women in the decision-making process		and month 30)		and qualitative analysis Software (such as Nvivo) will be used for the thematic analysis. Data will be stored in ShareDocs platform	conduct novel analyses on women and providers' decision-making relating to caesarean sections.	institutions
	IDIs with women and companions during post-partum period [WP3 and WP5]	semi-structured interviews guide covering the following topics: perceptions, preferences, and decision-making processes for mode of childbirth; perceived risks and benefits with different modes of childbirth; values and needs surrounding the childbirth period; fears related to pregnancy and childbirth; and preferences and perceptions about labour companionship	Face-to-face interviews with women	At baseline and at the end of the intervention period (month 6 and month 30)	Local research team (one data collector per country)	Interview responses will be recorded on paper by the researcher qualitative analysis Software (such as Nvivo) will be used for the thematic analysis. Data will be stored in ShareDocs platform		
Existing documents	**Clinical guidelines and protocols on caesarean sections**	Clinical guidelines and protocols on caesarean sections available at a national or local	National or local authorities	All along the project	Local research team (one data collector per country)	Documents will be available in plain text, .PDF or .docx	**Policy-makers and hospital managers** will be able to use the document repository to compare guidelines	≈ 1500 health institutions

	[WP4 and WP6]	level.					for managed of labour and pre-labour caesareans, and tailor their own guidelines.	
	Other relevant policy documents [WP6 and WP7]	National or local policy documents	National or local authorities	All along the project	Local research team	Documents available in plain text, .PDF or .docx	**Researchers** can use policy documents to gain a better understanding of the clinical context in which providers practice in different settings.	
Additional developed documents	**Decision-analysis tool (DAT)** to support women in decisions on mode of delivery (tailored to each study country) [WP5 and WP7]	A meaningful dialogue between clinicians and women on preferences, options, concerns, risks and benefits of planned C-section vs. vaginal delivery leads to an informed and more satisfactory decision for both.	Developed by the research team in each country after formative research	During the 2-year intervention period (month 7 to month 30)	Developed by the research team of the project	Booklet and Apps for smartphone	**Civil society organisations** (including those concerned with respectful maternity care) will be able to use and adapt the decision-analysis tool, and training and clinical guidelines for information and advocacy purposes.	
	Training materials [WP7]	PPT presentations, brainstorming exercise, role playing game, card game	Developed by the research team in each country after formative research	During the 5-days training before, before implementation of intervention (month 6)	Developed by the research team of the project	Materials will be available in plain text, .PDF, .docx or pptx. And stored in ShareDocs platform	**Regulatory bodies and professional medical associations** can use clinical guidelines and training materials for skills and education	≈ 1500 health institutions

							purposes. **Health facility managers** will be able to review clinical guidelines and tailor guidelines in their facilities, as required.	
	Films and animations for families, communities and health facilities [WP7]	Films and animations to inform about factors contributing to unnecessary caesareans and intervention to reduce them	Developed by the research team in each country based on the results of the formative research, and during post-intervention period	During the 5-days training before, before implementation of intervention (month 6) and during the post-intervention period (month 31 to 60)	Developed by the research team of the project with the help of a web designer	Material will be available in mp4 and directly viewable on the QUALI-DEC website	**Civil society organisations, members of the public and health facility managers** will be able to view films and animations describing the factors contributing to unnecessary caesareans and what steps can be taken to reduce these.	
Dissemination materials	**Policy briefs** [WP7]	Policy brief will include a short text, written in clear language (French, English and Spanish) and displayed in an attractive format to summarize the results of the project and express operational (actionable) recommendations intended for non-specialist	Developed by the overall research team and in each country based on QUALI-DEC project's results	All along the project (month 1 to 60)	Developed by the research team of the project with the help of a knowledge broker	Policy brief available in plain text, .PDF, .DOCX and on the QUALI-DEC website	**Policy-makers and programme managers** will be able to access policy briefs on the online repository, with clearly outlined recommendations for practice.	≈ 1500 health institutions

		audiences, with the objective of their being used in professional practices or for policy decision-making						
	Reports [WP7]	Reports, including the reports sent to the EU as deliverables, as well as national reports presenting the results of QUALI-DEC			Developed by the research team of the project	Reports available in plain text, .PDF, or docx and on the QUALI-DEC website	**Policy-makers and programme managers** will be able to access detailed study findings in reports for each work package.	≈ 1500 health institutions
	Peer-reviewed articles [WP7]	Peer-reviewed articles to publish the project's results to maximize the scientific impact of QUALI-DEC			Developed by the research team of the project	Peer-reviewed articles available in plain text, .PDF, or docx and on the QUALI-DEC website	Open access peer-reviewed publications from this project will be freely accessible online, including to **researchers and policy-makers.**	Researchers and policy-makers
	Conference presentations [WP7]	QUALI-DEC results and the intervention process will be presented at international and national conferences on maternal health, public health and social sciences			Developed by the research team of the project	Conference presentations available in plain text, .PDF, .docx or pptx and on the QUALI-DEC website	**Policy-makers and programme managers** will be able to view conference presentations and posters summarising study findings.	Researchers and policy-makers

2. FAIR data

Table 2 summarizes how, when, where and by whom the data collected and generated will be made reusable and accessible and how the data will be made findable and interoperable.

Table 2. Summarize of how QUALI-DEC data will be made FAIR.

	Type of data collected or generated **[WP]**	Re-use and accessibility of data				Make data findable and interoperable
		How?	When?	Where?	Who?	
Aggregated quantitative data	Monthly hospital summary statistics including Ten Groups Classification System (TGCS) and maternal and perinatal outcomes (per facility/month) [WP4]	Data will be cleaned and made openly available after anonymisation alongside meta-data Data will be licensed for reuse under a Creative Commons Attribution 4.0 (CC BY 4.0)	At the end of the project	Available in Zenodo repository	The principal data manager will put the data on Zenodo	Data produced in this project will be a Digital Object Identifiers (DOI) and made discoverable through standardised search keywords Metadata, based on DMCI (Dublin Core Metadata Initiative), will include information on how the data were collected, a data dictionary with definitions and categorisations used for each variable in the dataset, and links to relevant literature The datasets will be available in standardised formats: txt, csv, xml. Others documents will be readable in MS Office, pdf viewer or image viewer
Individual-level quantitative data	Questionnaires to post-partum women [WP5]	Data will be cleaned and made openly available after anonymisation alongside meta-data Data will be licensed for reuse under a Creative Commons Attribution 4.0 (CC BY 4.0)	At the end of the project	Available in Zenodo repository	The principal data manager will put the data on Zenodo	
	Caesarean audits and feedback [WP4 and WP6]	Data will be cleaned and made openly available after anonymisation alongside meta-data Data will be licensed for reuse under a Creative Commons Attribution 4.0 (CC BY 4.0)	At the end of the project	Available in Zenodo repository repository	The principal data manager will put the data on Zenodo	
Qualitative	IDIs with health professionals	Qualitative interview transcripts in original	At the end of the project	Available in Zenodo repository	Access upon request to the	

	[WP3 and WP6] IDIs with women and companions during post-partum period [WP3 and WP5]	langage and first transalation into English of the first thematic analysis will be made available for QUALI-DEC members after removal of any identifying information Only IDI thematic analysis will be made available to the public Data will be licensed for reuse under a Creative Commons Attribution 4.0 (CC BY 4.0)			study team and approval by the data access committee for QUALI-DEC members	
Additional developed documents	Decision-analysis tool (DAT) to support women in decisions on mode of delivery (tailored to each study country) [WP5 and WP7]	Users will access the DAT application after downloading it	During the 2-year intervention period and the post-intervention period and at the end of the project	Available in Zenodo repository and on the DAT application (on iOS or android)	The principal data manager will put the data on Zenodo	
	Training materials [WP7]	These documents will be available to the public without restriction	During the 2-year intervention period and the post-intervention period and at the end of the project	Available in Zenodo repository repository and to the public on the QUALI-DEC web site (www.qualidec.com)	The principal data manager will put the data on Zenodo and members of the coordination team will input documents to the website	
	Films and animations for families, communities and health facilities [WP7]	These documents will be available to the public without restriction	During the 2-year intervention period and the post-intervention period and at the end of the project	Available in Zenodo repository repository and to the public on the QUALI-DEC web site (www.qualidec.com)		

Dissemination materials	Policy briefs [WP7]	These documents will be available to the public without restriction	During the 2-year intervention period and the post-intervention period and at the end of the project	Available in Zenodo repository repository and to the public on the QUALI-DEC web site (www.qualidec.com)	The principapl data manager will put the data on Zenodo and members of the coordination team will input documents to the website	
	Reports [WP7]					
	Peer-reviewed articles [WP7]					
	Conference presentations [WP7]]					

2.1. Making data findable, including provisions for metadata

2.1.1. Are the data produced and/or used in the project discoverable with metadata, identifiable and locatable by means of a standard identification mechanism (e.g. persistent and unique identifiers such as Digital Object Identifiers)?

Open QUALIDEC results and data that are deposited in the open access repository (Zenodo, see 2.2.5.) will be assigned a Digital Object Identifier (DOI) automatically and will benefit also from Zenodo's DOI versioning support.

Scientific publications will be assigned a unique identifier like DOI, Publisher Item Identifier (PII), International Standard Serial Number (ISSN), etc. depends on the open access chosen by the editors and thus also on the respective scientific publisher and the chosen research repository.

The results of QUALIDEC (reports, policy brief, scientific articles, film...) will also be available on the QUALI-DEC website (www.qualidec.com) in order to be widely shared with the public and policy makers.

2.1.2. What naming conventions do you follow?

Naming convention will be define as following (each elements are separated by an underscore: _) :

- Indication if a metadata (META)
- Dataset name (short)
- Date of the last upload into the Repository in DDMMYYYY format.

Ex : Name_26032020 ; META_Name_01042020

2.1.3. Will search keywords be provided that optimize possibilities for re-use?

All QUALI-DEC data deposited in a Zenodo repository will provide search keywords together with their metadata. Data produced in this project will be made discoverable through standardised search keywords (including caesarean section, Robson classification, audit, companionship, among others). These keywords will be defined by the data producer in agreement with the consortium.

2.1.4. Do you provide clear version numbers?

All open data, publications and metadata will be deposited in the Zenodo repository, allowing to obtain for each one a DOI to make them easily and uniquely citable.

2.1.5. What metadata will be created? In case metadata standards do not exist in your discipline, please outline what type of metadata will be created and how.

Metadata, based on DMCI (Dublin Core Metadata Initiative), will include information on how the data were collected, a data dictionary with definitions and categorisations used for each variable in the dataset, and links to relevant literature. The full set of Dublin Core metadata terms can be found on the DMCI website (https://www.dublincore.org/specifications/dublin-core/dcmi-terms/). The repository we will use, Zenodo, allows to export directly metadata in Dublin Core format.

2.2. Making data openly accessible

2.2.1. Which data produced and/or used in the project will be made openly available as the default? If certain datasets cannot be shared (or need to be shared under restrictions), explain why, clearly separating legal and contractual reasons from voluntary restrictions. Note that in multi-beneficiary projects it is also possible for specific beneficiaries to keep their data closed if relevant provisions are made in the consortium agreement and are in line with the reasons for opting out.

Quantitative datasets will be cleaned and made openly available in an open access online repository (Zenodo, see 2.2.5.) after anonymisation alongside meta-data, to facilitate data sharing and re-use.

Qualitative interview transcripts will be made available for QUALI-DEC members upon request to the study team and approval by the data access committee (see 2.2.8.), after removal of any identifying information (only country, facility type and provider cadre will be maintained given the small number of participating facilities). Due to the small number of health facilities participating in the study in each country, we prefer to use voluntary restrictions on access to qualitative data on the condition of legitimate research purposes, in order to protect anonymity of interview and focus group participants. Upon approval by the data access committee, researchers will have access to the transcripts in the original language in Word .doc format and to the translation into English of the first thematic analysis of IDIs. Only the translation into English of the first thematic analysis of IDIs will be made openly available to the public on the Zenodo repository at the end of the project. The purpose is to avoid misinterpretation due to out-of-context analysis and possible identification of interviewees despite anonymisation of the data. Moreover, if IDI transcripts are available to the public in a repository, the participants should be inform about this before starting the data collection. This will likely directly negatively impact their willingness to participate and their selection of the examples of experiences and perceptions that they will discuss in the interviews.

Results from quantitative and qualitative data, as well as documents developed during the project (DAT, training…) will be available to the public on the QUALI-DEC web site (www.qualidec.com).

2.2.2. How will the data be made accessible (e.g. by deposition in a repository)?

Data will be made accessible by deposition in the Zenodo repository. Further, results and documents developed during the project (DAT, training materials, publications, films and animations, policy brief…) will be available to the public on the qualidec web site (www.qualidec.com).

2.2.3. What methods or software tools are needed to access the data?

The following software are needed to access the data: Microsoft office (or OpenOffice), Adobe PDF Reader, image viewer.

We will develop a comparator software that will be freely accessible on QUALI-DEC website to allow other resarchers or healthcare providers or managers external to QUALI-DEC to compare their own hospital-based statistics on caesarean sections to the QUALI-DEC hospitals results.

In case users want to access the DAT application, they must first download it (on iOS or android). If necessary, to interpret data, clinical guidelines and protocols on caesarean sections will be available on the QUALI-DEC website and on the Zenodo repository.

2.2.4. Is documentation about the software needed to access the data included? Is it possible to include the relevant software (e.g. in open source code)?

No additional documentation is needed for the software. For the application or software developed in the project, the open source code will be deposited in the repository (e.g. Zenodo).

2.2.5. Where will the data and associated metadata, documentation and code be deposited? Preference should be given to certified repositories which support open access where possible.

The data produced and published during QUALI-DEC project will be accessible as every datasets in Zenodo (https://www.zenodo.org/), a general-purpose open-access repository developed under the European OpenAIRE program and operated by CERN. Zenodo will allow the deposit of datasets, reports and any other digital artefacts related to research. For each repository, a persistent DOI will be created to easily cite the stored items. Metadata of each record is indexed and searchable directly in Zenodo's search engine immediately after publishing.

2.2.6. Have you explored appropriate arrangements with the identified repository?

Yes, the principal data manager has already created a user account on Zenodo repository (https://www.zenodo.org/). The repository is compatible with the medata format we will use (Dublin Core).

2.2.7. If there are restrictions on use, how will access be provided?

All data will be made available at the latest three years after the end of the QUALI-DEC project, but there will be different access levels. Anonymized data will be made openly available. Users will be required to acknowledge the consortium and the source of the data in any resulting publications. Sensitive data will be available only after approval by the data access committe, according to data protection law of each country.

2.2.8. Is there a need for a data access committee?

This project will have a data access committee in order to allow access to sensitve qualitative data on a case-by-case basis. This committee will be composed of the Principal Data Manager, Principal Investigators and Country Data Managers from each of the four countries. The data access committee will follow Standard Operating Procedures (SOP) describing the conditions and procedures for allowing access to sensitive qualitative data. These procedures will be deposited on Zenodo.

2.2.8. Are there well described conditions for access (i.e. a machine readable license)?

There is no specific condition for access to quantitative data. A SOP will be available on Zenodo and will describe the conditions and procedures for accessing sensitive qualitative data.

2.2.9. How will the identity of the person accessing the data be ascertained?

Users need to register to access the Zenodo deposit in order to use data.

2.3. Making data interoperable

2.3.1. Are the data produced in the project interoperable, that is allowing data exchange and re-use between researchers, institutions, organisations, countries, etc. (i.e. adhering to standards for formats, as much as possible compliant with available (open) software applications, and in particular facilitating re-combinations with different datasets from different origins)?

Yes, the data produced in the project will be interoperable. The datasets will be available in standardised formats: txt, csv, xml. Others documents will be readable in MS Office, pdf viewer or image viewer.

2.3.2. What data and metadata vocabularies, standards or methodologies will you follow to make your data interoperable?

The datasets will be interoperable following Dublin core metadata and standard vocabularies. Any specific vocabularies needed to analyze and use the data will be available in the guidelines and protocol produced during the project. These document will be available on the QUALI-DEC website and on the Zenodo repository.

2.3.3. Will you be using standard vocabularies for all data types present in your data set, to allow inter-disciplinary interoperability?

We will use standard data formats (e.g., Stata .DTA format and Excel .XLSX format for quantitative data and plain text, .PDF or .DOCX for qualitative data and diverse documents) and standard metadata (Dublin core metadata). This will allow to improve interoperability with external users and reusability of the data.

2.3.4. In case itis unavoidable that you use uncommon or generate project specific ontologies or vocabularies, will you provide mappings to more commonly used ontologies?

We do not plan to use uncommon or project-specific ontologies or vocabularies. But if we do, we will provide mapping to more common ontologies.

2.4. Increase data re-use (through clarifying licenses)

2.4.1. How will the data be licensed to permit the widest re-use possible?

Quantitative and qualitative data will be licensed for reuse under a Creative Commons Attribution 4.0 (CC BY 4.0) (https://creativecommons.org/). This license will allow others to distribute, remix, adapt and develop our work, even commercially, as long as they give us credit for the original creation. This license is recommended for maximum distribution and use of the licensed material. In addition, users will be required to acknowledge the consortium and the source of the data in all subsequent publications.

2.4.2. When will the data be made available for re-use? If an embargo is sought to give time to publish or seek patents, specify why and how long this will apply, bearing in mind that research data should be made available as soon as possible.

The data used in scientific publications, posters and oral communications will be made available for re-use as soon as they are published. Data will be made openly accessible on the online repository at the latest one year after the end of the QUALI-DEC project, to allow for publication of the findings.

2.4.3. Are the data produced and/or used in the project useable by third parties, in particular after the end of the project? If the re-use of some data is restricted, explain why.

Data are intended to be re-used by third parties after the end of the project; all quantitative data will be openly accessible. For qualitative data, only translation into English of the first thematic analysis of IDIs will be made accessible.

2.4.4. How long is it intended that the data remains re-usable?

The data will remain reusable for at least 10 years after the end of the project.

2.4.5. Are data quality assurance processes described?

Yes, data quality assurance processes are described in the manual of operation documents (Appendix 7 : Monitoring visit checklist). This manual will be deposit on the Zenodo reposit.

3. Allocation of resources

3.1. What are the costs for making data FAIR in your project?

There are no anticipated costs to make the results of the QUALIDEC FAIR project. No costs are foreseen for storing the open results in Zenodo since this deposit is free.

If additional costs are envisaged, they will be described in future versions of the DMP.

3.2. How will these be covered? Note that costs related to open access to research data are eligible as part of the Horizon 2020 grant (if compliant with the Grant Agreement conditions).

Any unforeseen costs to make the data fair will be claimed if they are in accordance with the terms of the Grant Agreement (Article 6 and Article 6.2.D.3).

3.3. Who will be responsible for data management in your project?

Data management will be conducted by a Country Data Manager (CDM) in each of the four study countries, as well as one Principal Data Manager (PDM) based in Paris.

The CDMs are responsible for:

- the implementation of the data management policy in their respective countries
- monitoring data management activities and deadlines and sending reminders to partner hospitals
- providing customized assistance and additional guidance in completing surveys
- asking partner hospitals for missing information or clarifications

- contributing to the data management plan
- participating in the quaterly monitoring visit to regularly check the quality of the collected data, evaluating the implementation of the QUALI-DEC strategy and identifying barriers to implementation (see 2.4.5.)
- helping with the implementation of the intervention (participation in a 5-day training session for opinion leaders, implementation of the collection of caesarean audit on REDCap, participation in the creation and implementation of the DAT)
- offering customized help and further guidance for publishing open data and being a member of the data access committee (see 2.2.8.)

The PDM is responsible for:

- developing, writing and updating the data management plan
- coordinating the technical realisation of the project (data survey, data repositories, metadata catalogues, ...)
- monitoring data management activities (both collection and publication) and deadlines and sending reminders to CDM
- providing support to CDM
- participating in the quaterly monitoring visit to regularly check the quality of the collected data, evaluating the implementation of the QUALI-DEC strategy and identifying barriers to implementation (see 2.4.5.)
- helping with the implementation of the intervention (participation in a 5-day training session for opinion leaders, implementation of the collection of caesarean audit on REDCap, participation in the creation and implementation of the DAT)
- offering customized help and further guidance for publishing open data and being a member of the data access committee (see 2.2.8.)
- providing solutions for specific issues in accordance with project management

3.4. Are the resources for long term preservation discussed (costs and potential value, who decides and how what data will be kept and for how long)?

No immediate costs are anticipated for open data that are stored for long-term preservation in the Zenodo repository. The data will be stored in the CERN data centre. Data files and metadata are stored in multiple independent online replicas.

4. Data security

4.1. What provisions are in place for data security (including data recovery as well as secure storage and transfer of sensitive 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.

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.

The host institution (IRD) has an appointed Data Protection Officer (DPO), whose contact details will be made available to all data subjects involved in the research. The DPO is Pierre Bos (dpd@ird.fr).

At the end of the project, all data will be stored on the Zenedo repository.

4.2. Is the data safely stored in 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.

5. Ethical aspects

5.1. Are there any ethical or legal issues that can have an impact on data sharing? These can also be discussed in the context of the ethics review. If relevant, include references to ethics deliverables and ethics chapter in the Description of the Action (DoA).

All personal data collected during the course of the study will be processed in accordance with EU-GDPR principles and the laws of the study countries. All data including data collection forms, observation grids and transcripts will be pseudonymised using unique participant numbers, with identifier codes stored in a password-protected folder accessible only to designated study team members. Data will be permanently anonymized by deleting the identifier codes after the end of the study. Participants will be informed that quantitative data will be reported in aggregate and any information possibly identifying a participant or health facility will be removed from reported quotes collected during qualitative interviews and focus groups. Detailed pseudonymisation techniques will be described in a deliverable (D1.2).

Anonymization process will be done 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 resoluation that risks identification).

All data collected or generated during the QUALI-DEC study will be imported from the four study countries into the EU. Governmental authorisation for data importation will be obtained from the four study countries through national ethics approval or government licenses, as applicable.

Confidentiality will be respected by storing confidential data in password-protected files accessible only to a small number of research team members, and by irreversibly anonymising qualitative and quantitative data (permanently erasing decoding keys) after the end of the project.

5.2. Is informed consent for data sharing and long term preservation included in questionnaires dealing with personal data?

Research participants will be informed of their rights and of the intended use of their data during informed consent procedures, including consent for data sharing and long-term preservation.

Fairness and transparency will be ensured by clearly and comprehensively communicating to participants how their data will be used; we will ensure data minimisation by collecting only information useful for this project.

6. Other issues

6.1. Do you make use of other national/funder/sectorial/departmental procedures for data management? If yes, which ones?

Data management will be compliant with the national procedure management of each country and with European laws about data security and the protection of privacy (e.g. GDPR).

Thailand ethics authority requires that every researchers of the QUALI-DEC project who works on Thai data complete The Good Clinical Practice (GCP) course from the NIDA (National Drug Abuse Treatment) Clinical Trials Network. This training course is based on International Conference on Harmonization (ICH) Guidelines as best practices and regulatory requirements for conducting clinical research trials in the United States. It includes a module on informed consent, on confidientiality and privacy and documentation and record keeping (https://gcp.nidatraining.org/resources).

In Argentina, there is a 10 year regulatory requirement for data re-use at the end of the project. We will lift this regulation for all the data in our project.