''HESVIC project

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

Deliverable D 1.2.b

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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 pertains to governance of health systems in policy and practice. The project will conduct this investigation through a comparative study of three Asian countries – Vietnam, India and China – using 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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LIST OF CONTENTS

LIST OF ABBREVIATIONS

Acronym	Definition
CSO	Civil society organisation
EmOC	Emergency obstetric care
FGD	Focal group discussion
GP	General practitioner
HESVIC	Health system stewardship in Vietnam, India and China
HIS	Health information system
MDG	Millennium development goals
MMR	Maternal mortality rate
RQ	Research question
SBA	Skilled birth attendant
SSI	Semi-structured interview

1. Introduction

1.1 The overall research process

The current document assesses the findings of Phase One, in particular the lessons learned from this Phase, in order to feed it into Phase Two. It elaborates the research framework and updates the research process for Phase Two. As with the previous research methodology deliverables, it has been conceived as an inclusive document aimed at encompassing the concerns of all consortium partners, to the extent that they weren't contradictory.

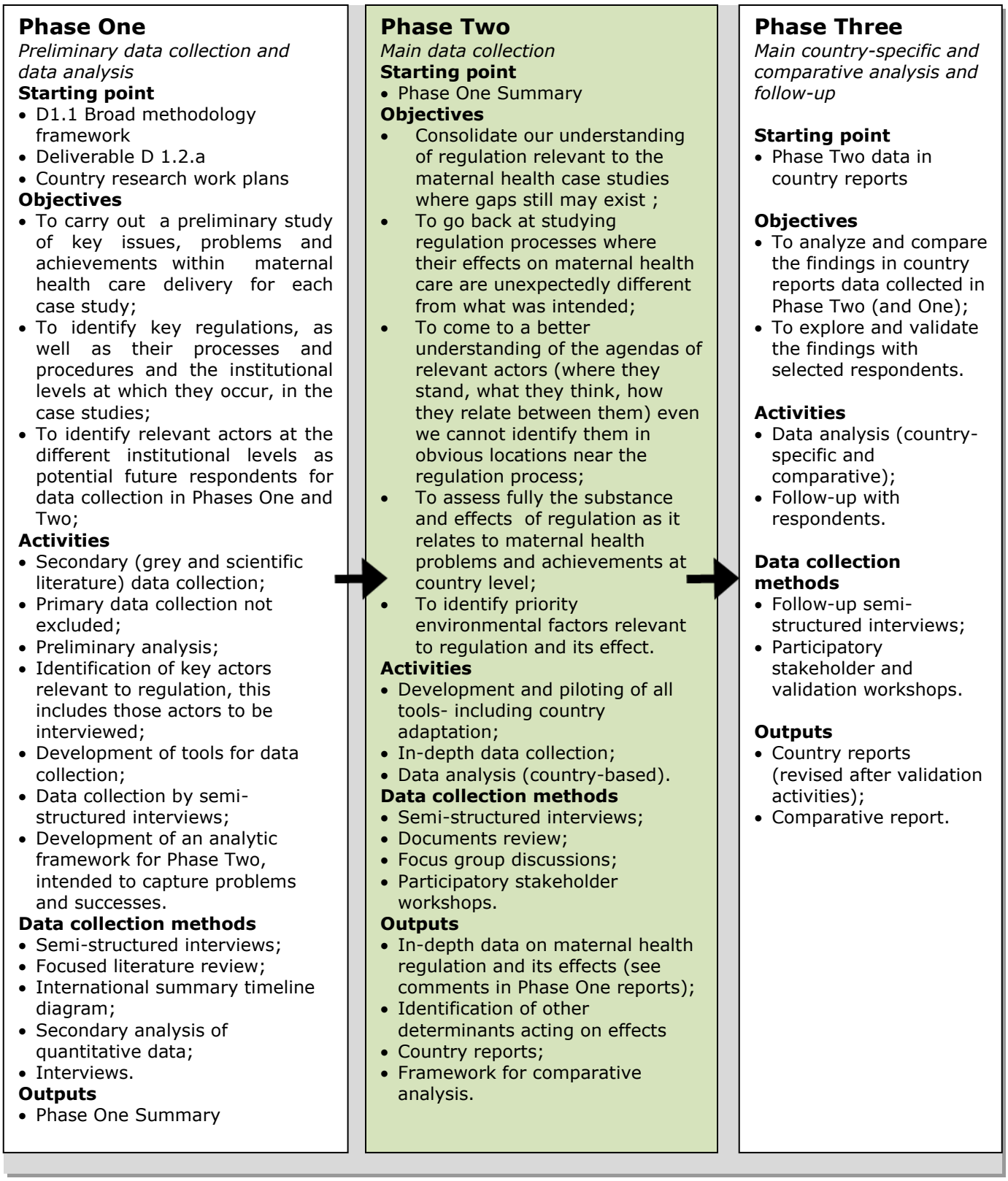
Figure 1 on the next page, already presented in D1.2.a, provides an updated overview of the overall HESVIC research process. Phase One enlightened us on the processes of regulations and the actors involved in these. Phase Two will respond to the following, agreed to, objectives:

1. Consolidate our understanding of regulation processes and approaches relevant to the maternal health case studies, where gaps might still exist;
2. Return to studying regulation processes where their effects on maternal health care are different from the regulation goal;
3. Arrive at a better understanding of the agendas (intentions) of specific (sometimes hidden) actors in terms of where they stand, what they think and how they relate to each other;
4. Assess fully the effects of regulation as they relate to maternal health problems and achievements at country level;
5. Identify the most relevant environmental factors pertaining to the selected regulations and their effects.

In Phase Two, Step 1, further tools are to be developed and added to those which have already been used in Phase One (See also D1.2.a, p. 36) these will be based on findings from Phase One, the gaps identified and lessons learned. These tools will play a key part in the assessment of regulation[1].

[1] To this end, findings from Phase One were reviewed and analysed. Comments were made by ITM on the three Phase One reports in January 2011 and discussions were held in March 2011 in Amsterdam between the ITM and KIT teams, as well as during the 4th HESVIC Project Meeting in Hanoi in March 2011. The resulting research methodology for Phase Two in its current form (identified gaps and ways forward) is presented in this document. Deliverable D1.2.b is thus updating Deliverable D1.2.a, but was conceived as a stand-alone document guiding the consortium partners through Phase Two.

Figure 1: Updated summary of phased HESVIC research design



The document structure continues to follow the logic sequence of our RQs. As a reminder, Phase One aimed mainly at answering RQ 1, 2 and partially 3. Phase Two will aim at providing answers to RQ 3, 4 and 5, while revisiting RQ 1 and 2 where there are any gaps from Phase One. In the true manner of a case study approach, answering the five RQs is an interwoven process that entails going back and forth between the research questions for a better understanding of the whole perspective of the research – the effect of regulation on equitable access to quality maternal health care.

1.2 A reminder on HESVIC research methodology

The research methodology is largely qualitative and interdisciplinary in essence. The roles of the respective disciplines are the following:

1. Health systems research: to assess access to and quality of health care services, interventions and resources, etc.;
2. Epidemiology and demography: to provide data on maternal health, sex ratios, etc.;
3. Political sciences: to identify and understand actors' strategies and get an insight into power relationships, e.g. knowledge of government structures, power relationships with professional associations, representation of the discriminated (the poor, women, outcasts, etc.) in local governments;
4. Economic sciences: to help delineate the markets in health care delivery and identify actors involved;
5. Ethnology and sociology: learning from insights into society and culture to understand regulation actors.

With this interdisciplinary approach we do not intend a mere coexistence of methods of different disciplines but we actively look for synergies between them. To achieve this we consider the following principles:

1. Interviews tell a lot about the interviewees' social position and strategy but much less about (organisational, political, social) structural features. Information from different sources and disciplines thus need to be cross checked. Regulation processes and the relationship between actors need to be explored in the light of their contrasted effects, which *also* need to be fed-back during interviews.

2. As researchers in this qualitative methodology, we are part of the social reality surrounding the study of health regulation. We need to be aware of this and make explicit where needed the possible consequences of this on aspects of the research (e.g. our own agenda's be need to be regularly scrutinized).

3. The actors, in many situations, tend to continuously adjust to each other (to maximise power or benefit, to protect one's job, etc.) be they visible or not. We need to be able to understand the red thread of this process (e.g. sometimes they say what they think we want to hear or their bosses would like to hear or the opposite of what happened in reality).

Some a priori knowledge of the context surrounding maternal health regulation is already present for some important facts and needs to be taken into account. For example, knowledge of regulation effects (from Phase One and from secondary literature) and of actors in a particular context needs to be used to gauge what other actors say or do not say in an interview.

1.3 Broad ethical considerations

An important point is that planning ahead and ensuring consent with knowledge that there will be protection from fear and psychological harm will also produce better scientific results. Following the ethical advice with great care increases the integrity of the research AND its improves its scientific value.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

The most difficult part of any field work is the identification of reliable interviewees and priming them for the study, including and especially sorting out the informed consent. This should be done without delay by all the teams. It is also vital that all potential study participants receive the (translated) information letters in advance and are given sufficient time to decide whether they want to take part.

As we learned from Phase One, women who have recently had a poor delivery experience will be in distress arising out of a stillbirth or complicated delivery. On the issue of the need for time lag between the occurrence of such a mishap and the moment when people can be considered ready to be interviewed; it is advised that interviews should take place *at the earliest 3 months after the delivery* and never at the location where the bad experience happened. The chosen time lag will depend on the individual cases and national research teams would have to ascertain this with care and sensitivity.

In view also of the sensitivity and the confidentiality issues involved when opinions are sought on matters that are very personal, the HESVIC ethics advisor strongly recommends that these should happen only in semi structured interviews (SSI) and not in focus group discussion (FGD), whether the issues relate to users or to providers.

It is advised to use SSI to make optimal use of interviewee and responses, likely to provide much richer materials. FGD could be used when responses are

technical and descriptive rather than of opinion. Mixing professions in this sense is not a good idea.

There is a need for well-versed interviewers and researchers with sound experience of field work. This may involve several training sessions with field workers. The challenge is not to miss things during the actual interviews or not to rush issues and especially not miss any important subtext to follow up.

The environment during an interview is crucial. Nothing should ever be hurried whether it is in SSI or a FGD. All interviewees need to feel unhurried, comfortable and safe. Often when there is an impression given of being hurried, then the quality of the information can be seriously compromised.

To take account of the decision that user perspectives will be investigated via SSI rather than FGD, some minor amendments were made to the information letter for potential interviewees. The amended letter is attached in Annex 1.

In the consent form it is also added that in the user category a female friend could accompany the interviewee, especially in cases where sensitive issues might be discussed with women who have recently delivered. The amended consent form is attached in Annex 1.

2. Updating the research conceptual framework

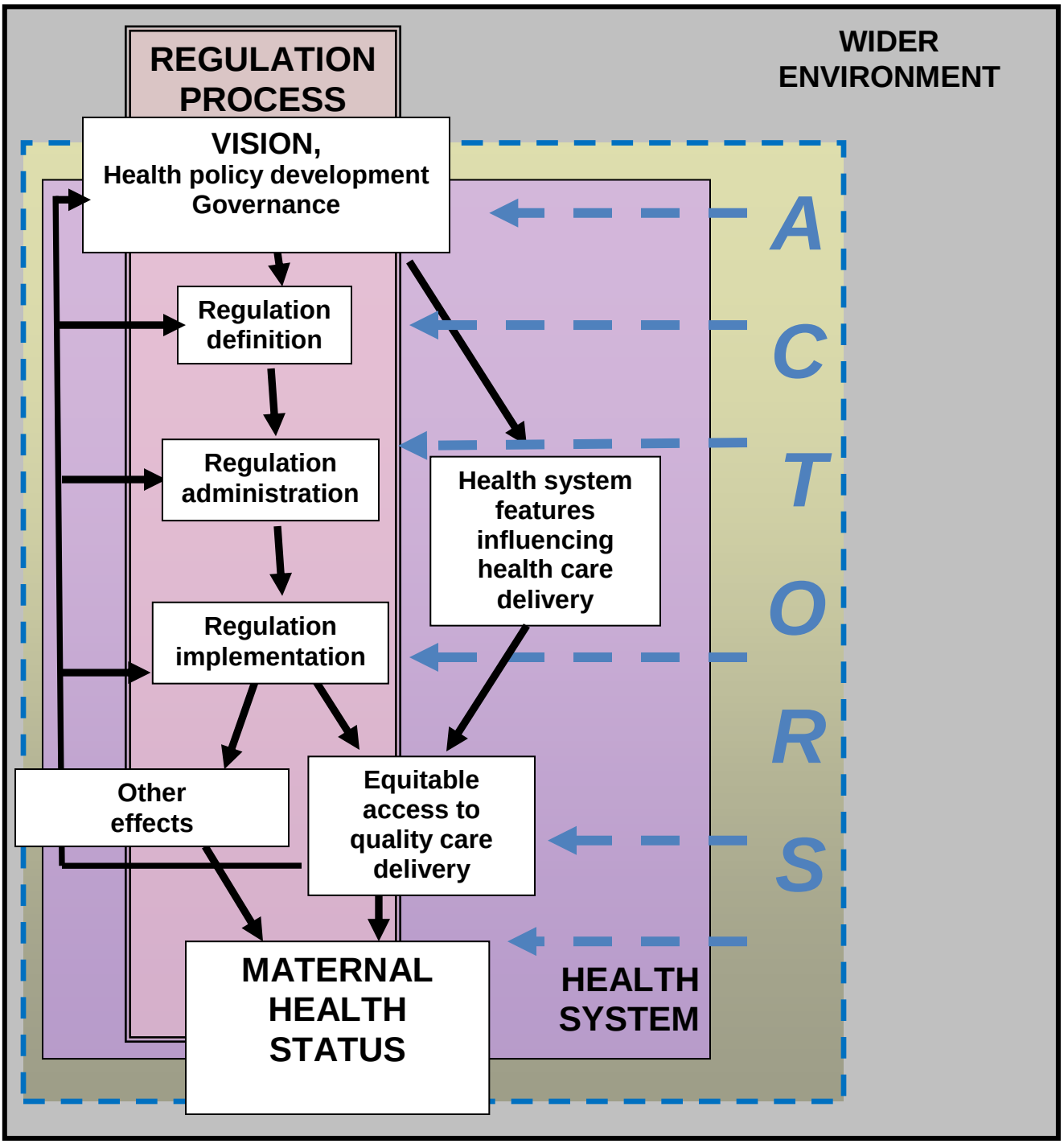
After Phase One, we amended along two lines the conceptual framework presented initially in D1.1 (page 8) used so far throughout HESVIC research:

1. We substantiated some concepts (health policy and governance, regulation process, actors, environment and equitable access to quality health care) and their relationships;
2. We tried to make the framework helpful to derive research tools answering the RQs.

The objective of this conceptual framework is to orient the analytic stage of the study (starting in Phase Two and through Phase Three) and tools development for Phase Two. It should be understood by all interviewers.

Figure 2 on the next page represents how actors (including hidden ones) intervene and inter-relate in regulation processes in (maternal) health care, how they could be seen in the context of the health system and its wider environment and how regulation effects are linked to regulations.

Figure 2: The conceptual framework of the HESVIC research



Notice that the framework expands since other policies and regulation may also influence maternal health. Examples are how education-related legislation influence women's literacy through compulsory enrolment at school; or how work-related regulation measures, like maternity leave and maternity financial benefits, influence a pregnant woman's well-being.

Conversely, some outputs from health services may be achieved in the presence of poor regulation or even in its absence. For instance, one could observe a particularly well-functioning maternity service or program though no apparent (operating) regulation is responsible. Clearly, other health system features influencing health care delivery - possibly not linked to regulation processes - may exist and need to be identified. Examples of such health system features are the following:

- Health system inputs – investment in drugs, infrastructure, quality of staff, etc.;
- inputs of maternal health services, political will and financial capacity.

In the next section we shall elaborate the following concepts of the research framework:

- vision, governance and health policy;
- regulation process and its stages: definition - administration - implementation;
- (in)visible actors;
- equitable access to quality health care;
- wider environment: health system and broader.

2.1 Vision, governance and health policy

Governance, as used in HESVIC describes how public decisions are made and implemented. Regulation processes and content are used to provide insight into and assess governance. As the project evolves towards its analytic Phase, it is important to discuss how.

Universally applied definitions often do not exist and current "quality" features of "good governance" have been difficult to apply to the reality of three countries as varied as Vietnam, India and China. They couldn't be translated for example accurately from a western political model into researchers' terms. Thus, it proved even more difficult to try to turn them into specific research tools or into prompts for interview questions during Phase One.

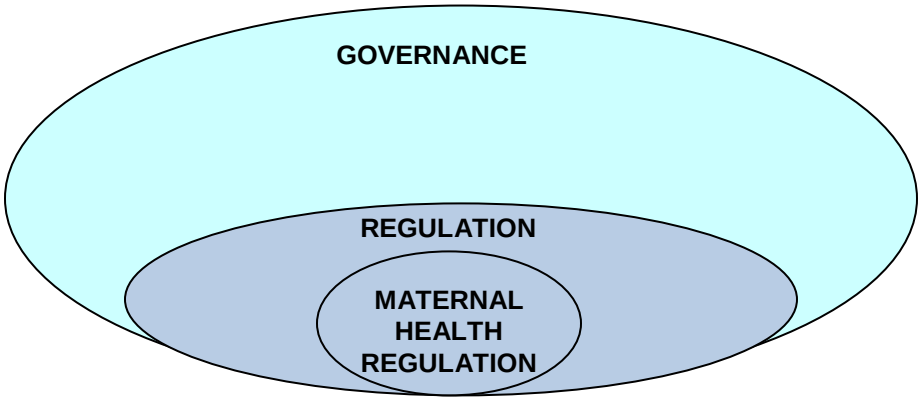
Since these concepts are also ideological and embedded in particular cultures, we felt that it would be important to explore opinions with regard to local criteria alike. In China, for instance, criteria to assess governance and regulation encompass people centred policy, and social harmony.

An alternative is then to examine the meaning of ‘’governance” through the views of the decision-makers in each country. Their views will be asked regarding how decisions are made and should be made in the public sector, as well as the content of the decisions made.

Bearing this sociological understanding in mind, governance becomes a culturally embedded, value-driven concept. This view opens the door to studying bureaucratic and political structures through the discourses of their agents.

Assessment of regulation and regulation effects will also shed light on governance, both being a ‘product’ of governance. Figure 3 below represents the concept hierarchy of governance, regulation and maternal health regulation.

Figure 3: Health regulation and governance



We now elaborate two different approaches to study governance through regulation – one more direct and objective and the other through the discourse analysis of its actors. These two approaches are not mutually exclusive. Instead, their output should be contrasted during the research analytical phase. They are presented below.

2.1.1 Method using indicators for governance quality criteria

At the side of the above mentioned sociological exploration, partners have expressed their comments on the suitability of quality criteria formulated by Siddiqi et al to assess governance.

To make the quality criteria from the analytic framework by Siddiqi et al valid and verifiable, some examples of indicators and studies were provided in Annex 3 of D1.2.a (Section C – Box B). They are updated and copied below in Table 1.

Table 1: Governance quality criteria and indicators to make them operational

GOVERNANCE Principle*	**What information is needed?**	**How to verify?**
'Equity and inclusiveness'	Regulation objectives and definition are fit to tackle some of the following maternal health issues: 1) High variance in maternal mortality rate (MMR) across population strata, e.g.: - Migrant/ floating vs. residents in Shanghai; - Minorities vs. majorities in Vietnam, - Majority and scheduled tribes in India where relevant), - Among social strata in general population; 2) High variance across population strata in the following: - Access to skilled birth attendance (SBA), - Institutional deliveries, - C-section rates, - Access to good quality abortion; 3) social strata specific catastrophic health expenditure; 4) Inequitable distribution of resources; 5) Variance in quality of EmOC according to social and geographical criteria; 6) cost of EmOC episodes compared to income across social/geographical strata; 7) Sex ratio at birth compared across geographical entities with time trends.	Analyse mapping reports, Phase One summary reports, regulation documents. Use data from health (HIS) and geographical information systems. Estimations from local level studies.
'Effectiveness and efficiency'	How does local health management deal with issues of care quality and administrative efficiency? For instance: if there are accreditation procedures do they merely relate to investments, information systems and/or also to quality of clinical decision making?	Analyse regulation documents. Use data from HIS.
'Quality assurance procedures'	Which practice – if any - exists with audits of maternal casualties?	Analyse regulation documents. Use data from HIS. Consult audit reports.
'Intelligence and information'	How is the performance if any of the HIS? For both public and private providers. For instance: what is the proportion of registered ultrasound equipment?	Use data from HIS.
'Responsiveness'	Which methods are used to identify and correct major maternal health problems? For instance, with regard to EmOC: compare the detection rate of pathologies associated to pregnancy (e.g. urinary track and gynaecological infections) to epidemiological surveys outputs. Check for users' perspective.	Analyse the methods used for population's needs assessment. SSI
'Rule of law', 'ethics'	What perception do actors have on control, repression and regulation? For instance, how has evolved across time the frequency of legal procedures against those who practice sex selection practices?	SSI

'Participation and consensus orientation'	What is the role of States, regions and districts in defining and enforcing regulations? What is the role of consumers' associations and users' surveys in regulation and control, exploration of their effectiveness?	Studies on decentralisation of decision-making. Studies on the role of consumers.
'Transparency'	How do you assess the degree of independence and impartiality of any professional associations participating in actual control and corrective procedures? Are self-serving interests watched by governments in self-regulation[iiiiiiiv]?	Studies on membership procedures, contracts, recruitment process and praxis of professional associations.
'Accountability'	are regulation objectives and definition fit to tackle with the variance in implementation and enforcement of financial and administrative standards according to health facilities?	Analyse the procedures for overseeing adherence to financial, administrative rules
'Strategic vision'	What is the degree of compatibility between different preoccupations at the level of local and national government in relation to quality maternal health care? is there a clear strategy to deal with such concerns in the long run (e.g. on MDGs?)	Studies on the political stability, population centeredness, definition of maternal health policy.

* Adapted from Siddiqi et al analytical framework.

2.1.2 A more actor-driven approach to the study of governance

A more sociological approach to study governance would compare at the analytic Phase how the concepts of regulation and governance (despite the intrinsic difficulties) are currently understood in the three countries. It would consider if there are any political functions of the discourses in the broader context of policy making. The way regulation and governance are understood under this approach then emerges through the lenses of actors at the national and local level (view, perception) rather than by any other verifiable criteria.

In practice, during Phase Three we could do the following:

- Utilize 3 key governance principles that are best understood and suitable for the settings in any country, e.g. "participation and consensus orientation", "accountability" and "rule of law". These concepts are then translated into questions using concepts more easily grasped by the interviewees than otherwise;
- We would then organise the answers into a matrix, with responses to RQs in columns and the governance principles in rows;

- At the analytical Phase, among others the use of discourse analysis would shed light on the role and strategy of interviewees, administrations and governments.

Table 2 below is an example of such a matrix.

Table 2: Example for country governance assessment from answers to RQ

	RQ 1	**RQ 2**	**RQ 3**
Participation	*The definition of Regulation X started off with a broad consult of different layers in the society.*	*Users are largely involved in social control during the implementation of regulation X.*	*Patients' association receive a lot of complaints on the lack of effect or undesired effects on maternal care.*
Accountability	*Regulation X does not foresee any procedures or mechanisms to control the adherence to its content, it is a mere guideline.*	*Some actors are part of administration to Regulation X but have also a hidden agenda not to make it successful.*	*Regulation administrators are themselves controlled by the Ministry of Health*
Rule of Law	*Actors have not understood the content of Regulation X, it was not explained to them when it was implemented.*	*Some actors are undermining regulation X.*	*Though regulation X is useful, there are actors who make sure it is not enforced in their constituency.*

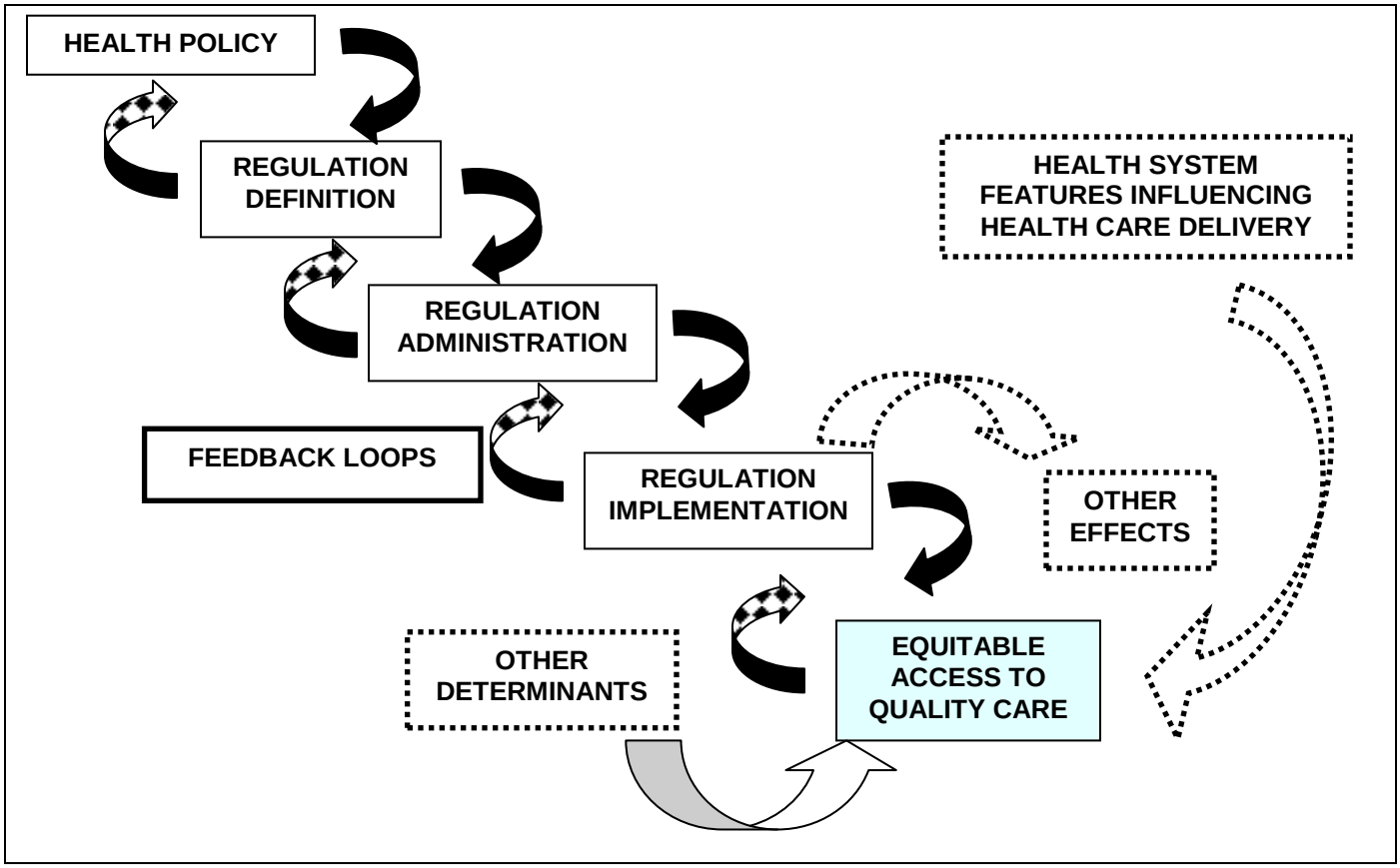
2.2 The regulation process

We updated the definition of regulation processes (see glossary circulated to the consortium separately).

The regulation process in part reflects a flow of guidance and authority for example, from the level of policy (top) to regulation implementation (bottom). In some instances, the existence of a bottom up flow of information can't be ruled out. Ideally; this flow happens through management control systems and information, planning and liaison devices (e.g. formal and informal meetings).

Figure 4 below captures this bi-directional flow in the regulation process.

Figure 4: Relation between different stages of the regulation process



However, while drafting a regulation, the underlying health policy is not always made explicit, although there may be a general vision underpinning it. Introducing a new regulation may or may not entail the creation of a specific administration, which in turn may or may not lead to intended effects.

Furthermore, unintended effects may appear. For instance, the fear of repression of sex selection practice amongst Indian general practitioners (GP) has had unintended consequences on their will to apply the regulation of the legally permitted medical termination of pregnancy (MTP).

Problems and achievements at any stage in the regulation process may have repercussions at any point along the flow represented above. In theory, when management control, information systems and liaison devices detect problems, they should convey it upwards and trigger some adaptation. Interviews should reveal such examples if HIS and liaison devices function properly.

EXTRACT FROM D1.2.a

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.'[1] To this end, the project will also collect and analyse (secondary) data on prevailing maternal health practice in Vietnam, India and China.

Understanding the features of maternal health practice will inform the 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(as in phase one)
- Consideration of social and professional practice: e.g. problems and achievements in maternal health in the three study countries.

2.3 Actors

The actors belong to the categories identified in D1.2.a (page 25) and copied on the next page.

By definition, actors have a role in the maternal health regulation process. Their role can often be clearly identified. Some were already interviewed during Phase One. It may be more difficult to identify some other actors or to fully understand their role. (as in category 5 below). In some instances it may even be the actor's intention to stay "behind the scene", as an "invisible or hidden actor[2]".

[2] The term of "invisible actors" is used throughout this document in this same way.

EXTRACT FROM D1.2.a

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 of regulation (operationalizing, adapting and keeping 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. Some of them (some invisible actors), however, may not be open to interviews.
6. UN agencies were raised for the context of Vietnam and India only as an important separate group.

How do relations between actors impact on their decisions? Several mechanisms and factors may play a role. We have identified the following:

1. *Power*: power may not be a characteristic of an individual only. It may also be defined in terms of relationships and transactions between people. Power is crucial to the achievement of individual goals, the resolution of conflicts, and for the communication of competency within a group. Power may be measured by the degree of access one has to information, the political influence one exerts, by the way one controls resources (see overlap with resources below), the relative freedom with which he/she is able to make a decision, his/her authority on others decisions, etc.;
2. *Resources*: commercial and administrative agents generally benefit from particular resource allocation through resource management. The "physical" resources can be financial, human, material (equipment) and infrastructural. "Virtual" resources may include time, information, reputation, social network, alliances, etc. Resources are usually closely related to power: the more resources an actor has, the more powerful he/she will be – and vice-versa. But this is a fluid situation and needs analysis under given circumstances;
3. *Incentives*: material and symbolic incentives are diverse. One possible typology could be as follows:
    a. *Personal incentives* - in the form of remuneration, moral incentives or coercion. These may all be implicit elements of a regulatory mechanism

or procedure. A branch of economics is called “incentive regulation”. It is used in regulating public affairs,

b. *Institutional incentives* are organisational. People can identify themselves with institutions and with their purpose and permanence. Institutional incentives transcend individual human lives and intentions, making and enforcing rules that govern cooperative human behaviour.
c. *Social incentives*: are related to customs and behavioural patterns important within the relevant society, as well as to particular formal organizations of government and public service (overlapping with institutional incentives). As with institutional incentives, these customs and patterns can be both formal (e.g. documents underpinning the running of an organization) and informal (e.g. spontaneous mechanisms or procedures emerging from daily interaction) or embedded in social and/or institutional arrangements;

4 *Identity:* can be viewed as the psychological face of an incentive. It represents the image a person has of him/her self in terms of belonging to groups defined on social, economic, professional, cultural, religious and other grounds. Identity is a powerful psychological motor in the sense that it drives people to behave in a way that is compatible with the norms prevailing in the group he/she ambitions to integrate;
5 *Motivation* is in this sense the psychological result of a complex mix of incentives, identities and other factors pushing and pulling someone to act and behave in a certain way.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

During analysis it is our aim to understand the dynamic relations amongst actors – how they adjust to each other across time. These relationships belong to categories such as agreements, contracts, pacts, favours, threats, retaliations, denunciations, alliances, patronage, illegal payments, exchange of information, competition, etc.

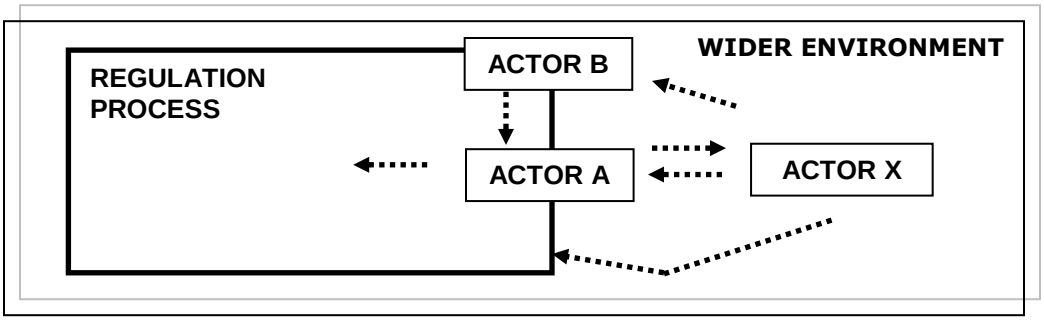
To the extent that the HESVIC research aims at better understanding the environment, we need the following:

- to explore as far as possible these actors dynamics;
- and to do this at the light of the regulation effects as they offer some kind of verifiable, determinate reference points, as presented in figure 5 below.

Interviews with actors should address the incentives that are relevant to the given regulation, as well as questions about how the actors perceive themselves in terms of power, identity, motivation, etc. We could use them as coding key concepts for analysis.

These relations can lead to some degree of mutual adaptation and generally express power relationships. These interactions between actors could be called *dialectic*, in the sense that confronting views, opinions and interests do lead to a settlement shaping the proceedings or the outcome of regulation in maternal health care.

Figure 5: Possible dynamics of interactions between actors



Below follow some illustrations of these dynamics.

1. For the GR case study:
    a. A local politician (Actor X), contacted by an affected political ally, intervenes with the district medical officer's office (actor A) to muffle the handling of a complaint registered through the GR process. In this case the local politician may not have been directly involved in the regulation process;
    b. A journalist (Actor X) may judge newsworthy a particular complaint and change its course by bringing it to the attention of the public;
    c. A particular media (actor X) may treat as newsworthy only those complaints directed against private (or conversely public) services;
    d. Hospital manager (Actor A) may be compelled by one of his bosses (Actor B) to handle with great discretion a specific GR case.

2. For ANC and Abortion case studies:
    a. an ultrasound or laboratory diagnostic kit manufacturer (Actor X) may lobby to their own benefit with regulation designers (Actor A) to expand legal indications of ultrasound, amniocentesis or serum marker testing within a given regulation;
    b. The regulation designer (Actor A) may want to elude this influence from the manufacturer (Actor X) but the latter insists by contacting his or her boss (Actor B).

3. For EmOC case study:
    a. in some instances, a health manager, say a district medical officer, can act both as a (public) regulation administrator (Actor B) and a (public and even private) health provider (Actor A) and can use EmOC rules to his own advantage or the advantage of his fellow providers.

2.4 The 'equitable access to quality care' effect on maternal health status

"Equitable access to quality care" is a critical issue relevant to those regulations aiming at securing a right. We will call them *promoting* regulations (e.g. to secure universal access to quality EmOC). It is not a critical issue when regulations are designed to deter practitioners from wrong doing, though they may have a long term effect on quality of care. We will call them *deterring* regulations (e.g. to prevent sex selection).

For the ANC case study in Vietnam for example, RQ3 sub questions c and d do not assess the effect of regulation on access and on quality of prenatal care but the extent to which professionals still perform sex specific abortion despite the regulation prohibiting it.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

To assess the effects of promoting regulations on quality of care at the point of contact, we as researchers want to know if providers are able to organize health care with the best standards of quality of care, as a consequence of regulation and the extent to which people can access this care.

Care quality can be defined from accepted best practice standards and/or from patient perceptions, e.g. a user may perceive an injection to be better 'quality' than pills even if it is not necessary.

In fact, the two perspectives are complementary. The aim is to collect additional information on quality of care with some of the criteria provided here and to complement this list with ad hoc criteria on users' perspective decided by the three research groups.

When answering RQ3, it is necessary to disentangle the concepts of 'equity' and 'access'. For instance, the overall institutional delivery rate may be 80% in a population but some of its subgroups (say, minorities members) may only have a 40% such rate.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

When regulations yield contrasted effects, with rather positive achievements together with much poorer performance in other groups, the reason must be understood, which requires going back to RQ 1 and 2. Therefore, phase two encompasses early attempts to analyse interviews.

At times, regulation processes may have other, sometimes unexpected and/or unintended effects that are not closely related to equitable access to quality care. They are represented in Figure 2 in the box at the side of "equitable access to quality care delivery". Such effects may occur under influence of actors, health system features and even the wider environment.

2.5 The wider environment

The wider environment influences regulatory processes and effects and conversely, insights into regulatory processes enable us to better understand aspects of the wider environment. This environment includes health system-specific factors as well as from the socio-cultural, (national and international) political, historical and economic context.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

The study of how the wider environment influences regulatory processes and effects and what knowledge of this environment can be gained by our study will mainly be an issue of analysis at Phase Three.

Virtually anything belonging to the environment could be explored with reference to regulation, its processes and how actors behave. It would therefore be impossible to analyse each actor within a regulation process from the multiple layers of that wide environment. The challenge is to focus on the ones that are most relevant. The priority environmental features that were identified for study in Phase Two are represented in Table 3 below.

Table 3: Priority environmental factors

1. Political culture and relations : how politics or politicians are likely to have a stake in a specific regulation;
2. Health system: how its very organisation is a possible matter of influence on regulation processes and its outcome. In particular, changes to the system will be a key to understanding the raison d'être of a regulation.
3. Priorities given to policy within the system
4. Economic factors: how economics of a particular context and investors within, may be affected by a particular regulation
5. cultural- behaviour and perception and how they relate to structural factors
6. Societal dimension (structures processes- level of existing inequality, or deprivation etc
7. Speed of change over the past two decades though mapping is from

Table 4 below provides some suggestions about where and how to look for ways of studying the possible effects of such factors on one or more regulations and their possible effects. We should bear in mind that some factors from the environmental context can operate individually or interact with each other. There may be an evolution in the influence from some factors, etc.

Table 4: Priority environmental factors and how to probe for their influence

Environmental factor	**Ways of probing for their degree of influence on regulation process**
Political ideology	What are the dominant opinions about the meaning of democracy? How is the relative role of market vs. state perceived and acted out? What are the views on the relationship between state and citizens? What is the perception of respondents on governance(translated for local meaning), and how does this impact on the way actors understand and work with or use regulations? Are there independent civil society organisations (CSOs) and How are CSOs involved in the policy process?
Health systems[3]	What are the country specific settings of private vs. public sector? How are the proportions of public/preventive health vs. curative care, of first line primary care vs. hospital care? How is the nature of the relationship between health providers vs. patients, e.g. how users are treated, if they voice their (dis)satisfaction? Is there a lot of high technology available in health services? Are there any influential on-going decentralization processes at hand? Are there important health insurance players in the system? What is the importance given to maternal health compared to other health sectors, are there any links to important actors (e.g. UNFPA)? Which priorities are set for resource allocation, e.g. Is HIV/AIDS getting more funding? Is maternal health a high priority in the country fiver year plan? Is this related solely to achieving MDGs?
Economic factors	What is the dominant economic rationale : e.g. for a service economy? What is the impact of migration?
Cultural	What are prevailing attitudes, beliefs, perception of services and women's status? Society in general and among health workers? Is there any difference in these attitudes according demographical background? Rural vs. urban divide?
Social structures[4]	Levels of inequality, in health, education, labour market and income (who does what where and how do they relate to each other) in particular on minorities (migrants, lower classes and castes).
Speed of change	One criteria to assess these could be the speed of urbanisation, intra and international migration, use of mobile phones, TV and the internet, Degree of women education over two decades.
Information systems	If they contribute to implementing regulations, e.g. HIS channels available, medical techniques available and how that has a bearing on the regulation.
Role of the media	Levels of literacy and access to most common form (TV, print media, radio, etc.), national versus international channels, spread of ownership of media.
Individual level factors	The world of the actor: family, community, etc.

[3] Also refer to the international review paper on Maternal Mortality.
[4] Also refer to the international review paper on Actors.

As an example illustrating the need for more concern about the environment, China mentions health regulations that are based on the country's overall political and legal system. However by just concentrating on the technical problems of maternal health this context is not brought into play although it is likely to have a substantial impact.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

When crossing different environmental factors and describing how they contribute to the effect, or lack of it, of regulation, there is no need to carry out the full scale of realistic evaluation research methods. At any rate, the information already requested in the project methodology would allow consideration of some of its features at the analytic Phase.

3. Overarching issues from Phase One to Phase Two

In Phase Two we will have to collect complementary data to those from Phase One, particularly on *why* the processes identified in Phase One occurred, and on the role of feed-back and evidence-based processes. Information from Phase One and key thematic issues should thus be incorporated in Phase two through principles listed below.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

We can expose Phase Two respondents to Phase One findings and give them the opportunity to express their opinions on problems and achievements detected to date

Therefore, we have to ensure that the interviewer is well and duly informed prior to the interview, so that he/she has enough knowledge of the case study, its key areas and maternal health problems and achievements;

We have to ensure a well-versed and experienced interviewer in all cases so that he/she knows when and how to probe and prompt the respondent in order to produce the desired information.

The three Phase One summary reports raised some overarching findings and issues, listed below by research question. For RQ 1 and 2, we look at these Phase One findings and formulate some proposals on the ways forward to deal with gaps during data collection in Phase Two.

3.1 Research Question 1

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?

As an overview, what we have learned from Phase One regarding RQ 1 has been summarized in Annex 2 at the end of this document.

3.1.1 Gaps identified in Phase One

3.1.1.1 The study of regulation

There was a strong rationale behind the selection of each case study-specific regulation. Now there may be a need to reconsider the selection of an additional regulation for each case study as the findings from Phase One showed that in some instances the selected regulation did not produce sufficient information to answer our RQs. This is specially the case for RQ 3, about the possible effects of the regulation on equitable access to quality health care.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

Some 'fact and indicator finding' comments were made on the Phase One summary reports of every research country.

This could be done before going back to the study of another regulation process, content and structure, so as to avoid endlessly expanding the study of related regulations without ever answering RQ3.

A concerted effort should be made to access data – however limited - on the private health market and its regulation in each research country.

3.1.1.2 Regulation approaches

In Phase One, the “state-controlled command and control” regulation approach received much attention in all three country reports, as it is normally built into the management of public services. In general, this is the most common approach to regulation in LMICs. The IPH GR case study is perhaps an example of a regulation studied within a consumer-oriented approach, for reasons specific to the state and the country.

However, little attention has been given to the apparent conflicts between a command and control approach and, for example, the availability of resources required to implement the relevant regulation. The three Phase One summary reports do mention some pitfalls of inadequate resourcing, as well as of insufficient knowledge and awareness of each regulation at the different levels of implementation. It is important to remember this point whilst embarking on the next phase in relation to regulation approaches.

3.1.1.3 The regulation process

In HESVIC we consider three interlinked stages through which the regulation process passes in order to become real, namely the following:

i) definition;
ii) administration, which includes control;
iii) and implementation. (Notice that absence of control of a particular sector implies a probable absence of regulation implementation in this sector.)

In Phase One, the focus was more on stages (i) and (ii), with the exception of control. There was less focus on step (iii), and on the interaction between providers and users in step (iii). In RQ3, the effects of the three stages should be assessed e.g. with regard to the consistency and relevance of regulation definition, the appropriateness of administration and actual control, and the real implementation by providers (see also Annex 3 of D1.2.a, which has been inserted in the present D1.2.b – see Annex 3).

3.1.3 Suggestions for Phase Two

3.1.3.1 The study of regulation

Starting from the early country mapping reports through to the summary reports from Phase One, some (mainly secondary) information has been gathered on achievements and problems in equitable access to maternal health care. At the beginning of Phase Two we need to process that information as in the cases mentioned below.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

Check maternal mortality rates: what is their evolution in time, how is its distribution across countries' administrative entities (e.g. states, provinces, etc.).

Check sex ratios: how is its distribution across countries' geographical units, evolution across time, etc.?

Check data - where available - on women with insufficient access to good quality abortion care: describe this group according to their age, origin, social economic status, etc. - if possible.

Phase One findings also gave us the knowledge about the problems and achievements with the regulation definition and/or administration.

Since data on a single regulation may not adequately answer RQs 1 and 2 it may be necessary to use the concept of a *regulatory continuum*. Regulations within a defined field such as maternal health overlap and it is not often possible to pinpoint where the process of one regulation ends and another begins.

Therefore, *the degree of embeddedness* of a particular regulation in a series of others should be described (e.g. one major and others which are not so major but are overlapping) This degree of embeddedness is related to the fact that regulations share the same objectives. The degree of embeddedness could, for instance, be illustrated by research on regulation in general health services and on the application of the relevant regulations.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

The originally selected regulation has to stay at the centre of our enquiry but we ask questions about related regulations in the continuum until we have enough data to answer our RQs, and;

This does not mean starting all over again to look for the related regulation. Rather, it means acknowledging that we are aware that there are related regulations. Notice that the existing secondary information should in most cases be sufficient to establish the connections and interrelationships between regulations.

The regulation continuum that we study can be explored based on the following principles:

a. The problems that have been identified in the maternal health service provision. For instance, in India, the synergy of two regulations on selective sex abortion and medical termination of pregnancy (Indian Public Health standards and The Clinical Establishment Act) may cause a reduction in access to abortion due to doctors' fear of being sued under the former act;
b. The issues that come up during the research on the regulation process (definition, administration and implementation). For example, are there resources for implementing the regulation as intended at the different stages of the process?

3.1.3.2 Regulation approaches

Three different types of approaches to regulation were identified from the literature. These are: Command and control approaches; Consumer oriented approaches; and Market oriented approaches. Self-regulation, as is the case with professional associations self-regulating on ethical principles, has also been reported during Phase One.

Phase One's focus was a lot on command and control, while hopefully Phase Two will enlarge it to other approaches. All regulation is initiated by the state but the approach to regulation can be that the state does one or more of the following to impose restrictions and penalties to regulate market mechanisms:

- provide incentives to consumers to choose services or to complain;
- provide incentives to providers to orient service delivery;
- regulatory power delegation from state to professional associations.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

In fact, even when a regulation document suggests that the operant approach is command and control, we might encounter in practice in addition other approaches, which need to be identified and explored further in Phase Two.

We will therefore need to explore the mix of approaches in each case study in each country and disentangle them across the process.

Phase Two will further look at effects of regulation. Furthermore, the fit between a regulation and a particular medical technique and its use in the market should be assessed, bearing in mind that regulations should evolve together with technology. For instance, historically, amniocentesis appeared before ultrasound. Regulation for the use of the former should have preceded those geared to the use of the latter.

The assessment of a regulation value can also be found in its direct examination – loss of measuring its effect. An example can be found in the China GR case study. The regulation is initiated by the state, but "there is no mechanism for monitoring and punishment to strengthen the management system in the regulation (FU Phase One Summary Report, p. 60)". Furthermore, there are no mechanisms in place to permanently reorganise services according to grievance redressal outputs. Instead, the consumer is given ways to complain (consumer oriented). In the implementation of the complaints procedure, we see that not only individuals complain[5] occur, but that they are assisted by third parties ranging from market oriented insurance organizations and legal agencies to other groups who mediate between physician and patients.

3.1.3.3 The regulation process

In Phase Two, we need to give all three stages in the regulation process careful attention. Therefore, we need to investigate in greater depth how the market, both directly and indirectly, affects the regulation process and with what implications. An example can be found in the Vietnam ANC case study. Facilities reveal foetus gender, which the regulation forbids, in order to increase revenues, improve reputation and increase their number of clients. Market mechanisms have taken over from command and control approaches, which are no longer able to regulate knowledge of foetus gender (HSPH Phase One Summary Report, p. 21).

As stated above, mechanisms to ensure compliance mentioned in a particular regulation, such as sanctions, or norms, may not have the intended effect because resources may be insufficient to administer them (e.g. c-EMOC at Vietnamese provincial level).

3.2 Research Question 2

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.

[5] Notice that a lone voice of a woman user without power may not get a long way - which needs to be explored further in Phase Two.

As an overview, what we have learned from Phase One regarding RQ2 has been summarized in Annex 2.

3.2.1 Gaps identified in Phase One

3.2.1.1 On the incorporation of key actors with respect to regulation processes

During Phase One not all actors who play a key role in the regulation process were identified. In particular, actors that weren't directly involved in the regulation process stages (or invisible actors[6]) were not included.

Users of maternal health services were underrepresented in the interviews, e.g. because ethical clearance was not obtained. In other cases it proved difficult to find them.

Information is also lacking on private sector provision in the three study countries. At this point we have little insight as to whether the detailed information on private providers is available to regulatory authorities (e.g. their addresses). As a consequence, there is not enough clarity on the role of private providers within the case studies, nor on how they operate in relation to public providers. The possible pitfall would be that little will be known on how they are regulated and controlled, if at all.

We need to better analyse how actors are related, what alliances exist and what power relationships are known to affect the regulation process. We need to find out which regulation processes they impact on, and how.

3.2.2 Suggestions for Phase Two

3.2.2.1 Defining actors and mapping them

At each level in the regulation process, actors, their activities and relationships shape and interpret the regulation. To ensure in Phase Two that all relevant actors, including the invisible ones, are identified at different stages in the regulation process (definition, administration and implementation), we suggest looking for answers to the questions below.

[6] These include the category of "other actors" within the categories of actors already defined (D1.2.a). Some actors are hard to miss. Others have the clear intention to "stay behind the scene" or could be called "invisible" actors though they have an influence on actions of other (visible) actors. Section 2.3 in this document specifies some conceptual considerations regarding the relationships between actors and clarifies further on the use of the term "invisible actor".

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

Which are the bodies (government, semi-government, private, non-governmental, mass organizations etc.) and who are the actors involved in formulating, administering and implementing the regulation?

- For example, on definition: who was involved or consulted in defining the regulation?
- On interpretation: who is involved/consulted/given the responsibility for administering the regulation?
- On implementation: who is involved in implementation of the regulation?

Which are important actors, both social, political and economic, that have a specific interest - officially or otherwise - associated with any stage of the regulation process? It is important to understand the relationships between visible and invisible actors. For instance, economic actors likely to have vested interests in antenatal diagnosis are medical equipment makers and the lobby of gynaecologists.

Here it is important to map which role is being played by which part of the health system and its actors and who might have a financial advantage in the present state of regulation definition, administration and implementation.

More users should be interviewed. Their views or opinions on access to care which are regulated can be contrasted with what regulation actors or regulated staff tell us.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

Maternal health service users can be found in formal health care services ('exit interviews'), community-based support organisations, and in consumer organisations (e.g. patient or user groups where they exist).

A possibility would be to carry out exit interviews with users after their health care consultation. This has definite ethical implications and also limits the depth of the experiences that users may report on with post-hoc events of health care delivery. Users found through patients' associations and consumers' organisations are expected to better represent the ones with negative experiences or mishaps, but such organisations may be unevenly present in each country.

The research country CRAGS should have good advice on this issue.

Actors should be identified for each case study separately, though some actors may play a role in more than one. New ones can always be identified during

interviews. For example, when interviewees talk about public consultations in the regulation process, new actors can emerge who attended these consultations.

Respondents are sampled as representatives of actors or actor groups. We need to keep in mind that not all actors can be represented in interviews. They should, however, still be identified as they may play an essential role in the regulation process.

Also, not all respondents can represent the views of the actors they represent e.g. because some interviewees will represent more than one group, as would be the case of private gynaecologists with professional and commercial interests.

3.2.2.2 The public and private sector divide

The division between public and private is blurred as there are many mixed categories. For example, there are providers in the public sector who are also providing services based on commercial principles. Therefore, it is necessary to make *country specific typologies* representing their main providers' categories. Phase Two sampling should be based on this typology (e.g. public services with a commercial rationale, private services with a social rationale, etc.). This typology should consider at least the status of ownership (e.g. government, NGO, denominational, etc.) and the mission (commercial and/or social) of the relevant providers.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

We suggest focusing the research on what medical services are being "bought and sold",
- by who (defined in terms of actor typology);
- and in what relationship with the regulation studied.

As an example, the Vietnam mapping report showed that although public and private clinical spaces are separated in Vietnam, medical personnel in the public sector also work in the private sector. More information on this issue is required, as they do have different statuses and the government has different possibilities for acting upon their functioning, even if public and private institutions share a key feature such as commercialisation of health care, Therefore, it is important that sampling reflects these different statuses. As another example identification of actors within the market who issue their own regulations (e.g. market oriented regulatory approach) might be relevant in some instances, as this has bearing on equity.

3.3 Research Question 3

RQ3. What are the effects of regulation on equitable access to quality maternal health care?

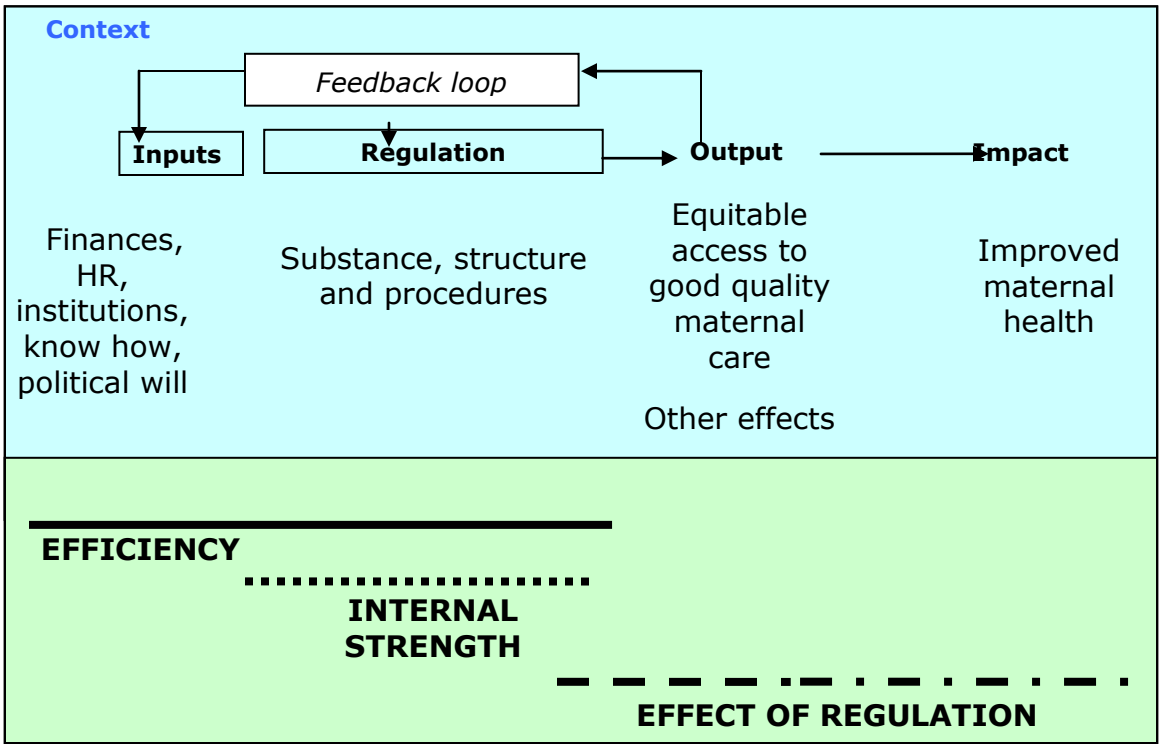
a. What is the current status of and obstacles to equitable access to quality maternal health care?
b. To what extent are these obstacles addressed in existing regulations?
c. What are the effects of regulation (approaches and processes) on quality of maternal health care?
d. What are the effects of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

RQ 3 was not central in Phase One but will be in Phase Two. The issue is to explore the relationships between the administration and implementation of a regulation and its putative effect.

An overview of the findings and lessons learned from Phase One concerning RQ3 is presented in Annex 2.

In the Annex 3 of D1.2.a some hypothetical criteria to assess effect of regulation were provided that were organised along Donabedian lines of thinking. This is illustrated in Figure 6 below.

Figure 6: The assessment of the regulation system



Accordingly, we identified the following categories in which to organise the assessment criteria (see also Annex 3 of D1.2.a for more details, here repeated in Annex 3 of this document):

1. Criteria to assess whether or not a regulation fits the context requirements;
2. Criteria to assess the capacity of actors to carry out relevant regulation processes. 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 the effects of a regulation.

In this group of 4 criteria, criteria 4 are probably the one that most directly answers RQ3. Below are some examples of how researchers can incorporate these criteria into the research tools.

3.3.1. Examples of how we are answering RQ 3 by using these criteria

The desired effect of a regulation can be either positive (promoting a conduct for instance) or negative (prohibiting one).

3.3.1.1 Is a regulation fit to tackle a problem (see criteria 1)?

Any regulation document should have a set of objectives in its definition and subsequent design. These objectives, as well as the way the content of a regulation would ideally not only have a bearing on a specific situation in health care delivery but address technical, economic or social problems related to this health care delivery situation when needed.

Technical hindrances may prevent a regulation to achieve its objectives. For instance, an ANC regulation may specify control through tracing or differentiating the use of ultrasound when it is applied for mere sex determination, but in practice, tracing such forbidden use of ultrasound may prove to be technically impossible.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

What we need to check for is to what extent regulation designers – when defining a regulation - make proper use of any available, relevant information.

3.3.1.2. Is a regulation well administered (see criteria 2)?

The regulation may be well or poorly administered, or not at all. Actors that have to administer a given regulation may simply not be well-equipped to do so.

This is the case when the following situations presents (based partially on Phase One findings, and to be checked in other cases/countries):

- There are no resources available for its control or no control staff. This would be an input deficiency, as in the Donabedian diagram in Figure 6; As a consequence, private providers may never be visited by controllers in our domain of concentration (EmOC and ANC);
- There is no well identified target. This would be the case when no available addresses exist of private facilities and professionals, or when no field visits take place as a result of the lack of addresses or lack of staff. In Figure 6 this would be a process deficiency;
- There is not enough information available (statistics) on forbidden activities (available in the administration or in the consumers organisations or in the professional associations), or no quality assurance mechanisms;
- In the absence of command and control mechanisms, as is the case with the private sector, there are no available incentives for desired health care delivery or no actually performed punishment for forbidden health care delivery.

If the answer to one or more of these questions is “YES”, then the regulation administration would be likely to have sub-optimal effects or even no effect at all.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

There is thus a need to describe in-depth the structural weaknesses and strengths of all that is needed to have a regulation implemented.

The attribution of resources to the regulation process definitely influences its outcome. To assess this, it is not required to do actual cost quantifying of these resources - only a good, semi-quantitative description.

3.3.1.3. Problem mitigation

The way in which health problems, such as maternal mortality, sex imbalance, poor access to safe abortion and grievances, are mitigated can be sub-optimal. This means that equal distribution of impact indicators at regional or provincial level may or may not have been modified by the introduction of a regulation. For instance, the disparity of sex ratio across Vietnamese provinces may have been stable or possibly deteriorated across time, even after a particular regulation had been issued and actually administered (See also Section 3.1.3.1).

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

The chronology of impact indicator and introduction of a new regulation should thus be matched at regional but also national levels. The idea isn't to seek a statistical association as such, but to pinpoint specific features in time that are worth being studied in detail.

3.3.1.4. Discrepancy of findings between assessment criteria

There may be a discrepancy between some of the assessment criteria. If a regulation effect is sub-optimal in the health sector, it is relevant to wonder why. Is it, for example, because the regulatory structure did not communicate sufficiently about its ineffectiveness to policy makers? Is it because policy makers did not adjust the regulation content or structure to make it work?

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

We should aim, when possible, at triangulating information and at explaining discordant results.

Consequently, answering the different RQs (across phases) should not be seen as separate within the research processes.

Sub-optimal effects offer possibilities for detecting idle answers in administrative speeches, for grounding discourse analysis in verifiable facts and for deciphering the relationships between visible actors with their environment and with invisible actors.

3.3.2. Consequences for the overall research architecture

Answers to RQ3 can lead interviewees to scrutinize eye-catching findings while answering questions related to RQ1 and 2. Such findings could be e.g. unreliable key indicators, inequitable access to EmOC and safe abortion, disparity of sex ratio across a country, etc.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

It is necessary to elicit the opinion of interviewees on indicators, qualitative observations, care features and insights into equitable access to health care when asking them to appraise regulation definition, content, structure, administration and actual implementation.

To summarise, it is necessary to clearly separate regulation addressing public (possibly specifying 'public for profit') and private structures, if not at definition

level, at least at the administrative level. It is further necessary to examine other providers' categories (if any) and get more information on inputs, processes and outputs of regulations in these two sectors.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

It is necessary to establish early in Phase Two a typology of main categories of providers in each country and base the sample design on this typology.

3.4 Research Question 4 and 5

As far as RQ4 is concerned, the domain of general health care is recognized as a different area altogether. The consortium will adapt a pragmatic approach in responding to it. Some data could be collected during interviews from Phase Two 'see also Section 7) so that RQ would then be dealt with mainly at the analytic Phase (Phase Three).

It should be possible at the end of Phase Two to identify some respondents who could give their views on the comparability of regulation in maternal and general health care.

To answer RQ5 interview questions can be included during Phase Two on wanted changes. It will be answered in-depth at the analytic Phase Three, when opinions of some interviewees can be collected during follow-up interviews on how to improve a regulation.

4. Overarching issues for Phase Two and Phase Three

4.1 Sampling for interviews in Phase Two

The total number of interviews needed to be performed by each research country was estimated in D1.2.a to be around 60 (see extract from section 5.2.2.1 below).

EXTRACT FROM D1.2.a

As in Phase One, purposive sampling will be used. Respondents 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).

This number was to be divided by actor group' per case study. In light of our knowledge from Phase One we need to revise this number in Phase Two. During Phase Two, 4 project months are available to collect information and 4 others for analysis, making up a total of 8 months for Phase Two (see also Gantt chart in section 6.2). Within this time line, Table 5 below provides an optimal, but indicative number of interviews per research country and per case study.

Table 5: Revised total number of interviews to be carried out, per actor group and per case study

		Vietnam	India	China
EmOC	**Designers**	3	3	3
	Administrators	3	3	3
	Regulated staff	9	9	9
	Users	6	6	6
	Other and invisible actors	6	6	6
	SUBTOTAL	27	27	27
ANC	**Designers**	3	-	3
	Administrators	3	-	3
	Regulated staff	9	-	9
	Users	6	-	6
	Other and invisible actors	6	-	6

	SUBTOTAL	27	-	27
Abortion	**Designers**	-	3	-
	Administrators	-	3	-
	Regulated staff	-	9	-
	Users	-	6	-
	Other and invisible actors	-	6	-
	SUBTOTAL	-	27	-
GR	**Designers**	3	3	3
	Administrators	3	3	3
	Regulated staff	9	9	9
	Users	6	6	6
	Other and invisible actors	6	6	6
	SUBTOTAL	27	27	27
	COUNTRY TOTAL	81	81	81

Please be aware that the number of interviews may be divided another way around amongst the sample strata selected by a country team. Here we make some suggestions on how to break it down.

1. There should be some representation from every group of actors at different stages of the regulation process:
    - at definition stage: a designer,
    - at administration stage: a regulation administrator,
    - at implementation stage, i.e. regulated health staff - a manager, a public health provider and a private provider;
2. There should be at least 2 interviewees from the users' group, given the requested contrasted sampling. Priority should be given to having sufficient users interviewed to achieve saturation in the assessment of the equitability of access to quality maternal care. If invisible actors, for instance, cannot be interviewed, priority would be given to increase the number of users interviewed.
3. We should allow for at least 2 interviewees from the "other actors" or invisible actors.
4. All together this makes a minimum of 9 actors in the different groups to be considered for sampling.
5. We need to interview at least 3 actors per sampled actor group to achieve saturation.
6. Therefore, for each case study, we need to interview at least 27 actors.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

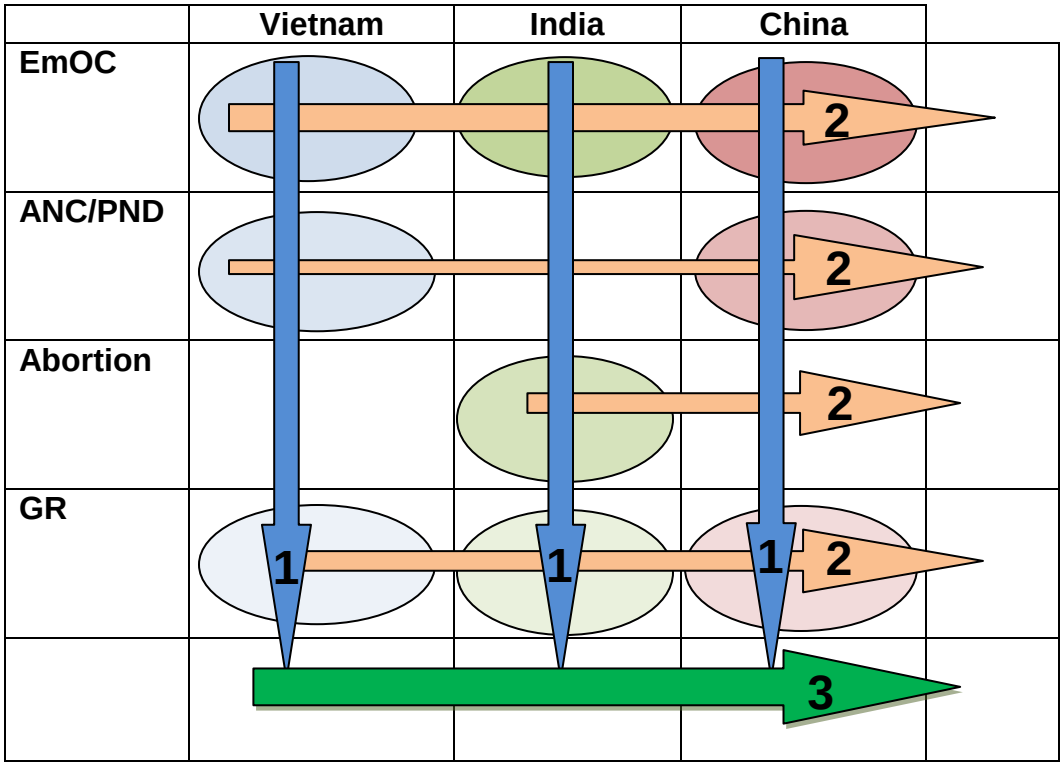
A new revised total of about 81 interviews has to be carried out in the 4 project months for data collection and obviously the same amount to be analysed in another 4 months. However, early analysis will start soon after the first interviews and data collection will start running concurrently.

5.2 The unit of analysis[7]

As a reminder, the main aims for analysis in our study are the blue arrows (N° 1) in Figure 7 on the next page. They will help us to reach conclusions for each research country about effects of regulation processes on maternal health, based on the three case studies carried out. This analysis started already in Phase One and will continue during Phase Two.

When doing the final comparative analysis between the three research countries during Phase Three, we shall focus on the green arrow N° 3 in figure 7. We will only take advantage of possible comparisons when it happens to be feasible (as a by-product), e.g. because one of the three case study isn't the same across the three countries or because priority EmOC topics are also different. When looking at orange arrows N°2 we compare the same case studies across the three countries, which is not the main aim of our study but would be an interesting by-product of HESVIC research.

Figure 7: Different levels of unit of analysis



Therefore, we will not insist on comparability between countries at the expense of reducing each country's autonomy in formulating research tools and questions that might be most relevant to its own situation, without diverging too much from core research methods.

[7] See also section 6.4.1 in D1.2.a.

IMPORTANT RESEARCH ACTION POINT IN PHASE TWO

Each research country with its paired partners thus have a certain degree of autonomy during Phase Two when developing its Phase Two research tools.

To ensure some coherence in these research, these will have to be transmitted to ITM, as well as data collected at the end of phase two to enable for some exchange on additional data needs.

The oval shapes in Figure 7 inside every case study for each research are countries' predesigned case study sampling units. They are defined in Table 6, providing a summary.

Table 6: Case-study specific choices of unit of analysis for Phase Two

	Vietnam	**India**	**China**
EmOC	2 districts in 1 Province in northern Vietnam 2 districts in 1 Province in southern Vietnam	1 district in the North of Karnataka (Bagalkot) with poor health indicators 1 district in the South (Tumkur) with relatively good indicators	Migrant vs. resident population in Shanghai
ANC/PND	Same		Rural vs. urban population, migrant vs. resident population in Shanghai
Abortion		Same	
GR	Same	Maternal health services in the same districts	Mother and Child Health hospitals

6. Next steps for Phase Two

Here follow some general principles on the next steps as they apply to Phase Two. Specific tasks are presented on a Phase Two time line in the second part of the section.

6.1 Basic principles

6.1.1 Phase Two will build on Phase One

Phase Two builds upon information collected during Phase One, on what is already known about regulation as a process, and aims at getting more information on regulation effects in relation to understanding regulatory failures and/or achievements.

6.1.2 Information gathered will not be repeated

In general, information gathered during Phase One on RQs 1 and 2 will not be collected again during Phase Two, with 4 exceptions:

1. Any regulation continuum to which the initial regulation belongs that needs to be considered will be identified either through secondary data analysis or a limited number of interviews;
2. In India the selected regulation (IPHS) for the EmOC case study does not apply to private providers. Therefore, Phase One information that was gathered to answer RQs 1 and 2 will be looked for during Phase Two as far as private providers are concerned[8];
3. the country specific mix of regulation approaches will have to be disentangled when needed
4. Decision makers (e.g. regulation designers and administrators) will be asked to explain regulatory failures and ways to improve the situation (helping to answer RQ5).

6.1.3 Contribution from research countries

The Southern partners will contribute actively to decide on priorities related to the information needed and on tools development (from generic to adapted forms). As a consequence':

1. The list of information needs defined below in Section 7. is not exhaustive.
2. The same goes for any information need suggested in comments on Phase One Summary Reports, which are integrated in Section 7.
3. When the country or the case study is not specified in the information requested below, Southern partners will contribute to decide on country-specific priorities.

The ITM team will provide general orientations. In coordination with paired partners, the ITM team will be in regular dialogue with VIC partners to help decide upon country-specific priorities.

6.1.4 D1.2.a remains valid

The D.1.2.a instructions on the approach to Phase Two (see p. 36 to 43) and to the following Phases (see p. 44 to 52) remain valid, which implies a stepwise approach to Phase Two data collection. We have summarized their contents below.

[8] A new regulation, based on incentives provided to the private sector will be fully explored. Related questions are not detailed below as they are similar to what was used in Phase One for the IPHS regulation in India.

6.1.4.1 Phase Two, step 1

In Phase Two, step 1, some tools developed and used in Phase One will be amended and new ones developed. This D1.2.b presents an information need matrix which opens the door to developing tools (see Section 7 below). The process of adapting tools to a country context will be done through collaboration between research teams, paired partners and ITM. If necessary, tools may be properly piloted.

6.1.4.2 Phase Two, step 2

In Phase Two, the actual data collection starts at its Step 2. Further secondary information on the socio-economic, political and historical context can be incorporated during the preparation of Phase Two data collection. Findings from Phase One data collection should also be drawn in where relevant, e.g. on critical events in the domain of regulation. Important ethical issues are to be considered from Section 7.1 in D1.2.a.

6.1.4.3 Semi structured interviews

Interviews will enable a range of respondents to report on their knowledge, experiences and perceptions of the “why?” of the regulation impact (strengths/weaknesses) on maternal health. Annex 4 provides an updated guideline for the interview itself.

6.1.4.4 Focus groups

As said in Section 1.3 above, FGD should be used mainly when responses are technical and descriptive rather than of opinion. These can be knowledge on the regulation procedures, their impact upon maternal health care delivery and actors’ experiences. Analysis of the interviews and focus group data will be achieved with Nvivo version 7.

6.1.4.5 Stakeholders workshop

There is a possibility of holding stakeholder workshops, after the main data collection in Phase Two, to get an insight into the dynamic between stakeholders (conflicts, concerns, consensus, etc.).

6.1.5 Early writing and publishing

We should bear in mind the need to start writing and analysis as soon as possible and concurrently with data collection. This is with a view to ensure that we have some publications *at an early stage*. In this case early initial findings

will be very useful. The writing, both for analysis reports and academic abstracts or papers, could be articulated around specific, innovative themes and could build upon observations and/or explorations and/or verification of hypotheses. We refer further to the HESVIC knowledge management work package to broaden the nature of possible writing outputs. Some of these will be reinforced by a planned for writing workshop.

As far as reporting on analysis of interviews is concerned, there will be a need to disentangle more effectively description of researcher's views and narratives (opinions of interviewees) in Phase Two.

Also, in Phase Two, document review proforma will be used. 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 7 below repeats the overview of how to organise a document proforma, already provided in Section 4.2.1.1 of D1.2.a.

Table 7: 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 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

Category	Information
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.

6.2 Time Line for Phase Two

WP	Activity	2010							2011												2012							Responsible	Notes
	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		
		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																													
D1.2.a (M7) development and submission																													
D1.2a - submission to the EC as a milestone (M7)							30																					NCIHD	
D1.2b - development and submission																													
D1.2b - draft circulated for comments											15																	ITM	1 month after Phase One summary reports from V.I.C.
D1.2b - preliminary comments from partners (as inputs to next meeting)											26																	All partners	Meeting ITM with KIT.
D1.2b - discussions at project meeting																													
D1.2b - 2nd draft circulated for comments																													
D1.2.b - second round of comments																													ITM held Skype conferences with VIC.
D1.2b - finalization including guidance on conceptual framework, on operationalization per RQ, develop information needs and generic tools, etc.																												ITM, All	D1.2.b is stand-alone document for Phase Two, D1.2.a remains valid.

WP	Activity	Month	2010							2011												2012							Responsible	Notes
			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		
			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		
Country Research work plans (D2.1; D3.1; D4.1; M9) for Phase Two																														
	CRWP guidelines and format from ITM																												ITM	
	Comments from V.I.C. on the draft format							5																					HSPH, IPH, FU	
	ITM to revise the outline for CRWPs							15																					ITM	CRWP outline are part of D1.2.a and also valid for D1.2.b
	Development of CRWPs for Phase One							30																					HSPH, IPH, FU	A project deliverable.
	Development of CRWPs for Phase Two																												HSPH, IPH, FU	Not an EC deliverable but could be helpful.
	Ethics expert inputs																												ITM	
	Project meeting - Shanghai (25-29/10/10)																												NCIHD + FU	
	Project meeting- Hanoi (28/03/11-01/04/11)																												NCIHD, HSPH	
	Project meeting (Phase Two)																												NCIHD, IPH	Scheduled Venue - Bangalore, India. To include a field visit.
WP 2-4: Research in V,I,C																														
	Helpdesk set up and implemented																												ITM: Guideline how to consult help desk were posted on HESVIC website.	
	In-Country ethics reviews and approval (Phase One and Phase Two)																												IRB approval to be foreseen at delivery of D 1.2.a, at piloting of tools and at data collection. May be different for different partners. Additional Ethics clearance for Phase Two at delivery of D1.2.b) to be gained locally if required.	

WP	Activity	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	Responsible	Notes
			2010							2011												2012								
			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		
	Phase One data collection and analysis																													
	Step 1 - Identifying problem/achievements and selecting one regulation for each case study																												HSPH, IPH, FU + paired partners	
	Step 2 - Description of regulation by document review																												HSPH, IPH, FU + paired partners	
	Step 3 - Identifying actors leading to respondents in Phase One																												HSPH, IPH, FU + paired partners	
	Step 4 - Adapting + piloting of tools for Phase One data collection																												HSPH, IPH, FU + paired partners	
	Step 5 - Phase One data collection and analysis																												HSPH, IPH, FU + paired partners	Data collection, analysis, writing Phase One Summary
	Phase One Summary (drafting, commenting, editing as needed)									31																			HSPH, IPH, FU + paired partners	
	Phase 2 data collection and analysis																													
	Step 1 - Adapting Generic Phase Two tools; Piloting Adapted Phase Two tools																												HSPH, IPH, FU + paired partners + ITM for overview	Starting from Information needs matrix in D1.2.b, through paired partner's consultations.

		2010							2011												2012							Responsible	Notes
	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		
Step 2 - Data collection and analysis																												HSPH, IPH, FU + paired partners	4 project months for data collection, 4 months for analysis, in reality will run concurrently.
Mid-term review of data collection and start of data analysis (M10)																												HSPH, IPH, FU + paired partners	Suggested timing only. Times are flexible and to be arranged between partners
Phase Three (data analysis)																													
Steps 1-3 - Data analysis for RQ 1 - 3, 4 - 5 and follow up																												HSPH, IPH, FU + paired partners	Data analysis will also be done during Phases One and Two
Country reports written, drafted, commented, revised (D2.2 D3.2 D4.2 M12)																												HSPH, IPH, FU + paired partners	
Final Country Reports Completed																												All	
Workshops: In-country analysis																				?		?						HSPH, IPH, FU + paired partners	May also be required during Phase Two
Paired partner research visits											?				?	?	?	?	?	?	?							HSPH, IPH, FU + paired partners	Pairs to decide.
WP 5: Comparative research																													
Comparative analysis of country findings																													Unit of analysis = country reports
Comparative analysis workshop																												ITM	

		2010							2011												2012							Responsible	Notes
	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		
Comparative report (D5.1), commented, revised, submitted																												ITM to draft, all to comment/ input	EC Deliverable due end of May 2012. Spill over into June possible.

7. Information needs for Phase Two

The matrix below offers clues to proceed with generic and adapted research tools development for Phase Two (and partially Phase Three, if any follow up needed).

The matrix has been organized according to the logic of our five RQ. It makes an approximation of the current level of knowledge and states the additional domains of information needed to further answer the RQ. It is the intention that the domains for information needed are kept rather general, though in some cases country-specific examples have been inserted. The information needed amounts to examples of questions to be asked when we develop tools, without pretending to be generic research tools' questions as such. The matrix ends with a choice of research tools that are ticked when they are considered useful to collect data on the RQ-related domain. In the case of SSI and FGD, an indication is given with which interviewee(s) this needs to be done. The ethical expert reminded that it is important to carry out SSI with one interviewee only at the time.

For RQ 1 – 3, examples for questions have been added to look for criteria of assessment of regulation. These criteria are the same that were presented in D1.2.a, repeated in this document in Annex 3.

In doing so, the matrix provides the logic steps to which research countries and their paired partner can develop their Phase Two research plan and tools. We repeat that the information needs are identified from a perspective of looking for information on effect of regulation on maternal health. As such it builds in domains that have to do with all five RQ, taking into account the leitmotif of maternal (and general) health care.

Please be reminded that Table 4 in Section 2.5 of this document also provides a number of questions to be considered when looking for the influence of priority environmental factors on the effect of regulation on maternal health care.

It is understood – as said in Section 6.1.3 - that research country teams will use the matrix in this section 7 to start developing adequate and adapted research tools at the beginning of Phase Two. They will get help from their paired partners in the first place and also from the HESVIC helpdesk. We refer to earlier e-mail communication and information available on the HESVIC website how best to contact the helpdesk manned by ITM. The ITM team will be kept informed of all research tools developed and revise them prior to their use.

RQ1 – What approaches and processes exist to regulate MH care and how do they operate in practice?
Criteria to assess whether or not a regulation fits the context requirements. How appropriate are the regulation mechanisms / procedures for this maternal health problem? Assess the degree of relevance of the regulation with the main maternal health problem. Are the objectives of the regulation based on evidence? How appropriate are these mechanisms / procedures of regulation for the current context? Assess if the regulation can be adapted to local needs.
Criteria to assess the internal strength of regulation. Assess if the regulatory procedures and mechanisms (incentives, punishment, etc.) are applied for performance / non-implementation of the regulation. Is there any difference between the implementation and the rules? If yes, how to explain this difference? Is there cohesion between the regulatory procedures (incentives, punishment, etc) and the regulation's objectives? Assess if the implementers and end users of the regulation are clear on the contents and the procedures of the regulation. Are there any doubts / confusions? Assess the resources required to implement the regulation, in terms of money, HR, time, simplicity of procedures.

Research Questions	**Status of information**	**Information needs in Phase Two**	**Examples for questions in Phase Two**	**Sources of information**		
				Doc Rev	**2nd data**	**SSI FGD and respondents**
RQ1 – What approaches and processes exist to regulate MH care and how do they operate in practice?						
What are the strengths and problems of these approaches and processes? .	*Description carried out, without using assessment criteria.* *"Why" question needs to be*	Assessment of regulatory design and procedures: Consistency between design, administration and implementation.	**Identify inconsistencies between the regulation objectives, administration and clinical practice. How could this be improved?** *Do present interviewees with effect indicators to comment, e.g. qualitative data showing lack of equity in EmOC, access to safe abortion, province*		**Judiciary information (in Vietnam)**	**Mixed FGD: at least designer, administrator, health care manager and health care professional, if feasible.** **If not, SSI**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				Doc Rev	2nd data	SSI FGD and respondents
RQ1 – What approaches and processes exist to regulate MH care and how do they operate in practice?						
	asked.		*specific sex rate at birth, low number of GR ,etc.*			**individually.**
		Assessment of regulatory structures and institutions Resources managed by regulatory structures to do their job.	**Describe the key available resources (operating budget, human resources) made available to your regulatory organisation.** **Give examples of achievements and problems linked to the level of available resources.**	**X**	**Budgets in national accounts**	**Regulation administrators / inspectors (and designers)**
		Description of heterogeneity in the administration & implementation of a regulation across territories.	**To your best knowledge, which are the most striking evidence that the regulation is not administered and not implemented in the same way across the country?**	**X**	**Distribution of inspectors over the territory**	**Regulation administrators, designers** **Service users**
		Assessment of regulation of private providers: Description of processes and outputs of regulations applicable to the private sector.	**Describe the indictments and sanctions ever applied on private providers in your constituency. How frequently have these happened?**	**General press**		**Regulation administrators / inspectors** **Service users**
		Assessment of monitoring and health information used by regulatory authorities to adapt regulation to the evolving features and problems of health systems. Existence of feedback mechanisms to	**Describe the information used to define an amendment to regulation. Describe the information used to modify mechanisms and procedures of regulation administration and**		**Amendment made to a series of regulations in the health sector over**	**Regulation administrators / inspectors and designers**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				Doc Rev	2nd data	SSI FGD and respondents
RQ1 – What approaches and processes exist to regulate MH care and how do they operate in practice?						
		the regulators. Occurrence of amendments to regulation due to feedback.	**control.** **Describe the items belonging to the health information system consulted by you. Can you provide statistics / data on forbidden activities? Which are the HIS items that you would need and are not made available?**		**a period**	
		Analyse regulation process in order to facilitate assessment: For example establish a flow chart to describe GR procedures as theoretically foreseen and practically implemented. Assess if and how the context (political, social, economic, etc.) affected / altered the regulation and the processes. Assess if the regulation had an unexpected influence on the context.	**Analyse steps taken by a service user to introduce a GR complaint and those taken by the administration to verify its basis and possibly redress it.** **Contrast theory and practice.**	**X**	**Data on evolution of GR treated in your country**	**Regulation administrator and/or health care manager** **Service users**
		Exploring a case of policy / regulation capture, were political interventions make a regulation not, less or otherwise applicable to the private sector?	**What is known of debates and conflicts preceding the definition of a regulation?**	**General press during period of issuing a regulation**		**Regulation designers and administrators**

RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?
Criteria to assess the capacity of actors to carry out relevant regulation processes. Also to assess the capacity of invisible actors to interfere with regulation processes. Do the regulators have adequate resources to implement the regulation; i.e. money, HR, time, capacity, etc.? Who were the actors of debates described above? Assess how the regulator supports the implementers of the regulation in terms of dissemination of information, share experiences, etc. Assess whether the administrators and implementers have the knowledge and skills to carry out their duties. Are the right people administering the regulation? Can the absence of the right people explain a failure of implementation? Are the designers, administrators and implementers free of pressure from political or economic forces?

Research Questions	**Status of information**	**Information needs in Phase Two**	**Examples for questions in Phase Two**	**Sources of information**		
				DR	**2* data**	**SSI/ or FGD and Respondents**
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
Who are the actors in the different processes?	*Description carried out, with actors missing – especially those who want to stay behind the scenes* *Users as actors' category under*	List all the possible actors for the stages of the regulation process and check the ones that were left out during Phase One. Pay attention to obvious actors, as well as less obvious ones ('other' or invisible actors). Are there any obvious and key actors who are left out? If so, why?		**Economic policy and history (invisible actors)**	**X**	**All actors interviewed**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/ or FGD and Respondents
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
	represented. *Private providers under represented.*	Actors' description: Self-assessment and self-identification of interviewees.	**Each interviewee will be asked to present his/her own function and position as far as behaviour drives are concerned (power, resources, incentives, legitimacy, identification with the institution, expectation and identity, etc.**			**All actors interviewed**
		The private providers and the extent to which regulation applies to them.	**Describe the information that you collect on private providers in terms of 1) who they are (individual identification and gaps) 2) With which frequency they are visited 3) Which information they regularly provide 4) Which qualitative information is collected on their activities.**		**MOH information kept or not on private practice**	**Regulation administrators / inspectors**
How are these actors involved in the various processes and to what extent?		State clearly what the missing actors do at every stage of the regulation process.	**Do the actors understand clearly the objectives of the regulation, its vision and mission?** **Do actors understand the influences of other actors on their roles? Which are the economic and political stakes of this or that regulation**	**X**		**All actors interviewed**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/ or FGD and Respondents
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
			design? **How do these actors monitor the implementation / output of the regulation?** **Can the actors provide feedback to a higher level to strengthen / weaken the regulation?**			
What are the aims and priorities of these actors?		Role, thinking and behaviour of administrators and designers of regulations: 1. Their assessment of regulations and governance, using 3 Siddiqi's principles. 2. Their assessment of regulations and governance, using values belonging to national ideologies. 3. Their assessment of regulations and governance, - using indicators of effects - using qualitative description of obstacles met by users when looking for care. Expose a decision maker to	**How do you know that a regulation has failed or succeeded?** **1. - (Rule of law) To which extent is the maternal health regulation under study actually enforced in your constituency? Are there actors aiming at undermining this enforcement?** **(Participation) Besides regulatory institutions and inspectors, are there any service user associations, professionals and/or workers agencies involved in monitoring how this regulation is administered?** **(Accountability) How are**			**Designers, administrators, inspectors of regulations.** **Service users.** **Representatives of consumer associations, professionals and/or workers agencies.**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/ or FGD and Respondents
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
		what we found with secondary data on the regulation results and ask to comment) – This is an essential part of any interview.	**regulation administrators themselves controlled by health authorities or the public?** **2. - How does this regulation contribute to promote national vision and ideology, e.g. harmony and people centeredness (China)? Give examples of other good such regulations.** **3. - Explain secondary data on sex ratio, C-section rate, morbi-mortality linked to unsafe abortion, etc. Explain obstacles met by users.**			
How do these actors relate to each other?	*Relationships between actors have not been studied in-depth.*	Understanding behaviours and strategies of actors involved in regulation administration and implementation: Describe the mutual adjustments of actors in applying a particular regulation.	**Have you been adversely affected (conflicts, personal career consequences) due to your role in this regulation? If yes, who was responsible for this?** **Please describe the underlying conflicts. Do you have any benefit of the existence of this regulation?**			**Regulation administrator, health care manager and health care professional**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/ or FGD and Respondents
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
		Assessment of actors' power relationships: Description of professionals' power in autonomously managed hospitals (also answers RQ 3)	**What do you do to retain highly qualified staff in your hospital?** **How many staff are working both in your hospital and outside on their own account?** **What are most conflicts, if any, in your hospital about?**			**Hospital manager**
What is the level of influence of these actors on the regulation?		Understand actors' influences key to regulation design and administration: Identify political, social and economic forces (having been or currently) involved in regulation design and administration. List the gaps in the formulation, administration and implementation of the regulation. Understand the reasons why these gaps exist? What are the roles of the actors in filling / not filling these gaps? To what extent is the gap because of omission (not doing what they are supposed to do, because they do not have the knowledge, skills and power)	**To your best knowledge, are you aware of external interventions exerting an influence on how the regulation has been designed and/or is administered?** **Who does this regulation advantage and who is prejudiced?**	**General press on who is winning and losing with a regulation**		**Regulation administrators / inspectors and designers** **Member of consumer association**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/ or FGD and Respondents
RQ 2 – Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?						
		or wilful commission (actively weakening the regulation). Is there a regulatory mechanism for the regulators? Who are they accountable to?				
How are these actors involved in the various processes and to what extent?		Identification and role of invisible actors: How important is the (commercial) market for prenatal diagnosis, for sex selection, etc.? In what order are the sizes of volumes of equipment sold?	**Could you provide information on the evolution of the equipment market for prenatal diagnostics? Does the regulation on antenatal diagnosis have an impact on this business and if yes, how?** **The sex ratio in this province X is negative for women. What is the running cost for antenatal sex diagnosis and a selective abortion. Where, in which geographical area, does it happen more often? How does the average cost compare to a family's income?**	**General press on who is winning and losing with a regulation**		**CEO of major medical equipment distribution company** **Member of professional associations** **Inspector in charge of regulation administration**

RQ 3 – What are the effects of regulation on equitable access to quality maternal health care?
Criteria to assess the effects of a regulation – see Section 3.3.

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/FGD/etc. + Respondents
RQ3 – What are the effects of regulation on equitable access to quality maternal health care?						
I What is the current status of and obstacles to equitable access to quality maternal health care?	*Partially done*	Coverage in terms of EmOC (institutional deliveries, SBA, C-section rates, etc.) / ANC (ANC3, TT2, etc.) / Abortion (abortion services, frequency teenage pregnancy, mortality due to unsafe abortion, etc.). Quantification of EmOC outputs and achievements in selected populations and countrywide: Coverage in terms of access to EmOC services?	**What are the time trends for EmOC/ANC/GR indicators across the last decade?** **What are the MMR trends by province comparing before and after a regulation?** **How is the geographical distribution for EmOC/ANC/Abortion indicators across the country provinces / states?** **In each of these indicators, explore for equity (rich/poor, illiterate/literate, urban/rural, others).**	**X**	**Strata - specific epidemiological data**	
	Not yet done	Prohibition of sex selection (interesting inter-countries comparison): Description of sex ratio distribution across country (for smallest available administrative units): How has the province-specific sex ratio evolved across the last decade? Which are the	**Please provide a table with 4 rows (e.g. provinces, 2000, 2005, 2009) and one row per State/Province/District.**	**X**	**X**	

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/FGD/etc. + Respondents
RQ3 – What are the effects of regulation on equitable access to quality maternal health care?						
		other factors that have affected this sex ratio locally (e.g. migrations)?				
		Description of obstacles met by users belonging to target population when looking for care: Comparison of obstacles in selected, contrasted populations (see examples above) Examples of possible obstacles to be explored with users: geographical access, opening hours, waiting lists or -/time, costs compared to daily income, language barriers or attitude of care providers, prescribed drugs not available or linked to authorisation of care delivery by insurance. Sampling should carefully distinguish users of high vs. low level hospitals, floating vs. residents, rural vs. urban, northern vs. southern Karnataka, poor vs. rich Vietnamese provinces.	**In which health structure did your delivery take place? How much did you pay for it (total cost, direct and indirect)?** **What are the different obstacles met by pregnant women when delivering in a health service?** **Are you aware of the existence of others in accessing general health care?**	**X**		**Users- women having recently (<2 weeks) delivered or their proxy.** *Ethical advice is that SSI should not be less than 3 months after delivery.*
		Implementation of GR regulation: frequency of formal GR procedures in the geographical entities studied in the three countries. Description of the nature of informal GR procedures.	**How is the geographical distribution for access to GR mechanisms across the country provinces/states/districts?** **Compare the province/district - specific number of yearly**	**X**	**X**	**Regulation administrators and implementers (to triangulate)** **Hospital or health service**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/FGD/etc. + Respondents
RQ3 – What are the effects of regulation on equitable access to quality maternal health care?						
			formal GR procedures 1) to its population size and 2) to its institutional delivery rate. Establish chronological trend. **What are the most striking differences in the common procedures used to redress grievances in your hospital? How could they be improved?**			**manager (both public and private)**
		Describe the financial obstacles to legal and illegal abortions, the related bio-psychosocial suffering and long term consequences. Sampling should be done through identification by civil society organisations.	**How much did you pay in total for a (legal vs. illegal) abortion?**			**Women-users who have aborted (legally and illegally) or their proxy.** *Ethical advice is that SSI should not be less than 3 months after delivery.*
		Description of quality of care met by users belonging to target population: Comparison of perceived quality in selected, contrasted populations. Sampling should carefully distinguish users of high vs. low level hospitals, floating vs. residents, rural vs. urban, poor vs. rich.	**In which health structure did your delivery take place? Can you describe what happened? How was your communication with health staff? Were you satisfied with the care given?** **What are the differences in care provided during institutional**			**Users- women having recently (<2 weeks) delivered or their proxy.** **Ethical advice is that users women after**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/FGD/etc. + Respondents
RQ3 – What are the effects of regulation on equitable access to quality maternal health care?						
			delivery? What prevents women from accessing quality EmOC, ANC and abortion services?			**delivery cannot be interviewed less than 3 months later.**
		(Theoretical) Evidence to suggest that the regulation has actually increased access and quality of maternal health services. How is reality? Evidence of any other effects.	**In your opinion, how does the regulation remove or reduce the above obstacles?** **Who is monitoring for side effects? How? What action do they take if they discover unexpected effects? Is there a mechanism for acting on such feedback?**	**X**		**Medical providers** **Regulation administrators**
To what extent are these obstacles addressed in existing regulations?		Describe the undesirable synergetic effects of two regulations. Here is an example for India.	**When deciding a legal abortion, do you fear being sued under the sex selection act? Are you aware of some colleagues having had this problem?**			**Gynaecologist (public and private)**
		Use of GR output to constantly improve health care organisation.	**Could you describe a case whereby a GR procedure has led to modifying maternal health care delivery and/or management?**			**Health care manager** **Women-users**
What are the effects of regulation on equitable access			**What in your view is/are the effect(s) of this regulation on this case study or problem / achievement more generally?**			**Regulated staff,** **Regulation administrators**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				DR	2* data	SSI/FGD/etc. + Respondents
RQ3 – What are the effects of regulation on equitable access to quality maternal health care?						
to and quality of maternal health care?			**What in your opinion are the main effects / results of this regulation more widely?**			**Women - users**
			Are there any unintended effects of this regulation i.e. those not explicit in the objectives?			**Regulated staff, Regulation administrators**
		Environmental factors that affect the production of effects. Prompts: examples of facilitators and obstacles, additional resources, increased political will, availability of a cooperation project, changes in key staff, cultural changes, etc.	**What are the facilitators and obstacles affecting the achievement of objectives of this regulation?**			

RQ 4 – What are the differences or similarities between regulation of maternal health care and health care in general?
In a number of the information needs and examples for questions for the above research questions, an additional question may be asked "Contrast your answer with regulations applicable to general health care?".

Research Questions	**Status of information**	**Information needs in Phase Two**	**Examples for questions in Phase Two**	**Sources of information**		
				Doc. Rev.	**2nd data**	**SSI FGD and respondents**
RQ 4 – What are the differences or similarities between regulation of maternal health care and health care in general?						
What are the differences or similarities between regulatory approaches, processes, actors and effects?	*Not yet done*	What are the predominant approaches of regulation in general health care compared to maternal health care? Are there any differences in the administration of the regulations vis-à-vis general health care? Who are broadly the actors involved in regulation of general health care? Are they different from those involved with the regulation of maternal health care? How effective is the regulation for general health services in terms of equitable access to quality health care? See criteria above (categories of obstacles to access to care)	**Are health care effectiveness, quality and cost any different when treating a pregnancy related vs. a non-pregnancy related health problem in a woman? Does it make any difference whether she is pregnant or not?** **Are some patient users of public services enjoying better health care than others?**			**Health professionals**
If there are differences, why is it so?		Any explanation about the reasons for this difference? If so, why? Prompts: Maternal health programs financed by international aid? Political concern of governments?				**Health service managers and professionals**

Research Questions	Status of information	Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
				Doc. Rev.	2nd data	SSI FGD and respondents
RQ 4 – What are the differences or similarities between regulation of maternal health care and health care in general?						
What are the implications of HESVIC findings for equitable access to quality health care in general?		What (if any) are the lessons that we can learn from regulation of the general health care services? Are these lessons applicable for maternal health care services? If yes, how?				

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

Research Questions Information needs in Phase Two	Examples for questions in Phase Two	Sources of information		
		Doc Rev	2nd data	SSI FGD and respondents
RQ 5 – How could regulation be improved to enhance equitable access to quality maternal health care?				
What are the main problems in the existing regulation? How can each of these be solved / reduced?	Summary of the above findings. Right from formulation, to administration, to implementation, to effects. What can be done for each of these gaps?	X		X

ANNEX 1 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. We will conduct interviews with key people, like you, who work as policy makers, designers of regulation, implementers of regulation or health services managers, as well as with users of maternal health services. The topic of these interviews will be the quality of maternal health care in your region/country and/or the regulation in this field.

One of our collaborators will plan one interview with you, which will last about no more than 60 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 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 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, 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,

(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 been told a female friend could accompany me during the interview.
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.

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 suit 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 centres 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.

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 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,

(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 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 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! (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 2 Findings and lessons learned from Phase One concerning RQ1 - 3

	Vietnam	India	China
Research Question 1			
EmOC CASE STUDY	**Decision 385/2001: technical assignment among levels in the health system.** - Regulation selected without prior knowledge of equitable access to quality health care –here rather well justified – but not baseline available to MOH to evaluate the regulation - Regulation issued in 2001 and later amended. - Regulation intends to tackle a justified problem/achievement: lack of clear EmOC procedures - Regulation not entirely related to quality maternal health care. - Three stages of regulation process studied, including amendment. - Regulation lacks clear mechanisms and procedures for administration. - State control and co-institutional	**2005 Indian Public Health Standards Related regulations identified** - Issued in 2005, revised in 2010. - Selected regulation only applicable to a minority of service users, those using the public health sector. - Regulation intends to tackle a justified problem/achievement concerning high MMR in Karnataka and the lack of clear EmOC procedures. - Three stages of regulation process documented. - Regulation content does not foresee control or punitive action. - Generally good description of regulation process, somehow less on approaches.	**2008 Notice of issuing the work principle of consultation, referral and treatment process for EmOC in Shanghai.** **Continuum of regulation identified.** - Regulation intends to tackle the justified problem of increased demand for deliveries by increasing number of migrants and the higher MMR in migrants, due to impractical consultation and referral system. - Regulation intends to improve the treatment of Critically Ill Pregnant Women, protect maternal and child health and maintain social and family harmony. - Puts emphasis on first contact care system, on principles of timely referral and defines responsibilities. - Regulation related to quality maternal health care. - Generally good description of regulation process, somehow less

	Vietnam	India	China
	approach to regulation. - Generally good description of regulation process, somehow less on approaches.		on approaches.
ANC CASE STUDY	**Decree 104/2003/ND-CP: guidance for implementing the Population Ordinance (Art. 10 related to prohibition of sex selection procedures.** - Regulation selected without prior knowledge on distribution of sex ratio at birth across provinces (to be checked) - Limited availability of primary and secondary data prior to design the regulation you mean?. - Regulation does not intend to tackle broad problem/achievement of population growth, only sex selection – which is a justified problem. - Regulation related to quality maternal health care. - Three stages of regulation process studied, no amendment. - Regulation lacks clear procedures	-	**2002 Administrative Regulation of Prenatal Diagnosis Technology and related accessories** - The issue of comparative study of PND regulation and genetic diagnosis regulation has been selected and not. PND as sex selection. - Regulation intends to protect child health and to ensure effectiveness of PND by regulating supervision and management of PND services. Thinking it twice, it may be a problem since we are talking about child health and not maternal health… - Regulation uses mechanisms and procedures to licence PND institutions but does not regulate its clinical use. - Generally good description of regulation process, somehow less

	Vietnam	India	China
	and mechanisms for administration. - State control approach to regulation. - Generally good description of regulation process, somehow less on approaches.		on approaches.
ABORTION CASE STUDY		**1971 Medical Termination of Pregnancy Act** **Related regulations identified : Pre Conception & Prenatal Diagnostic Test Act** - Regulation intends to tackle a justified problem/achievement of existing barriers to access to abortion services. - Its main objective is legalizing abortion, defining the legal indications, stating who can do it, where, etc. - Regulation issued in 1971; amended in 2001 and 2003.. - Generally good description of regulation process, somehow less on approaches. - Regulation uses mechanisms and procedures for a one time governmental licence to abortion services, periodic inspections of	

	Vietnam	India	China
		standards. - Regulation does not foresee monitoring.	
GR CASE STUDY	**Decision 44/2005: regulation on solving complaints.** - Regulation selected without prior knowledge on complaints related to equitable access to quality health care – here rather well justified. - Limited availability of primary and secondary data with regard to the use of the regulation?. - Regulation related to quality maternal health care. - Three stages of regulation process studied, no amendment. - Regulation has clear mechanisms and procedures for administration. - State control approach to regulation. - Generally good description of regulation process, somehow less on approaches.	**1986 Consumer's Protection Act Related regulations identified: Grievance cell** - Regulation issued in 1986, in 1996 amended to include medical services. - Regulation not related to quality maternal health care. - Regulation intends to protect the consumer. - Three stages of regulation studied. - Regulation uses mechanisms and procedures that define rights and responsibilities, involve consumer courts at different levels and by simplifying standards. - Mechanism of control through court, including medical officers when a health complaint is filed. Appeal is possible.	**2009 Measures of Management to Patients Complaints in hospital (on trial).** **Continuum of regulation identified.** - Regulation intends to tackle the justified problem of increased tension and disputes between medical services and patients and of the lack of legal basis in hospital complaint management. - Regulation intends to improve management of patients' complaints in hospitals and to protect the rights of patients and providers. - Three stages of regulation process studied. - Main mechanisms and procedures through enhancing timely communication system, setting up office and staff and clarifying responsibilities at different levels. - Alternative patient complaint

	Vietnam	India	China
			systems do exist, with strong Chinese characteristics: “letters and call to administration” and people petition system – need to take them into account. - Regulation concentrating on general health services, limited relevance for maternal health care. - Consumer-oriented approach to regulation. - Generally good description of regulation process, somehow less on approaches.
Research Question 2			
EmOC CASE STUDY	- Insufficient understanding for correct sampling frame locally: quid provinces? - Important role played by government agencies. - Several actors are missing. - Data collection possible, on public and somehow private sector. - Several health staff are unaware of	- Overview of key actors and their relationships - Several health staff are unaware of the existing regulation. - Several actors are confused the regulation with it being issued by the National Rural Health Mission. - Private actors not included. - Several actors are missing.	- Overview of key actors and their relationships. - Selection of service users mainly done from hospital files. - Several actors are missing. - Difficulties in obtaining data from direct service users. - Triangulation of information from patients, their relatives and hospital

	Vietnam	India	China
	the existing regulation.		is needed. - hospital's arrangements. - Alternative user sampling through community based postnatal care schemes. - Several health staff are unaware of the existing regulation.
ANC CASE STUDY	- Insufficient understanding for correct sampling frame locally: quid provinces? - Difficulties adapting tools to actors, because of confusion on key concepts. - Difficulties accessing private sector - Data collection missing mainly in private sector. - Important role played by government agencies. - Several actors are missing. - Several health staff are unaware of the existing regulation.		- Some overview of key actors and their relationships - Several actors are missing. - Several health staff are unaware of the existing regulation.

	Vietnam	India	China
ABORTION CASE STUDY		- Overview of key actors and their relationships - Several health staff are unaware of the existing regulation. - Several staff are confused because also the PC-PNDT Act. regulates aspects of abortion in a contradictory way. - Poor service users still use informal abortion services because of barriers. - Several actors are missing.	
GR CASE STUDY	- Insufficient understanding for correct sampling frame locally: quid provinces? - Difficulties accessing private sector - Missing data collection mainly in private sector. - Important role played by government agencies. - Several actors are missing. - Several health staff are unaware of the existing regulation.	- Regulation definition mainly initiated by consumer activist groups. - Several health staff are unaware of the existing regulation. - Medical officers take part in the consumer courts when a medical complaint is filed. - Medical professionals are unwilling to testify against each other. - Several actors are missing.	- Limited response from regulation designers and administrators - Several health staff are unaware of the existing regulation. - Several actors are missing.

	Vietnam	India	China
Research Question 3			
EmOC CASE STUDY	- Partial indication of effect on equitable access to quality care. Not sure: it seems that there are solid differences amongst provinces according to whether an international cooperation is operating or not. - No information on institutional delivery and skilled birth attendance rates, c-section rates, etc. the same for the three countries; - Lack of key data for evaluation should be mentioned in this otherwise excellent summary - Therefore, users become key to assess access to quality maternal health care -	- First time that uniform standards were issued.. - Number of FRUs increased. - Marginal increase of skilled staff. - No information on institutional delivery and skilled birth attendance rates, c-section rates, etc. the same for the three countries; - Lack of key data for evaluation should be mentioned in this otherwise excellent summary - Therefore, users become key to assess access to quality maternal health care	- Service users regarded as most important source of information for assessing effect, but because of sampling users, triangulation is important for evaluating effects in terms of equity, accessibility and quality (see above). - Risk for selection bias from hospital arranged sampling methods for service users. - Consultation, referral and rescue principles clearly described - Network for EmOC services established and 5 new EmOC centres built - Capacity of obstetric first aid in primary institutions improved by forming teams. - No denominators for inputs - More smooth consultation and referral coordination. - Better coordination between departments in health services. - Rate of successful rescue of CIPW

	Vietnam	India	China
			improved.
ANC CASE STUDY	Insufficient knowledge on effect on sex selection. Additional data were promised.		- Significant development of PND institutions and their engagement of personnel - Irrational prenatal screening without necessary follow up still exists - Little change in targeted diseases by PND - No significant breakthrough in technology - No information on institutional delivery and skilled birth attendance rates, c-section rates, etc. the same for the three countries; - Lack of key data for evaluation should be mentioned in this otherwise excellent summary
ABORTION CASE STUDY		- Access to quality abortion services has increased, but without equity. - A lot of confusion throughout the regulation process, affecting its potential effect. - Lack of qualitative and quantitative	

	Vietnam	India	China
		data to assess access	
GR CASE STUDY	Insufficient knowledge on effect on equitable access to quality care	- Positive effect confirmed on patient protection. - Patient's voice is heard. - Medical complaints mainly filed by the better off. - Consumer courts tend to favour the medical profession. - Induced medical doctors being more careful - Induced defensive medicine and unnecessary referrals	- Improved complaints management effectiveness. - Regulation is equal and accessible to all people. - Open and transparent administration. - Lack of subsequent assessment and improvement measures. - Unfair to service users that complaints are managed by hospitals or health administration agencies.

ANNEX 3 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 information needs matrix in Section 7). 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:
  1. 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,
  2. Whether or not any contribution schemes as defined in the regulation are related to income and wealth rather than to health status,
  3. Clarify social vs. economic objectives: economic objectives relevant from an economical viewpoint, such as reality of competition, anti-competitive behaviours being limited,
  4. 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.),

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

ANNEX 4 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)..
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 Section 7 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,
- 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, 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.

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