HESVIC PROJECT

China Country Report

Grant agreement number	222970
Project acronym	HESVIC
Project title	Health system stewardship and regulation in Vietnam, India and China.
Funding scheme	FP7–HEALTH–2007-B
Due date of deliverable	14 May, 2012
Actual submission date	14 May, 2012
Version	Final
Dissemination level	Public

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Acknowledgements	The HESVIC Country Report of China is the result of great efforts made by many people and a variety of organizations. The Fudan team is sincerely grateful for the valuable input and kind help it received during the three years' research process. We send our special thanks to our colleagues from the Department of Public Health, Prince Leopold Institute of Tropical Medicine, Belgium for their technical guidance. We are also thankful to our colleagues at the Nuffield Centre for International Health and Development, Leeds University, for their effective coordination throughout the whole research process. We also appreciate having received insightful contributions and passionate support from our paired partner, Social Development and Gender Equity, Royal Tropical Institute (KIT), Netherlands, as well as from our Asia partners from the Hanoi School of Public Health and the Institute of Public Health, Bangalore, India. The continuous exchange and sharing of different creative ideas throughout the process has been very beneficial in shaping this final country report. We are grateful to all the respondents and facilitators in the research field. Respondents from Shanghai and other cities have also informed us in great detail on matters relating to health regulation. We would also like to give sincere thanks to all members of the Country Research Advisory Group who gave us many valuable suggestions and comments at every stage of the research. All provided us with not only valuable information but also great hospitality. In the absence of their comprehensive support, our work would not have been as smooth or successful. We would also like to express our appreciation for the general sponsorship of the European Commission under Framework Seven and to the School of Public Health,Fudan University for its administrative support. Finally, the leadership and contribution of Prof. Xu Qian has been indispensable for the completion of this report, as well as many other deliverables. Fudan team members comprising Yingyao Chen, Xiaohua Ying, Xiaoguang Yang, Hong Jiang, Yuan Tian, Chuanlin Li, Yishi Jiang, Qian Zhang, Qian Gu, as well as many others, have also dedicated themselves to numerous facets of the project, including academic research, administrative work, financial management, meeting arrangements and other daily tasks. The commitment of all team members greatly contributed to the success of HESVIC.
Suggested citation	School of Public Health, Fudan University (2012), Country report on health system stewardship and regulation in China, Deliverable 4.2

HESVIC	HESVIC is a three-year research project (2009-12) implemented under the European Community Seventh Framework Programme (FP7). The project aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice through a comparative study of three Asian countries – Vietnam, India and China. The project uses maternal health care services as a case study of stewardship and regulation. The goal is to support policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage of health care in the three countries. HESVIC partner organizations: ● 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, Prince Leopold Institute of Tropical Medicine, Belgium ● Social Development and Gender Equity, Royal Tropical Institute (KIT), Netherlands
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Acronyms

AC: Amniocentesis

ANC: Antenatal Care

BOH: Bureau of Health

CCP: Chinese Communist Party

CD: Capacity Development

CIPW: Critically Ill Pregnant Women

CVS: Chorionic Villus Sampling

EmOC: Emergency Obstetric Care

GR: Grievance Redressal

HII: Health Inspection Institute

ICU: Intensive Care Unit

KM: Knowledge Management

LVs: Letters and Visits

MAPCH: Measures for the Administration of Patient Complaints in Hospitals

MCH: Maternal and Child Health

MDAS: Maternal Death Audit System

MHII: Municipal Health Inspection Institute

MMR: Maternal Mortality Rate

MWHI: Municipal Women's Health Institute

MOH: Ministry of Health

NTDs: Neural Tube Defects

PD：Prenatal Diagnosis

PFPC: Population and Family Planning Commission

MPW: Migrant Pregnant Women

1. Project Background

1.1 Overview of key HESVIC research elements

'Health system stewardship and regulation in Vietnam, India and China' (HESVIC) is a multidisciplinary and multi-partner project implemented over a period of three years (July 2009 – June 2012) with the financial support from the European Commission FP7.

The project is a follow-up of the EU-funded HEPVIC project (Health Policy-Making in Vietnam, India and China: key determinants and their inter-relationships), which researched (2005–2009) ways to enhance health policy-making processes through a comparative study of the three countries' policy processes in the field of maternal health. The HEPVIC research suggested that the governance and regulation capacity of the three governments is pivotal for their dealing with the changing health sector.

The health systems of many low- and middle-income countries (LMIC), including China, are changing. One particular aspect of this change relates to the governance of health systems, with the old assumptions of a dominant public health delivery system (free at the point of use) alongside a smaller private sector now being challenged in many countries. Increasingly the make-up of such systems is becoming complex, with three particular characteristics. First, there has been a significant growth in the private sector (often run by public sector professionals) at national and international levels, with it becoming a much more significant provider. Second, the public sector itself has often had to adopt revenue-generating methods, particularly drawing on user fees for cost recovery, and as such introducing dangers of conflict in objectives between income-generation and pursuit of health. Third, decentralisation of health care has become a common feature of governance arrangements, with a variety of models being implemented in different health systems.

These changes in the structures and governance arrangements of health systems bring new challenges for the overall regulation of the sector and in particular for the role of the government. While bureaucratic and administrative control methods have traditionally been at the heart of Ministry regulation, there is today increasing recognition that effective regulation in LMIC requires a wider range of tools, and involvement of non-government Health actors. This report will focus on the dynamics of stewardship and regulation in China, the health systems of which cover close to one-sixth of the world's population. It will use maternal health as a case study for studying stewardship and

regulation policies and practices, with a focus on the range of participants in policy processes, the diversity of their understandings of the situation and problems, the way in which they interact with each other, and the outcomes of this interaction. Policy processes in this project are interpreted as a constant struggle over criteria for classification, boundaries of categories, and the definition of ideas that guide the way people behave.

Stewardship in health, an integral part of the wider governance system, is defined by WHO as “the effective trusteeship of national health.” Stewardship has been described as an expression of the role of the state as an agent for its citizens. Stewardship has been promoted as being capable of bringing together efficiency of organisational operation and ethical, trust-based representation. As such, government’s stewardship is ultimately concerned with an oversight of the whole health system including all actors - public and private - involved in the provision and financing of health care services. The concept of stewardship includes the tasks of defining the broad vision and strategic direction of national health policy, exerting influence through regulation and advocacy, and collecting and using information. In other words, the core function of stewardship is to establish the ‘rules of the game’ and enforce them through provision of strategic direction for all involved stakeholders.

Regulation comprises a large, but by no means the only, part of stewardship. Within the health system, regulation is performed either through government responsibility, reliant on bureaucratic and administrative control—which may or may not be reinforced with enabling incentives—and/or through participation of non-government stakeholders by private bodies that regulate their members. Regulation can thus take either the form of control or incentives, with the majority of health systems having various combinations of the two. Whether regulation is based on control or incentives, it inevitably enforces the principles of accountability of all actors involved in the provision and financing of health care services.

Our overarching question: How does regulation, and through it, governance, affect equitable access to quality health care?

Specific questions follow below. Key research elements include the regulation process and approaches to it, actors and their interrelationship in the process, regulation effects, implications to the general health system, and recommendations for improvement.

RQ1. What **approaches and processes** exist for regulating maternal health care and how do they operate in practice?

a. What are the various approaches (A, B, C, D) to regulation across the maternal health system?

b. How is regulation interpreted and implemented in practice?

c. What are the strengths and problems of these approaches and processes?

d. Why do these approaches and processes exist in these contexts?

e. What does regulation intend to achieve? For whom, to what end?

f. What is the role of information in regulatory processes?

RQ2. Who are the **actors** involved in the regulation of maternal health care, and what are their roles and power relations?

a. Who are the actors in the different approaches and processes of regulation?

b. What are the aims and priorities of these actors?

c. How are these actors involved in the different approaches and processes, and to what degree?

d. How do these actors relate to each other?

e. What is the level of influence of these actors on regulation of equitable access to quality maternal health care?

f. What is the relevant context and history of such regulation?

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

a. What is the current status of and obstacles to equitable access to quality maternal health care?

b. To what extent are these obstacles addressed in existing regulations?

c. What are the effects of regulation (approaches and processes) on quality of maternal health care?

d. What are the effects of regulation (approaches and processes) on equitable access (to quality maternal health care)?

RQ4. What are the **differences or similarities** between regulation of maternal health care and regulation of health care in general?

a. What are the differences or similarities between regulatory approaches, processes, actors and effects?

b. If there are differences, why is it so?

c. What are the implications of HESVIC findings for equitable access to quality health care in general?

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

1.2 Summary of the HESVIC research

1.2.1 Prenatal Diagnosis (PD) case summary

As a significant part of antenatal care, particularly in the context of rapid reduction of infant and child mortalities, prenatal diagnosis (including prenatal screening) is in increased demand. We chose prenatal diagnosis (including prenatal screening) for the HESVIC study on regulation because it is a case based on a wide spectrum of prenatal diagnosis: from technological development to service provision and utilization. Prenatal diagnosis not only embodies people's actual health needs, involving the development and management of medical technology (e.g. new technologies, the balance of safety with effectiveness, etc.), but also provides insights into the behaviour of service providers and the choices they make, the "shadow" market presence influencing the decisions and interests of medical institutions as they operate in the environment of our country's unique institutional mechanisms. We hope that we can find useful information and evidence for health system regulation through our study on the regulation of prenatal diagnosis technology and services.

This case selected the "Administrative regulation of prenatal diagnosis technology" (including related annexes), hereinafter referred to as "PD Regulation," as the target regulation to study. "PD Regulation" was issued in December 2002 by China's Ministry of Health (MOH), and was implemented in May 2003. The purpose of "PD Regulation" is to regulate the supervision and management of prenatal diagnosis services in order to ensure that the population throughout the country benefits from safe, effective technology through a series of articles based on the requirements of "Maternal Law" and its "Implementation Measures."

1.2.2 Emergency obstetric care (EmOC) case summary

Improving maternal health services and further reducing the maternal mortality ratio (MMR) is an important part of the Millennium Development Goals: it is also China's main objective in the area of maternal and child health (MCH). In China, MMR is one of the core concerns of The Law of the People's Republic of China on Maternal and Infant Health Care and the National Plan for Action on Women (2001-2010).

To reduce maternal deaths, the health system needs to focus on many aspects: maternal health care management, institutional delivery, the rescue of critically ill pregnant woman (CIPW), etc. EmOC is central to safe motherhood; hence equitable access to quality EmOC is an important means of ensuring safe motherhood.

Routine reporting data from the three-level MCH network in Shanghai from 2000 to 2007[1] points to obstetric haemorrhage as the main cause of maternal death. Many factors are associated with obstetric haemorrhage death, but to prevent such death, one must have access to good quality EmOC. Indeed, the management of obstetric haemorrhage is a composite indicator of obstetric service quality, and improving the quality of EmOC is key to reducing MMR. Consequently we choose to focus on EmOC for this case study.

Shanghai's BOH issued many regulations focused on improving the quality of EmOC and reducing the MMR. The selected regulation, "Notice issued on work principles related to emergency obstetric care (EmOC) consultation, referral and treatment process in Shanghai" (Shanghai BOH [2008] No.12), was emitted by Shanghai's BOH in April 2008. The regulation issued principles regarding the consultation/referral and treatment of CIPW during EmOC, including the responsibilities of new EmOC centers and related health agencies. The regulation intends to achieve appropriate consultation/referral, accountability, coordination between EmOC centers and all other related agencies. Its ultimate goal is to ensure all pregnant women, including migrants and the poor, have equitable access to quality maternal care. The selected regulation is more relevant to the EmOC thematic area than other regulations.

The objectives of this regulation are to solve EmOC problems in Shanghai (where delayed referral causes many maternal deaths) through: regulation of the consultation, referral and treatment process; reconstruction of the network; and enhancement of EmOC capability. The main content of this selected regulation is directed at the improvement of EmOC quality and accessibility, especially regarding migrant women's maternal health care. A comparison between local and migrant women's utilization of maternal health services will help answer equity-related questions.

1.2.3 Grievance redressal (GR) case summary

GR is an important part of the quality of medical services. Emphasis on patients' GR reflects a patient-centered approach in health care service delivery. Patients' GR provides important feedback on health care services delivery as a supplement to peer review and administration, so it can be a useful tool to improve health care quality. Hospitals are not only where patient complaints are delivered but also the main site of GR services. Patient complaints that do not encounter good management can easily deteriorate into medical dispute, resulting in exaggerated physician-patient conflict. Therefore, it is necessary to develop a clear hospital complaints management process, standardize hospital complaint management, and ensure patients with GR demand can go into a formal complaint system where each grievance gets redressed easily, quickly, timely and directly. In theory, a standardized process of hospital complaints management could help improve the equity and accessibility of GR. The MOH issued "Measures for the Administration of Patient Complaints in Hospitals" (MAPCH: Trial, 26 Nov 2009) to address patient complaints in hospitals at an early stage, for most of the surging number of medical disputes are not based on medical technology issues.

We selected the MAPCH regulation for study because although not a strong force for change in hospital management, it does aim to standardize the complaint process in hospitals and protect the rights of both patients and providers. As a guideline, it contains *no mandatory requirements*, such as access and assessment mechanisms. Yet this regulation applies to all types of hospitals at every level and is also a reference for other medical institutions. As defined, it involves such mechanisms as: consistency in relevant regulations, multi-actor participation, multi-department collaboration, GR information systems, hospitals' incentive mechanisms, and others.

1.3 Purpose and structure of the research report

1.3.1 Research goal

The report's research aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice and to equitable access to care. It aims to do so by developing an integrated approach to improved stewardship and regulation in the area of maternal health in China, in order to support policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage of health care in China.

Specific project objectives are:

Research-related

1. To review international state of the art stewardship and regulation in areas of general health, and in maternal health in particular;

2. To develop a typology of private and public practitioners involved in maternal health in the study countries, including China;

3. To identify and specify needs for stewardship and regulation in maternal health activities in China based on an analysis of service delivery problems;

4. To assess capacities, approaches to, and practices of, stewardship and regulation in maternal health care, services and systems within and across the cases; and to propose recommendations on improving stewardship and regulation in the field of maternal health and broader areas;

5. To disseminate the results and recommendations widely to the government and other key health sector stakeholders in China and in wider domains.

Other objectives

6. To enhance the capacity of the partner research institutions in health systems and policy research;

7. To increase sustainable collaboration amongst country research institutions in pursuit of the FP7 objectives.

1.3.2 Overview of the research process:

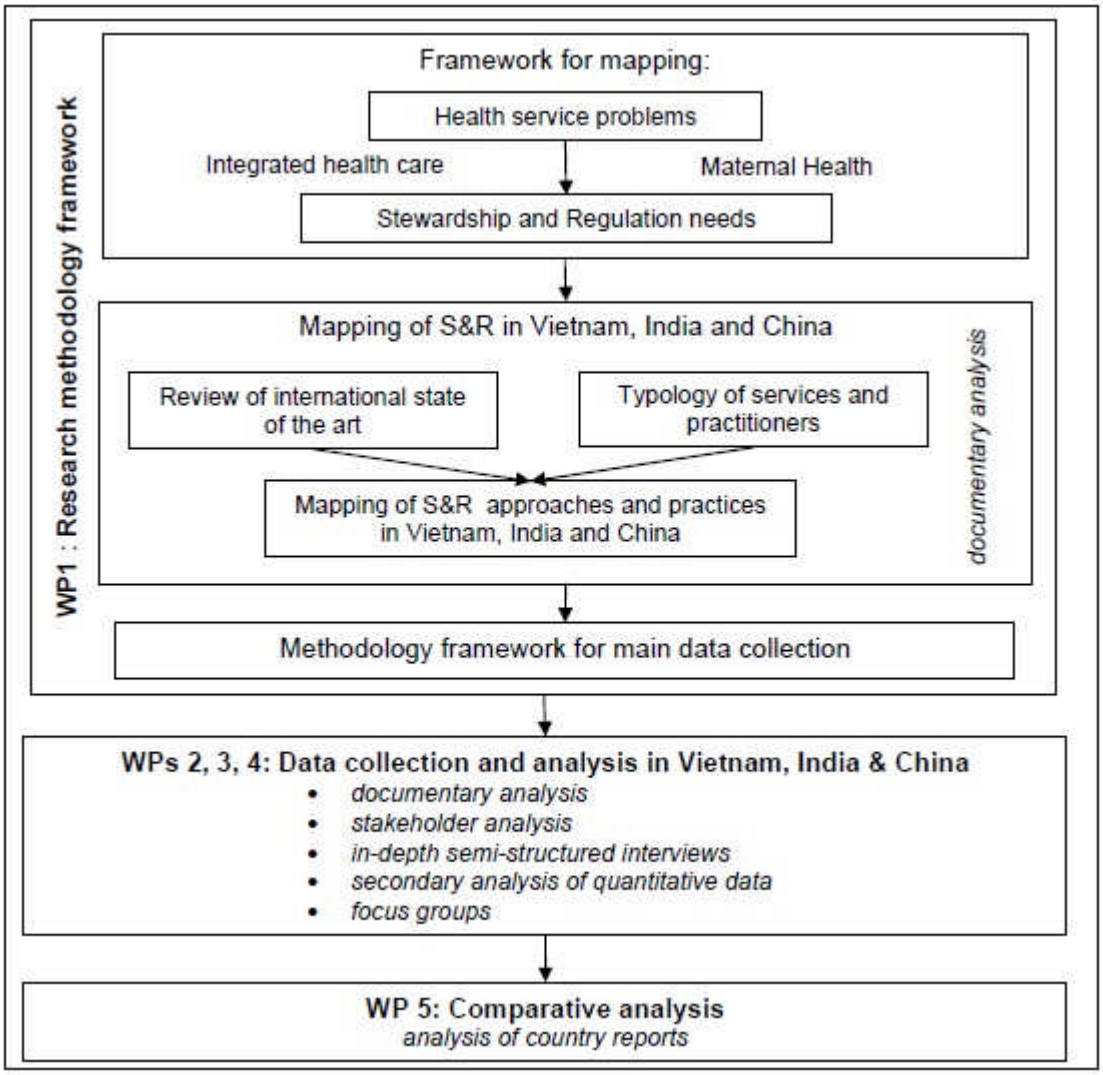


Figure 1.3.1 The HESVIC research process

This research report is mainly the result of Work Package 4, as above, plus a comparative analysis of the three China case studies. Main methods and the conceptual framework are shown in Figure 1.3.1. Then the case-specific results and comparative analysis of the three cases are reported. Finally, the overall conclusion is given.

2. Research Methods

The HESVIC study is an exploratory, descriptive-interpretative qualitative study with nested secondary, probabilistic quantitative data.

Based on our research methodology, this section provides an overview of the case-specific research methods used for both primary and secondary data collection during country-mapping, Phase One and Phase Two. It also describes and systematizes the country research process.

2.1 Secondary data collection:

For data, the PD case drew on national research literature on prenatal diagnosis technology and service delivery as well as on its regulation in China; it also drew on international research literature on experiences with prenatal diagnosis technology and service regulation. We searched literature in the Pubmed database, using “prenatal diagnosis" and "prenatal screening" along with "regulation" as keywords, and obtained 32 related references in English. We also searched the Chinese database CNKI, using "prenatal diagnosis," "prenatal screening,” and “birth defects” as keywords, and obtained 44 related references in Chinese. Lastly, we obtained one national investigation report focusing on prenatal diagnosis providers' capacity and service delivery, as well as, through personal relationship, one provincial statistical report on local prenatal diagnosis service delivery.

The EmOC case also drew on secondary research data. Such data were drawn mainly from the ***China Health Statistics Yearbook (2005-2010)***, ***National Health Service Survey***, and ***Shanghai Statistics Yearbook (2005-2010)***. Key words used in the literature review were as follows: shanghai, critically ill pregnant women, emergency obstetric care, obstetric service quality, maternal health, maternal death/maternal mortality rate, rescue/emergency rescue, etc. A total of 31 references were found relevant to the EmOC case, of which 20 core references were eventually cited.

The GR case drew on national and international research literatures regarding the handling of patient complaints. We searched in the Pubmed database and Web of Science, using “grievance redressal," "patient complaint," "health care complaint" and "hospital complaint" as keywords, and obtained 38 English publications. We also searched in the Chinese CNKI and WANFANG databases, using "patient complaint," "hospital complaint,” “health provider-patient dispute,” and “medical dispute" as keywords, and obtained 36

Chinese publications. In addition, as current statistics on medical malpractice and medical disputes were not disclosed, some literature to which we referred contained inconsistent statistical definitions. Interviewees also provided some second-hand data. For example, administrator participants provided corresponding declarative, interpretive, and administrative documents. Implementer participants provided implementation details related to this regulation, i.e. complaint handling and management system within the hospital.

2.2 Regulation document references

Besides the regulation each case study focuses on, related ones were also studied during the research process. Table 2.2.1 shows such related regulations in each China case study.

Table 2.2.1 Related regulations in each case study of China

Date	Level	Regulation Title
PD		
2002.12	National	Administrative regulation of prenatal diagnosis technology
2003.10	Municipal	Implementation notice on regulation of prenatal diagnosis technology in Shanghai
2004.6	Municipal	Measures on MCH-specific techniques and human-assisted reproductive technology in Shanghai
2008.6	Municipal	Measures on MCH-specific technology and service delivery in Shanghai
EmOC		
2004.6	Municipal	Service guidelines for designated migrant childbirth service delivery points (Shanghai BOH [2004] No.14)
2007.1	Municipal	Quality requirements for obstetric care and management in Shanghai
2007.4	Municipal	Notice issued to strengthen maternal healthcare management and designated migrant childbirth service delivery points in Shanghai
2007.4	Municipal	Notice issued to establish critically ill pregnant women consultation/ rescue centers under the BOH 2007 “Subsidy Projects” [directed at residents’ benefit and well-being]
2007.12	Municipal	Notice designating five municipal medical institutions as Shanghai’s five consultation/rescue centers for critically ill pregnant women [institutions such as

		Jiaotong University-affiliated Renji Hospital were included]
2008.4	Municipal	Notice issued to establish work principles for emergency obstetric care consultation, referral and treatment in Shanghai
2010.6	Municipal	Notice issued to further improve maternal health care and emergency obstetric care in Shanghai
2011.8	Municipal	Notice issued to establish an assessment device for critically ill pregnant women (Trial)
GR		
2002.09	National	Regulation on Handling Medical Malpractice
2002.09	Municipal	Several Opinions on Handling Medical Malpractice in Shanghai Medical Institutions
2002.09	Municipal	Implementation Plan for liability insurance of medical malpractice in Shanghai (Trial Implementation)
2003.01	National	Notice issued by the Supreme People's Court on Medical Disputes with respect to the “Regulation on Handling Medical Malpractices”
2005.09	Municipal	Guide to “Disputes over Compensation for Medical Negligence”
2007.02	National	Measure on the Resolution of Complaint Letters and Health Administrative Department Visits
2009.12	National	Measure on the Administration of Patient Complaints in Hospitals (Trial Implementation)
2010.01	National	Opinion on Strengthening People's Mediation in Medical Malpractice
2010.07	National	Tort Liability Law of the People's Republic of China
2011.06	Municipal	Opinion on Carrying out the People’s Mediation for Medical Malpractices

2.3 Sampling methods

All three cases adopted a purposive sampling method. According to the research framework, interviewees were divided into five categories: designers, administrators, regulated staff, patients and other actors, taking into account the research sites and information saturation. 84 interviews in total were carried out in the three case studies of China. The interviews of each case in Phase One and Phase Two are summarized in Table 2.3.1.

Table 2.3.1 Interviews carried out in case studies of China, Phase 1 and Phase 2

Case	Type of interviewee	Phase One	Phase Two
PD	**Designers**	1	2
	Administrators	1	1
	Regulated staff	1	9
	Users	0	6
	Other actors	0	7
	SUBTOTAL	**3**	**25**
EmOC	**Designers**	1	4
	Administrators	1	10
	Regulated staff	1	6
	Users	1	4
	SUBTOTAL	**4**	**24**
GR	**Designers**	1	1
	Administrators	1	3
	Regulated staff	1	9
	Users	0	5
	Other actors	0	7
	SUBTOTAL	**3**	**25**
COUNTRY TOTAL		10	74

2.3.1 PD case

In the PD case, based on the current status of prenatal diagnosis of China, we made two major modifications of the interviewee categories. One pertained to the implementation stage of the regulation process: we not only focused on service providers but also took regulatory bodies into consideration. The other major modification pertained to the location of thematic experts. Based on our knowledge, experts participated in almost the entire regulation process, from definition to administration and implementation. Of course, different experts played different roles, so we categorized them separately. PD case users were sampled based on difference in use of PD service (either prenatal screening, prenatal diagnosis, or both) and difference in socio-economic class, e.g. education, financial resources; the migrant population was also involved. Some users were recommended by their doctors.

2.3.2 EmOC case

A non-random purposive sampling method was used in Phase One. Respondents for our EmOC case in Phase One were a limited number of key informants with knowledge, experience and perceptions of EmOC in Shanghai. One respondent for each type of designer, administrator, implementer and user was interviewed. The information from these interviews was used to inform the design of the data collection tools for Phase Two, as well as to establish a way to identify other respondents. For the EmOC case, four respondents in total were interviewed during Phase One.

Phase Two used non-random purposive sampling, stratified by type of respondent. Respondents were identified from the following organizations, in light of the EmOC regulation process: Shanghai's BOH; two municipal districts' BOH; two municipal district MCH institutes; MWHI; and the Departments of Medical Affairs, Obstetrics, and other areas both in municipal EmOC centers and other medical institutions.

Interviews for each type of respondent started with key actors, and, as Phase One interviewees oriented us, proceeded through snowballing[a] from the lower level to the upper level. For instance, with the sampling of regulation administrators: based on the orientation of Phase One's interviewees, at the beginning of Phase Two, hospital-level administrators were identified and interviewed, then information about district administrators was collected and district administrators were sampled and interviewed; next, information about municipal level-administrators was collected, after which municipal-level administrators were identified and interviewed. In this way, we encountered key problems met during the regulation administration and implementation process and were able to explore deeper interview questions with high-level administrators.

Based on the record of CIPW rescues in 2011, each district MCH institute or obstetric hospital identified potential respondents among users. The inclusion criteria formulated by the research team specified that: users must have previously experienced emergency obstetric care (emergency rescue/consultation/referral) in a hospital or designated EmOC center, and if so should be contacted and given the choice to take part in the Phase Two interview process; interviewed users should include both Shanghai residents and pregnant women from the "floating" migrant population; users must be from a comfortable socio-economic group (i.e. of high income and/or holding medical insurance) and from the poor and/or disadvantaged (i.e. of low income and/or holding no medical insurance). Because of the confidentiality due users' information, users were invited for interviews by district MCH health institutes.

[a] A sampling method through which respondents identify and recommend further persons for sampling

Since district MCH institutes are in charge of following up CIPW within their district, it was feasible they sample the women and invite them to conduct the interviews. Women who agreed to participate were contacted by the research team and interviewed. According to the consortium's suggested ethics rules, all interviews with users were held at least three months after EmOC service.

The sample size was managed according to the saturation principle. In the EmOC case study, one regulation designer and one administrator were each interviewed twice, first in Phase One and then in Two. Ultimately, 28 subjects were interviewed in the EmOC case.

In the analytical Phase Three, some follow-up interviews were carried out through phone calls, emails, or face-to-face interviews via CRAG meetings and validation workshops. At one CRAG meeting in December 2011, many CRAG members commented on the primary research findings. From these comments, new problems were put forward and discussed; also, some preliminary results were verified. At a January 2012 validation workshop, certain key respondents brought together validated the findings from the case study report and provided deeper information about the EmOC case.

2.3.3 GR case

In Phase One, we selected key informants for the process related to "Measures for the Administration of Patient Complaints in Hospitals" (Ministry of Health, Trial) according to the main three categories of respondents, one of each type: designers, administrators and implementers. Phase One interviews were carried out following the semi-structured interview guidelines and aimed, preliminarily, to understand the process of this regulation. These interviews also served as a basis for the design of the Phase Two interview guidelines. Phase One interviewees also proposed Potential respondents for Phase Two.

Phase Two started with implementers. Key informants were interviewed regarding the handling of patient complaints in selected hospitals based on location, level and type. Following the snowball sampling principle, we also asked these interviewees to invite patients willing to participate in our study. Patients were selected from different GR channels, but shared one thing in common: all had first complained in the hospital. Other actors were identified according to interviews with implementers, and then likewise invited to take part in interviews. This sampling method continued until no new information could be obtained by increasing the interviewees (saturation principle). Then we interviewed administrators, and finally designers. The entire process ultimately formed a loop, best reflecting the process and effects of the regulation.

2.4 Study site

Shanghai was the site selected to assess the effects three different regulations, two of which were national ones (related to the PD and GR case studies) and one of which was a local municipal regulation (related to the EmOC case).

In the EmOC case, equity of access to maternal health services among different types of women, including the local (resident population) and the migrant ("floating" population) women in Shanghai, was a main concern; hence the geographic presence and location of migrant CIPW was an important co-factor in selecting our study area. Accordingly, one central district and one suburban district were deliberately selected. Data from the Sixth National Population Census showed that Shanghai residents in the central district were registered mainly as householders and accounted for 74.24% of this district's total population.[1] In the selected suburban district located in the northwest of Shanghai, residents were mainly migrants, accounting for 56.29% of that district's total population.[2]

In the GR case study's Phase Two sampling process, both urban and suburban areas were considered regarding the issue of equitable access to GR regulation. A tertiary general hospital and a tertiary MCH institution were selected in an urban district; and a secondary general hospital and a secondary MCH were selected in a suburban district. The unit of analysis used for comparison in the GR study case were GR services in urban and suburban areas, in tertiary and secondary hospitals, in general hospitals and in a MCH institution.

For the PD case study, quality, equity and accessibility of prenatal diagnosis service delivery were taken into consideration. Regarding providers, consonant with Shanghai's local situation, we involved both prenatal diagnosis centers and prenatal screening centers in interviews, since different technical requirements exist between these two kinds of health institutions. As for users, we tried our best to find women from different socio-economic situations with particular experience in the utilization of prenatal diagnosis services. We also made sure that migrant women and women from Shanghai district's more rural areas were involved.

Since private hospitals do not account for much market share of Shanghai's

medical services, as part of our comprehensive study, we conducted two different interviews with the same director of a private hospital in order to compare EmOC and GR services in public and private hospitals. In the PD case, one private hospital potentially dealing with prenatal diagnosis services delivery was identified. However, it refused our interview invitation. We had to interview those with possible information related to prenatal diagnosis service delivery and regulation in the private health sector. Along the way, differences in the regulation process as it pertains to public and private hospitals were also placed before other interviewees, including regulation designers and administrators, to help us better understand the regulation process in both public and private hospitals.

2.5 Analysis method

For case studies, key informants were interviewed in accordance with the semi-structured interview guidelines. Written informed consent was obtained from each participant for each interview. Digital recorded materials were transcribed verbatim. Written field notes were compared. The themes were defined in accordance with the research framework, and then coding and analysis were carried out using the thematic framework analysis incorporated in Nvivo9.0 software.

For the intra-country comparative analysis, content analysis was applied. Matrices were designed from the three case studies based on the research questions. The contents of the matrices were coded according to the node tree yielded from the report guideline and the comparison of themes sent by the consortium.

2.6 Ethical issues

According to best academic practice, and as a legal requirement in the project contract, research strictly adhered to an ethical framework. One month before the Phase One and Phase Two data collection, project protocol and informed consent forms were submitted to the Institutional Review Board (IRB) of the School of Public Health, Fudan University for approval. Our IRB is registered with the office for Human Research Protections, IRB00002408, and has a Federal Wide Assurance, FWA00002399. Ethical issues raised by the research were:

- **Informed consent**: An informed consent statement was explained to, and agreed upon, by all respondents.

- **Confidentiality**: Access to data (transcripts, records) was restricted to approved members of the research team who signed a confidential agreement with the country's principal investigator. Data were stored in secure electronic locations (access-protected directories on computers).

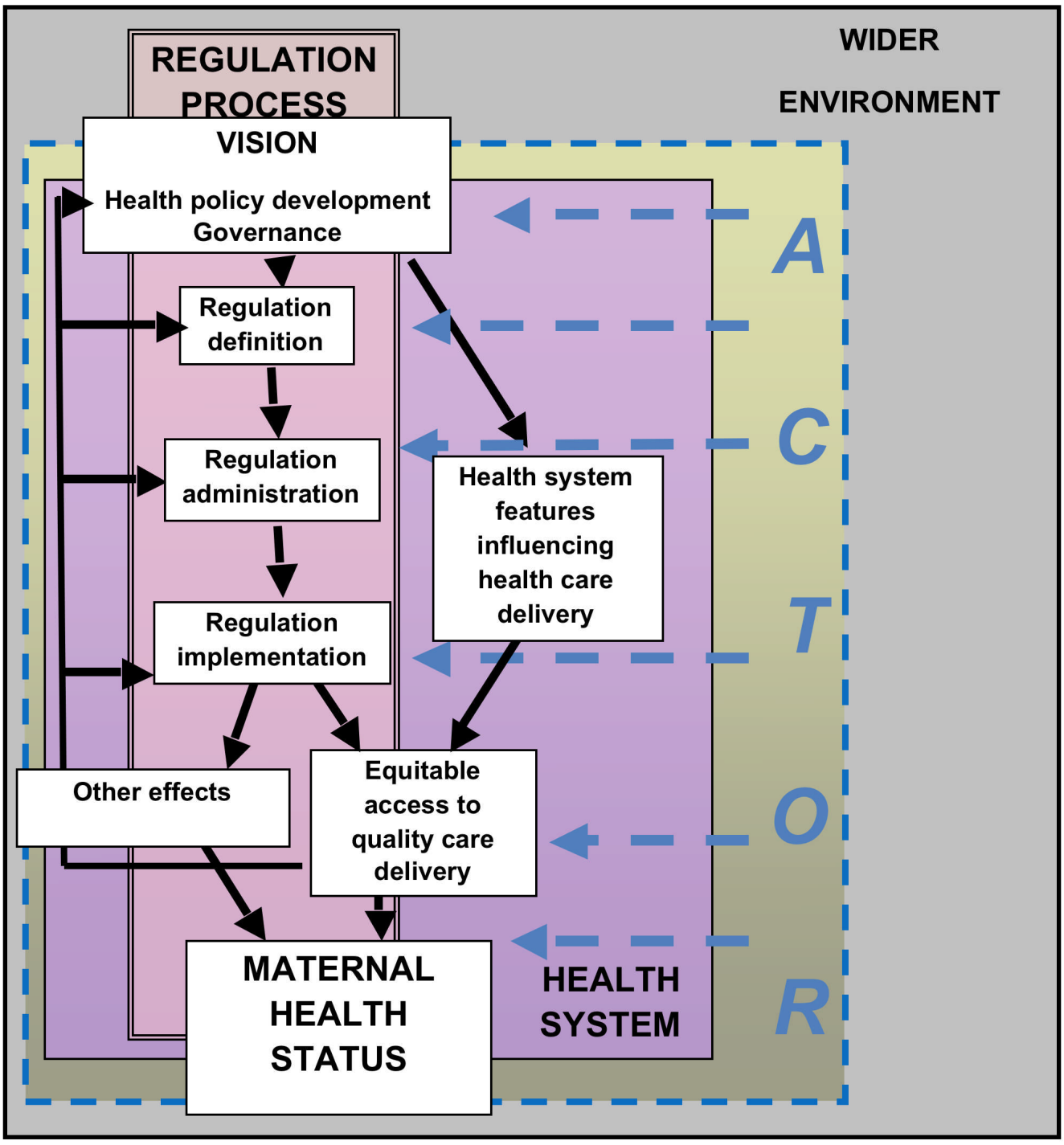
- **Anonymity**: The aim was to ensure that outputs arising from the research do not attribute information to any particular source unless prior agreement is given. Data processing was kept anonymously. The names of the respondents have been deleted from quotations in the written report so as to protect the identity of respondents. Later on, prior to publication, all unnecessary identifying details will be stripped from the research data.

- **Feedback**: Respondents will receive some feedback from the research once it has been completed, with acknowledgement of contribution.

3. Conceptual Framework for China

The conceptual framework below (Fig. 3.1.1) offers an ideal model for maternal health regulation and its interaction with actors and environment.

Figure 3.1.1: Conceptual framework of the HESVIC research



3.1 Vision, governance and health policy

Accordingly, the framework distinguished the following key components:

Assuming vision, and in alliance with governance, health policy development becomes the start-up point for regulatory mechanisms.

Governance, as used in HESVIC, describes how public decisions are made and implemented. Regulation processes and content are used to provide insight into and assess governance.
The regulatory effect (equitable access to quality maternal health care), the primary focus of this research study, is best understood through a study of regulation processes (definition, administration and implementation, mechanisms, approaches, actors and context).

Alongside the above-mentioned sociological exploration, partners have expressed their wish to apply the quality criteria formulated by Siddiqi et al to assess governance in the regulation of maternal health care. What we studied is listed in Table 3.1.1.

Table 3.1.1: Governance quality criteria and indicators to make them operational

GOVERNANCE Principle*	**What information is needed?**	**How to verify?**
'Equity and inclusiveness'	Regulation objectives and definition are fit to tackle some of the following maternal health issues: 1) High variance in maternal mortality rate (MMR) across population strata, e.g.: Migrant/ floating vs. residents in Shanghai; 2) social strata specific catastrophic health expenditure; 3) Inequitable distribution of resources; 4) Variance in quality of EmOC according to social and geographical criteria; 5) cost of EmOC episodes;	Analyse mapping reports, Phase One summary reports, and regulation documents. Use data from information systems. Estimations from local level studies. SSI
'Effectiveness and efficiency'	How does local health management deal with issues of care quality and administrative efficiency?	Analyse regulation documents, SSI
'Quality assurance procedures'	Which practice – if any - exists with audits of maternal casualties?	Analyse regulation documents, SSI
'Intelligence and information'	How is the performance if any of the Health Information System (HIS)? For both public and private providers.	SSI
'Responsiveness'	Check for users' perspective.	SSI
'Rule of law',	What perception do actors have on control,	SSI

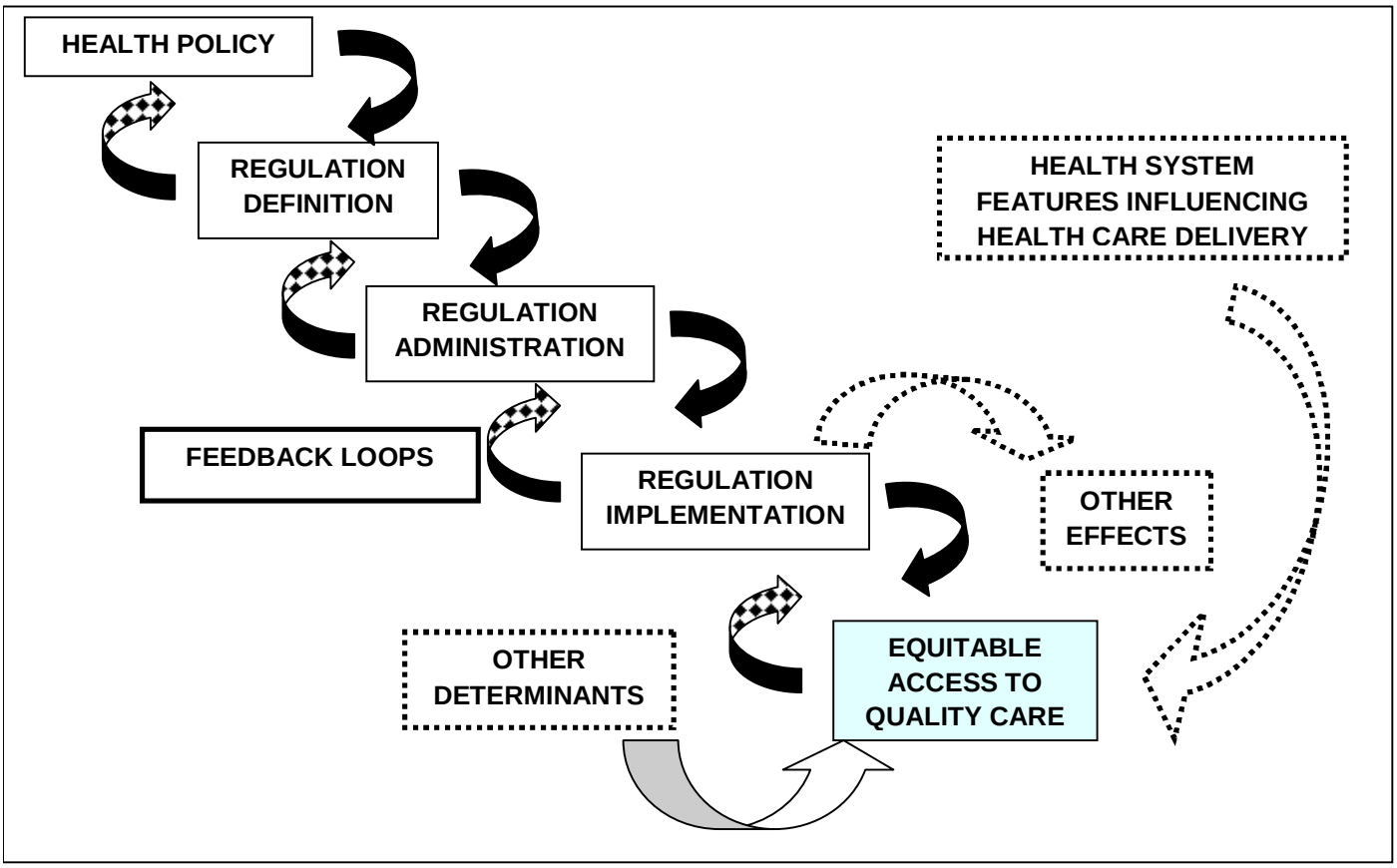
'ethics'	repression and regulation?	
'Participation and consensus orientation'	What is the role of States, regions and districts in defining and enforcing regulations?	SSI
'Transparency'	How do you assess the degree of independence and impartiality of actors participating in actual control and corrective procedures?	SSI
'Accountability'	Are regulation objectives and definition fit to tackle with the variance in implementation and enforcement of financial and administrative standards according to health facilities?	Analyse the procedures for overseeing adherence to financial, administrative rules
'Strategic vision'	What is the degree of compatibility between different preoccupations at the level of local and national government in relation to quality maternal health care? Is there a clear strategy to deal with such concerns in the long run (e.g. on MDGs?)	SSI

* Analytical framework adapted from Siddiqi et al[3].

3.2 Regulation process

The regulation process in part reflects a flow of guidance and authority from, for example, the level of policy (top) to regulation implementation (bottom). In some instances, the existence of a bottom-up flow of information can't be ruled out. Ideally, this flow happens through management control systems and information, planning and liaison devices (e.g. formal and informal meetings; see Fig. 3.2.1).

Figure 3.2.1: Relation between different stages of the regulation process



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

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

3.3 Actors

By definition, actors have roles in the maternal health regulation process, and their roles can often be clearly identified. Actors in the maternal health regulation process are as follows:

1. Policy and regulation designers, including, for example, policy-makers at different levels (country, province, state)—these actors are probably not directly involved in health policy processes;

2. Actors involved in the administration of regulations (operationalizing, adapting and maintaining oversight of regulations), including, for example, service quality control commissioners, licensing and accreditation authorities, etc.;

3. Regulated staff (those who abide by the regulation), including health facility managers, and district, hospital and province medical officers in the public and private sectors;

4. Users of services i.e. women, patients and communities;

5. Other actors with multiple (or less clearly defined) roles in regulation processes (for example, NGOs, civil society, insurance companies, international agencies). Note that the inclusion of these actors in the category “Others” does not mean that they are less important than the named groups. Some, however, may not be open to interviews;

6. UN agencies were raised in the context of Vietnam and India only as an important separate group.

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

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

3.4 Effect of “equitable access to quality care” on maternal health

“Equitable access to quality care” is a critical issue, relevant to those regulations aiming at securing a right. We will call them promoting or enabling regulations (e.g. to secure universal access to quality EmOC).

To assess the effects of promoting regulations on quality of care at the point of

contact, as researchers, we want to know: Can providers, as a consequence of regulation, organize health care that meets the best standards of quality of care, and if so, to what extent can people access that care?

Care quality can be defined both as that which is accepted as standards of best practice as well as that which derives from patient perceptions, e.g. a user may perceive an injection to be of higher “quality” than pills even if it is not necessary.

At times, regulation processes may have other, sometimes unexpected and/or unintended effects that are not closely related to equitable access to quality care. Such effects may occur under the influence of actors, health system features and even the wider environment.

3.5 Wider environment

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

4. Country Context

4.1 China's rapidly changing society

China has the largest population in the world, and the last two decades' change in that population indicates two major trends: a decelerating increase as well as more frequent movement within the country (internal migration). From 1990 to 2010, China's total population increased from 1.14 billion to 1.34 billion; however, the birth rate decreased from 21.1% in 1990 to 11.9% in 2010, and the natural population growth rate fell from 14.4% to 5.1%.

With the increase in the total Chinese population has come accelerated movement. According to Sixth National Population Census of 2010,[4] the number of urban residents was 665.6 million, accounting for 49.68% of the total population, and the migrant population measured 261.4 million, including 40.0 million inter-provincial migrants.

From 1990 to 2010, Shanghai's total population (including its migrant population[b]) increased from 12.8 million to 23.0 million and the natural population growth rate fell from 3.5% to -0.60%. In Shanghai, the migrant population grew to 9.0 million (those who live in Shanghai at least half a year), accounting for 39.0% of the total population in 2010.[5]

China's economy has grown rapidly in the last two decades. By the first half of 2011, its gross GDP had reached 20,446 billion CNY (or 3245.4 billon USD), the world's second largest GDP, just after that of the USA. In 2010, Chinese government revenue was 8308 billion CNY (or 1318.7 billion USD), a 21.3% increase over the previous year.

With such significant economic development, the government of China has acquired a greater capacity for health input (see Figure 4.1.1). In the last three decades, health expenditure in China has undergone rapid growth: total health expenditure increased from USD 13.7 billion (16.0 billion CNY, exchange rate 1.17 CNY:1 USD) in 1981 to USD 252.3 billion (1720.5 billion CNY, exchange rate 6.82 CNY:1 USD) in 2009 (a nineteen-fold increase) and health

[b] In China, migrant population statistics are usually related to the "household registration system," which requires that every newborn Chinese baby be registered with the local authority to gain "legitimate" status. The most crucial aspects of the individual's welfare—such as education, healthcare, and employment—are all linked to the household registration system (Hukou). Only under few circumstances may a Chinese resident move his/her "Hukou" to another location; an example of such a circumstance is recruitment by a local college, other public sector, or the military. Shanghai's official migrant population figure refers to those who have no Shanghai "Hukou" but have lived in the city for more than 6 months. However, because of this population's high mobility, it is very difficult to accurately estimate this figure.

expenditure per capita increased from $13.7 (16.0 CNY) in 1981 to $189.6 (1289.0 CNY) in 2007, a thirteen-fold increase (see Figures 4.1.2 and 4.1.3).

In 1990, China's urban health expenditure per capita was USD 33.2 (158.7 CNY), while rural health expenditure per capita was only USD 8.1 (38.7 CNY) (approximately USD 25 less [120 CNY]). In 2008, health expenditure per capita rose to USD 266.4 (1862.3 CNY, exchange rate 6.99 CNY: 1 USD) in urban areas and USD 65.1 (454.8 CNY) in rural areas, an approximately USD 201 (1408 CNY) difference. Between 1990 and 2008, health expenditure per capita increased by 8.02 times in urban areas and by 11.7 times in rural areas (China Health Economics Institute, 2009), but the per urban / rural capita differential remained 4:1.

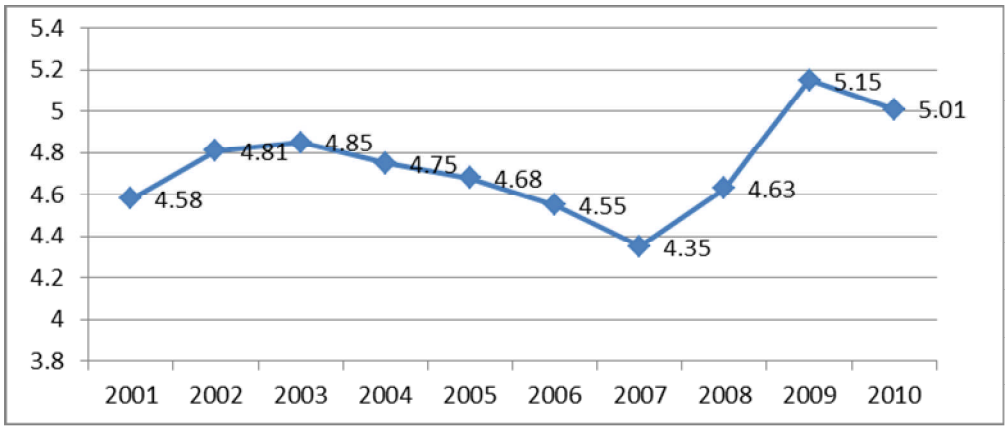


Figure 4.1.1 Proportion of China's GDP as Health Expenditure

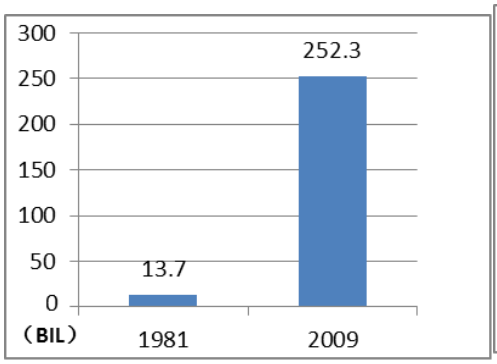


Figure 4.1.2 Growth of Health Expenditure in China (in Billion USD)

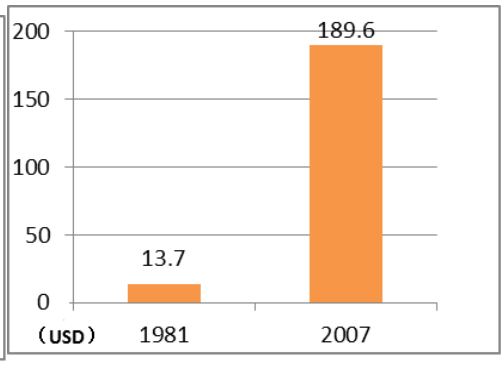


Figure 4.1.3 Growth of Health Expenditure Per Capita in China (in USD)

As a result of efforts throughout its health sector and entire society, China has continued to improve its population's general health status. In 2005, China's average life expectancy was 73 years, with females at 74 years and males at

70 years (***China Health Statistics Yearbook 2009***). In 2010, Shanghai's average life expectancy reached 82.1 years, with females at 84.4 years and males at 79.8 years (***Shanghai Statistics Yearbook 2011***). Meanwhile, the maternal mortality rate and infant mortality rate have been dropping continuously both in China and Shanghai (see Figure 4.1.4).

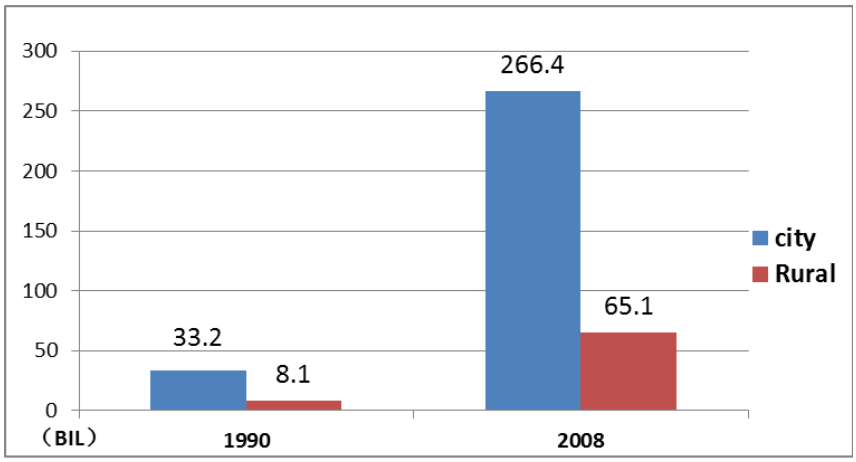


Figure 4.1.4 Urban and Rural Health Expenditure Per Capita in China, 1990 and 2008

From the above contextual information we can conclude that China is still in a phase of rapid change regarding its population structure, economic development and health conditions. As a result, demands from people seeking better access, quality and more efficient processes in health services provision are increasing. The three case studies of EmOC, PD and GR are probed under just such a social background.

4.2 Governance principle focus: "People-centered" development and social harmony

The case studies in China currently under this report's scrutiny exist within a broader governance framework having a fundamental influence over most specific regulations currently in practice. Generally, two basic governance ideas dominate policy-making and practice in China: a "people-centered" perspective and the principle of a "harmonious society."

Governance idea focused on the development of people

This "people-centered" perspective has been the dominant idea of Chinese governance these last ten years. China's governors used to put too much attention on economic growth, and social welfare was not equally emphasized.

Because of the less-developed social system and lack in public policy, the existing social gap tended to widen, increasing social tensions. Facing such a situation, beginning in 2000, the CPC began to promote its idea or principle of "people-centered" governance, often referred to as the "Three Represents" theory and the "Scientific Outlook on Development." This new governance idea places the greatest importance on the utilization of the country's economic growth and social development to fulfill the people's interest. In other words, the Chinese government has been putting increased emphasis on improving people's livelihoods and welfare. This governance principle has, in turn, promoted greater social concern in public affairs, including public health, from which have been derived many sub-principles, such as the "patient-centered" idea proposed by health services as a model for rebuilding the patient-doctor relationship.

Social stability and harmony

A peaceful and well-ordered society is another objective of Chinese governors; hence, the attainment of social stability and harmony is often addressed at the forefront of China's governance policies. Chinese governors have listed "stability" as a core governance value, the principle overriding all else, and the main criterion for evaluating the level of public governance success. As a CPC report states: we should "promote reform and development in a stable environment, and achieve social and political stability through reform and development" (CPC Central Committee, 1997). Accordingly, reform is the driving force for social development, development is the goal of the reform, and both reform and development are necessary to achieve social stability.

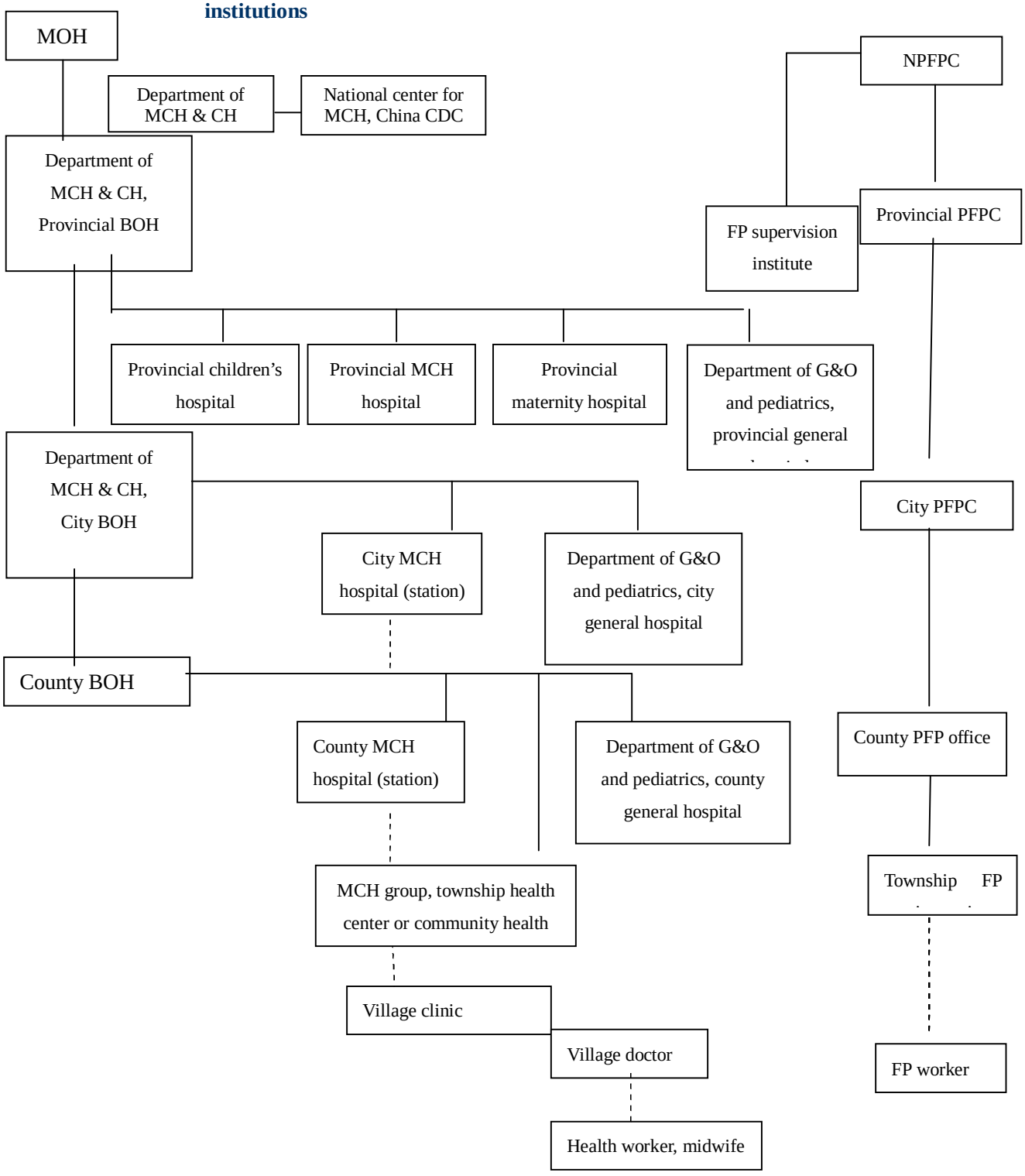
In recent years, "harmonious society" has become a term very popular in almost every aspect of Chinese public affairs. According to official documents, "harmonious society" includes and depends upon all of the following: coordinated development, social equity and justice, cultural harmony, ideologically and ethically-founded social harmony, as well as improved public administration, whose mission is to build a vigorous and orderly society (Sixth Plenary Session of the 16th Central Committee of the Communist Party of China [CPC], October 2006). Following this general principle, many public sectors have been promoting "harmony" to express an overarching advocacy, a drive embodied by slogans such as "harmonious schools," "harmonious hospitals," and so on.

The new governance ideas indicate that the Chinese government is now taking into consideration factors more related to social harmony and overall human development than those focusing exclusively on economic development. The emphasis of such factors likewise promotes social policy-making in terms of health, education and gender, and the implementation thereof.

4.3 On-going health system reform in China

China’s basic health service model is composed of a health care network structured by three levels. This model begins with tertiary health institutions (hospitals) at the province or city level, then secondary health institutions at the district level, and finally primary or community health service centers at the basic level. In rural areas within a county, this three-tiered model begins with the county health institution (as the highest tier), followed by the township health center, and then the village clinic, the anchor of the network. The network structure of China’s maternal and child health care and family planning service is shown in Figure 4.3.1.

Figure 4.3.1 Structure of China's maternal and child health and family planning service institutions



（Solid line denotes administrative leadership, dotted line denotes operational guidance.）

The health system in China is currently undergoing an important reform process, usually known as the "new health reform." Beginning in April 2009, this reform accorded the health system greater influence over almost all health

administrative agencies as well as health service providers. The primary aim of this reform is to place the focus on achieving universal access to basic medical care and health services, and to put more effort into solving those problems most causing people the concern, based on China's current national condition. By insisting on public health transparency, prioritizing prevention, focusing on rural areas, and attaching equal importance to traditional Chinese and modern Western medical treatments, the reform aims to construct a basic health system that covers both urban and rural residents, enhances people's health, and promotes social harmony. Additionally, a series of regulatory documents released by the Ministry of Health, and other related ministries, encourages private health care providers to support this same vision. However, private health providers still have long a way to go before becoming an indispensable force in China's health system.

Achieving universal coverage, promoting basic public health service, and reforming public hospitals are the central goals of this recent health reform, which is based on added governmental input, enhanced capacity of grass-roots health institutes, and renewal of various mechanisms. The three-year endeavor has seen the establishment of a health insurance system that covers the overwhelming majority of the population; also, the primary care system has been rebuilt, particularly in rural areas. This on-going health reform represents a significant change in context of China's health system, also closely related to the context of our three HESVIC case studies.

In China, MCH institutions are established based on administrative region. MCH hospitals (stations) are set up at the province, city and county levels, with an MCH office also in each township health center. Provincial and municipal MCH institutions take full responsibility for and command of the health status of women and children, coordinating between health administrative departments to institute plans, provide clinical services for women and children, train junior health professionals, effect health education, manage MCH information, and conduct scientific research and international cooperation projects.

Rural county-based MCH institutions take charge of guiding MCH and family planning services within county boundaries, assume scientific research within their powers, train junior MCH professionals and kindergarten personnel, give children health examinations upon kindergarten and school enrollment, and manage the MCH information of the entire county. The primary responsibility of each township health center's MCH office is to take command of basic MCH operations within township boundaries, to report in timely fashion to the appropriate senior institution, to manage pregnant women and children systematically, and, when possible, to train village maternal health workers. The township health centre is the lowest level of institutional delivery care for normal childbirth and certain low-risk pregnancies. Village maternal health

workers, administered by villager commissions and guided and managed by township health centers, take charge, operationally, of antenatal examinations of pregnant women, referrals, and postnatal visits.

In China, health institutions associated with maternal health include general hospitals, MCH hospitals, the CDC, and so on. The role of MCH hospitals and general hospitals in maternal health is to provide antenatal, prenatal, childbirth and postnatal health services, and to be responsible for the treatment of pregnancy complications. The CDC is responsible for the immunization of pregnant women and neonates. These sectors all assume their own specific responsibilities to protect the health of pregnant women, mothers and children alike. They exert their roles as independent units, functioning at both the county and above levels.

5. Case studies

5.1 PD Case Report

In the PD case report, we introduce the regulation on prenatal diagnosis technology and services. First the background and context of the regulation process is introduced. The second part covers the regulation approach and mechanisms. The third part introduces the actors involved in the regulation process and their functions. The fourth part analyzes the factors influencing the effect of the regulation on equitable access to quality care, and a comparative analysis between prenatal diagnosis regulation and genetic disease diagnosis regulation is made. In the final part, we provide conclusions and recommendations.

5.1.1 Background

5.1.1.1 Rationale for the choice in study regulation

As a significant part of antenatal care, prenatal diagnosis enables early diagnosis of congenital anomalies and genetic disorders in utero.[6] Methods of prenatal diagnosis can be divided into non-invasive and invasive techniques. Non-invasive procedures such as ultrasound, magnetic resonance imaging (MRI) and maternal serum biochemistry testing are used for the diagnosis of congenital anomalies and risk assessment of given genetic disorders (screening); invasive techniques include chorionic villus sampling (trophoblast cells analysis), amniocentesis (amniotic fluid cells analysis) and cordocentesis (Percutaneous Umbilical Blood Sampling).[7]

The prevalence of birth defects has risen in recent years in China.[8] As a result of the fall in both infant mortality and birth rate, the focus of health policy development has been shifting from acute problems towards management of non-communicable diseases. This change has been particularly marked in the area of reproductive and child health because an increasing proportion of infants born with potentially disabling conditions (who previously would have died undiagnosed) now survive and require medical and supportive interventions. Those disabilities due to birth defects and genetically-determined disorders are leading to a large disease burden.[9] Prenatal diagnosis can influence this disease burden.

We chose prenatal diagnosis for the HESVIC study on regulations as a case based not only on a wide spectrum of prenatal diagnosis services, from technology development to service provision and utilization, but also because of its relevance to the management of birth defects and assurance of quality of

prenatal diagnosis.

The effectiveness of prenatal diagnosis must not only rely on the development and improvement in prenatal diagnosis techniques (quality factors) but also must be based in the amelioration of the health service delivery framework (equity and accessibility factors).

5.1.1.2 Regulation summary

This case study is on the "Administrative regulation of prenatal diagnosis technology" (including related annexes), hereinafter referred to as “PD Regulation”. The “PD Regulation” was issued in December 2002 by the Ministry of Health (MOH), and was implemented from May 2003 onwards. It was developed based on the requirements of the "Law of the People’s Republic of China on Maternal and Infant Health Care" (hereinafter referred to as “Maternal Law”)[c] formulated by the NPC Standing Committee in 1994, and the "Measures for Implementation of the Law of the People’s Republic of China on Maternal and Infant Health Care" (hereinafter referred to as “Implementation Measures”) formulated by the State Council in 2001. As a ministry-level regulation, the “PD Regulation” is applicable throughout the country in all MCH-related areas.

The purpose of "PD Regulation" is to regulate prenatal diagnosis services delivery in a manner that ensures quality prenatal diagnosis services are provided and the country’s target population can benefit from them.

The "PD Regulation" has four chapters, a summary of which follows. Chapter One states the “General Principles”. It sets the legislative basis, defines prenatal diagnosis[d] and related technical services, and establishes the scope of the regulation, the requirement of institutional and personnel licensure, and the duties of health authorities. Chapter Two, entitled “Management and Approval,” sets the principles of tiered administration, the responsibilities of all levels of health agencies (state, provincial, and county levels), the institutional and personnel approval requirements for prenatal diagnosis services delivery, and the procedure for application and renewal of institutional licenses. Chapter Three regulates “Implementation” and elaborates the informed choice principle of prenatal diagnosis services delivery, the identification of high-risk pregnant women and the priority diseases for prenatal diagnosis. Chapter Four, “Sanctions,” establishes the circumstances under which penalties are issued and the specific disciplinary actions taken that are linked to related regulations. The regulation includes three annexes aimed at management (including

[c] All-China Women’s Federation. Availabe from <http://www.womenofchina.cn/Policies_Laws/Laws_Regulations/1478.jsp#2>

[d] Prenatal Diagnosis in this regulation means diagnostic testing for congenital defects and genetic diseases in a fetus or embryo before birth, including relevant screening tests (excerpt from Act 2 of “PD regulation”).

institutional duties, software and hardware conditions) and four technical guidelines (including genetic consultation, prenatal screening for Down Syndrome and NTD, prenatal diagnosis by ultrasound, and fetus karyotype analysis).

It should be mentioned that according to the “PD Regulation,” screening testing should be provided to low-risk pregnant women based on informed consent, and follow-up diagnostic testing should be recommended to those pregnant women at a higher risk for a particular birth defect (e.g. those 35 years or older at the time of delivery); moreover, of course women who receive a “positive” result from screening testing must be provided the option to receive diagnostic testing. In other words, both screening testing and diagnostic testing are voluntary consent testing (VCT). Priority diseases for prenatal diagnosis are also defined in the “PD Regulation,” representing those with high incidence, great disease burden, limited clinical treatment methods and mature technique methodology. Since the “PD Regulation” has been implemented for almost ten years now without modification, it offered us significant opportunity for the study of approaches, mechanisms, effects and influencing factors, as well as the relationships between regulation implementation and the diverse contexts associated with it.

5.1.2 Context

Changes in the socio-economic environment impact regulatory activities and their intended effects, and must be considered when studying a specific regulation.

5.1.2.1 Macro environment

It has been more than 30 years since China’s introduction of its “reform and opening up” policy. During this period the country has experienced rapid social and economic development, change that has raised people’s living standards and led to an improvement in the health situation. In 1997, the 15th CPC National Congress set forth a new governance concept referred to as the “rule of law” and "building a socialist country under the rule of law." This new governance concept emphasized: “Socialist democracy is gradually institutionalized and codified so that such institutions and laws will not change with changes in the leadership or changes in the views or focus of attention of any leader.” Since then, China's legislative framework has gradually strengthened and the juridical and legal system has been continuously improving. The 2008 introduction of "people-centeredness" and the concern for the "protection of people's lives" in social and public services has further changed and consolidated governance concepts these last four years.

Simultaneously, social and economic development has brought a series of problems not evident before. Gaps between urban and rural areas and among different regions, and high levels of migration putting pressure on public services are among some of the problems that have emerged. The improvement in economic conditions and living standards has also changed demands by the population for health services. These factors have in turn impacted health service delivery and utilization.

5.1.2.2 Maternal and child health system

The development of maternal and child health services has significantly progressed during this period. As the status of maternal and child health in China has improved, many major problems have been gradually resolved, yet this sector still faces complex and severe challenges. For example, significant gaps in maternal and child health still exist between urban and rural areas, among different population groups and different regions, and a relative lack of service capacity occurs at the grassroots level.[10] Birth defects are among the serious problems currently threatening maternal and child health.[11] Yet huge opportunities for maternal and child health development exist. The ongoing health care system reform in China has brought significant opportunity for development in the MCH area, for the reform movement attaches more importance to the field, integrates it as part of public health, and thus invests more resources in it.[12] The Chinese government's commitment to achieving the United Nations Millennium Development Goals (MDGs) has provided favorable conditions for gaining more support.

5.1.3 Regulation Process

5.1.3.1 Definition

At the beginning of the 21st century, several factors contributed to the development of the prenatal diagnosis services regulation (Fig 5.1.1). First, the existing regulation system needed improvement. Although "Maternal Law," issued in 1994, mentioned the requirement of prenatal diagnosis services regulation, until 2001 the MOH hadn’t issued detailed policy documents that included regulation approaches and mechanisms for prenatal diagnosis services. In 2001, however, the rule “Implementation Measures” was issued, reaffirming detailed statements about prenatal diagnosis services regulation. Second, the specific characteristics of prenatal diagnosis services made the regulation essential. Prenatal diagnosis technology and services (especially the invasive techniques) are high-risk, high-tech and of high uncertainty, hence need to be differentiated from routine antenatal care.[13] Third, with the international environment’s promotion of maternal health care and the

continuous research and development of prenatal diagnosis technology, prenatal diagnosis services were gradually and more widely introduced in China. But serious incidents during the service delivery process, based on the uncertain quality of prenatal diagnosis service delivery and resulting from limitations in techniques and/or supervision of related service delivery, created the need for better regulation. Last but not least, with the improvement in maternal and child health, especially the remarkable decline in maternal and infant mortality ratios,[e] birth defects and their prevention began to draw the attention and focus of the government and the general public; hence the health need for prenatal diagnosis for pregnant women likewise began increasing.

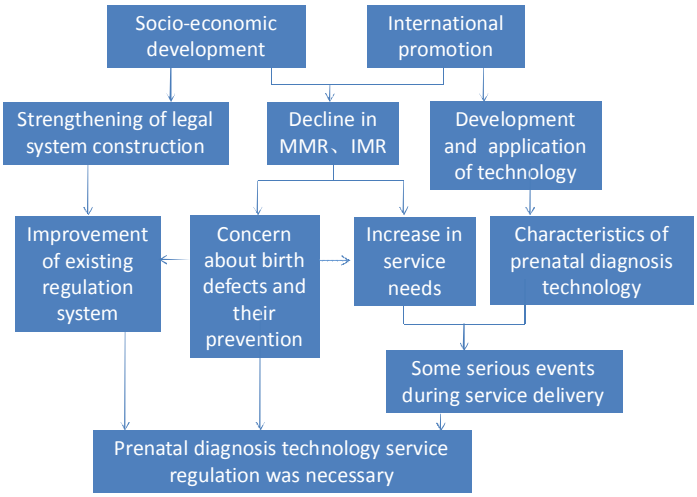


Fig. 5.1.1 Factors influencing regulation definition

Our findings from interviews indicate that multiple forces drove the development of the prenatal diagnosis regulation. These forces were both "bottom-up" and "top-down" initiatives, although dominated by the former. Of course, some peripheral influences and interests were also involved. A description of the specific situation follows.

During the latter years of the last century, prenatal diagnosis technology was introduced to China and some institutions set out to explore service delivery. Until the beginning of this century, however, prenatal diagnosis services were provided only in several provinces and institutions. At the time, as the technology was not yet perfect and its use potentially risky, several adverse events (e.g. negative result in screening testing but birth defect baby ultimately delivered) occurred in some hospitals, resulting in further negative impacts (e.g. disputes over the testing's efficacy and even public hospitals' social responsibility) within the health system. At a meeting of experts—specifically, an academic conference focusing on prenatal diagnosis—some experts in

[e] The MMR and IMR in 1995 were 61.9 per 100,000 live births and 36.4 per 1,000 live births respectively, while the numbers in 2002 were 43.2 per 100,000 live births and 29.2 per 1,000 live births respectively (data from ***China Health Statistics Yearbook 2009***, published in 2010 by the MOH).

prenatal diagnosis and relevant areas had heated discussions about how to deal with the issue. Finally, they concluded an urgent need for prenatal diagnosis technology and service regulation existed, and decided on several regulation suggestions. After the conference, they submitted both opinions and suggestions on prenatal diagnosis technology and services to the MOH. Meanwhile, a senior member of the national leadership received an internal reference document from an overseas Chinese expert specializing in genetic sciences. That expert also gave her opinion and suggestions on the importance of prenatal diagnosis services delivery and its regulation. The senior leader approved her proposal, added instructions to it, and tasked the MOH with developing regulation for prenatal diagnosis technology and services delivery. In addition, based on her clinical practice and foreign study experience in obstetrics and gynecology, a certain domestic prenatal diagnosis expert (also a front-line provider), was conducting prenatal diagnosis services delivery in her practice and promoted such training, eventually winning her professional reputation as a leader in the field. She too took active part in advocating for the regulation, and received support and recognition from the MOH. Finally, as a result of all of the above inter-twined factors, the MOH launched its prenatal diagnosis-related regulation formulation. Several interviewees provided information about the regulation definition. One key person said:

> *As I recall, during the academic conference in Hangzhou in 2000 that focused on prenatal diagnosis, we talked about the situation concerning prenatal diagnosis services delivery. At the time, several cities were providing some [prenatal diagnosis] services. And disputes and complaints were occurring [because of poor clinical outcome]. We discussed this and determined to develop a regulation. Yeah, it was up to our professional body to actively propose this idea [to the government…so] we developed suggestions incorporating lots of specifics points regarding prenatal diagnosis services delivery.*
>
> (Male, PD-Others-2, 29-08-2011)

One politician remembered:

> *First, Overseas Professor A, specialized in genetic science, wrote an internal reference [report] for national Scientific Institution Leader B. The title of the report was "Suggestions for prenatal diagnosis of, and autopsy on, birth defects in China." B presented the report to national Senior Leader C. After that, C instructed the MOH to deal with it.*
>
> (Male, PD-Designer-1, 30-08-2011)

An expert said:

> *At the time, the MOH knew I actively engaged in training activities in prenatal diagnosis technology. Actually, I had become good friends with the director of the MCH department of the MOH. And I often*

visited the MOH at that time […] They [the MOH] always provided support. My hope back then was that the MOH would develop regulations for the prenatal diagnosis services delivery of Down syndrome once we [practitioners] had acquired some [training]. Actually, national high-level leaders likewise wanted some kind of regulation. It was just well timed.

(Female, PD-Others-1, 29-08-2011)

Regarding the formal development of the regulation document, information from different interviewees was consistent and mutually reinforcing. The process was similar to that of general health policy-making nowadays, but in the 2001-2002 context could be considered somewhat advanced. It consisted of four main steps (Table 5.1.1).

Table 5.1.1 Steps to regulation definition

Date	Task	Actor/s
Jan – June 2001	Assignment of task	MOH (MCH department, Medical Science, Technology and Education (ST&E) department)
July - Oct 2001	Research design and field investigation Draft formulation	Health Technology Assessment Center of Fudan University (HTA Center) MOH (MCH department, ST&E department) HTA Center
Nov - Dec 2001	national validation	MOH (MCH department) Experts of prenatal diagnosis and related areas Provincial level BOH
Jan - Dec 2002	Revision and further validation	MOH (MCH department and other relevant departments)
13 Dec 2002	Regulation issued	MOH

5.1.3.2 Administration (Example: Shanghai)

According to the national regulation on prenatal diagnosis services delivery, regulation administration should not only bear the responsibility for managing prenatal diagnosis technology and services based on the requirements of national regulation but should also establish its own detailed regulation based on local health needs, service provision capacity, etc. Shanghai, as an East China metropolis, has profited from a more advanced socio-economic development than most Chinese cities, resulting in a related increase in health status. Shanghai's municipal BOH began to study and discuss prenatal diagnosis technology and services regulation as soon as the national regulation was introduced and promoted the local regulation administration

very efficiently.

The administration stage included two steps. One required the provision of a regional health-plan framework for the needed prenatal diagnosis services delivery. Though the national regulation does not clearly address this issue, the Shanghai's municipal BOH gave it more attention. Based on international experience with health resources specifically allocated for prenatal diagnosis, the municipal BOH evaluated the local population's need for prenatal diagnosis services and, with the support of experts, calculated the service delivery capacity of a single prenatal diagnosis institution. They concluded that Shanghai needed about eight prenatal diagnosis institutions for service delivery. According to information provided by one interviewee, the determination of health planning for prenatal diagnosis services delivery was based on two key parameters: the reasonable utilization of health resources and the feasibility of quality control activities. Evidence for calculations was drawn from international experience. The interviewee said:

> *As I recall, one professor provided international investigation information [some from the UK] indicating that most likely one [prenatal diagnosis] health center per 2.5 million people is suitable [or necessary]. That one reference was available […] So, during the first round we determined to establish 6-8 health centers providing prenatal diagnosis services, based on one center per 2.5 million people.*[f] *We determined it. We determined the total number of health centers providing prenatal diagnosis services […] The purpose of health planning is to distribute health resources reasonably. The number of newborns in Shanghai is currently stable. We should conduct health planning [incorporating] prenatal diagnosis services delivery. It will also make quality control much more feasible.*
>
> (Female, PD-Administrator-2, 21-12-2010)

The second step required the development of local service delivery criteria. Based on consultation with experts, the Municipal BOH developed local service delivery criteria for prenatal diagnosis services delivery that included a detailed service delivery process, criteria for prenatal diagnosis techniques, required staff qualifications, and institutional capacity for service delivery. The criteria were mostly based on the national regulation criteria, but also incorporated consideration of local experience in clinical practice, the specific characteristics of the prenatal diagnosis services provision, and the health needs of Shanghai.

In October 2003, the local regulation on prenatal diagnosis services delivery was formally issued in accordance with prescribed procedures. Although

[f] In 2003, the number of registered permanent residents registered in Shanghai was 13.42 million. The number of newborns occurring in the native population (registered permanent residents) was 83,000 and in the migrant population 26,000 (data from the ***Shanghai Family Planning Yearbook 2004***).

issued with its principle regulation consistent with the national regulation, the BOH still deliberated on how to deal with institutions solely providing screening testing and those institutions providing both screening and diagnostic testing, since the national regulation was not explicit in this regard. The national regulation indicates:

> ***Annex 1*** *Establishment and responsibility of health centers providing prenatal diagnosis technology and services*
>
> *Health centers solely providing screening testing should connect with health centers providing prenatal diagnostic testing so as not only to refer high-risk patients from screening to diagnosis but also to involve screening in the quality control system of prenatal diagnosis.*

Such a flexible statement left provincial BOHs a degree of choice regarding regulation administration. Different provincial and municipal BOHs thus developed different local regulations on this matter: some provinces were quite strict in their administrative rules while others interpreted the national regulation more loosely.

Shanghai's local regulation, issued in 2003, indicated:

> ***Act 4*** *Health centers applying (solely) for screening testing should develop work relationships with prenatal diagnosis centers and be involved in the quality control system of those prenatal diagnosis centers.*

Actually, even before the national regulation was issued, several health institutions were already providing prenatal diagnosis services in Shanghai, and the demand for prenatal screening testing was growing considerably during those years. Yet because the technical requirements for screening and diagnostic services delivery are different, the municipal BOH determined to design different requirements for screening and diagnostic testing, based on informal consultations with the MOH.

In June 2004, in order to meet health needs, improve the accessibility of screening testing along with necessary administration, the municipal BOH developed a new (and related) regulation on MCH-specific technology administration.[g] It sets forth:

> ***Act 8-4*** *On prenatal diagnosis: Prenatal diagnosis is divided into two administrative categories: one is prenatal screening testing, and the other is prenatal diagnostic testing […] Prenatal screening testing can be provided in secondary or higher level health centers (that also provide delivery service) and prenatal screening centers should establish work relationships with prenatal diagnosis centers so as to formulate a quality control system and administrative*

[g] Title of the new regulation is "Measures on MCH-specific techniques and human-assisted reproductive technology in Shanghai."

framework.

From 2004 to 2008, four prenatal diagnosis centers (for a total resident population of about 18 million, inclusive of the unregistered resident population[h]) received approval for service delivery while no prenatal screening centers entered the certification system. In June 2008, the new regulation was renewed (as an adapted regulation). The adapted regulation[i] sets forth:

> ***Act 7-4*** *On prenatal diagnosis (screening): […] Currently, Down Syndrome and NTD are among those diseases included for prenatal screening. Screening centers should be established in secondary or higher level health centers that satisfy the requisite technical capacity and standards. In principle, every Shanghai district may (though not obligatorily) establish one health center for screening testing delivery. And that screening center should establish work relationships with prenatal diagnosis centers so as to involve it in the quality control systems of those prenatal diagnosis centers.*

5.1.3.3 Implementation (Example: Shanghai)

After the local regulation was first issued in 2003, Shanghai carried out a series of preparations for its implementation. They began with the delivery of a special training program for the first group of medical staff who were to provide prenatal diagnosis services in the prenatal diagnosis centers, following the local regulation. Next, Shanghai carried out its initial round of approval for prenatal diagnosis personnel. Based on personnel certification in the first round of approval, by 2005 Shanghai had certified four institutions for prenatal diagnosis, including two MCH health institutions, one obstetrics and gynecology hospital and one general hospital. All four prenatal diagnosis centers were tertiary hospitals.

Generally, the implementation stage was two-fold (Figs. 5.1.2 and 5.1.3). One was approval and certification, and the other was evaluation and supervision of certified personnel and institutions. The procedure for approval and certification and the qualification standards for personnel and institutions for prenatal diagnosis services delivery were clearly defined in the local regulation. The procedure for evaluation and supervision stated that certified personnel must receive specific training in the specialized knowledge and practice of prenatal diagnosis every two years. Only a provider who passes an exam after training receives certification renewal for another two years of service delivery. Certified institutions must be annually evaluated, and certification renewal for the subsequent year is granted only after successful evaluation. During the certification and supervision process, all regulatory bodies (the municipal BOH,

[h] "Unregistered resident population" refers to the migrant population, those who remain in Shanghai for more than half a year.

[i] Title of the adapted regulation is "Measures on MCH-specific technology and service delivery in Shanghai."

Municipal Women's Health Institute (MWHI), and Municipal Health Inspection Institute (MHII), etc.) cooperate, embodying the regulation control function as the local regulation intended.

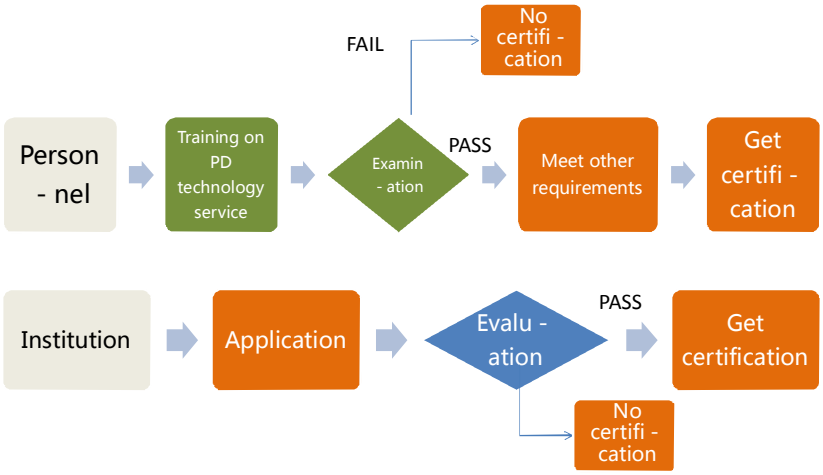


Fig 5.1.2 Certification process for personnel and institutions

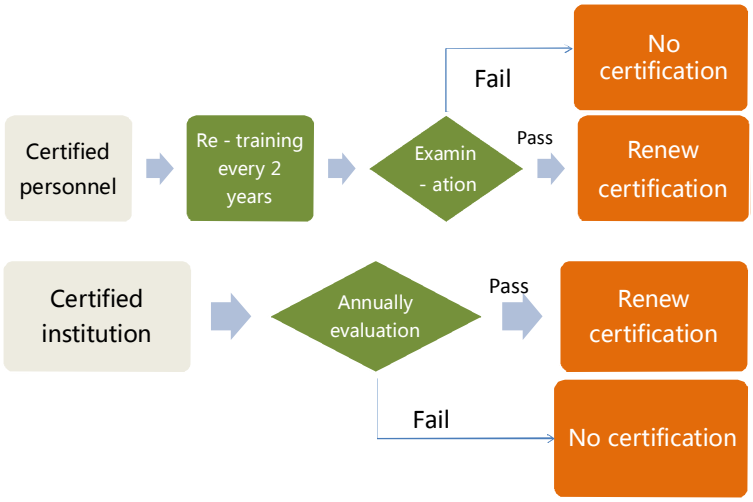


Fig 5.1.3 Evaluation and supervision process for certified personnel and institutions

In addition, the prices for screening and diagnostic testing are set and adjusted by the Municipal Bureau of Prices. The latest price for ultrasound screening (for major birth defect) is 220 CNY (approx. 35 USD), for serum screening (Down Syndrome, NTD, etc.)120 CNY (approx. 19 USD), for amniocentesis and amniotic fluid cells analysis from 800-2000 CNY (approx. 127-317 USD), depending on the techniques used.[j]

[j] Information is from the Price List for Health Services (provided by public heath institutions) in Shanghai, published in 2010 by the Municipal BOH, Municipal Bureau of Price, and the Municipal Office of Health Insurance.

5.1.3.4 Approaches

5.1.3.4.1 Introduction

	Specific PD services	General health services	General consumer services
State-centered	- Regulation setting - Entry and withdrawal of institution and personnel - Tier administration - Regional health planning - Clinical guidelines - Delivery system construction - Personnel system construction - Advisory committee	- Quality control, including supervision and evaluation - Pricing - Reimbursed payment	
Consumer-oriented	- Consumer participation in medical decision by informed consent	- Information disclosure	- Complaints
Self-regulation		- Capacity-building (institution and HR) - Quality control - Technology criteria	
Market-oriented	- Contract relationship		- Relationship between supply and demand - Information-sharing - Competition among providers

Generally speaking, the state-centered approach is the major regulatory approach in China's prenatal diagnosis services regulation. At the national level, the MOH has played a dominant role in the entire regulation process; at the municipal (or provincial) level, the municipal BOH has also played a dominant role in the same. With respect to the regulation's content, the national level set the responsibilities for provincial level health authorities, but also turned over some power to the provincial level. Power in this case has included implementing service institution and personnel certification or approval, setting technology and ethical criteria for health institutions to comply with when providing services, and constructing a monitoring system to control implementation in the health care system.

5.1.3.4.2 State-centered

Many categories of specific state-centered approaches exist in national and local regulation.

The first is the entry and withdrawal approach. Both the national regulation and the local Shanghai regulation provide minimum requirements for institutional and personnel qualification. If the institution and personnel cannot meet these requirements, the institution and personnel cannot provide prenatal diagnosis services. Moreover, if the certified institutions or personnel fail to meet requirements during their annual reviews, their licenses or certificates are suspended, even revoked.

The second is the tier administration approach, a form of power distribution among the administrative hierarchy. According to the "PD Regulation," each of the following has its own responsibility to monitor prenatal diagnosis services: the MOH, provincial BOH, and even the county-level BOH.

The third is the decentralized health planning approach. Drawing on regional health needs estimates, the Shanghai BOH uses local and regional health planning guidelines to set the maximal number of prenatal diagnosis institutions. This means that those institutions meeting the minimal requirements do not necessarily receive approval, on account of the number limit imposed by regional health planning.

The fourth is the clinical guideline approach. The regulation's annexes recommend certain clinical guidelines for prenatal diagnosis services delivery, which, as written, sound more powerful than those issued by the professional organizations; however, these haven't been modified since 2002 to accord with recent developments in technology.

The fifth is the delivery system construction approach. The regulation structures China's prenatal diagnosis delivery system at the national, provincial and county levels. Moreover, in order to assure quality, the regulation also designed a quality control system in which upper-level centers bear the responsibility for quality control of the lower-level centers.

The sixth is the human resources capacity-building approach. The municipal BOH carried out specialized training in prenatal diagnosis technology and services delivery according to the specific characteristics of each, including pre-service training for new employees and regular training for certified practitioners so as to develop their service delivery expertise.

The seventh is the advisory committee approach. After the national regulation took effect, the MOH set up a national prenatal diagnosis advisory committee whose responsibilities include: discussing hot prenatal diagnosis issues, sharing experience and information, proposing policy suggestions, etc. This national advisory committee holds a meeting every year. In Shanghai, the BOH has its own professional team, drawn from different specializations.

The eighth is the service quality control approach. The national and local regulations provided a clear definition of technology criteria and the service delivery process, establishing a form of preliminary or pre-service quality control. The municipal BOH relies on certain institutions to act as quality control centers (with laboratory tests, ultrasound, obstetric service delivery, etc.), a form of both intermediate and post-service quality control of prenatal diagnosis services delivery.

The price control approach and reimbursement payment approach were not mentioned in the regulation, and are not frequently used by the BOH. Those two approaches are governed, respectively, by China's pricing authorities and medical insurance authorities.

5.1.3.4.3 Consumer-oriented

The aspect of the "PD Regulation" that most highlights its consumer-oriented nature has to do with the issue of informed consent. As prenatal diagnosis testing is high-risk and related to people's basic civil rights, health authorities significantly emphasized the need for informed consent requirements, whether receiving services or not. This obligation stems from the requirements of basic civil rights protection. As potential risks exist in conjunction with user benefits, users' decisions must be taken predicated on a full understanding of the risks involved. The regulation sets such a requirement, reflecting its consumer-oriented nature.

In addition, given the specific characteristics of prenatal diagnosis services, in recent years consumer-oriented considerations have played an increasingly significant role in the approach to their regulation. There are two main categories of consumer-oriented considerations in prenatal diagnosis services. The first category has to do with information-sharing and disclosure. Health authorities, for instance, actively publicize information about the quality and qualifications of health institutions, so the public can take this information as reference and feel free to make choices in service delivery. In addition, public media network platforms exist through which people comment and communicate their feelings, experiences, opinions and suggestions regarding certain hospitals' or certain doctors' service delivery, providing further reference for users. The second category has to do with complaints and petitions. In this instance, the municipal BOH and Health Inspection Institute provide a variety of channels through which to collect public comments and external evaluations, including hot lines, public websites, etc. Finally, if the user or her family feels discomfort or is dissatisfied with service delivery, she or they can complain to the hospital directly, or to the regulators, etc.

Some approaches are not derived explicitly from the regulation itself. Certain ones, for instance, are based on the protection of users' rights and benefits, others on conceptions and considerations of governance, and still others on the effects of increasing population demand and on developments in information technology.

5.1.3.4.4 Self-regulated

Two self-regulation approaches are present in prenatal diagnosis. The first concerns the regulation activities of academic bodies, which includes conducting academic conferences to advance the dissemination of technology; conducting scientific activities in evidence-based clinical practice; developing service criteria for clinical improvement, etc. This category of approaches results in a positive effect. In fact, some interviewees expressed the view that the government should turn over even more power to academic bodies since the government cannot do everything.

The second concerns the regulation activities health institutions take regarding their staffs. For example, drawing on clinical practice experience, some health institutions providing prenatal diagnosis services establish specific requirements for prenatal diagnosis staff qualifications and capacity-building that are much stricter than the government's. All health institutions outline specific requirements for staff post-graduate education and training in order to improve their knowledge of and skills in service delivery. Some health institutions even apply internal performance assessment approaches to prompt their staff to improve their work. Certain such self-regulating and

self-advancing approaches can be found embedded in the culture of hospitals and doctors.

5.1.3.4.5 Market-oriented

Market-oriented approaches are also important in prenatal diagnosis services delivery. At one point, the Chinese health system context led to wide criticism of its heavy reliance on market mechanisms.[14] The national regulation states: “The health institution that provides screening testing should establish a work relationship with the health institution certified to provide prenatal diagnosis to ensure that screened pregnant women have access to prenatal diagnostic testing.” The flexibility in this rule was designed to employ a market-oriented approach by regulating the interaction between prenatal screening and diagnosis through contractual relationship. In other words, according to the “PD Regulation,” those health centers willing to provide screening testing must contract with a certified prenatal diagnosis center, and that certified prenatal diagnosis center must in turn provide diagnostic testing to pregnant women screened as high-risk (positive). Naturally, the prenatal diagnosis center can also provide screening testing and transfer positive users to its own diagnostic testing services. Nonetheless, the market-oriented approach embedded here is meant to support the prenatal diagnosis center’s choice of good service delivery partners. Theoretically, those screening centers with which a prenatal diagnosis center will most want to contract are those that provide consistent, high quality (low false positive rate) screening testing. In addition, if such work relationships are contractually based and built, prenatal diagnosis centers will maintain a quality control incentive with respect to their contracted screening centers.

Why use a market approach? Approving all screening centers in China is too labor-intensive; moreover, under the influence of market mechanisms, such centers can improve in convenience, accessibility and quality of screening. The regulation directed itself at institutions that provide prenatal diagnosis, distributing to them the role of quality controller for screening testing.

Meanwhile, under the existing regulation system, health institutions are expected to select good partners to meet user needs and capture a greater market share based on the principle of maximized interests. Such is not only the nature of collaboration/competition between hospitals based on free market principles, but also that of cooperative enterprises (provision of reagents, equipment, etc.) with respect to products and services. Companies can likewise influence health institutions through the market approach. In the specialized area of prenatal diagnosis, implementation of governance is quite difficult.

In Shanghai, users can choose antenatal care providers (including screening testing and diagnostic testing) and delivery institutions on their own. In reality, the market not only supports such users' decision-making through information sharing and disclosure but also improves the effect and efficiency of prenatal diagnosis services delivery through adjustments in the relationship between supply and demand.

5.1.3.5 Mechanisms

The regulatory mechanisms of prenatal diagnosis technology and services in China and Shanghai can be divided into three categories. The first is the incentive mechanism, used to spur all actors involved in the activities of prenatal diagnosis technology and services to promote their regulation. The MOH and Shanghai's municipal BOH established the Experts Advisory Committee, a professional team focused on prenatal diagnosis, and experts and scholars specializing in prenatal diagnosis-related areas were invited to join. These kinds of organizations are authorized by health authorities to engage in regulatory activities. They can also carry out scientific research activities on prenatal diagnosis technology and related areas to promote technology development as well as improve service quality and efficiency with the support of health authorities. Health authorities routinely hold theme conferences to listen to experts' comments and suggestions on service delivery and regulation so as to improve the quality, equity and access of prenatal diagnosis services delivery. In addition, health authorities much facilitate channels of public oversight of health service delivery (including prenatal screening testing and prenatal diagnostic services). According to the regulation, the general public, the health sectors and their staffs have the right to complain and report suspected violations to the relevant department.

The second is the control mechanism. Given the characteristics of prenatal diagnosis technology and services, the provision of some control approaches that guarantee the safety and effectiveness of the technology and the interests of all the actors is necessary. Health authorities provided the principal statement on the prenatal diagnosis services delivery process in the "PD Regulation" itself (e.g. licensure, informed consent, etc.), and indicated the clinical technical guidelines for the specific services (e.g. genetic consultation service). In Shanghai, the municipal BOH commission-related department also carried out strict supervision and evaluation of certified centers and personnel according to local regulation. Those that did not pass the evaluation did not receive renewal of their certification. The regulatory bodies of course also conducted oversight and sanction activities towards non-certified registered centers providing prenatal diagnosis services unauthorized by the regulation.

The third is the guarantee mechanism, used to provide material and policy

support during the regulation implementation process that will help ensure quality, access and equity of service delivery. Existing guarantee mechanisms stressed guarantee of service quality; others were somewhat weaker. Both the state and Shanghai pay much attention to the capacity-building and training of prenatal diagnosis staff. The state has established several training bases for various disciplines in the area of prenatal diagnosis that both provide training for prenatal diagnosis staff and also receive periodic evaluation by the MOH. Shanghai likewise established a system of periodic training for prenatal diagnosis staff, including new recruits and certified personnel. Training contents include clinical technology, criteria for diagnosis and treatment, law and ethical requirements, etc. Moreover, the training contents are continuously updated following developments in technology. Expenditures related to routine training activities are also covered by the BOH.

5.1.4 Actors

During the regulation process, many actors were involved in more than one stage, as noted in Fig 5.1.2.

Fig 5.1.2 Actors involved in regulation process

Actors	Stage		
	Definition	Administration	Implementation
Health authorities	MOH	BOH	BOH, MOH
Regulatory bodies		MWHI, MHII	MWHI, MHII
Consultation bodies	HTA Center, Experts, BOH	Experts	Experts
Providers	Potentially involved	Potentially involved	Public and private
Users	Potentially involved		General public, especially pregnant women and their families
Others			Companies with related equipment, reagents, etc.

5.1.4.1 Actors in the definition of the regulation

Generally speaking, definition of the regulation was carried out by the MOH, the academic HTA Center, and experts. Both the HTA Center and experts took an active part in consultations, with the HTA Center basing its recommendations on field investigation and the experts theirs on past experiences.

The MOH was the leading actor in formulating the "PD Regulation': it made the decision to define the regulation, chose a reliable professional team to conduct

investigation and provided financial and coordination support for the fieldwork. After the first draft of the regulation was developed, modifications were carried out based on discussion and consultation. Finally the MOH issued the regulation following standard legal procedures.

The HTA Center, authorized by the MOH to specifically research the definition of the regulation, developed a research design providing an evidence base. The HTA Center then delivered a report focusing on a situational analysis of prenatal diagnosis services delivery current at the time in China and offered suggestions for improvement to the MOH. The suggestion portion of this report became the prototype of the first draft of the “PD Regulation.”

Experts played an active role in regulation definition. The advocacy of a number of independent experts prompted the MOH to develop this regulation. One expert wrote an internal reference report to state leaders. Others came together at an academic conference focused on this theme. They submitted their opinion to the higher authorities at the MOH. In addition, several times and in different ways during the "PD Regulation" definition stage, the MOH and the HTA Center consulted many professionals specialized in clinical medicine (e.g. gynecology and obstetrics), preclinical medicine (e.g. genetic sciences), preventive medicine (e.g. epidemiology), health administration (e.g. health services) and law and ethics involved in. Such contacts entailed formal as well as informal discussions, validation conferences, etc. Since most clinical experts invited to provide suggestions came from health institutions providing prenatal diagnosis services, we consider that potential service providers were involved in regulation definition.

In addition, provincial level BOHs were also involved in the regulation definition stage, which incorporated local situation and experience into the validation of the draft regulation. Last but not least, the involvement of potential users must be mentioned: during the field investigation held by the HTA Center, users in the sampling area were included in the investigation and information about their experience and suggestions regarding prenatal diagnosis services delivery were collected and taken into consideration in the regulation definition process.

5.1.4.2 Actors in regulation administration

Generally speaking, the municipal BOH carried out the regulation administration, with local experts taking an active, consultative part. In addition, the MWHI and the MHII also took part in administering the regulation.

The BOH was the leading actor in the administration stage. In Shanghai, the municipal BOH adapted the national regulation to its local administrative shape

soon after its issuance. This local administrative adaption related mainly to the provision of detailed criteria the national regulation had left open.

With the support of experts and other actors, the BOH made decisions on regional health planning, local technology criteria and service process, procedures for prenatal diagnosis services delivery application and evaluation, regulatory tasks, and the power of all regulatory bodies involved. The Shanghai BOH first issued and administered the local regulation in 2003. Several years after its implementation, the municipal BOH twice amended the local regulation to meet local health needs and/or improve regulatory activities.

The municipal BOH invited experts to provide technical support in the regulation's administration stage. That technical support included both professional information on the international development of prenatal diagnosis technologies and also on local service delivery conditions and problems.

In addition, both the MWHI and the MHII took part in regulation administration. The MWHI, as a public MCH technical institution, importantly assists the BOH in dealing with professional MCH guidance in Shanghai. The MHII, as a public health supervisory agency, is a BOH subsidiary that carries our supervision and law enforcement on its behalf, and as such is regarded as the health sector's "policeman." In short, the MWHI is responsible for local administration of maternal health service delivery while the MHII is responsible for local health supervision.

During the regulation administration stage, both the MWHI and the MHII took part in the discussion and, based on their capacities and responsibilities, provided suggestions for regulation administration starting from the initial local regulation phase through its following two modifications.

Although providers didn't take direct part in regulation administration, they still voiced their opinions. Since most experts invited by the BOH to provide suggestions came from health institutions providing prenatal diagnosis services, we consider that potential providers were involved in regulation administration.

5.1.4.3 Actors in the regulation implementation

The MOH set up a national prenatal diagnosis professional advisory committee from which it receives technical guidance and suggestions. Under this committee, an office was embedded in a hospital in Beijing of national repute. The committee holds an annual conference on prenatal diagnosis, focusing mainly on technical developments and implementation, and information

exchange. Drawing on the establishment of national prenatal diagnosis training bases in different specialties of prenatal diagnosis technology, the MOH organized throughout the country different kinds of capacity-building and training programs for prenatal diagnosis personnel. In addition, since the national regulation was issued, the MOH has twice commissioned professional academic institutions to conduct national investigations of prenatal diagnosis services delivery.

Shanghai's BOH was the leading actor in the regulation implementation stage. According to national and local regulations, the BOH is responsible for: regional health planning for prenatal diagnosis services delivery, the development of local qualification criteria for personnel and institutions involved in prenatal diagnosis services delivery, the development of technology and service standards, and local prenatal diagnosis certification. The BOH is also in charge of regulation modification and other decision-making responsibilities.

In fact, Shanghai's municipal BOH commissioned the MWHI with the responsibility for technical administration, and the MHII with the responsibility for administrative management. Shanghai's district BOH bears some responsibility for administrative tasks related to local prenatal diagnosis services delivery. According to local regulation, the MWHI holds annual professional trainings in prenatal diagnosis technology and services delivery. The MWHI invites experts (from local prenatal diagnosis centers) to delivery training courses to enhance knowledge and methodologies of prenatal diagnosis. Afterwards, all staff having received such training must take part in an exam held by the MWHI with the support of experts. In addition, the MWHI is responsible for annual institutional evaluations of prenatal diagnosis services delivery, and conducts them at all four prenatal diagnosis centers. This annual evaluation includes field investigation of the service delivery process, staff capacity, and the audit of each prenatal diagnosis center's own annual report on the quality and quantity of its services delivery. The work for this annual evaluation of institutions is carried out with the support of experts: the MWHI has an expert team and almost all related experts in Shanghai are involved in it. To form a temporary team to carry out the annual evaluation, the MWHI selects several experts (usually five or six) from the larger expert team, each representing a sub-area of prenatal diagnosis.

As regards training, examination and evaluation costs, the annual training and exam is free for staff and the government pays for the work of experts invited by the MWHI. Specific subsidies are distributed to the MWHI for the training and exam; similarly, prenatal diagnosis centers don't pay for their annual evaluation. The government also covers fees for the experts' work through specific subsidies allocated to the MWHI.

The MHII is commissioned to handle the administrative management of prenatal diagnosis. According to local regulation, the staff and the institution that apply for prenatal diagnosis services delivery must submit their application to the MHII. The MHII is responsible for qualification accreditation based on local regulation: if the staff and institution meet the requirements for services delivery, the MHII will provide them with certification. The MHII also takes part in the annual evaluation of prenatal diagnosis centers; the result of this evaluation is taken into consideration at the time of each institution's certification renewal. In addition, the MHII deals with routine supervision work of prenatal diagnosis services delivery; for example, it receives complaints and reports of poor service delivery, and does supervision work. Finally, it also has the power to deliver sanctions.

Shanghai has four prenatal diagnosis centers, all of which are public medical institutions. According to the regulation requirements, prenatal diagnosis centers provide both screening testing and diagnostic testing. They also develop internal administration and regulation principles.

More than 10 health centers provide screening testing in Shanghai, all of which are public. Although beyond the regulatory framework, they are still involved in regulation implementation. They provide only screening testing, however, and must counsel high-risk pregnant women (positive result on screening testing) to receive diagnosis services. Screening testing is, in fact, profitable, with limited software requirements and hardware acquisition, so health institutions are quite willing to provide the service to meet increasing health needs.

In addition, one private medical institution should be mentioned which did not receive certification for prenatal diagnosis service delivery. It had adjusted its service procedure to escape regulatory constraints while providing prenatal diagnosis services: it collected samples, but sent them to Hong Kong or the USA for testing. This institution has been sanctioned by the BOH for its illegal behavior.

For local regulation implementation, the MWHI invites experts to take responsibility for personnel training, evaluation and institutional assessment of prenatal diagnosis technology and services delivery. Certain professionals also take part in the development of new technology and the formulation of professional standards.

In Shanghai, users have the right to select, according to their preference, the medical institutions at which they will receive prenatal checkups. Based on informed consent, users can choose to undergo screening testing or not. For those users receiving a positive result from screening testing, doctors must give medical advice (aid in the search for prenatal diagnosis); users have the

right to follow-up or not with prenatal diagnosis. Hence the requirements of informed consent are followed. Moreover, when users feel dissatisfied by medical services, they may protect their rights and interests, share their experience, and disseminate their health knowledge in a variety of ways.

Lastly, certain companies provide devices, kits and different service models mainly to health institutions to meet the needs of users. Others develop new technology, and promote prenatal screening and diagnostic services to users.

5.1.4.4 Actors' relationships

5.1.4.4.1 Experts and the government

Government officials rely on professional information, knowledge, and opinions during technology and services regulation. In the area of prenatal diagnosis, because of its complex technology, officials seem more reliant on experts. If officials receive consistent information from the experts consulted, they are more likely to follow the advice given. If, however, officials receive inconsistent information from experts, they take a suspicious stance. When experts' opinions differ, navigation of these discrepancies varies among officials.

Experts' roles rely on government officials' authorization. Whether such experts have any power to influence depends on many factors, including the personalities involved, their relationships, etc. Experts sometimes think that policy-makers are not easily convinced, as the following interviewee's perspective suggest:

> *The government should authorize a [prenatal diagnosis] related professional organization and association. Only then will professional opinion be adopted effectively.*
>
> (Male, PD-Implementer-3, 30-11-2011)

5.1.4.4.2 Regulatory agencies and hospitals

Regulatory agencies—including the BOH, the MWHI, and the MHII—act as legislators, administrators, and monitors, respectively. Hospitals follow related rules and accept supervision of regulatory agencies. However, hospitals also know how to take countermeasures in response to regulatory agencies' audits, supervision, etc. Hence, while regulatory agencies are always reliant on checks and audits to monitor hospital performance, sometimes they do not succeed without an appropriate sanction mechanism.

5.1.4.4.3 Companies and hospitals

Companies provide technology, information and training programs to hospitals to promote their products and improve their market share. Meanwhile,

companies constantly enhance product quality to meet hospital/market demand. Hospitals choose suppliers and products according to their experience as well as in response to regulation requirements. Statements by the following interviewees reflect the above:

> *We develop different service models according to the different situations of service providers... For example, if we organize quality control trainings, we invite hospital directors and staff to join in.*
>
> (Female, PD-Other-3, 24-12-2011)
>
> *The company sometimes provides you with certain new information, new technology [...] related kits [...] they came to tell me about international trends.*
>
> (Male, PD-Administrator-1, 28-12-2011)

5.1.4.4.4 Companies and experts

Because companies know professionals have very important roles that impact technology utilization and the platforming and popularization of technology and products, they like to develop cooperative projects with academic professionals. For them, moreover, experts are easier to communicate with than government officials. However, in the absence of any transparency mechanism, concern exists that under certain conditions, some experts may become unrecognized company spokespeople.

5.1.4.4.5 Companies and government

Companies wish for opportunities to popularize and promote their new technology and service models to government officials. However, such opportunities are minimal since the government prefers to avoid any such relationship with companies.

5.1.4.4.6 Hospitals providing prenatal screening alone, prenatal diagnosis centers, and the relationship of both to users

Currently, Shanghai has four prenatal diagnosis centers and more than 10 institutions that provide screening testing alone. As a whole, Shanghai's screening and diagnosis delivery model is not seamless: both groups of centers elicit similarly negative comments regarding relationship. In short, the "work relationship" mechanism does not work.

Of the more than 10 screening centers in Shanghai, only a few (about three) have established "effective" work relationships with prenatal diagnosis centers; users who receive a positive screening result at one of them can transfer to a contracted prenatal diagnosis center for diagnostic services. Users receiving screening testing in other screening centers, however, receive only the suggestion of further diagnosis; they must hunt down such follow-up diagnostic

services on their own. Moreover, if service demands are beyond the capacity of a specific prenatal diagnosis center, the user is refused and must turn to some other centers.

5.1.5 Effect

The core of regulation effect evaluation is to assess whether the expected goal of the studied regulation has been achieved or not and whether the users have benefitted or not. In the current study, the quality, equity, and accessibility of prenatal diagnosis services are the main indicators of evaluation. Taking Shanghai as an example, in general the effect of “PD Regulation” is good. Yet certain problems and potential issues should be taken into consideration for future policy modification.

5.1.5.1 Quality of service delivery

The regulation on prenatal diagnosis services was introduced mainly to solve problems of low capacity and disorder in service delivery, and gaps between the real and the ideal in terms of safety and effectiveness. Protecting maternal and infant health, the purpose of effective “PD Regulation,” means ensuring the safety and effectiveness of the technology and procedures necessary for successful prenatal diagnosis services. In short, improving the quality of service delivery is a major objective of “PD Regulation.”

Both the national regulation and the local regulation (which included a series of related regulatory documents) introduced many approaches to ensure the quality of prenatal diagnosis services, including technical certification, training and evaluation.

Moreover, results from evidence-based research activities have caused several prenatal diagnosis centers themselves to intensify emphasis on internal management in order to improve the quality of services and minimize the potential risk of service delivery.

If focusing exclusively on Shanghai’s four prenatal diagnosis centers, after the introduction of the “PD regulation,” better administrative framework and the rapid development of technology improved the quality of prenatal diagnosis services. Service process standards have optimized, technical applications in clinical diagnosis have been broadened, and safety and effectiveness of service delivery has increased. All of the above has benefitted users. Regulatory agencies, providers and users hold the same opinion on this matter:

As I see it, with respect to just the four prenatal diagnosis centers, their

service delivery became fairly standard [after regulation implementation]. They [now] have a set clinical process for prenatal diagnosis service delivery and conduct their service delivery according to it. It is relatively standard.

(Female, PD-Implementer-1, 07-09-2011)

Mainly, we regulated the four prenatal diagnosis centers according to the same standards. In addition to annual assessment, we also organized routine prenatal diagnosis meetings.

(Female, PD-Implementer-1, 07-09-2011)

When the [national] regulation was issued, we just followed the regulation [when providing prenatal diagnosis services].

(Female, PD-Implementer-5, 19-09-2011)

If focusing on the prenatal screening centers, however, the situation is highly different. Actually, modification of the local regulation was partly due to increased health needs for prenatal screening services. After district level prenatal screening services providers were established, access to prenatal screening services did improve. However, the screening centers met no pressure to develop work relationships with prenatal diagnosis centers.

Most newly established prenatal screening centers did not receive enough supervision from prenatal diagnosis centers. Hence, their service quality could not be assured. This meant that those that were not prenatal diagnosis centers but provided screening services did so without adequate supervision. Such prenatal screening centers had to take on the responsibility of quality assurance themselves, leading to uncertain quality standards.

In the end, improved access to screening testing was accompanied by decreased access to diagnostic testing and deterioration in the quality of such screening. Here is the experience of two users, and one got false negative result and one got false positive result:

For my first child, the result of his blood serum screening test meant not high risk. It was negative. But the outcome of my pregnancy was Down syndrome [false negative of screening testing]. The accuracy rate of prenatal screening tests is not very high. Why would I have done it?

(Female, PD-User-2，24-09-2011)

He [the doctor] had some material […] It said the result was possibly not accurate [perhaps a false positive]... If the result was high risk, and you thought it was necessary, you should do amniocentesis. If you thought it wasn't necessary, you were responsible for the result [a birth defect baby]... When I got the [high risk] report, I was nervous... I

thought about it for a long time. In the end, I didn't do amniocentesis.

(Female, PD-User-5, 24-09-2011)

The development and improvement of prenatal diagnosis technology is an important vehicle for the improvement of prenatal diagnosis services quality (safety, effectiveness). However, the “PD Regulation” didn’t give much attention to this matter. Furthermore, the national regulation, especially the annex on the technical criteria of service delivery, hasn’t been modified since its introduction almost ten years ago. A few interviewees felt that the “PD Regulation” was blocking the development of the technology, an unintended negative effect. One front-line provider said that:

Technology develops fast [...] in China, some regulations are outdated. And the clinical applications of some technologies are restricted.

(Female, PD-Implementer-9, 04-01-2012)

5.1.5.2 Equity of service delivery

In Shanghai, equity of prenatal diagnosis services is related to general ANC services.

The first matter related to equity of service delivery has to do with migrant pregnant women. In 2007, Shanghai’s BOH developed a new regulation on migrants’ delivery services. 24 delivery centers for migrants were established to provide delivery services to low-risk migrants in order to ensure those services are safe and affordable (detailed information provided in the EMOC case). Users delivering babies in Shanghai can now access essential ANC services at a relatively low cost. However, prenatal diagnosis and serum screening for birth defects are not included in these centers’ service package. This is a potential threat factor in terms of equity.

The second has to do with high-quality health resource utilization. In recent years, many Chinese cities have been experiencing a baby boom; yet local high-quality resources for ANC and delivery services are too limited to meet such high demand. The effects of this boom have radiated regionally, with Shanghai’s generally superior health resources attracting many non-resident pregnant women to the city for better ANC and birth services: Shanghai’s four prenatal diagnosis centers are widely recognized for advantages in service quality and capacity; the city also has several secondary MCH centers with reputations for good service and friendly environment. With this increasing demand for services, the workload of Shanghai’s MCH centers has been continuously increasing. To ensure quality of service by limiting demand, some district MCH institutions have had to institute a "threshold." For example, secondary (district level) MCH centers prioritize local (district) pregnant women’s registration. This is a further potential threat factor in terms of equity.

Lastly, some MCH centers carry out special needs services for users of high-income brackets, meeting the health needs of different levels. Through higher fees such users can opt for shorter waiting times and more comfortable service. However, the municipal BOH has already developed regulations for the scale of these kinds of services within public health centers, so until now such situations of inequity have not been overly serious, nor too specific to prenatal diagnosis services.

Yet just as great gaps exist in regions' social and economic development so too do great gaps also exist in the development of prenatal screening and prenatal diagnosis technologies and services delivery. Especially in China's central and western parts and in rural areas, screening and diagnostic testing are of simple and limited means. The effectiveness of such services clearly must be improved. With great focus and commitment from all, the equity of prenatal diagnosis services throughout the country should improve.

5.1.5.3 Accessibility of service delivery

As concerns Shanghai, generally, the accessibility of prenatal diagnosis services is mediocre at best, for the transfer system from screening to diagnostic testing needs considerable improvement. The geographic accessibility of screening services, however, has measurably improved. With the issue of distance partially resolved, pregnant women now receive screening testing more easily, with more services available. The geographic accessibility of prenatal diagnostic testing, on the other hand, has worsened, since Shanghai has only four prenatal diagnosis centers and all are located in the central urban area. In particular, because Shanghai's transfer system from screening testing to diagnostic testing is poor, pregnant women living in rural areas have especially difficult access to prenatal diagnosis services.

Moreover, resident pregnant women have easier economic access to prenatal screening services since such expenditures are covered by reproduction insurance in Shanghai. First they must pay for the service, then they receive reimbursement from their insurance agency; those not covered by the insurance system (e.g. migrant women) do not receive reimbursement. Economic access to prenatal diagnostic testing is relatively poor when compared to that of screening testing. As rather high-tech, prenatal diagnostic testing has fees that are much higher and fluctuate; meanwhile, up until now social insurance has not covered such fees. Across the country, different provinces charge different prices for screening and diagnostic testing; while fee discrepancies for screening are small, ones in diagnostic testing are large. Moreover, differences exist in provincial reimbursement policies for screening testing and diagnostic services are not covered by any provincial social insurance.

Actually, pricing and reimbursement policies for health services are covered neither in the national regulation nor the local regulation. Such powers are beyond the scope of the MOH and BOH. A variety actors expressing their opinions about the accessibility of screening and diagnostic testing consistently described imperfect conditions, as the below comments from interviewees drawn from the body of actors reflect:

Some institutions provide screening services, but we haven't established a good relationship between prenatal diagnosis and screening.

(Male, PD-Administrator-1，28-12-2011)

Pregnant women paid 220 CNY [approx. 35 USD] for it [ultrasound prenatal diagnosis]. In terms of doctors' services, that's quite cheap, but for pregnant women, especially poor people, it's expensive.

(Female, PD-Implementer-5，19-09-2011)

In recent years, we haven't been able to meet the demand [for prenatal ultrasound service].

(Female, PD-Implementer-5，19-09-2011)

Currently, prenatal diagnostic testing can only be done in certain tertiary hospitals. Shanghai has are only four prenatal diagnosis centers. Its capacity of service delivery for prenatal diagnosis does not match a large city's demand. Aside from the large permanent resident population, there are also other [non-resident] city dwellers, including students, workers, and even people on business trips. All may need services. These days, even foreign patients come to our hospital.

(Female, PD-Implementer-9, 04-01-2012)

I know in Municipality Z, the government pays for [prenatal screening] services.

(Female, PD-Other-3, 24-12-2011)

It seems there is nothing [prenatal diagnosis related services] reimbursed. Delivery expenditures can be reimbursed by rural cooperative medical reimbursement [...] but prenatal diagnosis-related services can't be.

(Female, PD-User-6, 26-11-2011)

5.1.6 Discussions

5.1.6.1 Comparison of regulation definition on genetic disease diagnosis and prenatal diagnosis

When the "PD Regulation" was initially designed, the incorporation of genetic disease diagnosis was planned; in fact, genetic disease diagnosis was included in the regulation's first draft. Ultimately, however, the "PD Regulation" didn't include such genetic disease diagnosis. And ten years later, regulation of

genetic disease diagnosis still hasn't been dealt with. How the policy window of “PD Regulation” compares with the regulation of genetic disease diagnosis greatly interests us.

Based on information from interviews, several points can add explanation to the matter. First, genetic disease diagnosis regulation is more complex because the population size potentially affected is larger. The affected group includes not only babies but also adults, hence is beyond MCH scope. Second, compared to prenatal diagnosis, the requirements for genetic disease diagnosis technology are much more complex and multi-disciplinary; thus the regulatory cost is higher. Yet the “PD Regulation” policy window, regarding the relationship between prenatal diagnosis and genetic disease diagnosis, was affected by more factors than just differences in population beneficiaries and technology requirements. For instance, during the regulation’s consultation and validation stage, far less experts involved in the latter specialization were invited to provide suggestions than experts specialized in clinical Obstetrics and Gynecology. Moreover, certain professors’ characters and behavior influenced the direction taken following the suggestions, with opinions of the more introverted experts always neglected. Last but not least, government leaders’ different attitudes also impacted the lack of inclusion of a design for genetic disease diagnosis in the resulting “PD Regulation”. The role of opinion leaders is always important.

One health manager provided his opinion on the regulation of genetic disease diagnosis as follows:

> *Genetic disease is complex, it's not only about screening [...] There will be trouble if you do genetic disease diagnosis without [proper] technology capability and human resources.*
>
> (Male, PD-Implementer-3, 30-11-2011)

Another policy-maker spoke as follows on the deletion of genetic disease diagnosis after the PD Regulation’s first draft:

> *Genetic disease diagnosis includes adult diseases, and is aimed at adults. Prenatal diagnosis-related genetics is aimed at pregnant women and infants. An added complexity: some genetic diseases don’t express themselves before women get pregnant […moreover,] diagnosis modes differ. Blood and certain other substances are used to diagnosis adult genetic diseases. Prenatal-related genetic disease diagnosis is based on amniotic fluid, cord blood, and so on.*
>
> (Female, PD-Designer-2, 31-08-2011)

An expert taking part in several consultation and validation conferences provided the following opinion on another important aspect regarding the separation of regulation definition between the two areas:

In the discussion [of regulation design], most prenatal professionals are obstetrics doctors; […], they are not ready, and don't recognize the potential of genetic disease diagnosis, [so] few people talked about it [...] Professor C was angry [about the lack of concern but] he didn't insist [...] At the time, D was the director of the ST&E department [of the MOH], and he did think about genetic disease. Some national [genetic diseases research] centers were established when he was the director. After D left the position, others never mentioned the regulation of genetic disease diagnosis any more.

(Male, PD-Other-2, 29-08-2011)

5.1.6.2 Factors influencing the regulation effect

One way a regulation's effect can be assessed is through the realization of its own goals. In the HESVIC study, the key issue in the PD case is equitable access of quality prenatal diagnosis services. According to the opinions of the above actors and information from certain documents (including gray documents), clearly "PD Regulation" implementation hasn't fully realized the objectives the "PD regulation" set for itself during definition. Factors affecting this kind of regulation effect include not only characteristics inherent to prenatal diagnosis technology and services but also related to the regulation's content and manner of administration and implementation. The macroeconomic policy environment, priorities set by the government, and limitations in health resources have also impacted the regulation effect.

The first factor has to with the special characteristics of prenatal diagnosis technology and services. Compared to other technologies for birth defects prevention, prenatal diagnosis is a specific MCH area; in particular, its invasive diagnosis techniques are high-risk and high-tech, which invites regulatory difficulties. Taking prenatal diagnosis of Down Syndrome as an example: current clinical procedure, based on informed consent, is first to provide prenatal serum screening testing to low risk pregnant women in general and then, also based on informed consent, provide further invasive diagnostic testing (amniocentesis karyotype analysis) when those initial screenings test positive. However, the existing prenatal serum screening techniques for Down Syndrome is not yet mature, and its cut-off value fluctuates when affected by different equipment, reagents, operators and other factors, causing deviations in the sensitivity and specificity of the screening testing. These deviations not only directly affect the quality of service but also indirectly affect providers' behavior and hence the availability of follow-up amniocentesis karyotype analysis service.

The second factor has to do with limitations in the regulation document itself. The national regulation document was developed at the beginning of this

century, ten years ago. While technology has improved with each passing day, the content of the regulation document hasn't accordingly been amended, especially with respect to clinical process and technology criteria for prenatal diagnosis services delivery. Moreover, certain specific technical standards lag far behind developments in technology. Lastly, during regulation implementation, many new problems arose in response to the current transition in macroeconomic policy environment, yet the regulation document had not incorporated target initiatives that could address these new needs. Consequently, local government could only develop and fine-tune local sub-regulation, compromising according to the local condition, an adaption that resulted to some extent in "evasion" of the regulation's administration.

The third factor has to do with macroeconomic policy environment constraints. For this MOH-developed regulation, during regulation definition, several initiatives were introduced focusing on equity, access and quality of prenatal diagnosis services; however, because reimbursement, social insurance, pricing and other regulatory initiatives are not entirely within the purview of MOH, those initiatives were weakened, as discussions with different actors indicate.

Partly for the same reason, gaps between targeted and realized outcomes have occurred in equity, access and quality of prenatal diagnosis services. Yet the specific nature and characteristics of prenatal diagnosis services has also had a share in impeding recognition at all relevant government levels that prenatal diagnosis is a key MCH regulatory issue. Consequently we currently face a lack of strong intensity in regulatory power and specific regulatory initiatives, which may be restricting the regulation effect. Moreover, in recent years, domestic public hospitals have relied mainly on income from service delivery to cover their costs, to a large extent doing so under a distorted compensation mechanism. Prenatal screening testing, relatively low-risk and of higher financial yield, have been a means of income generation, recognized, in general, as a good choice for cost compensation.

During a discussion about the effect of the regulation, one health manager said:

> *Looking back, we feel that the regulation document still has many limitations. It has been so many years since the formulation of the regulation document; meanwhile, prenatal diagnosis technology has developed rapidly […] Much of the regulation document's content is not suited to current developments in technology, [for such] more newly developed technology and concepts […] aren't covered in the regulation document [language]. If the regulation document isn't [routinely] modified in response to developments in technology, it will restrict the development of prenatal diagnosis technology.*

(Male, PD-Implementers-1, 30-11-2011)

Nonetheless, the problem of equity and accessibility of prenatal diagnosis was, in fact, involved in early ideas about the regulation and its scope. One designer said:

> *Originally, we [the consultation groups] wanted the regulation formulation to […] provide financial support [for prenatal diagnosis services delivery and utilization] in western, rural, and other poor areas. For example, we hoped that the government would provide some financial impetus to health centers, supporting their fee remission of service delivery […] But when these suggestions were submitted to the consultation conference, they were abandoned […] The reality was, the MOH was not able to do this […] Insurance was the key issue for service utilization. But that was beyond the purview of health authorities' power. Even if those initiatives had been included in the regulation document, we would not have been able to ensure that the related government departments implemented it. So that was a limitation.*
>
> (Male, PD-Designer-3, 18-12-2010)

5.1.6.3 Governance characteristics[3]

Participation and consensus orientation

Throughout the entire process of the regulation's definition, administration and implementation, direct participation of users has been minimal. A decade or so ago, as compared to now, the participation of consumers and/or the general public during regulation processes was less popular. Consequently, during the "PD Regulation" definition process, actors invited to take part in the discussion and consultation were mainly experts in prenatal diagnosis-related areas (including front-line medical staff) and administrative staff belonging to the health authorities. Users were not included. On a more positive note, however, interviews with users were an important method of information-collection during the national investigation led by the HTA Center before regulation definition. Their experiences and evaluations of prenatal diagnosis services were taken into consideration when it came to regulation formulation. And while users did not take part in regulation administration, more recently, during regulation implementation, the protection of their rights and benefits has become increasingly highlighted because of the related change in governance concept and concerns. These days, users are an important external supervisory force in the health system. They can claim their rights and expose illegal violations of health service providers in a variety of ways.

The aim of the regulation has stayed unified throughout the entire regulation

process: from definition to administration and implementation. Local provincial-level regulations were developed based on the spirit and requirements of the national regulation, with their key contents remaining closely consonant with those of the national one. For example, in Shanghai, the municipal BOH directly communicated with the MOH, and was recognized for its fine-tuning of the regulation. Moreover, the MOH holds periodic conferences uniting all the provinces in order to share practical experience and suggestions on prenatal diagnosis services regulation.

Transparency

Experts and professional academic organizations have taken an active part in regulation definition, administration and implementation. In most cases, their participation was commissioned or authorized by health authorities. In general, those health authorities attached importance to such opinions and suggestions during the regulation process.

In more recent years, as the concepts of “evidence-based medicine” and “evidence-based decision-making” have become much more popular, experts and professional academic organizations have increasingly turned to evidence-based research results in their decision-making processes.

As one expert from a Shanghai prenatal diagnosis center explains, according to her experience with conducting evidence-based decision-making:

> *The key question is how you trace these false-positive cases. What I did last year was to have two nurses help me try to follow up all cases, whether positive or negative screening [result]. So I can claim that my results are very accurate […] I submitted these results to our president for reference. Actually, as I see it, the present screening reagent is not very good, and the false-positive rate is too high.*
>
> (Female, PD-implementer-7, 12-12-2011)

Accountability

The accountability mechanism for prenatal diagnosis services is insufficient both nationally and in Shanghai. However, health supervision institutes can make inquiries and sanction health centers violations in behavior, based on national and local regulatory documents such as “PD Regulation” and others.

Strategic vision

Taken as a whole—from the national “Maternal Law” through “Implementation Measures” and “PD Regulation” to, and including, Shanghai’s local regulation—the regulation of prenatal diagnosis services is essentially

coherent and consistent. Moreover, the regulatory approaches used in “PD Regulation” are homologous with approaches used for other women and children health care issues.

5.1.7 PD Case conclusion

Generally, the major health problem that prenatal diagnosis services delivery represented before regulation definition included three components. One had to do with great gaps in the technical capacity of prenatal diagnosis services delivery and utilization that existed among different regions (problems of equity and accessibility). Another had to do with the quality of prenatal diagnosis services: users encountered insufficient benefits (quality issues). The last stemmed from the poor connection between screening and diagnostic testings’ delivery.[15]

In the 10 years occurring post-regulation definition, the example of Shanghai, one of China’s most impressive municipalities, reveals that as technology has prominently improved so too has the recognition and acceptance of prenatal diagnosis technology (not only screening testing but also invasive testing). As a result, four prenatal diagnosis centers have been established, their quality of service delivery is reliable, and, lastly, accessibility of screening testing has improved. The above are all positive (intended) effects of the regulation process, from definition and administration to implementation.

Nonetheless, the delivery capacity of the four Shanghai centers is insufficient to meet the current demand for prenatal diagnosis services. And within the municipality, migrant women’s prenatal diagnosis services accessibility is poorer than that of residents because of differences in insurance coverage. Furthermore, the quality of screening testing is not entirely reliable and the connection between screening testing and diagnostic testing is still uncertain.

We consider the regulation content for the most part evidence-based, as defined by existing knowledge of the problem of prenatal diagnosis services delivery at the time; yet the final version of the regulation omitted full consideration of several points whose relevance has been become clearer as time has passed.

From a process perspective, the regulation design stage was handled systematically, as were the administration and implementation stages; moreover, throughout the process, key actors shared the regulation’s essential objective. In its design, the regulation paid more attention to quality than accessibility and equity, for prenatal diagnosis services are perceived as a kind

of high-tech MCH services. Based on Shanghai's particular socio-economic situation, during regulation administration, the municipal government authorities tried to balance quality, equity and accessibility of prenatal diagnosis services delivery. Consequently, they modified the "PD Regulation" and established and administered the additional local one. So far, the entire process has been something of an exploration. We look forward to further improvements.

Nonetheless, certain characteristics inherent to prenatal diagnosis technology itself determined that the regulation implementation stage would face much difficulty. In addition, many stake-holders have taken part in the regulation process, which has resulted in a variety of implementation effects. Yet based on the current Chinese Health System, balance and coordination of economic interests among all stake-holders cannot be achieved overnight. Our recommendations include the follow points:

First: The regulatory process for prenatal diagnosis services is developing as fast as its associated technology. Both the state and the municipality are conducting exploratory activities. Experience with past and current regulation should be continuously matched to ongoing associated developments in technology.

Second: Many kinds of regulatory approaches and mechanisms are used in our case, whether of strong or weak intensity; their main objective is quality, equity and accessibility. Ideal approaches to and mechanisms in such regulation should not only be developed based on the regulatory aim but also should suit the specific characteristics and nature of the regulatory objectives (in our case, prenatal diagnosis services).

Third: In China, the voice of patients and of the general public is limited to the manner in and extent to which those voices catch the attention of today's decision-makers. Mechanisms related to market regulation, general public self-protection, and professional management should be cultivated so as to form multi-actor regulatory mechanisms.

Fourth: Analysis of this case indicates that one of the challenges of evidence-based decision-making is that the decision-makers lack professional knowledge and comprehensive understanding. This situation is not, in fact, unique to the area of prenatal diagnosis: it exists in other cases too. Based on our investigation of and experience with Shanghai practice, since evidence constantly accumulates, the decision-making process should likewise receive continuous renewal.

Fifth: Feasibility and relevance of regulation are significant for regulation effect.

Great gaps in social, economic and health status exist among China's different provinces. Hence the provincial and/or municipal BOH, based on local conditions, are responsible for formulating local health regulations that accord with national regulations (not only in terms of prenatal diagnosis but also regarding other national health regulatory documents). Such is the nature of regulation administration. Generally, national regulations establish the main demand, while local regulations refine it. Local regulations can sometimes with some flexibility (through approaches, mechanisms, specific standards, etc.) modify or adjust the national regulation; encouraged by the MOH, either they develop creative approaches or they formulate suitable procedures. Such are the dynamics of power decentralization. In this particular case—that of "PD Regulation"—the impact of this decentralized power function should be given more attention, for it affects both regulation implementation and its effect.

Finally: the problems in the area of prenatal diagnosis derive from the government's neglect of management. Both providers and users believe the government should be relied upon as the principal provider of solutions necessary to resolve the present problems in the area of prenatal diagnosis. Yet the government is not omnipotent; so this fairly widespread view has resulted in great challenges for the government. However the issue proceeds in the future, whether in the domain of government or market, transparency should be a necessary prerequisite for both.

5.2 EmOC (Emergency Obstetric Care)

5.2.1 Background

5.2.1.1 Regulation summary (title, contents, objectives)

The selected regulation is entitled "Notice issued to establish work principles for emergency obstetric care [EmOC] consultation, referral and treatment in Shanghai" and was delivered by the Shanghai BOH in April 2008 (No.12). The regulation established the principles of consultation/referral and treatment of critically ill pregnant women (CIPW) during Emergency Obstetric Care (EmOC), including the responsibilities of new EmOC centers and related health agencies (EmOC in this report always refers to comprehensive EmOC). The regulation intended to achieve appropriate consultation/referral, accountability and coordination between EmOC centers and all other related agencies. Its ultimate goal was to make sure all pregnant women, including migrants and the poor, have equitable access to quality maternal care.

5.2.1.2 Rationale for the choice in study regulation

1. Justification and rationale for selection of thematic area

- The improvement of maternal health services and further reduction in the maternal mortality ratio (MMR) is an important part of the Millennium Development Goals; together, the two form China's main objective in the area of maternal and child health (MCH). In China, the MMR is a core indicator of the *Law of the People's Republic of China on Maternal and Infant Health Care* and the *National Plan for Action on Women (2001-2010).*

- To reduce maternal deaths, the *health system needs to focus on many components*: including access to skilled birth attendance (SBA), institutional delivery, the rescue of critically ill pregnant woman (CIPW), etc. Shanghai, as one of China's most developed areas, has long offered both universal access to SBA and institutional delivery. EmOC, an important component in the reduction of maternal death, is also key to safe motherhood. Equitable access to quality EmOC is thus an important means of ensuring safe motherhood.

- According to data from Shanghai's three-level MCH network, *obstetric haemorrhage was the main cause of maternal death between 2000 and 2007.*[16] Many factors are associated with obstetric haemorrhage death, but prevention requires access to good quality EmOC; indeed, the management of obstetric haemorrhage is a composite indicator of obstetric service quality. Improving the EmOC quality is thus key to reducing the MMR.

Hence we chose EmOC as the focus of this case study.

How a specific regulation affects equitable access to quality care is the research question addressed by HESVIC. In Shanghai, the EmOC thematic area, many regulations have been issued since 1995.[17] Shanghai's BOH has developed a series of rules and regulations since 2007 focusing on the process of EmOC consultation, referral and treatment. Such regulations offered us much choice in the EmOC thematic area.

2. Notice issued to establish work principles for emergency obstetric care (EmOC) consultation, referral and treatment in Shanghai (Shanghai BOH, 2008, No.12) was ultimately selected for this EmOC case study for the following reasons：

- The Shanghai BOH has issued many regulations focused on improving the quality of EmOC and reducing the MMR. The selected regulation, compared to

others, is more relevant to the EmOC thematic area (Table 5.2.1).

The selected regulation aimed to solve EmOC problems in Shanghai by regulating the EmOC consultation, referral and treatment process; reconstructing the EmOC network; and enhancing EmOC capability. The three key words contained in the HESVIC research question are “equity,” “access” and “quality.” The main content of the selected regulation is directed at the improvement in quality and accessibility of EmOC for all CIPW in Shanghai, hence also includes improvement in the maternal health care of migrant women. Comparing local and migrant women’s utilization of maternal health services will both be useful and will also help answer the question of equity.

Having identified the rationale and justification of the selected regulation, in the next section, we will study the broader context of regulation formulation.

5.2.2 Context

There has been a great revival of interest in maternal health globally since the Nairobi Safe Motherhood Conference in 1978. The Millennium Meeting of the United Nations in 2000 approved the United Nations Millennium Declaration, which set the goal of a 75% reduction in the MMR between 1990 and 2015.[18] This advocacy of the United Nations, and successful political mobilization in particular, has led to Chinese government commitment.

With its rapid industrialization and urbanization, China is experiencing active population migration. Compared to registered urban residents, most migrants are poor, less educated, less aware of health and healthcare, and less capable of utilizing fee-based health services. Utilization of MCH care among urban migrants has been universally low, with the rate of prenatal check-up and institutional delivery often lower among migrant women. These past two decades, from 1990 to 2010, maternal healthcare services Shanghai has improved, with the maternal mortality ratio (MMR) decreasing from 23.76/100000 to 7.08/100000.[19] Yet these figures hide a challenging reality: from 1993 to 2002, the proportion of maternal death of migrant pregnant woman increased sharply from 26% (7/27) to 79.3% (23/29).[20] Migrant women accounted for a large majority of the overall number of maternal deaths: between 1996 and 2005 the average MMR for migrants was 57.98/100000 yet 15.58/100000 for local residents.[21]

In short, migrant pregnant women (MPW) disproportionately bear the burden of maternal death. Given China’s commitment to a “people-centered policy,” equitable access to quality maternal care is essential to address this problem, but as we show in this study, ensuring such equitable access is an immense challenge in Shanghai.

To address the challenge of migrant maternal health and improve the serious migrant MCH situation, Shanghai's BOH has issued a series of regulations. In 2004, to improve the quality of obstetric services, it issued a notice ensuring the provision of quality and low-cost institutional delivery in public hospitals for migrants. In 2005, a survey of those childbirth service delivery points was conducted;[22-23] it found that although the accessibility of quality MCH services for migrants had improved, the rate of prenatal check-up in MPW was still low. Expectedly, the survey also found that most pregnancies ending in complications/mortality had not received care before admission. In addition, it found that 60% of the delivery points were primary hospitals distant from tertiary ones and thus had limited technical capacity to achieve timely rescue. Inaccessibility to timely rescue emerged as the main cause of maternal death, and timely consultation, referral and rescue became key to reducing MMR in Shanghai. An obstetric quality and human resource survey in 2006 indicated a lack of a practical consultation and referral system for CIPW and a shortage in obstetric human resources and facilities. Referral of CIPW was in a state of chaos. On one hand, lower-level hospitals reported difficulties transferring CIPW to higher-level hospitals due, among other factors, to unavailability of beds and consultant experts, particularly surgeons and physicians. On the other hand, tertiary hospitals reported that many lower-level hospitals made inappropriate referrals: patients were referred without prior contact and/or transferred without prior necessary treatment or in conditions unsuitable for referral.[24-25] In addition, migrants were not involved in Shanghai's health insurance system. With low awareness of health care and low economic capacity, their utilization of perinatal health care was also low. They were the population at most risk of emergency yet economically and geographically usually had poor access to EmOC. It became increasingly clear that improved EmOC access was critical for further reduction of the MMR in Shanghai, especially for the migrant population.

To resolve treatment difficulties in Shanghai associated with severe pregnancy complications, in the 1990s, the Shanghai Bureau of Health (BOH) established three rescue centres with expertise in treating pregnancy-related heart disease, gestational diabetes mellitus and infectious disease. However, no specific operational scheme for EmOC consultation and referral existed at the time. The three rescue centers did not have the obligation to accept referrals from other hospitals. Furthermore, due to limited health resources, the three rescue centers lacked the capacity to provide rescue for all CIPW in Shanghai.

Beginning in 2006, several actions were taken and regulations made to improve the EmOC and maternal and child health care services in Shanghai. In January 2007, Shanghai's BOH issued "Quality requirements for obstetric care and its management in Shanghai" (2007, No.1), which emphasized

EmOC and regulated rescue information reporting, i.e. all EmOC occurrences had to be reported to the Municipal Women's Health Institute (MWHI) within six hours.

Next, in December 2007, Shanghai's BOH issued its "Notice designating five municipal medical institutions as Shanghai's five consultation/rescue centers for critically ill pregnant women," which formally announced five new EmOC centers. Four of those EmOC centers were required to conduct consultation and referral of EmOC within a specific geographic boundary and to provide support for health institutions' obstetric rescue within that same area. All health institutions could apply for consultation and conduct referrals to their designated EmOC center before agreement to such referrals was obtained. The fifth EmOC center provided EmOC services for infectious complications for all women during pregnancy in Shanghai.

Then in April 2008, Shanghai's BOH issued "Notice issued to establish work principles for emergency obstetric care consultation, referral and treatment in Shanghai" (2008, No.12). The regulation focused on the process of consultation and rescue for CIPW. Health institutions' responsibilities were now well defined at all levels and the principles guiding the rescue process were established for EmOC centers, health institutions, the Blood Bank and the Ambulance System.

Several years after this EmOC regulation implementation, two additional regulations were issued on 2010 and 2011; the former focused on MCH health management of the entire population and the latter on an assessment scheme for critically ill pregnant women. A brief introduction to these EmOC-related regulations is given in Table 5.2.1 below.

Table 5.2.1 Brief introduction to EmOC-related activities and regulations in Shanghai, China

Time	Activity and Regulation
June 2004	"Service guidelines for designated migrant childbirth service delivery points" was issued by Shanghai's BOH (2004, No.14). Ten delivery points were announced in the main migrant population areas.
Aug. 2006	**Obstetric quality spot-check findings (a form of obstetric quality control):** Previous consultation and referral system for CIPW was not practical; shortages in and waste of obstetric human resources existed, and quality of obstetric staff could not meet demand; most obstetric facilities lacked EmOC facilities. Some hospitals lacked qualified EmOC staff and/or were seriously deficient in comprehensive EmOC capacity.
Late 2006	**Preparation:** The difficulty of rescuing critically ill pregnant women was recognized by Shanghai's BOH. The MCH Dept. of the municipal BOH

	planned to establish EmOC centers through application to the BOH's "2007 Subsidy Project."
Early 2007	**Application:** The BOH and Women's Healthcare Institute of Shanghai organized experts to discuss the criteria for EmOC centers' construction, equipment, human resources, etc.
Jan 2007	"Quality requirements for obstetric care and its management in Shanghai" was issued by Shanghai's BOH (2007, No.1): The BOH issued this regulation, based on identified EmOC problems, to further improve the quality of obstetric services. It incorporated an information reporting system. However, Shanghai still lacked clear operational guidance for EmOC consultation and referral.
Apr. 2007	"Notice issued to strengthen maternal healthcare management and designated migrant childbirth service delivery points in Shanghai" was released by Shanghai's BOH. A total of 24 delivery points were established for migrants. The quality, accessibility and equity of institutional delivery for migrants greatly improved in Shanghai.
April 2007	**Official establishment of EmOC centers and network:** Shanghai's BOH released "Notice issued to establish critically ill pregnant women consultation/ rescue centers under the BOH's "2007 Subsidy Project," encouraging comprehensive tertiary hospitals to apply.
Dec. 2007	**Formation and designation of EmOC centers and network:** Shanghai's BOH issued "Notice designating five municipal medical institutions as Shanghai's five consultation/ rescue centers for critically ill pregnant women." The five EmOC centers were announced, as were the rules for consultation and referral. (Funding came from the municipal financial budget, not from the "Three-year action plan for public health.")
April 2008	**Issuance of the regulation：** Shanghai's BOH released "Notice issued to establish work principles for emergency obstetric care consultation, referral and treatment in Shanghai" (2008, No.12). The regulation focused on the consultation and rescue process for critically ill pregnant women. It well defined all levels of health institutions' responsibilities and the principles that the EmOC centers, the Blood Bank and the Ambulance System must follow during the rescue process.
Later 2008	**Training for EmOC personnel：** After the establishment of EmOC centers and the issuance of policy documents, training was initiated. Funds for training came from the "Three-year action plan for public health."
End 2009	**Book on EmOC cases：** The book ***Successful Rescue Cases in the Treatment of Critically Ill Pregnant Women*** was published. It included a summary of EmOC experiences and lessons. It also served as a feasible and practical reference for obstetric staff training.
June 2010	**Summary of experience, strengthened management of entire**

	population, and supplementary strategies identified for implementation: Shanghai's BOH released "Notice issued to further strengthen maternal health care and medical rescue in Shanghai." The regulation focused on health management of the entire population, and defined responsibilities throughout the health administrative sector at each level, including MCH institutes, community health centers, health institutions and health professional associations. Supplementary contents on the consultation/rescue of critically ill pregnant women include reporting both new and at-risk pregnancy cases, as well as conducting warning assessments.
Aug. 2011	**Improved management of near-miss cases:** Shanghai's BOH, released the "Notice issued to establish an assessment device for critically ill pregnant women." Current regulation now requires not only report but also assessment of near-miss cases. It aims to strengthen BOH and MCH institutes' responsibilities at all levels, with health institutions delivering assessment of critically ill pregnant women. The combination of report and assessment of near-miss cases has been strengthened by requiring assessment whether rescue is successful or not.

Key interview informants introduced details regarding the context of the EmOC regulation formulation. Their information indicated that problems of EmOC consultation and referral were very prominent before the EmOC regulation was issued in Shanghai. Access and equity to quality EmOC in Shanghai needed to be resolved immediately. As a regulation designer described:

> *In 2006 many problems regarding the consultation or referral of critically ill pregnant women were found in Shanghai. It was difficult to ask for consultations and make referrals […] Maternal and Child Health Institutions and secondary medical institutions were not capable of rescuing critically ill pregnant women. Many problems were found—especially through maternal death analysis—such as delayed diagnosis and delayed treatment… At that time [pre-EmOC regulation], without available EmOC experts, hospitals had to appeal to the Municipal Women's Health Institute [MWHI]. However, sometimes the MWHI was not successful mobilizing experts and so problems were all forwarded to me [Shanghai Bureau of Health]. I had to get up at 2:00 AM, call an expert, and go to the EmOC site in person. I was busy dealing with EmOC all day.*
>
> (Female, EmOC-Designer-3, 13-10-2011).

Another regulation designer said:

> *We encountered problems in EmOC work. The most prominent difficulty*

during the management of maternal mortality was to reduce the MMR. [Hospitals] all fear the on-site occurrence of maternal death. Referral was very difficult to do if the first contact hospital had no treatment capability. No hospital was willing to take the risk and be responsible for maternal death. Overall EmOC management was chaotic. There was a lack of timely treatment, difficulty with referral/consultation, problems in the rescue of critically ill pregnant women, no recourse for referral (to primary and secondary hospitals), and rejection by hospitals with the technical capacity to conduct the rescue.

(Female, EmOC-Designer-4, 22-12-2010)

One implementer who participated in the regulation design recalled:

Shanghai is a very large city with 180,000-190,000 newborns every year. There are both local residents and migrants in the city. Many problems were found in [EmOC] practice. Tertiary hospitals had many critically ill patients, [pregnant women] who would not have been so critically ill if they had been treated on time. Primary and secondary hospitals received critically ill women, but they were not capable of treating them and it was difficult for them to deal with these patients. [For] in the past, if the primary and secondary hospital did not have a good personal relationship with a tertiary hospital, [acceptance or rejection of referral depended exclusively on the tertiary hospital itself]. If the tertiary hospital accepted the critically ill patient, the secondary or the primary hospital was very happy. If the tertiary did not have enough beds or refused the referral for other reasons, the secondary or the primary hospital had to contact other tertiary hospitals until the referral was accepted. So the referral process was very complicated. Patients also did not know where they should go for critical cases. So in practice, there was a lot of insecurity [with EmOC].

(Female, EmOC-Implementer-3, 14-09-2011)

5.2.3 Process

5.2.3.1 Definition

Four key steps occurred in the process of regulation design: the Dept. of Disease Control and Maternal and Child Health (Dept. of CDC & MCH) of Shanghai's BOH and MWHI drafted the regulation; experts from EmOC centers and three municipal MCH hospitals discussed the draft; the revised regulation was submitted at a regular meeting of the BOH; lastly, the Shanghai

BOH issued the finalized regulation.

During the first step, the Dept. of CDC & MCH and the MWHI organized a seminar, which included directors of Obstetrics departments from the five EmOC centers and three participants from municipal tertiary MCH institutes and hospitals; then the Dept. of CDC & MCH drafted the regulation. Afterwards, they continued to discuss the draft through 4-5 rounds and the draft was revised. During this process, the project entitled "***Construction of consultation and referral network for CIPW in Shanghai,***" which stemmed from the ***Second Three-Year Action Plan for Public Health*** (2007-2009), provided some financial support for these seminars. As two EmOC designers said:

> *Our bureau's general process for regulation design [related to MCH] is as follows：the MWHI proposes basic rules to the BOH, Dept. of CDC & MCH staffs deal with this and propose a draft [regulation] to me [an administrator from the municipal BOH], then I give the revised draft to the bureau director. Finally the document is submitted at a bureau meeting and then issued as a normative document.*
>
> (Male, EmOC-Designer-1, 01-10-2011)

> *After the five EmOC centers were established, we [staff in the municipal administrative organization] organized an expert meeting to discuss the draft regulation; staffs from the MCH institutions were also involved. After every discussion, I revised the draft, then we discussed it again; we had four or five rounds of discussion.*
>
> (Female, EmOC-Designer-3, 13-10-2011)

Once the regulation contents had been perfected, the Dept. of CDC & MCH and the MWHI organized another seminar; directors of the 18 district MCH institutes as well as all the experts took part in that seminar. Then the revised draft was submitted at a bureau meeting for further discussion, and in April 2008 the regulation was finalized and issued by the Shanghai BOH (Figure 5.2.1). As a designer recounted:

> *When the content of regulation was relatively complete, I [municipal health organization staff] organized a meeting involving all 18 directors from the district MCH institutes. They took part in the discussion, and learned how the referral for CIPW worked, how to apply for consultation, and which types of CIPW are allowed in referral and which are not.*
>
> (Female, EmOC-Designer-3, 13-10-2011)

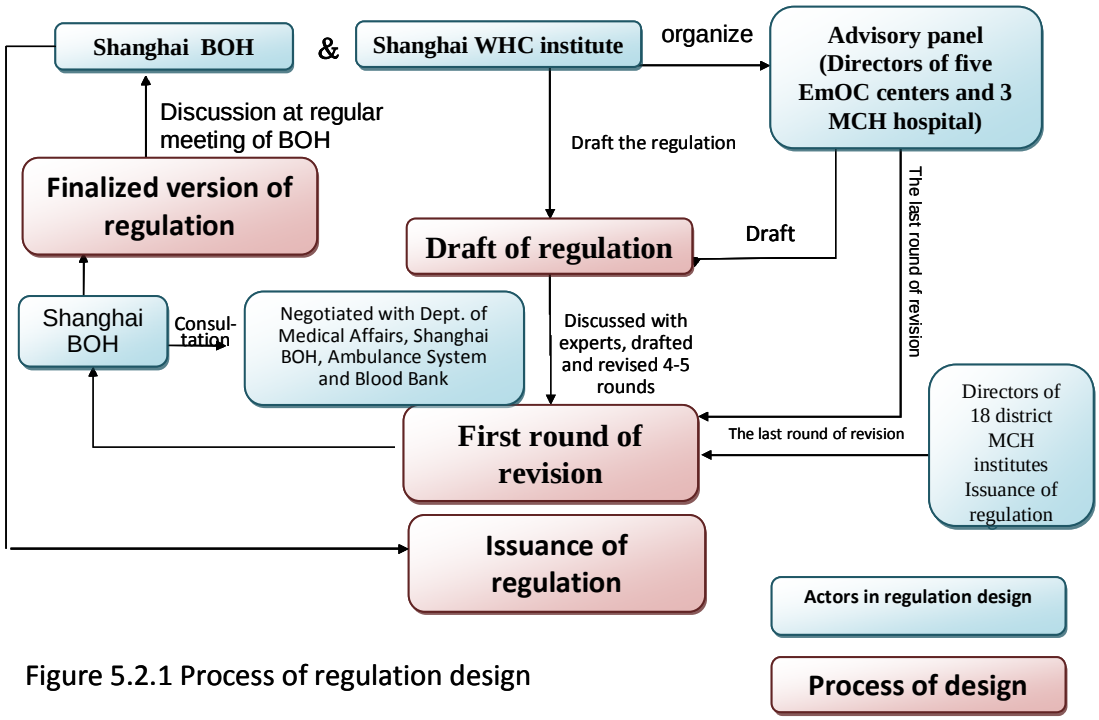


Figure 5.2.1 Process of regulation design

Summary of regulation design

Evidence-based regulation design： Before the regulation design, administrative organizations indentified the key EmOC problems in Shanghai based on an EmOC survey and evaluation. During the regulation design process, the objectives and contents of the draft, revised document, and the finalized regulation all closely related to the problems that had been identified, so clearly that information and evidence played an important role in regulation design.

Limited actors were involved: Actors involved in the full regulation design process included multilevel MCH administrators and EmOC experts from EmOC centers and obstetric hospitals; they provided suggestions regarding the administrative and technical aspects, which ensured the rationality of the regulation. Actors involved in this regulation formulation were mostly from obstetrics and had MCH practice and administrative background. Potentially important actors, however, such as other BOH departments, the district health administrator, other hospital departments and the Bureau of Finance were absent.

5.2.3.2 Regulation administration

The regulation has been administrated at the municipal, district and hospital levels. At each level, administration has included routine management, supervision and assessment. The regulation has been interpreted, moreover, at the district and hospital level. (Figure 5.2.2)

Municipal level: The Shanghai BOH and MWHI took responsibility for regulation administration at the municipal level. They were responsible for leadership and coordination of EmOC at that level: for supervision of EmOC quality in all districts through information management, regular meetings, obstetric quality checks, maternal death audit and training of obstetricians; and for assessment of the quality of EmOC in each district with incentives or sanctions delivered according to such assessment.

- **District level:** At this level, the regulation was interpreted and administered by the district BOH and district MCH institute. As two designers said:

  Because the studied regulation was just an EmOC guideline, it had to be interpreted, with adjustments made at the district level.

  (Female, EmOC-Designer-4, 22-12-2010)

  This [regulation] is an EmOC guideline. Because we have a three-tiered CIPW network in Shanghai, each district has its own rescue rules and principles […] I mean, detailed regulation. [Based on] the survey on obstetric service quality, we know that every hospital has detailed rules for CIPW rescue: how and when, for example, to open a green channel, who should be involved in the rescue [and under which] different circumstances […] so, this [regulation] is just a guiding document.

  (Female, EmOC-Designer-4, 22-12-2010)

Interpretation of the regulation at the district level included the issuance of detailed regulations such as district working principles, establishment of the CIPW rescue team and the EmOC network. Based on the example of the studied districts: both districts issued regulations related to CIPW rescue, including ***Work principles for CIPW rescue consultation and referral in [one central] district*** and ***Report system and flow chart of CIPW rescue in [one suburb] district***. As an administrator from a district MCH institute said:

The main content of my district's regulations is similar to that of the municipal regulation; it includes all the studied regulation's requirements, but is more detailed.

(Female, EmOC-Administrator-3, 15-08-2011)

In addition, both districts organized a clinical advisory group for CIPW rescue that was composed of senior obstetricians, with the district BOH's deputy-chief in charge of EmOC serving as group leader. As the following two district-level administrators explained:

> *Our district [now] has an advisory group, which is an innovation […] I think that only one hospital [the designated center] is not enough [for CIPW rescue] in our district. Why? What should you do if they [experts in the designated center] are rescuing their own patient, or there is no bed available for the referral? I thought we should establish good communication links with obstetrics experts in municipal MCH hospitals, so we have invited them as members of our advisory group. In this way, we have more choices [for CIPW rescue]. Now I can say that this advisory group plays an import role [in our district]."*

(Female, EmOC- Administrator-3, 15-08-2011)

> *We issued a series of documents in our district, requiring, for example, that all our district hospitals establish a CIWP rescue team and leadership group; all Departments of Obstetrics are expected to formulate their own working principles.*

(Female, EmOC- Administrator-9, 13-12-2011)

The district BOH and MCH institute took responsibility for regulation administration at the district level. They were responsible for leadership and coordination of EmOC at the district level, reporting CIPW cases to the municipal organization, organizing inspections to maintain the quality of obstetric care, and arranging training for obstetricians. Moreover, they assessed the quality of EmOC in each hospital and then delivered incentives or sanctions according to such assessments. Two administrators from the district level said:

> *In this district, management of EmOC regulation includes meetings and annual spot checks of the quality of obstetric care. We organize maternity experts to inspect the obstetric service quality in all health institutions, check if unreported risk cases exist, and find out problems occurring in consultation and rescue. Every March or April, we hold this meeting and highlight such problems at the meeting; we want them [obstetricians] to give suggestions for EmOC.*

(Male, EmOC- Administrator -1, 16-12-2010)

The responsibility of the MCH institute is to participate in the rescue and check if all from the rescue team are in their place. We also help doctors coordinate with experts [from the EmOC center] during the consultation process to ensure they arrive as soon as possible.

(Female, EmOC- Administrator-3, 15-08-2011)

- **Hospital level:** Regulation interpretation at the hospital level included the formulation of emergency preparedness, issuance of working principles **for CIPW rescue, and establishment of the CIPW rescue team.** One implementer from a secondary hospital said:

Maternal care management is very important in our hospital. In our department [the Obstetrics Department], we have done much for EmOC, such as formulated a preparedness plan, and established a rescue team and a "green channel" [for CIPW]; we have also issued some other rules and regulations for EmOC.

(Female, EmOC-Implementer-1, 24-12-2010)

A district-level administrator said:

Almost all obstetric hospitals established this kind of leadership group for CIPW rescue. They also organized an expert group which included not only the Department of Obstetrics but also that of cardiology, of surgery, of anesthesiology and so on. The Department of Medical Affairs is also involved in the leadership group, and generally, the vice-director of the hospital, who is in charge of EmOC, served as the team leader.

(Male, EmOC- Administrator-2, 13-09-2011)

At the hospital level, generally the hospital's vice-director in charge of EmOC or of the Department of Medical Affairs took responsibility for regulation administration, which included coordination of CIPW rescue, assessment of emergency rescue, incentives and sanctions.

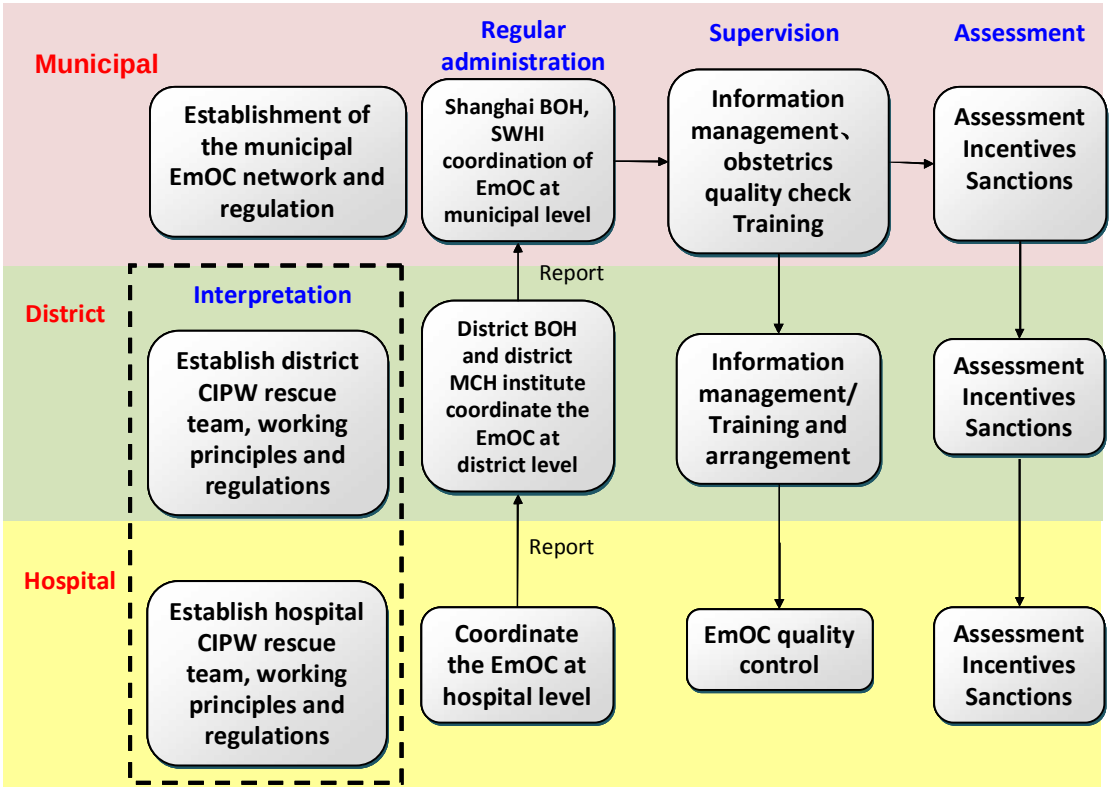


Figure 5.2.2 Regulation administration process

Summary of regulation administration and interpretation

- **Administrative management and technical administration**: Regulation administration included two components, each comprised of three levels: the municipal BOH, district BOH, and the hospital's Department of Medical Affairs. All played an administrative role and their administration was a strong guarantee of regulation implementation. As for the technical component, the MWHI, district MCH institute, and Obstetrics Department took management responsibility for ensuring the quality and efficiency of EmOC.

- **Regulation administration focused on supervision and assessment**: Many mechanisms were used to ensure the quality and effectiveness of EmOC. For example, administrators would identify problems through an information report system and would hold meetings assessing the quality of obstetric care; identified problems could be solved through the accountability system and the maternal death audit system (MDAS); an incentives and sanctions mechanism also could improve service quality and efficiency.

- **Local interpretation improved the feasibility of the regulation's implementation:** Interpreted at the district level, the regulation became more

feasible, and the district EmOC network was established, another guarantee of CIPW rescue. Interpretation at the hospital level aimed to improve the feasibility of the regulation's implementation; with this interpretation, detailed rules for CIPW rescue, consultation and referral were established, and the responsibilities of actors became clear.

5.2.3.3 Regulation implementation

The implementation of EmOC in Shanghai occurred at 3 levels, represented by the three-tiered network for CIPW rescue, consultation and referral (Figure 5.2.3). A designer from the municipal level explained:

> *Once emergency treatment has occurred, the hospital vice-director in charge of EmOC, the chief of the Obstetrics Department and all other technical support must participate in the rescue. This is EmOC at the hospital level. The second level is the district level; all districts have an EmOC network. The third level is the municipal level.*
>
> (Male, EmOC-Designer-1, 01-10-2011)

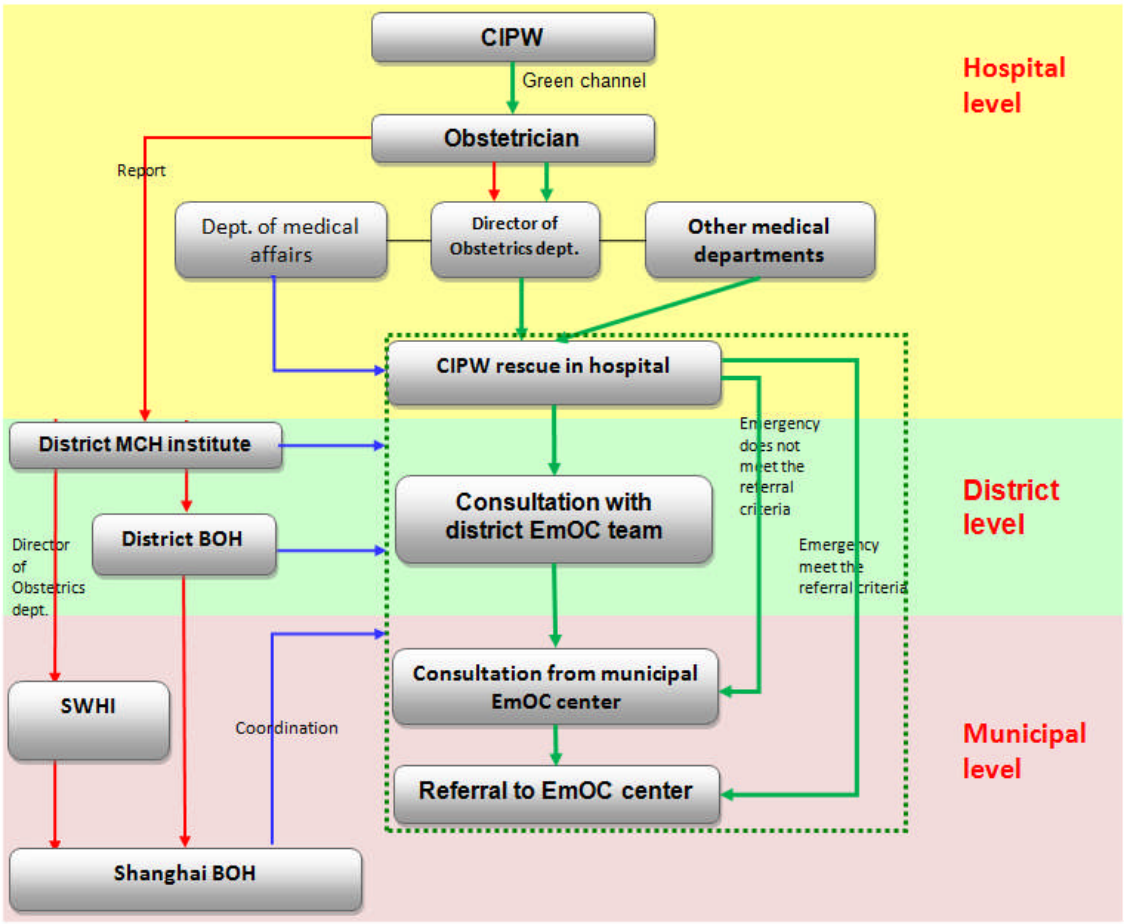


Figure 5.2.3 Regulation implementation process

- **General EmOC process**

When emergency rescue occurs in health institutions, the “green channel” and CIPW rescue preparations in the hospital must immediately be launched. According to CIPW rescue principles, after preliminary examination and treatment, the obstetrician must report the case to the chief of the Obstetrics Department and the hospital’s vice-director. During emergency rescue, doctors from related departments such as those of Aesthesia, of Haematology, etc., must provide assistance at any time. Meanwhile, the obstetrician must report the case to the district MCH institute and district BOH, which must take on responsibilities for coordination of consultation, referral, and/or other affairs or

such as blood or other medical resources.

If necessary, the district EmOC network and associated preparations much be launched, with the district advisory group involved; if the patient is in serious condition, then the municipal EmOC network must be launched and experts in the designated EmOC center must be involved.

During the implementation process, medical institutions at all levels carry out the CIPW rescue following regulation requirements, which means if the patient is at risk of death on the way to referral, then referral is not allowed, and emergency consultation and instant rescue must be launched in the hospital. When the patient is in stable condition, then referral is allowed and the patient must be transferred to the designated EmOC center, accompanied by a doctor. As an administrator from an EmOC center explained:

> *For example, if they [doctors in lower-level hospitals] want to refer a patient to the designated EmOC center when the patient is difficult or impossible to manage in their hospital, or they need consultation, generally we [doctors in EmOC center] send an expert to that [lower-level] hospital to decide if the patient's condition meets the referral criteria. If the patient is critically ill and at risk of death on the way to referral, or if referral is too distant, i.e., the CIPW is in a suburban area, then referral is not allowed. For those very critically ill patients, emergency rescue must be launched immediately in the local hospital and an expert from the EmOC center will assist the rescue. When the patient is in a stable condition, we refer the patient to the EmOC center for further treatment.*
>
> (Male, EmOC- Administrator-7, 21-07-2011)

- **Coordination of CIPW rescue, consultation and referral**

While medical resources and technical power are essential for EmOC, good coordination and effective communication are also very important for a successful rescue. Three levels of coordination exist for CIPW rescue, consultation and referral: coordination at the hospital, district and municipal levels.

In the hospital, coordinators are the directors in charge of EmOC and the Department of Medical Affairs; they are responsible for organizing doctors from all related departments, contacting the designated EmOC center for consultation and referral, and communicating with the patient's family members. As a district-level administrator described:

> *Our center has many critically ill patients. An Obstetrics Department alone is not enough; other related departments must be involved because these*

patients may have many other complications. We need multi-department coordination… It is difficult for the Obstetrics Department to organize all departments in such a multi-disciplinary cooperative rescue, so the Department of Medical Affairs must coordinate.

(Male, EmOC- Administrator-7, 21-07-2011)

Coordinators at the district level are the deputy chief of the district BOH, who is in charge of EmOC, and the district MCH institute. They play an important role in contacting other medical organizations such as the blood bank, and the medical rescue and care center.

As an administrator from district BOH said:

Generally speaking, if the CIPW has been referred to the EmOC center, we [the district BOH] are responsible for coordination only when necessary, as, for example, with a lack of blood. In fact, blood is the most important medical resource in rescue, and we help them solve this problem.

(Male, EmOC- Administrator-1, 29-12-2011).

If problems still exist that coordinators at the district level cannot solve, the Municipal BOH and MWHI can involve themselves in coordination to ensure rescue success. As a designer from the municipal level said:

As the MCH administration organization in our district responsible for the leadership and coordination of EmOC, most of the time the district MCH institute acts as liaison between district and municipal organizations. We [the district BOH] cooperate with them in rescue, and sometimes coordinate with them when organizing others; sometimes if a patient needs a referral but [the referral] is difficult for the tertiary hospital to accept, we will report this to the municipal BOH, and they [municipal BOH staff] may communicate with the tertiary hospital to ensure timely referral of the patient. ”

(Male, EmOC- Administrator-2, 13-09-2011)

The above interviewee illustrated the implementation process with many vivid cases, good examples that helped clarify the process of regulation administration and implementation, as well as Shanghai’s three-tiered EmOC network.

Box 1 Case story:

Successful rescue in a secondary comprehensive hospital

In August 2011, an emergency rescue occurred in a secondary hospital (I am not sure of the package of technical services they provide) in our district. The patient was diagnosed as DIC (Disseminated Intravascular Coagulation), complicated by amniotic fluid embolism. At about 8:40 am, we [district MCH institute staff] received a call from this hospital, and the person who received the call immediately reported the case to me [director of the Institute]. I went to this hospital quickly and reported to the MWHI as well as the district BOH. Following emergency preparations, the director of the department of medical affairs, the highest-ranking obstetrician and the vice-dean in charge of the hospital's EmOC all arrived; the dean of the hospital also arrived. Because the patient's condition was very serious, a consultation was necessary. With the coordination of the district MCH institute, the doctors contacted an expert who belongs to our district's expert advisory group. However, this expert was not in Shanghai. Then they contact another expert in the designated EmOC center. Consultations at the district and municipal levels were launched at the same time in this emergency situation.

Because this is a comprehensive hospital, before the expert had arrived, already doctors from the Radiology Department, the Hematology Department, the Anesthesia Department and another member of the CIPW rescue team had initiated the rescue. The radiologist considered whether it was possible to stop bleeding by arterial embolization, the anesthetist considered the possibility of hysterectomy; all of them were trying their best to save the patient.

The patient needed a blood transfusion. Because the district MCH institute has the responsibility to coordinate the rescue and resolve problems such as lack of blood, they [district MCH institute staff] immediately called the district blood bank to apply for 10 units of platelets. However, the district blood bank was short of platelets. They [district blood bank staff] immediately helped us contact the municipal blood bank, which informed that Shanghai only had 12 units of platelets in Shanghai, of which they provided us 10 units. As I was making the phone call, the driver had [already] left for the municipal blood bank. This way, we got the platelets in time. Since we still needed fibrinogen and other blood components, we continued to contact other blood banks in Shanghai… Finally, the patient received the hysterectomy.

During the emergency treatment, all blood components were used, and the expert from the EmOC center also arrived in time. Before the [arrival of the] blood and the expert, we had finished preliminary treatment, the patient had had a hysterectomy and her condition was under control. The expert checked the patient to identify if she was in any other danger. During the entire rescue process, we [all involved] worked against the clock and experienced a soul-stirring rescue.

(Female, EmOC- Administrator-3, 15-08-2011）

This case indicates the function of the three-tiered EmOC network and the roles related actors of different levels play in CIPW rescue, consultation and referral. As highlighted by this implementer, an important factor in this successful rescue was the high commitment to EmOC work. Based on good coordination and communication, the CIPW was saved.

Box 2 Case story:

Multi-department cooperation in an EmOC center's CIPW rescue

> I [an EmOC center director] can tell you another story that happened in an obstetrics hospital. One night around midnight, a patient who was to have a cesarean delivery felt abdominal pain. Doctors thought she was about to give birth, because she was full-term, so they performed the CS. After the delivery, the patient felt severe abdominal pain, and the doctor applied for consultation. Our center's surgeon went to the hospital, and the patient was diagnosed with acute pancreatitis. Because of her serious condition, she was referred to the EmOC centre, was admitted to ICU, and stayed for ten months, during which she was rescued several times and underwent three operations. During that period, the obstetrician was responsible for her postpartum care, the surgeon was responsible for her pancreatic disease, and all her vital signs were monitored by IC [...] We did a lot to save her life; before then, such [multi-department cooperation] in a specialized hospital was impossible.
>
> (Female, EmOC-Implementer-2, 19-07-2011)

This case indicates the importance of multi-department cooperation in EmOC. Because all EmOC centers are tertiary comprehensive hospitals, doctors in most departments of these centers have excellent medical skills, and their cooperation can ensure rescue success, especially when the CIPW has serious complications.

- **EmOC for impoverished women**

With Shanghai's increasing number of migrants, such migrant pregnant women account for most CIPW. Because some of them are poor, the high cost of emergency rescue is a heavy burden for their families. Based on humanistic principle and the concept of a people-centered service, all health institutions provide immediate rescue to these impoverished CIPW. Two hospital administrators said:

> *Sometimes the CIPW is very poor and has no money to pay for the rescue; however, we have to ensure her treatment and that she encounters no threat.*

(Male, EmOC- administrator-2, 13-09-2011)

We do not consider the money; that's clear. We definitely make great efforts to save the patient, and treatment is never delayed if the CIPW has no (or not enough) money.

(Male, EmOC- Administrator-6, 24-12-2011)

Box 3 Case story:

Rescue process of an impoverished, 35-year old migrant pregnant woman

On August 11, 2011, a migrant pregnant women aged 35 gave birth to her second child in a secondary comprehensive hospital. After delivery, she experienced an emergency rescue because of postpartum bleeding. For the rescue, she received blood transfusions, a hysterectomy, intensive care for one day, and hospitalization for nine days.

Patient： At about 4 am that day, I told my husband that I felt pain. My mother said maybe I was about to give birth, so we went to the hospital and arrived at about 5 am. I gave birth to a baby at 6:35 am. I was bleeding ten or twenty minutes after delivery, then I heard a doctor say: "This patient's condition is serious…she may die. Inform other doctors—be quick…" Then they were busy contacting other people… After that, I lost consciousness because of the serious bleeding. When I awoke, it was 2 pm that day and I was in the ICU.

Patient's husband: [When my wife was in emergency treatment] the doctor asked me to sign a critical condition list. My wife was rescued in the delivery room and had a hysterectomy there. When she was bleeding, doctors went to the municipal blood bank and very quickly brought back some platelets. The operation [hysterectomy] finished at about 12 pm and she was admitted to ICU. 24 hours later, she was transferred to the obstetric ward, where she stayed for 9 days.

The patient and her husband are grapefruit farmers. The family's annual income is 20,000-30,000 CNY (3150-4750 USD) apart from basic household expenses. The rescue cost 25,000 CNY (USD 4000). Because of their economic difficulty, they owe the hospital 12,000 CNY (1900 USD).

(To be continued)

Box 3, continued:
Summary of regulation implementation

> **The patient's husband**: when she was in ICU, the director of the Obstetrics Department told me they would make all efforts to rescue my wife without considering the money. When my wife recovered, she [the director] said we could get discharged from the hospital. We left and signed a bill acknowledging our debt, as she required.
>
> **Patient**: Upon admission, we paid 3,000 as a deposit. When I was transferred to the obstetrics ward, the doctors said we owed the hospital 20,000. However, we had no money at that time; the money from selling grapefruits is very limited and we used it up for the childbirth. I borrowed almost 10,000 from my sister and friends, but still owe the hospital 11,000. When we left, we signed a bill acknowledging our debt. The rescue cost is a heavy burden for us, because we don't have a regular income. Although I have participated in the New Cooperative Medical System, it did not reimburse the cost of the rescue. Six weeks later, when I returned to the hospital for a postpartum visit, I told the director that I still had no money to repay the debt. The director said: it doesn't matter, we can wait.
>
> (Female, EmOC-User-5-1, 11-11-2011)
> (Male, EmOC-User-5-2,11-11-2011)

Based on the description of regulation implementation, the key factors for successful EmOC can be summarized as follows:

- **Effective implementation under strict accountability:** In the regulation implementation process, the First Contact Care rule, the clear responsibility of each actor, a designated EmOC center for referral, and the accountability mechanism of district leaders were the main determinants of effective implementation.

- **Multi-department cooperation:** During EmOC, clinical departments other than the Obstetrics Department become more important; their participation provides strong technical support for CIPW rescue, and a good relationship among all actors is an important enabling factor for EmOC work.

- **Effective coordination and timely communication in EmOC:** In the rescue of CIPW, time is crucial: effective coordination and efficient communication is essential in order to convey accurate information and mobilize resources in time. This means that streamlined and smooth practice during the EmOC process is central to its success.

Next, we will explore the approaches applied in EmOC regulation and in which form they were embodied.

5.2.3.4 Approaches

Approaches to regulation include “State-centered,” “Market-oriented,” “Consumer-oriented,” “Institutional collaboration” and “Self-regulated.” Case study interviews indicated that the “State-oriented” approach played the most important role, though other approaches were concurrently at play during the regulation process.

- **State-centered:** The state-centered approach dominated during regulation.

As a regulation designer expressed:

> *For rescue [EmOC regulation], I think the government takes the main, important role; the patient [consumer-oriented approach] is second. I think the market [approach] is a necessary complement.*
>
> (Male, EmOC-Designer-1, 01-10-2011)

As an administrator said:

> *[The approach] should be state-centered, with institutional collaboration.*
>
> (Male, EmOC- Administrator-1, 16-12-2010)

As another administrator said:

> *Since most of us are public hospitals managed by the government, I think the most important governance of the regulation comes [from] the government. Therefore, government control is the most important approach during regulation.*
>
> (Female, EmOC- Administrator-3, 15-08-2011)

- **Market-oriented:** Hospitals lose money if they rescue women without the ability to pay, so hospitals generally have no enthusiasm for EmOC work. But if any negligence occurs during EmOC, hospitals have to pay for the outcome. So hospitals have to treat their EmOC work very seriously. Furthermore, rescue success can enhance the reputation of a hospital and hence its competitiveness. Health insurance plays only a weak role in EmOC.

  - **Hospital-paid compensation**

Only when the rescue is not successful is there a dispute between the family and the health institution. Health institutions usually pay compensation to calm such families, even when no mistake has occurred during the rescue. As a hospital manager said:

> *Market-driven, means that […] there's often a dispute if the rescue is not successful. Then the hospital runs into bad luck and it takes great energy to resolve this. So it's best if you do a good job beforehand, to reduce this unnecessary trouble. Now disputes cost a very high price. So, truthfully, we're really not able to pay. How could anyone afford to pay for 14 to 15 disputes every year?*
>
> (Female, EmOC- Administrator-3, 15-08-2011)

In some cases, to help the EmOC center make a profit, the district health institutions send a cheque to the EmOC center for the transferred woman if she is poor. This behavior by district health institutions aims to relieve the EmOC center of some of the financial burden: lower-level health institutions are eager to keep a good relationship with the EmOC center in order to gain support for their usual work. As an administrator at the district-level said:

> *Costs attached to this [regulation] have not been resolved, which means that hospitals run into bad luck when they encounter an EmOC case of a woman who is poor […] This problem may affect [the motivation for] rescue. We once had the experience […] Our [district] hospital sent a cheque for the rescue to the EmOC center, since we thought if the money issue were to influence our hospital's relationship with it, [next time] the EmOC center may not arrive so timely on site for consultation. Or something could happen with a referral to them next time. I am not sure.*
>
> (Female, EmOC- Administrator-3, 15-08-2011)

- **EmOC affects hospital reputation**

Successful EmOC can enhance a hospital's reputation and improve its competiveness. As a hospital director said:

> *Rescue is important. No driving factors exist for rescue. [So why is rescue important?...] It relates to a hospital's reputation.*
>
> (Male, EmOC- Administrator-8, 01-11-2011)

As a user said:

> *I am well, and they [my family] do not want to spend so much energy in a*

hospital dispute. They think the fact that I am alive is the most important. If I have a friend who is pregnant, I will certainly not recommend this hospital to her.

(Female, EmOC-User-2, 19-09-2011)

- **Health insurance's role weak in EmOC**

Health insurance will generally reimburse local permanent residents for about 1/3 to 1/2 of their EmOC expenditures. However, most EmOC expenditures are not likely to be reimbursed by the health insurance of migrant women at high risk of emergency care and most in need. As a regulation designer said:

[Permanent residents] have Urban Residents' Basic Medical Insurance. Their rescue is often covered by medical insurance. Medical insurance has a valuable function. General health insurance will assume the medical cost of maternal care. However, the group for whom medical costs will most likely be a burden, those most need of medical insurance, is those impoverished migrants. The social security system does little for them.

(Male, EmOC-Designer-1, 01-10-2011)

The interplay of market forces—loss of reputation, consumer activism, claims for compensation for loss of life, the fear of sanctions—puts tremendous pressure on health institutions to take their EmOC work very seriously.

- **Institutional collaboration:** Following the regulation, the EmOC consultation/ referral network was established through an institutional collaboration approach.

As a regulation implementer said:

Before, we didn't know how and to whom we should make referrals. Now, according to the referral principle, I only need to call or fax the designated EmOC center to ask for a consultation. Usually the problem is resolved in a very short time and the consultation always teaches us new things.

(Female, EmOC-Implementer-1, 24-12-2010)

- **Self-regulation:** A detailed and established operational EmOC framework exists at each district and hospital-level institution (please refer to section 5.2.2.1.2).

In the next section, we will explore the mechanisms used in EmOC regulation. We will try to convey to readers how and by what means the regulation achieved its effects.

5.2.3.5 Mechanisms

A number of mechanisms have been applied in the Shanghai EmOC regulation. These mechanisms have played an important role in ensuring health institutions' and related sectors' implementation of the regulation. The mechanisms have also helped administrative sectors carry out the necessary supervision.

- **Accountability:** Accountability was set up at every step of the process to promote smooth implementation of the EmOC regulation. For instance, in a district MCH hospitals' annual performance evaluations, events and issues such as malpractice suits related to maternal death, poor quality EmOC work, lapses in MCH management and inadequate obstetric training have each lead to a corresponding reduction in a particular hospital's assessment score: for each, from 3.5 up to 20.5 points have been deducted from a possible total score of 25 points. Moreover, once a particular maternal death has been determined as related to certain health institutions' neglect, each of those health institutions has lost corresponding points in its annual (100-point) performance evaluations. In other words, if a community health center failed in its management of a case, it lost 3.5 points for a local woman and 3 points for a migrant woman; if the blood center did not adequately ensure the EmOC blood supply in that case, it lost 5 points; and if the EmOC center did not ensure the green channel for the case and its smooth referral, it lost between one and 21 points, etc. In short, poor performance evaluations usually have meant less annual bonus for the health institutions from the related administrative bodies, less opportunities awarded to health institutions and their leaders, and also less opportunities for the promotion of such institutions' leaders. More thorough inspection and assessment has lead to more comprehensive accountability, particularly with regard to leadership issues, as the words of a regulation designer below indicate:

  We found it was important to attract government leaders' attention. [Leadership's attention] is the primary component. So we established the rescue of critically ill pregnant women as one indicator. If the [health institution's] leader did not reach the site in person, did not conduct effective coordination, we would make him/ her accountable. Before, we only held to account the institution where the woman died. Now we inspect every episode [thoroughly] and do our best to provide quality EmOC service.

  (Female, EmOC-Designer-4, 22-12-2010)

- **Evaluation and quality control:** Evaluation and quality control has included the Maternal Death Audit System (MDAS), inspection of obstetric

quality, EmOC training, general training, et al. This mechanism has been beneficial for summarizing the experience and improving the capability of obstetric staff in the provision of quality service. The MDAS has also been carried out by hospitals themselves and district MCH institutes, with all results submitted to the MWHI as a reference for the municipal MDAS. The MDAS organized by Shanghai's BOH and MWHI is the final judgment on the cause of maternal death.

- **MDAS** ： In Shanghai, a system of embedded pressures was introduced at the municipal level during the EmOC regulatory process. Each maternal death is now assessed through the MDAS. A comprehensive audit is carried out every three or six months. The cause of maternal death for each case is ultimately categorized according to three types: Type 1 - Avoidable Factors, Type 2 - Missed Opportunities, and Type 3 - Substandard Care. If the MDAS identifies the maternal death as Type 1 or Type 2, the related health staff, manager and leaders are held accountable.

As a regulation administrator said:

The Maternal Death Audit [MAD] is a three-tiered process. The first is the hospital audit. Then the audit result is submitted to the district. Here, I organize experts for its review. Then the audit result is either modified or maintained. After, we submit it to the MWHI, the tertiary institute and the highest MAD level. [Their assessment results] maybe be the same as ours, or may be different. The reason for maternal death is categorized according to three types: Type 1, Type 2 and Type 3. If the audit result is Type1 or Type 2, the Bureau of Health conducts special training sessions for that hospital's director and its directors of its Departments of Medical Affairs and of Obstetrics. The hospital's district then receives a lower score in its annual performance assessment, which impacts many things [career promotion, bonus, reputation, et al]…

(Female, EmOC- Administrator-3, 15-08-2011)

- **Quality control of obstetrics**: Hospitals' OBGYN wards meet once weekly to control the quality of obstetrics. In addition, health administrative and technical sectors at municipal and district levels carry out routine checks of the quality of obstetrics through regular meetings and review. Inappropriate practices found during the quality control process are corrected to improve EmOC service quality. As a regulation designer said:

Municipal inspection of the quality of obstetrics is held once a year. There

is no uniform format for the inspection. The inspection contents are decided depending on the most prominent current problem. Panel members are experts in obstetrics, directors of MCH institutes, and directors of hospitals' Obstetrics Department. Usually experts are from tertiary hospitals. There are also a few outstanding directors from secondary hospitals involved in the evaluation. Before the inspection, a unified protocol must be formulated and a unified training carried out. Generally, the assessment is completed within two to three weeks. It's best not to let hospitals prepare for the inspection. The inspection contents are different between first and last hospital inspected, so that we can limit their preparation time. Methods used in the quality inspection are role-play, scrutiny of patients' records, and visit to the on-site green channel. We also examine special areas, such as cesarean section. We check all the selective cesarean sections. We check to see if the cesarean section was reasonable. We check whether selective cesarean sections have been conducted over weekends and holidays, since [the procedure] is not allowed those days. We inspected cesarean sections this year and last year had an inspection of the green referral channel. The year before last we inspected obstetric wards' three rounds and also assessed the problem of neonatal resuscitation.

(Female, EmOC-Designer-4, 17-09-2011)

- **Training**: After the regulation was issued, the MWHI selected obstetric staff in primary and secondary hospitals for training at the EmOC centers, using funds from the "Three-year action plan for public health." The rescue capabilities of the primary and secondary maternity facilities accordingly improved. As a regulation designer said:

We selected and sent the obstetric staff [of primary and secondary health institutions to EmOC centers] to receive EmOC training. The staff person having received training then acted as the cadre responsible for his institution's EmOC […and] promoted its EmOC services there.

(Female, EmOC-Designer-4, 22-12-2010)

Another regulation administrator said:

The training by the EmOC centers helped primary and secondary hospitals improve their rescue capabilities.

(Male, EmOC- Administrator-1, 16-12-2010)

Municipal and district MCH institutes organize routine trainings to improve the service capacities of obstetric staff. Experts in EmOC centers are often invited

to other hospitals to deliver lectures, develop case analyses, etc.

- **Admission mechanism：** The five EmOC centers were selected according to specific criteria and were designated as responsible for EmOC consultation and referral within a certain geographic area.

- **Rapid response:** All related staff must arrive at the site on time to conduct the consultation or rescue. The rescue must be reported to the MWHI within six hours.

- **Contracting mechanism:** Each EmOC center was ordered to handle consultation/referral and rescue within a specific geographical area; some administrative districts set up their own referral networks. When an emergency case occurs, the district EmOC network rescue will first launch. If the district has an insufficient capacity to treat the CIPW, the CIPW is transferred to the municipal EmOC center.

- **Incentives and sanctions:**

■ **Incentives**

1. **Oral encouragement and honor**: Oral encouragement and honor has been the most common incentive mechanism in EmOC work. Since the huge burden of rescue and the risk of maternal death has often been transferred to EmOC centers, however, EmOC centers' heavy workloads has meant oral encouragement has been insufficient to support and maintain their obstetric staffs' work enthusiasm. As a regulation designer explained:

> *We have no money to cultivate incentive. Actually, our reward is an improved reputation. We made such indicators [appropriate consultation/referral, MMR] the basis of our assessment for district MCH institutes and the district BOH.*
>
> (Female, EmOC-Designer-4, 22-12-2010)

2. **Economic incentives**: Economic incentives were supposed to be effective. In some BOH districts, however, while a bonus for EmOC work within these districts had been established, interviews indicated that very few hospitals ever received such a bonus.

■ **Sanctions**

1. Reprimand and retraining: Once an audited maternal death has been classified as Type 1 or 2, the hospital's director, its director of Medical Affairs, and its director of the Obstetric Dept. are required to go to the BOH for a

conversation with the BOH leader. Afterwards, they are required to undergo a three-day training. All of this causes them to publicly lose face.

2. Post-event reflection: Notice can be given of low performance scores, but this is seldom implemented to avoid damaging the obstetrician's motivation.

3. Barrier to future promotion: The poor practice of EmOC work has negative effects on future promotion. As a regulation designer said:

> *I can only criticize [… If you do not do your EmOC work well,] I will not grant or support you for reward or promotion in the future. And if you apply for a related award, I will say you are not good at this [EmOC] work […] This is the only kind of administrative sanction possible.*
>
> (Male, EmOC-Designer-1, 01-10-2011)

In the next section, we will describe and analyze the role of each actor involved in the EmOC regulation process and their interrelationships.

5.2.4 Actors

5.2.4.1 Actors and their roles

Actors involved in Shanghai EmOC can be divided into four types: administrators at the municipal, district and hospital levels; implementers, including obstetricians and doctors in others departments both in EmOC centers and health institutions; staff of other medical organizations, such as blood banks; and users. Their roles in the regulation process have been as follows:

- **Administrative organizations at the municipal level**: Shanghai's BOH and MWHI were the main actors in regulation definition and administration. During regulation design, they were responsible for drafting the regulation and coordinating related organizations. For regulation administration at the municipal level, the two have been responsible—Shanghai's BOH administratively, and the MWHI for technical matters—for routine EmOC management such as the coordination of consultations and referrals, and contact with municipal medical organizations (e.g. blood banks) when necessary. Through regular meetings and routine reviews, they have carried out a quality control process incorporating both obstetric quality inspection and also maternal death audit, to which assessments they have accordingly responded with incentives or sanctions. Training of obstetricians has also been organized by municipal administrative organizations. As a designer said:

First, [the role of] our institute [in EmOC] is as information dispatcher; for example, the obstetrician must immediately report the CIPW case to the district MCH institute and district BOH; then the district MCH institute must report the case to the MWHI; and both the district BOH and MWHI must report to the municipal BOH. Second, we offer help to primary institutions […] with problems in green channels, medical resources or technical support.

(Female, EmOC-Designer-4, 17-09-2011)

- **Administrative organizations at the district level:** The district BOH and district MCH institute are included at this level, where they have acted as the regulation's administrator. They are responsible for the following aspects: coordination of rescue, consultation and referral, report of case to municipal organizations, establishment of the district EmOC network, issuance of detailed working principles for CIPW rescue, enactment of quality control for obstetrics through meetings and obstetric quality inspection, and organization of obstetricians' training at the district level. As an implementer from an EmOC center said:

  If the district MCH institute and district BOH participate in the rescue, then from an administrative perspective, it is easier to coordinate the rescue, because, for example, if the doctor cannot get blood, the district MCH institute and district BOH can help. [As an obstetric doctor] I am the organizer of medical rescue; you [the district MCH institute and district BOH] should play the role of coordinator, This is very important.

  (Female, EmOC-Implementer-2, 19-07-2011)

  In addition to coordinating [the CIPW rescue], we also take responsibility for communicating with blood banks, and reporting the case to the MWHI within six hours.

  (Female, EmOC- Administrator-9, 13-12-2011)

- **Administrative organizations at the hospital level**: The director or deputy director in charge of EmOC and the Department of Medical Affairs have acted as administrators. They play their roles in the following manner: coordination of the rescue between hospital departments, coordination of consultations and referrals between hospitals, establishment of the EmOC rescue team and green channel, issuance of the working principles for CIPW rescue, quality control of EmOC in hospitals, incentives or sanctions of related departments. As two administrators from a district MCH institute and an EmOC center said, respectively:

[The role of the Department of Medical Affairs in EmOC] is as implementer… they offer help applying for consultation and referral.

(Female, EmOC- Administrator-9, 13-12-2011)

Many specific things [occur] during referrals, so we [staff from the Department of Medical Affairs] must coordinate referrals between hospitals.

(Male, EmOC- Administrator-7, 21-07-2011)

- **Obstetrics departments of EmOC centers:** They act as regulation implementer. The directors of Obstetrics departments are the main actor in consultation. They also provide technical support and training for obstetricians in lower level hospitals. One doctor from an EmOC center said:

  Our hospital [an EmOC center] plays a leading role in CIPW rescue. Generally speaking, doctors in lower-level hospitals rescue the patient according to their ability; if they can't, they must turn to the EmOC center for help. I am also the director of the Obstetrics Department at this center, so I am responsible for the medical treatment and safety of all patients. Furthermore, directors of the Obstetrics Department in secondary and other tertiary hospitals stay in touch with me; when an emergency treatment occurs, they contact me as quickly as possible.

  (Female, EmOC-Implementer-3, 14-09-2011)

- **Related departments in EmOC center**: The departments of Internal Medicine, Surgery, Hematology, Neurology, ICU, etc. have all been involved as this kind of actor. Doctors in positions of senior title in these departments have been the main actors in CIPW consultation. One doctor from a secondary hospital said:

  If in addition to heart complications the patient has many other complications—such as respiratory failure and renal failure—a cardiologist alone is not enough in this case; we need specialists from other related departments to save the patient, from the departments of Respiratory Diseases, of Nephrology, for instance…

  (Male, EmOC-Implementer-4, 28-07-2011)

- **Hospital directors and obstetricians：** These have been the main actors in their hospitals' CIPW rescue process. When necessary, they apply for consultation and referral. One administrator from a district BOH said:

The responsibility of doctors in obstetrics hospitals is to identify the pregnant woman in the early stage of high risk; if the pregnant woman goes into emergency during childbirth, they [the obstetricians] must report the case to related organizations, and we [the administrator] will help them organize the rescue.

(Male, EmOC- Administrator-1, 16-12-2010)

- **Related hospital departments:** These have included the departments of Internal Medicine, Surgery, Hematology, etc. Doctors in positions of senior title in these departments provide assistance for CIPW rescue in their hospitals. An administrator from a district MCH hospital said:

  Departments involved in CIPW rescue in our [secondary] hospital include the departments of Anesthesiology, Cardiology, Respiratory Diseases, Endocrinology, and other internal medicine departments.

  (Female, EmOC- Administrator-3, 15-08-2011)

- **Other related medical organizations**: These have included medical rescue and care centers, municipal and district-level blood banks. They are responsible for providing necessary medical resource to ensure the CIPW is saved in time. One administrator from an EmOC center said:

  For example, if we [doctors in an EmOC center] have to refer a [critically ill] patient, the medical rescue and care center will assist us; if the patient needs a blood transfusion because of emergency surgery, or if her blood type is rare, then the [municipal or district] blood bank assists us, as the regulation requires.

  (Male, EmOC- Administrator-7, 21-07-2011)

- **Users and their family members:** They seek or receive emergency rescue, and make EmOC decisions based on doctors' suggestions.

Summary of the actors and their roles

Based on the above description of the actors and their roles in the regulation, clearly during regulation formulation, administration and implementation, almost all related actors have been involved at the appropriate stage of the regulation process, and their EmOC roles have been consistent with their function in the health system; hence they have been able to achieve the objective of each stage of the regulation process. In addition, most of the actors involved in the EmOC regulation were key persons in their organizations, such as the vice-director of the BOH, the department leader, the

vice-director of the hospital, or the director of Obstetrics Department, etc. Compared with others, they have had the both the power and capacity sufficient and necessary for the success of EmOC regulation.

5.2.4.2 Actors' relationships

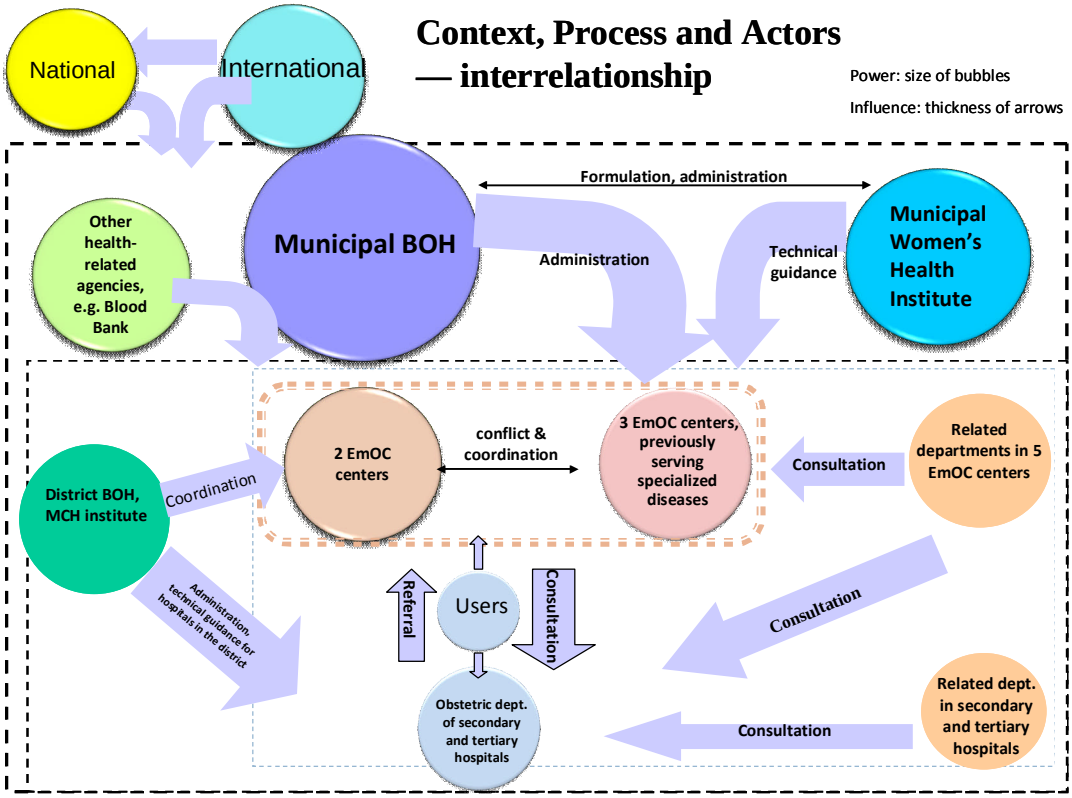


Figure 5.2.4 Inter-relationships of actors during EmOC regulation in Shanghai, China

The interrelationships of actors during EmOC regulation is illustrated above in Figure 5.2.4. The chart indicates the interrelationships among context, process and actors involved in the Shanghai EmOC regulation. All actors in this regulation operated within the same context of international and national safe motherhood initiatives. The MMR reduction was linked to the performance evaluation of all actors. The Shanghai Municipal BOH and MWHI have played leadership roles throughout EmOC work in Shanghai. They designed the regulation and conducted administrative management of and technical guidance for that EmOC work. In doing so, they coordinated with other health-related agencies in Shanghai, including blood centers and the ambulance system. During the implementation process, the EmOC centers and other health institutions worked together and supported each other to ensure EmOC services for users in accordance with the EmOC regulation. The chart pictures the variety of the actors involved in the regulation and the

complex interrelationships among them through which equitable access of quality EmOC has been ensured in Shanghai.

- **Relationship between Obstetrics and other related departments:** Almost every health institution involved hospital leaders and experts from multiple departments when establishing its leadership group. Each health institution also set up its own operational framework for their EmOC implementation. It was stated that EmOC work was not just the issue of Obstetrics in each health institution. Thus during implementation of the EmOC regulation, related departments have supported the Obstetrics Department and the Obstetrics Department has often been dependent on such related departments when making decisions or conducting rescue. As a regulation implementer from a secondary hospital said:

Well, the Dept. of Cardiology is behind the Obstetrics Department. They think we back them [and say]: "We will do it if you [the Dept. of Cardiology] say so. We will not do if you say not to." They [Obstetrics] always follow our [Cardiology] opinion.

(Male, EmOC-Implementater-5, 17-08-2011)

- **EmOC centers and health institutions of all levels:** During implementation of the regulation, the relationship between EmOC centers and health institutions has become much closer. The EmOC centers have changed their relationship with hospitals from "the provision of consultation/ referral alone" to "training, plus provision of consultation/ referral." EmOC centers have become much happier to provide training in EmOC services for lower-level health institutions. As a regulation designer said:

Here is what they have been doing… For example, one EmOC center has extended its EmOC work to four administrative areas. Now, the directors or cadres of its Obstetrics Department are invited to participate in four areas [of hospital support]: to give lectures, deliver trainings, hold discussions and conduct audits. Their relationship has been extended from "the provision of rescue alone" to "standard guidance plus provision of rescue."

(Male, EmOC-Designer-1, 01-10-2011)

- **Economic factors influence the relationship between health institutions and EmOC centers:** When the CIPW is an impoverished woman, the expenditure becomes a sensitive topic. Who pays her fee influences the EmOC process and the relationship between health

institutions and EmOC centers. As a regulation administrator said:

The problem is not whether doctors are willing to conduct the rescue or not but rather that it depends on the cost [of the rescue]. Sometimes patients haven't a penny, yet the rescue costs 10,000 to 20,000 CNY (1587 to 3175 USD)... [Sometimes] it costs even more. Costs have not been resolved in this [regulation], which means that a hospital runs into bad luck if it encounters an EmOC case [involving] an impoverished [woman…] This problem may affect [the motivation] for rescue. We once had an experience […] our [district] hospital sent a cheque to the EmOC center for the rescue. We thought if the money issue was to influence our hospital's relationship with the EmOC center, [next time] the EmOC center might not arrive at the site for consultation in a timely fashion. Or something might happen the next time we referred [someone] to them. I am not sure.

(Female, EmOC- Administrator-3, 15-08-2011)

This cost element responsibility could potentially cause a breakdown in the relationship between different levels of facilities.

- **Individual relationships influence efficiency:** In some case, hospitals resolve EmOC difficulties through personal relationship. This approach is often more efficient than the official one. As a regulation administrator said:

If a difficulty occurs with referral, we solve it by ourselves. If the patient [condition] is serious but the EmOC center is unable to come in time, that can be a problem... And what do we do if the corresponding EmOC center is unable to accept the referral…? [Under such circumstances] we make the referral to another EmOC center... [We have a] personal relationship with them... the relationship between the two hospitals' department directors is very good.

(Male, EmOC- Administrator-8, 01-11-2011)

- **Resolution of problems and conflicts during referral**: When a situation exists that cannot be resolved by the health institutions, the municipal, district BOH and district MCH institute are good coordinators. As a regulation designer said:

Hospitals inform me if there is any difficulty—if there's a lack of blood, for example, or lack of ambulance, etc., they tell me. I began to coordinate sectors. By doing this, [my department] here has now become the largest Medical Affairs Department, and I am like the director of the entire Shanghai Medical Affairs Department. [I needed] to do these very specific

things. If things turn out well, they do not call you. If they encounter difficulties, they come to me.

(Female, EmOC-Designer-3, 13-10-2011)

The regulation has operated by pushing actors to form relationships among all actors, including supervisors, EmOC service providers and users. It has also fostered circumstances leading to shared and joint responsibility across agencies and among departments within one institution. During the regulation process, roles amongst actors have changed and new lines of accountability have been created. This new accountability has helped ensure accessibility, whether users are able or unable to pay under circumstances when no additional funds have been allocated for routine EmOC work.

At the same time, actors have found their own ways to negotiate difficulties not well addressed in the regulation, e.g. what to do when the CIPW is impoverished: the EmOC center provides medical rescue through their EmOC expertise, and the lower-level hospital contributes financial support by sending a cheque to the center. In this way a life has been saved and the good relationship between the EmOC center and lower-level health institution has been maintained. Lower-level health institutions also use this informal mechanism to ensure accessibility to the EmOC centers' services next time and to hold them more accountable for EmOC work.

During the regulation process, EmOC centers have had the internal motivation to develop trainings for lower-level health institutions and to improve those institutions' own EmOC capacity, for such efforts reduce the demand for aid from EmOC centers. In one particular health institution, EmOC work has not only been the job of Obstetrics but has also become the joint responsibility of many departments, which has greatly contributed to the quality of services. In short, overall, actors have compensated for what the regulation did not contain by ensuring equitable access to quality EmOC on their own.

In the next section, we will explore the effects of the regulation from the perspective of equity, accessibility and quality. In addition, we will also present the intended effects, unintended effects and problems of the regulation.

5.2.5 Effect

5.2.5.1 Equity

During implementation of the regulation, actors at each level thought the regulation was a good reflection of health equity in maternal health care. As a regulation designer said:

We provided EmOC services for all the emergency obstetric cases, whether local permanent resident or migrant woman. At the hospital, we decide whether the woman needs to be referred to the designated EmOC center based on the severity of the case situation rather than any other criterion. Our purpose is to help women obtain quality EmOC services. The designated EmOC centers are all set in tertiary hospitals so that women can obtain quality EmOC services there.

(Female, EmOC-Designer-4, 22-12-2010)

As to the health equity the regulation reflected, a regulation implementer from a secondary hospital said:

We provide the same service for every pregnant women whether she is rich or poor, well educated or not, local permanent resident or migrant woman. We think each woman has the right to receive health services. We conduct the rescue for a critically ill pregnant woman [purely] from the medical perspective and make decisions on consultation and referral based on the actual case situation, not a patient's personal factors.

(Female, EmOC-Implementer-1, 24-12-2010)

A user replied to the question, "Do you think any difference exists between you and local people when receiving this [EmOC] services?" as follows:

[No,] it does not make any difference. I heard a doctor say: "I just came back. I just got off the plane this morning." I felt this was very important to my wife... in this [our] case, there was no difference between migrants and local people.

(Male, EmOC-User-5-2, 11-11-2011)

5.2.5.2 Accessibility

- **Economic accessibility:** For local women, health insurance will reimburse most of an EmOC expenditure. Migrants, however, have to pay for EmOC services on their own. Impoverished migrant women can access EmOC even if they cannot afford the treatment fee. The regulation language requires that health institutions provide treatment for critically ill women whether or not they are able to pay. This has ensured equity of service utilization for women, no matter where they come from.

As a service user said:

[On arrival] we gave a deposit of 3000 CNY (476 USD) to the hospital.

When I was moved from the ICU to the general ward, I was told we owed 20,000 CNY(317 USD) to the hospital. We did not have the money at that time [...] I borrowed money from others, i.e. I asked my sisters to transfer some money to me. We collected around 10,000 CNY (1587 USD), which we paid the hospital. The hospital did not say anything, and continued to provide treatment for me. Afterwards, when we left, we signed a bill in acknowledgment of debt to the hospital. We owed them around 11,000 CNY (1476 USD). When I returned to the delivery hospital for a physical check-up 42 days after childbirth, I found the director of Obstetrics and told her we could not pay the money since we had not earned much this year […] The director replied, "That's fine, we can wait…"

(Female, EmOC-User-5-1, 11-11-2011)

- **<u>Distance accessibility</u>**

  - **Institutions in urban areas:** Overall, the distance accessibility of institutions in urban areas is good, due to the geographic allocation of EmOC centers. Usually consultation/ referral can be achieved within an appropriate period.

  - **Institutions in suburb areas:** Institutions in suburban areas have relatively weaker distance accessibility to EmOC centers' support, due to their more remote geographic location. Because of this situation, a district EmOC network was established. As a regulation administrator explained:

It takes more than an hour for us to reach an urban area [by ambulance]. So we wanted to solve our problems on our own. First we developed training to enhance the capacity of all the doctors [...] another thing we did was to set up a group of experts. We established good relationships with those hospitals with superior capacities. We invited their directors to be our district experts [....] We also organized a district expert group, including the Emergency Department, Anesthesiology, and some experts in other disciplines. So [now] when a critical case arrives, first the obstetricians try to deal with it; if they are unable to treat successfully, then district experts come. The obstetrician only needs to tell me who is needed, e.g. an expert in respiratory illness or in hematology. I then coordinate and immediately assign experts to the site. If the case cannot be treated within the district network, then we seek support from the municipal EmOC center. So, we operate in full accordance with the municipal [EmOC] regulation, but we do not rely solely on the municipal EmOC centers.

(Female, EmOC- Administrator-3, 15-08-2011)

- **Private health institutions:** To promote EmOC accessibility, private health institutions usually solve problems through personal relationship. As a regulation administrator said:

  It takes us two hours to reach the blood center and pick up blood. So blood is the greatest threat to our [EmOC...] Now we have reached an agreement with a tertiary hospital [non-designated EmOC center]. We store five [units] of blood in our own inventory. If we do not use them up, we can [keep them to] exchange with that hospital. This [practice] is not accepted by the blood center. [But] I have a good relationship with the president of the hospital, and the relationship between the directors of the two hospitals is fine.

  (Male, EmOC- Administrator-8, 01-11-2011)

5.2.5.3 Service quality:

After EmOC regulation implementation, the consultation and referral process became more appropriate, and the rate of successful rescue increased year by year (see Table 5.2.2). Along with an improved EmOC service capacity in lower-level health institutions, a relative decrease in need for consultation and rescue support from EmOC centers occurred. Generally, users were satisfied with the EmOC services and most of them think the EmOC process is a patient-centered service. When asked “Which part of emergency services satisfied you?” a service user replied:

I think they were very rapid. Whatever I needed, or whenever I was uncomfortable, they [ICU staff] would immediately tell the doctors, or conduct a further examination of me.

(Female, EmOC-User-3-1, 08-11-2011)

5.2.5.4 Intended effect:

Feedback consistently reflects that the primary aim of the regulation has been achieved.

- **Appropriate referral and improved successful rescue：** First Contact Care was established in the EmOC regulation. It also provides specific guidance for the consultation and referral process. The EmOC regulation enabled health institutions to greatly improve the practice of consultation and referral. As a regulation designer said:

  Well, the direct effect of this [regulation] has been the increase of the rescue rate and reduction in the MMR. The MMR has now reduced to

under 10/100,000. That is relatively straightforward; of course, the experience obtained through the regulation process is also an outcome of this regulation.

(Female, EmOC-Designer-2, 01-09-2011)

As a regulation designer said:

The rate of appropriate referral of critically pregnant women in Shanghai has increased […] The rate of successful rescue of critically pregnant women has [also] increased and the MMR has reduced over the past 3 years. We think these changed indicators are effects of the regulation. Although we don't have direct evidence, a negative association exists between the rate of successful rescue and MMR.

(Female, EmOC-Designer-4, 22-12-2010)

The tables below show the rate of successful rescue from 2007 to 2009 and the change in the MMR from 2008 to 2010 in Shanghai. Overall, the rate of successful rescue rose and the MMR among migrants entered a falling trend after publication of the regulation.

Table 5.2.2 below indicates that the rate of successful rescue has improved from 2007 to 2009 and the rate of successful rescue has stayed at a high level.

Among the entire population, a reduction in the MMR occurred from 2007 to 2010. The MMR among migrants reduced markedly (although a reduction in MMR was a comprehensive outcome of all efforts, part of this reduction could reflect response to the EmOC regulation).

Table 5.2.2 Rate of successful rescue from 2007 to 2009 in Shanghai[26]

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

Table 5.2.3 MMR from 2008 to 2010 in Shanghai[27]

MMR(/100,000)	2007	2008	2009	2010
Entire population	12.67	12.23	9.61	9.61
Local residents	6.68	6.91	7.08	5.30
Migrants	-	16.81	11.69	13.54

Numerator: Number of successful rescues
Denominator: Total number of rescues attempted

- **Quick response:** Each EmOC center was made responsible for EmOC services within a certain geographical range and according to geographical distance or obstetric work burden. This has ensured a quick consultation and referral process. At the same time, each health institution has established a work system, which includes asking consultation experts to reach the site as soon as possible. In addition, the Ambulance System has made EmOC their priority and tries to transfer the critically ill women as soon as possible. As a service user said:

  After [the hospital] called for a pulmonary specialist, the lung specialist arrived in less than half an hour. Then [they] asked for a cardiology expert, who arrived in 20 minutes [...] I felt [they were] very fast. Some said the two experts had been resting at home. Their homes were very close [to the hospital]. They came to the hospital directly. Very quickly [...] it was fast.

  (Male, EmOC-User-3-2, 08-11-2011)

- **Robust consultation/referral linkage**: Implementation of the EmOC regulation cemented/strengthened the relationship between the EmOC centers and primary and secondary health institutions. A robust consultation/referral link has resulted from the regulation. In addition, implementation has also promoted inter-departmental collaboration within each health institution. As a regulation administrator said:

  Before, hospitals did EmOC work all by themselves. They solved few problems. They contacted other hospitals [for support], depending on the relationships they had. [But] they could do nothing if other hospitals or experts rejected [referral or consultation]. Now the EmOC network situation has changed dramatically. Now with [the existence of] our district expert group, we think first of them when we encounter an EmOC case. This was specified in [the district regulation document]. We know who to seek and from whom to get support.

(Female, EmOC- Administrator-3, 15-08-2011)

- **Improved capacity**： Implementation of the regulation has not only improved the EmOC capacity of primary and secondary hospitals, but also helped health staffs of EmOC centers gain more EmOC experience. As a regulation administrator said:

  Another effect has been to improve the business relationship between EmOC centers and hospitals [in the area of] obstetrics. This EmOC work has also driven EmOC centers to help hospitals with obstetrics improve their rescue capacity. The EmOC center now has a vested interest in strengthening the lower-level facilities.

  (Male, EmOC-Administrator-1, 16-12-2010)

  After we encountered several cases of pregnancy complications and experienced the treatment process, we benefited from the rescue experience—not only our Obstetrics Department but also our Cardiology Department. So this [EmOC work] actually improved the techniques in both our Department of Obstetrics and of Cardiology. Patients received the greatest benefit.

  (Male, EmOC-Implementer-5, 17-08-2011)

- **Equity** (reference to 5.2.5.1)

- **Others:** Most beneficiaries of the regulation have been the service users and primary and secondary health institutions, for the regulation resolved their difficulties with consultation/referral. As a regulation designer said:

  Primary health institutions are those happiest [with this regulation], [for it] resolved their difficulties with consultation and referral.

  (Female, EmOC-Designer-3, 13-10-2011)

5.2.5.5 Unintended effects

- **EmOC teaching material:** EmOC teaching material was produced in a collection of summarized EmOC cases and their treatments. As a regulation designer said:

  We didn't expect we could produce this EmOC case compilation and that it could later be used as teaching material. [The compiled material] is an unexpected fruit and is sustainable. We are supplementing it with new

EmOC cases and will publish a new version soon.

(Female, EmOC-Designer-4, 22-12-2010)

- **Subsequent regulations:** To maintain the success of the previous regulation implementation and attain universal MCH care in Shanghai, supplemental strategies were developed by Shanghai's BOH. Its "Notice issued to further improve maternal health care and emergency obstetric care in Shanghai" (2010, No.48) was delivered as a follow-up regulation targeting universal access to maternal care, and it defined responsibilities throughout the health administrative sector at each level, including MCH institutes, community health centers, health institutions and health professional associations. Supplementary contents on the consultation/rescue of critically ill pregnant women include reporting new and at-risk pregnancy cases and conducting warning assessments.

On August 2011, Shanghai's BOH delivered its "Notice issued to establish an assessment device for critically ill pregnant women (trial)." Current regulation now requires not only report but also assessment of near-miss cases. It aims to strengthen BOH and MCH institutes' responsibilities at all levels, with health institutions delivering assessment of critically ill pregnant women. The combination of report and assessment of near-miss cases has been strengthened by requiring assessment whether rescue is successful or not. As a regulation designer said:

The regulation issued in 2010 is definitely related to the 2008 [EmOC] regulation. We had two rounds of the "Three-year action [plan for public health] Project." These two projects (the "EmOC project" and the "MCH coverage for entire population project") both came from the second round of the "Three-year action plan" and were conducted simultaneously. The 2010 regulation is the direct output of the project [focusing] on MCH coverage for the entire population. It strengthened the importance of providing MCH care for all women, not only critically ill pregnant women. Meanwhile, we had also discovered certain problems and learnt certain lessons from the implementation of the 2008 regulation [on EmOC]. So we integrated those experiences into the 2010 regulation. We summarized the experiences from the two "Three-year action plan for public health" and integrated them into the new regulation [issued in 2010].

(Female, EmOC-Designer-4, 17-09-2011)

- **Undesired increased work burden in the EmOC centers:** In accordance with the regulation, the EmOC centers became responsible for EmOC within a certain geographical area. With the regulation's implementation,

EmOC centers' work burden has significantly increased since many rescues have been transferred to them. Furthermore, the strict MDAS and accountability system has put huge work pressures on the EmOC centers. As a regulation implementer from an EmOC center said:

I feel more pressure now. There are many migrants in Shanghai who seldom have prenatal care [...] Maternal death is monitored in Shanghai. Once a pregnant woman dies, the pressure is very, very [intense]. Especially when judgment of the death is unclear, [sometimes] it can be very difficult to prove the cause of death [is not a result of one's work]. So after we became the EmOC center, we felt very stressed when encountering such situations. Some patients were from outside Shanghai and they would not report certain diseases since they wanted to [complete the pregnancy and] deliver a boy."

(Male, EmOC-Implementer-5, 17-08-2011)

- **Priority of EmOC work:** Since a strict accountability system and the MDAS have been instituted for EmOC, many sectors and departments now pay high attention to obstetric work and have made EmOC a priority. As an obstetrician from a secondary hospital said:

  [Now] besides the OBGY Department, EmOC also draws the attention of other departments, including those of Internal Medicine and Surgery […] From the perspective of an obstetrician, other departments' transition in [EmOC] attitude has been related to this regulation.

  (Female, EmOC-Implementer-1, 24-12-2010)

- **Improved investment in prenatal care for migrants:** Health institutions have explored new approaches to reduce the pressure of EmOC work. More effort has been put into prenatal care, especially among migrants, to advance the critical point and reduce the need for EmOC work.

As a regulation administrator said:

Because our geographic location is a rather special suburb, newborns among migrants in our district account for 85 percent of total births. So our MCH care system is not the same as in urban areas. We manage our pregnant women by sticking to the following principles: advance the critical point, [give] continuous and seamless management and service [...] We try to identify new pregnancies, channel the woman into prenatal care and report the pregnancy to community health centers. Community doctors will pay attention as to whether a woman utilizes prenatal care. If the woman does not come, they call her and channel her into accepting maternal care

management. We developed a team at the village level to conduct this work. So now we manage around 85% of the pregnancies [among migrants] in our district.

(Female, EmOC- Administrator-3, 15-08-2011)

The combination of performance pressures (received from higher authorities) and risks related to maternal death has led MCH services to actively reach out to the most vulnerable groups, particularly migrant women, and to focus on improving their access to services.

5.2.5.6 Problems encountered during implementation of the regulation

- **EmOC regulation must not be the sole measure in MMR reduction**

Maternal death is a reflection of comprehensive social factors. Improvements in the systematic management of pregnancy are needed, including its earlier identification, timely recognition of high-risk pregnant women, and advocacy of antenatal health care. Attention given the above factors and other social ones is important, along with attention to service provision factors. Placing most of the pressures associated with maternal death solely on health institutions and health staffs is unreasonable. As an administrator from a tertiary MCH hospital said:

The regulation improved the comprehensive rescue capacity for pregnant women in Shanghai. All health institutions attach more attention to EmOC work now. Accountability was established to improve the behaviors of health institutions and health staffs. You are made accountable if the maternal death is judged as [stemming from] your malpractice. So every hospital attaches high attention to the MMR. However, the regulation did not resolve other problems. Many factors influence the MMR, e.g. personal factors, institutional factors and wider, social factors. [Yet] the current resolution to reduce the MMR transfers all responsibility to health staffs. It's wrong. Pressures on doctors obviously increase in this way. A maternal death may occur due to traffic conditions, for instance, or economic issues, [for] a woman's social status influences her health care. If all the poor in Shanghai were included in local health insurance, many pregnant women would come to the hospital to register their pregnancies, utilize antenatal care, and [hence] many high-risk cases would not occur. Furthermore, this regulation applies only to Shanghai, a well-developed area of China with high socio-economic conditions and a relatively lower MMR. The main challenge of the MMR is in the rural and western areas of China where, in many occasions, there is no road and a woman has to have childbirth at home. When a woman lives in a place where there is road, she had to

spend two hours getting to the county hospital for an antenatal check-up. Why not resolve this problem? I think it is far from enough to reduce maternal death only through the efforts of health staffs. The approach should be comprehensive.

(Male, EmOC- Administrator-10, 18-01-2012)

- **EmOC work places a heavy economic burden on hospitals**

The government should take responsibility for the economic burden of rescuing impoverished pregnant women. It is unreasonable for the hospitals who conduct such rescues to also assume responsibility for those costs. As a regulation designer said:

Although the EmOC centers received initial funding for EmOC work, it has not been enough to meet the daily expenditures of EmOC work. Patients unable to pay are one of the biggest problems. You mobilize many resources to successfully rescue a woman. But [if] she is a migrant or a very impoverished person unable to pay for the service at all, the hospital must assume the expenditure. Government has not found a way to subsidize the hospitals. For now, hospitals must assume responsibility [for recue expenditure].

(Female, EmOC-Designer-2, 01-09-2011)

A regulation implementer described:

The [cases of] critically ill women transferred by other hospitals are often very severe. These critically ill [patients] are usually very impoverished. Definitely we must save their lives at all costs. For example, a thrombocytopenia case was transferred here. We immediately conducted the rescue of this very severe case. The rescue cost was around 160,000 CNY (25,397 USD). She paid only a total of 20,000 CNY (3,175 USD) and owed us a 140,000 CNY (22,222 USD) debt. Finally the woman turned stable and her baby was good… She did not pay us that 140,000 CNY (22,222 USD). This kind of situation happens often. We never think of money when we encounter critically ill pregnant women. We always recue them first. We have talked about this situation with the upper-level administrative body, about how to solve this problem of arrears. We asked whether they could set up a fund to provide free treatment for these impoverished women. It is unfair for us to conduct the rescue not only spending our energy but also losing money. Then our upper level administrative body asked us to summarize [our] patients' unpaid bills and they would try to reimburse us. Our total unpaid bills were several million

CNY [in this EmOC center]. The unpaid bills are around 100 million CNY per year. But there was no feedback after we submitted the statistics. So we asked them, and were replied, "The unpaid amount seems not excessive. You are a tertiary comprehensive hospital, and very large. You can regard this as your contribution."

(Female, EmOC-Implementer-3, 14-09-2011)

- **Lack of incentive and sanction mechanisms for obstetric work**

Although actors of each level, when asked, think it important to establish an incentive mechanism to encourage the work of obstetric staff, in fact the EmOC regulation contains no such formal incentive mechanism. As a regulation designer said:

If you want the sustainable development [of EmOC work], you need more training and more staff assigned to this work. In addition, some incentive for staff should be considered. However, [currently] there is neither any incentive for obstetric staff nor any recognition of our work.

(Female, EmOC-Implementer-3, 14-09-2011)

- **Lack of continuous training for obstetric staff**

Due to lack of financial support, MWHI was unable to carry out the continuous training of EmOC staff once the first round of the "Three-year action for public health" Program finished. Hence, only one year of training in EmOC regulation took place, although the results of that training were very good and the need for training still exists.

- **Practice of report requirement leads to inconsistencies**

The regulatory process required that all obstetric institutions strictly obey the "Municipal Survey and Reporting System on Emergency Service for Critically Ill Pregnant Women." An information report system was also established during the regulatory process. That system stipulated that when an obstetric emergency occurred, each health institution must complete a "Pregnant Woman Report Form" and immediately report the case to the district (county) MCH institute. Then, within six hours, the district (county) MCH institute must complete a "Critically Ill Pregnant Women Report Form" and report the case to the MWHI and district (county) BOH [24]. This information report system has helped effect EmOC coordination. However, because of inadequate obstetric human resources, conflicts between rescues and reports often occur.

- **Inappropriate exclusion in the MDAS system, lack of mechanism to**

voice response to audit results, and inadequate feedback of audit outcomes to health institutions

Experts from the hospital where a maternal death occurred are not allowed to attend the MDAS. Since EmOC centers receive more critically ill pregnant women and have more risk of maternal death, experts from EmOC centers often cannot participate in the MDAS. Many experts involved in the MDAS are from the MCH hospitals and are less experienced treating pregnancy complications. Thus the MDAS conclusions are often controversial. Furthermore, audited hospitals have no channel to voice response or disagreement and must simply accept the MDAS result.

The channel for feedback from the municipal-level, MDAS to delivers its report back to the district MCH institutions and hospitals has not been well established. When issuing the MDAS results, only very brief notice is given health institutions, with no detailed analysis and/or guidance for improvement. As a regulation administrator said:

> *There is no channel for appeal. The problem is that several times audit comments [from upper-level administrative bodies] were not consistent with the facts. I do not know whether these experts had seriously read the case history ... There were some problems during the MDAS, e.g. experts did not have patience to read carefully [both] our description and our district MDAS results, [so] the comments provided by them [audit experts invited by upper-level administrative body] were sometimes wrong […A certain upper-level management institute] never used to give feedback [detailed explanation] on the audit. You did not know why a certain maternal death was assessed Type 1 […] Now they have begun to give us feedback, but it's very general. The documents just include which cases have been assessed Type 1 or Type 2 [and give] very simple reasons, like a notice […] We have a lot of things to report to them [the upper level institute]. But the channel for feedback is closed. Sometimes our district is informed that the audit results are not good. OK, we can accept that […] But why [not] give us your review comments? How can we improve under such a work mechanism? We just report our work to the upper level [administrative] body, but never get guidance from them.*
>
> (Female, EmOC- Administrator-9, 13-12-2011)

Based on the interviews, currently the flow of maternal death information reporting is one-way. The system contains no well-established systematic feedback loops. Hence a need exists for a more open, inclusive, transparent, participatory and learning-oriented MDAS exists. At the moment the system seems to work, but it does so largely through a sanctions-based mechanism.

- **Increased work burden with improved reputation, increased referral from outside**

Since implementation of the regulation, the rate of successful rescue in Shanghai has greatly improved, which has enhanced Shanghai's reputation. More and more critically ill cases are choosing to come to Shanghai from outside areas and without following an appropriate process; this has resulted in a greater burden on Shanghai's health institutions. As a regulation designer said:

> *Shanghai's excellent EmOC work has attracted more referrals from places outside Shanghai, which has greatly burdened Shanghai's EmOC work […] Now critically ill pregnant woman from outside Shanghai are all sent to Shanghai […] You cannot push them out. Taicang [a Jiangsu Province county near Shanghai] sends all of their critical cases to Shanghai [without advance notice. Yet] you cannot refuse them.*
>
> (Female, EmOC-Designer-3, 13-10-2011)

- **Lack of patients' understanding of disease significance and severity**

Since patients unsurprisingly have no knowledge of obstetric diseases, they think discomfort is common during pregnancy. They do not accept doctors' advice to receive therapy as soon as possible, even with obvious indications of disease. Their misunderstanding of pregnancy leads to more EmOC and makes it more difficult to achieve successful rescue. As a couple described of their experience:

> *When it was closer to delivery time [beginning of 3rd trimester], I was told by the doctor to have a physical examination every week. But my husband was very busy and did not have time to take me to the hospital. So we went for a check-up two weeks before the expected delivery day. At the end of the check-up, we were asked to have another check-up the following week. Since we thought delivery was not far off, we did not go [as required]. I felt uncomfortable after returning from the hospital. But I did not return to the hospital; we wanted to wait at home until delivery. We did not think about the potential risk since people around me all had similar symptoms, though not as severe as mine. My feet were swollen. I felt uncomfortable when sleeping. I could not breathe if I lay down. To sleep, I just sat on a chair [covered] with a carpet. I did not want to eat either. On my expected delivery day, I had my husband accompany me to my check-up. The doctor suggested I immediately admit myself to the hospital.*
>
> *[Husband continued:] We wanted to go home to make some preparations,*

then return [to the hospital] again. But the doctor did not agree. I quarreled with her. I took our things and went home. The day after we went home, the obstetric director and hospital director called my phone four times [to persuade us to return to the hospital]. Ultimately, I let them reserve one bed for us and we went to the hospital at around 6:00 pm. My wife had an operation [CS] that night.

(Female, EmOC-User-4-1, 11-11-2011)

(Male, EmOC-User-4-2, 11-11-2011)

[This woman was not able to lie down the last two weeks before childbirth. At her last prenatal check-up, her doctor had found her condition very severe and strongly suggested she immediately admit herself to the hospital. But the couple did not agree. They did not think her situation so dire. They were unsatisfied with the doctor's attitude and disliked feeling forced to admit the wife to the hospital immediately. So they left the hospital by their own choice. Due to the "First Contact Care" provision, the hospital recognized its duty to follow up the case to avoid maternal death. Indeed, the woman was diagnosed with heart failure during pregnancy and underwent EmOC.]

In the next section, we analyze: A) how contextual factors influenced the regulation process and its effects, B) what the enabling factors and barriers were, and C) how they acted on the process and its effects.

5.2.5.7 Contextual factors influencing the regulation process and its effects

1. Enabling factors

- **International basis of advocacy of "safe motherhood" and technical evidence for EmOC**

The Safe Motherhood Initiative, launched at an international conference in Nairobi in 1987, led to a great revival of interest in maternal health. The World Summit for Children in 1990 called for a reduction in MMR through substantial and concerted efforts by every country. Government leaders from over 190 countries, including Li Peng, the former Premier of the Chinese government, signed the "World Declaration on the Survival, Protection and Development of Children" and the "Plan of Action for Implementing the World Declaration." The Millennium Meeting of the United Nations in 2000 approved the United Nations Millennium Declaration, which set the goal of a 75% reduction in the MMR between 1990 and 2015.

International technical evidence and EmOC models provided guidance for the Shanghai EmOC regulation. As a regulation designer said:

> *Once I read some international literature containing EmOC guidelines and requirements about reduction of maternal death; it had been produced by the "WHO Perinatal Care Collaboration Center." The literature described an emergency service system, the process of referral, and [gave] a very good chart of these processes. [We] used these ideas, experiences, its emergency system set-up and conduct of referral. A few loops in the chart emphasized the importance of implementation and drugs, but it focused on timely referral and the smooth connection between general treatment, basic EmOC, and comprehensive EmOC. Rapid response during rescue was particularly emphasized. This information was of great guidance to us, when we encountered problems in our work. Then the external information gave us very positive inspiration.*
>
> (Female, EmOC-Designer-4, 22-12-2010)

As an administrator said:

> *From the UK we learnt the new technology "Uterine compression suture." It was first applied in one tertiary MCH hospital and now some secondary hospitals are doing it. Since we also try to improve life quality, for us to remove the uterus in times of emergency [can be] inappropriate. This technology has a good effect.*
>
> (Female, EmOC- Administrator-9, 13-12-2011)

- **National factors**

Ever since the 1980s, the Chinese government has attached great importance to the protection of women's rights and interests. Accordingly, a series of laws and regulations has been issued to create an environment conducive to an improvement in women's health status. The Law of the People's Republic of China on Maternal and Infant Health Care was passed in 1994. In 1992 China issued its "National Program of Action for Child Development in China (1995-2000)" and in 1995 its "Program for the Development of Chinese Women (1995-2000)." These latter two programs were issued also in recognition of the commitment made at the World Summit for Children in 1990. To fulfill the Millennium Goals, in 2001 the government issued its "Program for the Development of Chinese Women (2001-2010)"[28] and its "National Program of Action for Child Development in China (2001-2010)."[29] As mentioned in the Law of the People's Republic of China on Maternal and Infant

Health Care, issued in 1995:

> *People's governments at various levels shall exercise leadership in the work of maternal and infant health care. The undertakings of maternal and infant health care shall be included in the plans for national economic and social development. The administrative department of public health under the State Council shall be in charge of the work of maternal and infant health care throughout the country, put forth the guiding principles for the work in different areas and at different administrative levels in light of their specific conditions, and exercise supervision and management of the nationwide work of maternal and infant health care. Other relevant departments under the State Council shall, within the scope of their respective functions and duties, cooperate with the administrative department of public health to make a success of the work of maternal and infant health care.*

The indicators included in the “Two Programs” are important contents for performance evaluation of local governments, including the Shanghai Municipal Government. The targets in the “Two Programs” have always been the core work of the government.

- **Health system**

After the merger of the Department of Disease Control and the Department of MCH Care, the infectious diseases management model was applied to EmOC work, with very positive effect. As a designer said:

> *After the merger of the Dept. of Disease Control and Dept. of MCH Care in Shanghai’s BOH, [a certain] BOH director guided us in the management of MCH issues through the management model of infectious diseases. For example, case reports [are delivered] within 24 hours. At that time, I needed to participate in all meetings related to infectious diseases. I know our leader wished me to set up a new way of managing MCH work by using the infectious diseases model. That management model was thoroughly applied [to the EmOC work]. There has been a big change.*
>
> (Female, EmOC-Designer-3, 13-10-2011)

2. Barriers:

- **Economic factors**

Low economic status was a barrier blocking impoverished women from utilizing MCH care. Since such women have little opportunity for routine antenatal check-ups and some diseases are difficult to treat timely, they are at

high risk of needing emergency care. As an implementer said:

> *[Our] district in the western suburb of Shanghai faces a large amount of migrants in its population. Newborns among migrants account for 60-70% of deliveries and the proportion is still increasing. The large amount of migrants means more impoverished women with poor medical knowledge. They don't go for routine checkups and so more critically ill cases usually occur there, with more complications. So the proportion of high-risk pregnancy is elevated. It makes our work hard.*
>
> (Female, EmOC-Implementer-3, 14-09-2011)

This situation points both to the need for organized, targeted interventions addressing current conditions and to the need for long-term structural interventions that bring migrant women into the healthcare net.

- **Cultural factors**

Service users think delivery is a normal process. They do not realize pregnancy contains risks and have difficulty registering the possibility of maternal death. This cultural ideology puts health staff under great pressure. In addition, abortion is forbidden in some religious beliefs, which causes a dilemma for health staff, who may counsel abortion in high-risk pregnancies. As a regulation designer said:

> *People have a certain conception [that women cannot die during childbirth] and they cannot accept the possibility of maternal death. They think when women die in childbirth it's not normal, as compared to when people die of other disease.*
>
> (Female, EmOC-Designer-2, 01-09-2011)

An administrator at the district-level said:

> *An American woman had given birth three times in Shanghai. She went to a [private] hospital for her fourth baby. Actually, she had been diagnosed with cardiomyopathy in her teens while in the United States. Pregnant a fourth time, she felt very tired and did not want to experience childbirth again. After consultation, our doctors suggested she terminate the pregnancy and she agreed. But once she discussed the matter with her husband, he did not agree because of his religious beliefs; probably they were Catholic. Later, the pregnant woman suddenly died at home. Because of the MDAS, the (US-owned) hospital had to take part responsibility for this maternal death. We filled in our opinion in the district MDAS form as follows: "With more and more foreign residents in Shanghai,*

how do we develop interventions that can deal with different national and religious beliefs?" In some cases, although foreigners are counseled to terminate ongoing pregnancies, they have difficulty accepting the advice.

(Female, EmOC- Administrator-9, 13-12-2011)

- **Health system**

Due to a lack in ongoing, need-based investment in EmOC (particularly related to recurrent costs), medical institutions, especially EmOC centers, have had no enthusiasm for the implementation of the regulation: they seem to do just the work required by the rules. The heavy economic burden imposed on the medical institutions threatens the sustainability of their involvement in the provision of EmOC services. A regulation designer said:

The EmOC centers have lots of difficulties. Since women who happen to find themselves in [health] emergencies are often very poor, they are not able to pay for EmOC services. They owe money to EmOC centers. The government does not give subsidies to the hospitals for the conduct of EmOC. So the EmOC costs are borne by hospitals themselves, which negatively influences the income of obstetric staff.

(Female, EmOC-Designer-3, 13-10-2011)

5.2.5.8 Comparison with other emergency services

- **Similarities**

General emergency services and EmOC share the same needs for rapid response and multi-department involvement; these are their main similarities. Both services need rapid response to gain the time and opportunity to save lives. Moreover, cross-department cooperation is often needed in all emergency services since often multi-viscera failure occurs in the critically ill patient.

- **Differences in attention attracted**

More administrative attention has been given to EmOC: after publication of the EmOC regulation, much more attention was turned to EmOC work by district BOHs, MCH institutes, and also hospitals. Usually, the general emergency services just involves staff within a certain department or several related departments. But EmOC often attracts the dedication of other departments, the entire hospital, the district and even the municipal-level agencies.

- **Differences in the services' costs and benefits**

Compared with other emergency services, EmOC services encounter greater work pressure but less profit. Once a maternal death has happened, usually a dispute occurs between the maternal family and the health institution/s. Health institutions generally have to pay as a way to resolve the dispute, even absent any medical malpractice. For other emergency services, however, especially concerning severe disease (e.g. cancer), people have lower expectations of treatment, hence disputes seldom occur. In addition, health institutions have to cover EmOC costs if the user is very poor and unable pay for the services. On the whole, health care facilities operate and provide EmOC services at a loss, especially when compared to other emergency services.

5.2.6 Discussions

5.2.6.1 Assessment of the regulation

- **Whether or not the EmOC regulation matches the context requirements**

The political context, including international pressures regarding maternal death, triggered the Chinese government's concern about the issue of maternal health. The ultimate goal of the EmOC regulation was to make sure every pregnant woman, including migrants and the poor, have equitable access to quality maternal care. The achievement of this goal would contribute to a reduction in the MMR, which is consistent with international goals such as the Millennium Development Goals (MDGs) and the national programs "Program for the Development of Chinese Women (2001-2010)" and "National Program of Action for Child Development in China (2001-2010)."

Based on the local situation, equitable access of quality EmOC in Shanghai was the most prominent barrier to further reduction in the MMR. A demand was emerging that asked for the specific regulation of EmOC service provision. Based on the needs of EmOC services, First Contact Care was regulated and rescue became the obligatory responsibility of health institutions. The regulation's contents and devices were consistent with its goal, rather than related to the income and wealth of health institutions. Political support from governments at each level and social consensus on maternal death contributed to the regulation's smooth implementation.

Implementation of the EmOC regulation also influenced the context. Through the network and links established within and among health institutions involved in the EmOC regulation, close institutional collaborations were built. The regulation had a positive effect on the health system by providing a model of

close collaboration among health institutions and by integrating quality service with the equitable access of basic health care.

Thus, the EmOC regulation was appropriate for its context in many ways. The regulation was timely and informed by evidence from that context.

However, in some ways the regulation did not fit the context so well. Health institutions had to revise expectations along charitable models, in spite of their profit-driven nature. Opposing tensions occurred between the cost of risk management—the avoidance of maternal death—and health institutions' expected revenue/profit. During the regulation process, no financial support was provided to health institutions' for their free services to impoverished women. No accommodation for obstetric staffs' and other related agencies' increased workload was made. Insufficient recognition of frontline EmOC staffs' motivation and dedication was given. And the MDAS was not fully thought-through.

Based on the city's geographic location and technical advantage, the suggestion arose that Shanghai's health system might share EmOC resources to address EmOC service needs in neighboring counties. If so, necessary investment must be devoted to match that increased workload. And corresponding regulations should be established in those neighboring counties.

- **Actors' capacity to carry out their roles during the regulation process**

1. Extent to which actors had sufficient capacity to implement regulation

Most calamities were occurring in the primary, secondary and MCH hospitals, where, while sufficient capacity for normal deliveries does exist, such institutions do not have appropriate facilities, adequate skills or experience to treat certain pregnancy complications that often are fatal.

Some comprehensive tertiary hospitals, however, were qualified to save critically ill pregnant women, due both to the collaboration available among hospital departments and also to their experience with the treatment of complex pregnancy complications. To resolve the inadequate service capacity beyond such tertiary comprehensive hospitals and to ensure access to EmOC services, five EmOC centers were established and principles for consultation and referral were set up. Furthermore, to improve the rescue skills in primary and secondary hospitals and MCH hospitals, trainings of cadres were held by sending them to EmOC centers for practice and to attend lectures given by EmOC center experts. With years of regulation implementation, the capacities for treating critically ill women in health institutions of lower levels had been

greatly improved.

If disagreement occurred about EmOC services, first the hospital would organize and coordinate matters within the hospital itself. Then, the district BOH and MCH Institute would try to coordinate between health institutions in the district area. The Municipal BOH was responsible for final coordination. This coordination network was established according to the power and capacity of different management actors and worked well during the EmOC regulation implementation. Almost all problems encountered during implementation were resolved this way.

2. Were the right actors involved at the right stages of the regulation process?

In the regulation design stage, only obstetric experts and MCH care providers were involved. As a result, the regulation provides very good technical guidance for consultation and referral of EmOC. However, no careful consideration of continued financial backing for the regulation implementation was given, which has been the biggest barrier in sustaining the regulation effects. Neither district and hospital administrators nor user representatives were involved in the regulation design stage.

Before the draft regulation was submitted to the Municipal BOH, the Department responsible for MCH administration negotiated with the Dept. of Medical Affairs, the Blood Bank, and the Ambulance System to gain their support for future implementation. This negotiation ensured support from related agencies and contributed to the close institutional collaboration.

During interpretation and implementation, the Municipal BOH and MWHI conducted obstetric quality control, coordination and the MDAS in the Shanghai area. All district BOHs established corresponding systems, i.e. a leadership group and a group of experts. Some district BOHs also enacted an incentive mechanism for EmOC work. However, the incentive implementation appears to have been of insufficient effect, probably due to limited financial resources. Hospitals all established their own unique operational framework for regulation implementation. District BOHs and the MCH Institute were in close contact with hospitals during routine work. They checked the quality of obstetrics, and coordinated during EmOC and the district MDAS. A lack of necessary guidance from the municipal level to the districts and hospitals after an MDAS audit was felt. Similarly, a need for a more open, inclusive, transparent, participatory, and learning-oriented MDA became apparent, since obliging lower-level health institutions to work under a sanction-based mechanism was not effective.

- **Internal stresses of the regulation**

1. Appropriateness of the regulation

The objectives of the EmOC regulation–equitable access to quality EmOC—was established based on the existing problems in and achievements of Shanghai's maternal health management. The objectives of the regulation fit the context and MCH needs, indicating its evidence-based nature.

Each of the city's five EmOC centers received a certain quantity of resources—i.e. 1,500,000 CNY (238,095 USD)–for the purchase of facilities and hardware. So there was a degree of cohesion between available resources for EmOC regulation and its objectives. However, no further financial investment occurred during implementation to ensure the subsidy of impoverished pregnant women. The lack of obstetric human resources was also a prominent resources-related problem. The means to ensure implementation were the establishment of an accountability mechanism and the dedication of health professionals.

2. Internal consistency of the regulation

There was cohesion between regulation procedures: the regulation process underwent design at the municipal level, interpretation at the district level, and implementation at the hospital level. This procedure produced the design, from which implementers then received general guidance; drawing from that guidance is what yielded the specific operational framework at the interpretation and implementation stages.

Accountability and sanction mechanisms were established to help achieve the regulation objectives. However, due to the health system's limited resources, there was no effective incentive mechanism for EmOC work; also there was no clear financing guidance or mechanism, no workload assessment, no procedure for response to the increased workload, and no consistency in policies and practices of neighboring counties.

3. Has the regulation been duly implemented in all its aspects?

During the EmOC regulation process, strict accountability mechanisms were established through reprimand, retraining, post-event reflection, promotion barriers and loss of points in the annual institutional performance evaluation, etc. Hence, the regulation was duly implemented even without continued financial investment in the ongoing implementation.

4. Clarity and lack of ambiguity in the regulation

From the perspective of the regulation's designers, interpreters and implementers, the EmOC regulation filled a gap that existed in previous MCH

regulations. The EmOC regulation gave clear definitions of the principles involved and of the roles of each actor during EmOC service provision. So clarity and an absence of ambiguity existed with respect to the regulation's technical aspects. However, since other related actors were absent—e.g. no financial sector involvement in the design stage—no financial solution became available for the issue regarding the rescue of impoverished pregnant women. From this persepective, ambiguity did exist: in the allocation of necessary resources and in the assurance of the continued implementation of the regulation.

5. Extent of discretion vs. inflexibility

The EmOC regulation provided the principles and defined the roles of the health institutions and related agencies. It acted, in fact, as the municipal guideline for EmOC work in Shanghai. Space existed for district BOHs and health institutions to develop detailed schemes for administration and implementation. Due to the EmOC regulation's flexibility, almost all district BOHs and hospitals developed their own operational framework according to their available resources and situations. Thus, district BOHs established district EmOC networks for those areas far from a designated EmOC center; this resolved those areas' relatively weak distance accessibility to EmOC services.

6. Regulation efficiency

EmOC is one of the basic health care services to which every woman should have access when in need. EmOC is also a unique service: usually rescue consumes relatively high resources, including human and financial ones. Since EmOC situations are usually severe and complicated, experts with experience are often needed and therapy is complex and costly compared to other diseases.

Emergency preparedness was the model applied to the EmOC regulation. Institutions involved in the EmOC regulation mainly included health institutions with an Obstetrics Department and related health departments and agencies. It was not too complicated to mobilize these institutions to handle rescue.

Due to the nature of emergency care, the time spent in EmOC is usually shorter than with treatment of other chronic diseases. Rapid response to severe cases is very critical in EmOC. If the appropriate treatment and necessary resources are available, in a short time a life can be saved. Accordingly, after the EmOC regulation was implemented, institutional collaboration was promoted and rapid response established, greatly improving the efficiency of the regulation.

7. Existence of corrective feedback loops

Corrective feedback loops existed during EmOC regulation. Routine obstetric quality examinations were organized at different levels that included hospitals, district BOHs MCH institutes, the Municipal BOH and the MWHI. Examinations controlled the quality of obstetrics. The results of such quality control efforts were returned to the health institutions to help them improve service quality. Furthermore, the MDAS was followed at the district and municipal levels for each maternal death. The audit outcome delivered by the municipal MDAS was the final result. Interviews indicated, however, that although an established corrective feedback loop existed, feedback to primary and secondary health institutions needed further strengthening. More instructions and guidance summarized from the MDAS should have been actively delivered to hospitals.

Furthermore, problems found in the EmOC regulation were conveyed forward and generated changes and adaptations through two new regulations: the regulation on “MCH care management for the entire population” in 2010 and also the “near-miss audit” regulation of 2011 (“Notice issued to establish an assessment device for critically ill pregnant women”).

5.2.6.2 Analysis of governance principles through the regulation

Overall, the EmOC regulation process applied the principles of “accountability,” “transparency” and “participation.”[3] however, the regulation design process did not include certain related sectors, i.e. the financial sector, obstetricians in primary and secondary hospitals and users. Equitable access to quality EmOC services was reached through the regulation implementation, during which accountability played a very important role.

5.2.6.3 Comparison of Shanghai’s EmOC regulation model with other regions

The WHO divides health emergency obstetric facilities into two groups: basic EmOC (BEmOC) and comprehensive EmOC (CEmOC). Facilities that provide six signal functions (parenteral antibiotics, oxytocics, and anticonvulsants; manual removal of placenta; removal of retained products; and assisted vaginal delivery) are defined as BEmOC facilities. CEmOC facilities perform these six signal functions as well as cesarean delivery and blood transfusion. UN guidelines recommend at least four BEmOC facilities and one CEmOC facility per 500,000 in population.[30] These guidelines were updated in 2009 and the recommendation is now at least five EmOC facilities per 500,000 in population, at least one of which should be CEmOC.[31] Because Shanghai is one of China’s most developed cosmopolitan cities, almost all its health

institutions with an Obstetrics department can be defined as CEmOC facilities. However, EmOC services provided by most of its primary hospitals and by some secondary and MCH hospitals are far from sufficient quality. Furthermore, chaos existed in the referral process of CIPW to tertiary hospitals. Thus access to quality EmOC became a challenge for Shanghai. Based on an analysis of the situation, five specific EmOC centers with the capacity for quality EmOC services were selected and each was designated provider of those EmOC services for a certain specific geographic areas. The initial investment in the EmOC facilities and hardware of the five designated EmOC centers ensured a sufficiency of both for the centers' provision of services. The sufficiency of EmOC facilities, proper distribution of the centers' locations and quality of their emergency services were all consistent with the EmOC guidance delivered by the WHO and UNFPA.

Similar to EmOC regulations in other countries such as Rwanda, Ethiopia and Tanzania,[32-33] Shanghai's regulation achieved an upgrade in infrastructure and facilities, the development of training, and the establishment of a CEmOC network to ensure access to quality EmOC in Shanghai. As the Rwanda study suggested, cost of care is a serious barrier that limits women from EmOC utilization; in that country, economic capacity was an important factor in the inequity of EmOC utilization. In contrast, Shanghai's accountability system ensured that women who are poor do have equitable access to quality EmOC. Still, although the city's strict accountability system yielded better equity for service users, the related economic burden was transferred from families to health institutions. Impaired sustainability of the regulation's effects is foreseen as a consequence of Shanghai health institutions' assumption of an increasingly heavy EmOC economic burden. A suggested response to this situation is that the government should assume financial responsibility for the assurance of EmOC equity in Shanghai.

5.2.7 Case conclusion

5.2.7.1 Key messages

- **Key messages regarding EmOC regulation in Shanghai**

  - The EmOC regulation issued in April 2008 was the result of a series of systematic assessments and studies focused on identifying the determinants of the problem and obstructions to equitable access (including that of migrant women) to quality maternal health care. It was a regulation based on robust evidence.

  - The EmOC regulation issued in April 2008 had a clear focus in terms of the problems to be addressed, the population to be targeted, and the

roles and responsibilities of the different actors.

- The EmOC regulation built upon and complemented existing laws and regulations on the subject. In fact, it has become a key regulation within a continuum of policy and regulatory measures directed at improving/ensuring equitable access to quality maternal health care.

- The EmOC regulation issued in April 2008 was a necessary supplement to the regulation on obstetric quality issued in January 2007. It provided guidance to and principles of the EmOC process, including the requirements for consultation and referral, and the responsibilities of each participating actor. The regulation also provided practical guidance for EmOC work and made quality EmOC accessible and equitable in Shanghai.

- The regulation had a clear regulating issue: equitable access to quality EmOC care for all women in Shanghai. As the most vulnerable population in Shanghai, migrant women, often those with poor prenatal health care utilization and at high risk of critical illness, gained the most benefits from the regulation.

- Government priority: During the EmOC regulation process, government performance was linked to maternal health outcomes, as was health system performance. EmOC work became the priority of government sectors at different levels.

- User groups and civil society participation in the regulation formulation and implementation process was rather weak; improving participation could deliver useful gains.

- Follow-up regulations have been developed in response to emerging situations (e.g. “near-miss” audits, etc).

- While strict accountability was the primary mechanism through which the regulation achieved its effect, latitude existed to use other mechanisms to strengthen the regulation and to increase its sustainability [e.g. participation, ownership across different actors, shared responsibility].

- Strong leadership of the government and strict accountability ensured smooth implementation.

- The municipal health administrative sector played a leading, important role during the regulation process.

- Adoption of an emergency preparedness model as a response to EmOC cases has led to rapid response, better coordination, more efficient implementation and an overall improvement in service quality.

- Direction of accountability was largely upwards – the regulation should be modified to ensure greater bidirectional and horizontal lines of accountability.

- Workload capacity needs to be assessed given the newer and greater expectations of the regulatory framework; moreover, matching resources must be made available.

- A shift in the burden of costs occurred, i.e. from impoverished users [including those unwilling to pay] to the healthcare facilities. This is unsustainable according to the market conditions and poses risks to equity too.

- Political support: Since the EmOC work became the priority of the government, there was adequate political support for it at all levels, including the municipal and district governments and the health system. More resources were allocated to EmOC work after the issuance of the regulation than had been before. Experiences and lessons were integrated into continuing policy revisions to further improve the service provision.

- More efforts are needed to reduce Shanghai's MMR: response and reaction to medical emergency cannot be the only measure. It is necessary to improve maternal management, early identification of pregnancy, timely recognition of high-risk pregnant women, good antenatal health care (and its advocacy), as well as many other social factors.

- **Key messages with respect to governance**

  - The leadership role of the government was essential to ensure the "equity," "accessibility" and "quality" of basic health services.

  - Strict accountability during the regulation was an effective mechanism to reach the regulation goal, but bidirectional and horizontal lines of accountability may be needed for better governance.

  - Investment in appropriate resources is crucial to ensure the sustainability of the regulation effects.

  - Good communication and collaboration between regulation actors

effectively improved health service provision and achieved the regulation goal.

- Appropriate incentive mechanisms and the transparency feedback mechanism between lower and upper-level health institutions/institutes require improvement to further address service quality.

5.2.7.2 Recommendations for EmOC regulation

- Include more actors (especially user representatives) in the regulation design, through direct participation, by acquiring user perspectives through public notification, and/or other appropriate means.
- Improve the MDAS process, including the establishment of: reasonable criteria for the experts involved in the MDAS, a mechanism to voice response to the MDAS result, and active feedback to health institutions as part of the audit outcomes delivered to them by higher-level supervisory bodies.
- Resolve conflicts between each rescue and its resulting information report. An appropriate work mechanism must be in effect to ensure the rescue; then, reasonable time to deliver its information report should be given, depending on differences in rescue situation.
- Advocate for quality prenatal health care and the timely detection of high-risk pregnancy.
- Enhance obstetric human resources and financial investment in EmOC centers. Establish an appropriate mechanism for incentives.
- More financial and human resources are needed to ensure the sustainability of the regulation's effects. Scientific performance evaluation mechanisms, such as an incentive mechanism, should be established to improve providers' work enthusiasm for EmOC.

5.3 GR Case Report

5.3.1 Background

In this section, we briefly introduce the regulation on grievances redressal. Then we explain why we chose this regulation.

5.3.1.1 Regulation summary (Title, contents, objectives)

- **Title:**

Measures for the Administration of Patients' Complaints in Hospitals (MAPCH)

(Trial implementation,[k] Ministry of Health, 26 Nov. 2009)

- **Objectives:**

To improve the management of patients' complaints in hospitals, standardize the process that handles those complaints, and ensure the interest of patients and providers.

- **Contents**

The regulation document has six major contents: Definition of Grievance Redressal (GR) in hospitals; Communication between health provider and patient; GR Management Department in hospitals; Defining the GR handling process; Quality improvement and filing; and Administration.

The first part defines patients' complaints in a hospital (hospital complaint) as a formal, written or verbal grievance that is filed by the patient or his/her representative, to show dissatisfaction with medical services, nursing services or facilities.

The second part addresses communication between health provider and patient. The regulation requires that hospitals try their best to ease the tense relationship between physician and patients. It also requires that hospitals set up a special department (complaint office) and assign full-time professionals to handle complaints. Each department, moreover, should assign at least one person to cooperate with the complaint office to carry out complaint surveys and handle complaints.

The establishment of standards for handling the GR process highlighted several important concepts relevant to GR. **"First reception responsibility"** is one example**:** If a complaint comes to a department rather than the complaint office, staff there should welcome the complainant with enthusiasm, and solve the grievance on the spot if they can. If they cannot, they should take the complainant to the complaint office. The complaint office should clarify and verify the complaint with the relevant departments and persons involved as soon as possible. It may use assessments of quality and safety or other procedures to find out the facts and distribute the responsibilities, and present handling advice based on its findings. Relevant departments and individuals should cooperate actively. Another concept relevant to GR is **Feedback Time:** If a case is complex and needs investigation and verification, generally the complainant should receive feedback within 5 working days (if more than one

[k] Usually a national regulation's trial implementation (trial version) lasts two years.

department is involved in the investigation, 10 working days is acceptable).

The regulation also stipulated that the hospital should keep records of complaints while reporting serious medical negligence and medical malpractice. The records should feed into the assessment and awards of doctors. Health administrations at each government level should gradually establish local information systems of hospital complaints and medical disputes, and should strengthen their supervision and administration of hospital complaint management. According to “Regulations on Medical Malpractice,” if serious problems are caused by lack of implementation of the regulation, hospitals are punished by the health administration.

5.3.1.2 Rationale for the choice in study regulation

- **GR is an important part of quality health care, especially that of maternal health care**

Patients’ GR includes patients’ complaints and requests for good quality health care. Consumers are unsatisfied when they feel unfairly treated or have received inappropriate services. This dissatisfaction may be addressed, or not, through various channels and/or actions, including direct expression of discontent. When the patient makes a complaint he or she requests resolution and/or compensation.

Expressed grievance is a strong signal of dissatisfaction from patients or patients’ family. A good understanding of patients’ complaints is helpful to uncover patients’ demands for health care, identify health care delivery problems and improve health care quality. Consequently, good management of patients’ GR is an effective way to improve the quality of medical services.

An emphasis on GR reflects a patient-centered approach in health care service delivery. Such an approach entails: the regard of patient satisfaction as the core of health service delivery, the promotion of patients’ deeper participation in health care utilization;[34] the acceleration of hospitals’ improved service delivery process granting greater accessibility, responsiveness and equity;[35] and the expectation physicians assume more responsibility and adopt more effective activities[36] to reduce medical malpractice[37] and ensure patients’ safety.[38] As a supplement to peer review and administration, patients’ GR provides important feedback on health care services delivery; hence it can be a useful tool in health care quality improvement.

Maternal health care is not the same as general health services for a number of reasons. First, maternal health care has a special significance for families, for it represents not just medical care but also that process which produces a

new life. Second, it combines preventative services, care, mental health services, and medical services all together, throughout pregnancy and puerperium, and even a mother's entire life. Third, diverse factors such as culture, physician attitude, communication skills, model of care and medical technical quality all influence maternal health care quality. Fourth, people generally assume pregnancy and childbirth is a natural process and not related to disease. Fifth, because of China's one-child policy, families have even higher expectations of and more consideration for these services, as compared to general medical care. In all, then, maternal health care delivery is more susceptible to patients' complaints.[39] Conversely, since patients' feelings are indeed so much more invested in and concerned by maternal health care, how to improve patient satisfaction has high importance and value. In short, good GR services delivery is a key determinant of good maternal health care quality.

- **In general, patient complaints occur in hospital**

The Chinese government has issued a set of regulations over the past 25 years, during which time the GR system for medical cases has been established. Regulations began in 1987 with "Measures for the Handling of Medical Malpractice."In September 2002, a new one, "Regulation on the Handling of Medical Malpractice," replaced it. The GR system for medical cases originated in regulations handling medical malpractice; other supporting regulations were issued afterwards.

Hospitals are the main provider of medical services in China, whether inpatient or outpatient services. Physicians are employees of hospitals; accordingly, hospitals become the most common objects of patients' GR and the most frequent site of complaints. For this reason we chose MAPCH as the studied regulation: its specific aim is to resolve minor grievance cases in hospitals.

Complaints without good management easily deteriorate into medical dispute, which can result in exaggerated physician-patient conflict;[40] if complaints are dealt with promptly, efficiently and accurately, however, not only is the patient's grievance addressed quickly but also potential medical dispute may be avoided. Moreover, good GR management supports the early detection and correction of flaws in hospital management. It contributes to smoother physician-patient relationships and improved services quality and efficiency. Hospital complaint is the main form of patients' GR; consequently, its management is the key component when handling patients' GR. As an administrator said:

> *More than 90% of complaints in the health system are about medical institutions and their staff.*

(Female, GR-Administrators-4, 30-11-2011)

Moreover, a designer said:

> *70-80% of hospital disagreements are over small conflicts. We hope that such conflicts can be treated very well by the hospital, at the very first sign of complaint and at the low price of only a few sentences, so that escalated dispute is avoided.*

(Male, GR-Designers-2, 22-12-2011)

- **A process for routine management of hospital complaints improves the equity and accessibility of GR**

Handling GR is a service not a product, and therefore its process is difficult to measure and its value difficult to assess. Furthermore, each grievance handler has his or her own understanding of this service. Hence variations in the GR process occur, in the cost of patients' complaints and in the results obtained from them and that process. To improve equity of GR services, a regulation establishing a clear hospital complaints management process is needed, one that standardizes GR services provision and ensures that all patients with grievances undergo the same complaint handling process and are fairly treated .

5.3.2 Context

This section will address the context of the studied regulation: why the government decided to issue it, how it sprang from both international concept and China's own national concept of governance, and what specific elements (e.g. medical, managerial, etc.) inherent to the problem of patients' grievance redressal influenced the regulation's shape, in particular its serious imbalance in supply (i.e. redressal) and demand (i.e. grievance). Lastly, we will introduce its regulatory background.

5.3.2.1 International concept

Over the last two decades of the twentieth century, two powerful currents of social, economic and political change have altered many nations' understanding of governance. They have also influenced Chinese social and economic reform.

The first has been democratization. A great wave of transitions from authoritarian rule has occurred in countries in Latin America, Africa, Asia and

Eastern Europe, where generally more liberal, representative systems of governance have been adopted. These political changes have been accompanied by heightened expectations about the ability of representative government to improve respect for human rights and foster the redressal of past inequities. They have also influenced the Chinese government and Chinese citizens. As the role of the traditional single political party responsible for shaping inclusive policy platforms becomes undermined by corruption and/or a loss of faith in the Chinese Communist Party (CCP), the government faces profound, potentially destructive challenges with respect to citizens' high expectations of good governance.[41]

The second has been that of globalization. The present interconnected social, political and economic relationships that characterize a more globalized world have empowered a new range of actors—such as multinational corporations and transnational social movements—whose actions often escape popular and/or national control, yet greatly affect the survival prospects of the disadvantaged. Moreover, these new actors can severely limit government's attention, policy selection, and policy making. Meanwhile, globalization has heightened expectations in the realm of human rights, including that of the citizen's voice.[42]

The Internet has been another important factor influencing government. Information exchange through the Internet has accelerated globalization. It has also changed Chinese citizens' understanding of liberalism as well as increased their expectation of good governance.[43]

5.3.2.2 Governance concept: CCP and government's change in concerns

- **CCP's change in governance principle and government's increased concern with social issues**

China has experienced rapid economic growth these last 30 years. However, this growth has been accompanied by an increase in income disparity. Inequity of income not only results in citizens' dissatisfaction[44] but also interferes with high economic growth.[45] At the beginning of the current century, the CCP clearly stated its new governance principle of "building a harmonious socialist society" and declared that that principle should become one of the CCP's five governance capabilities. At the end of 2006, the "Resolution of the CCP on several important issues for building a harmonious socialistic society" was introduced as a guiding government document. It lists a people-centered approach as the first principle of building a harmonious society, underlines issues of people's livelihood, and intends to ensure social fairness and justice.

Hence the Chinese government's attention has turned from purely economic

development to a gradual and balanced development of all society sectors. Social affairs and people's livelihood issues have become the government's core concern. In 2010, the national financial expenditure on education, health care, social security and employment, affordable housing, culture and sports—all directly related to peoples' livelihood—was more than 2.9 trillion CNY (0.43 trillion USD) in total, a 21.1% growth from 2009. It accounted for 32.6% of total national financial expenditure. Joined to other expenditures closely related to issues of people's livelihood, total spending in 2010 on people's livelihood accounted for 2/3 of the national financial expenditure.[46]

- **Gradual improvement in the legislative corpus has increased protection of individual rights, including those of patients**

Legislative changes

The Chinese government has been facing expectations from international actors regarding democratization, as well as high expectations from citizens to reduce corruption, and improve equity and transparency. Accordingly, in recent years a set of laws to protect and liberalize individual rights were issued. 2007's **Property Law** announced the equal protection of private property and public property. 2009's **Tort Liability Law** provided comprehensive protection of citizen's personal rights of body and property, many of which appear as specific provisions in the Chinese law system. In 2009, the Chinese Government presented and initiated a program entitled "The National Human Rights Action Plan of China (2009-2010)," its first national plan focusing on the theme of human rights.

Enhanced legal education

China has put great effort in universal law education to develop people's legal consciousness. The Ministry of Justice set up a special department for general legal awareness and education. Since 1986, China has carried out two decades of national legal education activities, and now is in its fifth five-year plan. Meanwhile, the Ministry of Justice has also allocated resources for legal aid to help vulnerable groups protect their rights. Funding for legal aid has increased rapidly, with an average annual growth rate of 41.92% between 2001 and 2009. In 2009 it reached 757.6 million CNY (110.9 million USD).[47]

More attention on health care quality and patient satisfaction

One of the three goals intrinsic to The World Health Organization's framework for assessing health system performance is responsiveness to the preferences of patients. This responsiveness to preferences can be defined as the extent to which the health system meets people's overall, reasonable expectations of

their treatment process as well as their expectation of health outcomes. In other words, the health system should not only produce health results but also ensure that patients are satisfied with the health services delivery processes they encounter. In major health system assessment and evaluation programs, patient satisfaction is becoming an essential indicator. In the 2005 annual evaluation guidelines of the MOH on patient-centered hospital management, patient satisfaction in all hospital departments and medical services is highlighted. The "San Hao Yi Man Yi[l]" program introduced in 2011 by the MOH of the PRC regards people's satisfaction as the main target.

Clearly the current context and handling of medical disputes reveals much public concern and awareness, increasing pressure for good GR management: an urgent need now exists to regulate GR handling processes that ensure equity and effectiveness.

5.3.2.3 Increasing demand for GR from patients

The long term effects of law education are becoming more and more significant, and have a direct bearing on people's rising awareness of rights: legal aid agencies are now receiving more counseling cases than ever before. In 2009, about 36 cases (per 10,000 people) of formal counseling were conducted in officially recognized legal aid agencies, six times more than in 1999.[47] As more people have come to know the judicial hotline (12348), counseling cases seem to have increased.

In Qingdao city, there was a significant increase between the second half of 2009 and the first half of 2010. In the first half of 2010, the hotline received 9043 calls, 16.03 percent more than that in the second half year of 2009.[48] The Taicang hotline received 3506 calls or visits in 2009, the most since it began; its legal aid services achieved a historic breakthrough.[49] Although this widespread growth in cases may be influenced by factors such as population, policy changes and so forth, still it is evidence of an increase in complaints.

- **Tense relationship and lack of trust between doctors and patients**

Currently in China, people suffer from a tense physician-patient relationship. 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.[50] The incidence of medical disputes likewise continues to rise in this context: from 2002 to 2008, medical malpractice cases of first trial increased from 10,249 to 13,875.[51]

[l] *San Hao Yi Man Yi* is a regulation intended to improve medical service quality. It requires hospitals to provide good service (care) and good quality treatment by a professional of good medical ethics, as well as ensure patient satisfaction.

The increasing tension between doctors and patients reflects patient dissatisfaction with medical services delivery and considerably influences service providers. In September 2011, when a boy was seriously ill and received in-patient services at the Guangdong Maternal Hospital, his parents voice-recorded all his treatments. This case led to a lively discussion all over the country about trust, along the lines of: “Hospitals don’t trust patients and require signatures at each step of treatment; patients don’t trust hospitals and voice-record every minute.” At about the same time, the “BaJiaoMen” case in Shenzhen happened. This case originated in a patient’s suspicion that a hospital was providing excessive medical services, which caused great disturbance before being revealed as a misunderstanding rooted in lack of confidence in the physician-patient relationship.[52]

The “BaJiaoMen"[m] case launched public accusation against the hospital based only on suspicion, no evidence whatsoever. This seriously affected the hospital’s normal medical services delivery (over the following five days, three cases of parents refusing surgeries occurred there).[53] Hospitals are beginning to keep an eye on the role of the media in medical disputes. In another medical dispute in July 2010, when a physician initiated a libel suit in a local court, both the patient and representatives from two media were named as defendants.[54] An administrator recounted:

> *After the Sichuan earthquake, physicians were regarded [by the media] as angels in white. But when reporting conflicts between physicians and patients, the media always describe the physicians inaccurately. Hospital problems get exaggerated, and people form a negative impression…the media are a barometer [of public opinion].*
>
> (Female, GR-Administrators-3, 21-09-2011)

- **Perceptions about the health system**

As consumer health concerns have been increasing, so too has medical technological progress been augmenting patient demand. Yet resource allocation has become a serious limiting factor. In addition, consumer demand

[m] In 2011 this was top news in China. A six-day old newborn baby went to see a doctor because of stool difficulties. The hospital estimated about CNY 100,000 (USD 15,873)for surgery. The baby’s family refused treatment and went to another hospital. Then the baby’s father announced the child had been cured after using paraffin in that hospital, which had charged CNY 0.8 (USD 0.13). All media reported this news, and directed accusations at the first hospital. The event was a central social focus. However, this baby soon went to the third hospital, and did receive surgery. He was suffering from a megacolon tumor, the same diagnosis received from the first hospital. The baby’s parents and media publicly apologized to the first hospital.

is influenced by public opinion: Because of its inherent dynamic of asymmetric information and uncertainty, consumers cannot judge the true value of health services as a product. Instead, they estimate the value of health care by other indirect factors (such as price or reputation). Negative media reports can seriously affect a patient's judgment about hospital services quality and can decrease his or her confidence in the medical services.[53] Lack of confidence erupts when conflict (or the feeling of conflict) occurs during the service delivery process or if an unexpected outcome occurs. The patient and relatives with rising rights' consciousness assume that the fault lies with the service provider, and try their best to protect their interests and rights through communication or grievance redressal. Patients tend to actively release their grievances and consequently raise GR claims. Lack of confidence between physician and patient not only increases the occurrence of conflicts but also makes the grievance resolution more complex and difficult.

5.3.2.4 Insufficient supply of GR

- **Little concern from providers, and limited supply of GR**

While patients' demand for services in handling complaints is on the rise, administrative departments within the health system have not given GR corresponding attention. In its requirements of hospitals, health administration focuses on the quality and safety of medical services, ones judged usually by the service provider. In national hospital management activities themed "a patient-centered approach," those indicators related to responsiveness to patients needs and demands have never been regarded as core indicators. The supervision of medical disputes is relatively simple, and often only concerned with serious cases of medical malpractice. Without force requirements for complaint management, and with relatively scarce resources allocated to GR handling, "voting with your feet" usually cannot help consumers place enough pressure on hospitals.

In this context, hospitals as service providers can more or less decide for themselves the importance of complaint management. Yet in a hospital, the dean and department directors are in general clinical professionals. The traditional medical education they have received in biomedico-social medicine did not emphasize the physician-patient relationship, moreover, their clinical work experience induces them to ignore services only indirectly related to clinical treatment. Complaints and their management similarly fail to draw the hospital director's interest and attention. This general ignorance and indifference on the part of medical staff and administration directly leads to the insufficient allocation of human and material resources to hospital complaint management. The result is that the hospital cannot supply adequate GR services to meet patient demand. A grievance handler said:

In practice, the department chief influences implementation. If the chief regards it important, the front-line workers work harder, of course. Now the problem is that some department chiefs don't pay attention to it [complaint management].

(Male, GR-Implementer-7, 16-09-2011)

An administrator from a hospital owner agreed:

It's of course that, in a hospital, medical services is the core. Such work [complaint management] is boring for the hospital. To a hospital, the fewer the complaints, the better.

(Male, GR-Administrators-2, 18-08-2011)

- **Poor quality GR services**

Because insufficient value and hence attention has been accorded complaint management within the health system, most hospitals do not put much effort into GR handling. At the same time, limited research and few documented experiences about health-related GR services exist in China. Until now, hospital complaint management systems have been set up spontaneously, with the goal of controlling single cases, as they happened to arise. Complaint management has operated in different ways. There have been no formal procedures for case handling, no special window/mechanism to receive complaints, an unclear division of responsibilities for GR management within the hospital, and no standardized process to receive and handle complaints. Inappropriate and unscientific procedures have been widespread and the management process full of problems and obstacles caused by hospital departments passing the buck when it has come to their responsibilities. Therefore, the quality of complaint handling has been low and far from achieving patient satisfaction. In 2009's evaluation of current hospital complaint management, 77.5% of patients described it as "normal" and 16% said "not very good" or "very poor," while only 6.5% felt it was "good." [55]

5.3.2.5 Regulatory background

In September 2002, China's State Council issued the new national regulation "Regulation on the Handling of Medical Malpractice." Hospitals established dispute departments to receive patient claims and organized negotiations between hospital and patient in medical malpractice cases. At the same time, on the basis of the national regulation "Establishment of a Report System for Major Medical Negligence and Medical Malpractice," a medical malpractice report system was developed by the MOH. In October 2004, the Shanghai

municipal BOH established its own “Notice on Further Improving the Medical Dispute Registration System” in order to define the responsibilities of hospital departments and staff in medical dispute handling, specific registration contents, and the administration and evaluation of medical malpractice reports.

In December 2009, the MOH issued the national regulation “Measures for the Administration of Patients’ Complaints in Hospitals” (Trial implementation) to regulate the hospital complaint handling process; this had never before been the focus of any regulation.

In January 2011, the “Report system on medical quality and safety” was developed by the MOH and replaced the regulation on “Establishment of a Report System for Major Medical Negligence and Medical Malpractice.” That new regulation clearly defines the report system, report structure, personal liberties as well as supervision and management. The “Implementation Plan ‘Three Goods & One Satisfactory’ for the National Health System in 2011” was established in April 2011. Terms for handling medical malpractice and hospital complaints as a part of evaluation indicators were included in this plan; Shanghai’s municipal BOH interpreted it as the “Implementation Plan for “Three Goods & One Satisfactory” for the Shanghai Municipal Health System in 2011.”

Table 5.3.1 Regulatory background of MAPCH

Time	Regulations
2002.09	➢*1. Regulation on the Handling of Medical Malpractice (National)* ➢*2. Establishment of a Report System for Major Medical Negligence and Medical Accidents (National)*
2004.10	*-3. Notice on Further Improving the Medical Dispute Registration System in Shanghai (SH)*
2009.12	➢*4. Measures for the Administration of Patients’ Complaints in Hospitals (for Trial Implementation) (National)*
2011.01	➢*5. Report System for Medical Quality and Safety (replaces 2)*
2011.04	➢*6. “Three Goods and One Satisfactory” for the National Health System”(National)* *- 7. 2011 Implementation Plan of “Three Goods & One Satisfactory” in Shanghai’s Health System (SH)*

5.3.3 Process

This section addresses the regulation process. First, we address why it was formulated and the process of its definition. Following that, we turn to how the regulation was interpreted and administrated. A description of the regulation’s implementation comes last.

5.3.3.1 Definition

- **Process of Regulation Definition**

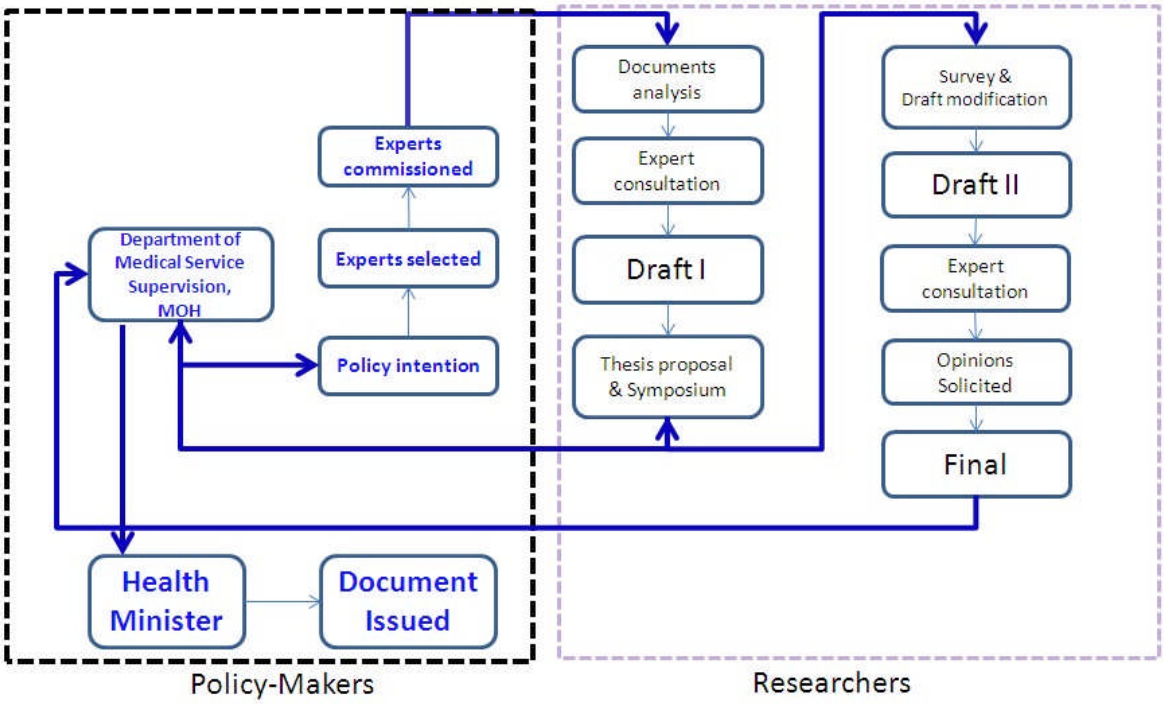


Figure 5.3.1 Process of MAPCH regulation definition

Phase 1: Policy intention

After 30 years of economic growth, the Chinese government is facing domestic challenges in meeting citizens' expectations of decreased corruption, improved social equity and good governance. Waves of international democratization and globalization have also been pushing the Chinese government to consider the liberalization of human rights. So the government is paying more attention to social issues and citizens' voices. Much social attention has likewise focused on medical health care utilization these past ten years, and how to improve health care accessibility, equity and patient satisfaction has arrived in a zone of governance priority-setting. GR service is both a key determinant of patient satisfaction and also an indicator of individual rights. The Department of Medical Service Supervision of the MOH clearly intended to form this regulation. Medical malpractice accounted for a low percentage of medical disputes, and the percentage of cases caused by medical technology was also low. Medical disputes were mainly associated with poor communication such as a provider's attitude, words, and/or behavior, as well as unreasonable service procedures. One designer said:

The proportion of medical malpractice in hospitals is low, maybe

accounting for one to two percent of all GR cases.

(Female, GR-Designers-1, 16-12-2010)

The Medical Doctors Association did a survey of these kinds of medical disputes. 50 cases were caused by an attitude in health care delivery, 25 percent were caused by technology (misuse), and others were related to management.

(Female, GR-Designers-1, 16-12-2010)

When unsatisfied patients complained to hospitals, the conflicts escalated if they could find no Complaint Reception department, or the hospital did not pay attention to redressal of the complaint. Another designer said:

Health service providers and utilizers reported that many medical disputes usually ended up trifles, not well addressed by hospitals. This [attitude] was obviously reflected in some hospitals' lack of much attention to patients' complaints, so the complaints turn into disputes… We think initially the complaints should be addressed properly right from the start in hospitals to prevent them [from escalating] into disputes. So we wondered: how can we set up harmonious doctor-patient relationships and how can we resolve conflicts? We wanted to first resolve them by strengthening the complaint management [process] in hospitals. That was the whole background[on policy intention].

(Male, GR-Designers-2, 22-12-2011)

Both health providers and patients perceived the mismanagement of patients' grievances as a problem. The Department of Medical Service Supervision of the MOH acknowledged the problem, and it became evident that the handling of patients' complaints within hospitals needed strengthening. The policy answer was the issuance of a normative document intended to regulate the GR handling process and its management within hospitals. A designer said:

Health service providers reflected that they paid such little attention to addressing grievances… [because] their pressures were big and the workload was too heavy […] If hospitals were to establish a new department, it would indeed increase costs. Hence complaint handlers reported that they hoped the Ministry of Health would issue the relevant normative documents [so] hospitals could more reasonably strengthen the related work […] With this preliminary background, we felt the most important thing was to set up a document handling small complaints in hospitals in order to foster a harmonious doctor-patient relationship and resolve conflicts. So when the MOH developed the 2009 work plan, we

incorporated “Measures for the Administration of Patients’ Complaints in Hospitals” into our schedule.

(Male, GR-Designers-2, 22-12-2011)

Phase 2: Policy drafting

After having acknowledged the problem of patient complaint management in hospitals, the MOH commissioned a university to set up a working group to analyze the problem in more detail and on that basis to prepare a draft regulation document. The researchers had a wealth of research experience on patient satisfaction and quality of health care. The working group carried out a literature review on patients’ complaints and conducted several GR case studies. The investigations were conducted with health providers and patients to understand their opinions and advice for handling complaints in hospital. Possible solutions for strengthening GR in hospitals were proposed on that basis. Additionally, some local experts were invited for consultation before the first draft was prepared. A designer explained:

At first, we combined our own preliminary thoughts with various hospitals’ GR management experiences, which [we found on] the Internet, and held certain small discussions at our institution. Because my profession is health law, I invited a few related experts from other institutions to discuss [it with us]. We drew up a first draft, and reported to him [the MOH].

(Female, GR-Designers-1, 16-12-2010)

Researchers were mainly involved in drafting the policy. Health administrative departments played a coordinating role in the research project. A designer from one such department said:

My doctoral research was related to health service quality, [which pertained to] several aspects of the complaint issue.

(Female, GR-Designers-1, 16-12-2010)

Several policy elements were proposed. One was "First reception responsibility"—this places the responsibility for handling or transferring the case to a hospital GR department squarely on that department which has initially received the patient’s complaint. The other element was a normalized process for complaint handling; this included: specification of feedback time to complainant, format for recording complaints, mediation, etc. Another designer said:

In fact, solutions were proposed based on the problem. Take "First

reception responsibility" as an example. It came about because many patients reflected that departments pass the buck among themselves, and they never knew which department was in charge. For example, one patient complained about slipping; [the Clinical department] said it was not their business but rather the Logistics department's, and the Logistics department said outside people were hired to mop the floor, so best complain to the cleaning company. Utimately, no one would handle this complaint. So we proposed "First reception responsibility": we don't care how hospitals handle the complaint internally. If a patient complains to a hospital, how you resolve that internally has nothing to do with the patient. If it is not the patient's fault, you have to give him feedback. […The regulation] stipulated how long it must take to reply to written complaints; for particularly complex cases, or if, still-unsatisfied patient--complained again, he or she should be told clearly what to do next. Complaint management can only solve part of the problem, not the whole. The regulation includes how to normalize the filing of complaints. In fact, it tells hospitals what standardized management of a complaint is.

(Male, GR-Designers-2, 22-12-2011)

Phase 3: Policy validation

First round of validation: After the first draft, expert consultation was carried out and the working group conducted further field research. They purposely sampled representative hospitals to carry out institutional surveys and an investigation of health providers. Then researchers revised the draft based on the study outcome.

Second round of validation: The Department of Medical Services Supervision of the MOH organized two validation meetings. Participants included members from MOH departments, hospital administration researchers, decision-makers from the local BOH and directors of hospitals from different levels. In addition, paper opinions were solicited from each provincial BOH, which collected comments from medical institutions and then passed them on to the MOH. Eventually the draft was published online for public comments. A designer said:

We first organized experts to conduct surveys in some places, in order to further understand the exact status of GR management in hospitals […] The experts investigated certain hospitals [with a record for] much attention to and good management of patients' complaints, to record their successful experience and finish the research report for the Health Minister […] We then organized experts to draft "Measures for the Administration of Patients' Complaints in Hospitals." Afterwards, public

opinion was conventionally solicited. We then collected that feedback, and modified it [the draft]. […]In fact the administrative department invited experts, and sometimes even administrative department heads led some investigations. This regulation was not the same as others: it was not completely designed by experts[….] Generally opinions were solicited (validated) from the provincial-level BOH, which then sought the views of hospitals and patients. Simultaneously we solicited opinions from certain directors in hospitals or related departments, such as the Department for Complaint Management.

(Male, GR-Designers-2, 22-12-2011)

Phase 4: Policy issuance

After soliciting comments, the draft was finalized by the MOH's Department of Medical Service Supervision. With the consensus of the Minister and all MOH departments, the regulation was issued. It was expected to resolve the difficult matter in hospitals regarding the redressal of patients' grievances. It established a guideline for hospitals to normalize their process of complaint handling and [through that] to resolve small conflicts. A designer said:

Assuming that the handling of all medical disputes is an entire process, this regulation represents the first stage of that process. It can address complaints within hospitals; if the complaints cannot be resolved there, other channels exist afterwards[…]This regulation is a normative document, to tell you what you should do.

(Male, GR-Designers-2, 22-12-2011)

The regulation is a department "Rule" rather than a Ministerial "Decree". It does not have a strong enforcement mechanism for changing hospital management. As a guideline, it contains no mandatory requirements such as access and assessment mechanisms. Because it took into account the difference in local conditions throughout China, specific contents were not stipulated. So the regulation can be interpreted according to local circumstances and situations. A designer said:

The room for adaption to local conditions within the regulation is quite large. What the regulation describes is the general process; specific provisions can be interpreted at the local level.

(Male, GR-Designers-2, 22-12-2011)

5.3.3.2 Administration

- **Administration process**

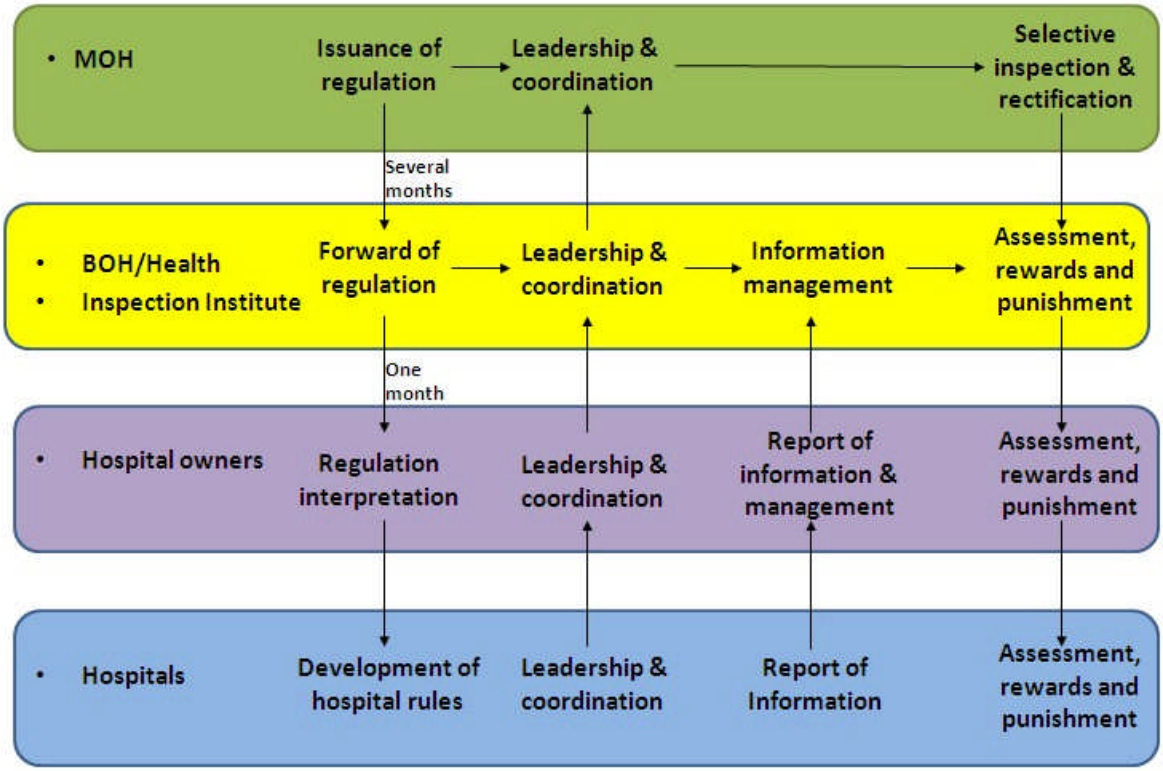


Figure 5.3.2 Administration process for MAPCH

The regulation was forwarded top-down in the health system. The interpretation and administration process is shown above. Within one month after it had been issued, the regulation was forwarded to hospital owners by Shanghai's municipal BOH, and then forwarded to hospitals by the hospital owners. In the forwarding process, Shanghai's municipal BOH did not release any supporting implementation details for the regulation. Explaining the circumstance, one designer said:

> *Because our country is so big, it's necessary to refine and deepen normative documents issued by the MOH according to [an] understanding of the local circumstances and conditions. Sometimes one person cannot understand the regulation. [if] hee can discuss with others [though], and communication between everyone facilitates the promotion and implementation of the regulation. […] Local health administration departments forwarded the regulation according to local conditions. Some of them may have invited experts to do some training.*
>
> (Male, GR-Designers-2, 22-12-2011)

An administrator from a provincial BOH affirmed:

> *We forwarded the regulation immediately after its release.*
>
> (Female, GR-Administrators-4, 30-11-2011)

Selective MOH inspection

After issuing the regulation, the MOH conducted one selective inspection without other assessment plans. It purposely sampled some areas at the national level, and some large public hospitals in those areas. Hospitals were only required to rectify and submit reports for improvement measures if found they had not implemented MAPCH well; the MOH also expected local health administration departments to interpret and administrate. A designer said:

> We conducted one selective inspection over the one-year after the regulation was issued. It aimed to inspect the full [scope] of the regulation's implementation. For example, we examined whether hospitals had a special department for complaint handling; whether hospitals had developed relevant rules in accordance with the regulation; whether special persons were responsible for complaint management, and [if so] how many; where to file and how to resolve complaints; how to give feedback to complainants. The key procedure is how to improve health services after complaint handling.
>
> (Male, GR-Designers-2, 22-12-2011)

The same designer was asked, "If a hospital didn't implement the regulation well, did you take any action?" He replied:

> *We required the local health administrative departments to improve immediately, and to supply a rectification report.*
>
> (Male, GR-Designers-2, 22-12-2011)

Administration with concurrent regulations

During the first year after it issued the MAPCH, the MOH launched other policy measures that intended, by insisting on high accountability, to improve the management of medical service quality. Two subsequent national regulations, "San Hao Yi Man Yi" and "Yi Liao Zhi Liang Wan Li Xing," [n] made it mandatory

[n] "Yi Liao Zhi Liang Wan Li Xing": This campaign focused on institution-building and public education. It combined the activities of hospital management and "Safe Hospital" construction, which it promoted through inspections. Its aim is to improve the quality of medical service, medical safety, and health services; to optimize the medical environment; and create harmonious health provider-patient relationships. Its core focus is the "Continuous Improvement of Medical Service Quality."

that hospital GR management follow the MAPCH. These two regulations emphasize each hospital's quality evaluation and supervision. Each year every hospital must conduct a survey, fill out quality questionnaires, and report certain key health service quality indicators. These regulations articulate GR management as a component of the quality assessment system, since it's intrinsic to the provision of quality. Administrative conditions in the Complaint Reception department, complainants' feedback time, the quantity of GR cases, and other such elements are included in the set of health quality indicators. Hospital directors are made accountable to the BOH for quality issues.

The provincial level administers several assessment systems, including hospital ratings, the inspection of comprehensive hospitals, and the evaluation of hospital directors. These assessments involve several MAPCH-related indicators. Hospital directors are accountable to hospital owners for hospital ratings and performance, both of which determinants influence a director's promotion or good reputation.

***Hospital ratings and inspections of comprehensive hospitals*:**

The "accreditation standards for tertiary comprehensive hospitals" (2011 version) instituted the following elements for complaint management of hospital services: Measures for the Administration of Patients' Complaints in Hospitals (Ministry of Health, Trial) must be implemented and "First reception responsibility" carried out; a special department must be established or designated to receive and handle complaints from patients and medical staff, with timely reply to complainants; information on the complaint management department, its location, working hours and contact details must be published, including the complaint telephone number of higher authorities; a system of complaint files management must be established and improved, and complaint handling procedures must be standardized; continuous improvement in medical services must be conducted, based on complaints from patients and medical staff; and all staff must undergo specialized training in the prevention and handling of medical disputes. In 2011, Shanghai BOH's "Notice on the delivery of comprehensive hospital inspection in Shanghai municipality" focused on the inspection of medical services, including the standardization of complaint management, timely investigation, and the handling of medical complaints and their rectification.

When an administrator was asked, "Which special inspections did administration of the regulation include?" she replied:

> *Both hospital ratings and also the inspection of comprehensive hospitals.*
>
> (Female, GR-Administrators-4, 30-11-2011)

A grievance handler in a hospital affirmed:

> *We began to study this regulation [MAPCH] because of "San Hao Yi Man Yi."*

(Female, GR-Implementer-3, 31-08-2011)

Municipal Shanghai's system to monitor quality and safety of medical services: Located in the largest economic center in the country, Shanghai's BOH set up a system to monitor the quality and safety of medical services. The system covers all medical institutions in municipal Shanghai, and at the outset effected the dynamic monitoring of quality and safety of medical services in medical institutions. Now medical institutions report medical dispute and malpractice information online and offline. Next Shanghai's BOH analyzes that data to understand shortcomings in the quality and safety management of medical services. Then the results are fed back to the medical institutions as early warning. An administrator said:

> *We now have an information reporting system for medical safety. Hospitals are required to register and file [the case], then to report. We have a citywide network […] This system has five components [functions]: the first is to collect information, then to analyze, give feedback, evaluate, and finally to give early warning—five elements.*

(Female, GR-Administrators-4, 30-11-2011)

5.3.3.3 Implementation

- **Implementation process**

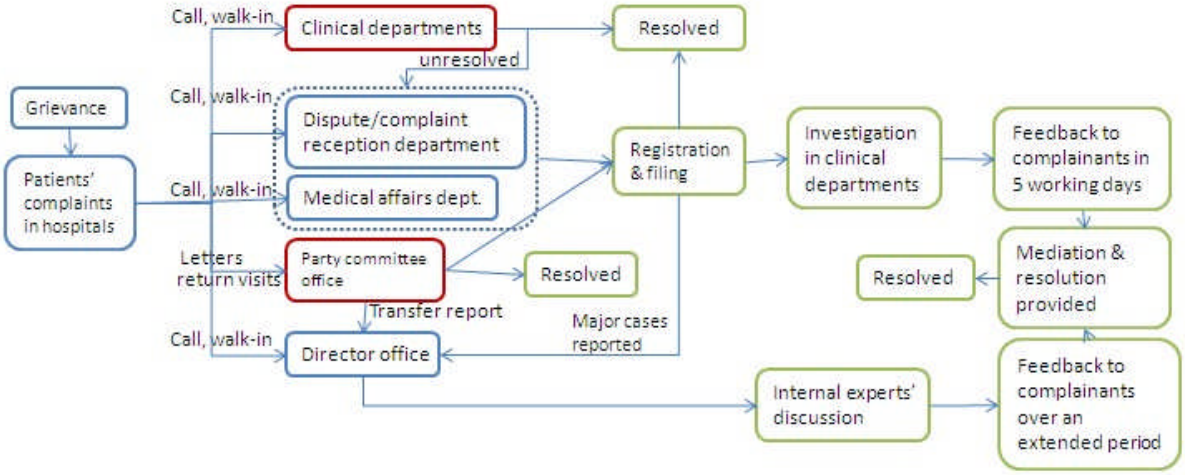


Figure 5.3.3 MAPCH's implementation

- **Hospital GR procedures**

- **Clinical departments:** When a patient is discontent with medical services received, he or she must first complain to the attending doctor or nurse in the corresponding clinical department. According to "First reception responsibility," the attending doctor or nurse has the immediate obligation to respond to the patient, and redress his grievance rapidly. If the attending medical staff cannot properly handle the complaint, the case must be transferred to the chief or the staff responsible for GR in the department, in an attempt to resolve the complaint on the spot. If it remains unresolved, then it must next be transferred to the Complaint Reception Department in the hospital.

- **Complaint Reception department**: The structure of the Complaint Reception department depends on the different types of hospitals and their different levels. The Complaint Reception Department in large hospitals is usually made up of three units: outpatient office, complaint reception office and the “spiritual civilization” office. The outpatient office mainly handles and tries to resolve the complaints of outpatients. Some complaint reception offices have been set up separately, others as part of the medical department. They mainly address the grievances of inpatients. The hospital’s “spiritual civilization” department is sometimes part of the communist party committee office and it deals mainly with the written complaint cases, including letters addressed directly to the hospitals, or ones transferred from higher authorities. The “spiritual civilization” department also carries out patient satisfaction surveys and satisfaction follow-up. Some hospitals integrate these three units into one department to handle all complaint calls, letters, and visits.

- **Handling Procedure:** After receiving a patient’s complaint, the handling procedure is basically the same: first, the basic information of the complainant and its contents is recorded and filed, and the complainant is informed of the feedback time. Before giving feedback to the patient, the Complaint Reception department investigates the concerned clinical departments and discusses solutions with them. The Complaint Reception department must give feedback to the complainant within five working days and make an appointment with the complainant and the clinical departments. The Complaint Reception department must also invite the concerned department chiefs and complainant to meet to discuss a mediation plan. Concerned medical staff is generally not invited. Both sides propose a solution to resolve the complaint. Finally, the agreed resolution is reported to the hospital leaders for their review and approval, and the case is filed. If medical malpractice has occurred, it will be reported to Health inspection institute (HII).

- **Hospital director in charge of handling complaints:** The director not only gives instructions at the final stage but also personally participates in certain major disputes. The Complaint Reception department reports serious

cases to the director. The director then immediately mobilizes the hospital's experts so that they can investigate whether the case is one of medical malpractices and so discuss appropriate and feasible solutions. Sometimes the hospital director also attends the mediation meeting to negotiate with complainants face to face.

Grievance handlers from different hospitals said:

> *The handling process in our hospital is mainly just as the regulation stipulates. For example, generally speaking, if the patient in the ward or outpatient department is not satisfied, health providers in that department will explain [matters] to him; if the grievance can't be resolved, it will be transferred to the department chief or the head nurse in charge of the department for resolution. In particular, if compensation is required or the complainant is too nasty, it may [then] be transferred to us [the Complaint Reception department], where dedicated staff will receive the grievance. That is one form [of the process]. Some complainants don't tell the clinical department, and come directly to the Complaint Reception department; or they go to the director's office, and are transferred to my department, too. Some people even don't complain to the hospital: they complain to the BOH, or the media. This form is less usual, [but is still] transferred to us. We also receive grievance calls because our telephone number is open to the public. There are also some complaint letters, not too many, and these are usually transferred [to us] from the health administrative department—they are petitions, so-to-speak. Nowadays complaints [also] come from the Internet—online complaints. Our district government has a portal, and people can complain online. These are often grievances about service attitude. We have to handle them, too. The government transfers them to the BOH, and then to our hospital, and then to the related departments. That's the case with the handling process after reception. If the grievance can be resolved on the spot, we will try our best to do so; if [more substantial] problems exist, especially if the patient is unsatisfied with a certain part [of treatment], we will solve problems associated with other departments. But if the grievance is about a quality issue and possible harm to a patient, it cannot be handled on the spot. We address this as soon as possible, with the clinical department reporting to mine to participate. We will quickly set up a small group, including the clinical department, to investigate the case and devise a handling approach. If the case is relatively serious, and could lead to significant compensation, relevant experts are organized after investigation to discuss the case, after which further contact with the complainant is held.*
>
> (Female, GR-Implementer-2, 25-08-2011)

If a patient is unsatisfied with the treatment, first he can communicate with clinicians; if that doesn't work, he can go to the Complaint Reception department. There are dedicated personnel to receive complaints. They record his dissatisfaction and requirements, and then communicate with the Clinical Department. They then report to the director office, which convenes clinicians to discuss the problem, how to improve, how to redress, and how to communicate with the complainant. The first [step] has to do with coordination and communication within the hospitals. If the patient is [still] not satisfied, he has other channels through which he may choose to complain, such as the channel for redressing medical malpractice.

(Female, GR-Implementer-4, 01-09-2011)

First, complaints may be transferred from higher authorities, since some patients complained directly to the government, including the mayor, BOH, Health inspection institute, and CDC. They all receive complaints from patients, and transfer them. Another [form] is medical disputes or medical complaints happening in the wards or outpatient department. We also have a follow-up mechanism, and the "spiritual civilization" office has special charge of it. Sometimes patients with some concerns are reluctant to complain when they are still in the hospital; later, when they are discharged from the hospital, they will give feedback on the entirety [of their] medical services, including environment, medical staff attitude, and medical ethics. That's direct feedback, and the Complaint Reception department collects it.

(Male, GR-Implementer-6, 08-09-2011)

- **Links to other channels**

• The hospital complaint department handles cases transferred by Letters and Visits (LVs) departments in accordance with the hospital's handling process.

• If the hospital cannot resolve certain conflicts itself, those cases may be transferred to external hospital mediation with the consent of both sides. That external mediation may take the route either of "Administrative mediation" or "People's mediation." ("Administrative mediation" is voluntary participation in a process through which—in accordance with national policies and laws, and by means of a clarification of responsibilities and discrimination of right and wrong—state administrative organs educate and persuade both parties concerned in a dispute as a means to promote mutual understanding, accommodation and agreement in the resolution of those disputes. "People's

mediation" refers to a process by which a people's mediation commission persuades the parties concerned in a dispute to reach a mediation agreement on the basis of equal negotiation and free will and thus resolves the dispute between them.) Patients can also bring civil actions to the People's Court.

• In addition, patients make use of non-statutory channels to express dissatisfaction, such as through the media and/or "Yi Nao" disruptions; this latter refers to individuals or groups employed by the patient (involved in the medical dispute) to make constant trouble for hospital. The "Yi Nao" group uses such tactics as setting up a "mourning hall" in the hospital, smashing and grabbing things, putting up obstacles to block other patients, even following and beating physicians, and occupying the clinic, physician offices and/or hospital manager's office.

- **Hospital implementation**

The implementation of the regulation in hospitals depends on the director's perception of the importance of patients' complaints. No standard mechanism for hospitals' administration of GR exists.

The typical implementation structure of GR in hospitals is shown below.

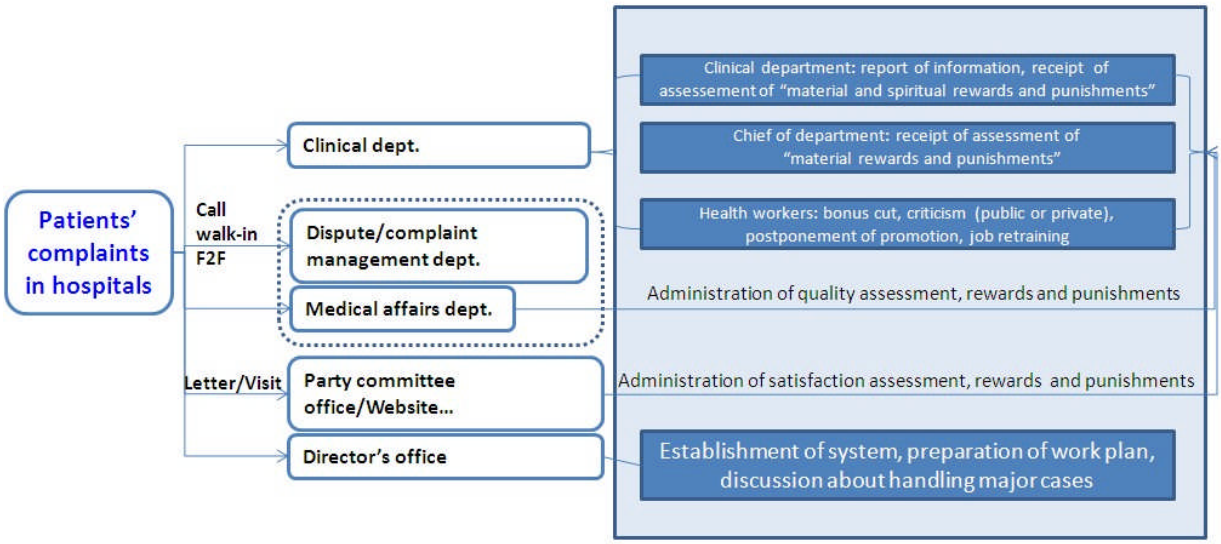


Figure 5.3.4 Typical GR process in hospitals.

- **For concerned departments:** The number of complaints a department receives is one of its performance indicators, eventually connected to its honor and material rewards or penalties.

- **For the department chief:** The chief needs to report medical disputes or patients' complaints occurring in the department, cooperate with the

investigation and mediation, and afterwards in the rectification involved in complaint handling. The number of complaints concerning a specific department is one of the performance indicators for both the department and its chief, eventually connected with the department's bonus and the director's personal bonus.

- **For concerned medical staff:** Each medical staff member needs to report any patient complaint caused by medical services he or she has provided, and must cooperate with the investigation. The number and degree of complaints received is one component of his or her performance indicators, eventually connected to bonus or public criticism (if serious) but also with career development, such as postponement of promotion, job retraining and so on.

A hospital director said:

> *We include valid complaints in the personal assessment. If one health provider receives more than two valid complaints a year, he is punished by [being sent to] for job retraining, or fired from the position.*
>
> (Female, GR-Implementer-5, 06-09-2011)

> *Our hospital has "three standards," evaluated once a quarter. The first one requires that your department cannot have received a valid complaint, which means the quality of medical services has been high. Another evaluation standard includes lots of indicators, such as your profits, health insurance etc.; it also occurs once a quarter. If a department meets each of the three standards, our hospital will reward it once a quarter. That is in addition to the [usual] bonus. Departments receive monthly assessments of medical care, nursing, disputes, health insurance, as well as "spiritual civilization" participation. The points for each [component] differ [but] the sum equals 100. The higher your score, the higher your bonus. This [particular] assessment determines your [monthly] bonus.*
>
> (Female, GR-Implementer-5, 06-09-2011)

> *Once a quarter, department chiefs also undergo assessment based on more than twenty items. The assessment contents are considerable [including], for example: whether your department has received no valid complaints; how many [positive] points your department has received; and [how high] the quality of its medical services has been during the quarter.*
>
> (Female, GR-Implementer-5, 06-09-2011)

5.3.3.4 Approaches

- **State-centered approach Concurrent administration:** MAPCH's contents were nationally administrated concurrent with other regulation in order to stimulate hospitals to pay more attention to GR services and to improve MAPCH's effect.

- **Quality regulation:** The government promulgated the regulation formulating service quality standards to normalize the complaint handling process in hospitals and to protect the interests of consumers. The purpose of quality regulation has been, first, to improve GR service quality and the efficiency of resource allocation, and, second, to safeguard people's legitimate rights and interests, promoting overall population health.

- **Administrative supervision:** This regulation has mainly relied on administrative supervision, with health administrative departments effectively administrating subordinate institutions.

- **Market-oriented approach**

- Market forces do not come into full play in the regulation's administration because most Chinese hospitals are public ones, owned by government.

- Private hospitals pay more attention to patients' complaints, and strive to establish good reputations.

- **Consumer-oriented approach**

- **Original intention of the regulation**: This regulation originally intended to strengthen public scrutiny of hospital medical services; regulate the establishment of consumer feedback channels; resolve small disputes within hospitals when consumers complain; and safeguard consumers' legitimate rights and interests.

- **Regulation publicity**: After issued, the regulation was published online immediately. Consumers can learn about the regulation from the Internet. Hospitals also publish complaint channels aimed at protecting the interests of consumers.

5.3.3.5 Mechanisms

- **Multi-actor participation in the definition of regulation:** Different actors were involved in formulating the regulation process: the MOH, the provincial BOH, experts, hospitals and patients. Each played a role in the

definition, but influenced it differently.

- **Concurrency with other regulations:** As a guideline, this regulation doesn't have strong force, and it contains no unified mandatory requirements for all types of hospitals. But it is concurrent with other regulations related to medical service quality, which as a whole constitute an integral assessment. They support each other, intending to improve health care quality.

- **GR Information System:** Shanghai's BOH established the first system to monitor the quality and safety of medical services. That system now covers all medical institutions in the municipality of Shanghai, and includes five elements—collection, analysis, feedback, assessment, and early warning—to strengthen and unify GR information management. The system helps understanding of the issues that result in patients' complaints with health care delivery; it is also necessary for a good supervision system and effective incentive mechanism.

- **Multi-department collaboration:** One department alone can't properly resolve all patients' complaints received from inside and outside the hospital. Within the hospital, effective GR needs close cooperation between clinical departments and the Complaint Reception department. The Complaint Reception department carries out investigation and verification, and puts forward solutions with various departments. When receiving patients' complaints, the majority of Complaints Reception departments respond quickly, in order to resolve the issue rapidly. When certain large medical disputes occur, the hospital will initiate a rapid response mechanism: hospital leaders will organize matters, joining panel discussions and complaint handling as soon as possible. Outside the hospital, effective GR also needs smooth connections with other channels, as well as efficient cooperation between institutions.

- **Incentives:** Effective GR administration in hospitals mainly relies on a range of department and individual incentive mechanisms, including those related to compensation, promotion, honor, and the spiritual.

5.3.4 Actors

Table 5.3.2 shows all the actors at different levels of GR regulation. These actors have different role inside the hospital and/or outside the hospital. In regulation definition, the MOH, BOH, and researchers are determinants for policy-making. Moreover, the BOH, HII, and hospital owner play the most important roles in administration. For regulation implementation, however, the internal hospital actors— especially the hospital director, the GR Reception

department, and the Clinical department—are key for GR service delivery.

Table 5.3.2 Actors in GR regulation

Actors	Process	Area	Approach	Influence Level
MOH	Definition, administration	Government	Command and control	****
BOH	Definition, administration	Government	Command and control	****
HII	Administration	Government	Command and control	****
Hospital owners	Administration	Government	Command and control	***
Hospital directors	Definition, administration, implementation	Internal hospital	Command and control	*****
Clinical department leaders	Implementation	Internal hospital		****
Complaint reception department	Implementation	Internal hospital		*****
Physicians	Implementation	Internal hospital		****
Patients	Implementation			*****
People's Court	Implementation	Government	Command and control	*
Medical associations	Implementation	Civil society		**
Hospital attorneys	Implementation	Enterprises	Market-oriented	**
People's mediation committee for medical disputes	Implementation	Government/civil society	Consumer-oriented	***
Insurance companies & process centers for medical malpractice liability insurance	Implementation	Enterprises	Market-oriented	*
Policy security department	Implementation	Government	Command and control	*
Local government	Implementation	Government	Command and control	*
Community	Implementation	Government	Market-oriented	*

5.3.4.1 External hospital actors involved in definition and administration

- **MOH**

The MOH's role is to propose health system development strategy, allocate resources, and organize and manage health care service delivery. It is accountable to the State Council and in charge of developing the Chinese health system, providing good health care services, improving citizen's satisfaction, and improving the accessibility and equity of health care.

The MOH is mainly responsible for policy-making. However, it plays a limited role in regulation administration and implementation. An accountability analysis of GR regulation indicates that GR is not a priority of the MOH, so obviously the MOH didn't pay much attention to it. This was evident in that no regular and powerful inspection system for its regulation application was established, nor any sanction related to GR service delivery. In short, for GR cases, no specific accountability exists.

- **Shanghai BOH**

Shanghai BOH's role is to propose health system development strategy, allocate resources, and organize and manage health care services delivery at the local level. It is accountable to the Shanghai Municipal Government. But still no specific accountability for GR cases exists.

The BOH is one of the key actors in GR regulation interpretation, powerful enough to influence GR service delivery. However, GR services are not a set priority of the BOH administration since the BOH isn't accountable to local government for GR. GR pertains only to evaluations, such as those of medical care quality, hospital ratings, and hospital directors'.

- **HII**

HII's role is to supervise health institutions' behavior on behalf of the government. It is the BOH executive body in charge of health inspection, such as receiving reports of medical malpractice from all local medical institutions, and assessing the quality of medical services. It also is involved in administrative mediation; addresses health insurance complaints it receives by forwarding them to the corresponding hospitals and urging they be handled; receives exposure of illegal activities of hospitals; inspects medical practice activities; and carries out administrative penalties for illegal activities.

The HII is accountable to the BOH. The HII administrates hospitals on behalf of the BOH. However, the HII has no authority to sanction or otherwise punish if a hospital has failed to deliver GR services.

- **Hospital owners**

The role of hospital owners, as government departments, is to develop and

enhance hospitals in Shanghai through budgetary means. They propose development strategies for certain hospitals, allocate health resources, and improve accessibility and equity of health care delivery in Shanghai. Hospital owners interpreted the GR regulation in terms of GR services. They forwarded the regulation and developed assessment details, such as those assessment indicators of the regulation that have currently become included in hospital directors' assessments.

Hospital owners are accountable to the Shanghai city government. A hospital owner can appoint a hospital director, affect the government's annual subsidies to hospitals, and is powerful enough to influence a hospital's behavior. However, each hospital owner operates just a small number of public hospitals, so has no power over other hospitals. Hospital owners also pay less attention on GR services because they aren't accountable to the government for GR services.

- **External hospital relationships:**

• Hospitals are accountable to the BOH or the hospital owner; these are the key actors in changes of hospital behavior. The HII supervises hospital behavior during regulation implementation. Hospitals are still accountable to the HII for quality issues or illegal activity.

• However, the BOH, the HII and hospital owners assume no specific GR accountability with respect to the hospitals. All bodies—the BOH, HII and hospital owners—are government departments, and have not set GR as a service priority.

• No actor except for government departments is powerful enough to influence hospital behavior, especially the behavior of public hospitals.

• Patients have no voice in hospital supervision. This may be one reason for patients' lack of impact on GR service delivery inside hospitals.

5.3.4.2 Internal hospital actors

- **Hospital leaders**

The role of a hospital leader is to propose hospital development strategy, allocate resources inside the hospital, and organize and manage health care services delivery. Accordingly, hospital leaders should develop a system for and administration of complaint handling for GR services within their hospital, and take part in the handling of major cases, such as organizing discussions by experts at the hospital and developing rectification measures.

The hospital director is a key actor in GR regulation implementation. He is accountable to government departments—such as the BOH, the hospital owner, the HII and so on—for hospital performance, operation and development; he is not accountable to the BOH/hospital owner, however, for GR services. Nonetheless, after the regulation, GR services have become a small measure of hospital performance or quality. So directors now pay more attention to GR services. This has somewhat improved GR service delivery. However, some issues in GR services still remain, particularly in meeting consumer demand.

- **Complaint Reception departments**

The Complaint Reception department's role is to provide GR services. It receives patients' complaints by call, letter, visit, and/or transferral from other departments or institutions, such as the LVs system; files patients' complaints; investigates and verifies complaints with the concerned clinical departments and the complainants; develop solutions; gives feedback to complainants within a fixed time; makes an appointment with them and the concerned clinical departments to organize mediation; files and reports the results of complaints; proposes rectification recommendations; assesses the performance of clinical departments and medical staff; and provides evidence for policy-making.

Complaint Reception departments are the main GR service providers. They are accountable to the hospital leaders. However, they do not have enough power to fulfill their responsibility. Complaint Reception departments cannot sanction or punish other key GR providers, such as physicians or clinical department directors, in the delivery of GR services. This indicates that Complaint Reception departments can provide neither sufficient GR services nor one of satisfactory quality.

- **Clinical department chief**

The role of the clinical department chief is to propose development for his or her department, to allocate resources within it, and to organize and manage specific health care delivery. For GR services, the clinical department chief resolves minor complaints on the spot; reports unresolved complaints to the Complaint Reception department, cooperates with the investigation organized by the Complaint Reception department, states the facts of the complaint, organizes discussions of medical disputes within the department, participates in mediation as the department's representative, and afterwards implement rectification.

The clinical department chiefs are accountable to their hospital leader.

However, no definition exists as to what accountability is being sought, nor any standard of what that accountability might mean to him or her. So other factors such as private relationships, intrinsic work value, good reputation, and so on are the key determinants that encourage clinical department directors to provide GR services.

- **Health providers:**

Health providers' role is to provide diagnosis and treatment services. For GR services, they provide exact information in GR case investigation. Health providers are accountable to their bosses or hospital directors for quality health care. However, currently, an absence of standards for sanctions or punishments exists, particularly one based on an exact classification of GR cases. Aside from generally preventing the grievances of patients, health providers encounter no clear-cut accountability mechanism that might improve health provider-patient communication, or perhaps provide biopsychosocial medical care.

- **Internal hospital relationships:**

The hospital leader is the key determinant of GR service delivery inside the hospital. However, a leader is not accountable to his boss for GR cases. No clear and strict measure (such as reward or punishment) exists to push such a leader to set GR services as a priority.

GR services operate best when provided through multi-department cooperation, with the Complaint Reception department acting as coordinator. However, clinical department directors are not directly accountable to the Complaint Reception department for GR services. This lapse is one obstacle in the coordination of GR service delivery inside hospitals.

There is weak or no patient's voice in GR service delivery inside hospital.

Importance of personal relationships in GR services within hospitals:

– In most hospitals, the Complaint Reception department functions at the same level as the clinical departments, so their power is almost identical. Sometimes the concerned clinical department can't entirely understand how the Complaint Reception department resolves its complaints. Proper resolution depends more on personal relationships and good communication than on power and hospital rules.

– This phenomenon is more common in tertiary hospitals: generally speaking, the clinical department chiefs of the tertiary hospitals have a wealth of clinical experience and superior capabilities. Their positions are

always high, and they judge cases more hard and fast. Handling complaints, the Complaint Reception department invites them to participate and support arriving at solutions through good personal relationships.

An administrator said:

> *These [complaints] are not very principled. We can handle them in the hospitals, but it often depends on your personal relationship.*
>
> (Male, GR-Administrators-2, 18-08-2011)

A hospital director said:

> *Because our hospital is a secondary hospital, the department chiefs are more cooperative than those in tertiary hospitals. Department chiefs in tertiary hospitals are experts so they are more arrogant. Sometimes even if the hospital director talks to the chief, the director will speak very courteously at first, then ask him to do something later. As for me, I was born and raised in this place, so everyone is relatively understanding and supportive.*
>
> (Female, GR-Implementer-5, 06-09-2011)

A grievance handler in a hospital said:

> *Recently a fierce medical dispute occurred. Because of a possible misunderstanding between administrative departments, (abusive) words erupted. Staff responsible for redressing grievances (almost) crashed emotionally, and wanted to resign—it was to that point. So we need understanding and support among colleagues.*
>
> (Female, GR-Implementer-3, 31-08-2011)

- **Patients**

The role of patients is to make payment in the purchase of health care services. Patients are one of most important actors in GR service delivery. They make complaints, and are later involved in GR.

Patients should demand accountability of hospitals and/or physicians through GR services. And they should be involved in the regulation process in more organized and active a manner. Currently, however, they have no power to influence hospital behaviour. This absence of power is probably related to patients' lack of agency.

5.3.4.3 External hospital actors involving other legal GR channels

- **People's Court**

If both parties concerned in a dispute are unwilling or fail to succeed at consultation or mediation, the parties may bring a civil lawsuit[o] before the People's Court. The complainant may directly bring a civil lawsuit, too.

Judicial departments are equipped with mediation centers before litigation. As a pre-litigation procedure, the People's Court carries out the mediation, on a voluntary basis. A lawyer from a community Legal Aid Center said,

> *[Judicial departments] are equipped with mediation centers before litigation. Yet this center is not only for medical malpractice but also for everything [...] In municipal Shanghai, the centers are categorized. [There is] for example, the Mediation Center for traffic accidents, the Mediation Center for medical malpractice […] Other areas also have mediation centers before litigation, because mediation before litigation is stipulated by the Ministry of Justice. All People's Courts have mediation centers before litigation […] Civil lawsuits go through a mediation procedure before litigation; [this] began in the second half of 2009 […] The first procedure before litigation is mediation.*
>
> (Female, GR-Other actors-6, 27-11-2011)

In addition to the above conventional judicial lawsuit procedures, one respondent said he had tried an innovation, i.e. a "simple court." It simplifies the process of mediation by the People's Court, facilitating the process for both health staff and patients. A grievance handler in a hospital described:

> *We have tried that kind of innovation. In 2008 we resolved a medical dispute properly [that way…] We had tried lots of consultation with the complainant [but] he was still unsatisfied. In discussion with the People's Court of our district, we adopted a new method. That is, simple court mediation, to streamline the process. The normal [judicial] process is: write an application; the court accepts; [the court] makes an appointment with both parties to investigate; finally a court session opens and mediation [occurs]. That process is time-consuming. So when we discussed the case with them [the court], they also wished to try the new method […] After the judge had [read and] understood the case, he came to our [hospital] wards to hold court. Both parties stood at either side, stating the case. And at last the court resolved the conflict, in our hospital.*

[o] Civil lawsuits are disputes over the status of property and persons among citizens, legal persons or other organizations respectively and mutually between citizens, legal persons and or other organizations.

(Male, GR-Implementer-6, 08-09-2011)

- **Medical associations**

The health administration department shall, after it receives a report on any serious medical fault from a medical institution or an application to settle a medical accident dispute from a party to a dispute, transfer that report or application to the medical association responsible for technical identification of medical accidents in order to organize whatever technical identification is needed for the medical accident; where both the medical institution side and the patient settle their medical accident dispute through consultation but require technical identification of the medical accident, they shall jointly invite the medical association responsible for technical identification of medical accidents to organize that identification.

- **Hospital attorneys**

Hospital attorneys provide legal counsel for hospitals, including legal consultation and legal advice. A hospital attorney explained:

> *[We provide services] according to the different demands of each hospital. Usually we act as legal counsel for them. They consult us on certain legal issues, such as how to handle this matter [or that]. We then give them legal advice, oral or written. If they want to contract with other institutions, they consult us. Some institutions pay for large projects, which [include] a procedure for lawyer review [and] comments.*
>
> (Male, GR-Other actors-2, 15-09-2011)

> *Especially when major medical malpractice happens, they will come first to us to discuss handling strategies and analyze risks. We are different from other lawyers. We were [originally] physicians, and then became lawyers [specialized in] medical disputes. We have a strong ability to determine whether the concerned hospital bears responsibility, and what the finding will be.*
>
> (Male, GR-Other actors-2, 15-09-2011)

Lawyers participate in civil actions based in medical disputes, on behalf of the hospital. When asked, “So, generally speaking, [if] litigation occurs between your client hospital and patients, the hospital will ask you to represent?” the hospital attorney nodded (in agreement).

- **People's Mediation Committees reconcile medical disputes**

These mediation committees composed of retired judges and physicians currently carry out “people’s mediations” of medical disputes occurring in local medical institutions; report findings on these “people’s mediations” of medical disputes to judicial and health administrative departments; analyze the causes of medical disputes; and offer advice on the prevention of medical disputes.

- **Insurance companies and process centers for medical malpractice liability insurance**

These insurance entities assist the investigation and handling of medical malpractice; oversee prevention guidance for medical risk of insured medical institutions; and take charge of determining the nature, responsibility, damage, and compensation of medical malpractice.

5.3.4.4 Other external hospital actors

- **Police security departments**

Police security departments maintain medical order when “Yi Nao” happens. A hospital director said:

> *When we call, [the police] come quickly. We dial 110 to call the police station, and the local police immediately come. When “Yi Nao” happens, police come soon. If [those “Yi Nao”] patients don’t affect the medical order, they won’t have to arrest them. They keep watch. If patients do disturb the medical order, they will arrest them.*
>
> (Female, GR-Implementer-5, 06-09-2011)

- **Local government**

Local government also receives complaint letters and visits (LVs) from patients, and then transfers related cases to the LVs office at the BOH.

- **Communities**

Certain communities help resolve a small number of medical disputes. A grievance handler in a hospital said:

> *We [agreed to] compensate a certain amount of money. But the complainant asked for more. The community or village supported [extra] compensation. Of course, that [extra] compensation was given to the complainant, alongr with our hospital’s [portion]. It was impossible to tell the complainant that [some] of the compensation had been paid for by the community, yet the community actually had joined in our financial compensation.*

(Female, GR-Implementer-2, 25-08-2011)

5.3.4.5 Actors' powers and relationships

- **Regulation definition: Actors' influence map (2009)**

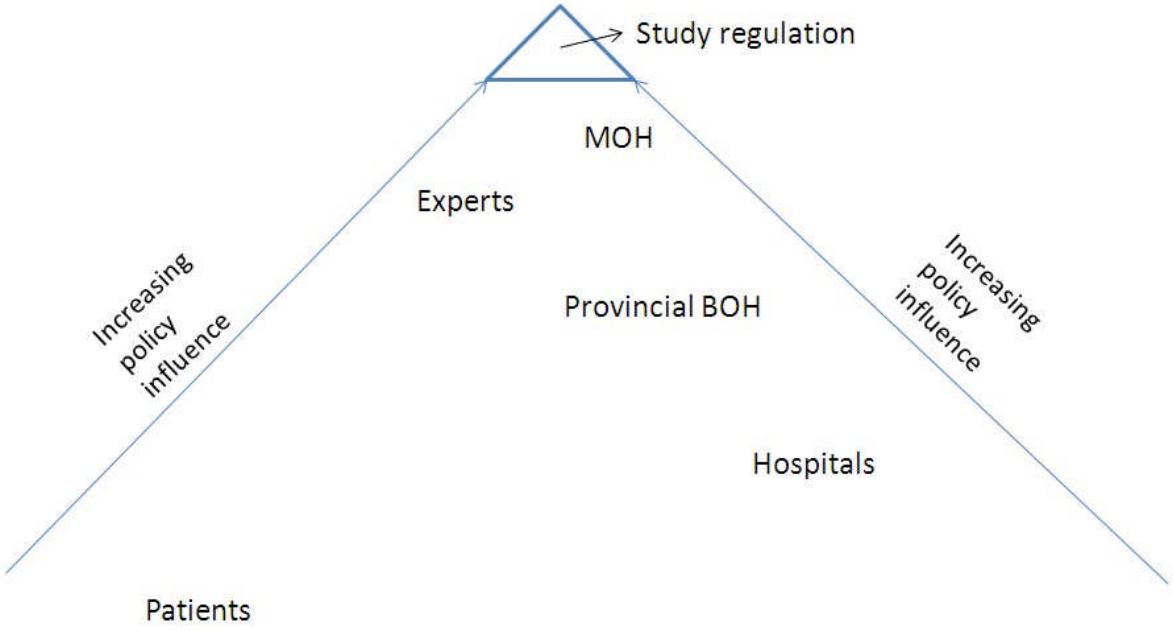


Figure 5.3.5 Actors' influence in MAPCH definition

The MOH was involved in the entire definition process. It made the final decision, modified the document and issued the regulation. It was the most important actor in this process.

Researchers and the provincial BOH were also involved in regulation definition. They collected evidence, wrote policy briefs, conducted consultations and so on. These actors were likewise important and necessary for policy-making: they carried out literature analyses and field investigations to find evidence for policy-making, and they conducted investigations of health providers and patients to understand their opinions on and advice for handling complaints in hospitals. Academic experts also attended several rounds of consultation meetings and validation meetings.

Although hospitals have been the main actors implementing the regulation, they were partly involved in regulation too. Compared to the MOH, BOH and researchers, however, hospitals were less important to regulation definition.

Unfortunately, consumers weren't directly involved in policy-making. Patients' opinions and advice were collected through a review of literature and

consultation with experts, and was mainly focused on their current awareness of how complaints are currently handled in hospitals. Consumers had a minor impact on regulation definition.

- **Regulation administration**

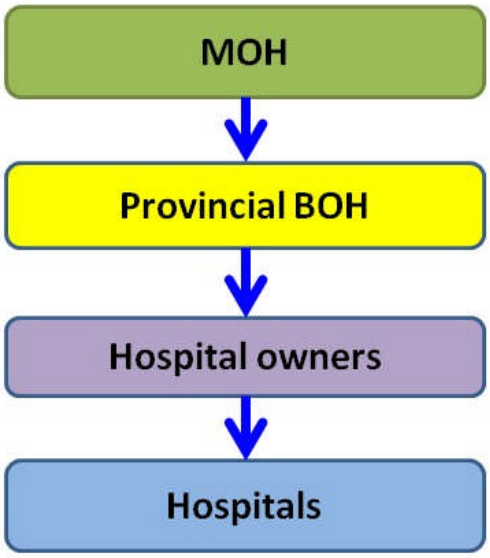


Figure 5.3.6 Actors' relationships in MAPCH administration

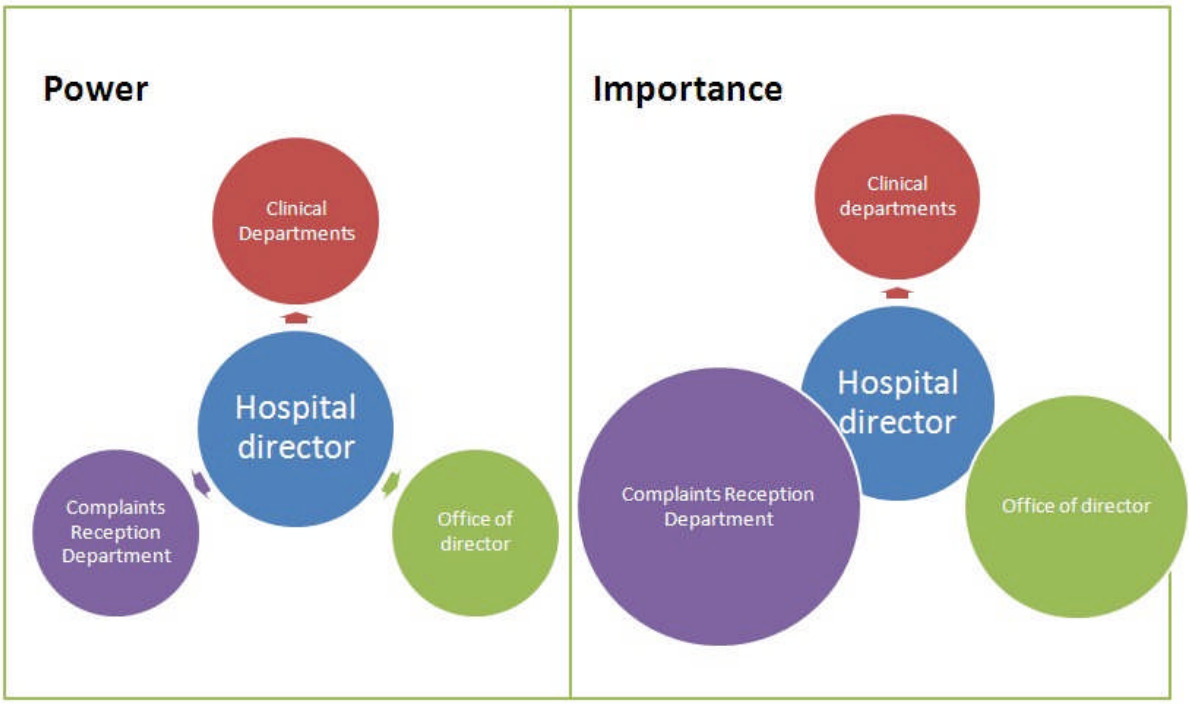
Administrative supervision was the main mechanism in the administration of the regulation, and it reflects a state-centered approach. Two other approaches have been present in regulation administration—market-oriented and consumer-oriented ones—but their influence has been relatively minor.

Hospital locations depend on regional planning, so each different hospital, especially the public ones, generally gets a fixed market share. In addition, GR services are not the main services provided by hospitals. So market discipline has not been able to play a meaningful role in regulation administration. Moreover, in competition with public hospitals, private hospitals have gradually become aware of (and use) their advantage in services experience: they pay more attention to patients' complaints as they strive to establish good reputations.

Lastly, the issue of patients' complaints belongs to the domain of public scrutiny, for it is by nature consumer-oriented. Currently, however, some hospitals do not as yet attach any importance to GR, nor do they include GR as an important service. Public scrutiny lacks power, so it cannot compete with medical institutions. Under these circumstances, not only do consumers not play the full role they might, but also conflicts grow more and more fierce. In particular, the news media can focus quite selectively, and tend to attract their

audience by highlighting reports of adverse events.

- **Regulation implementation**



Left: Size of bubbles represents power
Right: Size of bubbles represents importance

Figure 5.3.7 Actors' power and relationships in MAPCH

In terms of power, the director in charge of GR at the hospital is the most powerful actor in a hospital's complaint handling process. He manages different subordinate departments that also handle complaints. Subordinate departments in most hospitals are at the same level, basically equally powerful. In a few hospitals, the Complaint Reception department is set under the Medical affairs department, which assesses the performance of other clinical departments. This kind of Complaint Reception department may have more power, but that power depends on how much attention the hospital leaders pay to it.

In terms of importance, the Complaint Reception department handles most of the complaints from patients. The office of the director deals with return visits, patients' letters and satisfaction surveys. Clinical departments are responsible for handling minor complaints on the spot, according to "First reception responsibility." The director, in addition to guiding major cases, receives some patients' complaints on days designated "hospital director reception days.".

5.3.5 Effects

In this section, we will analyze different indicators of effects. For this case, the end effect of the regulation is represented by *accessibility, equity and efficiency* in GR service delivery. These effects are influenced by the results of regulation: *responsibility, participation, and accountability.* This section of the study will analyze accessibility, equity and efficiency, and then will address responsibility, participation and accountability. Lastly, *transparency* will be considered.

5.3.5.1 Accessibility

Intended effect on accessibility

Designers and administrators agree that the regulation defined clear complaint channels, encouraged hospitals to establish complaint management procedures on their own, improved hospitals' complaint services, emphasized the value of patients' complaints in hospitals, and established the concept of a "patient-centered" perspective in areas other than just medical services. Over the long term, the regulation has to some extent improved access to quality health services**.**

> *As a whole the regulation works well… It would be different if there was no this file.*
>
> (Male, GR-Designers-2, 22-12-2011)

> *Complaint reception has improved a lot; I'm quite sure about that.*
>
> (Female, GR-Administrators-4, 30-11-2011)

Designers, administrators and implementers agreed that hospitals had allocated enough resources to provide GR services, which basically solved the earlier problem that nowhere in hospital could patients direct their complaints.

Designers believe that, despite insufficient evidence, the regulation effect has significantly improved the accessibility of hospitals' complaint-handling services: Now every hospital has a department and staff designated specially to receive complaints. Administrators told us that while patients may perhaps not feel satisfied by the handling of their complaints, certainly they felt no problem expressing those complaints. Patients now have more routes by which to complain in hospitals, not just in complaint offices; on certain special days, for instance, they may talk face to face with the hospital director.

Implementers also indicated that besides increased availability of special

departments and staff in hospitals, signs for and information about complaint reception are apparent in hospital outpatient halls, in-patient buildings and other places patients frequent, whether guided there or not by hospital staff. So delivering a complaint can no longer be difficult for patients. This state of affairs indicates some improvement in accessibility to GR. Grievance handlers, health providers and administrators all expressed this same view:

> *Before, patients didn't know where the complaints management department was [...] Now, whatever [happens], you can find it in any hospital.*
>
> (Male, GR-Designers-2, 22-12-2011)

> *At least patients no longer feel they have nowhere to complain to. Complaints are accepted all-day, every hour except at night […] I can't remember any patient saying he or she had failed to find a department in the hospital to listen to him.*
>
> (Female, GR-Administrators-4, 30-11-2011)

> *In a hospital, the complaint management department's services are available during work hours, and there are branch offices for outpatients and in-patients. Plus, patients can talk face-to-face with the hospital dean on Wednesdays […] Our country has done this work quite well these [last several] years.*
>
> (Male, GR-Other actors-2, 15-09-2011)

> *You can see the poster at first sight when walking into the outpatient hall. There is a sign to show where the complaint management department is, where the health insurance department is, and also other related departments. It is very easy to deliver a complaint. Plus, you can express [yourself] to the hospital representatives in the hall, and volunteers help you to explain too.*
>
> (Female, GR-Implementer-5, 06-09-2011)

First reception responsibility is a key factor in improving GR service accessibility. It is expected to solve problems in lapses of responsibility caused by passing the buck and in uneven cooperation among hospital departments and staff. It is also expected to exert positive pressure on hospital staff to set up and maintain a complaint reception process easy for patients to handle; keep the patient's anger at the lowest possible level during complaint reception; avoid the case's escalation into a more serious complaint; and finally to achieve the goal of smooth complaint resolution. An administrator and a

grievance handler both expressed this:

> *The responsibility of who must accept the complaint first is outlined in the regulation; [it] hadn't been emphasized before. I recognize [this] as a highlight, for it means [you must] deal with complaints [right] at the very first.*
>
> (Female, GR-Administrators-4, 30-11-2011)

> *Q: How do you deal with complaints when they arrive in your department?*
> *A: Whoever receives the complaint [first] takes the responsibility. If the patient is up against the whole hospital, we invite related departments to discuss [the issue], and then investigate to find out what the facts are. At the end of the discussion, a conclusion comes out, with feedback we return to [whomever] the complaint originated from.*
>
> (Male, GR-Implementer-7, 16-09-2011)

Unintended effect on accessibility

Patients feel differently, however. Although providers said that the regulation improved accessibility, users do not always feel that means accessible to them. One user looked up the hospital telephone number on the Internet, then while on the call, complained to the hospital. She said the complaint redressal process was "very easy." However, other user interviewees, according to their experience, didn't think it was easy to access redress when they wanted to complain. Though all these users had a strong desire to complain, none was able to find signs directing them to the Complaint Reception department in the respective hospitals. They recalled their experience, and told us the signs to the complaint office failed to catch the eye, and in some cases there were even no signs at all. In short, finding the Complaint Reception department is not as convenient for users as providers have been thinking. Furthermore, sometimes during the complaint process, health providers (other than grievance handlers) couldn't provide sufficient help to complainants. In fact, from the time they first decided to complain up to the actual reception of their complaints, for some their anger became more and more serious:

> *I didn't know who to complain to. You see, the Complaint [Reception] department is in this building [rather than the one with the clinical department], which we had never heard of before, since I had been treated in another building. In the building where I was treated, who I could complain to?*
>
> (Female, GR-Users-1, 01-09-2011)

Q: Did you ever notice any sign or poster in the hospital showing where to complain to? Was there such information in the In-patient Notice?
A: No.
Q: So, through talks with hospital staff you got to knew all other GR channels, besides complaining in the hospital?
A: Yes.

(Male, GR-Users-5, 25-11-2011)

5.3.5.2 Equity

Intended effect on equity

Implementers believed that **the complaints handling process was equal for every patient**, and generally the process is not altered by patient's individual factors. Some interviewees mentioned that media and public supervision is quite strong nowadays, so hospitals ensure patient are treated equally, as much as possible:

Relative equity. Of course, in practice we value the hospital's interests more, but I should say it is more or less equal, since there is a [standard] process.

(Male, GR-Implementer-1, 15-12-2010)

Now the situation is different from before. Transparency in society has gotten better and better with the development of internet. We don't cheat patients.

(Female, GR-Implementer-3, 31-08-2011)

Unintended effect on equity

However, differences still exist in the mediation plans of similar cases, reflected mostly by different compensations. When dealing with a dispute, especially when normal medical service delivery is being affected by a complainant's radical behavior, hospitals try to quell the case as soon as possible. Hence, in the negotiation of compensation, they are likely to agree to a high compensation request from such a complainant, just to close the case. The tougher and more radical the actions a complainant took, the higher the compensation they would receive. An administrator and two grievance handlers explained:

If the patient feels dissatisfaction and starts a quarrel, usually he or she will get some money from the hospital. Strictly speaking, we do not need to pay

them, but we [do] have to pay a little to resolve the case. This may be not equal to other patients [nor] right, since no quarrel [means] no money.

(Female, GR-Implementer-2, 25-08-2011)

The fiercer the patient is, the more we pay. In the cases of hymen laceration, suppose there are two patients: [for the] easy-going one, the compensation will not be much; [for the] tough one who calls it a rip-off, the compensation is likely to the higher.

(Female, GR-Implementer-3, 31-08-2011)

The patient is sure to get less if he or she is too kind.

(Male, GR-Administrators-2, 18-08-2011)

Besides costs that patient must spend on his or her complaint and actions taken, **geographical differences impact compensation.** Differences in levels of economic development and rights consciousness impact the results of complaints handling, a difference made significant in a comparison between coastal and inland areas, and urban and rural areas: in a single hospital, claims raised by local and not local patients may be valued differently, taking into consideration the possibility that people from other areas have a smaller personal net and weaker power to influence, and cannot exert as great a pressure on the hospital as local people can. As a user said:

Q: You said it's partly because you are not local. Do you have evidence?
A: I just felt so. I felt some difference. But my feeling may not be the truth.

(Male, GR-Users-5, 25-11-2011)

A staff member from a process center for liability insurance supported that view:

There is regional difference. The compensation of similar cases must be different in central urban and rural areas.

(Female, GR-Other actors-5, 23-09-2011)

Nonetheless, health providers felt they might be treated unfairly in complaints handling. In some cases the patient experienced inconvenience when receiving medical services not because of any inappropriate attitude or behavior on the part of health providers. Too long a waiting time, or too little time spent with the doctor are caused by limited medical resources and/or imperfect resources allocation; these are health system issues rather than problems caused by individual hospitals or physicians. At other times,

dissatisfaction voiced in the hospital may be related to a health insurance policy rather than hospital or staff behavior. Currently, dispute cases resulting from health insurance funds trying to control health expenditures occur a lot. A physician said:

> *Complaints occur that the patient wants more drugs but the doctor has failed to meet his or her needs. Why? The health insurance institution sets a limit for drug expenditure for each hospital, and the hospital sets a limit for each doctor. So if a doctor has had too many patients with health insurance that month, he or she may very possibly have exceeded his/her limit.*

(Male, GR-Implementer-9, 16-09-2011)

In such a case, there may be no serious mistake or fault in the physician's behavior. But the patient doesn't know that, or even if the patient does know, he or she cannot find any better target to complain to. **So, to a certain extent, physicians and hospitals have become scapegoats of the entire health system**. Sometimes the hospital may even punish the physician in some way for such a case. A physician said:

> *Sometimes it's not us physicians who have made a patient angry. Certain factors are rooted in the context, but we physicians [end up] taking on the guilt.*

(Male, GR-Implementer-9, 16-09-2011)

5.3.5.3 Efficiency

Intended effects on efficiency

The regulation requires that deadlines be set for providing feedback to patients. While a clear time limit improves efficiency in handling complaints and ensures that patients are able to follow up on the complaint process, feedback deadlines do not limit overall processing time, so this requirement does not disrupt normal hospital work. A grievance handler from a hospital explained:

> *Feedback is part of the process of handling complaints […] feedback should be given within a set time period. But feedback is not necessarily the final result of the process. Of course patients should receive feedback [within the deadline].*

(Male, GR-Implementer-1, 15-12-2010)

One designer stated:

There was no feedback deadline, so hospitals reacted slowly. Now with the requirement, hospitals have to send feedback within a limited time period.

(Male, GR-Designers-2, 22-12-2011)

Grievance handlers from a range of hospitals whom we interviewed answered that their hospitals had indeed implemented feedback deadlines according to the regulation. Some noted that feedback is sometimes provided before the deadline. Statements from grievance handlers include the following:

Within five working days. We give feedback within five working days.

(Female, GR-Implementer-5, 06-09-2011)

We send feedback within seven working days at the latest.

(Male, GR-Implementer-7, 16-09-2011)

Every administrator and implementer reported improvements in the quality of healthcare after handling patients' complaints, and gave similar examples. Two of the five users interviewed reported improvements in their care after submitting complaints.

Unintended effects on efficiency

Regarding efficiency, the patients we interviewed provided a range of evaluative responses. (We did not select patients whose complaint had been submitted in the same hospital as the hospital where the staff members we interviewed worked). One user received feedback close to the deadline. Another user contacted the hospital a second time after many days of waiting, was welcomed and received feedback. Still another user never heard from the hospital again, even after the hospital promised to provide the required feedback. Patients' evaluations regarding hospital complaint management efficiency focus on whether hospitals provided timely feedback as promised. Three patients we interviewed were dissatisfied with the process and took other GR channels. Patients reported a range of results:

I think five days at least. I remember I got feedback after a week.

(Female, GR-Users-3, 20-09-2011)

A week went by and there was no message at all. [After] another week went by I got worried. I called them on the second Friday.

(Male, GR-Users-5, 25-11-2011)

Over the course of several months [the time between making the complaint and the birth…] there was no call, no visit from the hospital, nothing.

(Male, GR-Users-4, 24-11-2011)

5.3.5.4 Participation and responsibility

The first step in this study was to identify the actors involved in the processes of the regulation. We then analyzed and compared what each actor should do with what various actors have actually done. Next, researchers analysed responsibility and accountability, focusing on how and why the participants acted as they did.

Many actors were involved in the definition, administration and implementation of the GR regulation. Regulation documentation clearly defines main actors' responsibilities and standard procedures in GR service delivery. Actors from the central government and local governments played important roles in formulating and administering the regulation. Local government actors with power played influential roles in managing implementation and were a key determinant, though they did not participate in on-site regulation implementation directly.

Hospitals and health care providers, especially public hospitals, were the most important actors with regard to implementation, including the allocation of resources necessary to provide GR services, but they played a minor role in regulation definition.

Managing patients' complaints and improving satisfaction among patients is the regulation's objective. However, patients were not involved in the definition of the regulation or in its administration, and though they have been involved in the implementation of the regulation, they lack a strong voice and have little power.

In the GR case study, most actors were from the government or government-owned institutions. Few actors came from civil society or were market-based, possibly because of lack of representation by patients and the government's greater power.

5.3.5.5 Accountability

The document provides few definitions of strict accountability. According to the regulation, hospitals are accountable to the BOH for GR service delivery, and clinical department leaders and physicians are accountable to hospital directors for the quality of health care services, including GR services. However, there is no mention of what the status is of the type or degree of

accountability being sought, from whom such accountability would be granted or should be sought, or by what means those in positions of power are being held to account.

The regulation contains no mandatory national uniform requirements—as a general guideline, it doesn't include access, penalties or other enforcement mechanisms. There are no uniform requirements covering different types and levels of hospitals in different regions, so administration of the regulation has been attached to other regulations with stronger enforcement mechanisms, such as "Regulations on Medical Malpractice." In other words, the MOH has integrated MAPCH into other regulations and administers them concurrently. MAPCH implementation and a number of GR service quality indicators are a part of hospital quality assessments, hospital ratings, and hospital director performance assessments which, together, indicate that hospital directors, the BOH and the MOH have become more attentive to GR service delivery in the period since the regulation came into effect.

All of this, however, does not mean that they have made GR services a high priority. Indicators related to MAPCH and GR services are a small part of the overall package of assessment indicators, comprising less than 20 percent of hospital healthcare quality assessment, hospital ratings, and hospital directors' performance evaluations. Still, hospital directors are beginning to plan more for the provision of good GR services than they had before the regulation took effect. The amount of emphasis that hospital directors place on GR determines how hospital staff members interpret the regulation, which in turn affects GR service resource allocation, administration, departmental coordination, and so on. The incentive to prioritize GR remains weak among hospitals, and as a result, many hospitals don't consider GR a priority service.

A strong, precise means of creating accountability for GR service delivery within hospitals is lacking. Most departments that handle GR lack the authority and means to coordinate GR case investigations. Various means of holding clinical department directors and doctors accountable for providing quality GR services, including the threat of penalties such as sanctions or job reassignments, are lacking also.

In addition, consumers—another key actor—who wish to seek accountability from hospitals and their GR services lack the means to make their complaints heard or to assert and protect their rights.

In summary, there were no clear and strong accountability being sought in the regulation.

5.3.5.6 Transparency

- ***Transparency in definition***

During various phases of the regulation's definition, drafts were circulated at different levels of government for comment. The first draft was passed from the upper level, down to the health system at the lower level, beginning with the MOH, which passed it on to various levels of health administrations, then on to hospital owners and finally on to individual hospitals. Comments from regional administrators and implementers were collected and summarized by provincial health officials and then reported to the MOH; In addition, throughout the process, hospital and health administrators served as representatives, experts, and consultants in the process of project preparation, policy drafting, and regulation validation. After being circulated publicly throughout the health system for comment, a revised draft was posted to the Internet by the MOH with a request for comments from the general public. One administrator stated:

> *Before the file was published, during the definition process, we did participate. They were required to collect comments from us.*
>
> (Female, GR-Administrators-4, 30-11-2011)

After being issued, the regulation was posted as a public document to the Internet. Interpretations and comments from provincial health administrators, other local health administrations, and hospital owners are available to the public online too, as one designer explained:

> *The file is open to the public on the Internet. Everyone interested in can download it from the MOH website.*
>
> (Male, GR-Designers-2, 22-12-2011)

And a grievance handler said:

> *I read it as soon as it was available on the MOH website.*
>
> (Female, GR-Implementer-2, 25-08-2011)

Though users are free to view the regulation on the Internet, few have actually done so.

- ***Transparency in administration***

Hospitals do not make public the complaints they receive from their patients**.** Although most hospitals have set up systems for recording complaints and analyzing the cases, the resultant statistical data are also not made public. The

public release of complaints would benefit patients by helping them choose hospitals; public supervision of management of the hospital complaint system would also provide social benefits, but there are currently no institutions besides hospitals themselves that can perform this task. Individual hospitals do not have enough incentive to make public any negative information about themselves. Additionally, hospitals are too busy delivering medical services to allocate resources to make complaint information public. The municipality of Shanghai launched a pilot project in 2004 to make the information on complaints covering all Shanghai medical institutions available to the public. The project was welcomed by the public, but was shut down soon after launch due to heavy pressure from among members throughout the health system.

Furthermore, data on GR services has been utilized in assessments of hospital performance, healthcare quality, and so on. This means that the more that GR case information is reported, the worse the evaluations received by hospitals for their GR services are. Finally, hospitals are not held responsible for reporting complete and accurate GR information, so more and more hospitals are inclined to report selective GR data.

The municipality of Shanghai established the first system to monitor the quality and safety of medical services and the routine collection of GR information, including analysis and early warning. However, the lack of a standardized classification system for hospital complaints has resulted in a huge systematic bias in favor of individual hospitals in current analyses, presenting a major obstacle to creating meaningful comparisons among hospitals. And more importantly, none of this information has been provided to the public.

- ***Transparency in implementation***

Complaint channels are included in the information that hospitals make public. Posters are placed in outpatient halls and inpatient buildings, in complaint offices, and in related administrative offices, publicizing complaint channels. Complaint office locations are featured on signage throughout hospital departments. In addition, hospitals provide a mailbox in which patients can place letters of complaint, and hospital staff members guide patients with GR demands regarding available complaint channels. Complaint office telephone numbers are printed on inpatient notices and often featured in information booklets provided to patients. Some hospitals post complaint office contact methods on their own websites.

Hospitals publicize available complaint channels in a variety of ways, but differences among hospital practices influence the degree of transparency. A poster on the door of a complaint office is not as useful for patients as one on the wall of inpatient room, especially when the complaint office is located in a

remote corner of the hospital far from areas frequented by patients. Transparency is not often adequate at district level hospitals, for example, as a grievance handler from a secondary hospital explained:

> *I visited another hospital, a higher-level hospital, where I saw signs showing the complaint department location and process on walls of inpatient areas. Considering that in our hospital the only sign was in our office upstairs, I suggested putting signs downstairs, too. But the hospital director said it was not necessary, so we didn't do it.*.
>
> (Female, GR-Implementer-2, 25-08-2011)

Usually, the complaint handling process is not truly open to the complainant, and information exchanges are largely limited to hospital staff and administrators, not doctors or other staff more directly involved in the issue. In fact, a complaint office staff member generally provides a rather non-committal description to those patients who arrive wishing to be updated with specifics on their complaint process. If asked, the staff member will merely reply in a slightly off-hand manner that the hospital's quality commission has been discussing the case or yes, perhaps a certain clinical department may have committed a mistake. The complainant has no opportunity to directly engage in the handling of the complaint or to meaningfully participate in the process. In addition, hospitals tend to somewhat oversimplify cases, assuming that the complainant's role is simply to report their complaint and then receive compensation if justified. All this means that hospitals see little need to explain any details of the handling process.

After the reception of a complaint, investigation and validation are organized by the complaint management department and related departments. Sometimes, serious cases may be discussed by hospital experts and reported to hospital executive management, and even announced to all staff members as instructive examples. However, the entire handling process is disclosed only within the hospital. Therefore, the process becomes a "black box" to patients. It is easy for a hospital to manipulate a complainant by providing limited or selective information to gain advantage in negotiations, as grievance handlers have reported:

> *Sometimes you have to avoid something, and use negotiating skills. Mistakes in medical services do not necessarily harm patients' health, but they can be very serious for the provider [...] for example, someone may not be very careful when writing a medical record and alter it by accident. But you are likely to lose a lawsuit on the grounds of having tampered with records. In such a case, transparency is difficult.*

(Female, GR-Implementer-2, 25-08-2011)

After a complaint has been received and all related investigation, validation and discussion have taken place, hospitals come to a conclusion regarding the case and the recommended response, including, in some cases, plans to improve hospital processes. If the case involves a recurring or urgent problem, the results of the handling process may be shared with all staff for purposes of education and warning. But disclosure to complainants themselves remains selective. Results deemed of direct interest to patients, including compensation amounts and medical service privileges, are provided. Other results, however, including penalties imposed upon physicians and departments or improvement plans regarding hospital service processes, are often withheld from patients. Grievance handlers reported:

> *In individual patients' cases, what are the results of their complaints? How might a physician be punished? Such information is requested by patients occasionally, but not frequently.*

(Male, GR-Implementer-7, 16-09-2011)

> *Therefore, we cannot be completely transparent. But we can tell patients what they want to know if they ask.*

(Female, GR-Implementer-3, 31-08-2011)

5.3.6 Discussion

5.3.6.1 Is MAPCH a good case to study relevant GR regulation in China?

MAPCH is a guideline for hospitals' GR management and GR service delivery. It covers the basic GR process and was issued by the MOH. Previous analysis of this regulation in the context of policy background and policy goals shows that the regulation provides a real response in social and political contexts to government needs and the needs of hospitals and patients.

Definition of the regulation included several rounds of consultation and validation involving researchers, administrators, and hospital managers. It is not a compulsory regulation but rather a guideline, and content of the regulation is in accordance with its nature as a guideline. The GR regulation's procedures and processes have directly correlated with concurrent social and political conditions, at the municipal and national level, as well as those locally within Shanghai's health administration system, all of which both shaped and were also inherent to the GR regulation context.

To improve the effectiveness of this regulation, the MOH concurrently administers it with other regulations. MAPCH's contents were compulsorily incorporated into overall performance factors in hospital evaluations, health care quality assessments, and hospital directors' assessments.

5.3.6.2 How to best assess the capacities of actors in the regulation process, and identify direct relationships between actors and effects?

It is hard to identify the impact of various actors on the regulation with precision. In this study, actors were identified as playing roles in the regulation's definition, administration and implementation. The significance of various actors was estimated or compared (ranked) during the definition of the regulation. The power and influence of all actors during administration and implementation were analyzed.

Because there is no good quantifiable tool for analysis of power and influence, a qualitative analysis tool was used based on information derived from a strictly constructed interview. We distinguished three levels of actors' capacity: institutional capacity, individual role capacity, and skill capacity. Our samples cover all three. High-quality evidence regarding actors' capacities and impacts on the regulation forms the basis of the analysis and its conclusions.

5.3.6.3 What differences and similarities exist between the regulation's effects in maternal health care and health care in general, as well as between public hospitals and private hospitals?

- **Maternal healthcare vs. healthcare in general**

  - General case comparison

– **High risk of complaints:** Because of the special attention given pregnant women and children, higher expectations are placed on maternal and child healthcare, which results in more grievances. An administrator stated:

> *Complaints about child healthcare may be raised more often [than about other services], because people are more concerned about children. Parents and grandparents all regard the child as a treasure, so when relatives are not satisfied, they will complain. That may be why complaints are raised more frequently in children's hospitals. Children attract more attention.*
>
> (Male, GR-Administrators-2, 18-08-2011)

– **Confidentiality:** When medical disputes occur in the context of maternal and child health services—including disputes involving

abortion—patients pay more attention to personal privacy. As a grievance handler from a people's mediation committee stated:

> *I feel a difference in confidentiality and privacy. There was mediation, and how did it go? A girl had a surgical abortion, but she was unmarried. She did not want to expose this. During the mediation, she didn't come, but her mother did. She wanted to defend her rights, but not to disclose the case. She had this [contradictory] state of mind. Note that this kind of case cannot be made public.*
>
> (Male, GR-Other actors-1, 25-08-2011)

– **Postponement:** the handling of some medical disputes regarding maternal and child healthcare can be postponed because of uncertainty regarding damage to a fetus or child caused by medical services. As one user said:

> *He said that the hospital couldn't handle this now. I had to wait until my wife gave birth. And then it depended on whether the kid had any problems; if he had any problems, the hospital would further handle it.*
>
> (Male, GR-Users-4, 24-11-2011)

• GR management comparisons

– The regulation is universal for all hospitals, so handling processes related to maternal health and general health are basically consistent with the regulation. However, it becomes more controversial when we calculate compensation for disputes over maternal and child health care. A staff member from a processing center for liability insurance stated:

> *If medical malpractice happens to pregnant women, [when you compute the compensation,] do you count one or two? A lot of [compensation] costs are a bit different, and they are still not stipulated. But it is not the same for general medical malpractice. For example, dystocia eventually leads to child death. How can we compute death compensation?*
>
> (Female, GR-Other actors-5, 23-09-2011)

– The reduction of maternal mortality is a United Nation Millennium Development Goal and a significant indicator used to assess national health status. Moreover, as mentioned above, people are often more concerned about maternal health than about any other health issue. Therefore, cases of maternal and child health often attract more attention from the government, hospitals, and the public. A grievance handler from a tertiary hospital stated:

Medical disputes over maternal and child health are subject to the Law of the People's Republic of China on Maternal and Infant Health Care, which differs from laws governing general health care. Maternal or infant death for a family is unbearable, and for a country it is also very important. So patient death in our hospital [maternal and child hospital] is not the same as in general hospitals. Patient death [generally] results from illness in general hospitals, but in our hospital it is a very, very terrible thing.

(Female, GR-Implementer-3, 31-08-2011)

– For the reasons above, the amount of compensation is usually higher for medical disputes regarding maternal and child health.

– More actors are involved in maternal GR cases, with the Women's Health Institute playing a leading role. As an administrator stated:

More actors are involved in [medical disputes] in maternal health care. One additional actor is the Women's Health Institute.

(Male, GR-Administrators-2, 18-08-2011)

- **Public hospitals vs. private hospitals**

  - GR cases

– Medical disputes in private hospitals mainly involve illegal medical practices such as illegal advertisement and illegal techniques and implementation. Easily preventable mistakes occur more in private hospitals.

– Very often complicated pregnancy-related diseases are treated in tertiary maternal hospitals, along with the more typical needs of maternal care. The intense, unexpected condition of a patient's sudden adverse reaction can become confused with medical malpractice, making it difficult to tell the two apart, likewise obscuring issues of cause and responsibility if a dispute ensues. . Two staff members from the HII stated:

Complaints about private hospitals usually concern illegal advertisement and excessive medical care.

(Female, GR-Other actors-4, 21-09-2011)

Cases in [private hospitals] are more about silly mistakes, and omissions in management.

(Female, GR-Other actors-5, 23-09-2011)

- GR Management

Management: Complaint management is basically consistent across public hospitals and in accordance with the regulation. But it is different in many private hospitals. With regard to the complaint handling process, private hospitals generally pay more attention to their reputation and patient satisfaction by cooperating with patients and handling their complaints in a more active manner. An administrator and a staff member from a liability insurance processing center reported that:

> *The most important thing [for private hospitals] in handling such things [medical disputes] is to reduce the exposure.*
>
> (Male, GR-Administrators-2, 18-08-2011)

> *Private hospitals are very aware of the need for insurance, but insurance companies do not accept them. Why? The risk is too high.*
>
> (Female, GR-Other actors-5, 23-09-2011)

5.3.7 Case conclusions

5.3.7.1 Key messages

- **Political and social factors shaped the main context for this regulation**

The Chinese Communist Party and government have shifted their attention from economic development to harmonious social development. The health system reform launched in 2009 with a focus on health care utilization has become one of society's top priorities. The government aims to reduce tensions between physician and patients, and improve citizens' satisfaction. These factors have provided the basis for the regulation's attention, definition and implementation.

- **Policy definition was relatively evidence-based; consumers, however, were not involved.**

Many actors, including local policy-makers, hospitals, and researchers, were involved in the definition of the regulation. The policy designers collected information from powerful actors and conducted several surveys and validation meetings to review the draft policy document. However, actors with minimal power, such as consumers, were not involved in the regulation definition. Hence the GR content defined in the regulation document may not tally precisely with consumers' demand for GR services.

- **Inconsistent understanding of the regulation in actors of different levels**

The availability of GR services has increased because of the regulation, for it specified the implementation of specific GR department and full-time professionals in hospitals and defined certain principles for GR services. However, the document lacked an exact definition both of those services at the hospital level and also of the role of the regulation itself. So policy-makers and administrators of various levels and/or in different regions interpreted the regulation differently. This inconsistent understanding in different actors of their roles decreased its effect and resulted in disparities in GR services among different regions of China.

- **Regulation's concurrence with related regulations, its implementation and effects**

Central government policy-makers defined this regulation as a guideline for GR management in hospitals, and it was implemented simultaneously with several related regulations. Contents of this regulation were used as indicators to evaluate hospital performance and health care quality, and were used as key determinants in assessing whether hospitals merited reward. The regulation encouraged hospitals to allocate more resources to GR service delivery, and to improve GR accessibility. The process for handling complaints is the same for all patients, as are the GR services they receive; however, differences among mediation proposals for similar cases remain inevitable. Certain regulatory measures, such as "First reception responsibility" and "Feedback deadlines," have increased the efficiency of GR services. Yet the GR handling process is still not transparent to patients.

- **Information**

Information availability is a key determinant of good GR service delivery in hospitals. However, information failures in GR were evident in numerous areas. Hospitals had no systematic way to collect exact GR information, no appropriate tools to analyze GR information, no models to publish GR information to the public, no good mechanisms to inform consumers about GR, nor any sanction or incentive mechanisms to encourage the delivery of GR reports to government and patients. These failures were mainly caused by information asymmetry between administrators and hospitals, as well as between hospitals and patients. More regulation is needed in the area of information management: the smooth flow of accurate information will much improve the sanction or incentive mechanism.

- **Enhancement of role of civil society**

Civil society should have played a more important role in the regulation's definition, administration and implementation. Members of society should join in and negotiate with other actors throughout the regulation cycle to protect consumer and other rights, especially with respect to information management and hospital monitoring.

5.3.7.2 Recommendations

- **Involvement of more actors and improved operational guidelines needed in the GR regulation definition and publication**
    - **All actors, especially consumer/patient representatives, should be involved in the regulation definition**

Researchers, local decision makers, hospital managers and experts were all involved in the definition of the regulation and their opinions were considered in its finalization. Policy-makers also conducted several surveys and validation meetings to review the regulation document. Lastly, the document was published on the MOH's website for several months to gain feedback from the public. So the definition of the regulation was relatively evidence-based, apart from its lack of consumer involvement: patients, in fact, were entirely absent throughout the policy-making process. The opinions of consumers/patients about and demand for GR in hospitals were only indirectly obtained through review of literature review, consultation with experts and estimations of hospital managers. The regulation, therefore, did not represent consumer demand for GR. As a result, discrepancies exist between how GR services are defined in the regulation (such as first reception responsibility and feedback in five to ten days) and what the demand for GR is from the consumer's point of view.

Policy-makers should invite consumers' involvement in policy definition. Consumer's opinions and expectations regarding GR services should form a part of robust, evidence-based policy-making, and their views gauged on issues such as: the GR management process, the appropriate time interval for feedback, the nature of information made available to the consumer, reimbursement standards, and so on. Granted consumers' eventual presence in the process, questions such as the following ensue: How might representative consumers be selected to participate in the policy process? And how might such consumer involvement in policy-making ensure consumers' rights are protected and realized? In response, we suggest developing aspects of civil society, such as consumer associations and/or patient associations. Such civil associations could participate in policy-making as consumer representatives.

- **Improved operational guidelines needed to address regulation**

contents and develop consistency among different actors

Policy-makers and administrators had different perceptions about the role and function of the regulation. Since the regulation had no operational mechanisms, local government regarded the regulation as just a guideline (or manual) on GR management in hospitals. Based on that perspective, the regulation is, and has been, hard to implement effectively. Central government policy-makers, on the other hand, considered the regulation only a guideline and in fact expected administrators and implementers themselves to come up with the appropriate and necessary operational mechanisms. Based on this latter perspective, the regulation did not need to offer operational guidance. National level policy-makers' main objective had been to cause contents of the regulation to transfer locally into important indicators in evaluations of hospitals' performance and the quality of health services and hospitals. This inconsistent understanding of policy content at different levels of government has impacted the regulation's effect and resulted in disparities among regions.

In the definition of health system regulations, a regulation's role, function, and explicit operational mechanisms should be clearly specified as the basis for drawing up guidelines during its administration. Operational mechanisms for policies need to be directly defined in policy documents and provided in supporting measures or by concurrent regulations. Clear definition and identification of such mechanisms will ensure consistency in the regulation's administration.

- **Define each actor's responsibility and set up incentive mechanisms for administration**

    - **Responsibility and accountability**

The GR study revealed differences in the status of GR handling and management among regions and hospitals, along with a difference in effects. These discrepancies may have resulted from an inadequate definition of each actor's responsibility during implementation of the regulation as well as from the regulation's insufficient focus on accountability mechanisms. A good regulation clearly specifies each actor's responsibilities i.e. what each actor should do and how to do it. In addition, a clear definition of accountability is essential. Such accountability should be grounded in specific incentive mechanisms.

    - **Improve operational mechanisms and supporting measures to ensure the regulation's effect**

Good definition and effective administration are two key determinants in the

effects of policy and regulation. Effective administration of a good GR regulation depends, either through supporting measures or other concurrent effective regulations, on the clear definition of each actor's power, rights and management tools. Moreover, good cooperation and good coordination among different departments at the hospital level are also determinants of good GR regulation. Such cooperation and coordination is especially important in China since its health care delivery system involves so many hospital departments. An alternative to the current poorly defined position of GR management is to place it within a hospital's performance evaluation, giving it higher weight. If so, the health system administrator would then have enough power to improve GR management.

- **Establish good incentive mechanisms**

Incentive mechanisms are another determinant in regulation administration, along with responsibility, accountability, and power (management tools). Good incentive mechanisms should be composed of rewards as encouragement, and penalties. Incentive mechanisms in GR management should target the hospital, hospital director, local decision-makers, and local administrators (such as the Health Inspection Institute). They should be grounded in local realities, and issued through supporting measures.

- **Improve GR information management and publication**

The GR study found that information failure is a serious issue in China's GR management. Policy-makers and administrators meet difficulties obtaining accurate hospital GR information, i.e. GR frequency, degree and reimbursement at resolution. Consumers likewise encounter difficulties knowing a particular hospital's GR status. Patients who experience grievances have a hard time receiving appropriate and sufficient information, such as results from a hospital's survey of GR cases, its GR case handling process, its censure or punishment of physicians, etc. Information failure is often the root of an absence of accountability in GR cases. It also destroys incentive mechanisms, affects the hospital or hospital director's evaluation outcomes, and decreases the equity and effectiveness of GR management.

More attention needs to be paid to developing and instituting a functional, effective GR reporting system. The establishment of multi-report channels outside the hospital for GR handling would serve such a system. In addition, a responsive system of sanctions needs to be developed, one that replies to mismanagement by imposing penalties upon hospitals that, for instance, do not report GR cases. GR information exchange and analysis tools are also needed. Hospitals' GR information should be made available publicly on a regular, routine basis and over the long-term, enabling consumers to select

hospitals according to their GR status. Hospitals' GR information should be published gradually, considering feasibility and the nature of the regulation.

- **Increase civil society's contribution to GR administration**

The GR study indicates that civil society should play a more important role in this regulation's administration, particularly in the areas of evaluation, public information and the transfer of information to consumers. Moreover, civil society—in the form of a variety of hospital, physician and patient associations—can join in hospital performance assessment. Such health-related civil associations and/or consumer associations can also openly publish hospitals' GR information. Lastly, civil society should more pro-actively assist patients to access more information and specific GR services.

- **Establish civil society monitoring mechanisms and increase administrative transparency to ensure GR equity and transparency.**

  - **Establish civil society monitoring mechanisms and increase administrative transparency**

Hospitals are not accustomed to making all GR information available to patients, including the GR handling process and results of previously handled GR cases. Because of this inherent information asymmetry in health care, patients are likely to misunderstand health care providers' behavior when they are not satisfied with those providers' performance. This potential misperception on the part of patients, which sometimes leads to conflict, negatively impacts hospital managers' regard for transparent communication: they seem to believe that selective information given the public better supports the physician-patient relationship. However, such selective information decreases transparency in administration: hospitals should give all available information to patients. Establishment of a civil society monitoring system ensuring hospitals do, in fact, transfer all such information to patients might well improve fairness and transparency in GR handling and administration.

  - **Develop good incentive mechanisms for hospital physicians and GR managers**

Since hospital physicians and GR managers are two groups of actors in close, direct contact with patients, good incentive mechanisms for these two groups are necessary for effective implementation of the GR regulation. Frequency and level of GR associated with a physician should be evaluated as part of his/her performance. A physician's promotion and rewards should be based on such a performance evaluation.

  - **Pressure hospital directors into higher regard for GR**

GR implementation and GR status should be evaluated as part of a hospital's overall performance and of that hospital director's performance. A hospital director's performance should be the main determinant in his or her promotion and rewards. This model would encourage hospital directors to pay more attention to GR implementation.

- **Improve physicians' communication skills and knowledge of the law**

Most GR cases are related to poor communication on the part of the physician. To address this lack in capacity, health communication skills should be developed during medical university education as well as later on through continuing health professional education. Lastly, knowledge of legal and regulative frameworks in the area of GR needs strengthening throughout the health system.

- **Encourage hospitals to report GR information and improve civil society's role in regulation implementation**

The GR study shows that it is important for the effective implementation of the GR regulation that hospitals report their GR case information to the public. Consumer associations or similar civil society associations can support the hospital in collecting and reporting on GR cases. They can also function as GR receptor, receiving patients' grievances and contacting hospitals as consumer representatives.

6. Comparative analysis of the three case studies

6.1 Influences on the three case studies: social, political, economic and cultural factors in China as well as features of its health system and services

China's three case studies focused on three regulations. First studied was "Administrative regulation of prenatal diagnosis technology" [PD], a regulation issued nationally in 2002 and in Shanghai in 2003. The aim of this "PD Regulation" was the application of appropriate supervision and management of PD services to ensure their safety and effectiveness. Investigated second was "Notice issued to establish work principles for emergency obstetric care consultation, referral and treatment in Shanghai" (EmOC), emitted by the Shanghai municipality in 2008. The aim of this EmOC regulation was the reorganization of the EmOC referral/consultation system in the city to ensure universal access to EmOC care, which would not only increase the successful rescue rate but also reduce the MMR in Shanghai. Explored third was "Measures for the administration of patients' complaints in hospitals (Trial implementation)," issued nationally in 2009 and in Shanghai in 2010. The aim of this regulation was to strengthen Grievance Redressal (GR) management in hospitals to ensure a standard process that protects the rights of both patients and providers.

All the studied regulations in China share the same international context of safe motherhood. The three regulations likewise have met the same national policy environment in China. All have aimed to improve MCH care and enhance the health situation of Chinese women.

In addition, all the studied regulations intended to solve issues derived from socio-economic changes in China. The regulations were developed in the context of China's current transition in governance ideology from a focus on economic growth to an emphasis on the construction of a "harmonious society" rooted in a "people-centered" philosophy. Initiative for the three regulations' definition was borne of these specific problems and of both internal and external pressures.

With China's decline in the MMR and IMR, the health demand for prenatal diagnosis (PD) technology and service increased; meanwhile, developments in PD technology made PD service available in some hospitals and distributed to others. PD technology and services—including genetic counseling, biochemical testing, ultrasound examination, karyotype testing and molecular genetics testing—are cutting-edge, high-tech and high-risk procedures full of

high uncertainty. Successful PD service delivery demands qualified medical staff with special competence; however, prior to 2003, qualified staff were limited, with especially large gaps in expertise occurring between rural and urban areas, and among regions and hospitals. Some provinces did provide prenatal screening and prenatal diagnosis services, based on their local context and capacity, yet the connection or referred system between screening and diagnosis was poor. Development of the “PD Regulation” was placed on the agenda mainly to establish some form of quality assurance that would ensure safe and effective use of PD technologies.

The Chinese government has attached great importance to the protection of women’s rights and interests. In the recent twenty years, a series of laws and regulations has been issued to foster an environment that will improve women’s health. With China’s commitment to the MDGs, maternal and infant health care has been included in national plans for social and economic development. Meanwhile, rapid industrialization and urbanization in China has sparked active population migration from rural to urban areas. Compared to registered urban residents, however, most such migrants have less financial capacity to use fee-based health services. So utilization of MCH care among urban migrants has been universally low. With migrant women accounting for the large majority of maternal deaths, a reduction in maternal death amongst migrants has thus become key to a reduction in Shanghai’s overall MMR average. International guidelines from organizations promoting “safe motherhood,” experience with equity-related approaches and evidence available from EmOC intervention all informed the development of Shanghai’s EmOC regulation.

As a key component of health care utilization, the physician-patient relationship has represented a major challenge for health system governance in China, drawing attention from the government. Service users hold increasingly high expectations of quality of medical care even as they have improved awareness of rights protection, an inherently tense dynamic. Grievance Redressal (GR) has thus become an evitable issue facing the government. Yet GR is a comprehensive social issue rather than a health-specific matter. Most hospitals haven’t known how to deal with GR properly and so have not put much effort into GR management. As a result, national GR regulations were recently formulated to guide the GR process in hospitals and to protect both provider and patient rights.

China’s social and cultural context has differently impacted the processes and effects of the three regulations under study. National targets associated with MDGs and two national “Plans” were highly linked to the EmOC regulation, which was not the case with the two other regulations. As for the GR regulation, it was deeply connected to China’s current philosophical focus on governance

as “people-centered” in its mission to bring about a “harmonious society.”

6.2 Links common to the three country case-studies: between regulation contents and processes, effects of regulations and their contexts, and among actors’ roles

6.2.1. Regulations issued at different levels tend towards different definition processes

Of the three studied regulations, only the national regulation for prenatal diagnosis was a ministry-level rule, issued by the Minister. As an MOH Rule, its legislation level is higher than the regulation of the GR case, which was issued as a MOH department regulation, and the EmOC regulation, which was issued as a provincial-level regulation. Two additional national level regulations were formulated based on research designed and carried out by university academics. Their actors included users whose interests were collected through specific processes such as surveys or public announcements. However, the contents of those two national regulations are both quite general, offering only guiding principles rather than detailed measures; in contrast, the EmOC regulation established specific actors and directed their responsibilities towards problem-solving. The EmOC regulation definition relied mainly on administrators and clinical experts, though the issues regulated originated at the grassroots-level. In this case, little opportunity existed for users, user representatives or health providers from obstetric hospitals to express their views.

6.2.2. Regulation interpretation and administration played key roles in the effects

Regulation commands delivered top-down were interpreted at each implementation level, which decided efforts at administration. In the GR case study, the national regulation was simply promoteded to different hospital groups. No specific administrative and/or accountability system was set up to implement the regulation. Many administrative activities existed concurrent with hospital service quality control in order to satisfy patients. In the PD case study, the “PD Regulation” was interpreted at the level of the Shanghai municipality, which then established a service delivery system plan, an admission mechanism for institutional and service providers, as well as a list of

technology. But less accountability and sanction mechanisms were mentioned in its interpretation documents or enacted during its implementation process; one such sanction item occurred in the national level regulation. In PD administration, efforts were mainly directed at training, admission evaluation and quality control. As for the EmOC case, its regulation was interpreted at the district level based on Shanghai's current MMR situation, obstetric resources and at-risk population. Because of the commitment to MDGs made by every level of government in China, strict accountability and sanction mechanisms were set in this regulation process, ones that were consistently applied all the way from the municipal level, through the district level, and into each hospital's OBGY department. Because administrators at each level paid great attention to maternal death, more intensive monitoring and evaluation efforts were implemented to attain equitable access to quality EmOC care for the entire population.

As a whole, good mechanisms efficiently applied and administered contributed to the regulation's effect. During the PD case's regulation process, several mechanisms were drawn upon. For instance, regional health planning on local PD service delivery was held to ensure health resource were utilized efficiently; service admission and routine regulatory activities were conducted to control the quality of PD service delivery; price guidelines was used to regulate the market behavior of public hospitals. Both quality and access were at issue in this case study since, whereas the reproductive health insurance coverage of permanent residents and employees in the study city of Shanghai ensures access for them to (quality) prenatal screening, most migrants, lacking local insurance, have been disadvantaged at access because of the high expenditure for prenatal screening relative to their means.

As for the GR case, the regulation itself became the guideline for the standardization of hospitals' GR process. Multi-actor participation is another GR case mechanism that has ensured access to GR services. Other important mechanisms, however, such as those of accountability and incentives/sanctions were generally absent, which created a reliance on other, related regulations that ultimately could not effectively substitute for the GR regulation's lack of clear textual definition and meaning in those domains. Hence the administration of GR in hospitals was limited mainly to incentive (more so than sanction) mechanisms directed at those departments and individuals who reduced GR demands, and resulting in rewards usually related to compensation, honor, promotion and the spiritual.

In the case of EmOC, again, unlike migrants, local permanent residents could receive health insurance reimbursement for around 1/3 to 1/2 of EmOC expenditures, facilitating economic access. Subsidies for the poor were helpful at improving their access to care, but no government budget exists for such

subsidization, so hospitals have assumed heavy economic burdens. EmOC centers' admission mechanism ensured care quality and equitable access. The regulation itself acts as a specific guide for the referral and consultation process, which functions in tandem with regular monitoring and evaluation procedures and strict accountability and incentive/sanction mechanisms to improve equitable access to quality EmOC services.

All the China case studies drew on several kinds of approaches during the regulation process, each playing a different role in its own way. Across all three case studies, the state-centered approach was dominant and had recourse to numerous mechanisms. The market-oriented approach was also important to each case, one mostly applied by institutions themselves. Its for-profit role operated inside the institutions during the service process. For instance, after the successful rescue of a critically ill impoverished woman transferred from a district MCH hospital to an EmOC center, since the government has no budget subsidizing the cost of her rescue, the district MCH hospital would proactively send a cheque to the EmOC center to cover its expenditure for her EmOC services. The district MCH hospital would assume such a financial burden because helping the EmOC center to cover its expense would maintain the good MCH hospital-EmOC Center working relationship, an advantage for the MCH hospital. As for the consumer-oriented approach, it was relatively weak in all case studies of China. As a whole, they revealed a lack of agencies that could fully represent consumers. Moreover, those agencies related to consumers' rights and benefits that did exist, collectively lacked the power to give adequate voice to consumers' interests. The self-regulated approach was found in all the case studies of China, and was a useful supplement to the state-centered approach. If the self-regulated approach was relatively strong in the PD and EmOC case studies, it was weaker in the GR case study. The institutional collaboration approach was observed only in the EmOC case study, was not applied in the GR case study, and was brought into play in the PD case only through negative examples.

6.2.3. Health system factors influenced implementation of the regulations and their effects

Financing resources for implementation and administration of the regulations differed at the outset, during the process and were unsustainable in general. For the EmOC regulation, a one-time grant (1,500,000 CNY=238,095 USD) from the Shanghai municipal government was invested in each of the five EmOC centers for equipment appropriation. Subsequent project funding for obstetric cadre training was allocated at the municipal level. No maintenance fund for the EmOC Centers, subsidy for the poor, or incentive for the

obstetricians was either instituted or allocated on a continuing basis, which has resulted in an over-heavy economic burden on the EmOC centers to save pregnant, impoverished women and a lack of any incentive to obstetricians to give their best to EmOC services; notably, an interviewed designer mentioned that the financial department had not been invited in the regulation definition process. As for the PD case, routine financial resources were established only for biannual trainings and regular inspections but not for incentives or supervisions; occasionally, the BOH did provide financial support for related academic research on prenatal diagnosis to improve service quality. Lastly, for the GR case, individual hospital resources were the only resources for GR services. Most hospitals did not, in fact, allocate sufficient material resources for complaint management, though GR services depend upon them.

The competence of human resources has significant influence on the quality of service. In the EmOC case, both shortages in and waste of obstetric human resources exist. The number of qualified obstetric staff has increased slowly and has not been able to meet increasing demand. Training of obstetricians from lower-level hospitals occurred during EmOC regulation, the effects of which were very good; however, not all obstetric staff was offered the opportunity. As for the GR case, most hospitals did not allocate human resources with sufficient or appropriate professional background, such as in communication skills, key to successful complaint management.

Well-organized service delivery systems contributed to the effect of equitable access to care. In the PD case, referral from prenatal screening to prenatal diagnosis was not efficient because of an unbalanced distribution of PD institutions and under-estimated demand. On the other hand, in the case of EmOC, to solve the referral bottleneck issue, EmOC centers were reorganized based on geographic areas and designated referral routes. Every actor had clearly defined tasks assumed and accomplished under the pressure of accountability mechanisms. After the merger of the Dept. of Disease Control and the Dept. of MCH, now within the municipal administrative system, the former’s infectious disease management model for quick response was applied to EmOC work with a very positive effect on the regulation.

Information and feedback were key to service quality improvement. In the PD case, for many years no specific information collection or report of prenatal diagnosis service delivery occurred. Shanghai’s BOH just started statistical information reporting in 2011: The city’s four prenatal diagnosis centers now must report their service delivery information (both quantity and quality) to the health authority every three months. One prenatal diagnosis center gave much attention to follow-up activities assessing the delivery outcome of users (especially those receiving prenatal screening services) in order to provide evidence-based information for clinical decision-making. The EmOC case, by

insisting on the timely report of the rescue process for the audit, revealed that evidence and information play a key role not only in the regulation design stage but also in the process of regulation administration and implementation. Nonetheless, complaints did occur that insufficient feedback on the audit results could affect the quality of care. Lastly, for the GR case, complaint channels were public for patients but the handling process was not open or transparent to the complainant. Results revealed selective disclosure to complainants and hospital patients found fault with the absence of information openly published for their review or for wider public consumption.

Active coordination improved both the effect and efficiency of regulation implementation. Such coordination was weak in both the PD and GR cases but very prominent in the EmOC case, where active coordination happened at each level. Coordinators in hospitals were responsible for organizing doctors from all related departments, contacting the designated EmOC center for consultation and referral, and for communicating with the patient's family members. Coordinators at the district level played an important role in contacting other medical organizations such as the blood bank and EmOC centers. Municipal organizations involve themselves in coordination if problems persist that cannot be solved by coordinators at the district level. In the GR case, a hospital's Complaint Reception department would coordinate cases transferred to it by different first reception departments, unable to deal with them properly and refer them to upper-level GR.

6.2.4. Actors roles and relationships determined the effect of the regulation

We studied five types of actors in three cases. They were: policy-makers such as the responsible persons from different levels of the MOH and the BOH; administrators, including both management and technical administrators at the operational level; experts and academicians, including professional associations; service providers at the hospital level; and service users. Two types of regulation processes exist: One is for national-level regulations, which rely on research evidence from academicians; another is for local, issue-specific regulations such as Shanghai's EmOC regulation, in which definition policy-makers and administrators play a key role. Nonetheless, during both official processes—local and national—service users had little voice, which may stem from the fact that these regulations were intended to focus only on the provider-side. Another important issue for these regulations is that not all stakeholders—such as financial departments, human resources departments and/or civil society organizations—were invited into the regulation process, a significant lack which may affect the sustainable implementation of

these regulations. At the implementation and administration stages, actors' power and resources determined the effect of the regulation. In the EmOC case, the more powerful the coordinator was, the more successful the referral result. In the GR case, those actors who have power and resources are often not on the frontline dealing with GR, which may lengthen the GR process. The powers of all actors in the three regulations are shown in Table 6.1.

Table 6.1 Actors in China's three case studies: Comparison of degree of participation

Case	Actor	Definition	Administration	Implementation
PD	MOH	+++		+
	HTA center	+++		
	Professionals	+++	+++	+++
	Municipal BOH		+++	++
	MWHI		++	+++
	MHII		++	+++
	Prenatal diagnosis centers (4 in all)			++
	Consumers			++
	Companies in prenatal diagnosis area			+
	Academic groups			+
EmOC	Municipal BOH	+++	+++	++
	Consumers	+++	+++	+
	District BOH		++	+
	District MCH institute	+	++	+
	Department of Medical Affairs in EmOC centers		++	+
	Obstetric department of EmOC centers	++	+	+++
	Related medical departments in EmOC center			++
	Department of Medical Affairs in hospitals		+	+
	Directors and Obstetricians in			+++

	hospitals			
	Other related medical departments in hospitals			+
	Related medical organizations (Ambulance Center, Blood Bank)			+
	Consumers and their family members			+
GR	Consumers	+		+
	Hospital Complaint Reception department	++		+++
	Hospital clinical departments			++
	Hospital leaders	++		+++
	Other people who have personal relationships with the above actors			++
	MOH	+++	++	
	BOH at different levels	++	+++	
	MHII	+	+++	
	Hospital owners	+	+	
	Academic groups	+++		

6.3 Differences and similarities between regulations on maternal health care and on health care in general

For the PD case, prenatal diagnosis is a high-tech (potentially high-risk) MCH service. Hence “PD Regulation” focuses not only on the quality, access and equity of service delivery, but also on the development and supervision of related technology. The safety and effectiveness of the technology is a precondition of the effect of PD service delivery. This fact underlies the approaches and mechanisms of “PD Regulation,” which focus on the qualifications of institutions and personnel for prenatal diagnosis service delivery. During its regulation definition, a market-oriented approach was used.

The national regulation states: “The health institution which provides prenatal screening must maintain a work relationship with the health institution certified to provide prenatal diagnosis to ensure screened pregnant women have access to prenatal diagnosis.” This flexible rule employed the market-oriented approach, regulating the interaction between prenatal screening and diagnosis through contracting. However, the regulation itself does not work well if without other supporting policies.

Great gaps in social, economic and health status exist among China’s different provinces. So either the provincial or municipal BOH is responsible for the local interpretation of national regulations, based on local conditions. This regulatory pattern exists not only in prenatal diagnosis but also for other national health regulatory documents. Generally, national regulations address a main demand, while local regulations respond with more detailed provisions. Sometimes, too, local regulations can enact flexible modifications or adjustments, responses encouraged by the MOH. Lastly, the regulation process—from definition and administration to implementation—was similar to that of other general health regulation.

For the EmOC case, rapid response and multi-department involvement embody the similarity between general emergency services and EmOC services. Yet obstetric emergency can cause maternal death, one of the MDGs that has attracted much attention from the government and health institutions.

Comparatively, more administrative efforts have been put into EmOC than into general emergency services. After the EmOC regulation was issued, district BOHs, MCH institutes and hospitals gave much more attention to EmOC services. General emergency services tend to just involve staff from a certain department or from several related departments. But an EmOC center often attracts the entire service delivery system: from frontline obstetric department services to those throughout the hospital, from the district level to the municipal level, and from there, eventually to all related departments.

Another difference is represented by the cost-benefit relationship of the service. Compared with other emergency services, EmOC services encounter greater work pressure but less profit. Once a maternal death has happened, usually a dispute occurs between the maternal family and the health institution/s. Health institutions generally have pay as a way to resolve the dispute, even absent any medical malpractice. For other emergency services, however, especially concerning severe disease (e.g. cancer), people have lower expectations of treatment, hence disputes seldom occur. In addition, health institutions have to cover EmOC costs if the user is very poor and unable pay for the service. On the whole, health care facilities operate and provide EmOC services at a loss, especially when compared to other emergency services.

For GR cases, no special regulation exists for redressing grievances related to maternal health care. MAPCH, the regulation governing general health care, contains no references specific to the interpretation or implementation of maternal health care. Because of MAPCH's language and scope, whether related to maternal health care issues or health care issues in other domains, all complaints and grievances throughout the health care system are handled in the same way.

6.4. Recommendations for improvements to the studied regulations likely to enhance equitable access to quality maternal health care

For the PD case study, significant differences of prenatal diagnosis services between urban and rural areas and among different regions still exist. These barriers must vanish and China's western areas must receive financial support to develop PD technology and improve PD service coverage.

The service provision capacity of qualified hospitals cannot meet service demand in some areas. Waiting times, transport times and fees vary among pregnant women of varying social and economic levels. The service delivery system for PD should be redesigned so as to increase its efficiency; a needed, increased allocation of PD resources would support such positive change. The quality of prenatal diagnosis-related services (especially in the four prenatal diagnosis centers) has indeed improved, yet problems in implementation remain. An example: the current regulation specifically directs itself at qualified prenatal diagnosis centers while ignoring those hospitals that provide only prenatal screening services. To increase both safety and also the positive effects of PD, all health sector institutions providing prenatal screening services should be included in the regulatory framework. Improvement in the quality of prenatal screening services is needed close to or as much as developments in prenatal diagnosis-related technologies are. Moreover, constructive redesign of the regulation's quality control approaches will intensify the regulation's beneficial effect. Lastly, the responsibilities of the government and the market need to be redefined based on contemporary conditions and more recent experience.

For the EmOC regulation, several aspects should be considered to enhance equitable access to quality maternal health. First, government should take a much stronger and more effective role through the reform of reproductive health insurance and increased financial investment in the hospitals, etc. to ensure the equity of basic maternal health. Second, since direction of

accountability was largely upwards in the current regulation, the regulation should be modified to ensure greater bidirectional and horizontal lines of accountability. While strict accountability has been the primary mechanism through which the regulation has been achieving its effect, room for other mechanisms to strengthen the regulation and to increase its sustainability exists, such as participation, ownership across different actors and shared responsibility. Third, workload capacity needs to be assessed given the newer and greater expectations of the regulatory framework. Fourth, matched resources, including human and financial resources, must be made available both to ensure continuous access to EmOC and also its sustainability. Fifth, scientific performance evaluation mechanisms such as incentive mechanisms should be erected to improve work enthusiasm for EmOC. Lastly, more efforts are needed to reduce Shanghai's MMR, such as improvements in maternal management, early identification of pregnancy, timely recognition of high-risk pregnant women, good antenatal health care (and its advocacy) as well as many other social factors.

With respect to the GR case, all actors, especially consumer/patient representatives, should be involved in the regulation's definition, administration, and implementation. Accordingly, the government should develop civil society groups and associations as representatives of certain actors. Actors' accountability must be made explicit both in the contents of the regulations and also in their administration. Efficient mechanisms such as those of incentives and sanctions should be applied; by the same token, the government should set up mechanisms that more transparently collect, manage and deliver exact, relevant information to users. Lastly, resources are needed for the training of GR service providers' communication skills: quality GR service depends on not merely improved but preferably superior communication competence.

6.5 Key messages from study of China's three cases

1. The regulations' development, administration and implementation were a government-oriented process.

2. A more scientific regulation design process (more evidence-based, and more transparent) is gradually establishing itself in China.

3. The regulations under study usually provided only principles for dealing with health problems; local government has had to establish detailed interpretation and/or an operational framework.

4. The regulations indicate increased concerned with accessibility, service

quality and equity of health care.

5. The regulations were all aimed at resolving issues, but focused on regulating the service-provider side; voice channels from the demand side were not measurably open or direct.

6. The subject of the regulations focused on the hospital-doctor entity, which made it difficult to separate responsibilities and assign (or receive) individual accountability. Leaders lacked any incentive mechanism to maximize efficiency and minimize cost; similarly, health practitioners similarly lacked any incentive mechanism to prod them into optimizing services.

7. Consumers and/or their representatives were absent during the regulations' definition, so the regulations cannot fully reflect their benefit.

8. Multi-sector collaboration during regulation implementation and administration became a challenge, an existing issue of the Chinese health system.

9. Resource sustainability was given no consideration during the regulation process.

10. An imbalance in access to and receipt of information existed for the different actors. Regulation makers and experts usually obtained more information than service users, an unequal and inadequate provision of information that lead to confusion among service users.

11. The role of civil society and professional associations should be enhanced throughout the process of regulation definition, administration and implementation.

6.6 Conclusions from the study of China's three cases

Specific findings of the five research questions asked in China's context are summarized as following:

RQ1. The regulations' approaches and processes

Approaches

The state-centered approach was dominant across all three case studies of China and had recourse to numerous mechanisms. The market-oriented approach was also important to each case, one mostly applied by institutions themselves. As for the consumer-oriented approach, it was relatively weak in

all case studies of China. As a whole, the case studies revealed insufficient agencies capable of fully representing consumers. The self-regulated approach was found in all the case studies, and was a useful supplement to the state-centered approach.

The dominant role of the state-centered approach suits the Chinese political and social context as well as China's health system. "Command and control" proved a very effective approach to accelerate reaching certain targets in China. But the consumer-oriented approach needs to be further strengthened during China's health regulation process.

Processes

The "PD Regulation" is a MOH Rule, the GR regulation a MOH department regulation, and the EmOC regulation a provincial-level regulation. The contents of the two national regulations (PD and GR) are both quite general, offering only guiding principles rather than detailed measures; in contrast, the provincial-level EmOC regulation established specific actors and directed their responsibilities towards problem-solving. Regulation definition was an evidence-based process, one that relied on previous investigation and the solicitation of opinions.

Regulation commands delivered from top to down were interpreted at each implementation level, an interpretation process that decided efforts at administration. Only the EmOC regulation received adequate interpretation at the district and hospital levels; in turn, relatively better implementation of the EmOC regulation occurred as compared to that of the GR and PD cases.

RQ2. Actors' involvement in the regulations' processes

Actors in the three cases included: policy-makers, such as the responsible persons from different levels of the MOH and the BOH; administrators, including both management and technical administrators at the operational level; experts and academicians, including professional associations; service providers at the hospital level; and service users. Nonetheless, during both official processes—local and national—service users had little voice, which may stem from the fact that these regulations were intended to focus only on the provider-side. Another important issue for these regulations is that not all stakeholders—such as the financial department, the human resources department and/or civil society organizations—were invited into the regulation process, a significant lack which may affect the sustainable implementation of these regulations. At the implementation and administration stages, actors' power and resources determined the effect of the regulations.

RQ3. Effects of the regulations

The three studied regulations revealed different effects in terms of equitable access to quality maternal health care. The PD regulation ensured the service quality of prenatal screening and diagnosis. The EmOC regulation ensured universal access to EmOC in Shanghai through a re-organization of the referral/consultation system. The GR regulation ensured a standard service process for consumer complaints.

Contributing factors to the effects of the EmOC regulation drew on a wide context: on international and national emphases on safe motherhood, which aroused a like high attention from government and health institutions, and on a well-established mechanism for maternal death reduction. The regulation's effects were largely determined by effective management and control during implementation. There were strict controls during EmOC regulation implementation, but not so for the PD and GR regulations. Typically, accountability and monitoring mechanisms play a very important role in public policies. In the case of the EmOC regulation, however, a lack of resources undermines the likelihood of a sustainable effect. As for the PD and GR cases, a lack of attention from administrative leaders, accompanied by a parallel lack in resources, has been their major obstacles in achieving more beneficial (and lasting) effects. Local government played key roles in adapting regulations for implementation to suit each specific context, thereby influencing the effects of the regulation.

RQ4. Differences and/or similarities among regulations on maternal health care and health care in general

As with regulations on health care in general, the state-centered approach has been the dominant one in regulations on maternal health care. Other approaches, such as the market-oriented and consumer-oriented ones have also been embodied in health regulations, as have been self-regulation and institutional collaboration.

Similarities exist between the regulation processes of maternal health care and those of health care in general. Almost all regulations experience definition, administration and implementation phases. The definition process is now becoming more evidence-based. Interpretation at the administrative level is key to the effect of implementation.

The actors involved in these health regulations were very similar. They included: the MOH and BOHs of different levels; operational administrators, including both managerial and technical; experts, academicians and professional associations; service providers at the hospital level; and service

users. But the participation of each actor varied according to the health issue at hand.

Because maternal death is one of the MDGs, health problems linked specifically to maternal health care attract more attention from the government and health institutions than those belonging to general health care. Accordingly, regulations directed at maternal health care, as is EmOC, benefit from more substantial administrative efforts.

RQ5. Recommendations for improvement in the effects of regulations

In terms of China's political and social context, the government should play a major role in ensuring equitable access to quality maternal health care, especially for primary health care, as represented by EmOC. Consumer/patient representatives and civil society, as the representatives of certain actors, should be involved in the definition, administration, and implementation of maternal health care regulations. When addressing health problems through regulation, essential resources—including financial and human—must be considered to achieve the regulation goals. The consumer-oriented approach needs further strengthening during the regulation process, as a supplement to the state-centered approach. Appropriate and effective mechanisms such as those of accountability, incentives and sanctions et al., should be established to achieve better regulation implementation.

With clear objectives set forth and appropriate accountability mechanisms embedded in the regulation, the resolution of those urgent problems the regulation is meant to address could accelerate, achieving its effects. Regulations should be flexible enough to adapt locally and should include a procedure for the updating of contents. A well-established information system is needed in order to strengthen control procedures and effective evaluation throughout the regulation process.

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