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

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Periodic Technical Report

Part B

Period covered by the report: from 01/01/2020 to 30/06/2021 (18 months)

Periodic report: 1st

Revision as per 9th December 2021

1. Explanation of the work carried out by the beneficiaries and Overview of the progress

- Explain the work carried out during the reporting period in line with the Annex 1 to the Grant Agreement.
- Include an overview of the project results towards the objective of the action in line with the structure of the Annex 1 to the Grant Agreement including summary of deliverables and milestones, and a summary of exploitable results and an explanation about how they can/will be exploited11 .

Despite long-standing international concerns and debates, the proportion of caesarean births continues to rise. This trend is not limited to high-income countries, but is largely concentrated in low- and middle-income countries. Overuse of caesarean section (C-section) has adverse consequences on maternal and child health. It also deviates essential resources worldwide and hinders universal access to healthcare services.
Reducing caesarean sections will have a significant impact on quality of care for women and new-borns by reducing short-term and long-term complications. It will also reduce unnecessary healthcare expenditure.

We have partially achieved our objectives for the funding period. One (D 5.1) of the sixteen expected deliverables was not delivered and three (MS 5 & 6; MS 11) of twelve milestones were not met on time. The COVID-19 pandemic limited our travel from Europe to the countries participating in the study and within the countries themselves. For this reason, some field activities could not be carried out, which caused delays in project progress. We planned to conduct a preliminary survey at Month 6 among women who gave birth in the participating hospitals to measure specific indicators before the intervention was implemented (MS 11). This survey could not be completed due to the pandemic, so the training of health professionals was postponed (MS 5&6). Meeting was held in each country with stakeholders to discuss the results of the formative research and adapt the intervention, but no European researcher was able to participate. For this reason, adapted guidelines based on WHO recommendations for companionship (D 5.1) was completed in June 2021 instead of December 2020 and scalability assessment (MS 9) was postponed.

On the other hand, we set up at the start of the project (and the pandemic) a communication system based on video-conferencing that allowed us to work together (but slowly) and produce all the tools necessary for the implementation of the intervention and its evaluation. The coordination team at IRD was quickly put in place with the recruitment of an European Project Manager (Delia Visan) in and a Principal Data Manager (Marion Ravit), both in March 2020. The multifaceted intervention was tailored to different contexts after the formative research, most of which was collected before or just at the start of the pandemic. We set up a health information system in the 32 participating hospitals to collect monthly statistics since January 2020. This system is based on a secure web application (REDCap) that does not require travel to the field. To compensate for the inability to travel and train healthcare providers on site, we have developed an online training course that will be ready for use as soon as the post-partum survey is completed. Furthermore, we have developed our dissemination and exploitation plan based on new information technology, including social networks, tools widely used in this pandemic context.

1.1. Objectives

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 healthcare providers, women and health organizations to reduce unnecessary caesarean sections in Argentina, Burkina Faso, Thailand and Vietnam. The specific objectives of QUALI-DEC project are under the responsibility of seven work packages (WPs):

- To structure, coordinate and monitor the implementation of the QUALI-DEC strategy which aims to enhance the adoption of non-clinical interventions (WP2);
- To develop, adapt, implement and extend to new settings in low-, middle- and high-income countries the four active components of the QUALI-DEC strategy. (WP3);
- To evaluate the QUALI-DEC strategy at the health professionals and system levels in terms of participation, acceptability, implementation and empowerment of clinicians in the audit approach, costs at the organization level, and scalability (WP4);
- To evaluate the QUALI-DEC strategy at the women's level in terms of participation in activities targeting them, acceptability and empowerment of women in decision-making for planned mode of delivery, fear of childbirth, decisional conflict score and satisfaction with care (WP5);
- To assess the effectiveness of the QUALI-DEC strategy in terms of changes in caesarean practice at the hospital level without worsening maternal and perinatal health outcomes (WP6);
- To enhance utilization of the project findings through engagement of stakeholders including women, men, healthcare providers and policy-makers (WP7).

1.2 Explanation of the work carried per WP

We have followed the planned outline of the Grant Agreement and reported the work carried out in each work package against the set objectives. We also report the contribution of participating countries to each work package.

Work package 1

This work package sets out the 'ethics requirements' that the project must comply with. It is led by IRD. The ethic requirements are included as six deliverables, of which four were part of this funding period: D1.1 H - Requirement No. 1; D1.2 POPD - Requirement No. 2; D1.3 NEC - Requirement No. 4; and D1.4 H - Requirement No. All these ethics requirements were delivered in June 2020. This includes:

- The procedures and criteria that will be used to identify/recruit research participants
- The informed consent procedures, including the procedure for women under 18th year old
- Templates of the informed consent/assent forms and information sheets
- The measures to protect vulnerable individuals/groups
- Copies of opinions/approvals by ethics committees and/or competent authorities for the research with humans
- The contact details of the Data Protection Officer (DPO) at IRD
- Respect of the 'data minimisation 'principle
- A description of the technical and organisational measures that will be implemented to safeguard the rights and freedoms of the data subjects/research participants
- A description of the security measures that will be implemented to prevent unauthorised access to personal data or the equipment used for processing
- Description of the anonymisation techniques that will be implemented
- An explicit confirmation that the beneficiary has lawful basis for the data processing

- Detailed information to demonstrate that fair benefit-sharing arrangements with stakeholders from low and lower-middle income countries are ensured
- Details on the materials which will be imported to/exported from the EU
- Copies of import/export authorisations, as required by national/EU legislation
- Final version of study protocol as approved by first regulator / ethics committee(s),
- Registration number of the study: ISRCTN67214403

Work package 2

This work package includes project management and coordination of the consortium. It is led by IRD and aims to ensure efficient implementation of the work plan and achievement of project objectives and impacts; to ensure efficient and effective communication between partners and WPs and with the EC; to monitor progress of the project (planning and budget); to ensure the implementation of the data management plan (DMP), and to guarantee optimal access to interested parties; to oversee risk management; to coordinate the dissemination plan; and to coordinate and organize the intervention implementation and evaluation.

Objective 2.1 (Task 2.1): Internal communication, project monitoring & reporting

We set up an effective communication between partners. Since travels were not possible during this reporting period due to COVID pandemia, communication was mainly based on weekly visio-conferences, E-mails and telephone (WhatsApp group). We have opened a secure internal collaborative workspace (https://sharedocs.huma-num.fr), accessible with Login and password, for sharing of documents and data. We also created the QUALI-DEC website (www.qualidec.com) in 2020 for sharing knowledge, results and interesting literature with other researchers, healthcare professionals and pregnant women. The information is available in French, English and Spanish. Then the website has been redesigned and improved in 2021, its content has been adapted for three main targets: women, healthcare providers and researchers.

The first international General Assembly at month 3 (Kick-off meeting) and the second one at month 9 (inter-country wokrshop) to discuss the findings of the formative research, the two meetings of the Advisory Board, and weekly internal project management Team (PMT) meetings were held using visio-conferences. Agendas, minutes and action lists are available on our internal collaborative workplace (Sharedoc).

Due to force majeure, COVID-19 disruption in March 2020, the kick-off meeting did not take place face-to face, in Paris, as foreseen. However, beneficiaries did book the travel tickets and communicated with the travel agencies to postpone them. Since the situation is still very uncertain in July 2021, when this report is submitted, the consortium is asking the application of article 51 of Grant Agreement and charges the costs of travel to the H2020 action.

Objective 2.2 (Task 2.2): Ethics

Between January and March 2020, we developed in close collaboration with all consortium members the original research protocol, informed consents, forms, and other documents for Ethics Committees' assessment. The protocol was published a September 2020 in the Implementation Science Journal: Dumont et al. Dumont et al. https://doi.org/10.1186/s13012-020-01029-4

Ethical clearance was obtained from the French Research Institute for Sustainable Development and the Research Project Review Panel (RP2) in the UNDP/UNFPA/UNICEF/WHO/World Bank Special Programme of Research, Development and Research Training in Human Reproduction (WHO study No. A66006). Ethical approvals was also obtained in each participating country providing the relevant authorizations for the activities conducted in collaboration with non-European participating countries (Table 2.2).

Table 2.2: Ethical clearance in participant countries

Ethical clearance	Argentina	Burkina Faso	Thailand	Vietnam
For the formative research	31 Jan 2018	6 Nov 2019	10 March 2020	15 Aug 2018
For the whole QUALI-DEC project	27 Jan 2020	13 March 2020	3 Dec 2020	25 Aug 2020

Objective 2.3 (Task 2.3): Financial, legal & administrative management

IRD made the payments of the Grant to other beneficiaries at the beginning of the project in March-April 2020. At this time, we opened at the beginning of the project a risk register related to each task/milestone/deliverable. We then coordinated this first periodic technical and financial report.

Objective 2.4 (Task 2.4) Organization of intervention implementation and evaluation in participating countries

IRD developed the original Manual of Operation to implement the four components of the intervention. This document is available at our collaborative platform (Sharedoc).

We contributed with Country partners (CREP, IRSS, KKU and PNT) to the organization of the first Country-level steering committee (Stakeholder & dissemination meeting) to discuss and disseminate main findings of the formative research and to adapt the intervention to the context of each country (Table 2.4).

Table 2.4 Stakeholders meeting in participating countries

Work Program	Argentina	Burkina Faso	Thailand	Vietnam
Stakeholders meeting	17-18 June 2021	20-22 Oct 2020	11-12 Jan 2021	22-23 April 2021 and 4-5 May 2021

We developed the Decision-Analysis-Tool that can help pregnant women making an informed and thoughtful choice about the mode of delivery. This tool is available on the QUALI-DEC website here: https://www.qualidec.com/wp-content/uploads/2021/03/Generic-DAT-booklet_9Nov2020.pdf; and is registered in the Decision Aid Library Inventory (DALI) using International Decision Aids Standards (IPDSA). This generic DAT has been used by country PIs to adapt the tool to their specific context.

We contributed with FB partner to the development of the electronic portfolio for the 5-Days training (Task 3.1 of WP3). Particularly, we design the following training materials:

- Two short videos addressed to health care professionals and service managers explaining how to assess the appropriateness of caesarean section indications and how to organize a meeting to feedback the results (in French, English and Spanish).
- A short video to inform women and men of the risks and benefits of planned vaginal delivery vs planned C-section and on the use of the Decision-Analysis-Tool (in French, English and Spanish):
- A Role playing game to sensitize healthcare professionals on fear of childbirth. This role playing game is an adaptation from the French version of “Mafia” game (Davidoff, 1986) entitled “Les Loups-Garous de Thiercelieux” (des Pallières et Marly, 1986) inspired from “Inside Out” film (Docter, 2015)

- A card game which is an adaptation from the French version of “Touring” card game (Roche, 1906) entitled “Mille bornes” (Dujardin, 1954). The object of the game is for each player to perform as many deliveries as possible, especially satisfactory and outstanding vaginal deliveries.

IRD contributed with WHO to the implementation of the formative research and the post-partum cross-sectional surveys in each participating country (Task 5.2 and 5.3 of WP5).

IRD conducted between January to April 2021 secondary analyses of individual interviews in Thailand, Vietnam and Burkina Faso to develop a women’s empowerment measurement scale that will be used at the second postpartum survey (after the intervention period).

Using the data collected during the postpartum survey in Burkina Faso, we conducted between April to June 2021 psychometric analyses to validate the satisfaction measurement scale (Form 2 of the postpartum questionnaire)

Objective 2.5 (Task 2.5): Data management

IRD ensured that data to operationalise the Ten Group Classification System (TGCS) is available at hospital-level, regularly checked the data quality with support from local data managers.

The principal data manager at IRD (Marion Ravit) developed the data management plan (DMP) at the beginning of the project. This DMP was approved by all partners.

IRD with the support of Karolinska Institute set up of a secure web application (REDCap) for building and managing online surveys and databases. All datasets are placed on this platform. At this time, monthly hospital-based statistics derived from the TGCS and the data from the post-partum cross sectional surveys in the four countries are recorded on REDCap.

Summary of work

- MS1 (M3): The kick-off meeting was held online in March 2020
- MS2 (M6): The REDCap application was available online in June 2020
- MS3 (M1): The ethic clearance for the whole QUALI-DEC project was obtained for all participant countries in December 2020
- D2.1 (M3): The Risk Register was delivered in June 2020
- D2.2 (M3): The ethics report was delivered in June 2020 providing detailed responses to the ethical questions raised by local and international ethics committees.
- D2.3 (M6): The Data Management Plan was delivered in June 2020
- D2.4 (M3): A first version of the QUALI-DEC website was delivered in March 2020. It was designed initially for communication & dissemination among researchers. The website was updated in March 2021 to also inform pregnant women and health care professionals.

Work package 3

The WP3 aims to develop, adapt and extend to new settings the four components of the QUALI-DEC strategy (opinion leaders, audit & feedback, decision-analysis tool and companionship during labour). It is led by FB, but all partners contribute to the design and develop the intervention tools that will improve clinicians’ adherence to evidence-based clinical guidelines and the doctor-patient decision-making process.

Objective 3.1 (Task 3.1, 3.2 and 3.3): To training opinion leaders and data collectors in participating hospitals and create local audit committees.

To compensate for the inability to travel and train healthcare providers on site, we have developed an online training course. Training materials, including videos, Powerpoint presentations, role

playing game and interactive workshops, has been adapted to each context and translated into local language. These materials will be used to train the trainers in each participating country and to deliver the 5-Day training to healthcare providers (opinion leaders and data collectors) as soon as the post-partum survey is completed (see WP5).

In each participating hospital, opinion leaders and data collectors have been identified to implement the four component of the intervention. At this time, only the Ten Group Classification System (TGCS) as been implemented to collect hospital-based monthly statistics on the REDcap system (see WP6). Due to COVID-19 pandemic and delayed 5-Days training, opinion leaders and data collectors were not yet trained in the interpretation of the TGCS, neither in launching the audit approach to review caesarean section indications.

Objective 3.2 (Task 3.4): To encourage use of Decision-analysis Tool

Based on the findings of the formative research, the generic DAT booklet was adapted to each context and translated into local language. Since knowledge improved on the risks and benefits of caesarean section, the content of the DAT booklet was updated in January 2021 using a systematic review of the literature. Based on this tool, WHO developed a web application (see WP5) and FB designed a flipchart that will be used to inform women and providers on the usefulness of the DAT in participating hospitals. In Thailand, the DAT was included in the Thai national antenatal care booklet.

Objective 3.3 (Task 3.5): To encourage companionship during labour

Based on the findings of the formative research, we identified important gaps between WHO recommendations and local practices in companionship. We also identified opportunities to support the introduction of companionship in each context and revised existing national guidelines or protocols in this way.

Summary of work

- MS4 (M6): WHO clinical algorithms to guide healthcare providers in the caesarean section decision-making process are available on our QUALI-DEC website since March 2021.
- D3.1 (M6): Training material for opinion leaders (OLs) and data collectors (DCs) in ready, adapted to each context and accessible online since June 2021.
- D3.2 (M6): The Data-Analysis Tool (DAT) translated in local language is delivered to participating country since June 2020.
- D3.3 (M12): The tailored strategy to implement companionship is delivered to participating country since June 2021.
- MS5 (M7): 5-Day Training of OLs and DCs will start as soon as the post-partum survey is completed.
- MS6 (M7): Training of the members of local Audit committees by OLs in each participating hospital as soon as the 5-Day training is completed.

<u>Work package 4</u>

The WP4 aims to understand the health system context and the readiness of the countries and hospitals to implement the QUALI-DEC strategy. Further, we aimed to identify critical aspects to adapt the intervention to country context. A second objective is to evaluate the intervention at health system level which was not part of this funding period. Also an extended cost-effectiveness analysis is planned for which preparatory work was started. The WP4 is led by Karolinska Institute (KI).

Objective 4.1 (Tasks 4.1 to 4.3): Characterise the institutional readiness and the policy context.

Together with WP 5, KI explored the readiness of the facilities to implement the intervention from the health providers' perspective. KI developed, in close collaboration with all consortium members, the detailed methodology for the readiness assessment and the analysis of the policy context between October 2019 and March 2020, then conceived a desk review (context assessment) tool and the health facility assessment. Both tools aimed to better understand the readiness of the countries and the facilities to implement the intervention. We used the framework developed by WHO (WP5) and published by Bohren et al. in 2019 in the Reproductive Health Journal: https://doi.org/10.1186/s12978-019-0827-1.

In addition, KI used an iterative process to collect more data and to understand the context in sufficient depth. The process did not follow the intended time plan as we had to adapt to the COVID-19 pandemic.

KI trained the Burkina Faso and Thailand team on the facility readiness assessment and the interviews with healthcare professionals, as part of the formative research (WP5). More exchange was during the regular consortium team meetings throughout 2020 and 2021. Specific time periods are as below:

Table 4.1: Context and readiness assessment in participating countries

Work Program	Argentina	Burkina Faso	Thailand	Vietnam
Conduct of the context assessment	28 Aug 2020	Feb 2020	27 Apr 2020	8 Nov 2019
Zoom sessions to further understand the context	1 Dec 2020	10 June 2020	23 June 2020	18 June 2020
Training for the readiness assessment	No formal training	Nov 2019	30 Oct 2019	No formal training
Conduct of the readiness assessment	May to Nov 2020	Feb to Mar 2020	June 2020	18 Oct- 5 Nov 2020
Individual interviews with health care professionals and administrators	Nov 2018-June 2019	Feb-May 2020	April-June 2020	Feb-March 2019

Meetings were held with main stakeholders, online in Thailand and Argentina, and face-to-face in Burkina Faso and Vietnam, to discuss the main results of the formative research (Table 2.4).

We did not perform feedbacks or further focus group discussions as we had to ease the total work of the teams. Instead, we use the individual interviews of the formative research and zoom conferences. Thus the work also described as task 4.2 including the scalability assessment were not yet fully implemented as meetings are not possible to schedule and policy makers are difficult to reach.

The work to analyse the collected data is still ongoing as the data were partly received late in response to COVID-19. We have prepared first table summarising the health context parts and are in the process to prepare a full publication with all different aspects using the framework by Bohren et al, 2019. We are continuously complementing the knowledge based during our monthly team meetings.

Objective 4.2 (Tasks 4.4.) Undertake an extended cost-effectiveness analysis

An initial intervention costing framework was developed based on the intervention components proposed. This work is ongoing and will be refined based on the adaptations that will be undertaken in each of the sites. A generic data collection tool was developed to collect time spent on certain activities related to the intervention. Cost related questions has also been incorporated into the monitoring form that will be used during the educational outreach visits (WP3).

A literature review of the Out of Pocket (OOP) costs in each country associated with maternity care was conducted. Hospital based fees were also collected in the context assessment. Based on this information, the initial OOP module was designed. Consultations with each country team took place to discuss the relevance and appropriateness of the OOP questions (Table 4.2). The questions were revised, and 11 questions were included in the women's cross-sectional survey (WP5) depending on the country's context (i.e., four questions in Thailand and Argentina and 11 in Burkina Faso and Vietnam). A standard operation procedure (SOP) was also created for this module. Training and implementation of this module was completed in Burkina Faso, as part of the cross sectional survey (see WP5). Data collection teams in Thailand and Vietnam were trained. The module was collected for three hospitals in Thailand and piloted in Vietnam.

Table 4.2: Development of the questionnaire of out-of-pocket costs

Work Program	Argentina	Burkina Faso	Thailand	Vietnam
Consultation for OOP and wealth index module	25 May and 12 June 2020	21 May 2020	22 May 2020	8 Nov 2019
Training on REDCap (data collection software)	15 June 2020	15 June 2020	15 June 2020	15 June 2020
Training on OOP and wealth index module		25-26 Nov 2020	24-25 Feb 2021	24-25 March 2021

A similar process to the OOP module was followed in order to create a series of questions that would estimate each of the women's wealth status i.e., a wealth index. This is necessary for the ECEA analysis and to understand the effect from an equity perspective. A literature review was conducted to identify the most effective set of questions followed by in-depth consultations with each of the country teams. The questions are specific to each of the settings. A SOP was developed and the teams with the exception of Argentina were trained (Table 4.2).

Together with WP 5, we developed the survey tools and the data entry into REDCap, trained the team, and supported the troubleshooting during the data collection"

Contribution to activities of WP3 and WP5

We co-supported the formative research of WP5 (Task 5.1) and supported the data collection under objective 5.2

We contributed to the review of the electronic portfolio for the 5-days training (Task 3.1 of WP 3).

Together with WP5, we developed the survey tools for the baseline post-partum survey and the data entry into REDCap, trained the team, and supported the troubleshooting during the data collection.

Summary of work

- MS7 (M5): Baseline in-depth interviews with health care professionals and administrators were finalized in August 2020 for all participant countries
- MS9 (M9): Stakeholders meetings were held between October 2020 and June 2021
- MS8 (M18): Scalability assessment started in June 2020 but not yet fully implemented
- D 4.1 (M6): Recommendations to adapt the different components of the strategy to institutional and policy context. A draft summary of the institutional and policy context of the QUALI-DEC intervention was delivered as a first version in June 2020 and as an updated version in December 2020.

Work package 5

The WP5 aims is to understand the context from the perspective of women and their relatives. Further, WP5 aims to identify critical aspects to adapt the intervention to societal context. Secondly, a process and effectiveness evaluation at women's level is planned for which the baseline survey was started in 2021 and was part of the funding period. The WP5 is led by WHO which is not beneficiary of the EC grant, but funds all the activities of this work package. WHO worked in collaboration with all WPs and particularly with WP4 for the formative research and the cross-sectional survey conducted with the reported time period. WHO also contributed to activities of WP3 to design specific tools for the intervention implementation.

Objective 5.1 (Tasks 5.1): Characterise the societal context and explore the feasibility to implement the intervention from women's perspective.

In collaboration with KI and country PIs, WHO conducted a formative research in each country to understand the context, based on the framework designed by Bohren et al. 2019. The protocol includes a policy review, a readiness assessment and individual interviews with women, potential companions, health care professionals and administrators. The formative research was partially carried out in Argentina with WHO funds in 2018-19 and in Vietnam with IRD funds in 2019. The research was completed in 2020 with EC grant. The formative research was conducted entirely in Thailand and Burkina Faso with WHO funding in the first semester of 2020. Specific time periods are as below

Table 5.2: Formative research in participating countries

Work Program	Argentina	Burkina Faso	Thailand	Vietnam
Training of data collectors	2018	Nov 2019	30 Oct 2019	Feb 2019
First round of data collection	Nov 2018-June 2019	Feb-May 2020	April-June 2020	Feb-March 2019
Second round of data collection (to complete)	July 2020	N/A	N/A	Oct-Nov 2020
Report of the formative research	April 2021	May 2021		June 2021

Based on the findings of the formative research, WHO supported the interpretation and writing of the results for design of the components of the intervention. We also carried out secondary analysis of qualitative data to better understand and take into account the pregnant women's perspective in Burkina Faso, Thailand and Vietnam.

Objective 5.2 (Task 5.2 and 5.3): Process and effectiveness evaluation at women's level

WHO developed, in close collaboration with all consortium members, the detailed methodology for the first postpartum survey (baseline) between June to November 2020. We conceived a screening form, a questionnaire to collect the data from medical records (Form 1), and a questionnaire to interview postpartum women (Form 2). Both questionnaires aimed to collect information on characteristics of the women, outcomes of pregnancy and birth, preferences and knowledge on mode of birth, labour companionship, gender dimension, satisfaction with birth experience, out-of-pocket expenses and wealth.

WHO also prepared a Manual of Operations for the implementation of the cross-sectional survey. Given the impossibility for travelling, a virtual training of trainers was conducted for Burkina Faso, Thailand and Viet Nam (Table 5.2). The survey was conducted in December 2020 in the 8 participating hospitals of Burkina Faso. In Thailand, it was conducted in April 2021 in 3 hospitals in Khon Kaen region. In the other 5 hospitals, the survey is expected to be completed by 30th June 2021. It was delayed because of COVID-19 situation in Thailand which limited traveling. In Vietnam, the survey was delayed because of COVID-19, the survey is expected to be completed by July 2021. In Argentina, the survey is expected to start in June 2021 for the same reason.

Table 5.2: Cross-sectional survey in participating countries

Work Program	Argentina	Burkina Faso	Thailand	Vietnam
Training of the trainers	June 2021	Nov 2020	April 2021	April 201
Data collection	Not started	Dec 2020	April-June 2021	Not started

Contribution to activities of WP3 and WP6

WHO designed, developed and tested the online Robson Classification Platform. This platform will facilitate the use of the data on caesarean section for the study. It will produce automatically graphs and tables at hospital and country level for discussion in each hospital. It is intended as a clinical dashboard.

We contributed with FB to the development of the electronic portfolio for the 5-Days training (Task 3.1 of WP3). Particularly, we design two short videos addressed to health care professionals and service managers explaining how to build and interpret the Robson classification Table and how to use the Robson classification Platform.

Based on the paper decision-analysis-tool, WHO designed and developed a DAT application which will be adapted to the local language in each participating country.

Summary of work

- MS10 (M5): Baseline in-depth interviews with women and potential companions were finalized in November 2020 for all participating countries
- MS11 (M38): The cross-sectional survey at baseline was fully implemented in Burkina Faso in December 2020 and in Thailand in June 2021, but still ongoing in Vietnam and Argentina
- D 5.1 (M6): Recommendations to adapt interventions to societal context. A draft summary of the societal context of the QUALI-DEC intervention was delivered as a first version in June 2020 and as an updated version in December 2020.

Work package 6

This work package aims to monitor caesarean section rates, maternal and perinatal outcomes, as part of the effectiveness evaluation of the intervention. During the funding period, the three main objectives of WP6 were: to collect monthly data in participating hospitals using the Ten-Group classification System (TGCS); to control data quality and develop the data analysis plan; and to develop the Maternity dashboard that will be used by participating hospitals during the intervention period. The WP6 is led by UCD, buthas involved all partners with special links to WP2 to set up the TGCS in participating hospitals, and the four country partners (CREP, IRSS, KKU & PNT).

Objective 6.1 (Task 6.1): To collect monthly statistics in participating hospitals

UCD developed the detailed methodology to set up the TGCS in participating hospitals. Key principles, obstetric concepts and parameters of the classification were presented to all partners during our kick-off meeting in March 2020. More exchange occurred with country PIs during the regular consortium team meetings throughout 2020.

During June 2020, all Country Data Managers (CDMs) were trained by the Principal Data Manager (PDM) to enter data on the REDCap web application. Data collectors in each site were trained by the CDM to extract information from routine records at the study sites. The CDMs regularly enter the aggregated monthly data into the REDCap web application. At month 16 (April 2021), all but two facilities in Vietnam have entered aggregated monthly data.

Objective 6.2 (task 6.3 and 6.4): To control data quality and develop the data analysis plan

UCD organized regular online meetings with IRSS in Burkina Faso to discuss the TGCS and the data quality. There were also three online meetings with CREP in Argentina, with PNT in Vietnam and with KKU in Thailand in 2020. Due to COVID situation, the set up of the TGCS was delayed in Vietnam

The PDM performed quality checks on the data received from all the study countries, including examining the data for outliers, unrealistic patterns and internal consistency between different numbers reported for the same month. In case of problems or missing data, the PDM contacted the relevant CDM and asked them to check the data again with the data collector. The PDM also reminded the CDM to enter the data regularly on RedCap if necessary.

The principal data manager (IRD) developed with support of WP leaders and country PIs the Data Analysis Plan. This plan describes: 1) the interrupted time series analysis to assess the effect of the intervention on primary and secondary delivery care outcomes (excluding maternal and perinatal death); 2) the analysis of socio-economic inequalities in C-section rates; 3) the comparison of adverse maternal and perinatal outcomes between periods (before, during and after intervention).

Objective 6.3 (Task 6.2): To develop the Maternity Dashboard

WHO has designed, developed and tested the Robson classification platform to facilitate the use and interpretation of the TGCS during the intervention period. This platform will automatically produce graphs and tables at hospital and country level for discussion in each hospital. It is designed as a clinical dashboard.

To update the maternity dashboard, the PDM must upload the data entered into RedCap by the CDMs onto the Robson classification platform, and will then be able to send an email to the OLs to inform them that new data is available. Once entered by the data collectors on the study platform,

the monthly data will be summarised for each participating hospital in interactive displays facilitating monitoring and encouraging reflexivity of practices.

Due to the COVID situation, the opinion leaders (OLs) in each participating hospital have not yet been trained in the use of the Robson classification platform and the intervention is expected to start after this training.

Summary of work

- MS13 (M7): Monthly statistics are available for each participating hospital. Dataset is uploaded on REDcap application since June 2020.
- MS14 (M7): Maternity dashboards produced automatically by the Robson classification platform using data extracted from REDCap. Access will be provided to country PIs, CDM, opinion leaders and data collectors before the 5-days training
- D 6.2 (M18): The Data Analysis Plan was delivered in June 2021.

Work package 7

This work package includes knowledge transfer activities. It aims to apply FAIR Principles to all research outputs and make QUALI-DEC outputs 100% Open Science compliant; to ensure that the project results are channelled and understandable to the three targeted audiences – women, health care professionals and policy-makers; to proactively involve any stakeholders taking part in the project to work together to achieve the targeted impacts.

Objective 7.1 (Task 7.1): Branding & Portfolio of Communication Assets

IRD developed with all partners between March to June 2020 the QUALI-DEC logo and graphical charter of QUALI-DEC website. Photos addressed by researchers in each participating country are stored on our collaborative platform (Sharedoc) to support the website and our social media strategy.

IRD developed a social media communication strategy from January to June 2021 to communicate on QUALI-DEC products. Messages, photos, videos are regularly posted on:

- LinkedIn: https://www.linkedin.com/company/quali-dec-project
- Twitter: @quali_dec
- Facebook: https://www.facebook.com/QualiDecProject
- Instagram: @QUALI_DEC_project
- YouTube: https://www.youtube.com/channel/UC6EN-WSIvjrQZSuVrfqTkDg

Objective 7.2 (Task 7.2): Capacity building in knowledge transfer

Two members of the Project Management Team (Delia Visan and Marion Ravit) took an online course (MOOC) on knowledge transfer available on EDUlib platform (http://www.equiperenard.ca). The content of the MOOC did not fully meet the needs of participants to build capacity in knowledge transfer. It is not adapted to the context of QUALI-DEC research. For this reason, we decided not to translate the existing MOOC into English and Spanish.

To build the capacity of country partners to disseminate and exploit the results of QUALI-DEC research, the PMT conducted between January and June 2021 a round of interviews with each Country PI to identify the main users of the research results and products, the results and products that will be communicated and potentially usable, the measures to be used to communicate these results and products and when, and effective information channels and communication platforms to be used for potential users of research in a long-term perspective. The findings of the interviews will allow to review the D&E plans developed in June 2020, and make them more strategic and specific to each context.

Objective 7.2 (Task 7.3): Knowledge transfer strategy

Country PIs decided that they and some of selected opinion leaders will play the role of knowledge brokers in their own country. They are in contact with main stakeholders (Ministry of Health, medical and midwives/nurses schools, associations of Ob-Gyn and midwives, women's associations). They have regular meetings with them to disseminate results and products of QUALI-DEC research and to promote the use of these results and products. For example, in Thailand the Department of Health has included the decision-analysis-tool in the Thai antenatal care booklet to be disseminated among all pregnant women in the country.

All country PIs have expressed the need for a communication manager in their team to support implementation of the D&E plan and further revisions. IRD described the job of the future QUALIDEC Communications Officer who will be responsible for all communication and dissemination activities for the QUALIDEC project in each country. They will report to each country PI and work closely with the QUALIDEC team in participating country and IRD, and external stakeholders to ensure high quality, fit for purpose dissemination and promote QUALIDEC research uptake in each country. The post holder will lead the implementation of the D&E plan for 2021, including a social media campaign to inform of the risks and benefits of different modes of delivery, and will lead its annual review and update.

Summary of work

- MS16 (M1): The " Knowledge transfer" workshop was held online during the kick-off meeting in March 2020
- D 7.1 (M6): Portfolio of Communication Assets was delivered in June 2020
- D 7.2 (M6): The MOOC on knowledge transfer was not delivered because it did not meet country needs; A more adapted MOOC will be developed later based on training materials form the electronic portfolio for the 5-days training.
- D7.4 (M6). Communication and exploitation Plan. IRD with support of each country partner developed a dissemination & exploitation plan at the beginning of the project. This plan was revised in December 2020 and is still in progress.

Contribution of study countries to the each work package

We present here the work carried out in each country during the reporting period, according to the objectives described in the Grant Agreement.

Argentina

WP2: Project management and coordination

- We reviewed and translated the original research protocol, informed consents, forms, and other documents for Ethics Committees' assessment.
- We obtained the endorsement from "Dirección General de Hospitales" (Hospitals´ General Direction), Ministry of Health of the Buenos Aires city.
- We participated in all weekly meetings of QUALI-DEC.
- We reviewed the summary protocol for publication. We translated the summary protocol into Spanish.
- We obtained permissions from the directors of participating hospital to conduct QUALI-DEC study.
- We submitted the study protocol, inform consents and forms to Ethic Committees in all participating hospitals.
- We organized the Stakeholder Consultation Workshop.
- We revised the QUALI-DEC Webpage and updated the webpage information from Argentina, CREP's logo, bios and photos.

WP3: Coordination of intervention implementation

- We completed the formative research to inform the study implementation.
- We wrote the Formative Research Report.
- We presented a summary of the formative research and the theory of change for Argentina in the Consortium weekly meetings.
- We reviewed and translated into Spanish the Decision Analysis Tool (DAT)
- We reviewed and translated into Spanish the DAT App.
- We recruited Opinion Leaders and Data Collectors in all participating hospitals.
- We conducted a revision of existing WHO and other existing algorithms (NICE, RCOG) useful to be applied in evidence decision making in clinical practice for mode of delivery at participant hospitals.
- We collaborated with WP3 with the Portfolio activities for the train of trainer's sessions for the 5- days training workshops in all participating countries.
- We developed the 5-days training evaluation tool
- We translated the IEC materials for companionship into Spanish

WP4: Evaluation at health system's level

- We conducted a document review for exploring local context for study implementation in Argentina. (Document Review Report)
- We assessed participating hospitals' readiness for study implementation. (Readiness Assessment Reports)
- We completed the formative research (focus group discussions with health care providers)
- We organized a stakeholder meeting to disseminate the results online in June 2021
- We contributed to the writing of a Policy brief with WP7 team

WP5: Evaluation at women's level

- We conducted the formative research (focus group discussions with midwives in representations of women's and companions' voices)
- We collaborated with WP 5 for the post-partum cross sectional survey with the screening form development, the new design of Form 1 (data from medical records) and development of its Manual of Operation.
- We collaborated with WP 5 in the train of trainers for cross sectional survey implementation for Burkina Faso, Thailand and Vietnam.
- We review the Form 2 for local adaptation for face-to-face interviews with women.

WP6: Monitoring C-section rates, maternal and perinatal outcomes

- We developed and review monthly Robson classification tables from each participant hospital (2020 completed, Jan-March 2021 completed, April and May in process). We entered the aggregated data on the REDCap web application.
- We developed the annex of Form 1: Classification for caesarean indications.
- We developed the form for Maternal and Perinatal Outcomes data collection.
- We collaborated with WP6 with the revision of the Data Management Plan, the configuration of RedCap App, and the piloting of all QUALIDEC forms for calculation of the number of human resources and time required to fill them and the design and testing of screening process for Form 2.
- We tested the tablet version of Form 2 for Argentina.

WP7: Knowledge transfer

- We developed the Knowledge Transfer Plan for Argentina. We planned the objectives, profile and tasks for the recruitment of the Communication manager.
- We planned a call for a Communication manager

Burkina Faso

WP2: Project management and coordination

- We regularly joined the weekly meeting of QUALI-DEC for effective communication and coordination.

- The research protocol including information and consent forms was already approved by the ethic committee for health research in Burkina.
- We obtained permission from the director of each participating hospital to conduct QUALI-DEC project.

WP3: Coordination of intervention implementation

- We presented the summary of a formative research and theory of change in Burkina in the weekly meeting.
- Data-Analysis Tool (DAT) was adapted and translated into French.
- We are in discussion with the ministry of health in order include the DAT in the national childbirth preparation plan.
- Clinical guidelines and algorithms have been adapted for Burkina on based on WHO recommendations.

WP4: Evaluation at health system's level

- To evaluate the QUALI-DEC strategy at the health professionals' and system's level, we have done the following:
- A formative research (baseline in-dept interviews with health care professionals.
- Document review, using a structured approach to identify important barriers and enablers to implementing interventions to reduce unnecessary caesarean section.
- Readiness assessment of each participating hospital was conducted.
- We organized stakeholder meeting to discuss the results of formative research (20-22 October 2020).

WP5: Evaluation at women's level

- A formative research was conducted (baseline in-dept interviews with women and companions)
- Cross-sectional postpartum survey (baseline period) has been carried out in all the eight participating hospitals from 8 to 30 December 2020.

WP6: Monitoring C-section rates, maternal and perinatal outcomes

- Each month, data collectors extracted information from routine records in participating hospitals. These data were always checked by the data manager who had regular field visits to ensure data quality. The validated aggregated data were then entered on the REDCap web application by the data manager (January 2020-May 2021).

WP7: Knowledge transfer

- We are currently finalizing QUALI-DEC Knowledge Transfer PLAN for Burkina.
- We are in discussion with the ministry of health in order to include the DAT in the national childbirth preparation plan.
- Ministry of health have a positive perception of the QUALI-DEC intervention and support it.

Thailand

WP2: Project management and coordination

- We regularly joined the weekly meeting of QUALI-DEC for effective communication and coordination.
- The research protocol including information and consent forms was already approved by Central Research Ethics Committee and Ethic Committees of all eight participating hospitals in Thailand.
- We obtained permission from the director of each participating hospital to conduct QUALI-DEC project.

WP3: Coordination of intervention implementation

- We presented the summary of a formative research and theory of change in Thailand in the weekly meeting.
- Data-Analysis Tool (DAT) was adapted and translated into Thai.
- DAT was included in the Thai national ANC booklet.

- Clinical guidelines and algorithms have been adapted for Thailand based on WHO recommendations.
- A new guideline/protocol for companionship was developed based on WHO recommendations and local practices (findings of a formative research).

WP4: Evaluation at health system's level

- To evaluate the QUALI-DEC strategy at the health professionals' and system's level, we have done the following:
- A formative research (baseline in-depth interviews with health care professionals.
- Document review, using a structured approach to identify important barriers and enablers to implementing interventions to reduce unnecessary caesarean section.
- Readiness assessment of each participating hospital was conducted.
- We organized stakeholder meeting to discuss the results of formative research (22-29 January 2021). Unfortunately, because of the COVID-19 situation we had to organize this meeting online.

WP5: Evaluation at women's level

- A formative research was conducted (baseline in-dept interviews with women and companions)
- Cross-sectional postpartum survey (baseline period) is expected to be conducted in all eight participating hospitals by 30th June 2021. It was delayed because of COVID-19 situation in Thailand which limited traveling.

WP6: Monitoring C-section rates, maternal and perinatal outcomes

- Each month, data collectors extracted information from routine records in participating hospitals and enter the aggregated data on the REDCap web application (January 2020-May 2021).

WP7: Knowledge transfer

- We have developed the KT Plan for Thailand.
- DAT was included in the Thai national ANC booklet.
- Ministry of Public Health accepted the policy of reducing unnecessary caesarean section as the national agenda

Vietnam

WP2: Project management and coordination

- We have regularly participated in the weekly meetings of QUALI-DEC project for effective communication and coordination.
- The research protocol including information and consent forms has been approved by Pham Ngoc Thach University's Ethic Committee and the Ethic Committees of the 2 largest participating hospitals in Vietnam.
- We have obtained approval of the receipt of funding for the research project by the People's Committee of Ho Chi Minh City.
- We have travelled to the 10 hospitals for explaining the project and getting their permission to participate in QUALI-DEC project (in which two hospitals initially agreed to participate and then declined so that we had to change and involve two other hospitals)
- We obtained permission from the director of each participating hospital to conduct QUALI-DEC project.

WP3: Coordination of intervention implementation

- We have sent an abstract and presented a preliminary version of the results of our formative research and theory of change for Vietnam to the coordination group of Quali-Dec project.
- Data-Analysis Tool (DAT) has been translated into Vietnamese. We are adapting the DAT to follow the Vietnamese context through the qualitative research and the readiness assessments of each hospital.
- We encourage hospitals to develop local guidelines according to WHO protocol standards through local leadership research projects.

- We have encouraged hospitals to develop a labor companion protocol according to the standard protocol developed by WHO and adapted to follow the context of some other hospitals (Ex. requesting medical students to act as labor companions whenever a companion of choice cannot participate).

WP4: Evaluation at health system's level

- Conduct a formative research (baseline in-dept interviews with health care professionals.
- Perform a document review, using a structured approach to identify important barriers and enablers to implementing interventions to reduce unnecessary caesarean section.
- Conduct a readiness assessment of each participating hospital.
- We organized a stakeholders meeting for 8 participating hospitals in the training course for the postpartum survey in Northern and Southern cities in Vietnam (22 – 23 April 2021 and 4 – 5 May 2021) to discuss the results of the formative research.
- We are writing an article about barriers related to the delayed application of evidence-based practice in the Vietnamese context.

WP5: Evaluation at women's level

- A formative research was conducted (baseline in-dept interviews have been conducted with pregnant women, post-partum women and their relatives).
- Cross-sectional postpartum survey (baseline period) is expected to be conducted in all eight participating hospitals by 14th May 2021. It has been delayed because of the COVID-19 situation.

WP6: Monitoring C-section rates, maternal and perinatal outcomes

- Due to the large number of patients, the lack of a complete electronic data system, and the poor quality of information related to the onset labor, we encountered many difficulties in collecting Robson classification data. We have improved the data collection system by training hospital's coordinators and directors. This should enhance their commitment in systematic data entry regarding Robson classification variables. It will help us to implement the intervention of the project and to effectively use Robson classification in hospital management in the future.
- Each month, data collectors extracted information from routine records in participating hospitals and entered the aggregated data on the REDCap web application (January 2020-April 2021).

WP7: Knowledge transfer

- We developed the KT Plan for Vietnam.

1.3. Impact of the work

The organisational structure we have put in place for the QUALI-DEC project will facilitate communication between partners and reduce the impact of the COVID-19 pandemic on the progress of the project. Particularly, the electronic portfolio will be used by our partners to organise the 5-days training for opinion leaders and data collectors. The portfolio will also contribute to develop a MOOC for health care professionals from hospitals participating or not in the QUALI-DEC project.

The findings of the baseline formative research and cross-sectional survey will be used to build research capacity for analysis and writing of scientific peer-review publications at country level. As planned in the original protocol, these results were already used to adapt the QUALI-DEC intervention.

We expect that the implementation of the QUALI-DEC intervention will be beneficial for:

- empowering women and improving women's participation in the decision-making process regarding mode of birth (with the information provided through the DAT);
- supporting women at labour and delivery (by fostering companionship in all hospitals and the information provided through the DAT);
- implementing best practices in clinical care (with the help of the opinion leaders, the audit cycles for caesarean section indications in low-risk women and the use of clinical protocols);
- promoting better knowledge and attitudes of health professionals and women for an improved decision-making process and quality of care;
- optimization of caesarean section use;
- improvement of maternal and perinatal outcomes.

Specifically, the findings of QUALI-DEC project will help to change the national guidelines in Vietnam whom update is rather slow. It also helps Vietnamese policy managers to develop quality of care indicators that hospitals could document afterwards.

In Thailand, the decision-analysis tool was included in the Thai national antenatal care booklet. For this reason, we expect that the impact will extend beyond the participating hospitals in this country.

Reducing C-sections will have a significant impact on quality of care for women and new-borns by reducing short-term and long-term complications. It will also reduce unnecessary healthcare expenditure.

Reduction of unnecessary C-section (QUALI-DEC project) should be scaled up to other hospitals in participating countries.

The first 18 months of the project have been very challenging for the consortium, taking into account the worldwide pandemics. Despite the challenges, the partners had developed very tight relations, a very comprehensive and fluid communication, always keeping in mind the goal for which they put their efforts together: quality of care for women. The consortium is happy to work together and no problems have been encountered at this stage.

1.4. Access provisions to Research Infrastructures (if applicable)

Not applicable.

1.5. Resources used to provide access to Research Infrastructures

Not applicable.

2. Update of the plan for exploitation and dissemination of result (if applicable)

The plan for exploitation and dissemination of results as described in the DoA does not need to be updated at this stage of the project.

3. Update of the data management plan (if applicable)

The data management plan as described in the DoA does not need to be updated at this stage of the project.

4. Follow-up of recommendations and comments from previous review(s) (if applicable)

Not applicable.

5. Deviations from Annex 1 and Annex 2

Explain the reasons for deviations from the DoA, the consequences and the proposed corrective actions.

Due to Covid-19 pandemics the project's activities are delayed by 19 months overall: for Burkina Faso, there is a 12 months delay, for Thailand, 15 months, for Vietnam 18 months and for Argentina 19 months. These delays affect the implementation of the tasks of the project, as field work couldn't be done as planned. For some activities, we proposed instead online platforms, such as for the training of Opinion Leaders and Data Collectors in the 4 countries. However, some activities, such as field work in the hospitals, cannot be done online, so we wait for an improvement of the Covid-19 situation. At the moment, we cannot foresee what additional time the project will need to be completed, this will depend on the activities implemented in the following years to come.

5.1 Tasks

Include explanations for tasks not fully implemented, critical objectives not fully achieved and/or not being on schedule. Explain also the impact on other tasks on the available resources and the planning.

FB: The task 3.1 Training opinion leaders and data collectors, led by beneficiary FB is aiming at providing training tools (such as clinical guidelines, Robson classification table, audit report and decision-analysis tool) to the Opinion leaders and Data collectors from the 4 study countries in the project: Argentina, Burkina Faso, Thailand, Vietnam. Due to Covid-19 situation, the trainings couldn't be made face-to-face, hence FB purchased an e-learning platform to set-up the online 5-days training sessions. Therefore, this platform will be used to do the online training for OL & DC throughout the project to train the OL and DC. The information has been added in Participant Portal System, in the "Short description" section for the corresponding item, because in the explanations section it didn't allow it (arguing that the box was intended for those costs only if not foreseen in Annex I).

IRSS: IRSS beneficiary had to rent a room with a stable enough connection for effective participation in the kick-off meeting organized online in March 2020, due to the COVID -19 pandemics, since the IRSS internet connection was instable and couldn't allow the participation in the meeting. Sometimes in Burkina Faso the internet connection is not good enough to participate in visio conferences.

PNT:

Deep Interviews (169.00 €) corresponds to the purchasing of two recording audio devices on 25/08/2020. These devices are used to record interviews with pregnant women, healthcare providers and the relative of the pregnant women in the qualitative study (WP 4 and WP5).

Hall and device for training (1,270.00 €) corresponds to the cost of renting a venue (Hall) and speakers, microphones, Wi-Fi in Hai Phong and Ho Chi Minh City for training the social scientists on April 23-24, 2020 and May 04-05, 2020. This activity aims to train social scientists and data abstractors for perform the postnatal surveys in WP5.

5.2 Use of Ressources

Include explanations on deviations of the use of resources between actual and planned use of resources in Annex 1, especially related to person-months per work package. Include explanations on transfer of costs categories (if applicable). Include explanations on adjustments to previous financial statements (if applicable).

IRD: IRD's personnel costs budget intends to cover salary cost for the project manager, and also knowledge transfer personnel (as of P2), while IRD's total project efforts include work efforts for also project coordinator and senior researcher (WP2) as well as knowledge transfer personnel (WP7). IRD's personal cost is broken down into two work packages:

- **W2:** 155 PM corresponds to time spent of project manager (Delia Visan), of the project coordinator (Alexandre Dumont) and a senior researcher (Myriam de Loenzien) from IRD. Both IRD researchers spent time on the Quali-Dec project, but do not claim a reimbursement from the EU grant. The personnel costs claimed in the current report comprise the costs for the project manager only (Delia Visan), which corresponds to IRD salary of a category A personnel, according to French law. These same costs will occur in the future.

- **WP7:** 169 PM corresponds to knowledge transfer personnel (Sub-Task 7.3.1, M31-M60) to be recruited in Argentina, Burkina Faso, Thailand, Vietnam, to implement knowledge brokering activities. The working contracts are made directly in the respective countries, according to the national law and their costs are approximatively 1000-1300 euros. The costs have not been claimed in period 1, but might occur starting period 2. The average personnel costs will evolve during the next periods, given that the average cost for a knowledge transfer personnel is 1.000-1.300 €, according to the countries (Argentina, Burkina Faso, Thailand, Vietnam).

Other direct costs: we acknowledge receipt of the information provided regarding the "internship gratification", the cost claim is removed from the Participant Portal.

Other direct costs: we acknowledge receipt of the information on Mac computers, the cost claim is removed from the Participant Portal. Since travels have not been possible, a specific software NEW NVIVO FOR WINDOWS and CLOUD subscription (4 005,05€) has been to collect and transcribe data for Quali-Dec research project social science study Women's empowerment and mode of childbirth (WP5, task 5.1. Characterization of societal context (M1-M6). This study leans on a secondary analysis of interviews done during the performative research in Burkina Faso, Thailand and Vietnam.

NUID- UCD: The person-months of 0.54 and personnel costs of €11,418 as stated in UCD's financial report are correct. This corresponds to professor Michael Robson's effort, who devoted 78 hours to the project in the first reporting period. His hourly rate during that period was €146.39 per hour. The UCD budget allocated to personnel costs for the whole project is €29,700. For the remainder of the project following on from RP1 the input will reduce accordingly.

5.2.1 Unforeseen subcontracting

In Sections 5.2.1 Unforeseen subcontracting, specify in this section for each unforeseen subcontracting: a) the work (in what WP/the tasks) performed by a subcontractor which may cover only a limited part of the project; b) explanation of the circumstances which caused the need for the unforeseen subcontract, taking into account the specific characteristics of the project; c) the confirmation that the subcontractor has been selected ensuring the best value for money or, if appropriate, the lowest price and avoiding any conflict of interests.

IRD reports unforeseen costs of subcontracting (2 960.96 €) which corresponds to the translation of the Decision Analysis Tool (DAT) from English into Thai language. The DAT is one of the component of the intervention, which targets pregnant women in each participating country. For this reason, it had to be translated into local languages (Thai, Vietnamese…). Each document was about 20 pages. This is part of WP3: intervention implementation. KKU beneficiary has selected the subcontractor (translator) ensuring the best value for money.

5.2.2 Unforeseen use of in kind contribution from third party against payment or free of charges*, if applicable.*

Since COVID epidemics started, IRD researcher (Myriam de Loenzien) has not been able to travel to work with social scientist on the field (WP5, task 5.3). For this reason, IRD needed to involve our social scientist colleague in Burkina Faso. Hence, *IRD reports unforeseen costs of subcontracting (1 542.17) which correspond to* short-term contracts with a social scientist in Burkina Faso, to conduct secondary analysis of qualitative interviews with pregnant and post-partum women, their relatives and healthcare workers. This study allowed us to document potential links between women's empowerment and the decision process regarding childbirth that results in caesarean section. It helped us to design the survey that will be conducted after the intervention to measure its impact from a gender perspective.

6. Impact on SMEs (Option for all projects with an SME)

Fundacion Blanquerna beneficiary is an SME.

Fundacion Blanquerna	Turnover of the company at the beginning of the project/most recent accountability period from the beginning of the project	Number of employees at the beginning of the project/ most recent accountability period from the beginning of the project	Turnover of the company at the most recent accountability period	Number of employees at the most recent accountability period
Fundacion Blanquerna	2018-2019 (closing date Aug-2019) 47.711.497,29 €	720	2018-2019 (closing date Aug-2019) 47.711.497,29 €	720