JLN PRIMARY HEALTH CARE INITIATIVE

PRIVATE SECTOR ENGAGEMENT COLLABORATIVE

REGULATION OF PRIVATE PRIMARY HEALTH CARE

Lessons from Six JLN Countries

Joint Learning Network
For Universal Health Coverage

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CONTENTS

ABBREVIATIONS AND ACRONYMS

AMO	l'Assurance Maladie Obligatoire (Morocco's mandatory medical insurance)
BPJS-K	Badan Penyelenggara Jaminan Sosial Kesehatan (Indonesia's social security agency for health)
CHE	current health expenditure
GDP	gross domestic product
GHS	Ghana Health Service
HeFRA	Health Facilities Regulatory Agency (Ghana)
JHIC	Joint Health Inspections Checklist (Kenya)
JKN	Jaminan Kesehatan Nasional (Indonesia's national health insurance)
JLN	Joint Learning Network for Universal Health Coverage
KePSIE	Kenya Patient Safety Impact Evaluation
MOH	Ministry of Health
NHIA	National Health Insurance Authority (Ghana)
NHIF	National Hospital Insurance Fund (Kenya)
NHIS	National Health Insurance Scheme (Ghana)
PHC	primary health care
RAMED	Régime d'Assistance Médicale (Morocco's medical assistance scheme)
TWG	technical working group
UHC	universal health coverage

KEY TERMS

ACCREDITATION. A formal process by which a recognized body, usually a nongovernmental organization (NGO), assesses and recognizes that a health care facility meets applicable predetermined and published standards.[1]

CAPITATION. Payment to a health care provider based on an agreed-upon amount per person covered or enrolled for a specified package of covered services.[2]

CREDENTIALING. The process of obtaining, verifying, and assessing the qualifications of health care providers to authorize them to provide specific patient services.[3]

DECENTRALIZATION. The transfer of power arrangements and accountability systems to lower management levels. In public health care, this ranges from the transfer of limited powers to lower levels within current health management structures and financing mechanisms to political transfer of responsibility for government health service delivery from the national government to subnational governments (such as states, provinces, or municipalities).[4]

PRIMARY HEALTH CARE (PHC). The provision of outpatient nonsecondary and nontertiary preventive, promotive, and curative care, with a particular focus on ensuring the delivery of quality health interventions to address the highest disease burdens.[5] PHC services include:

- **Preventive services** that protect against illness or diseases (e.g., family planning, prenatal care, immunizations)[6]
- **Promotive services** that encourage well-being and healthy living (e.g., sanitation, good nutrition, smoking deterrence, mental health)[7]
- **Curative services** that treat and reduce the probability of disability and death due to entry-level and common high-burden diseases (e.g., deliveries, respiratory illnesses, childhood illnesses)[8]

PRIVATE HEALTH SECTOR. Generally, all nonstate health providers, including for-profit and nonprofit entities. These include hospitals, doctors, pharmacies, traditional healers, faith-based organizations, private health insurance mechanisms (including community-based and employer-sponsored voluntary insurance), and corporate philanthropic organizations created by the private sector for social responsibility.[9,10]

PRIVATE-SECTOR ENGAGEMENT. A government's deliberate, systematic collaboration with the private health sector according to national health priorities, beyond individual interventions and programs.[11]

REGULATION. Broadly defined as the imposition of rules backed by the use of penalties or incentives to ensure compliance with standards. In the case of PHC, regulation covers the safety and quality of health services and diagnostics and may also include licensing for the opening of facilities, certification or accreditation of ongoing provision of services, and incentives to promote quality service provision.[12]

REGULATORY MECHANISM. An activity, process, procedure, requirement, or standard that is used to regulate a targeted actor and/or activity.[13]

REGULATORY REGIME. The actors involved in developing, interpreting, and implementing health-sector regulations.[14]

UNIVERSAL HEALTH COVERAGE (UHC). Ensuring that all people can use the promotive, preventive, curative, rehabilitative, and palliative health services they need, of sufficient quality to be effective, while also ensuring that the use of these services does not expose the user to financial hardship.[15] This definition of UHC embodies three related objectives:

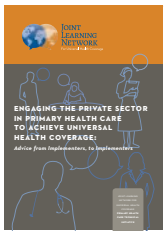
- **Equity** in access to health services: Those who need the services should receive them, and services should not be available only to those who can pay for them.
- **Quality** of health services: Health services should be good enough to improve the health of those who receive services and should also ensure patient safety.
- **Financial risk protection:** The charges to users for health services should not put them at risk of financial hardship.

INTRODUCTION

In the march toward universal health coverage (UHC), countries are recognizing that strengthening primary health care (PHC) is a cost-effective way to ensure access to quality health services for their populations.[16,17] At the same time, policymakers recognize that the public sector alone cannot provide all necessary PHC services to cover country populations and that countries need to engage and effectively steward both the public and private health sectors.[18,19,20]

A critical element of health system stewardship is an effective regulatory system, which includes protections and incentives that promote access to quality care.[21] But despite recognizing the importance of effective regulation, few low- and middle-income countries are successfully regulating private PHC.[22,23,24] Private providers, while frequently used by consumers, are also potentially underutilized in terms of advancing national health priorities.[25,26]

In 2015, a group of committed country practitioners in the JLN PHC Initiative joined together to address the lack of international guidance on engaging with the private sector to achieve PHC-oriented UHC. These practitioners formed the JLN's Private Sector Engagement (PSE) Collaborative and began sharing experiences and knowledge and compiling practical advice to support private-sector engagement. To help fill the gaps in guidance in this area, the collaborative is authoring a guide titled *Engaging the Private Sector in Primary Health Care to Achieve Universal Health Coverage: Advice from Implementers to Implementers*. The completed guide will have five modules:

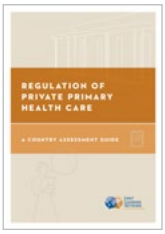


Module 1. Initial Communications and Partnership Around PHC (complete)
Module 2. Provider Mapping (complete)
Module 3. Provider and Facility Regulation, Accreditation, or Empanelment (in development)
Module 4. Provider Contracting and Payment (in development)
Module 5. PHC Systems Monitoring and Evaluation (planned)

In 2016, the collaborative members completed Modules 1 and 2, which are available on the JLN website at *www.jointlearningnetwork.org*. In compiling Module 3, which focuses on ensuring the quality of private PHC through provider and facility regulation, the collaborative members conducted a literature review and found few documented experiences on regulation of private providers in low- and middle-income countries. To help fill this gap, six JLN countries—Ghana, Indonesia, Kenya, Malaysia, Mongolia, and Morocco—chose to conduct country assessments using a methodology developed by the collaborative.

The resulting assessment reports (available at *www.jointlearningnetwork.org* and via the QR code in Annex B) address the following questions about regulation of the private health sector:

- What types of regulations are in place?
- How are the regulations implemented?
- What outcomes are achieved by those regulations?
- What resources are available for developing and implementing such regulations?



The PSE Collaborative designed the methodology and implementation process for the country assessments using a collaborative learning approach, and the members met in person in Yogyakarta, Indonesia, in 2016 to validate these processes. As part of this study design work, the collaborative developed a country regulatory assessment guide to ensure that the country assessment processes in the six countries were similar and collected comparable data. (The guide is available at *www.jointlearningnetwork.org*.)

In outlining the scope of the assessments, the group chose to look at regulation of both the public and private sectors. Similarly, they agreed to focus on PHC service delivery, while recognizing that in describing the regulatory system they would inevitably touch on secondary and tertiary care. More information on the assessment scope and joint learning process can be found in Annex A.

This report provides an overview of the country health regulatory systems, including key economic and political information that can affect the will and ability of stakeholders to regulate the health sector. It also provides information on regulatory actors and institutions that are responsible for developing and implementing regulations, as well as the resources available to them. The report goes on to describe the primary and secondary data collected on regulation activities and measures of performance. While the indicators used in the assessments highlight the diversity among the health systems, many of the countries face similar challenges in regulating private PHC. The report moves on to synthesize lessons and insights from the country assessments and concludes by highlighting innovative solutions that the countries are implementing to better regulate private PHC.

THE DEMOGRAPHIC AND REGULATORY LANDSCAPE IN THE SIX PARTICIPATING COUNTRIES

In *Getting Health Reform Right,* Roberts et al. cite four key determinants of regulatory success: cultural attitudes, capacity of government, political support, and design of regulatory institutions and processes.[27] The PSE Collaborative's country assessments collected data on all of these determinants in the six participating countries.

Table 1 shows key demographic and health outcome data for the six countries, including rural population distribution, infant mortality rate, and maternal mortality ratio. Ghana, Indonesia, Malaysia, Mongolia, and Morocco have predominantly urban populations, while Kenya's population is predominantly rural. Based on data from the World Bank, the infant mortality rate ranges from 7 per 1,000 live births in Malaysia to 41 per 1,000 live births in Ghana; the maternal mortality ratio ranges from 29 per 100,000 live births in Malaysia to 510 per 100,000 live births in Kenya.

Table 1. Demographics and Health Outcome Indicators

Country	Population *(World Bank, 2016)*	Rural Population *(World Bank, 2017)*	Infant Mortality Rate (per 1,000 live births) *(World Bank, 2016)*	Maternal Mortality Ratio (modeled estimate, per 100,000 live births) *(World Bank, 2015)*
Ghana	28.2 million	45%	41	319
Indonesia	261.1 million	46%	22	126
Kenya	48.5 million	74%	36	510
Malaysia	31.2 million	25%	7	29*
Mongolia	3.0 million	26%	15	44
Morocco	35.3 million	39%	23	121

** World Bank, 2017*

Table 2 provides health expenditure data, including gross domestic product (GDP) per capita, current health expenditure (CHE) per capita, CHE as a share of GDP, and out-of-pocket expenses as a percentage of CHE. CHE ranges from US$70 per capita in Kenya to US$386 per capita in Malaysia. CHE as a share of GDP ranges from 3.3% in Indonesia to 5.9% in Ghana, while out-of-pocket expenditure as a percentage of CHE ranges from 33.4% in Kenya to 53.1% in Morocco.

Table 2. Health System Indicators

Country	GDP per Capita (in current US$) *(World Bank, 2016)*	Current Health Expenditure (CHE) per Capita (in current US$) *(World Bank, 2015)*	CHE as a % of GDP *(World Bank, 2015)*	Out-of-Pocket Expenditure as a % of CHE *(World Bank, 2015)*
Ghana	$1,513	$80	5.9%	36.1%
Indonesia	$3,570	$112	3.3%	48.3%
Kenya	$1,455	$70	5.2%	33.4%
Malaysia	$9,508	$386	4.0%	36.7%
Mongolia	$3,694	$153	3.9%	49.3%
Morocco	$2,892	$160	5.5%	53.1%

Table 3 provides a brief overview of the country health systems, including the type of financing for providers and the degree of government decentralization as it relates to regulation. The country's health systems range from highly centralized and controlled by the national government (Malaysia) to highly decentralized, with much responsibility, including regulation, placed on subnational entities (Indonesia, Kenya).

Table 3. Overview of Country Health Systems

Country	
 Ghana	• Ghana's health system is stewarded by the MOH, which sets policy and guidance; the Health Facilities Regulatory Agency (HeFRA), which accredits and monitors health facilities; Ghana Health Service, the public health service provider; and the National Health Insurance Authority (NHIA), which manages the National Health Insurance Scheme (NHIS). • The health system includes a mix of public and private providers. • HeFRA exists to register, inspect, license, and monitor public and private health facilities for the quality of care provided. • The single payer, the NHIA, reimburses all accredited public and private providers for services used by NHIS enrollees. • Health service management is decentralized to the regional and district levels for GHS (public-sector) providers.
 Indonesia	• Indonesia has an integrated health system with a single benefits package, Jaminan Kesehatan Nasional (JKN), that is comprehensive and includes primary, secondary, and tertiary levels of care. It is managed by a single payer, Badan Penyelenggara Jaminan Sosial Kesehatan (BPJS-K), the social security agency for health. • JKN services are provided by local government outpatient health clinics (*puskesmas*), national government facilities, and private facilities that have the option of providing care for JKN members. • JKN providers are paid through capitation for PHC and through case-based payment for advanced-level services.
 Kenya	• Kenya has a highly decentralized health system in which 47 county governments provide health services (mainly outpatient and secondary hospital) that are different and separate from those offered by the national government (mainly tertiary and specialized services). • The private sector provides 42% of PHC and owns 51% of the health infrastructure. • Health services are financed through fee-for-service, public taxes, donor funds, and health insurance (private and public). • The National Hospital Insurance Fund (NHIF) is a mandatory social insurance program for the private sector and public sector. There are also schemes for 1) civil servants, police, and the military; 2) the poor, the elderly, and people with disabilities; and 3) women and infants.
 Malaysia	• Malaysia has a PHC-focused health system that includes a mix of public and private financing and service delivery. • Health services are financed by 1) the public sector, through direct and indirect taxes and nontax revenues, and 2) the private sector, through out-of-pocket spending, private health insurance, and employer health benefits. • Nationwide, 60% of PHC utilization is through the public sector and 40% is through the private sector.
 Mongolia	• Mongolia's private health sector began growing in 1990 as the country transitioned to a market economy following 70 years under a socialist system. • Under the Health Law, PHC is provided free of charge, through private family health centers and *soum* (district) health centers. While both types of health centers are financed through the government budget, the private family health centers are funded with capitation payments and the soum health centers are funded from line-item budgets.
 Morocco	• Morocco's health system has a mix of public and private financing and service delivery. The government oversees the basic public health programs, hospital services, and regulation of the health sector. • Health care is financed by a combination of general government revenues (via lump sum), social health insurance, and private spending. • Two main national health insurance schemes cover the population: 1) a mandatory scheme (AMO) that covers public-sector employees, formal private-sector employees, retired pensioners, and students, and 2) a scheme targeted at poor and vulnerable populations (RAMED).

Regulatory Mechanisms

A *regulatory mechanism* is an activity, process, procedure, requirement, or standard that is used to regulate a targeted actor and/or activity.[28] Such mechanisms are often grouped into three categories: command and control, incentives, and self-regulation[29]; these are also referred to as "prohibit," "encourage," or "constrain" approaches.[30] These types of regulatory mechanisms are detailed in Table 4.

Table 4. Types of Country Regulatory Mechanisms

Type of Regulation	Example
Command and Control: Legal requirements accompanied by sanctions for noncompliance.	A law requiring licensing of health personnel or minimum facility conditions in order to obtain and maintain authorization to operate.
Incentives: The use of rewards or penalties, either financial or nonfinancial, that encourage behavior change.	Performance-based payments to providers for meeting quality targets or recognition for meeting quality standards.
Self-Regulation: Provider and professional groups setting their own standards for member behavior and offering recognition for compliance.	Voluntary facility accreditation and personnel certification/recertification by professional organizations.

Table 5 summarizes the number of these types of regulatory mechanisms in each country.

Table 5. Regulatory Mechanisms in Use, by Type

Country	Command and Control	Incentives	Self-Regulation	Total
Ghana	6	1	0	**7**
Indonesia	4	2	1	**7**
Kenya	22	9	11	**42**
Malaysia*	5	0	1	**6**
Mongolia	5	1	1	**7**
Morocco	5	2	0	**7**

** Malaysia has five major acts that directly regulate private providers and 20 other health-related acts.*

Most of the six JLN countries use more command and control regulatory mechanisms than incentives or self-regulation. The command and control mechanisms include national legislation requiring private facilities to have a minimum number of clinicians with specific qualifications and a minimum amount of infrastructure and equipment to provide health care services. Three of the countries—Kenya, Indonesia, and Mongolia—use incentive mechanisms to regulate provider and facility quality of care. More information on these incentives can be found later in this report.

The Regulatory Regime

The actors involved in developing, interpreting, and implementing health-sector regulations make up the health system's *regulatory regime*.[31] The regulatory regimes vary by country but generally consist of four types of actors: 1) legislators who enact regulations, 2) regulators, including government agencies, self-regulatory bodies, and professional associations, 3) providers and third-party payers, including doctors, nurses, health facilities, and insurance funds, and 4) consumers, including patients, the insured and uninsured populations, and any consumer organizations. (See Table 6.) The country assessment teams collected data across three groups of actors (regulators, providers, and consumers).

While the country regulatory assessments focused specifically on the health system regulatory regime, private-sector facilities and providers may also be subject to other regulations that are beyond the scope of this report, including business and environmental regulations, fire codes, tax registration regulations, and local governance.

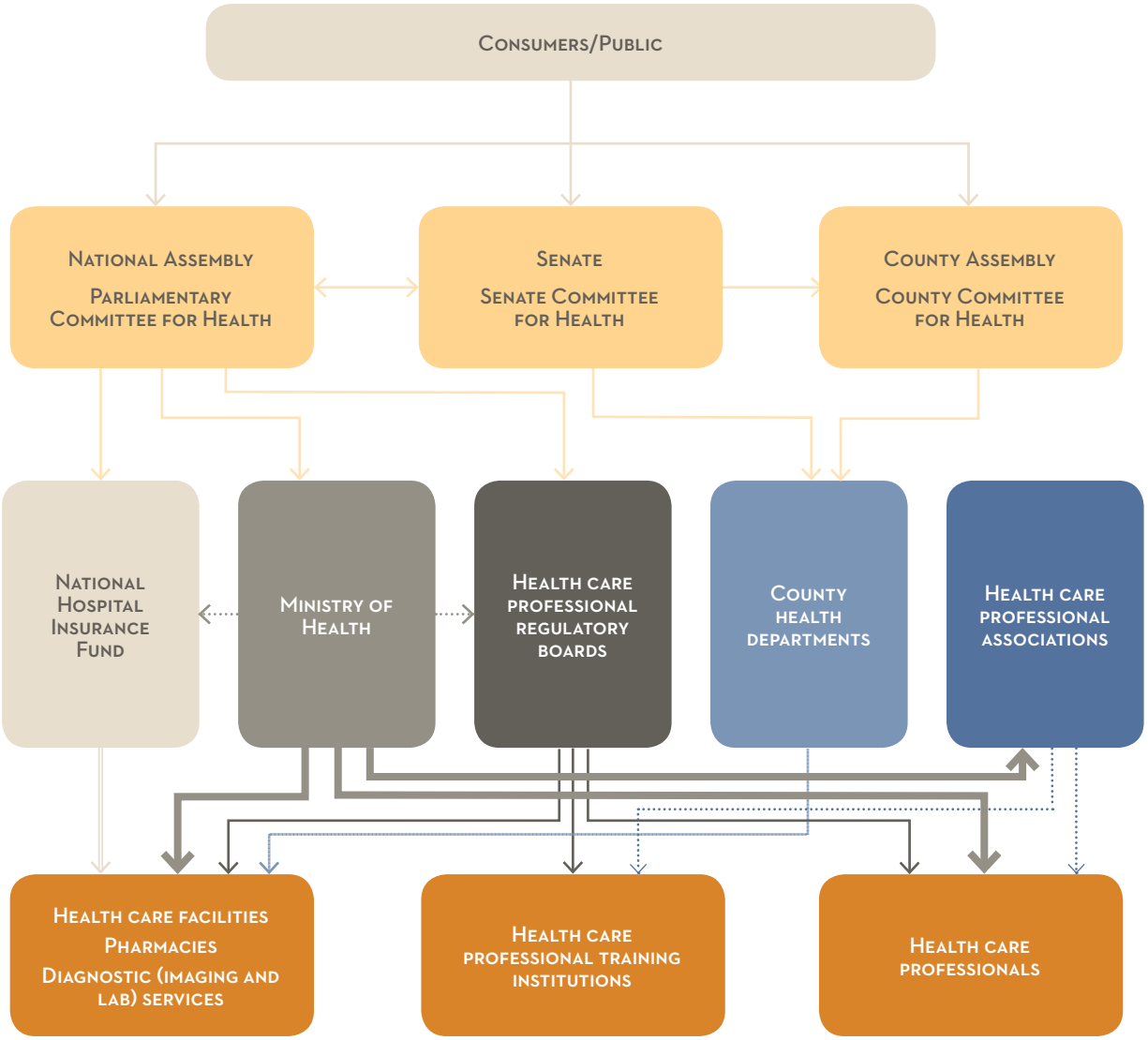
Table 6. Types of Regulatory Actors

Actor	Description
National legislative bodies	Legislative bodies that are responsible for developing and updating health-sector regulations (e.g., health committee of the national assembly).
Ministry of health	The ministry most often charged with supporting development of regulatory policies and providing guidance for implementation. Units within the ministry may also be responsible for regulating private providers by issuing licenses to personnel, licensing and authorizing provider facilities, and conducting inspections.
National health financing agency	The agency that oversees a country's health financing scheme, which may require credentialing of providers and facilities for participating in the scheme.
Subnational government	Local-level (e.g., county, municipality, state) legislative bodies that are responsible for developing and updating health-sector regulations.
Statutory boards	Autonomous bodies created through legislation to perform a specific function, such as overseeing the safety of drugs and medical equipment.
Accreditation organizations	Autonomous bodies that use a certification process to ensure that facilities or practitioners meet a base level of quality or training.
Professional associations	Autonomous bodies that represent different health care professions (e.g., doctors, nurses, midwives, pharmacists) and often perform self-regulatory procedures through association bylaws and other mechanisms.
Consumers	Any groups or individuals that use the health sector, whether insured or uninsured. Consumers may contribute to health-sector regulation through complaint mechanisms, legal recourse for malpractice, and pressure on providers and the government to provide comprehensive and quality care.

In Kenya, the health system is decentralized and relies on county governments to develop and implement local-level service delivery regulations. Figure 1 illustrates the complex nature of interactions among regulatory actors in Kenya. Citizens elect the members of the National Assembly, Senate, and county assemblies. These representatives enact legislation that affects the Ministry of Health, health care professional regulatory boards, NHIF, and county health

departments. These agencies, in turn, develop regulations, policies, and statutes that guide health care professionals, training institutions, and health care facilities and diagnostic services. Kenya has 47 county assemblies that each develop legislation specific to that county. The Senate is also responsible for developing legislation that affects counties. The counties and the Senate therefore have overlapping mandates and could end up developing duplicative, overlapping, or conflicting legislation if they are not well coordinated.

Figure 1. Kenyan Regulatory Regime



Indonesia also has a decentralized health system. The primary operating agent of national health insurance in Indonesia is BPJS-K, which is the chief developer of technical operational regulations, with input from the Ministry of Health. But because the health system is decentralized, local government district health offices lead implementation of the regulations.

By contrast, Malaysia and Morocco's centralized systems give the ministry of health responsibility for facility regulation, complemented by local-authority requirements for establishing private clinics. While the ministry is the main regulator, regulatory power over the private health sector is compromised due to a lack of resources for enforcement.

In Mongolia, the two primary actors responsible for developing and implementing regulation are the Health Insurance General Department, which is responsible for all policy implementation and health insurance, and the Health Development Center, which is responsible for registration, professional training, accreditation, and data on health provider licensing.

Resources for Effective Regulation

All six participating countries noted the scarcity of resources—both human and financial—for regulating health care providers and facilities.

Human Resources

At the national level, most of the countries have between 25 and 100 staff members devoted to regulation across a number of agencies, including the national governing entity (usually the ministry of health), national health insurance agencies, statutory boards, local governments, accreditation organizations, and professional organizations. They include clinical staff (doctors, paramedics, and other medical professionals) and nonclinical staff (administrative and clerical staff). For example, Malaysia has about 77 regulatory staff at the Ministry of Health for a population of 32 million. In Kenya, about 35 staff at the Ministry of Health's Department of Standards, Quality Assurance, and Regulations are responsible for regulation for a population of 43 million. At the subnational level, countries have wide variability in regulatory staffing. In Kenya, for example, marginalized counties in the north have fewer regulatory staff than urban counties.

Financial Resources

In both Malaysia and Mongolia, the national government includes a line item for regulation in the ministry of health's national budget. In Mongolia, the ministry's budget is about US$5.4 million. Kenya does not include a specific line item for regulation; rather, the budget of the Ministry of Health's Department of Health Standards, Quality Assurance, and Regulations supports salaries and other operational expenses for regulation under the larger ministry budget. In Ghana, Kenya, and Malaysia, national regulatory boards are expected to raise sufficient funds through fees to meet their operational expenses, with little supplemental funding from the government.

Despite these differences, nearly all of the countries noted a lack of financial resources for adequate regulation of the health sector. However, Morocco notes that regulators receive sufficient funding for operations. Table 7 shows rough estimates of total line-item funding for regulatory activities in Kenya and Mongolia, the two countries with available data. These estimates are totals for all documented funding, including from national and subnational government budgets and regulatory boards.

Table 7. Total Funding for Regulatory Activities

Country	Funding for Regulatory Activities			
	Total	Per Capita	As a Share of GGHE* per Capita	As a Share of CHE** per Capita
Kenya	US$59 million***	US$0.37	1.6%	0.5%
Mongolia	US$760,000	US$0.25	.23%	.13%

** General government health expenditure*
*** Current health expenditure*
**** National government only (excludes county budgets)*

Regulatory Activities and Performance Indicators

A variety of regulatory activities are stipulated in the country regulatory mechanisms described above. For example, under national legislation such as a private health care facilities and services act, activities might include processing applications to opening a new facility, facility inspections, and sanctions imposed on facilities for not meeting the stipulated requirements. Table 8 lists the regulatory activities in the six countries. Most fall into the command and control category described earlier. The performance indicators listed alongside each activity are the means by which the country tracks the performance of each activity.

The countries carry out many similar regulatory activities. For instance, many of them use accreditation surveys for health facility registration. Other common activities include processing applications to open a new facility, conducting facility inspections, registering and licensing health personnel and health facilities, and imposing sanctions on personnel and facilities.

Table 8. Regulatory Activities and Performance Indicators

Country	Regulatory Activity	Performance Indicators
Ghana	Conducting accreditation surveys	• Number of health care facilities accredited
	Processing applications to open a new facility	• Number of applications
	Inspecting facilities	• Number of facilities inspected
	Registering and licensing health personnel	• Number of health facilities inspected
	Registering and licensing health facilities	• Number of health facilities accredited
	Imposing sanctions on facilities for failed inspections	• Number of sanctions imposed on facilities for failed inspections
	Imposing sanctions on provider personnel due to complaints	• Number of sanctions imposed on provider personnel

Table 8. cont'd

Country	Regulatory Activity	Performance Indicators
Kenya	Conducting accreditation surveys	• Number of health care facilities accredited
	Processing applications to open a new facility	• Number of applications
	Inspecting facilities	• Number of health facilities accredited • Number of health facilities jointly inspected
	Registering and licensing health personnel	• Number of registered doctors and dentists • Number of part-time and full-time private practice licenses
	Registering and licensing health facilities	• Number of registered health facilities
	Imposing sanctions on facilities for failed inspections	• Number of health facilities closed down
	Imposing sanctions on provider personnel due to complaints	• Number of personnel arrested and charged with offenses related to the practice of medicine or dentistry
Indonesia	Conducting accreditation surveys	• Number of districts/municipalities ready for primary care accreditation • Number of public primary care facilities (*puskesmas*) accredited
	Registration and licensing of private health facilities and providers	• Number of clinics and physicians that are licensed
	Coaching primary health providers	• Number of individual physicians or dentists meeting the standard
	Developing and revising regulations	• Number of regulations developed or revised
	Making "commitment-based" capitation payments (pay for performance)	• Number of districts/municipalities with commitment-based capitation
Malaysia	Processing applications to open a new facility	• Number of new applications
	Conducting facility inspections	• Number of inspections conducted for pre-registration, post-registration, surveillance, and complaints
	Imposing sanctions on facilities for failed inspections	• Number of sanctions imposed on facilities for failed inspections

Table 8. cont'd

Country	Regulatory Activity	Performance Indicators
Mongolia	Processing "certificate of need" applications to open a new facility	• Number of certificates of need
	Processing applications to open a new facility	• Number of applications
	Processing applications to open a refurbished facility	• Number of applications
	Conducting accreditation surveys	• Number of health care facilities accredited
	Conducting facility inspections	• Number of facilities inspected
	Conducting facility monitoring and evaluation	• Number of facilities monitored
	Registering and licensing health personnel	• Number of health personnel licensed
	Imposing sanctions on facilities for failed inspections	• Number of sanctions imposed • Number of health facilities closed down
	Receiving complaints	• Number of complaints received
	Reviewing complaints	• Number of complaints reviewed
	Imposing sanctions on provider personnel due to complaints	• Number of sanctions imposed
	Imposing sanctions on facilities due to complaints	• Number of sanctions imposed
Morocco	Conducting accreditation surveys	• N/A (law to enforce accreditation not yet published)
	Conducting facility inspections	• Number of health facilities inspected
	Imposing sanctions on facilities for failed inspections	• Number of sanctions
	Imposing sanctions on provider personnel due to complaints	• N/A
	Receiving and reviewing complaints	• Number of complaints addressed by Ministry of Health
	Paying incentives	• N/A

Regulatory Implementation and Performance

Data on the level of implementation of the activities listed in Table 8 are limited. Only 10% of private hospitals in Malaysia have been accredited (according to 2010 government figures), compared with 40% of Ministry of Health hospitals. In Kenya, of the 5,312 facilities accredited by NHIF, 67% are public and 33% are private. In addition, 130 health facilities were sanctioned or closed and 40 providers were arrested and charged with offenses related to unregulated practice.

To help shed light on regulatory implementation and performance in the six countries, the country teams conducted in-depth interviews and focus groups involving national and subnational government bodies (ministries of health, health financing agencies, regional health directors), regulatory boards and medical councils, professional associations and representatives of provider groups and unions (for both public and private providers), members of the media, academics, and civil society organizations (representing consumers). This qualitative data informs much of the information and guidance in this report.

This section offers lessons and insights from the regulatory assessments and joint learning sessions of the PSE Collaborative. Some of these apply to more than just PHC regulation, and indeed are applicable to regulation across the health system—for both the public and private sectors and for different levels of care.

Overlap of Regulations

Many countries report that their regulatory mechanisms overlap and are duplicative, resulting in inefficiencies. Often these mechanisms stipulate regulation of facilities and providers in slightly different ways or by different actors but with the same purpose. For the private sector, these duplications can add prohibitive costs to starting up a private-sector facility or gaining accreditation or consume too much of private providers' time that could otherwise be devoted to providing services (and thus earning money). An example of this is the health facility registration process in Kenya, in which health facilities are registered by the Kenya Medical Practitioners and Dentists Board. If a private health facility has additional units, such as radiology, laboratory, and pharmacy, it must also register these units with their respective boards. Units within a private health facility, such as radiology, laboratory, and pharmacy, must also be registered by their individual respective boards. The additional registrations lead to high costs for those facilities due to multiple licensing fees.

Ghana has a similar issue. The country has no single guiding document on quality assurance and regulation, which results in duplicative processes among the various regulatory actors. Specifically, there is confusion surrounding the differences in processes for accreditation and credentialing. For instance, a private-sector facility might be required to obtain accreditation from HeFRA, credentialing as part of the NHIS, and credentialing by a private health insurance scheme.

Overlap of Regulatory Actor Roles and Responsibilities

Countries also have overlaps in regulatory actor roles and responsibilities, which increase fragmentation and inefficiency in the system and ultimately put a greater burden on those being regulated. In Malaysia, for instance, various regulatory bodies (Ministry of Health and state health departments) have duplicative roles and responsibilities and often create additional burdens for providers and facilities. Some requirements are also subjectively interpreted by enforcement officers and are inconsistent between central and state regulators. In addition, some of the enforcement activities are not well coordinated to address duplications or inconsistencies. For example, local authorities might specify certain requirements for the building of a clinic that differ from requirements imposed by national-level actors.

Ghana faces similar challenges of overlapping roles and responsibilities, primarily between the NHIA and HeFRA, as described above. While HeFRA is the main health care regulator, the NHIA inevitably acts as a de facto regulator by imposing certain credentialing requirements on facilities and providers from whom it purchases services. For instance, both agencies require separate inspections of staff and equipment, as well as separate licenses for renewal. The lack of defined responsibilities between the two agencies creates redundancies and additional burdens, especially for the private sector. Mongolia faces a similar challenge, with private-sector hospitals requiring accreditation and licensing by the Health Development Center (part of the Ministry of Health) as well as indicator tracking that overlaps with the accreditation requirements through the Health Insurance General Office, which is responsible for generating revenue for the Health Insurance Fund and operates as an independent agency that reports to the Ministry of Health.

Perceived Overregulation of the Private Sector

In some of the countries, the private sector has a perception of being regulated more than the public sector, including being subject to more duplicative inspections and visits, which lead to increased operating costs. In Malaysia, private providers perceive enforcement activities (specifically those of the Ministry of Health) as micro-managing and unfairly regulating the private sector more than the public sector. Respondents from academia and the private sector report having limited opportunity to provide input on laws and regulation. The same sentiments apply in Ghana and Kenya, due to the duplicative nature of regulatory mechanisms and overlapping roles of actors that create additional burdens, primarily for the private sector. In Ghana, most public facilities have not been accredited by HeFRA despite accreditation being the prerequisite to credentialing by the NHIA. This has led private providers to perceive that the public sector unfairly receives preferential "blanket accreditation."

Some countries report that regulatory policies are poorly adapted to the private sector. In Mongolia, for example, regulatory guidelines have historically been developed based on large public-sector facilities (with an average of 200 beds and 300 to 600 employees), so smaller private-sector providers with less capacity (private hospitals with an average of 20 to 50 beds and 30 employees) are unable to meet these requirements. The private providers are, in a sense, blocked from the market, and they cannot receive funding from the national health insurance fund.

Promising Results from Incentives but Continued Dominance of Command and Control Mechanisms

Most of the participating countries report promising results from implementing incentives, both financial and nonfinancial, to improve health care regulation. In Indonesia, financial incentive mechanisms include capitation with pay-for-performance for PHC services and incentives for private providers that are credentialed as part of the national health insurance scheme, JKN, to provide services in underserved areas where public facilities are scarce.

Like Indonesia, Kenya has developed incentives that show promising results in improving provider behavior. In 1998, under the NHIF Act, Kenya established an accreditation system that is linked to reimbursement for service delivery. NHIF accredits and then contracts private providers to provide services. Private providers receive higher reimbursement levels for investing in facility infrastructure upgrades. With support from the World Bank, Kenya also implements performance-based payment through direct financial incentives to health care professionals to improve the quality of maternal, prenatal, and child health services. However, interviews in Kenya reveal that a broader incentive system to encourage providers to deliver high-quality services is still needed.

Despite encouraging results from the use of incentives, most regulatory instruments used by the six countries are still command and control mechanisms that enforce sanctions for noncompliance.

Need for Strong, Integrated Data Management Systems for Performance Monitoring

The six countries recognize the importance of strong, integrated data management systems to ensure efficient data collection and data use, but they all note challenges with data management for performance monitoring. In Indonesia, BPJS-K tracks health facility registration using the Health Facility Information System, but the system is not integrated with the two data collection systems that PHC facilities use to enter service delivery data. This leads to a fragmented data landscape. In addition, the Health Facility Information System is used only in public PHC facilities, which results in lack of data capture from private PHC facilities and limits the government's ability to monitor quality of care. Kenya, Malaysia, and Morocco also note challenges with the availability of timely and

high-quality data. In Malaysia, there is little data sharing between the public and private sectors; in particular, little information is available about the private health sector's capacity and the range of services provided. In Morocco, facility inspection reports are often confidential and are unavailable outside the Ministry of Health, which limits their use by academia, consumers, and other regulatory boards.

Limited Human and Financial Resources for Regulatory Enforcement

Most of the countries report a lack of human and financial resources for adequate regulatory enforcement, as well as inequitable allocation of resources among agencies. In Indonesia, the main challenge in regulatory enforcement and implementation is lack of staff, which affects both the development of regulations and implementation. With a large population and expansive geography, Indonesia has particular difficulty regulating facilities and providers in hard-to-reach island areas. Indonesia also cites financial constraints of private-sector PHC providers to pay for accreditation, which for public-sector *puskesmas* is paid for by the government.

In Kenya, most regulatory enforcement staff are in the Nairobi-based secretariat and are largely engaged in registration and licensing activities. Morocco reports a shortage of human resources at all levels of the health system. In Malaysia, about 336 clinical and nonclinical staff are devoted to regulatory activities across the Ministry of Health, statutory boards, and state health offices. These staff are responsible for regulating private PHC facilities, which number more than 7,000.

Limited Knowledge About Regulation Among Enforcement Officers

Several countries note limited knowledge about regulatory processes among enforcement officers, due in large part to a lack of training. This leads to differing interpretations of regulations at various levels of enforcement (national, subnational, local) and thus delays in licensing. Trainings that do occur may not be compulsory or well structured.

Morocco notes gaps in knowledge among enforcement staff, which often lead to inadequate or disproportionate application of certain legal provisions. Fewer than half of the regulatory actors interviewed in Morocco (including Ministry of Health officials in both central and regional offices, chief officers of health centers, and members of professional bodies) were able to cite the texts and authorities that govern regulation of the private health sector.

Lack of Public Knowledge About Regulations

The country assessments also showed low public awareness of existing regulatory laws, resulting in patients lacking knowledge about their rights and about health care standards and the prices they are entitled to receive. If patients have such knowledge, they can report providers that do not adhere to these standards and prices.

While some of the countries report data on the use of consumer complaint mechanisms—for example, about 152 consumers in Malaysia lodged complaints about private PHC facilities with the Medical Practice Division in 2017—all six countries report that patients are often not informed about regulations and therefore may not know their rights. In some cases, lack of public knowledge about regulations leads providers to take advantage of patients. For example, in Ghana and Kenya cases have been reported of clinical staff practicing under false certifications. In Malaysia, service fee schedules are often not posted at the clinic and billing is not itemized. The public also lacks awareness about regulations in the private sector, including patient rights, appropriate channels for complaints, and legislation that directly affects them.

Summary of Lessons from the Regulatory Assessments

The country assessments document a variety of challenges and opportunities that corroborate global literature and country anecdotal evidence. While the countries have robust regulatory frameworks, implementation of these frameworks has been less than successful. Furthermore, regulation of the private sector remains particularly challenging due to several factors, including persistent system fragmentation (overlapping regulatory mechanisms and duplication of mandates), inadequate funding for enforcement, financial burdens of compliance for the private sector, the government's lack of knowledge about private providers (including where they are and how to regulate them), and lack of knowledge about regulation among providers and patients.

PROMISING INNOVATIONS

The PSE Collaborative members identified several innovations used by JLN member countries that can help mitigate the inevitable challenges of regulating private PHC. These innovations are currently in use by at least one of the countries involved in developing this report. These innovations were identified by PSE Collaborative members from the country assessments as well as during an in-person joint learning exchange in Seoul, South Korea. The innovations described in this section are accompanied by documented country examples where available.

Form a national regulatory technical committee to streamline regulatory oversight. The committee would bring together all parties involved in regulation, including national and subnational government agencies, accreditation bodies, professional societies, representatives from public and private providers, and the community. The committee would be responsible for reviewing and interpreting laws when they are passed, proposing modifications to laws, and determining the most effective and efficient way to apply those laws. This would involve mapping, reviewing, and harmonizing existing regulatory instruments, interpreting and translating laws for greater understanding by providers and the public, and making better use of human resources (streamlining and reorganizing roles and responsibilities).

Kenya: Streamlining Regulatory Oversight

Kenya began exploring health regulatory reforms in 2008 by initiating dialogue between the public and private sectors. The Ministry of Health, in collaboration with the World Bank Group and USAID, subsequently engaged the private health sector in mapping its operations within the overall health sector and exploring ways for private providers to help advance national health goals. Public and private stakeholders then collaborated on a set of reforms to the sector's regulatory framework, including making health inspections more efficient and effective. From 2010 to 2012, the Ministry of Health, health professional regulatory boards, and the private health sector engaged in a participatory process to develop a Joint Health Inspections framework. Regulatory bodies agreed to jointly carry out inspections of health facilities, and the Joint Health Inspections Checklist (JHIC) was published in 2012.

After the JHIC was piloted, an improved version focused on patient safety launched in 2015 along with a toolkit with clear implementation guidelines, a scoring system for facilities, a risk framework for categorizing facilities, and warnings and sanctions to accompany each risk category.

With support from the World Bank Group, Kenya used the JHIC toolkit to conduct the Kenya Patient Safety Impact Evaluation (KePSIE), which tested the effectiveness of two ways of conducting quality and patient safety inspections in three counties: 1) conducting a single intensified inspection of every facility and 2) conducting an initial inspection with a peer-support mechanism and a follow-up inspection. Findings from KePSIE have led to a marked improvement in adherence to infection prevention practices and other patient safety standards.

The Ministry of Health intends to scale up KePSIE to the other 44 counties, with support from the World Bank. The KePSIE project also led to the development of procedures that have been included in electronic versions of the JHIC and a web-based inspection monitoring system.

KePSIE has reduced the burden of inspections by multiple agencies. One individual conducts inspections and shares the results with the regulatory agencies and health providers. Providers receive regular supervision visits and receive continuous feedback on areas for improvement.

KePSIE is a donor-funded project and will need significant investment by the Ministry of Health to expand nationally.

Develop regulatory operating procedures at subnational levels. Even in countries where national laws are well articulated, interpretation of these laws, including laws that govern operating procedures at the subnational level, are often unavailable. Collaborative members have suggested outsourcing the development of standard operating procedures and provider capacity-building trainings to academics and health professional bodies at the local level. Countries might also consider observing the initial implementation of regulations and then revising operational guidance based on these experiences. Countries should expect some time lag between passage of laws and their actual implementation using these standard procedures.

Indonesia: Translating Laws for Local Levels

Indonesia is implementing workshops in local regions on specific pieces of regulatory legislation. ADINKES, an association of more than 500 district and city health office leads, collaborated with the Association of Health Insurance Professionals (PAMJAKI) and the Center of Coding Excellence on a series of collaborative workshops in 2018 in Jakarta to translate a Ministry of Health law to local levels. The law relates to preventing fraud in Indonesia's UHC scheme, the JKN. Representatives from nearly every district and city attended the workshop.

Use purchasing as a regulatory mechanism. While most country regulatory systems are dominated by command and control mechanisms, some countries are using the power of purchasing and contracting to engage the private sector in providing PHC and encouraging improvements to PHC service quality. For example, government purchasers can reduce payment rates if providers do not achieve agreed-upon performance standards. Government purchasers can also encourage private providers to provide more comprehensive PHC (preventive and promotive care in addition to curative care) by requiring providers that receive government payments to provide a specific package of care.

Indonesia: Contracting with Private Facilities

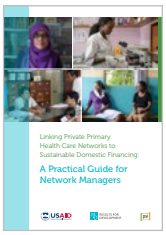
In Indonesia, the JKN purchases PHC services from both public and private-sector facilities using capitation. For private facilities, the payment covers PHC costs as well as operating and variable costs, while for public facilities the payment covers PHC costs only. Contracting with private facilities for PHC services is managed by regional BPJS-K offices. By contracting with private facilities, the government has greater power to control private facility staffing, facility, and equipment standards.

Mongolia: Contracting with Private Facilities

In Mongolia, PHC services are provided free of charge by the government through both public and private-sector facilities. To purchase services through private family health clinics, the Mongolian government contracts directly with private facilities. District governments manage these contracts locally and assess provider performance annually against a set of indicators that include input standards (e.g., number of clinical professionals on staff) as well as outcome indicators (e.g., vaccination rates). The government's purchasing power allows it to better regulate the quality of care provided at private facilities and enforce data and reporting requirements.

Resources on Using Purchasing as a Regulatory Mechanism

Assessing Health Provider Payment Systems: *A Practical Guide for Countries Working Toward Universal Health Coverage*



Linking Private Primary Health Care Networks to Sustainable Domestic Financing: *A Practical Guide for Network Managers*

JLN/GIZ Case Studies on Payment Innovation for Primary Health Care

Financing and Payment Models for Primary Health Care: *Six Lessons from JLN Country Implementation Experience*

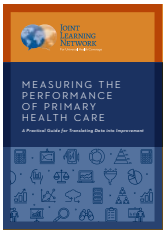
Include line items in government budgets for regulatory activities and have the government finance private-sector credentialing and accreditation. Several countries note the importance of including line items in national and subnational budgets for regulatory activities, as well as being transparent about budget formulation and expenditures to promote greater government accountability. A few countries have suggested having the government finance regulation of the private sector—for example, by paying for the credentialing or accreditation of private providers, who see the fees as a barrier to contracting with the government.

Strengthen data management and data sharing across the public and private sectors, using technology to increase transparency. Countries might consider developing a publicly available facility and provider database that allows regulators to monitor facilities and allows providers and consumers to research health facilities and providers to ensure that they are seeing qualified providers. The database would include basic information about the name and location of the facilities and providers and could include photographs so patients can confirm the identity of the provider they see. The database would also include information on licensing requirements (numbers of qualified staff and equipment), adherence to clinical guidelines, health care outcome indicators (e.g., percent vaccinated), sanctions issued, complaint rates, and other measures. A master database that includes both public and private facilities and providers would allow regulators to better monitor quality.

Indonesia: Standardizing Data Entry

Indonesia is developing a national system called SIKDA Generik to standardize data entry. Data collected using SIKDA Generik will be published on the Ministry of Health website as well as in an annual report, which will be publicly available. The aim of this standardized data system is to increase accountability through active monitoring while also raising public awareness.

Resource on Strengthening Data Management



Measuring the Performance of Primary Health Care:
A Practical Toolkit for Translating Data into Improvement

Inform the public about regulatory requirements through strategic communications efforts. It is important to increase public understanding of health facility and provider regulations and help patients understand their rights through the use of appropriate media platforms.

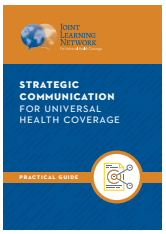
Indonesia: Engaging Citizens Through Technology

Indonesia uses technology-based interaction between the government and citizens, also known as eParticipation, to engage citizens in regulatory activities across multiple sectors. The primary purpose of eParticipation is to increase transparency, inclusiveness, and accountability in decision-making. Each subnational government is also required to develop websites containing information on regulatory products, infographics, financial reports, and online services such as licensing applications. In addition to the regional websites, Indonesia has a more integrated website platform known as LAPOR! ("REPORT!") and is integrating it into the Public Service Complaint Management System in all provinces, districts, and municipalities. The platform has been widely used by citizens to voice their aspirations, raise issues, and submit complaints about public policy and public services. The platform has also provided a way to monitor and evaluate policies, programs, and performance of relevant authorities (e.g., ministries, directorates, national agencies, regional governments, and regional offices).

Kenya: Publishing Information About NHIF Facilities

The *Kenya Gazette* publishes information about accredited NHIF health facilities to help inform the public of where they can access quality care under NHIF. NHIF also publishes information about health facilities that have been sanctioned and can no longer provide services to NHIF members.

Resources on Strategic Communications



Strategic Communication for Universal Health Coverage: *Practical Guide*

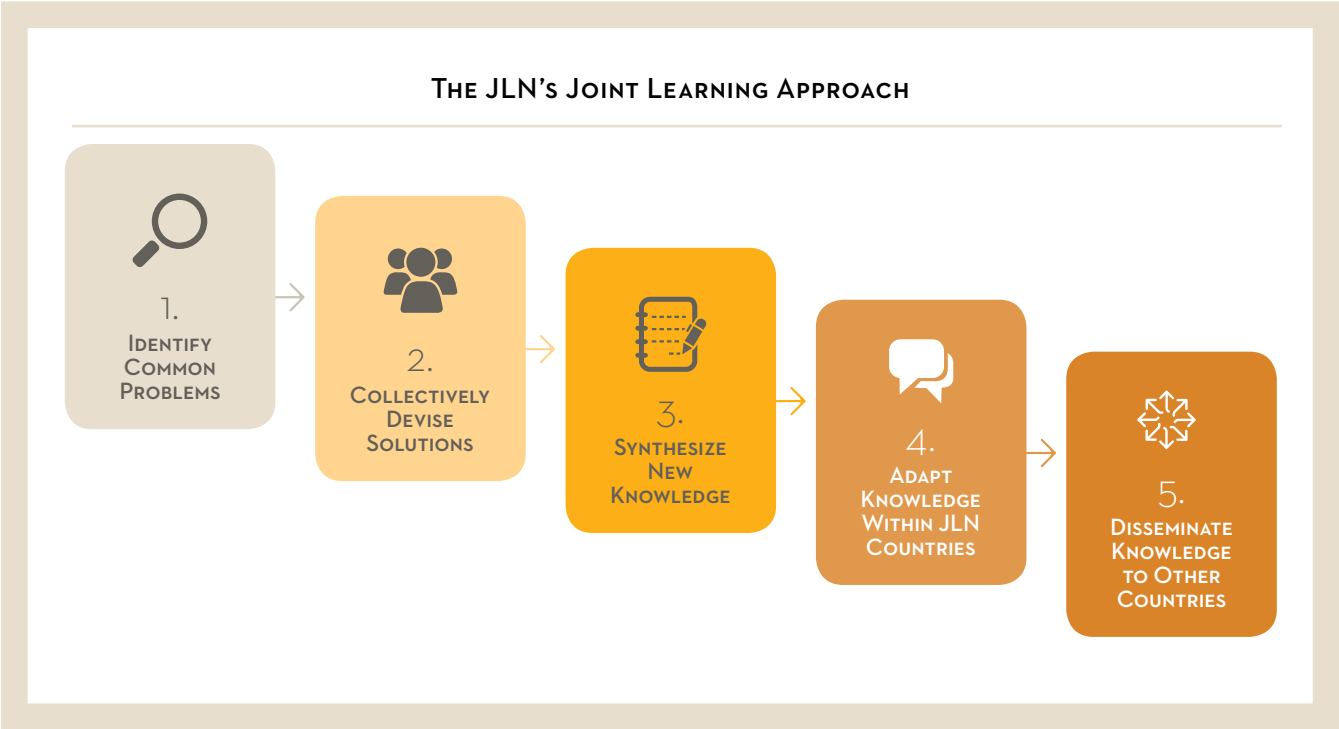
Strategic Communication for Universal Health Coverage: *Planning Tool*

CONCLUDING THOUGHTS

As countries work toward achieving UHC, many country governments are engaging with the private sector to increase population access to quality PHC. Countries that actively engage with the private sector are also recognizing the need to improve regulation of the sector. The JLN PSE Collaborative is helping to capture practical experience and lessons on regulating private PHC from member countries and sharing these experiences globally. The insights and innovations documented in this report can provide helpful guidance for countries, but many challenges remain. JLN countries will continue to jointly seek and share innovations and solutions. Information from this synthesis report will be used to inform Module 3 on regulation in the collaborative's *Engaging the Private Sector in Primary Health Care to Achieve Universal Health Coverage: Advice from Implementers to Implementers.*

ANNEX A: THE JLN'S JOINT LEARNING PROCESS

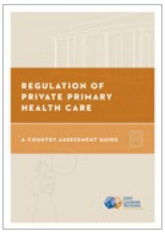
The JLN uses a country-led participatory approach that includes identifying a common technical challenge, collectively working to solve it, synthesizing new knowledge, adapting this knowledge within JLN countries, and disseminating it to other countries outside of the JLN.



The JLN PSE Collaborative identified the challenge of engaging the private sector to provide PHC. In the process of working together to solve this problem, the group drew on lessons and insights from the country regulatory assessments to create this report. This knowledge will be disseminated to JLN countries as well as countries outside the JLN.

Designing the Country Assessments

The PSE Collaborative solicited country interest in participating in the assessments, and Ghana, Indonesia, Kenya, Malaysia, Mongolia, and Morocco applied. The collaborative brought these countries together in Yogyakarta, Indonesia, in February 2017 to share their experiences with regulating private PHC, discuss existing global resources on regulation, and review and discuss drafts of the country assessments.



At the meeting, participants suggested that a style and qualitative methods guide be developed to help the country assessment teams conduct their research. Participants also agreed on a timeline for implementing the assessments. (A final version of the guide for broader use by other countries is available at *www.jointlearningnetwork.org*.)

Based on the discussions in Yogyakarta, the PSE Collaborative set out the following scope for the country assessments:

- ***Focus on regulation of both the private and public health sectors.*** While government may play a lead role in regulation, many other actors are involved, including professional associations and consumer organizations. Regulation of the private health sector is linked to regulation of the public health sector, so these must be examined together. In many cases, specific laws, regulations, and regulatory units govern private providers while public-sector providers are assumed to be regulated by government. In other cases, both private and public providers are subject to the same regulations. The regulatory assessments cover both of these scenarios.

- ***Focus on regulation of service delivery.*** The assessments focus on regulation of the process of providing PHC services and treatments, not on regulation of training institutions, pharmaceuticals, or medical equipment.

- ***Focus on PHC.*** The assessments may inevitably touch on secondary and tertiary care since regulation often covers the provision of any health service without specifying the level of care, but the focus should remain on PHC.

Implementing the Country Assessments

With support from the PHC Initiative technical facilitation team, the six countries began implementing the assessments in June 2017 by first identifying institutions and individuals to carry out the assessments. This process included designating a principal investigator, assembling a team of researchers, informing the team about the background and objectives of the assessments, and delegating tasks. Based on the assessment team's availability to conduct the assessment in a timely fashion, some countries chose to hire consultants for the bulk of the data collection and analysis, while other teams led the work themselves.

Once countries identified their primary research teams, the teams prepared for the data collection process, which involved two distinct phases: 1) document review (secondary data collection) and 2) interviews, workshops, and focus groups (primary data collection). Countries determined how to structure and format the interviews based on their unique context.

Throughout this process, the technical facilitation team was available to provide support on data collection methods and techniques and answer any questions. Countries that were farther ahead in the data collection process were able to share tools with other countries and answer questions.

Sharing the Findings

In November 2017, the six countries participated in a virtual learning exchange to discuss lessons learned from the data collection process as well as initial findings. All of the countries completed data collection by the end of that month and met in person in Seoul, South Korea, in December 2017 to share findings, conclusions, and recommendations from the country assessments. Each country brought a poster that detailed their data collection methodology, findings, and early recommendations.

In early 2018, the countries drafted their assessments with feedback and additional support from the technical facilitation team. In partnership with the technical facilitation team, the PSE Collaborative extracted lessons and guidance from the individual country assessments to inform this report.

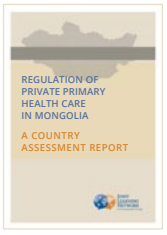
ANNEX B: COUNTRY ASSESSMENTS OF PRIVATE PHC REGULATION

The country assessment reports from the members of the PSE Collaborative are available on the JLN website at *www.jointlearningnetwork.org*. The QR code shown here can be scanned for quick access to the main webpage for the reports.

Regulation of Private Primary Health Care in Ghana
A COUNTRY ASSESSMENT REPORT

Regulation of Private Primary Health Care in Malaysia
A COUNTRY ASSESSMENT REPORT

Regulation of Private Primary Health Care in Indonesia
A COUNTRY ASSESSMENT REPORT



Regulation of Private Primary Health Care in Mongolia
A COUNTRY ASSESSMENT REPORT

Regulation of Private Primary Health Care in Kenya
A COUNTRY ASSESSMENT REPORT

Regulation of Private Primary Health Care in Morocco
A COUNTRY ASSESSMENT REPORT

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