Regulation of Quality of Health Services in India

The Universal Health Coverage context

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The Outline

- The present UHC Context and debates in India
- Mixed Health Systems Syndrome Context
- UHC and quality
- The regulatory provisions currently existing in India for QoC and the gaps
- The implementation
- Conclusions with prognosis for UHC in India vis-à-vis QoC
“I have often referred to the 11th Five Year Plan as an education plan. We will lay the same emphasis on health in the 12th plan as we laid on education in the 11th plan”

&

“...Funds will not be a constraint in the important areas of education and health”

- Prime Minister Dr. Manmohan Singh

Independence day speech 2011
The UHC Context

Processes

- A high level expert group (HLEG) constituted by Planning Commission in Oct 2010 to suggest a roadmap for UHC in India.

- The HLEG group submits its report to the Planning Commission of India in October 2011. HLEG recommends:
  - Increase in finances for health sector to 3% of GDP
  - Strengthening public sector
  - Provision of free drugs
  - Rejection of User fees of any kind
  - Rejection of insurance route and Public Private partnerships (PPPs, purchasing arrangements) in their present forms
  - A slew of Management and Institutional reforms to strengthen regulation and improve quality and access

- Sticky point between HLEG and Planning Commission – Form of Private involvement with HLEG having rejected PPP
The UHC Context

- Another committee, led by a corporate chain, formed by the Planning Commission to get alternative view on Public-private partnerships. The committee endorses the PPP route for rolling out UHC

- The Steering group on health within the Planning Commission meets in Feb 2012 and publishes a subsequent report which proposes a ‘managed care’ model and suggests rolling out on a larger scale (including the non-below poverty line populations as well) the national health insurance scheme (RSBY)

- Debate in the country with the Ministry of health also not happy with the proposal of the Planning Commission

- Meanwhile in the first budget of the 12th Five year plan in Feb 2012, no visible increase in the budgetary provisions for health and no mention of UHC

- Subsequent revision of the draft report in July 2012 with many modifications but the ‘managed care’ model still remains in place.
The UHC Context

- A final report which drops the ‘managed care’ model explicitly but still mentions the PPP route to be taken for the short to medium term till public sector is strengthened and also talks about implementing regulatory reforms to ensure access and quality.

- Meanwhile a second budget of the 12th five year plan is presented in Feb 2013 and again no visible increase in budget for health and no mention of UHC.
Indian Context - The Mixed Health Systems Syndrome

- Mixed Health Systems – Private sector operate side-by-side with the centrally planned public health sector. Most countries’ health systems are mixed

- LMICs like India have some specific characteristics

- Heterogeneity and diversity of providers
  - Formally trained western medicine providers
  - Formal trained providers of Indian systems of medicine
  - Local health tradition providers
  - Informal untrained providers

- Weak Public Health Services
  - Chronic underinvestment in public health systems (less than 1% of GDP)
  - Lack of staff and infrastructure for proper delivery of services
  - Poor quality of service delivery
Indian Context - The Mixed Health Systems Syndrome

- Poorly organized private markets
  - Highly unregulated
  - Inequitable, high Out-Of-Pocket payments dominate
  - Most of the care is in the private sector (nearly 80%)

- Blurring of boundaries between public and private
  - Public personnel ‘moonlighting’
  - Private providers ‘contracted-in’

All these result in

- Unnecessarily High costs of care
- Variable, often poor Quality of Care
- Irregular ethical conduct of the providers
- Unavailability of Care

All these together make up for ‘Mixed Health Systems Syndrome’ (Nishtar 2010)
UHC and Quality of Care

- Quality of Care recognized an important dimension to UHC in addition to financing and access (WHO, 2010)

- Recognizing the importance of quality, the HLEG whose principal objective was to recommend on financial protection mechanisms, expands to include quality along with infrastructure and Human Resources for Health (HRH) issues (HLEG 2011)

- The definition provided by the HLEG has quality as an important dimension and recognizes as one of the ten principles of UHC (HLEG 2011)

- Planning commission plans to incentivize states with extra 3% of the outlay if Quality Assurance (QA) taken up by states (NAC Report 2013)

- Planning Commission in its 12th five year plan document has made achieving quality standards as one of the core principles (Planning Commission 2012)
Regulatory provisions for the QoC in India

Voluntary

- No specific provisions on clinical guidelines / protocols
- No provisions for Continuing Medical Education (CME)
- No provisions for Quality Improvement

Self-regulation

- There are specific ethical guidelines and provisions for complaints against providers for violation of ethics of all the recognized systems of medicine (Various medical council acts).
- No specific provisions for peer review; performance indicators; benchmarking and public disclosure.
- There is a provision for community action for health in certain states in which the communities could monitor and plan public health services
Quality of Care in Health Services

Regulatory provisions for the QoC in India

Economic incentives

There are various purchasing arrangements in place mostly under the rubric Public Private Partnerships (PPP). Earlier it used to be only for central government employees but now schemes are evolved for Economically weaker sections (EWS)

- Chiranjeevi scheme for maternal services;
- National Health insurance scheme (RSBY, Rashtreeya Swasthy Bima Yojana) for secondary and tertiary care;
- Various state Arogyasree schemes for tertiary / quaternary care.

Meta Regulation

- Accreditation body National Accreditation Board of Hospitals and Health care providers (NABH) established at the national level by the government as an autonomous body
- Accreditation also through ISO and JCI (Joint Commission International). Accreditation happening on a voluntary basis
- No credible greivance redressal system with an Ombudsperson in place
Regulatory provisions for the QoC in India

Command and Control

- Licensing and registration of the facilities through the Clinical establishments Act (federal level) and various state level acts (not all states)
- Licensing and registration of the providers through the various council acts – medical council; nursing council; dental council and so on
- The state of Assam has a Public Health Act, which protects the Health Rights of the citizens.
- Consumer Protection Act for dealing with Medical negligence.

Donabedian framework for assessment of QoC

Based on structures (inputs), process and outcome (mortality, morbidity rates) (Donabedian 1982)

In India there are regulatory provisions available only for the structures side of it (registration, licensing etc.,) but very little on the processes side (with accreditation just about having started) and nothing on the outcomes side

In essence, there are gaps at every level of the Regulatory Pyramid !!
Voluntary

- Formal Continuing Medical Education for practitioners is undertaken by certain state chapters of the Indian Medical Associations for their members and that too with the support of the pharmaceutical industry (Sheikh, K et al., 2011).
- Most of the professionals depend on the promotional material supplied by the drug industry representatives for their clinical knowledge updation (Sengupta, A 2013).
- Rising antibiotic resistance due to absence of clinical protocols and the irrational, improper prescription practices (Sahoo, KC et al., 2010).

Self-regulation

- The regulatory bodies have remained more or less loyal to their peers and their close proximity with the medical associations is another added problem. Also there is an active resistance to any form of regulation by the medical associations (Sheikh, K et al., 2011).
- The president of the Medical Council of India (the self-regulating council) had to resign in a corruption case and the MCI was abolished by the government and brought an ordinance to dissolve it in its present form!! (The Indian Express, 2010 http://www.indianexpress.com/news/president-signs-ordinance-to-dissolve-mci/619294/)
- Community Action for health in its nascent stages but has shown promise of better accountability of public health services but oversight of the large private sector is absent due to lack of an entitlements framework.
Evidence (Contd.)

Economic incentives
- Purchasing of services not necessarily from accredited facilities.
- Payment on a fee-for-service basis and not on performance based. Unethical behaviour from the providers doing unnecessary hysterectomies and Appendicectomies under RSBY (Mishra, U 2013).
- Cream skimming by the providers of maternal services under Chiranjeevi (Acharya & Mcnamee 2009)

Meta Regulation
- Accreditation mostly happening on voluntary basis in a small minority of facilities (big corporates) because of the costs involved. Most of the public facilities are not accredited.
- Absence of a credible and responsive grievance redressal system (HLEG 2011)

Command and Control
- Not all states have the CE Acts in place. Where it is there, contested by the medical bodies and modified.
- Lack of regulatory capacities (both finance and staff) to implement the regulatory provisions.
- No concerted action against unregistered facilities. Closure of facilities are rare for want of inter-departmental coordination.
- Very little action on unlicensed practitioners. Revocation of licenses of registered providers are also rare (Sheikh, K et. al., 2011)
- Consumers are averse to approaching the courts for ‘medical negligence’. Compounded by the fact that the courts refer the cases back to the medical ‘experts’ (Bolam test) for opinions and mostly ruled in favour of the defendants (Bhat, R 1996)
Regulation of QoC in India
The Missing top and base of the Pyramid!

License Revocation?

Accreditation of Individual hospitals in minority, public mostly not there

Purchasing arrangements but not PBI

Ethical guidelines; Benchmarking; peer review? Performance indicators; disclosure

? (CME? Clinical guidelines;
Prognosis for UHC

There is a general recognition, in all the reports pertaining to UHC in India, that ‘business as usual’ in a futuristic UHC scenario will only exacerbate the scale of irrational, unethical practices becoming ‘universal’ (HLEG 2011; Planning Commission 2012; NAC 2013)!

Some of the measures to be taken on a priority basis to improve the QoC in India would be to:

- Strengthen the regulatory institutions with adequate staff, infrastructure and financing for better contractual enforcement
- Develop legal and regulatory norms for staff, facilities, access, rationality and costs of care of services
- Formulate standard treatment protocols and rational prescription norms with the help of professional organizations
- Implement a system of regular prescription audits; death audits and in-patient records audits;
- Establish a credible and responsive grievance redressal system based on Patients’ charter of rights
Prognosis for UHC
Some of the measures recommended by HLEG for ensuring QoC in a future UHC system are (HLEG 2011)

- Special cadre of Health Systems Management for taking up such tasks as quality assessment, contracting-in, private provider management etc.,

- Proposal for a National health information Technology network

- Establishment of a National Health Regulatory and Development Authority (NHRDA) with the following sub-units
  - The System Support Unit (SSU) – for development of clinical protocols, QA standards and so on
  - The National Health and Medical Facilities Accreditation Unit (NHMFAU) – for meta regulation of both public and private facilities
  - The Health System Evaluation Unit (HSEU) – monitoring and evaluation of both public and private facilities
Prognosis for UHC

The Planning Commission report proposes to (Planning Commission 2012):

- Enact a National Commission on Human Resources for Health (NCHRH) bill (in draft stage) superseding all the previous councils with more stringent norms

- Upgrade Indian Public Health Standards (at present only for staff and infrastructure) to include QA standards as well.

- Build Quality Management Systems into each facility

- Put in place - Community Action for health; Citizen’s charters; patients’ rights; social audits; public hearings and grievance redressal mechanisms
THANK YOU !!