

Are the laws learning?

A case study of the adaptability of
Health Data Regulations in India

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What is Adaptive Regulation?

“A structured regulatory process that **enables learning** and **modification of policy over time** via adjustments informed by data collection and analysis” Or: “laws built to learn.”

Benbear and Wiener (2019)

Why Adaptive Regulations?

- Static versus dynamic laws/policies

How do laws learn?

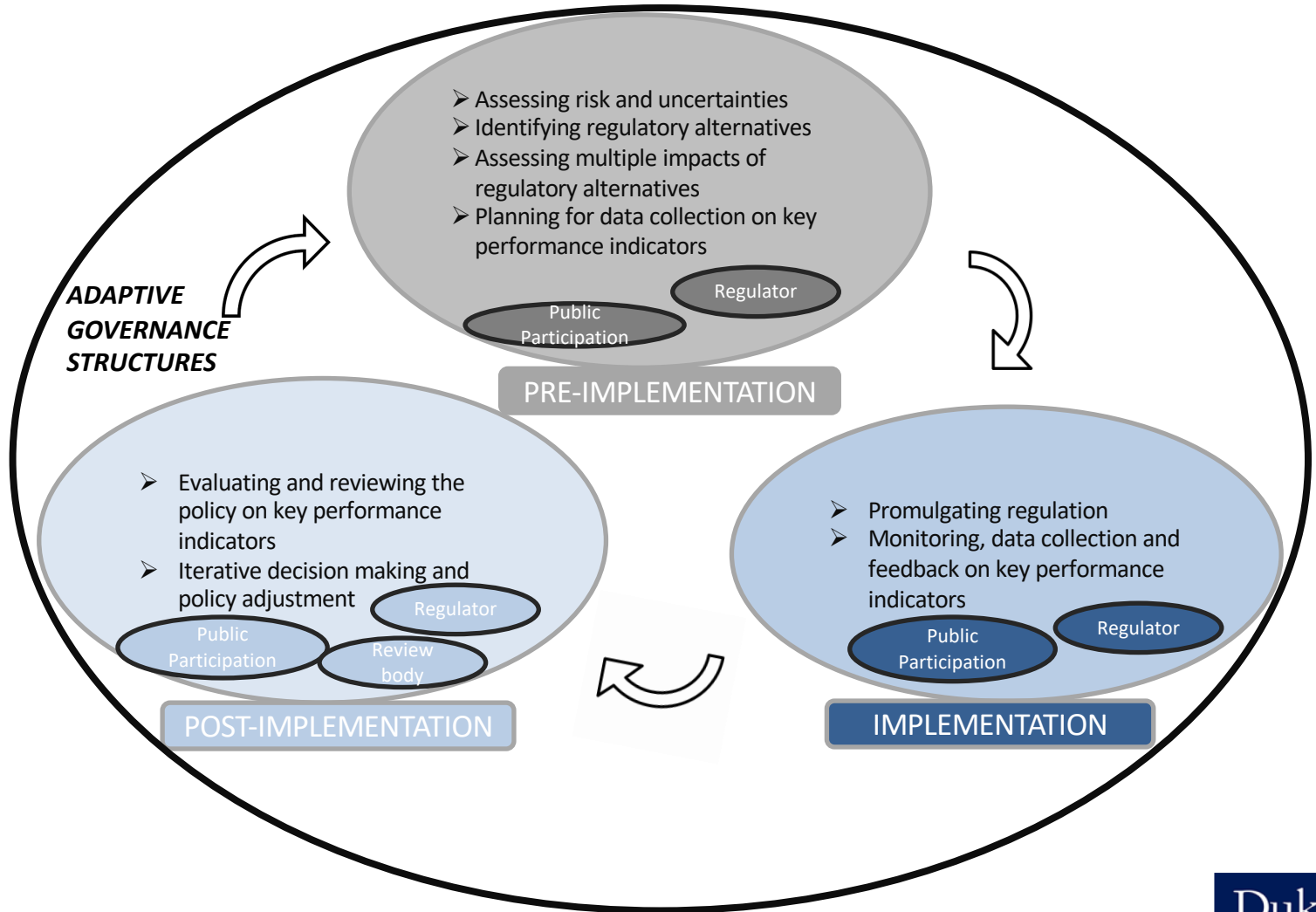
Six Broad features of Adaptive Regulation

1. Assessing risk and uncertainties
2. Broader and fuller impact assessment
3. Monitoring and Evaluation
4. Iterative decision-making and policy adjustment

Two overarching features

5. Public Participation
6. Adaptive Governance Structures

ADAPTIVE REGULATORY CYCLE



Outcome of Systematic Literature Review

Health Data Sector in India (Document Analysis)

Adaptive feature	Health Data
Assessing Risks and Uncertainties	Low
Broader and Fuller Impact Assessment	Low
Monitoring & Evaluation	High
Iterative Decision-making	High
Public Participation	High
Adaptive Governance structures	Low

Low
Medium
High

Criteria- Directed content analysis of the documents to identify law/policy provisions indicating the presence of six adaptive features.

Health Data Sector in India (Interview Analysis)

Adaptive feature	Health Data
Assessing Risks and Uncertainties	Medium
Broader and Fuller Impact Assessment	Medium
Monitoring & Evaluation	Medium
Iterative Decision-making	High
Public Participation	High
Adaptive Governance structures	Low

Low
Medium
High

Criteria- Directed content analysis of the interview transcripts to identify law/policy provisions indicating the presence of six adaptive features.

Health Data sector in India (Document and Interview Analysis)

Adaptive feature	Health Data (On books)	Health Data (In practice)
Assessing Risks and Uncertainties	Low	Medium
Broader and Fuller Impact Assessment	Low	Medium
Monitoring & Evaluation	High	Medium
Iterative Decision-making	High	High
Public Participation	High	High
Adaptive Governance structures	Low	Low

Low
Medium
High

Health Data laws in US and India (Document Analysis)

	Health Data
US and India SIMILARLY adaptive	1. Assessing risks and uncertainties 4. Iterative decision making
India LESS adaptive	2. Broader and Fuller Impact Assessment 3. Monitoring and Evaluation 5. Public participation 6. Adaptive Governance Structures

Similar	
Less	

Criteria- Subjective assessment of the overall presence of six adaptive features in the analyzed Health data law/policy documents.

Normative Framework of Adaptive Regulations

Assessing Risks and Uncertainties

Risk focused and risk proportional regulations

Objective and data driven risk assessment

Multi-risk assessment and management

Outcome-based regulations with risk as an indicator

Considering all evidence on risk-objective and subjective

Transparent public engagement on risk

Enabling legislation

Broader and Fuller Impact Assessment

Regulatory impact assessment in all regulatory stages

Policies with clear problem identification and objectives

Full portfolio assessment

Simple and flexible methodology

Stakeholder engagement and communication of results

Behavioral insights in policy making

Independent regulatory oversight body

Enabling legislation

Monitoring and Evaluation

M&E as an integrated part of policy cycle

Institutional framework for M&E

Identifying data and indicators

Criteria to identify policies for M&E

Criteria of evaluation

Culture of M&E and learning

M&E information publicly available

Iterative Decision-making

Built in provisions of ex-post reviews

Institutional mechanism of conducting ex-post reviews

Criteria to identify regulations for ex-post review

Multiple-rule assessment

Allocated resources for ex-post reviews

Public participation and dissemination of results

Guidance on retrospective reviews

Public Participation

Right to access information

Right to participate in decision-making

Right to review procedure (access to justice)

Inter Agency Coordination

Independent decision-making by agencies

Communicating with other agencies

Consulting other agencies

Avoiding differences between agencies

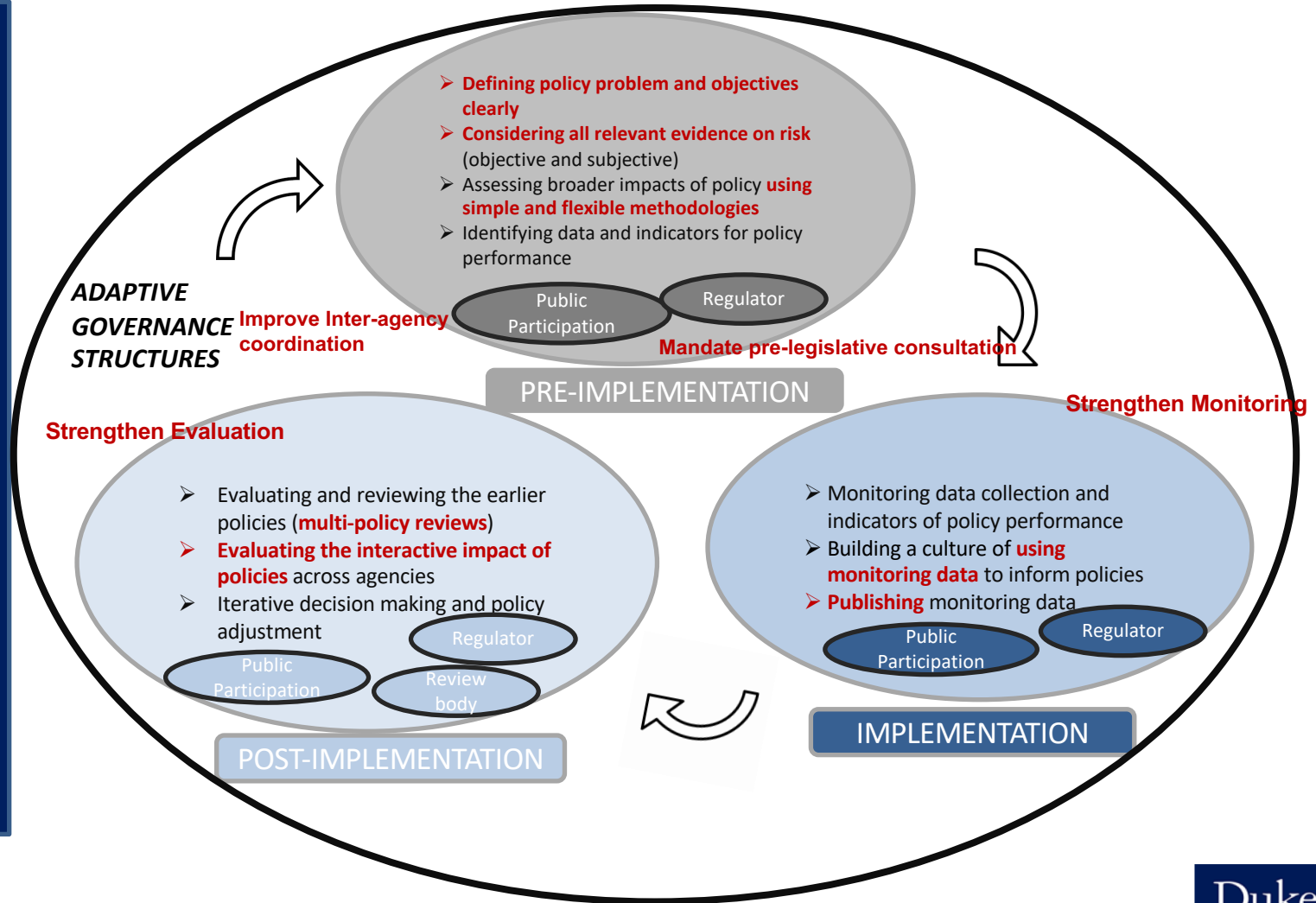
Finding inter-agency agreement

Judging divergencies between agencies

Determining clear government priorities

Whole of government strategy

RECOMMENDED ADAPTIVE REGULATORY CYCLE FOR INDIA



Recommendations for Health Data sector of India

Identified gaps	Source	Recommendations
Limited risk assessment and limited broader impact assessment	Document Analysis	Introduce structured decision-making processes e.g. risk assessment, regulatory impact assessment (suitable to context and capacities such as formalizing and building on the existing agency practices)

Recommendations for Health Data sector of India

Identified gaps	Source	Recommendations
Less structured and less transparent Monitoring & Evaluation (M&E)	Interview Analysis	(i) Identify data and indicators of policy performance in advance (ii) Publish and use M&E data to inform future policies

Recommendations for Health Data sector of India

Identified gaps	Source	Recommendations
Iterative decision-making not informed by formal evaluation	Interview Analysis	(i) Focus on policy evaluation and publish results (ii) More built-in provisions of periodic reviews (Dynamic sector and laws/policies are still evolving).

Recommendations for Health Data sector of India

Identified gaps	Source	Recommendations
Less inter-agency coordination	Document and Interview Analysis	Strengthen inter-ministerial consultation process and multi-agency reviews

Going forward, **adaptive regulatory learning** is the key to improve law and policy performance in dynamic sectors like AI and Healthcare.

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