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GOVERNANCE OF THE TECHNOLOGY-DRIVEN HEALTHCARE SECTOR A COMPLEX SYSTEMIC PERSPECTIVE

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Dominance of technology in healthcare sector has made modern healthcare very different from its predecessor. Modern day complexities of healthcare are owed to its adoption to ever changing technology. From a people centric care by the early healers, modern healthcare system has morphed into a completely different institution where there is increasing interaction of multiple actors and nonhuman players like the products of technologies. There are spheres of dominance and operation for each actor which bring about the ultimate outcome of the system. Dominance of technology and its very fast penetration into the healthcare domain all over the world has of course invited serious debates over its safety. The debates have emanated from two important angles- first, how technology has emerged as an instrument of social control and secondly, how technology has facilitated the process of commoditisation of health. Such concerns have also brought into being the demand and rationale for governance of healthcare technology. This paper examines governance and regulations from the perspective of complexity and shows why healthcare should be considered as a complex adaptive system. Further to its theme of attributing complexity character to healthcare system this paper also examines the theoretical concepts of negotiating the course for good governance through maze of complexity to deliver the desired outcome.

Keywords: *Governance, regulation, Assisted reproductive technology (ART), Complexity theory, Complex Adaptive system.*

Health, Medicine and Technology: Emerging Concerns

Emergence of modern healthcare system, which is accompanied by both medicines and technology, brought about a revolution on peoples' perception about health, diseases and curability. The medicine and technology driven modern healthcare system has by now achieved a degree of complexity and sophistication making healthcare almost incomprehensible by the common masses, and also almost entirely dependent on specialists of health, is mostly perceived as a tool of liberation from disease and therefore a facilitator of longer life. However, the critical discourses on modern health care system, particularly on medicine and technology have pointed out that the tools of healthcare have themselves emerged as instruments of social control. It has also been pointed out that healthcare itself has attained the status of a commodity, particularly under the neo-liberal market economy. Both these concerns have been used as rationale for a regulatory mechanism of the modern health care system,

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particularly the healthcare technology which is in a state of chaos and complexity today. It is interesting to point out that medicine itself has been used to regulate the human body and thereby the society. Regulatory mechanisms often defined as governance is to ensure that rather than allowing medicine and technology to regulate the society, it is high time that society develops mechanisms to regulate both medicine and the technology.

Michelle Foucault and Vincent Navaroo have pushed the concerns on medicine and commodification of health to the centre-stage.

Foucault perceived medicine as a form of social control. Foucauldian concept[1] sees role of medicine as part of a wider social requirement for the regulation and surveillance of bodies. The term bodies mean body of an individual in physical sense and in the more abstract sense the of bodies of populations. According to Foucault, the demand for regulation grew as society became more complex – especially as it became urbanised and brought people together in one large mass. Urban areas have both public and private 'spaces' that dictate appropriate behaviour for the bodies that occupy them. Medicine, and public hygiene, has to be understood within this broader context of public control. Emergence of modern medicine – was central to the disciplining of people as public and private bodies. Technological advancement in medicine or healthcare has given new insights to the physician to exert influence in all forms of social planning for sanitation, city planning, food production and storage, industrial hygiene, recruitment of workers or soldiers, so on and so forth. Thus Foucauldian concept sees healthcare through the eyes of social control, enabling the practitioner of medicine to exercise coercive power over the society.

There are alternative perspectives of healthcare that too needs consideration. If one considers healthcare as a market commodity, to be bought and sold like any other product in the neoliberal era – the need to regulate the same seems justified. Vincent Navaroo[2] has discussed the emergence of medicine and healthcare as Neoliberalism has replaced old social order. It is now well understood from various ongoing debates that healthcare generates profit for two dominant capitalist interests: the finance sector, through private insurance provision; and the corporate sector, through the sale of drugs, medical instruments and so on. In this view modern day healthcare is seen as an industry-state nexus for profiteering.

Both the views concerning healthcare warrants that there be a form of regulation or guidance to effectively nullify the excess or ill effects and promote the desired good effects to human society.

Of late Chaos theory or the concept of complexity have been utilised to improve the understanding of nonlinear or random systems, and healthcare systems are a good place to study the theory of complexity, to deliver controls or interventions more effectively. Complexity science can be understood as a set of ideas that deals with randomness of events emanating from interactions of multiple agents- both human and non-human that will ultimately have a bearing on outcome of a system over a

period of time which is not necessarily repetitive. Modern healthcare system, which is now driven by multiple agents at various levels both horizontally and vertically, is a definite case of a complex system. Understanding the technology-driven healthcare system from the perspective of complexity will facilitate to evolve a mechanism of good governance having implications for a better world of people-centric healthcare system.

Understanding Governance in the Domain of Technology-driven Healthcare System

For us "Governance" is multidimensional concept to begin with. Governance can be understood as a process whereby societies or organizations make their important decisions, determine who the stakeholders are and how they are involved in the process and also how the stakeholders are made accountable.

Modern healthcare system is marked by multiple agents having exposure to and interactions among themselves. Governance of health in this context will imply bringing into such set of rules and regulatory mechanisms which be beneficial to the grater masses. This will also facilitate the healthcare system to come out the chaos. The stakeholders for global health issues now extend far beyond any government. It includes private or commercial entities (multinational corporations); academia; non-governmental organizations such as private foundations, humanitarian groups, multilateral organizations such as the World Health Organization (WHO), the World Bank, and the U.N. development agencies; and bilateral aid structures. Even at the level of local or national healthcare governance the plurality of authority spheres apply.

Technology governance in such a context concerns itself with three important questions:

(a) That a process of good governance should provide a conductive atmosphere for development and deployment of technology.

(b) Identification of the risks associated with technology & its use, and

(c) Resolution of conflicts arising from public perception of risks associated with technology vis-à-vis the perception of the developer or stakeholders in the technology.

We need to concern ourselves with some important facets of the concept of governance to examine its character & extrapolate the concept to theoretical constructions of complexity. The following five facets of governance have been adopted from Garry Stokers [3] work:

1. Governance refers to a set of actors that are drawn from and also beyond the government.
2. Governance identifies blurring of boundaries to tackle social and economic issues.

3. Governance identifies the relations between the institutions or actors.
4. Governance is about autonomous self governing network of actors.
5. Government sees the capacity to get things done by using new tools, which is otherwise not within its capacity.

Healthcare Governance is a mixture of ingredients the sum of which may not be sum total of its individual ingredients. The various actors or institutions in governance system may work with certain autonomy. The following generalizations are inferred based on plurality of authority in healthcare systems–

- There is possible conflict in justifying decisions, and interpretation of rules.
- Blurring of boundaries result in blame game and mud slinging and culture of "scape goat".
- Emergence of autonomy or self regulation might victimize accountability.
- Even after all the effort governments fail to produce results and desired outcomes due to complexity of system issues, failure in understanding the interplay of factors.

Let us now apply these understanding to the state of healthcare in India. Indian healthcare scenario can be understood in different ways and we shall examine it from a system perspective of multitude of players like the population in general, the healthcare provider both public and private consisting of the multitude of workers, the various drug and device manufacturers, regulatory institutions like the Medical Council or Accreditation Organisations, the policy makers and their policies, the social action groups and NGOs, the aid providers like WHO, World Bank, the healthcare activist and interest groups, so on and so forth. To understand the healthcare scenario at any given time we need to include disciplines of public health engineering, industry, environment, economy, so on and so forth – all these having considerable influence on healthcare. We can go on and enlisting the factors or players that will still leave some loco-regional factors, political or socioeconomic factors that has a direct or indirect bearing on healthcare outcomes. If one needs to design a system of Governance in Indian healthcare we can immediately identify the long list of stakeholders. It is not very difficult to argue that the individual participants are enjoying certain degrees of autonomy of function (The population seeking healthcare has a free choice, the aid-givers or device and drug manufacturers have their preferences, the financial institution has a free will of providing support or non-support, so on). It can also be understood that the participants also has dependence on each other in certain cases and their relationship may not be in simple linear argument (viz- like if A produces B, then B is solely due to A) : an example – Population in general are dependant on drug/device manufacturers to get the items that ensure their health, but it is well known fact that the industry do not always produce only what people need, they also manufacture and produce designs that earns more profit and then they create a market for it.

Demand Supply Equation for Regulations vis a vis Complexity Perspective

'Regulation' is by and large a very complex subject in itself. We shall adapt a laypersons understanding of the term in order to concentrate on our topic of complexity of healthcare systems in governing and regulating them. We shall adapt the concept of Johan Dan Hertog as enlisted in the article *on General Theories of Regulation*[4] taking *regulation* to mean the employment of legal instruments for the implementation of social-economic policy objectives. Hertog proceeds to state that legal instruments allow government to ensure compliance of individuals or organizations to comply with prescribed behaviour under penalty of sanctions. Legal instruments can regulate market forces or corporations for pricing, quality control at production by introducing sanctions for violation of prescribed norms.

For our understanding of Complexity perspective of healthcare regulation we first need to understand things from the popular economic theory of regulation[5]. To borrow Richard Posner's description, the economic theory of regulation "asserts that legislation is a good demanded and supplied much as other goods, so that legislative protection flows to those groups that derive the greatest value from it, regardless of overall social welfare."[6]

In the 'demand supply' model of regulation we identify the Interest groups like healthcare providers, Industry, Insurance corporations etc on the demand side of the equation while the legislators and legal institutions populate the supply side of the equation. Legislation flows to interest groups from the legislators in return the interest group provides various support to the legislators to remain in the business. By this we mean that legislators will continue to supply legislation to favoured groups until the benefits in the form of increased political support are outweighed by the costs, which take the form of opposition to such legislation from rival groups. It is felt that Demand supply model is oversimplification of a complex process of regulation where the present day scenario is not well represented. In healthcare issues there are large sections of activists, informed public and interest groups that evolves in to a much complex situation.

Complexity of healthcare regulation or specifically healthcare technology regulation is illustrated in the following example. In India the process of regulating conceptive technologies (like artificial insemination, in vitro fertilisation and surrogacy) commonly known as Assisted Reproductive Technologies (ARTs), are presented as the Draft Assisted Reproductive Technologies (Regulation) Bill & Rules-2008[7]. The supposedly well intended bill tries to ensure that the legitimate rights of all concerned are protected, with maximum benefit to the infertile couples/individuals within a recognized framework of ethics and good medical practice. Women and health rights activists have been looking forward to the drafting of this Bill in light of the unregulated practice of these technologies and the increasing commercialisation and commodification of women's reproductive tissues. The domain of Assisted Reproductive Technology is including the public or infertile couple, the service provider, the technology, the interest groups like Women's right activist, Women's

health activist, the legal community on issues of surrogacy so on. After the draft bill is floated interest groups put the allegation that the Draft Bill tends to regularise and promote the interest of the service providers rather than actually monitoring these facilities. The Bill is seen to be inadequate on many counts like health hazard to women donors, surrogates and the children born through these techniques. The legislation is self-contradictory when it comes to protecting the anonymity of the surrogate. The document, while insisting on a number of measures to be taken to ensure the anonymity of the surrogate, states that the surrogate mother should register under her own name for the purpose of medical treatment and provide the name of the couple for whom she is acting as surrogate. If the legislation makes it mandatory for the surrogate to disclose her identity, then it is unclear as to how her privacy and anonymity will be maintained. The legislation is silent on the regulation of the semen banks in spite of giving them important roles[8]. The document is still ambiguous on certain key areas like the maximum age of women who can opt for ARTs (while mentioning the minimum age to be 21 years), the eligibility of persons from different sexual orientations for accessing these technologies, and listing the disorders/diseases that a gamete donor and surrogate need to be screened for[9]. The Bill contradicts itself at several places.

The point we need to understand is complexity of issues, range of the players in the game of reproductive technology, the complex interplay of factors and dependency and non-dependency of actors amongst themselves, blurring of borderlines so on and so forth. Like in a complex system regulating few steps of the process or few facets may not evolve into the ultimate desirable outcome – in a chaotic environment the initial conundrum itself impinges upon the end product.

Complexity Science Perspective of Healthcare Governance & Regulation

The inherent limitations owing to technological complexities of present day healthcare has resulted in errors in care delivery to patient[10]. Both at micro level of patient care & the macro-level of global governance principles healthcare can at best be termed a complex interplay of forces and agents. The importance of complexity in health care is recognised by the World Health Organisation (WHO), who mandate "Understanding systems and the impact of complexity on patient care" in their curriculum on patient safety for medical schools (World Health Organisation, 2009)[11].

Furthering our understanding of healthcare as a complex system will be difficult without defining "system & complex". In a biological perspective they talk of ecosystem– comprising of plants, animal, land, water and so on. Similarly we can understand healthcare as system made of patient, care giver, drugs, devices, manufacturers, policy makers and so on – all these elements have a common thread in a certain domain . We shall proceed to learn what makes it complex. We shall be brief in attributing the complexity character to healthcare system, and a theoretical discussion on Chaos theory or Complexity science is beyond our scope[12]. A complex system is said to result when they have the following attributes[13] (Table 1).

Table 1
Some features of complexity of health system

Attributes	*Complex system*	*Healthcare system*
Network	Large number of interacting actors	Patient, Doctor, Hospital authority, Drugs, Equipment, Industry, Government, Finance....
Rich interaction	involve human –human or human-material (nonhuman)	Doctor-patient interaction, Devices – patient interaction, Patient-drug interaction, Healthcare administrator-doctor interaction, Policy-manufacturer interaction...
Independent interaction	Actors interact between and amongst themselves independent of other interactions , and are ignorant of the behaviour of the system as a whole	Patient gets treatment without knowing the manufacturing practices, Population in general do not understand the intricate network of whole health system
Nonlinear interaction	Small interaction may produce large results, vice versa	Exempting regulatory control or taxes on vaccine may avert an epidemic
Open system	Complex system are open system and progress over time and changes	Health system is closed only at global level, local disease spread effects global outcome. Even at global level large scale changes in health system occur as in global warming, pollution etc.
Non equilibrium	Complex system are not at rest, they evolve	Health system has evolved from a simple visit to the doctor, to an all encompassing *medicalization* of life. System have more and more actors today than a century or decade ago.
History	Complex system exists over time and has a history, their past has a bearing on their future	History of healthcare shows how discoveries and inventions have shaped the modern day medicine.

In the earlier days Complexity perspective of healthcare, a series of articles published in British Medical Journal , started the debate and understanding of complexity concepts in health care. Healthcare as complex adaptive system (CAS) was proposed in the *British Medical Journal*[14,15,16] in 2001. For our understanding Attributes in a complex adaptive system are summarised in Table 2.

Table 2
Attributes of Complex Adaptive System

Attribute	*Complex Adaptive System*	*Healthcare system*
Fuzzy boundaries	Boundaries are blurred (fuzzy), rather than fixed, and well-defined	In healthcare system multiple authority sphere is seen. *A patient is simultaneously treated by different specialities.*
Internalised rules	• Agents' actions are based on internalised rules	Different actors are operating based on their own rules. *Nursing management and medical administration are subsets in each other's domain.*

Contd...

Attribute	*Complex Adaptive System*	*Healthcare system*
Adaptability	• Agents and system(s) can adapt to local contingencies	Depending on resources work practice differ. *Different Nurse patient rations in different wok environment.*
Embeddedness	• Systems are embedded within other systems and evolve over time	Drug dispersion system comes under nursing administration which in turn is inside the general management, which is operating with state health regulatory frame work.
Tension & paradox	• Tension and paradox are inherent, and do not necessarily need to be resolved	There are different view points between specialities and they co-exist. *Patient can get treated conservatively or by radical surgery in many diseases- both are valid.*
Non-linear interaction	• Interaction leads to continually emerging, new behaviours • Non-linearity is inherent	The actors interact amongst themselves continuously and level of interaction is not related to outcome. There might be well intentioned policies brought in by administration, results are not tangible on account of new behaviour pattern.
Unpredictability	• Unpredictability is inherent	How healthcare outcome will actually happen is not predictable with specificity, but the outcomes are actually understandable.

In the CAS concept as proposed in BMJ, the idea of Self-organisation is contested. The initial proposal was that self regulation in a complex system means the actors regulate themselves locally. The alternative views of complexity agree with several of the attributes listed above, but they do not go as far as resorting to complexity science to find the solution[17].

Understanding complexity in healthcare will be incomplete without realising some of the source of complexity. There is some agreement about the sources of complexity in health care, even though there is no single definitive list. This is partly because of the wide range of stakeholders involved in health care, many of whom will have different perspectives on the issue of complexity. From our own experience in healthcare industry a tentative list (Box 1) is prepared which can be seen as an indicative list, far from a complete one.

Box 1
Indicative List of Source of Complexity in Healthcare System

(a) People factor at healthcare provider: Poor training and lack of expertise
(b) Work environment factor: Work Volume, including workflow, time pressure.
(c) Technology factors: Dependability, usability and the operational issues
(d) Team factor: Effective communication, clarity of roles, and leadership
(e) Environmental factors: Including physical layout, lighting, and heating
(f) Organisational factors: Including organisational structure, culture
(g) Policy factor: Scope of policies and enforcement
(h) Regulatory factor: Presence or absence of regulation & their enforcement.

Discussion: Working through complexity of healthcare system

There are few, if any, examples of how complexity science has been applied to solving the problem of complexity in health care. There are many ways of dealing in complexity of healthcare systems without using complexity science. One obvious working idea may be reducing complexity, minimising source of complexity to encourage linear system of interaction which is better controlled. Few suggestions may be:

- Improved understanding of the working of system and performance shaping factors;
- Simplifying operations, where possible.
- Monitoring and managing complexity as it changes over time.
- Understanding that complexity changes as the system evolves over time.

To improve our understanding on intervening in complex system we shall use simple diagrams. BMJ article used these illustrations, which are being reproduced without modification here.

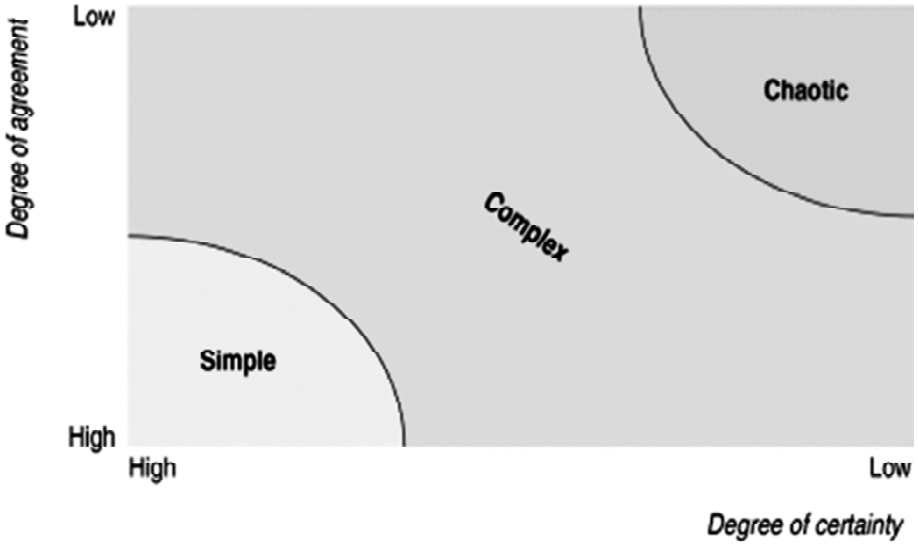

Figure 1: The Certainty-agreement Diagram[13]

Figure 1 states the effective concept of complex system as an area of intermediate agreement and certainty. Once the disagreement as well as uncertainty of outcome rises systems become chaotic. Most health system is in the area of complexity, rather than in chaos. Chaos theory predates complexity thinking, and discussion of chaos in this article is avoided. Figure 1 can be referred to see behaviours of actors in the system and the level of certainty of outcome. When the various factors or actors of the healthcare system disagree the observer is uncertain of outcome, and vise versa.

How do we chart our course in complex healthcare environment is a big question. There are views and suggestions, in Figure 2 (adopted from BMJ).

From the perspective of regulation and governance in complex system it can be said that complex system should have simpler rules, to produce an outcome. Inherent complexity of healthcare system will not benefit from complex sets of interventions whose final outcome is less predicable. Chunking is a term used to understand that not all problems or concerned needs to be addressed at once , if some are addressed the system complexity will change and a new environment with new factors and actors will emerge. Healthcare systems needs to be studied over a period of time to understand the complex interactions of nonlinearity to device regulatory controls in small little steps.

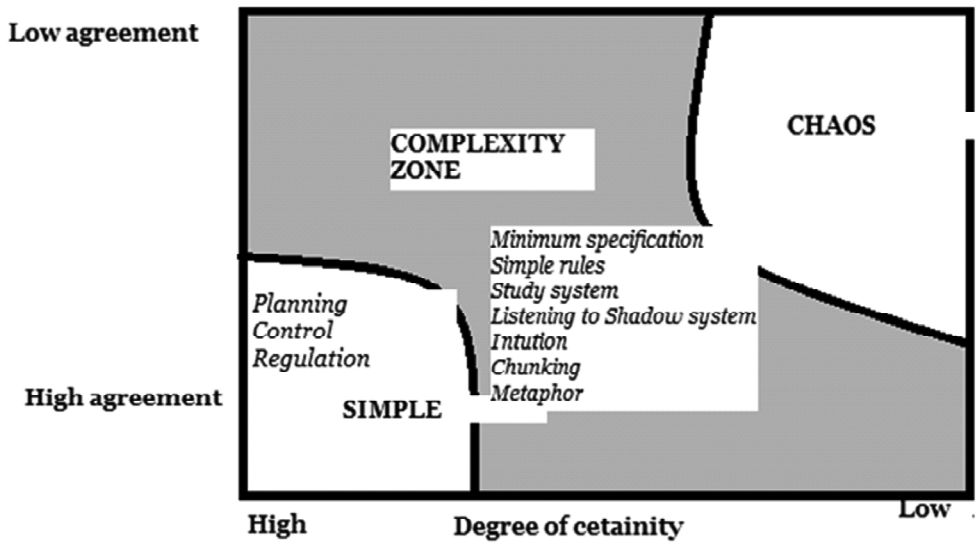

Figure 2: Charting Course in Complexity (Adapted and Modified from BMJ[18])

To act on complex system of health it is imperative to build capability in the process of governance. Any attempt at good governance must bring in capability – the the ability to adapt to change, generate new knowledge, and continuously improve performance. Regulating a familiar technology or system in a level of certainty is competence whilst regulating a system which is not familiar and evolved over time needs capability.

Learning takes place in the zone of complexity, where relationships between items of knowledge are not predictable or linear, but neither are they frankly chaotic. Learning which builds capability takes place when actors Interact.

For example there has been an attempt in understanding the Global regulatory efforts of medical devices and technology by the Indian regulatory institutions. There

is an attempt to classify medical devices based on global learning experience, and the in new set rules are trying to regulate them effectively. The process of learning complex regulation of today's medical devices is building capability to regulate Nano-medicine in the next decade. Efforts at regulating packaging or labelling of medical devices changes a whole lot of practices at the end of manufacturerer, that is expected new system of complexities. Thus one can see regulations change the system a bit, settle down to newer level of complexities – thus reinforcing the concept of need for continued observation and adoption.

Final prescription to chart complexity of healthcare will include suggestions like–

1. Identifying the sources of complexity. This includes noting where simple approaches break down.
2. Understanding the strategies used by individuals, teams and organisations to cope with complexity.
3. Creating better ways of coping with complexity based on learning.
4. Simple rules and specifications to increase compliance and reduce variations.

Conclusion

The perspective of complex adaptive systems brings in new concepts that can provide fresh understandings of troubling issues in the organization and management of delivery of health care. We have planted the idea that governance of healthcare system needs to consider healthcare as a complex interplay of factors and actors where changes are not proportionate to interventions. Complex healthcare system is adaptive and tends to evolve with each new input or change in environment. Those who seek to change an organization should harness the natural creativity and organizing ability of its stakeholders through such principles as simple rules, minimum specification, constructive approach to variation in areas of practice where there is only moderate certainty and agreement.

Barrier to more inclusive Governance process seems to be the age old hierarchical command and control methods. Researchers on Indian healthcare system will agree that the command control approach to governance is not yielding results, rather it has created numerous new complex subsystems fuelling corruption.

Stakeholder participation and building an adaptive system that complies with simple rules & specifications can reduced complexity of Indian health system where more issues will fall to high agreement and certainty zone.

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