HESVIC project

Maternal health regulations in Vietnam, India and China

A comparison across case studies and countries
Deliverable 5.1

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Disclaimer	This report has been prepared by ITM as the team responsible for the comparative analysis work package. Its process has involved all members of the consortium through inviting comments on two drafts. However, given the complexity of the topic and different academic traditions, there remain some elements of the report where there are different judgements between partners as to the analytical conclusions reached. As such the final deliverable report is solely authored by the ITM team.
HESVIC	HESVIC is a three-year research project (2009-12) being implemented under the European Community Seventh Framework Programme (FP7). The project aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice through a comparative study of three Asian countries – Vietnam, India and China. The project uses maternal health care services as a case study of stewardship and regulation. The goal is to support policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage of healthcare in the three countries. **HESVIC partner organisations** • Nuffield Centre for International Health and Development, Leeds Institute of Health Sciences, University of Leeds, UK • Hanoi School of Public Health, Vietnam • School of Public Health, Fudan University, China • Institute of Public Health, Bangalore, India • Department of Public Health, Institute of Tropical Medicine, Belgium • Social Development and Gender Equity, Royal Tropical Institute (KIT), Netherlands
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Table of contents

Caveat: We have deliberately repeated some information in certain sections for the sake of their self-containment.

0. List of abbreviations

AAP-I	Abortion Assessment Project – India
ANC	Antenatal care
ANM	Auxiliary Nurse Midwife
BOH	Bureau of Health
CCP	Chinese Communist Party
CD	Capacity Development
CEHAT	Centre for Enquiry into Health and Allied Themes
CHC	Community Health Centre
CIPW	Critically Ill Pregnant Women
CPA	Consumer Protection Act
C-section	Caesarean Section
EBM	Evidence Based Medicine
DHO	District Health Office
EC	European Commission
EmOC	Emergency Obstetric Care
FGD	Focus Group Discussion
FRU	First Referral Units
GATS	General Agreement on Trade in Services
GOI	Government of India
GOPFP	General Office of Population and Family Planning
GR	Grievance Redressal
HEPVIC	Health Policy making in Vietnam, India and China
HESVIC	Health system stewardship and regulation in Vietnam, India and China
HIC	High Income Countries
HIV	Human Immunodeficiency Virus
HRH	Human resources for health
HSPH	Hanoi School of Public Health
INR	Indian Rupee
IPHS	Indian Public Health Standards
ITM	Institute of Tropical Medicine
KIT	Royal Tropical Institute
KM	Knowledge Management
KPMEA	Karnataka Private Medical Establishment Act
LMIC	Low and Middle Income Countries
MAPCH	Measures for the Administration of Patient Complaints in Hospitals
MCH	Maternal and Child Health
MDG	Millennium Development Goals
MIC	Middle Income Countries
MMR	Maternal Mortality Ratio
MO	Medical Officer
MOH	Ministry of Health
MPW	Migrant Pregnant Women
MTP	Medical Termination of Pregnancy
NCIHD	Nuffield Centre for Health and Development
NGO	Non-Governmental Organizations
NRHM	National Rural Health Mission
OBG	Obstetrics and Gynaecology
PCPNDT	Pre-Conception and Pre-Natal Diagnostic Techniques (Regulation and

	Prevention of Misuse) Act (2003)
PNDT	Pre-natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act (1994)
PHC	Primary Health Centre
RCH	Reproductive and Child Health
RHC	Reproductive health care
SRB	Sex ratio at birth
UN	United Nations
UNFPA	United Nations Population Fund
UPA	United Progressive Alliance
USAID	United States Agency for International Development
VND	Viet Nam Dong
WB	World Bank
WHO	World Health Organisation
WP	Work Package

Acronyms used to identify the studied regulations	**Vietnam**	**India**	**China**	**Intercountry comparisons / generalisations**
EmOC	EmOC-V	EmOC-I	EmOC-C	EmOC-INT
Sex selective Abortion	SSA-V			
Abortion		AB-I		
Prenatal diagnosis			PND-C	
Grievance redress	GR-V	GR-I	GR-C	GR-INT

1. Introduction

The HESVIC project aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice. It aims to do so by developing an integrated approach to improved stewardship and regulation in health services in Vietnam, India and China.

1.1. Project objectives and methodology

The HESVIC project used maternal health as a case for the study of governance and regulation of the health system. The research approached regulation through selected case studies: emergency obstetric care, antenatal care, abortion and grievance redress. It assesses effects, if any, of regulation on equitable access to quality care[a] within and across the three study countries; identifies gaps; studies determinants and suggests ways forward for achieving regulatory objectives, possibly with non-regulatory policies.

The study outputs include policy recommendations for national standards and recommendations for actors (such as policy makers, health managers, regulation administrators and members of professional and users' associations). The project hopes thereby to contribute to improved health policy decisions related to the provision and financing of equitable maternal health services in Vietnam, India, China and beyond.

Other outputs/products of HESVIC observations are hypotheses for future studies regarding the impact of regulations on access to and quality of care in public and private health facilities and regarding the place of regulations in health policies.

This research aims to investigate regulation as it relates to governance, health systems policy and care delivery. The research consortium defined governance of health systems[1] as the way in which decisions are made and implemented in both local or national health systems. It used the concept of "regulation" often implicitly as the activities encouraging compliance in the health (care) sector.

We conducted this investigation by developing an integrated methodological approach in the area of maternal health in Vietnam, India and China.

While writing the present comparison document, we bore in mind the need to:

1. Examine the application of international standards in governance and regulation of maternal health activities – to the extent that such standards exist;

[a] With "equitable access to care" as a yardstick of regulatory effectiveness, we postulate that health care regulation should aim at equitable access to good quality (e.g. individual, discretional) curative and preventive health care. Such a formulation enlarges the benefit of regulations beyond "the poor" whatever the meaning of this concept: the entire population equally deserves access to good quality health care.

2. Compare the regulatory requirements of private and public services (see definitions in section 3.1.1) involved in maternal health in the three study countries;

3. Outline national standards for governance and regulation of maternal health activities in the three study countries;

4. Explore the effects of governance and regulation of maternal healthcare, services and systems on equitable access to quality maternal healthcare, within and across each study country;

5. Disseminate the results and recommendations widely to the government and other key health sector stakeholders in the three study countries and to the professional/scientific community.

Key steps in the project research were as outlined below.

a. A literature review identified the state of the art in maternal health governance and regulation;

b. We analysed the maternal health problems that were the object of a studied regulation and its rationale for tackling it in the three study countries;

c. We identified current regulatory approaches, processes, actors and effects of regulation in the three study countries through selected case studies

d. We performed a comparison of findings across case studies and study countries;

e. We formulated recommendations on the role of regulation in health policy in the three countries.

The last two steps are the object of the present comparative deliverable.

The HESVIC research process has been cyclic, to enable exploration and validation, allowing us to add complementary information, depending on initial findings. For the reader interested in the details of the study methodology, please read the HESVIC work package deliverables D.1.1, D.1.2.a and D.1.2.b. The key methodological features will be reiterated in section 2.2, in which they will be articulated with the methodology of the present inter-country comparison (section 2.3).

1.2. Objectives of the comparative analysis deliverable (WP5)

The HESVIC Project Technical Annexure conceptualises this deliverable as a comparative report[2], summarising the evaluation of (stewardship and) regulation, its problems and facilitating factors in Vietnam, India and China, its composite determinants and relationships (as presented in the three country research reports).

This report will also propose recommendations for improving the quality of regulation in relation to maternal health services and beyond. Finally, it is also anticipated that the report will provide the basis for the development of specially tailored materials, such as policy guides and the like, for national and international health policy-makers on improving the quality of stewardship and regulation in study countries and beyond.

Consequently, in writing this deliverable special emphasis was given to:

1. A comparative assessment of regulation effects, problems and facilitating factors in Vietnam, India and China;

2. A comparative analysis of the health, social, economic and political determinants of regulation content, definition, administration and implementation, as well as the inter-relationships between them;

3. Recommendations for improving effectiveness of regulation and governance of maternal health and wider services;

4. Provision of a basis for the development of policy guides, briefs and other knowledge products tailored to the three countries and beyond.

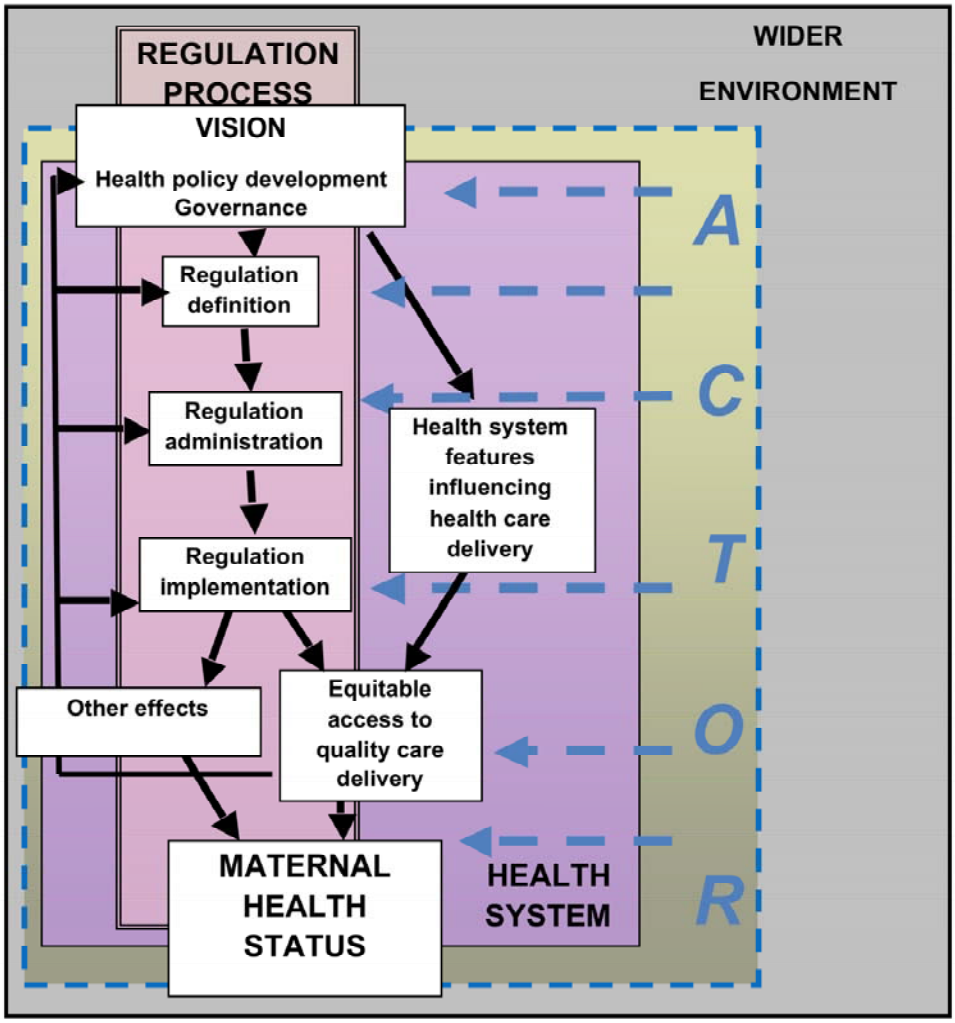
2. Methodology

This section articulates the methodological features of the HESVIC study and those of the present comparison.

2.1. Overall project research conceptual framework

As a reminder, this section presents selected elements of the HESVIC project work package 1[3,4]. The framework displayed in Figure 1 was used as a guide for structuring the country research reports. It had also been constructed to enable the present inter-country comparison, presented in sections 2.2. – 2.4. Figure 1 shows that the regulation process is seen as beginning with the development of a (health) policy, possibly impacting on maternal health through regulation of healthcare delivery.

Figure 1: Summary of the HESVIC research conceptual framework[5].



The project methodology therefore comprised four key tasks:

a. Exploration of the regulation effects on “equitable access to quality healthcare delivery”, as well as any other desirable/undesirable effects;

b. Analysis of how the regulation processes (from definition and administration to implementation, including monitoring and evaluation) might explain the features of the regulation effects. In this regard, we paid special attention to ‘critical events’ (relatively rare incidents revealing some systemic or systematic error);

c. Exploration of the relevant actors’ roles for their ability to explain issues with regulatory processes;

d. Analysis of the environmental features (of transition economy countries, for instance) determining the behaviour of the above actors.

As a reminder, let’s recall that the project (purposive) sample (see deliverable D.1.2.b, section 5.2.2.1) envisaged 60 interviews per country. Sampling was defined in terms of respondents’ roles in regulatory contexts. In reality, the project research teams carried many more interviews.

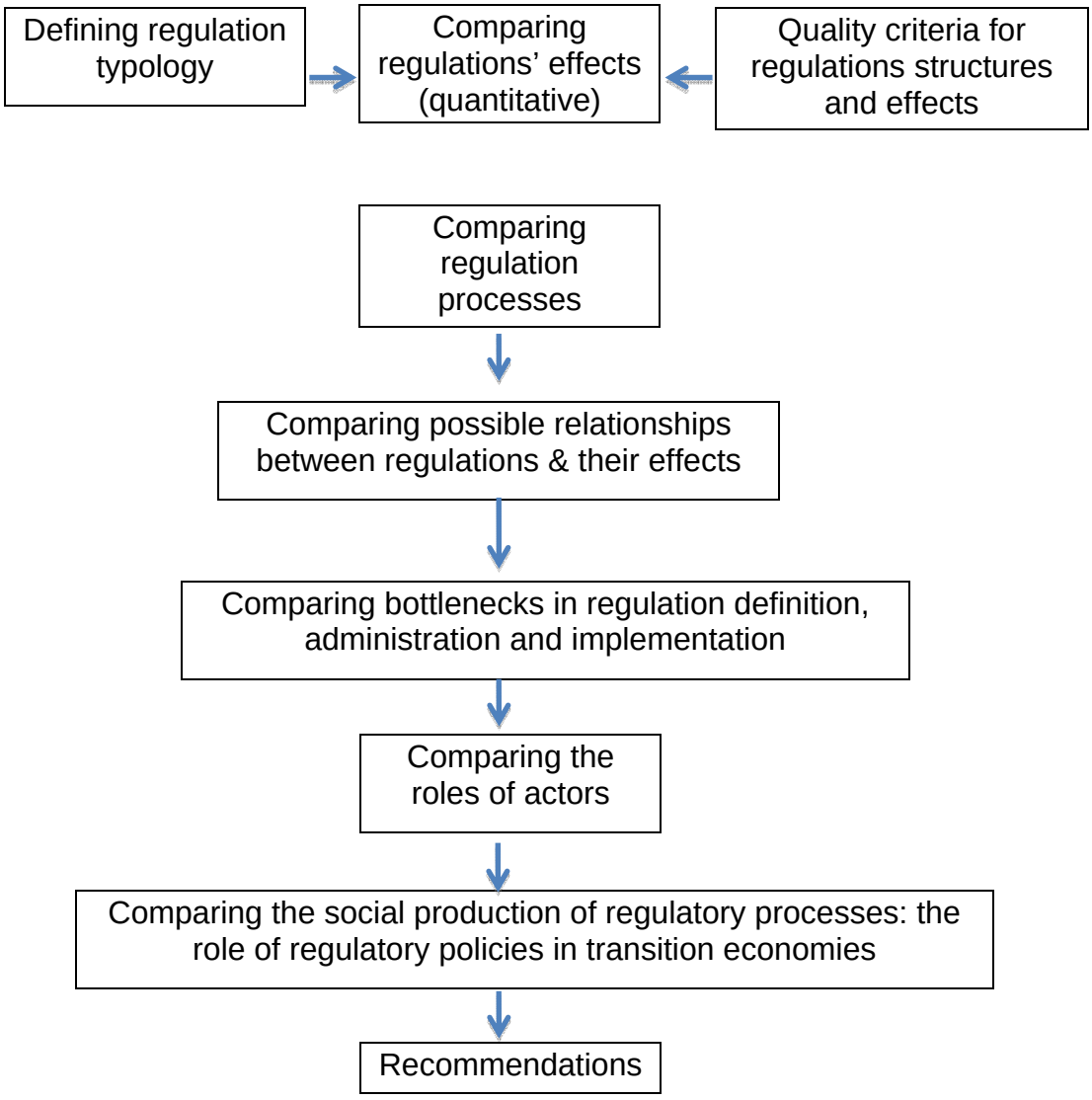
The units of comparative analysis for this deliverable are the research countries as well as the case studies, or groups of case studies, to the extent that comparing case studies contributes to the project objectives and in particular to the inter-country comparison.

2.2. Methodology of the inter-country comparison

We aimed to produce information that will guide decision-making in health policy and management in a stepwise process, focusing on mechanisms and relationships between study findings with respect to events in regulation chains, both within the three countries and through comparison between them.

Figure 2 presents the steps used in this comparative analysis of countries and case studies.

Figure 2: Steps used when comparing relationships between regulation findings across case studies and countries



Below follows an elaboration of these steps, used to compare the social production of regulations in (maternal) health in the three countries and thereby to formulate policy orientations:

1. To quantitatively compare the level of regulation effects indicators (cfr. HESVIC research question 3), we:

    a. Classified the regulations studied according to a typology that would at a later stage circumscribe the validity domain of our results and recommendations. This typology is provided in section 3.1.1;

    b. Applied HESVIC regulation assessment criteria to the regulations studied.

We designed our own set of ad hoc assessment criteria for regulation structures and administration (see annex 1). Because we could not find one in the literature that aimed at being detailed and practical, we also adapted governance criteria proposed by Siddiqi et al[6]. These criteria were already defined in the HESVIC deliverables D.1.2.a and D.1.2.b. In the present document, they are primarily used in the sections 5 and 6.

We classified the regulatory effects in three categories: those desired and achieved, those desired but not achieved, and undesirable effects.

We assessed quality of healthcare in terms of the growing international consensus that views care quality as including safety, effectiveness, patient-centeredness and timeliness through seamless service coordination, efficiency and equity[7-11]. We used these criteria but added others, including:

- Care accessibility, affordability, effectiveness, continuity and integration;

- Care delivery should also aim to balance effectiveness and efficiency, as well as undue medical treatment of health problems ('medicalization' of complaints) and autonomy of the patient;

- Dangerous clinical behaviour ('primum non nocere' is implicit in the above mentioned safety domain), useless care and care that leads to demographic unbalance (e.g. sex selective abortions) should be averted.

In this report, we identified '*prohibitive regulations'* as those regulations aimed at forbidding reprehensible clinical behaviours (such as sex selective abortion). We considered as a quality criterion that they should not only be repressive but should also tackle the environmental features primarily responsible for fostering reprehensible clinical behaviour e.g. irrational demand[b] created by clinicians and psychosocial / socioeconomic population features.

[b] Irrational demand: a demand for health care voiced by a patient that is not substantiated by a health need, that is, defined by health professionals.

In theory, all these criteria should be applied equally to public and private health facilities with a social, non-commercial rationale[7]. In practice, however, regulation design and administration should take into account the sector specific problems to be solved in applying these criteria. To visualise the specificity of these problems, consider the following differences between public and private health services (see also section 7.2.1):

- Unlike private for-profit health services, publicly oriented ones can host community participation, conceived as co-management of health facilities, and can accommodate negotiations between health professionals, health workers, users' associations, community associations, managers and owners;

- By law, private companies in some countries are obliged to maximize the investors' return, which can run against an appropriate balance of the care quality mentioned above.

As an important equity criterion, we compared regulation effects across social groups and across country regions, when possible.

2. We determined the effects across the regulations under study and identified commonalities, systematic differences and exceptions amongst these effects (cfr. HESVIC research question 3). In so doing, we summarized the key findings of each case study and presented them in terms of themes, organized into sub-sections.

3. Straightforward comparison of effects could not be conducted because of limited comparability of regulation objectives (for example, EmOC-V addressed services' tier-specific standards, while EmOC-C addressed a strategy to reduce mortality amongst critically ill pregnant women) or because of lack of available data (no quantitative data were available on utilization of GR-C).

Instead, to contrast effects, we had to compare the mechanisms whereby regulation design and implementation explained these effects (cfr. HESVIC research question 1). We made this comparison across the case studies, using sub-groups of regulations, and also assessing any possible weaknesses in their design. For the sake of being reader friendly, we presented these data in comparative tables.

4. To establish the nature of the relationship between the effects of a regulation and its design and administration, we bore in mind the assessment criteria defined in section 3.3 of D.1.2.b. We further assessed resources made available for achieving regulatory objectives using both quantitative proxies, when available, and findings from research reports with semi-quantitative insights when not; and we assessed feedback loops used as a learning system to improve regulations' effectiveness.

We compared these effects and mechanisms across the 3 countries and case studies, paying special attention to whether they were tailored to regulation and control of public and/or private sectors or addressed them equally, and to the blurred boundaries between these sectors.

5. Using the findings of the analysis of interviews presented in the country reports, we aimed to identify common or discrepant weaknesses in regulation design and implementation and analysed common / discrepant roles and interpretations of key actors (cfr. HESVIC research question 2) in explaining those mechanisms that constrained or enhanced regulation effects (see relationships with the project methodology in section 2.3).

6. We aimed to generalize these observations to well defined domains of validity so as to produce a theory of social production of the health sector regulation in LMIC[c], with implications that extend beyond the health functions of the studied regulations. To this extent, we aimed to understand:

    - the social mechanisms that made these regulations necessary and shaped the form that they took, e.g. factors acting upon regulation designers, administrators and health professionals;

    - expected non-health effects.

7. To this end, we explored the relationships between actors and processes on the one hand and the social, political, economic and cultural development of these rapidly evolving transitional countries on the other.

8. We explored these relationships in the context of inter-country comparisons of country-specific findings, and included the use of inter-case study comparisons in our examination of the material (see abbreviations list for their abbreviated names).

9. We aimed to generalize recommendations within defined domains of validity (cfr. HESVIC research question 5). To this end, we took into account any relevant information from secondary data and especially from international scientific literature.

10. Finally, we contrasted the relationships prevalent in the maternal health sector with those in general healthcare delivery (cfr. HESVIC research question 4).

With regard to chronology, the comparative analysis developed the time line below.

[c] We consider Vietnam, India and China as belonging to the LMIC and not MIC countries group as several states, regions, provinces totaling tens of millions of people remain below 1000 USD per capita.

1. From February 20 to March 23 2012 we conducted a preliminary comparative analysis of the case study-specific and country level findings from WPs 2, 3 and 4[8-10]. This resulted in comments distributed to the Vietnamese, Indian and Chinese research teams. These comments were adapted and incorporated into the next version of the countries' research reports.

2. During the second stage, from March 26 to 30, 2012, we presented and discussed findings from country reports - initial comparative results and comparison of methodological issues - at a project-level meeting in Shanghai. On the basis of this meeting, we produced a basic structure and matrix for the Phase Three inter-country comparative analysis.

3. During the third stage, between April 16 and July 6 2012, the ITM team wrote the comparative analysis report, circulated it within the Consortium for partners' comments and then revised it accordingly.

2.3. Comparing regulatory requirements and challenges of public and private sectors

There are numerous reasons to believe that regulation in health of public and private sectors raises contrasting objectives (with regard to market regulation, to non-governmental regulation, to competition) and challenges. Given the extent of the contrasts, we devoted one full section to formulation of concepts in public vs. private regulations (section 7) and to comparison of the regulatory requirements of both sectors (as they appear in sections 5 and 6 of the present document). The areas dealt with are as follows:

a. The problems to be solved in both sectors to secure equitable access to healthcare;

b. The resources and organization devoted to the regulation of public and private sectors;

c. The regulations' "software", i.e. their planned modus operandi;

d. The probable mismatch effects identified in section 4, for instance with regard to lack of basic information needed to regulate both sectors;

e. Particular difficulties raised by regulating services in which public and private sectors' borders are blurred (e.g. with dual employments, contracting out, development of open private practice in public services, commercial strategies in government facilities).

We were then able to describe the existing limits of common and specific regulations of public and private healthcare services and to assess the degree to which these are desirable. We also studied the extent to which there is a need for different regulation

criteria, designs, implementation mechanisms and administrative infrastructural features in the regulation of these sectors - i.e. whether or not the public - private dichotomy is relevant to the domain of health regulations.

2.4. The inter-country comparison as it relates to the project's conceptual framework

How does the methodology of the present inter-country comparison relate to this general project methodology?

Essentially, the methodology for the inter-country comparison reconciles two research approaches already present in the general project, namely an inductive and a deductive one, employing them together in a dynamic way.

In deductive reasoning, a conclusion is arrived at through application of a general theory to specific examples. As argued by Bourdieu[11], such a deductive approach thus builds on verifiable facts (featuring the specific examples).

In the HESVIC project framework, we use this term (ascending reasoning in Figure 1) when we use unsolved maternal health epidemiological problems to identify issues with regulation definition, administration and implementation.

Here follow two examples of deductive reasoning in the project:

- Maternal health indicators at a weak level may reveal faulty design and / or administration of the relevant regulation (together with other determinants). Beyond faulty design / administration, they expose actors acting collectively and individually to promote different agendas, resulting in ineffective regulation. Ill functioning regulations also reveal features of the socio-political and economic environment in terms of which key actors structure their actions so as to maximize particular interests. For instance, under the influence of a market environment, a general practitioner or a psychiatrist can systematically prevent his / her wealthy, psychosomatic patient from becoming self-reliant because such independence may reduce his / her consultations income[d]. Existing regulations proved unfit to amend such clinical behaviour;

- The positive effects of a regulation permit determination of the (social, economic, political) validity conditions of its use.

By contrast, inductive reasoning builds on or evaluates propositions that are abstractions of observations of individual instances of members of the same class (e.g. a regulation largely recognised as being effective or ineffective). The project methodology is inductive when we verify the assessment of a regulation based on its intended effects with other data and observations e.g. undesired effects possibly

[d] Notice that in doing so, this doctor acts in accordance with the central axiom of neo-classical economics

predicted from regulation content and administration features (descending reasoning in figure 1) and from clues in the scientific literature.

Deductive approaches offer a convenient entry point into problem analysis, due to their basis in phenomena accessible to probabilistic research and related to people's / patients' direct experiences.

Inductive reasoning follows deductive reasoning:

- To check the links in the research deductive reasoning;
- To expose other, often undesired, consequences of a particular regulation mechanism that needs to be verified.

The effect of sex selective practices in India upon the implementation of the MTP law illustrates this point. Chart 6 reveals a rebound in (probably illegal) abortions after introduction of the PNDT Act. Inductive reasoning would lead to verification of whether or not the abortion rebound observed at the end of the nineties was indeed linked to sex selective practices. This case is handled with more detail in section 4.

In our regulations comparison, deductive reasoning is one of the entry-points. Subsequent inductive reasoning in inter-country comparison enables us to formulate hypotheses on actors' adjustment to their environments.

2.5. Specific methodological challenges

Building cases with plausible conclusions required tackling several methodological challenges. This is how we addressed them:

- We needed to study the broader health context with particular attention to chronological trends in relevant indicators and dates of issuing and implementing regulations under investigation, in order to assess the significance of some of their effects.

We thus used quantitative (statistical, probabilistic) data wherever possible, preferably using United Nations estimates[12], when available, and Gapminder[13] data when time trends were needed. Trends were identified to provide an overview of the effects of regulations and, on occasion, to reveal the opinion nature of interviewees' statements and to facilitate understanding of the regulations' "raison d'être".

- Some evidence was conflicting and some data were known to be of limited reliability.

We triangulated data with other sources. In those instances in which additional sources were not available, we acknowledged these limitations and crosschecked the validity of our findings with semi-quantitative information on related processes ('indirect evidence'). We thus used a wide array of data on social, political, health and economic processes and we often referred to the relevant sections of country reports.

In this sense, the HESVIC work packages 3, 4 and 5 represented the raw material for the present comparison exercise.

- We had to attribute effects to a particular regulation.
    - We considered, in some cases, a family of regulations encompassing the one under investigation, as well as the effects of competing policies;
    - We used a wide array of evidence to validate our findings with regard to cause and effect relationships, e.g. plausibility of the mechanism identified, statistical, geographical and chronological arguments, consistency with scientific literature, etc.
- In the comparative analysis of the effects of regulations, we adopted a praxeological approach to examine the relationships between individual behaviours and the social production of these mechanisms. This approach assumes that social, political, economic and linguistic structures featuring in the prevailing social hierarchy are mirrored in structures internalized by people. These internal features represent the conditions of social structures' and hierarchies' reproducibility and can thus be accessed through discourses employed by decision makers, health professionals and administrators / managers.

3. A summary of studied regulations

In HESVIC, a total of nine regulations were studied. The features of our studied regulations are summarized in Table 1, which provides their title, the overarching policy framework or related regulations group, amendments (if any) and their guideline vs. prohibition mandate. These regulatory features are then compared and analysed across countries.

We established a typology of regulations in order to delineate a validity domain for the associated recommendations. Table 2 (section 3.1.1.) proposes such a typology and orders our studied regulations according to its criteria.

Table 9 in section 5.2.1, Table 10 in section 6.2 and Table 11 in section 6.3 respectively compare regulations' content and design; implementation features and structural problems with these features of regulations across the three countries.

Table 1: General characteristics of the studied regulations in Vietnam, India and China

		VIETNAM	INDIA	CHINA
EmOC CASE STUDY	**Central regulation**	**MoH-MCH Dept. Decision 385/2001 on technical assignments at different levels in RHC, incl. EmOC**	**Government Of India (GOI) Indian Public Health Standards 2005 to ensure that minimum standards of care are available and accessible at all levels of the rural public health system (1)**	**Shanghai Bureau of Health notice BOH (2008) N° 12 on "issuing the work principle of consultation, referral, and treatment process for emergency obstetric care in Shanghai"**
	Type of regulation	Enabling guidelines (2)	Enabling guidelines	Enabling guidelines
	Overarching policy framework	1. National RHC strategy 2001-10 2. National Strategy on RH and Population 2011-20 (draft 2010)	1. International Council of Population and Development 1994 on paradigm shift for maternal health - from family planning to reproductive and child health 2. RCH-I ((1998-2004) and RCH-II (2005-2010) programme: latter integrated into NRHM 3. UPA Government political manifesto: common minimum programme 2004 4. GOI National Rural Health Mission 2005	1. Law of the People's Republic of China on maternal and infant healthcare 2. National Plan for action on women 2001 - 2010
	Continuum of regulations	1. MOH Decision 220/1993/BYT/QT on technical responsibility in RHC was replaced with 385/2001, with changes to fit the context, the MCH network reform, the MDG 2. Decision 3519/2000/QD-BYT on instruction for diagnosis and treatment of 5 emergency obstetric complications	1. Karnataka State Programme Implementation Plan (2011 – 2012) 2. Karnataka Private Medical Establishment Act 2007: issued in 2007 but only implemented in 2009 due to high resistance from private sector representatives	1. Shanghai BOH service guideline 2004 N° 14 on designating 10 childbirth delivery service points for migrants 2004 - in 2007 to be expanded to 23 points 2. Shanghai BOH regulation 2007 N° 1 on quality requirements of obstetric care and management 2007

		VIETNAM	INDIA	CHINA
		3. National Standards & Guidelines for RHC services 2002 4. MOH Decision 23/2005 on delineation of technical levels + list of medical services, incl. RHC (incl. EmOC)	3. NRHM Mission Document 2005 4. Guidelines for utilization of untied funds	3. Shanghai notice on establishment of five municipal medical institutions as EmOC rescue centres 2007 4. Shanghai BOH notice on further strengthening of maternal healthcare and medical rescue 2010 5. Shanghai BOH notice on establishment of a near miss audit for critically ill pregnant women 2011
	Amendment	1. In 2008: an update of the technical EmOC procedures and of responsibilities in the aftermath of changes to the health system, especially at the district and commune levels 2. In 2011: to provide RHC services content from 23/2005 into 385/2001	None so far	None so far
ANC / ABORTION CASE STUDY	**Central regulation**	**Population Ordinance and Government Decree 104/2003/ND-CP on prohibition of prenatal sex determination in any form and with any method, as well as abortion on the grounds of sex selection**	**MOH- Central Family Planning Board Maternal Termination of Pregnancy Act 1971, to enable access to safe abortion services by laying down conditions concerning when, where and to whom abortion services should be given**	**MOH order on administrative regulation of prenatal diagnosis technology 2002, addressing supervision and management of PND services to be followed in the nationwide field of mother and child health**
	Type of regulation	Prohibitive regulation (3)	Mixed enabling / prohibitive regulation	Enabling guidelines
	Overarching policy framework	1. Only regulation dealing with SRB through ANC services 2. National Strategy on RH and Population 2011-20 (draft 2010) to	1. Indian Penal Code 2. Indian Code of Criminal Procedures	1. Law of the People's Republic of China on maternal and infant healthcare 1994 2. Law of the PRC on maternal and infant healthcare or 'Implementation measures'

		VIETNAM	INDIA	CHINA
		stabilize SRB to 115 by 2020 3. UN assisted review of SRB regulation 2011-16		2001
	Continuum of regulations	1. National Decree 114/2006/ND-CP on administrative sanctions for violation of population and child issues 2. MOH circular N° 3698/BYT-SKSS (2006): concrete guidance on implementing ND104 3. MOH circular N° 5476/BYT-TCDS (2008) concrete guidance on monitoring and inspection for prevention 4. MOH circular N° 3121/BYT-BMTE (2009) concrete guidance on prohibition of use of high technology	1. Pre-natal Diagnostic techniques 1994 to curb malpractice of identifying sex of a foetus and sex-selective abortion. Amended in 2003 to include pre-conception diagnostic sex-selective techniques 2. Indian Code of Medical Ethics Regulation 2002	1. Implementation notice on regulation of prenatal diagnosis technology in Shanghai 2003 2. Measures on MCH-specific techniques and human-assisted reproductive technology in Shanghai 2004 3. Measures on MCH-specific technology and service delivery in Shanghai 2008
	Amendment	A revision by the GOPFP is scheduled in the near future to overcome the absence of instructions for detection of violating behaviour.	In 2002: following the Abortion Assessment Project (2000): to simplify and decentralize registration of legal abortion services, make medical abortion available as a method and define stricter penalties for non-legal abortions	None so far in the national PND regulation
GR	**Central regulation**	**MOH instruction QD 44/2005, inspired by Law on complaints and denunciations 1998.**	**GOI 'Consumer Protection Act' to protect the rights of consumers against unfair trade, to promote their rights to be heard and to seek redress 1986.**	**MOH regulation 'Measures for the administration of patients' complaints in hospitals (MAPCH)' 2009 (on trial).**

		VIETNAM	INDIA	CHINA
	Type of regulation	Enabling guidelines.	Enabling guideline (4)	Enabling guidelines.
	Overarching policy framework	1. Constitution 1992: recognizes right to complaint regarding violations of regulations; 2. Law on complaints and denunciations 1998; amended 2004 and 2005; 3. Law on inspection 2004, amended 2010; 4. Law on complaints 2011 5. Law on denunciations 2012.	1. Indian Medical Council Act 1956: recognition of medical qualifications 2. Indian Penal Code 1860: defines criminal acts in medical service 3. Law of Torts; addresses malpractice by medical professionals	1. CCP "People-centeredness" 2003: "a decision on major issues concerning rural reform and development "approved by the Third Plenary Session of the Sixteenth Party Central Committee in 2003 2. CCP governance principle "socialist harmonious society" 2004': "important program for enhancing the governance capability of the Party" approved by the Fourth Plenary Session of the Sixteenth Party Central Committee in 2004 3. Property Law 2007 4. Tort Liability Law 2009 5. National human rights action plan 2009 – 2010
	Continuum of regulations	MOH Circular on guiding the examination, inspection and settlement of complaints and denunciations by heads of agencies 2009	1. Supreme Court ruling 1995, including medical profession under the CPA 2. Indian Code of Medical Ethics Regulation 2002 3. Right to information Act 2005	1. China State Council Regulation on the Handling of Medical Malpractice 2002 2. MOH Establishment of a Report System for Major Medical Negligence and Medical Malpractice 2002 3. Shanghai BOH Notice on Further Improving the Medical Dispute Registration System in Shanghai 2004

		VIETNAM	INDIA	CHINA
				4. MOH Report System for Medical Quality and Safety (replaces 2) 2011 5. MOH "Three Goods and One Satisfactory" for the National Health System" 2011
	Amendment	None so far	None so far	None so far

Notes for Table 1:

(1): Study focus was limited on IPHS at first referral units (FRU) and 'Taluka' hospitals only.

(2): Enabling guidelines are defined under section 3.1.1. (3): Prohibitive regulation defined under section 3.1.1.

(4): The Indian GR regulation studied is actually a Supreme Court ruling on an existing enabling regulation for consumers' protection.

Seven out of nine studied regulations are enabling guidelines. This means that they lack the legal mandate to force the targeted actors to act upon the regulation through sanctions and that they aim rather at influencing regulated behaviour through prescriptions and incentives. The two exceptions are the prohibitive regulations in the SRB case study in Vietnam and the MTP Act in India. Actually, the MTP Act in India is "mixed": enabling and prescriptive, but with a prohibitive connotation with sanctions (see section 3.1.1).

Of the three countries only China has no prohibitive regulation amongst those studied. Notice that we will deal in more detail with comparative issues regarding the design of the studied regulations in section 5.

In most cases, our studied maternal regulations are embedded in a continuum of related regulations (that we did not investigate at length), often issued by the same institution, be it the MoH (in Vietnam) or at the municipal level (in China). In India, the associated regulations were often issued by the Karnataka state.

The implementation years of GR regulations range from 1986 in India, 2005 in Vietnam to 2009 in China. Vietnam amended its EmOC regulation and is shortly planning a first evaluation of the first SBR regulation after 10 years of existence. India amended its Abortion MTP Act for the first time 40 years after implementing it. After ten years, the Chinese national PND regulation has not yet been amended. We compare these amendments in greater depth in Table 11 and under section 6.3.

Our regulations thus cover a wide range of issues across countries that encourage objectives or prescribe behaviour for providers or institutions. These are in general nested in a national policy framework, possibly encompassing several interventions to improve maternal health (see Table 1).

3.1. Regulations objectives and methods

The HESVIC case studies reveal a variety of regulation approaches and processes. To deal with this large array, we proposed a regulations taxonomy that defines groups to delineate the validity domain of comparative observations and recommendations.

3.1.1. Characteristics for a proposed typology of regulations

Leatherman and Sutherland (2007)[14] classified the objectives of regulations in healthcare as trying to improve performance and quality; to provide accountability, both for levels of performance and value for money; and to ensure that minimal acceptable standards are achieved. Consequently, they distinguished regulatory interventions as being institutional, professional or market in nature, depending on whether they concentrate on institutions providing healthcare, on providers and their competences or on market imperfections, respectively.

Another way of differentiating regulations is to define their distinct actions[15]. These actions can be directive measures, performance surveillance or assessment and compliance enforcement through advice, sanctions, penalties and rewards. When grouping these actions, regulations are often referred to as 'prohibitive (deterrent, sanctions based), 'enabling (compliance oriented, encouraging, incentive based) or as 'responsive', which implies that they define actions that tend to be responsive to a regulated organisation's culture[16]. Often one regulation content may combine several of these distinctive characteristics.

Our proposed typology includes both the first two criteria, but not the last one, because regulation responsiveness does not appear to be a feature that can easily be validated scientifically. Rather, we added others. However, before presenting them, we first clarify below the meaning of certain terms used.

a. Command-and-control: In the HESVIC study "command and control" was defined as one of the possible approaches to regulation, implicitly based on the use of sanctions to be enforced and issued by a (local or national) government. In health, the term "command-and-control", sometimes used to describe a regulatory mechanism, refers to a government attempt to impose clinical behaviours, care or input standards on public services (using internal mechanisms such as management control systems and liaison devices[17]). In State networks of health services, the 'command-and-control' regulation mirrors the 'managerial standard' commonly found in commercial entities as it refers to (more or less centrally-) planned activities;

b. Government versus public interest. We use the term 'public interest' in the sense of 'social mission', as opposed to commercial advantage. There are private institutions with a social mission and government ones with a commercial aim. Government regulations may be designed with an aim that departs from public interest, e.g. to enrich well-connected firms or to benefit merchants and politicians in their attempts to capture a market. Notice that ideally, such a conclusion can only be drawn after a careful legal and/or journalistic debated enquiry;

c. Private regulations are voluntary regulations that may be applied in the private sphere. A caveat about the scope of our study is that it does not address private regulations.

Having said this, we present below five non-mutually exclusive categories (from I to v) of regulations, each with their own criteria. The category-specific criteria are numbered from (1) to (13) in the following paragraphs. Afterwards, they are used in Table 2, and referred to throughout the document.

i. Regulation purpose

(Local or national) government regulations may be used for various political and/or economic purposes, such as:

- To (centrally) plan a sector (criterion 1),
- To remedy market failure e.g. with regard to accountability in performance and value for money (e.g. efficient pricing)[e] (criterion 2),
- To generalize a public (e.g. health) benefit such as access to standard treatments (criterion 3),
- To secure the availability of public goods (e.g. immunizations to avoid an epidemic) (criterion 4),
- To prescribe standards for performance and quality,
- To improve political mechanisms for decision making (e.g. users' or health workers' participation in co-management of public services (criterion 5).

ii. Regulation ambit

The regulation ambit may be specific to general or maternal healthcare delivery or not specific to the health sector (criterion 6). The relevance of all the above distinctions lies in the attempt and capacity of a regulation to address:

- Differences between maternal vs. general healthcare markets,
- Differences in the motivational structure of publicly-oriented (or socially motivated) health services / systems / sectors as opposed to commercial ones[f],
- Health market characteristics in LMIC, such as information asymmetry, market capture linked to insufficient number of sellers.

The regulations tackling health market issues should in theory reduce moral hazard and adverse selection, that itself limit efficiency of health insurance and care markets. Health care markets face particular information problems as medical information is complex and thus not equally shared between buyers and sellers. Furthermore, most illnesses do not repeat themselves, so that the cost of gaining the information is very high…while the costs of a mistaken choice are much greater and less reversible than in other cases. It is also often difficult to postpone treatment and so virtually impossible to shop around, inasmuch as continuity of care between sickness episodes is a care quality criterion. Finally, in a free market situation where the

[e] Efficient pricing is where demand and supply is in equilibrium.
[f] Publicly oriented services are defined in section 7.2.1

doctor is primarily motivated by the profit motive, the possibility exists for doctors to exploit patients by advising more treatment to be purchased than is necessary - supplier induced demand.

iii. Undesirable / desirable objects of regulation and the related means of achievement.

- Borrowing from Macleod and McSherry (2006), we distinguish regulatory actions that seek to enable or promote desirable clinical behaviour and health services, as opposed to prohibiting dangerous ones (criterion 7). This distinction refers mainly to the object that is the target of the regulation.

- As said earlier, another characteristic lies with the use of incentives, persuasion and information, as opposed to sanctions, as part of the regulation design (criterion 8). It does not interfere with the previous criterion as this distinction refers mainly to the means made available to achieve the regulatory objective.

iv. Targeted providers.

All studied regulations target health providers and institutions. Accordingly, regulations can be defined by their target, say, a particular profession. With regard to institutions, their status is traditionally seen as being government, private or both (criterion 9). We would add one more category based on the actual institution / provider's mission. We distinguish commercial aims (where maximizing income is the goal) and social aims (where it is not) (criterion 10) [g] – aims compatible with community participation and co-management of health facilities. Consequently, regulations can be classified according to the (government vs. private) status and (social vs. commercial) mission of their targeted providers / organizations[h,7].

v. Input vs. process vs. output regulations

The last category we use to classify regulations is the place of their objective in healthcare production, a place defined according to the now classical Donabedian diagram:

- Inputs are, for instance, standards for resource allocation, accreditation criteria and mandates for health professionals (criterion 11);

[g] As a parenthesis we notice here that a social mission or one that seeks benefits for the public is compatible with benefits for the provider if he/she does not aim at maximizing it.

[h] Accordingly, we can have, for example, local government hospitals that adhere to a commercial rationale (e.g. one that enables private investors to contribute to the hospital's funding, or in which benefits are shared amongst health professionals) and private health centres with a social mission (e.g. belonging to non-governmental organizations with unambiguous not for-profit status). Consequently, regulations can be classified according to the (government vs. private) status and the (social vs. commercial) mission of their targeted providers / organizations.

- Processes are enforceable guidelines (as in the UK National Health Service) or non-opposable decisions (as in the French health system). Notice that the former impose a set of clinical decisions in well-defined situations, while the latter prohibit some decisions but allow all others (criterion 12);

- Outputs regulations prescribe quality standards for health products, population coverage and access to population as measured by ratios, the standards being fixed by regulations (e.g. proportion of deliveries in institutional settings or skilled birth attendance rates) (criterion 13).

Other criteria and thus categories could be defined. However, a close look at Table 1 reveals the absence of regulations in our sample specifically targeting the private commercial sector, addressing community and user participation, addressing coverage and access to care, remedying market deficiencies and addressing fair pricing issues. In section 5.2.2, we shall analyse the meaning of these absences.

3.1.2. Applying the proposed taxonomy to the regulations studied by the HESVIC project

Table 2: Categorization of regulations studied in HESVIC according to our proposed taxonomy characteristics (see list of acronyms)

Criteria to group regulation characteristics		**Category of regulation**	**EmOC-Vietnam**	**SRB-Vietnam**	**GR-Vietnam**	**EmOC-India**	**Abortion-India**	**GR-India**	**EmOC-China**	**PND-China**	**GR-China**
1	*Objective to (centrally) plan a sector*	**Objectives – related**	No	No	Yes	No	No	Yes	Yes	No	No
2	*Objective to remedy market failure to provide accountability (both for levels of performance and value for money);*		No	No	No	No	No	No	Debatable	Debatable	No
3	*Objective to generalize a public health benefit*		No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4	*Objective to secure the availability of public goods*		Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5	*Objective to improve political mechanisms for decision making;*		No	No	No	No	No	No	No	No	No
6	*Targeting services in the ambit general healthcare vs. maternal healthcare vs. non-health*	**Ambit-related**	Maternal	General	Maternal	Maternal	Non-Health	Maternal	Maternal	Maternal	general
7	*Seeking actions that enable desirable health services interventions vs. those that prohibit dangerous ones;*	**Availability of means by objective or by design to implement regulation**	Prohibit	Enable	Enable	Prohibit + Enable	Enable	Enable	Enable	Enable	Enable
8	*Seeking means to use incentives, persuasion and information vs. to use sanctions as part of the regulation design*		Sanctions	Sanctions	Incentives	Incentives + Sanctions	Sanctions	Incentives	Incentives+ Sanctions	Incentives	Sanctions
9	*Does the regulation distinguish providers by government vs. private vs. both status?*	**Targeted providers-related**	Government + Private	Government + Private	Government + Private	Government + Private	Government + Private	Government	Government+ Private	Government+ Private	Government + Private
10	*Distinguishing the targeted providers with commercial vs. social institutional mission;*		No	Commercial (by definition)	No	No	No	No	No	No	No
11	*Prescribing 'inputs' or input standards of health interventions;*	**Management-related**	No	No	Yes	No	No	Yes	Yes	Yes	No
12	*Prescribing 'processes' standards of health interventions*		No	No	Yes	Yes	No	No	Yes	Yes	Yes
13	*Prescribing 'outputs' standards (for performance, quality access, coverage) of health interventions*		No	No	No	No	No	No	Yes	No	No

Acronyms: P: promoting regulation; I: inhibiting regulation; Pu: public; Pr: private;

3.2. Regulation families

In this document, we use the term 'regulation families' or continuum of regulations for those groupings of regulations with an ambit similar to or possibly contradicting some of the goals of the regulation under study (continuum of regulations, see also Table 1).

Regulations belonging to a family do not necessarily share the same criteria as in our proposed typology (see Table 2). For instance, one EmOC regulation may stress inputs and another belonging to the same family rather underlines processes, but the difference may be a nuance only.

As said before, Table 1 summarizes the HESVIC findings on regulations identity, policy frameworks and regulation continuum. Each studied regulation relates to others that were issued either prior to or after those studied. In our case studies, we could not generally pinpoint inconsistencies or contradictory objectives in these relationships, except with the interference of the PNDT act with the Indian MTP regulation[18].

During the implementation stages of several of these regulations, however, some opportunities to refresh a previous, related regulation or to point out possible synergies to implementers and/or regulated staff were missed. In some cases also the time lapse between the issuing of two related regulations was insufficient.

3.3. Comparing regulations using the proposed typology

We apply here the proposed regulation typology in order to define the domain of validity of our observations and recommendations.

3.3.1. Studied regulations' objectives:

All studied regulations seek to generalize a public health benefit and to secure the availability of public goods deemed important. The public good domain is maternal health and wellbeing of women *understood* as equitable access to quality maternal healthcare[i].

Less obvious are the presence of regulations seeking:

- To remedy market failures, e.g. to secure accountability in performance and value for money;
- To prescribe standards for performance and quality of care and to improve participatory mechanisms for decision making.

[i] In general, regulations do not treat equitable access to care of the husband as a public good.

EmOC are the only studied regulations compatible with a systemic view of health services, in that they explicitly refer to the relationships between health facilities and between tiers.

3.3.2. Studied regulations' ambit

As can be expected, all studied regulations but GR ones are directly related to maternal health. However, the Indian GR regulation is not born in the domain of healthcare at all, with consequences discussed in section 5.3.2.4.

Problems specific to healthcare markets such as information asymmetry, market capture and monopolies are not dealt with by the studied regulations. Across the three countries, only minor attempts were made to tame the effects of information asymmetry although it would have been logical to do so in several circumstances (see section 7.3).

As an example of this omission, the only mandatory information sharing under the Indian Clinical Establishment Act is to ensure that all private hospitals publicly display their charges - so that patients know what to expect. Similarly, outside the regulations studied, there is in Vietnam an obligation to display tariffs in health facilities and the MOH promulgated a regulation on medical professional ethics (with 12 items). Finally, the Vietnamese government decided that all regulations, including health regulation drafts, should be posted on a website for public comments before issuing.

3.3.3. The modus operandi of studied regulations

Some of the regulations studied enable desirable health services interventions and others prohibit dangerous ones (SRB regulation in Vietnam and, to some extent, the safe abortion regulation in India).

Regulation means are incentives (including persuasion and information sharing) and sanctions. Both incentives and sanctions are used in an intertwined way in all three countries. They are not always well defined or even well implemented. As a result, for example, medical abortions (acknowledged as having fewer side effects than surgical ones) are unwittingly promoted as a regular contraception method, because the MTP regulation loosely defined "illegal" abortions as an object of punishment in a context where contraceptives were not universally accessible.

3.3.4. Providers targeted by our studied regulations

Some targeted providers operate in government facilities, others in private and some have a hybrid status. The typology distinguishes regulations targeting providers with a commercial vs. social institutional mission. Accordingly, we can have, for example, local government hospitals that adhere to a commercial rationale (e.g. one that enables private investors to contribute to the hospital's funding, or in which benefits are shared amongst health professionals) and private health centres with a social

mission (e.g. belonging to non-governmental organizations with unambiguous not for-profit status).

This status and mission of regulated providers' organizations raises a theoretical problem. A regulation may well, for example, pay lip service to private practitioners, for example with regard to input standards. If, however, the regulation does not prescribe the allocation of resources to them by public authorities, the private sector is often unlikely to abide by it, especially when monitoring is weak. The detection of this type of inconsistency allows us to treat the political function of a regulation as its real, primary function and to analyse it as such, using concepts from political science[j].

3.3.5. Addressing inputs, processes or outputs?

None of the studied regulations tackles the outputs of (maternal) health interventions. We interpret the absence of key topics in our studied regulations in section 5.2.2., e.g. the following:

a. The absence of regulations specifically targeting the private commercial sector;

b. The low presence of regulations addressing community and user participation;

c. The small proportion of regulations addressing coverage and access to care as output of regulated (maternal) health interventions;

d. The quasi absence of regulations that seek to correct market deficiencies and pricing issues.

[j] For instance, conflicting economic interests; class- and caste-specific use of public expenditure on health; cultural dimensions of regulatory praxis; strategies of sociopolitical and professional organizations; and political importance of international commitments, e.g. MDGs

4. Effects of Regulation

4.1. Summarizing regulation effects as a basis for comparison

Across the cases studied, the effects expected from regulations implementation were

- Inputs and processes of EmOC regulations, prenatal diagnosis of congenital defects and abortion conforming to certain standards;
- Effective prohibition of clinical behaviour such as sex selective abortion;
- And redress of patients' grievances in health care delivery abiding by standard processes.

The importance of the effects of regulation in our reasoning is here reiterated. A generally positive result for a regulation permits the derivation of concepts for a successful strategy and its enabling conditions. A regulation that scores poorly can lead similarly to concepts regarding ineffective strategies and unmet conditions, particularly with regard to the social actors and their roles in regulatory processes.

This is what puts the results of regulations at the core of the present research project. We define regulation effects as those events (whether they be the desired results of the regulation or not) that can be convincingly related to the existence of the relevant regulation or family of regulations.

How do individual case studies of regulations and their effects contribute to knowledge production in the present inter-country comparison? Basically, knowledge of country differences in regulatory effectiveness and their conditions is derived from comparing the country's research reports and the conditions in the three countries, while using the analysis of individual case studies to support the comparison. In addition, this analysis is obviously enhanced by freely comparing any of the 9 case studies, or some of their features, two by two or more, according to different criteria, justified on intellectual grounds.

To ease their comparison and for the sake of report self-containment, we summarize here the key features of case-specific effects on maternal health, sex selection and professional behaviour with patients. In order to assess these effects, we contrast the data provided by country research reports with other information available in the grey and scientific literature.

Not all regulations aim to promote equitable access to care (see Table 2). Even in those cases in which a regulation aims to promote equitable access, it may yield undesirable effects. Examples of such effects are inappropriate/unwarranted referrals (EmOC-I), health system segmentation (PND-C) and the practice of "defensive" medicine (IPHS and CPA regulations, for instance[19]). In this report, 'defensive medicine' specifically refers to clinical practice of doubtful effectiveness and efficiency, denial of access to care and unwarranted referrals - possibly due to fear of a legal consequence and sometimes to the economic benefits that will accrue to providers.

4.2. Inter-country comparison of effects

With the HESVIC data, international comparison of effects, albeit limited, is possible only with the EmOC and GR cases since the three other regulations studied are specific to one country only. We thus:

- Compared the effects across the EmOC and GR regulations on equitable access to quality care;
- Contrasted regulations with well-known trends in country- and region-specific maternal mortality; data on abortion and sex ratios at birth; legal, illegal and unsafe abortion; and fertility data;
- Assessed grievance redress in terms of population-based ratios, when possible.

4.2.1. EmOC

As a short reminder, the objectives of the three studied EmOC regulations are the following

- Although the regulation words explicitly include the private healthcare services in their ambit, as is the case with Vietnam, the Indian and Vietnamese regulations are in essence input standards for government services - which we discovered during the study, see section 5);
- By contrast, the Chinese regulation addresses an operational issue – reducing maternal mortality mainly in the group of migrant women.

Their modi operandi also differ:

- The Vietnamese regulation conveys, conceptually at least, an explicit way of achieving an impact: when government hospitals with managerial autonomy manage to gather the required investments to belong to a quality assessment category, they are entitled to increase their prices and the remuneration of their doctors and staff;
- By contrast, the Indian regulation has not, or at least does not make explicit, any such modus operandi;
- The Shanghai regulation intends to make the referral chain a free lane for critically ill pregnant women e.g. by improving financial and technical accessibility of care, standardizing inter-institutional coordination, improving health information systems and by liaison devices.

This reminder of key features of the three regulations under investigation permits an understanding of our particular interest in some aspects of maternal health in the three countries – as expressed in the present section 4.2.1:

- In India we questioned if the regulation has had any impact on its alleged central objective, namely to reduce maternal mortality, and if not, where its modus operandi failed to work properly;
- Similarly, in Vietnam, we started examining demographic and epidemiological indicators. We then questioned if the regulation was dually administered and if

so, we assessed the relative importance of its impact on equity in access to care;

- We wondered if improvements were sufficient to yield an effect at country level and if not, why not; and finally
- In China, we aimed at assessing whether the implementation of the regulation under study and of its family was compatible with the explanation of its apparently good results.

The three countries reduced their maternal mortality[k] between 1995 and 2006, although with variable efficiency with regard to country expenditure on health (Chart 1) and equity. MMR was still 6 times higher in 2006 in India than in China. WHO[21] reported reductions in maternal mortality in the 3 countries between 2000 and 2008 (table 3) but India lagged way behind the two other countries and its progress during the last two decades has been generally slower. Notice that the evolution of Sri Lanka, also dotted on this chart, suggests that this evolution is not naturally linked to general, economic development and that a voluntarist health policy may curve this probably natural 'development' trend.

Chart 1: MMR vs. per capita expenditure between 1995 and 2006 in Vietnam, India and China[13]

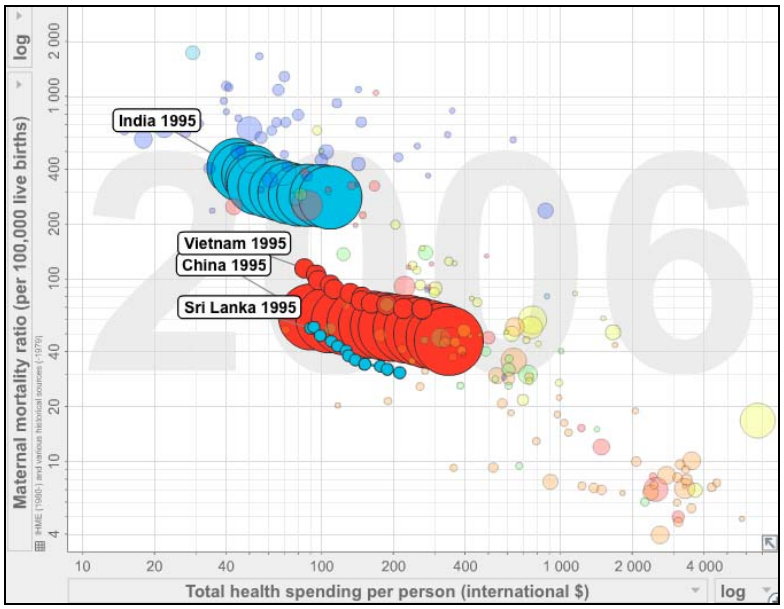


Table 3: Comparison of 2000, 2005, and 2008 estimates of MMR (maternal deaths per 100 000 live births) by country.

[k] As explained in the HESVIC international review paper "Maternal Mortality and Maternal Services: An Overview" (HESVIC, ITM team, 2010), there are three different ways of measuring maternal mortality. The most common one is the maternal mortality ratio (MMR) and the life time risk of a maternal death. The MMR is the number of maternal deaths during a given time period per 100,000 live births[k]. This is the measure of a risk of death associated with each pregnancy or live birth, i.e. the obstetric risk [20]. The maternal mortality rate, on the other hand, is the number of maternal deaths in a given period of time per in a population divided by the number of women of reproductive age during the same time period. This dimension reflects the frequency with which women are exposed to risk through pregnancy (as does MMR) but also taking into account fertility.

	2000	2005	2008	Annual % change in MMR between 1990 and 2008
China	60	44	38	-6%
India	390	280	230	-4.9%
Vietnam	91	66	56	-6%

China, in particular, made strides in reducing maternal mortality, with a consistent annual decline of 5% and a targeted reduction of 70% over 25 years. This Chinese success is to be explained, by and large, by the substantial effort to improve access to obstetric care *across the health care pyramid*[22].

With regard to equity, these global trends mask variable achievements within countries.

In 2008 in Vietnam, 7 years after the EmOC- V regulation was issued, there was still a striking imbalance between rural and urban MMR – respectively 145 and 79 per 100.000 live births. MMR in Vietnam over the last two decades has shown a steady decline from 165/100,000 in 2000 to 69/100,000 in 2009. However, the MMR in remote areas and mountainous regions was still three to ten times higher in 2009, standing at 411/100,000, as compared with that in the mainland region, where the MMR stood at 45/100,000[23].

Apparently, the existence of EmOC-V standards did not facilitate narrowing of this gap. The increase in equipment has been limited. Institutional capacity to address EmOC grew only from 63 to 68% of health districts in 10 years, a 0.5% increase per year only. Blood banks increased from 47 to 60% of health districts, unfortunately not necessarily in those regions in which the distribution of EmOC problem-solving capacity increased. Therefore, in 2010, only 55.1% of district hospitals provided both services at the same time[24].

With regard to human resources, information is lacking but shortage is known to be widespread in rural district hospitals[25], contributing to the inequity in maternal mortality distribution. Furthermore, the Decision 385/2001 (see Table 1) sought to secure a high turnover of C-sections and thereby to maintain the needed skills in provincial hospitals may have hampered quality of care in those district hospitals located close to these provincial hospitals.

The regulation did, however, trigger training in obstetrics across the health pyramid.

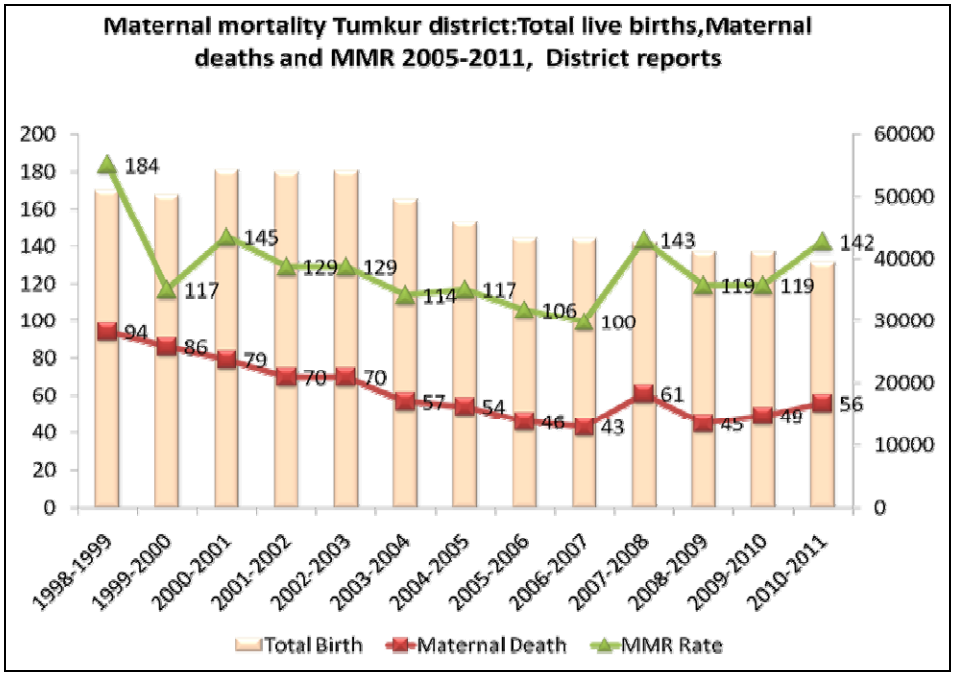
Again in Vietnam, the regulation under study did not manage to improve access to basic EmOC in primary care services (100-150 deliveries per year in early 2000 to 10-30 deliveries per year in 2010). In the context of maternal health, this is an issue particularly for those women who cannot afford to go to provincial hospitals and thus negatively affects equity in access to care. Clearly, many factors determined this evolution in patterns of health services utilisation, such as patients' expectations and

buying power. Amongst these factors, planning health inputs and processes (e.g. with technical guidelines) proved to be the only one in some way susceptible to our studied regulations.

This has resulted in patients bypassing district hospitals and in unjustified referrals to provincial hospitals for deliveries, for those who can afford it. In addition, low reimbursement rates by the public health insurance schemes have not motivated staff to provide EMOC services at CHC. Combined with the common perception that the quality of services is better at the provincial level than at the district level, this situation has also resulted in the over-burdening of provincial hospitals.

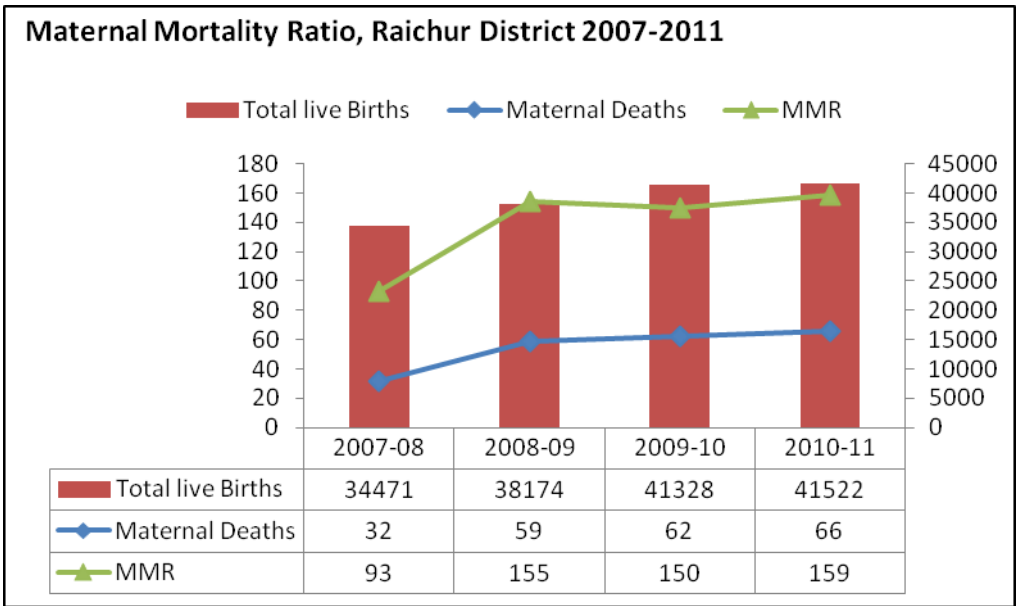
In India, where the regulation under study was issued in 2005, similar disparities are likely to have occurred. MDGs are not within reach and improvements in the MMR, in particular, dramatically stagnated (perhaps even decreased) during the past decade in the two districts under study (see Charts 2 and 3 below).

Chart 2: Maternal mortality and MMR 2005-2011, Tumkur district



Data source: District Health reports

Chart 3: Maternal mortality and MMR 2007-2011, Raichur district



	2007-08	2008-09	2009-10	2010-11
Total live Births	34471	38174	41328	41522
Maternal Deaths	32	59	62	66
MMR	93	155	150	159

Data source: District Health reports

These data reflect a failure to promote safe delivery, for example with cash incentives, quality care supply (24/7), auditing and referral systems as defined by the EmOC regulation. Human resources appear to be the key bottleneck in improving access to I-EmOC[26]. Patient interviews revealed fragmented accountability that led doctors to play with unjustified risky referrals in order to shift the blame when things went wrong.

Notice that in Shanghai, by contrast, interviews revealed that obstacles to access to care related to health system fragmentation and segmentation had been relatively successfully lifted, at least for critically ill pregnant women, be they resident or not. In China, progress is evident in many regions, even in some of the most remote and poor provinces, and there is little evidence of a widening gap between better-off and economically more deprived regions. Nevertheless, MMR in the western region remained twice as high as in the eastern region[22].

Still, in India, most deaths were thus recorded during inter-hospital transportation. Another mechanism, the transfer of patients from public to private institutions, proved difficult to control. Contracting out and patient poaching may have led to under-utilization of available resources in Indian public services[27].

In Shanghai, according to official data, the MMR in the resident population declined dramatically from 22.47 per 100.000 in 1996 to 1.64 per 100.000 live births in 2005 ($P < 0.01$), while the MMR in the migrant population shrank from 54.68 to 48.46 ($P > 0.05$) only during the same period[28]. The causes of maternal deaths reflect the following imbalance: postpartum haemorrhage (39.9%), pregnancy-induced hypertension (9.8%), and puerperal infection (9.3%) were dominant in migrant populations, whereas the main causes of maternal death of Shanghai residents were

chronic heart and liver disease (20.0%), postpartum haemorrhage (12.9%), and amniotic fluid embolism (12.9%).

Migrant women thus died more frequently of direct obstetric reasons than residents and most of the deaths are avoidable, as their access to quality EmOC seems jeopardized even before becoming critically ill. Indeed, the interaction between their health and migration status is known to be complex and dynamic. It is influenced by the health insurance status, socio-economic and cultural background of migrants and their previous health history, but above all, by their experiences of access to healthcare[27].

While the regulation under study was issued in 2008, the MMR in the migrant population had already decreased threefold, as shown in Table 4. In Shanghai, an estimated 180,000 babies are born every year[29]. The number of migrants' babies born in Shanghai is almost the same as that of the registered population. For the period from January to September 2011, of the 137,000 live new-borns, 75,000 were resident babies, while the remaining 62,000 migrants. That means that in Shanghai in 2011 around 11 pregnant migrant women died, out of a total migrant population of 9.000.000). With levels comparable to industrialized countries, variations across years are likely to reflect random fatal cases that remain at a very low level[30,31].

Although data are sometimes inconsistent (see Table 4), MMR fell significantly between 2005, when the EmOC regulation family (see Table 1) was initiated, and 2010. Even if the number of successful EmOC-rescues increased over the years (Table 5), it is difficult to disentangle the effect of each regulation (see section 2.4, third bullet) and to single out the effect of the regulation addressing the rescue of critically ill pregnant women e.g. because the MMR was already low in migrants in 2008.

It seems more likely that another health planning move made in 2004, when the Shanghai Bureau of Health issued the regulation “Notice of strengthening maternal healthcare management and designated childbirth service delivery points for migrants in Shanghai,” - had a more significant impact on the MMR of migrant women. In accordance with this regulation, 23 specific EmOC delivery points were established for migrant women, significantly improving their access to quality healthcare.

Table 4: MMR from 1996 to 2005[28] and from 2007 to 2010 in Shanghai[32]

MMR	1996	2001	2005	2007	2008	2009	2010
Whole population				12.67	12.23	9.61	9.61
Local residents	22,47	8,99	1,64	6.68	6.91	7.08	5.30
Migrants	54,68	47,58	48,46	-	16.81	11.69	13.54

However, if the mix of these regulatory interventions appears to have been effective, there is a risk that the results will not be sustainable without effective first line services, improved migrants’ access to hospitals, a dense urban primary care level

and a solution to the financial burden of unpaid bills at EmOC-centres for poor patients.

The analysis of operational data on the rescue – the emergency referral and treatment - of critically ill pregnant women (Table 5) raises other questions. It is unclear whether the increased number of rescue operations after 2007 is the result of a greater demand due to more critically ill pregnant women and/or a better access to the rescue operations. Furthermore, the number of rescues of critically ill pregnant women could not be broken down by resident / migrant women as these data were not available. Therefore, it remains impossible to establish the proportion of critically ill women rescued for resident and migrant population and thus to indirectly compare and assess access to EmOC hospital care in the two populations.

Table 5: Successful rescue rate from 2007 to 2009 in Shanghai[33]

	2007	2008	2009
No. of rescue	158	234	285
The rate of successful rescue (%)	93.7	95.3	96.1

Nevertheless, because migrant women have no health insurance, there is reason to fear that the proportion of migrant women becoming critically ill is much higher than that among residents - up to 50% of residents' costs are covered by their health insurance.

To conclude this comparison of the effects of the EmOC regulations in the three countries (see chart 1), they are unlikely to have had any significant impact on maternal health in India (see data above) and Vietnam (since progress in EmOC infrastructures was so slow) while in Shanghai, the regulation family (see section 3.2) has had a positive impact on mortality.

4.2.2. Grievance redress

Data from the three countries reveal that GR regulations are not used much for health-related complaints. Furthermore, they indicate that the use of GR regulations in the three countries, indeed quite limited, does not reflect the importance of grievances that people and service users in particular, direct to health services.

In Vietnam, the yearly average of GR cases reported between 2006 and 2010 was 1961 cases, which corresponds to a $2.2.10^{-5}$ GR / population/year ratio (one grievance redress case by 2.2 hundred thousand people per year). About half of these cases were treated in Hanoi, because of the nature of the complaints, but this also suggests a lack of effective resolution at provincial level. Many provinces did not send reports on any GR cases, indicating its inequitable use.

If we cannot rule out the possibility that some GR cases were actually handled without producing a report (through absent-mindedness, lack of interest, etc.), their

absence is an indication per se of the limited importance given to this regulation by the country's administration. No time trend was detectable in the GR regulation utilization rate, which suggests that this regulation probably remained idle across time: almost no use, no amendment, and apparently no complaint about its lack of effectiveness. The Vietnam research report mentions that for solving cases, the law on grievance redress was used more regularly than the MOH regulation[34].

About half of the (rather rare) GR cases dealt with quality of care issues and the other half with prices. However, the motives mentioned by the interviewees[35] - poor intra-institutional accessibility, long queuing and waiting times, unacceptable attitude of care providers and poor hospital environment - are likely to be widespread[34-37].

The contrast between press and scientific journals reporting population discontent on healthcare in the three countries and the actual, quite limited, use of GR regulations by health services users suggest that these GR regulations are not prone to easy utilisation (in particular, expectedly, by the poor because of administrative difficulties). Indeed, it is likely that social factors were pivotal in defining who could take advantage of the regulation. As one Vietnamese interviewee[36] put it: "The family accepted the conclusion because they are a 'low status' family and could not take the case to a higher level.". Clearly, the social profile of Indian private sector users is more likely to give them a voice. Other factors may also be suspected, though. For instance, the 1/5 anonymous complaints in Vietnam may be interpreted as revealing users' fear of retaliation in healthcare delivery.

In India, the utilization rate of the GR regulation (a 1986 regulation open to health in 1995) is close to zero. For instance, over the 10-year period between 2001 and 2011, 8 medical cases were recorded in Tumkur district (2011 population = 2.7 million) and 88 in Karnataka State (population = 61 million) [37]. In statistical terms, this regulation is thus virtually unused for medical purposes, although motives that people and users have to complain about accessibility to and quality of healthcare are countless (as revealed, for instance by a 230/100.000 MMR). This reasoning is further strengthened by a survey made by the Indian project teams: newspapers reveal collective actions (mob action) and individual retaliations against doctors in instances of strong dissatisfaction with healthcare delivery – but the regulation remains unused (48% of grievance redress were through informal mechanisms[38].

The same paradoxes could appear from the utilization of the regulated Chinese GR procedure, although data on GR cases in Shanghai were unavailable to the research team. Notice that China does not have the required data on reported GR cases because the hospitals do not collect them, although the GR regulation has determined that the related files should be registered, treated and archived. Per se, this is an indication of the limited political importance of this regulation

According to a survey by China Hospital Management Community in 270 hospitals all over China, not less than 73.33 % of hospitals experienced cases of violence, assault,

threats, and abuses by patients and their relatives. However, the incidence rate of medical disputes brought to court rose slowly: from 2002 to 2008, the number of medical malpractice cases accepted by the courts in China increased from 10249 to 13875[39]. By comparison, by the end of 2007, China had 298,408 health institutions, of which 19,852 were hospitals[40].

In conclusion, although the GR regulations were promulgated to give users a voice, they did not apparently improve commensurately the quality of care in the three countries, as suggested by their low utilization. Rather, the persistence of other mechanisms, often unforeseen and not desired by authorities, suggests that they have not fully contributed to achievement of this objective.

4.2.3. Sex ratio at birth imbalances through sex selection in Vietnam

The implementation of this 2003 regulation was delayed until 2006 (see Table 1) due to reorganization of the government office for population and family planning (GOPFP). Its implementation did not curb the sex ratio at birth disparities. Regional disparities in sex at birth ratios appear to have increased not only since 2003 but also since 2006 (Table 6).

Table 6: SRB trend by year and region in Vietnam 2001- 2009

	2001	2002	2003	2004	2005	2006	2007	2009
All over the country	109	107	104	108	106	110	111	110.5
Hong river Delta	106	110	105	107	108	108	113	115.3
North East	112	107	102	108	105	122	112	
Northwest	110	104	102	111	98	108	106	108.5
Northern Centre	113	102	102	100	98	114	114	109.7
Southern Centre	112	106	118	116	113	111	111	
High Land	96	104	98	107	109	108	111	105.6
South East	111	111	100	111	108	102	110	109.9
Mekong river Delta	111	105	105	107	104	110	110	109.9

Confirming this impression, the proportion of women aware of the infant's sex at birth was 63% nationwide and 83% in urban areas in 2006.

As an example for the year 2006, when taking into account Vietnam's crude birth rate for that year, it can be estimated that the total number of sex selective abortions was 31,835[I]. Table 7 shows the entire equation.

[I] We normally expect the number of boys to be 104 to 106 for 100 girls. The actual 2006 ratio in Vietnam was 110 boys for 100 girls. The 2006 crude birth rate is 17 °/°° (table 6). Use two equations with two unknown (x+y = 1.434.851; x/y= 1.05). The difference gives the number of selective abortions against female foetuses.

Table 7: determining the total number of sex selective abortions in Vietnam in 2006

Total number of births expected in 2006	Total number of expected girls born in 2006	Total number of observed girls born in 2006	Total number of sex-selective abortions
Vietnamese population of 84.403.000 x crude birth rate of 0.017 = 1.434.851	784.424	752.589	31.835

By comparison, the number of ultrasound violations detected is quite limited: 151 out of a total of 6361 regulatory controls (2.4%) in 2009, 108 out of 67751 in 2010 (0.2%) and 1 out of 83192 in 2011 (0.001%). What this comparison suggests is that even if more facilities were controlled across time, they were controlled with detection methods (such as haphazard, advertised home inspections) unlikely to reveal unlawful practices. In addition, corruption and poorly designed inspections may have limited detection: administrative data reveal more controlled facilities but demographic data reveal less cases detected since sex imbalance remains constant across time.

Finally, to put in perspective the role of the private sector (where it is said that the majority of sex selection takes place[41]), it is important to remember that 80% of private professionals also work in the public sector. Since information on Decree 104 (ANC-V regulation) is largely available in the public sector, and because of these 80%, it seems unlikely that spreading more similar information to the private sector would modify the practice of sex selective abortion. The Vietnam research report discusses the operational consequences of the societal/cultural determinants of sex preference in Vietnam (see also section 10.3.2). In conclusion, the anti-sex selection regulation did not alter the unbalanced sex ratio prevailing in most of Vietnam because of a flawed modus operandi – which militates against further elaboration on the value of this regulation regarding its effectiveness.

4.2.4. Abortion in India

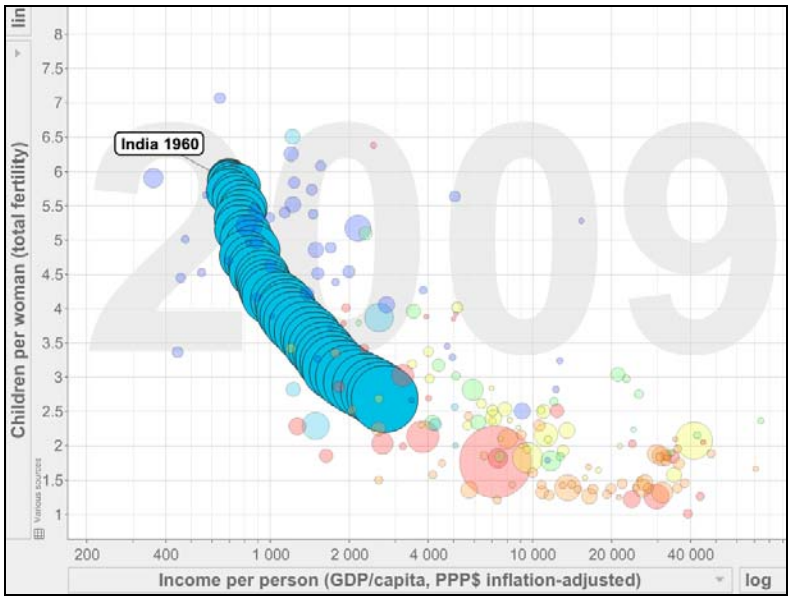
Central Southern Asia is now the region of the world with the largest number of safe and unsafe abortions (10.5 million a year, ahead of Eastern Asia) and with one of the highest proportions of unsafe abortion in those countries in which it is legal (65% in 2008, as compared with 66% in 2003 and 78% in 1995[42]).

While most authorized data reveal the predominance of Central Southern Asia in unsafe abortion, one should recognise that the reliability of the underlying data is limited by the validity and accuracy of those from India, that represent the bulk of it. Indeed, as will be seen below, figures depicting abortion epidemiology in India offer a wide array of estimates. The contradictions in quantitative data were so striking that we tried to explain this phenomenon (in section 8.2.2.)

Nevertheless, abortion represents a major public health problem in India. Surveys put unsafe abortions at 15-20 times the number of safe ones, and they are reported to

account for 17% of total maternal mortality (approximately 11,000 yearly)[43]. Progress in family planning is evident in India, with the fertility rate having dropped significantly over the last 50 years (Chart 4). There is thus a need to understand a paradox, inherent in the factors behind the high proportion of unsafe abortion in a country in which abortion was legalized more than 40 years ago and that is reducing fertility relatively well.

Chart 4: Evolution of fertility and income in India between 1960 and 2009



Since the Medical Termination of Pregnancy (MTP) Act was issued, the number of reported abortions increased 100 fold - from 25 thousand in 1972 to 2.5 million in 2010[44-46] (Table 8).

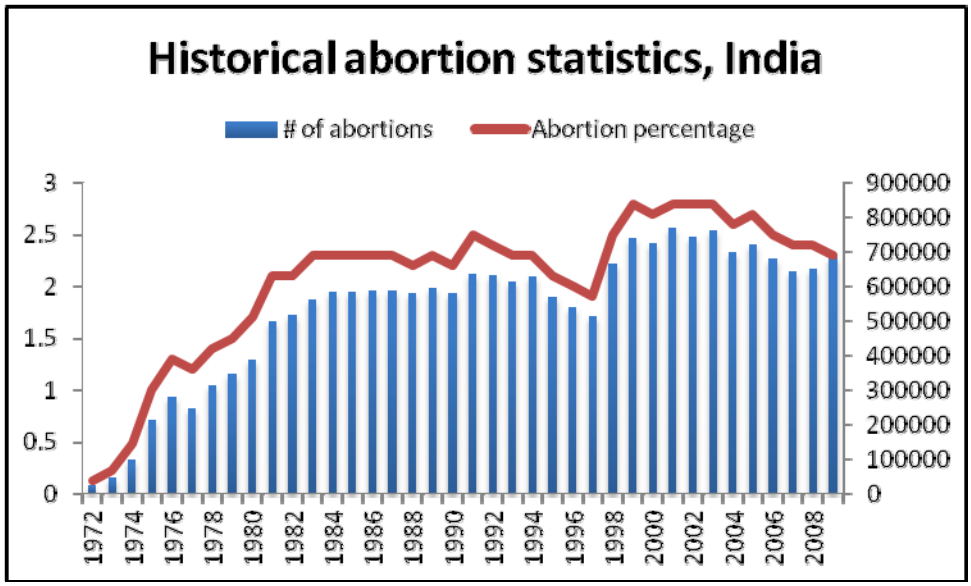
Table 8: Abortion epidemiology in India

Indicator	1972	1975	1980	1985	1990	1995	2000	2003	2007	2010
Abortions, reported	24300	214197	388405	583704	581215	570914	723142	1229937	1895721	2529979
Birth rate, crude (per 1,000 people)	37,69	36,89	35,45	32,90	30,20	28,30	25,80	24,80	23,10	22,22
Population, total (millions)	573	613	687	765	850	932	1016	1064	1125	1171
Population ages 15-44, female (millions)	119	128	145	163	184	207	229	242	259	271
Population, male (millions)	299	320	358	398	442	484	527	551	582	605
Live births (millions)	22	23	24	25	26	26	26	26	26	26
Abortion rate (per 1.000 females, aged 15-44))	0,20	1,67	2,69	3,58	3,16	2,76	3,16	5,07	7,32	9,33
Abortion ratio (per 1.000 live births)	1,12	9,47	15,94	23,19	22,65	21,64	27,59	46,59	72,96	97,24

Source: http://www.johnstonsarchive.net/policy/abortion/ab-india.html

After slightly decreasing over the 1990 – 1995 period, abortions increased significantly after 1995. This happened after the introduction of another abortion-related regulation in 1994: the PNDT act, prohibiting sex-selective abortions (see chart 5). With the number of live births in India stagnating around 26 million from 1995 onwards, this means that the reported abortion ratio (reported abortions per 1.000 live births) has risen significantly, from 20 to almost 100. However, After the PCPNDT act was introduced in 1994, we noticed a decreasing number of (reported) abortions for a two year period, which may reflect the strong, initial fear of being indicted on this act while performing any kind of abortion.

Chart 5: Total abortion statistics India[45]



As stated above, available data on unsafe abortions lack consistency. At national level in India, surveys report that about 6.7 million unsafe abortions per year occur in unhygienic conditions or by untrained abortion providers[47], suggesting inconsistency in available data. The health information system, as is to be expected, reports much fewer cases: 8% of maternal mortality according to one national source[48], and 4% according to the Karnataka NRHM Program Implementation Plan 2009-2010.

A 2010 retrospective study of patients admitted after unsafe abortions (a review of hospital records of patients admitted between 2005 and 2008) showed that unsafe abortions constitute 11.6% (n=132) of total abortion cases admitted over 3 years, probably reflecting some under-reporting. It also showed that with 231 women dying from unsafe abortion, their share of the institution's maternal deaths rose to 12.55%. The majority of women admitted due to unsafe abortions (70.45%) were in their thirties, married (89%) and had wanted abortion for birth spacing (60%), which confirms the failure of the family planning program in spite of its coverage progress.

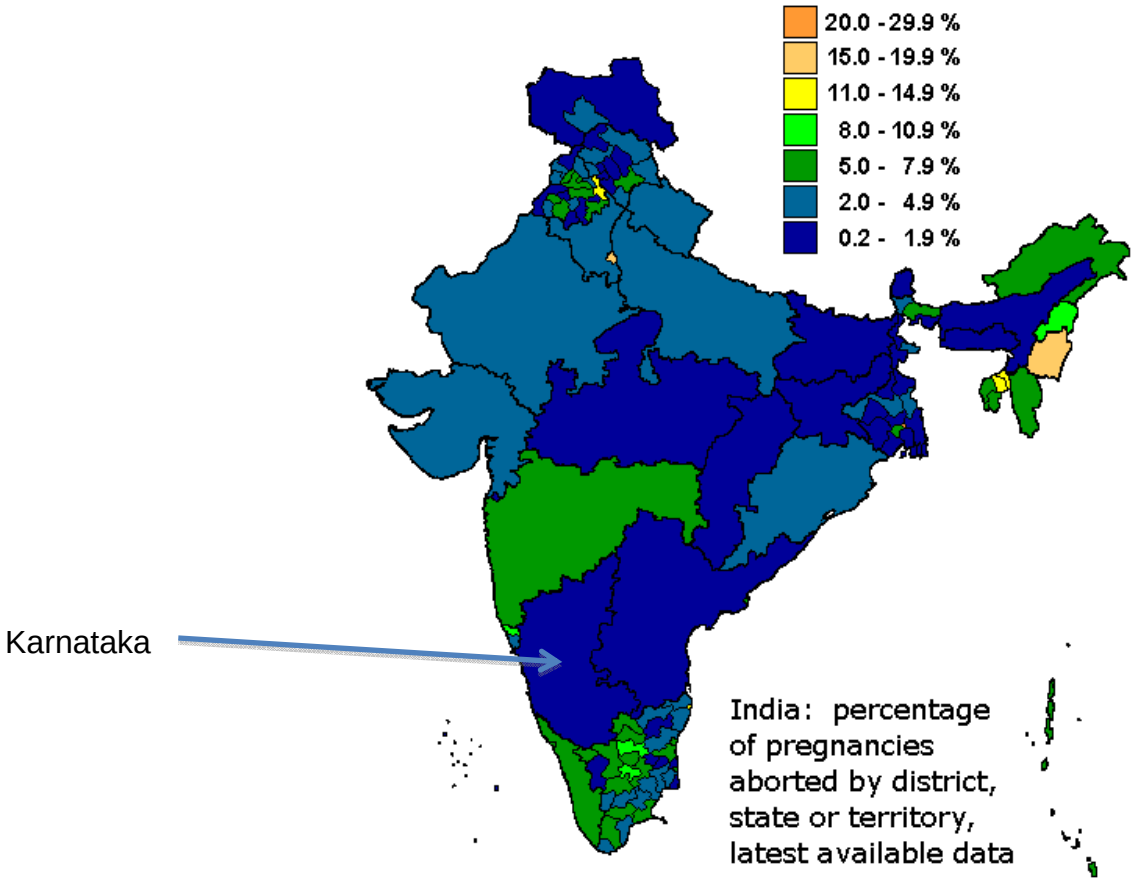
About 60% of abortionists were unqualified[49]. The proportion of abortions leading to generalized sepsis amongst illegal abortions was known to be high and to have decreased recently[50], as it has amongst institutional abortions. However, by

legalizing medical abortion, the 2002 amendment of MTP Act made it available to a larger public (these attractively packaged pills, popularly known as 'MTP kit' pills, are available over the counter) and was followed by an increase in incomplete abortion and subsequent heavy bleeding, shocks and convulsions, due to misuse of abortion pills[51].

It should be noticed that access to safe abortions is limited because primary health centres cater to populations of 30,000 each but can provide abortion only if the Medical Officer is trained. They do not therefore automatically become abortion centres. Unfortunately, the next level of abortion centre that can provide abortion is a FRU catering to populations of 400,000 - 500,000.

Map 1 provides state specific abortion rates (as a percentage of pregnancies, excluding foetal deaths and miscarriages). Besides the high variance across the country, this map shows that Karnataka is one of the States with the lowest abortion incidences. This suggests that problems detected with MTP implementation are much more serious in other regions of India.

Map 1: India abortion percentages by state and territory, 1991-2007



In conclusion, the old, almost traditional MTP regulation, although designed to legalise abortion, is probably an associate factor of very high, although unevenly

distributed, unsafe abortion rates and may thus be co-responsible for a (traditionally estimated) abortion death rate amounting to a 15% of total MMR.

4.2.5. Prenatal diagnosis in China

We here study the regulation of a “therapeutic system” geared to avoid mongolism and spina bifida cases in the population, and made of a tier of 4 PND centers for screening and diagnosis in Shanghai. This 2002 document regulates prenatal diagnosis technology, supervision and management of PND services. From a health perspective, one would expect that if a problem is sufficiently prevalent and causing sufficient morbidity, mortality and dyscapacity, the related control devices would be made available to the largest possible population.

Although, in general, prenatal diagnosis based on screening of maternal blood samples has been found to be more cost-effective than using the discriminatory criterion of maternal age, this appears not to be the case in China[52]. The reasons include low population uptake rate of the maternal serum strategy, low uptake rate of chorionic villus sampling and amniocentesis, and the high price of serum screening. Chen and colleagues (2004) found that health system factors concerning technology utilization are important determinants of the technology’s efficiency.

The key difference from Western Europe is the lower government financial coverage in China of most prenatal preventive and early detection programs. The limited reimbursement of serum screening and diagnostic services by the Chinese government is probably justified by the pre-eminence of other priorities (e.g. chronic diseases) in a country undergoing a rapid epidemiological transition. While no output data are available, it is likely that, because of the technical standard and cost of service delivery, those women who actually take the amniocentesis / chorionic villus sampling programs are urban and relatively wealthy.

At the end of the day, the regulation ensured that those who would use early detection medical techniques would be those who can afford it, and that public funds would be invested in building and equipment as a subvention to scientific and industrial policies, for instance. From a public health viewpoint, judgment as to whether or not the government investment in the four Shanghai prenatal diagnosis centers has been an equitable choice depends on whether benefits generated by these investments were transferred to health facilities development, general healthcare delivery and sound public health activities, or merely used to increase doctors’ remuneration.

As a conclusion for this section, of the nine studied regulations, only one could have achieved a significant part of its objectives.

5. From effects to content and content to design

This section examines how the above described regulations effects are to be related to their content, and then, the ways in which their design process explains content problems. Issues with their implementation will be studied in chapter 6.

Reminder: annex 1 presents the assessment criteria for regulation content, administration and implementation that were used by research teams.

5.1. Issues with contents of studied regulations

As is to be expected, content characteristics influence the failure or success of a regulation. The content characteristics of the regulations studied are listed below and consist of mismatches between regulation content and objectives and of content 'blanks'.

5.1.1. Content mismatches

Content mismatches may lead to incompatibility between a regulation's conception and its objectives because of the following:

- Regulation focus on providers and neglect of health financing and user behaviour - sometimes root causes of the problem;
- Regulation focus on institutions and their resources while neglecting populations;
- Insufficient definition of healthcare quality criteria;
- Inconsistencies between related regulations and between groups of regulations;
- Inconsistencies between regulations and underlying policies, as well as between regulations and requirements for health systems development;
- Insufficient attention to determinants outside healthcare services as possible roots of a problem;
- Flawed design due to regulations not being originally conceived for the health sector.

Table 9: Key regulations mismatches with regard to the content across the case studies

Criteria used to assess regulatory design and content	Vietnam	India	China
Imbalanced focus on: • Providers, • Institutions, • Population, • Health financing, • User behaviour.	The three studied regulations focus on provider behaviours rather than on that of users (no resources / population ratios provided, no population-based access objectives, lack of sociocultural knowledge). The EmOC regulation did not properly take into account the preference of middle class users for high tech healthcare. Their preference for C-sections (health seeking behaviour) is shared with professionals who probably created this demand in the population. Confidence in primary care was already low and this did not improve after issuing the regulation. Rather, three times less institutional deliveries at CHC and overburdened provincial hospital maternity wards. In the case of the SRB regulation, the content actually goes against the grain of middle class aspirations to	The three studied regulations for India focus on providers – primarily public healthcare providers. Though needs and demands of users were said to ground regulatory opportunities, they do not seem to have exerted much influence on regulation content. The EmOC regulation does not take into account the multiple obstacles that exist to access EmOC in the public sector. Quality is looked at from an infrastructure point of view. Besides, the regulation design lacks an obligatory mandate. The MTP Act treated abortion within the scope of family planning policies (contrary to the opinion of those who designed it) and largely emphasizes providers and institutions. Only during the 2002 amendment did socio-political organisations have a say in its content. The GR regulation is located outside	The technical nature of the EmOC and ANC/PND regulations justifies the focus on providers and healthcare institution. Though rooted in widespread user dissatisfaction vis-à-vis the health system, the GR regulation provides more administrative procedures for users' complaints than solutions.

	have small families, preferably with sons. The GR regulation is largely underused, though originally intended to guarantee a consumer's right. Whether they target private and/or public institutions, regulations suffer from inappropriate mandates, poor technical and administrative definitions, ill adapted administrative and technical mechanisms. Monitoring and evaluation are generally weak, including the means for verifying violations in the case of prohibitive regulations.	the health system and is complex and therefore largely underused, although intended to guarantee the consumer's right.	
Level of consistency amongst regulations	There is a degree of overlap between the studied EmOC regulation and the more general reproductive healthcare decision 23/2005 of the MOH, which leads many actors to ignore or to confound the two. Until recently, the SRB regulation was the only prohibitive regulation with an ANC viewpoint that dealt with the issue of gender balance at	The design of the studied regulations does not sufficiently consider historic ambiguity between central GOI and State relations regarding implementation of health service regulations. There is some conflict between MTP regulation and the PNDT Act prohibiting sex-selective abortion. In some cases this may lead to defensive behaviour from providers.	The EmOC case study reveals a high degree of embeddedness of the studied regulation in a series of other regulations issued by the Shanghai BOH. A number of these regulations use evidence from studies as a basis for their design. The PND regulation, on the contrary, was the only enabling regulation so far that dealt with the issue of delivery of prenatal screening and

	birth. However, it does not specify concrete violation behaviours or concrete fines, in spite of a section addressing sanctions and rewards. A related administrative MoH regulation, issued 3 years later, defines administrative sanctions when violating population and children's issues, but did not properly address the gap in the SRB regulation design.		diagnosis.
Level of consistency between a regulation and an underlying policy or other requirements of health systems development	The EmOC regulation is integrated into the national RHC strategy. However, it focuses on technical characteristics of EmOC in terms of care inputs. It is less clear on care management, for example overlooking the two tiers needed by obstetric care delivery and issues with financial accessibility of care. The SBR regulation study reveals a conflict with other government policies, namely the small family policy, implemented since the 1960s. The regulations deal with a number of standards and service procedures required for health care facilities, but do not consider the overall needs of the healthcare *system*.	Both EmOC and Abortion regulation are embedded in a prior policy making on reproductive healthcare and safe abortion. The IPHS, inside NRHM, belongs to a long term national reproductive health strategy. It is supported by an election, political promise and by the current GOI health strategy. Both regulations deal with standards for care and service but overlook the overall needs of the public healthcare system (such as strengthening primary healthcare). They leave the dominant private sector outside the scope of the regulation.	There seems to be consistency between national policy frameworks and the studied regulations. The absence of users' representation in regulation design is conspicuous (see consequences in 5.3).

Consistency between a regulation and the resources available for its implementation. Notice: we distinguished resources for the regulation implementation and those for care delivery.	The EmOC regulation effectiveness was hampered by a lack of health resources for EmOC and health in general. Besides, in the first years only 10.000 USD per year were allocated for regulation administration to each of eleven provinces with the worst SRB imbalance. Since 2011 more provinces are receiving the same resources. Probably the most serious weakness in the regulation's design is the flaw in its Article 10, which does not specify in concrete terms the means to detect violation behaviours or concrete fines, in spite of a section addressing sanctions and rewards.	IPHS untied funds for health infrastructures, taking advantage of the NRHM as an ambitious national strategy. Insufficient EmOC human resources, however, remained the ultimate bottleneck.	All regulation processes seem to benefit from some resources from the local municipal health budgets. EmOC-C benefited from a one-time investment, PND-C mobilized inputs for training and supervision and GR-C received some local government resources. Some technical solutions in regulations are debatable. Implementing high-cost EmOC-rescue and fee for PND without the provision of a gatekeeping function in the health system jeopardizes the financial sustainability of the former and equitable access to the latter.
Consideration of determinants outside healthcare services.	None of the Ministries of Education and of Labour studied how to complement the SRB regulation with policies against unequal gender relations (that even permeate health institutions and policies) such as initiatives in education, job opportunities and better salaries for women.	MTP remains associated with family planning strategies and is not treated from a 'right to health' perspective.	The Ministry of Justice should have been, but is not involved in GR regulation. The regulation states that when malpractice is involved, the ad hoc department should direct complainants to specific medical malpractice channels (involving technical identification, mediation and civil actions).

Flaws due to regulations originally not conceived for health.	Not relevant	The GR regulation, originally a consumer's protection Act, was later extended to the health sector following a Supreme Court ruling.	Not relevant

Notice: if Table 9 above summarizes country-specific comparative findings on content mismatches across case studies, not all findings are addressed here - only relevant ones. Below we draw a comparative analysis of these findings across the three countries.

5.1.2. Inter-country comparison of content mismatches (and related design)

5.1.2.1 Imbalanced focus on providers / institutions / population / health financing / user behaviour

All studied regulations across the three countries predominantly focus on providers and healthcare institutions, except for one: the 2002 regulatory amendment to the Abortion MTP Act, in which socio-political organisations played a role. Strikingly, though sparked by the concept of grievance redress as a consumer or citizen right, the GR regulations did not shift this focus towards the population or the users in any of the three countries. Deficient health financing as one of the root causes of maternal deaths and unsafe abortions is given some consideration, for example in the IPHS and MTP regulations in India, but quite insufficiently.

5.1.2.2 Consistency amongst regulations

Most studied regulations are embedded in regulations families (see Table 1). While several regulations may address different aspects of health systems, their consistency will depend on due care in design and implementation. The Chinese administration and government aim at consistency across some regulations (EmOC in our sample). By contrast, we observed little such efforts in Vietnam and India, resulting in regulations becoming obsolete or overlapping with higher ranked (MoH vs. a MoH department, national vs. state or local) related ones.

Some studied regulations remained isolated efforts, despite addressing important societal and epidemiological issues, like SRB and PND. The MTP Act in India remained the only regulation dealing with illegal abortion, until the launch of the prohibition of sex selective abortion, nearly 30 years later.

In fact, the regulated staff and even administrators were often puzzled by the regulatory architecture in the three countries. As a consequence, many regulations fail to achieve their intended effect or may even remain unread.

Regulations cannot be equally coordinated over national territories of countries decentralising their design. The consistency between our studied regulations and others related to them is patchy. In this sense, the EmOC-C regulation represents an exception.

5.1.2.3 Consistency between a regulation and an underlying policy or other requirement of effective health system development

As is the case with regulations families, most cases studied reveal an underlying policy and political thinking, shared by a relatively large number of decision makers. We'll see with the EmOC-C case that the government can actively promote this collective thinking.

Most international reproductive health policies on EmOC draw the attention of governments to EmOC. With a strong focus on providers and institutions, the studied regulations emphasized technical aspects of care delivery and place relatively little emphasis on the related managerial and social aspects of maternal healthcare, otherwise addressed by mother and child health policies.

The time lapses between definition of an underlying policy and the actual issuing of a related regulation vary across countries, from short (as with EmOC-C) to long delays in Vietnam and India. Variable delays also occurred with regulation amendments (see section 6).

A striking feature is that key (for example, human and financial) resource needs of healthcare system development remain unmet, although this is uneven across the three countries. The lack of first line services capable of offering acceptable and accessible primary healthcare to their citizens – certainly in poor, urban neighbourhoods, but probably also beyond these areas - is one of the most important such structural deficiencies. Apparently, policy makers believe that family medicine is too expensive for middle-income countries – although there are techniques (coaching, training audits, etc.) that enable delivery of bio-psychosocial care with a network of nurses and health officers, not necessarily family doctors. Such lack of consideration for systems requirements directly affects negatively the likelihood that a regulation will be implemented and has the intended effect.

5.1.2.4 Consistency between a regulation and resources available for its implementation.

We distinguish the resources allocated to regulation administration and those earmarked for healthcare delivery (known to be, as stated above, insufficient). The former are very unevenly provided across territories and regulations by the government in Vietnam (SRB-V) and through local governments in China.

Expectedly, no funds results in no regulation administration. On the ground, with no or limited funds available, the implementation of a regulation is left to the discretion and priorities of district medical officers or district executive teams – which, in principle, is not necessarily bad. From the perspective of decentralising health system development, as is needed in big countries, the right of district executive teams to decide on priorities is key to effectiveness[53]. Their perceived priorities can be improved, however, by in-service training that does not promote blind implementation of regulations, but leadership in health system development. Even so, the SRB case in Vietnam shows the concomitant importance of national policies. Like them, making regulations requires two articulated planning moves, one top down and the other bottom up. China appears to have experience in their coordination.

Health financing regulations rarely conceive health services development in a *systemic* way that is by articulating health facilities within integrated networks. For instance, making PND services financially accessible at the point of primary patients'

contact with health systems is neither sustainable nor equitable. Some gatekeeping mechanism is needed. Unfortunately, the current architecture of first line health services in the three countries works against effective implementation of such gatekeeping mechanisms. None of the three countries offer access to bio-psychosocial and patient-centered care (as in family medicine practice) to the majority of their citizens. And health officers, nurses and GPs are thus not in a position to advise their patients in their utilisation of health systems resources.

Thinking in terms of the same systemic vein, successfully providing EmOC rescue in China led to financial pressure on overburdened EmOC rescue centres - in the absence of a systemic financial framework. Reportedly, in Vietnam, India and China collaboration between designers and financial departments was not common during the definition of regulations – which detracted from the effectiveness of the regulations.

The EmOC-C regulation reminds one that effectiveness has an efficiency cost. For the sake of efficiency, coordination mechanisms achieved under the EmOC-C regulation should be progressively expanded to address general care delivery. Likewise, solutions to critical incidents observed during the audit of critically ill patients' trajectories through healthcare services could lead to structural and managerial changes favourable to systemic development initiated at grassroots level[54]. In general, studying the rescued women's careers could lead to improved efficiency of Chinese health services, if improvements in coordination between health facilities were expanded beyond the strict limits of maternal health.

5.1.2.5 Addressing determinants outside healthcare services.

Equitable access to quality care is known to be the most important factor in safe motherhood and maternal health. This is compatible with a holistic approach to the social determinants of these problems[55] if there is a strategy for integrating their control in curative care delivery. Yet we saw very little consideration in the studied regulations for determinants outside healthcare services. For instance, sex selective abortions are regarded as a problem that can be regulated through antenatal care choices; safe abortion is reduced to a family planning device/issue; and GR procedures are viewed as the answer to disseminating the human right to decent care.

Healthcare is not one more consumer product. While commodities are subject to the law of supply and demand, lack of access to care leads to avoidable mortality, suffering and anxiety. Yet we cannot detect a 'right to health' perspective across our case studies in all three countries.

5.1.2.6 The flawed design of regulations not originally conceived for the health sector.

With regard to this criterion, only one case study stands out: grievance redress in India. Originally conceived as a (paying) consumers' law, the whole procedure in consumer courts remained cumbersome for healthcare users. Consequently they are not much used to settling general health related grievances. Instead, the issue has gained the attention of lawyers mainly seeking financial compensation.

5.1.3. Blanks in regulation contents

As said before, a close look at Table 1 reveals the absence of regulations in our sample:

a. specifically targeting the private commercial sector;

b. addressing community and user participation;

c. addressing coverage and access to care;

d. remedying market deficiencies and addressing fair pricing issues.

These absences were to be expected since, because respectively:

a. In India, there is indeed a regulation (Karnataka Private Medical Establishment Act, KPMEA) that would enable an EmOC-I regulation to be applicable to the private sector. However, private practitioners' associations have thus far managed to block its implementation. It was introduced in the state of Karnataka in 2007 to regulate the private sector and replace the Karnataka Private Nursing Home (Regulation) Act, 1976. Because this Act faced a lot of resistance from professional medical associations and representatives of private hospitals, the government took two years to frame the rules of its implementation, which were completed in 2009[56];

b. Contemporary politics in the three countries prevent the existence of a sector made up of a network of members that are community- and publicly oriented and socially motivated, and that is not defined merely by a government-vs.-private disposition. Instead, managerial autonomy is granted to government services, as in Vietnam and China. No more than in the private, commercial sector, the staff paid from the hospital establishment is not keen to submit its remuneration to discussion with users' associations or with other representatives of the public interest;

c. Applying the Donabedian categories to the 9 regulations reveals that 4 sets of standards are concerned with inputs (3 EmOC + 1 PND-C) and 3 with processes. None are concerned with population ratios of resources or of health outputs. In other words, none of the regulations under investigation

incorporated a service coverage rate or a utilization rate as an indicator for reaching their regulatory objective.

Regulating outputs in terms of population coverage (for example, in respect of C-section rates, with maximum and minimum boundaries, ANC coverage, or hospital admission rates) or with reference to demographic or epidemiological impacts, assumes outstanding commitment and integrity, as it exposes politicians to evaluation on the basis of their measurable social achievements. In practice, such regulations are thus rare.

For instance, in India, the IPHS includes some elements of output regulation but these are not population based. It states that PHCs should see at least 40 outpatients per day; it should be open 24x7; PHCs should conduct at least 10 deliveries per month…but not that institutional deliveries should remain above 95% or C-sections between 2 and 15% of total deliveries, for instance. Also in India, while the PC-PNDT Act is not exactly a population-based output regulation, sex ratios at birth are regularly monitored and alarm bells ring if this crosses dangerous levels (for example less than 950 females for 1000 males).

d. Regulation of pricing in India tends to deteriorate over time. One important feature in the health sector is the pricing of essential drugs. The Drug Controller of India used to fix the prices of essential medicines and would not allow market forces to act on these prices. Pre-2000, more than 400 medicines were under price control; but after India switched from process patents to product patents (in 2000), this number has steadily decreased. Today it is less than 200. Besides, there is no price regulation of medical procedures or doctor's fees. These are left entirely to market forces.

In China, most healthcare services prices are regulated, be they public or private institutions. However, we lack information as to how this is actually enforced.

In Vietnam, the MOH issued a regulation for the highest costs of healthcare (including ultrasound and abortion) in both public and private facilities. For instance, the price of a simple 2D ultrasound is 20,000 VND (1 USD) and a color 2D ultrasound is 80,000 VND – 150,000 VND (4 USD – 7.5 USD). The highest cost of an abortion up to 7 weeks is 155,000 VND (8 USD) and of an abortion from 13-22 weeks is 430,000 VND (22 USD). However, in practice, these prices may be higher in private facilities.

5.2. From regulation design to content in Vietnam, India and China

Tables 8 a to c summarize the country specific findings in regulations content and design respectively in Vietnam, India and China. The three GR case studies are compared across the three countries insofar as their characteristics allow for such comparison.

5.2.1. Regulation design in the three countries

Table 9 in section 5.1.1 identifies key challenges to regulation content and design, specifically where there seem to be mismatches between a regulation's content and its objectives across case studies and countries. Below are detailed some of our findings on regulatory design in the three countries.

5.2.1.1. Vietnam

Table 8a: Regulatory design in Vietnam: key findings

Vietnam Case studies	Vietnam regulatory design findings
EmOC	The MOH MCH department coordinated the replacement of MOH Decision 220/1993/BYT/QT - originally conceived for mother & child health and family planning -by the EmOC regulation 385/2001. It was updated to address private providers, in accordance with health and MCH reform and with the MDGs. The regulation is exclusively technical. It prescribes assignments and resource standards to reproductive health facilities, from commune to central level, while also targeting non-public ones. Provincial Departments of Private Practice Medicine Management are in charge of administering the regulation of private providers. They are expected to make use of the Law on private health practice (1993), the Ordinance on private health practice and other legal documents. This particular regulatory architecture has resulted in keeping private obstetric providers outside the scope of the EmOC regulation 385/2001, as in 2001 their importance was still limited[57]. The EmOC-V regulation does not regulate pricing or drugs distribution, with respect to which other laws exist, for example on health insurance. The absence of a population-base defined distribution of the regulated RHC resources limited its impact on the EmOC services[57] . So did the absence of a mandate to demand these RHC standards and of resources that could enable private actors to abide by them. From scratch, the regulation was unlikely to control private EmOC services because, if its regulation content actually dealt with the private sector, it did not address monitoring and evaluation. That fell under a separate set of regulators. The complexity of the studied regulations, with different approaches to EmOC, is reported as a design problem[58].
SRB	The sex ratio at birth regulation 104/2003/ND-CP was a new regulation, originated by the National Assembly's Population Ordinance and coordinated by the General Office of Population and Family Planning (GOPFP). It was conceived to stabilise the population size and structure - including

	balancing SRB. Several government actors, women's union representatives and mass organisations were called to participate in the drafting process. However, the government representatives who were intended to participate, including vice ministers or heads of ministry departments, often delegated the task to their technical staff. This could partially explain the somewhat limited policy options considered in the regulation design. Also, the regulation's inconsistency with other policy frameworks, such as the state 'small family size' policies, could be the consequence of the predominant participation of technical staff in its formulation, despite the fact that the Ministry of Justice and the Prime Minister's office had the opportunity to revise the regulation prior to its launching.
GR	The MOH issued the GR regulation QD 44/2005 as an amendment to the national Law on complaints and denunciations. A second MOH circular issued in 2009 (see table 1) regulated the appointment of a leader's inspector in each state institution, in order to assist the institution's leader with respect to control and inspection. Section 5.2.3 compares the Vietnamese GR regulatory design to those of the 2 other countries.

Vietnam defined "consensus governance" as a principle of close cooperation and coordination in state policy-making. This implies consultation with relevant actors and eliciting of public responses in policy design. In practice, however, it often amounts to posting a regulation draft on the MOH's website prior to issuing it. This drastically limits interactions and dialogue, for example because no mutual adjustment is possible and most Vietnamese do not access internet (access was said to be 34% in 2012)[59].

In conclusion, it appears that the negotiated political culture that prevails in Vietnam could result in political agreements on regulation content that tend to overlook technical concerns. This may be justified in many instances, but not when a firm political decision (on sex selection or safe maternity for instance) has to be taken. We shall see in section 9.3 that in such circumstances, technical options should be evaluated in experts' debates, with experts representing different stakeholders such as the users, the government and health professionals, for instance.

As in the other countries, the origin of the GR regulation, external to the health sector, prevented the regulation from fully taking into consideration the specific features of the product - healthcare delivery – and the idiosyncrasy of its inherent relationship between a patient and a provider. At the end of the day, it appears that in this regulation as probably in others the regulator knows less about the concrete situation of health care delivery than the regulated staff.

5.2.1.2. India

Table 8b: Regulatory design in India: key findings

Indian Case studies	Indian regulatory design findings
EmOC	With the highest maternal mortality burden in the world and a slow and uneven decline of maternal deaths across Indian states, the GOI launched a nationwide initiative to remedy the situation. India had been intensifying its reproductive and child health strategy since 1994, but in 2005 the current United Progressive Alliance government integrated that strategy into its own political agenda. This agenda was known as the "common minimum programme.'' It sought large-scale reforms in the social and health sectors and promised increased public spending on health. This combined agenda was framed in the NRHM. The central GOI level defined the NRHM, to which IPHS belongs, through a series of consultations between state and non-state actors, represented in different task force groups. Government representatives, academics, socio-political organizations and political representatives were included in the task force. Though designed in 2005 at the central level, the implementation of IPHS was delayed until 2006 or 2007 in a number of states. It is possible that this delay accounted for some perception of the national IPHS amongst State officials as being too ambitious and idealistic. Furthermore, issuing of regulations within the conflict-ridden central – state relations is often prone to ambiguous regulation content. - To understand the limitations of the Indian regulations design, it is necessary to explore the policy thinking prevailing at the time of the definition of both NHRM and IPHS. That context was one of political thinking on health system problems. The factors seen as highest priorities to curb maternal deaths were the following: - Deficiency in skilled and specialized human resources to provide good EmOC; - Unavailability of secure blood banks; - Unregulated private sector; - Patients' general mistrust of poorly performing public health services; - High out of pocket health expenditure (as a consequence of the 2 former issues). The IPHS (the EmOC-I regulation) applies to the public sector facilities and to rural India only, and its guidelines are non-mandatory. In other

	words, the private and urban public sectors remain outside its regulatory scope. A separate state level Act, the Karnataka Private Medical Establishment Act 2007 (see Table 1 and section 5.1.3) was intended to regulate the private sector as of 2007, be it only in the areas of registration, infrastructure standards and services information display. The NRHM encourages contracting out (for example of ambulance services and C-sections) to private services. The EmOC-I regulation does not address the management of existing resources but only creates additional ones. Optimization of available funds would arise from creation of untied funds, which would give local authorities a say in managerial decision making. Still, it must be acknowledged that in general, these initiatives, in particular the National Rural Health Mission, brought in fresh financial resources - but they were unevenly distributed over the territory for example within Karnataka (see section 4.2.1). The IPHS design provides guidelines as to the quantity of human personnel required to secure quality care delivery. The issue of specialized human resources, such as anaesthetists and obstetricians, however, remains unresolved. The root causes of this deficiency are lack of proper training; poor distribution of available specialists[60]; and lack of support from local hospital administrators, which the regulation does not address.
Abortion	With regard to abortion, on the basis of a first-hand survey and a review of international abortion policies and family planning studies, the "Shah" committee recommended in 1966 that permission should be granted to qualified practitioners to terminate pregnancies while "acting in good faith". This was the basis for the MTP formulation in 1971. Contrary to the original view, the MTP act had a double agenda: one explicit, namely to curb high maternal mortality, and one possibly hidden, namely to bring in abortion as a family planning method[51]. This was observed and confirmed by the Indian research team in their country research report. The MTP Act targets both public and private providers when defining who is eligible as a practitioner, under what service conditions and where MTP should be performed. With respect to training needs, the act specifically refers to the need to have performed at least 25 MTP's in an established health service. The gestation period is an important design element in the regulation's

	content. The Act states that all MTPs have to be carried out before 20 weeks of gestation. Professionals based in both primary care facilities and hospitals can do this until 12 weeks of gestation but only hospital-based providers can after 12 weeks. In practice, however, this led to a task distribution whereby primary care providers terminated the less than 12 weeks pregnancies while increasingly using medical abortion methods (pills), the other pregnancies being left to hospital gynaecologists. Unfortunately, the severe deficit in rural hospital specialists led many women to private facilities, where little is known about who is licensed to perform MTP. Over the period of its 41 year existence, this regulation came to be understood by providers as a restrictive one[60] - contrary to its original design. The strong involvement of socio-political organisations led to its amendment in 2002. Today, it is almost impossible to know how many private facilities are licensed to terminate a pregnancy, nor how many physicians have actually received the MTP training (see above). It seems that many primary care health workers, both medical and paramedical, are still providing MTP services without being properly trained as per the regulation[61].
GR	Even if health transactions have been incorporated to some extent into the CPA regulation for GR, it remains remarkable that only judiciary and consumer courts played a partial role in trying to influence healthcare practices[52]. The diverse formal and informal out-of-court ways of settling conflicts, as reported by the Indian research team, are a sounding board that something is profoundly wrong in the way grievances are being dealt with about healthcare practices. Section 5.2.3 compares the Indian GR regulation design to that of the 2 other countries.

In India, both government policy and regulatory agencies have consistently ignored the existence of the dominant segment of healthcare providers: the private sector, be it qualified or not. But India is also facing difficulties in effectively regulating its public sector, as health planning goes against the political culture and dominant paradigms of private healthcare delivery. It is likely that the design of maternal health regulations dealing with public services suffered from the otherwise deeply rooted public sector decadence.

5.2.1.3. China

Table 8c: Summary of findings on regulatory design in China

Chinese Case studies	Chinese regulatory design findings
EmOC	The Chinese EmOC regulation (Shanghai BOH (2008) No.12), issued by Shanghai BOH in April 2008 intends to amend clinical processes and healthcare management while availability of equipment and human resources is already partially secured. At the moment of designing the regulation, the situation of human resources in primary and secondary care health institutions was still inadequate, although this situation had improved in EmOC centres established earlier. The regulation aimed to reduce mortality in critically ill pregnant women by improving consultation/referral, accountability and coordination between the existing EmOC-centres and all other related maternal health agencies. A 2005 survey carried out in the 23 Shanghai migrant childbirth delivery services revealed that timely EmOC rescue remained largely inaccessible and, as such, a main cause of maternal deaths for MPW. A 2006 situational survey on care quality and human resources reflected the chaos in the existing referral system of CIPW, especially MPW[62,63]. In 2007, 5 geographically designated EmOC rescue centres were thus established for CIPW. In 2008, the Shanghai BOH and SWHI organized an Advisory Panel of obstetric experts from these 5 EmOC rescue centres and 3 tertiary MCH hospitals. During a seminar they gave their views on the required processes for consultation, diagnosis and treatment of EmOC for CIPW. This was a first input for the regulation that was eventually designed. The Shanghai BOH financed the entire drafting process from its second '3 year action plan on public health 2007 - 2009'. The same Advisory Panel of experts participated in a second seminar, joined by 18 directors from district MCH hospitals. Finally, the draft regulation was reviewed, discussed and issued by the BOH.
PND	Due to problems with gradual increase of PND service delivery since 2000, to prior incomplete PND policies and to increased focus on birth defects, a group of national PND experts advocated joining multiple forces to define a new regulation, under MOH guidance. Senior politicians and influential experts took an interest and the MOH tasked its MCH department, with the department of Medical Science, technology and education, with development of the regulation. The Fudan University's Health Technology Assessment Centre was

	asked to conduct research to summarize the state of PND diagnosis service provision. The draft regulation was discussed by more experts, including legal experts, and was revised through an internal institutional revision process by MOH departments. The specific health planning approach to enable regulation implementation was devolved to municipal and regional levels. The whole process took about one year and the regulation was finally implemented in 2003. Since then, the national PND regulation has not been modified or amended. According to the regulation content, both public and private facilities can apply for registration as a PND service provision centre. However, there is no private facility in Shanghai that meets the requirements for health sector grading as a tertiary institution. Users were not directly involved in the design phase, although the Health Technology Assessment Centre did involve users as sample respondents in its research. We will see in Section 5.3.3. the social and political implications of this choice.
GR	Defining this guideline regulation involved a process of several rounds, during which policy makers gathered information from stakeholders, including researchers, administrators and hospital managers, conducted surveys and attended validation meetings to review the draft document. Actors with little power, such as consumers, were not involved in the regulation definition. Section 5.2.3 compares the Chinese GR regulatory design to those of the 2 other countries.

It appears from the Chinese case studies that when the objective of the targeted institutions is commercial, (and unless conflicting commercial interests say otherwise, as in the PND case), regulations merely put into administrative terminology a laissez-faire policy, demonstrating thereby a lack of governance capacity.

When the objective is healthcare delivery, and (local) government policy makers have a strong will, policy is designed from the top, while allowing some bottom-up planning mechanisms for technical decision making. However, this did not prevent tensions from appearing among professionals, concerning their income in relation to the regulation, because they have a political voice (that users generally lack, see section 9.3). Nevertheless, the existence of such tensions suggests that the regulation will not stagnate.

What can be said of the health policy beyond the EmOC-C case? The fragmentation of the obstetrical pyramid appears between the lines of this regulation, for example in

the problems of referral that had to be solved. Rather than treating services fragmentation as a problem to be managed according to global strategy, we learned that the regulation aimed at solving one particular problem – maternal mortality amongst critically ill women.

5.2.2. Features common to design across the three countries

As is the case with most health policy in LMIC, regulatory design in Vietnam, India and China is mostly carried out by state actors. Distinctively, China organized seminars with field professionals ahead of drafting the EmOC-C regulation. However, discussions on regulatory decisions with non-state actors (representatives of social organizations, politicians, external advisers, academics) are not frequent. Users are rarely involved or represented in regulation design.

Consequently, flaws in regulatory design and content echo the absence of some key actors: some regulations are out of focus; others are out of money and others out of tune with existing ones.

Besides, once the regulation is designed, too often the administration seems to consider the regulatory mission as accomplished. Alongside problematic implementation, some regulations are out-dated (while costs of health technology are skyrocketing), unknown or confounded with others.

The case of EmOC China reveals that a timely, experience- and evidence-based design, strong on accountability, in a context of management property split, can make a meaningful difference and lead to an *impact.* It thus seems that in this particular case two key aims were achieved:

a) Priority was given by the local government to the health problem that was the origin of the regulation;

b) There was commitment to MDG 5;

It remains to be seen how financially sustainable the regulation will be. *In addition, a regulation handling a relatively narrow technical field is arguably an indicator of success;*

In conclusion, we identified frequent content features that strain the regulations' capacity to improve equity in access to quality care, especially in a context of blurred private / public borders. We shall see in section 9 that these characteristics are a feature of the political economy of the said "transition countries".

5.2.3. The particular case of GR regulations

Because of rising costs, persisting inequalities and poor care quality (evidenced in critical incidents), equitable access to care is increasingly becoming a political issue. The three countries reported how governments feel this growing pressure, both

nationally and internationally, when defining policies and regulations aimed at improving quality of care. In Europe, Spencer and Walshe[64] found 18 out of 24 countries to be able to count on the necessary statutory legal framework for constant quality improvement strategies for healthcare.

However, while healthcare quality is receiving growing attention and governments are increasingly leaning on regulation in their attempts to achieve it, the literature unanimously concludes that the extent to which regulation works in practice has not been sufficiently researched: no evidence has been produced over the last 20 years to suggest that regulation can have an impact on quality[65].

Indeed, regulators may be challenged by the complex nature of healthcare delivery for example its services system, the multiple actors and the lack of specific sets of measurable objectives. The lack of concern for many aspects of healthcare accessibility suggests that this may have been the case with the GR regulations, as with the EmOC-V and –I cases. And we have seen that several unintended / undesirable effects could have been foreseen because of the public services status: “public services have been transformed into state enterprises, i.e. doing what is economically profitable”[66]. Their initially social mission thus became a commercial one, erasing differences with the functions of the private sector.

The concepts of care quality that underlie the three GR regulations are limited in both quality and quantity. Regulation designers appear to understand responsive care as care during which the patient is greeted cordially (allegedly in fee-for-service systems). A smile is needed but this does not equate to patient-centered care.

In fact, a simple simulation can show that GR regulatory systems were not really tailored to work. The expected monthly GR cases and related workload can be calculated using, as the product of the health services, utilization rates and the proportion of complaining patients – changing the level of both parameters. This exercise reveals that GR could not be widely used, even if many more resources were allocated to its administration. If 1% of hospital users complain, and if the utilization rate of an outpatient clinic is 1 sickness episode per person per year, a district hospital (Pn = 300,000) should process 3000 complaints per year.

In India, the absence of a credible community-based forum for users’ grievance redress, related to quality of care and conduct of providers, emerges as a gap in regulation design. The medical conduct of providers is increasingly regulated through recourse to consumer courts (and is thus, implicitly, limited to the middle class capable of affording a lawyer). Furthermore, no regulatory mechanism was able to limit medical practice by unqualified providers. To improve care quality in existing health services, policies such as the IPHS exist. They do mandate standards for infrastructure and hospital staff but have few (if any) rules and procedures to ensure the quality of services or of specific interventions. Inequalities in health workforce distribution that contribute to uneven access to care are seldom regulated. This

would require alternative policies of incentivizing or supporting rural health practice and improving working conditions in rural areas.

5.3. Regulation design: where political and technical issues meet

Ideally, the conception of a health regulation (and of its implementation) should be in line with a consistent health policy. As such, it should be the result of rational decision-making (for example, Cochrane and other EBM sites; plus reference centres) and the product of negotiations between key social and commercial stakeholders (see section 9.3).

In Vietnam, India and China the approach to defining regulations seems to be 'traditional' in that their design largely relies on state actors, yielding almost exclusively state-directed regulatory mechanisms. Non-state actors are involved at some stages of the drafting of a regulation, but this is not systematically the case throughout the design process. More importantly, users are often not directly nor visibly involved. When they are, their financial position does not enable them to afford independent, high level experts capable of advising them on complex health policy and technological choices, nor to negotiate in their name.

Of the HESVIC case studies, the PND-C is probably the most didactic in revealing the limits of expert advising in increasingly pluralistic and marketized health systems dealing with high tech investments. Regulation content should be evidence-based and should use evidence from a wide array of disciplines. Apparently, the following procedure was followed: The key regulatory authority commissioned a university and appointed expert advisory panels to perform situation and technical analysis studies. Results from these studies and any recommendations were carefully considered when drafting the regulations. During the drafting process, contents were constantly checked with the same or new experts. The use of evidence in the form of international experience of best practices thus played a key role in the case of PND technology. In other cases, the design experts were also future implementers or even to-be-regulated staff.

However, designing relevant health regulations not only requires considerable multifunction skills: in addition, these skills should be mobilised in a way that secures some acceptable level of impartiality in decision-making. This involves issues surrounding the social production of evidence, for example, who pays these experts and the consequences of their material dependence. This is where technical and political issues in health regulation design meet each other (see also section 9.3).

Health policymaking in LMIC appear to have been often closed, confined to discussions within groups of bureaucrats, politicians and external advisers making up a techno-structure. Granting users a voice in the policy making process may help regulations to work better for them.

In theory, broader consultations with groups representing and working with users, such as non-governmental organisations, religious organisations and other specific interest groups, could help[67]. However, most NGOs cannot be controlled by their beneficiaries, either because they are not really non-profit organizations or because of power issues. Rather, these features (non-participatory structure, possible hidden employment and financial benefits and advertised social mission) often characterize charity organizations and their involvement in regulatory designs.

In conclusion to this section, our analysis has thus far identified features of regulation content that hamper equitable access to quality care (GR regulations, EmOC-V and –I)[70-74] and favour undesirable clinical practice (sex selective abortion in Vietnam, unsafe abortion in India)[68,69]. The key feature of their design process appears to be the intervention of technicians, specialists in the issue to be regulated. Their selection and the nature of their skills were implicitly treated as politically neutral: specialists involved in regulation design were not appointed by social groups and were not supposed to defend their interests. Rather, they were intended to make decisions on the basis of a debatable "common societal interest" and "scientific truth". Both are debatable in essence.

We shall next examine the implementation of regulations and the allocation of resources to regulatory structures, as well as other determinants (such as health resources made available) and the larger mix of policy background relevant to the problems under study.

6. Regulation implementation

6.1. Introduction

This section examines how regulations content and design are related to the way they are implemented - to detect (in a deductive way) and explain (in an inductive way) regulatory failures and/or successes.

Observing a regulatory failure cannot automatically lead to a diagnosis of flawed, inconsistent regulatory design: implementation accounts for many organizational outcomes, contingencies and conflicts, which is why multiple actors need to be studied[m]. This exercise thus assumes that the regulation under study passed its first test: its content is compatible with its effectiveness. More specifically, we examine if, how and why the regulation was implemented as it was conceived, and whether this explains its effects.

Here follow our steps in comparing the implementation of the regulations studied across countries. After an epistemological consideration (see section 6.2), we compare the structural problems faced by the regulatory administrations of the 3 countries (section 6.3) and identify the country-specific paradigms of their implementation (section 6.4). The problems raised by lack of control resources are examined in section 6.5 and the implementation management feedback loops in section 6.6. Only once regulations' contingencies have been studied can the assessment of their design and implementation be formulated.

At times, lessons can be learned from regulation implementation failures. These lessons can be fed back into the design in the form of regulation amendments and, more importantly, normative policy advice. Regulation processes are not rational, linear chains of events. Their nature is equivocal because their processes undergo contingencies and organisations' / individuals' conflicts. Our study thus did not aim to produce policy norms but to advise social organizations and policy makers on strategies to achieve the regulations' objectives – i.e. socio-political strategies in the health sector.

In general, the project country reports identified regulation malfunctions, but this has not prompted suggestions on how to "fix" them. We appreciate this fact considering that in regulation design, there is a need to consider policy variables, people and organisational features (in line with the Mazmanian-Sabatier model [n] of implementation study[70]) and look beyond the transitional circumstances and, in particular, the rapid economic expansion, of the three research countries'.

[m] This could be called a contingency-responsive perspective. It is treated with more detail under Section 8.1 when studying the roles of actors in regulation processes.

[n] The Mazmanian-Sabatier Model is an example of second-generation implementation research, focusing on typologies for predicting policy outcomes. It concentrates on 16 variables in case study approaches to understand the degree of congruency between outcome and policy.

Through the study of regulation implementation, we thus aimed to reveal actors' and organisations' roles and relationships. We also looked for inconsistencies between regulations and the resources available for their administration. When studying regulation implementation, we mainly focused on the experience of its implementing actors, which will be dealt with in section 8.

We shall start the presentation of this study of implementation with a short recap on some HESVIC terminology of healthcare regulation processes:

- The design ("definition") of a regulation is the activity of defining it;
- The administration of a regulation consists of its management by local inspectors;
- The application of a regulation is the extent to which professionals and health organisations abide by it in their clinical and managerial practices.
- The implementation of a regulation is made up of its administration and its application by health professionals.
- The interpretation of a regulation is the way controllers administrate the regulation, and health professionals implement it in their daily practice.

We have seen that designing a regulation amounts to giving its content a legal, policy and programme framework that sets up objectives, specifies who should benefit, and who is accountable and how this will be achieved. The next step consists of its administration. At this point, the administrative system and service delivery develop some interface (reciprocal relationships, for example bargaining) while the actors are interpreting the regulation in respect of, say, entitlement.

Finally, at implementation stage, professionals (tentatively) abide by the regulation in healthcare delivery, which again entails interpretation. The study of implementation problems thus examines how interpretation in professionals' practice puts the attainment of the regulation's objectives in jeopardy.

6.2. How does regulation administration and implementation explain its effects?

The administration of a regulation and its possible, subsequent implementation by health professionals depends on human factors such as the density and intellectual / technical preparation of controllers, and their income and integrity.

Beyond this, there is a second category of determinants that make the administration effective or not. These determinants include the administrative density and strength, the features of administrative decentralisation (deconcentration, devolution, etc.), the administrative and social culture[71], the characteristics of the control modus operandi and the evaluation feedback loops foreseen to improve the regulation implementation,

the incentives and punishments, and the way they are actually mobilised, to mention but a few. These are the parameters of our comparative study of regulation implementation.

Table 10 summarizes key findings on how regulations implementation explains their effects across the three countries. To visualize this relationship, it is useful to bear in mind the field activities that implementation of regulations involves in healthcare delivery, described above.

Table 10 elaborates the implementation features in each of the countries.

Table 10: Summary of main findings on how regulations' implementation explains the balance of their positive / negative effects

	Studied regulations		
Case study	Vietnam	India	China
EmOC	Was the complexity of the Vietnamese administration a factor of poor regulatory effectiveness? Different government levels were intended to work together in order to implement the EmOC regulation. The driving actor at central level was the Mother and Child Health department of MOH. The lack of coordination between these actors could explain why many in the administration chain were unaware of the EmOC decision. : ten years had elapsed since it was issued, while the exercise had never been repeated. Indeed, many implementers confused the EmOC regulation with another MOH decision. At hospital level, the EmOC technical guidelines were implemented at the discretion of the hospital directors.	Is the Indian administrative decentralisation compatible with regulatory effectiveness? As often in India, the stumbling block was between federal and state administrations. IPHS was introduced nation-wide by the central government as one of the core strategies under the NRHM. To this end, the central MOH set up a structure empowered to manage its administration. One of the tasks of this structure is to provide capacity development and decentralisation for effective interventions. The States' Health and Family Welfare Society oversees the decentralized planning through appraisal of district health plans. At district level, programme management units implement, monitor and evaluate progress. The health services' implementation strategy is based on skilled birth attendance at primary care level,	What is the modus operandi that could explain the possible success of this regulation? The Shanghai municipality plaid an important role in the coordinated management of both administrative and technical regulatory structures. Supervision and assessment are vital components of the regulatory choices and were carried out. EmOC-rescue has been put in action, as designed. High hospital bills for poor pregnant women are being waived. However, EmOC-rescue centres are becoming overburdened due to a rising numbers of rescues. At the end of the day, the objectives of the regulation may have been achieved, but there are operational problems in the EmOC rescue structures that remain insufficiently evaluated.

	Studied regulations		
Case study	Vietnam	India	China
	The implementation of the EmOC regulation suffered from scarce financing for regulation administration and implementation effort. Notice that the EmOC services suffered from the same deficiency of resources (also staff) as the (public) health sector in general. The incomplete health reforms, specifically at district level, turned out to be an obstacle to the regulation's implementation, especially in the provision of EmOC at the communal health centres level. The same applied to the hospital autonomy and the market-oriented care model. Monitoring and evaluation (feedback loops) were scantily carried out and almost always lacking in a supportive methodology. Private sector EmOC monitoring was supposed to happen separately, but was not carried out frequently. Sanctions for	institutional deliveries at basic level facilities and comprehensive EmOC at first referral level. These functions were only partially implemented through the maternal healthcare system. The IPHS objectives were interpreted in a minimalistic way by local administrators and the regulation was implemented accordingly, while equipping the FRU for EmOC services. At the end of the day, the structural bottleneck - the lack of specialist (obstetricians) - was not addressed – so EmOC services often became idle.	

	Studied regulations		
Case study	Vietnam	India	China
	underperforming on EmOC services were almost non-existent and were not specified in the regulation.		
ANC / ABORTION	Poor design and/or poor implementation? We saw that the ANC-V regulation is flawed by design since it does not provide a way to identify sex selective diagnosis offenders. Is this the only reason why the regulation does not work? With regard to the GOPFP, regulatory authority for the SBR regulation, a change in the Vietnamese institutional setting proved to have a major impact on the future of this regulation. The GOPFP was originally an authority equal to the MOH but falling outside its jurisdiction. Since then it has become part of the MOH. This has hampered and delayed the continued administration and implementation of the SBR regulation	To what extent is the culture amongst managers and health professionals compatible with liberalization of the abortion regulation? In health services, the District Health Officer has the power to give and revoke MTP licensing to private health facilities. Public facilities are considered licensed automatically. The DHO also inspects both private and public facilities as frequently as deemed necessary and may extend or cancel a certificate of approval. Monitoring and feedback is carried out through MTP abortion reports. However, this takes place only to a very limited extent. It has been reported that health professionals (all categories, including illegal) adapt abortion price	An effective regulatory implementation of a reasonable policy? The Shanghai municipality planned and funded PND centres. These were required by a national regulation. Standards for the PND care and services were optimized. This is not the case for the prenatal screening services where, for example, quality assurance was largely left to self-regulation and management. PND services for migrant pregnant women were not provided in the designated hospitals for migrants. Due to the success of PND and prenatal screening services, some MCH centres became overburdened.

	Studied regulations		
Case study	Vietnam	India	China
	for 3 years. Resources allocated to implementation and monitoring were considered to have come from routine funding. Any extra financial effort from GOPFP has been insufficient and has only been made available to half of the provinces - those with the highest sex imbalances. Very few cases of regulation violation have been reported, as funding for inspection is very low and visits are scarce and always announced. The actual implementation of visits is complicated by the unsuccessful integration of GOPFP inspectors into the provincial and district health authorities. Monitoring and evaluation (feedback loops) are carried out, but almost always lack a supportive methodology. This is reported to be a reflection of the lack of importance given to SRB imbalance at the time. The private	to the woman's status (married, divorced, widow, teenage, etc.)[72]. Currently there is scarce information on the number of private facilities that are fully MTP-licensed. The exact number of physicians working in public facilities that have received the compulsory MTP training is also unknown, though most of them do provide MTP (strictly speaking, illegally). The MTP Act is in essence a prohibitive regulation, as far as providing non-legal abortion services is concerned. It has an exclusive prescriptive content, stating sanctions for prohibited behaviour. However, it has been interpreted and implemented as an exclusively restrictive regulation meant to prohibit abortion, especially for users not falling within the values patterns of local implementers.	

	Studied regulations		
Case study	Vietnam	India	China
	sector, though targeted by the regulation, has remained uncontrolled.	The absence of reporting information is striking and causes a lack of oversight and monitoring.	
GR	Did the regulation remain idle? In provincial and district hospitals staff had little or no knowledge of the GR regulation. It was often confounded with the broader Law on GR. Though the entire GR complaint filing procedure was defined in the regulation, very few GR cases were actually registered and treated. The level of anonymous complaints remains high.	Did the regulation remain idle? India has a set of outdated legal instruments for handling health complaints, but these are cumbersome to enforce. Healthcare users' protection was not a priority for policy makers until the Supreme Court's ruling in 1995. Even now, the procedure of settling a health complaint takes place entirely outside the health system and occurs through litigation in Consumer Forums or out of court financial settlements.	Did the regulation remain idle? The regulation was administered in a timely and top-down manner. The MOH carried out selective inspections soon afterwards. Municipal level, however, did not provide any support, unlike during the other regulation processes. It is not clear to what extent the GR functions, as designed in the regulation, were being implemented as no data are available on how many cases have been reported or how these were managed. This in itself is a reflection of the incomplete regulatory implementation. Reporting on GR cases is scarce and said to be adapted in order to achieve good

	Studied regulations		
Case study	Vietnam	India	China
			assessments.

6.3. Country specific implementation characteristics

6.3.1. Implementation in Vietnam

Consider EmOC-V. Ten years after being issued, the administration had not yet been updated. New managers and health staff had come in, without being acquainted with the EmOC regulation, so that only a few actors were still aware of its existence and many confused it with another regulation. Such updates might have included repetition of dialogue, discussion and debate in such a way as to facilitate internalization of the regulation and experience-based amendments.

The administration of this regulation consists of monitoring EmOC assignments in health services. Facilities have to apply for EmOC service registration and get it approved and updated yearly. Monitoring and supervision visits to public health facilities are supposed to be carried out by teams manned by different state institutions. In practice, these visits happen irregularly. Different teams supervise the private health facilities. All supervising activities face human resource shortages and insufficient supportive supervision skills.

Data from 2010 reveal persistent deficiencies in the coverage of required EmOC services at hospital level (comprehensive EmOC), as well as of primary care services (basic EmOC). The main reason is a shortage of human resources and inadequate facilities, which affects health services in general. This situation is particularly worrisome for basic EmOC in primary care community health centres. Delivery in these centres has decreased over the years, partially as a result of insufficient basic EmOC provision, consequent lower EmOC competencies, and decreased trust by the community in their CHC.

Since the director of the hospital plays a key role in motivating and managing its activities, the wide variation in regulation implementation across Vietnam depends very much on the motivation of local health managers to achieve the technical standards of EmOC.

6.3.2. Implementation in India

The NRHM and IPHS management bodies at district and block (taluka) level lacked proper training for decentralized planning and management, as well as an allocation of sufficient funds. In addition, the IPHS lacked an obligatory mandate and sufficiently clear definitions of what needed to be done through NRHM.

As far as the KPMEA Act (see section 5.1.3) is concerned, its implementation suffered major gaps, as did the three studied Indian regulations. These included low registration coverage of clinical establishments and inefficiencies in implementing corrective procedures for erring establishments and medical professionals.

Scarce reporting of abortion cases, lack of information on the number of licensed private facilities and insufficient legally trained public physicians characterize the MTP implementation. No quality follow up is carried out, as the MTP act is not a priority for the main implementers, namely the district health offices.

6.3.3. Implementation in China

Implementation of EmOC and PND regulations was efficient and timely, probably because devolution gave the Shanghai local government a role in health planning. It accomplished this task well because significant resources were committed: because Shanghai has a population larger than that of 172 countries in the world and a relatively high per capita income, its local government could afford a sophisticated central planning system.

In the case of the PND regulation, however, the control of working relations between PND centres and prenatal screening centres, went awry. We can assume that the local level did not clearly support the GR administration, since little is known about the GR implementation at hospital level: no GR cases were actually reported in spite of GR cases having to be carefully archived.

Other studies in China revealed more frequent strategies to maximise revenues, whereby users' and public health interests are pushed aside in order to generate more income for the facility and its staff [80-82]. This has led healthcare providers to take advantage of patients' buying power, providing, for example, unnecessary drugs, treatments, consultations, references, medical images and laboratory tests.

The organisation of the health system has been held responsible for this, as fees for service became established practice, while inputs and revenues benefits were largely managed and controlled by staff. Lacking control, providers could easily maintain their wealthy patients under unnecessary treatment for unnecessarily long periods.

The EmOC-C regulation may have achieved its technical and social objectives (see section 4.2.1) but at the cost of weakening the financial situation of involved health facilities, because (high) EmOC-rescue costs were either partly covered by the patient's insurance scheme (for resident users) or completely covered out-of-pocket for migrant users. Migrant users who are employed in informal sectors or unemployed do not have health insurance in Shanghai, only in their permanent registration places or hometowns. As in Europe, only officially employed migrants have insurance comprehensive enough to include health insurance.

At the same time, costs for rescuing poor migrant women were often waived by the first line EmOC-centers vis-à-vis the user, without being excluded from the expense budget. As a result, the economic burden for these centres grew. Recently, when lower grade maternity hospitals refer an EmOC patient to one of the EmOC-centres, they send a lump sum together with the patient as an informal way of sharing the costs for their patients. This raises two questions: What will be the ultimate

consequence of this growing economic imbalance? And why was this undesired economic burden not foreseen when designing the subsequent EmOC regulations to secure equitable quality EmOC-services to poor migrant women? This burden could have been predicted from better financial simulations.

With regard to impact of regulation on prenatal diagnosis (see section 4.2.5), the ANC case study shows another picture. While it may have achieved its core objective to simplify and structure PND services, its impact on the entire area of prenatal screening was deficient. Specifically, referrals between the income generating prenatal screening centres and the prenatal diagnosis centres remained disorganized. In a better resourced system, it would have been logical to integrate prenatal screening and PND, and to make their services available to all those in the population who would have been found to need them on the ground of standard risk criteria. As we have seen, the policy decision has been to make them accessible, without a gatekeeping function, to all those who could afford it.

In the case of the PND regulation, the issue is thus not mainly implementation. Rather, the problem lies in the underlying policy decision that was socio-economic in essence, as it intended to:

- Steer and promote the national high-tech medical equipment sector;
- Offer high quality care to those who can afford it;
- Let patients pay a proportion of the costs.

10 years after the PND regulation was issued, the policy economic determinants remain. The regulation has not been amended but evaluated twice. However, it is not out-dated because it remains responsive to the three non-health concerns mentioned above. The rapid rise in PND costs and technological development only change the return rate, without substantially modifying the policy determinants.

With respect to the PND strategy, the political concerns are thus:

- Whether the surplus is equitably shared amongst public hospital doctors and health professionals (to allow them to have a decent life) and patients (to allow them to access decent quality care).
- How should solidarity mechanisms be mobilized, for example between residents and migrants; rich and poor; low and high risk women?
- How to avoid sacrificing the costly PND benefits of lower mortality, morbidity and physical and psychosocial suffering and incapacity to the opportunity for economic advantage.

6.4. Comparing the problems with regulations implementation in Vietnam, India and China

In what ways do the administration structures differ in the three study countries in hampering / facilitating regulation implementation? Table 11 provides a description of structural problems in the three countries organised around questions that are thereafter discussed in a comparative way.

6.4.1. Structural problems in the 3 countries

Table 11: An inter-country comparison of structural problems with implementation of regulations

Structural problems with regulation implementation	Vietnam	India	China
Uneven implementation of a regulation as the necessary result a social configuration: **Who are the key players in and outside the health system?**	The complexity of the Vietnamese health system is reflected in the multitude and ambiguity of actors' roles involved in implementing the regulations. The 'consensus' culture amongst decision-makers leads to manoeuvring and to negotiating the administration and implementation of regulations according to the actors' or their constituencies' interests. In turn, this reduces prospects for effective regulations.	By virtue of the Indian democratic system, parties leading States and the Union are not necessarily the same. Unfortunately, there is ambiguity in the regulation process between central level and state level as the central GOI does issue national regulations, but depends on the States to implement them. State administrations generally decentralize the regulatory administration down to the district (in charge of the regulatory management) and the "block" level (of health	China retained a central planning capacity at the level of local governments such as Shanghai. We saw that the size of the town and its wealth may explain the success of its EmOC-C regulation. Shanghai municipal health authorities thus played an important role in the timely implementation of the regulation. A large number of actors were all too aware of the political cost of the alarming levels of maternal deaths among pregnant migrant women in a city like Shanghai. The 'local'[o] government administration channelled these energies.

[o] We use the quotation marks because the population of Shanghai is bigger than 162 countries in the world – which suggests that if central planning may be too big for China, some such capacity is needed in smaller public entities.

Structural problems with regulation implementation	Vietnam	India	China
	A striking feature, shared with India, is how the private health sector stays well outside regulatory fields in Vietnam.	care services). Some regulatory administration units were installed - without proper skills or sufficient training Though diverse actors participated in the design, implementation was entirely left to public officials, mainly at district health office level. Since most studied regulations are of the enabling type, with no obligatory mandate, these offices adjust decisions to their own local priorities, which may depart from the regulatory theoretical objectives. As said earlier, the private healthcare sector mainly stays outside the regulation fields	For the professionals, it worked for other reasons. The heterogeneity of (public) actors led to combined efforts in the case of EmOC regulation, under tight state-led control by BOH and SWHI - perhaps because the regulation offers a solution to a political problem without acting upon health system integration and coordination or changing most work habits. This is less the case with respect to the PND regulation, where discrepancies persist between providers of lucrative screening services and actual PND. With regard to GR regulation, its implementation is left to the discretion of hospital directors, as control or reporting does not happen systematically. Control

Structural problems with regulation implementation	Vietnam	India	China
			and reporting thus inevitably occur inequitably across the territory.
Whether regulations are implemented in good time or with delays	Delays were observed in the implementation of the sex selective abortion regulation.	Delays in the case of EmOC IPHS were due to ambiguity between national and state-level interpretations of the same regulation content. The GR CPA act was really never intended for the health case user's benefit.	No delays were observed.
Appropriateness of regulatory decentralization	Decentralization of regulation administration did not lead to improved effectiveness in detecting offenders because of excessive workload and lack of skills at the periphery. The move rather reinforced the already	Inspection, verification, and approval of private establishments for conducting MTP were decentralized to the district level but in practice, they were not fully undertaken, due to low prioritization of the issue.	In Shanghai, regulatory decentralisation from national to municipal level enhanced and led to success in the case of the EmOC regulation – but not in the case of the PND regulation - that appears out-dated. Amendments

Structural problems with regulation implementation	Vietnam	India	China
	existing ambiguity between the roles of actors at different levels. Delays in implementation (for example with the SRB regulation) were due to incomplete health reform processes and/or reorganisation of main regulatory actors (GOPFP). As a result, the already scarce resources for monitoring and evaluation prevented due control activities.	Waiving a private institution's MTP registration requires it to be registered under the Clinical Establishment act - which it may not always be. As a result, under-reporting and non-adherence to MTP norms are frequent. Of the CPA cases that get adjudicated for health, the "benefit of the doubt" is often given to doctors, due to the subjective nature of the cases related to medical negligence.	could be on their way. At the municipal level, the regulation implementation is 'state-led' by the Bureau of Health.
Other administrative features of control and sanctions / incentives management.	Poor health facility performance in implementing a regulation can be used as ground to cut down on its funds.	Unknown.	Poor health facility performance in implementing a regulation can be used as ground to cut down on its funds.
Extent to which regulatory implementation is sufficiently financed -	The three studied regulations were insufficiently financed. Staffing for inspection and control was generally	IPHS had the advantage of being at the core of the national strategy (the NRHM programme). EmOC in FRU hospitals became	The regulation process was sufficiently resourced. However, this cannot be said of the conditions under which the

Structural problems with regulation implementation	Vietnam	India	China
including financing of control and sanction	insufficient, of poor quality or poorly motivated.	well-equipped in that sense, but other resources were not made available. Implementation of MTP was hampered by poor collaboration at district level and by providers' lack of reporting.	regulated services are provided. Most health facilities have to generate their own income, which can work against the regulation's expected effect.
Extent to which regulations were evaluated and consequently amended	In all studied regulations, the government has been slow in reacting to, updating or amending regulations, although they had obvious and multiple flaws in design or administration.	Only MTP has been properly evaluated in its 40 years of existence. Regardless of disappointing results, this has led to one amendment only, of dubious effectiveness.	EmOC regulation is part of a consistent continuum of regulations. Poor maternal health among migrants in Shanghai has prompted both evaluation studies and consequent updating and amendment of relevant regulations. This is in contrast to the PND regulation. At the time of issuing, it was the only regulation for birth defects detection. More than 10 years later, PND service costs are outdated and technology is way ahead of the regulatory content. Yet no amendment has been carried out.

Structural problems with regulation implementation	Vietnam	India	China
			Even if a true concern for birth defect control had sparked the definition of PND services' regulation, its implementation (without updating or amendments) did not reflect such a concern for PND as a public good.

6.4.2. How does the configuration of key actors (in and outside health systems) prevent a homogeneous implementation of regulations?

Stakeholders in regulatory processes advance their interests by using authority, manoeuvres, negotiations, and persuasion. The current status and conditions of health facilities are prone to such freedom in regulation administration: health facilities are on the blurred border between a public and a private status, which leads to the involvement in regulatory processes of multiple actors with opposing visions and interests.

The freedom of actors' to manoeuvre is compounded In Vietnam and India by ill-planned, incomplete health reforms and, in India, by the state vs. central government rivalry. Centrally-designed regulations and guidelines are 'handed over' to provincial and district authorities (in China and Vietnam) and to States in India. This difference is important since political homogeneity is greater in Chinese and Vietnamese administrations than in India. Even if it is acknowledged that Vietnamese and Chinese history and geography have resulted in powerful, large regions, the homogeneity of regulation implementation is nevertheless expected to be greater than in India because of a more homogeneous control of Vietnamese and Chinese administrations by the political power (parties governing India and its States are not necessarily the same). Technical issues were also at stake. Regulations were generally disseminated without sufficient explanation, expanding the room for interpretation by the actors (see section 8). In this process, structural weaknesses of government administrations limited accountability and reflexive utilization of control outputs.

Distinctively, China retained a relatively strong, central planning capacity, combined with an effective administrative devolution to the (Shanghai) municipal health authorities. This arrangement defines and reduces fields for interpretation, manoeuvring and negotiation by local actors. The Municipal BOH is key in health planning. Its planning capacity, probably enhanced by a long involvement in healthcare delivery, has been used to allocate regulatory resources.

The Shanghai BOH stressed accountability of regulation inspectors (recalling thereby the importance of controlling them) and health professionals, which proved to be a key asset for the EmOC regulation. If it did not work for the two other regulations, it is probably because of the PND regulation design and low political priority put on GR. Notice that the PND design had to be compatible with the interests of numerous economic actors, for example those selling high tech medical equipment to the government, and to hospital and prenatal screening unit directors.

A strong commonality across countries is the little regulated private sector. The EmOC-V regulation pays lip-service to it without implementing it at all. In Karnataka as in Vietnam, the private sector is not registered and the illegal one is huge. In China, it is said that there is an important, unregistered private sector. However,

hospital autonomy limits the regulatory capacity of government administrations, although less so than with purely private structures (section 9.2, table 14).

6.4.3. Why are (or are not) regulations implemented in good time?

Our appraisal of timeliness in implementation of the studied regulations is limited by their lifespan. Of the 3 countries, China scores best on timely definition, implementation, monitoring and evaluation – although with problems in feedback and amendments. It is probably the relative degree of political importance of the underlying problem that resulted in EmOC-V and EmOC-C being rapidly amended, but delayed in the case of SBR-V and MTP-I. With regard to the PND regulation, its lengthy, untouched existence suggests that it continues to fulfil the same economic role as a decade ago.

6.4.4. How does decentralization impact on regulatory implementation?

A priori, decentralisation (e.g. of regulation administration and detection of offenders) raises issues with increased operational and administrative costs while in theory promoting gains in effectiveness.

Regulatory implementation has been decentralized in an intended and organized manner in the case of EmOC-C. With regard to GR-C, its administration was not decentralized. Rather, its implementation was left to the discretion of hospital directors.

Regulatory decentralization may be a component of global devolution of government administrations – with the Indian CPA Act being an exception. As stated earlier, diverging political agendas are likely to bias the interpretation of a centrally designed regulation and to skew or minimize its effects.

In Vietnam, decentralization of regulation administration reveals peripheral instances coming to themselves – giving rise to variable implementation with few rules of the game.

Finally, Vietnam and India regulation administrations disseminate regulations as information-giving processes, while debate and exchange of experience appears more frequent in China.

6.4.5. How do administrations manage control, sanctions and incentives?

Vietnam and China have an appraisal system to identify well-performing health institutions, which are rewarded with extra funds[57,73]. These may be institutional or targeted to providers. Poor performers may lose these extra funds, with a possible catch-22[p], leading under-financed health facilities to sub-standard performance and further punishment by having their funds cut further.

[p] A catch-22 is a logic term for a dilemma or a paradoxical situation.

It is likely that these reward and sanction mechanisms influence providers' and controllers' interpretation and implementation of regulations, as well as reports on their effects. Furthermore, performance beyond the target may not be encouraged and indicators may sometimes be manipulated. At least in the domain of Chinese family planning and population policies, cases have been reported where collection of statistics and record keeping were subject to manipulation to conform with regulations, since the process is overseen by officials who are often unwilling to uncover any violations of the rules[74,75]. This situation was reported to exist in the case of the China EmOC regulation.

While reportedly seldom used, it may have encouraged the manipulation of indicators by street bureaucrats. During the HESVIC study, researchers in China found it difficult to access relevant data on performance-based indicators in all three case studies, because of confidentiality rules. In the matter of MMR statistics, we were advised that critical assessment of the accuracy of the vital registration data was warranted[22].

6.4.6. Is regulatory administration sufficiently financed?

We refer here to the cost of control, sanctions and rewards. In general, health budget and resource allocation can vary from being based on history (for instance the previous year's health budget plus 10%) to an objective responsive (for example to district health plans).

In the three research countries, funding of regulatory administration was generally insufficient although much better in China. As a result, in most cases, resources were not available to finance simple inspection and control visits by designated inspectors. This situation affects the entire regulatory structure in Vietnam and India.

In India and Vietnam, inspectors are civil servants (such as district medical officers) who receive a budget for healthcare delivery and regulatory administration. Its use requires trade-offs bearing opportunity costs (see Section 6.4 for more details).

6.4.7. Are regulations evaluated and consequently amended?

We have seen that factors of implementation gaps include the influence of medical and industrial interests (regulatory agencies are often constituted of medical professionals, and always rely on their cooperation), of discord in inter-departmental relationships, and of severe constraints in numbers and capacities of personnel for control and regulation administration. The above description thus indicates that in Vietnam and India, and to some extent in China, most regulations are flawed from design and their implementation lacks financial support. They are hindered by ambiguities in actors' and institutions' roles, in particular in controlling healthcare services[76,77]. The private sector often escapes the regulations' sphere of influence, even when it is intended to be regulated as per EmOC-, Ab–I, and SS-V.

To analyse these hindrances, common sense and debate amongst decision makers are unlikely to result in effective regulation of a complex sector, as is healthcare delivery: regulatory effectiveness needs to be tested in practice because the complex environment and the conflictive nature of regulatory processes often strain their operationality. In other words, there is a need for a managerial loop designed to control the attainment of objectives and to periodically adjust regulations. Besides, implementation strategies have to be constantly readjusted. However, several policy makers and inspectors appeared to believe that once properly designed, and with the right policy goals, regulations are implemented by themselves.

Conceptually, we may distinguish three types of feed-back loops: monitoring of the regulation effects; processing feedback on issues detected in regulatory processes and policy evaluation. Our study found that the first two were absent or incomplete and we suspect that regulatory policies are not policed either. According to country research reports, information on (poor) regulatory results is rarely available to regulation administrators and regulated staff. In some cases policy makers do have the required information, but it is not used to amend or otherwise update the regulation content[78-80]. Our study gave limited answers as to why this is the case, and we cannot rule out an issue of administrative culture.

The creation of unintended and undesired providers' defensive behaviour as a result of regulatory control has been reported mainly in the GR cases in India and Vietnam [58,81] . Evasive conduct by health staff was noted in the case of the SBR regulation in Vietnam[q].

6.5. Conclusions on issues with implementing regulations in the three countries

Behaviour of health systems is difficult to predict. The reasons often cited for this observation are persistent resistance to change; differences in values and interests; and changing clinical and reporting behaviours in response to regulations[82]. The scientific literature generally agrees that there is an absence of research into health regulation processes, especially in LMIC. The few available studies tend to agree that there has been very little impact of such regulatory approaches on healthcare quality[67,91]. As was reported for a series of health sector reforms carried out over the last 20 years in seven countries, the reasons for this lack of impact can be very varied and would apparently show few commonalities across different countries[83]. We shall challenge this view in our section 9.

Our studied regulations were generally not implemented effectively, which generated a series of unintended negative consequences (see section 4).

[q] where doctors spoke in codes to make the gender of a fetus known to its mother

In health districts and services, implementation is led by an administration, theoretically in charge of disseminating the regulation amongst thousands of professionals. If the regulation is to be internalised by these professionals, controlled in its application and evaluated in terms of its effects, it should not simply be disseminated to the relevant professionals but should be discussed with them.

In theory, these activities will lead health professionals, who enjoy the privilege of the "black box" consultation (protected by medical confidentiality), to adjust their clinical decisions in accordance with public benefit regulations. However, health professionals often become (think and behave as) economic agents – in line with both prevailing health reforms and economic transition. This represents a challenge for updating and making operational medical ethics. In spite of their theoretical raison d'être, professional associations are not inclined to embark in this (new?) mission (see section 10.1.4).

Professional organizations in India have been accused of self-serving interests that make them unfit to host self-regulatory mechanisms (see section 5.2.2 and 5.3.2) and users' associations are either too fragmented (in India) or virtually non-existent (in China and in Vietnam) to finance the top level, independent expertise needed to assess and negotiate government investments in health.

In fact, the scientific literature does not contain evidence-based experiences suggesting that professional self-regulation and users' control of health care delivery would be more effective than government administration to tame the effects of health markets in LMIC[84]. The 2008 Rockefeller Foundation report "Public Stewardship of Private Providers in Mixed Health Systems"[85] proposes regulating the system through professional associations. These associations have often tried to turn health policies and regulations to their own advantage; regulation by professional associations is fraught with conflicts of interest[86].

Indeed, the myth that self-regulation was somehow superior to governmental regulation[87] has been shown false in cases documented long ago[96,97]. The Lagomarsino Rockefeller Foundation report itself later mentions several drawbacks of self-regulation, namely:

- "Self-regulation by medical professionals has been prone to regulatory capture. Regulation is then misused to serve professional interests rather than those of the public.

- Medical associations have been anything but proactive in taking disciplinary action against medical malpractice or patient complaints; this is especially true when cases are so bad that they need to be taken to court. Professional associations have not publicized cases of malpractice for fear of damaging the medical profession's reputation.

- Registration and licensing of professional and accreditation of medical facilities, although necessary, have been inadequate in reorienting the private sector‘s contribution towards efficiency, affordability, and equity in health care; even licensed practitioners misuse privileges and are responsible for medical malpractice and medical negligence.

- There is limited empirical evidence supporting the effectiveness of professional certification. Accreditation of private health facilities has had a mixed record of success in low-income countries.

- Control over the behaviour of private practitioners has been shown to be ineffective unless underlying financial incentives are corrected.”

7. Regulations aimed at “public” and “private” sectors

7.1. Section objective

We devote this chapter to comparison of the public and private sectors’ regulatory paradigms across the 3 countries and across the case studies. This theme sheds an unusual but, we believe, an important light on commoditization of healthcare in LMIC, the most significant feature of contemporary (inter-) national policies.

From experience, and press reading, it can be reasonably assumed that challenges in regulating the two sectors are not similar. For instance, accreditation in the government sector may be biased by political affiliation, while enforcing tariffs and prohibiting dangerous behaviours appear to be more common in private facilities.

By hypothesis, we will compare regulatory challenges between the two sectors in what we believe to be the most important determinants of discrepant performances:

- The nature of (preventive vs. curative; general vs. specialized; etc.) care activities;
- Human factors, such as motivation, professional and political identity;
- Managerial characteristics, such as health services statutes and organization; and
- Planning capacity.

In this section, we shall discuss the features that distinguish the regulation of public vs. private sectors in the three countries, with the aim of advising political and managerial decisions.

7.2. Resources and organizations: an insight into regulation implementation

There seems to be a general agreement on the role of regulation vis-à-vis private sectors, that includes State for-profit hospitals (in the context of management property split). These key functions were delineated in our Table 2. They appear in our proposed regulation taxonomy (see section 3.1.1.). Some of its regulations types are by definition mainly relevant to the commercial sector. Notice that some NGO as well as government services may develop commercial activities, which we shall here equate to the arrangement where hospitals’ benefits are shared amongst their professionals.

7.2.1. Private vs. commercial and public vs. social: a terminology caveat

We distinguish the mission and the status of health facilities[88]. Hence the following Table 12, a two by two one that disentangles these two dimensions:

Table 12. Mission and status of health facilities

Mission/Status	Government	Private
Commercial	A	b
Social	C	d

In the present document, we use the terms

- Commercial as for-profit, for example when profit is not socialised but is private. Notice that in some countries, commercial entities are by law obliged to maximize their benefits so as to maximise the benefits to their shareholders. Even if this is not the case in China, India and Vietnam, it is a reasonable assumption that many sectors involved in healthcare (insurances, pharmaceutical and medical equipment sectors, hospitals and care delivery, etc.) tend to abide by this rationale.

- Social as publicly-oriented. Principles describing the features of healthcare when they are delivered with a concern for a balance between public and patients interests were formulated to distinguish them from healthcare delivery with a commercial objective. Notice that other such principles were developed in the same document for the publicly-oriented management[7].

- Government status encompasses national, federal, provincial, state, municipal health facilities or organizations, private being all the others.

The highly prevalent Chinese and Vietnamese public hospitals endowed with a for-profit mission thus fall in the “a” category of Table 12.

7.2.2. A priori specific features of regulatory requirements in the private and commercial sectors

One listed regulation purpose is specific to the commercial sector, namely, in remedying market failure, for example on efficient pricing, Other purposes are shared with not for-profit, such as generalizing a public health benefit, securing the availability of public goods and prescribing technical standards or political mechanisms for decision making.

The relevance of the social / commercial distinction lies in the attempt and capacity of a regulation to address differences in the motivational structure of healthcare facilities (see section 7.2.2);

Regulations may aim at correcting health market characteristics in LMIC, such as information asymmetry, market capture linked to insufficient number of sellers trading identical products, equal chance that stocks are under –or overvalued according to healthcare accessibility, and biases linked to the existence of public goods. We shall see that these characteristics are generally absent from regulators’ concerns in our nine studied regulations (see section 7.3).

With regard to regulatory means, a government that owns hospitals has a direct leverage on its health professionals – their wage. Another specificity of the private sector is that its professionals generally refuse injunctions not supported by sufficient payment, and that, with regard to prohibiting regulations, their autonomy makes them particularly difficult to monitor and control. In Vietnam, for instance, most interviewees agree that sex selection is done in private facilities, although often by professionals with dual practice.

The targeted providers of healthcare delivery or financing represent our fourth category of criteria. They were the object of a discussion above. [7].

None of the studied regulations are really administered and implemented in the private commercial sector (although the GR-I regulation is more frequently used in the private sector, this probably remains a rare event). One could argue that private service users mobilize the Indian GR regulation more often than public service users. However, the very low utilization rate of this regulation (see section 4.2.2) does not make this difference significant.

In theory, Chinese local government, Vietnamese provincial and Indian district health authorities are responsible for monitoring and controlling private services. Yet the interviewees generally acknowledged the existence of an unregistered (sometimes unqualified) private health sector. The country case study in Vietnam learns that in practice, there are numerous unregistered facilities. In addition, there is a far larger and mobile group of private medical providers including those who are traditional healers and without a fixed clinical location. These groups are very active, especially in rural areas, and often visit patients in their homes[89]. But, on the number of personal communications on this issue, it is reasonable to assume that in none of our study regions were government administrations able to produce a list of existing private practitioners and clinics - possibly suggesting lack of interest.

In India, private services dominate the health sector. For instance, a study in Madhya Pradesh (a state in Central India) by Karolinska Institute discovered that 75,6% of the 24,807 qualified doctors works in the private sector. In addition there are another 94,019 qualified non-doctors and another 55,393 SBAs and 89,090 untrained healthcare providers, last two categories operating for 90% in rural areas[90]. There is no estimate of the number of legal private practitioners. If the KPMEA Act (2007) had been implemented nation-wide, India might have had an idea of these figures. But its implementation in Karnataka State, for example, remains blocked by private interests[56].

Since this information is key to measuring regulatory effectiveness for the private sector, and since it is often recognised to be such, one may deduce weak political will to regulate the private sector in the three countries. This is confirmed by the project findings that regulatory control services for private care delivery are badly lacking resources in all three countries.

There is another hint that might lead one to suspect a political function of some regulations. For instance, one might wonder why it is that, as in the EmOC-V case, a regulation on maternal health planning standards should be amended only to include the words, “regulation of the private sector,” without any clear intention to implement it in the Vietnamese setting. Notice that this political, discursive function of a regulation in no way implies some conspiracy theory: it may simply denote a political culture.

The argument that a regulation has a primarily political role can only be considered a valid hypothesis if a regulation does not achieve its objectives, is not implemented reasonably, and is insufficiently resourced – and is nevertheless not amended (as is the case with several of our studied regulations, see table 1). Otherwise, the satisfactory functionality of a regulation may be assumed as the raison d’être for its long-standing existence.

We have seen that the private sector prefers to avoid being regulated (see section 9.4.2) – which may, to a variable extent, and according to countries and regions, result in a total lack of regulatory effectiveness. By hypothesis, the political raison d’être of these sets of private sector regulations that remain unused in practice could be to give a floor to ‘public private partnerships’ by convincing citizens that:

- Public services are sufficiently equipped in maternal health departments (EmOC regulations) and that private and public services are sufficiently responsive (GR regulations);

- Private healthcare delivery can be regulated. This political message is central to facilitating market expansion, the key feature of “transition” economies.

7.3. Regulatory “software”: an insight into regulations content and modus operandi

We examined regulations’ modus operandi in terms of what they do and what they do not do (see section 3.1.2), with reference to categories of our regulation typology (see Table 2).

The three EmOC regulations provide standards for resources. In so doing, they are obliged to limit their ambit to government services. Indeed, these standards apply to those services enjoying a certain level of inputs. In the three countries, (local or national) government services are the only ones that receive a core funding and may thereby not need additional resources to apply some of these standards.

As far as EmOC-V is concerned, private hospitals could in theory have paid for an increased insurance reimbursement but under the prevailing financial circumstances, this would not have been an economically sound decision.

Thus, although the regulations' wording claims to address both sectors, health planning standards, as in the case of the EmOC-V and EmOC–I regulations, cannot be applied to private sectors unless the government contracts maternal care out. This is not the case in Vietnam and China. Recently, the Indian Government has tried to purchase care from the private sector at fixed costs. For example, a National Health Insurance Scheme (RSBY) that has enrolled more than 29 million families (150 million individuals) has fixed the price of more than 600 procedures and reimburses private and public hospitals according to these fixed prices. Those hospitals that need the business do, in theory, provide the services, while the others opt out. This initiative appears to have failed and to be currently abandoned[91].

Similarly to the Chiranjeevi scheme in Gujarat[92], the Karnataka government had introduced the Thayi Bhagya scheme in the districts of northern Karnataka. Private obstetricians were paid a flat rate of Rs 2,000,000 if they conducted 100 deliveries in their private hospitals, irrespective of whether these were normal deliveries or Caesarean sections. The idea was to improve access to maternal care by using private providers, while at the same time assuring quality by using financial deterrents to curb unnecessary Caesarean sections. While these schemes are still under review, contracting-out and health-insurance schemes in India, were deemed a failure in a recent evaluation[91]

In fact, even industrialized countries are facing huge difficulties with contracting out procedures to equitably distribute healthcare professionals within their borders (for example, 'medical deserts' in France and the USA). This is because markets lack effective devices for redistributing professionals and generally lack the tools needed for effective planning[93,94].

The EmOC regulations, because they are enhancing regulations and because they largely address health systems inputs in regions where no resources have been directed to private providers, are by nature tailored to public services. As explained at the beginning of this section, their input standards are simply irrelevant for regulating the private sector, except in China where the EmOC regulation does apply to the private sector as well. In addition, of the three regulations, only the Chinese one addresses process as well as inputs. It is therefore the only regulation whose content has the potential to have an impact on the role of health professionals' knowledge in securing quality care. Because maternal care is in practice a quasi-monopoly of "public" hospitals, it is in government hospitals that this regulation impacts on quality of care - although it is formulated to address both sectors.

Remark: The doctor patient information asymmetry is probably the most important threat to health market efficiency. By definition, only regulations also addressing (clinical) healthcare processes (criterion 12 in our typology) are potentially capable of correcting its effects.

None of the studied regulations address another important market failure, namely unfair pricing in private, commercial services. In India, for instance, such pricing can possibly be related to monopoly positions in poorly served areas. It appears that Vietnam and China may have managed to enforce a pricing policy in the public (autonomously managed) hospitals. However, the project information suggests that none of the three countries appear to be willing to enforce a pricing or care quality policy in their private commercial sectors. In Vietnam, for instance, the Law of examinations and treatment specifies that private health facilities have the right to decide on pricing (but that they should publicly post the prices of services).

To what extent are actual prices in autonomously managed government hospitals more easily regulated than those of purely private commercial services? The Vietnam report[95] states that: "…, there is poor compliance in the private sector with reporting and ensuring quality of services. Moreover, no sanctions were applied to this poor compliance."

To cope with their relatively weak regulatory capacity, Vietnam and China retained some direct authority over the hospital network and planning capacity, which enabled their hospitals to operate partly under market mechanisms and partly under centrally planned economic mechanisms, the latter enabling more effective regulation than the former.

All (but the SS-V) regulations promote access to a social benefit. With regard to General Agreement of Trade of Services negotiations (India and China signed in their health sector[96,97]), social benefits are acceptable in domains defined as public goods. The three countries treat quality of maternal care as a public good. This is not the case with general care. The consequences of this will be elaborated in 10.5.

The 3 Grievance Redress regulations, the SS-V regulation and the Indian MTC are concerned with private services (table 1). In practice however:

- The MTP regulation is largely circumvented by illegal abortions in private services (see effects chapter);
- The SS-V regulation has failed to curb sex selective practices in Vietnamese private outlets;
- From a quantitative viewpoint, none of the three GR regulations is significantly used.

Virtually none of the privately aimed/targeted regulations studied by HESVIC was actually implemented in the private for-profit sector. Whether this category of regulation is ''manageable' in the three countries remains a burning question but available data suggest that the answer might be negative.

None of the regulations studied by the HESVIC project targeting the private sector envisages communities' or users' participation as a key mechanism in regulation implementation or in the management of (publicly oriented, socially motivated) health care services. This was to be expected: For-profit clinics are unlikely to recruit or even tolerate any community participation as it could lead to cost-accounting transparency. In several industrialised countries, mutual aid associations proved capable of enforcing some external control on healthcare providers when they achieved an administrative and financial development compatible with purchasing high level expertise and when their representatives managed to penetrate state administrations involved in regulatory activities. By contrast, co-management with users/communities representatives could be a clause in regulations and in contracts with publicly-oriented first line services and peripheral hospitals in the context of management contracts issued by public administrations.

7.4. Appraisal of the effects of probable regulatory mismatches in public and private sectors

As mentioned above, observations emerging from the HESVIC study can be viewed as plausible hypotheses to be confirmed by future studies regarding the impact of regulations on access to and quality of care and the place of regulations in health policies.

1. **The three GR legislations are those that (in our sample) come closest to non-technical quality of care.**

These regulations, however, conceptually refer to avoidance of mistreatment, inhuman behaviour and psychological and verbal violence, rather than promoting a positive model of healthcare delivery (notice that people centered policy is not synonymous with, and does not automatically imply, patient centered care). Furthermore, they make no differentiation as to the quality of care expected from public and private services. Laypersons tend to equate decent, human welcoming with patient-centered care. Obviously, private and public services would need more than smiles to reach acceptable standards.

Even so, an important proportion of complaints submitted to GR regulatory administrations are related to poor quality of care. The fact that in India the GR regulation is mainly used in the private sector may not indicate less acceptable care but rather that it is primarily the wealthy who benefit from this regulation, since:

- Some administrative literacy is needed to mobilize it; and,
- The wealthy are uniquely exposed to a wide variety of clinician behaviour that influences consumers' expectations and that may simply not be available in overcrowded, under-resourced public facilities (in Vietnam and China) or in public facilities that offer a limited array of disease control and MCH interventions (in India)[98]. Generally speaking, there is probably a

gradient in variety of healthcare exposure. It increases with the buying power of social groups, which influences expectations in healthcare delivery and thus the use of GR regulations.

2. **The EmOC-C regulation appears to have been more effective than the two others. Could this mirror the difference between public as opposed to private targets?**

Possibly. However, the EmOC-C regulation has an important, yet narrow, health problem focus while the two other EmOC regulations provide general standards for an entire maternal health system. The former is therefore expected to achieve its objectives more easily. With regard to our conclusions, this feature limits the potential for comparison of the effects of the three EmOC regulations.

Besides, EmOC regulations are the only ones that actually describe processes, for example clinical, managerial and pedagogical. Narrow scope and process orientation could thus be seen as enabling conditions for public services in a market (economic and political) environment. Alongside health outcomes, these features can be viewed as indicators of:

- Political will boundaries;
- A concern with social harmony understood as social stability (seen as a public good);
- A will to handle economic interests as a key health sector issue.

An alternative policy choice in China might have aimed at reducing the incidence of critically ill pregnant women in migrant populations as a key strategy to reduce maternal mortality. This more equitable but ambitious approach would have reduced morbidity and suffering in the migrant population. If it was confirmed that most rescues were of migrant women, this would indicate important differences in obstetrical morbidity between resident and migrant pregnant women, and a health policy conceived to reconcile contradictory, non-health objectives and constraints common to contemporary policies[99], for example:

- Avoids subsidizing some but not all actors of healthcare markets;
- Supports a public sector, largely self-financed, that permits, at low cost, the government to:
    i. keep a control and regulation capacity,
    ii. channel operational, public health interventions through healthcare delivery (as in EmOC-C) thanks to targeted financing,

iii. thereby minimize operational budgets of social affairs ministries,
iv. retain a health planning capacity (of PND centres, for instance),
v. devote most of the government budget for social ministries to capital investments;

- Avoid prejudicing doctors' interests; and,

- Achieve a minimal degree of social solidarity compatible with economic development and social stability.

3. Poor regulatory effectiveness promotes commercial practice in healthcare delivery in both public and private health facilities – but with heavy human consequences.

A key consequence of lack of regulatory capacity is to be found in quality and accessibility of healthcare in commercial health facilities (as in the definition above). The HESVIC project confirms a statement often found in international literature: Equitable access to healthcare cannot be expected in unregulated or poorly regulated markets[85].

7.5. Regulatory difficulties raised by blurred public / private borders

This section examines problems specific to regulating health facilities and care delivery in settings that feature "increasingly blurred public / private borders'.

We use the expression "blurred public / private borders" to refer to:

- Underfinanced public services with a social mission (for example, as a consequence of structural adjustment-like programmes) leading to dual employment. Where doctors can practice in the public and private sectors and where regulation and control are weak or non-existent, dual employment is likely to generate, for example, patients' poaching; absenteeism; private, unpaid use of public investments; and material theft;

- Health facilities autonomously managed (with a management split from its property status);

- Services being contracted out.

While other features such as franchising are not explored here, these economic patterns amount to progressively expanding care commoditization within public facilities. In theory, the term "blurred borders" could also refer to situations in which commercial healthcare delivery becomes imbued with public concern (tentatively leading to more equitable access to care). However, as put by Lagomarsino et al this can only be the result of an effective regulation of the commercial sector, which is

unlikely to be the case in the three countries. Rather, be it by virtue of resource starvation or contract, clinical practice in government services tend to become commercial and unlikely to deliver publicly-oriented individual healthcare[7].

The comparison across countries of the mechanisms explaining regulation effectiveness / failure in the three countries sheds a light on the particular challenges faced by regulations geared to make these blurred public private boundaries work – in terms of their impact on access to care, cure rates and avoided suffering; inefficient use of public funds; health professionals' and workers' frustrations known to be associated with expanding health markets[r].

a. Dual employment in under-financed public services

Dual employment often[100] entails poaching patients; illegal contracts (between public sector professionals and commercial ones, or between two private entities); selling unnecessary care; unfair pricing; raising household expenditure on healthcare; inappropriate use of health facilities; and referrals of dubious relevance.

Other issues include unlawful use of public equipment and drugs and misuse of public funds, for example with commercial arrangements between providers – which are not prohibited by most regulations in the world[111-113].

What do these issues with dual employment entail for the patient in his/her experience with healthcare delivery? In short, three categories of issues need to be avoided (i.e. subjected to regulations) if patients are not to pay the price of this transition:

- Unnecessary use of healthcare and denial of useful care;
- Paying for stolen equipment in public services;
- Higher insurance premiums resulting from inefficient use of funds.

GR regulations do not promote collective action to improve access to care (for example negotiations between doctors and users, co-management of public services or community participation) but rather address individual complaints.

Finally, dual employment could prove to be a condition preventing effective regulation administration, because civil servants administrating the regulations may have vested interests in those services that they are supposed to control, producing major opportunity costs.

Two key strategies for overcoming this difficulty are legal prohibition of dual employment for regulation administrators (which does not often exist in LMIC) and higher salaries to compensate for opportunity costs not incurred through not

[r] A vast scientific literature is devoted to this issue

engaging in commercial partnership with private clinics. This latter condition could prove to be a lethal one:

- Governments often face administrative, labour and legal difficulties in granting a substantial wage increase to a specific category of civil servants and therefore financial conditions do not often permit such compensation;

- More importantly, governments face financial difficulties to reduce the income gap between government and private sectors.

b. Management property split

The EmOC-C regulation addresses a management property-split problem while imposing selected processes and procedures on autonomously managed hospitals (for example bearing a negative impact on doctors' income). The fact that doctors' complain about the implementation of this regulation suggests some vigorously implemented regulation and a trade-off between patients' and doctors' interests.

We cannot rule out the possibility that government regulation of autonomously managed hospitals is comparatively easier than that of purely private ones. This is because the government's inputs (for example investments, equipment and constructions) carry leverage and because information on health inputs and processes in hospitals that "belong" to the MOH is readily available to it.

In the future, it would be interesting to establish whether or not there is a gradient in regulation feasibility, from centrally planned health services to private commercial ones, with autonomously managed hospitals (as in China and Vietnam) and, to a lesser extent, facilities contracted out and lying somewhere in between. This gradient would be related to the amount of inputs placed and authority held by the government in the health services, and thus to its leverage for exercising control over them (see Table 14).

8. The challenging role of actors in regulation design and implementation in LMIC

8.1. General considerations

To recapitulate, we have identified, from their effects, failures – and one success - in the content, design and implementation of various studied regulations. We next intend to understand the contingencies that enable certain actors (individual, social, group, etc.) to influence the regulatory processes concerned. We thus compare these roles and processes as to their effectiveness in being able to tackle successfully the administrative, technical and political challenges of regulating healthcare markets and public services.

The question underlying the discussion of contingencies is whether the actors' roles reveal structures typical of transition economies that would not be amenable to healthcare regulation – which will be addressed in section 9.

In what Elmore[101] called in 1979 a 'backward mapping exercise', our study thus analysed regulation processes and actors' roles from regulations' failures and achievements, assessed against their initial goals. We studied the role of regulation implementers, regulated staff, policy makers and regulation designers vis-à-vis the regulation's consistency with the health problem for which the regulation had been defined. To explain unsatisfactory outputs, we explored how the actors and networks view implementation problems. Such problems were found to originate from the lack of congruence between a central level policy and the local institutional setting that a regulation had to deal with[102]. We thus studied regulations as components of health policy and we interviewed policy makers to gain insight into these problems.

To be put into action, regulations, like policies, need resources and a structure of organizations and institutions. They also require a complex set of enabling social and political determinants that result in conflicts, communication and alliances between multiple actors. The actors' roles can either be studied from a top-down or a bottom-up viewpoint[103]. The former approach studies linear, (often state-led) prescriptive or prohibitive regulation implementation, to arrive at a normative viewpoint. The latter explores the settings in which multiple organizations exist and engage in dynamic interactions, which can lead to recommendations for socio-political strategies. With different case studies, our study addressed regulations' dynamics adopting both bottom-up and top-down perspectives.

Our study design did analyse and reveal power relations and dependency between actors, but did not go into a socio-psychological study of regulatory actors, for example how actors' values and agendas influence the course of a regulation process (with the exception of the Indian abortion case study that showed how professionals' values influence abortion pricing). This could represent an area for future research.

Different categories of actors were identified in HESVIC that may enjoy some degree of capacity to make decisions and take actions:

1. policy and regulation designers at different levels;
2. actors involved in the administration, implementation and oversight of regulations: service quality control commissioners, licensing and accreditation authorities, etc.;
3. the regulated staff abiding by the regulation: health facility managers, district, hospital and province medical officers in the public and private sectors, etc.;
4. users of services: women, patients and communities;
5. other actors with multiple roles in regulation processes: NGOs, socio-political groups, insurance companies, international agencies, etc.;
6. UN agencies in the context of Vietnam and India only.

Two cross-cutting categories need to be described. Firstly, recognizing actors' capacities and discretion leads to acknowledgement of the role played by street-level bureaucrats in implementing laws and regulations[104]. The HESVIC Glossary defines them, with Lipsky (1980)[104], as public service employees who interact directly with citizens in the course of their jobs and who have substantial discretion in the execution of their work. Public health workers (like social workers, judges, teachers) are typical street-level bureaucrats who grant access to government programmes and provide services. They do not simply implement the decisions of elected officials and other policy-makers but exercise power in interpreting regulations. They may or not act in line with the spirit of the regulations that they interpret. According to their culture, relations, knowledge and, more importantly, interests, they contribute to determine citizens' eligibility for government services.

Secondly, the invisible actors are those who aim at influencing a regulation, or at using it to their benefit or the benefit of their constituency. They may be economic agents, representatives of professional associations or of institutions. Their common feature is that they do not want their intervention to be disclosed. By definition, they are thus difficult to be identified and interviewed.

8.2. Summary of country findings on actors' roles and their effects

Table 13 on the next page summarizes findings in the three country research reports regarding actors' roles. We then examine how they pose challenges to healthcare regulation in the three countries.

Table 13: Main findings on the role of regulatory actors in Vietnam, India and China

The role of actors		
Vietnam	**India**	**China**
The role distribution between population inspectors and health inspectors is ambiguous. The existence of two administrations down to provincial level (GOPFP and MOH) makes the SRB regulation difficult to control, as it inhibits feedback. This is exacerbated as violation reports involve colleagues from public services working in private settings. When a violation is detected, the enforcement of sanctions still depends on the provincial health director. In the case of the GR regulation, inspectors are known to influence decision outcomes in favour of	Private providers are dominant in the Indian health sector. They operate in a highly fragmented and segmented system and in heterogeneous ways, making it difficult to regulate them, let alone to register them. Given the virtual absence of control, private providers' interpretations of any regulation are key to its effectiveness. Inspectors and health professionals in general have interpreted the ('enabling') MTP regulation in a very restrictive way. Their economic agenda could explain this: public OBGYNs did not want to encourage competition from primary care physicians; primary care physicians did not want to encourage competition from lay health workers private specialists did not want to encourage competition from public providers, etc. These actors thus often interpreted the regulation to mean forbidding competition from less qualified professionals on the grounds of skill	The EmOC regulation was intended to overcome the consequences of EmOC care fragmentation[s] in patient referral. 1st and 2nd referral hospitals lacked the capacity to rescue CIPW, leading to delays and deaths, mainly amongst migrant women. The problem addressed by the PND regulation was to improve the PND providers' capacity and the service quality in general. The Shanghai municipal BOH issued the EmOC-C content, requirements and objectives. The Shanghai municipality together with EmOC- and PND- specialists (and with MCH institutes), initiated and accompanied the regulation process. Inclusion of a university in the regulation design ensured that its technical rationale was based on evidence. Some observations in the regulation outcome

[s] We define system segmentation in terms of breaches in care continuity linked to the existence of parallel health systems (generally for different social categories of patients). We use the term system fragmentation to define health services that are not co-ordinated with one another, lack effective systems for the transfer of information between them and are inaccessible to one another's patients, despite belonging to the same system (for example, a social security network of health facilities).

The role of actors		
Vietnam	**India**	**China**
health personnel. Public providers are reported to strictly follow sex selection prohibition. However, to the extent that about 80% of them work in the private sector, it is possible that they do violate the regulation in their private practice (section 4.2.3). Women's union representatives and mass organisations were involved to a small extent in the drafting of the SRB regulation. Users and patients are not an organised collective actor, being unable to form associations capable of mobilizing their members around common objectives[105].	requirements. The same mechanism has led abortionists to misreport abortions and perhaps to promote abortions by unqualified providers when some health professionals refused to abort, even though they were entitled to do so. Factors acting upon MTP actors have economic cultural and technical dimensions and do interact. For instance[51], health professionals may increase their abortion prices when the patient is an unmarried girl, a widow or a divorced woman. Their behaviour mirrors a fine combination of cultural judgement on the perceived legality/morality of abortion and profit seeking clinical practice. The CPA regulation only addresses healthcare that is paid for by the user. According to this definition, medical negligence is considered only when it occurs in the private sector and in public referral hospitals (in which healthcare is paid for). Public primary health facilities are officially free of charge and thus remain excluded from	expose key actors' roles. - Expensive EmOC-rescue in tertiary EmOC hospitals may not be the most rational option for curbing maternal mortality, as it does not address morbidity and secondary prevention. - Though actors from EmOC centers, municipal BOH and municipal Women's Health Institute advised on regulation content, they were not in a position to ensure that the work capacity of rescue centres would be sufficient or increased. The regulation thus resulted in excessive workloads in the five EmOC-rescue centres. - The EmOC regulation caused a financial burden which reveals a lack of foresight into the operating costs of the programme. There is today a significant increase in unpaid bills linked to the regulation's implementation[t]. EmOC rescue-centre

[t] In the HESVIC China Country Report (pp. 91), one migrant patient mentioned a hospital bill for EmOC rescue worth 24.000 CNY (4.000 USD). The average income of her family of grape fruit pickers was from 20.000 to 30.000 CNY per year. This user had to borrow from family and ended up paying the EmOC-centre 13.000 CNY out of her pocket - 12.000 CNY short. On pp. 117 of the same report, one interviewed EmOC-implementer mentions that unpaid bills (resulting from his EmOC-centre waiving bills for poor users) amount to around 100 million CNY every year, for just one EmOC rescue centre.

The role of actors		
Vietnam	**India**	**China**
	the regulation application field. In practice, however, district level administrators and lawyers tend to bar all public health facilities from CPA implementation, in terms of contradictory jurisprudence. Interviewees mentioned that scarce resources of public facilities justify their exclusion of the regulation ambit, "as seeking medical negligence redressal without resources is a misnomer"[106]. Even when controls are planned, monitoring and evaluation remain absent (as with the MTP regulation), incomplete (as with the GR regulation), or monitored results do not reflect the reality. This explains why grey and scientific data on abortion in India are so contradictory (see section 4.2.4). Lay health workers in public services represent the point of first contact for 800 million mainly rural Indians[107] who live on less than 20 INR a day. They are accredited social health workers, auxiliary nurse midwives. They were not given the permission to provide basic EmOC or	administrators and general financial planners were not invited to participate in design. The PND cost pricing has not been adapted / updated, which suggests that the EmOC-obstetricians in rescue centers and PND-experts - the staff to be regulated - were pivotal actors. Indeed, both took advantage of the regulation, as opposed to doctors in small units, who may have taken on an opportunity cost because peripheral hospitals reimburse some patient's unpaid bills to the detriment of their own finances and to the benefit of the large health facilities and their staff. The GR regulation is altogether different. It has not been a priority for the MOH, which reveals a regulatory focus on health institutions, and is targeted away from users. Although the EmOC regulation makes explicit the expected interactions and procedures, informal, individual relationships were sometimes reported to be more effective. Good personal relationships between officials from different institutions are an important aspect of

The role of actors		
Vietnam	**India**	**China**
	abortions. Still, most do it -illegally. Their patient referral patterns do not depend on the content of the MTP and PNDT regulations, of which they are barely aware, but on their commercial and health priorities. Notice that we discuss elsewhere the influence of another Indian key player in regulations: the professional association (in section 9.4.2). Involvement was reported from socio-political organisations in the IPHS drafting and in the amendment of the MTP Act in 2002, making it more restrictive. Throughout the Indian regulatory context, users do not seem to have the joint social strength to direct healthcare production toward their objectives	inter-agency relations in China. In the EmOC case, it is understandable as perhaps serving to maintain clear, effective and informative referral channels – and thereby to attract clients. An EmOC-C regulation administrator confirmed eagerness to maintain good personal relationships. This intention prompted a district hospital, when referring a poor migrant patient to an EmOC centre, to “send a cheque to the EmOC centre to influence our hospital’s relationships with it.”

8.3. Power and agenda of key actors

Most studied regulatory processes are top-down. The (national vs. regional vs. local) instance that defines the regulation also defines the actors' picking order and power. In general, users always have less presence than the others. Other actors consistently absent from the regulatory screen in the three countries were resource technicians (such as financial experts).

The role of street level bureaucrats in success and failure appears crucial, although power, as explained below, is unevenly distributed amongst them.

Possible invisible actors identified were lay health workers and professional associations in India, insurance companies in Vietnam and providers of medical high tech equipment in China.

We shall now discuss the features of actors' categories interviewed in HESVIC (see section 8.1).

Policy definition and regulation design is the task of a selected few policy makers and regulation designers. Besides, we have seen that down the administration, some civil servants may also have discretionary power to interpret it.

In China, thematic and university experts were invited by central level civil servants to feed regulation design with evidence. Sometimes these experts took the initiative to lobby. This was not the case in Vietnam, where most regulations were designed at the central level of MoH and GOPFP. In the 70's in India, after having commissioned some studies, the Shah committee defined the MTP Act. The main difference is that Chinese regulatory authorities follow thematic expertise almost to the letter. The Shah consensus was followed, except on one important issue: namely, the MTP act did not treat abortion as a woman's right.

Regulation administrators in India were district health officers. In Vietnam, they were public hospital directors. Their regulatory discretion is especially important when regulations are not strictly mandated (EmOC) or when violation is not well defined (SRB). In China, the discretionary power of hospital directors depends on control and legal enforcement defined by a regulation. In the case of EmOC, they enjoyed little room for discretion. For GR on the contrary, hospital directors were given a lot of discretion in their ability to choose the degree of implementation.

Across countries, health facility managers, like hospital directors, or local health authorities, like district or provincial health directors, find themselves manoeuvred into a dual position: as managers of healthcare delivery and as regulatory administrators.

These actors thus have other priorities than to ensure that regulations are implemented effectively. Most of them are in charge of both regulatory

implementation and monitoring, responsible for the entire service delivery and coordinate health programmes' organisation. Due to these commitments, they are often overburdened, lack time and set their own priorities according to a large array of variables.

In Vietnam and China, regulation administrators have to consider income generation for their institutions since public resources are in general insufficient. In India, where informal payments thrive[51,108], the result may have been the same.

Regulatory administrators often earn less than private providers. For them, controlling private providers entails a high opportunity cost. In India this often leads to a complete absence of inspection visits from the district health office to the private sector. In Vietnam, regulation inspectors are not well paid and carry these visits out more perfunctorily.

Regulation inspectors and controllers usually do not have the necessary skills or experience to perform their tasks. Limitations in their function may also be compounded by ambiguity as to their legal validity.

In Vietnam, there is tension between population and health inspectors. Besides, both often lack the necessary skills and experience to perform their tasks. In India, district health officers are supposed to carry out the bulk of inspections, but, as noted above, they are overburdened and often insufficiently trained. In China, we saw that inspection efforts depend on control and legal reinforcement measures.

As a striking commonality across the three countries, inspectors and supervisors rarely see their contact with regulated staff as a learning experience for either of them, whereby mutual support and skill transfer is important.

Regulated providers face poor working conditions in public services, which limits their motivation. Many public physicians In Vietnam and India have dual practices, while in China, they are compelled to contribute to hospital income generation.

Dual employment of regulatory administrators who are public sector physicians and also work in commercial settings could prove to be a negative arrangement with respect to their control functions, as exchange of patients, equipment and information is often key to success in private practice. Notice that although dual practice may reduce the need for informal payments[109], its influence on such payments in the public sector in India is unknown.

Topic experts have had preponderant roles in the early stages of designing regulations and often became regulated staff afterwards, which can entail some conflict of interest.

Users are not or are rarely treated as regulatory stakeholders, though of course their demands are high. Users' representatives, socio-political or community organisations

have not taken part in most regulation processes, at least not directly and/or visibly. This is a strong commonality across countries, with the exception of the amendment of abortion regulation in 2002 in India and a sample of user-respondents to regulation design surveys in China.

Although no users' intervention was reported, it can be assumed that the expanding middle class has more political leverage to demand care quality than the lower social classes, ethnics and castes. Middle class patients probably make better use of GR regulations. Representative organisations, representing less privileged classes, are considered hard to find (in China), insufficiently matured in Vietnam (Women's union), and highly segmented (In India).

Commercial and economic agents are likely to act as invisible actors. We had hearsay evidence about the influence of insurance companies, of medical equipment makers and professional associations but we did not manage to interview anyone claiming to act as, or reputed to be, an invisible actor of regulatory processes.

Finally, mass media are acquiring an increasing role for addressing non-compliance and slow responsiveness across the three countries.

8.4. Government political will

Political will appeared variable within and across the studied countries, which suggests that this may be a necessary (as with EmOC-C) but insufficiently prevalent condition for regulatory effectiveness.

The Vietnamese government reacted quickly to curb maternal mortality by regulating EmOC provision. However, it failed to deliver well-designed regulatory content. SRB imbalance was clearly not a top government priority at the time that the regulation was issued, and it was rather under pressure from UN agencies that the central level picked up related regulatory efforts. However, it still lacks the necessary decision making power to allocate resources and the regulation content does not facilitate detection of offenders.

In India, the political will is questionable in the three case studies. Ten years elapsed between the development of the MDG and that of the EmOC IPHS regulation. To date, India does not have a proper EmOC regulation for the public, let alone the private sector. The MTP regulation, a very progressive one for its time, took almost 40 years to be amended despite a poor record in unsafe abortion mortality. The GR CPA does not properly address users' complaint procedures and does not suggest that the central government is willing or able to intervene in health market related issues.

In China, the EmOC regulation effect reveals a prompt and sustained government and municipal effort to curb maternal deaths among migrant women in Shanghai (while the situation in other provinces is reportedly uneven). By contrast, the

government political will remained hypothetical in the case of PND and prenatal screening. The former was issued ten years ago and hasn't been updated since. The contrast between regulatory effort on PND and screening is striking. Finally, GR represented a tentative solution to perceived population grievances about healthcare, but did not involve users' representatives in its design and Implementation - leading GR procedures to remain underused.

Overall, it remains unclear as to whether governments are unwilling to intervene in health market failures or whether they are not capable of doing so. Both political speeches and regulatory objectives suggest that in none of the countries is intervening in health markets a political priority.

Finally, the case of EmOC regulations in India and China is interesting from the perspective of the decentralization effect on political will. In China, there is a central government commitment to maternal health, leading to enforcing EmOC regulation. The policy-making regarding EmOC regulation was centralized, but the actual regulation came from the municipal level in Shanghai. In India, EmOC regulation followed the usual bureaucratic link: the regulation is framed at the central level and is passed on to State and local level for implementation.

With such decentralized enforcement of EmOC regulations in India and China, agents who make decisions on standards are peripheral medical officers (district managers, etc.). This de facto decentralization of regulatory decision-making raises questions about equity of access to healthcare, and skills available to meet control requirements. But, just as importantly, it also raises questions as to the political control of state administrations, particularly in countries where the federal and state governments do not respond to the same political party.

8.5. Administrative and technical requirements of effective healthcare regulation in LMIC

Regulatory administrations have to successfully tackle several parameters to achieve their objectives:

- The factors influencing the behaviour of street level bureaucrats who administrate a regulation. Notice that these factors belong to social categories (cultural, economic, political, professional etc.) and strongly interact. One such key factor is the control of regulatory inspectors, which was never mentioned in our interviews except with the only successful regulation (EmOC-C);

- Regulation costs. In a comparative cost study[110] of the health regulatory environment in six European countries, the average cost of institutional healthcare regulation was between a low of 3,92 (The Netherlands) and a high of 7,28 (Norway) USD per capita;

- Errors in regulation administration. A Dutch study[111] showed how validity of inspectors' judgments was constrained and their reports not always reliable. As stated earlier, designing and implementing relevant health regulations requires a large array of (juridical, financial) skills and (clinical, healthcare) knowledge. In addition, these skills should be mobilised in a way that secures an acceptable level of impartiality in the making and implementing of decisions.

The key question here is whether or not the administrative structures in place allow regulation controllers to do their jobs in their particular environment. In the three countries, several administration features appear to have strained regulatory effectiveness:

- Blurred and overlapping responsibilities, as between GOPHP and MOH in Vietnam;

- Complexity of architecture (see section 8.3 and Table 11);

- Precarious financial situations of public administrations (see section 6.5); dual employment (as in India and Vietnam);

- Dual responsibilities of regulation controller and clinical agent (as in Vietnam districts);

- Issues with health information, management control systems and liaison devices (see section 5.3.2.3).

The only studied regulation that managed to overcome some of these difficulties (EmOC-C) did so by:

- Narrowing both its objectives (mortality, but not morbidity or treatment and secondary prevention only to a limited extent,) and the regulated clinical processes;

- Refraining from tackling the structural health system fragmentation and segmentation.

Did skills and expertise mobilized in regulatory processes enable sound decisions and appropriate actions? The same factors that constrain healthcare delivery appear to have had an even greater effect on the administration of regulations, for example because controllers have no financial incentive related to their performance, and no professional incentive to improve them, since control activities do not require significant use of their knowledge and do not enjoy wide social recognition.

Besides, the administrative setting and culture appeared not very responsive to reflexive techniques. We discovered that most actors hardly appreciate the regulation

process as a learning opportunity for behavioural change (see section 6.6). For instance, maternal death audits and grievance redress procedures offer the possibility for managerial feedback loops but these are rarely used in practice for this purpose. Control and inspection take the upper hand over support. As a result, human resource management and policy-making do not learn from regulatory failure or success.

The PND-C case raises a particularly important issue. Obviously, there is a need for gate keeping (in all three countries) but this has to be assessed against the absence of first line services and the consequent difficulty of managing screening mechanisms in Shanghai. Besides, what is at stake is the capacity of regulatory systems to keep pace with technological development. In this case, the deficient use of evidence in regulatory design raises the issue of the processes required to adjust regulations to high tech medicine and the parallelism needed between technical, administrative and political development. We address this challenge in section 9.3.

At the end of the day, we suspect that inspectors and in general regulators are better informed on the situation to be controlled than the regulated staff. Besides, the absence of control upon regulation inspectors themselves is striking.

9. The social production of regulatory systems in transition economies

We have seen that most studied regulations cannot justify their content and administration characteristics by the success of their effects. Lay people know this through experience or because the general press reports major problems with the objects of regulations, for example the existence of collective and sometimes violent ('mobbing') GR mechanisms[38]. According to a 2005 survey by the China Hospital Management Community, of 270 hospitals all over China, 73.33% experienced cases of violence, assault, threats, and abuses by patients and their relatives[112]. The Vietnam report states[35] that, "The contents of denunciation cases on the other hand are about corruption in a health institution, poor attitudes/unresponsive attitudes of health workers, noncompliance with socio-economic policies for people and a violation of private practice rules." The worst situation is to be found in India, where the regulatory architecture could not significantly reduce maternal deaths (see above charts 3 and 4, copied from the Indian report), with access to emergency obstetric care remaining unsatisfactory.

In section 7.4, we suggested that the failure mechanisms that we identified could be related to some features of the economic transition. We thus studied the regulatory systems as they are produced in practice - by a complex social body, featured with conflicts and alliances typical of transition economies.

LMIC have specific problems to guarantee the necessary regulatory structures in health sectors. The numerous regulatory problems with the design and administration of the studied regulations, and the government's incapability to remedy them, raise a question about their common determinants in the three countries and beyond, in middle income countries:

- Which (if any) mechanisms that are common to LMIC and less so to industrial countries, hamper the regulation and control of healthcare delivery, be it commoditized in government or private services?

- If we understand these mechanisms, we might better define the domain of validity of the recommendations derived from this study.

A key issue in transition countries is the dynamics between their economic and political structures. In point of fact, regulations lie at the intersection of the two because their operational function has to do with economic issues (for example, health care delivery), while at the same time, they have a political function: health regulations may yield non-health benefits (see 9.6.1). When regulations remain operationally idle, observers are logically entitled to explore their other raison d'être, such as their political function. Hence the following question:

- Are there any specific political functions of health regulations in LMIC?

To answer these two questions, this section examines the social production of regulatory systems for health care delivery in the studied regions. With the aim of generalising the study conclusions to transition economies, it attempts to validate three characteristics of transition economies (see section 9.1 to 9.3) for predicting the operational effectiveness of regulatory policies. Without ruling out others, these three particular parameters of LMIC are the administrative problem-solving capacity of the State organization, the representation of lower social classes, ethnics and castes in Government constituencies and the political credibility of the State as an institution.

9.1. Institutional problem solving capacity of States and regulatory effectiveness

State administrations are endowed with a variable capacity to effectively address social, health, educational and other essential citizen needs.

More than in India and Vietnam, Chinese regulations are embedded in regulatory families, suggesting a real concern for the objectives of some regulations but at the same time some lack of coordination[113].

The mechanisms beyond uneffective regulations in India and Vietnam raise the issue of whether the institutions of these countries are capable of successfully tackling regulatory challenges, especially in the health sector, which is known to be complex.

Both countries used their EmOC regulations to secure some equipment investment. However, this was not sufficient to significantly modify healthcare processes - although Vietnam did manage to modify health services operations to some extent, for example with in-service training and institutional support provided by provincial hospitals to district ones.

One of the three regulations studied in China (EmOC-C) represents a possible success story, which suggests that this country may have the capacity to enforce a law regarding the operations of its public services, even if not in the most efficient way. While our study remains inconclusive as to whether China can regulate and control its private sector, this country retains a capacity to act upon its government-financed but self-managed health facilities.

On these grounds, the following hypotheses can be formulated:

Indian and Vietnamese public services may suffer administrative disorganization resulting in substandard performance (beyond provincial levels in Vietnam and in the entire pyramid in India). These services also do not have the capacity to compensate for this disorganisation by effectively contracting out and regulating private providers. In general, the key resource constraint proved to be redistribution of skilled human

resources. In China, by contrast, the government retained the capacity to plan for public services, although they were largely managed autonomously.

In India, the multi-party system has not favoured policy continuity in its administrations because of underlying weak job stability amongst senior ranking civil servants. In addition, managerial positions in health services were granted to non-professionals, which further weakened their healthcare delivery and regulatory problem solving capacity. Besides, the multi-party system in a federal, large country like India generates contradictions between national policies and States ones.

Finally, the status of health care services (government, autonomously managed, private, contracted or otherwise) is likely to be a factor in predicting regulatory effectiveness. Since any input provided by a government to a health facility can be used as decision-making leverage, it is useful to list those invested by MoHs in hospitals and health centres. Table 14 shows the leverages that public authorities can use in respect of different categories of health facilities with commercial activities (even MOH hospitals not enjoying management property split can sell healthcare).

Table 14: Government leverages and feasibility of healthcare regulation according to health facility status

Leverage	Government planned health facilities	Autonomously managed public hospitals	Health facilities contracted out by governments	Non subsidized, private for-profit health facilities
Direct control	X	X	(X)	-
Operating budgets	X		X	-
Investments	X	X	-	-
Acting upon careers	X	X	-	-
Material sanctions and incentives	X	X	X	-
Symbolic sanctions and incentives	X	X	X	X
Regulatory feasibility in LMIC	**+++**	**++**	**+**	**-**

While symbolic sanctions can be applied to any health facilities rated by an accreditation institution, incentives can be used to the extent that governments invest in the regulated facilities. The distribution of these leverages makes the above-

mentioned hypothesis of a feasibility gradient in government regulation a reasonable one, feasibility being linked to the volume of government inputs in each category of health facilities.

9.2. Socio-political strength of lower social classes, ethnicity and castes within State constituencies and regulatory effectiveness

Governments and administrations must arbitrate decisions against conflicting interests, for example between commercial stakeholders and representatives of those receiving social benefits from the State. The outcome of public health vs. economic trade-off in designing regulatory health policies will thus depend on the capacity of the latter to defend the interests of lower social classes, ethnicity and castes in health policy design. How does this concept apply to the studied regulations?

In India, users of the GR regulation reveal a gradient in income associated with enjoying its regulatory benefits, with most users probably belonging to the urban middle class, since most complaints were recorded in the private commercial sector[114]. This is consistent with the fact that use of the regulation potential to redress a grievance requires administrative and legal knowledge, funds and probably connections. By hypothesis, in middle-income countries, GR regulations are mainly tailored to satisfy the needs of those who can make best use of administrative resources, rather than those of the poor.

Consider the PND-C regulation. The reporting system for PND service delivery in Shanghai was established in 2011, well after the creation of the diagnosis centres. There is thus as yet no information on screening and prenatal diagnostic rates available in Shanghai. However, the design of the prenatal screening and diagnosis regulation does not appear to address early detection of Down's syndrome since the government does not include the related pre-screening (serum and / or age discriminant factors detection) in the ANC package. With regard to (transition) epidemiological priorities, this is probably an efficient decision. However, investing in four high tech, presumably expensive prenatal diagnosis centres therefore amounts to the government subsidizing a market for Chinese and international equipment makers and for the wealthy users - those women capable of affording the full recovery cost of these examinations. Of the two stakeholders, the one more crucial for investing in high-tech PND is likely to be the former, since there is probably no strong demand for accessing this test amongst young, middle class women – an hypothesis to be checked. Either way, public financing of private, applied medical research is common practice in both MICs and HICs.

Without regulation and control, this economic argument could lead to seriously unbalanced health policies because of the major opportunity costs entailed in high tech medical investments. In the final analysis, multiple and contradictory socio-political representation could be a condition for regulations to keep pace with technological progress. To achieve some impartiality in technical choices, information

gathering and evaluation, some high-income countries[115] approached this contradiction / tension by:

- Considering the investment decision as a matter of prioritization and technology selection in an area of conflicting interests, due to the existence of opportunity costs that render technical decisions in health a political issue;
- Systematizing the related socio-political negotiations;
- Systematically introducing a third party in negotiations on health care and pharmaceutical priorities;
- Inviting social groups with different interests (e.g. the rich and the poor, the urban and the rural, health professionals and users, employers and workers) to participate;
- Favouring the financial independence of organized associations of users (for example mutual aid associations) and contributing to their coalescence with appropriate incentives so that they could hire high cost experts;
- Assuming that professionals employed in the administration are sufficiently highly paid to work independently of economic agents with vested interests.

Bearing in mind the criterion of need for contradictory appraisal of medical techniques and policies, and for negotiation between independent top experts hired by social groups with conflicting interests, decision-making in China, as perhaps in Vietnam and India, could reveal a mismatch between technological and political transitions. While, to get a relatively objective assessment of medical equipment tentatively purchased by the government, lower social classes, ethnicity and castes should have their say mirrored in the appraisal because health needs, demand and offers are specific to social groups and investments and because hi-tech medical equipments convey major opportunity cost for access to care amongst “the poor”.

Unfortunately, the capacity to finance independent, high-level expertise is limited in most LMIC users’ associations. In China and Vietnam, no large-scale organization exists to represent social services users: “Furthermore, executive dominance, bureaucratic fragmentation and the lack of an organisational platform for an independent watchdog within civil society, along with lack of correspondence between the delegation of authority and the new accountability mechanisms at the local government level has contributed to the limiting of effects of anti-corruption measures”.[116,117]

In India, this sector never managed to overcome its immense fragmentation and to achieve the financial capacity needed to balance commercial influence on government purchase. The community associations remained fragmented because of their weak political definition, which prevented them from negotiating alliances based

on political and philosophical preferences, for example on agreed criteria for long term social development.

In conclusion, there are reasons to fear that because of their weak labour, social and users' organizations, the lower social classes, ethnicity and castes in transition economies are insufficiently represented, with a too limited capacity of mobilization, too poorly financed, and not sufficiently independent. They thus probably lack political leverage to be treated as key health policy decision players.

9.3. State political strength and regulatory effectiveness

How does the credibility of state institutions impact on regulatory effects in the three countries?

For the sake of this discussion, we view the State political strength as being in essence the respect inspired by State institutions in its citizens. As such, it is an immaterial, symbolic phenomenon of collective psychology, a phenomenon determined by history, For instance, most newly independent countries devoted sufficient resources to hospital development because hospitals represented some kind of flag.

Building State political credibility is thus an issue of national decision. In most of the world the establishment of highly trained administrative, executive, or directive classes has made public administration a distinct profession. In the United States and a few other countries, the elitist connotation traditionally attached to the civil service has been consciously avoided, with the result that professional recognition has come slowly and only partially.

Perception of State institutions will vary according to the individual's position in terms of social class, ethnic group and caste (where relevant) and according to the capacity of the individual's own group to influence state decision-making.

State political strength plays a role in regulation effectiveness while interplaying with culture. It favours operational effectiveness of regulations to the extent that people tend to equate State establishments to the common good. From this viewpoint, there is a deep difference in Europe between Mediterranean cynicism and Nordic countries' trust in government institutions[118].

Credibility of State institutions is thus linked to historical and contemporary issues. This political strength of States is a key stake in the global political economy, since regulations are a central issue in international trade agreements.

If State political strength favours regulatory effectiveness, failure of regulatory policies can be predicted in failed nations, states and provinces (unless a foreign organization takes over the job; but then sustainability, national sovereignty and opportunity costs are at stake), as well as in states with significant administrative, social, political and

technical weaknesses (see below). This rule predicts that failed states are unlikely to have any regulatory capacity, could perhaps apply to MIC (or some of their regions) as well and could apply to any regulatory capacity.

Besides, general policy orientations appear to also influence regulatory effectiveness. As it reflects in overall maternal mortality figures, political concern for maternal mortality appears to be lower in India and Vietnam than in China. This phenomenon might be explained over the last two decades or so by international strategic and internal political considerations.

What are the political concerns beyond regulatory policies in the 3 countries? In a context of international tensions on the relationships between commercial and social policies in global trade, the Shanghai government stressed equity in access to EmOC in order to score well on international indicators (MDGs). International alliances did not drive India and Vietnam to abide so strongly by the same factor.

While integrating the World Trade Organization, the Chinese and Vietnamese governments were probably keen to retain leverage on their health care systems – to somehow keep their health facilities under the MoH umbrella. PND had an important economic significance to China to the extent that this sector might be viewed as a government-subsidized outlet, with the government steering the medical equipment industry, an apparently important economic sector[119] (see section 6.2.3). Finally, we have seen that the GR Regulations were often justified by a concern for stability and civil peace (see section 7.4).

All these factors are conducive to health policies (e.g. regulatory ones) abiding by the requirements of the economic transition. In these circumstances, building the State's political strength may not necessarily require successful regulatory policies, when political objectives such as the need to convince people that an economic rationale is needed in the health sector for better access to care prevail.

These observations are compatible with the phenomenon of regulatory success illustrated with the EmOC-C regulation and the failures of Indian regulations under scrutiny. However, the relative success of the EMOC-C regulation in Shanghai does not permit the prediction of similar results in rural provinces, for example because the State political strength is not homogeneous across its territory.

9.4. Regulations to discipline health markets or health markets to tame regulations?

The HESVIC study suggests that government administrations are not in a position to regulate the private sector. Regulating health care delivery is known to be particularly difficult because of the important information asymmetry that features doctor-patient relationships, likely to be more important in LMIC than in HICs because of much lower access to Internet and lower education on health matters[120]. Other obstacles are issues with medical confidentiality; the complexity of care processes; and the fact

that each professional is a craftsman, rather than a worker applying standard procedures.

However, there are also reasons to suspect market agents' influence (e.g. professional and producer associations, medical equipment companies,…) that aim to neutralise government regulatory capacity in the three countries:

- The Indian professional association managed to block the implementation of the private practitioners act (Karnataka State Private Establishment Act 2009) – without patients being aware of the detrimental consequences that this would have for their health.

- In theory, the GR regulations aim to strengthen the capacity of individual health care consumers to act upon quality of care. However, they allow no room for collective attempts to address quality of care – which self-employed doctors and commercial hospitals generally dislike.

- No pre-diagnosis screening criterion is used by the PND-C regulation. Besides, this regulation is apparently not concerned with supplier-induced demand, which is compatible with some commercial influences on decision-making.

- The ANC-V and ABO-I regulations were incapable of limiting illegal (respectively sex determination and selective abortion) practices in the private sector. In India, the MTP law could not prevent most illegal abortions (systematically done in private settings). These facts reveal the political strength, at least locally, of private actors and their capacity to successfully interfere with a weak administration.

- We saw that no accreditation has been effectively enforced. This has resulted in a large illegal private sector in the three countries. In China, private practitioners and clinics have to register in the health administrative sectors but there are still illegal health providers underground.

To understand the weak regulatory capacity to steer private care delivery, we need to explore the impact of health markets on regulatory administrations in LMIC. As elsewhere, market stakeholders are unlikely to wish being regulated and even less to finance a strong regulatory body. Regulations may be viewed as conflictive processes in essence. Some regulations are based on incentives to finance providers who aim to minimize the workload and purchasers who want to minimize their budget. Others provide standards (EmOC-I and –V, PND-C) and support providers who want to enlarge their market shares, and social organizations that are out to minimize the opportunity costs of high tech investments.

In this conflictive perspective, the government's technical and administrative capacity to regulate health care (see 8.3 and 8.4) may be an hindrance to economic rationale

in health policy decisions. Since the government structural capacity to regulate is probably more important than the political will at a particular moment, the development of the government regulatory capacity is thus likely to be a bitter issue of social conflict.

In the future, it will be interesting to further study systematic differences in regulatory effectiveness between industrialized countries and LMIC, and its relationship to the capacity of users to organize associations capable of developing appropriate, independent expertise - which is a function of the particular country's industrialization / transition history.

9.5. History and changing political economy, policy[121] and governance culture in Vietnam, India and China

9.5.1. Regulatory speeches to prepare economic transition

For the last two decades or so, according to the principles of new public management[122], governments were supposed to "steer rather than row" [123]. In LMIC, however, steering has proven to be more challenging than direct healthcare provision[124], and even more so in contexts characterised by 'less government', rapidly changing societal values and rising expectations from the public.

One way for governments to steer health markets has been to attempt to regulate them. To control the consequences of market failure and limit market inefficiencies, HIC and, to a lesser extent, LMIC governments have, over the last two decades, developed economic regulations. In response to changing social needs, they have opted for social regulation out of a concern for the wider goals of equity, quality, diversity and solidarity in health care delivery and financing (see section 3.1.1) - while holding accountable stakeholders with multiple interests.

Our study reveals in LMIC the difficulty in adjusting regulatory policies to rapidly evolving health technology. If regulation is a concept that encompass norms, habits and customs, it is reasonable however to assume that the transition political economy in the three countries also constrained regulatory progresses and prevented them from promoting equity in access to care – a fact consistent with European countries' requirement of one century of chaotic social history before they achieved some regulatory capacity[125].

How does the identified inadequate regulatory effectiveness enlighten the political, and governance transition features in the three countries?

Ineffective / little used regulations that remain unchanged during long periods of time (for example, the three GR regulations) not only reveal their operational idleness, they also reveal their political / ideological function (see section 9.5.1). If a regulation is not aimed at improving health, it is reasonable to wonder whether it merely serves

social reproduction e.g. spreading and justifying a particular social model of production.

We have seen that implicitly, GR regulations have the ideological function of advertising the quality of care expected in expanding health markets and of allowing people to believe that significant changes can result from individual complaints. Such regulatory discourses based on the role of regulation in health care commoditization might then be assumed to have a political economy function, for example to convince people that public goods (such as discretional healthcare) delivered by public services should be entrusted to the expanding, regulated health market.

The political message of Indian and Vietnamese EmOC regulations is evident in the contrast between their standards and reality. This message – 'government services resources meet a minimal threshold' – is of special importance in transition phases geared to reduce the public services size – precisely because along some economic rationale, these services need to be downsized if not eliminated. To be acceptable, this move should echo the poor experience of patients and users and the contrasts with the resources allegedly allocated to it. This is how regulatory speeches contribute to prepare economic transition. This function is of particular importance in China and Vietnam because many social services were publicly provided until recently and people therefore demand decently operating public services. In India, health services were decent for only two decades after independence[126].

9.6. Lessons of HESVIC findings for governance studies

The conflictive nature of regulatory processes sheds a critical light on the concept of governance: rather than merely the consequence of political will, governance appears to be by and large the product of dialectic relationships between interest groups. The public (PND-C) or private (ANC-V) medical market is a battlefield for manufacturers, who lobby worldwide to orient public purchase of high-tech medical goods. With regard to the PND-C regulation, the government addressed the issue of whether to purchase high-tech medical technology, while releasing only limited public information . Obstacles preventing regulations from keeping pace with social, political, economic and technological changes were revealed in the PND-C and ANC-V case studies (for example with respect to the use of echography, amniocentesis and serum tests for early detection of Down's syndrome).

Weakness of health care users' associations and lack of involvement of trade unions in sector specific policies in Asia, and fragmentation of community organizations in India prevent these organizations from playing a significant part in technological and health policy assessment. This factor, closely linked to transition countries features, could prove to be a key impediment to getting the health regulatory structure to keep pace with technological progress and may explain the difficulty in regulating health care delivery in LMIC, long recognized as being more difficult than direct delivery by government agencies[127].

The governance weakness evident in the failure to regulate health care commoditization in the private sector is thus the social product of conflicting interests (see section 9.4.1) between providers and patients; administrators and professionals; urban and rural dwellers (e.g. residents, migrants and temporary migrants).

To contribute to "good governance", these conflicts need to have had the time and opportunity to translate into state governance structures capable of processing complex information (as in health care production) and enforcing the related complex regulations. As is to be expected, these conflicts thus determine the extent and depth of market regulation.

From an epistemological perspective, the large array of these factors demonstrate the need to use concepts from history and political sciences, but also from health systems research, to study governance and the factors determining regulatory effectiveness discussed here (conflicting economic interests; class- and caste-specific use of public expenditure on health; vested social and individual interests; cultural dimensions of regulatory praxis; and political importance of international commitments, e.g. MDGs).

The social production of regulatory processes leads us to reconsider the definition of "governance". This term relates to decisions that define expectations, grant power, or verify performance. It consists of either a separate process or part of government leadership processes. Defining expectations, the 'governance' concept is used with quality criteria[6] often originally defined by multilateral organizations. The concept of good governance therefore represents some yardstick against which actual governments' policies and practices can be judged. However, governance quality criteria were judged by academics as ill-defined, not validated and perhaps "un-validatable"[128]. For instance, responsiveness, transparency, and rule of law are values often used in contemporary policy speeches. These terms 'rubbed off' on scientific studies, although they were deemed invalid and unverifiable criteria.

Governance should thus be studied with a social science lens and not just through policy studies. If research ought to contribute to sound health development strategies, the concept of governance might then be viewed as a social process resulting from interactions between groups with differing interests - rather than in terms of desirable features (an "ideal") ascribed to State decision-making.

Public policy concepts that do not explicitly refer to social sciences concepts or to operational quality criteria that can be validated merely represent beliefs, convictions and biases of decision-makers and academics, as they construct a knowledge made possible by the historical a priori conditions that ground their discourses (see below consequences for health systems research in section 10.3).

More importantly, this complex panorama justifies that recommendations encompass health sector strategies for socio-political and professional organizations and not only orientations for policy makers (see sections 10.1.4 and 10.1.5).

10. A normative insight into health regulations

10.1. Recommendations for key actors

10.1.1. General criteria for regulation quality

In annex 2, we presented criteria to analyse the quality of regulation content and implementation. In annex two, we adapted criteria used by Siddiqi[6] to describe governance quality criteria, trying to make them operational and validatable, while adjusting them to regulation requirements (copied from the HESVIC project deliverable D.1.2). These criteria, initially used for the purpose of this study, may be viewed as yardsticks to be used in constructing regulations in the health sector. In addition, we formulated recommendations specific to defined target populations. Those below do not replicate the ones presented in the three country reports because these were related to a particular environment.

As said before (see section 8.1)[101], our study analysed regulation processes with respect to their failures and achievements, assessed against their initial goals, and to the various actors' roles in their administration and implementation. The total of 9 relatively diverse case studies in three largely heterogeneous LMIC gives weight to the recommendations emerging from this study.

10.1.2. Policy makers in charge of health sector governance and regulation

The most important finding of this study is probably that **regulations should be nested in larger health policies** because:

- They are not very effective on their own, certainly under LMIC conditions. For instance, input standards require actual financing of regulated items, whereas prohibitive regulations of clinical behaviour often require larger, associated sociocultural and economic policies.

- They can yield undesirable effects. For instance, in Vietnam, combined with the common perception that the quality of services is better at the provincial level than at district level, the EmOC-V regulation has resulted in the over-burdening of provincial hospitals. The larger policy therefore encompasses strategies to improve efficiency in resource utilization.

- Health professionals cannot merely be motivated and deterred by material incentives and punishments, and need symbolic incentives in addition to these. The larger policy thus needs to tackle professional ethics.

Besides, the effective LMIC private providers' resistance to regulation suggests that **competition with an acceptable publicly oriented health care delivery system could** disseminate quality standards in health care delivery and thereby **be one**

important way of regulating the private, commercial sector. Indeed, during the consultation, public service doctors can educate patients on irrational health care demand created by market forces, if dual employment is not permitted.

To illustrate this point, consider the diagnosis of tuberculosis. Physicians with a commercial rationale aim to convince their patients to undergo chest radiography and tend to undermine the use of bacilloscopy because profits associated with higher technology are more important[142]. Similarly, in commercial health care delivery, many useless but profitable examinations are regularly prescribed to pregnant women.

Health education in public service needs to tackle such irrational demand. Besides, **governments can empower consumers' associations** with technical capacity (e.g. with regard to participating in the selection of health input priorities). In order to do so, however, they need to consider the specific features of their 'civil society'.

Ambiguous permissive/repressive regulations (e.g. the Indian MTP regulation) generated restrictive interpretations related to professionals' cultural prejudices and greed[u]. **There is a case for the redesign of their content while using action research tests**. In fact, all regulations should be tested with pilot experimental methodologies.

Our experience with the EmOC-C regulation shows the importance for command-and-control regulations of some bottom-up planning mechanisms. These could include **associating the regulated staff with the regulatory design operation** –to give them technical insight and a part in the decision-making process, and to avoid the need to test new regulations in pilot experiments. .

Our experience in Vietnam suggests that **regulatory authorities should receive their own budget and staff**, and that these teams should not be too decentralised, especially while attempting to adjust to available resources and skills.

Governments should organise the control of regulatory inspectors themselves.

Finally, policy makers should conduct the gathering of intelligence on medical technology and health strategies, using the **contradictory analysis of experts financed by social groups with contradictory interests** (see section 9.3).

10.1.3. Managers of health care and of regulation and control

Feedback loops based on assessment of regulation effects (their outputs and outcomes) are not only useful for amending regulations. In addition, **grievances, for instance, can be used as input in the form of critical incidents for managerial reorganization**. Traditionally, the person in charge of collecting grievances and of using them to feed a managerial reorganisation is called an **ombudsman**.

[u] Let's remember that abortion prices will depend of the (widow, divorced, adolescent) status of the patient and the attached moral judgment of the professional (see table 10).

This function has not yet been created in the studied countries, in which GR regulations are merely used to redress grievances and to provide users with material compensation, without using these regulations to ensure that the causes of problems are known and avoided in the future, and that health services management take advantage of these grievances to systematize health care organization amendments. Notice that such a system would require that ombudsmen are given a mandate larger than merely verification of the basis of complaints. They would thus require ad hoc training.

Studying the rescued women's careers could lead to improved efficiency of Chinese health services, if improvements in coordination between health facilities were to be expanded beyond the strict limits of maternal healthcare. In particular, **this reflexive approach should be applied to the use of audits and health supervision**[54].

10.1.4. Professional associations

With regard to non-regulatory approaches to amending professional praxis, **professional associations could disseminate a professional ethic** amongst their members. Such an ethos would complement regulations because of their inherent limitations. Admittedly, conflicts of- and self-serving interests (see section 9.4.2) could render this recommendation wishful thinking, because professional (and health workers') organizations generally associate corporatist defence with ethical watchdog functions. However, some organizations in other parts of the world (e.g. in Latin America and Europe[129-131]) have contributed to disseminating a professional ethos without any commercial concern. These efforts were often inspired by political motives. Furthermore, governments of some countries (e.g. Belgium) have steered (and continue to steer) in-service training in medical ethics.

As a priority for action, motivated academics should target groups of professionals and trade union activists keen to promote universal access to and quality of care and to promote debates on medical ethics. Professional associations should aim to ensure that regulations and a professional ethos are debated in the largest possible circles.

10.1.5. Community and socio-political organizations should develop large-scale users' associations capable of affording and using relevant top-level expertise

The key challenges faced by community and socio-political organizations (such as mutual aid associations, trade unions, women's associations, etc.) involved in the healthcare sector are:

1. To maintain their **existence**;

2. To be sufficiently **independent** to represent their members' interests;

3. To acquire **sufficient funds and organizational structure** to be able to afford and use independent expertise;

4. To acquire the **political leverage** necessary to have a voice in political and regulatory decision-making circles.

From this viewpoint, India contrasts with China and Vietnam as it lacks large-scale political organizations. Instead, Vietnam and China host Women's Federations. In theory, **these are political organizations potentially capable of hosting the above independent expertise and related bureaucracy. Ascertaining the reality of this is an issue for action-research**.

In India, the myriad of community organizations has not thus far proved able to form a federation. One possible reason for this might be a lack of political discourse. Indeed, social history and an organized set of philosophical criteria comprising conflicting ideologies (social-Christian, social-democrat, liberal) has proved to be requisite for organizing alliances that host long term societal projects[146,147]

In India, trade unions such as Sewa could be contacted to ascertain their interest in testing the development of such a new function, namely a patients' watchdog of healthcare delivery. **Members of such new structures could contact mutual aid associations with long term experience** of contributing to regulation of healthcare delivery and health financing sectors in Europe.

10.2. Research perspectives for the future

10.2.1. Topic and themes definition

This section consists of recommendations for academic units involved in health systems research.

The absence of field tests to assess regulatory effectiveness in the three countries is striking. It indicates a lack of dissemination of action research methodology in both administrative and academic circles and a lack of academic involvement in field tests of health services organization and management. As seen in section 5.3 on actors involved in the regulation design process, one of the most striking features of these research findings is the partial absence of bottom-up planning to disseminate regulatory mechanisms. In India the sex selective abortion regulation is one of the few exceptions to this. It was not, however, studied by the HESVIC project.

The following are some themes and questions emerging from the project findings:

a. How valid is the hypothesis that the structures, problem solving capacity and social representativity of LMIC governments do not allow them to regulate markets effectively?

Notice that decisions and standards in centrally planned health systems (such as EmOC-C and –I regulations) are not pure regulations but can be viewed as a component of (health services) central-planning. Having withheld (from health services providers) competence to carry out supply-side financing, the Chinese government, unlike the Indian government, retained moderately effective regulation and control leverage. India has almost none. (see Table 14).

b. Can the Indian Medical (or any other) Association, after it has been so effective in blocking any regulation of the private sector[56] and has seen its top leaders imprisoned[132], be a neutral, non-self-serving institution in regulatory processes? To what extent is this Indian tale a critical incident indicating the need to revisit the role of professional associations in health regulation?

c. What are the health consequences of unregulated or poorly regulated commercial medical practice in both public and private health facilities in MIC vs. LIC? Here we refer to the consequences of economic transition - blurring of public private borders leading to unnecessary use of health care, denial of useful care, stolen equipment, inefficient use of insurance funds and related higher premiums. How effective is competition with good quality healthcare delivery in publicly oriented health services in regulating healthcare markets?

d. Verify the following hypothesis: it is easier to regulate a health facility receiving significant inputs from governments because these represent leverage. Therefore there is a gradient in regulation feasibility, from centrally-planned health services, to autonomously managed hospitals (as in China and Vietnam), to contracted out facilities, to un-contracted private commercial facilities?.

e. How effective are regulations in controlling healthcare pricing in the three countries (the key to patients' access to care)? The scarcity of available information on this issue necessitates further study.

f. How effective are attempts to tame the effects of information asymmetry in LMIC?

g. Do GR regulation users mainly belong to the new middle class in LMIC?

h. To what extent are the Womens' Federations in Vietnam and China fit to host and finance independent expertise in health policy decision-making?

10.2.2. Methodological gains enabled by the HESVIC inter-country comparison

This section amounts to a discussion of the methodology of the present comparison, its achievements and limitations. The methodological rationale of the HESVIC

comparative analysis lies in a particular approach to descriptive studies in health systems research[133], linking public health and health systems research to three sociologists' and philosophers' contributions, to descriptive studies methodology, and to selection of research topics: Morin[134,135], Foucault[136] and Bourdieu[137].

a. Inter- / multi-disciplinarity

According to Edgar Morin, descriptive social science studies and representation in general should be inter- rather than multi-disciplinary in essence[138,139] (Morin 1973, 1990) – meaning that instead of mere parallel use of disciplines to address a problem or a question (which is multi-disciplinarity), each discipline should influence the methods and concepts used by the other disciplines. This latter is what characterizes inter-disciplinarity. For instance, we used a multidisciplinary approach when we studied the combined character of geographical factors (e.g. stronger gender preference in Northern Vietnam), sociological characteristics (e.g. preference for male children in middle classes) and cultural factors (Confucianism culture), while exploring the primary determinants of a demographic problem (sex imbalance at birth). But we used an inter-disciplinary approach when we proposed:

- Amendment of a public health (discipline-specific) concept with sociological concepts, while revisiting the understanding of governance (see sections 9.6.2);

- Amendment of the analysis of a medical / public health issue with a political concept, while considering the role of large users' associations in health sector regulation of high tech devices in China (see sections 5.3.3).

b. Topic selection (Foucault)

We aimed to make the acquired knowledge relevant to health systems research and action. Therefore, we examined the relations between underlying (economic, social, institutional and political) conditions of health policies and actors' internalized structures (linguistic, ideological, behavioural). Beliefs (opinions, statements, discourses) on regulation and regulatory policies were thus treated in HESVIC as objects of interpretation in order to decipher their economic stakes, symbolic valence (e.g. "governance", "stewardship") and linguistic characteristics (e.g. "harmony") (see section 7.4). An example of an economic factor that we studied is development of an industry of high tech medical equipment in China. Social factors include the higher use of grievance redress regulation in the private sector in India. And institutional factors include decentralization of regulatory administration in Vietnam.

We did not only focus on procedures and processes but also on the social construction of health systems and policies (in Foucault's terms, on conflicts and not only on rules). Paraphrasing Foucault, we could not study regulatory norms, rules

and systems without concurrently studying their functions, the underlying conflicts and their meanings.

c. Praxeology (Bourdieu)

This section provides a brief discussion of the features that Bourdieu proposed should characterize a praxeological study.

System failures (sometimes deliberate), lack of relevant information and sustained ineffectiveness provided verifiable evidence for studying the mechanisms whereby infrastructure (e.g. economic and linguistic) and superstructure (political and social) factors influence each other, while determining the effectiveness and efficiency of regulatory systems. Before conducting the interviews, we tried to ascertain the system productivity, efficiency and people's access to quality healthcare[v]. We treated these data as:

- A prerequisite for exploring the social, political and economic determinants of health regulations; and
- A precondition that allows questioning of official speeches aimed at justifying policies, that is, self-apologetic discourses based on alleged functionality.

What are the methodological lessons that can be learned from this approach?

In a quest for independence vis-à-vis contingencies, and for the sake of distancing ourselves from expected stakeholders' self-apologetic speeches, we treated regulation failures as possibilities, the existence of which requires evidence to establish. We avoided any (phenomenological) a-priori ignorance of environmental features, sometimes advocated to secure researcher's objectivity. Rather, ahead of researching the nine regulations, we carefully explored the countries' features from different discipline-specific viewpoints (epidemiology, history, health systems, anthropology and medical sociology), aiming to make the findings of this publicly financed research more relevant.

We refrained from representing regulatory systems (their modus operandi) as thought objects and from treating these representations as a cause of praxis. Rather than emphasizing the structure of the regulatory systems under scrutiny, we aimed to explore their actual functions. Rather than emphasizing the relationships between concepts such as 'governance', 'accountability', 'transparency' and 'stewardship', we stressed their health, social and political functions – a concept at the core of the study of health systems and policies.

[v] Notice that we would have wished to explore primary data to pull out those indicators and criteria used in health systems research that would have allowed documentation of health problems resulting from regulation issues. However, we had to rely on secondary data because of project organization constraints.

The experience of the HESVIC research confirmed that predetermined programs of discourses and actions ('governance', 'stewardship', 'accountability' or 'rule of law') are adaptable to some 'cultures' but not to others. For example, the difficulty in translating these words into Vietnamese and Chinese reveals the fact that social hierarchies use different concepts in reproducing themselves.

10.3. Regulating maternal vs. general health care: two faces of the same coin (cfr. HESVIC research question 4)?

For political reasons discussed in section 10.4, China, and to a lesser extent Vietnam, treat maternal health as a public good. Therefore, those public services delivering the related care are relatively better resourced than most other hospital activities. In fact, maternal health is the main hospital activity that can be financed under the MDG priorities. This has two consequences:

- Maternal health indicators are somehow biased indicators of access to care in general;

- Hospitals benefiting from special funding due to their maternal health activities can improve the quality and problem solving capacity of their healthcare delivery.

In China and Vietnam, health objectives for centrally planned processes are formulated in terms of output. For instance, in Vietnam, service coverage rate, institutional delivery rate and trained birth attendance rate were used as objectives for development of health plans annually by the MCH department. In addition, prevailing coverage rates were used in the development of the strategy of safe motherhood 2003-2010 and the Strategy for Population and Reproductive Health 2010-2020 (although not in the Regulation 385).

This suggests the existence of a much stronger political will to achieve health objectives in maternal care than in general care, probably due to international competition to achieve MDGs. However, infant and maternal mortality (MDGs 4 and 5) mirror only a fraction of total avoidable mortality. This situation suggests that instead of several, partial MDGs, there is a need for one single formulated goal in terms of universal access to quality individual and community healthcare.

11. Research conclusions

The nine regulations analysed by HESVIC all bear consequences for care quality, demographic equilibrium and social stability. Their effects were examined and interpreted in section 4. Though health regulation can potentially protect users and societies from harm, they generally appear not to work at the moment, and there are multiple areas in which they need to be strengthened. We explored these in section 10, while making recommendations to key regulatory actors. We have also identified areas that need future research into (health) regulation to understand this better.

One of our studied regulations may have largely reached its objectives, while others have at times had unintended effects. The bulk of our case studies reveal a failure to significantly amend avoidable mortality and morbidity by regulating healthcare delivery. While the EmOC-C regulation has been successful in attaining its objectives (e.g. to reduce inequity in maternal mortality, table 4), its ambit is limited, as seen above. Other regulations (EmOC-V, PND-C) were reported to have only barely reached their objectives.

The importance of what these case studies reveal is not so much the observation of the proportion of success and failure, but a new insight into the failure mechanisms of health regulation and their relations with some features of the economic transition. We have discussed these in section 9 while examining the characteristics of LMIC that make it difficult for regulation to work at the moment. We have also examined the extent to which the mix of these factors is different from HIC.

Repeating our research questions, the international comparison revealed in section 4 that the effects of our studied enabling regulations (and their families) on equitable access to quality maternal health care were modest (EmOC-V), incomplete (EmOC-I, PND-C), unintended (MTP-I) or almost non-existent (GR cases), with the exception of the EmOC-C regulation. The same can be said of the effects of the prohibitive regulations (SRB-V). In sections 5 and 6, we discovered that, according to the regulation, the mechanisms explaining these implementation failures were related to their content and structure and, beyond that, to their design.

The EmOC-C regulation worked well, probably because its ambit was limited to avoiding maternal mortality and not morbidity, and because its implementation did not require thorough reorganisation to tackle health services fragmentation. In addition, and importantly, reducing maternal mortality was seen as a top policy priority. We compared the actors involved in the regulation of maternal health in section 8 and explained in section 9 how the environment of transition economies was featuring in their roles.

How is maternal healthcare different from general health care with regard to regulation? We saw in section 10.4 that because of the MDG commitments, the political will of presentable outputs is probably much stronger in maternal healthcare

than in general healthcare. This suggests that other regulations in the health sector might not even achieve the limited output observed in our case studies.

The recommendations that can be derived from our study, presented in section 10, thus stress the development of consistent health policies hosting regulations. It is likely that a key issue in regulatory effectiveness concerns the relationships between:

- the government and private services - for example, with respect to the consequences of dual practice);
- commercial and social health organizations - because, for example, competition with an acceptable publicly oriented healthcare delivery system could represent a factor of market regulation.

With respect to the ambit of regulations, this report requires a health policy conclusion. As stated in a recent Rockefeller Foundation report, "Without a mechanism to intervene and control health markets, this distribution of wealth and disease perpetuates the inequitable delivery and financing of care"[85]. The problem is that to date there is a lack of field evidence that these regulations and controls are working in LMIC.

The HESVIC project unfortunately did not add new field evidence that regulation and control is currently working (and thus possible) in LMIC settings, outside of services that are partially centrally planned. In India, regulation of private outlets was so new that public regulatory authorities could generally not produce a list of private practitioners operating in their area[69]. In Vietnam, unregistered facilities are numerous[89]. In this context, the project shed light on regulation - hampering mechanisms that are structural to historical, socio-political and administrative conditions in LMIC.

In such circumstances, in our opinion, the social and political issues that emerge from our study are the following:

- Whether, and how, users' associations should become internal partners, controllers and co-managers of those health services in which healthcare is not commoditized (publicly-oriented services);
- Whether, and how, users can contribute to avoidance of such commoditization in government services, in order to ensure their status as facilities with a social mission;
- Whether governments should promote a publicly oriented sector, possibly made up of public and private facilities, and entitle it to compete with the commercial sector in decent conditions;
- Whether, and how healthcare regulation should be strengthened

- Whether healthcare delivery should be commoditized when health care users are structurally not in a position to be an effective regulatory stakeholder.

In our view, the political question for public health strategies not aimed at health but at health economics is whether the benefit is equitably shared amongst public hospital doctors and health professionals (to enable them have a decent life) and patients (to give them access to decent quality care). We believe that such public health strategies may overlook solidarity and put the economic rationale above dealing with health, life and suffering in hospitals.

By identifying the limitations of regulating healthcare markets in LMIC, this study sheds an unusual light on equity in access to healthcare - the most significant feature of contemporary (inter-) national policies - as it relates to the commoditization of care in these regions.

In many health districts and services, the studied regulations were administered by a staff theoretically in charge of transmitting the regulation to hundreds of health workers and professionals. This administration should preferably be discussed and debated by the regulated staff, if the regulation is to be internalized, controlled in its application and evaluated in its effects.

Professor Ann Mills, from the London School of Hygiene and Tropical Medicine, repeatedly said during her professional life that, "…for a health administration, it is easier to directly deliver health care than to steer it…", …because, we would contend, health professionals are capable of taking relevant managerial initiative when their tasks and duties are compatible with their professional identity[124].

Annex 1: Criteria for assessing regulations

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 out the relevant actions. Also to assess the capacity of actors behind the scenes to interfere with regulation processes.**
3. **Criteria to assess the internal strength of regulations.**
4. **Criteria to verify the effects of a regulation.**

An overview of how best to proceed with these criteria in the process of assessing regulations is provided below. In the first instance, consideration should be given to what needs to be assessed and how. The sources of verification should orient the actual development of research tools and modes of analysis used in assessment of regulations (see also the information needs matrix in Section 7). The 4 categories of criteria identified are not intended to have an order of priority between them, nor to possess any intrinsic 'weight' that differentiates their importance.

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

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

a. The extent to which the 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 the context in an unintended way.

How should analysts go about assessing this possible fit between a regulation and its context?

Evaluators need to examine three hypotheses here:

- Do the regulation procedures and processes properly address contextual features?
- Do political, economic and psychosocial contextual features contribute to altering the regulation process, its procedures and its effects?
- Does the regulation have unintended effects on the context that could hinder attainment of its objectives?

- Depending on the chosen regulation, some of the elements that evaluators can look for in assessing this fit are the following:
    1. Whether or not access to care is defined within the regulation according to a demand approach (what are people asking for?) or according to 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 of the regulation: economic objectives relevant from an economic viewpoint, such as reality of competition, limiting of anti-competitive behaviour;
    4. What are the technical merits of local rules, as compared with internationally accepted ones?
- Sources of verification to assess the above include opinions from actors obtained through individual interviews and FGD, triangulated with a review of regulation documents and literature;
- Based on the actions above, the researcher should be able to make a judgment call on the extent of fit and continuous adaptation of regulations to their context (for example to market changes, etc.).

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

Analysts need to assess the extent to which actors possess the required capacity to implement or be engaged in a chosen regulation. Some aspects of the 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. Extent to which the appropriate actors are involved at the various stages of a regulation's processes;
c. The role of actors who remain deliberately hidden.

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

Researchers 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;
- The extent of their skill capacity.

In order to assess the actors' institutional capacity, analysis should ascertain 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 regulations, and to

which sharing of experiences and dissemination of information is made possible. To measure the actors' individual role capacity, analysts should find out whether people with the relevant job descriptions and authority are carrying out the steps that correspond to them within the regulation process. To assess the actors' skill capacity, researchers need to know more about the way regulatory staff are prepared as far as training is concerned.

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

- They need to identify problems and achievements in regulatory processes and procedures that can help pinpoint issues important to 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;

- Identification of issues in the regulation processes may help us to understand interventions and the role of actors;
- Sources of verification for assessing all this include opinions from actors obtained through individual interviews and 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 of the capacity of actors to engage in implementing the regulation.

b. Are the appropriate actors involved at the appropriate stages of a regulation's processes?

Here researchers need to appraise whether the appropriate actors were and are involved at the right time and place in the chosen regulation process. This appraisal is premised on the degree to which the presence or absence of actors, or of a particular actor, can explain the internal strengths and weaknesses (see also below) of a chosen regulation and its effects.

How should analysts go about assessing the extent to which the appropriate actors are involved at the appropriate stage? The following are some examples for you to follow:

- Sources of verification for assessing this include opinions and perceptions of the range of interviewees (one to one and through FGD), cross checked with the review of regulation documents and literature;
- 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 actors who intentionally stay behind the scenes?

Such actors act as the 'hidden hand' of influence. Understanding this element thus enables us to understand the degree of independence of the chosen regulatory processes and procedures from political and 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 large 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 insufficiently sympathetic to the needs of users. Regulatory capture may also be suspected when there is discrimination in the way in which regulated staff and institutions are handled by the regulatory agencies (for example some with favouritism).

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

- Sources of verification for assessing this include actors' opinions collected from interviews and FGD, triangulated with review of regulation documents and literature and analysed with discourse analysis;
- Based on the actions above, the researcher should be enabled to make a judgment call on the actors involved in regulation.

3. Criteria for assessing the internal strength of regulation

Evaluators need to define how we can measure the internal strength of a chosen regulation. 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 interviews and FGD, together with the review of regulation documents and literature, analysed with discourse analysis.

a. Appropriateness of the regulation

Here researchers 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? Are the particular regulation's objectives relevant to the existing problems and achievements in health services and healthcare delivery? Are the objectives of regulation evidence-based?

- Based on the above, the researcher should be able to assess the relevance of a regulation, the independence of its funding and the related transaction costs of regulation agencies, if any.

b. Internal consistency of the regulation

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

- Based on the above, the researcher should be able to assess the extent of cohesion between a regulation's procedures and objectives.

c. Is the regulation duly implemented in all its aspects?

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

- Based on the above, the researcher should be able to determine whether or not a regulation is implemented as intended.

d. Clarity and lack of ambiguity in the regulation

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

- The researcher should be able to assess the degree of ambiguity through critical reading of regulatory documents, analysis of organograms and assessment of the simplicity of regulatory institutions.

e. Extent of discretion vs. inflexibility

Here the researcher will assess the degree of freedom with which a chosen regulation's content or even a regulation's process can be adapted locally (by people involved in administration, operationalization, adaptation and oversight of regulations). He/she also needs to ascertain the extent to which that degree of freedom is matched with their capacity (see above).

- Based on the above, the researcher should be able to assess the degree of freedom.

f. Efficiency of the regulation

Assess the extent to which a regulation consumes as few resources as possible (for example administrative burden, etc.) to achieve its objectives. To estimate the degree of efficiency of a regulation the analyst 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 these. Any measurement of efficiency needs to be simple.

- Based on the above, the researcher should be able to assess the efficiency of a regulation process.

g. Existence of corrective feedback loops

A feedback loop is any internal monitoring mechanism or device according to which the design and implementation of the regulation can be or is being amended, as per 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 able to ascertain the existence of rent-seeking behaviours in response to regulations, and of corrections within the regulation process in response to monitoring results.

Annex 2: Governance quality criteria and indicators to make them operational

GOVERNANCE Principle	What information is needed?	How to verify?
'Equity and inclusiveness'	Are regulation objectives and definition able to tackle some of the following maternal health issues: 1) High variance in maternal mortality rate (MMR) across population strata, for example: - 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. Estimates 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'	What is the quality of 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'	What methods are used to identify and correct major maternal health problems? For instance, with regard to EmOC: compare the detection rate of pathologies associated with pregnancy (for example urinary track and gynaecological infections) to that of epidemiological surveys. 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 the frequency of	SSI

	legal procedures against those who practice sex selection evolved across time ?	
'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, and to what extent are they effective?	Studies on decentralisation of decision-making. Studies on the role of consumers.
'Transparency'	How is the degree of independence and impartiality of any professional associations participating in actual control and corrective procedures assessed? Are self-serving interests watched by governments in self-regulation[93,95-97]?	Studies on membership procedures, contracts, recruitment process and praxis of professional associations.
'Accountability'	Are regulation objectives and definition able to tackle the variance in implementation and enforcement of financial and administrative standards between 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 healthcare? 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 and definition of maternal health policy.

* Adapted from Siddiqi et al analytical framework.

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