

Innovation Risk Assessment

(Background Material)

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Problem Statement

“An appropriate balance must be reached between government oversight and market innovation.” – IOM Report

- Innovation and government oversight are in tension with one another
- “Balance” is the keyword

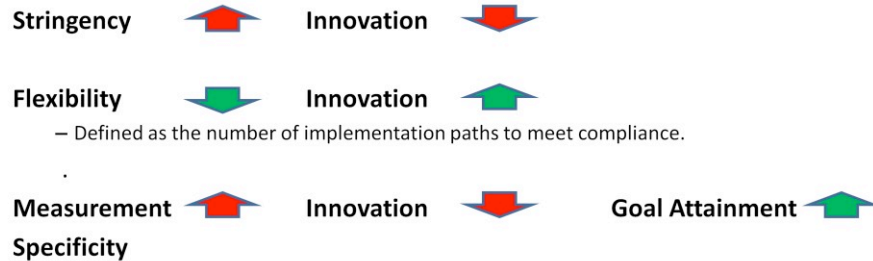
Problem Statement

Innovation is self-sustaining. People, by their nature, are creative. There will be thoughts and actions to improve products and processes. This innovation includes the end users of HIT who combine technologies to fit their purpose and processes as well as developers of individual technologies and software.

Regulation, by its very nature, constrains innovation. Regulation restricts the degrees of freedom in innovation by either prohibiting practices or by prescribing “best practice”. The IOM Report (page 8) states “the government needs to provide guidance and direction to private-sector efforts and to correct misaligned market forces. An appropriate balance must be reached between government oversight and market innovation.” “Balance” is the keyword of the statement. It requires that government oversight and market innovation are in tension with one another. Not all risks, therefore, require the same government response. Rather, the government response should be made in full consideration of not only the source and nature of the risk, but also the impact of the regulation on innovation.

Nature of Innovation Risk

IOM Report, Appendix D



Nature of Regulatory Risk to Innovation

Dimensions of Risks to Innovation

The IOM report *Health IT and Patient Safety: Building Safer Systems for Better Care* includes a study on the impact of regulation upon innovation (see *Appendix D*). The appendix discusses the Innovation Dimensions of regulation. These are:

- **Stringency.** The more stringent the regulation the
 - Less degrees of freedom for innovation
 - Increased risk of disruptive radical innovation to meet compliance
 - Divergence of resources – missed opportunities
- **Flexibility.** The number of implementation paths to meet compliance.
 - The more paths to accomplish compliance the more degrees on innovation
 - The more prescriptive the regulation in describing, or even moving from describing to specification, the desired behavior, the less innovation. In extreme, the software is designed by regulation.

To this list and even implied by this list from Appendix D is to add the dimension of

- **Measurement.** A tenet of creating effective goals is to have effective measurements of the goal.

The more unambiguous the measurement the better for goal realization.

The more unambiguous the goal the less degrees of innovation.

The Measurement methods inherent in the regulation are critical in the assessment.

The tension is between making the measurement method as explicit and, therefore,

reproducible as possible to insure attainment of the goal and innovation that favors a less explicit measurement method.

Nature of Innovation Risk

Progression

–Theory

–Policy

- “provide guidance and direction to private-sector efforts” (IOM Report, page 8)

–Regulation

- “correct misaligned market forces” (IOM Report, page 8)

–Compliance Measurement

Nature of Regulatory Risk to Innovation

Progressive impact to innovation – so not just the intent, but the implementation

There is a natural progression from intent to measurement as follows:

- **Theory.** Recognition of the risk, determination of a goal, and some hypothesis of method to accomplish the goal.
- **Policy.** Statement of goal and marketing of goal. This sets priorities. These priorities “provide guidance and direction to private-sector efforts” (IOM Report, page 8).
- **Regulation.** This it’s the explicit face or implementation of the policy and usually contain consequences for either meeting the regulation (incentives) or failing to meet regulation (penalties). Regulation is the direct way to “correct misaligned market forces” (IOM Report, page 8).
- **Compliance Measurement.**
 - Test cases
 - Consistency and fairness

Policies almost always start out with good intent and represent worthy goals. At this level, it is a incentive to innovation to solve the accomplish the goals of the policy. The challenge is to not let the regulation and particularly the measurement methods overshadow the policy intent by over-prescribing a particular solution.