HESVIC project

INDIA 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
Dissemination level	Public

Deliverable authors	**Institute of Public Health, Bangalore**
Suggested citation	**Institute of Public Health (2012) 'India Country Report on Health system stewardship and regulation in Vietnam, India and China', NCIHD and Leeds Institute of Health Sciences, University of Leeds, UK**
HESVIC	**HESVIC is a three-year research project (2009-12) being implemented under the European Community Seventh Framework Programme (FP7).** **The project aims to investigate stewardship and regulation as it relates to governance of health systems in policy and practice through a comparative study of three Asian countries – Vietnam, India and China. The project uses maternal health care services as a case study of stewardship and regulation. The goal is to support policy decisions in the application and extension of principles of accessibility, affordability, equity and quality coverage of health care in the three countries.** **HESVIC partner organisations** **Nuffield Centre for International Health and Development (NCIHD), Leeds Institute of Health Sciences, University of Leeds, UK** **Hanoi School of Public Health (HSPH), Vietnam** **Fudan School of Public Health (FU), Fudan University, China** **Institute of Public Health (IPH), Bangalore, India** **Department of Public Health, Prince Leopold Institute of Tropical Medicine (ITM), Belgium** **Social Development and Gender Equity, Royal Tropical Institute (KIT), Netherlands**
Website	**http://www.leeds.ac.uk/nuffield/research/HESVIC.htm** **www.hesvic.iphindia.org**
Copyright	
Acknowledgements	**We wish to acknowledge all the study participants for giving us the time and sharing their views and experiences, the Government of Karnataka for giving us the permission to do the study, members of the Technical Advisory Committee for their suggestions and comments and finally to Ms. Alyssa Salaciak from Simon Fraser University for doing the nested study on media coverage on grievance redressal in Karnataka during her internship at IPH.**

Table of contents

List of Tables

List of Figures

List of Abbreviations

AAP-I	Abortion Assessment Project – India
ANC	Ante Natal Care
ANM	Auxiliary Nurse Midwife
ARS	Arogya Raksha Samiti
ASHA	Accredited Social Health Activist
AYUSH	Ayurveda, Yoga and Naturopathy, Unani, Sidha, Homeopathy
BIS	Bureau of Indian Standards
BPL	Below Poverty Line
CEHAT	Centre for Enquiry into Health and Allied Themes
CFPB	Central Family Planning Board
CHC	Community Health Centre
CMO	Chief Medical Officer
CPA	Consumer Protection Act
D&C	Dilation and Curettage
DHO	District Health Officer
DLHS	District Level Household Survey
EC	European Commission
EmOC	Emergency Obstetric Care
FLHS	First Line Health Services
FOGSI	Federation of Obstetrics and Gynecology Societies of India

FRU	First Referral Units
FGD	Focus Group Discussion
GOI	Government of India
GDP	Gross Domestic Product
GR	Grievance Redressal
Hb	Hemoglobin
HEPVIC	Health Policy making in Vietnam, India and China
HIV	Human Immunodeficiency Virus
HMIS	Health Management Information System
ICMR	Indian Council of Medical research
ICPD	International Conference on Population and Development
IEC	Information Education and Communication
IMA	Indian Medical Association
IMR	Infant Mortality Rate
IPC	Indian Penal Code
IPHS	Indian Public Health Standards
ITM	Institute of Tropical Medicine
KHSDRP	Karnataka Health Systems Development and Reforms Project
KIT	Royal Tropical Institute
LHV	Lady Health Visitor
LSAS	Lifesaving anaesthetic skills
MO	Medical Officer
MBBS	Bachelor of Medicine and Bachelor of Surgery
MCH	Maternal and Child Health
MMR	Maternal Mortality Ratio
MOHFW	Ministry of Health and Family Welfare
MTP	Medical Termination of Pregnancy
MVA	Manual Vacuum Aspiration
MDG	Millennium Development Goals
NCIHD	Nuffield Centre for Health and Development
NFHS	National Family Health Survey
NGO	Non-Governmental Organizations
NRHM	National Rural Health Mission
OBC	Other Backward Castes
OBG	Obstetrics and Gynecology
OPD	Outpatient Department
PCPNDT	Pre Conception and Pre Natal Diagnostic Techniques

PHC	Primary Health Centre
PIP	Programme Implementation Plan
PRI	Panchayat Raj Institutions
PROM	Premature Rupture of Membranes
QOC	Quality Of Care
RCH	Reproductive and Child Health
RMP	Registered Medical Practitioner
RTI	Reproductive Tract Infection
Rs.	Rupees
SBA	Skilled Birth Attendant
SC	Scheduled Caste
SN	Staff Nurse
SSLC	Secondary School Leaving Certificate
ST	Scheduled Tribe
STI	Sexually Transmitted Infection
TBA	Traditional Birth Attendant
TFR	Total Fertility Rate
UN	United Nations
UNFPA	United Nation Population Fund
UPA	United Progressive Alliance
USAID	United States Agency for International Development
VHSC	Village Health Sanitation Committees

1. Background of the project

1.1 Overview of key research elements

'Health system stewardship and regulation in Vietnam, India and China' (HESVIC) is a multi-disciplinary and multi-country project, implemented over the period of three years (July 2009 – June 2012) with financial support from the European Commission FP7. HESVIC involves three Asian and three European partners. The Institute of Public Health in Bangalore led the study in India.

The project followed the EU-funded HEPVIC project (Health Policy-Making in Vietnam, India and China: Key determinants and their inter-relationships 2005-2009), that examined ways to enhance health policy-making processes through a comparative study of policy processes in the three countries. The HEPVIC research suggested that governance and regulation capacity of the three governments is pivotal for dealing with the changing health sector and ensuring universal health coverage.

Following HEPVIC study finding, HESVIC aimed to investigate the role of regulations, and through it of governance to equitable access to quality health care. As a tracer condition, it focused on maternal health. More specifically, it examined three case studies and corresponding regulations to understand the ways maternal health services are governed in three Asian countries. These case studies are namely Emergency Obstetric care (EmOC), Abortion and Grievance redressal (GR). These cases studies were studied in each of the three countries i.e. Vietnam, China and India. Results of the larger HESVIC study are based on an analysis of comparison between and across case studies and countries.

The methodological steps involved understanding the regulation process from formulation-administration-implementation. The purpose was to understand these processes to examine the "*what* and the *why* "of the effects of regulations. A systematic analysis of actors' power relations was an integral part of the methodological steps. A comparative analysis of case studies and countries aimed to help understand the main problems in governance in health services in general and maternal health services in particular. Following the broader objective of the project, it sought to ask the following research questions (Box 1.1.).

Box1.1 Research questions and sub-questions

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

1. What approaches and processes exist for regulating maternal health care and how do they operate in practice?
2. Who are the actors involved in the regulation of maternal health care, what are their roles and power relations?
3. What are the effects of regulation on equitable access to quality maternal health care?
4. What are the differences or similarities between regulation of maternal health care and health care in general?
5. How could regulation be improved to enhance equitable access to quality maternal health care?

1.2. Summary of HESVIC research

This section summarizes the key regulations that were selected and studied to answer the aforesaid research questions. Three regulations were selected for an in-depth analysis of their role in improving access to quality maternal health care and through this, reflecting on the larger question of the health system governance in the Indian study context. The following table offers a summary view of the specific aspects of maternal health and corresponding regulations studied in India.

Table 1:Overview of Regulations studied

Case study	EmOC	Abortion	GR
Research Theme	Equitable access to quality EmOC services	Equitable access to safe abortion services	Equitable access to grievance redressal
Regulation	Indian Public Health Standards (IPHS 2005) Karnataka Private Medical Establishment Act (KPMEA 2007)	Medical Termination of Pregnancy Act (MTP - 1971)	Consumer Protection Act (CPA 1986)
Sectors under regulation ***(public and/or private)***	Public (rural) Private	Public and private	Public and Private
Regulatory approach	Consumer oriented, Market oriented and collaborative	Command and control	Consumer oriented
What is being regulated	Quality	Quality	Quality

1.2.1 Equitable access to Quality EmOC services: Role of Indian Public Health Standards (2005, 2010)

Emergency obstetric care is an essential service required for providing safe motherhood services and reducing maternal mortality. There is plenty of evidence suggesting the effectiveness of EmOC interventions in reducing maternal deaths (Fournier et al 2009; Paxton et al 2005). The literature on EmOC services in India highlights a number of barriers including financial, cultural, geographical and technical to equitable access to quality EmOC resulting in poor maternal health outcomes (George, Aiyer and Sen 2005; Jeffery and Jeffery 2008, 2010; Mathews et al 2005; Mavalankar 1996, 2000, 2005, 2008, 2009; Singh 2009).

Indian Public Health Standards (IPHS 2005) were introduced as part of the National Rural Health Mission (NRHM) that sought to undertake architectural corrections in the current health service delivery mechanisms in rural India. IPHS were introduced at all levels of health facilities to ensure minimum standards of care that should be available and accessible to the community. We focused on IPHS at 50-100 bedded hospitals that are known as sub-district hospitals that aim to provide comprehensive secondary and referral services at taluka level including CEmOC. As is well indicated in existing literature, access to c-sections and life saving obstetric surgeries is critical to control maternal mortality (Ronsmans, Holtz and Stanton 2006; Paxton 2003; Fournier et al 2005).

Sub-district (taluka) hospitals in India are below the district and above the block level (CHC) hospitals and act as First Referral Units for the Tehsil /Taluk /block population in which they are geographically located. Specialist and referral services are provided through these sub-district hospitals. These hospitals covering on an average 400,000 -500,000 population have an important role to play as First Referral Units in providing specialist and referral services including emergency obstetrics care and neonatal care, saving the travel time for the cases needing such emergency care and reducing the workload of the district hospital.

IPHS provide guidelines for standards pertaining to infrastructure, human resources, drugs and equipment. These standards pertain to all specialist services. IPHS hence is not an EmOC specific regulation. Further, the standards address the issue of improving quality of service delivery and do not necessarily aim to ensure equitable access. NRHM through its other interventions seeks to improve access to public health facilities by providing emergency transport service for referral, strengthening Primary Health Centres to provide round the clock services, incentivising health workers and families to utilize services in public facilities.

The state Government has initiated another regulation exclusively aimed at the private sector i.e. Karnataka Private Medical Establishment Act (2007). This Act makes all private facilities mandatory for registration; ensure conformity to certain standards in terms of infrastructure as laid down in the Act, mandatory display of information relating to services, fees and waste disposal. We studied this Act as a related regulation having a bearing on access to provision of EmOC services in the private sector.

Evaluation studies of IPHS/NRHM indicate a) relatively better infrastructural development (physical buildings) though uneven across and within states b) human resources particularly specialists and availability of blood storage units again remain critical though some states fare better than others c) lack of adequate information on dissemination of guidelines and hence inappropriate interpretation of the provisions of many components of NRHM including IPHS and d) ambitious nature of IPHS vis a vis NRHM.[1] HESVIC through an in-depth analysis seeks to make a departure from such evaluation studies by exclusively looking at IPHS from the point of view of regulations and governance in ensuring quality maternal health care.

1.2.2. Equitable access to safe abortion services: Role of the MTP Act

The Maternal Termination of Pregnancy Act (MTP) 1971 came in to facilitate access to safe abortion services and control maternal mortality and morbidity caused due to unsafe abortions. MTP Act (1971) with amendments in 2002 is an enabling act which

[1] See Husain 2011; Gill 2009; Bajpai, Sachs and Dholakia 2009

legalizes abortion services by decriminalizing both the abortion seeker and practitioner. It aims to provide safe abortion services by clearly laying down conditions on a) who could provide abortion services (practitioners with recognised medical qualifications and necessary training apart from gynaecologists/obstetricians) b) when should abortions service be given (under what indications including medical, social and mental) and c) where should MTP be done (licensed facilities). The amendment of MTP Act in 2002 introduced two major revisions in the act i.e. a) decentralization of registration and approval of facilities at the district level and b) stricter penalties for MTPs being done in an un-approved site or by a person not permitted by the act. The regulatory approach of MTP is a state command and control approach which is supposed to work through mechanisms like licensing and registration of health facilities, training of personnel and strict monitoring to ensure conformity to respect the provisions of the Act failing which strict penalties/punishments are imposed. The Act is applicable to both public and private health sectors.

Though the progressive approach of the regulation has been largely applauded, limited effectiveness of the Act in promoting safe abortion services across different groups of women in different parts of India has been voiced as a concern by researchers. A large body of research on MTP focuses on the provisions of safe abortion services in the community highlighting the persistence of service by untrained personnel, stigma around abortion (more so for unmarried abortions), lack of knowledge of the Act among the community, high cost in private facilities, unwarranted practices specifically in public health facilities i.e. coercive contraception following MTP, judgmental attitude of providers and seeking mandatory consent from spouses and reduced access to abortion due to struggle against sex selection (Bhatia 2007, 2010; Ganatra 2003; Gupte, Bandewar and Pisal 1997; Guleria et al 2006; Hirve 2002; Mallick 2003; Patel 2007; Patel et al 2009; to cite a few). These studies additionally have also indicated the medicalization and restrictive nature of the Act, under reporting of MTP in health facilities and weak monitoring as explanatory notes to the effects of MTP. HESVIC seeks to extend these studies by situating the effects of MTP in the state of Karnataka and trying to explain the limited effects of the MTP Act from a governance point of view.

1.2.3 Equitable access to grievance redressal mechanisms: Role of the Consumer Protection Act 1986

The CPA as a general Act seeks to protect the rights of consumers against unfair trade (marketing of hazardous goods, lack of information on quality, quantity, price and standards of goods) and to promote their rights to be heard and seek redressal (Government of India-CPA 1986). Following these objectives, the CPA made provisions for instituting quasi-judicial bodies and consumer councils like the District, State and National Consumer Forums. Consumer Forums consist of a three member jury each at all the three levels. They are a) Former district judge (for the state and national forums, it is a former judge of the state high court and national supreme court respectively) b) a lawyer and c) a woman social worker.

CPA aims to ensure speedy and timely redressal of grievances and offer financial compensation to the patients when a case of medical negligence is proved in the forum. These three forums operate at different levels based on the amount of compensation claimed by consumers i.e. the National Consumer Forum addresses cases with a claim of more than Rs. 10 million, State Consumer Forum between Rs 2– 10 million and the District Consumer Forum with a limit of Rs. 2 million. It was through the Supreme Court Ruling of 1995, medical profession was exclusively included under the provision of CPA. CPA through this judgment therefore sought to: a) empower patient-consumers with a voice to seek redressal for poor quality of service delivery b) protect them from unfair trade and deficiency in health care services thus ensuring quality of health care and c) through this process establishes greater accountability and responsiveness of health care providers. The regulation is applicable to both public and private sectors.

Few existing studies on the effectiveness of CPA point out the a) urban reach of the Act b) medical bias of the working of the regulation c) limited awareness of the Act among community and providers and d) defensive medicines as a side effect of the Act (Bhatt 1996; Misra 2003; Muraleedharan and Prasad 2003; Sheikh 2011; VOICE 2000). The Act is a general regulation pertaining to all consumer issues and not a health specific regulation.

1.3 Purpose and structure of the report

This report is the consolidated exercise of HESVIC research undertaken at country level. It involves an analysis of individual case study regulations and comparison across these regulations to answer the sub-research questions and the overarching research question on the role of regulations in ensuring equitable access to quality maternal health care.

This report is composed of seven main sections, namely:-

1. Background of the project
2. Conceptual framework used by the country research team
3. Methods
4. Introduction to the relevant country context
5. Case study analysis
6. Comparative analysis across case studies
7. Conclusion and recommendation

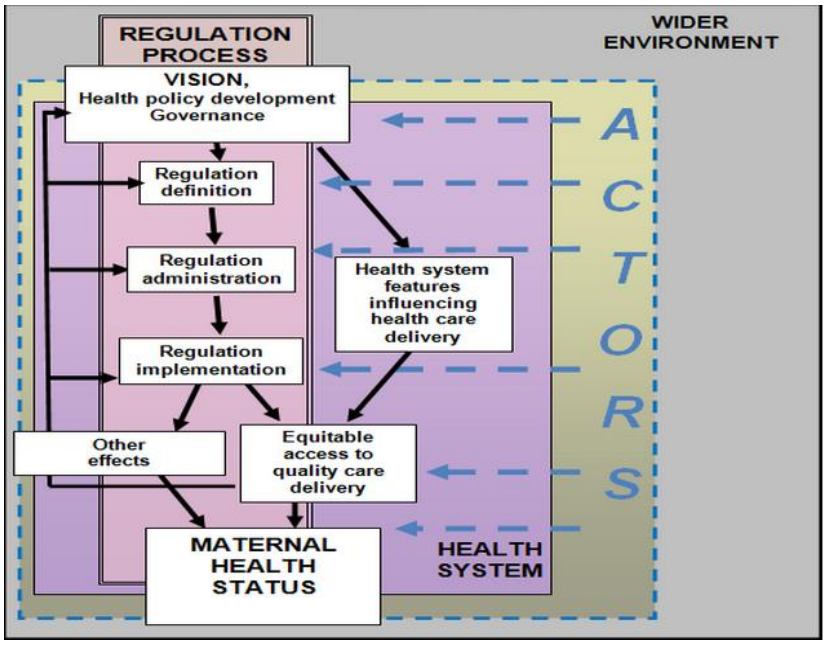
The first section introduces the objective and research questions of the study followed by the section on the conceptual framework used in the study to examine the research questions. Section three on research methods covers the detailed description of the methodology adopted for the study (Focus Group Discussions, semi structured and in depth interviews, observations of meetings and events and document analysis of both scientific and grey literature). Section four provides a summary overview of the demographic, health policy and health system context of India. Section five on the case studies follows four main sub-sections. These are: a) descriptive overview of the regulation that includes objectives, content, prescriptive procedures of administration and implementation. This sub- section based on a document analysis of the regulation tells the readers what the regulation intends to achieve and how b) effects of regulations c) explanations for these effects and d) discussions and recommendations. Section six offers a comparative analysis across the case studies. The report ends with an overall conclusion of the study on governance and regulations of health care in India.

2. Conceptual framework

HESVIC research is guided by a conceptual framework given in Figures 1 and 2. It is informed by theoretical perspectives of political rationalism and policy as discourse (Shaw 2010). These analytical perspectives enabled us to examine the processes of regulations, the larger social and political context in which such regulations are situated, interpretation of regulations among different actors involved in the regulation process and effects of regulations.

Health policy development is seen as a start-up point for regulatory processes. The stages of regulation processes which are the primary focus of the study are understood by exploring their characteristics such as whether they rely on mechanisms like incentives, sanctions, control and monitoring for instance and processes like definition, administration and implementation. The wider environment is a key element in this framework, since other policies and regulation also influence maternal health. Conversely, other health system features influencing health care delivery, possibly not linked to regulation processes are identified and their role analyzed. The following illustration shows the conceptual framework of the HESVIC research.

Figure 1. Conceptual framework of the HESVIC research



As seen in Figure 1, the framework expands since other policies and regulation may also influence maternal health. For example, how education-related legislation influences women's literacy through compulsory enrolment at school; or how work-related regulation measures, like maternity leave and maternity financial benefits, influence a pregnant woman's well-being. The following section looks at each of the components of the framework and builds up the overall framework:

Vision, governance and health policy

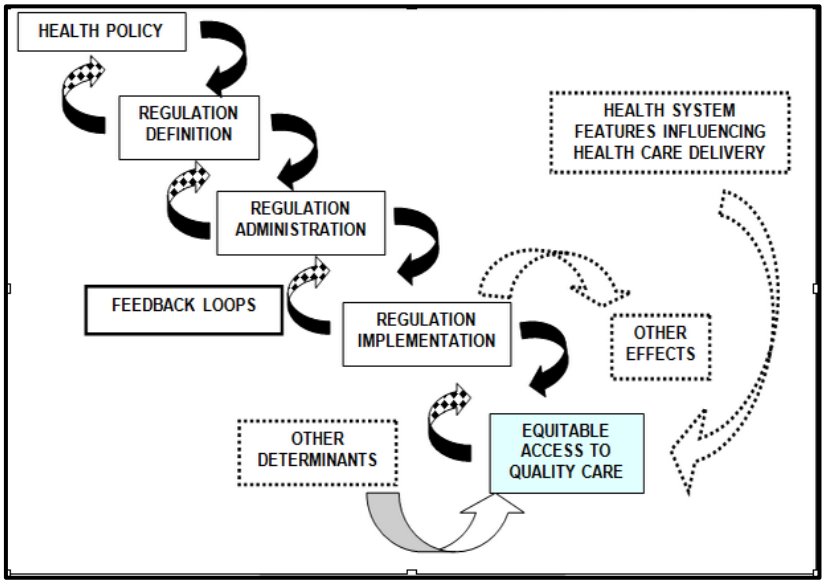
Governance, as used in HESVIC describes how public decisions are made and implemented. Regulation processes and content are used to provide insights into and assess governance. However, universally applied definitions often do not exist and current "quality" features of "good governance" are difficult to apply to the reality as related criteria of governance may not always be validable (Grindle 2011). These concepts further are ideological and embedded in particular cultures. Bearing this sociological understanding in mind, governance becomes a culturally embedded and value-driven concept. This view opens the door to studying bureaucratic and political structures through the discourses of their agents. Hence two different approaches to study governance through regulation were used in the present study. One was more direct and objective that examined the meaning of ''governance" through applying the analytical framework of Siddiqi et al (2009) which identifies ten principles of governance including the rule of law, effectiveness and efficiency, equity and inclusiveness, quality assurance procedures, responsiveness, participation and consensus orientation, transparency and accountability.[2] The other approach was through the discourse analysis of actors involved in different processes of regulation. The way regulation and governance are understood under this approach then emerges through the lenses of actors at the national and local level (view, perception) rather than by any verifiable criteria. These two approaches are not mutually exclusive. Instead, their output was contrasted during the research analytical phase.

[2] See Siddiqi et al 2009 for applicability of this framework to study health system governance in Pakistan

The regulation process

The regulation process in part reflects a flow of guidance and authority for example, from the level of policy (top) to regulation implementation (bottom). Figure 2 below captures this flow in the regulation process. This flow is not bi-directional by definition but can have this feature when feedback loops exist.

Figure 2. Relation between different stages of the regulation process



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. In theory, when management control, information systems and liaison devices detect problems, they should convey it upwards and trigger some adaptation. In order to identify the effects of regulation, other factors affecting access to health care and outputs of the substance and structure of the regulatory environment were also examined.

Actors

By definition, actors, both visible and invisible have a role in the maternal health regulation process. We tried to reveal and characterize the intentions or interests of the identified actors. What can be characterized with the terms invisible are the interests of actors, they may indeed be hidden, multiple, and/or even in contradiction

with the stated aims or objectives of the organizations to which the actors belong. Several mechanisms and factors played a role such as Power, Resources, Incentives, Identity and Motivation in understanding the relations between actors and their roles in the regulation process and its effects. An analysis of the dynamic relations amongst actors and the role they play in the regulation process has been central to HESVIC research.

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

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

The wider environment

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

3. Methods

As elaborated in the previous section on conceptual framework, HESVIC followed a qualitative enquiry to examine how governance and regulations operate in everyday contexts, what effects they do produce and why. HESVIC fell back on four main methodological tools running through both Phase 1 and Phase 2 of the research process. These include a) document analysis of relevant published literature b) content analysis of regulations and related policy guidelines c) field work through semi-structured interviews, Focus Group Discussions and observation of meetings and other events and d) document analysis of grey literature like Consumer Protection Act judgments, Maternal Death Audits, Government circulars and pamphlets, policy evaluation reports, workshop and conference reports. In addition,

websites of ministries, organizations, professional medical associations were also visited frequently to situate their activities and contributions to the study of select regulations. Quantitative data from secondary sources (NFHS, DLHS, and SRS) and compilation of data collected from sub-district hospitals, Primary Health Centres, state training institute were also collected and analyzed.

3.1 Document analysis of secondary published literature

Search and analysis of relevant published secondary literature ran through the whole research period. This secondary data base included three major thematic domains a) conceptual and empirical literature on governance, health policy regulations and health policy analysis[3], b) case study specific literature review[4] on EmOC, abortion and GR and c) evaluations of specific regulations like MTP, Consumer Protection Act, IPHS and Medical Code of Ethics Regulations.

3.2 Content analysis of regulations and related policy guidelines

Content analysis of select and related regulations preceded the field work conducted in phase two. The analysis followed the post-structuralist postulate that "all discourses are *textual* or expressed in texts, *inter-textual* drawing upon other texts and their discourses to achieve meaning and *contextual* embedded in historical, political and cultural settings" (Lupton 1994:18). Analysis of specific regulations led us to other policy documents and guidelines to situate the meanings and interpretations of the regulation objectives, intentions and approaches. For example, the analysis of the regulation of the Indian Public Health Standards necessitated a close reading of the larger program of the National Rural Health Mission, background documents like the civil society policy brief, the Government's Election Manifesto which had resulted in framing the program. Since no regulation works in isolation, we

[3] Key words like governance, health systems, stewardship, accountability, citizen participation, health policy studies, anthropology of policy, discourse analysis, health regulations and India were used to begin with and cross references were noted down for specific search of articles.

[4] Key words like emergency obstetric care, c-sections, maternal mortality, maternal morbidity, abortions, sex-selective abortions, grievance, patient satisfaction, medical complaints, quality care, access, equity in health care, private sector, public sector health care, ANC, utilization of health care were used.

analyzed the content of related regulations as well, for example, Karnataka Private Medical Establishment Act (2007) and PCPNDT Act (1994). The following table provides an overview of the core regulations and related regulations and guidelines analyzed during the course of research.

Table 2: Content Analysis of Regulations

Content Analysis	Regulation	Related Regulation/Guidelines
Emergency Obstetric Care	IPHS (2005)	KPMEA Act, Guidelines for implementation for NRHM, Guidelines for utilization of untied funds
Safe Abortion Services	MTP Act (1971)	PCPNDT Act (1994), Indian code of Medical Ethics Regulations, 2002
Grievance Redressal	Consumer Protection Act (1986)	Indian code of Medical Ethics Regulations, 2002

3.3 Field work

Field work consisting of Focus Group Discussions with health workers, semi-structured interviews with users, implementers, administrators, professional bodies and policy makers was done in July- December 2011. In order to elicit quality data, interviews were preceded by warm up visits to primary health centres and *taluka* hospitals. These visits by the research team helped in many ways: a) establish rapport with health care personnel b) get a first-hand experience of these health facilities and c) understand the larger picture of issues that are at stake in different health centres. Though the issues shared with the research team reflected one kind of perspective (that of health providers and managers), it nevertheless provided valuable information which served as clues to be probed in detail later during interviews. The warm up visits most importantly gave us an opportunity to explain the purpose and orientations of our research to the study respondents.

3.3.1 Focus Group Discussions

We followed a bottom up approach in the chronology of interviews i.e. users-implementers-administrators- to planners. We began with Focus Group Discussions with frontline health workers to learn about their experiences of delivering care at the primary level and implementing many health programs. Though they did not have defined formal role in any of the regulations selected, they nevertheless played an important role in driving many of these regulations at the community level. The FGDs with health workers also enabled us to identify users for different case studies.

3.3.2 Semi-structured Interviews

The interaction with the users took the shape of in-depth interviews giving them enough space and time to narrate their experiences of specific EmOC/MTP/Grievance episodes and beyond. The interviews with users hence took a longer time, an average of one and half hours (in maternal death cases it exceeded this time as a number of relatives inevitably joined to narrate the episode). These were followed by implementers of regulations in the primary health centers (this is only for abortion case study), taluka level hospital, and private sector hospitals at the taluka level followed by sub-district, district level administrators, state and national level policy makers. Table 4 gives an overview of the total number of interviews conducted. The chronology of interviews from bottom up enabled us to identify the effects of the regulations at the level of users which were then taken back to the implementers and administrators to situate and explain these effects. The tools were modified according to the issues, factors, ideas identified at each level (users, implementers at taluka, district and state levels). Since the data analysis went along with data collection, the key themes and issues were identified at each level of transcripts. Such iterative process of data collection helped us to constantly validate the findings from one set of interviews with another.

3.3. 3 Observations of meetings and events

We regularly observed the monthly supervisory meetings of the health Department held at the taluka and district levels. In addition, we attended the Maternal Death Audits meetings and Community Health Days. We obtained consent from the District

administrators to attend these meetings. Observations of these meetings and events served several purposes. These include: a) these meetings are important platforms for translations of policy priority and ideas, disseminations of guidelines and circulars b) observations of meetings enabled us to watch governance in action as this is the forum which discusses the kind of information received, for e.g. maternal deaths, how such adverse events are handled, what are the ensuring mechanisms and how regulations are interpreted, negotiated and why and c) these also helped us to contextualize the tools (through relevant probes) and validate the views of respondents shared in interviews. The team responsible for data collection covered all the three case studies (two researchers per each taluka) as most of the implementers and administrators were responsible for all the three regulations. The data collection was closely coordinated and supervised by two senior researchers. The state and national level interviews were conducted by the senior researchers.

3.4 Sampling

Following HESVIC's methodological approach, respondents were selected through purposive sampling. The principle of purposive sampling was followed at different steps. For instance, considering the North and South differences in the state of Karnataka (Table 3), we chose one district each in north and south. Within each district, one taluka hospital ((First Referral Unit) was chosen for in-depth analysis of the three sets of regulations. Within each district, the taluka served as the unit of analysis as it represents a health service functional unit made of two health care tiers representing minimal structures that are needed to impact on maternal health. Further, all the regulations were applicable to the taluka level.

Figure 3. Study sites

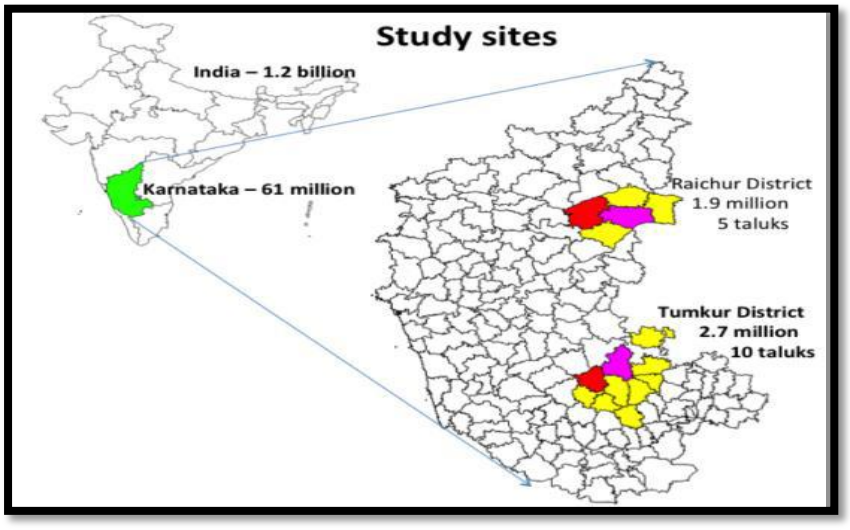


Table 3:Disparity between the north and south Karnataka districts

Indicators	North Karnataka	South Karnataka
Number of districts[5]	12	15
Number of districts below the State average in per capita income (2002)	12	7
Average of Composite development index (2000)	75	86
Number of districts below the state average of Teacher / Pupil ratio (2003)	11	1
Number of districts below the state average in female literacy rate (2003)	9	6
Number of districts below the state average in number of PHCs (2003)	6	1
Number of districts above the state average in IMR (2002)	11	7
Number of districts below the state average in % of families with access to drinking water within the house (2001)	10	9

Source: Karnataka Development Report 2007

For the users for each of the case studies, we considered several representative criteria such as a) background of users (caste, religion, residence in terms of geographic proximity/remoteness from taluka level hospitals, education), b) medical outcomes (for EmOC a range of complications and outcomes were covered like still birth, c-sections, twin pregnancy, maternal death) and c) characteristic of facilities i.e. public/private, 24*7 /non 24*7. For the district and state level administrators, no sampling was required as these are fixed positions served by specific personnel. For all the category of users and implementers which involved sampling, we followed the principle of saturation.

While HESVIC methodological framework required interviews with personnel at each stage of the regulation process i.e. planning, administration and implementation, in India considering the multi-layered health system, multi-tasking health managers and

[5]This data was collected in 2007 by the Karnataka State before 3 of the districts were bifurcated. Hence at that time, there were only 27 districts.

the specific equations in terms of the responsibility of planning between the Centre and the state, there was no strict boundary between planner and administrator and administrator and implementer. For instance when one looks at the regulation of IPHS which is planned centrally but giving the flexibility to innovate and implement at the state level, the NRHM Directorate becomes a planner at the state level (as health is a state subject) but when looked at from the point of the view of the centre, he/she becomes an administrator. Similarly the Administrative Medical Officer (AMO) at the sub-district level is both an administrator and an implementer as he/she is also a practitioner responsible for implementing the regulations and is being regulated. To make it contextually relevant, we understand by the term administrator as someone who is responsible for the implementation of the regulation (who has to ensure that it is being implemented and can impose sanctions positive or negative) while an implementer is one who is regulated. The following table offers the total number of interviews conducted for the study. The merging of cells in the table below shows the overlapping boundaries between case studies (the same set of administrators would be responsible for IPHS and MTP or all the three regulations).

Table 4: Total number of interviews conducted

<table>
<tr><th rowspan="2">Category of Respondents</th><th colspan="3">Total number of Interviews case study wise</th></tr>
<tr><th>EmOC</th><th>Abortion</th><th>GR</th></tr>
<tr><td>Policy makers</td><td>4</td><td>3</td><td>2</td></tr>
<tr><td>Administrators</td><td colspan="2">11</td><td>4</td></tr>
<tr><td>Implementers</td><td colspan="3">28</td></tr>
<tr><td>Professional bodies</td><td colspan="3">6</td></tr>
<tr><td>Others</td><td colspan="2">3</td><td>3</td></tr>
<tr><td>Users</td><td>11</td><td>11</td><td>8</td></tr>
<tr><td>FGDs</td><td colspan="3">8</td></tr>
<tr><td>Total</td><td colspan="3">94</td></tr>
</table>

3.5 Data coding and analysis

All interviews were transcribed verbatim. Four professional transcribers were hired for transcriptions of interview material from the audio recorded version. Each transcription was then crosschecked by the researcher who conducted that particular interview to ensure that no context is missing and highlighted the significance of non-verbal gestures, if any. Each transcript then was analyzed by a senior researcher who is a trained medical anthropologist. This analysis involved a) coding based on main, sub-research questions and the themes emerging from the interviews. Coding also took adequate care to include material on accountability, responsiveness, the understanding of which preceded a thorough reading of existing literature on similar subjects and its contextual interpretations and practice, b) data were organized based on case studies within each interview and finally c) key findings that came from each interview were prepared. Such coding helped us to identify the themes and sub-themes that came prominently through the interviews. Preliminary analysis of individual transcripts was shared with other team members in its weekly meeting to check biases or discrepancy in analytical views, if any.

The analysis then followed each level and then across levels (case study specific users, users across districts, case study across different levels). This then led to a holistic and comprehensive analysis across case studies and across the two districts. At each level, data were duly triangulated with other sources (interviews with meetings, with grey literature). The analysis followed a larger discourse analysis to examine connections across several texts (interview, grey material etc.) and contexts. The interpretative lens of the analysis enabled to study interconnected actions and meanings of such action across levels.

3.6 Ethical Issues

The study proposal had received ethical approval from the Institutional Ethics Committee of IPH. The suggestions of the institutional ethics board as well as the guidelines provided by the International ethics expert of the project consortium were followed during the course of the study. Before conducting the study in the state, permission was obtained from the state Directorate of Health. Informed consent was

obtained from the respondents and confidentiality was maintained throughout the course of the study. However, we faced some issues during data collection. Initially we had difficulty in locating users for abortion services and grievance redressal. There was a great resistance from health staff in identifying the abortion and GR users, so the team used multiple channels to locate users eg. Women's Associations, *Anganwadi* (crèches providing preschool with supplementary nutrition services) workers, *Dalit* (caste based) welfare association, local media members, and District Consumer Forum Records.

Some of the users, we interviewed, asked for assistance. One GR user asked for information and guidance in order to address his/her grievance, some users (maternal death cases) requested us to mediate in offering some financial help and avail of the benefits Government schemes. Though no financial assistance was given, information and counselling on the existing mechanisms of grievance redressal and other Government schemes were shared with them. Many participants saw the research as a potential means to intervene in correcting the system. The benefits of such research and evidence were shared with them in detail.

In addition to the core field work, we carried out two nested studies on grievance redressal. One of these was a content analysis of print media coverage on grievance redressal in Karnataka (September-December 2011). Two search engines were used i.e.Factiva and Times of India Online Archive Search. Key terms like 'medical, health, negligence or negligent or grievance or complain or complaint' were used. The search covered the last ten year period (2001-2011) and covered five English daily newspapers. The second study involved mapping the grievance redressal pathways through a patient satisfaction survey done in the district hospital in Tumkur with 400 patients (exit interviews). This study was conducted in July –September 2011.

4. Introduction to the relevant country context

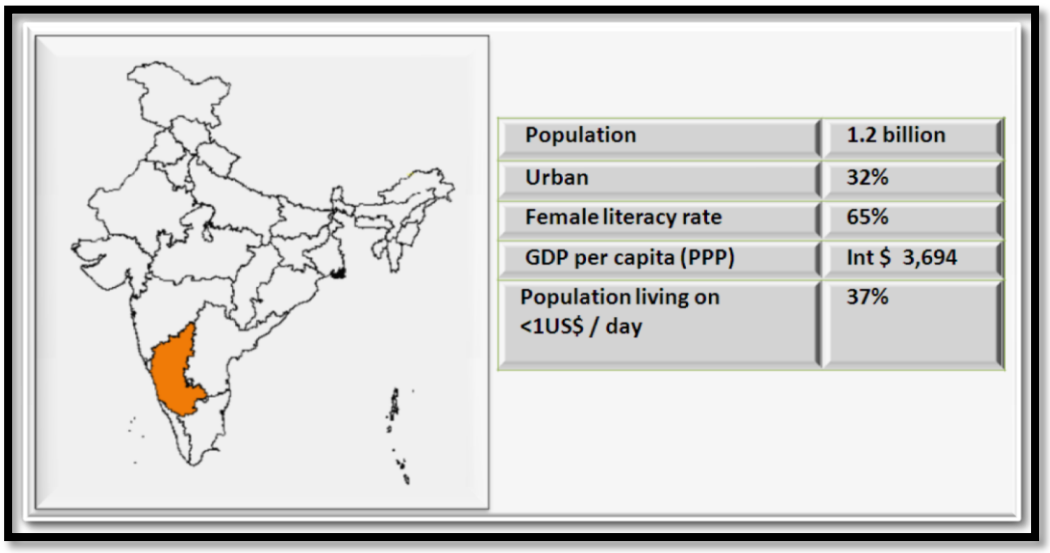
As per the Indian constitution, India is a Sovereign, Secular and Democratic Republic. It promises to secure for its citizens justice, liberty and equality. It is a federation of 28 states, with a clear division of roles. The central government is

responsible for foreign affairs, defence, international trade, banking, insurance, mineral resources, standards in education, elections, major highways, railways and the Supreme Court. The state government maintains law and order, local governments, communications, agriculture, industries, taxes and judiciary, up to the Supreme Court. Whereas public health, health services and hospitals are the responsibility of the state governments, the medical profession, medical education, food safety, population control, epidemic control, and social security are the responsibilities of both central and state governments.

While India is seen as an emerging global economic power, this development is distributed inequitably. India has one of the largest number of dollar billionaires in the world, however, 37% of its population live on less than US$ 1 per day. While its warehouses are overflowing with surplus food grains, India is the home to the largest number of malnourished children in the world.

India has 14 official languages and is home to people following Hinduism (84%), Islam (13%), Christianity (2%), Sikhism, Buddhism, Jainism, etc. Each language or religious group has its own culture that makes it difficult for a planner to organize services for the people. Karnataka is one of the southern states with a geographic area of 192,000 km. It has been divided into 30 districts and 176 taluks (sub-districts). Karnataka's population in 2011 was 61.1 million individuals.

Figure 4. Map of India showing Karnataka state



4.1 Health system in India & Karnataka

Health is the responsibility of mainly the state government. National and local governments also have a role to play, albeit a smaller one. Most states have a three tier system with a primary health centre (PHC) for 20,000 to 30,000 population, a community health centre (CHC) for 100,000 to 120,000 population, a taluka hospital for 400,000 – 500,000 population and finally a district hospital for a 1 – 2 million population. Above this, are the tertiary medical college hospitals that provide specialised and super-speciality services and where medical and para-medical professionals are trained. This is the health service organisation in most states with small variations.

The PHCs have a doctor and a team of nurses and are expected to provide primary care. Patients that need referral are referred to the CHC which has 30 beds and is supposed to have five specialists (Obstetrician, Paediatrician, Surgeon, Anaesthetist and Physician). The CHC also has an operation theatre and a labour room and is expected to manage common surgical, paediatric, obstetric and medical conditions. It is also expected to provide round the clock services. Those who require specialist treatment, e.g. Oto-rhino laryngology, ophthalmic, orthopaedic, dermatology and psychiatry can approach the district hospital for their needs. Other than the above mentioned services, the government also implements various national health programmes for specific diseases or conditions, e.g. immunisation, maternal health, TB, malaria, filarial, leprosy, diabetes, etc. These centrally financed programmes are introduced usually in a vertical manner with their own personnel and resources. They get integrated into the health services only at the PHC level.

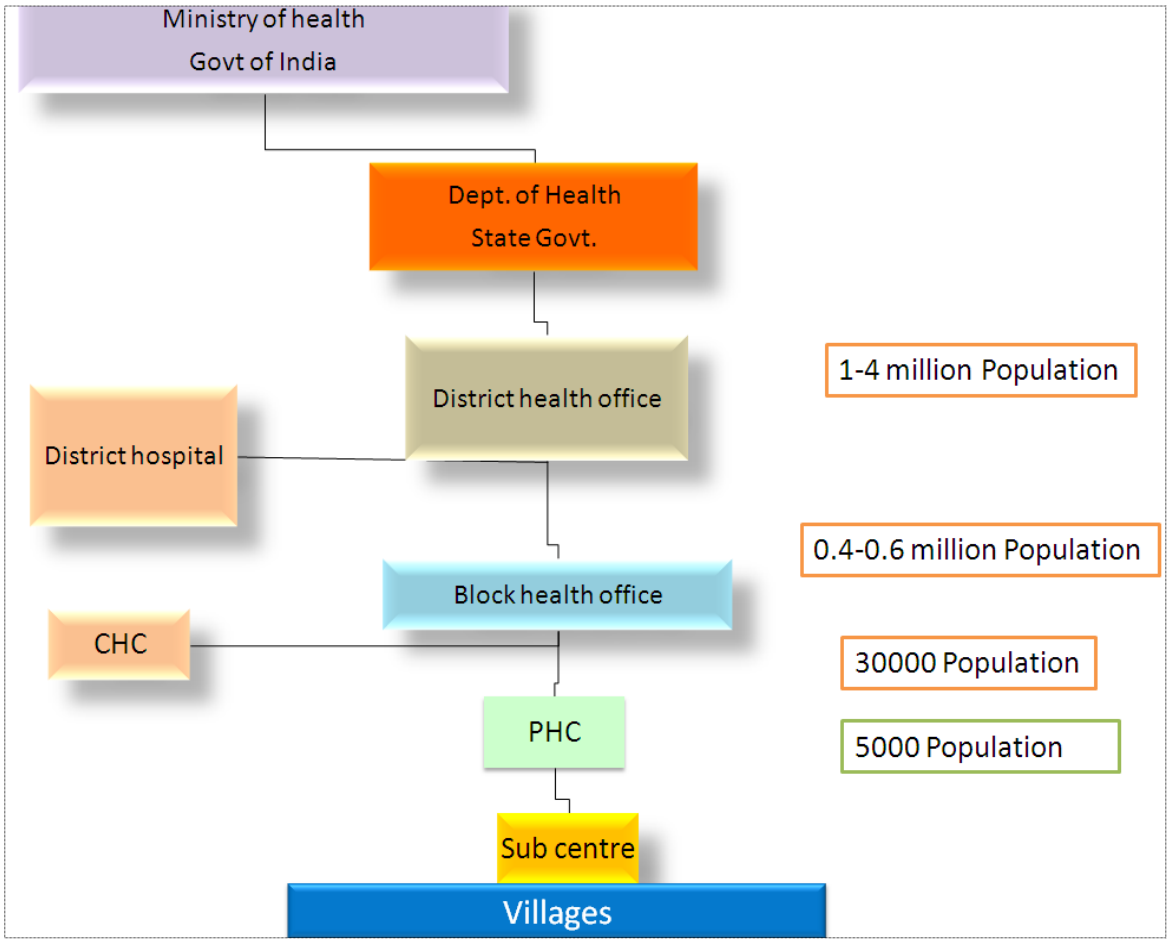
There are millions of private providers who also provide health care to the patients. These private providers can be broadly divided into certified and uncertified practitioners. The former have undergone a formal training and have been certified by the university as well as the professional council to practice medical care. These practitioners are further divided into practitioners of modern medicine (Allopathy) and traditional Indian Systems of Medicine like Ayurveda, Homeopathy, Unani, Siddha and Yoga. The certification is usually life-long and there is no need for any re-certification. It is estimated that 93% of all hospitals and 64% of the hospital beds are

in the private sector (Nandraj et al 2001) along with 80-85% of the allopathic doctors and a similar proportion of practitioners of Indian systems of medicine (Nandraj, Khot, Menon and Brugha 2001; Nandraj et al 2001). The uncertified practitioners are those who do not have any formal certification and practice based on some experiences in the health sector. While majority of the qualified practitioners practice in urban areas, untrained practitioners including traditional birth attendants, traditional healers cater to the needs of the poor populations in rural areas (*ibid* 2001).

These pluralistic health care providers focus mainly on curative care, most of which is irrational. The government is the main provider for preventive and promotive care. Unfortunately, most of this is limited to reproductive and child health; with some resources for contraception, TB control, etc. Individual households finance most of the health care through direct payments at the time of illness. 72% of total health expenditure is met by this mechanism (Devadasan et al 2004). This has serious repercussions in terms of indebtedness and impoverishment of families. It is estimated that each year more than 60 million Indians are pushed below the poverty line because of medical expenses.

There is very little information about the quantity and quality of both formal and informal practitioners in the country. A WHO report on human resources in India states that 643,520 doctors were registered with the Medical council up to 2005. Of which 76,925 (12%) were employed in government services. As per these statistics, there is one doctor per 1,598 populations and one government doctor per 13,000 populations. However, this does not reflect the inequitable distribution of these doctors. In rural areas, there is only one doctor per 31,000 populations. A census of all practitioners conducted in state of Madhya Pradesh estimates that of all the practitioners, 1% is in government service, 9% are in the private sector and the remaining 90% are uncertified practitioners, also in the private sector (De Costa and Diwan 2007).

Figure 5. Health service organization in India



NB: at each level, there are private providers ranging from individual practitioners to hospitals to super specialty facilities (the last at the national and state capitals).

4.2 Health services in Karnataka

One of the main thrusts of the government health department is maternal health. Starting with the Child Survival and Safe Motherhood programmes to current day Reproductive and Child Health programme (RCH II), the government has been trying hard to reduce maternal mortality and morbidity. The strategies ranged from training traditional midwives to promoting institutional deliveries. In 2005, the National government launched the National Rural Health Mission (NRHM) in an effort to improve access to quality health care. There was considerable infusion of financial and human resources, new strategies to provide services and an attempt to integrate all the various vertical programmes under a single umbrella. Some key maternal and child health indicators before and after NRHM are provided in Table 5.

Table 5:Key health indicators in India and Karnataka, before and after NRHM

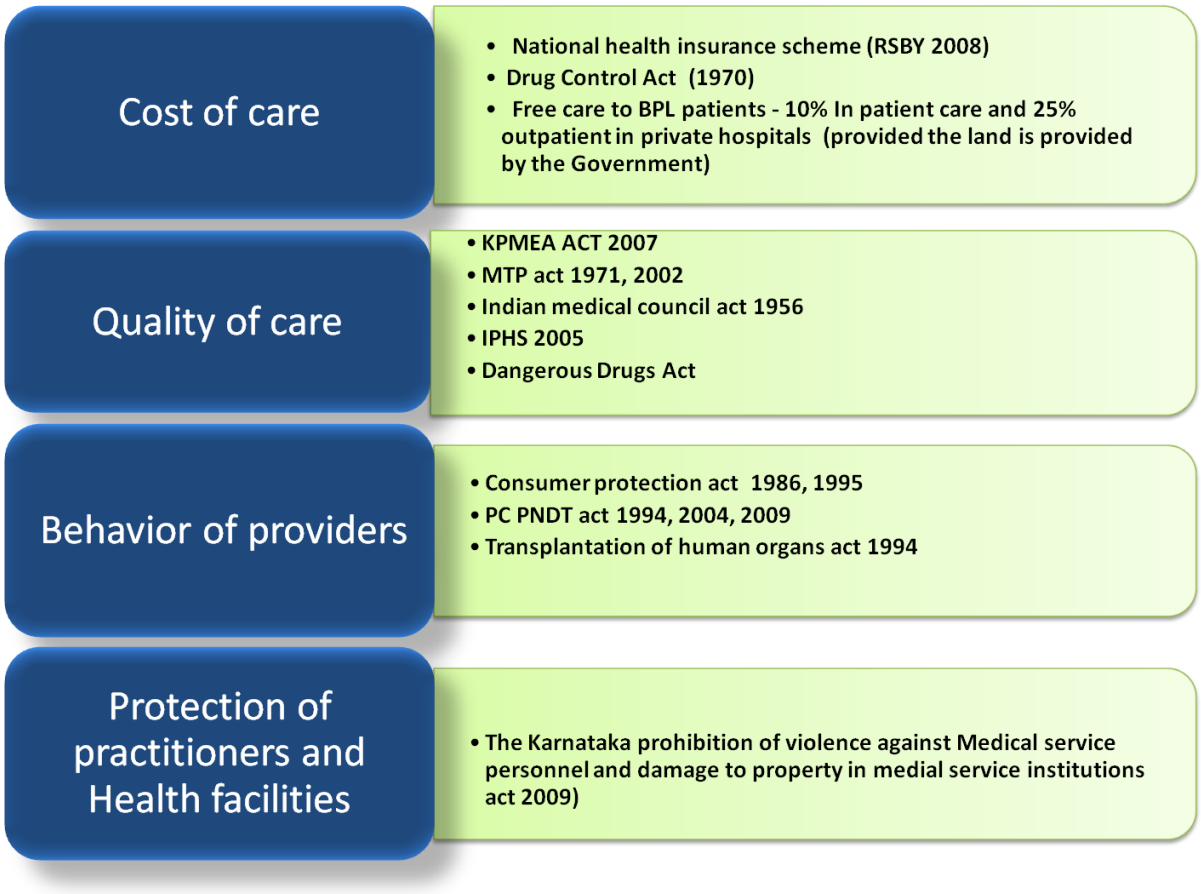
	India		Karnataka	
	2003	2009	2003	2009
Sex ratio (F per 1000 M)	933	940	964	968
Infant mortality rate	60	50	52	41
Maternal mortality ratio	301	212	213	178
Total fertility rate	2.9	2.6	2.3	2.0
% of institutional deliveries	39	73	65	86
% of children (12-23 months) fully immunized	43	61	55	78

One of the striking features of the above indicators is the wide disparity across social, economic and cultural groups. For example, 75% of children belonging to high-income families in India have been fully immunized compared to only 47% of children from low-income families. One gets a similar picture for most indicators and in most states of India.

Existing regulations in health care in the country and Karnataka state exist largely in relation to specific components of health care. Thus some regulations are related to drugs: controlling the sale, price and quality of drugs (Drug Control Act, Drugs and Cosmetics Act, Dangerous Drugs Act), practice (Indian Medical Council Act, Human Organ Transplant Act, Medical termination of pregnancy Act) and facility related (Nursing Home Registration Act, Nurses, Midwives and Health Visitors Act). These formal regulations mostly use command and control approaches to achieve their objectives. The weakest link is the poor implementation of these regulations. Studies indicate that there is hardly any effective regulatory framework for quality assurance in the health sector and regulation of private institutions is extremely varied across states (Peters and Muraleedharan 2008, Sheikh et al 2011). While medical practitioners across the country are required to register with their respective state Medical Councils, affiliated to the Indian Medical council, state laws for licensing of

hospitals exist only in a few states (Bombay Nursing Home Registration Act 1949, West Bengal Clinical establishment Act 1950, Delhi Nursing Homes Registration Act, 1953, Karnataka Private Establishment Act 2007, The Karnataka prohibition of violence against Medicare service personnel and damage to property in medicare service institutions act 2009). We chose to study three sets of regulations that have an impact on maternal health care. The following illustration offers snapshot view of regulations in Karnataka.

Figure 6. Health regulations in Karnataka



5. Case studies

5.1. Ensuring access to quality Emergency Obstetric care: Role of Indian Public Health standards

5.1.1. Overview of the regulation content and implementation procedures

5.1.1.1 Background of the regulation: Policy and Legal Environment

Reduction of maternal mortality Ratio (MMR)[6] has been a major public health concern worldwide, more so in the low income countries. India accounts for more than 20% of the global burden of maternal mortality and the largest number of maternal deaths for any country (Mavalankar 2008). The current MMR 212 per 100,000 live births in India (2007-2009) is still relatively higher than that of many of its Asian counterparts like China (56), Thailand (44) and Sri Lanka (92)[7]. Evidence shows that the decline in MMR in India has been rather slow and uneven across states and regions. It varies from as high as 359 in the state of Uttar Pradesh to as low as 81 in Kerala. The five most commonly reported causes of maternal deaths in India are haemorrhage (38%), sepsis (11%), unsafe abortions (8%), hypertensive disorders (5%) and obstructed labour (5%). Most of these complications and resulting deaths can be avoided by providing good emergency obstetric care (hereafter referred to as EmOC). There is plenty of evidence to suggest that access to quality EmOC is essential to save the lives of women who develop complications of delivery and pregnancy (Fournier 2008; Mavalankar 2005; Paxton 2005; Ronsmans, Haltz and Stanton 2006). Existing literature highlights a number of barriers including financial, geographical, technical, administrative, social, psychological and cultural, to quality EmOC in India (Chaturvedi and Randive 2011; George 2007, 2009; George, Aiyer and Sen 2005; Jeffery and Jeffery 2008, 2010; Mavalankar 1996, 2005, 2008).

[6]Maternal mortality ratio (MMR) is the measure of number of women aged 15-49 years dying due to maternal causes per 1, 00,000 live births. Maternal causes would qualify for the death of a woman while pregnant or within 42 days of the termination of pregnancy (delivery or abortion), irrespective of the duration and site of pregnancy, from any cause related to or aggravated by pregnancy, but not due to accidents or trauma

[7] UNFPA, State of World Population 2007, New York: UNFPA

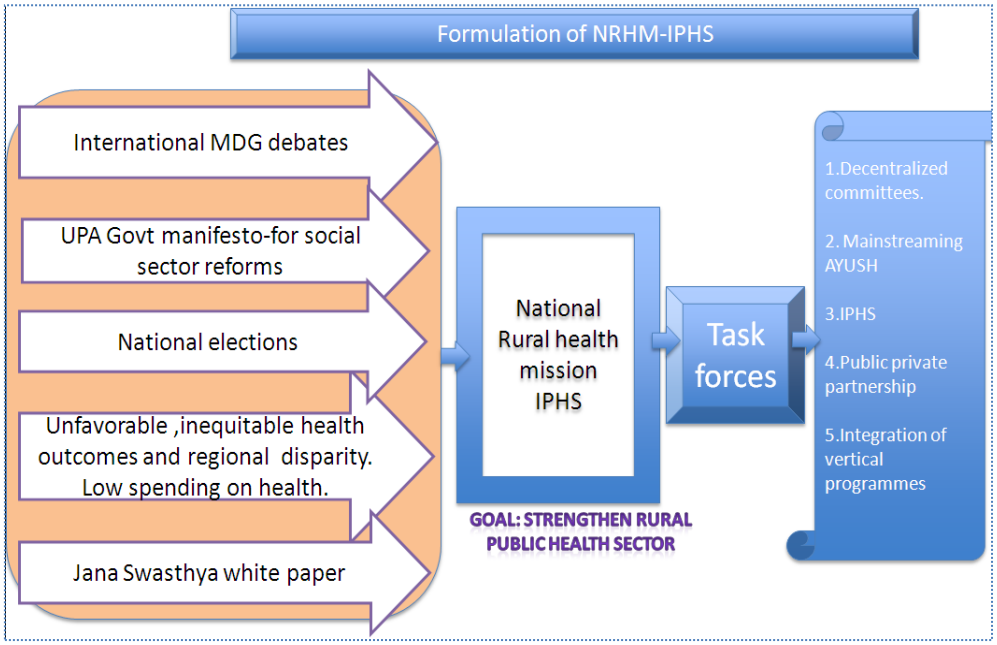
Several policy and programmatic efforts have aimed at improving the status of maternal health and reduce the MMR in India. Initially GOI's maternal health policies primarily focused on family planning program beginning with the passive, clinic based approach of the 1950s which gave way to a more proactive approach in 1960s. The International Council of Population and Development (ICPD) conference in 1994 led to a paradigm shift from target oriented family planning programs in India to integrated Reproductive and Child Health (RCH) programme (Fotso 2009; Mavalankar 2008; Pachauri 1999; Visaria, Jejeebhoy and Merrick 1999). The RCH Programme is an umbrella programme to provide need based, client centered, demand driven, high quality services to the beneficiaries with a view to enhancing the quality of reproductive life of the population and enabling the country to achieve the population stabilization. GoI launched RCH-I Program (1998-2004) which broadened the agenda of reproductive health to include RTI, STI treatment and addressing gender disparity. Although EmOC was one of the strategies in this program, it was not implemented due to lack of focus and limited management capacity (Pachauri 1999). Later RCH-II (2005-2010) was launched and was integrated under the National Rural Health Mission (NRHM, 2005-2012). The integration of RCH II with the NRHM was a major development in maternal health policies in India as it situated maternal health within strengthening of the overall health system in rural areas and the Government of India's commitment to achieve MDG 5.

5.1.1.2 Formulation of IPHS

The NRHM is perhaps the most ambitious public health program of the GoI, launched under the leadership of the United Progressive Alliance (UPA) government in April 2005. NRHM comes through as part of the promises outlined in the Common Minimum Program (the election manifesto of the UPA Government). The UPA Government expressed its commitment to create a government that is 'corruption free, transparent and accountable and to provide an administration that responds and is responsive at all times' (CMP 2004:3). It sought to undertake large-scale reforms in the social sector, including health. On health more specifically, it committed itself to increase spending on public health to at least 2-3% of GDP with a focus on primary health care, a national health insurance scheme for poor families and regulating the prices of essential drugs. These specific objectives outlined in CMP were framed as large-scale interventions in the NRHM Mission Document. The Mission document

and its specific components were prepared through a series of consultations with several stakeholders represented through the different Task Force Groups. The Mission Document articulates the main goal of NRHM as 'to improve access of rural people, especially poor women and children, to equitable, affordable, accountable and effective primary healthcare' (NRHM 2005:4). NRHM claims to set a departure from earlier health programs in India through seeking an integrated and synergistic approach to primary health care. It sought to do so through several core strategies like a) appointing a village level health worker in each village b) strengthening the capacity of the local government to plan and own public health c) strengthening rural public health facilities at all levels by establishing Indian Public Health Standards d) strengthening disease control programs e) mainstreaming traditional systems of medicine and e) promoting public-private partnerships (Government of India 2005). Thus IPHS was introduced (2005) as one of the series of interventions under NRHM. Like other components of NRHM, IPHS was also prepared at the Central Government level through a Task Group (Task Group III) consisting of different stakeholders representing the Government, academics, civil society organizations and elected political representatives. Figure 7 offers an overview of the process of formulation of IPHS as part of NRHM.

Figure 7. NRHM-IPHS policy formulation



5.1.1.3 Objectives and content of regulation

The major objective of IPHS is to provide care that is ***quality oriented*** and ***sensitive*** to the needs of the people

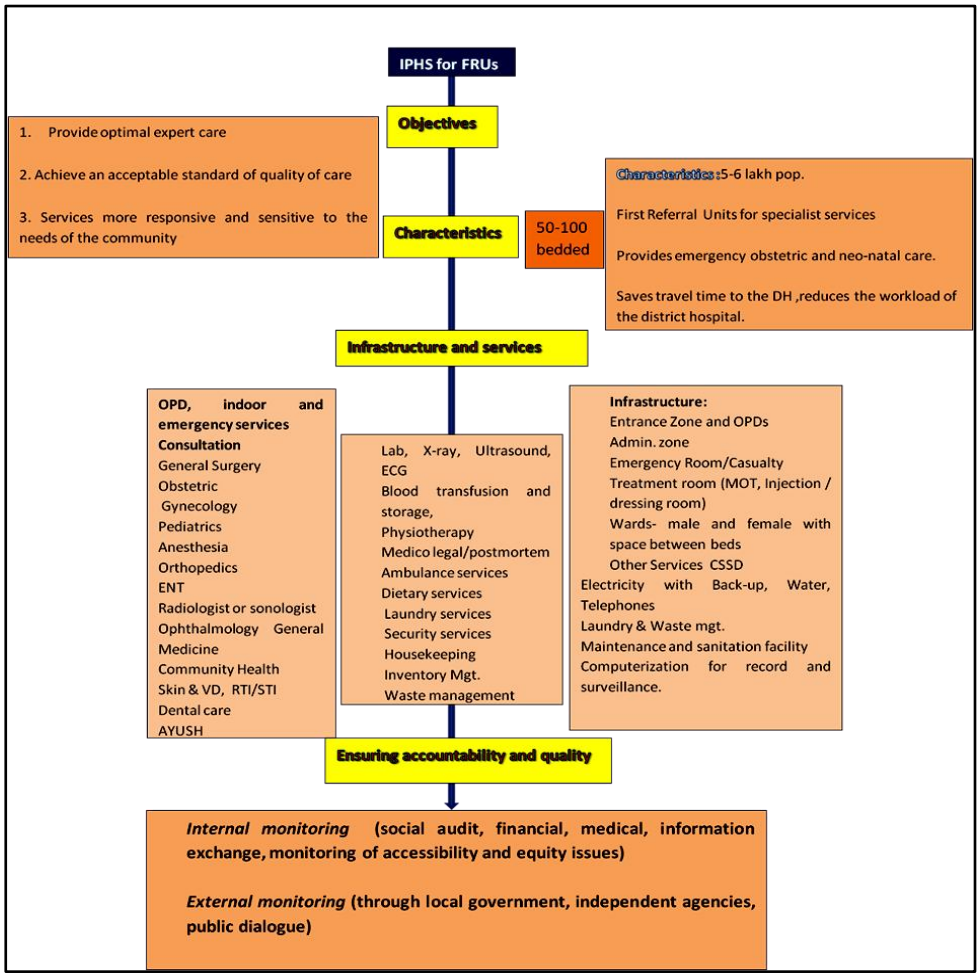
Specific objectives of IPHS for the Sub divisional hospital are the following:

- To provide comprehensive secondary health care (specialist and referral) to the community through the taluka hospital
- Achieve and maintain acceptable standards of quality of care
- Make the services more responsive and sensitive to the needs of the community (NRHM 2005:5)

Following these articulations, the content of the regulation elaborates guidelines on infrastructural improvement, services and monitoring mechanisms. The guidelines pertain to the following:

1. **Infrastructure** (physical building, no of beds, space arrangement of different units like blood storage unit, new born unit, diagnostic labs, residential quarters etc)
2. **Human personnel:** IPHS prescribes the number of specialists, para medical staff, support staff at different levels of rural public health facilities and hence has sought to standardize personnel available in facilities. The shortage of staff and more specifically specialist services is sought to be addressed through different measures like hiring in specialists from private health sector, contractual appointments and training of medical officers in EmOC and LSAS.
3. **Service guarantees-** it lists the kinds of services that need to be provided in a rural public health facility. For sub-divisional level, the guidelines list the various curative including emergency, different specialist and referral services, preventive, diagnostic and para-clinical services. The facilities at this level are expected to guarantee the provision of such services. It also provides a standard treatment protocol that lists suggested actions for different illnesses under different specialties.
4. **Drugs/equipment-** enlists the drugs, different equipments that need to be made available to deliver health care in public health facilities

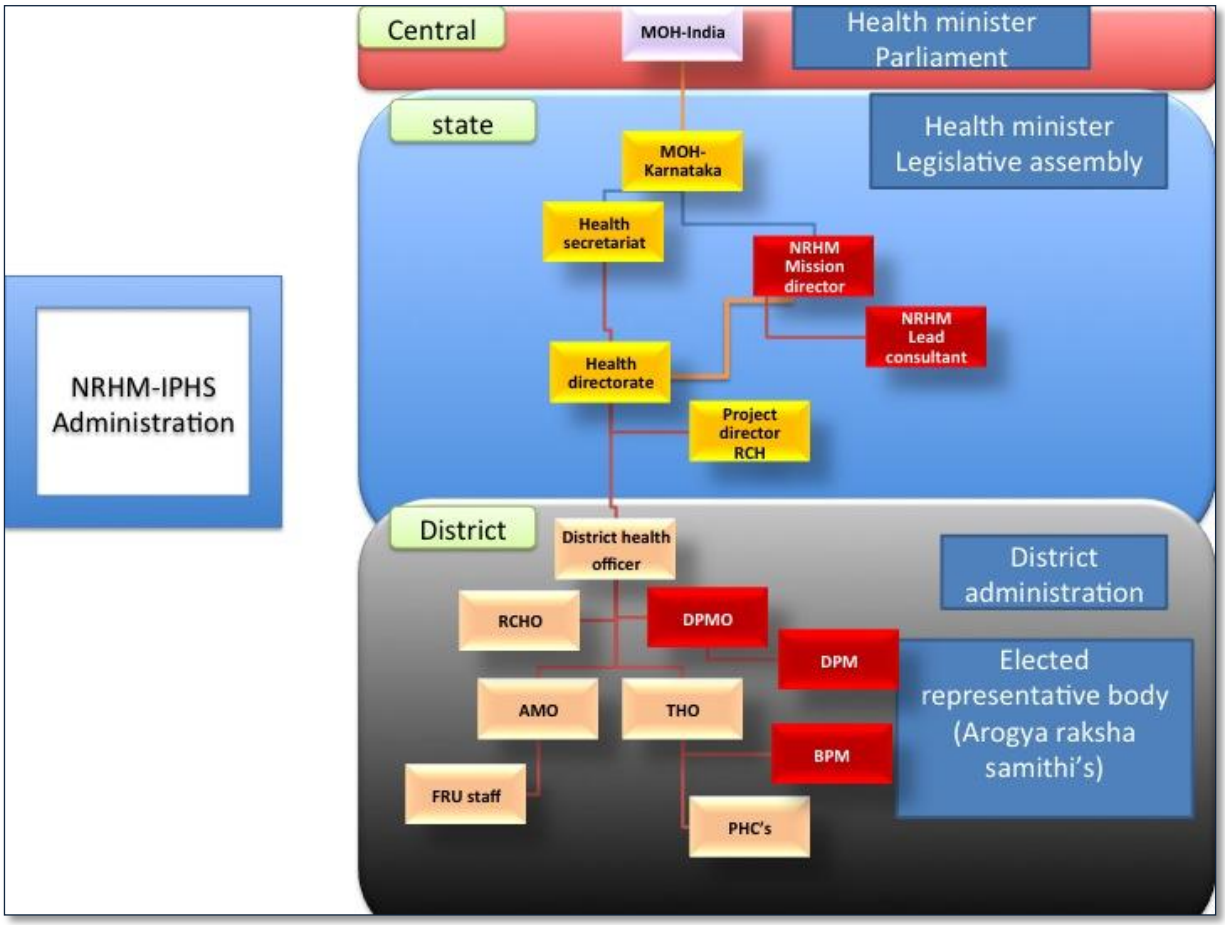
Figure 8. Summary flow chart of Indian public health standards



5.1.1.4 Procedures of Administration and implementation of the regulation

This section provides the various mechanisms envisaged by the regulation to establish standards under IPHS and the activities laid down at different levels. Following is the proposed institutional mechanisms of NRHM from the national to local level:

Figure 9. NRHM-IPHS Administration



National level management of NRHM: Being a program of the Government of India, NRHM is managed by the Ministry of Health (Department of Family welfare) and is headed the by the Minster of Health. In order to carry out the functions under the Mission, the Mission has an empowered structure, The Mission Steering Group (MSG) and the Empowered Programme Committee (EPC). Centre is responsible for developing Regulations, issuing guidelines, development of partnership with nongovernmental stakeholders, developing framework for effective interventions through capacity development and decentralization. A National Health Systems Resource Centre (NHSRC) is being set up to serve as an Apex body for technical assistance, dissemination and for functioning as a Centre of Excellence for facilitating the Centre and the States in the Programme.

State level management of NRHM: State Health Mission is headed by the Chief Minister of the State. The functions under the Mission are carried out through the

State Health and Family Welfare Society under the leadership of the state Mission Directorate. It provides support to District health mission and appraises District health plans. State Health Systems Resource Centre (SHSRC) is being set up to serve as an Apex body for technical assistance for the state. Programme management support centre (State Programme Management Unit (SPMU) and District Programme Management Unit (DPMU)) are established to augment the programme management capacity of the state and district levels respectively.

District level management of NRHM: It is responsible for planning, implementing, monitoring and evaluating progress of Mission activities at district level. It is responsible for preparing an annual plan for the district and suggesting district specific interventions. It is supposed to carry out Health Facility Surveys to identify the gaps in the health system resources.

Block level management of NRHM: At this level, the responsibility of officials at the block level is to amalgamate primary, secondary and tertiary care, ensuring proper distribution of supplies to PHCs, ensuring proper and prompt communication, transport and referral linkages. It is also responsible for organizing public hearings and conducting health facility surveys.

NRHM through RCH II envisages a holistic strategy to bring down MMR, encompassing **c**are during pregnancy, childbirth and new born which are to be provided at any of the three facility levels as below:

Level 3 Institutional Delivery (Comprehensive Level-FRU): where Comprehensive Emergency Obstetric and New born Care (CEmOC) is provided

Level 2 Institutional Delivery (Basic Level): where delivery will be conducted by a skilled birth attendant in a 24x7 PHC level

Level 1 Skilled Birth Attendance: This refers to a delivery conducted by skilled birth attendant in all Sub-Centres and in some Primary Health Centres (PHCs) which have not yet reached the next level of “24 x 7 PHC”.

Table 6:RCH II three level strategies

Level 1	Level 2	Level 3
-Normal delivery with use of Partograph - Infection prevention -Identification and referral for danger signs -Pre-referral management for obstetric emergencies, e.g.eclampsia, PPH, shock -Assured referral linkages with higher facilities	All in Level 1 + Availability of following services round the clock -Episiotomy and suturing cervical tear -Assisted vaginal deliveries -Stabilisation of patients with obstetric emergencies, e.g. eclampsia, PPH, sepsis, shock -Referral linkages with higher Facilities	All in Level 2 + availability of following services round the clock -Management of obstructed labour -Surgical interventions like Caesarean section -Comprehensive management of all obstetric emergencies, e.g. PIH/Eclampsia, Sepsis, PPH, retained placenta, shock etc. - In-house blood bank/blood storage centre -Referral linkages with higher facilities including medical colleges

The above service delivery is expected to be supervised at all three levels- Block, District and State levels with the following process adapted: (i) Periodic review meetings (ii) Monthly analysis, validation and feedback of HMIS data generated (iii) Facility visits: using supervisory protocols (iv)Training: on-the-job, refresher and supplementary. Our study mainly focuses on Level -3 which provides CEmOC. Administrative Medical Officer is the nodal person who monitors the service delivery at the FRU level.

5.1.1.5 Regulatory approaches

A careful reading of the IPHS guidelines shows that IPHS adopts a mix of regulatory approaches. These approaches are: a) consumer oriented (through articulations like

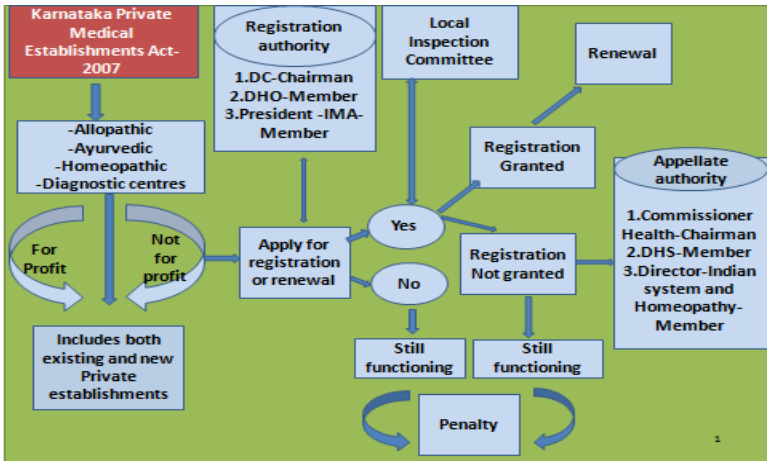
community monitoring, charter of patients' rights, public dialogue), b) market oriented (outsourcing of ancillary services like laundry, waste management, housekeeping, sanitation etc, contracting in and out of personnel/specialist services) and c) collaborative (involvement of a number of stakeholders in planning and implementation of IPHS). As is stated earlier, IPHS are mere guidelines and hence lack a mandate.

5.1.1.6 Related regulations

We studied a related regulation on Karnataka Private Medical Establishment Act - (KPMEA) which has been introduced in the state of Karnataka in 2007 to regulate the private sector. This act has replaced the Karnataka Private Nursing Home (Regulation) Act, 1976. This Act has faced a lot of resistance from professional medical associations, representatives of private hospitals and it took two years for the Government to frame the rules of its implementation in 2009.

Under this act, it is mandatory that all private medical establishments are registered with the registration authority located in each district. Before issuing the registration certificate, the district-level regulatory committee inspects the establishment. The certificate will be issued only if stipulated minimum standards are fulfilled. The registration will be valid for a period of five years. Any individual running a private medical establishment without registration is liable for imprisonment up to three years and a maximum fine of Rs 10,000. Besides, the department can order closure of the establishment under the Act. The content and implementation procedures are described in Figure 10 below.

Figure 10. Content and Administration of KPMEA



HESVIC lens of IPHS

We chose IPHS to ask a) how the setting of Indian Public Health standards has helped to facilitate access to quality maternal health care and b) how different accountability mechanisms within IPHS have resulted in better governance of health in general and maternal health in particular. The focus on IPHS helps us in two ways a) through its general focus on strengthening the health systems in rural areas, it enables us to examine the effects of this regulation on general health governance and b) through its commitment to MDG 5, and it enables us to examine its specific role in ensuring quality maternal health care.

5.1.2 Effects of regulation

The effects of IPHS need to be contextualised in the larger effect of NRHM as it is unfeasible to isolate IPHS from the larger program.

5.1.2.1 Visibility of maternal health as a policy priority

Though not stated as an explicit objective, IPHS through NRHM has provided greater visibility of maternal health as a state policy priority. Such visibility is materialized through a range of cash incentives and material benefits to pregnant women[8], strengthening health institutions (updating infrastructure of existing buildings, making them function 24*7 by additional personnel, services), organizing events like community health days (that celebrate pregnant women with traditional marital

[8] These benefits include

Prasoothi Aaraike program:

This programme initiated by Karnataka provides an assistance of 30.7 Euros in 1st and 2nd instalment during 2nd& 3rd trimester @ 15.3 Euros respectively to encourage rest, nutritious food and medical care during 1st and 2nd live births for BPL mothers. The funding is from Govt. of Karnataka

Janani Suraksha Yojana:

JSY is a safe motherhood intervention under NRHM being implemented with the objective of reducing maternal and neo-natal mortality by promoting institutional delivery among BPL mothers during 1st and 2nd live births. Amount is dispersed in one instalment @ 9.23 Euros. JSY is a 100 % centrally sponsored scheme.

Madilu kit scheme is an initiative of Karnataka government to provide post natal care for the mother and the child. This kit contains 19 items such as Mosquito curtain, Medium sized carpet, Medium sized bed sheet.

symbols), appointing front line health workers called ASHA in each village responsible for mobilizing women for ANC check up and accompanying them for institutional delivery apart from other activities, conducting regular maternal death audits, instituting awards like best FRU award in the state for facilities offering good EmOC services. A state level planner thus states:

> *What RCH could not do, NRHM has done it. The state's commitment to prioritize maternal health is beyond doubt (EMOC_PLANNER_01_02)*

5.1.2.2 Increase in institutional deliveries

NRHM through IPHS at different levels sought to increase access to public health facilities. This was done through strengthening health facilities at first line and second line services and also instituting cash incentives to promote utilization of public health facilities including institutional deliveries. Cash incentives are offered both to the health workers and families to mobilize women to deliver safely in health facilities. There is a substantial increase in the number of institutional deliveries in the state and in these two districts studied (Figure 11). However the increase is slower in Raichur than Tumkur as seen in the Figure 12.

Figure 11. Trends in Institutional deliveries, Karnataka State 1992-2010

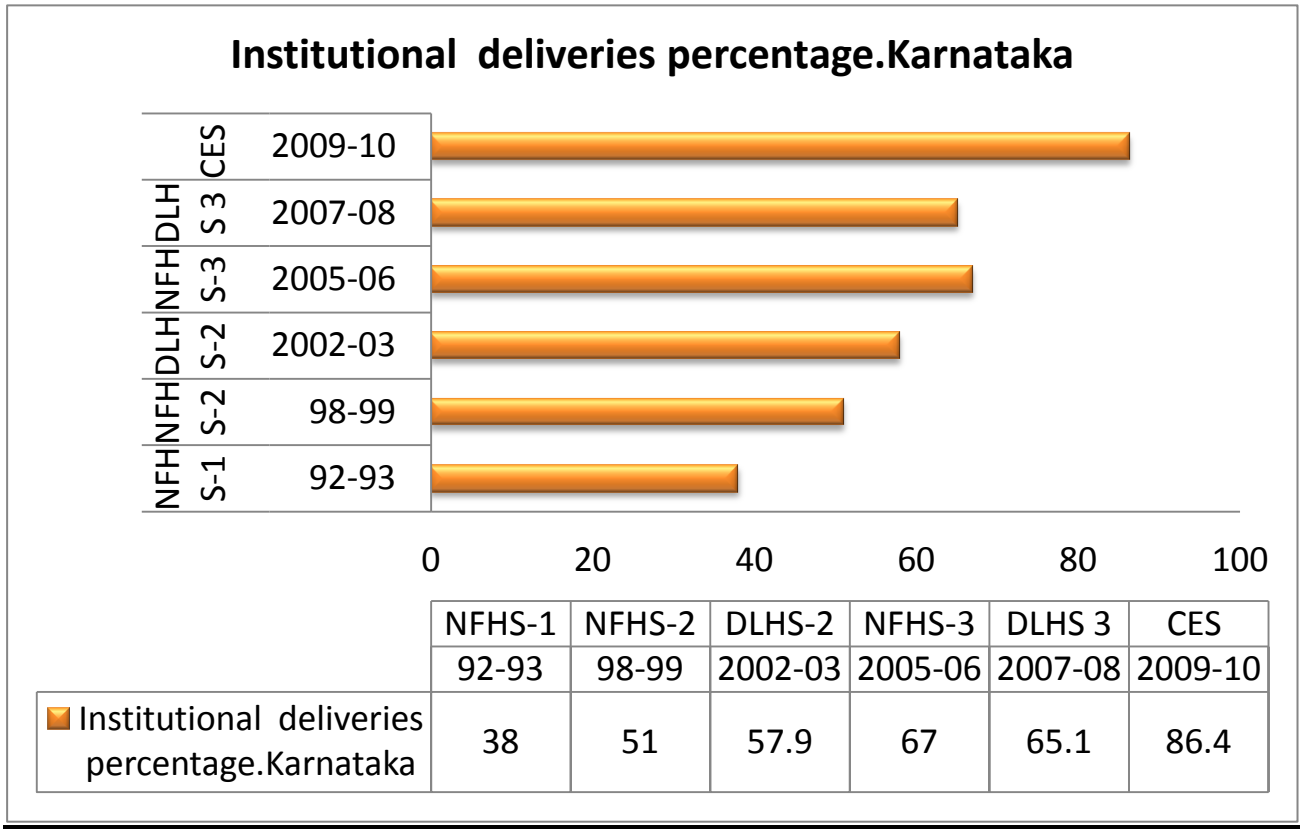
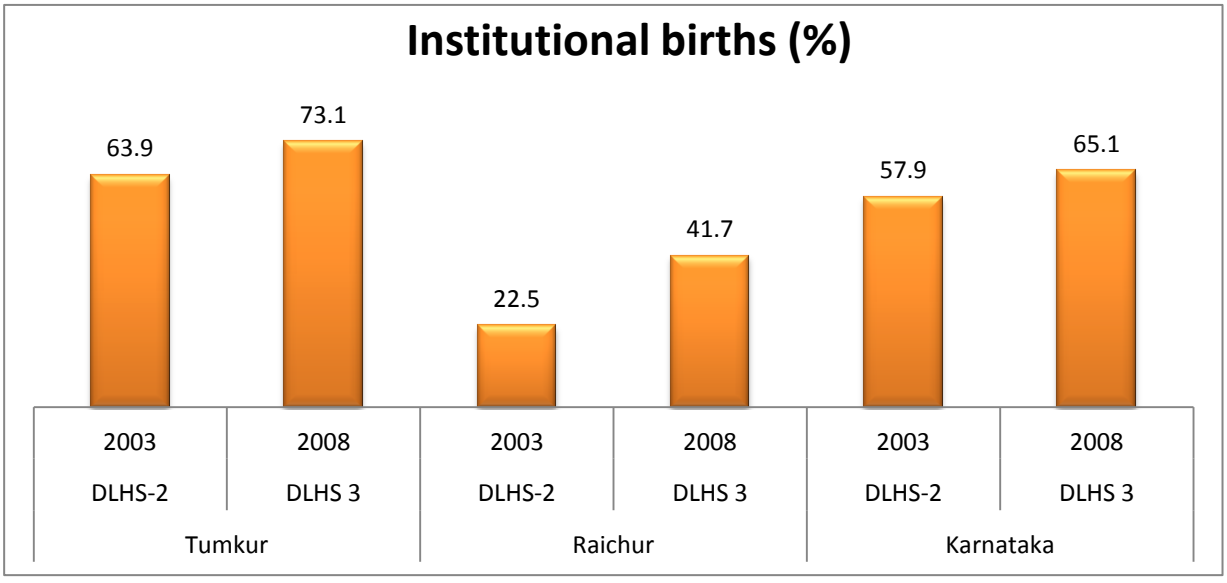


Figure 12. Institutional births (%) Tumkur, Raichur and Karnataka



5.1.2.3 Creation of resources: Ununiform

Unlike the other two regulations, IPHS does not work on existing resources. Rather, one of the objectives of IPHS is to create more resources including infrastructure,

human resources, blood storage units, functional operation theatre etc to provide EmOC. Hence the working of the regulation depends on its ability to have created these resources. The regulation can hence be assessed through this objective of establishing resources as envisaged in the guidelines for implementation. As discussed in the text below, these resources are not uniform either in terms of nature of resource (financial, human, infrastructure for example) or in terms of region.

Table 7:Infrastructure for EmOC care Karnataka state & study districts

	Infrastructure	**Status-2011**		
		Karnataka State	**Tumkur**	**Raichur**
FLHS Basic EmOC services provided MTP services subject to provider training	Total Population	61,130,704	26,81,449	1924773
	Primary Health Centres (PHC)	2193	141	46
	PHC/population ratio	27,875	19,027	41,842
	Standard	30,000	30,000	30,000
	Difference	-2,125	-10,973	11,842
FRU Comprehensive EmOC services provided MTP services provided	FRU/Sub district hospital/50-100 bed hospitals	149	9	5
	FRU/population	4,10,273	297,938	384,954
	Standard	500,000	500,000	500,000
	Difference	-89727	-202062	-115046
Functional FRU	FRU with CS facility	131	6	2
	Functional FRU /population	466646	446908	962387

Source: Census 2011, PIP 2011-12 Karnataka

NRHM made its mark through the Government's commitment to increase its spending on health from 0.9 to 2.3% of the country GDP. Hence increase in financial resources has been a significant change in the health care infrastructure. Under NRHM, attempts are made to fill the gaps in areas like infrastructure, manpower, supply of drugs and equipments, optimal utilization of funds through devolution of funds to PRI (Panchayat Raj Institutions-Local Governments) by creating committees like ARS (Aarogya Raksha Samiti- Patient welfare Committee) and VHSCs (Village Health sanitation committees).These initiatives have brought in better financial resources than before with greater flexibility and authority through untied funds. There is better physical infrastructure compared to what was earlier in the government hospitals before the launch of NRHM, a finding discussed in other studies that were undertaken to evaluate NRHM in the state (Bajpai, Sachs and Dholakia 2009; Gill 2009; Husain 2011). In Tumkur district for instance, all the First Referral Units have been upgraded to 100 bedded general hospitals with physical infrastructure. However as the above table shows, there is huge discrepancy in terms of physical infrastructure in the districts of North and South Karnataka. Raichur suffers from critical shortage of public health facilities at both first line and second line health services representing the principle of inverse care law. Only two FRUs with the capacity to offer c-sections currently cater to a population of 962,387 in Raichur district.

Despite the relatively better physical infrastructure in the southern district, FRUs are critically deficient in human resources particularly of specialists for offering specialist and referral care for EmOC. Either the FRUs in a district like Tumkur function with one OBG, one anaesthetist (or hence 24*7 EmOC care can't be given) or in places like Raichur, many FRUs don't function or partially function because of lack of availability of specialists. Either sanctioned posts are not filled up or when they are filled, specialists are either on long leave or running private practice. Considering the significance of human resources particularly specialists, NRHM made provisions for training (three months of training) of M.B.B.S doctors in CEmOC to conduct caesarean sections and LSAS (Life Saving anaesthetist skills) to facilitate provision of EmOC services in FRUs. This provision has received mixed reactions from specialists and M.B.B.S doctors. The trained personnel in the FRUs studied indicate

lack of adequate training, lack of team support as reasons for not being able to offer EmOC services.

Data from the field suggest that in a situation of scare specialist resources, provision of EmOC services depends on individual motivations of administrators to look for other arrangements, equations with private practitioners in the area and support of the staff (team support was looked upon as critical to manage a hospital and offer health services, more so services like EmOC, the role of team support will be elaborated further in the next section). Table 8 elaborates on the status of the three FRUs studied in both the districts which indicate the failure of the regulation to address issues of access to C-EmOC service.

Table 8:Status of First Referral units to offer CEmOC

Resources	**Tumkur**		**Raichur**
	FRU-A	**FRU-B**	**FRU-C**
Obstetricians **Posted** **Working**	2 1 EmOC services provided partially	1 1 No EmOC services provided	1 1 No EmOC services provided
Anesthetists **Posted** **Qualification** **Working**	- Posted - MD - Working	- Posted - LSAS trained - Not working	- Posted - MD - On call and need basis
Operation theatre facility			
Availability	Available	Available	Available
Functioning	Yes	No	No
LSCS-EmOC	Yes	No	No
Blood storage unit	Available	Not available	Not available

5.1.2.3 Provision of EmOC service by 'chance' and 'luck' often resulting in multiple referral

While there is a rise in institutional deliveries; upgraded FRUs have not been able to ensure 24*7 EmOC service due to several reasons like lack of specialists (one OBG or the OBG on leave), lack of blood storage unit and lack of availability of blood. The good outcomes have been due to 'good luck' and 'chance' where all these resources have been made available at that particular time and place. Most of the EmOC episodes lead to multiple referrals with varying outcomes. In fact the six maternal death cases interviewed and heard in the study involved multiple referrals from one facility to another in public and private facilities.

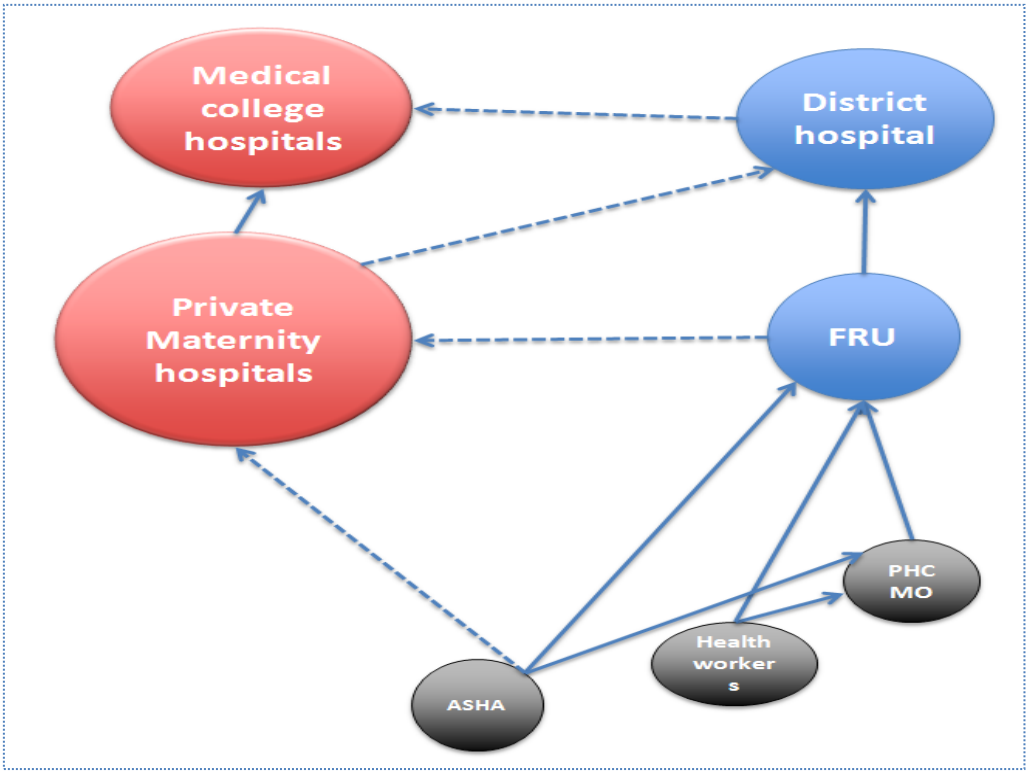
The FRU level implementers and administrators were of the view that though there is an increase in handling of referred cases, referrals (which otherwise could have been handled at the FRU level) still take place particularly those that come during night time (because of one OBG and one specialist who cannot afford to provide round the clock service) and/or lack of availability of blood for transfusion.

> *These days our referrals are caesarean sections which we get during the night time. We are not able to handle. Because of strain of gynaecologist, they have to come in the morning and work you know. General emergency we take, if the patients can wait we will do it in the morning. Another reason is those who require more of blood transfusion, severe anaemia during pregnancy, even in day time we are referring, if it is one or two bottles we can manage with our blood storage but not more (EmOC_ADMINISTRATOR_04_01)*

In fact while both the users and health workers shared the view that Government hospitals including the PHCs can be relied upon for normal deliveries, they are unpredictable when it comes to provide EmOC care. One is not sure when and where such cases are managed successfully and when they are referred out. The analysis of users' experiences, interviews with health workers and others shows that a number of factors have played a role in accessing care in such emergency

situations, which also bring in home the role of different actors. These factors include a) suggested referral by the health care providers to specific higher centres b) role of the family in weighing options between going to the referred government hospital and nearby private centre c) health workers and informal providers such as RMPs (especially in Raichur) facilitate such decision keeping other considerations in mind such as trust of the community, suitability of patients' needs, distance, time, pressure of management of complicated case, easier disbursement of incentives, etc. and d) past bad obstetric history and resultant preference for private facilities. The following figure shows how EmOC service is provided in these two districts and the role of different actors. The health workers play an important role in deciding the referral path of the woman seeking EmOC service. The following figure shows the larger role of private sector in providing EmOC service in the areas studied, a finding pointed out in other studies as well (Bhatia 2004; Mathews 2005; Metgud 2009).

Figure 13. EmOC service providers in the districts



The analysis of the user experiences also shows the involvement of additional actors like caste based organization such as *Dalit Sangharsh Samiti* and transporter's union. A careful reading of the involvement of these actors shows that their involvement varies resulting in different outcomes. For example, in some cases the

senior administrator responsible for maternal and child health program personally intervenes to ensure management of a particular EmOC case. In other cases, health staff accompanies the patient till the last point of referral, auto-unions intervene to ensure availability of an ambulance or a caste based association intervenes to ensure timely EmOC in a FRU. However these interventions are ad-hoc than systemic.

In the northern district, where access to a public health facility is worse than that of the south, the provision of EmOC is ad-hoc. In the study taluka, the public sector FRU doesn't offer EmOC care due to lack of specialists though the same specialists offer similar services in the private nursing homes. EmOC processes and outcomes are managed by few nursing homes where barring one, none of the nursing homes had a full-fledged obstetrician. Many of the specialists in public sector are available on 'call' (24 hours on call duty on rotation implying one day of call will be followed by a day off). Due to non-availability and non-accessibility of specialists, EmOC in the study taluka is provided by non-specialized doctors.

> *In FRU there is no specialist working, which causes lot of problems. We cannot refer also… so what we do is, we try to handle the case ourselves; so many cases have become still births. Patients will be ready for that, because they are not ready to go to private. They know that they may have to spend around Rs. 20,000- 25,000 (US$ 359-449) if they go to a private OBG specialist* (EmOC_IMPLEMENTERS_27_02).

Some of the non-specialized doctors go to the extent of deceiving the patients with what is called a 'lower caesarean section' after doing episiotomy[9]. Health workers and RMPs play an important role in directing the patients to one private doctor or other where it is the commission or the equations with the private doctor matters. The

[9] Doctors who are not trained to conduct caesarean sections do episiotomy while delivering the baby. However, they deceive patients saying they have done lower caesarean section and have helped the patient from undergoing an elaborative abdominal surgery. This is done to capitalise on the preference for normal deliveries among women in villages in northern district.

study showed that apart from a crisis of the public sector hospitals, factors like personal equations with private doctors, ability to negotiate with patients' demands for a normal v/s caesarean section, professional jealousy, caste and gender equations, and access to local political support decide the fate of EmOC care for patients. Many EmOC cases resulted in multiple referrals of patients from one facility to another.

> *Yes, what is happening here is that patients move from facility 1 to 2 to 3 and finally land in graveyard. A lot of referrals are unnecessary (EmOC_ADMINISTRATOR_03_01)*

> *She visited X PHC a couple of times. Since the labour pain was delayed, we did not take chance and brought her to taluka hospital. Labour pain was induced and the delivery happened nicely but problem began after that. She developed severe bleeding, which could not be stopped in taluka hospital. She was referred to district hospital in an ambulance accompanied by the nurses. The doctor did the operation in district hospital but had to be referred to Bangalore again in 5 hours' time. In Bangalore, they transfused blood, but patient was not responding to medicines. She was not conscious. She delivered on July 9th and passed away next day, on the 10th (EmOC_USER_07_01)*

Analysis of all the episodes of maternal deaths showed that all these cases made serious efforts to seek EmOC services in different facilities yet they died, a finding reinforced in other in-depth studies of individual cases of maternal deaths (George, Aiyer and Sen 2005). All cases of maternal deaths witnessed, heard and interviewed had died as an effect of multiple referrals- either they died in transit or in the process of being hopped from one hospital to another. Following is a narrative from the family members of a young woman who died during child birth after trying to seek services repeatedly in different health facilities.

Box 2: ***Case of a maternal death of a 24 year old tribal woman***

She missed her periods, consulted the village health worker who advised for urine pregnancy test. After confirming the pregnancy, health worker referred her to Taluka hospital X to get the blood tests done. Had her first ANC in Taluka hospital X by a specialist, who prescribed her protein supplements. She left for her maternal home when she was 4 months pregnant and had regular ANCs from a private practitioner in that area. On completion of 8 months of pregnancy, one day she complained of abdomen pain at 8.30am. Accompanied by her husband, reached taluka hospital, which was around 45 kilometers away at 12 pm by using 108 ambulances (free transport provided by Department of health and Family welfare services). The obstetrician examined her and declared that it is false labor pain and she was asked come to hospital after a week. She had second episode of abdominal pain after a week at around 5.30pm. By using 108 ambulances she again went to Taluka hospital X at 6.30pm with her husband. The same obstetrician who had examined her earlier was on duty that day. She referred the pregnant woman to higher centre even without examining her by stating the reason that 'she is short stature and she needs caesarian section'. Husband and wife did not know what to do and they sat in a corner thinking whether to go to higher centre or not. Meanwhile a nurse who was on duty came and examined her at 9pm and told that it is false labor pain.

Next day, worried by repeated abdominal pain, the woman's father in law took her to a scanning centre run by a private practitioner in a neighboring taluka. Later they went to Taluka hospital Y, which was perceived to be a better functioning hospital. A specialist examined her and sent her home back saying that, it is false labour pain. After three days, she had a third episode of abdominal pain at 4 pm. They reached taluka hospital X by 6 pm using 108 ambulances and delivered a healthy baby at 7pm by normal delivery. She was discharged after 3 days. She went to her maternal place, where she developed abdominal pain and fever very next day. Her mother took her to a nearby PHC at 11am, where she was referred to Taluka hospital X. She reached Taluka hospital X around 4pm accompanied by husband, mother in law and father in law. Here she was admitted for a day and later referred to Taluka hospital Y, which was around 45 kilometers away. However, family members made a decision to go to a private hospital expecting better quality of care. Reached a private nursing home Z by paying Rs. 1000 to ambulance at 1 pm. There she was admitted for 4 days and treated with antibiotics. Blood transfusion was advised and family members had to arrange for the blood. The woman was discharged on the 5th day but developed abdomen pain and fever again. She passed away after 2 days of being at home after the discharge from the hospital.

Such narrative bears testimony to the violations of basic principles of quality of care as patient-centred, continuous, reduction of suffering, anxiety and premature deaths[10].

5.1.2.4 Averting risk causes deaths

While lack of resources definitely has been a major reason for referral, a tendency to avoid high risk cases has also caused a number of unnecessary referral. The visibility of maternal health perhaps has led to this unintended effect. For instance, the health workers (ANMs) who used to do a number of deliveries earlier are scared to handle any potentially risky cases and they refer the women to either a PHC or a FRU. They say they are scared of the mob attack (in case of the worst outcome) and maternal death audit which is humiliating for health workers. They are terrified about the audit.

> *Better to refer the patient, than get caught up in the unnecessary problems of audit and the humiliation that we experience (EmOC_OTHER_09_01).*

Since many specialists (non OBGs) do casualty duties and need to attend any emergency that comes, they categorically state that while they are able to handle non-obstetric cases, they are not willing to take the risk of managing a delivery case, given its sensitive nature.

> *We are in between the mob and the maternal audit. Why should we take any risk? All we have to do is refer the patient and the district hospital is only half an hour away. And there is a '108' ambulance at the doorstep. So patient is happy and the doctor is happy* (EmOC_IMPLEMENTER_04_01)

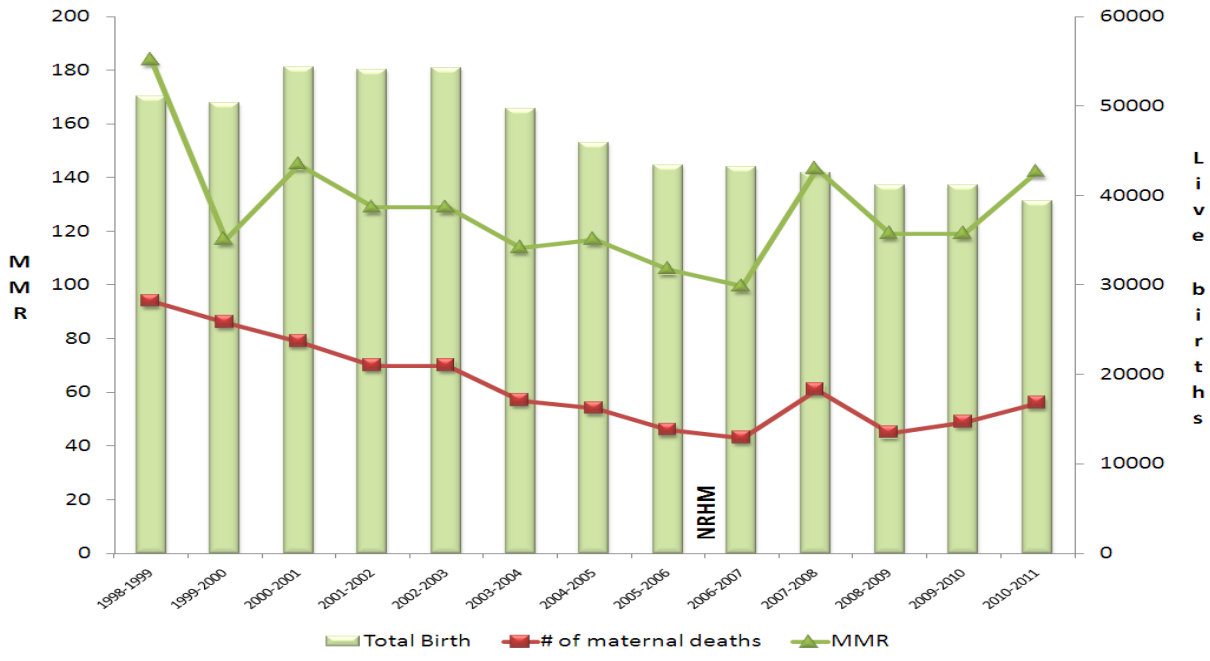
5.1.2.5 Maternal deaths continue to persist

Though in the last five year period, maternal deaths have become less at the all India level and state level, these are not controlled as expected as per the MDG 5 goal by 2012. The following table gives maternal mortality ratio in the study districts in the last five years after the introduction of IPHS through NRHM. In fact, both these districts showed an increase in maternal deaths reported. The administrators opined

[10] See Unger, Marchal and Green (2003) for a discussion on principles of the basis of health care delivery in 'publicly oriented' health systems

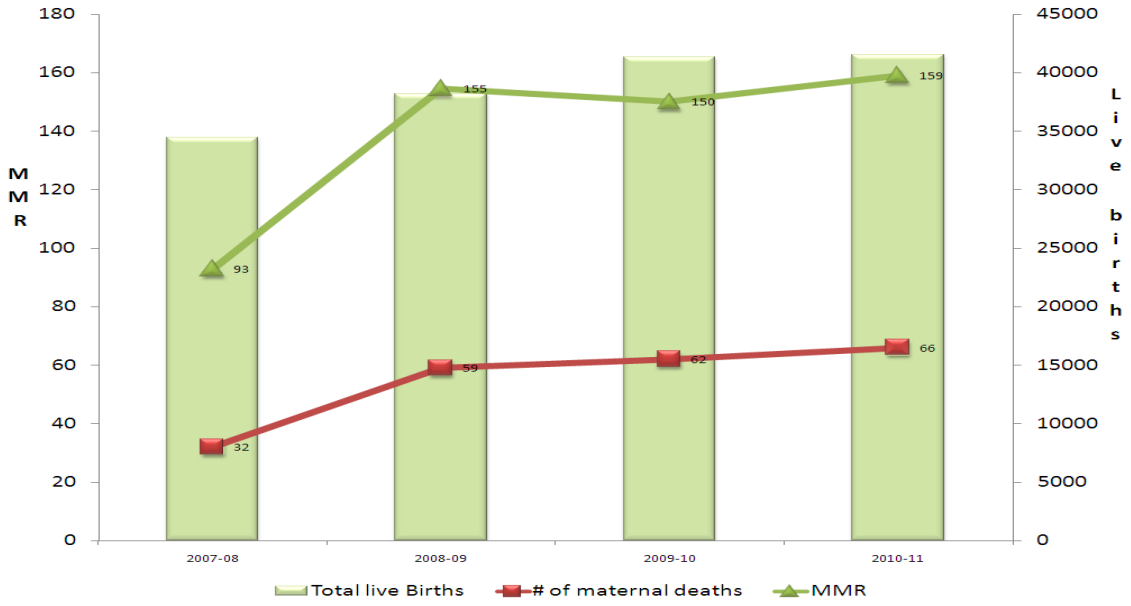
that this is due to better reporting of maternal deaths and maternal death audits. Though this opinion might be valid to better understand statistical trends, the fact remains is that maternal deaths continue to take place.

Figure 14. Tumkur district: Maternal mortality ratio 1998-2011



(Data source: District Health reports)

Figure 15. Maternal Mortality Ratio, Raichur District 2008-2010



(*Data source: District Health reports)*

5.1.3. Explaining the effects: An integrated analysis of actors, context and process

There are several factors that contribute to explaining why EmOC services have been ad-hoc and not ensured. An analysis of these factors and processes would also enable us to understand why an overtly aggressive commitment to MDG5 and a huge public health program to strengthen overall health system have not really achieved the desired results of ensuring equitable access to quality EmOC and preventing maternal deaths.

5.1.3.1Gaps at the level of design

IPHS as a regulation do not address the multi-facetted constraints to access EmOC. These focus merely on strengthening services at the level of facilities. Even while addressing quality of care, the standards pertain more to the physical infrastructure than developing specific guideline on clinical, humane and ethical aspects of care. To reiterate, another design deficit has been the lack of a mandate for these standards. Such lack of mandate has swiftly given rise to defensive practices of evading risk to treat a woman in labour requiring emergency obstetric care.

5.1.3.2 Interpreting the regulation: IPHS an 'ideal type'[11]

State level planners and administrators interpret IPHS as highly ambitious and unfeasible.

> *IPHS is too idealistic and hence impractical. The choice for us as a state is to decide between creating few institutions with excellent standards as per IPHS or more number of institutions with minimum standards. Obviously we would prefer the latter as the whole purpose of NRHM is to reach out to as many people as possible. IPHS again could be more appropriate to urban areas,*

[11] IPHS's articulation of standards roughly corresponds to the German Sociologist Max Weber's (1904) notion of Ideal type which as an analytical construct helps to understand and interpret reality. Ideal type as Weber emphasizes does not claim its validity in terms of its reproduction in social reality.

NRHM is improving access in rural areas. I know IPHS should happen – that is an ideal situation but not in a practical situation (EmOC_ADMINISTRATOR_01__03)

We at the state level have rejected IPHS as these standards are too ambitious. Since we are receiving financial assistance from the central Government for NRHM, we respect these guidelines but it is not for implementation. We are planning to prepare something like Karnataka Public Health Standards which suit our context and which is feasible (EmOC_PLANNER/ADMINISTRATOR_02_03)

The unpractical character of IPHS was reinforced by all state level administrators. Such feedback on the regulation (that is designed at the central level) needs to be read in the context of center-state relations in the health care delivery services in India and the absence of feed-back loops enabling regulation designers to correct regulatory deficiencies. As has been stated earlier in the report, health in India is a state subject and it is the state's responsibility and prerogative to implement national programs in ways suitable to the state and its resources. However, this does not mean that the states could exercise the flexibility to disregard any national health program goals. For example, all states had to commit to NRHM goals and the Central Government provides funds for the same. The states are also expected to generate additional funds and introduce innovations in carrying out such goals. This typicality of centralized planning with flexibility of innovations in implementation at the state level provides space for malleability of interpretations of regulations in the light of resources at state level.

We *cannot implement IPHS as we do not have the resources for it but since we are receiving funds from the center for implementing NRHM, we kind of respect it* (EmOC_ADMINISRATOR_02_03)

Such respect for guidelines (that are designed at the center) is meticulously reflected in the state Program Implementation Plan (PIP) which details ways of adhering to IPHS in different health facilities in Karnataka as per the central Government

guidelines of implementation of NRHM vis a vis IPHS[12]. This also shows how planning of implementation of programs including regulatory mechanisms is a negotiated process among different stakeholders concerned. This also indicates the role of actors at the state level in implementation of the regulation who have power to interpret the regulation in ways that effects its implementation. If dissemination of guidelines and feedback loops from the state to the centre was problematic, the state's decision on the implementation (or lack of it) was never disseminated to the district and block level administrators too. This was evident as the administrators and implementers at the district level had no clue to what IPHS was all about though all of them indirectly referred to selective content of the regulations in terms of up gradation of FRUs. Apart from the centre-state relations, the excerpts above also reflect a distinct urban bias of the administrators.

5.1.3.3 IPHS dwarfed by the larger umbrella of NRHM: Blurring of implementation of regulation and implementation of service

The NRHM through increased financial investment and innovative experiments to improve health services in rural areas is distinctly visible in terms of prioritization of programmatic efforts in the field. Hence for all implementers and administrators, implementation of several components of NRHM is seen as the implementation of the program as a whole. Since NRHM is also largely understood through its goal of achieving MDG 4 and 5, all efforts in the field are interpreted in line with improving neo-natal and maternal health services.[13]

If IPHS as a regulatory component to improve quality health service does not really operate as per the intended objective laid down in the written document, how do administrators and implementers talk about the provisions of NRHM in terms of

[12] See Karnataka State Program Implementation Plan 2011-2012 available at http://stg2.kar.nic.in/healthnew/NRHM/PDF/PIP%202010-11.pdf Accessed on January 20, 2012

[13] Achieving MDG 4 and 5 are one of the goals of NRHM. NRHM in essence sought to make 'architectural corrections' to the existing health care delivery modes and structures in rural areas. For some planners and administrators at the state level who are part of the existing health bureaucracy find the MDG focus of NRHM as a misplaced priority indicating lack of coordination in agenda setting.

facilitating access to quality EmOC service? All of them refer to it in terms of up gradation of a First Referral Unit and up gradation of 24*7 Primary Health Centers.

Up gradation of First Referral Units in terms of building, blood storage unit, human resources, equipments and guaranteeing specialist and emergency obstetric care was the major point of reference by all implementers. Provision of EmOC was hence discussed and assessed in terms of the functioning of an FRU. Any discussion on EmOC with the administrator hence begins with how many FRUs function and how many do not.

> *A full- fledged FRU means 24 hours labour room, 24 hours operation theatre, 24 hours blood bank, new born stabilization unit (NBSU). If all these things are there, then only it is a FRU which has happened in our taluka just one year back (2010) (EmOC_ADMINISTRATOR_02_01)*

> *When will you call a FRU functioning? Only when it is providing 24*7 obstetric care. If I look at it that way, none of our FRUs are functioning (EmOC_ADMINISTRATOR_01_01)*

The implication of such selective reference to the content of regulation is that IPHS is implemented as a program mode of delivering service and not implemented as a regulation. This has an implication on ensuring that provisions of IPHS are adhered to.

5.1.3.4 Explaining failure to ensure 24*7 EmOC: Problem of resources in FRUs

While physical resources like buildings and financial resources have improved under NRHM along with other support programs like KHSDRP[14], human resources particularly specialists (OBGs, pediatricians, and anesthetists) remain a critical

[14] Karnataka Health Systems Development and Reforms Project is a World Bank supported program to strengthen infrastructure at the primary and secondary level of health care delivery in the state.

concern and prove an obstacle to ensure EmOC care when needed. The shortage of specialists and its impact on barriers to EmOC has always been a serious concern in India (Chaturvedi and Randive 2011; Mavalankar and Rosenfield 2005; Mavalankar et al 2008, 2009)

There seems to be two issues around the availability of specialists for EmOC which were shared by different respondents during the course of our interviews. These are i.e. a) mis utilization of specialist skills in the public sector and b) critical shortage of specialists in public sector rural hospitals compared to the private, urban hospitals. We elaborate on these two points in the following text.

Misutilization of specialist skills

Misutilisation of specialist skills was voiced as a major concern by all specialists in both districts but more specifically in the southern district where all the FRUs have one OBG at least. All specialists inevitably treat all general OPD cases, all casualty services and hence an Ophthalmologist on casualty duty also attends to a delivery case. This is in addition to doing administrative work (filling up several records) and attending to medico-legal cases if any. Since no one specialist can be available for 24*7 hours, EmOC service can be accessed only when the specialist is around and other facilities are also available.

Public and private: Perceived crisis in service orientation?

It is commonplace in many low and middle income countries that there is a lack of incentives for specialists to serve in public sector hospitals. Many of these specialists in public sector practice simultaneously in private sector. We came across specialists in public hospitals while being on unauthorized leave did practice in private sector. What lures practitioners to serve in private than public? Organizational theorists continue to grapple to theorize these differences in these two sectors (Anderson 2012). A popular explanation has always been that the better financial incentives in private sector act as a strong motivator for health professionals. However, our discussions with practitioners in both public and private sector hospitals point to a range of factors and explanations, for relative preferences and experiences of

working in these two sectors. We also observed that apart from the tertiary care hospitals, public and private sector don't necessarily exist as two mutually exclusive categories in all places and the dividing line is often blurred. For instance, when there is a crisis of HR, private practitioners will be requested to assist the doctors in Govt hospitals and vice versa. But such blurring has had different consequences in the provision of health care services particularly EmOC care in both the districts.

As our interviews findings show, the blurring between public and private happens in several ways. In the absence of systemic ensuring mechanisms to prevent absenteeism, long leave and unauthorized leave of practitioners in the public sector, individual motivations of administrators, support from other staff, and professional equations with private practitioners in a particular area become important factors in facilitating delivery of EmOC services. In some FRUs, administrators with team support negotiate with private practitioners in the same area to exchange EmOC services to let the FRUs run.

> *Whenever Dr. X required my services in the sub-district hospital, I even have left my OPD and attended to the emergency services there. Even when I need some help, he comes. We have developed a very healthy and mutually understanding relationship (EmOC_IMPLEMENTER_09_01)*

Such strategies are interpreted as mutually beneficial for both the FRU personnel and the private practitioner. There are various incentives for these kinds of negotiations. For example, one major incentive is to require each other's support in medical adverse outcomes, for example, maternal deaths. Both the public and private hospitals would come under the scanner of the maternal death audit (the private practitioner also will be summoned to clinical audit meetings to explain the circumstances leading to such outcomes). For FRU administrators, this is important to sustain the image of a best FRU and provide EmOC service in a HR resource shortage environment. Many private hospitals at the sub-district level are run with one OBG and other support staff and hence dependence on others specialists to deliver services (either on contract or on consultancy or other ways) becomes important to sustain the practice and retain clientele. Such mechanisms however are rare and individualised strategies. These depended on the individual, professional commitment of the administrator and did not appear to be a norm in the areas we studied. These kinds of negotiations (partly to address resource constraints) by lower

level health functionaries have been cited in other contexts too (Walker and Gilson 2004).

The northern District, where two FRUs out of five are being able to partially deliver specialist EmOC services, boasts of a large number of OBG specialists serving in the private sector in urban areas of the district. In the sub-district/taluka where we did field work, only one OBG specialist has been offering services in a private nursing home. Other private nursing homes and clinics are manned by graduate medical doctors but not specialized in OBG.

While shortage of resources like blood storage unit and other specialists are often given as a reason for not offering EmOC services in the public FRUs, the same shortage of resources is handled very effectively in the private nursing homes as not all of these private hospitals have blood storage facilities nor well equipped with specialists. This raises a larger question of the nature of 'publicly oriented' health systems in public sector establishments. Here individual motivations of practitioners to deliver care in the private sector at the expense of public sector (as in Raichur) has grave repercussions for women accessing EmOC care who have had to shuttle between different private providers or travel a long distance to reach the District hospital.

While clarifying the reasons for relative commitment to private sector, the practitioners cited a number of reasons: a) better team support in private sector than public b) too much of interference due to the highly bureaucratic nature of the Government health system d) delayed decision making processes in the Government which has cumbersome processes e) relative stability of private sector compared to frequent transfers in the Government sector f) better financial incentives specially when one weighs the risk of taking risks against incentives and g) public sector's greater vulnerability to be questioned by the public.

> *In the private sector people pay money to access services and if anything goes wrong they think that the doctor must have tried his/her best, as he/she has taken money while in the Government, any lack of services is immediately interpreted as negligence of Government doctors and the state in general (EmOC_PLANNER_03_03)*

However, many other state level administrators read the disinclination to serve in public sector as a larger crisis in 'service orientation' of medical professionals.

> *The public sector is guided by service orientation model while the private is by business model. The team support that everyone is talking about emanates from this difference in basic orientations. You are fired when u don't perform in private, while nothing of this can happen in the Government. Additionally, the image of the state and how one relates to the state also becomes important when delivering service in public sector (EmOC_ ADMINISTRATOR_04_03)*

Others see the crisis in service orientation being linked to the mushrooming of private medical colleges which charge hefty fees for entering the course. It is as a compensatory measure for such fees, that medical professionals try to practice in private sector so that they can justify their education expenses. In addition to the private and urban bias of specialists, others have drawn attention to issues around policy barriers to facilitate access to EmOC by other than specialists (Mavalankar 2005, 2008, 2009). Drawing evidence from other low resource settings like Mozambique, Congo, Nepal, Mavalankar (2005) strongly advocates the need to train others like the M.B.B.S doctors in providing EmOC service. Though the NRHM has instituted alternative provisions like training the M.B.B.S doctors with three months training in LSAS and EmOC to redress the specialist shortage, in the talukas studied, the trained LSAS do not administer anaesthesia on grounds of limited training. The ability to perform these specialized services also depends on individual motivation, supportive and conducive environment of other specialists. However, one needs much more systematic evidence on evaluations of such experiments in task shifting.

5.2.3.5 North and South: Legacy of the past, messiness of the present: Role of Actors and Environment

Historically, Raichur along with some other districts in north Karnataka were part of Hyderabad presidency and later on integrated with the rest of the part of Karnataka when the state was formed. Being part of a different administrative division, it had always received a separate treatment from the point of view of governance.

What one witnesses now in north and south in terms of huge discrepancy in number of health centers can be attributed to our benevolent kings of Mysore. They being from south had opened several primary health centers as part of their reign in south only and very few in north. These centers have been converted into the current day PHCs following the Government of India's model of three tier health centers (EmOC_PLANNER_01_03)

Such administrative neglect is reinforced by the larger economy of north and south. Raichur is a dry region and is prone to frequent droughts. The economy is poorer compared to the south which has a history of rich agriculture.

The whole problem with these districts is that for a long time it suffers from a culture of bad governance. One can't look for reasons for poor health governance only in the sector of health... What I mean is the quality of life in Raichur is very poor, quality of educations in schools, colleges is poorer if one compares it to the south. If one looks at the recruitments of services in any field, one sees that these services are being filled with human resources from the south as they are being able to compete and get it. Further, the divide between the rich and poor is very wide. There is practically no middle class (EmOC_PLANNER_03_03)

Such multi-dimensional differences of these two districts have created an image of a biased state and felt discrimination among people of north compared to south. State level administrators and planners based in south reinforce the stereotypical images of the northern districts as 'backward' and 'poor'. It is therefore not surprising that a regulation chiefly oriented towards public services which are socially and geographically biased would not be capable of changing the odds if the managerial aspects of system reorientation are not properly tackled. It is ironical for a state because these districts are labeled as 'Category C' districts which receive additional funds for improvement in services. However such branding has further reinforced the 'under privileged' image of north compared to the south.

This larger environment played an important role in the implementation of regulations. What we observe is that when the state is relatively weak in terms of delivery of health services (as already stated, public sector hospitals and FRUs do not function effectively) in the northern district, many other local actors and local dynamics come into play to govern health services and shape the directions of the implementation (lack of) of regulations. The role of these different actors in the northern district is elaborated in the following text.

The health care service market in Raichur is driven to a large extent by *health workers.* These health workers by virtue of their proximity to the community and being in service in the area for a long time a) exercise the power to treat women in labor themselves b) to divert resources of the Government like cash incentives and other material benefits by paying the women even without their directly utilizing the Government services and c) deciding where to refer the patient which depends on their individual equations with private practitioners and amount of commission received. Few *untrained practitioners* usually practice on the basis of hands on experience and they do make themselves easily available in the villages. They are constantly mobile visiting from one village to another and are familiar with disease burden and history of villagers. They provide all kinds of health services and play a role in facilitating referral of the patients for emergency services including EmOC. Their similar role in neighbouring district of Koppal in north Karnataka is highlighted in other studies as well (George 2007). In fact as George discusses, the RMPs gain more popularity than the Government and other private practitioners in these areas.

The *dais* (traditional mid-wives) continue to gain legitimacy and trust of the poorer community in rural areas for delivery of maternal health services. Delivery in rural Raichur is still looked upon as a natural process that needs hospital interventions only when complications arise. In fact *Da*is are trusted to the extent that they accompany women in labor to the hospital when complications arise. *Dai's* role is so naturally associated with maternal service that OBGs in the private sector are referred to as Dai amma' (mid-wife-mother). This term of address also implies women's expectations of personalized care from professional practitioners. The *local politicians* play an important role as their support both to health workers and

practitioners is looked upon as a significant cultural resource. *Qualified but non specialized practitioners* in private nursing homes influence EmOC service in the *taluka* studied. These varied actors have played an important role in facilitating EmOC service in the private sector. In the absence of partially functional or non-functional FRUs, the health care market (more importantly EmOC) thrives with these actors at the forefront. The vested interests of profit and local control (over the region and community) of these actors prevent recruitment of personnel (medical officers or specialists) from other region to serve in the public sector.

There is also a vested interest among private practitioners not to let the KPMEA Act to be implemented in full swing. A major drawback of this regulation is a very slow process of implementation. The public sector personnel on the other hand run private practice citing many constraints in the FRUs. Ownership of resolution of all constraints and deficiencies is attributed by these implementers on the 'Government'. The government term is used as referring to the 'other' often implying the state level planners. Such perceived distance and lack of ownership act as barriers to achieve public health goals in the larger interest of the patients and the community.

As the data from the field suggest, all these actors' role in health services and particularly for EmOC services is played out along local dynamics that includes equations of caste, gender, being 'local' (belonging to the region contrasted with those who come from outside Raichur), ability to patronize the community (images of few individual 'good doctors') and professional equations/jealousy. All these leave the community in a very vulnerable position of being guided and shifted from one place to another by whosoever they step into and the effect is lower access to lower quality health care in the absence of regulation impact.

To add to the historically different administrative origin, in the contemporary context, the Government district hospital (which is a tertiary care center) is a teaching hospital that comes under the administration of a different ministry than district hospitals in most other parts of Karnataka. Usually the district hospitals are run by the administrative supervision of the state ministry of Health and Family Welfare while in Raichur this is run by the Department of Medical Education. This health system context of

administration of the hospital under a separate ministry results in lack of coordination between this hospital and other health centers at the primary care level. Hierarchies are created between teaching hospital faculty vs. practitioners in other Government set ups (the former are better paid), prioritization of teaching over clinical services and prioritization of clinical over public health services (commitment to NRHM goals is not seen as a concern for the district hospital staff). As a planner reflects:

*NRHM is suffering because of this. It has been like a historical battle arguing for integration of these two ministries and departments. This has been brought about and discussed in several forums but the fact that these two have traditionally been two different ministries/departments/secretaries; it is not so easy to integrate so easily. But that is the best solution. Secondary care is neglected in these teaching hospitals as they prioritize teachi*ng (EmOC_PLANNER_02_03)

5.1.3.6 Interpreting risks: Situating multiple referral

Due to the visibility of maternal health issues and regularity of maternal death audits through NRHM, high risk cases are usually referred out. While deficient resources (availability of specialists, blood transfusion facility, complications that cannot be handled with the existing level of knowledge and skills, lack of confidence of trained 'specialists' on EmOC and LSAS) are offered as reasons, it is also true that multiple referrals result due to a tendency to evade risks.

> *The FRU has less no of normal deliveries too, only 10 C-section per year. I refer both high risk and low risk cases, because patients cannot go in the middle. She will be 1 to 3 cm cervix dilated and by the time delivery occurs, it takes a long way or time. So I cannot assure 100% whether it will be normal, sometimes she will go for arrest of labor, fetal asphyxia, meconium stained liquor, that time we cannot take the risk at all. If anything goes wrong, I am accountable and answerable to the DC (EmOC_IMPLEMENTER_12_01)*

Even I have been assured by the chairperson of the Hospital Management Committee who is an elected political representative that "don't assure the patient, instead refer (EmOC_IMPLEMENTER_13_01)

As an anesthetist, I would say going out of the way and doing heroic things is not possible, so referring is better (EmOC_IMPLEMENTER_11_01)

Team support both in treating a case and sharing responsibility of the patient is looked upon as critical to take risks and where such team support is fragile, EmOc cases are referred out. While ideally, a public sector overtly holds normative value orientations of promoting equity and access and hence is accountable to its citizens; in the field such accountability to the public/community is submerged by a sharper sense of accountability to the seniors in the bureaucracy. One hence evades risk and potential individual blame. One comes across frequent mention of such transfer of blame along the hierarchy – individuals or even spatial categories. For instance, health workers often claim that no deaths happen in the 'field', these happen in hospitals, hospital officials would like to say 'deaths often happen in transit not in hospitals' – *as long as it is out of my area (facility), then I am not bothered. I should not get into trouble (EmOC_IMPLEMENTER_09_01)*

Now maternal death cases are occurring during transit there are no deaths because of not receiving health care in the hospital. If they visit one institution and if there is unavailability of service there, they will have to go to another place. During the transportation, there are chances of death. Previously maternal death cases used to occur at home now it is reduced. As per my knowledge, now deaths happen in transit than hospital (EmOC_ADMINISTRATOR_05_01)

Thus deaths in transit do not amount to owning up the responsibility for the patient. Far from care being continuous, it is looked upon by the administrators in fragments. Implementers take responsibility for only a fragment of care (ANC, EmOC, referral, post-partum) with little coordination among these personnel.

5.3.6 Maternal death audits: Enforcing accountability, Role of Information

For any regulation to be effective, a robust information system is a prerequisite. NRHM has perhaps taken due attention to the role of information in strengthening health system by instituting mechanisms like the Health Management Information System, Public display of Citizen's charter, regular auditing (financial, social) including maternal death audits. While weak information system in terms of under reporting of maternal deaths has been highlighted in earlier studies (George, Aiyer and Sen 2005), the reporting of maternal and infant deaths has become much better post-NRHM as we observe the regularity in maternal death audits from both the districts.

Though maternal deaths are better reported than before, what purpose do the maternal death audits serve? Ideally, these audits are undertaken to identify the gaps that happen in each case of death and redress these gaps in future. Though the audits take place regularly, this is done more like a ritual in itself than a fact finding exercise to strengthen the health system and prevent deaths. Respondents interviewed talk about several problems with the ritual of auditing maternal deaths which have deterred these audits from being a learning exercise. Some of these are a) the audits focus too much on verbal autopsy which is not a genuine account of the situation rather what the health system wishes to hear b) the procedure which targets individual lower level functionaries (health workers for instance) who confess that they face a crisis in legitimacy of trust with the community after such audits as they need to interact with the community c) it is conducted in a very threatening way 'someone keeps a gun at your head' d) skewed understanding of the purpose of such audits as fault finding than fact finding hence informal mechanisms to mask causes of deaths are played out. For instance, these mechanisms and practices include giving reasons as due to cultural factors (lack of hygiene, delay in seeking care) than systemic ones, manufacturing non-preventable causes (showing deaths due to acute renal failure than PPH) e) though these audits take place regularly, no follow up is done on such audits and f) some doubt the validity of the mechanism of auditing of the health system by the system itself and if such audits should be conducted by an independent team.

5.1.4 Discussion and Recommendations

The analysis indicates that IPHS have failed to *ensure* equitable access to quality EmOC services in the public sector in rural areas. Due to defunct FRUs, EmOC provision is driven by market mechanisms. The implementation of the KPMEA Act has been very slow due to the stiff opposition of professional medical bodies, private hospital associations. Three years after its birth, it is barely at its initial phase of receiving applications for registration and inspection of facilities. The following recommendations emerge from the study.

Recommendations

- Regulations need to address issues of equity and universal access to EmOC service. Political commitment to achieve MDG5 should represent commitment to ensure universal access
- Mere focus on rural public health sector cannot control MMR in the whole state, need to expedite implementation of KPMEA to regulate the private sector in both rural and urban areas
- Stricter accountability mechanisms in public sector to regulate health care delivery and service management. The regulation must be strict to make sure that patients are managed in the FRU as per the Standard treatment Protocol and not referred out unnecessarily
- Promote participative health planning with bidirectional feedback loops
- Development of enhancement of reflexivity (a capacity to learn lifelong from one's own experience) amongst health professionals through in-service trainings.

5.2. Equitable access to safe abortion services: The role of the Medical Termination of Pregnancy Act 1971 (MTP)

5.2.1 Overview of regulation content and procedures

5.2.1.1. Background of the regulation: Policy Environment

Until the enactment of MTP act, the Indian Penal Code and the Code of Criminal Procedures governed abortion services in India. Both these regulations had their roots in the 19th century British law and they considered abortion to be a punishable crime for both the woman and the abortionist, except if it was to save the life of the woman (HEPVIC 2009). Since abortion was looked upon as a criminal offense, abortion seekers had to depend on discrete back door services and those were usually offered by untrained and unqualified providers. Often these services were provided in unsafe conditions and a number of women ended up having post abortion complications, which needed further medical care (Chhabra R, Nuna SC, 1995, HEPVIC 2009).

The process to legalize abortion in India began when the Government noticed these high numbers of septic abortions and post abortion complications leading to high maternal mortality and morbidity. To understand and address this issue, the Central Family Planning Board of the (then) Ministry of Health and Family Planning, Government of India recommended the formation of a committee, which was constituted under the chairmanship of Dr. Shantilal Shah. After reviewing abortion policies of various countries and various longitudinal studies on family planning and collecting first-hand information by conducting a survey, the Shah committee submitted the report to the then government in 1966. It recommended that a qualified practitioner should be permitted to terminate pregnancy while *"acting in good faith"* of saving a woman's life. Based on its recommendations, the Medical Termination of Pregnancy Act was formulated in 1971 (HEPVIC 2009).

5.2.1.2 Formulation of MTP Act

As stated above, based on the recommendations of the Shah committee, the MTP Act was formulated with a clear mandate in both houses of parliament in 1971. The rules of the Act were framed and it was brought into force from April 1972.

The MTP is a law which is applicable to both public and private sectors. The major objectives of the Act are to:

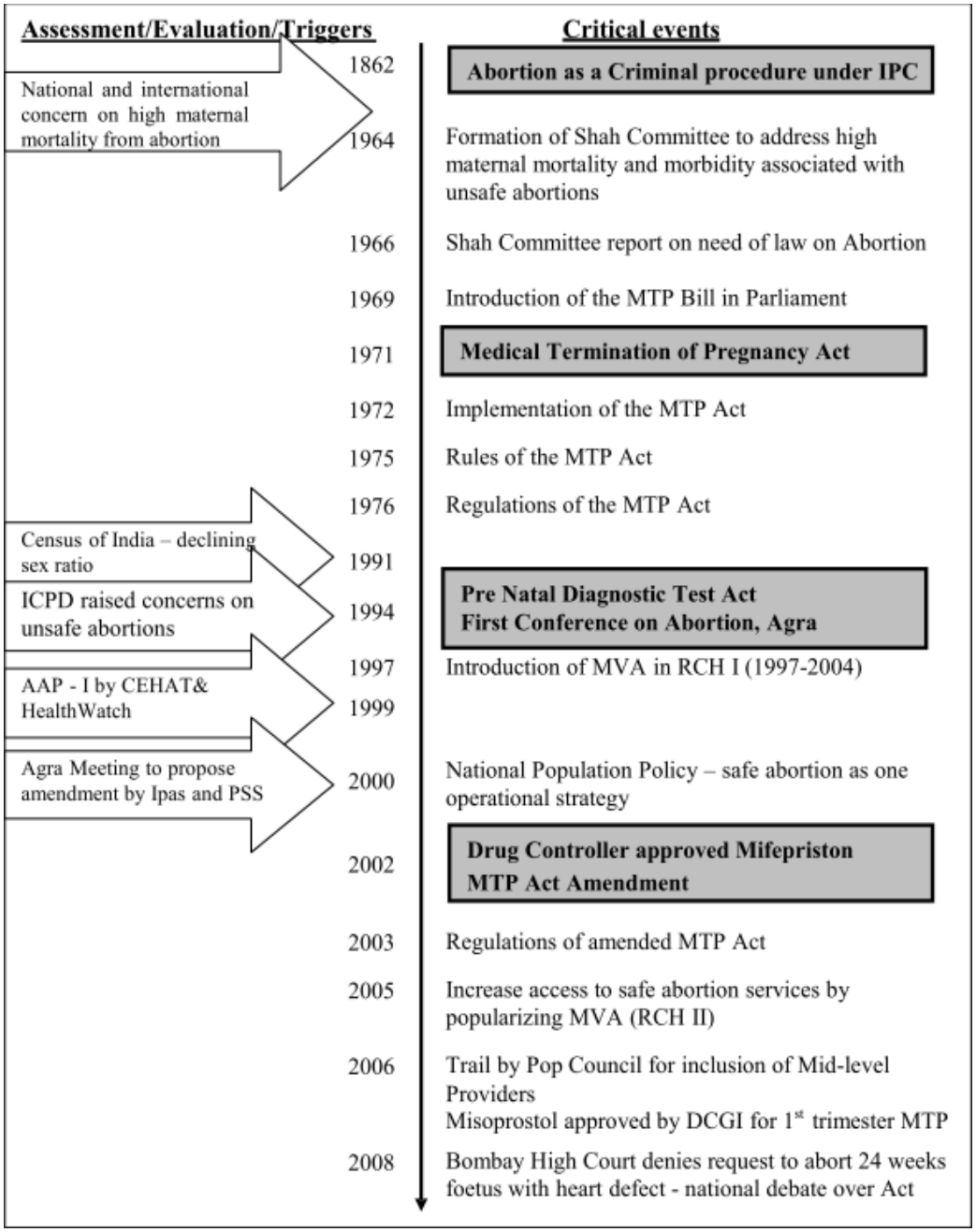
1. Legalize abortion services
2. Decriminalize abortion service seeker
3. Offer protection to medical practitioners who have the necessary training and skills in conducting MTP, who otherwise would be penalized under the Indian Penal Code (sections 315-316).
4. Ensuring the quality of care of abortion services by necessitating training of practitioners, registration and inspection of facilities and by offering punishment to the violators.

The first abortion conference in 1994 and the Abortion Assessment Project (2000) were the two important milestones in the history of abortion care in India, which also paved the way for the amendments of MTP act. The Abortion Assessment Project (2000), the first ever country wide collaborative study looked into various aspects of abortion care and identified some of the major issues around abortion services. The need for newer and simpler abortion technology, less cumbersome procedures for private clinics registration and the need for comprehensive post-abortion care were some of them. This also gave a momentum to the civil society movements in abortion care. Various civil society organisations including Ipas and CEHAT and professional bodies such as FOGSI started engaging themselves in continuous dialogues with the government. These discussions led to the amendment of MTP act in 2002. (HEPVIC 2009)

The 2002 amendments of the MTP act were to a) replace the term lunatic with “mentally ill person", b) decentralize the approval authority for registration to the district level committee and c) make the punishment stricter for the violators of the act. As per this, an unregistered medical practitioner and the owner of the unregistered place could be punished for 2 to 7 years. To reduce the administrative delays, the amended MTP Rules defined a time frame of two months for the registration of facilities. MTP Act is considered to be an enabling regulation which allows MTP on both medical and social grounds and thus liberalized access to

abortion services. India was one of the pioneers to do this in the early 70's as only a few countries had legalized abortion services then. Further amendments brought in simpler formalities and newer technologies in the regulation for its better implementation. The following illustration offers an overview of the formulation process of the MTP Act including the process of amendments.

Figure 16. Timeline of MTP Act



Source: HEPVIC (2009)

5.2.1.3 Content of the Regulation

The content of the Act deals with defining conditions about a) **who** is eligible to provide MTP services b) under **what** indications MTP should be done and hence are considered legal and c) **where** should MTP services be offered.

a) Who can perform MTP?

As per the MTP Act, for a provider to be able to terminate the pregnancy, he/she has to be a registered practitioner who belongs to any of the following categories:-

a) He/she has completed six months of 'House Surgency' in Gynecology and Obstetrics
b) He/she has had experience at any hospital for a period of not less than one year in the practice of Obstetrics and Gynecology
c) He/she holds a Post Graduate Degree or Diploma in Gynecology and Obstetrics
d) He/she has assisted a Registered Medical Practitioner in the performance of 25 cases of MTP out of which at least five have been performed independently in a hospital established or maintained, or a training institute approved for this purpose by the Government. But this training would enable him/her to do only 1st trimester terminations i.e. up to twelve weeks of gestation.

b) Where can MTPs be performed?

Termination of pregnancy could only be done at either "a hospital established or maintained by the government" or in "a place which has been approved for the purpose of this Act by the government". Later as per MTP rules in 2003, the requirement of the place to conduct for first and second trimester was clearly spelt out. These included a) an operation table and instruments for performing abdominal or gynecological surgery, b) anesthetic equipment, resuscitation equipment and sterilization equipment and c) drugs and parental fluids for emergency use (MOHFW, 2003).

c) When can pregnancies be terminated?

As per the MTP act, pregnancy can be terminated up to twenty weeks and under the following conditions:-

Where the length of the pregnancy does not exceed 12 weeks and one medical practitioner is of the opinion formed in good faith or
Where the length of the pregnancy exceeds 12 weeks but does not exceed 20 weeks and if not less than 2 registered medical practitioners are of opinion, formed in good faith that the continuance of the pregnancy would involve a risk to the life of the pregnant woman or a risk of grave injury to her physical or mental health; or there exists a substantial risk that, if the child were born, it would suffer from some physical or mental *abnormalities so as to be seriously handicapped.*

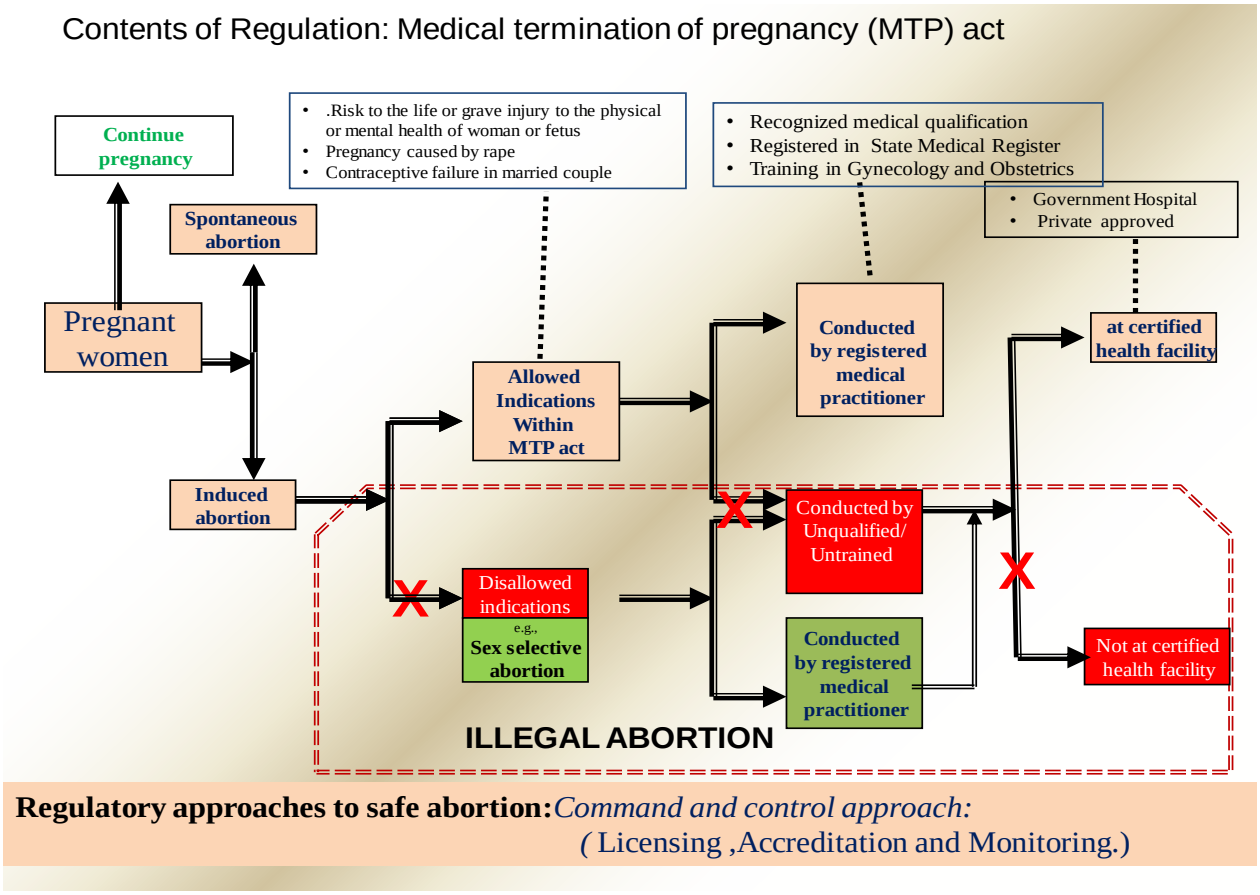
The term “grave injury or substantial risk” remains undefined in the legislation, the gravity of the injury or the extent of the risk being left to the interpretation of the clause by the medical practitioner. The MTP Act provides some guidance for doctors in the form of two explanations to the Section. These explanations clarify situations where grave injury to the mental health of the pregnant woman can be deemed to have been caused. They are:

1. Where any pregnancy is alleged by the pregnant woman to have been caused by rape, the anguish caused by such pregnancy shall be presumed to constitute a grave injury to the mental health of the pregnant woman and
2. Where any pregnancy occurs as a result of failure of any contraceptive device or method used by any married woman or her husband, the anguish caused by such unwanted pregnancy may be resumed to constitute a grave injury to the mental health of the pregnant woman.

Thus these two situations – where pregnancy is a result of rape or where for a married woman contraceptives have failed – would amount to causing grave injury to the mental health of the woman. The second explanation would also pre-suppose that an unmarried woman cannot avail of the failure of contraceptive devices as having caused her mental anguish. The MTP rules specify that the consent of the woman is necessary for the termination of pregnancy. In case of minors and

mentally ill, the consent of guardian in writing is required to carry out MTP. Figure 17 summarises the content of the regulation.

Figure 17. MTP approach and content



Under the MTP Act, no termination of pregnancy is permitted after 20 weeks of pregnancy. In cases where 20 weeks have lapsed, pregnancy can be terminated only if required to save the life of the pregnant woman and not for any other reason. It states that the conditions laid down relating to length of the pregnancy and requirement of opinion of not less than two registered medical practitioners will not be applicable in case where such doctor is of the opinion, founded on good faith that the termination of such pregnancy is of immediate necessity to save the life of the pregnant woman.

Courts have been very strict in interpreting this section and do not permit any termination of pregnancies beyond 20 weeks unless in exceptional circumstances. In

a recent decision, the Delhi High Court upheld the decision of the Ethics Committee of the Medical Council of India directing that the concerned doctor should be punished by removing her name from the Indian Medical Register for three months as she had conducted an abortion after the 20 week period on a pregnant woman, who thereafter died due to complications. The Court found that there had to be in the first place an opinion formed by the doctor that such termination of pregnancy is necessary to save the life of the patient, and in the said case no such opinion was made and recorded by the doctor(Dr. Raj Bokaria v. Medical Council of India and Anr 2010).

5.2.1.4 Procedures of administration and implementation as laid down in the Act

The following procedures of administration and implementation of the regulation are laid down in the Act.

1. The power to give/revoke the license: The power to give/revoke the license to the private facilities is entrusted with the Chief Medical Officer (known as the District Health Officer in Karnataka) of the district. To obtain such a license the facility has to have a) An operation table and instruments for performing abdominal or gynecological surgery b) anesthetic equipment, resuscitation equipment and sterilization equipment c) drugs and parenteral fluids for emergency use. On receipt of an application, the Chief Medical Officer of the district has to verify or inspect the place with a view to satisfying himself that the facilities referred in the Act are provided therein, and that termination of pregnancies may be made therein under safe and hygienic conditions.
2. Inspection of a place- A place approved to conduct MTP may be inspected by the Chief Medical Officer of the District, as often as may be necessary with a view to verify whether termination of pregnancies is being done therein under safe and hygienic conditions. If the Chief Medical Officer has reason to believe that there has been death of, or injury to, a pregnant woman at the place or that termination of pregnancies is not being done at the place under safe and hygienic conditions, he may call for any information or may

seize any article, medicine, ampoule, admission register or other document, maintained, kept or found at the place.

3. Cancellation or suspension of certificate of approval - If the Chief Medical Officer of the District is satisfied that the facilities are not being properly maintained therein and the termination of pregnancy at such place cannot be made under sale and hygienic conditions, he shall make a report of the fact to the Government giving the detail of the deficiencies or defects found at the place. On receipt of such report the Government may, after giving the owner of the place a reasonable opportunity of being heard, either cancel the certificate of approval or suspend the same for such period as it may think fit.

5.2.1.5 Approach of the Regulation

The MTP Act adopts a state command and control approach. It is a centrally planned act which clearly lays down the conditions under which MTP can be done, by whom and where. This regulation clearly spells out the processes of monitoring and supervision and the negative sanctions by the state in case of failure to comply with the guidelines. The day to day administration of the Act is decentralized and the power is given to the district authority for monitoring and supervision of the Act in the field.

5.2.1.6 Related Regulation: PCPNDT Act

After the MTP Act was enacted in 1971, there was a huge incidence of sex selective abortions where female foetuses were selectively being aborted using the liberal grounds under the MTP Act. As it became progressively easier to identify the sex of the foetus at an early stage by amniocentesis, ultrasound scans and other tests, pre-natal diagnostic techniques began to be deployed for identifying the sex of the foetus which led to an increase in sex-selective abortions.

With the rise of pre-natal diagnostic techniques especially through amniocentesis and ultrasound scans, due to the relentless efforts of activists, a law to prevent sex determination tests was first passed in Maharashtra known as the Maharashtra

Regulation of Pre-natal Diagnostic Techniques Act, 1988. Finally after intensive public debate all over India, the Parliament enacted the Pre-Natal Diagnostic Techniques (Regulation and Prevention of Misuse) Act on 20th September 1994 (PNDT Act) to curb the malpractice of identifying the sex of the foetus, which led to sex-selective abortions (HEPVIC 2009).

Although the PNDT Act was passed banning sex selection, the implementation of the PNDT Act was very poor and sex selective techniques were going on unabatedly. At the same time techniques were developed to select the sex of the child before conception. Such pre-conception sex selective techniques, which were not banned under the PNDT Act, were being used on a large scale. These developments were also taken note of by the Supreme Court in its various orders in the case of *CEHAT & Others. Vs. Union of India and Others (2001)* and the Court observed that amendments to the PNDT Act were necessary. The PNDT Act was then amended in 2003 and was called "The Pre-conception and Pre-natal Diagnostic Techniques (Prohibition of Sex Selection) Act". The main purpose of the amendment was to ban the use of sex-selection techniques before or after conception as well as the misuse of pre-natal diagnostic techniques for sex selective abortions and to regulate such techniques.

HESVIC lens of MTP

We chose MTP Act to ask a) how far the legalization of abortion services has facilitated *access* to safe abortion services? b) Has it enabled women to access this service as a matter of right? and c) how has MTP through access to safe (hence quality) abortion services contributed to improving maternal health? This Act through addressing a medical yet a highly culturally sensitive aspect of women's health enables us to see the dynamics between medicine, technology and culture that are at play in health governance.

5.2.2 The regulation in practice: Effects of the regulation

5.2.2.1 Restricted access to safe and legal abortions: Incidence of a large number of 'illegal' abortions

As per the Act, the availability of trained providers and registered facilities is a prerequisite to facilitate access to safe abortion services. Apart from the Government health centers and hospitals which automatically become licensed to provide MTP services, District Administrators did not have any precise information on the number of licensed private facilities to provide MTP services. While the Government facilities automatically become eligible to provide MTP services, the practitioners particularly the M.B.B.S doctors in primary health centers need to be trained in MTP. However, very few of the doctors were actually trained in MTP in both the districts (of the 11 providers interviewed only 2 were trained) though most of them did provide the service.

Table 9:Details of interviews- case study abortion

Category of respondents	Total number of Interviews
Policy makers	3
Administrators	11
Implementers	28
Others[15]	8
Users	11
Total	**61**

We interviewed 12 women who had utilized MTP services. All the women interviewed were married and were from SC/ST/OBC castes. 3 users were 35 years old and all others were less than 30 years of age. One respondent belonged to Muslim religion, rest all were Hindus. One had a graduate education, whereas all others had studied up to or less than high school. All except two respondents were from poor socio economic status; their families were engaged in informal labour work or employment in informal sector. Only one of them had regular employment.

[15] Others include informal providers, village level health workers and members of professional bodies.

However, from the experiences of the users, what guided the choice of practitioner and facility, was not so much education or caste status per se but other factors like a) extent of family support (to what extent the husband and mother-in-law were involved in the decisions to abort) b) proximity and equations with the health workers and c) gestation period. Village level health workers being the first point of contact for all Government health services played an important role in offering services themselves or taking the patients to a Medical officer in PHC or private clinic. In addition to the users' experiences, practitioners interviewed also confessed that health workers, staff nurses who are not trained, do provide the MTP services.

> *The health workers are offering MTP because our doctors are not providing the services, where would the women go? The women also trust the health workers as they are closely in touch with them through their frequent visits for other health related services (MTP_ADMINISTRATOR_02_02)*

> *For MTP services, first, women try with traditional birth attendants, they go and meet ANMs, the field staff, first point, if not they will come here (MTP_IMPLEMENTER_12_01).*

Some of the implementers in the Government sector reported that health workers mainly do medical abortion and sometimes vacuum aspiration. Since the village level health workers are not trained to provide MTP services, these abortion services could be potentially unsafe as indicated in earlier studies (Bhatia 2010; Patel et al.2009; Ramachandar 2002).

NRHM has envisaged a prominent role for health workers in registering pregnant women, providing ANC and mobilizing women to deliver in hospitals. The village level ASHA workers and ANMs play a significant role in maternal healthcare as they act as the first point of contact for a variety of services including MTP. Their knowledge of the act would be critical in facilitating access to safe abortion services. None of these health workers had any clear knowledge of the provisions of the Act. In fact they had

some vague knowledge of the act which translated MTP as a restrictive regulation as seen in the following excerpts from interviews with village level health workers.

> *It is like this. If a case comes to me, I can't do MTP and the medical officer of the PHC will also not do MTP. I send the case to the taluka hospital which has a gynaecologist (MTP_OTHERS_04_01)*

> *Even if that (unwanted pregnancy) happens, if the mother is alright, we won't do MTP, that kind of wrong thing we have never done (MTP_OTHERS_05_01)*

Their knowledge and interpretation of the Act were shaped by cultural understanding of abortions as morally wrong. They also had a haphazard understanding of the Act which they might have heard here and there as none of their training included awareness of the MTP act. They hence denied giving MTP services saying 'it might become a case (case meaning legal case)'.

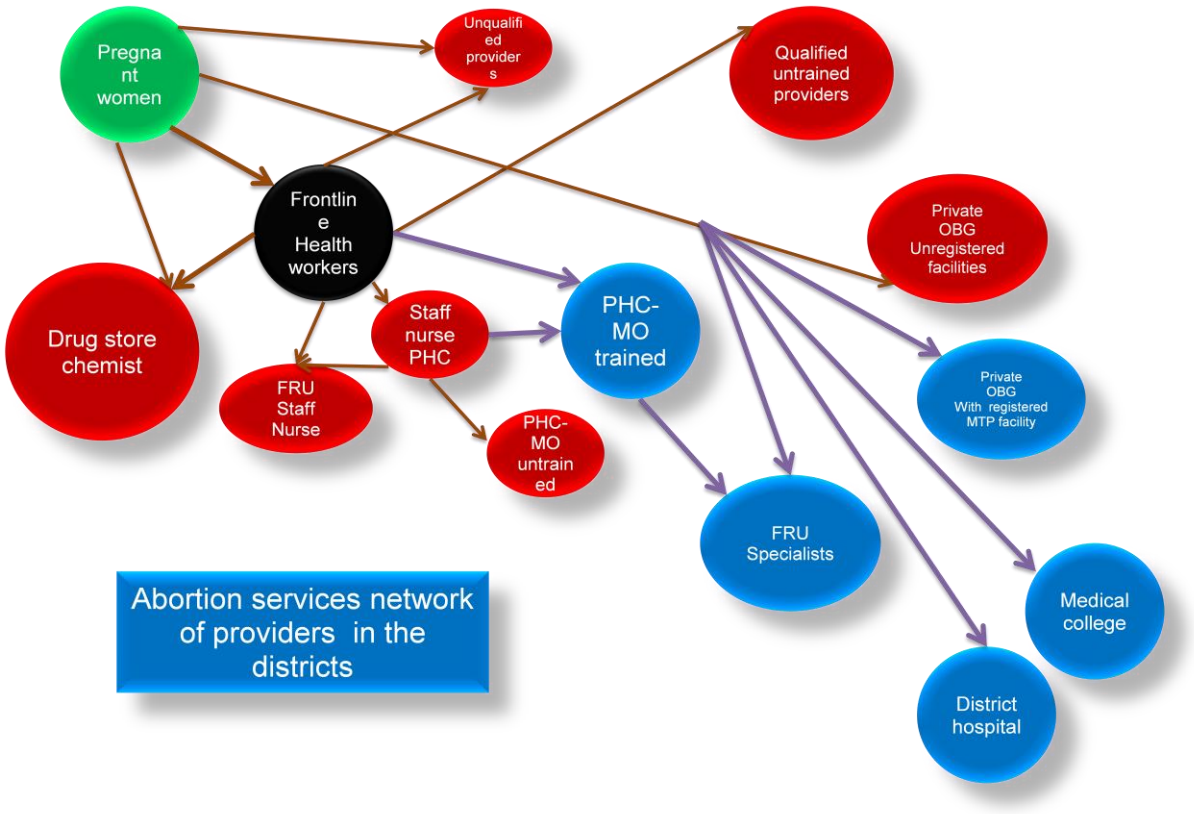
The PHC medical officers shared their dilemma of providing abortions services when women demanded it though they did not have the MTP training.

> *What does one do when a patient comes to seek abortion services? If I don't give because I am not legally trained, the patient will perhaps go to a quack. Isn't that worse? So as a doctor when there is a demand for a service and if I have the clinical expertise to provide the service, I should do (MTP_IMPLEMENTER_06_01)*

They pointed out the disjunction between clinical skills (MTP taught in medical education curriculum) and legal skills (through the MTP training which they felt it was for legal protection). Gestation period is an important indicator for deciding where women seek the services. Since more than 12 weeks gestation period is considered as largely illegal by health workers and medical officers (12 weeks is the limit to which they do medical abortion and they are allowed to do MTP only up to 12 weeks as per MTP Act), patients would inevitably be referred to the gynecologists in sub-district hospitals. Considering the shortage of Gynecologists in public sector hospitals

as discussed in the section on EmOC case study, many women land up in private nursing homes for gestation period beyond 12 weeks. Figure 18 offers pathways of access to abortion services for pregnant women. The red bubbles represent untrained personnel who offer the abortion services themselves or facilitate by referring the woman to either a private facility or a sub-district hospital. The greater number of red bubbles, particularly at the primary level health care (below the sub-district hospital) shows the restricted access of women to safe abortion services.

Figure 18. Providers' network: Abortion services



5.2.2.2 Septic abortions due to unsafe illegal conditions still present, though less in numbers

Many studies done on abortion services have reported that septic abortions are still a matter of concern and maternal mortality and morbidity due to septic abortions are not the issues of the past (Guleria et al., 2006). A recent cross sectional study conducted at a teaching hospital at Darjeeling reported 15% of the hospital's

mortality to be due to septic abortion and 72% of the septic abortion cases were performed by untrained persons (Chatterjee, 2007). Pathfinder International, an NGO working in reproductive health carried out a project (2003-2007) in three northern districts of Karnataka to improve access to safe abortion services. They conducted facility assessment surveys during their baseline study and found the infection prevention to be sorely deficient both in public and private hospitals (Pathfinder International 2007). The Karnataka state Government data report 4% of the maternal deaths to be due to complications from septic abortions (MOHFW, 2009). The interviews with the users were not conclusive on the incidence of septic abortion. Most of the respondents had accessed MTP services from a variety of providers in Government and private sectors. Their narratives focused more on the trajectory of the process of seeking care, abortion procedure for the particular episode and less on the post-abortion care. Seeking abortion was looked upon by them as an independent episode.

The providers in both Government and private reported that the number of septic abortions due to illegal, unsafe conditions has come down in the last 4-5 years and added that their witnessing of septic abortion cases recently is very rare.

> *Yes, we could see it, we could take out the foreign body, which was inside, and we could take out the foreign body when we did PV. It was like ball made of cow dung and so many other things, it was horrible. But I should say these cases are rare (MTP_IMPLEMENTER_04_01)*

However, the providers in the northern district mentioned that they still witness abortions done by traditional providers resulting in septic abortions usually 1-2 cases in a month in the district tertiary hospital. In the absence of systematic data on causes of deaths (medical audits started recently), it was difficult to assess the proportion of septic abortion causing maternal deaths. There was a tendency among administrators of MTP both at district and state levels to undermine the significance of septic abortion as a cause of maternal deaths.

5.2.2.3 Misuse of medical abortion: Unintended effect of MTP

The 2002 amendment of MTP Act made medical abortion as a legal method to conduct MTP. Medical abortion is a method of elective abortion with the use of pills. This is a non-surgical method of abortion and as per the MTP act, is permitted up to 7 weeks of pregnancy. Though introduced as a safer method to provide abortion services, implementers and administrators raised serious concerns over the misuse of these tablets, which leads to large number of incomplete abortions. Many cases were shared by respondents at all levels about the use of abortion pills resulting in incomplete, septic abortions and consequent heavy bleeding, shocks and convulsions. These pills are nicely packaged, which is popularly known as 'MTP kit'. Since these tablets are available over the counter, people have easy access which is also a reason for its misuse. The users as well as health workers use these kits without any prescription. Since this is consumed without any supervision, women often land up in heavy bleeding and shocks.

> *They will take half tablet, one tablet and they get incompletely expelled and then come running to us. The factor is cost, they will get cheap tablets, but, they will not be effective enough to expel the complete thing (MTP_IMPLEMENTER_10_02)*

> *It's a fancy now, they say they have had tablets given by ANMs, medical shops and they take it (MTP_IMPLEMENTER_05_01)*

All the OBGs shared their experiences of such cases and lamented that they had been receiving a large number of incomplete abortions.

> *If you ask me frankly, it is very costly and many a time I have hardly seen anybody getting complete abortions with tablets. Many don't know that it is effective only when taken during forty or forty five days of conception. They come only after nearly six weeks and many a time they will not abort. (MTP_IMPLEMENTER_05_02)*

Sometimes they come and they go on bleeding for many days and become anemic. If D and C is done immediately, bleeding will be controlled and things will go easily. (MTP_IMPLEMENTER_10_02).

5.2.2.4 Marketing of abortion services

Large scale marketization and commercialization of abortion services have become a matter of concern all over the world. A study conducted in Poland highlighted the economic consequences of stigmatization and illegality of abortion and how a woman's private worry is turned into a marketable profit (Chelstowska, 2011). The study estimated that the providers make about $ 95 million per year from unregistered MTP services. A study in Jamaica (where abortion is against the law) reported that abortion pills in black market are in huge demand and the cost can go up to anywhere up to $15,000 for a course of treatment, which is about the same as the cost for invasive surgical abortion done by a medical doctor. In India the misuse of pills is widespread as they are available over the counter (Whyte, 2011). Pharma companies play a major role in popularizing the usage of these pills. The local drug vendors are often the first contact point for the users and they also act as intermediaries between the users and the providers. They create a demand for MTP pills by making the drugs available without prescription, providing incomplete doses and subsidising prices. The unmonitored circulation of MTP pills and their advertisements indicates how the regulation fails to bring a market feature under regulatory control. This feature also shows how there is a disconnect between different regulations (here in this case MTP and the drug regulation that prohibits sale of MTP kit without prescription and the kit is made available only to gynaecologists). The advertisements by the pharmaceutical companies are not in compliance with the MTP regulation. For eg, we found the following information about the usage of MTP pills in a leading pharma company website:-

Dosage and administration- MTP kit is indicated for the medical termination of intrauterine pregnancy up to 63 days of gestation…. The misoprostol may be administered by a clinician or self-administered by the woman (www.cipla.com accessed on January 27, 2012)

This kind of information is not in compliance with the regulation and often misleading because the MTP Act permits the medical abortion only up to 49 days of pregnancy. Though it is not legal and often clinically ineffective to use these tablets for advanced stages of pregnancy, there is widespread usage of these tablets irrespective of the gestation period. Though a packet of drugs for MTP costs about thousand rupees at the drug store, they are available in the black market at a much lower price and the medical companies distribute the packets for about 300 rupees to the clinicians. The rampant use of abortion pills has given rise to different variants of these tablets; they are available in the market for cheaper price, which is often of less quality i.e. Ayurvedic variants of the pills.

> *M.T.P. kit costs about four hundred rupees. As per my knowledge M.T.P kit is available at Rs.150 in black market without a receipt. Otherwise only misoprostol 4 tablets are available at the rate of Rs. 80. Women will prefer that only. (MTP_IMPLEMENTER-07_01)*

The users we interviewed had spent between Rs. 1500 to Rs. 10,000 to avail MTP services. As narrated by the users and health workers who accompanied them to different facilities, the cost for abortion depends on a) the gestation period, b) method adopted and c) the type of facility used.

> *Some women go to the sub-district hospital and say that it is very costly like for 2 months it is Rs. 2000-3000. Here in clinic X manned by a pharmacist they charge Rs 800-1000 for the same case* (MTP_OTHERS_02_01)

> *In the Government hospital, it might be Rs. 500-600. I went to a private hospital and paid Rs 2000 (MTP_USER_09_01).*

Sundar's study (2003) in Delhi provides detailed information on the provision of MTP services in different facilities and the cost of these services. The study showed how price varies with the type of facilities, period of gestation, procedure and marital status. For instance, MTP up to 12 weeks of pregnancy in a private nursing home costs in the range of Rs 3000 while the same gestation period when terminated by

untrained providers costs around Rs 800-1000. Further, while for married women, MPT could cost in a smaller private clinic Rs 400-600 (for gestation up to 10 to 12 weeks), the same clinic would charge double the amount at Rs 1200 (and four time for medical abortion at Rs 2500) for unmarried women (Sundar 2003). A similar trend was observed in the narratives of the users and implementers in our study. The perceived legality of abortions determines the cost of MTP. If the women are unmarried, widowed, or separated, their pregnancies are considered 'illegal'. None of the users we interviewed belonged to this category though the providers confessed that there is a huge demand of abortions among unmarried women in southern district.

Unmarried pregnancies are very common these days. Actually it is more common in rural areas (MTP_IMPLEMENTER_10_01).

Considering the cultural stigmatization of unmarried pregnancies in the Indian context, such abortions are priced higher than abortions for married women.

5.2.2.5 De-criminalization of abortion services at the level of obstetricians only

A major objective of MTP Act was to decriminalize abortions through legalizing it. This would enable a practitioner to give the services (within the defined conditions of the Act) without any hesitation or guilt as abortion services are no more a criminal offence. The act protects the trained practitioners in the registered facilities who act in good faith to terminate the pregnancies on conditions laid down by the act. However after forty years of the Act in place, how comfortable are health care practitioners (those who are legitimate to provide under the ambit of the Act) to provide MTP services? Our study showed that only obstetricians and other specialists are at ease in offering MTP services. Obstetricians interviewed both in Government and private sector (N=8) were very clear of the indications for abortions, legal requirements of procedures as well as recent amendments of the Act. They expressed no hesitation to talk about MTP services, the kinds of cases they receive, methods used and fall out of the Act in terms of reporting of MTP services. However, there is a general discomfort in doing abortions for unmarried women.

Sometimes I also feel it is below my dignity to do abortions especially for unmarried women but what happens is that after some time they go to quacks or ANMs. There they land up in problems. If we don't do it here, they will be in a bad situation. That is why I again started doing it (MTP_IMPLEMENTER_13_02)

While for other practitioners like the medical officers who work in the primary health centers particularly those who are untrained, there is a discourse of denial. All the health workers during our Focus Group Discussions clearly denied that the medical officers conducted any MTP services. The medical officers interviewed later (N=11) in both the districts expressed initial discomfort to talk about MTP services. Researchers had to ask many general questions reflecting about general health services, their views on the changes after the recent policy before embarking on questions related to MTP services. They confessed that they offered these services either due to a pressure of demand from the patients or they used only medical abortion procedures which is abortion but not MTP. According to them, if the termination of pregnancy was done by using drugs and it was an outpatient consultation, it is just abortion and does not amount to MTP. In their view, the abortions done by using surgical methods such as D&C are to be considered as MTP.

5.2.2.6 Weak oversight and monitoring: Absent information

Despite clear monitoring procedures on registration, licensing and reporting laid down in the Act, monitoring is practically non-existent in the field; an issue indicated earlier studies as well (Duggal 2004; Johnston 2002). HESVIC sought to elicit explanations for such underreporting.

Until now I have not heard anybody monitoring MTP at District level meeting or Taluk level meeting (MTP_IMPLEMENTER_06_01)

Two types of information which are critical for proper information feedback and monitoring were conspicuous by their absence. One is the number of medical officers

trained to conduct MTP. Despite our persistent efforts to get the number of Government medical officers who are trained in MTP, we were directed from one department to another. We heard all tentative and often contradictory answers from administrators.

> *I don't know the exact number but can say that the number of trained medical officers is very less in this sub-district (MTP_ADMINISTRATOR_04_01)*

> *Well, I think we have enough number of MOs trained (MTP_ADMINISTRATOR_06_01)*

> *I think 30% of the medical officers are trained in our district (MTP_ADMINISTRATOR_08_01)*

In the Northern district, MTP services were provided mainly at the private nursing homes and the provision for MTP at the Government sector was limited to the general hospitals at taluka level. The district authorities there reported that the PHC medical officers are not given training on MTP. This raises a serious concern with regard to access to safe abortion services at the primary health care level.

Second kind of information was on reporting the MTP cases. The Act demands detailed reporting of MTP cases by the facility on a monthly basis to the District Health Administrator of the District which then gets passed on to the state. The report should contain the details including a) total number of cases by gestation period (within 12 weeks and after 12 weeks) b) religion of the woman c) termination with acceptance of contraception (sterilization and IUD) d) the reason for conducting MTP and e) outcome. As per the Act, the admission register in the facility also should contain socio demographic details of the woman, the duration of pregnancy, reason for MTP, dates of termination and date of discharge and results/remarks. The facility is expected to keep the documentation available for 5 years.

Uniformly all administrators and implementers (private and Government) confessed that MTPs were underreported. When asked about the documentation, most of them

do not keep any documentation, especially if they perform medical abortion, and the providers who keep documents reported that they keep it for a short period and then dispose it. Though the private facilities do send the monthly reports on MTP (which contains the number of cases seen, outcome), most of the time the actual numbers are not mentioned in the report.

> *Actually what we report is much less than what we do. MTP done with tablets, we don't report. Only thing which needs 3rd month 4th moth is surgical abortion. Otherwise all other cases will be OPD cases (MTP_IMPLEMENTER_06_01)*

> *Within three months, no record, I am writing it in OPD that's all, I write it and refer them, I don't now I may have to maintain record also (MTP_IMPLEMNETER_02_01)*

Most of the time the records in government facilities are noted down as spontaneous abortions (and hence not MTP) and not induced abortions.

5.2.3. Explaining the effects: An integrated analysis of actors, context and process

Many socio cultural, legal and policy level factors affect the way MTP regulation was implemented in everyday practice.

5.2.3.1 Ambiguous location of MTP: Caught between safe abortions and safe family planning

MTP has not only been caught between a pro-life and pro-choice approach (Patel 2007), it also sits ambiguously between population policy (as a family planning measure to control population), health policy (promoting quality maternal health care by facilitating access to safe abortion services) and a law that seeks to legalize an otherwise sensitive issue in a context like India.

As has been pointed out, the framing of the Act was triggered by concerns for curbing population growth and curbing maternal mortality due to unsafe abortions by giving protection to medical practitioners who offer the services. Thus it was initiated more by concerns of demographers and the medical fraternity than feminist movements which was the case in other countries (Ganatra 2003). This is perhaps the reason why framing of MTP as accessing abortion as a matter of right has been problematic in India. The Shah Committee whose recommendations led to the formulation of the Act had cautioned that legalizing abortion for demographic goals was counterproductive and that abortion should not be considered as a method of population control. Though the sixth five year plan categorically stated that MTP is not a family planning method, the eighth plan again brought it under the ambit of family planning services. As reported by Phadke, the legalization of MTP services was done more as a population control strategy than a maternal health concern. Evidence on providing MTP services conditional to post abortion sterilization in public health facilities bears testimony to this point (Phadke 1998). Limiting family planning to maternal *health* leads to a conceptual and medical mistake as it rules out as a key success factor the relationship between the care provider and the service user e.g. the quality of their communication on existential issues at the side of psychological and psychosocial issues.

The larger interpretation of the Act as we observed in the field among all levels of administrators and implementers was predominantly in terms of MTP as a family planning measure. Its association with maternal health like other components such as ANC, institutional delivery, post-partum care was rather vague. Even as a poor family planning measure (most of the MTP were sought on grounds of unwanted pregnancies followed by contraceptive failure and congenital deformities) MTP services do not entail any kind of counseling at the primary health care level.

Location of MTP as a family planning measure shifts its attention away from a right perspective (to access quality abortion services) to that of a duty of a citizen to contribute to efforts towards population control.

The medical officers do not realize the significance of MTP as a family planning. They should not hesitate to give the service as failure to do so would cause additional burden to the family and the nation. They must understand that (MTP_ADMINISTRATOR_02_01)

Yeah, MTP, we have not emphasized much on family planning but we must. This is perhaps because Karnataka has reached the TFR 2.1. (MTP_PLANNER_02_03)

At the *taluka* and district level monthly meetings that we attended, there was hardly any mention of MTP while maternal health was a significant topic of discussion (issues around hospital births, number of ANC registered women, disbursement of cash incentives, referral of EmOC cases, maternal deaths if any). Even when MTP was rarely discussed, it was limited to just the numbers (on reporting of MTP cases). No other issues related to MTP were discussed in any of these meetings. Explaining the reasons for such absence of MTP, administrators reported that MTP is a point of discussion only if there is a maternal death due to MTP or septic abortion. Though the Act overtly articulated the need for controlling maternal mortality and morbidity by promoting safe abortions (as sepsis abortion was seen to have been one of the major causes of maternal deaths), its linkage with maternal health is obscure in the field.

We referred to the current policy documents to locate MTP among other maternal health services. Indian Public Health Standards mention of MTP as a necessary service to be provided in 30-50 bedded hospitals and in hundred bedded hospitals. However, in primary health centres MTPs are not a necessary service; only *'counseling and referral to a safe abortion centre'* are to be provided as a necessary service at the primary health centres.

A primary health center caters to 30,000 populations but the center can provide abortion only if the Medical Officer is trained. So a PHC does not automatically become an abortion center. Hence the next level of abortion center which can provide abortion is a FRU catering to 400,000 -500,000 population. Such adverse population and abortion center ratio explains why users seek the services in private

facilities and or clandestinely from health workers and untrained medical providers. The provision of MTP is mentioned as a service to be provided '*wherever'* trained personnel and appropriate facility are available. This clearly shows that MTP is not looked upon as a priority service which has to be provided through primary care facilities.

> *Well, safe abortion services are important but frankly speaking it is silent. Neither have we told our officials that MTP should be practiced as a part of family planning measure nor do we say this needs to be treated strictly as a part of maternal health. This Act has been in place for a long time and abortions services are accessed by the community. The Act works rather silently. Of course abortions services are also a matter of right as we talk about right to health (MTP_PLANNER_02_03)*

It is partly because of this ambiguous location, MTP is de prioritized in policy terms in relation to maternal health.

5.2.3.2 Interpreting the regulation: MTP as a restrictive regulation

Baldwin and Cave (1999) discuss how 'regulations can be thought of as an activity that restrict behavior and prevents the occurrence of certain undesirable activities (a red light concept) but its influence may be enabling or facilitating (green light)'. MTP seeks precisely to do this. It facilitates access to safe abortion services by restricting conditions under which this can be done, preventing it from being done by untrained and unqualified practitioners. However, the larger interpretation of the regulation tilts towards the red light concept masking the green light effects. Hence among the village level health workers, medical officers in primary health centers and other primary health care providers in the private sector, MTP is seen as a regulation that controls behavior i.e. in this case, provision of abortion services. Partly because of the interpretation of the law that forbids certain behavior/activities (refers to the specific conditions under which MTP is allowed), there is a large amount of hesitation to talk about MTP among providers.

We can't do abortions as this might otherwise be a case (MTP_FGD_HW_01).

We underreport because if we report the actual numbers which is higher as there is a huge demand for abortions, then the Government will look at us in a way that we have done something wrong (MTP_IMPLEMENTER_05_01).

The women who have used abortion services narrate their experiences in a tone trying to justify an otherwise forbidden activity (a lot of justification on why the abortion was sought in the first place). Such interpretation of regulations as restricting and controlling activity can be situated in two contexts a) a skewed reading of the Act which raises the larger issue of dissemination of the Act and b) a cultured lens of understanding the provisions of the Act.

'Legal' was translated as abortions sought among married women only while 'illegal' denoted pregnancy among unmarried, divorced and separated women. This is certainly a cultural reading of the Act as pre-marital sex is highly stigmatized and pregnancy in a marriage is only considered as culturally acceptable in India. This is typical of the ambivalent nature and response to social changes in India. While familial changes like live-in relationships are gradually accepted by the emerging middle class in urban areas of India, a law like MTP is obscure on provision on abortion outside marriage. While emerging forms of sexuality (homosexuality) are legalised, moral policing of women by illegalising abortions particularly unmarried abortions presents a complex picture of the relationship between law and society.

5.2.3.3 Morality over legality: Role of culture

The critical reading of the Act in terms of legal and illegal is through the lens of culture. This is in addition to the distinctions between legal married pregnancy and illegal unmarried pregnancy. As has been stated in many studies on abortions, there is very little knowledge of the Act (Hirve 2002). Our study with detailed interactions with 11 users reinforced this finding. None of them knew about any legal provision that exists. In fact their reflection on abortions was little to do with the need for an existence of a law that facilitates abortions. Rather, their concern revolved around how the act of abortion is unethical and morally wrong. The users mentioned about

MTP as something that should be avoided if possible; some of them mentioned that it is a 'sin' to do abortion. They also reported that MTP is not something that can be openly discussed in the community.

> *No one told me if it is legal or illegal. But I felt bad, inside my mind (MTP_USER_01_01)*

> *Some of my relatives said that I used to go out during eclipse; it has happened like this* (It is believed that during eclipse, if the pregnant woman comes out of the house, it will lead to the fetal anomaly) *I felt disappointed. So, didn't discuss with anybody. We discussed within ourselves and decided to undergo abortion (MTP_USER_09_02)*

This spills over to the health workers as well who lower their voices when speaking about abortions and MTP. The reason why these services need to be given clandestinely is partly to do with the culturally forbidden nature of abortions. Such moral lens of MTP Act certainly restricts access to quality abortion services. We observed that where medical officers in primary health centers do not provide MTP services, users have accessed services from informal providers including health workers who provide the services themselves or refer them to private nursing homes.

5.2.3.4 Disjunction between clinical and legal training: Bearing on access

As per the MTP regulation, Medical Officers (M.B.B.S) in primary health centres have to undergo MTP training to be eligible to conduct MTP procedures. This training enables them to conduct MTP up to 12 weeks. As is clear from the field, the number of trained MTP providers is very less in the primary care centres and this limits the legal access to care at primary care level. However, all the Medical officers (trained and untrained) spoke about how MTP training is just a legal licence.

> *While we can offer all other services, why not abortions? MTP training is just a legal cover, it does not add to our clinical skills. Hence even if we are clinically trained to offer MTP, we are not legally trained. So when we give the services, it will be treated as illegal. That is why neither we can confess that we are conducting MTP nor we can report (MTP_IMPLEMENTER_02_01)*

Clinically MOs do have the skills as this is already a part of the graduate medical curriculum; MTP training is merely to empower them legally (MTP_ADMINISTRATOR_02_01)

The graduate medical curriculum does cover the provisions of MTP Act extensively during the four years of training. Abortion procedures are taught in courses like Obstetrics and Gynaecology, preventive social medicine or community medicine and forensic medicine. These are all compulsory subjects. The mandatory training and hence provision of MTP services through qualified practitioners in the original Act perhaps aimed at quacks who are not qualified professionals and not clinically trained. However the Medical Officers though qualified are looked upon as 'illegal providers' from the point of the view of the Act. While sharing this observation with obstetricians, we got mixed views. While some of them in the Government and private sectors do feel that Medical Officers with their current clinical training should be able to provide abortions services up to twelve weeks, Some other OBGs in the private sector felt that though in theory they should be able to do it, the quality of medical education in the proliferating private medical colleges is a concern and one cannot trust the skills they gain from such education.

Further, the quality of MTP training in this regard, was also raised as a matter of concern by the implementers. Though the provisions of the Act demand extended training, in practice, MTP training is done for 15 days only. Apart from the limited duration of training, the procedures for training of private practitioners in MTP are not clear. The obstetricians in private sector are allowed to do MTPs if their facilities are registered, but an MBBS doctor who is working in a private nursing home is not eligible to do MTP unless he is trained. This again reduces the trained manpower in abortion services.

The MTP Act is also restrictive in the sense of not creating any scope for training and provision of MTP services by non-allopathic doctors. It not merely medicalizes as some have commented (Duggal 2004; Ganatra 2003; Harvey 2002; Johnston 2002) but also allopathizes it, as it clearly states that only allopathic doctors are authorized

to do the same. This conflicts with the recent policy efforts to mainstream traditional systems of medicine and hence many primary health centres are additionally manned by AYUSH doctors. AYUSH doctors like the allopathic doctors provide other services in the primary health centres. This provision of MTP only by allopathic doctors further restricts access to abortion services.

Considering the prominent role played by health workers as many studies have shown, civil society had recommended the training of health workers in MTP. The evidence on such training to facilitate quality abortion services was drawn from other contexts as well (Mavalankar et al 2009). While the civil society organizations tried to advocate for such a move in India, the Government rejected it saying it lacked context specific evidence (HEPVIC 2009). The health workers hence do not have the required training for providing or counseling for abortion services.

5.2.3.5 Role of information: Reasons for underreporting

The feedback loop of the regulation exists mainly in the form of inspections and reporting of MTP cases and outcomes. Both the Govt. and private facilities providing MTP services are expected to submit MTP reports monthly to the District Health Office. The district Health Officer needs to periodically inspect the facilities to ensure that they are maintaining the standards laid out by the MTP Act. It was evident from the interviews that there is gross underreporting of MTPs in the field. This issue was discussed in detail with the actors at different levels and they gave various reasons for this. At the level of Medical officers, who are the implementers of the regulation, it is mainly because they are not trained and they are not supposed to provide the services and hence they do not report. Some of them said they provide medical abortion and that does not account for MTP so they don't report. This was further corroborated by the district level administrators as well. Yet another reason for under reporting is the fear of coming under the scanner of PCPNDT. The fear of PCPDNT is widespread among the doctors, and this is more due to the hearsay about the disciplinary actions taken against providers who do sex selective abortions.

If something clearly exceeds from the anticipation of records from an institution, they suspect and they randomly check what is happening (MTP_IMPLEMENTER_04_01)

According to the district level administrators, the providers do not record the cases mainly to protect the confidentiality of patients and for profit motive. The obstetricians in private sector reinforced these reasons for underreporting. As reported by the respondents, under reporting also happens because of the mandatory following of protocol for gestation period beyond twelve weeks. Such procedures include taking second opinion, well-equipped infrastructure for any emergencies.

For cases requiring surgical interventions specifically for cases more than 12 weeks, the Act has cumbersome procedure. The whole procedure becomes too fussy. Also if you report all the cases, the Govt health officials who check the records react as if we are doing something wrong. In many cases MOs are not trained and they do provide services that is why they mask reporting (MTP_IMPLEMENTER_05_01)

Another reason that the private practitioner mentioned for underreporting is that if the number of reported abortion cases are more, it obtains unwanted suspicious attention from the district administration of potential wrongdoing.

5.2.3.6 Role of related regulation- PCPNDT

Though the role of PCPNDT in collusion with MTP Act is often spoken about (Bhatia 2007, 2010; Mallick 2003; Patel 2007), our findings offer a blurred and hazy picture. At the level of users and health workers, they do talk about a preference for son and demand for sex-selective abortions but this is always addressed in a very general sense and in a third person. ‘People might be doing it we don’t know where’. Always some distant places are referred to saying this is does not happen here.

While asking the implementers (practitioners) about the relative place of these two Acts, they categorically mentioned that these are two different Acts. They also reinforced their position firmly saying that they do not entertain any sex-selective

abortions demand. The need to be politically and ethically correct on issues of sex-selective abortions was prominent among these actors. Reflections of administrators and planners show that PCPNDT has got greater visibility compared to MTP (the NRHM office, the DHO office having PCPNDT Cells but no MTP cell). Our respondents at various levels reported that the officials are more alert about PNDT act and there is stricter monitoring of PCPNDT in the field. PCPNDT has better resource allocation for sensitization training while MTP has none. The visibility of PCPNDT eclipses the MTP Act.

> *Yes it* (PNDT) *does get more visibility. This is because a number of private players (international organizations, religious organizations) are involved and interested in implementing PCPNDT. That is why it gets more visibility. Ideally both MTP and PCPNDT should synchronize with each other but it does not happen like that* (MTP_PLANNER_01_03)

> *PCPNDT's role in policing the moral horizon is very visible…*Because of the involvement of religious organizations, PCPNDT has received a lot of attention. These organizations have highlighted it as a moral issue (MTP_PLANNER_01_04).

5.2.4. Discussion and recommendations

The analysis indicates the following key messages that emerge from the study. Even after forty years of the Act, equitable access to quality abortion services particularly at the primary health care level has still been problematic. Access has been restricted due to certain provisions of the Act itself a) making training mandatory for clinically trained providers b) restricting it to only Allopathic doctors and c) not providing training to paramedical staff who could play a role in facilitating access to safe abortion services and perhaps counsel and provide post-abortion care.

In addition to the restrictive consequences of an otherwise progressive law, abortion being culturally sensitive is further restricted as it is seen as unethical and wrong. Hence the support of the husband, other members of the family, specifically mother-

in-law (most of the women interviewed stayed in extended families) is critical for a woman to decide to abort and to access abortion services.

Considering a clear command and control approach of the Act with rules and regulations for administration and implementation, this Act is implemented in ways that produce a different set of effects. Factors like culture, ambiguous policy focus, interests of medical professional bodies (who do not perhaps wish to let para medical, non-allopathic practitioners provide MTP) and pharma companies (who do brisk business selling self-administered drugs including MTP kit), and the role of other players (political parties, NGOs, denominational health services, aid religious organizations) who silently condemn pro-choice approach, explain why the Act has been working rather clandestinely. Neither information on trained providers, number of MTPs, quality check nor consent procedures are strictly adhered to. The Administrators who are responsible for monitoring a long list of health programs learn to prioritize some and deprioritize others. MTP falls into the second category.

Recommendations

- There is clearly a need to overcome environmental constraints. The ethical and cultural barriers need to be addressed by awareness creation among the community about the Act and its provision.
- Sensitization training for grass root level health workers and paramedical staff on MTP regulation for counseling, addressing psychosocial aspects of abortion care.
- More involvement of civil society organizations in abortion related issues at the level of implementation through their role at the formulation stage has been commendable
- More accountability from district authorities in facilitating training of primary health care providers
- Periodic refresher training for the trained doctors to sensitize them on newer technology and also on amendments of the regulation time to time

- MTP pills have to be made a prescription drug and there needs to be stricter monitoring of over the counter purchase. Government should take necessary measures to stop misuse of the pills.

5.3. Grievance Redressal Mechanisms: Role of the Consumer Protection Act 1986

5.3.1 Overview of Regulation: Content and procedures of implementation

5.3.1.1 Background of the regulation: Policy and Legal Environment

India has had a set of legal instruments for regulating health care. These are Indian Medical Council Act (1956) that aims at granting recognition of medical qualifications and maintenance of a medical registration in every state, the Indian Penal Code (1860) that defines criminal acts and liabilities for punishment in medical service, and the Law of Torts that addresses the issue of malpractice by medical professionals. Studies have shown the limitations of these legal instruments in protecting the interests of citizens, more specifically vulnerable groups (Bearak 2000; Peters and Muraleedharan 2008; Verma et al 2002). These legal instruments suffered from several limitations i.e. limited ability to enforce the laws, limited access to these mechanisms by majority of citizens and very lengthy period of adjudications (*ibid*). Apart from these legal instruments, health care is regulated by self-regulatory bodies like the professional medical councils (Medical Council of India, State Medical Councils). Literature shows that self-regulation through professional medical councils and medical code of ethics is ineffective. These professional councils have proved to be self-interest serving bodies than regulatory councils enforcing accountability in the profession (Aiyer 1996; Derbishyre 1983; Jesani and Nandraj 1994; Peters and Muraleedharan 2008). It is in this environment of inaccessible legal mechanisms and idle professional medical bodies; the passing of the Consumer Protection Act (1986) bears significance for the present study.

The Consumer Protection Act (hereafter referred to as CPA) was introduced in the Indian parliament in 1986 following the guidelines of the General Assembly of the United Nations (UN 1985, Consumer Protection Resolution No 39/248). These guidelines provided a framework for national Governments in developing countries to

use for elaborating and strengthening consumer policies and legislations. Following these guidelines, the CPA in India was put in place to protect the rights of consumers against *unfair trade and deficiency of services* (marketing of hazardous goods, lack of information on quality, quantity, price and standards of goods) and to promote their rights to be heard and seek redress, when faced with any unfair trade practice and/or deficiency of services (Government of India-CPA 1986).

5.3.1.2 Formulation

Though CPA was passed in 1986, it is only in 1995, by a landmark judgment of the Supreme Court of India, the medical profession was included under the purview of the Act.[16] This implied that health care rendered by individual medical practitioners and health institutions constitute 'service' and patients availing of this service are called 'consumers' within the definitions of the Act. This judgement was preceded by a number of previous arguments and counter arguments about the justification of inclusion of medical profession in this Act. While some state High Courts argued in favour, the National Commission (National Consumer Forum) had ruled against it in 1989 (December 5, 1989, First Appeal (2) 1989, Dr. A.S Chandra V union of India 1992, ALT 713 and Dr. C.S. Subramanian V Kumaraswamy 19941, MLJ 438).The judgment was initiated by the civil appeal filed by the Consumer Unity Trust Society (a consumer association)[17] against the verdict of the National Commission (National level consumer forum) that had ruled against the inclusion of medical profession within CPA. The appeal to such inclusion faced flak from the Indian Medical Association and representatives of private hospitals who had filed a case arguing against the inclusion (M/S Cosmopolitan Hospital Vs Vasantha P. Nair and Vinitha Ashok Vs Lakshmi Hospital and others, Indian Medical Association vs. V.P. Shantha and others 1995).

The main points of contention voiced by the private hospital representatives and the Indian Medical Association were a) if CPA should be applicable to medical

[16] Indian Medical Association VS V.P Shanta and Others 13, November 19995, Supreme Court of India Judgments

[17] This consumer association is an international NGO with its head office in Rajasthan, India. Started at 1984, it has expanded its mandate to advocacy and collaborative partnerships on international trade issues that would have an impact on consumers and good governance

practitioners as they are already regulated by self-regulatory measures (like the Indian Medical Code of Ethics, Medical Councils like the Medical Council of India) to prevent professional misconduct b) if providing health care could constitute 'service' and the patient a 'consumer' within the definitions of the Act as the relationship between a medical practitioner and patient is of trust and confidence and is different from a merchant and buyer c) if Government hospitals should come under the purview of the Act as the Act excludes within its ambit services rendered free of charge and d) if deficiency of services could apply to medical care as the proof of deficiency follows certain fixed norms on quality, nature and manner of performance of service which is different from other goods.

The judgment clarified these contentious issues and asserted the spirit of the Act to 'achieve and maintain adequate protection of the population as consumers and encouraging high levels of ethical conduct for those engaged in the protection and distribution of goods and services to the consumers' (AIR 1995: 18). In this spirit, the judgment also clarified that the medical profession like any other profession is deemed fit to come under the purview of the Act. The Act that was passed with a mandate of the parliament was disseminated through Gazette notification to the administrative bodies concerned. The Administrative bodies also rely on the Law journals for previous judgments. Figure 18 offers an overview of the process of the formulation of the CPA.

5.3.1.3 Objective and intentions of the Act

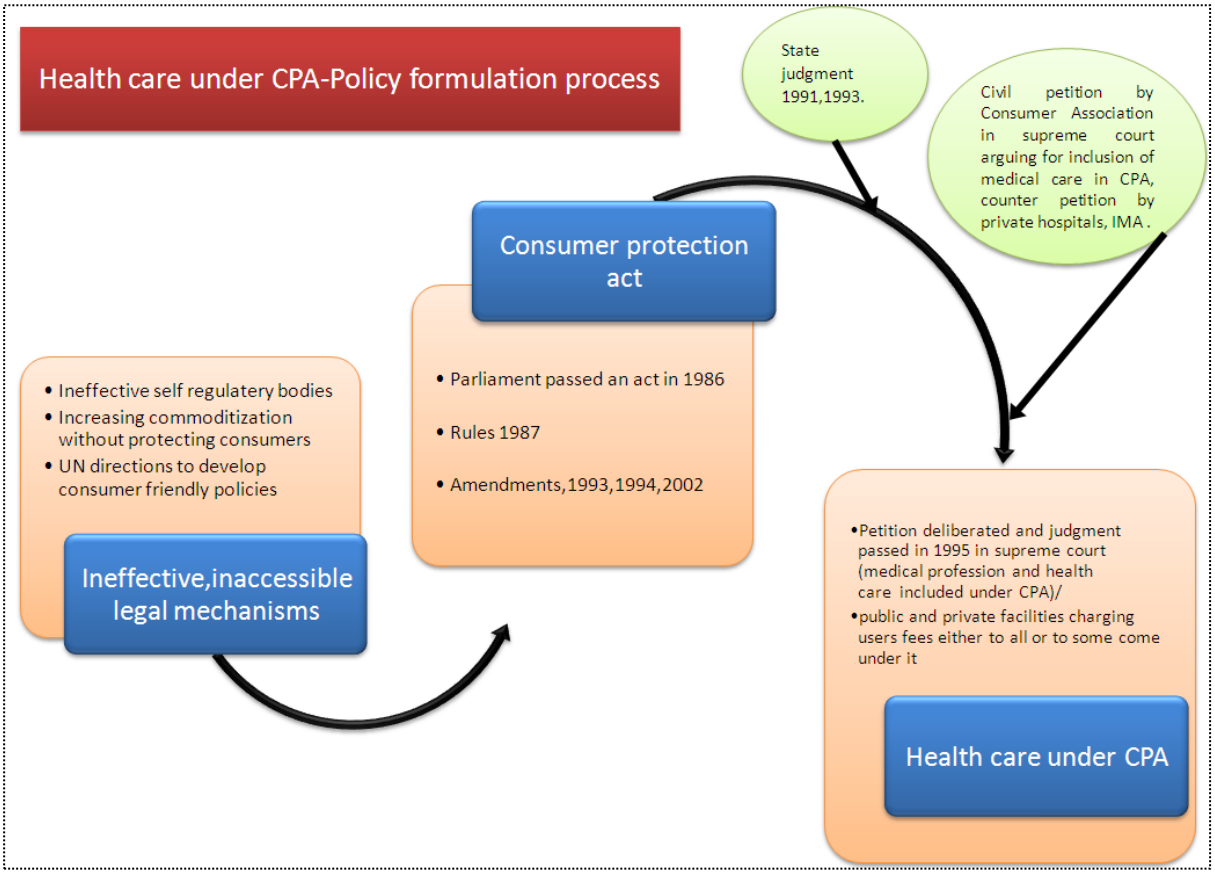
CPA through the significant 1995 Supreme Court judgment sought to

1. Empower patient-consumers with a voice to seek redressal for poor quality of service delivery

2. Protect the patient-consumers from *unfair trade* and *deficiency in health care services* thus ensuring quality of health care

3. Establish greater accountability and responsiveness of health care providers

Figure 19. Health care under CPA –policy formulation process



5.3.1.4 Content of the Regulation

The regulation has three main sections. The first section clarifies definitions of key terms like consumer and service. The second chapter talks about establishment of Consumer Protection Councils and modalities of selection of these councils and the third section lays down modalities of grievance redressal. The Supreme Court judgment (1995) clarifies the criteria of inclusion and exclusion of service and consumers in different medical establishments.

The Act defines a *consumer* as someone 'who buys any goods for consideration that has been fully paid or promised payment or partly paid. This also includes a person who hires or avails of services for a consideration which has been paid or promised or partly paid'. This implies that a consumer is defined in relation to *buying* of

services in return for payment full or part. *Services* are defined in the Act as 'service of any description which is made available to potential users and includes the provision of facilities in connection with banking, financing, insurance, transport, processing, supply of electrical or other energy, board or lodging or both, (housing construction, entertainment, amusement or the purveying of news or other information, but does not include the rendering of any service free of charge or under a contract of personal service' (Government of India 1986:9).

The provision of health care services in terms of payment of fees in India falls into three categories. These are a) where service is rendered free of charge to everyone like in the missionary hospitals b) establishments where everyone pays fees, say for instance, the private for profit clinics/hospitals and c) Government establishments where it charges users fees for registration and nominal fees for some services however these charges are waived for people below poverty line. Those hospitals/nursing homes/dispensaries that provide service free of charge to everyone (category A here) are excluded from the Act. This would imply that Government Primary Health Centres, missionary hospitals which provide services free of charge would not qualify to render service within the meanings of the Act. However other Government hospitals/nursing homes which provide services free to some patients (poor patients for example) and charge fees to others would come under the Act. These would include apart from the private sector medical establishments, Government hospitals like the sub-district, district hospitals and teaching hospitals. All these Government medical establishments charge user fees for diagnostic, surgical and medical interventions and token fees for entering the health system. Since health is a state subject, the amount of fees charged, for which services and for whom (Below Poverty Line and Above Poverty Line) varies among different states and within the state depending on the administration of different government hospitals[18]. The private sector is clearly included under the Act. Hence with the select exceptions of public health facilities, the Act is applicable to both public and private sectors.

[18]In Karnataka for example, Government medical establishments come under three different types of administration i.e. a) autonomous b) State Department of Health and Family Welfare and c) Bangalore City Corporation.

5.3.1.5 Procedures of administration and implementation of the regulation as per the Act

Following these definitions of 'consumers' and 'services' and with the objectives of protecting the interests of consumers, the CPA made provisions for instituting quasi-judicial bodies and consumer councils at the District, State and National levels which provide *speedy and simple* redressal of disputes including financial compensations wherever appropriate (emphasis added). Unlike other health regulations, CPA being a general Act comes under the Ministry of Consumer Affairs, Food and Public Distribution at the centre. Consumer protection councils at the centre, state and district levels are formed with the Heads of the ministry at the Central level, stat level and District Head at the District level. The objectives of these councils are to promote and protect the rights of consumers against marketing of hazardous goods, rights to be informed about the quality, quantity, standards of goods, right to seek redressal and the right to consumer education. Apart from the fact that these councils are supposed to meet at least a year, the Act does not say much on their roles in terms of administration vis a vis the consumer forums.

The Act is mainly administrated by the Consumer Forums formed at the national, state and district levels. These three forums operate at different levels based on the amount of compensation claimed by the consumers i.e. the National Consumer Forum addresses cases with claim of more than Rs. 10 million, State Consumer Forum between Rs 2– 10 million and the District Consumer Forum with a limit of Rs. 2 million. Though the upper limit is set at different levels of consumer forums for administrative purposes, the actual amount of compensation to be paid is decided through the process of litigation in the consumer forums. A consumer needs to know and decide how much he/she wishes to claim in order for the person to file the complaint in the relevant consumer forum. The actual entitlement is decided in the consumer forum itself. There are three points that are discussed and decided in each case of complaint: a) if the complainant (patient or relative) is a consumer as per the definitions of the Act and the SC judgment b) if the complaint constitutes deficiency of service (decided in the light of preceding judgments) and c) if the first two are proved, then it is decided if the claim demanded by the consumer is justified or not. The decision on the compensation takes into account the intensity of injury (physical and

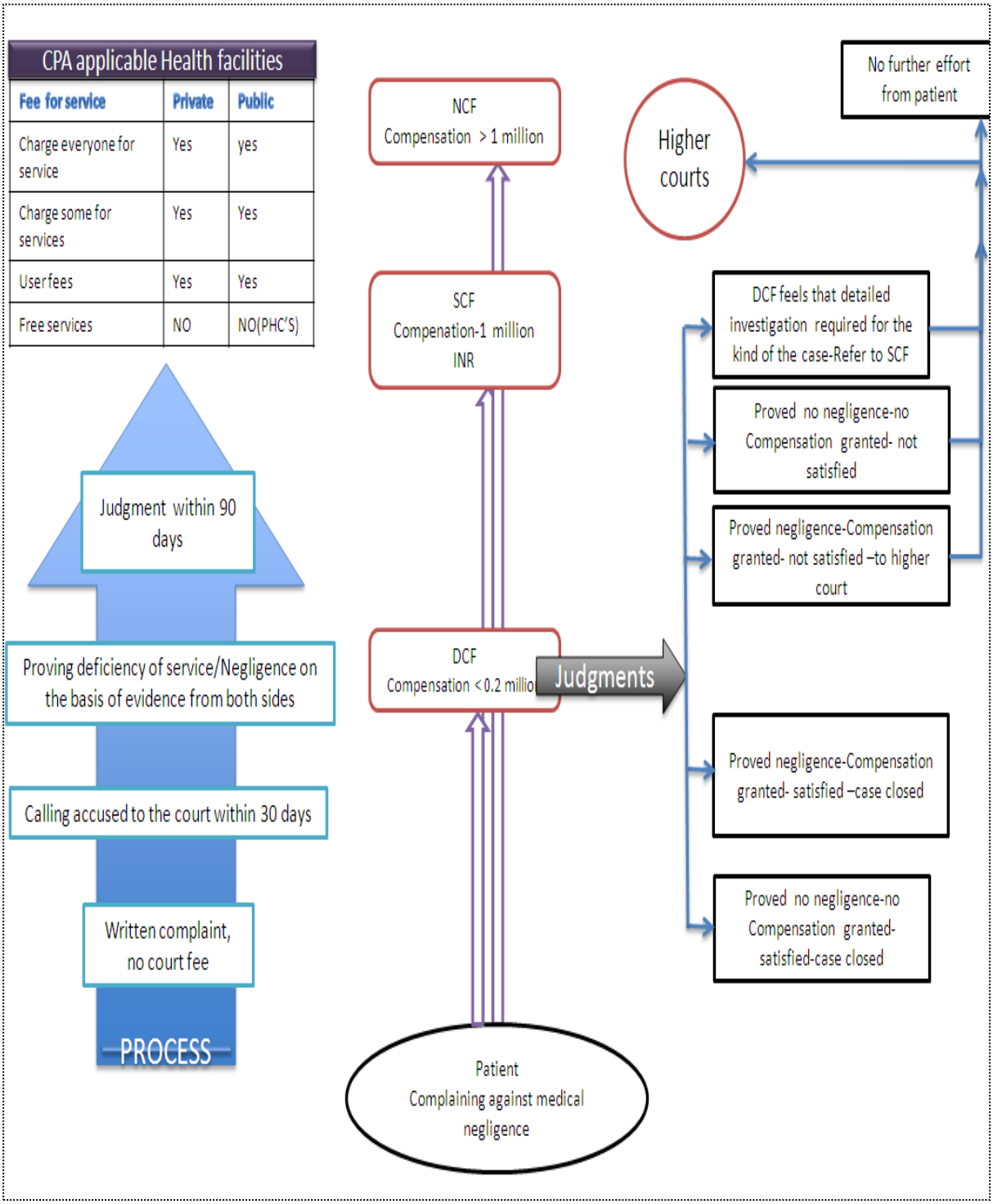
mental) suffered by the consumer due to negligence. If the consumer is not satisfied with the judgment of the district consumer forum, he/she has a right to appeal to the State commission or even to the state High Court. Similar procedures are followed in the state consumer forums. The consumer files a written complaint stating the nature and circumstances of the grievance. On receipt of this complaint, the forum sends a notice to the opposite party mentioned in the complaint asking for an explanation within thirty days. The case is then heard and supposed to be disposed within three months. If the case is complicated requiring a number of tests and evidence, it is then referred to a civil court.

The National Commission has the administrative control over the state commissions on calling for returns of the institution, disposal and pendency of cases, issuing instructions for uniform procedure of hearing cases and to ensure that the objects and interests of the Act are best served without interfering in the quasi-judicial freedom of the forums. The Act does not foresee any reflexive and evaluation mechanisms. It restricts itself to a particular episode of complaint (following a complaint of alleged medical negligence) and decides the merits of the case. The following illustration describes the grievance redressal process in CPA.

5.3.1.6 Regulation Approaches

The CPA has a consumer oriented approach which means that the Act provides ways of enhancing the consumers' ability to articulate their views and lays down mechanisms where consumers can express their complaints and seek redressal of disputes.

Figure 20. CPA: Procedure to file a complaint



5.3.1.7 Actors

The regulation process of the CPA Act brings home the roles played by key actors like the consumer associations, professional medical associations, representative of private medical hospitals, courts, consumer forum administrators and the central Government.

At the formulation level, the role of the Central Government, consumer associations and professional medical bodies was critical, albeit with different interests each of these actors had. The central Government passed this Act in the parliament as a response to the UN Resolution. The Act represented a state-led responsive mechanism to allow its citizens to have a constructive voice. This was also necessitated because of increasing consumerism, commoditization of services including health care. However, despite the consumer friendly approach of the Act, the medical fraternity (mostly professional bodies) had resisted it for long to keep medical profession at bay from CPA (till the 1995 judgment). Even after seventeen years of this judgement, the medical professional bodies are not convinced about the utility and necessity of such an act.

> *Bringing this Act was more of a political agenda pushed by some of the leftist parties. Medical practice is being regulated and can be effectively regulated only by professional code of ethics. The Act introduces American consumerism into Indian context. The only thing that the medical councils did not offer was the financial compensation to the patients. CPA is being misused than used because of the monetary compensation* (GR_PROFESSIONAL BODY_O1_04).

Their resistance is expressed in attempts at controlling grievance procedures through instituting trade union like associations that offer legal aid and protection to medical practitioners or handling complaints by the council itself where they are in a better position to suppress the merit of medical negligence cases. The consumer associations have sought to serve the interests of consumers by filing civil petitions and ensuring protections of patients by extending the coverage of CPA to medical profession. At the level of administration, the consumer forum officials including the

judge at all levels of consumer forums, possess the power to interpret cases of medical negligence where they draw on judgments selectively over others. They play a key role in achieving (or defeating) the objectives of the Act. The medical practitioners who are the implementers of the Act, specifically in the private sector feel this Act is a 'sword dangling over our head'. They fear damage to their own reputation and that of the hospitals in case of alleged medical negligence; hence they often prevent cases going to the consumer forum. Since there is information asymmetry between patients and doctors, the role of the latter (preventing cases to go to the consumer forums) is critical for meeting or defeating the regulations objectives. Figure 20 maps the role of these and additional actors in terms of their power of influencing the regulation Vis a Vis the positive/negative interests on the regulation.

HESVIC lens of CPA

We chose CPA to explore how the intentions of the regulation have worked out in practice asking the following sets of questions:

1) Has the CPA been able to empower patients with a voice to demand quality health care by suitably expressing their grievance when faced with poor service delivery?
2) Has such empowerment resulted in better accountability of health care providers?
3) Is the CPA design compatible with empowering patients and developing accountability?

Though this regulation is not specific to maternal health, an examination of health care provision in general would throw light on maternal health as well. During the course of field work, we also realised that empirical studies on CPA and medical negligence are rare. HESVIC study seeks to fill in this knowledge gap.

5.3.2 The regulation in practice: Effects of the regulation

5.3.2.1 CPA rarely used in practice for expressing grievances relating to medical negligence

Data on number of cases filed under CPA in different consumer forums in the state of Karnataka shows that CPA is not often used as a mechanism to express grievance. During 2001-2011, only 486 and 438 cases have been filed in the consumer forums in Tumkur and Raichur districts respectively (with a population of 2.7. million in Tumkur and 1.9 million in Raichur) and 88 in the state consumer forums in Karnataka (with a population of 61 million). The district consumer forum records further show that of the 486 cases, 44 cases are categorised as 'medical' of which only 8 cases address issues relating to medical negligence. Other cases of grievances in this medical category relate to insurance claims. Such rising number of insurance claims also reflects how health care delivery is increasingly driven by market mechanisms, in which a large number of private health care providers and private insurance companies play a very important role. Misra (2000) in a detailed study of grievance redressal mechanisms in three cities in India shows that profile of the consumers who had approached the consumer forums on health issues tended to be from well educated, wealthier families and forward castes.

As is seen in table below, medical negligence forms a miniscule of 1-3% of cases filed in different consumer forums in the country.

Table 10:Cases filed in different consumer forums (2001-2011)

	National Consumer Forum (country)	State Consumer Forums (country)	District Consumer Forum (country)	Total Cases	Karnataka state consumer forum	Tumkur district consumer forum	Raichur district consumer forum
Total Cases	1609	25101	106340	133050	88	486 (2.7 million population)	438 (1.9 milion population)
Medical Negligence	154	877	1391	2422	1	8	7
Percent Medical Negligence cases	10%	3%	1%	2%	1%	2%	2%

Source: Authors' compilation from data available at http://confonet.nic.in/ accessed on January 18 2012

This finding from the field reinforces existing studies on CPA that argue that medical negligence forms a very small proportion of consumer cases filed in different forums (Bhatt 1996; Muraleedharan and Prasad 2003; Misra 2003; Peters and Muraleedharan 2008; VOICE 2000).

5.3.2.2 CPA cases mostly from private sector

The limited cases of medical negligence grievances that are filed under CPA are mostly from the private sector. In practice, the public sector gets excluded for several reasons. Private sector practitioners interviewed (Specialists N= 10) do perceive CPA a 'potential threat' to their reputation and hence do take cautionary measures e.g. getting additional informed consent from husband for giving abortion services (where the additional consent is not mandatory in the law), ensuring sharing of information on side effects in surgical cases, eliciting trust of patients, for example by increasing the proportion of 'booked' cases and/or settling for out of court settlements in cases where things go wrong[19].

Members of the professional medical body did share the view that CPA has to some extent sensitized practitioners in the private sector to the need for documentation of information and following treatment protocol but this is more in urban areas than semi-urban and rural areas. Such positive change in the attitude and practices relating to increasing documentation of information is also cited in Muraleedharan and Prasad 2003.

However, the medical fraternity largely perceives the Act as a potential harassment of doctors. This was shared by all the practitioners interviewed in the private sector. Hence the need to defend and protect the interests of the medical fraternity is more acutely felt though this is more explicitly expressed in Raichur than Tumkur.

[19] Booked cases are referred to the patients who visit the same physician regularly. This colloquial term is used in the context of private providers' attempts to retain their clientele base (the term is used by the private providers).

Contrasted with Tumkur district, where professional medical bodies like the Indian Medical Association remain indifferent, such bodies in Raichur played an active role in two ways. The first a) the professional medical body seeks to ensure adequate protection of doctors from unnecessary harassment on medico-legal cases through instituting a professional legal aid cell and what they call 'a crisis management group'. Such crisis management group which has no responsibility in medical ethics and in self-regulation is a trade union kind of initiative. It is expected to operate in a reactive manner to protect and guide the doctors alleged to have been framed in a medical negligence case. This looks like a defensive measure as the fear of improper use of the CPA act by users is very strong among the doctors. This development should also be read in the context of specific stories of alleged medical negligence cases that are talked about in Raichur and have become part of the everyday discourse. The second, the Association seeks to take on the regulatory function of addressing grievances and resolving it at the community level. This is more of a token gesture to establish the legitimacy of the association and eliciting trust of patients as most of the members of the association are private practitioners.

5.3.2.3 Practice of defensive medicine

Private practitioners also categorically stated that CPA has encouraged and necessitated practices of defensive medicine. Defensive medicine implies here getting a number of clinical investigations to rule out any potential risk, taking informed consent even when it is not mandatory by law (husband's consent in MTP for instance) and evading risk to treat a patient at a high risk. The following quotes from respondents clarify the practice.

> *CPA is clearly a money making business for corporate hospitals as they will go on asking for clinical investigations* (GR_IMPLEMENTER_08_02)

What happens is that, after this CPA Act, the burden again goes to the patient. To protect ourselves we have to make the patients undergo all unnecessary investigations because we have to rule out everything. There is no other option. The Court may ask why a particular investigation has not been done so we have to rule out all possible problems and causes for the particular symptom or disease. That is an unnecessary burden". (GR_IMPLEMENTER_05_01)

The practice of defensive medicine in CPA is cited by Muraleedharan and Prasad (2003) in their study of the implementation of CPA in the state of Tamil Nadu. It shows an increase in defensive medicine. One indicator of this practice, as the authors argue, is the medical malpractice insurance scheme –Professional Protection linked Social Security Scheme initiated by the Indian Medical Association in 2001. This scheme was initiated to provide legal and financial assistance to doctors and hospitals. Their study showed that 64% of physicians in the state had purchased this insurance. 80% of the physicians in the study admitted that there was a moderate to substantial increase in defensive medicine resulting in increased use of diagnostics and other practices.

CPA also has led the practitioners to avert risk of treating patients with complications.

Private practitioners have stopped taking risks. We just explain the situation, and tell them to take the patient elsewhere, if they want to (GR_IMPLEMENTER_10_02)

*She had bled so much in his clinic, she was papery white. Then they brought the patient. My cousin stays upstairs here. I told that she (the patient) must be made to sleep outside and should not be taken inside. BP was not recordable and so I refused and said I cannot do anything and she must be taken to the district hospital. They requested me to try to do something. I said sorry and told them that it was not in my hands. They reached the district hospital, she died. Nowadays I refuse flatly (*GR_IMPLEMENTER_09_02)

Such averting risks distinctly lead to limiting access to health care.

5.3.2.4 CPA: A profit game (Negotiating compensation and out of court settlement)

Since the mechanisms of the regulation are through seeking redressal for financial compensation, CPA in the field boils down to demanding and negotiating for money. Experiences of users, practitioners clearly show the mediating role of lawyers. The lawyers selectively fight cases on behalf of users where compensation amount is guaranteed so that they claim the majority share of the money. There is no fixed percentage of such share but is negotiated in each case depending on the amount of compensation. In fact accounts of practitioners and state medical association on specific episodes of medical negligence show that in many grievance redressal cases, it is not the patient's voice but the lawyer's voice that is protected. Patients are instigated by lawyers to file cases against doctors.

> *If the doctor is booked in the Consumer Protection Act, there is no fee. Only a signature on a blank paper is taken. There are so many advocates without work now. That advocate will tell the patient that, the doctor has got some money, and take the patient's signature without charging any fee. He will also tell the patient that he will fight the case and get him the money. The advocate will fight the case and suppose a compensation of four lakhs is awarded, the relative of the patient will get only one lakh. Seventy five percent of the amount will go to the advocate (*GR_IMPLEMENTER_11_02*).*

Doctors too prefer out of court settlement. Patients shared their experiences of being offered money as part of out of court settlement on behalf of the doctors.

5.3.2.5 Muted Grievance

How are health related grievances expressed then, if not in the consumer forum? Despite the consumer oriented approach of CPA, in most of the cases, grievances are not expressed at all. Findings from our study show that several factors like perceived powerlessness of individual voices, unfeasibility due to lack of resources (time and money), inequitable power relations between patients and doctors, limited scope of the Act itself explain why grievances don't get redressed. These factors would be explained in the next section. Our experiences with locating users for

grievance redressal perhaps indicate the culture of grievance redressal in the rural areas of the southern and northern district. The research team spent considerable time locating users who had taken steps to express their grievance. However, this is not due to low expectations from health system but they lacked a clear knowledge on mechanisms of redressal and articulation of their own rights to express grievance.

5.3.2.6 Grievance redressal through ad-hoc and informal mechanisms

In select cases, when expressed, this is done through informal mechanisms. These informal mechanisms show the extent to which the CPA act is relevant. The informal mechanisms are: approaching a local leader/local government representative/union/association; sharing it with higher authorities in health centres; mobilizing all the villagers who go collectively and express their grievance and putting up strike to put pressure to express grievance. The HESVIC nested study on an analysis of media coverage on grievance redressal mechanisms in Karnataka shows that 48% (N = 94) of the grievance cases were through informal mechanisms.

5.3.3. Explaining the effects: An integrated analysis of actors, context and process

Several factors explain why the Act has had minimal impact in empowering the consumers with a voice to express grievance and ensuring quality care. These factors range from the larger cultural, political and medical context to the lack of internal consistency of the regulations and the scope for multiple interpretations of the Act by different actors.

5.3.3.1 Gaps at the level of design and interpretation of the regulation

Excludes everyday forms of deficiency of services

While the objectives of CPA are to enable the consumers to express grievance against *unfair trade* and *deficiency in services* in health care, the mechanisms of the regulation (the quasi-judicial bodies set up handling different amount of claims to compensation) are structured to allow grievance cases that involve claims to financial compensation. The fact that it is not tailored for health itself is a problem. The amount

of compensation, as implementers interviewed explained, is in practice linked to the amount of money paid (for care in private facilities) or the severity of grievance suffered which can be weighed in terms of money. Deficiency of services under CPA for health sector then translates as medical negligence where such negligence has resulted in severe consequences i.e. death, permanent disability or acute mental agony including financial cost. The focus on claim to financial compensation as a criterion for expressing grievance in effect excludes more routine and everyday forms of negligence that could lead health services to improve their organization and training. While there are other mechanisms outside CPA that seek to address such routine forms of deficiency of services, studies show the limited effectiveness of such mechanisms (Misra 2000, 2003). Misra's study in three cities in India shows that a complaint box/book was physically found in only 33% of the private hospitals and 22% of public hospitals. Only 17% of the private hospitals and 15% of public sector hospitals had guidelines for receiving and processing complaints.

Patients and relatives interviewed in our study shared their grievances in terms of long waiting time in hospitals, informal money charged, refusal to admit patients, non-availability of health staff specifically specialists, non-availability of medicines and blood transfusion facilities, improper or delayed communications resulting in emergency complications, lack of basic facilities like drinking water, toilet facilities and rude behaviour of the staff. These problems could not be properly addressed by a more appropriate regulation because of the required administration to handle the huge amount of such cases and because lack of access is not an issue within CPA. Furthermore, CPA addresses quality of care through redressing adverse medical outcomes while for many patients and others, quality of care relates to the process of seeking care as well. Through focusing on cases of severe cases of medical negligence, CPA assumes that service has been received though deficient. However most of the grievances as mentioned above relate to accessing care/service in the first place. The limited scope of the Act however is justified by the regulation designers.

Basically the CPA's aim was to protect the person who pays, he should get good, quality service, right product in terms of quality and quantity. This is a small act with 30 sections in it. It cannot envisage the whole ambit of grievances (GR_PLANNER_01_04).

Excludes primary health facilities

Since the Act protects the rights of consumers in hospitals/clinics which charge user fees, patients accessing primary health centres (which is the first point of seeking health services by majority of poor in rural areas) get excluded from the purview of the Act. Such exclusion itself contributes to muting of grievances. Patients accessing primary health centers are not considered 'consumers' since the services in these institutions are provided free. However, the interviews findings from our study show that in a majority of the cases, particularly those that involve surgical operations, the patients did pay for the services availed though this payment is *informal* and there is no receipt for such payment.

Exclude public sector facilities: Selective interpretation by administrators and implementers

The interpretation of the Act's definition of consumers and services through the 1995 Judgment clearly includes public sector hospitals that charge user fees (sub-district hospitals, district Hospitals and teaching colleges/hospitals). However, interview findings from our study show that district level administrators (Judiciary), lawyers defending specific cases of medical negligence often interpret the act in ways that excludes Government health facilities. In such cases, some other legal precedents are referred to in order to argue that services in the Government health facilities are availed of free of charge and hence patients accessing Government health facilities are not consumers. The legal precedent in one of the states that argued in favour of the inclusion of Government health facilities on grounds that doctors in these hospitals are paid from public money and hence patients pay indirectly (Sukanti Behera vs Dr. Sashibhusan Rath 1993, Part II CPA 633/634) is read as an exceptional judgement and is excluded from consideration.

While clarifying such confusion about inclusion/exclusion of Government health facilities under CPA, health providers and administrators interviewed both in the public and private sectors in Tumkur (N = 13) shared the view that exclusion is a norm in practice. They expanded saying that though public health facilities clearly do come under the purview of the Act in definitional terms, practically they are excluded because most of these facilities operate in resource-scarce conditions and hence alleging medical negligence in the absence of adequate resources is a misnomer. In such cases, deficiency of resources becomes a ground for justifying the deficiency of services for the implementers. This is a selective interpretation of the Act as repeated judgments in several forums while deliberating on deficiency of services and breach of duties of providers, do take into account limitation of medical technology and limitations of resources (Bhatt 1996).

Defining Medical negligence under CPA: Lack of clarity

Since the Act has broad definitions of negligence and deficiency of services, medical negligence needs to be proved in each case. Each case then is subject to interpretation by actors involved in the implementation of the act i.e. lawyers, judges, other members of the consumer forums, medical professionals and consumer association if involved. Thus each case of alleged medical negligence follows proving a) if the complainant is a consumer b) if the complaint qualifies for medical negligence and c) if the compensation claimed is justified and sound. The onus of proving the case of medical negligence largely lies on the patient/complainant which could be very difficult for a layperson to do.

> *Proving medical negligence in private sector is difficult due to complexity of medical science and in government sector it is nearly impossible as there is lack of human resources, infrastructure and consumables (GR_IMPLEMENTER_04_01).*

Bhatt's (1996) study of cases filed in District Consumer Forum in the state of Gujarat shows that 71% of cases have gone in favour of the doctors. This finding is reinforced by more recent studies (Misra 2003, Muraleedharan and Prasad 2003). Though proof of medical negligence supposedly follows the *Bolam Test* (McNair J in

Bolam v Friern Hospital Management Committee (1957)1 WLR 582), the assessment of the duties of a doctor and the skills exercised by him/her at a particular time for the particular case is subject to varied interpretations in several judgments. The obscurity and fuzziness of the Act in terms of definitions of deficiency of services in medical care often works against the interests of patient-consumers who need to have the medical know how to prove medical negligence. It lowers the access of patients to the process of grievance redressal.

The following table on an overview of the eight cases of medical negligence in the District Consumer Forum shows that four cases were dismissed due to lack of evidence on medical negligence. Three of these cases were on maternal health (maternal death in transit due to post-partum haemorrhage, post caesarean and post-tubectomy complications). While some judgments (that have dismissed cases of medical negligence) refer to legal precedents that talk about the need for expert medical evidence, other judgments offer a contrary view saying such inevitability of medical expert evidence goes against the spirit of the Act.

Table 11: Overview of medical negligence cases in Tumkur district forum

	Medical negligence cases in Tumkur district Consumer forum							
Case No	cc/10/59	cc/189/2010	cc/10/52	CC.No.91/2009	CC.No.88/2009	CC.No.44/2009	CC.No.168/2008	CC.No.227/2007
Date Of Judgement	6/9/2011	4/28/2011	2/22/2011	1/28/2010	1/6/2010	10/6/2009	5/5/2009	1/29/2008
Govt/private	Private	Private	Private	Private	**Govt**	**Govt**	Private	Private
Place of treatment: Rural/Urban	Urban	Urban	Urban	Urban	Rural	Rural	Urban	Urban
Compensation given	Yes	Yes	No	Yes	No	No	Yes	Yes
Nature of Greivance	Disability (deafness)	Fail to diagnose the grave heart disease	Post LSCS complication leading to repeated surgeries and cost	Post LSCS death	Death (PPH died on transit)	Post tubectomy complication Death	Post injection gas gangrene	PPH death

Data source :(District consumer forum Tumkur)

5.3.3.2 Perceived power inequity between patients and doctors: Asymmetry of information

Apart from the limited scope of the Act, one also needs to locate the effects of CPA in the cultural context of the relationships between patients and doctors. Respondents shared the view that the relationship between patients and doctors is not like a merchant and buyer and a patient can never be strictly like a consumer as understood in other fields, as a straightforward buyer of goods and services. Doctors are looked upon as healers who have the power to set the wrong right. Administrators fall back on such cultural feature to justify the limited medical negligence cases in consumer forums.

> *Doctors in India are considered as Vaidya Narayana' (God) and people would hesitate to complain as this might also mean jeopardizing your own and that of your family's health at stake (GR_AMINISTRATOR_02_01)*

> *Cases of medical negligence are very few. This is because health seeking behaviour between patients and doctors is based on trust. In every possibility, the patient would visit the same doctor next time when he/she falls ill. So he/she would not like to formally file a complaint and risk the danger of losing trust with the doctor which might prove costly for him and his family members (GR_ADMINISTRATOR_01_01)*

Administrators and implementers reinforce this cultural feature, thus actively contributing to the process of muting the grievances. The inequity in power is expressed in two ways i.e. patients expressing the level of dependence on the doctors for their health needs (more so where patients cannot afford to exercise many choices in accessing health care) and their lack of technical expertise. Patients see themselves as dependent on the doctors for their own and their family members' health.

We have to come back here again for further treatment, if we complain they will not treat us properly when we come back in future. So I am scared to complain against anybody here (GR_NSTD_PT1_01)

There is no use of complaining, nobody listens to people like us. The voice of small animal down the hill will not reach up to the top of the hill (GR_NSTD_PT3_01).

These remarks should be read in the context that many of these patients interviewed hailed from rural areas and travelled far to reach the district hospital. Apart from the level of dependence, the expert knowledge of the doctors, their belonging to a health system (with similar fraternity) adds to the power. As one of the respondents says, 'What is the point of complaining against anyone here? They are all part of the system and they will protect each other'. These remarks indicate the futility of token gestures of professional bodies in Raichur that attempt to redress community level grievances while simultaneously instituting mechanisms to protect the doctors.

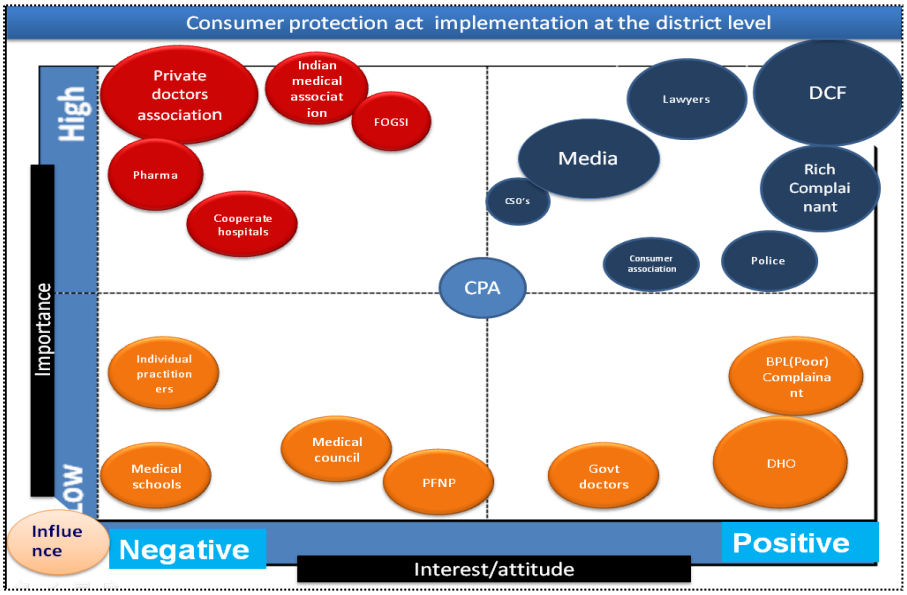
Further, expressing grievance is termed as complaining against the doctor, which is a derogatory expression.[20]In fact, practitioners look upon those who express their grievance as 'troublemakers' 'quarrelsome' or those 'who wish to show off their political connections'. Again, this shows that not everybody can use the regulation in practice. Complaints are referred to colloquially as '*galata*' in local language which means quarrel. Such framing of the language of expression of grievance in terms of complaints potentially suppresses the voices of the patients. It distorts the intentions of the Act of empowering the patients with the right to seek redressal. In fact it is such framing of the term grievance in terms of complaints has led to two contrasting views expressed by the community (patients and their relatives) and medical fraternity. While the former mostly expresses helplessness in accessing good quality health care and perceive the lack of power in demanding such quality, the latter sees the users through the CPA lens as potential trouble makers. However as the medical

[20]Our nested study on Media coverage on grievance redressal showed that the initial search using key word like grievance, medical, health did not yield any results. When we used key words like complaints and health, several related articles were displayed. This also shows the cultural specificity of terms used and meanings understood.

professionals themselves discuss, in many cases, such trouble is mediated by others be it lawyers, local politicians or fellow practitioners who benefit from such incidents. The role of such actors in reinforcing distortions of the intentions of the Act is much clearer in Raichur. In Raichur, specific incidents were shared by practitioners where such incidents were alleged to have been instigated by fellow practitioners. Such incidents also get influenced by the gender, caste and residential status (local vs. outsiders) of practitioners involved. Hence lobbying across different lines and loyalties shapes the course and outcome of any incident of negligence if any and in which case the real interests of the consumers get diluted as the different actors involved in such lobbying have varied personal and professional interests.

Apart from the inequitable power relationships between doctors and patients, a few patients also shared the view that it is impractical to voice one's grievance either in consumer forums or through any other means because of lack of resources – time and money. This is considered unfeasible when the prospect of investing time and money in the process of seeking redressal and losing daily wages is weighed against the uncertainty of the outcomes of such redressal. The following figure sums up the role of different actors in the implementation of CPA (following from the aforesaid elaboration of their roles and the effects of CPA).

Figure 21. CPA implementation-actors at the district level



As is seen in the above figure, the size of the bubble shows the extent of influence an actor has on the implementation of the regulation. Y axis shows the degree of importance (power to influence) of the actors in relation to the regulation and x axis shows the degree of positive or negative interest actors have towards the regulation. The poor patients though have high positive interest in this regulation; they lack power to exercise their rights of seeking redressal. On the other hand the rich patients/complaints either independently or in coordination with others (accessing the media, police, and lawyers) could exercise their right to demand quality care by seeking redrssal under CPA. Professional medical bodies like Indian Medical Association have a negative interest (as they never wanted this regulation come in the first place) and have the power (independently or in coordination with each other) to influence the regulation from preventing to achieve its objectives.

5.3.3.3 Not individual but collective voice can seek redressal: Ineffective GR regulations

Another factor that acts as a barrier to voicing grievance is the perceived lack of power in an individual voice, especially a poor individual's voice. Patients and relatives interviewed unanimously shared that it is only a collective voice that can make an impact.

> *What can I do alone? Nothing! Nobody listens to one poor man (GR_NSTD_PT05_01)*

> *Our friend (an auto driver) met with an accident, and he needed surgery of the leg bone. The doctor was demanding Rs.2500/- for admitting. We the auto union people (around 25 of us) gathered and went to the District hospital head. He called up the doctor concerned. Then only the surgery was done (GR_NSTD_PT06_01)*

Many such instances were shared which had the whole village going and putting pressure on the hospital to redress specific grievances. In other cases, grievances were mediated by farmers' associations, an auto union and caste based associations. However in all these cases, the nature of grievances had a collective

dimension. Interviews with community members who had sought redressal corroborated this – they were cases triggered by a single episode of negligence, but one which resonated with the experiences of many in which no redressal action was taken. While these associations and unions act as potential pressure groups to mediate, their actions are ad-hoc and informal.

Collective voice does not merely imply groups or associations but also a powerful voice where the power resides in elected political representative, local government (*panchaya*t) representatives, religious leaders and the media. Some of the incidences discussed during the course of our study had sought interventions of these powerful voices for specific episodes. Access to these powerful voices is considered an important resource to be able to demand health care. This is significant as this indicates the perceived problematic of exercise of individual right. While CPA sought to empower the citizen-consumer through a right to seek redressal, such exercise of rights is perceived to be mediated by collective and powerful forces.

5.3.3.4 Interpreting accountability: Building trust and reciprocity

It has been argued that accountability can't be seen as a set of disembodied rules, standards and enforcement mechanisms. Accountability in practices always is a mixture of formal regulations and informal understanding of such regulations, established behaviour patterns which are based on norms and mutually understood principles (Mackintosh 1999). Further, empirical studies have sought to demonstrate that accountability is a 'fluid social phenomena characterised by dynamic social actors and power relations located in specific political economy context' (George 2009:205). In a similar vein, our study also shows how accountability in health care is interpreted in the larger political economic context. Such interpretation of accountability connotes a process of building of trust and reciprocity between patients and doctors. Several mechanisms are employed to build such trust. Informal payment to the doctors in Government facilities is one such mechanism of building trust and access services. Informal payment to the doctors is a very common phenomenon among the patients and their relatives. The fact that it is normalized is clear from the excerpts below:

You need to pay for getting services, if you pay, they will attend to you nicely (GR_NST_PT_08_01)

They ask money from everybody. The system is like that. "Lanchada mele mancha" (the patient gets all services only when he pays informal payment), If we take care of them, they will take care of us (GR_NST_PT_05_01)

Informal payment is justified by patients as the immediate concern and priorities of the patients are taken care of – attending to the patient at that time for that particular illness. However it goes beyond that to ensure access to services for future consultations for self and family members. Informal payment is also justified by patients in the context of weighing options between paying a much higher amount in private hospital or paying the 'speed money' in a public hospital (locally informal payment is referred to as speed money) to receive care. This practice must be related to the fact the access to affordable and quality health care is critical for many of these patients. Informal payment is considered as part of the 'expected' and the 'normal' token fees to the doctors and perhaps goes a long way in ensuring access to services and hoping to get attentive care. Such trust building mechanisms help to create disciplined patients (who are non quarrelsome, don't complain) in the long run. Such disciplined patients are likely to attribute adverse medical outcomes to one's own fate. It is not merely good patients but such socially embedded, trust building establishment produces images of good 'doctors' who customize care, occasionally redress minor grievance and elicit trust of the patients. Images of such good doctors are discussed by the patients and service users by referring to how these doctors pay attentive care, ensure coordination among the health staff when offering care to the patient (visible better coordination among the hospital staff is looked upon as indicator for good quality care), uses his/her own car as for transporting to a referred centre and cater to the patient's expectations of certain services.

Such trust building process undermines the formal accountability mechanisms instituted through CPA that sought to bring about systemic changes by giving patients the right to demand quality health care. In fact accountability and

responsiveness are interpreted as applying, and are in fact maintained, not through patients' rights but through informal mechanisms of building trust and reciprocity Such mechanisms of building trust need to be understood in both cultural and health system contexts i.e. perceived social position of doctors in society (doctors are healers), the role of trust in the doctor is key to the efficacy of particular treatment, unequal power relations between them, problem of access to health services and heterogeneity in standards of care in different establishments.

5.3.4 Discussion and Recommendations

The following key messages emerge from the analysis of the role of the CPA in addressing grievances.

Governance outcome is exclusion

CPA is a significant regulation that sought to create a space for patients' right to demand quality health care. Such voice potentially could lead to more responsive and accountable health care. However our research shows that CPA in reality is interpreted and implemented in ways that exclude the voices of many patients-consumers for different reasons and through different practices as elaborated above except perhaps a few "clients" in affluent urban circles.

Muted grievance is a norm more than an exception

Far from having a constructive voice to express grievance, data show how such grievances are muted in the majority of the cases again for several reasons discussed in the aforesaid text. Grievances could be expressed when of collective nature and that too through ad-hoc and informal mechanisms. CPA hence has rarely been able to empower the patient-consumers barring a few who are privileged being urban, educated and/or access to the powerful voices.

Disjuncture between normative notions of accountability and field practices

The analysis also shows how there is a disjuncture between normative notion of accountability in CPA and informal practices of accountability that negate such normative notions. While CPA sought to establish accountability through giving

patients the right to seek grievance for poor service delivery, accountability in the field is understood more as a form of building of trust between patients and providers through informal mechanisms which unfortunately contribute to impoverish patients. While trust is important as a component of inter-personal relationships in clinical care, here the process of building trust (through informal payment) itself becomes so central that it potentially justifies poor service delivery rather than ensuring it. This disjuncture takes place in a context of the CPA trying to address systemic changes, while accountability mechanisms in practice focus on specific episodes.

Another form of disjuncture in normative and practical accounts of accountability is also expressed in a constant fear of the regulation being misused and potential distrust of the patients against doctors that leads to counter-productive accountability mechanisms like averting treatment of risky cases and practicing defensive medicine.

Recommendations

Grievance redressal mechanisms towards ensuring quality health care could be better designed and implemented through:

- Addressing information asymmetry between patients and doctors by making all related information in health services both in public and private hospitals accessible to the public

- Clear guidelines regarding provision of different medical establishments to prevent misinterpretation of the exclusionary practices of the Act

- de-”court”-ing grievance redressal i.e. foresee it at the service level with access, smoother procedures and efficient feedback to provoke corrective measures - both at the wrong-doing level and more importantly at the level of the health service

- Consumer education on expected standards of care, deficiency of services and legal protection available to consumers

- More involvement of community based organization/civil society groups/other collective group associations and media at the local level both in information disclosure of medical facilities on quality of care and facilitate greater participation of vulnerable groups in informed decisions making on seeking care.

6. Comparative Analysis between case studies

The previous sections discussed in detail how each of the three regulations studied is situated in the larger context of framing of health policies, health delivery structure, dissemination and interpretation of regulations by different actors and the social and cultural factors that render meanings and feasibility to such regulations in everyday contexts. This section would reflect on some of the key elements of comparisons between and across the three regulations. Such comparative analysis aims at understanding the *why* and *how* of their effects in ensuring quality maternal health care and through that reflecting on the larger role of governance in health care.

6.1 Addressing maternal health problems: Locations of regulations

Though the case study aspects of maternal health (provision of EmOC care, safe abortion services and the right to seek grievance redressal to demand quality care) are comprehensive to reflect on equitable access to quality maternal health care, there is however a paucity of regulations directly corresponding to addressing these aspects. Of the three regulations studied, only the MTP Act (1971, 2002) addresses the provision of safe abortion services in order to control maternal morbidity and mortality (caused due to unsafe abortion services). Unlike MTP, the IPHS under the NRHM are aimed at strengthening health infrastructure and delivery mechanisms by prescribing a set of standards at all levels in rural areas, by securing national health planning mechanisms and providing resources to be organized according to this planning. The IPHS at both the Primary Health Centres and sub-district hospitals aim to deliver all health care services including basic EmOC and comprehensive EmOC in these two facilities respectively. As one can see, IPHS hence are not EmOC (or maternal health) specific regulation. However, IPHS are embedded in the larger program of NRHM, one of the goals of which is to achieve MDGs 4 and 5. It however seeks to achieve this goal through strengthening health delivery mechanisms in

public sector in rural areas only, excluding both private sector and urban areas. Apart from the geographical and health sector (private) exclusion, IPHS do not address the multi-facetted constraints to access maternal health care.

Contrasting with MTP and IPHS, CPA is a general Act for overall protection of consumers' rights from deficiency in services. It covers all sectors of markets and goods (construction, housing, insurance, electronics, food etc.). Its application to the field of health care was explicated only through a judgment of the Supreme Court of India in 1995. This entry point of the regulation is significant as has been explained in the case study section, the working of the regulation is caught between the generality of the Act and the specific case laws that interpret notions of 'medical negligence', 'consumer' and 'service' (preceding judgments on specific cases). In an act like CPA hence, the regulation itself creates ample space for different actors involved in administration and implementation to interpret the provisions of the regulations as per specific circumstances. Apart from the generality and fuzziness of CPA, it is also exclusionary of primary health centres and missionary hospitals. These three regulations then seek to address maternal health issues through different entry points. The comparative overview on aims of these regulations shows that, these do not directly address issues concerning equity and access to maternal health care. The aims of the regulations are skewed either in terms of geographical coverage (rural/urban), health sector coverage (public/ private) or in terms of its objective (access/quality).

6.2 Comparative effects

The study examined effects of the regulation through the lens of its objectives and intentions. In this process, it identified different types of effects i.e. a) those which are desired (as per the objective of the regulation) and achieved or not achieved, b) unintended but positive effects and c) undesired effects. The analysis of effects of regulations indicates two methodological challenges. The first, it is difficult to attribute some effects directly to the regulation concerned. For example, effects like increase in institutional deliveries, c-sections rates, up gradation of First Referral are not directly and only due to IPHS. The up gradation also happened in combination with other programs like NRHM, World Bank supported program on health system reforms in the state. This implies that one needs to locate the effects in a family of regulations

and policies which could together impact health outputs. The second, it is difficult to measure the effects of some regulations like CPA. For example, could more number of cases of redressal necessarily imply empowered consumers or does it indicate health care providers being necessarily accountable? The study hence has documented effects in terms of the process of the regulation.

How have these three regulations then affected equitable access to quality maternal health care? As shown in the case study sections, IPHS through the NRHM set out to achieve MDG 5 by 2012 (100/100,000). While infrastructural improvement in terms of physical buildings has to a larger extent taken place (145 out of 192 FRUs upgraded since the regulation period), it has not matched with other resources. Though not stated as clearly as an objective, IPHS through NRHM has given visibility to maternal health through many material and documentary practices. Reporting of maternal deaths and audits of these deaths also has been regular. This has strengthened the information base of causes of maternal deaths (there used to be sporadic information on causes of deaths earlier). Yet, these token effects in terms of process do not ensure EmOC care to all users and do not bring down maternal deaths. The visibility of maternal health and clinical audits has led to an unintended effect of the regulation in terms of evading risk to treat high risk pregnant women by regulation implementers resulting in unwarranted referral.

Similarly for MTP, a regulation which has been in place for close to four decade has not ensured safe abortion services at least for the poor in rural areas, more so for unmarried women. Information on rate of abortion, proportions of unsafe abortions, methods used and outcomes are sorely missing as many of the abortions are done by untrained (MTP training) providers. Qualified practitioners when they do MTP, underreport cases of MTP for purposes of profit, patient confidentiality and cultural stigma. The maternal health visibility of NRHM did little to give a boost to the implementation of MTP. The regulation which was introduced as an enabling regulation in fact restricted access to services for many women in rural areas at the primary health care level. The CPA, on the other hand, on a positive note, sensitized the practitioners in private sector to the need for documentation, attentive care and informed consent. This was an unintended positive influence of the regulation. However, the meagre cases of negligence filed in the consumer forums are an indication of the lack of access to such formal legal mechanism for patient-

consumers. As the study shows, either grievances were muted or they were expressed through informal mechanisms. The incidence of such informal grievance redressal itself shows the limited effectiveness of the regulation. While not achieving what it set out to, CPA led to the unintended and undesired effect of the practice of defensive medicine (unnecessary diagnostic prescriptions, evading treatment of high risk patients). Thus all the three regulations, when examined from an equity lens, have not been effective to ensure equitable access to quality maternal health care.

6.3 Regulation interpretation and implementation

The way regulation objectives and mechanisms were interpreted by actors involved in the process of its implementation, played a key role in producing regulation effects. All these three regulations are framed at the central level. Its implementation is sought through a bureaucratic structure linking the centre-state-local level. Following Lipsky (1980)'s street level bureaucracy theory, the study examined how actors at different levels of implementation process, interpreted the regulations in certain ways and how their personal and professional world views shaped the process of implementation.

There are several factors that emerged from our study that influence actors' interpretation. MTP is designed as an enabling regulation a 'green signal' (Baldwin and Cave 1990) that promotes safe abortion services by prohibiting certain practices (practices of abortion by non-trained provider, non-licensed facilities). However the regulation is interpreted at the level of primary health providers as a restrictive regulation and hence abortion services are provided clandestinely and underreported. Such interpretation of 'restrictive' can be situated in a number of factors. The study shows that factors like the mode of dissemination of the regulation, professional training of MTP , availability of abortion services in the health facilities and scope for referral, morality surrounding issues around sexuality, marriage and abortions, providers' own religious background (favouring pro-life or pro-choice), monetary profit (informal payment en cashing on the moral character of abortions) and prioritisation of one's own roles and responsibilities (MTP comes on a low priority compared to promoting antenatal care, institutional deliveries) lead to such interpretation. MTP apart from being taught in the curriculum is disseminated to the

primary health care providers through short duration training. Such training is organised ad hoc and irregularly. A number of them hence remain non MTP trained restricting them to provide services legally. The health workers on the other hand who remain the first point of contact for the users are not entitled to be trained either to provide or counsel them. This is ironical as these health workers are responsible for all other aspects of maternal health. When faced with a request from the women, they provide services themselves or refer women to either the private hospital/ sub-district hospital (for the former in return for a commission). The restrictiveness of the regulation is also shaped by the providers' own world view on sexuality and marriage. For all providers (irrespective of gender), pregnancy outside marriage is considered 'illegal'. The non-allopathic providers do not come under the ambit of the regulation. Their interpretation of restrictive hence draws from being left out of the mainstream health care. Thus such interpretation completely altered the intention and objectives of MTP. In such a situation, MTP provision is left to negotiating mechanisms among different actors i.e. patients, health workers, private providers, PHC officers, chemists and nurses.

Similarly for CPA, the administrators and implementers interpret CPA in ways that exclude public health facilities. Such interpretation needs to be understood in the context of the perceived power inequity between patients and doctors. Patients' power to seek grievance in theory is stated as desirable by providers though with the intention to be politically correct. But in reality they do resent such power. Implementers particularly in the private sector clearly see the power of the patients through the right to seek redressal as threatening and potentially destabilising social equilibrium. Such interpretation to protect the status quo by the administrators is also facilitated by the design of the regulation. Definitions of deficiency of services/medical negligence, service and consumer lack clarity leaving scope for individual interpretations.

6.4 Evaluation, monitoring and feedback loops

Most of the regulations in theory have prescribed monitoring mechanisms and feedback loops to be fed into the life cycle of the regulation process. However in practice, these mechanisms operate in ways that cripple the regulations to achieve

its objectives. Two points emerged from our study specifically on the role of monitoring in regulations i.e. monitoring is done ad-hoc (and skewed) and information from such monitoring mechanisms is not used for corrective measures. IPHS through NRHM has elaborate monitoring mechanisms like internal monitoring (regular information on all aspects of the program that are collected from the sub-centres to national levels) and external monitoring (social audits, mid-term evaluations by Government bodies with involvement of public health specialists). At the national level, the Mission Steering Group and the Empowered Program Committee (with the Central Minister of Health as the chair with health bureaucrats, public health professionals) are the apex bodies for monitoring the program. However the ways these bodies do the monitoring of the program are ad-hoc and do not lead to any action of corrective measures.

> *If we look at the common review mission reports, every year, the same criticisms are made, but are they acted upon. You should look at the reports for each state and start with the 1st report and see broadly what was said in the first report. And then what was said in the 2nd report and …. You will find that most of the recommendations are similar across the years. So nothing has changed, because nobody is monitoring and taking corrective action (EmOC_PLANNER_02_04)*

At the district level, clinical audits like the maternal death audits face a similar fate. While all these audits are being conducted on a regular basis, there is no follow up of these audits and no corrective measures are taken. As is well known, the role of these clinical audits is to identify gaps in the delivery of service through systematic and continuous reflections which is to be done in a constructive, transparent manner. Such participatory learning mechanism however is reduced to a punitive process that encourages blaming. As the respondents shared, the focus of this exercise is to evade the blame and obstruct learning by attributing maternal deaths to unpreventable causes. Such lack of corrective measures following monitoring is not specific of NRHM/IPHS only but is a characteristic of the health system in general. The health system monitoring focuses on inputs only. Hence inputs in terms of finance, human resources, technical (training) are closely monitored. Only in few cases output indicators are monitored. For example, in case of IPHS/NRHM, number

of ANC coverage, institutional deliveries, up gradation of FRUs is closely monitored. Thus IPHS has few elements of output regulation. It states that PHCs should see at least 40 outpatients per day; 24x7 PHCs should conduct at least 10 deliveries per month; etc. While the out-patient part of it is rarely monitored, the delivery part is closely monitored. PHCs which do not meet the target of 120 deliveries in a year are de-recognised as 24 x 7 PHC; which means that their 3 staff nurses are transferred out to other PHCs. Other than this, there is no punitive action against the doctor or the staff nurses. This has obvious side effects: if a doctor does not want to take the responsibility of providing 24x7 services, he / she just refers the pregnant women to a higher centre. The subsequent year, his / her PHC reverts back to a 'normal' PHC and so he/she does not have to provide 24x7 services.

Hence the health system monitoring is not equipped to reflect on the health system performance in terms of quality, equity and access.

> *NRHM has been able to closely monitor the number of institutional deliveries, ANC coverage, registered pregnant women, number of trained skilled birth attendants. We have been able to get the number, now is the time to focus on quality (EmOC_ADMINISTRATOR_09_03)*

MTP on the other hand lacks complete oversight and monitoring at the district level. At the central level, evaluations of MTP, PCPNDT and provision of abortion services by civil society organizations, international NGOs have been used as evidence to amend the Act, more with PC-PNDT than MTP. While PC-PNDT act is not exactly an output based regulation; sex ratios at birth are monitored regularly and alarm bells ring if this crosses dangerous levels (< 950 females for 1000 males). Then immediately orders are sent to the districts concerned to strengthen the implementation of the Act. Once again, not much punitive action against the health staff for their lack of performance. To add to this, monitoring of private sector information is a big hurdle as shared by the district and state level administrators.

The collection of information on mostly input indicators, lack of corrective measures of monitoring lead to one sided feedback loop i.e. producing information as expected and demanded from the higher levels in the health system. There is no scope for the users, health providers at different levels of health care to share their experiences

with seeking or delivering care. Such one sided feedback loop is translated by district and below as ‘pressures’ from top.

> *We compare the records of the Health Management Information System and the records that come from the field from area based reporting and see whichever has better coverage number, we send those to the state* (EmOC_IMPLEMENTER_12_01)

Here the whole purpose of an elaborate health management information system towards better transparency and better governance defeats its purpose.

6.5 Role of actors in regulation process

The analysis of the three regulations showed two major observations on the role of actors and the way the actors’ dynamics influences the process and effects of regulations. The first, there are a number of invisible actors with varying interests who influence the regulations and the second due to typical hierarchical and multi layered health bureaucratic structures, multiplicity of regulatory functions are formally concentrated in few actors. For example, the District Health Officer who is the highest administrative authority at district level is responsible for overseeing implementation of all national health programs (roughly more than twenty national programs including health related regulations and all other programs having a bearing on health). Overseeing each national program further requires monitoring of innumerable components of each of these programs (for example the reproductive and child health program has 43 components). Though he is supported by other district level officers, supervisory and monitoring authority lies in the DHO. In other words, regulation control is not possible due to administrative weaknesses. In a situation like this, usually administrators selectively prioritise programs/components depending on their understanding of policy priority, pressures of monitoring of specific programs from above (state level here) and feasibility in day to day contexts. Hence, general health care hardly regulated.

The implication of this, as we observed in the field, is that monitoring of MTP was a least prioritized agenda (administrators were at a loss when asked to share information on the number of Medical officer trained in MTP services in public and private and the number of private facilities licensed to provide MTP services) while other maternal health components (like institutional deliveries, maternal death audits, up-gradation of FRUs and 24*7 PHCs for providing maternal health services) become a prioritized area in the wake of the recent National Rural Health Mission.

Similar is the case for a relatively distanced regulation like CPA which in any case has remote links with the ministry of health. Hence in such a case the power of an administrator does not necessarily translate in a positive influence on the working of the regulations (weak oversight and monitoring of MTP for example). Such de-prioritization does not merely happen for specific programs or regulations but also aspects of a particular regulation. For example, financial monitoring under NRHM is prioritized to the extent that other kinds of information are under played and hence even one program is looked at in fragments.

Apart from this, we also observed that a specific regulation has a host of other actors (beyond the ones enlisted and empowered within the provisions of the regulation to undertake specific functions), who influence the regulations. For example the lay health workers have an important influence in the implementation of both MTP and IPHS (though indirectly in the latter). These health workers including the recently recruited ASHAs and ANMs are the first level of contact for the community both for general health (particularly for minor ailments) and more elaborately for maternal health. Hence their knowledge of different regulations (like health programs) is important for translating it into the community. Because of their proximity to the community, the ANMs and the LHVs are contacted to offer abortion services and/or refer to specialists in public or private sector if the gestation period is longer. From the point of view of the Act, they are unauthorized to provide MTP services. Our interactions with the health workers showed that their knowledge of the MTP act is very sketchy. In fact they knew that they were not allowed to do but they knew little about the legal provision of abortion services and the facilities and providers who could legally provide abortion services. Further, since they are paid to perform illegal abortions, it is not in their interest to drive anybody to legal abortion centres. Such patchy knowledge and vested interest translate MTP Act as a regulation that restricts

abortion services and hence there was a complete lack of transparency in the provision of such services offered by them (all these services were provided clandestinely). Through giving such services which are believed to be culturally immoral and yet demanded by women, the health workers sustained trust of and power over the community.

> *I know health workers do it but as an administrator I can't do much as where is the evidence that they are providing the service? The community will never come forward to say this. In the end both the health workers and the communities she works with will deny its incidence* (MTP_Administrator_04_01)

Similarly for EmOC, the health workers played an important role in guiding the women to seek services in a particular facility. At times, such role has had positive effects (accompany the women to seek timely emergency services at the FRU or even counselling during the ANC period if the woman is detected as a high risk case) and at times negative effects by sending the women to private facilities in return for some commission. Similarly at a local level, the informal health care providers, local government representatives, caste based associations, social activists played a role though in an ad-hoc manner in influencing the regulations.

Similarly the medical professional bodies (FOGSI, IMA, KMC) at the state and district level played an important role in all the three regulations in different ways either by silencing themselves, playing an active role in one of these more than the other or even influencing it in an indirect way. FOGSI for instance has played a major advocacy role in pushing for the recommendations of the MTP Act in 2002. While it emphasizes on popularising medical abortion as a safe method of MTP, it is least interventionist in the incidence of wide misuse of medical abortions. Here the pharmaceutical company has an upper hand in popularising and making medical abortion kit widely available and accessible. FOSGI, IMA at the state level invest their attention more to popularize the PNPNDT Act than so much MTP (on this they get the support of many other actors like a spiritual organization, UN agency, Christian based organisations).

The state medical council which is the regulatory authority of medical profession and practice (through self-regulations like the Indian Code of Medical Ethics and regulations 2002) plays a role by not being pro-active on initiating continuous medical education programs which are in theory a forum for disseminating content of many state led regulations like MTP and PCPNDT.

While many of these actors are common to the three regulations, CPA exclusively had a set of different actors. Unlike MTP and IPHS, CPA though applicable to public and private health sectors comes under a different Ministry, i.e. Ministry of Consumer Affairs, Food and Public Distributions and had a separate administrative structure (the Consumer Forums at District, State and National). This ministry has little to do with the Ministry of Health and Family Welfare which is responsible for all health programs in the country. The problem of inter-ministerial and inter-departmental coordination impinging the working of regulations has been well brought out in the literature (Sheikh et al 2011; Siddiqi et al 2009). The distance from the health department and health bureaucracy is reflected in the administrators' initial uneasiness to dwell on CPA in relation to medical negligence at length. Apart from the consumer forum administrators, the lawyers play a very important role. Both the state level administrators and professional medical bodies and users' experiences corroborate the view that in many cases filing of CPA has been instigated by lawyers who file those cases which potentially can settle for higher compensation. The share of the lawyers in all these cases of compensation is pre-decided. The unintended effect of such interventions of lawyers is that CPA is reduced to being a 'money game' and the spirit of protecting the rights of consumers is submerged under the profit motive of other actors. Users hence get excluded from the very Act that promises them the power to seek redressal and demand care.

6.6 Consolidated recommendations

The analysis across these three regulations has drawn attention to some of the common features of these three regulations. Following this, a set of recommendations could be put forward:

- Formulating regulations that ensure equitable access to quality care

- Instituting regular mechanisms for continuous feedback on regulations to create a transparent and accountable health system

- Periodic evaluations should take into account the need for adaptability of regulation to the growth of the market and social change

- Clearly laid down mechanisms for enforcing regulations not merely by the state but collaboration with other partners including civil society, market, media and private providers

- Promoting integrated and constructive notions of accountability through participative health planning, strategies to improve health management, development of enhancement of reflexivity (a capacity to learn lifelong from one's own experience) amongst health professionals

- Effective coordination among different regulations, regulations and policies.

7. Conclusion with reference to the overarching research questions

HESVIC made its entry to interrogate why despite an elaborate health system in place and a host of health policies, India lags behind in ensuring equitable access to quality health care across regions, ethnicity and class. It hypothesized that the answer to this question perhaps lies in poor governance of the health system. Existing literature does attribute poor health outcomes and wide inequity in access to healthcare to poor regulatory mechanisms of health care in India (Muraleedharan and Peters 1985; Sheikh 2011; Mudur 2004). Nishtar (2010) talks about the 'mixed health system syndrome' as insufficient funding, poor regulations of the private health sector and lack of transparency in governance of public sector plaguing health systems in many low and middle income countries including India. Though the role of poor regulations has often been cited as important explanatory factor for poor health

system performance, empirical studies on these subjects are very few in India. Despite governance being a buzz word in developmental literature, empirical evidence and contextual influences on understanding such concepts are sorely neglected. HESVIC filled this gap. It began with an overarching question on how do regulations and through these of governance effect equitable access to quality health care. In order to be able to answer this question effectively, HESVIC thus made an entry point of examining the effects of regulations and governance on equitable access to quality maternal health care. This research question as is already discussed in the beginning section of the report proceeded through five main research questions. These aimed at answering the content of regulations (its objectives, contextual relevance, internal consistency), actors involved and their dynamics to examine how do they effect the working of the regulations to produce certain kinds of effects, what are these effects, what does a focus on maternal health tell us about governance in general health care and how could regulations be improved to enhance access to quality maternal health care.

Answer to these research questions required a conceptual framework that takes into account an actor centred framework of policy. Such a framework implied situating regulations in an integrated site where actors, context, process intertwine one another to produce effects. Hence explicating each of these factors (actors, context, and process) was important to unravel the context specific aspects of regulations. The sensitivity to the role of larger environment/context (including policy, social, economic and cultural contexts) in this research framework drew attention to the fact no regulation exists in isolation. Similarly the actor driven approach to governance showed how regulations are understood by different actors (visible and invisible) at different levels of the health system and society who interpret, negotiate and/or resist specific elements of regulations for several reasons. An integrated analysis of the role of actors, contexts and processes of regulations thus enabled us to understand why and how a specific regulation results in certain kinds of effects i.e. both desired as envisaged in the regulations and sometimes undesired/ unintended effects.

7.1 Paucity of regulations

As our analysis in the previous section showed, there is a relative paucity of maternal health related regulations covering both public and private sectors. While committing the political will to achieve MDG 5, the state frames policies and regulations that are ill equipped to achieve such commitment. For instance, achieving MDG5 through focusing on strengthening rural public health sector is unfeasible. MTP is the only regulation that addresses maternal health concerns focusing on unsafe abortion services. However the paucity of regulatory framework is not specific of maternal health but is true of general health too. The existing health regulations in India address some specific components only. Regulations were limited to either specific components of health (drug, infrastructure, medical practice), specific sector (public or private) or specific and skewed objective (seeking to regulate quality without access or vice versa). These regulations often worked in isolation from one another. For example, all the three regulations studied, existed independently without being integrated as a governance principle into maternal health or health care in general. The existing regulations are not merely inadequate but ineffective and inefficient. These regulations do not address issues of access, equity and quality in an integrated manner. Jeffery and Santosh (2009:13) in their analysis of drug regulations in India wonder if in India 'whether regulatory bodies are able to build public health concerns- especially those that affect the poor- into their deliberations'. The health system hence operates mainly with central planning. Given the social nature of Indian states political apparatus, this central planning process is heavily influenced by the interests of those (doctors, middle classes, government parties, etc) who have a political influence. Hence what one witnesses in IPHS (NRHM) is an attempt to establish credibility of the state by populist means i.e. investing in material resources like cash and material benefits to the poor. Though the regulations like IPHS, MTP, and KPMEA address provision of *quality* of care, these confer to a notion of quality that relies on instituting infrastructural resources than a patient-centered care. There was an overall resistance from the administrators in monitoring quality of care.

There are two things in terms of regulation: quality of process and quality of service. The latter like for example if you have a nursing home you must have these minimum standards, this is part of service. This can be regulated. But when you say that once the OBG is there and doing a c-section and how she is doing it, if he/she follows any treatment protocol that becomes quality of process which is difficult to regulate. This is also a question of ethics and can't be regulated (EmOC_Planner/Administrator_04_03).

Such views render monitoring like the Health Management of Information Systems, Maternal death audits, community monitoring, financial audits etc within NRHM for instance, mere cosmetic exercises. On a general note of health care provision and their regulations, administrators often spoke about a disjunction between monitoring and controlling authority. Thus while the district administrator is responsible for monitoring the performance and outcomes, he/she claims that they do not have any authority to act on in the wake of either failure to deliver the service or even when one compromises on the quality of services. Hence many occasions and incidences (informal payment charged from patients, manufacturing causes of deaths) were shared by the administrators to make the point that formally they are tight lipped about such incidences as they do not have the controlling authority (to take actions). Such understanding promotes a culture of protectionism among health professionals that compromises service delivery, a finding reinforced in another ethnographic study of managerial supervision in north Karnataka (George 2009). Hence regulations like policies do have a political function of establishing social peace, albeit through protecting the interests of the powerful actors in society. Sheikh et al (2011:5) shows in their study of regulations in two states how the inadequacies of regulation implementation rested on the pervasive influence of medical political interests (regulatory agencies either are largely constituted of medical professionals or reliant on their cooperation).

7.2 Culture, polity and governance

Regulations do not operate in a vacuum but in the larger social, economic and political and cultural context. Ineffective and inefficient monitoring mechanisms in the regulations for example can be understood in the health system context of a delivery

structure which is vertical, multi-layered and hierarchical in India. It is also related to the target culture of evaluations of health system performance. The target culture would imply coverage and meeting targets. Such target setting is used as a measure of individual health administrator/worker/provider's performance. The target then translates in putting pressures down the hierarchy. Thus at each level, health officials feel vulnerable to produce records on adequate 'coverage' to defend health system performance. Few ethnographic studies have shown how such monitoring mechanisms have been distorted on the ground levels often being reduced to 'non-transparent policing tools' (George 2009). Both the interpretations of the purposes of such monitoring mechanisms and the practices around reporting and feedback at local levels over-emphasize mathematical coherence and internal validity of reporting forms and the numbers themselves gain primacy over the events and process (Coutihno, Bist and Raje 2000; George 2009; Mishra 2011).

Apart from organizational and target culture of the public health system, notions around regulations, their purpose in the larger society is also important to locate distorted notions of accountability and governance. Very rarely literature on regulations has looked at the role of values in regulations and their contexts (Jing and Grahm 2007). Jing and Grahm's (2007) is a rare piece of work that looks at the role of culture in regulations. Through an analytical framework, they demonstrate why and how the culture of a society makes it prone to specific ways of approaching regulations and practice corruption. Our analysis shows how regulations to a large extent in India are looked upon as 'controlling' others which is seen in a negative light. This is reflected in different actors' narration of different regulations and what would work and what would not. For example CPA is looked upon by the medical professional body as the control of the medical fraternity by the state (through giving powers to the consumers). It is in this light that their response to the Act was more defensive saying this could be achieved better by self-regulations than a framework of CPA. Similarly KPMEA was looked upon by the private sector as the state control of the private sector which was resented by private sector officials and the Indian Medical Association.

> *It depends a lot on how the private sector has understood and interpreted it. If they think all this while we have been practicing the way we like why is the Govt coming in to curb our freedom, then it is wrong. It is not about curbing freedom per se but the purpose of setting up a transparent and responsive health care system in the country. In this situation, even the Government officials also have a role to play to make sure that they don't act as dictators trying to regulate someone. There has been a lot of resistance from the private sector but there is no other solution. It is a not a choice. We have to have an act like this (*EmOC_PLANNER_04_03)

Such potentially negative connotation of regulations gives rise to practices of manoeuvring with regulation purpose and practices, informal understanding and interpretations of regulations and lead to a culture of protectionism. Thus when it comes to community grievance redressal episodes, respondents say 'we need to protect the system. The junior health officials are like my children' (the hierarchical relationships within the health system get submerged in contexts of proving vertical accountability- health system to the community). Maternal death audits hence ultimately lead to what one of the administrators says 'it is to protect the status quo'. It is in this larger context also one can comprehend the rare incidence of cases of medical negligence in consumer forums through CPA. Participation of the community/citizens through grievance redressal processes is seen in a negative light. In fact this is rarely seen as participation. Grievance redressal is translated as 'complaints' which evokes a derogatory connotation. Such cultural connotations need to be understood in the context of existing power relations across and between different categories of actors in a society. These findings reinforce and extend some of the existing ethnographic studies that show how working of regulatory mechanisms like managerial supervision and disciplinary action, far from being implemented in a straightforward manner, is negotiated in a variety of ways depending on informal relationships that might sustain the health system. George discusses how 'informational relationships based on political leverage and corruption can deform regulatory mechanisms in ways that obstruct service delivery' (George 2009: 221). In such contexts, supervision is understood as a control mechanism while it can be a continuous medical education technique based on clinical observations and corrections.

The culture does not restrict itself to the health system alone but to the larger polity, market and social change. Regulations need to respond and adapt to societal changes. Our study shows that there is disconnect between the regulations and changes in society. For example on the one hand, the use of medical abortion pills is in tandem with an increasing consumerism culture in India. Hence pills are commodities to be consumed which are made freely available by the pharmaceutical industry. Here the market mechanisms have moved faster than the regulations.

The study demonstrated why despite a host of policies and elaborate health system in India, ensuring equitable access to quality care remains a challenge. The answer lies in a poor governance of the health system. There is no short cut to ensure good governance. As the study shows, the factors that impede and/or facilitate are multi-pronged and complex and hence it would take a number of bold measures and mechanisms to put in place to create a culture of good governance. Political commitment of the state is not enough in this regard. It needs to be supplemented by commitment from different actors including civil society, private health sector and the media. A collaborative approach to governance could go a long way to have a positive influence on good governance and performance of the health system in ensuring universal health coverage in India.

8. References

Anderson, S. “Public, private, neither, both?: Publicness theory and the analysis of healthcare organizations”. *Social Science and Medicine*, 74 (2012):313-322.

Aiyer, Aditi. “Crisis of Credibility, The tale of Medical Councils”. *Health for the Millions,* 22, 4 (1996).

Bajpai, N. Sachs, Jeffery and Dholakia, Ravindra. *Improving access, service delivery and efficiency of the public health system in rural India: Mid-term evaluation of the National Rural Health Missio*n 2009, CGSD Working Paper No. 37 pp: 1-154

Baldwin, R., Cave M. *Understanding regulation: Theory, strategy and practice*. Oxford: Oxford University Press, 1999.

Bearak, B. “In India the wheel of justice hardly moves.” New York Times, June 1, 2000.

Bhatia, Jagdish and Cleland John. "Health care of female outpatients in south-central India: comparing public and private sector provision." *Health Policy and Planning*19, (2004):402-409.

Bhatia, Reema. “Health Policy plan and implementation: The role of Health workers in altering sex-ratio” In Tulsi Patel ed. *Sex-selective abortion in India: Gender, society and new reproductive technologies.* Delhi: sage, 2007.

Bhatia, Reema. “Situating declining sex-ratio: Evidence from North India” In Arima Mishra ed. *Health, Illness and Medicine: Ethnographic Readings*. Delhi: Orient Blackswan, 2010.

Bhatt, Ramesh. “Regulating the private health care sector: The case of the Consumer Protection Act”. *Health Policy and Planning* 11, (1996):265-79.

Bloom,Shelah, Wypij D, Gupta M. “Dimensions of women’s autonomy and the influence on maternal health care utilization in a north Indian city.”*Demography* 38, (2001):67-78.

Bonu, Sekhar, Bhushan I, Rani M et al. “Incidence and correlates of ‘catastrophic maternal health care expenditure in India.”*Health Policy and Planning* 24, (2009):445-56.

Brinkerhoff, Derrick W. “Accountability and health systems: towards conceptual clarity and policy relevance.” *Health Policy and Planning* 19, 6, (2004): 371-379

Chatterjee, Chitra.,Jardar, GK., Mukeherjee, G., and others. “Septic abortions: A descriptive study in a teaching hospital, North Bengal, Darjeeling.” *Indian Journal of Public Health* 51, 3, (2007): 193-194.

Chaturvedi, Sarika and Randive B. “Public private Partnerships for Emergency obstetric care: Lessons from Maharashtra.*” Indian Journal of Community Medicine* 36, (2011):21-26.

Chełstowska, Agata. “Stigmatization and commercialization of abortion services in Poland: turning sin into gold.” *Reproductive Health Matters* 19, 37, (2011): 98-106.

Chhabra, Rami and Sheel C. Nuna. *Abortion in India: An Overview.* New Delhi: Veerendra Printers, 1994.

Coutinho, Lester., Bisht, Suman., and Raje, Gouri. “Numerical Narratives and documentary practices: Vaccines, targets and reports on immunization coverage”. *Economic and Political Weekly* 35, 8, (2000): 656-666

Derbyshire, Robert C. “How effective is medical self-regulation?” *Law and Human Behaviour* 7, 2/3, (1983):193-202.

Declaration of Chennai: Review of The Medical Termination of Pregnancy (MTP) Act 1971 in the context of Halting Sex Selective Abortion. 18TH August 2007, Chennai. www.cassa.in/pdf/Chennai declaration.doc (Accessed on January 10, 2012).

Devadasan, N., Ranson K, Van Damme W., Criel B. “Community health insurance in India: an overview”, *Economic and Political Weekly* 39, (2004):3179-3183.

Duggal, Ravi. “The Political Economy of Abortion in India: Cost and Expenditure Patterns.” *Reproductive Health Matters*12, 24 (2004): 130–147.

Fotso, Jean-Christophe., Ezeh Alex, Essendi H. "Maternal health in resource-poor urban settings: how does women’s autonomy influence the utilization of obstetric care services?." *Reproductive Health* Matters 6, (2009) doi: 10.1186/1742-4755-6-9(Accessed on July 16, 2011)

Fournier, P et al., “Improved access to comprehensive emergency obstetric care and its effects on institutional maternal mortality in rural Mali.” *Bulletin of World Health Organisation* 87, (2008):30-38.

Ganatra, Bela., Elul Batya. “Legal but Not Always Safe: Three decades of a Liberal Abortion Policy in India.”*Gaceta Médica de México*. 139, 1, (2003): S103-108.

George, Asha. “Persistence of high maternal mortality in Koppal district, Karnataka, India: Observed service delivery constraints.” *Reproductive Health Matters* 15, (2007): 91-102

George, Asha. “By papers and pen, you can do only so much: Views about accountability and human resource management from Indian Government health administration and workers”. *International Journal of Health planning and management,* 24: (2009): 205-224.

George, Asha., Aiyer A, Sen G. “Gendered health systems biased against maternal survival: Preliminary findings from Koppal, Karnataka.” IDS Working Paper 253, University of Sussex, UK, 2005.

Gill, Kaveri. A Primary Evaluation of Service Delivery under the National Rural Health Mission (NRHM): Findings from a Study in Andhra Pradesh, Uttar Pradesh, Bihar and Rajasthan, Working Paper 1/2009.

Government of India. National Consumer Disputes Redressal Commission. New Delhi,Ashok Kumar Upadhyaay and ANR VsD.N.Mishra, *Consumer Protection Judgements March* 1, (*2011)*: 195-208.

Government of India.“The Consumer Protection Act (Rules and Regulations), Department of Civil and Consumer Affairs, New Delhi (1986).” http://ncdrc.nic.in/1_1.html (Accessed on January 15 ,2011).

Grindle, M.S. “Good Enough Governance Revisited”. *Development Policy Review,* 29, (2011): S199-S22.

Guleria. K., Bansal, S., Agarwal, N., et.al. “Women with Septic Abortion: Who, How and Why.A prospective study from tertiary care hospital in India.”*Indian Journal of Public Health*, 50, 1,(2006):95-96

Gupte, Manisha.Bandewar, Sunita. Pisal, Hemlata. “Abortion Needs of Women in India: A Case Study of Rural Maharashtra.” *Reproductive Health Matters*, 9, (1997): 77-86.

Hardee, Karen. *The Intersection of Gender, Access, and Quality of Care in Reproductive Services: Examples from Kenya, India, and Guatemala*. GAQ task force of USAID Agency, 2005.

HEPVIC. *Country report on health policy-making in India, its determinants and the inter- relationships.* HEPVIC, 2009.

Hirve, Siddhivinayak S. “Abortion Law, Policy and Services in India: A Critical Review.” *Reproductive Health Matters*, 12, 24, (2004):114–121

Husain, Zakir “Health of the National Rural Health Mission.” *Economic and Political Weekly*, XLVI, 4, (2011): 53.

Jacob K.S. “Towards a new and improved NRHM.” 2011. www.tnmgrmu.ac.in/VC/NRHM (Accessed on April 16,2012).

Jeffery, Patricia and Jeffery Roger. “Money itself discriminates: Obstetric emergencies in the time of liberalization.” *Contributions to Indian Sociology*42 (2008): 59-91.

Jeffery, Patricia and Jeffery Roger. “Only when the boat has started sinking: A maternal death in rural India.” *Social Science and Medicine* 71, (2010):1711-1718.

Jeffery, Roger., Santosh, M.R. “Architecture of drug regulation in India: What are the barriers to regulatory reform?”. *Journal of Health Studies* 2, (2009):13-32.

Jesani A. and S. Nandraj "The Unregulated Private Health Sector" in *Health for the Millions*, Vol.2, 1, (1994), pp. 25-28.

Jing, Runtian., Grahm, John L. “Values versus regulations: How culture plays its role”. *Journal of Business Ethics,* (2007).

Johnston, Heidi Bart. “Abortion practice in India: A review of literature.” *Abortion Assessment Project, India, 2002*. CEHAT, Mumbai.

Johnston, Heidi Bart., Ved, Rajani.,Lyall, Neena and Others. *From community to action. Post abortion Complications in rural Uttar Pradesh, India*. Prime II Despatch, 2, 2001.

Kamdar, Seema. “Doctors welcome medical abortion pill.” Times of India, April 16, 2002.

Lipsky. M. *Street level bureaucracy: Dilemmas of the individual in public Services*. New York.Russel Sage Foundation, 1980.

Lupton, Deborah. *Medicine as culture: Illness, disease and the body in western societies.* London: Sage publications, 1994.

Mackintosh, Maureen., Roy R.“A conceptual framework and application to decentralised mixed care systems.” In Edward Elgar: Cheltenham. *Economic Decentralization and Public Management Reform,*(1999).

Mallick, Rupsa. “Negative choice’ sex determination and sex-selective abortion in India” Abortion Assessment Project 2003, CEHAT.

Mathews, Zoe., Ramakrishna J, Kilaru A et al. “Birth rights and rituals in rural South India: care seeking in the intrapartum period.” *Journal of Biosocial Science* 37, (2005):385-411.

Mavalankar, Dileep.“Can PHC System in India Deliver Emergency Obstetric Care?: A management perspective on Child Survival and Safe Motherhood Programme.” *Social Change* 26, (1996):14-29.

Mavalankar, Dileep V, "Policy and Management Constraints on Access to and Use of Life-Saving Emergency Obstetric Care in India."*Journal of American Medical Women’s Association* 57, (2000):165 - 168.

Mavalankar, Dileep., Rosenfield A. “Maternal Mortality in Resource-Poor Settings: Policy Barriers to Care.”*American Journal of Public Health* 95, 2, (2005): 200–203.

Mavalankar, Dileep and Vora K. “The changing role of auxiliary nurse midwife (ANM) in India: implications for maternal and child health (MCH).”Working Paper, IIM, Ahmedabad (2008).

Mavalankar, Dileep., Vora K, Prakasamma M. “Achieving Millennium Development Goal 5: is India serious?,” *Bulletin of World Health Organisation* 86, (2008):243.

Mavalankar, D., Callahan K, Sriram V et al. “Where there is no anaesthetist: Increasing capacity of EmOC in rural India: An evaluation of a pilot program to train general doctors*.” International Journal of Gynaecology and Obstetrics* 107, (2009):283-88.

Medical council of India. “Code of Medical ethics”. (www.mciindia.org/rules and regulations/code of medical ethics regulations 2002.aspx). (Accessed on January 14, 2012).

Ministry of Health and Family Welfare Government of India. Handbook on Pre-Conception & Pre- Natal Diagnostic Techniques Act, 1994 and Rules with Amendments, 2006. http://rajswasthya.nic.in/PCPNDT. (Accessed on May 1, 2012).

Ministry of Health and Family Welfare. "Indian Public Health Standards" , Ministry of health and Family Welfare,. http://mohfw.nic.in/NRHM/iphs.htm. (Accessed February, 2, 2012).

Ministry of Health and Family Welfare. "Karnataka NRHM PIP 2009-10: Chapter –3. Reproductive and Child Health Programme –II". Ministry of Health and Family Welfare.http://mohfw.nic.in/NRHM/PIP_09_10/Karnataka/RCH_Text.pdf. (Accessed January 31, 2012).

Misra, B "Consumer Redress in the health sector in India" In A Yazbeck and D. Peters eds *Health policy Research in south Asia: Building capacity for reform*. Washington: The World Bank, 2003.

Mishra, Arima. "Reports, numbers and signatures: Documentary practices of immunization in Orissa", Paper presented at the International Workshop on 'Explaining immunization coverage in India and Malawi', University of Delhi and University of Oslo, IIC, Delhi, 2011.

Muraleedharan, V.R. and R. Prasad. *Regulation in health care in Tamil Nadu (India): A study of the implementation of transplantation of Human Organs Act 1994 and Consumer Protection Act 1986.* Madras: Centre for Sustainable Development, IIT ,2003.

Nandraj, S. Khot, A, Menon, S and Brugha R. "A stakeholder approach towards hospital accreditation in India*".* *Health policy and planning* 16, S2, (2001): 70-79.

Nandraj, S. Muraleedharan, V.R. Baru, R and others. *Private health sector in India: Review and annotated bibliography.* CEHAT, Foundation for Sustainable development/IIT/CSSM JNU.2001.

Ministry of Health & Family Welfare, Government of India. *National Commission on Macroeconomics and Health Publication.* 2005.

Newell, Peter and Bellour, Shaula.*Mapping Accountability: Origins, contexts and implications for development.*IDS Working Paper 168, University of Sussex, 2002.

Nishtar *S. "*Mixed *Health Systems* Syndrome"*. Bulletin of World Health Organization, 88, (*2010)*:74-75.*

Pachauri, Saroja. *Implementing a Reproductive Health Agenda in India: the Beginning.* Population Council New Delhi, 2009. http://www.popcouncil.org/pdfs/implementing.pdf. (Accessed on July 16, 2011).

Pandit, MS and Pandit S."Medical negligence: Coverage of the profession, duties, ethics, case law and enlightened defence- A legal perspective."*Journal of Urology* 25(2009):372-378

Patel, Lisa., Bennett, Trude A., Halpern, Carolyn Tucker. et.al. "Support for provision of early medical abortion by mid-level providers in Bihar and Jharkhand, India". *Reproductive Health Matters*, 33 no, 17, (2009): 70 – 79.

Patel, Tulsi. *'Introduction' In Sex-selective abortions: Gender, society and New Reproductive Technology* Ed. Tulsi Patel Sage: New Delhi, 2007.

Pathfinder International. *Improving Access to Safe Abortion Care and Services In Northern Karnataka, India*, 2007http://www.pathfind.org/site/DocServer/Karnataka_Pathfindings.pdf?docID=9481. (Accessed on December 12, 2011).

Paxton, A., Maine D, Freedman L et al. "Evidence for emergency obstetric care." *International Journal of Gynaecology and Obstetrics* 88(2005): 181-193.

Peters, D. H.; Muraleedharan, V. R. "Regulating India's health services: To what end? What future?."*Social Science and Medicine* 66, 10 (2008). 2133-2144.

Phadke S. "Pro-choice or Population Control: Study of the Medical Termination of Pregnancy Act, Government of India, 1971." Cited in Siddhivinayak Hirve, "Abortion Policy in India: Lacunae and Future Challenges." *Abortion Assessment Project – India,* CEHAT: Mumbai, 2002.

Raj Bokaria v. Medical Council of India and Anr. Writ Petition (Civil) No. 7905/2010 decided on 25.11.2010, available at http://www.indiankanoon.org/doc/44092/

(Accessed on April 20, 2011).

Ramachandar Lakshmi, PeltoPertti J. "The Role of Village Health Nurses in Mediating Abortions in Rural Tamil Nadu, India." *Reproductive Health Matters* 10, 19, (2002): 64–75.

Ronsman, C., Holtz, Sara, Stanton, Cynthia. "Socio economic differentials in caesarean rates in developing countries: a retrospective analysis." *The Lancet*, 368, (2006):1516.

Saha, Pradip Kumar., Prabhakar, Sonil.,Goel Poonam and others. "Misuse of abortion pill by unauthorized persons is a serious concern in India." *Journal of*

Obstetrics and Gynaecology 36, 6, (2010): 1265 (letter to the editor).

Satpathy, SK., Venkatesh S. “Human Resources for Health in India's National Rural Health Mission: Dimension and Challenges.” Regional Health Forum 10, (2006):29-37.http://www.searo.who.int/LinkFiles/Regional_Health_Forum_Volume_10_No_1_03-Human_Resources_for_Health_in_Indias_National.pdf (Accessed on June 15, 2011).

Satish Kumar. “Challenges of Maternal Mortality Reduction and opportunities under National Rural Health Mission.”*Indian Journal of Public Health* 49, 3, (2005).

Say, Lale and Raine, Rosalind. "Public health reviews a systematic review of inequalities in the use of maternal health care in developing countries: examining the scale of the problem and the importance of context Public health reviews." *Bulletin of World Health Organisation* 85, (2007).

Sen, Gita and P.Ostlin. eds. *Gender equity in health: The shifting frontiers of evidence and action*, London: Routledge, 2010.

Sheikh, Kabir, Saligram, P and Prasad L.E. *Mapping the regulatory architecture for health care provision in LMIC mixed health systems,* Report, New Delhi: Public Health Foundation of India, 2011.

Shaw, Sara. “Reaching the parts that other theories and methods can’t reach: How and why policy-as-discourse can inform better health related policy.”*Health* 14, (2010): 196

Sheriar N. “Manual vacuum aspiration decentralizing early abortion services.” Paper presented at the National Conference on Making Early Abortion Safe and Accessible, Parivar Seva Sanstha. Agra,11–13, October 2000.

Siddiqi, Sameen, Tayeeb I Masud, Nishtar, Sania et al "Framework for assessing governance of the health system in developing countries: Gateway to good governance", *Health Policy 90,* (2009): 13-25.

Singh, Susheela et al., "Barriers to Safe Motherhood in India (June 2009)." http://www.guttmacher.org/pubs/2009/07/29/Safe-Motherhood-India.pdf (Accessed on January 11, 2012)

Sundar, Ramamani. "Abortion costs and finance: A Review". (2003) http://www.cehat.org/go/uploads/AapIndia/work5.pdf (Accessed on December 15, 2011)

The Supreme Court of India."Indian Medical Association vs. V.P. Shantha&Ors on 13 November, 1995, AIR 550, 1995 SCC (6) 651."(1995). http://indiankanoon.org/doc/723973/ (Accessed on July 26, 2011).

Unger, Jean-Pierre., Marchal Bruno., and Green Andrew. "Quality standards for health care delivery and management in publicly oriented health services". *International Journal of Health Planning and Management*, 18,(2003): S79-S88.

Verma, S.K. Srivastava S.C. and Jilani S.S. *Legal Framework for health care in India* New Delhi: Lexis Nexis Butterworths, 2002.

Visaria, Leela., Jejeebhoy S, Merrick T. "From family planning to reproductive health: challenges facing India." *International Family Planning Perspectives* 25, (1999).

VOICE. *A study on the regulatory framework for consumer redress in the health sector in India,* Study report prepared by VOICE in collaboration with Ministry of Health and Family Welfare, World Bank and Indian Law Institute, 2000.

Visaria Leela., Bhat Meera. Public provisioning of Health and decentralization in Gujarat. *Economic and Political weekly*, XLIV, 49 (2011).

Vora, Kranti., Mavalankar D, Ramani KV et al. "Maternal Health Situation in India :A Case Study."Journal of health population and nutrition 27(2009):184-201. http://www.ncbi.nlm.nih.gov/pubmed/19489415(Accessed on June 5, 2011).

Whyte, Donna Hussey . “Black market abortion pills in high demand.” Jamaica Observer, May 29, 2011.

Websites:

Government of India (2004) National Common Minimum Programme of the UPA Government http:/www/pmiindia.nic.in/cmp.pdf (Accessed on May 10, 2011).

Government of India (2005) NRHM: Mission Document, www.mohfw.nic.in/nrhm (Accessed on April 15, 2011).

Government of India (2005) Guidelines for Implementation www.mohfw.nic.in/nrhm(Accessed on May 4, 2011).

Government of India (2005) Guidelines for IPHS. www.mohfw.nic.in/nrhm (Accessed on May 16, 2011).

Government of India (2005) Guidelines for utilisation of untied funds www.mohfw.nic.in/nrhm (Accessed on May 18, 2011).

Government of India (2005) Guidelines of constitution of Village Health and Sanitation Committee, www.mohfw.nic.in/nrhm (Accessed on June 16, 2011).

Government of India (1986) ‘Consumer Protection Act, Rules’, Ministry of Consumer

Affairs, Food and Public Distribution http://www.ncdrc.nic.in/1_1.html (accessed on April 4, 2011).

NRHM (2007, 2009) Common Review Mission (I,II, III), Ministry of Health and Family Welfare, Govt of India (www.mohfw.nic.in/nrhm Accessed on July 14, 2011).

Indian Kanoon.Medical termination of Pregnancy Act, 1971.http://www.indiankanoon.org/doc/634810/ (Accessed on April 10, 2011).