HESVIC project

Project methodology for studying and assessing regulation and governance in Vietnam, India and China

Deliverable D 1.2.a

Grant agreement number	222970
Project acronym	HESVIC
Project title	Health system stewardship in Vietnam, India and China
Funding scheme	FP7–HEALTH–2007-B
Due date of deliverable	August 2010
Actual submission date	November 2010
Version	Final
Dissemination level	Public

Deliverable authors	HESVIC ITM Team
Acknowledgements	Thanks to all HESVIC partners for their contributions.
Suggested citation	Public Policy and Management Unit, Department of Public Health, Institute of Tropical Medicine, Antwerp (2010). Project methodology for evaluating stewardship and regulation in the study countries. Deliverable D 1.2. HESVIC project 'Health system stewardship and regulation in Vietnam, India and China.
HESVIC	HESVIC is a three-year research project (2009-12) being implemented under the European Community Seventh Framework Programme (FP7). The project aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice through a comparative study of three Asian countries – Vietnam, India and China. The project uses maternal health care services as a case study of stewardship and regulation. The goal is to support policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage of health care in the three countries. **HESVIC partner organisations** Nuffield Centre for International Health and Development (NCIHD), Leeds Institute of Health Sciences, University of Leeds, UK Hanoi School of Public Health (HSPH), Vietnam Fudan School of Public Health (FU), Fudan University, China Institute of Public Health (IPH), Bengaluru, India Department of Public Health, Prince Leopold Institute of Tropical Medicine (ITM), Belgium Social Development and Gender Equity, Royal Tropical Institute (KIT), Netherlands
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Table of contents

TABLE OF CONTENTS **3**

LIST OF ABBREVIATIONS **5**

1. INTRODUCTION **6**

2. SCOPE, BOUNDARIES AND RESEARCH QUESTIONS OF THE STUDY **7**

2.1 UNDERLINING THE MAJOR PRINCIPLES 7
2.2 RESEARCH QUESTIONS 8

3. RESEARCH PROCESS, CASE STUDIES AND PHASED APPROACH **11**

3.1 THE DEFINITION OF CASE STUDIES 11
3.2 PHASED APPROACH 11

4. PHASE ONE – CASE STUDY AND REGULATION ANALYSIS **16**

4.1 STEP 1: IDENTIFYING MATERNAL HEALTH PROBLEMS AND ACHIEVEMENTS AND SELECTING ONE REGULATION FOR EACH CASE STUDY 17
4.2 STEP 2: DESCRIPTION OF REGULATIONS BY DOCUMENT REVIEW 18
4.3 STEP 3: IDENTIFYING AND INTERVIEWING ACTORS INVOLVED IN REGULATION 25
4.4 STEP 4: ADAPTING TOOLS FOR DATA COLLECTION (PILOTING IF NEEDED) 31
4.5 STEP 5: PHASE ONE DATA COLLECTION AND ANALYSIS 34
4.6 PHASE ONE SUMMARY 34

5. PHASE TWO – MAIN DATA COLLECTION **36**

5.1 STEP 1: DEVELOPING, ADAPTING AND PILOTING RESEARCH TOOLS 36
5.2 STEP 2: DATA COLLECTION AND IN-COUNTRY ANALYSIS 38

6. PHASE THREE – MAIN DATA ANALYSIS AND FOLLOW-UP **44**

6.1 STEP 1: ANSWERING RESEARCH QUESTIONS 1, 2 AND 3 44
6.2 STEP 2: ANSWERING RESEARCH QUESTIONS 4 AND 5 45
6.3 STEP 3: VALIDATION OF ANALYSIS 45
6.4 APPROACH TO ANALYSIS USED IN PHASE THREE 45

7. KEY METHODOLOGICAL ISSUES **53**

7.1 ETHICAL ISSUES IN ANALYSIS 53
7.2 COMPARABILITY ACROSS COUNTRIES 54
7.3 DATA COLLECTION 54
7.4 DATA ANALYSIS 54
7.5 LANGUAGES 55

8. PERSONNEL **57**

8.1 RESEARCH TEAMS 57
8.2 PAIRED PARTNERS 57
8. 3 SCIENTIFIC LEAD (WORK PACKAGE 1) 58
8.4 COUNTRY RESEARCH ADVISORY GROUPS (CRAGS) 58
8. 5 TRAINING 58

9. EQUIPMENT AND SUPPLIES **59**

10. TIMELINE, DELIVERABLES AND MILESTONES **60**

ANNEX 1 ..... **I**

ANNEX 2 ..... **VIII**

ANNEX 3 ..... **IX**

ANNEX 4 ..... **XVIII**

ANNEX 5 ..... **XXII**

ANNEX 6 ..... **XXXII**

ANNEX 7 ..... **XLI**
ANNEX 8 ..... **XLV**
REFERENCES ..... **LV**

List of abbreviations

Acronym	Definition
ANC	Antenatal care
CD	Capacity Development
CRAGs	Country Research Advisory Groups
CRWP	Country Research Work Plan
EC	European Commission
EmOC	Emergency Obstetric Care
FGD	Focus Group Discussion
FLS	First Line Services
FU	Fudan University (Shanghai, P.R. China)
GR	Grievance Redressal
HEPVIC	Health policy-making in Vietnam, India and China
HESVIC	Health system stewardship and regulation in Vietnam, India and China
HSPH	Hanoi School of Public Health (Hanoi, Vietnam)
IMMPACT	Initiative for Maternal Mortality Programme Assessment
IPH	Institute of Public Health (Bengaluru, India)
IRB	Institutional Review Board
ITM	Institute of Tropical Medicine (Antwerp, Belgium)
KIT	Royal Tropical Institute (Amsterdam, The Netherlands)
KM	Knowledge Management
NCIHD	Nuffield Center for International Health and Development (University of Leeds, United Kingdom)
NGO	Non-Governmental Organization
PI	Principal Investigator
SBA	Skilled Birth Attendant
SSI	Semi-Structured Interview
UN	United Nations
UNFPA	United Nations Population Fund
USAID	United States Agency for International Development
WHO	World Health Organization

1. Introduction

The current Deliverable 1.2.a (D 1.2.a) is a detailed follow up of Deliverable 1.1 (D 1.1) which provided the broad research framework.

This document details the research methodology and methods, describing the research phases and associated research steps. It also explains the logical relationship between research phases and steps - and between research questions, tools, and overall research objectives.

It is acknowledged that parts of this document draw on previous HEPVIC research manuals.

D 1.2.a will be updated (to become D 1.2.b) once the case studies of maternal health and the related regulations have been explored (end of Phase One).
At the end of this D 1.2.a, in its Annex 8, a HESVIC terminology glossary is provided aiming at facilitating a common understanding of key concepts and themes among partners. This glossary will be a dynamic work in progress as the research process will go along. Therefore its current version in Annex 8 is not to be regarded as a definitive one and will be constantly updated as need arises.

2. Scope, boundaries and research questions of the study

The consortium has agreed on a number of important principles, which underpin the research methodology.

2.1 Underlining the major principles

Box 1: Major principles of HESVIC research

1. The primary research focus for HESVIC is on regulation and the secondary focus on governance. This was confirmed in D 1.1 on the broad research framework;

2. The study of regulations (procedures, processes, approach and effects) will be informed by problems and achievements with respect to equity in access to quality maternal health care. The aim is to study how key issues in these domains are influenced by regulation and by governance. These issues will be identified and studied mainly from secondary data and from the country mapping reports;

3. Governance principles will be examined through insights into regulations;

4. The research methodology will be flexible enough to accommodate information needs, while remaining feasible in the three study countries;

5. The study will attempt to achieve an optimal balance between context-specificity and comparability of results across the three study countries;

6. The research process will be cyclic, to enable exploration and validation. This means that complementary information could be added, depending on initial findings. Any additions will, however, respect the main research objectives and take into account the feasibility of data collection and need for comparative analysis;

7. The overall research methodology will be largely exploratory and interpretative;

8. A case study approach will be used to explore the effects of regulation on equitable access to quality maternal health services and to assess governance.

9. The research process will be incremental i.e. phased ;

10. The study of the relationship between maternal health and regulation will be a complementary one. For example, we will study regulation of EmOC using access to quality care as an entry point. We will also study grievance redressal with respect to identified regulations. .

Both public and (formal and informal) private sectors will be scrutinised, taking into consideration the contexts and history of health policy and practice. The focus will be on formal regulatory procedures. Informal procedures will, however, also be considered if and when they are detected.

2.2 Research questions

We define 'regulation' as a way of intervening in both the public and private provision of health care to ensure that certain quality and equity standards are met, and to enhance the social role of its actors. We will thus address regulation as it relates to the specific context in which health care is provided.

Health system regulation is a responsibility of governments and relies on bureaucratic and administrative control. It may or not be reinforced with enabling incentives and/or through the participation of non-governmental stakeholders and the private bodies that regulate their members. Regulation can thus take the form of control or incentives, the majority of health systems being subject to various combinations of the two (HESVIC technical annex).

The effect of regulation on equitable access to quality health care represents the core of the HESVIC study. However, in order to identify the effects of regulation, other factors affecting access to health care and outputs of the substance and structure of the regulatory environment also require consideration. In order to effect change in access to quality care, it may, for example, be necessary to re-organize administrative processes.'[a] To this end, the project will also collect and analyze (secondary) data on prevailing maternal health practice in Vietnam, India and China.

Understanding of the features of maternal health practice will inform subsequent study of current approaches, practices and capacities with respect to regulation. These areas will be explored within each of the three study countries and. comparisons will be made across countries.

This implies a dialogue between the following:

- The study of regulations and their determinants;
- Consideration of social and professional practice: e.g. problems and achievements in maternal health in the three study countries (HESVIC technical annex; B.1.3.1 page 14).

The consortium has agreed that the research scope will be based on a set of research questions, bounded by a shared understanding of definitions of governance and regulation. A set of one overarching and five research questions with their sub questions is presented in Box 2 on the next page.

[a] L.Kumaranayake. effective regulation of private health sector service providers. LSHTM, 1998.
[a] Marquez P, 1990. Containing health care costs in the Americas. Health policy and Planning, 5 4), 299-315 (p23)

Box 2: Research questions and sub-questions defined in D 1.1

Overarching Question: How does regulation, and through it governance, affect equitable access to quality health care?

RQ1. What **approaches and processes** exist for regulating maternal health care and how do they operate in practice?
- a. What are the approaches (A, B, C, D) of regulation: comparison across the maternal health system?
- b. How is regulation interpreted and implemented in practice?
- c. What are the strengths and problems of these approaches and processes?
- d. Why do these approaches and processes exist in these contexts?
- e. What does regulation intent to achieve? For whom, to what end?
- f. What is the role of information in regulatory processes?

RQ2. Who are the **actors** involved in the regulation of maternal health care, what are their roles and power relations?
- a. Who are the actors in the different approaches and processes of regulation?
- b. What are the aims and priorities of these actors?
- c. How are these actors involved in the different approaches and processes, and to what degree?
- d. How do these actors relate to each other?
- e. What is the level of influence of these actors on regulation of equitable access to quality maternal health care?
- f. Context and history.

RQ3. What are the **effects** of regulation on equitable access to quality maternal health care?
- a. What is the current status of and obstacles to equitable access to quality maternal health care?
- b. To what extent are these obstacles addressed in existing regulations?
- c. What are the effects of regulation (approaches and processes) on quality of maternal health care?
- d. What are the effects of regulation (approaches and processes) on equitable access (to quality maternal health care)?

RQ4. What are the **differences or similarities** between regulation of maternal health care and health care in general?
- a. What are the differences or similarities between regulatory approaches, processes, actors and effects?
- b. If there are differences, why is it so?
- c. What are the implications of HESVIC findings for equitable access to quality health care in general?

RQ5. How could regulation be **improved** to enhance equitable access to quality maternal health care?

All research questions will be the same across all three countries. However, exploration of specific additional areas of interest relevant to the research questions in particular countries will be considered (opportunities for marginal, different research issues). For instance, the issue of abortion could be explored in India, as it represents an issue of particular relevance there.

To answer the research questions, three case studies will be conducted in each of the three countries. Each case study will reflect an area of maternal health services with respect to which the regulation is to be studied, or an area of regulation, as applied within maternal health care. The idea is to study key issues (problems and achievements) in these domains and to explore whether and how they are influenced by regulation and governance.

Our study will describe processes of regulation. Study of maternal health services and its delivery problems and achievements will inform assessment of regulatory issues and of the role of actors and the environment.

The research will be phased, with a possibility also of iterative loop (for instance when answering research question 1, 4, and 5).

3. Research process, case studies and phased approach

3.1 The definition of case studies

The proposed research will approach regulation and its effects on maternal health care outcomes through case studies.

The selected case studies are represented in Table 1a below.

Table 1a: Case studies in each of the study countries

	Vietnam	India	China
Emergency obstetric care	●	●	●
Grievance redressal	●	●	●
Abortion		●	
Antenatal care[b]	●		●

All 3 Asian partners will study emergency obstetric care (EmOC) and grievance redressal (GR) procedures. In addition, China and Vietnam will study antenatal care (ANC) and India will study abortion.

In order to ensure inter-country comparability, certain areas of focus will be addressed by all case studies in all countries. These thematic areas are represented in Table 1b below.

Table 1b: Thematic areas and associated regulations, by country

	Vietnam	India	China
EmOC	Techniques for comprehensive EmOC and its regulation	Comprehensive EmOC and its regulation	EmOC management issues and its regulation
GR	Processing of complaints within GR and its regulation	Processing of GR complaints within the consumer protection act	Processing of GR complaints in hospitals and its regulation
Abortion		PND, e.g. for sex selection and its regulation	
ANC	Prenatal diagnosis (PND), e.g. for sex selection and its regulation		PND, e.g. for birth defects, and its regulation

3.2 Phased approach

The consortium has agreed on a methodology in terms of which research questions will be answered through sequential research phases, each consisting of a number of

[b] The technical annex of HESVIC has foreseen the exploration of antenatal, postnatal and EmOC case studies.

steps. The overall HESVIC research design will be structured around the following phases:

- ***A preparatory phase*** – in which the broad research framework (D 1.1) and the research methodology (current D 1.2.a) are elaborated;
- ***Phase One*** – in which preliminary data collection and data analysis is conducted to achieve a broad overview of the regulatory environment (who, what) within the different countries;
- ***Phase Two*** – in which the main country-based data collection and analysis is carried out;

- ***Phase Three*** – in which the main country-specific and comparative data analysis and follow-up is conducted.

The advantage of this phased approach is that it allows research work to be organised in a timelier manner, while maintaining an overview of the broader project. A potential disadvantage is the possibility of some overlap between phases and steps, which needs to be continuously checked and accounted for.

During these phases, the data collection will be the primary responsibility of the study country partners, supported by their respective paired partners. Data collection will occur during the three Phases of the research process. Dissemination of preliminary and final results will be an integral part of each Phase.

Figure 1 on the next page represents an overview from Phase One to Phase Three of this phased approach. It shows how Phase Two and Phase Three are informed by the results of the previous phases.

Figures 2 and 3 on the following pages give a summary and time-line of the development of the overall research methodology.

Figure 1: Summary of phased HESVIC research design

Phase One
Preliminary data collection and data analysis

Starting point
- D1.1 Broad methodology framework
- Deliverable D 1.2.a
- Country research work plans

Objectives
- To carry out a preliminary study of key issues, problems and achievements within maternal health care delivery for each case study;
- To identify key regulations, as well as their processes and procedures and the institutional levels at which they occur, in the case studies;
- To identify relevant actors at the different institutional levels as potential future respondents for data collection in Phases One and Two;

Activities
- Secondary (grey and scientific literature) data collection;
- Primary data collection not excluded;
- Preliminary analysis;
- Identification of key actors relevant to regulation, this includes those actors to be interviewed;
- Development of tools for data collection;
- Data collection by semi-structured interviews;
- Development of an analytic framework for Phase Two, intended to capture problems and successes.

Data collection methods
- Semi-structured interviews;
- Focused literature review;
- International summary timeline diagram;
- Secondary analysis of quantitative data;
- Interviews.

Outputs
- Phase One Summary

Phase Two
Main data collection

Starting point
- Phase One Summary

Objectives
- To understand regulation relevant to the maternal health case studies;
- To assess the substance and effects of regulation as it relates to maternal health problems and achievements at country level;
- To understand the agendas of relevant actors (where they stand, what they think);
- To identify environmental factors relevant to regulatory mechanisms and processes.

Activities
- Development and piloting of all tools- including country adaptation;
- In-depth data collection;
- Data analysis (country-based).

Data collection methods
- Semi-structured interviews;
- Documents review;
- Focus group discussions;
- Participatory stakeholder workshops.

Outputs
- In-depth data on maternal health regulation processes and procedures;
- Country reports;
- Framework for comparative analysis.

Phase Three
Main country-specific and comparative analysis and follow-up

Starting point
- Phase Two data in country reports

Objectives
- To analyze and compare the findings in country reports data collected in Phase Two (and One);
- To explore and validate the findings with selected respondents.

Activities
- Data analysis (country-specific and comparative);
- Follow-up with respondents.

Data collection methods
- Follow-up semi-structured interviews;
- Participatory stakeholder and validation workshops.

Outputs
- Country reports (revised after validation activities);
- Comparative report.

Figure 2: The process of developing research methodology – part 1

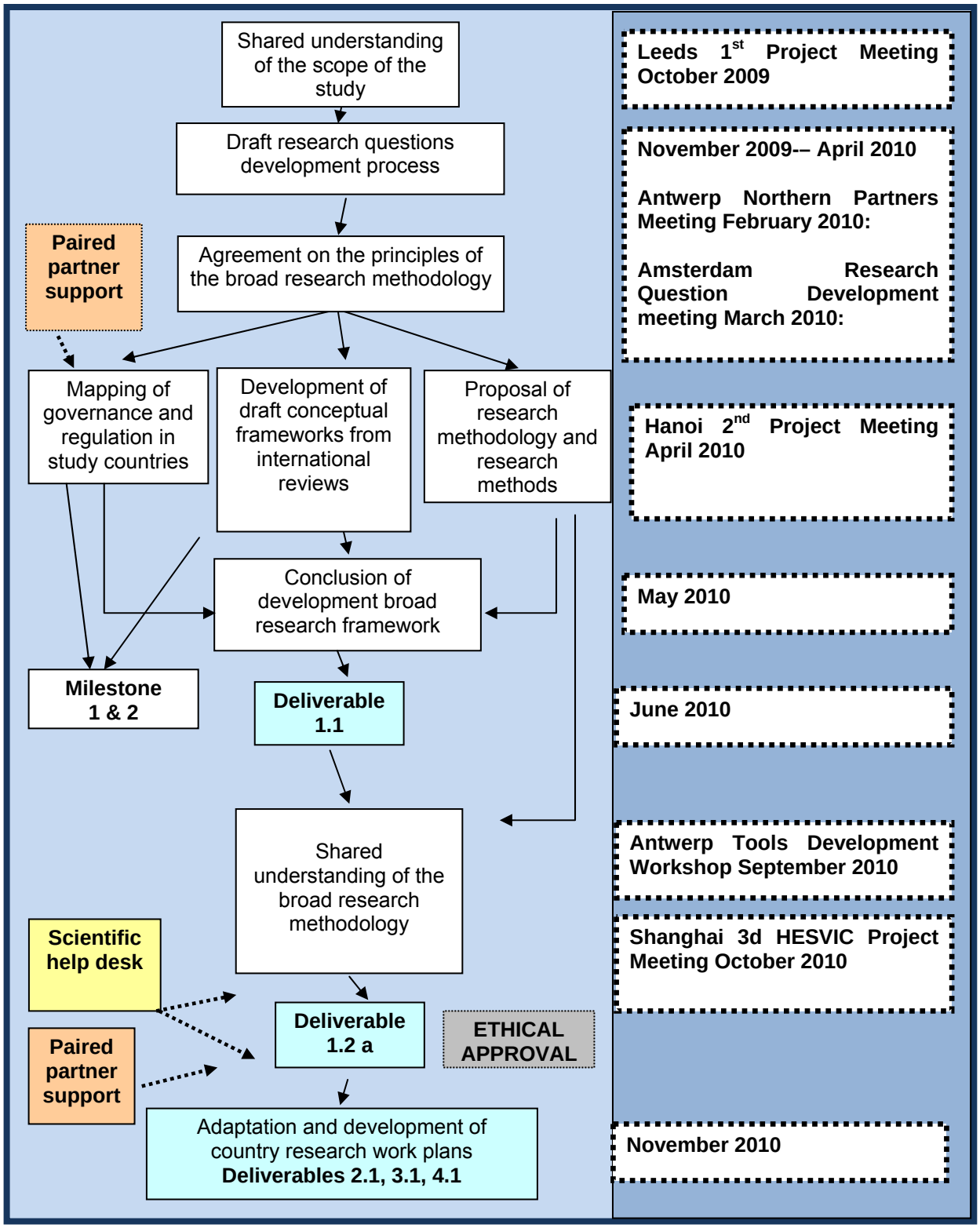
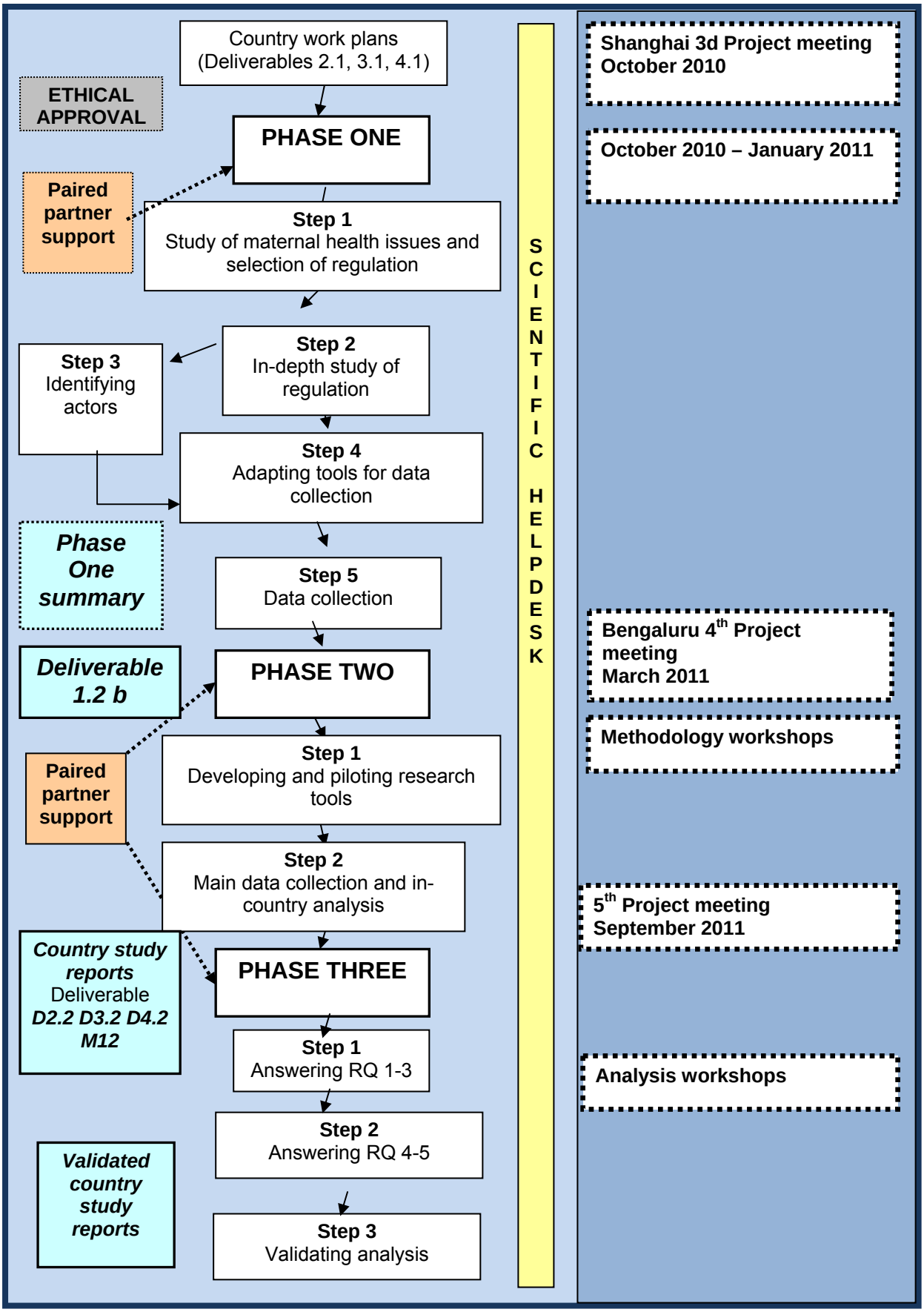


Figure 3: The process of developing research methodology – Part 2



4. Phase One – Case study and regulation analysis

The aim of Phase One is to study regulation procedures (content and substance), processes and approaches) through document review and from the perspectives of identified groups of respondents. This study will be informed by a preliminary study of prevailing maternal health practice in the research countries.

Phase One looks mainly for an answer to the questions “what?”, “who?” and “how?” with respect to regulation. Through the in-depth understanding of regulation that the answers to these questions will provide, Phase One aims further to provide a solid basis for the assessment of regulation during Phase Two.

The specific objectives of Phase One are the following:

- A case-specific preliminary study is carried out (3 per country) to explore key issues, problems and achievements within prevailing maternal health practice in services and care delivery;
- Key regulations are identified in the case studies. Their processes and procedures as well as the institutional levels at which they occur (formulation or definition of the regulation, its administration and implementation thereafter) are described with reference to case-specific problems and achievements;
- Relevant actors are identified at the different institutional levels, to be considered as future respondents for data collection in Phases One and Two;
- The tools required to implement the methodology are developed and used for data collection.

Phase One consists of 5 steps. Some of these will be conducted sequentially. Others, such as step 4, will run concurrently.

This section details the methods to be used in Phase One, in step-by-step sequence. Most of these methods will involve collection and analysis of secondary data. In some cases, a limited quantity of primary data might be required at the beginning of Phase One, step 1. This decision should be made in each case by the Southern partners. For example, the IPH partner in Bengaluru reports that it faces a lack of secondary data in some areas of maternal health service. It proposes, therefore, to perform a limited number of interface flow process audits. To this end, it will use the patient's experience as a way of defining a. his/her access to quality care and b. the relevance of regulations for understanding quality of care and system organization. Although this data may not be comparable across the three countries, they are important for the research process in India.

4.1 Step 1: Identifying maternal health problems and achievements and selecting one regulation for each case study

In Phase One, step 1, problems and achievements in maternal health practice for each of the case studies will be identified through a review of secondary literature and the mapping reports. The case studies will be EmOC, ANC, abortion, and GR. It is important that the focus of each case study is clearly justified in terms of the review of maternal health problems and achievements. Similarly, the choice of regulation on which each case study will focus needs to be linked to the identified problems and achievements and needs to be justified in terms of its potential impact on equitable access to quality health care. Relevance of the case study and regulation for the maternal health problem should also be clarified, as should the feasibility of each study for the respective research team. Partners will utilise Annex 1 of D 1.2.a in their rationale but are not restricted to this.

The emphasis should be on key maternal health problems and achievements, especially those of critical significance to the HESVIC objectives. Special attention will be given to the selected populations (e.g. resident vs. floating population in Shanghai, minority versus majority Kinh ethnic populations in Vietnam, scheduled casts vs. others in India) and to facilities (e.g. North vs. South Karnataka in India, private vs. public) across the spectrum of the health care system.

Box 3: Examples of problems and achievements in maternal health care and regulation

	Problems	Achievements
Generic definition	*In maternal health, problems result mainly from poor functioning of health care delivery services.*	*A health system outputs may be surprising when for instance it is relatively good although regulation is assessed as being poor*
Maternal health care	Deficient health status, inequities among population strata. Malfunctioning of health care delivery services, lack of access to C-sections in some population segments, poor quality of care, such as excessive C-section rate in others[c].	As an example at a macro level: the Karnataka and Kerala maternal mortality rates are amongst the best in India[d]; the Chinese maternal mortality rate is an outlier in the international MMR / GDP curve. Wide variations in MMR exist between VIC countries. Good results of health care systems may be unexpected / paradoxical when, for instance, a health service functions better than another although its professionals earn less. Another such paradox is when facilities with a social or public mission do better then those that aim to fit supply to demand.
Regulation	Generally, malfunctioning of an existing regulation mechanism can be traced to flaws in the regulation processes .	Successful implementation of a regulation and demonstrated achievement of a desired maternal health care outcome, e.g. implementation of three antenatal control

[c] Purposely, we used this example (derived from mapping reports) to show that one same parameter (C-section rate) can be used as an indicator of care quality and of access, while making an explicit link to regulation. If a C-section rate for example, is quite high, the regulation of it (e.g. guidelines on their indication and related legal texts) and its implementation will have to be scrutinized – together with its eventual capacity to generate complementary income to health professionals.
[d] HESVIC, India mapping report.

		visits during pregnancy with an acceptable capture of high risk deliveries and higher SBA rate in this group than in the rest of the population.

Box 3 (above) offers an illustrative overview of problems and achievements in maternal health care and regulation, with some examples. In order to organize the required information, the current D 1.2.a provides (in Annex 1) a matrix with indicators and quality criteria for assessing the issues faced by women who use health services in the context of these case studies. In this Annex 1, indicators are ordered in a sense of essential to non-essential indicators of quality of care. Countries will be free to make the final choice. Annex 1 should be used in accordance with the guidelines presented for this step below. Annex 2 offers a model for assessing accessibility to health care, if needed. This model disaggregates healthcare by type of facility[e] and by type of case study.

Step 1 will provide essential information to guide the regulation study in step 2. It will also provide some information relevant to answering sub-questions a and b of research question 3, in that the chosen approach views achievements and problems as possible markers of the quality of regulation in practice. Problems and achievements are thus treated, to some extent, as an outcome of regulatory substance and structure.

4.2 Step 2: Description of regulations by document review

In Phase One, step 2, the procedures (content, substance and structure), and processes of identified regulations will be explored by document review and described in-depth in order to answer questions on 'what' and 'how'[f]. Step 2 will produce some aspects of the answers to research questions 1 and 2. Differences between national patterns and regulatory features observed in the research regions will be explored.

It should not be forgotten that when selecting a relevant regulation, it may be desirable to identify a variety of regulations dealing with quality, equity and rights to health across the three case-studies and (inter-)nationally. This will allow for comparative study.This will in turn inform the administration of regulation processes. All this will contribute towards assessment of regulation, of the regulatory approach in particular, and of governance, at a later stage (Phase Two).

The regulation document review will identify the following:
- the regulations to inform data collection in Phase One, step 5, and in Phase Two;
- a content analysis of regulations.

[e] Besides its clinical function, the type of facility can be defined by its status, i.e. public (Ministry of Health and public insurance schemes, etc.) or private (for profit or not for profit). This way of defining the type of facility by institutional affiliation pre-dates more recent literature. Publicly owned hospitals in Vietnam and China can provide different services to fee paying delivery clients. In India informal payments in public facilities are well recorded. See HESVIC International Review Paper *Reversing the Gaze: Street level realities of health markets,* pg 8-9. In other words, the type of facility can also be defined by its status and mission (being social, commercial or mixed).

[f] Their assessment will be explored in-depth later, during data collection in Phase Two and at the analysis in Phase Three (see further), when researching the effects of the regulations under scrutiny.

The description will encompass both regulations and guidelines. Annex 3 presents a detailed framework for assessing procedures (content, substance and structure), and processes of regulation. The description will address their objectives, underlying principles, the way they are enforced or promoted (the regulation substance) and the institutions involved (the regulatory structure). Substance and structure that is unlikely to be effective (identifiable by the lack of supportive evidence) will be discussed in the process description and in the analysis of the relationships between actors and the environment.

Problems and achievements with regulation procedures (content, substance and structure), and processes will be studied at this early stage as relationships will have to be established between the maternal cases and the regulations being analysed. Problems with the design and implementation of a regulation may be critical for certain aspects of maternal health care delivery and access. These potential consequences of a regulation will be considered in Phase Two – partly on the basis of hypotheses formulated at the end of Phase One (for instance, the very high C-section rate is due to problems with the implementation of an existing, well-conceived regulation, in turn related to the poor salaries of controllers).

The description will be based on direct analysis of relevant regulations and on secondary literature analysis.

4.2.1 Methods used in step 2: focused review of documents, grey and scientific literature and collection of secondary, quantitative data

The above issues will be identified mainly through a review of secondary literature, including scientific papers, grey literature and other sources, such as government reports and media.

Although somewhat underutilised in health systems research, documents have particular strengths not captured by the other research methods to be used in this project. First, unlike speech and action, documents persist beyond the local context of their production[g]. As documents are produced before the research, they are unaffected by and unresponsive to the research process. Second, documents are a form of formalised communication. They provide information about the people who produced them (e.g. knowledge, interests and position) and about the social and historical context within which they were produced. They are produced (often with input from multiple actors), circulated and consumed by a variety of different parties. Documents also represent a further data source to be triangulated with other sources.

Literature review and document analysis have to be considered in relation to the identified case studies (Phase One, step 1), providing an overview and ways in which to approach them. Scientific papers will provide material relevant to our study and help orient the search for reliable grey literature[h]. Ministry of Health and other grey literature could then help to specify where necessary.

[g] Miller FA, Alvardo K (2005) Incorporating documents into qualitative nursing research. *Journal of Nursing Scholarship*, 37(4), 348-53.

[h] As an example: Zhu et al report a lack of equity in maternal health status amongst resident vs. floating populations in Shanghai. Zhu L, Qin M, Du L, Jia W, Yang Q, Walker M, Wen S. Comparison of maternal mortality between migrating population and permanent residents in Shanghai, China, 1996–2005. BJOG 2009;116:401–407

National data sets and statistics can also be used while performing the case studies. We know from our reviews and mapping reports that there is an abundance of literature on maternal health (see international review of Actors, Maternal Health and Regulation and governance). We do not know, however, the extent to which this literature applies to the case studies separately or to the umbrella of studies on maternal health care. Both should be searched using Google Scholar and the methods utilised in the country mapping reports. Paired partners will offer help, support and advice where needed. Checking the references from country mapping and the international reviews will be a good first step.

4.2.1.1 Sampling of literature

Details of criteria for selection of literature are outlined in this section. Secondary analysis of quantitative data will rely on easily available data to assess problems and achievements in the case studies. We hope that we will be able to identify and document data available either through health management information systems, or elsewhere, in research reports and studies. Findings from this data will be triangulated with findings from other data sources.

Documents should be obtained during all three Phases of the study and should be identified for the case studies in Phase One, step 1, using the following methods:

- Identification of relevant documents in the mapping report;
- Asking interview respondents to suggest useful documents;
- A search of any available bibliographic databases or libraries;
- A keyword search of newspapers with online archives.[i]

The research team should keep a log of which documents they have tried to obtain, in accordance with the criteria provided in the manual for tools. The unavailability of a certain document identified as relevant, or particular difficulties in obtaining a document, may be of interest in the analysis. It is difficult to predict how many documents will need to be collected and analysed. As a guide, a total of 45 or possibly more documents per study country (i.e. 15 per case study) is likely to be sufficient. A document should be selected for inclusion in the sample if it provides information about some aspect of the regulations or regulation processes that is relevant to the maternal health case studies. It is likely that some of the literature will overlap between case studies. In such instances, reference to the particular case study should be extracted in the summaries.

Specific methods are recommended for the selection of literature for the case studies:

Time Frame

The first step is to set a time frame. We suggest that all literature from approximately the past ten years be collected for each case study - as with the country mapping reports. It is understood however that in Vietnam, for example, regulations were adopted many years ago. Documents produced within the last 10 years may therefore not capture the development/design stage.

Key words

The second step will be to identify key words for each case study. Some key words will apply to the country settings in all three research countries, while others might be

[i] Alternatively, some NGOs may operate newspaper clipping services.

specific to particular countries. These key words should be selected by partners based on their prior knowledge and on the country mapping reports, including those in national and local languages.

Key words will include both a general reference to maternal health care and, more specifically, (as a sub set) to EmOC. Where there are renowned authors or agencies with specialisation or remit in maternal health services (e.g. IMMPACT or a national level entity), their establishment of criteria of good practice and / or regulatory functions should be explored. We request that partners respond in such instances by inserting key words that are nationally, regionally or locally relevant[j];

Box 4: Key words for literature selection

EmOC

Prefix search with maternal health services followed by EmOC.

EmOC- maternal health, C sections, referral systems, EmOC Indicators, quality of care, financing maternal health care, MDGs and maternal health care policy, Maternal Health-EmOC from a comparative perspective, cross national studies, in. maternal health care, maternal health care and access, maternal health care, quality, maternal health care regulations, maternal health care, user charges, maternal health care access, maternal health care,, Websites for national ministries of health, state level health organisations, WHO, UNICEF, UNFPA, EU funded Maternal health care, USAID, World Bank; IMMPACT, etc. There may be many more key words that are relevant specifically to each country setting.

Ante Natal Care

Always prefix search with ANC-

National laws, state laws and rules, services, type of services, variations in services, problems of access, floating populations, vulnerable women reach, regulations of, Alma Ata, primary health care, community participation, women's participation, community ownership, informal fee's, NGOs and delivery of health services, International comparative, contracting, public, private, non-profit, privatisation, commercialisation, user charges effect of, international comparative, maternal mortality, training primary health care workers, quality of care, cross national studies, comparative delivery of, best practice, etc.

Abortion

Always prefix with Abortion

Laws and regulations, policies on., national, regional, state level, services available, changes to laws and rules, public, private, commercial, advertising of, Pre natal diagnosis, access to, awareness of services., women's rights to, illegal abortion, sex selection, stigma of, reproductive health, reproductive right, cost of, access to, vulnerable women, problems of data, definition of complications of, cases of negligence, informal payments, state prosecution, NGOs involved in, comparative perspectives on access to and right of, best practice, etc.

Grievance Redressal

[j] These should be carefully recorded so we can document the process when writing up the methodology

Always test with prefix of grievance redressal. This case is not common in many LMICs so we will have to pre-test the identification of literature with more than one prefix.

Grievance procedure, laws, regulations, standards, health services, cases (name local state, national) reporting complaints procedure maternal health services, public sector, private sector, patients rights, medical negligence cases of, lawyers medical negligence,(meaning those dealing with cases of failed grievance)
Media cases, success stories, maternal death, accidental death or injury, treatment refusal, quality of care standards, exclusion from services, poor quality of service, etc.

4.2.1.2 Labelling documents

As a third step, all documents should then be numbered and labelled (the total search results vs. downloaded vs. speed read) so that we can select a sample of these based on more stringent criteria. As advised earlier in this document, we will need to look in-depth at a minimum of 15 documents per case study, thus a total of 45 per country. A folder in share point will allow partners to share literature through the HESVIC website, for example when documents are peer reviewed papers or represent part of an international report.

4.2.1.3 Document proforma

The final step for the review will involve documentation of the selected cases, following the HESVIC adapted proforma. Some triangulation between documents and interviews will be needed, hence the necessity of using a proforma.

Table 2 gives an overview of how to organise a document proforma:

Table 2: Organisation of a document proforma

Category	**Information**
1. Basic information	
Document code	At the top of each document, write a document number (e.g. doc4), and use the same number, together with the first author, when referring to it in the analysis
Name of researcher(s)and date or period of document analysis and on which Proforma completed	
Full reference of document	Complete citation of document (Author, date, title, series title, publisher, etc.)
Audience for document	Who in your view is the document aimed at? The general public? Academics? Policy makers District health officers? Is it an internal document, only intended for one organisation? Or a multiple audience?
Literature review criteria applied	Key words, date and quality
2. Content and context	
Which maternal health case studies does the document refer to?	Name the case study and country to which this document refers to e.g. EMOC, GR, ANC, Abortion or more than one case

Category	Information
	Type: descriptive, clinical, epidemiological study, report, policy analysis or evaluation, etc.
Brief summary (abstract) of relevant information	The following sections should be brief summaries of content in the document related to the four key determinants in this proforma. This will help the researchers to familiarise themselves with the document, without having to go back to the full-text.
Maternal health problems and achievements	e.g. related to structure, process, outcome or output of services over a period in time with a focus on problems and achievements where mentioned.
Regulation procedures	Brief description if possible
Regulation processes	Brief description if possible
Key actors (who made the policy and who is responsible for implementing it?)	Brief description if possible
3. Information gaps	
Are there any obvious gaps in content?	What is not mentioned in the article on issues of structure, process, outcome and output of maternal health services; their regulation and the quality of care? This would include user perception and voice, the absence of mention of equity and even the absence of mention of regulation where there is an obvious need.
Is this document related to any other documents analysed for HESVIC? If so, which documents, and how?	We are also interested in links between documents. For example, are standards based upon a previously published policy document? Or is a document derived from a national data set and report?
4. Any other comments	
	Anything else about the document you think is relevant to the HESVIC research objectives.

The list of reviewed literature is an evolving one. Additional information may be included at a later stage, if there are important documents published during the course of the study or if gaps are identified during the course of Phase One.

4.2.1. 4 Analysis of documents

The analysis of documents requires some interpretation by the researcher. Some of analysis may be conducted with reference only to one document, whilst some may involve comparing two or more documents. Some analysis may also require comparing information provided in documents with that from other data sources. Analysis will focus both on the content of documents, and on the contexts within which they were produced.

The proforma can only ever act as a simplified summary of the document, and the full-text document should be available (marked and numbered) and consulted during the analysis. The secondary literature will act as the backdrop to the analysis of semi structured and unstructured interviews. Using the proformas and NVivo analysis of data collected to help manage the data (while still referring back to the full-text documents if and when needed), the documents could be analysed in three ways:

1. Content analysis: what are the key patterns, themes and categories emerging from one or more documents, and how do these illuminate the regulatory process and procedures? What are the weaknesses of the proposed regulation and regulatory procedures? What can we learn about the relationship between regulation, its practice and the delivery of quality maternal health services?

2. Triangulation: how does the information contained in the documents compare with information collected from other data sources, such as published materials? For the regulation documents themselves, we may want to undertake a more detailed content analysis. For example: What terminology is used? Are HESVIC concepts, words or phrases mentioned? Are there any obvious gaps in the content, or surprising inclusions?

3. Are there any political or economic aspects of regulation, referred to in answering the above questions, which tell us about the ideology (political standing or position) behind the document, and the regulation process? What is the researcher's assessment of the consistency of regulation and its relevance to problems and achievements?

Methodological notice: putative effects of regulations are also caused by other environmental factors. For instance, fertility, female literacy and income are known to contribute to the state of maternal health. Relevant determinants such as these should also be identified on the basis of a literature review.

4.3 Step 3: Identifying and interviewing actors involved in regulation

Through identification of pertinent issues in maternal health and description and assessment of related regulations, key actors with respect to regulation processes will be identified. They will be interviewed individually in Phase One and later, in Phase Two, in focus groups. Actors interviewed will in turn help to identify other potential interviewees.

These actors include a wide range of individuals, from government officials to women users to the entire spectrum of health care providers (public, private and mixed). A total of six categories of actors were identified during the August 2010 Antwerp Tools Development Workshop:

1. Policy and regulation designers: including, for example, policy-makers at different levels (country, province, state). These actors are probably not directly involved in health policy processes;
2. Actors involved in administration, operationalization, adaptation and oversight of regulations: including, for example, service quality control commissioners, licensing and accreditation authorities, etc.;
3. The regulated staff (those who abide by the regulation) include;
    - health facility managers,
    - district, hospital and province medical officers in the public and private sectors;
4. Users of services i.e. women, patients and communities;
5. Other actors with multiple (or less clearly defined) roles in regulation processes (for example, NGOs, Civil Society, Insurance companies, International agencies). Note that the inclusion of these actors in the category 'others', does not mean that they are less important than the named groups.
6. UN agencies were raised for the context of Vietnam and India only as an important separate group.

Each country (with its respective paired partner) will ensure representation of the views of each of these groups during the Phase One data collection.

Interviews and focus group sessions to be held with these key informants will help to:

- Provide an overview of relevant regulations;
- Identify potential actors to be interviewed in Phase Two;
- Describe and assess how regulatory processes and procedures are carried out;
- Understand:
    - how the problems and achievements of regulatory substance and structure are explained by problems and achievements in their formulation and implementation, and
    - how both explain the maternal health issue under scrutiny;
- Study the ways that health professionals and managers cope with work and regulations;
- Explore aspects of the quality of maternal health care services and health outcomes not covered in the secondary literature review (for instance, problems known through investigators' own experience);

- Understand interests, perspectives and priorities relevant to these processes and identify influences of external stakeholders, such as political parties, trade unions and commercial interests.

Step 3 will provide insights and answers relevant to research question 2.

4.3.1 Methods used in step 3

A limited number (to be determined by the country research teams) of key respondents from each category specified above will be interviewed in Phase One.

4.3.1.1 Sampling of respondents

Sampling of respondents must be a continuous process – starting with an analysis of actors, and followed up with an attempt to discover key actors (yet unknown to researchers/ to us) during the process of interviewing. A snowballing like approach could be considered.

The principles of purposive sampling[k] will be used to select respondents for each case study. Sampling will be based on need for saturation rather than by specific numbers. Initial estimates for planning would be based on judgement and past practices of paired partners. Specific criteria will be used in each country for the purposive sampling, depending on the nature of maternal health service provision.

Key respondents for Phase One may include actors who were actually involved in developing a regulation. In cases where such key actors are not available for interviewing (e.g. retired) their immediate colleagues who have a comprehensive knowledge of the regulation processes could be approached.

4.3.1.2 Semi-structured Interviews

Semi-structured interviews are aimed at obtaining in-depth information on issues relevant to the research questions from single individuals. Key informants can, for example, provide a detailed picture of the extent of the use of evidence in regulatory decisions and of the role of (internal and external) actors. They can, in addition, explore ways of improving these. Interviews will encourage open discussion of sensitive issues, such as the limitations and achievements of regulatory structure, procedures, processes and their outcomes in relation to the capacity to deliver high quality maternal health care.

The interviews will be semi-structured, allowing respondents to raise issues of importance to them but not necessarily anticipated by the research team. Respondents will be allowed to move from one question to another, with limited intervention from the researcher. Participants will be asked about their knowledge, experiences and perceptions of regulations related to the case studies, with particular emphasis on description and assessment of processes and procedures. The interviews will aim to elaborate the findings of steps 1 and 2. Issues of quality of and access to care[l] may be touched on during interviews with health professionals. Quality of communication may similarly be addressed with services users, to the extent that it has a bearing on the description of relevant regulations. Each interview

[k] See glossary in Annex 8.

[l] As examples: maternity case fatality rate, early perinatal mortality, C-section rate, skilled birth attendance rate, institutional delivery rate, etc.

tool will contain a checklist of information to be collected, suggested questions and prompts to semi-structure the interview. This will facilitate gathering of information, perceptions and facts that address the research objectives.

In some cases, the same key respondents might be important for different case studies. In these instances, interviews should be structured so as to cover each relevant case study in one sitting and thus avoid interviewing the respondent twice. Partners can adapt the tool to enable questions on both case studies, as well as comparative questions. If this becomes too complex and, for example, topics become entangled, additional interviews may be required.

Findings of the interviews will be triangulated with other data sources/respondents, internal contradictions, other interviews, country mapping information, the maternal case study under scrutiny, international and grey literature and other secondary data.

Some detailed instructions for preparing and conducting interviews are provided in Annex 7.

Information requested from interviewees concerning the regulations within defined case studies

During these interviews the following issues should be borne in mind:

- The description and assessment of regulatory procedures. These are the regulations themselves, the activities entailed (controls, monitoring, sanctions, incentives, appeals lodging, etc.) and institutions (government inspectorates, professional and users' associations with a regulatory responsibility);
- In addition to the effects of regulation procedures, criteria for assessing regulatory procedures are presented in Annex 3;
- The description and assessment of regulatory processes (formulation, administration, implementation). Alongside the official process of regulation making and enforcement, the intervention of actors and lobbies will be explored;
- Quality criteria of regulatory processes include the existence of corrective feedback loops and of quality assurance mechanisms, the qualities of related health system information components, the absence of regulation capture and whether the design of a regulation is evidence-based;
- The administration of regulations by actors directly involved will be explored so as to understand how their interests influence regulation implementation;
- Governance should be assessed using some of the Siddiqi principles, in the light of the evaluation of regulations;

Table 3 below presents as guidance, a non-exhaustive list, (organised per case study), of information expected from interviewees within each category on key regulatory agencies, procedures, approaches and substance. This information should be related to a problem and an achievement.

Table 3 below should be used together with Annexes 3 and 5 (see further) when developing various research tools.

Table 3: non-exhaustive list of information expected from interviewees

CATEGORY OF ACTORS	ON EMOC, ANC, ABORTION	ON GRIEVANCE REDRESSAL
Policy and regulation designers	▪ Objectives of overarching policy and roles of regulations relevant to this policy; ▪ Consistency with general government policy. Historical legacies; ▪ Orientations provided by policy makers to regulation makers (if and when this distinction makes sense); ▪ Assessment of variations in implementing and enforcing regulations; assessment of regulatory systems, procedures, substance and impact; ▪ Awareness of problems and achievements with respect to the policy under scrutiny, regulation procedures and relevant processes, other determining factors of maternal health issues - and their relationships; ▪ Role of stakeholders and actors in these problems and achievements; ▪ .Awareness/assessment of problems and achievements with respect to policy, regulation procedures, non regulatory factors (information systems, importance of different categories of inputs), maternal health and their relationships. Differences between public and private sectors;	▪ Objectives of GR policy and roles of regulations at stake in this policy; ▪ Orientations for GR regulation makers and design – if any. ▪ Assessment of variations of implementation and enforcement of GR regulations; ▪ Consistency with general government policy. Historical legacies; ▪ Assessment of GR regulatory systems, procedures, substance and impact; ▪ Awareness of problems and achievements with GR policy, with regulations procedures and process, with maternal health and their relationships: ▪ Role of stakeholders and of direct actors (to which groups interviewees belong) in these problems and achievements; ▪ Awareness/assessment of problems and achievements with GR policy, with regulations procedures, (as well as with non regulatory factors), with maternal health and their relationships. ▪ Differences if any between public and private sectors.
Actors involved in administration, operationalization, adaptation, oversight of regulation	▪ Description and assessment of regulation procedures, including financing (see criteria page 20), key institutions, groups and associations involved. Assessment of variations in implementation and enforcement; ▪ Assessment of variations in implementing and enforcing regulations; assessment of regulatory systems, procedures, substance and impact. ▪ Based on these, explanation of regulatory processes. Monitoring and prevailing evaluations of procedures. Differences between planned and real processes. Historical legacies; ▪ Role of stakeholders and actors in problems / achievements and influence on regulatory procedures. Assessment of issues such as dual practice, for profit practice, absenteeism amongst professionals; .	▪ Description and assessment of regulation procedures, key institutions, groups and associations involved; ▪ Assessment of variations in implementation and enforcement practice from one institution to another; ▪ Assessment of variations in implementing and enforcing regulations; assessment of regulatory systems, procedures, substance and impact. ▪ Based on these, explanation of regulatory processes. Monitoring and prevailing evaluations of regulatory procedures. Differences between planned and real processes. Historical legacies, traditional practices in country or within an institution. ▪ Role of stakeholders and actors in problems / achievements and influence on regulatory procedures.

CATEGORY OF ACTORS	ON EMOC, ANC ABORTION	ON GRIEVANCE REDRESSAL
Regulation implementers: Health managers	▪ Main problems and achievements in professional practice (health services management). Perception of professionals and users views on the same; ▪ Awareness/assessment of problems and achievements with respect to policy, regulations procedures, maternal health and their relationships. Differences between public and private sectors; ▪ Experience with regulations implementation. Professionals' perception of regulation, control, incentives and sanctions. How do professionals perceive role of professional associations in the regulation process? ▪ Role of stakeholders and actors in problems / achievements and influence on regulatory procedures;	▪ Awareness/assessment of problems and achievements with respect to policy, regulations procedures, non regulatory factors, actual use of GR, perception of professionals' and of users' views on grievance redressal. Differences between public and private sectors; ▪ Role of stakeholders and actors in problems / achievements and influence on GR regulatory procedures
Regulation implementers: Health care providers	▪ Main problems and achievements in professional practice (health services management) in maternal health services. Perception of managers' and users' views on the same. ▪ Awareness/assessment of problems and achievements with respect to policy, regulations procedures, non-regulatory factors / health services inputs, maternal health and their relationships ▪ How do professionals and health institutions work with existing regulations (if any)? ▪ Assessment of issues such as dual practice, for profit practice, absenteeism amongst professionals ▪ Experience with regulations implementation ▪ Role of stakeholders and actors in problems / achievements and influence on regulatory procedures ▪ Determinants and consequences of critical incidents	▪ Experience with regulations implementation. Professional's perception of regulation, control, incentives and repression. How do professionals perceive professional associations?
Users of services: women, patients and communities	▪ Cases of negligence; ▪ Women's experiences with access, quality of care, cost of care; ▪ Knowledge and awareness of rights;	▪ Women's experiences with grievance redressal - knowledge, awareness, ability to use, quality of process (e.g. a struggle, done with ease or fear of acting, for example), satisfaction with redress where appropriate

CATEGORY OF ACTORS	ON EMOC, ANC ABORTION	ON GRIEVANCE REDRESSAL
Other actors with multiple roles in regulation	▪ Stakeholders such as mutual aid associations, trade unions, etc.; ▪ Social dimensions of regulations under scrutiny; ▪ Description of putative actors involved in regulatory processes; ▪ Description of lobbying possibilities and effectiveness; ▪ According to relevance of stakeholders in health care financing delivery, or pharmaceuticals manufacturing, etc.; ▪ Economic stakes of regulations under scrutiny; ▪ Stakeholders such as members of political parties; ▪ Political stakes of regulations under scrutiny;	
UN Agencies	▪ Description of lobbying possibilities and effectiveness; ▪ Economic stakes of regulations under scrutiny;	

4.4 Step 4: Adapting tools for data collection (piloting if needed)

In practice, step 4 of Phase One, in which research tools are adapted to suit the variety of actors and contexts, will run concurrently with steps 1 to 3. The process of tools development is described for the semi-structured interviews only, but can be applied to other methods, such as the focus groups. The key principles informing methods development for Phases One and Two include the following:

- To build on partners' expertise in different areas (such as project case studies, country context, socio-political context);
- To ensure adequate input from all members of the Consortium at the relevant stages of methods development;
- To ensure consistency of approach in methods development across all three study countries[m];
- To ensure sufficient support and guidance for study country partners from paired partners and ITM.

It is proposed that two types of tools be developed for the semi-structured interviews, namely *generic* and *adapted* tools. The aim in developing generic tools is to guide study country partners in constructing the adapted tools and to ensure consistency of approach in tools development across all three study countries.

4.4.1 Generic tools

A generic tools matrix for Phase One, developed during the August 2010 Antwerp Tools Development Workshop, is provided in Annex 5. The Phase One (and to some extent Phase Two) generic interview tools have been structured to ensure that each of the research objectives is addressed. The sections will vary slightly depending on the respondent group, but will have an overall common structure:

- Description of principles of regulation and regulatory approaches and procedures;
- Institutional or functional stages of the regulation process (formulation, administration, implementation);
- Assessment or opinion on effects of regulatory procedures;
- Opinion on role of actors and environment in the design and effective application of regulation procedures (context);
- Political, socio-economic context and case study – related relevance and weight;
- Relationship of health system in the overall schema of regulatory processes.

The generic tools matrix also provides an overview of issues to be included in Phase Two interviews, but does not refine them in detail. The definitive versions of generic tools for Phase Two interviews and other research will be provided near the conclusion of Phase One. These will be presented in the updated deliverable D 1.2.b and will be discussed in the HESVIC consortium during the 4th project meeting to be held in Bengaluru in March 2011.

m Special attention will have to be given to the way the India IPH team wishes to collect data during Phase One.

Generic questions (not specific to the case study area or to any particular regulation) have been divided into 5 broad areas (corresponding to HESVIC research questions). These are presented in the first column of the matrix in Annex 5:

1. Contents of the regulation;
2. Processes of regulation;
3. Actors in the regulation;
4. Approaches to (and practices of) regulation – this includes the procedures of regulation;
5. Effects of regulation.

Each of these broad areas of enquiry has been further divided into sub areas, presented in the second column of the matrix.

The generic tools matrix will serve as a starting point for development of research tools for Phase One data collection. Country research teams, in collaboration with their paired partners and under guidance of the ITM help desk, will adapt these generic tools to the local contexts, the specific case studies and to the selected actors. This is an on-going process that began at the Antwerp Tools Development Workshop and was continued and consolidated at the Shanghai Project meeting.

4.4.2 Adapted tools

The adaptation of tools (translation and local relevance) will involve making the generic tools suitable for the particular contexts in which they are to be used. This process also includes developing specific questions and prompts based on information collected during Phase One.

Adaptation of the tools will take into account the following:

- the specific case study,
- the type of respondent,
- level of respondent,
- role of respondent within regulation process,
- country context,
- language,
- terminology and
- type of regulation studied.

The choice and order of questions in the adapted tools (and the actual interviews) should be decided by the country teams in consultation with their partners.

The adaptation of tools will be split into two consecutive stages. In the first stage, each study country partner will adapt tools for *each* case study for their own country (totalling 3 sets of adapted tools per study country). It is planned that these tools will be circulated for comments from *all* Consortium partners.

In the second stage, after the adapted tools have been commented on, study countries will have time to revise, develop and translate *all* adapted tools. Study countries may develop adapted tools directly in the local languages but will need to ensure the availability of the English version where inputs from paired partner(s) and/or ITM are sought. It is expected that primary responsibility for the adaptation of

tools will lie with the study countries, but the paired partners and, where needed, ITM, will be available to provide guidance and support

4.4.2.1 Some tips on adaptation

To ensure that enough detail is collected to address the research objectives, the methods need to be focussed on particular aspects of the maternal health case studies. This section gives guidance for focusing the data collection methods but final decisions rest with paired partners, in consultation, where possible, with ITM.

It is important to consider the following principles when using the matrix in Annex 5 in adaptation:

- The issues in the matrix represent suggestions for each theme. However, some of these questions may fall outside the agreed scope of key areas and key issues;
- Procedures (content, substance and structure), and processes of regulations should be clearly distinguished. Content analysis and assessment comes first. Descriptions of processes should not be spurious exercises: they are expected to shed light on the reasons for which regulatory procedures may be ineffective and/or on the ways in which they could be improved. Governance analysis is an integral part of data collection. Prompts should be used during the interviews to ensure that information on the appropriateness of principles of governance, with respect to the relevant regulation, is collected;
- Many suggestions are made from the perspective of the particular theme. Integration of the different conclusions in different case studies will come at the end of the research. Questions can, however, also be asked from this integrated perspective.

Inappropriate questions

While an attempt has been made to word all questions in the generic tools matrix of Annex 5 as clearly and sensitively as possible, some questions could, in your own country, appear intrusive or inappropriate. If possible, such questions should be re-worded rather than omitted.

Adapted tools and their numbers

We need to ensure that adapted interview tools are feasible, and in particular that the number of questions is manageable. The points given below have the potential to add questions but testing interviews should ensure that they are not too long:

a) The primary concern should always be to collect enough data to address the HESVIC research objectives and to answer the research questions;
b) The focus should range from maternal health problems and achievements to understanding and assessing regulatory procedures, processes and approaches;
c) Identify in advance how long you will have with a respondent, and adapt the tools accordingly, i.e. the most important question first, following the introduction;
d) The last question will address the maternal health problems and achievements;
e) Prioritise what to ask a particular respondent, while still addressing the primary research objectives. Think about the respondent's organisation, their role and responsibilities in the organisation and identify the most relevant questions accordingly. For example, for a member responsible for ensuring regulation, prioritise questions on organisation tasks and their possible synergy with other

key determinants of the expected maternal health services output. This needs to be thought about prior to the scheduled interview;

f) Think of other data sources – for example, some information may be available from documents. If these documents are reliable, we do not need to waste time in interviews verifying the information. It is hoped that answers to most of our research questions should emerge in data analysis, as long as relevant data and information is collected;

g) If needed, for the sake of maintaining a smooth dialogue with the interviewee, feel free to modify the order of questions on the spot.

A short piloting step can be introduced at the end of step 4 of Phase One, with the aim of testing the questionnaires.

4.5 Step 5: Phase One data collection and analysis

In Phase One, step 5, the developed tools will be used on a limited yet representative selection of actors (those key respondents identified in Phase One, step 3).

The data collection and its analysis will aim to describe and assess in-depth regulatory issues (procedures (content, substance and structure), and processes). In Phase Two the same tools will also help to assess the effects of regulations on access to care. In terms of the objectives of Phase One, this analysis can be conducted without computer software, using the principles of qualitative data analysis outlined in the section on Phase Three. The information obtained will be assessed and contrasted with the processes described in the country mapping reports.

Phase One data collection will start after obtaining ethical clearance in all Consortium partner countries. Data collection should begin in December 2010.

Last but not least, there are some important ethical matters to be considered before beginning the data collection. These are discussed at length in Section 7.1.

4.6 Phase One summary

At the end of Phase One, summaries of the findings of the review of grey and scientific literature, the secondary quantitative analysis and the interviews will be prepared for each case study in each research country.

These summaries will identify problems and achievements with respect to regulation of maternal health care delivery. They will focus on topics such as relationships between regulation and maternal health and between regulation and relevant actors. They will also focus on the regulation approaches, processes and procedures themselves.

This Phase One summary represents a written systematisation of what occurred in Phase One. The Phase One summary will include:

1. Description of main problems, achievements with respect to access to and quality of maternal health services. The identification of one problem or achievement and one corresponding regulation per case study to ensure that these are linked to country context and the country mapping reports. Also international reviews should be used as background. Examples of problems and achievements are

provided in some detail in Box 3. Some recent examples of problems and achievements as described above would be useful.

2. Broad description and partial assessment of procedures of regulations, including their main objectives, target groups, etc. This will be obtained from the document review undertaken already as step 2 of Phase One with the guidelines provided in Table 2 of D 1.2.a.
3. Broad description of processes (design, administration and implementation) in regulation. This could be possibly in the form of a timeline diagram with explanatory notes and this will entail the illustration of when a chosen regulation was designed and applied. To be done either in the documentation or involving the interviews in Phase One, step 3;
4. Broad description and partial assessment of approaches to and procedures of regulation. This entails the kind of approach, what category does the regulation fall into, is its function dependent upon incentives, public monitoring or upon sanction, etc.?
5. Identification of the main actors involved (directly or indirectly) in regulation, including their roles and, where possible, relationships. A stakeholder analysis will be used for this (e.g. matrix). Who is responsible for ensuring that the chosen regulation is applied and whether those responsible are linked to one another professionally.
6. Broad description of and partial assessment of the context of regulation processes, approaches and procedures.
7. Identification of any gaps in information and implications for Phase Two.

A detailed outline for the writing of Phase One output for each of the three case studies is provided in Annex 4. It is suggested that data from literature reviews be integrated into the Phase One summary in a matrix similar to that presented in Annexes 1 and 3.

5. Phase Two – Main data collection

Phase Two is informed by the findings of Phase One. The main objective of Phase Two is to collect in-depth data about the regulatory procedures and processes relevant to the maternal health case studies, in order to assess their contents and effects on the chosen maternal health problem or achievement. Regulatory successes and problems, as well as their 'raison d'être', will be identified. Implementation will be contrasted with formulation and administration of regulations. Phase Two also aims to understand the agendas of key actors (where they stand, what they think) and to identify environmental factors relevant to regulatory procedures and processes.

Phase Two will aim to provide the material necessary to answer the following research questions:

- research question 3: on the effect of regulation on equitable access to quality care, as perceived by users and providers;
- Research question 5: on exploring how to change and improve the performance of regulation.

In so doing, Phase Two looks mainly for an answer to the questions "why?" and "to what effect?", with respect to regulation and maternal health.

Methods to be used in Phase Two include a review of documents; secondary analysis of data and other information, such as published papers; semi-structured interviews; focus group discussions; and participatory stakeholder workshops.

5.1 Step 1: Developing, adapting and piloting research tools

In Phase Two, step 1, the tools developed and used in Phase One will be amended according to their performance during the Phase One data collection. Furthermore, tools will be developed to facilitate the assessment of regulation. These new tools will be properly piloted. Findings of this important exercise in step 1 will be reviewed and analyzed during a 4th Project meeting (to be held in IPH, Bengaluru, in March 2011 (between end of Phase One and beginning of Phase Two).

The new questionnaires, together with the amended Phase One tools and a detailed description of their development, will be constructed for Phase Two data collection. These will be outlined in an update to the current Deliverable D 1.2.a. The updated version will be called D 1.2.b. The tools will be developed through an integrated consortium effort. This process will be guided by ITM and Asian partners will work closely with their respective paired partners.

Thereafter, semi-structured interviews and focus group protocols, specific to each category of actor, will be finalised for use during the main data collection of Phase Two.

Important issues to consider in amending the tools (see also section 4.4.2) include use of appropriate language and terminology, compatibility of questions with the local culture and health system, and appropriate handling of sensitive issues.

Some partners may decide not to develop all adapted tools immediately and to collect the data for Phase Two in parallel with the adaptation of the rest of the interview tools. This decision should be made by each study country partner in consultation with their respective pair.

5.1.1 Incorporating information on the socio-economic, political and historical context

Information on the socio-economic, political and historical context can be incorporated during Phase Two data collection, for example through prompts and follow-up questions. In an interview with a professional association member, you could prompt the respondent to justify his / her choice of the main actors discussed and to explain why he / she feels that these actors represent the needs of professionals. These issues will also be drawn out in analysis during Phase Three.

5.1.2 Incorporating information from Phase One

Phase One will reveal problems and achievements in the domain of health care delivery and critical events in the domain of regulation[n]. It will also produce descriptions of regulatory procedures. Phase Two (main data collection) should provide the opportunity to further explore emerging areas.

Phase Two will collect complementary data, particularly on *why* the processes identified in Phase One occurred, and on the role of feed-back and evidence-based processes. Phase One information and key thematic issues should be incorporated in Phase Two through:

- Informing the interviewer, so that he/she has enough knowledge of the case study, its key areas and maternal health problems and achievements;
- Ensuring that the interviewer knows when and how to probe and prompt the respondent in order to produce the desired information;
- Exposing respondents to the Phase One findings and giving them the opportunity to express their opinions on problems and achievements detected during this phase.

When adapting the tools to incorporate the information produced in Phase One, country paired teams should remember that not all questions need to be asked of all respondents.

[n] Critical incidents are related to health services while critical events on the other hand will relate more to policy and country context- These are now added to the glossary.

5.2 Step 2: Data collection and in-country analysis

Before any data collection is undertaken there are some important ethical issues to be considered before beginning the data collection. These are discussed at length in Section 7.1.

5.2.1 Document reviews

Documents will again be reviewed in Phase Two. For instructions on the process of document review, refer to the guidelines presented with reference to Phase One.

5.2.2 Semi-structured interviews

Interviews will enable a range of respondents to report on their knowledge, experiences and perceptions of the regulation processes and procedures, and to give their opinions on their possible impact (e.g. their effects on the maternal health case studies). Interviews will thus be used to explore and validate issues that emerged in Phase One and to help assess some of the effects of regulation.

5.2.2.1 Sampling of respondents

As in Phase One, purposive sampling will be used. Respondents will have been categorised and identified during Phase One, step 3. Sampling will again be undertaken in terms of respondents' roles in particular contexts. If professional bodies and self-regulation predominate in regulation (as evidenced by secondary data), for example, we would consider holding more interviews with members of this category than with those in other categories less important in terms of the relevant regulations and processes.

Some respondents interviewed during Phase One, such as planners and policy makers, will identify people who have designed a regulation or are responsible for its implementation. Interviewing these people will provide insight into how the regulation was intended to be applied. Implementers, on the other hand, will recommend respondents from implementation. Interviews with these individuals will give insight into actual application of the regulations. We hope also, where possible, to verify findings through interviews with independent people, such as patients and user groups. Phase One respondents could also be contacted for interview and focus groups during Phase Two (and for follow-up activities during Phase Three).

Table 4 below provides guidance for the number of semi-structured interviews and focus groups to be conducted in each country during the main data collection in step 2 of Phase Two. The number would amount to 57 if the combined case studies are EmOC, ANC and GR and to 58 if the combined case studies are EmOC, Abortion and GR; two interviews per day, three days a week, during 10 data collection weeks.

Table 4: Number of interviews and focus group discussions for Phase 2, step 2

	EmOC	ANC	Abortion	GR	*Total*
Actors' categories					
Policy and regulation designers	3	2	2	2	***9***
Actors involved in administration, operationalization, adaptation, oversight of regulation:	3	2	2	2	***9***
Regulation implementers					
- Health managers	4	3	3	2	***12***
- Health care providers	4	3	3	2	***12***
Users of services: women, patients and communities	4	3	3	2	***12***
Other actors with multiple roles in regulation	3	2	3	3	***11***
Un Agencies	2	2	2	2	***8***
Total	***25***	***17***	***18***	***15***	

The number of interviews conducted may be fewer than suggested in the table, as data will be collected according to the saturation principle[o] (see also Section 4.3.1.1), in terms of which data collection should cease when interviews are no longer revealing much new information. To ensure feasibility of data analysis when collecting the Phase Two data, the primary focus during this phase will be on key respondents. Consideration should also be given to those actors engaged in socio-economic and political organisations.

5.2.2.2 Procedure

Interviews should provide in-depth understanding and assessment of regulations and of their procedures, and processes - from their formulation through to administration and implementation. They should also provide information about feed-back or evaluations used to improve regulation. The experience of women users and patients' organisations will be critical to our understanding of the effect (if any) of regulatory processes on the quality of care and on overall governance of the service. The overview should also enable us to identify key actors and environmental factors involved directly or indirectly in regulation in each country. These key actors may be interviewed at a later stage within Phase Two, step 2.

The maximum number of questions recommended is 15 per interview. This may vary depending on the particular case study. The final decision should be made by each country study team, in consultation with the respective paired partners and ITM. Again, key respondents may be the same for more than one case study. In such cases a 'hybrid' semi-structured interview tool could be used.

[o] We hope that the purposive selection of interviewees will need to reflect their sectoral position in the delivery of health services for example- predominantly public in China whilst predominantly private in India in accordance with information given in the country mapping reports.

For more detailed instructions for the interview method, refer to the section on interviews for Phase One (see from section 4.3.1.2 onwards) and to Annex 7.

5.2.3 Focus group discussions

Focus groups will be used in Phase Two of the research process. Focus groups will be useful for investigating actors' knowledge and opinions on the regulation procedures and revealing their experiences of maternal health care delivery.

Focus groups play a key role in qualitative research, allowing researchers to investigate both people's knowledge and opinions and also how they interact with each other with reference to the relevant issues. The group interaction itself is of interest, illuminating, for example, areas of disagreement, conflict and resolution. Focus groups can also be useful for discussion of sensitive issues, as some individuals in the group break the ice, and others are encouraged to voice their opinions. Disadvantages of focus groups include the fact that some participants may be inhibited by other members of the group, who may dominate the discussion, and that they may be more difficult to organise and analyse than individual interviews.

The process of developing the focus group tools (and data analysis) will be similar to that outlined with reference to the semi-structured interviews (see also Section 4.4).

5.2.3.1 Sampling of participants

The suitability of a focus group approach will be assessed for each of the respondent groups. A total of 3 focus groups with actors from the most important categories will take place in the later stages of Phase Two. Participants will include people who have knowledge or experience relevant to the case studies.

It is important to choose participants carefully. Focus groups can include homogeneous (including people from the same or similar groups) or heterogeneous (comprised of people from different groups) participants. Homogeneous groups should be considered first for this project, as they avoid some of the problems caused by hierarchies in heterogeneous groups. For example, in a group of doctors and nurses, nurses may be reluctant to discuss problems in front of doctors. Participants in less hierarchical, homogeneous groups may speak more freely. Homogeneous groups also allow discussion of shared experiences. The groups may either be natural groups of people who already know each other, or may be composed of people who are strangers to one another. Focus groups usually consist of 7-12 participants. It is proposed that 2 focus groups take place per case study, producing a total of 6 focus groups per study country. Focus groups will only take place in the latter stages of Phase Two. There may also be a need for follow up focus groups during Phase Three.

5.2.3.2 Procedure

Focus groups will require careful planning in terms of participants, location and the topics to be discussed. The facilitator needs skills in listening, responding to group discussion and encouraging all participants to join in. It is also important that the facilitator is fluent in the language of the focus group and is familiar with the local culture.

Scheduling a time for the focus group may be difficult due to the number of participants and the suggested 60 - 120 minutes duration. Potential participants

should be contacted with information on the project, what happens during a focus group and contact details of the researchers. The methods used to contact people and schedule focus groups will depend on the type of respondent. For service users, it may not be possible to telephone or send a letter, and the researcher will be required to meet potential participants face to face to discuss the project and their willingness and availability to take part in a focus group. This should be done with clear guidance from ethical criteria developed by HESVIC (see Section 7.1 and Annex 6).

The focus groups should be conducted in a neutral setting (for example, nurses should not be interviewed at work, where they may fear being overheard). The groups should be assured that their discussion will be private. This may be a challenge in some settings (for example, other people may gather to watch what is happening). The set-up should be relatively informal, for example with chairs in a circle to encourage interaction. The focus groups should be carried out in the local language or in a language that all participants speak.

The focus group facilitators should ensure that they have the necessary resources, including a recorder, a note book to record their observations and refreshments for the participants. The facilitators will first introduce themselves to the group, brief participants again on the aims of the research and what to expect in the discussion. Informed consent will be sought from all participants, individually and collectively. Participants will be reminded that everything they say within the group will be kept confidential and will be reported anonymously. Each participant can be given a copy of the project flier or a shortened version, which contains information on the project and contact addresses. There should also be a brief time at the beginning and end for any queries that participants have.

Introductory questions or exercises will be used to 'break the ice'. A topic guide will be developed based on the findings from Phase One. The facilitator will use the guide, along with prompts, to ensure discussion on the topics of interest (while allowing some flexibility for digression), to encourage interaction and debate or to get the group to expand on ideas. The opportunity for an individual follow-up interview with the facilitator will also be provided if a participant wishes to add information that they were not comfortable speaking about in the focus group.

The focus groups will be recorded and transcribed in the local languages. The facilitator will make notes of their observations, in particular of the dynamics of the group, and the type of discussion generated (for example, areas of conflict).

5.2.3.3 Analysis

Analysis of the focus group data should be similar to that of interview data, with the additional element of analysis of the group dynamics. A key element of the overall analysis will be the ability to use NVivo v7 in a systematic manner. Each country should conduct a country-specific analysis of the focus group data. Transcriptions should be analysed together with the facilitator's notes. In addition, attention should be given to the interaction between participants. Codes for types of interaction may be used to aid analysis (for example, 'joking' and 'conflict'). Data from the focus groups should not be analysed as single units. Rather, the data from each participant should be analysed in the context of the group. The techniques described to improve

the quality of analysis of interview data should also be applied to the analysis of focus group data.

5.2.4 Participatory stakeholder workshops[p]

There is a possibility of holding stakeholder workshops, after the main data collection in Phase Two. Such workshops could be useful to further illuminate issues, observe the dynamic between stakeholders and note conflict, contest or consensus.

A meeting of government officials, health professionals and user representatives could present an appropriate environment in which stakeholders could describe or assess regulatory procedures in each case study. The presence of different stakeholders would allow conflicting views to be raised, justified and re-examined (similar to a focus group). In India and Vietnam, this type of meeting is a common forum for stakeholders to attend and, with sufficient incentives, is likely to attract valuable participants. The workshop would also overcome the difficulties involved in collecting data contained in the unpublished, internal documents of relevant organisations. If representatives of the organisations are invited to speak at the workshop, they are likely to describe and explain the views and experiences of their organisation with reference to policy processes.

5.2.4.1 Procedure

Study country teams are more familiar with the appropriate procedure for organizing participatory workshops, so this section merely raises the following issues to consider:

- Schedule: when would be an appropriate time and date, and how long should the workshop last? Should separate workshops be held for each case study, or could they be combined?
- Participants: what mix of actors would be most appropriate? Ideally, members of the Country Research Advisory Group (CRAGs) will be invited, and perhaps representatives from some other HESVIC partners.
- Incentives: what incentives can we offer to incite stakeholders to attend? Covering transport costs and food are examples. Would stakeholders be more likely to present at the workshop if its proceedings were compiled and published under the HESVIC name?
- Format: how can the workshop encourage participation and interaction? What activities are appropriate – presentations with slides; plenary discussion; small group work?
- Ethics: Participants must be clearly informed in advance (or at the beginning) of the event of the purpose of the event, and of how information presented at the event will be used (see also Section 7.1).

5.2.4.2 Analysis

The procedure for analysis of data from the workshop depends partly on the format in which the data is collected. The following are possible options:

- All speech at the workshop is recorded, and transcribed. Other data collected include written presentations, slides, exercise outputs or workshop proceedings, etc.

[p] Where the situation arises with keen interest in such an event from one particular set of interviewees. It is not compulsory but can only complement ideas about the study and research objectives.

- Notes are taken on all speech at the workshop. Other data collected include written presentations, slides, exercise outputs or workshop proceedings, etc.

Whatever method is used for recording data, the participants should be informed and consent to this method. Study country teams will need to consider the confidentiality and anonymity issues raised by using data collected at this workshop.

Once the data have been collected, they could be analysed using the procedures suggested for the qualitative data collected with interviews or focus groups. Researchers will need to remember, and take account of, the context within which the data were collected. For example, would certain participants bias their presentations or speech, because of the nature of the audience? The data collected through the workshop also can be triangulated with other data sources.

More information on the approach to analysis can be found above in the following section on Phase Three.

6. Phase Three – Main data analysis and follow-up

As stated before, the consortium agreed on a methodological approach in D 1.1, based on two main phases: Phase One and Phase Two. The Third Phase will deal with the main country-specific and comparative data analysis and follow-up.

The objective of Phase Three is thus to perform a valid and reliable analysis of data collected during Phases One and Two. Phase Three aims to explore and validate these data and findings, and thus to inform the development of country-specific and comparative research reports and other project outputs.

Political economy is concerned with how countries are managed, in terms of both political and economic factors. This project aims to describe the political economy of regulation approaches, processes and procedures, and of regulatory governance in the health sector of the three countries. Such a description requires understanding of the dialectic relationships between the actors and the environment. In order to achieve this, the data will be analyzed as stipulated below.

Study country reports will also be written during this phase, in parallel with workshops to be held in 2012.

6.1 Step 1: Answering research questions 1, 2 and 3

In Phase Three, step 1, research questions 1, 2 and 3 will be answered for each study country. Data analysis will aim to assess the regulations and to describe the political economy of the regulatory approach, procedures and processes, and of governance. This step will also include further comparative analysis and interpretation of data from Phases One and Two. The analysis will then be validated with reference to focus group discussions and to conclusions from scientific literature, when available.

Data will be analyzed thematically, assessing governance in terms of principles such as accountability, transparency, responsiveness, rule of law and use of evidence. Some indicators and methods for assessing governance in terms of these principles are proposed in Annex 3. Both regulation substance and structure will be re-assessed in the light of findings concerning their impact on equitable access to quality maternal health care. Issues concerning substance and structure will lead to scrutiny of regulation design and implementation.

The analysis will use historical, socio-political and economic perspectives (books and articles to be consulted on an ad hoc basis). At certain stages the analysis will also employ an approach based on critical discourse analysis to interpret interviews. The aim is to support its focus on the political economy of regulation processes[q] and procedures, and of regulatory governance in the health sector of the three countries.

Dissemination will run concurrently with other activities and will not be limited to this third and last phase of the project, as outlined in the HESVIC knowledge management strategy and in country plans.

[q] An updated glossary is provided in Annex 8.

6.2 Step 2: Answering research questions 4 and 5

In Phase Three, step 2, research questions 4 and 5 will be answered for each study country. This will include some final data collection through workshops in each study site, in order to validate data and develop recommendations.

After a comparative analysis, findings will be assessed in terms of their generalizability.

With respect to research question 4, information related to regulations on access to EmOC, ANC and abortion and their effects will be compared with information on the regulation of access to general (family medicine and hospital) care and its effects. ITM will provide additional analysis activities on an ad hoc basis and in a timely manner. These will be derived from the above comparison and from technical standards of maternal health activities.

In answering research question 5, we will build on the existing identification of strengths and deficiencies in regulatory procedures and processes. We will provide technical solutions from other countries facing similar challenges. There may also be a need for an ad hoc literature review at this point. Where appropriate, interviewees' suggestions will further be taken into consideration.

6.3 Step 3: Validation of analysis

Finally, the analysis will be validated and finalized, e.g. through a workshop of key actors. Notice that there will be a similar workshop at the end of Phase Two. This validation will be conducted at country level first. Country reports will then provide the basis for comparative analysis.

The knowledge management strategy for HESVIC is demanding in terms of the organization of stakeholder workshops throughout all research stages. It is therefore advisable that validating workshops be included throughout other research Phases as well.

6.4 Approach to analysis used in Phase Three

Any preliminary analysis during Phase Two will largely be country-specific. Final comparative as well as inter-country analysis will be carried out in Phase Three. Country-specific data analysis will be carried out by Asian partners, supported by their paired partners. Comparative analysis will be conducted by all partners and written up by ITM after an ad hoc workshop. The comparative analysis report will be shared with all partners for comments through the HESVIC website. Paired partners, the ITM help desk and circulation of drafts among other teams will ensure that the researchers have the capacity to undertake the analysis effectively.

Analysis of the semi-structured interview data will be an on-going process, starting during the interview itself. The researcher (and note-taker, if present) should make notes during and immediately after the interview, noting interesting themes, contradictions and potentially useful data sources that the respondent has mentioned. Notes should also be taken on the dynamics of the interview, e.g. whether answers are spontaneous and extensive, body language of the interviewee, reactions to questions and emotions. The notes will help researchers to re-contextualise the interview during later analysis.

The interviews should be transcribed, either by a project researcher or by a professional typist. All transcriptions should be checked in order to 'clean' the data, and confirm the accuracy of transcription. The transcripts will contain an interviewee identity number and personal names should be removed from the transcripts. Personal names should be indexed and stored separately for purposes of anonymity. Transcripts should then be imported into the computer software. For all three study countries, transcribing should be done in the local language(s) and one sample transcript will be translated into English.

6.4.1 Unit of analysis

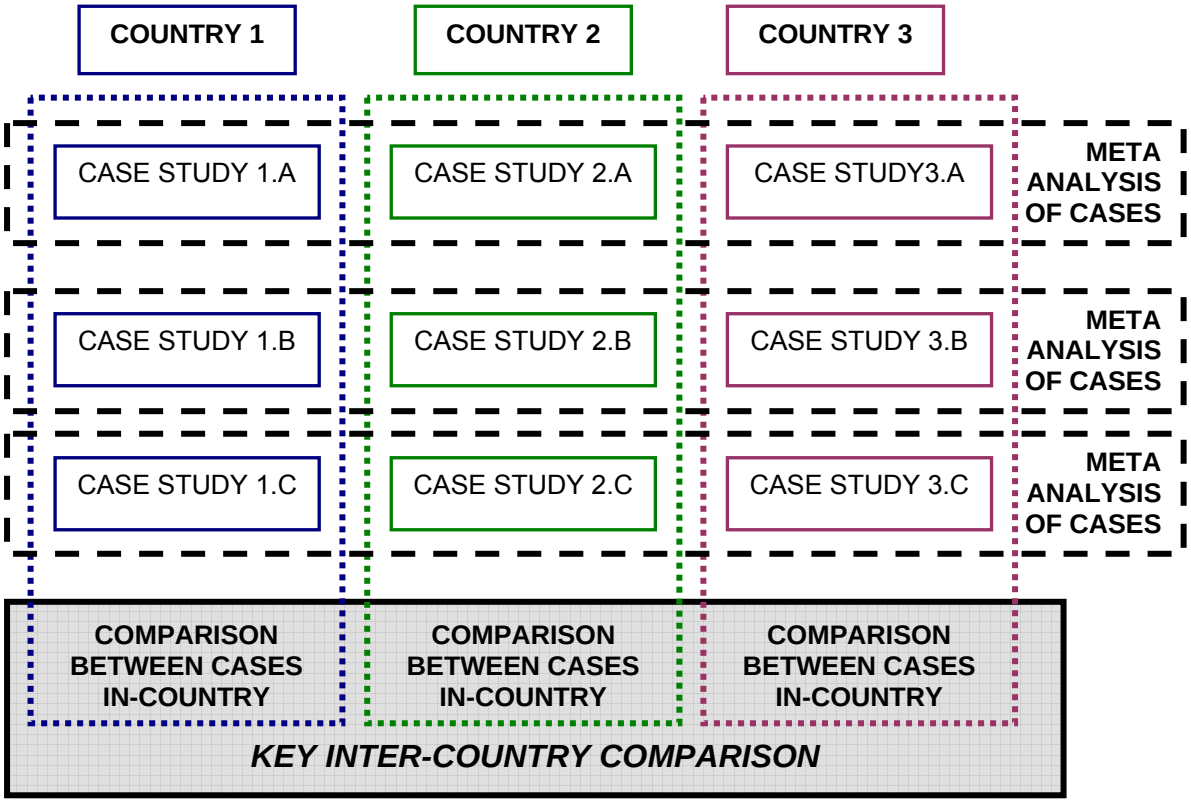
The unit of analysis is important for guiding sampling and data collection in both Phases One and Two. It is also important to distinguish between the different levels of analysis (within and across case studies and countries).

The actual unit of analysis depends on the overall goal of HESVIC research. It can be any one of the following:

1. Study case-based comparisons:
   - Should enable assessment of specific regulation procedures and processes (for example control of unlimited use of C-sections);
2. Country-specific overall analysis of several regulations assessments:
   - Should allow conclusions to be drawn with regard to strategies for regulation and to the effects of regulation in a particular health systems design;
3. Inter-country comparisons of strategies and effects:
   - Should enable conclusions to be drawn with regard to regulation in LMIC health systems.

The overall goal of HESVIC research is to draw conclusions on the role, feasibility and relevance of regulation in health systems and in particular contexts. In spite of LMIC having had extensive experience with regulation, evidence-based assessments are rare in the scientific literature. This lack of knowledge makes the study of the technical features of regulation (e.g. prenatal diagnosis) less relevant for HESVIC overall objectives. In other words, units of analysis 2 and 3 (country specific and overall country comparison) have a specific added relevance, as compared with unit of analysis 1. Figure 4 below gives a schematic presentation of the different levels of comparison and the associated units of analysis.

Figure 4: Levels of comparison of research results and associated units of analysis for overall HESVIC research



Inter-country case comparison of case–study based regulations will be an interesting by-product of HESVIC research. Opportunities for comparisons should be identified after data collection and preliminary analysis. Such comparisons can be made easier by ensuring consistency in the coding of research data. An EmOC-based comparison for example, would certainly benefit from the use of well-established standards for comparison across health systems. The HESVIC research approaches to prenatal diagnosis are also similar across the three countries. This would benefit key comparison of inter-country case–study based regulations.

With reference to the unit of analysis and the phased approach of the HESVIC research, in-country analysis will be conducted, during Phase One, within case studies only. In Phases Two and Three analysis will be conducted across the case studies (comparison of cases) and across all three countries (meta-analysis). The unit of analysis for the comparative report will be the key inter-country comparison and analysis from the three countries.

6.4.2 Criteria for quality of qualitative analysis

To ensure that qualitative analysis is trustworthy and of a high standard, the analysis should meet the following criteria:

- Systematic: more than one coder should be used wherever possible, to allow discussion and joint decisions over development and application of the coding frame;

- Comprehensive: analysis should account for all the data: researchers should consider whether quotes are typical or unusual;
- Comparative: researchers should continuously compare between and within study cases, asking themselves why things are the same or different;
- Critical: researchers should test emerging hypotheses, look for disconfirming evidence and be able to account for deviation;
- Transparent: country teams should record and report the steps taken, why codes were chosen, etc. ;
- Flexible: analysis should be open to change to accommodate new knowledge and developments.

6.4.3 Four types of analysis[r]

First, a thematic analysis will be conducted. Adherence in governance to principles such as accountability, transparency, responsiveness, rule of law, and use of evidence, will be assessed through examination of research findings on regulations. Criteria and indicators are proposed for each of the categories used by the Siddiqi model (see Box 5). Where possible, interviewers will also prompt for elaboration in these areas during the semi-structured interviews (see also Annex 5).

Annex 3 provides a set of parameters for understanding and assessing the degree of 'good' regulation in the context of governance. These parameters might need to be adapted to individual countries or specific (thematic) areas of maternal health.

Second, analysis of the historical context will help us to understand current regulation and governance in the studied domains. For instance, the general strategy adopted for economic development during the last two decades in China may give insight into the approach to regulation of health care and health services. According to the mapping reports, the government has attempted to obtain visible social, epidemiological and demographic results, and has thereby influenced the nature and course of regulations and the principles in terms of which the health sector is governed.

Third, interviews will be examined using critical discourse analysis to relate process description and assessment of regulatory procedures to key social, political and economic factors. As in any routine social science study, the discourse of interviewees should be related to their social position, interests and occupational status. The analysis will aim at understanding the dynamic relationship between key actors (their background) and the overall environment, and will not simply take the interviews at face value.

[r] In the view of NCIHD the analysis of historical context and of how the achievements and problems in regulation are related to its procedures and processes – both currently referred to as separate types of analysis – can be separate 'themes' within the thematic analysis they also disagree with the interpretation of discourse analysis in the document (to relate process description and assessment of regulatory procedures to key social, political and economic factors). NCIHD finds the use of the term discourse analysis unhelpful and would prefer the use of thematic analysis throughout (if necessary with a footnote to remind that this includes an analysis of the wider socio-political context and the roles and attitudes of interviewees). ITM suggests, as in the glossary, that CDA can be used as a framework to approach the socio political dynamics behind the implementation of regulation as a follow up to what is already there in the country mapping exercise.

Fourth, the analysis will explain how the achievements and problems of a regulation under scrutiny are related to its procedures (substance, and structure) and processes, and how these are influenced by external actors and the environment.

6.4.4 The use of software for analysis

Analysis of the interview data will be aided by the use of the computer software NVivo 7 to manage, process and code the data, and to perform searches across transcripts.

For Phase Three, assessments, hypotheses and concepts will be made explicit before transcripts are analysed with computer software and scientific assistance, to develop key concepts based on glossary and field evidence to date.

6.4.4.1 Coding

Transcripts will be systematically coded using NVivo v7. Coding data is the process of labelling sections of the text by theme. This needs to be undertaken by someone in the country team with specialist knowledge. This person should work closely with the PI where possible, since there are likely to be common elements across research countries in terms of key concepts related to the overall methodology. Some variation by country is also likely. These issues will be further discussed at each stage of the process of data collection.

Coding is a useful way of organising the data and allowing researchers to retrieve key chunks of text easily. Coding will be carried out by the country teams, with support from the other project partners. Coding should start with data collection to allow revision of the coding frame and to allow researchers to determine where further investigation may be useful. During coding, researchers may develop analytical ideas and should note the location of quotes that might be useful when reporting the data.

The stages of coding data using computer software can be summarised as follows:
- Becoming familiar with the data - listening to recordings and reading transcripts several times;
- Writing notes on themes in the text;
- Sorting notes into categories and subcategories (smaller, less common themes may be combined and/or larger, common themes may be subdivided);
- Developing a coding frame (a coding frame is a list of the categories and subcategories) using the computer software;
- Applying the coding frame to the transcripts. Using computer software, this is done by selecting sections of text and associating them with the categories in the coding frame;
- Repeatedly reappraising and revising the coding frame as more data are analysed.

Codes to be used can draw on the following:
- Aims and objectives of the research;
- Views/experiences of the respondents;
- Analytical ideas of the researchers;
- Visual materials (diagrams, graphs, photographs) can be incorporated into the final analysis using NVivo v7;
- Country specific issues related to history and context.

As analysis proceeds, more data may need to be collected and the coding frame adjusted, followed by more data analysis, etc. The analysis process is cyclical. The process should be stopped when the analysis is 'saturated', i.e. when analysing new data does not reveal further insights. Analysis may also be undertaken jointly with paired partners.

Since HESVIC is making comparisons between case studies and across countries, certain important elements of the coding frames will be common to all case studies and all study countries. This will enable comparison between case studies and countries, while still allowing the analysis to highlight country-specific issues.
The end of Phase One Project meeting (see Figure 3) presents an opportunity to discuss and develop a draft coding frame. However, study country partners will need to have translated a few interviews into English for this coding frame development to be effective[s].

6.4.4.2 Managing the data with NVivo v7

The search functions available in NVivo v7 will be used to explore the data. Different combinations of codes will be searched for in the transcripts to develop analytic ideas and conclusions. Some of the different searches available include the following:

- Node searches: searches for text coded by code 1, e.g. 'civil society organisation' and a range of other concepts, words and relations between them;
- Intersection: searches for text coded by code 1 AND code 2, e.g. text which contains information about 'regulation initiation' AND 'challenges';
- Union: searches for text coded by code 1 OR code 2, e.g. text which contains information about 'regulation initiation' OR policy and service development';
- Combinations of intersection and union searches;
- Matrix: searches that allow you to create a table of results, specifying the rows and columns, e.g. columns: stage of policy processes ('regulation initiation'; 'problem analysis), rows: government vs. professional associations vs. users associations for instance).

However, the NVivo v7 software can only help researchers manage, sort, filter and search the data in the transcripts – the description, explanation and analysis of findings depends much on the researchers' knowledge, reflections and thoughts. These should therefore be drafted before using any computer assisted analysis. There will need to be capacity development support in the use of NVivo v7 software.

6.4.5 Interpreting data

Systematic searches of the data can assist the researcher in identifying relationships and finding patterns in the data and in developing draft conclusions.

Relationship between studied themes that researchers will look for in the context of maternal health care and regulation include the following:

- Association and similarities between themes;
- Contrasts and variation, if any;
- Explanation of a theme;

[s] Translating a few interviews into English would also allow paired partners to comment and input on the interviews, to improve future data collection.

- Contradiction between themes;
- Political capture, i.e. of regulation;
- Power dynamics and conflict of interest between actors and their environment (e.g. social mission and commercial practice).

6.4.6 Follow-up

Phase Three will include shorter follow-up interviews with a few Phase One and Two respondents, mainly for exploration and validation purposes. Interactive workshops with actors will also be held. One objective of these activities is to allow respondents to provide feedback on the accuracy of the findings, fill in any obvious 'gaps' in the findings, and comment on whether they are being reported on fairly (a useful way of improving the validity of research findings).

A second objective is to document and assess the reaction of actors to the research findings, particularly the project's preliminary recommendations for improving regulatory processes. Follow-up interviews will be conducted with only a limited number of respondents (say, a total of 3 per study country). Feedback from the workshops will both improve the feasibility of recommendations and act as a mechanism for disseminating findings.

Preliminary results of the analysis will be discussed at stakeholder workshop(s) and a few of the same respondents may be used in different phases of the research. Both follow-up interviews and stakeholder workshops will only take place once the main data analysis has been completed.

One to two follow-up interviews with key respondents are recommended for each case study. This makes a total of 3-6 follow-up interviews per study country where there are gaps.

There are two options for selecting respondents for Phase Three. One option is to use the same respondents interviewed during Phase One. Another option is to select respondents from the key actors interviewed during Phase Two. We suggest that the final decision on this is to be made at the end of Phase Two, when study country researchers will better know which respondents should be followed-up.

In participatory stakeholder workshops - meetings of government officials, professionals, professional associations, social organisations, etc. - stakeholders could give their opinion on the early results of each case study and on whether the regulations are effective. Study country teams will decide the appropriate format for such workshops (the extent to which groups can be mixed across categories of interviewees, for example) and how data will be recorded (audio recording, written presentations, workshop proceedings etc.). All this will be undertaken in line with the HESVIC knowledge management strategy.

6.4.7 Writing up findings

Analysis of data will be undertaken with the objective of publishing different aspects of the study in peer reviewed journals and with the contractual obligations of the Consortium with the EC (country-specific and comparative reports) in mind. A draft structure for country research reports will be delivered in due time by ITM to facilitate consistency and comparability of results between study countries.

Writing up findings is an important part of the analysis procedure. As a guide, the maximum length of a report should be 4000 to 5000 words. Reports should be prepared after a rough draft of the findings has been completed. Sections should be structured along the lines of a scientific paper, while allowing for findings to emerge from the respondents' reports. Key issues need to be placed in a summary, using quotations from individuals interviewed.

Whenever possible, findings from qualitative data should be triangulated with other data sources. To ensure comparability between the three countries, key aspects of the three case studies will have to be common to all, e.g. the situation with regard of caesarean section and related regulations. Short excerpts from transcripts will help illustrate findings for readers. Paired partners will assist in proof-reading and editing a draft of the country reports.

7. Key methodological issues

This section highlights a number of key methodological issues pertinent to all three phases of the research. In the first place, there is the need to consider the ethical dimensions of the overall research, which is the red thread that needs to run through this whole methodology.

7.1 Ethical Issues in analysis

Ethical issues have been detailed separately in the HESVIC Ethics terms of reference that were circulated to the consortium earlier and are on the HESVIC SharePoint. These need to be followed with careful consideration throughout the study.

First and foremost, when carrying out interviews and FGD, all those to be interviewed should have read and signed the consent form, whether they are being interviewed individually (e.g. for manager, policy maker and regulation designer) or collectively (such as those in FGD). All interviewees must also be aware individually as follows:

- about the key issues of the study;
- about the objectives of the study;
- about the risks involved in participation in the study;
- about the efforts that will be undertaken by the team to prevent risk and protect confidentiality of data in terms of its collection and storage.

Interviewees also need assurance that every effort will be made to protect them through ensuring confidentiality in order to prevent harm. This includes not providing information that would allow a reader to identify whom we are referring to (e.g. Minister of Health).

In addition, teams should envisage the specific risks involved in (collective) participation need to be highlighted and how these will be dealt with should also be explained prior to interviews and during the planning of interviews. The background information and consent forms in Annexe 6 should enable this process. This is especially relevant during main data collection, but also during Phase One of the HESVIC study. The specific issues raised in this paragraph will need to be relevant to the local context, where factors will vary in accordance with local conditions.[t]

Among key issues that continue to be of relevance at all stages of the study include the following factors: ensure that all individuals, and not just users of services, are aware of the risk of participating in the study. All participants in the study should be given clear information on how they will be protected. This should be put in writing prior to the interviews as described in the letters of consent presented by the ethics advisor to HESVIC in Annexe 6. Whilst this is never a fool proof guarantee of a total reduction of risk, interviewees need to be aware of the voluntary nature of their participation. They should not have financial inducements to participate. Participants should also be aware of the degree to which researchers and organisers can ensure their protection from threat or harm within the local context. This is also outlined in the consent forms

[t] See deliverable I Review of the methodology of the HESVIC project and the need for absolute clarity in letters of consent (also in Annex 6)

Consent forms (one for each type of interview - one to one and another for the focus group) is provided in Annexe 6.

Each of these forms has information letters to accompany them. Although the FGD information letters only addresses women, it is not excluded that the same letter be used for male participants if separate FGDs (or even mixed ones) are foreseen[u]

There are steps to follow prior to and during the course of interviews. The relevant ethical issues are, however, equally applicable during the course of analysis, with regard to data protection, and represent a consistent approach to confidentiality across all the study sites.

On the issue of organizing participatory stakeholder's workshops (see also Section 5.2.4) an ethical element of utmost significance would be to ensure the confidentiality of informants, as will be the case throughout the study. Thus, if a study participant attends the meeting of their own will, they should not be identified as such during the course of the discussion.

7.2 Comparability across countries

Comparability of research findings across the three study countries is an important component of the project. A key challenge will be balancing the need to maintain comparability across the countries with the need for countries to tailor research to fit their context. Maintaining comparability across countries will require consistency in data collection and data analysis, at least for some items/issues in the common case studies.

7.3 Data collection

Ideally, each study country will use this unified research methodology in order to maintain comparability between countries. Study country partners may choose to translate some (or all) of D 1.2.a into a local language. The tools were developed at the Tools Development Workshop, held in late August in Antwerp, with input from partner countries. Country partners will tailor the tools to their country contexts and translate them into the local languages.

Analysis of the data gathered in Phase One will feed into the development of the Phase Two tools. Each country will incorporate their findings and the themes that they want to pursue into the Phase Two tools. The Phase Two data collection tools will have the flexibility to be adapted by the country teams, whilst maintaining the same overall structure as the other study countries.

7.4 Data analysis

The analysis of data should be conducted in a similar way in each country. The analysis procedure gives study countries the flexibility to explore different themes in the data. The general structure of country reports will be agreed in advance with input from all partners, facilitating comparative analysis of the country findings. It is proposed that the comparative analysis be based primarily on the three country reports, although occasional forays into the original data will be necessary.

[u] We are advised (by the international ethics advisor) that ideally for the best information to be obtained of women's experience of maternal health services, the mixing of groups (e.g. including some male relatives) may not work. Teams need to decide what is most appropriate in each circumstance.

7.5 Languages

The HESVIC project includes partners from 6 countries. Data will be collected in three countries, each with different local languages. Reporting to the EC will be in English. The tools in each Phase will be developed and agreed on in English. The tools will then be translated (if appropriate) prior to their use in a study country. Qualitative data will be collected in local languages in China, and Vietnam, and mostly in Kannada in India. Two issues require consideration: the stage of translation and the reliability of translation.

7.5.1 Stage of translation

Data will be transcribed in the local language(s). One sample transcript will be translated into English. The coding frame will be prepared in English.

7.5.1.1 Translation of key issues prior to analysis

The advantage of translating key issues prior to analysis is that transcripts are available in a language understood by all the project partners. This is valuable for cross-country collaboration in analysis, and to enhance the opportunity for support, comment and research skills capacity-strengthening between countries. The possible disadvantages are time consumption and the loss of meaning in the text through translation, due to different grammatical structure, dual meanings of phrases, metaphors, and other subtle differences between languages. This could reduce the quality of analysis.

7.5.1.2 Translation after analysis

The advantages of translation after analysis are that loss of meaning through translation is reduced and it saves time. The possible disadvantages are the following:

- Lack of data in a common language could pose problems for comparative analysis;
- Analysis of qualitative data in Phase One and Phase Two occurs primarily in the local language, so translation into English occurs after analysis;
- Prior to Phase Two, study country partners need to ensure NVivo v7 is fully functional in their chosen language;
- A sample of transcripts are translated into English at the early stages of analysis, to allow other project partners to contribute to the analysis framework, searches, findings, etc.;
- All transcripts will be in local language. Everything thereafter will be in English.

Difficulties (if and how these were overcome and what kind of capacity support might still be needed across the study countries) can be shared with the ITM technical help desk.

7.5.2 Reliability of translation

Several techniques will be employed to increase the reliability of translation, including the following:

- Translation, like data collection and analysis, should be a reflexive process. The role of the translator should be acknowledged, including whom the translators were, the stage at which translation occurred, and the techniques used to ensure the quality of translation.

- Translators should be chosen carefully, with attention to their level of fluency and the dialect spoken (to improve understanding of local phrases and culture).
- Ideally, more than one translator should be used, with collaboration and consultation between translators to enhance the quality of the translation. The quality of translation should be checked using back-translation. The transcript is translated by one translator, then back-translated to the original language by another translator. The back-translation is compared with the original transcript and inconsistencies are discussed until agreement is reached.

8. Personnel

8.1 Research teams

Each study country team is responsible for recruiting, training, managing and supervising the team of people required to undertake the data collection and analysis for this project. Ideally, for qualitative analysis, the same researchers should be involved in data collection and analysis. Some tasks in this work package can be assigned effectively to individuals. Discussion and debate between two or more members of the research team about the research process and emerging research findings is, however, also an important aspect of qualitative analysis.

In each study country, likely research team members and their responsibilities include:

- **Principal investigator(s)** – responsible for managing research work package activities within their country, supervision of the research team, some data collection (for example, senior key informants) and data analysis.
- **Research assistants** – their responsibilities will be set by the principal investigator(s), but could include logistical and organisational activities, data collection and data analysis. Research assistants should ideally be educated to university or higher level, have experience of conducting health research, and preferably experience of qualitative health research.
- **Typists** trained in audio typing, for transcribing the qualitative data.
- **Sorting and storing data involves clear awareness of ethical issues**

Given the topics being researched, the research team will ideally include men and women at senior and junior levels.

8.2 Paired Partners

Each study country has been paired with a European partner as follows:

- HSPH paired with NCIHD
- IPH paired with ITM
- FU paired with KIT

The European partner should aim to assist and support their Asian partner as required during data collection and analysis. Support can be offered through the usual communication channels (e-mail, phone calls), and funds have been allocated in the budget for staff visits in both directions. Potential roles include advice and support in piloting, input into Phase One preliminary analysis, and input into the main data analysis.

Partners have the right to approach other partners for support (for example “cross” specialities). However, this will be subject to partners’ resource constraints and the need to work within the overall Consortium framework (scientific and management). The Consortium will seek to promote opportunities for linkages, joint reflection and mutual support between Southern partners. To the maximum extent possible, southern partners will share their experiences of data collection.

8. 3 Scientific lead (Work Package 1)

ITM is the lead partner for work package one on 'research methodology development'.

In addition to its other responsibilities, the ITM will:

- Update this deliverable D 1.2.a, based on discussions in the coming weeks
- Take the lead on producing deliverable D 1.2.b 'Revised unified research methodology'.

8.4 Country Research Advisory Groups (CRAGs)

CRAGs have various important functions, being their advisory role in terms of input into research the main one. Decision-making rests ultimately with partners and with the wider Consortium. CRAGS also have a valuable role in knowledge management, both in terms of content (e.g. what to put in policy briefs) and process, as well as in dissemination. CRAGs are also important for political support.

The Country Research Advisory Groups can also provide input during data collection and analysis, acting as a source of technical advice to the study country team where necessary and possible and helping to identify and recruit suitable respondents where needed.

It is important that partners give feedback and explanations to CRAGs with respect to any decisions made. This will ensure that CRAGS continue to play a strategic role in the HESVIC research.

8. 5 Training

Capacity-building in health systems research is a stated objective of this project, and resources have been allocated accordingly. Deliverable 6.2 sets out the broad strategy for capacity strengthening. As part of the knowledge management and research capacity development work package, each partner has been asked to self-assess their capacity to undertake health systems research. The capacity development needs assessment highlighted the following areas with greatest need:

- Assessment of maternal health areas
- Data collection and analysis skills
- Dissemination, including writing skills

The results of these assessments will be presented at a meeting, and the scope, timing and location for research-capacity strengthening activities, discussed.

9. Equipment and supplies

Prior to applying Phase One tools, study countries should have:

- Stationery, computer, printing and photocopying facilities, as required;
- 2/3 recorders, external microphones and batteries.

The suggested specifications for the recorder are:

- It should be portable, and should work on batteries;
- Ideally it should have a background noise reduction function (in case the interview takes place in a noisy environment);
- The choice between tape and digital should be driven by cost and functionality;
- Recording equipment should be tested, and interviewers and focus group facilitators should be thoroughly familiar with the equipment.

Prior to transcription of data, study countries might also consider obtaining 1 or 2 audio transcribing devices. These players have features such as foot pedals and speed control, easing the demanding process of data transcription.

Phase One data analysis will be conducted manually. Phase Two analysis will be conducted using computer software. Prior to Phase Two data analysis, study country and European partners should have computer software for qualitative analysis. NVivo version 7 was chosen as the most appropriate package, as it has functions for handling documents in non-English formats and several partners have experience using this software. Each partner has identified how many copies of the software are required and the software has been distributed by NICHD.

10. Timeline, deliverables and milestones

Refer to the overall project Gantt chart with the various milestones and deliverables.

	Year	2010							2011													2012							Responsible
	Month	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37		
WP	Activity	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul		
WP 1: Research methodology framework																													
1	D1.1 draft circulated for comments																												All partners
	D1.1 finalised	D1.1 M1 M2																											ITM
	D1.2a draft circulated for comments																												All partners
	D1.2a finalized						D1.2a M7																						ITM
	Glossary																												
	D1.2b draft circulated for comments																												All partners
	D1.2b finalized																												ITM
	CRWP guidelines + comments																												ITM
	Development of country work plan (phase 1)						D2.1 D3.1 D4.1 M9																						VIC + paired partners
	Development of country work plan (phase 2)																												
	Ethics expert inputs					*	*			*						*													
	Project meeting - Shanghai (25-29/10)																												NCIHD + FSPH
	Project meeting (Phase One to Two) – Bengaluru March 2011																												NCIHD
WP 2-4: Research in V,I,C																													
	Helpdesk set up and implemented			+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		ITM
Phase 1																													
Step 1	Identifying problems/achievements and selecting one regulation for each case study																												VIC + paired partners

Step 2	Description of regulation by document review																											VIC + paired partners
Step 3	Identifying actors leading to respondents in Phase One																											VIC + paired partners
Step 4	Adapting tools for Phase One data collection (piloting if needed)																											VIC + paired partners
Step 5	Phase One data collection and analysis																											VIC + paired partners
	Phase One Summary (drafting, commenting, editing as needed) due by end of February 2011																											
	Ethics IRB approval			**			**	**			**																	
Phase 2																												
Step 1 & 2	Developing and adapting Phase Two tools + Data collection + Analysis																											VIC + paired partners
Phase3																												
Step 1 to 3	Data analysis for RQ 1 - 3, 4 - 5 and follow up																											VIC + paired partners
	Workshops: In-country methodology development																											VIC + paired partners + ITM
	Mid-term review of data collection and start of data analysis															M10												
	Country report written (drafted, commented, revised)																					D2.2 D3.2 D4.2 M12						VIC
	Workshops: In-country analysis																											VIC
	Paired partner research visits																?						?					VIC + paired partners
WP 5: Comparative research																												
	Comparative analysis of country data																											
	Comparative analysis workshop																											
	Comparative report written																									D5.1		

WP 6: KM and CD																												
	Implementation of KM strategy																											
	Development of KM country plans																											
	Production of dissemination materials																											
	Dissemination of project results to national and international health policy-makers																						M13					
	Workshops: In-country dissemination																											
	Workshop: international dissemination																											
	Implementation of CD strategy																											
	Development of CD country plans																											
	Workshops: In-country CD																											
	Workshop: project-level CD / training																											
WP 7: Project management																												
	Project management committee meetings																											
	CRAG meetings																											
	Partner teleconferences (management and scientific)																											
	18 month report to EC							M9/11																				
	Final report to EC																										M14	

Annex 1

A framework to explore issues of equity in access to quality health care as a way to detect chosen regulation Phase One, step 1

A. Introduction

The framework presented in this Annex 1 is intended as a way of organizing step 1 of Phase One, during which problems and achievements in maternal health care practice will be identified in order to determine relevant regulations. We will use the country mapping reports as a basis for step 1 as these already present a substantial amount of information on equity in access to quality maternal health services.

B. Important notes

- The objective is to come up with a general view of achievements and problems related to regulation of equity in access to quality (general and) maternal care.
- This framework is intended as a menu: each country team is expected to do its best to find information for each cell below.
- When no information is available in health information systems on features of access to and quality of (maternal) health care, this should also be treated as a result of Phase One, step 1.
- The information is to be gathered from secondary data sources: scientific publications, government and NGO reports, etc.
- The framework should apply to public, private non-profit and private-for-profit across the spectrum of health care providers.

The listed indicators are organized in order of importance, with the more essential parameters at the top of the list and the less essential ones at the bottom. Each research country will have discretion for the final choice, in accordance with the feasibility of collecting such secondary data.

C. Framework

	1 **Information needs HEALTH INPUTS**	2 **Information needs HEALTH CARE PROCESS**	3 **Information needs OUTPUT (ACCESS TO CARE)**	4 **Information needs OUTCOME - (PUBLIC HEALTH IMPACT)**
A. GENERAL HEALTH SERVICES				
A **Primary Care**	▪ Average population assigned to health centre; ▪ Average population assigned per general practitioner; ▪ Proportion of population with access to drugs within health services and outside; ▪ Governmental and private expenditure on general first line health services per capita; and as a % of GDP; ▪ Performance of first line health information system.	▪ **Quality of care** 1. Clinical decision making: ➢ universal clinical standards ➢ health care negligence complaints procedure 2. Doctor patient communication*: ➢ Patient-centred care, bio-psycho-social care: home visits, etc. 3. Technical skills (attitudes, etc.) • **Costs of care** ➢ costs of a frequent illness episode ➢ costs compared to monthly household expenditure • **Efficiency of care**	• **Utilization rates** ➢ Globally as N° of new consults/year/inhabitant; ➢ Proportionally as % of population using first line health services at least once/year ➢ Into sub-categories: financial, geographical, etc. (see Annex 2) ▪ **Continuity of care** ▪ **Equity****** ➢ Unbalanced access and quality of care when population segments are compared	▪ Case fatality rate of tuberculosis, AIDS, malaria, diabetes*** ▪ Life expectancy

B. HOSPITAL HEALTH SERVICES				
B **HOSPITAL**	▪ Average population per hospital ▪ Average population per surgeon, ▪ Average anaesthetists per hospital ▪ Average population per anaesthetist ▪ Proportion of population with access to drugs within hospital and outside ▪ Governmental and private expenditure on hospitals per capita; and as a % of GDP ▪ Performance of hospital-based health information system	▪ **Quality of care** 4. Clinical decision making: ➢ universal surgical standards ➢ medical audits ➢ health care negligence complaints procedures 5. Doctor patient communication: ➢ Patient-centred care, bio-psycho-social care 6. Technical skills (attitudes, etc.) • **Costs of care** ➢ costs of a common surgical procedure: e.g. appendectomy • **Efficiency of care** ➢ Average duration of hospitalisation	• **Utilization rates **** ➢ Globally as N° of new cases/year/inhabitant; ➢ Proportionally as % of population using hospital at least once/year ➢ Into sub-categories: financial, geographical, etc. (see Annex 2) ▪ **Admission rates** ➢ Threshold? 60-80 new hospitalisations per 10.000 inhabitants/year ▪ **Continuity of care** ➢ % completed referrals ➢ % self-referrals to hospitals by-passing primary care)	▪ Early mortality of heart infarct, ▪ Mortality of breast and cervix cancers if treated at general hospital level ▪ Life expectancy

Remarks

* A2 and B2: to check on issues concerning doctor-patient communication: a literature search with key words “patient-centred care”, “bio-psycho-social care”, etc.

** B3: utilisation rates at hospital level are only relevant if hospitals have out-patient departments, offering primary care services

*** A4 and B4: these are examples of public health problems that need access and continuity of care both at primary care and hospital level as a prerequisite to be controlled

**** A3: insight into equity is possible when information enables comparing two populations (e.g. floating and resident in China, tribal and ethnic Vietnamese or rural and urban in Vietnam, scheduled tribes and casts vs. others in India).

EmOC CASE STUDY				
EmOC	▪ Average population per operating theatre ▪ Average population per maternity ; ▪ Average population per midwife ▪ Average population per OBS & GYN specialists ▪ Proportion of population with access to drugs within maternities and outside ▪ Governmental and private expenditure on maternal health per capita; and as a % of GDP ▪ Operating Budget of hospitals and maternities compared to investment costs (if available) ▪ Training in EmOC practice ▪ EmOC-equipped health services ▪ 24/7 availability of obstetric functions ▪ Availability of referral resources	▪ **Quality of care** 7. Clinical decision making: ➢ universal EmOC guidelines available at maternities ➢ standardized surgical procedures C-section ➢ maternal death audits 8. Doctor patient communication*: ➢ Patient-centred care ➢ Bio-psycho-social care 9. Technical skills: to perform normal delivery, C-section • **Costs of care**** ➢ costs of a normal delivery; costs of a C-section ➢ costs compared to monthly household expenditure ▪ **On efficiency of care** ➢ Proportion obstructed labour as a cause of maternal mortality ➢ timely maternal referral from first line health service to hospital	Global: ▪ C-section rate ▪ proportion of skilled birth attendance (SBA) ▪ Unmet obstetrical needs ▪ Referrals completion rate ▪ % institutional delivery Sub categories of access see FLS and hospital	▪ MMR ▪ Early neonatal mortality (as a Proxy for neonatal mortality) ▪ C-section success and fatality rate

Remarks

* EmOC/2: check on issues concerning doctor-patient communication: a literature search with key words 'patient-centred care', 'bio-psycho-social care', etc.

** EmOC/1 to 4: to secure some inter-country comparability: suggest concentrating on: C-section rate (in different population segments), costs of a normal delivery; costs of a C-section. Ideally, the total cost of a delivery (or a C-section) includes transport, services fees, drugs, purchase of material, accommodation costs (of relatives for instance), etc. These costs should be compared to monthly household expenditure.

*** EmOC/3: SBA, numerator = births attended by skilled health personnel during a specified period; denominator = total number of live births during the specified period

ANC CASE STUDY				
ANC	▪ Average population assigned to HC ▪ Average population assigned to maternal services	▪ **Quality of care:** ➢ women-centred care, treated with respect; cultural appropriateness ➢ technical skills; acid folic supplements, Vitamin D, Anti-Tetanus Vaccination ➢ Screening for sickle cell, thalassemia, Down syndrome gestational diabetes: ▪ **Costs of care** ▪ **Efficiency of care** ➢ detection of pregnancy risks ➢ treatment of pregnancy diseases ➢ Additional care made available to pregnant women with high risk factors, complicated obstetric history	▪ Coverage rates with 4 antenatal consultation ▪ achievement rate (% of those receiving 4 over those who received the first ANC) ▪ Access to effective treatment for women suffering disease during pregnancies (not pregnancy-related but detected during ANC)	No outcome indicator ? Proportion of maternal mortality due to avoidable morbidity

Remarks

* Obtain local guidelines on how to perform antenatal care. Check if the following criteria are included. Identify changes and deficits compared to the following criteria used by the NHS[v]. Obtain information on implementation of local criteria.

[v] NHS and National Institute for Health and Clinical Excellence (NICE). Clinical Guideline 68, 2008.

ABORTION CASE STUDY				
ABOR	Average population per equipped health centre where abortions can be carried out	NHS Guidelines*: ▪ Ultrasound confirmation of gestational stage of pregnancy ▪ information on risks is provided to candidates ▪ suitability of method according to pregnancy stage ▪ appropriate pre-tests: anaemia, STD, papanicolao ▪ Appropriate post-information: contraceptives, etc. ▪ Consent form signed	Any statistics welcome ▪ Gestational stage of pregnancy when first contact candidate ▪ N° of maternal deaths due to informally induced abortion	Complication due to termination of pregnancy
Remarks * Obtain local guidelines on how to perform an abortion. Check if the following criteria are included. Identify changes and deficits compared to the following criteria used by the UK NHS[w].				

[w] NHS choices. How an abortion is carried out? Available from: http://www.nhs.uk/Conditions/Abortion/Pages/How-is-it-performed.aspx. Accessed on June 6, 2010.

	1 INPUT	2 PROCESS	3 OUTPUT	4 OUTCOME
GRIEVANCE REDRESSAL CASE STUDY				
GR	The regulation procedure should be designed in advance. Availability of trained staff for GR procedure Availability of sufficiently hierarchic staff for GR procedure Over loaded with other work- Inadequate resourcing	Specifications of conditions to be addressed by GR policy Complexity and clarity of GR policy Description of the GR filling procedure Description of the post GR filling procedure (delays, enquiries, referrals, judicial referrals, use of representatives, mediations, information, advisory procedures, decisions, punishments, appeals, justification of administrative decisions, data collection)	GR policy to be made available to users and staff in all health facilities (with summaries duly posted in wards). GR policy known in advance esp. to women users Policy needs financial input from complainant	Ideally, an analysis of organizational issues at stake should follow grievance treatment – which, from this angle, should be handled as a critical incident\- or perhaps it is simply not applied. Existence of GR issues of critical significance for regulation procedures.
These criteria were based on an analysis of the grievance procedure of the State of Connecticut, Department of Mental Health[x].				

[x] State of Connecticut, Department of Mental Health. Grievance procedure, 2002. http://www.ct.gov/dmhas/cwp/view.asp?a=2902&q=335180 accessed June 6, 2010

Annex 2

A referenced suggestion to explore issues of accessibility to health care within a chosen regulation

This framework is not to be viewed as a proposal for a more structured approach to select MH issues and relevant regulations. It is provided merely as an intellectual frame to understand the dimensions in terms of which accessibility to health care can be studied.

Model of analysis and strategic orientation[y]	
Type of accessibility	Indicators
Total	New curative consultations per year per inhabitant. Proportion of population with at least one curative consultation yearly. For hospitals in-patient wards: admission rates.
Geographical	% of total population living at less than 5 km from health centre. Natural obstacles (mountains, rivers, etc.) on the way to a health centre
Pharmaceutical	% of prescriptions bought outside the health centre. Range of pharmacy stocks interruptions.
Intra institutional	Average duration of consultation. Average time of stay in health centre and obstacles encountered within.
Psycho-social and cultural (obstacles perceived by the users)	Results from observation of consultation, post-consultation findings from patients through interviews
Chronological	Degree of compatibility of opening hours with users activities Patients refused during consultation hours
Financial	Price of sickness episode according to family income[5]

Notice: The cost of a normal delivery or a C-section should be established while including costs of admission, professional interventions, tests and drugs but also indirect costs such as those of transportation.

[y] Adapted from: International Health and Aid Policies. Section 6, Chapter 2. Cambridge University Press, in press. J.-P. Unger, P. De Paepe, K. Sen, W. Soors

Annex 3

Criteria for assessing regulation

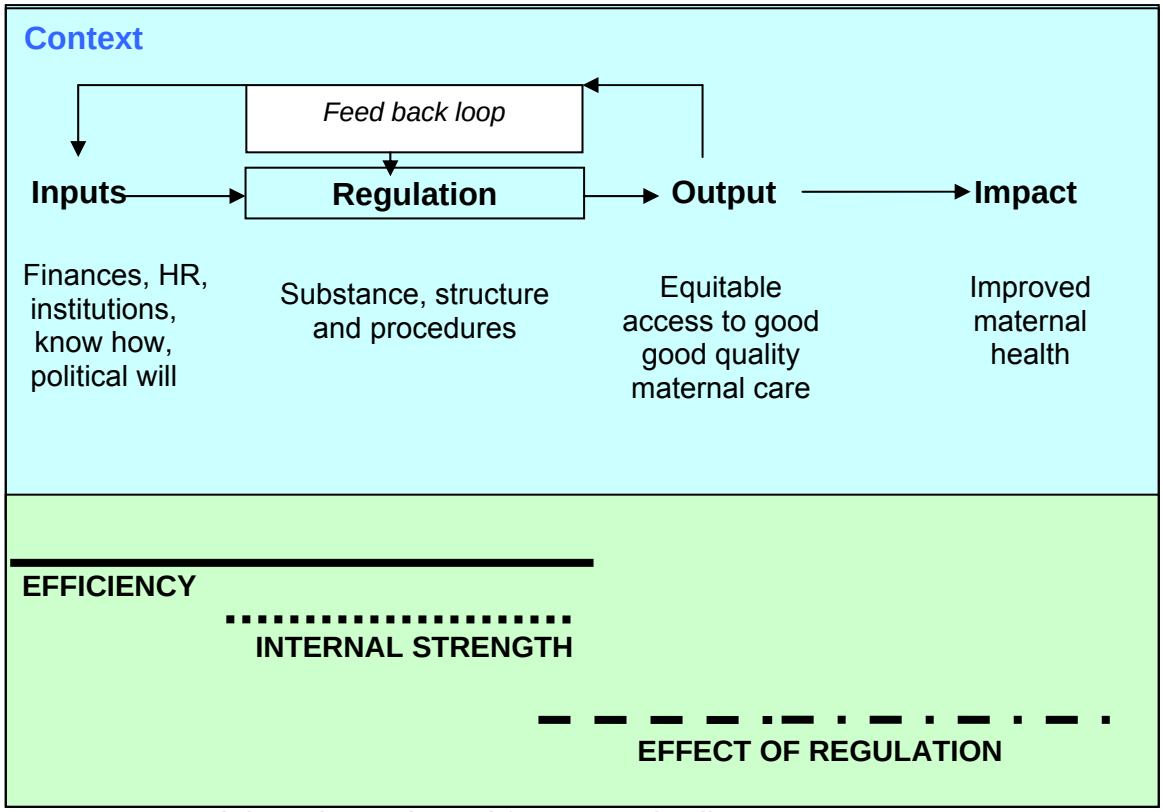
A. INTRODUCTION

This annex is about defining criteria that can be used for organizing research methods that aim at assessing regulation. It will help us when preparing research tools for interviews; and when we collect secondary data. This annex when read should therefore be closely linked to Annex 5.

If the effect of regulation on equitable access to quality health care represents the core of the HESVIC study, then the consortium needs a set of criteria to assess regulation processes and their effects on health. The literature on assessing regulation and its effects on health services in LMIC is limited.

Using the Donabedian quality of care assessment model[z], figure A below, (presented at the October 2010 Shanghai project meeting), aims to provide an overview of issues to be considered when assessing regulation as a process.

Figure A: The assessment of the regulation system



Source: Own elaboration, adapted from Donabedian

Regulation, as illustrated in the above model, could be seen as a linear process model, taking in inputs and structure (resources, institutions, know how, political will,

[z] Donabedian A: *Explorations in Quality Assessment and Monitoring, Volume I. The Definition of Quality and Approaches to its Assessment.* Ann Arbour, MI , Health Administration Press; 1980:1-164.

etc.) at the start and producing a certain output (equitable access to quality health care), leading to an ultimate impact (improved maternal health). In real life, however the regulation process is unlikely to be linear, as it is related to the context and actors and constantly influenced by feedback.

In order to assess a sequence from inputs to the regulation process, we want to look for the *criteria to be identified* for the efficient working of a regulation. If we are to assess the regulation process in itself, we would want to assess its internal strength. Lastly, if we want to know more about the relationship between a regulation and an outcome, we would want to assess its effect. The sections below elaborate on this.

B. CRITERIA FOR ASSESSING REGULATION

At the Shanghai project meeting the HESVIC consortium decided on 4 main categories of criteria for the assessment of the regulation system. These 4 broad categories of criteria for *assessing* regulations are identified in Box A below.

Box A: Four categories of criteria for assessing regulation

1. **Criteria to assess whether or not a regulation fits the context requirements**
2. **Criteria to assess the capacity of actors in regulation processes to carry these out. Also to assess the capacity of invisible actors to interfere with regulation processes**
3. **Criteria to assess the internal strength of regulation**
4. **Criteria to assess if a regulation has any effect**

An overview is provided below on how best to proceed with these criteria in the process of assessing regulation. In the first instance, consideration should be given to what needs to be assessed and how.

The sources of verification will orient the actual development of research tools and ways of analysis that assess regulation (see also the generic research tools matrix in Annex 5). The research tools for verification are associated with the next step in the research methodology process: the development of research tools. The generic tools in Annex 5 of this D 1.2.a, developed at the Antwerp Tools Development Workshop, have therefore been amended and completed accordingly.

The 4 categories of criteria identified are not supposed to have an order of priority between them nor should they possess an intrinsic 'weight' that differentiates their importance.

1. Criteria for assessing whether or not a regulation fits the context requirements.

We need to find out whether a regulation is appropriate for its context. In order to do this, some aspects of a chosen regulation have to be taken into consideration. These include:

a. The extent to which a regulation is timely and informed by evidence from the context. In particular, the fit between a regulation design, its procedure and the actual contextual features;
b. The extent to which the effects of regulation are being modified by the context;

c. The extent to which regulations are influencing their context in an unintended way.

How now should we go about assessing this possible fit between a regulation and its context? The following are some examples for you to follow:

- We need to look for three possible fits here:
  - the degree of fit between regulation procedures and processes on one hand and context features on the other,
  - how do (political, economic, social, etc.) context features contribute to alter the regulation process, its procedures and its effect,
  - Did the regulation possibly influence in an unintended way the context?
- Depending on the chosen regulation some of the elements that we can look for to assess this fit are the following:
  - Whether or not the way that access to care is defined within the regulation is according to a demand approach (what are people asking for?) or a technical judgment on people's needs,
  - Whether or not any contribution schemes as defined in the regulation are related to income and wealth rather than to health status,
  - Clarify social vs. economic objectives: economic objectives relevant from an economical viewpoint, such as reality of competition, anti-competitive behaviours being limited,
  - What are the technical merits of local rules as compared to internationally accepted ones?
- Sources of verification to assess all this are opinions from interviewees and through FGD, triangulated with review of regulation documents and literature and discourse analysis;
- Based on the actions above, the researcher should be enabled to make a judgment call on the fit and continuous adaptation of regulations to their context (e.g. to market changes, etc.).

2. Criteria for assessing the capacity of actors of regulation processes to carry the regulation out. Also to assess the extent to which (invisible) actors have the capacity to interfere with these processes.

We need to assess if actors possess the required capacity to implement or be engaged in a chosen regulation? Some aspects of that regulation to be taken into consideration are the following:

a. Extent to which actors have sufficient capacity: institutional, individual role and skill capacity (see below);
b. The right actors being involved at the stages of a regulation processes;
c. The role of invisible actors.

a. Extent to which actors have sufficient capacity to implement regulation

We can distinguish three levels at which actors can exercise their capacity:

- As an actor within an institution: their institutional capacity;
- As an individual actor: their individual role capacity;
- In the way that they are given skills: their skill capacity.

To judge on the actors institutional capacity, we need to find out the degree to which the institutions involved in regulation and control as well as the regulated staff are provided with sufficient support to carry out regulation, and the degree to which sharing of experiences and disseminating information is made sufficiently possible. To measure the actors' individual role capacity, we need to find out whether people with the proper job descriptions and authority are carrying out the steps that correspond to them within the regulation process. To see how the actors' skill capacity is, we need know more about the way regulatory staff is being prepared as far as knowledge transfer is concerned.

How now should we go about assessing these different aspects of actors' capacity? The following are some examples for you to follow:

- We need to identify problems and achievements in regulatory processes and procedures that can help pinpoint us at issues important for the actors. Examples are:
  - checking for attrition and turnover rates of regulatory as well as regulated staff,
  - checking on separation of roles in case of regulation of government facilities by a government agency,
  - etc.;
- When we identify issues in the regulation processes they may help us to understand interventions and the role of actors;
- Sources of verification to assess all this are opinions from interviewees and through FGD, triangulated with review of regulation documents and literature and discourse analysis;
- Based on the actions above, the researcher should be able to make a judgment call on the capacity of actors to engage on regulation.

b. Are the right actors involved at the right stages of a regulation processes?

Here we need to appraise whether the right actors were and are being involved at the right time and place in a chosen regulation process. The appraisal is premised on the degree to which the presence or absence of actors or a particular actor can explain the presence or absence of internal strength and weaknesses (see also below) of a chosen regulation and possibly its effect?

How now should we go about assessing if the right actors are involved at the right stage? The following are some examples for you to follow:

- Sources of verification to assess all this are opinions and perceptions of the range of interviewees (one to one and through FGD). These will be triangulated with the review of regulation documents and literature, an assessment of speech and interviews through use of thematic and discourse analysis;
- Based on the actions above, the researcher should be enabled to make a judgment call on the actors involved in a regulation.

c. What is the role of invisible actors?

Invisible actors act as the 'hidden hand' of influence. This element thus points us to understanding the degree of independence of a chosen regulatory process and procedures from political, economic pressures and influences. Examples of such influences are:

- existence of political appointments among regulators,
- nepotism,
- patronage,
- interference in management,
- hints with regard to informal payments,
- regulatory capture (lobbying, pressure, counter-productive regulations, etc.),
- etc.

One may suspect regulatory capture when for example, a high number of facilities do not appear to answer to the criteria set by regulations or when the draft of a regulation appears too sympathetic to providers' needs and in sufficiently of users. Or when there is discrimination in the way in which regulated staff and institutions are handled by the regulatory agencies (e.g. some with favouritism).

How now should we go about assessing the role of invisible actors? The following are some examples for you to follow:

- Sources of verification to assess all this are opinions from interviewees and through FGD, triangulated with review of regulation documents and literature and discourse analysis;
- Based on the actions above, the researcher should be enabled to make a judgment call on the actors involved in a regulation.

3. Criteria for assessing the internal strength of regulation

We need to define how we can measure the internal strength of a chosen regulation in itself. Some aspects of that regulation to be taken into consideration are the following:

a. Appropriateness of the regulation;
b. Internal consistency of the regulation;
c. Is the regulation duly implemented in all its aspects;
d. Clarity and lack of ambiguity in the regulation;
e. Extent of discretion vs. inflexibility, i.e. the capacity to amend the regulation locally;
f. Efficiency of the regulation;
g. Existence of corrective feedback loops – internal mechanisms whereby the design and implementation of the regulation is amended according to its performance / output.

As with the previous assessment criteria our sources of verification will come from the opinions and perceptions of interviewees and through FGD, triangulated with the review of regulation documents and literature and discourse analysis.

a. Appropriateness of the regulation

Here we will need to assess the presence and degree of cohesion between available resources for a regulation and its objectives. In particular: are the means to ensure implementation available? Secondly, whether there is a degree of relevance of a particular regulation's objectives associated with the existing problems and achievements in health services and health care delivery. In particular, are the objectives of regulation evidence based?

- Based on the above, the researcher should be enabled to make a judgment call on the relevance of a regulation, the independence of its funding and the related transaction costs of regulation agencies, if any exist.

b. Internal consistency of the regulation

We need to judge the cohesion between regulation procedures (incentives and disincentives) and its objectives. In particular, are a regulation's process and procedures evidence based?

- Based on the above, the researcher should be enabled to make a judgment call on cohesion between procedures and objectives of a regulation.

c. Is the regulation duly implemented in all its aspects

Can we find out for example if a regulation's procedures (e.g. payments, etc.) are really rewarding clinical activities? In particular, are rewards, penalties and sanctions really applied (e.g. in case of best or poor performance or non-implementation of contracts)?

- Based on the above, the researcher should be enabled to make a judgment call if a regulation is implemented as intended.

d. Clarity and lack of ambiguity in the regulation

We need to appraise the degree (or better, absence) of ambiguity in the regulatory document from the point of view of both regulating staff, regulated staff and services users (see also section 4.3 of D 1.2.a).

- Based on the above, the researcher should be enabled to make a judgment call on the degree of ambiguity through critical reading of regulatory documents, analysis of organograms and on the simplicity of regulatory institutions.

e. Extent of discretion vs. inflexibility

Here we will assess the degree of freedom with which a chosen regulation content or even a regulation process can be adapted locally (by people involved in administration, operationalization, adaptation and oversight of regulations). We need to find out also whether that degree of freedom is matched with their capacity (see above).

- Based on the above, the researcher should be enabled to make a judgment call on the degree of freedom.

f. Efficiency of the regulation

Assess the extent to which a regulation consumes as little as possible resources (e.g. administrative burden, etc.) to achieve its objectives. To estimate the degree of efficiency of a regulation we will need to include at least 4 different levels or aspects: the resources consumed by regulation, the time spent on regulation, the actual use of available resources for regulation and the level of simplicity of regulation procedures and the institutions involved in it. Any measurement of efficiency needs to be simple.

- Based on the above, the researcher should be enabled to make a judgment call on the efficiency of a regulation process.

g. Existence of corrective feedback loops

A feedback loop is any internal monitoring mechanism or device available whereby the design and implementation of the regulation can be or is being amended according to its monitored performance or output. To assess this we need to find the existence and degree of performance of quality assurance mechanisms and the related support given to them by any health system information components.

- Based on the above, the researcher should be enabled to make a judgment call on the existence of rent-seeking behaviours in response to regulations; on corrections within the regulation process in response to monitoring results

4. Criteria for assessing whether or not a regulation has any (positive and negative) effect

The effect of regulation on equitable access to quality maternal health services is an important quality criterion for regulation. It was agreed at the Shanghai project meeting that HESVIC will include identification and assessment of the effects of regulation. This involves addressing questions about whether or not regulation is achieving what it sets out to achieve, and identifying any unintended effects.

How do we know that a particular regulation is having a particular effect in terms of equitable access to quality care? We need to build a *plausible case* by gathering different kinds of clues through the following:

1. Study the nature of the regulation / output, in particular possible processes that might explain the impact of a regulation:
    a. e.g. incentives (and available resources), and
    b. punishment / threats;
2. Assess the internal strength and relevance of regulatory substance, structure and mechanisms;
3. Knowledge of confounding variables - other determinants of the output under scrutiny;
4. Time factor (modification of effect *after* introduction of regulation) – historical patterns;
5. Geographical patterns;
6. Congruence of verbal sources with literature.

At analysis level, international comparisons with countries not relying (much) on regulation to deliver equitable access to maternal health care will help assess the potential of improving regulations.

C. CRITERIA TO ASSESS GOVERNANCE PRINCIPLES THROUGH REGULATION AT ANALYSIS LEVEL

After setting the criteria for assessing regulations, associated with development of research tools, there remains a need for criteria to assess governance with respect to its achievements in regulation. At the Shanghai project meeting, it was felt that the quality criteria for governance, as derived from Siddiqi et al, would be difficult to turn into specific research tools or into prompts for interview questions. It was decided that they should rather be used during the overall research analysis (Phase Three).

Again little literature exists on how to apply criteria to do so. Borrowing from the analytic framework offered by Siddiqi et al, some indicators are provided below to make the Siddiqi et al governance quality criteria more operational. The aim of Box B below is to provide researchers with some practical handles in terms of where to look and what to look for when they analyze regulation and want to make the necessary association to the larger framework of governance in health. In the left hand column the 12 governance principles are listed, as singled out by Siddiqi et al. The middle column provides some practical guidance on what we need to look for within the studied regulation or indeed maternal health to reach an assessment on the degree to which each principle is represented within the chosen regulation. The right hand column gives a hint on where to look for these elements of information. These will need to be utilized only at analysis stage.

Box B: Governance quality criteria and indicators to make them operational

GOVERNANCE CHARACTERISTIC*	INDICATORS TO DETECT TO WHICH DEGREE REGULATION DEALS WITH IT	SOURCES OF VERIFICATION
'Equity and inclusiveness'	• With high variance of maternal mortality rate across population strata (e.g. floating vs. residents in Shanghai; minorities vs. majorities in Vietnam, between the majority[aa] and scheduled tribes in India where relevant); • With high variance in access to skilled birth attendance SBA, institutional deliveries and C-section across population strata; when there are excessively low or high C-section rates; • With high levels of catastrophic health expenditure; • With inequitable distribution of resources • With variance in quality of EmOC according to social and geographical criteria; • With commercial clinical practices (with effects on health status)	Regulation documents Health (HIS) and geographical information systems
'Effectiveness and efficiency'	With issues of local management related to care quality and administrative efficiency	Regulation documents HIS
'Quality assurance	With practice of audits of maternal	

[aa] And among the majority, by social stratification

procedures'	casualties	Regulation documents HIS and audit reports
'Intelligence and information'	With performance of HIS structure and content	HIS
'Responsiveness'	The type of methods used to identify and correct major maternal health problems	Analysis of methods for needs assessment
'Rule of law', 'ethics'	Actors' perception of control, repression and regulation	Study of perception
'Participation and consensus orientation'	With the role of States, regions and districts in designing and enforcing regulations. With the role of consumers' associations in regulation and control, exploration of their effectiveness.	Study of decentralisation of decision-making Analysis of role of consumers'
'Transparency'	With the degree of independence of professional associations in actual control and corrective procedures	Study of e.g. membership procedures, contracts, recruitment process and praxis
'Accountability'	With variance in implementation and enforcement of financial and administrative standards according to health facilities	Analysis of procedures for overseeing adherence to financial, administrative rules
'Strategic vision'	With the degree of compatibility between government-stated preoccupations	Analysis of political stability, population centeredness, design of maternal health policy

* Adapted from Siddiqi et al analytical framework.

Annex 4

Phase One Summary

A reading of the current D 1.2.a with its annexes, matched with on the ground realities faced by maternal health services in each country context, represented by the case studies, will provide practical direction to understanding how to locate and use information being collected This will be undertaken through documentary review, country mapping and the selected interviews.

Page numbers and sections refer to the post shanghai version of D 1.2.a. Please remember the more accurate and systematic the collection of information, the easier it will be report.

A. Outline for Summary structure
Suggested length: between min 27 and max 35 pages, excluding annexes.

1° INTRODUCTION/BACKGROUND
Suggested length: 4 pages.

- Background Information (as in country research work plans), including research questions;
- Description of overall research approach for Phase One *(RQs addressed, data collection methods, approach for analysis)*.

2° CASE STUDY-SPECIFIC SECTION
3 for each country. Suggested length: 5- 7 pages per case study.

- Case study-specific methods for data collection;
- Justification and rationale for:
    - Selection of thematic areas within the case studies (Section 3 of D 1.2.a),
    - Selection of regulation (Section 4.1 of D 1.2.a);
- Findings and analysis on problems/achievements of prevailing maternal health care delivery within each case study (*not applicable to GR)*;
- Findings and analysis of the regulation procedures processes and approaches;
- Findings and analysis on actors' roles and interrelationships in regulation.

3° CONCLUSIONS AND WAY FORWARD
Suggested length: 8-10 pages.

- Reflections on Phase 1;
- Field work issues *(problems and achievements, see section 4.3)*;
- Ethical Issues;
- Gaps and inconsistencies that will shape large elements of main data collection;
- Conclusions and ways forward - suggests next steps for research countries.

Phase One Summaries need to be made compatible with the structure of the overall country study reports, due at the end of Phase Three.

B. Outline for content

Main Issues[bb]	Elaboration – How	Examples
Description and some analysis of main problems and achievements in relation to access to quality maternal health services and one corresponding regulation per case study.	Focus on country context *through mapping reports, international reviews and documentary analysis* in addition to summarizing information from *interviews* concerning the regulation within defined case studies, as described in section 4.3.1.2. When writing up it is always useful to check that you have covered the points listed in the document. On problems and achievement in particular, please note both well established and the unexpected.	Examples of problems and achievements as given in Box 3 of D 1.2.a, in particular some recent examples from each country, which relate to structure, process and outcome of regulation and also of maternal health services.
Broad description and partial assessment of the regulation document.	To be obtained from the document review already undertaken for regulation to be explored in Phase One, Step 1, and from interviews where feasible.	Check Annex 3 and Section 4.3 of D 1.2.a for direction prior to the collection of data / information and identification of gaps, which will all be part of the process of compiling the report
Broad description of processes of regulation as a process: the design, administration and implementation of the regulation.	Focus on documentary and literature review as well as interviews where relevant and useful information has been obtained.	

[bb] It is assumed that in this phase primary data will not be the main focus but rather existing literature as identified in this table. The focus of the phase 1 report will be descriptive with a systematic approach, but not excluding the team's appraisal of why some things happened in relation to problems and achievements. We do not expect this report to be more than 30 pages plus annexes where needed. Gaps identified at different levels and in concept or their application will shape D12b

Main Issues[bb]	Elaboration – How	Examples
Broad description and partial assessment of approaches to and procedures of regulation.	To describe the balance between consumer-market and state orientation, the extent of incentives versus controls. This entails a description of the category under which the regulation falls i.e. whether the regulation is based on incentives, sanctions or upon some level of public monitoring from citizens or the state. It could also entail more than one approach.	Please refer to Annex 3, Figure A of D 1.2.a
Identification of actors involved directly or indirectly in regulation.	We need to have in depth information on who, what and where for the actors. Much is already available in country mapping and international reviews (in particular) but also will be obtained during the Phase One, Step 1 documentary reviews. The relationship between actors, formal and informal, should, where possible, be highlighted.	See Section 4.3 Criteria 2 a-c, on Identifying and interviewing actors involved in regulation.
Gaps in information - in the content analysis of documents.	In the reporting you will need to identify what is missing in terms of HESVIC research objectives and terminology themes. If they are missing in the literature or some issues appear not relevant in your context, you need to say this is the case, why when you are writing up.	We have already had some examples of these in Shanghai in relation to some terminology (e.g. mechanisms) or concepts such as *transparency and accountability* and *governance.* We have tried to address these as best as we can. However, some of the gaps may not apply- to all contexts. Where they have a glaring mismatch you need to raise this in your reporting and suggest alternatives as suggested in D1.2.a. We also suggest assessing gaps in the practice of

Main Issues[bb]	Elaboration – How	Examples
		regulation through *User Voice.* This should therefore be part of the report where possible.
Ethics	Throughout the reporting we need to have highlighted both anticipated and actual problems with the selected interviews, once you have used the consent form as a test and a taster for the main study.	You need to gauge the concerns over ethics, especially where there is risk of breaching confidentiality or imposing a risk including that of psychological harm. We would like to see a section on ethics in the report which identifies the strengths and weaknesses of our approach towards ethics in phase-one, however limited.

Annex 5

Generic questions matrix

The following matrix of 44 generic questions was developed at the end of August 2010 at a Tools Development Workshop held in ITM Antwerp.

It lists the questions that we need to obtain answers for in order to have answers to research questions 1, 2 and part of 3 (referring to the research in Phase One).

These questions are generic in the sense that they seek to get answers for the RQs, irrespective of the case study area and the regulation that might be eventually chosen for the study. This thus means that the actual phrasing of the questions can be (this will actually almost always be the case) different from the phrasing of the questions in this matrix. Questions could also be formulated so that they elicit responses that can help answer one or more of the questions in Annex 5 matrix.

Not all of the 44 questions are meant to be asked of all respondents. Answers to some questions can be derived from secondary sources (literature, mapping report etc.); one could however test and verify some of the findings from the secondary review by asking pointed questions to specific respondents. Similarly, not all questions need to be asked of all the respondents. It is important to remember that not all of the questions selected for a particular group of respondents can be answered by all the respondents in that group.

These questions have been developed with the HESVIC research questions (with all sub-questions for research questions 1 and 2 and some sub-questions from 3) in mind and, where possible, building on relevant parts of D1.2.a.

The questions were organised into a matrix as follows:

- Questions have been divided into 5 broad areas (corresponding to HESVIC research questions). These are presented in the first column of the matrix:
    1. Contents of the regulation,
    2. Processes of regulation,
    3. Actors in the regulation,
    4. Approaches to (and practices of) regulation – this includes the procedures of regulation,
    5. Effects of regulation;
- Each of these broad areas has been further sub-divided into sub areas of enquiry (E.g. questions exploring the context and factors influencing the particular broad area and questions exploring the overall impression of the respondent, etc.). These are presented in the second column of the matrix;
- Each question is followed by “Prompts and Cues” for these questions. These are cues for the interviewer and also for analysis. The ten principles of governance proposed by Siddiqi et al, and cues around ‘equitable access’ and ‘quality of care’ are included in the prompts. Advice on the sequencing of questions and feedback on earlier questions and answers is also included in these prompts. Prompts have not yet been elaborated in detail;

- For each question we have proposed a method (E.g. interviews, FGDs, review of documents, etc.);
- This inventory is not exhaustive at present. There is room for adaptation when generic tools are adapted at country level.

Detailed prompts need to be developed for all questions. These need to be tailored according to the respondent. The criteria for assessment of regulation provided in Annex 3 will serve as guidance for developing these prompts. These criteria will have to be used to develop prompts in a manner that they elicit responses which can help us use these criteria during the analysis. Also the justification for the case studies and regulations will be used during the research process (e.g. as prompts during interviews).

The other component of the matrix is the columns related to the broad groups of respondents (see Section 4.3). Research countries have worked together to identify the important categories of respondents that need to be approached to seek answers to the research questions. There is room for including/removing respondents in these categories of respondents according to country setting/context. They have also discussed which of the respondents (categories) will be asked which question(s). Though ticks were made in the matrix, it was agreed that country teams will need to refine this further.

This matrix will form the basis for identifying the sets of questions for the adapted tools (see also Section 4.4.2). The choice and order of questions in the adapted tools (and the actual interviews) should be decided by the country teams in consultation with their partners.

The following underlying principles were agreed upon and guided the development of the matrix below:

- The matrix is mainly for Phase One, covering, in the main, answers to ‘what’ and ‘how’ (research questions 1 and 2 and part of 3). In other words, the aim of Phase One is to provide an overview of how regulation processes are designed, enforced and implemented;
- Phase One will involve a limited number of interviews (to be decided by the country teams);
- It is recognised that ‘effects’ questions, though included here, are mostly relevant to Phase Two;
- The focus/application of regulation needs, where possible, to be explored in relation to, and compared between, the case studies (particularly when respondents are the same for more than one case study);
- Some prompts (e.g. references to Siddiqi’s principles) are not to be covered in the interviews/documents but should be looked for in the analysis;
- The question/prompt ‘What would you change and why?’ is applicable to most questions.

Not all questions will apply to all regulations. This is important for the adaptation.

Matrix of generic questions

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
Contents of regulation	**Objectives of regulation**	1. What is the formal / explicit objective(s) of this regulation? 2. Are there any implicit objectives/values of this regulation?	Ref to assessment criteria in Annex 3.	SSI, Doc. Review SSI	√ √	√ √	√			√ +/-
		3. How do you interpret the regulation objectives at your (and other) level?	Any differences between the levels?	SSI, FGD	√	√	√			√
		4. Who in your view will benefit from this regulation and in what way?	Ref to assessment criteria in Annex 3. Any difference with regulatory documents?	SSI, Doc. Review, FGD	√	√	√		√	√
	Contents	5. Are there one or more such laws, rules, standards and procedures involved in regulating this issue?	If more than one – what is the hierarchy (and consistency) of these documents?	SSI, Doc. Review	√	√				√
		6. What procedures are referred to in relation to enforcing / implementing the regulation?	Compare with actors' views of actual practices	Doc. Review	√	√	√			√
	Overall impression RE contents	7. How appropriate are the purpose/objectives of this regulation to the context of this country/state/province?	Do you think it needs updating/amending?	SSI, FGD	√	√	√			√
		8. How appropriate do you think	What would you change	SSI, Doc.	√	√	√			√

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
		the contents of this regulation is in relation to what it intends to achieve?	in it and why?	Review, FGD						
		9. In the country mapping or in the maternal health case study, we found the following as an IMPORTANT achievement: " XXX". To what extent do you think that this regulation is linked to this achievement or is somehow responsible for it?		SSI	√	√	√	√		
		10. We also found the following as a problem: "YYY". Do you think that this regulation is somehow responsible for it"?		SSI	√	√	√	√		
		11. Do you think the contents of this (document) need amendment and why?	What processes are in places for this? What actors are involved in this amendment? How could it be amended to reduce the maternal health problem?	SSI, FGD	√	√	√			√
	Factors affecting regulation contents (incl. context / environment)	12. What factors, if any, may have affected the purpose and objectives of this regulation?	Context, national priorities, international influences, commitments, etc.	SSI, Doc. Review	√	√	√	√(I)	√	√
Processes of	**Stages of the**	13. How do you think this	History, context, legal	SSI	√	√				√(V)

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	*Regulation operationalization / administration / oversight*	*Implementers (health manager, service provider – both public and private)*	*Users of services*	*Others with less defined roles (NGOs, Media,)*	*UN agencies (V,I)*
regulation	**process**	regulation came about (and from whom)? Is this typical of other regulations?	framework, international agreements/influences							
		14. Can you describe the process of formulating / defining this regulation / decree?	Ref to assessment criteria in Annex 3.	SSI	√	√				√(V)
		15. How is this regulation interpreted / adapted (operationalized) at your level (and how does this compare to other levels)?	Also, how it is explained?	SSI, FGD	√	√	√			+/-
		16. How is this regulation enforced and/or monitored at your level (and other levels)?	What sanctions apply in case of non-compliance?	SSI, Doc. Review	√	√	√			
		17. How this regulation is implemented at your level (and how does this compare to other levels)?		SSI, Doc. Review	√	√	√		√(Media)	
		18. How easy is it to update/amend this regulation?	From the perspective of processes	SSI, Doc. Review	√	√			√(V,C-Researcher)	√(V)
		19. Are there any differences between your practice(s) and regulatory guidelines / instructions (if exist)?	Does this difference, if any, explain the maternal health problem?	SSI, Doc. Review	√	√	√			
	Overall	20. How appropriate, in your view,	for your practice and for	SSI, Doc.	√	√	√	√(I)	√(I)	√(V)

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
	impression	are the procedures of enforcing / implementing this regulation?	others more generally	Review, FGD						
	Factors affecting (incl. context / environment)	21. How appropriate in your view are the existing procedures of regulation to the context of this country /state / province?		SSI	√	√	√	√(I)	√(I)	
		22. What is the role of information / evidence in regulatory processes?	Ref to assessment criteria in Annex 3.	SSI, Doc. Review	√	√(IC)	√(I)			
		23. What if any are the factors that may have influenced processes of this regulation? How do these factors explain health problems and achievements identified in questions 9 and 10?	Processes are: regulation design, administration / operationalization / enforcement and implementation Factors: e.g. health system, political, social and economic forces; lobbying by users or patient groups Processes: formulation, administration (operationalization) / enforcement, implementation and (if applicable) amendment	SSI	√	√	√	√(I)	√	
Actors in Regulation		24. Who (and how) initiated this regulation?	Bureaucrats? Parliamentarians?	SSI	√	√(I)				

Broad Area	Sub-area	Questions	Prompts	Method	Respondent groups					
					Policy / Regulation designers	Regulation operationalization / administration / oversight	Implementers (health manager, service provider – both public and private)	Users of services	Others with less defined roles (NGOs, Media,)	UN agencies (V,I)
			Public?							
		25. Who (and how) is/was involved in: a) designing, b) administration / adaptation / oversight, c) implementing this regulation? Also – why?	To cover both public and private sectors Examples of 'designers' - professional bodies, NGOs, etc. Example of 'interpreters' - insurance companies / pharma industry, etc. Example of 'implementers' - service providers (public, private), Financiers, managers, professional bodies, etc.	SSI, Doc. Review, FGD	√	√	√		√(VC)	√(V)
		26. Who is/was excluded but should be part of it?	And why? Ref to assessment criteria in Annex 3.	SSI						
		27. Who is/was involved but is/was not appropriate in your opinion?	And why? Ref to assessment criteria in Annex 3.	SSI						
		28. Who this regulation is targeted at (and how)? i.e. who are the subjects of this regulation?	Ref to assessment criteria in Annex 3.	SSI, Doc. Review	√	√	√	√(I)	√	√
	Characteristi	29. What are the characteristics of	E.g. technical	SSI	√	√(IC)	√	√(I)	√(IC)	√

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
	cs of actors	key actors involved (or excluded) in this regulation? What characteristics in your view determine a good regulator?" followed by "How does this compare with existing actors/regulators?"	competence, power, motivation, independence, (political) influence, level, etc.							
		30. What are actors' agendas' interests, aims and priorities Who are the actors who may have influenced (negatively or positively) the design and/or implementation problems discussed in sub question 23? How and why did they so?	And how do these affect a) regulation procedures and b) ability of this regulation to ensure equitable access to quality MH services and c) regulation process?	SSI, Doc. Review	√	√	√	√(I)	√(IC)	√
		31. How in your view these actors relate to each other?	Networking, coordination, alliances Ref to assessment criteria in Annex 3.	SSI, Doc. Review, FGD	√	√	√		√(IC)	√
		32. What is the level of influence of these actors on regulating equitable access to quality MH services?		SSI	√	√	√		√(I)	
	Factors affecting	33. What factors affect actors' roles and interrelationships in	Include advocacy from users, interest groups,	SSI	√	√	√	√(I)	√(IC)	√

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
	actors' roles (incl. context / environment)	this regulation?	kinships, media, etc.							
Approaches to (and practices of) regulation	**Origin / history of regulation**	34. What underlying issues / concerns led to establishing current approaches to this regulation?	Principles/values Market failures, market pressures, etc. Ref to assessment criteria in Annex 3.	SSI, Doc. Review	√	√	√			
	Approach to regulation	35. What is the main approach in this regulation?	State, market, consumer-oriented, etc.	SSI, Doc. Review	√	√(I)				
		36. What are the practices of enforcing this regulation?	Incentives / encouragement vs command / control	SSI, Doc. Review	√	√	√		√(I, VC-Researcher)	+/-
		37. What means exist for ensuring this enforcement / implementation? Are these adequate / appropriate and, if not, what do you do about it at your level (and why)?	Human resources, finance, information system, legislature/judiciary support, coordination of actors, etc.	SSI, Doc. Review	√	√	√		√(I-Judiciary)	
	Influencing factors (incl. context / environment)	38. What factors affect the choice and success of the current approaches?	Positively and negatively	SSI	√	√	√	√	√	
		39. Why do these approaches exist within this context?	State, market, consumers… Also, incentives vs.	SSI	√	√(IC)				

Broad Area	*Sub-area*	*Questions*	*Prompts*	*Method*	*Respondent groups*					
					Policy / Regulation designers	***Regulation operationalization / administration / oversight***	***Implementers (health manager, service provider – both public and private)***	***Users of services***	***Others with less defined roles (NGOs, Media,)***	***UN agencies (V,I)***
			control							
	Overall impression RE approaches	40. How appropriate are the existing approaches to regulation in the context of this country / state / province?	And why?	SSI	√	√	√			√(IV)
Effects of the regulation	**Main effects**	41. What in your view is/are the effect(s) of this regulation on this case study or problem / achievement more generally?	Both positive and negative. For example: half of the blood banks in EmOC are not implemented	SSI, Doc. Review, FGD	√	√	√	√(IC)	√	√
		42. What in your opinion are the main effects / results of this regulation more widely?	Both positive and negative effects/results Effects on equity, quality, access to MH services. Ref to assessment criteria in Annex 3.	SSI, Doc. Review	√	√	√	√	√	√
		43. Are there any unintended effects of this regulation i.e. those not explicit in the objectives?	Can be both positive and negative	SSI, FGD	√	√	√	√(IC)	√(V-Researcher)	√
	Factors affecting (incl. context / environment)	44. What are the facilitators and obstacles affecting the achievement of objectives of this regulation?	Wider context: e.g. political priorities; financial commitment; media, user expectations, health system, human resources, information	SSI, FGD	√	√	√	√(I)	√(V-Researcher, Media)	√

Annex 6

ETHICAL INSTRUMENTS

INFORMATION LETTER FOR PARTICIPANTS IN THE INTERVIEWS

ORGANIZED IN THE CONTEXT OF THE HESVIC STUDY

(HEALTH SYSTEM STEWARDSHIP IN VIETNAM, INDIA AND CHINA)

Dear Sir, Madam,

We are providing you with this information letter because we would like to interview you in the context of the HESVIC study, a research project on maternal health. We kindly ask you to read this information in order to decide whether you would agree to be interviewed. Should you have any further questions regarding the project in general or any information mentioned in this document, we will be happy to answer them (contact details: see below).

Goal, funding and partner organizations of the research project

HESVIC is a three-year research project (2009-12) which is funded by the European Union (EU) Seventh Framework Programme.

The project aims to investigate the governance of health systems, focussing on policies as well as practices. We use maternal health care services as our case study and we will undertake a comparative study of maternal health services in three Asian countries – Vietnam, India and China. The goal of this study is to understand the relationship between regulation and the quality of maternal health care in order to suggest possible improvements. For this purpose, a number of interviews and group discussions will be organized.
The six partner organizations in this project are:

- the Nuffield Centre for International Health and Development, University of Leeds (UK);
- the Hanoi School of Public Health (Vietnam);
- the Institute of Public Health, Bangalore (India);
- the Fudan School of Public Health, Fudan University (China);
- the Department of Public Health, Prince Leopold Institute of Tropical Medicine (Belgium); and
- the Department of Social Development and Gender Equity, Royal Tropical Institute (The Netherlands).

What would be expected of you if you participate?

As noted above, a number of interviews and group discussions will be organized in the context of the HESVIC study. We contact you with regard to an interview (not a group discussion – these will be organized only with patients in maternal health services).
We will conduct interviews with key people, like yourself, who work as policy makers, designers of regulation, and implementers of regulation or health services managers.

The topic of these interviews will be the quality of maternal health care in your region/country, as well as the regulation in this field.

One of our collaborators will plan one interview with you, which will last about … minutes. The interview will take place at a date, time and location that suit you. If you agree to be interviewed, one of our collaborators will contact you to make an appointment.

What will happen with the information you provide in the interview?

To ensure that we have a complete record of the information you provide, we intend to record the interview with your informed consent (see separate consent document). However, you may end the conversation at any time and you may request that the recorder be turned off for some parts of the interview. You do not need to give reasons for any such request.

Only questions specifically required for the purposes of the HESVIC research project will be asked. The recordings of the interviews will be transcribed. The resulting information will be anonymized and will subsequently be shared between the research groups from the above-mentioned partner institutions, in order to gain a wider international perspective.

All data will be stored on computer in encrypted and password-protected form at the research centres involved in the HESVIC study. Appropriate access controls will be put in place to ensure that only researchers actively involved in the study can access the data.

All documents generated on the basis of the interviews will identify participants only by a coded number (the participant code), to maintain participant confidentiality. Any documents that contain names of participants or other personal identifiers (such as the informed consent forms) will be stored separately from the transcripts of the interviews and focus group discussions. In the publications that are intended to derive from this study, any quotes from the interviews will be anonymized.

Everything you say will thus be treated as confidential and your name will not be used in any research reports or publications.

Voluntary nature of the participation

Participation in this study is entirely voluntary. If you refuse to participate, you do not need to give any reason and this will have no consequences whatsoever for you. If you agree to participate, you maintain the right to withdraw your participation at any time. No reasons need to be given for this.

Risks

Participation in this study is not expected to entail any risk. Even though, in other contexts, expressing unfavourable opinions regarding specific regulations or the way they are implemented and/or enforced might sometimes lead to negative action at a later stage by employers or superiors, this risk does not apply in the case of the HESVIC study, in view of the strict confidentiality measures described above.

Benefits

The benefits of participation to you, personally, are limited. From a societal and scientific point of view, however, there are clear benefits. As explained earlier, the goal of this study is to understand the relationship between regulation and the quality of maternal health care in order to suggest possible improvements. This may provide

benefits to society at large, in addition to the benefits brought by improved knowledge of what "good quality maternal health services" means in your regional/national context.

Remuneration

Participants in the HESVIC study will not receive any remuneration. Transport costs will be reimbursed, if applicable.

Feedback

If you are interested in receiving information in the future regarding the results of our study, we will be happy to send you a summary after the research is finalized in 2012. In that case, please let us know (contact details: see below).

Ethics Committee

Research projects such as these must be submitted to an ethics committee for approval. The ethics committee that has granted approval for this study is:

Name of the committee

Address

Telephone number

Email address

Contact

As mentioned at the beginning of this information letter, we would be happy to answer any questions you may still have regarding the study and/or to clarify any information in this document that may not be entirely clear to you.

For any questions, please contact:

Name(s) and contact details of the person(s) to be contacted

If everything is clear and you agree to participate, please let us know [unless a HESVIC researcher will take the initiative to contact the person rather than the other way round] and we will contact you to schedule the interview.

We will ask you to complete and sign an informed consent document before the start of the interview, in order for the interview to be able to take place.

Thanking you in advance for showing interest in our project,

Yours sincerely,

X (PI for the study country in question)

INFORMED CONSENT DOCUMENT FOR PARTICIPANTS IN THE INTERVIEWS ORGANIZED IN THE CONTEXT OF THE HESVIC STUDY (HEALTH SYSTEM STEWARDSHIP IN VIETNAM, INDIA AND CHINA)

Declaration by the participant (interviewee):

I have been asked to take part in an interview, lasting approximately … minutes, on the topic of the quality and regulation of maternal health services.
I have carefully read the information letter regarding the HESVIC study. I have been given an opportunity to ask any questions regarding this study. The questions I have raised, if any, have been answered to my satisfaction.
I understand the information provided to me and I hereby voluntarily agree to be interviewed. I also agree to the recording of the interview.
Name of the participant:
Signature of the participant:
Date:

Declaration by the researcher (interviewer) obtaining informed consent:
The participant has been provided with an information letter regarding the HESVIC study. I have verified that the participant has understood that participation entails that (s)he will be interviewed.
I hereby confirm that the participant has been given the opportunity to ask any questions regarding the study or the interview. To the best of my knowledge, these questions, if any, have been answered fully and accurately.
I hereby confirm that the participant's consent has been given voluntarily.
Name of the researcher:
Signature of the researcher:
Date:

INFORMATION LETTER FOR PARTICIPANTS IN THE FOCUS GROUP DISCUSSIONS ORGANIZED IN THE CONTEXT OF THE HESVIC STUDY (HEALTH SYSTEM STEWARDSHIP IN VIETNAM, INDIA AND CHINA)

Dear Madam,

We are providing you with this information letter because we would like to invite you to take part in a group discussion in the context of the HESVIC study, a research project on maternal health. We kindly ask you to read this information in order to decide whether you would agree to take part. Should you have any further questions regarding the project in general or any information mentioned in this document, we will be happy to answer them (contact details: see below).

Goal, funding and partner organizations of the research project

HESVIC is a three-year research project (2009-12) which is funded by the European Union (EU) Seventh Framework Programme.

The project aims to investigate health systems, focussing on policies as well as practices. We use maternal health care services as our case study and we will compare maternal health services in three Asian countries – Vietnam, India and China. The goal of this study is to understand the relationship between the rules applicable to and the quality of maternal health care, in order to suggest possible improvements. For this purpose, a number of interviews and group discussions will be organized.
The six partner organizations in this project are:

- the Nuffield Centre for International Health and Development, University of Leeds (UK);
- the Hanoi School of Public Health (Vietnam);
- the Institute of Public Health, Bangalore (India);
- the Fudan School of Public Health, Fudan University (China);
- the Department of Public Health, Prince Leopold Institute of Tropical Medicine (Belgium); and
- the Department of Social Development and Gender Equity, Royal Tropical Institute (The Netherlands).

What would be expected of you if you participate?

As noted above, a number of interviews and group discussions will be organized in the context of the HESVIC study. We contact you with regard to a group discussion (not a one-to-one interview). The other participants in the group discussion to which you are invited will be users of maternal health services, like yourself [here it should also be specified whether or not male users of these services and/or other relatives will be involved – I would suggest that male participants should not be included in order not to influence the females' freedom of speech].

One of our collaborators will plan the group discussion, which will last about … minutes. The discussion will take place at a date, time and location that suits the participants. If you agree to take part, one of our collaborators will contact you to make an appointment.

What will happen with the information you provide in the discussion?

To ensure that we have a complete record of the information you provide, we intend to record the discussion with your informed consent (see separate consent document). However, you may interrupt or end your participation in the discussion at any time. You do not need to give reasons for doing so.

The recordings of the discussions will be written out. The resulting information will be anonymized (that is, the names of the participants will be removed) and will subsequently be shared between the research groups from the above-mentioned partner institutions, in order to gain a wider international perspective.

All information will be stored on computer in encrypted (that is, coded) and password-protected form at the research centers involved in the study. Appropriate access controls will be put in place to make sure that only researchers actively involved in the study can access the information.

All documents based on the discussions will identify participants only by a code number (the participant code), to maintain participant confidentiality. Any documents that contain names of participants or other personal information which could identify them, will be stored separately from the written texts of the group discussions. In the publications that may result from this study, any quotes from the group discussions will be anonymized.

Everything you say will thus be treated as confidential and your name will not be used in any research reports or publications.

Voluntary nature of the participation

Taking part in this study is entirely voluntary. If you refuse to take part, you do not need to give any reason and this will have no consequences whatsoever for you. If you agree to take part, you maintain the right to withdraw at any time. No reasons need to be given for this.

Risks

Taking part in this study is not expected to cause any risk to you. However, we cannot guarantee that other participants will maintain confidentiality as strictly as we will. For this reason, your name will not be revealed to the other people taking part in the discussion. Your health providers (for example doctor, nurse, midwife or hospital administrator) will not be informed of anything that you say. [In my view this should be guaranteed to the participants, which implies that data which has not yet been anonymized should not be available to any such health providers who are HESVIC collaborators.]

Benefits

The benefits of taking part for you, personally, are limited. From a societal and scientific point of view, however, there are clear benefits. As explained earlier, the goal of this study is to understand the relationship between the rules applicable to and the quality of maternal health care, in order to suggest possible improvements. This may provide benefits to society at large, in addition to the benefits brought by improved knowledge of what “good quality maternal health services” means in your regional/national context.

Remuneration

Participants in this study will not receive any payment. Transport costs will be reimbursed.

Feedback

If you are interested in receiving information in the future regarding the results of our study, we will be happy to send you a summary after the research is finalized in 2012. In that case, please let us know (contact details: see below).

Ethics Committee

Research projects such as these must be submitted to an ethics committee for approval. The ethics committee that has granted approval for this study is:

Name of the committee

Address

Telephone number

Email address

Contact

As mentioned at the beginning of this information letter, we would be happy to answer any questions you may still have regarding the study and/or to clarify any information in this letter that may not be entirely clear to you.

For any questions, please contact:

Name(s) and contact details of the person(s) to be contacted

If everything is clear and you agree to take part, please let us know [unless a HESVIC researcher will take the initiative to contact the person rather than the other way round] and we will contact you to plan the group discussion.

We will ask you to complete and sign an informed consent document before the start of the discussion, in order for the discussion to be able to take place.

We thank you for showing interest in our project,

Yours sincerely,

X (PI for the study country in question)

NOTE FOR THE TRANSLATOR: the words used in the translation of this document must be accessible to general members of the public.

INFORMED CONSENT DOCUMENT FOR PARTICIPANTS IN THE FOCUS GROUP DISCUSSIONS ORGANIZED IN THE CONTEXT OF THE HESVIC STUDY (HEALTH SYSTEM STEWARDSHIP IN VIETNAM, INDIA AND CHINA)

Declaration by the person taking part in the group discussion:

I have been asked to take part in a group discussion, lasting approximately … minutes, on the topic of the quality of and rules relating to maternal health services.

I have carefully read the information letter regarding the HESVIC study. I have been given an opportunity to ask any questions regarding this study. The questions I have raised, if any, have been answered to my satisfaction.

I understand the information provided to me and I hereby voluntarily agree to take part in a group discussion. I also agree to the recording of the discussion.

Name of the person taking part:

Signature of the person taking part:

Date:

Declaration by the researcher obtaining informed consent:

The participant has been provided with an information letter regarding the HESVIC study. I have verified that the participant has understood that participation entails that she will take part in a group discussion.

I hereby confirm that the participant has been given the opportunity to ask any questions regarding the study or group discussion. To the best of my knowledge, these questions, if any, have been answered fully and accurately.

I hereby confirm that the participant's consent has been given voluntarily.

Name of the researcher:

Signature of the researcher:

Date:

DATA HANDLING

HESVIC Project
Information regarding confidentiality and data handling

This document aims to provide all the researchers and participants in the European Union funded HESVIC research project with information regarding confidentiality and handling of the data generated in the context of this research project.

The six partners in this project are: the Nuffield Centre for International Health and Development, University of Leeds (UK); the Hanoi School of Public Health (Vietnam); the Fudan School of Public Health, Fudan University (China); the Institute of Public Health, Bengaluru (India); the Department of Public Health, Prince Leopold Institute of Tropical Medicine (Belgium); and the Department of Social Development and Gender Equity, Royal Tropical Institute (The Netherlands).

Focus group discussions and interviews will be conducted in the study countries (China, India and Vietnam), with the informed consent of the participants. These interviews and focus group discussions will be recorded and transcribed in the study countries. The resulting data will be anonymous and encrypted and will subsequently be shared between the research groups from all the above-mentioned partner institutions, in order to gain a wider international perspective. Only data specifically required for the purposes of the HESVIC research project will be gathered.

All data will be stored in encrypted form on password protected computers at the research centers involved in the HESVIC study. Appropriate access controls will be put in place to ensure that only researchers actively involved in the study can access the data.

All documents generated on the basis of the interviews and focus group discussions will be identified by a coded number only (the participant code), to maintain participant confidentiality. Any documents that contain names of participants or other personal identifiers (such as the informed consent forms) will be stored separately from the transcripts of the interviews and focus group discussions. The documents containing identifiers and the documents that only contain the (non-identifying) participant codes will be kept in separate locked cupboards, in an area that is only accessible to the HESVIC researchers from the study country in question.

The 'keys' required to link participant codes to participant names will only be accessible to ***ADD NAME (normally the PI in the study country in question).***

In the publications that are intended to derive from this study, any quotes or paraphrases from interviews or focus group discussions will be anonymous.

NB Following EU FP 7 Rules, the DATA STORAGE PERIOD needs to be specified! (FYI: The general rule is that data must be stored only for as long as the project lasts. Storage beyond the life of the project is possible but must be closely supervised.)

General for policy maker, designer of regulation, regulation implementer and health manager

Annex 7

The interview itself

To ensure some cross-country consistency, the interview guidelines and interviewer training will aim to ensure that interviewers are able and confident to facilitate the interviews and to ensure that they generate useful findings. A simplified information sheet will be developed by ITM and KIT to inform respondents about HESVIC.

Scheduling the interview

Once a respondent is identified they can be formally approached in writing, requesting an appointment for an interview. It is recommended that the letter contains:

a) Brief description of the project aim and objectives.
b) Reference to some prominent names of Country Research Advisory Groups (where applicable).
c) Reasons for selecting this person for the study and the topic for the interview.
d) Suggested options for the date and time of the interview, while clearly indicating these may be changed according to the respondent's schedule.
e) Brief description of research partner and, if applicable, individual researchers.
f) Ethical Aspects: Consent forms should have been read carefully and signed. We advise that it is best to repeat confirmation of the anonymity and confidentiality of the interview, including the possibility of conducting the interview outside of the respondent's office (e.g. at the partner institution).among other specific directions provided in Annexe 6.
g) Contact details of the researchers in case of intermediate queries and for the formal response.
h) The HESVIC project flyer and an adapted and shortened version of the folder for interviewees, as part of the introduction process where e.g. the ethical dimensions are made clear.

Before the interview

Be familiar with the question guide, mark the priority questions and, most importantly, ensure that the key ethics issues are addressed. Interviewers must know the subject and the questions that we need answers for (questions in the Annex 5 matrix) thoroughly. This is because the answers to one question could sometimes cover answers to yet unasked questions; the interviewer should be able to recognize this.

This entails 5 steps taken at the interview itself to ensure the interviewee of the following:

- They need to be clear about the objectives of the study,
- They need to be clear about the possible benefits in the broadest sense,
- Participants can stop the interview if they feel uncomfortable(ETHICS)
- They need to be clear on why they were selected,
- They need to be informed about how the information will retain confidentiality, while being stored, written up and disseminated,
- If interested in results, how they will be kept informed (feedback).

Once the date and time of the interview are confirmed, the researcher may also need to adjust the number of questions to fit the agreed duration. It is recommended that an interview should last (maximum) 60 minutes - this will vary depending on the individual and the case study. In some cases they may last for 90 minutes or more (e.g. for the focus groups). It will be important to be familiar with the background of the person who will be interviewed and their role within the organisation as far as possible.

Be familiar with the glossary. The interviewers should ensure that they are familiar with the definitions in the HESVIC glossary (circulated as a separated working document through the consortium partners). However, it is also important to remember that we are interested in the views, knowledge and perception of the respondent and to allow respondents always to give their explanation first. Keep in mind also that we will be using NVivo v7 software for the analysis so the manner, quality and duration of interviewing and recording are important.

Check the technical equipment. All interviews should be recorded where consent has been given and issues are not sensitive. Recording equipment, including spare batteries, should be available. Copies of the interview flyer, informed consent agreement and other key documents that are deemed useful should be available for each interview.

During the interview

How many researchers should attend an interview? The final decision rests with study country teams, as it depends on the skills and confidence of the researchers, the status of the respondent, and resources available. It is important for senior researchers to be involved in conducting some/many of the interviews.

One option we would like study countries to consider is to have two researchers attend each interview. One researcher could act as the interviewer; the second researcher could act as note-taker or shadow the interview and prompt if required. One must also remain alert to the possibility that some respondents may not feel comfortable in speaking openly in the presence of two interviewers, or in the presence of junior researchers. The PIs should deliberate upon this likelihood and if appropriate ask the respondents about how they would prefer the interview to be organized.

It is important to take formal and informal steps to gain the confidence and trust of the respondents. This is central to the process of eliciting credible and nuanced responses. This is also central to the process of knowledge translation in the long run.

If the interview is being recorded, the note-taker will keep track of the following:

- the questions asked;
- any important emergent issues that the interviewer should ask follow-up questions on (reminding the interviewer near the end of the interview);
- any non-verbal interactions observed (e.g. mood or body language).

If the interview is not being recorded (due to respondent refusal, or equipment failure), the note-taker's priority is to summarise the content of the interview. It should be ensured that interviewers have already had good practice in this prior to embarking

on the interview. In this case, the interview should be recorded in a special format legible to all in the team, and stored separately in an interview file.

Introduce yourself and the research. At the beginning of an interview, the researchers need to introduce themselves and any other participants from the research team, and ask the respondent to introduce any additional people from his or her side (e.g. colleague or secretary). The interviewer should briefly outline the objectives of the research.

Obtain an informed consent for the interview. The interviewer should read out the suggested informed consent agreement in Annex 6, and ask the respondent if they agree to participate. The interviewer may need to spend a few minutes for any general queries that the respondent has on the project, topic, etc. Efforts should be made to keep this short and where possible further project or institution documents should be provided or promised.

It might be a good idea to start off with an open question to get a sense of what the respondent knows about the topic. The interviewer should be attentive to answers given by respondents and not repeat questions for which answers have already been given. Similarly, if the interviewee during the course of his/her responses raises issues which are not foreseen to be covered in the interview, but are of interest to HESVIC and relevant to getting answers to the questions in Annex 5, then the interviewer must pick up these cues and probe the interviewee to get a complete picture from the interviewee on the subject.

This links to the understanding that the interview should not appear as a test of the respondent's knowledge of the regulation. It is important to remember that if a respondent has no explicit knowledge of the contents of the regulation (even this is a finding), then we should explore the implicit/practice aspects of his/her knowledge/understanding of the regulation.

Immediately after the interview

At the end of the interview it is advisable to do the following:

- Thank the respondent;
- Check that the recording has worked (If not, immediately make detailed notes on the interview content). Code and mark the recording;
- Reflect on any other issues (e.g. respondent's mood during a pause) that may be important for the analysis (see 'Analysis' section below);
- It is extremely important at this stage to arrange the notes you have taken and your reflections on these in a format comprehensible to all, and especially to those who will conduct the analysis. Familiarity with NVivo v7 at this stage will be useful, if not essential, to ease the process of qualitative data coding and entry.

All interviews will be recorded and transcribed in the local language. One option is to take interview notes by theme and then elaborate afterwards, when listening to the recording.

After the interview: analysis

As mentioned earlier NVivo v7 software will be used to analyse the semi-structured interviews and focus group information. The information and data collected in Phase One will be analysed first, and the findings will inform the content of the tools for

Phase Two. Phase Two will also include the in-country analysis of data collected. Phase Three will include the overall analysis of qualitative data collected in Phases One and Two. Each study country will need to conduct this. Comparative analysis will then be carried out by an integrated effort of all HESVIC partners, guided by ITM.

The aim of qualitative analysis will be to find associations (not statistical) between maternal health problems and achievements and regulations procedures, processes and approaches. It will describe complex phenomena utilising the basic principle of critical discourse analysis and a political economy approach with regard to regulation, the health system and quality maternal health care.

Annex 8

HESVIC GLOSSARY

The aim of this glossary is to facilitate a common understanding of key concepts and themes among HESVIC partners prior to data collection and analysis. These working definitions have been formulated in the context of the HESVIC project and will continue to evolve in the coming months.

Many of the words are standard terms (e.g. Actors, Case Study) but some are adapted slightly in the context of HESVIC and have been derived from international reviews and the body of D1.2.a.

This glossary is divided in two parts, a first one with explaining the understanding of general terminology, a second one specifically on regulation-related terminology. The first section is organized in an alphabetical order; the second section is centred on several aspects of regulation.

A. GENERAL TERMINOLOGY

Actors
Persons or institutions who are associated with, and involved in, different aspects of the health system including policy making and services provision and using services; examples include politicians, policy makers, civil servants health professionals, service users, private and NGO health providers, trade unions and media. So one can be an individual actor or represent a group of actors (e.g. NGO or Civil Society or the Government are all actors).

Access
Accessibility to health care is measured by the spontaneous propensity of people to use them. Indicators of general health care accessibility are new cases per year per inhabitant (for first line services), admission rates (for hospitals), or the coverage rate of antenatal consultations (the proportion of pregnant women using them). Among the components of general accessibility are financial (affordability), geographical cultural (appropriate to local needs) and intra-institutional.

Case study
A case study is an approach to research methodology based on in-depth, empirical investigation of a group of events within its real-life context, to explore causation in order to find underlying principles (why a particular instance happened as it did, and what might become important to look at more extensively in future research). Case studies can include quantitative evidence, and can rely on multiple sources of evidence. HESVIC case studies for example will include aspects of EmOC, of abortion, pre natal care and grievance redressal.

Conflict of Interest
A conflict of interest is part of the analysis of political economy and an understanding of social context. By definition[cc] it is about the opposition of incompatible wishes or

[cc] Conflict :The Oxford Dictionary and Thesaurus (1997) edited by Sarah Tulloch

needs in a person. An example from HESVIC would include the existence of personal relations among professionals involved in either monitoring or applying a particular regulation. It might also involve persons who are regulators, having a commercial interest in health services that they are supposed to regulate.

Contextual issues

Contextual issues are features of the social, political, and economical environment. They include gender, politics, power relationships, social classes and identities, culture, and religion. These are issues which help explain the context within which service provision or policy processes take place.[dd]

Country Research Advisory Groups (CRAGs)

CRAGs in HESVIC will advise and support the research teams in each country. CRAGs within HESVIC will also have a valuable role to play in knowledge management and the publication of outputs.

Critical events and Critical incidents

Critical events are related to the policy environment (e.g. an unexpected change in a policy environment) in relation to regulation or maternal health services in this case.

A critical incident on the other hand relates to an unexpected negative or positive event in relation to maternal health services, in the country context.

Discourse and Critical Discourse Analysis (CDA)

Analysis of research would routinely involve assessing for context- what people in authority stated in relation to where they are placed socially (providers, politicians). In the course of analysis the researcher needs to reflect on their speech and sayings in relation to what the interest of each might be. Here language or discourse is viewed as reproducing social relations, particularly those who have power over others. Thus when analyzing the content of interviews we may need to reflect critically on the existing hierarchy of power, as described below:

"CDA is a type of analytical research that studies the way social power, abuse, dominance, and inequality are enacted, reproduced and resisted by text and talk in the social and political context…" [ee]

Documentary research

Documentary research entails the use of texts and documents as source materials (public records and reports, newspapers, certificates, reports and also visual materials) as one of three core methods of social science research. In HESVIC other than literature searches, during field work it will also involve assessing the written records of some aspect of health services and policy processes for the maternal health case studies.

Efficiency

Efficiency is productivity with minimum waste of effort.[ff] In HESVIC efficiency will involve studying issues in relation to local management and care quality. Local

[dd] Britannica concise Encyclopedia: political economy
[ee] Van Dijk, T.A. Critical Discourse, Studies in website of Van. Dijk, TA: www.discourses.org; we agree that CD will be provided in this domain.
[ff] Oxford Dictionary and Thesaurus edited Tulluch, S. January 1997

management here includes 4 levels: resources, time, use of resources and simplicity of procedure and institutional facility.

Emergency Obstetric Care (EmOC)
EmOC is the term used to describe the elements of obstetric care around the clock needed for the management of normal and complicated pregnancy, delivery and the postpartum period. For the services at a facility to be considered functional, the elements of care must have been provided during the 6 months previous to data collection. EmOC provides a number of indicators to measure progress in a programmatic continuum: from the availability of and access to EmOC and quality of the services. Among the indicators are included: sufficient facilities, well distributed with a locality of critical and good quality emergency services (WHO 2009).[gg]

Equity
Equity in the context of access refers to the comparative utilization of services across different population segments and to the comparison of components of care accessibility (for instance, the cost of a C-section compared to monthly income in the first and last revenue quintiles of the population). The focus in HESVIC is on the former (utilization) aspect of equity.

Floating Population
In HESVIC we refer to a population that is not in one place, fluctuating or not fixed in number size and in location. An example is the migrant workers in Shanghai. The Macmillan[hh] Dictionary- defines a floating population as "migrant workers on the move".

Focus group and Focus Group Discussion
FGD is a discussion in a group of approximately 7-12 persons guided by a facilitator, during which group members talk freely and spontaneously about a certain topic. A FGD is a qualitative method. Its purpose is to obtain in-depth information on concepts, perceptions and ideas of a group. A FGD aims to be more than a question-answer interaction. The idea is that group members discuss the topic among themselves, with guidance from the facilitator.

Framework Approach
A framework approach is a structure that describes the most important features of a project. It has been used in HESVIC to develop a number of matrices around selected themes, as represented by Annexes 1 to 3 in particular.

Generic Research Tools
Generic tools are characteristics of or related to a particular class of matters and in the case of HESVIC, questions and themes relating to the regulation of quality maternal health services.

Governance
The governance of health systems is the way in which decisions are made and implemented in the health system as a whole. This will include both policy (macro

[gg] WHO, Unicef, AMMOD (2009) Monitoring EmOC: a handbook
[hh] http://www.macmillandictionaryonline.com

level) and practice (micro level), depending on context or area of focus in the research process.

Governance Principles
Governance principles are the values that inform decision making in the health system especially at the macro level, as described for example in the principles adapted from the Siddiqi et al framework: transparency and accountability being the core ones in HESVIC.

Grievance Redressal
A grievance is a complaint or resentment, as against an unjust or unfair act: to have a grievance against someone or in the adequacy of a service or the quality of that service. A redressal is the ability to deal with that unjust act or complaint about a poor quality of service and have it resolved to the satisfaction of the person(s) who have made the grievance.

Health System
A health system comprises all the organizations, and institutions, including actors and resources, whose primary purpose is to improve health through the delivery of health care. Within HESVIC the focus of research will be on the overall health system and on maternal health services in particular. The research will consider the aspects of both the supply and demand led aspects of health care delivery.

Indicators
Quantitative or qualitative information or sets of information that enable us to understand or predict the overall status and functioning of a system.

Inter-country comparability
Themes or issues that might be comparable across research sites e.g. the nature of health service provision (structure, process or outcome) or in the history of health service related regulation or even in the role and function of actors in regulation. Many of the themes are embedded in the research questions of HESVIC (see also Box 3 of D1.2.a).

Maternal Health
Maternal health refers to the health of women during pregnancy, childbirth and the post-partum period. The major and direct causes of maternal morbidity and mortality include haemorrhage, infection, high blood pressure, unsafe abortion and obstructed labour.[ii]

Maternal mortality
The tenth revision of ICD-10 defines a maternal death as the death of a woman while pregnant or within 42 days of termination of pregnancy, irrespective of the duration and site of the pregnancy, from any cause related to or aggravated by the pregnancy or its management, but not from accidental or incidental causes.[1]

Participatory stakeholder workshops
Participatory stakeholder meetings consist of meeting with the range of actors being consulted and interviewed over the HESVIC study. The workshops would provide an

[ii] WHO- http/www/int/topics/maternal_health/en November 15 2010

avenue to present findings which, if feasible, could be utilised as a reference or as evidence, by the relevant authorities in public, private or other sectors involved in regulation and maternal health service provision. The workshops would also allow explanation of the benefits of study findings and serve the ethical aspects of HESVIC.

Phased approach
These are the different steps within a study design in the HESVIC study. It describes a logical relationship between the different steps of the research and where some steps overlap.

Policy process
Policy is a written or unwritten statement of intent determining decisions and guidance on the future course of action(s) for a specific issue. Policy processes would include formal and informal mechanisms through which policies are developed and implemented. In HESVIC these are mainly related to the formulation of regulation in relation to quality maternal health care.

Political Economy
Formally political economy is an academic discipline that explores the relationship between individuals and society and between markets and the state using methods drawn from economics political science and sociology. The term is derived from the Greek terms *polis* (city or state) and *oikonomos* (one who manages a household). Political economy is thus concerned with how countries are managed, taking into account both political and economic.[jj]

A political economy *approach* involves an understanding of the political and economic processes in society, the distribution of power and wealth between different groups and the factors that create, sustain and transform these relations over time. When applied to regulation one needs to take into account how regulations, their process and procedure may be affected by the balance of power between different social political and economic, forces in a society at any given time.[kk]

Political Capture
A number of conceptual terms such as political capture are used to suggest themes to focus on in the interpretation and analysis of data. Political capture is expressing the will to manipulate or influence an issue. “Capture” in the Oxford dictionary denotes “force”, but political capture is usually an implicit phenomenon. In the context of HESVIC, the term is used as a more subtle form of influence on content of or in the application of a regulation.

Power Dynamics
The power of one authority (individual or institution) over another within the dynamics of influence in a particular context in HESVIC is described as the conflict of interest

[jj] Britannica concise Encyclopedia: political economy
[kk] This approach has already been taken in all three of the country mapping reports which have explored issues of power and conflict of interest in the allocation of resources.(see also addition to glossary) and provides a natural depth to any study in order to avoid providing simple description. The applied definition is taken from UK think tank the Overseas Development Institute-Power, livelihoods and Conflict 2009,OD1, London UK

between actors and their environment. One example of this would be providers (or one provider) with a social mission and another working with a commercially driven practice.

Problem and Achievements Based Research

Problem based research is defined in the literature as research aimed at solving problems or exploring an issue based upon the study of a particular problematic area. Its main strength consists of linking research to facts and events in a way that such that concepts and theories are used to solve practical problems. It has been agreed through discussion at the consortium to examine both achievements and problems in maternal health services, hence "problem and achievement based research".

In the context of HESVIC, an example of the problems to be studied are the degree of effects of regulation (as an outcome) and of regulatory procedures – which translates into achievements in as well as possible problems within maternal health services.[ll]

Purposive Sampling

Purposive sampling is a research method where sampling elements are chosen based on the purpose of the study. It may involve studying an entire population or a limited group of the population. In HESVIC the sampling focuses on selected case studies in each country as well as six categories of a stratum of the population involved in the design and implementation of regulation in maternal health services.[mm]

Quality of Care

Quality of care refers to clinical decision making, doctor patient communication and bio-psychosocial care, and the technical implementation of decisions. In the context of HESVIC, accessibility of care will be treated separately. Quality of care will be assessed through one of more inputs (manpower, knowledge, drugs, staff, facilities, systems), processes (quality of C-sections for instance, prices, efficiency). Outputs will be addressed as featuring access to quality health care.

Research Methods

The techniques used to collect data. For HESVIC, methods are interviews, documentary analysis, focus groups, secondary analysis of quantitative data, and participatory stakeholder workshops.

Semi-structured interviews

Semi-structured interviews are conducted with a fairly open framework that allows for focused, conversational, two-way communication. They can be used both to provide and receive information and adjust with the flow of the information. In HESVIC semi-structured interviews are aimed at obtaining in-depth information on issues relevant

[ll] Malfunctioning of regulations can be due to undesirable definition, interpretation or implementation of regulation, yielding negative effects (e.g. inefficiency, poor health care quality, and access and health status).

Achievements in policymaking in the health sector or service delivery activities which have worked in accordance with laws, rules and polices also need to be documented to highlight their effective functioning and effective implementation and as examples of good practice.

[mm] http://ccnmtl.columbia.edu/projects/qmss/samples_and_sampling/types_of _sampling

to the research questions from single individuals. Key informants can, for example, provide a detailed picture of the extent of the use of evidence in regulatory decisions and of the role of (internal and external) actors.

Street-level bureaucrats[nn]

The term *street-level bureaucrats* refer to public service employees who interact directly with citizens in the course of their jobs and who have substantial discretion in the execution of their work. In their jobs they perform the actions that implement laws and regulations. Public health workers are typical street-level bureaucrats who grant access to government programs and provide services within them (other examples are social workers, judges, teachers).

Street-level bureaucrats play a significant part in policy processes. They do not simply implement the decisions of elected officials and other policy-makers but exercise power by making policy choices. They have considerable influence of peoples' lives. Beliefs and knowledge of street-level bureaucrats influence their treatment of (different) citizens. They determine the eligibility of citizens for government services.

Thematic area (of case study)

Service or policy areas, to which a case study belongs. For instance, C-sections belong to EmOC which in turn belongs to maternal health care activities; while grievance redress on the other hand belongs to the thematic area of good practice in administration.

Research Tools

The instruments used within each method to collect data. For example, a 'Phase Two interview guide for a health professional respondent' is one tool.

Triangulate

To look at a research process and its findings from more than one perspective Triangulation is a core part of mixed methods in research. Mixed methods are an attempt to be more critical and reflective of the research context and outcome. Thus triangulation tests the consistency of findings through comparing and contrasting varied outputs (literature, document review, statistics, interviews etc.) as in the case for HESVIC.

Transcription

Mapping the sounds of one language to the best matching script of another language.

Unit of Analysis

The unit of analysis is important for guiding sampling and data collection in both Phases One and Two. It is also important to distinguish between the different levels of analysis (within and across case studies and countries). For more see section 6.4.1 in D.1.2.a.

[nn] LIPSKY, M., 1980. Street-level bureaucracy: dilemmas of the individual in public services. New York: Russell Sage Foundation.

B. REGULATION-RELATED TERMINOLOGY

B.1 Regulation

In this research, the concept of "regulation" has often been defined as a way of encouraging compliance in the health sector (public, private and other providers where relevant) and in HESVIC to ensure that the existence of health markets do not undermine the public objectives of social development.

Within the health system regulation is performed either as part of the responsibility of government reliant upon bureaucratic and administrative control which may or may not be reinforced with enabling incentives and/or through participation of non-governmental actors, and by private bodies which regulate their members. Regulation can thus take either the form of control or incentives with the majority of health systems having various combinations of the two.[oo]

Process of regulation

These are the processes of making, interpreting and implementing regulation, similar to health policy processes as studied in HEPVIC. The stages include 'definition', 'interpretation' and 'implementation' level (in other words, the design, the production and the dissemination of a regulation).

Formulation or Definition of regulation

Legal, policy and programme framework that sets up the nature of the regulation, who should benefit, and who is accountable for making sure the regulation does what it says it will.

Interpretation or Administration of regulation

The administrative system and service delivery channels through which the regulation is delivered, interpret the nature of the entitlement and who is entitled.

Implementation of regulation

The regulation is implemented through the actions of project staff shaping further the nature of the regulation and who should benefit.

Procedure of regulation

These include a wide variety of specific and general methods that can be used by different actors (government, private providers, consumers etc.) to regulate health care. [pp]

The mapping reports identified many different procedures e.g. performance-based payment in Vietnam, control of patient fees in China and accreditation of providers in India. International reviews consider the following: contracting out to other (private) providers, advocacy activities with other agencies, financing or resource generation and distribution.

[oo] Technical Annex Part B, HESVIC, p6/7

[pp] Mills and Ranson, 2001 suggest main areas: Market entry and exit (including PPPs) - Remuneration of providers - Quantity and distribution of health services - Standards and quality of health services.

Formal Procedures
Formal Procedures are ways and processes of managing regulation in a particular health system. The term "formal" refers to laws, rules and standards - as opposed to informal mechanisms (such as competition between providers on quality of care to attract patients).

Informal Procedures
These are processes which are not set in law or in writing but based on relationships and often on traditions established within a particular social group or profession (which can be a group of actors- say the medical and allied unions). Informal mechanisms can be positive in that people follow self-imposed standards of practice but could also negative when devising ways of bypassing rules and regulations in an informal way (through corruption for example).

B.2 Approaches to regulation

State-centred approach to regulations[qq]
These are regulations led and initiated and monitored by the state. This is the most common form in most countries.

Consumer-oriented approach to regulation
A consumer-oriented approach to regulation is described as the ability of the population and recipients of health services to articulate their views in choosing health providers. This could occur through better information and disclosure of performance of particular providers, or through mechanisms in which the population is able to process complaints and disputes through the use of consumer courts on malfunction or non-operational regulation.

Included among these is the role of the media (where the media is free which may pose problems in some contexts), the consumer groups, report cards, etc. All of these are being used and tried out with varying degrees of success. Government has a role to play in setting mechanisms for enhancing consumer voice and redress.

Market-oriented approach to regulation
These are methods that increase the scope for competition among providers, usually to encourage improvements in quality or efficiency of services, but also to increase coverage of services. Consumer empowerment would impact the market. In addition market approaches organized around providers, often through third parties are being tried out.

Common methods include contracting for services and professional self-regulation including voluntary accreditation, both of which can be reinforced by financing mechanisms to provide additional incentives for pursuing certain agreed objectives.

Institutionalized co-production approach to regulation
These are collaborative approaches where public services and its regulation are shared through a regular long-term relationship between the state and organized groups of citizens such as civil society organizations and NGOs The relationships between the agencies involved are often undefined, informal

[qq] The 3 examples of Approaches to Regulation are taken from the KIT international review.

(unwritten) or renegotiated, pending on changing circumstances on the ground. Institutionalized co-production is defined to include regulation through a regular long term relationship between state agencies and organized groups of citizens where both make substantial resource contributions.[rr]

[rr] Joshi A. and Moore M (2004) Institutionalized co production: unorthodox public service delivery in challenging environments. Journal of Development Studies Bol. 40.No.4 April 2004 pp.l31-49

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