Effective Regulations in Health Systems

Selected implications for policymakers from HESVIC, an international collaborative research project into the role of regulation in maternal health in low to middle income countries.

Key Messages

1. Regulation is a key and under-performing part of health systems in low- and middle-income countries, not least due to the blurred distinction between public and private sectors.
2. Well-designed and effectively implemented regulation may contribute to enhancing the performance of the health system in achieving its objectives, such as universal health coverage and better health outcomes. In contrast, poorly-designed regulations can negatively influence the achievement of health outcomes.
3. Policymakers need to give greater attention to regulatory processes and selected issues are provided for consideration.

Governance is a key element in ensuring effective health systems performance. Regulation, one governance mechanism, is particularly important for transitional Asian economies experiencing major changes to their health systems. Effective regulation is an important factor influencing equitable access to quality health care. However, regulatory processes and their potential effects have been understudied.

Health System stewardship and regulation in Vietnam, India and China (HESVIC) is a three-year (2009-2012) collaborative research project involving six Asian and European institutions with financial support from the European Commission[1]. It aims at developing better understanding of regulations and assessing their impact on maternal health services in Vietnam, India (Karnataka State) and China (Shanghai city). Although maternal health was used as a project focus, the research findings have implications for strengthening health regulatory practices more generally.

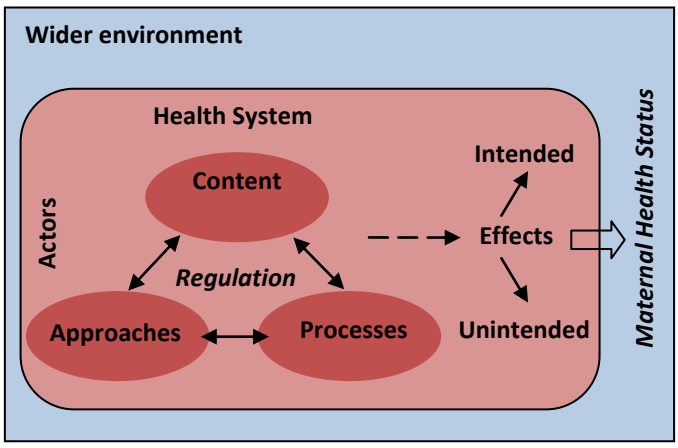
This policy brief aims to inform national and international efforts in improving regulation within national health systems. The target audience is: national policymakers, planners and legislators, civil society and policymakers in different international organizations (such as European Commission, WHO, other UN agencies, bilateral donors and International NGOs) with responsibility for the design and implementation of regulatory processes.

We summarise selected findings from the HESVIC project, then identify key attributes of effective regulatory processes, considerations for policy-makers, and practical implementation issues.

Experience from HESVIC Research

Regulation is typically used within national health systems to support aims of respective national health policies or programmes (such as Safe Motherhood Policy in Vietnam) or wider governance principles (such as the concept of a harmonious society in China). As such, conceptually it is an integral part of the health system though some functions of regulation (such as monitoring) can be independent from the health system.

The Concept of Regulation



Regulations contribute to achievement of *intended* or *unintended effects* within wider health systems. Intended effects usually reflect the regulation objectives. Unintended or unforeseen effects – either positive or negative - can be on the performance of the wider health system, or the achievement of health outcomes such as maternal health.

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Examples of Intended and Unintended Effects of Regulation of Emergency Obstetric Care (EmOC)

	Intended Effects	Unintended Effects
Vietnam	Modest increase in coverage of EmOC services, including training for OBGYN doctors, and availability of services; improvement in quality of services.	Lower utilisation of commune health centres for basic EmOC and overburdened hospitals; poor monitoring and evaluation (especially at private hospitals) with unintended high C-section rate and high out-of-pocket costs for users; confusion on multiple EmOC regulations.
India	Increased visibility of maternal health as policy priority and clearer focus on EmOC in maternal health programmes; increased deliveries at health facilities; (inconsistent) creation of resources (e.g. infrastructure, human resources, facilities); improved health information system performance.	Inconsistent provision of EmOC services across facilities, resulting in multiple referrals; unnecessary referrals due to avoidance of high risk cases; all leading to persistence of maternal deaths; fragmented accountability affecting integration of maternal health services.
China	Appropriate referral and improved EmOC successful rescue rate; quick EmOC response; robust consultation/ referral linkage; improved capacity; equity of service provision, all leading to improved maternal mortality.	Creation of EmOC teaching materials and subsequent regulations; increased work in EmOC centres; increased economic burden for facilities and patients; tension between rescue activity and reporting workload, controversial maternal mortality audits; prioritised EmOC work; investment in migrants' prenatal care.

Regulations are designed and implemented by *actors*. These actors may include national policymakers, programme managers, health staff or service providers; service users or the public are often excluded. Different actors are interrelated within the health system and the same policy actors can be involved in different stages of the regulation process (e.g. the design and monitoring of implementation).

Different *approaches* to regulation exist. These include differences in: a) *target focus group* of a regulation (such as public or private service providers or service users), b) *nature* of a regulation, such as enabling (e.g. encouraging institutional deliveries) or prohibiting (e.g. prohibiting sex-selective abortions) regulations, and c) *implementation mechanism* (such as the balance between incentives vs sanctions, degree of actors' 'independence').

Effective *regulatory processes* are essential in ensuring that regulations achieve their objectives, whether these are directly related to quality of services or other policy goals (such as addressing patients' rights to complain in grievance redressal processes, or creating a balanced society in regulating sex-selective abortions).

Regulations operate within the wider national and international contexts. Different contextual factors – such as cultural and social norms, economic climate and national and international political goals and priorities – can facilitate or prohibit effectiveness of regulation processes and ultimately achievement of a regulation's objectives.

The study provides insights into under what conditions and how a regulation works or does not work to achieve its intended objectives. The wider socio-cultural environment, coherence with wider policies, and relationships between overlapping and inter-related regulations are examples of causes that can affect development and implementation of a regulation.

Policy and Socio-Cultural Context: Son Preference and the Small Family Policy in Vietnam

The Population Ordinance and Decree 104/2003/ND-CP are regulations designed to reduce Vietnam's increasing sex-ratio at birth (SRB) of 110.6 male births per 100 female births (2009 census), by prohibiting prenatal sex determination and sex selective abortion during antenatal check-ups. However, the means of detection and sanctions are undefined.

One factor influencing the increasing SRB is the tension between the government's goal to reduce family size and their effort to ensure a balanced sex ratio. At the same time, a social context of son preference is prevalent. A son-preference culture, combined with pressure to keep families small, encourages families to seek sex determination services and sex-selective abortion, constraining the implementation of the above two regulations.

There are examples of good practice in relation to regulatory processes (such as systematic nature of the processes for addressing patients' complaints about quality of health services in the Vietnam Grievance Redressal Law). However, there are many areas where regulation is ineffective and improvement in regulatory processes may enhance performance of the health system. Further, ineffective regulatory processes can have negative implications on health system performance, through their unintended effects (see table above).

What should regulatory processes look like and what are their key attributes?

We suggest that for a Regulation to be effective, it must be *Fit for Purpose* or, in other words, be:

- *Consistent* with wider policy objectives and underpin values of other policy and governance instruments and the wider health system.
- *Designed and resourced appropriately* to meet the set objectives.
- *Feasible* in terms of the organization of the health system and country (or local) context.
- *Efficient* in operation to ensure regulatory resources are cost-effective.

What constitutes effective regulatory processes will vary between contexts and different actors. Policy makers need to determine their views on this and the following attributes could be considered as a starting point:

1. ***Transparent****:* to ensure all stakeholders (including citizens, service providers, and policy-makers) are clear as to how the processes operate, what their main purpose is, and any related incentives and sanctions applied within the regulation.
2. ***Inclusive****:* to ensure adequate participation of key stakeholders. The precise manner of such participation may vary between health systems but should also reflect the rights of citizens to participation in regulation and, ultimately, to quality health services, within the health system.
3. ***Evidence-driven:*** to ensure that the regulatory processes are based on the use of appropriate evidence. This evidence can be generated from ongoing mechanisms and two-way feedback loops to monitor and evaluate health system or programme performance.
4. ***Accountable:*** with clear mechanisms according responsibility for the operation of the regulation to appropriate authorities, including health managers, local governments, and the public.
5. ***Contextually sensitive:*** with the design taking full account of the specific context in which it operates, and including ongoing monitoring mechanisms to adjust the regulation as necessary to respond to contextual changes.

Considerations for improving regulations

Further in this document we propose ten considerations for national policy-makers to improve regulations. These are developed in an attempt to ensure that regulations are fit for purpose. The interpretation of effective regulatory processes is context-specific (for example, transparency can have different meaning to different actors even within the same country). Therefore, the proposed considerations are not exhaustive but provide a starting point for improving health regulations. These considerations need to be interpreted in conjunction with the interpretation of effective regulation. They are related and may reinforce each other (for example, different actors' involvement in regulatory processes can help make the regulation more responsive to the needs of both service users and service providers). The considerations are phrased as questions for regulation designers, to reinforce the complexity of the issue of regulation and the need for context-specific solutions.

How do policymakers address these considerations?

The below considerations are related, suggesting a need for a set of integrated strategies to address related 'sets' of considerations. Three integrated strategies are proposed for policymakers to consider in ensuring effective regulations:

1. Establishing inclusive working groups for reviewing existing and designing new regulations using the considerations below. These groups ideally should include different policy actors (such as managers, service providers, and service users) to ensure representation of different perspectives within the health system.
2. Monitoring of effectiveness of regulation implementation *processes.* Where possible it should be done through existing structures and processes (e.g. system of management review meetings) rather than new structures.
3. Conducting periodic evaluations of the achievement of regulation objectives (such as improvement to equitable access to, and quality of, services) and a*ny unintended effects* are important to assess whether a regulation is achieving its purpose. Using routine data and existing management meetings could ensure the sustainability and feasibility of periodic evaluations.

The list is not exhaustive and combinations of strategies may be appropriate in different contexts. Although we assume the national Ministry of Health would spearhead the below strategies, their efforts alone will not be sufficient to improve regulation within complex health systems. Thus, involving different actors (such as service users, health managers, service providers, policymakers, and other social and educational sectors) is essential.

Ten Considerations for Improving Regulations	
Key Considerations	**Issues to Consider**
1. Is the purpose underlying the regulation clear and appropriate?	• Regulation is not an end in itself but a means to, for example, ensure, or improve, equitable access to quality services. • The regulation needs to have an appropriate nature (e.g. enabling versus prohibiting) for the given context.
2. Is the regulation consistent with other governance mechanisms and health system values?	• Regulation is typically part of a wider governance family of policy and management mechanisms; internal consistency is crucial. • The key values underpinning the regulation should be consistent with those of the wider health system, in particular equity and the pursuit of health rights.
3. Does the regulation consider both the citizen and provider (demand and supply) perspectives?	• Regulatory processes are typically focused on the supply-side when demand-side interventions may be more effective. • Citizen's rights and needs are important in designing regulations. Citizen's participation in regulatory processes can help ensure regulations address citizen's rights and needs.
4. Are the regulatory processes known to, and understood by, all relevant key actors?	• Key actors include users and their representative bodies such as NGOs, media, managers, and service providers. • Understanding of processes may differ between actors and could affect whether a regulation is used for the benefit of the targeted group.
5. Are the most appropriate stakeholders involved in the regulatory processes?	• This includes both designing and implementing a regulation. • Actors' capacity, ownership, awareness, and agendas are important in their effective involvement in regulatory processes.
6. Do the regulatory processes take appropriate account of differences between public and private providers?	• Regulations need to recognise differences between public and private providers (these can be related to their motivations, behaviour, or the availability of information about their performance). • Adequate resourcing is needed to monitor performance and ensure consistency of regulation in both public and private sectors.
7. Is the regulation feasible within a given context?	• Adequate resourcing of all regulatory processes (including design and implementation) is essential. • It is important to consider roles of potentially facilitating government structures, such as Finance or Justice Ministries. • Feasibility includes: technical, legal, cultural, and ownership issues.
8. Is there a well-functioning system to monitor and evaluate the regulation processes and performance?	• Monitoring and evaluation are key elements in the process, which needs to respond to changing contexts. • Resources are needed to monitor not just the expected impact of a regulation but also its unexpected effects. • Monitoring and evaluation outputs should be used as evidence to strengthen the regulatory process.
9. Are the rewards and sanctions used in the regulations appropriate?	• Balance between different types of rewards and sanctions within regulatory processes can be used to ensure accountability. • Development of an appropriate organizational culture, such as through peer pressure, may be important as part of a regulation or alongside it to achieve regulatory purposes.
10. Does the regulatory system achieve an appropriate balance between independence of operation and integration with the health system?	• There are advantages in regulatory systems being integrated within wider health systems (for example, in terms of information flow and supervision). • Some independence from the ongoing system may also be needed to ensure independent operation of the regulation (e.g. in grievance redressal). • Different regulations and contexts will achieve this balance in different ways.

This document was developed by the HESVIC Teams from: University of Leeds (UK), Royal Tropical Institute (Netherlands), Hanoi School of Public Health (Vietnam), Fudan University (China) and Institute of Public Health Bangalore (India). We gratefully acknowledge comments from the HESVIC Team from the Institute of Tropical Medicine (Belgium) in developing this document though the views expressed here are of the authors only.

Published by the University of Leeds, UK, 2012. With any questions or comments on this brief please contact Dr Tolib Mirzoev t.mirzoev@leeds.ac.uk