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EDITORIAL

# The Future of Health and Science: Envisioning an Intelligent HealthScience System

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## 1 Introduction

The term "healthcare system" is commonly and loosely used to describe the existing disconnected, inefficient, ineffective and expensive approach to health management, including disease prevention, diagnosis and treatment. The unfortunate reality is a complex array of proprietary enterprises, from individual and group medical practices, hospitals and medical centers, to networks of affiliated centers and practices. These range from small to huge in both size and complexity, all attempting to use technology and best-practices to deliver evidence-based care to a variety of patient populations with varied economic means and accessibility. Simply put, even without delving into technological, administrative and financial realms, clearly, a healthcare *enterprise* exists, but it falls far short of a true healthcare *system*.

A recent article in the *IEEE Systems Journal* bluntly notes: "The definition and characteristics of systems have eluded recognition and understanding for a very long time, as different people refer to the concept of *system* in various ways," adding that one survey of experts used "100 definitions of system and formed assumptions and hypotheses about the different worldviews represented by different groups of definitions." [1]

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The consequences of not understanding a true systems approach to healthcare and biomedical research plague the health endeavor today as evidenced by the ongoing COVID-19 pandemic. From a systems perspective, the COVID-19 pandemic has fostered confusion as to what is and what is not a systemic intervention even while also offering useful insights into how the situation might be improved.

Systems thinking, grounded in systems engineering principles, has been utilized by "high hazard" enterprises to deal with identification and prevention of catastrophic events in mission-critical situations, e.g., a nuclear reactor core meltdown or prevention of aviation accidents. Systems thinking and engineering have improved transportation and distribution systems and banking operations, benefiting many. Even today's automobiles are themselves elaborate systems capable of transporting their occupants in comfort and safety, sometimes without a driver!

Despite decades of discussion, application of systems thinking and design principles to health and science remain elusive at best. In some microcosms, success has been achieved by limiting the scope of the size and complexity of the endeavor. Yet, to be effective, a systems approach to health and science must encompass the entirety of healthcare and biomedical research–the people, processes, policies and technologies, and the many stakeholders, each with their own agendas and vested interests. Ways that healthcare and biomedical research currently affect each other and how they should in the future can be improved through enhanced systems development.

## 2 Looking Beyond the Current State

At present, promising work is being done in developing the Learning Health Systems (LHS) concept [2–5]. As conceived, a LHS is an evolving health, research, and technology ecosystem that is potentially transformative for all stakeholders. This requires understanding what exists and how it operates, all while promoting a vision of a future state, leveraging identification of critical pain points, pressures, and operational gaps. Measurements of progress and adaptations learned from failures within the healthcare environment are valuable. The intentions of the LHS approach are laudable, but its impact has as yet been marginal.

Expanding and more rigorously applying systems-thinking and systems engineering principles to the conceptual underpinnings of a LHS, one can envision a future state that can be characterized as a comprehensive *Intelligent Health-Science System*. Through systems thinking and design, health and science can be more than merely integrated. Beyond people, processes and technologies working together in a fully coordinated and synergistic fashion, application of advanced analytics, artificial intelligence and machine learning, error analysis and other tools can render the system "intelligent"--that is, capable of actually augmenting our limited human abilities to search, analyze, interpret and apply data and real world experience. Doing so would likely improve outcomes, identification of risk factors and prevention of disease across diverse populations, optimize care (both precision and personalized), while also optimizing safety, accessibility and economics. Indeed, such an integrated 'intelligent system' could revolutionize our approach to healthcare, public health and medicines development, all while saving enormous amounts of resources, enhancing productivity, equity and quality of life.

Any design for an Intelligent HealthScience System must include what has traditionally been called "hard" and "soft" systems dimensions. "Hard" systems dimensions are those at the focus of systems engineering, predicated on a clear picture of the problem(s) at hand and the desired future state, which allows for clear steps to be followed to reach this outcome. "Soft" system dimensions identify issues that all agree need resolving but consensus on what the root problem is cannot be found, nor is the desired outcome agreed upon by all parties, e.g., global warming. Soft systems methodologies are useful for solving such complex "wicked" challenges.

Soft systems are often equated with and intimately related to human factors. These are exemplified by the difficulties of dealing with an event like the COVID-19 pandemic, where there are significant and diverse social, political, economic, equity, healthcare, and research aspects that cannot be dismissed. Underlying each position there is a worldview that arises from individual and group cultural beliefs, values, assumptions, and personal experiences. Each worldview is the filter through which the world is interpreted and assists in decision-making [6]. A hard systems approach alone is not equipped to deal with this type and extent of complexity. Together, hard and soft system perspectives provide an understanding of what happens among components of a true system, reinforcing its fundamental and essential integrated, i.e., interconnected and interdependent nature.

The value proposition of an integrated Intelligent Health-Science System is powerful. Well before the COVID-19 pandemic, the biomedical research and development and healthcare ecosystem had been confronting challenges of leveraging such technologies as artificial intelligence, machine learning, and natural language processing. Difficulties in collaborating, both within and among organizations, overcoming "silos" and resistance to deep process transformation posed challenges to progress, as did slowly-responding regulatory actions to address problems posed by the development and adoption of new technologies. The pandemic merely heightened awareness of these shortcomings and intensified calls for action.

## 3 Core Challenges

Numerous platforms, applications and algorithms have been developed to improve healthcare, but core challenges persist. The abundance of these challenges requires systemic understanding and attention. Creating an Intelligent HealthScience System requires public trust and engagement beyond that currently addressed in non-systematic "patient-centricity" initiatives. The direction of personalized medicine reinforces this necessity in both research and care–the ultimate decentralized clinical trial (DCT), "trials of one", and analysis of what is now appreciated as "real world evidence."

Historically, the healthcare enterprise as we know it bears little resemblance to a true integrated system. Rather, it is a maze of healthcare and research silos, proprietary and competitive networks and business endeavors that effectively work in opposition to, rather than in support of, system integration. The current state reflects stakeholder self-interest, and intentionally limited interconnectivity, optimizing one part at the others' expense. An integrated systems approach to health, science and business, supported by technological innovation, could positively impact wellness, disease management, knowledge creation, outcomes, productivity, quality of life, medicines development, and, yes, cost.

To securely acquire, share and apply knowledge in the current healthcare environment is challenging. For example, chaotic and episodic acquisition and application of both new knowledge, and confronting misinformation, has greatly challenged an effective response to the COVID-19 pandemic. The trajectory of the pandemic, and of health more broadly, is influenced by multiple agents, each acting upon, and is acted upon, by other agents in the system, often in unknown ways. Systems on the other hand are designed to deal with multiple, potentially flawed data streams affecting complex interactions of humans, hardware, and information to overcome such shortcomings.

Multiple data streams and varying types of data from disparate technologies contribute to an ongoing need for standardization. Limited progress toward harmonizing healthcare and data standards with existing global research standards is inadequate. A better understanding of the value and challenges around data formats and data sharing should encourage pressure for vendors to support standards that enable interoperability among technologies to support a true systems approach.

Security and trust are essential. A collaborative enterprise-wide therapeutic ecosystem spanning care, research, medicines development, regulatory and ethical oversight, and broad public access requires a robust, secure and trustworthy systems approach by stakeholders, simultaneously addressing comprehensive change management and transformation.

Decision makers too often confront vested and short-term (i.e., typical bottom line) interests and impediments to change. Impediments to potential benefits and gains from greater longer-term socially purposeful planning and bridging operations could be overcome through systems thinking. Unfortunately, decision makers in the current environment are not inherently systems thinkers and the disconnected, highly siloed enterprise is not conducive to an integrated systems approach.

## 4 Elements of Systems Modeling

Development and delivery of effective therapeutics are embedded in complicated subsystems that need to be orchestrated into an integrated system, as opposed to the currently fragmented environment. The current state is a collection of loosely integrated entities and functions at best. Too often, one element may be optimized while ignoring, and detrimentally impacting, its connectivity and interoperability with others. For example, most healthcare guidelines and clinical trials are disease-focused rather than person-focused, failing to address multiple health challenges associated with an individual patient. Similarly, well-intentioned efforts to protect the privacy of patient information has unintentionally, but knowingly, impacted the ability to access, share and analyze patient data–what many cancer patients refer to as “protecting us to death”.

Most essential to effectively bridging healthcare and research is this fundamental principle: A system is “an arrangement of parts or elements that together exhibit behavior or meaning that the individual constituents do not” [7]. Put simply, the performance of the whole exceeds the capability of the individual parts–together they produce *synergy*.

### 4.1 Modeling an Intelligent HealthScience System

One approach to facilitating systems thinking is modeling. A systems model or map can represent the various agents and their interactions, allowing both analysis and aggregation of their individual functions and behaviors using tools such as Agent-Based Models (ABM) and Systems Dynamics Models (SDM).

The validity of ABM is well established [8]. The complexity of healthcare makes it difficult to identify and understand all the potential interactions that occur, but “ABM can also incorporate ongoing learning from events whereby patients can be influenced by their interactions with other patients or health workers and by their own personal experience with the health system” [9]. Hybrid models may produce better results by taking advantage of the strengths of different methods and mitigating their weaknesses [9].

Similar models can be created to bridge healthcare and biomedical research. Although such an undertaking may seem overwhelming, there are established systems languages and methodologies, such as Object-Process Methodology (OPM), to support the effort that have been adopted as a standard by the International Organization for Standardization (ISO) [10].

The OPM model integrates the functional, structural, and behavioral aspects of a system in a single, unified view. Although the model is not the solution to a problem, methods like OPM allow expression of all the components of the environment and the different kinds of interactions among them.

OPM is based on a minimalistic universal ontology, in which “everything … is either an object or a process, and a process is not necessarily a method of a single object class… open[ing] the door for the possibility of modeling systems so that both their structural and procedural relations are represented within the same frame of reference without suppressing each other” [11]. In brief, visualizing what must be done significantly helps to realize the transformation.

As an example of this approach, Figure 1 presents a top-level Object-Process Diagram (OPD) of an Intelligent HealthScience System and the health promoting processes that it would enable. A unique feature of OPM is its bimodal representation in both graphics and natural language text. In this OPM depiction, objects are presented as green rectangles and processes are presented as blue ellipses. Inter-relationships and exchanges are illustrated by directional arrows.

Data to support this model come from multiple sources, including known interactions among identified agents and components, but many of these can, should and in all likelihood will change. As new agents and interactions are identified, they can be added to the model and their impact (effects of new data, estimating consequences if flawed) assessed.

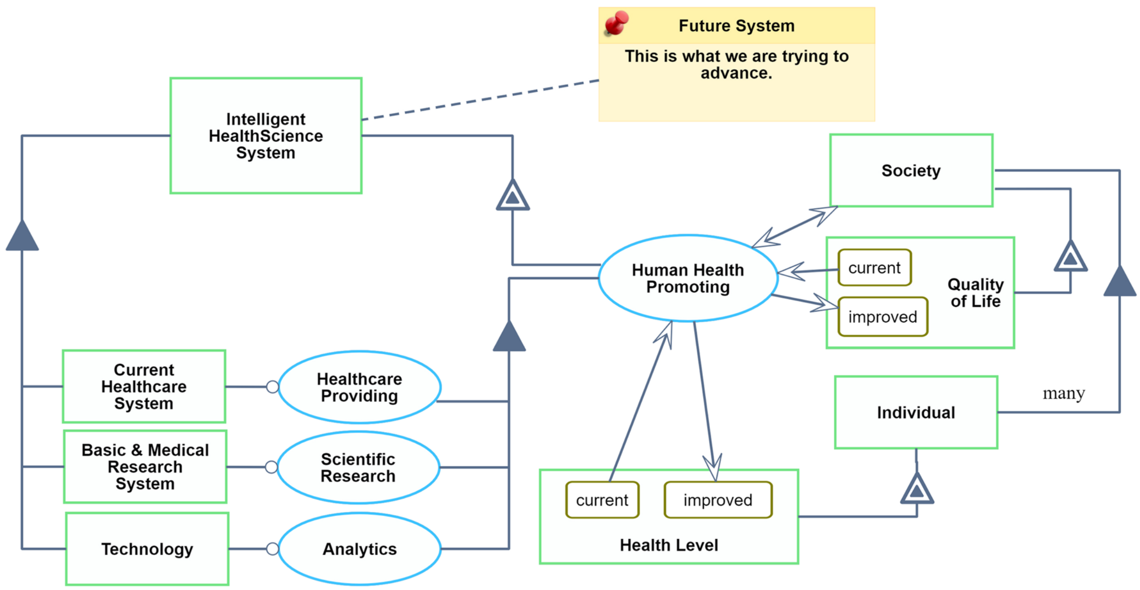


**Fig. 1** Top-level Object-Process Diagram of an Intelligent HealthScience System. Objects are presented as green rectangles and processes are presented as blue ellipses. Inter-relationships and exchanges are illustrated by directional arrows. Society consists of many Individuals. Intelligent HealthScience System exhibits Human Health Promoting. Human Health Promoting of Intelligent HealthScience System affects Society. Society, which is the assembly of its many individuals, is expected to be affected by the process Human Health Promoting, which is the service enabled by our envisioned Intelligent Health System. Human Health Promoting consists of Analytics, Healthcare Providing and Scientific Research. The Human Health Promoting process comprises three sub-processes: Healthcare Providing, Analytics, and Scientific Research, the integration of which is expected to generate the synergy and promote human health. Intelligent HealthScience System consists of Basic & Medical Research System, Current Siloed Healthcare Environment and Technology. Scientific Research requires Basic & Medical Research System. Healthcare Providing requires Current Siloed Healthcare Environment. Analytics requires Technology. Intelligent HealthScience System has three parts: Basic & Medical Research System, Current Siloed Healthcare Environment, and Technology, each enabling a corresponding sub-process of Human Health Promoting. Individual exhibits Health Level. Health Level of Individual can be current or improved. Society exhibits Quality of Life. Quality of Life of Society can be current or improved. The Society's Quality of Life is the result of the health level of its Individuals. Each has two states: current and improved. Human Health Promoting of Intelligent HealthScience System changes Health Level of Individual from current to improved. Human Health Promoting of Intelligent HealthScience System changes Quality of Life of Society from current to improved. Human Health Promoting improves an individual's Health level, and consequently, the whole Society's Quality of Life improves

The model does not do the work, rather it creates a framework to represent the thought process brought to the problem. It also allows prediction of the impact of an intervention or a change in one of the agents to the extent the model is valid. Experience with predictions from the models, true or false, provide some of the most essential feedback to amend an approach and the model. Models may not be perfect but properly formed – and informed – models provide valuable insight.

Requirements for effective modeling include:

- Standards for all data collection and formats for patient medical data representations, as well as for managing fundamental processes, beginning with addressing the continuing proliferation and ad hoc development of formatting and collecting;
- Structures, both internal to and across stakeholders, for interaction and information exchanges;
- Solution innovations enabling aggregation, integration, analytics, and decision-making; and,
- Identification of systems dynamics in both hard and soft system/human factor terms considering aspects like scale, randomness, and diversity of perspective.

Clearly, effectively modeling a system also requires both an understanding of the current state and a clear vision of a future state, identifying and leveraging critical pain and pressure points, gaps, as well as measurements for progress. Adaptation learned from failures and acceptance of less-than-optimal results promotes continuing evolution of the health-science ecosystem [12].

A fresh look at improving the current status, includes consideration of the following:

- Data accessibility, variety and analytical capacity;

- "Silos" both internal to an organization and across organizations and disciplines;
- Collaboration models spanning business, investment, and science;
- Person-centeredness/empowerment toward achieving a "social compact" of law, regulations, and ethics;
- Comprehensive change management rather than the typically narrowly-focused efforts, including social and human dimensions like "de-innovation" (overcoming ingrained practice and process biases); and,
- Innovation for substantive transformation overall across the multi-stakeholder ecosystem, emphasizing safety and effectiveness mutually.

A true systems approach is inherently oriented toward understanding and managing complex and larger-scaled challenges and discovering unintended consequences that well-intentioned "low-hanging fruit" solutions do not address. In systems thinking terms, discussions should be refocused away from simple delivery of services and population-based research protocols toward meeting needs of specific patients on the one hand and those of the entire enterprise on the other. This can be achieved by expanding and more effectively using data generated by the care process, stimulating fresh thinking beyond the basic notion of delivering care.

An example of such expanded learning and application of Human Health Promoting, as illustrated in Figure 1, encompasses wellness promotion, disease prevention, care optimization, and patient level research including analysis of real world evidence. Such modeling helps one envision how a fully integrated system operates to constantly improve outcomes.

## 5 Moving Forward

While existing healthcare and research organizations are making progress, the road to a true integrated system is challenging. The COVID-19 pandemic has emphasized understanding health and its intersection with research differently than in the past, for example:

- Focusing on individuals in addition to larger cohorts – why some victims are asymptomatic while others die, experience such a range of adverse events, recover only partially, or become "long-haulers";
- Dealing with the current state of fragmented and inadequate data, in which clinicians are grasping for solutions without the time or ability to undertake "precision COVID-19 medicine," the extreme duress and intensity of contending with an unknown disease entity, and the uneven distribution of health care resources;
- Understanding health status as the result of a multitude of agents or influencers – each interacting with the others in known and unknown ways, like, in the case of COVID-19, political views and attitudes toward public health, which played important roles in the pandemic's development; and,
- Taking on the challenges of information silos, since meaningful data standards and interoperability are often identified as major barriers to progress in medical care and research.

Individual providers cannot hope to evaluate all the different kinds of data that may be relevant to the individual patient. Doing so requires a system-based analytic process to provide patient-specific insights for the patient and clinician to consider in making decisions in addition to sound population and cohort-based recommendations. The potential is enormous, and the motivation is powerful, but commitment to build consensus among essential parties has as yet been insufficient. There are many reasons for this limited commitment to change, including concerns about requisite technical skill, uncertainty about the purpose or value of proposed changes, professional liability, and comfort with the status quo [13–15]. The complexity and magnitude of the challenge is simply overwhelming to many, but these concerns are not compelling reasons for inaction.

Computational power and tools such as machine learning and artificial intelligence put an Intelligent HealthScience System in reach technologically. An opportunity to apply systems thinking to these challenges is before us, but success requires bringing together essential stakeholders and processes, in addition to technology. Fostering the will and commitment to do so is essential. Together, systems-oriented leaders can envision a future in which all the essential components are interconnected, data is securely and privately exchangeable, mechanisms for observing and analyzing events and patterns are developed, and the different perspectives, needs, and constraints impacting stakeholders are delineated. A data-driven, standards-based systems approach was recently proposed to manage COVID-19 and better prepare for future pandemics, but a coordinated and engaged effort to realize such an approach remains elusive [16]. The vision we offer for an Intelligent HealthScience System is even more challenging, as its goals are more far-reaching and comprehensive.

Energized and informed by the COVID-19 pandemic, stakeholders could come together to further envision and design an Intelligent HealthScience System. Yes, they face formidable challenges. Action requires leadership and shared commitment, and now, with a global pandemic as a catalyst, an opportunity exists to accept the challenge of leadership.

Convening a group of committed stakeholders is an essential first step. An initial 'envisioning exercise' among diverse stakeholders can set the stage for establishing cross-functional teams of experts to undertake the design and development of the system and to generate resources needed to build it. We propose this as a logical next step and are currently working to make it a reality.

Yes, we can more effectively integrate healthcare and research to benefit all–the question remains, will we seize this promising opportunity?

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