

# Standards as a tool for health policy and regulation

Which standards, and why?

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# Standards as a tool for health policy and regulation

- Context
- Trends in regulation
- Use of standards in regulation
- Opportunities for global standards in healthcare

# Context

- Relevance to ISO?
  - Which health policy issues are
    - a) Global
    - b) Best suited to regulatory approaches
    - c) Agnostic of differences in health systems
    - d) Best handled by ISO rather than other agencies?

# Context

- Policy instruments include:
  - Advocacy (informing, persuading)
  - Money (spending and taxing)
  - Government action (delivering services)
  - Regulation (legislative power)
- Government procurement and government service delivery are powerful levers
  - What is the track record of government agencies in adopting voluntary standards in healthcare?

# Context

- Choice of policy instrument is critical
- When is regulation appropriate as a policy instrument?
  - When compliant and/or non-compliant behaviours can be observed/ measured
  - When government has the capacity to regulate, and compliance can be enforced/encouraged
  - When the risk to/impact on society of non-compliance is high
  - When the environment to be regulated is uniform enough that uniform rules can be applied and regulation does not result in discrimination

# Context

- Health systems are complex, adaptive systems:
  - Social complexity: many diverse agents, each with high autonomy, interacting with each other and capable of spontaneous and dynamic self-organisation
  - Technical complexity: in terms of both number and nature of technologies used
  - Rapid change

# Context

- Health services are “credence” services
  - Providers have specialised knowledge
  - Difficult for consumers to verify this
  - Consumers in a position of dependence
- Many different ways of organising health services;
  - Public/private
  - Institutional/community

# Trends in regulation

- In many countries, “light touch” regulation and self-regulation becoming favoured:
  - Governments trying to restrain expenditure
  - Politicians prefer less coercive methods
  - More flexible, easier to adapt to rapidly changing market conditions

# Trends in regulation

- Regulation can be applied at the planning, acting or output stages:
  - Technology based regulation:
    - Applied at acting stage – specifies technologies to be used or steps to be followed
  - Performance based regulation:
    - Applied at output stage – specifying social outputs that must/must not be attained
  - Management based regulation:
    - Applied at planning stage – regulated organizations compelled to improve internal management so as to meet public goals

# Trends in regulation

- Responsive/adaptive regulation:
  - Regulators more likely to succeed if they use strategies tailored to the cultures being regulated
  - Uses a continuum, from voluntary compliance through increasingly more formal (and punitive) methods
  - Prepared to move up or down the continuum as required

# Use of standards in regulation

- Light touch regulation references standards rather than embedding rules and norms:
  - Standards can be adapted without changing the legislation
- Voluntary standards are the starting place for responsive/adaptive regulation
- Standards can be technical, performance or management based

# Will voluntary standards satisfy policy needs?

- Does non-compliance pose unacceptable risk?
- Is the policy contentious?
- How often is the product/service used, do consumers value high quality, and can consumers discern compliance/non-compliance?
- Is the price low or high?
- Is it clear who should produce standards?
- Does the industry/sector have a good track record in managing compliance?
- Are there divided opinions on the need for/means of change?

# Standards in service sectors

(Blind, 2003)

- The more innovative & dynamic the service sector, the higher the demand for standards
- The more fragmented the service sector, the greater the benefit of uniform standards
- Service operating internationally have greater needs for standardization
- Need for quality & safety standards is higher in labour intensive, risky services or where communication is important
- "formal standards have a major impact on the success of service companies"

# Standards in service sectors

- Categories of standards for services:
  - Service management
  - Service employee
  - Service delivery
  - Customer interaction
  - Data flows and security

# So....

- Health is complex, adaptive, subject to rapid change
  - Regulation is more flexible and adaptive where it references standards
- The culture of health is to resist encroachment on professional autonomy
  - But greater accountability and transparency are desired
  - Adapting to the prevailing culture is more likely to succeed – implies voluntary (professional consensus) standards

# So...

- There are information imbalances, but communication is crucial
  - Standards are common ground for expectations
- It is difficult for regulators to measure outcomes on a case by case basis, and there may be many paths to a given result
  - So formal regulations are hard to apply

# Opportunities for global standards in healthcare?

- Global policy issues:
  - Globalisation of disease/biosurveillance
  - Population mobility:
    - Health professionals
    - Citizens
  - Quality and safety
  - Mitigating fragmentation – continuity of care
  - Mitigating increasing costs of healthcare

# Opportunities for global standards in healthcare?

Service management	Quality management in healthcare; Risk management in healthcare; Accreditation frameworks
Service employee	Professional competencies; Credentialling
Service delivery	Clinical handover; Device standards; Product (e.g. drug) naming and labelling; Service level classification; Decision support protocols; Incident reporting and disclosure

# Opportunities for global standards in healthcare?

Customer interaction      Measuring customer satisfaction, Accreditation of online health information

Data flows and security      Health concept representation for critical, attestable health data, secure communication, privilege management and access control,

# Opportunities for global standards in healthcare?

Type of Standard	Technical	Performance	Management
Service management			
Service employee			
Service delivery			
Customer interaction			
Data flows and security			

# Opportunities for ISO?

- Partnering with professional groups
- Partnering with clusters of nations with similar reform goals and timeframes

# Challenges for ISO?

- Partnering with professional groups
- Competition between SDOs

# Standards as a tool for health policy and regulation?

- “Success usually comes to those who are too busy to be looking for it”  
(Thoreau)
- We have a great deal to be busy with!