



# Multidimensional Evidence Generation: A Paradigm Shift Post-Pandemic Enhancing Policy Implementation for India's Health System

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## ABSTRACT

COVID-19 is having a profound impact on healthcare and society. The crisis has drastically shifted our focus and defined a new normal in terms of way of thinking and process of evidence gathering. Across the landscape of health, the response in future will see transformation on data, methodology, and experiences based on all stakeholders. The future of health care not merely will depend on convenience and less expensive technology but also will be multidimensional evidence-based while enhancing patients' personal health and needs in real time. This will require integrated evidence-generation rather siloed functioning of departments, disciplines, markets, and geographies. There will be radical ways to operate that will smoothly connect evidence generating process from randomized clinical trials to patients' medical and non-medical history, health economics and outcomes research, market access, and precision prevention strategies. That is, the paradigm shift incorporating partnership model will simultaneously enhance data engineering platforms, advanced analytics capabilities, modeling-based decision process, and cross-functional collaborations.

**Keywords:** Evidence-driven, Decision modeling, Learning lessons from historical Healthcare challenges, Economic Evaluation, Cost Categories

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## INTRODUCTION

### COVID and Its Impact on Evidence Gathering

The COVID-19 pandemic highlighted a key role played by data in guiding effective decisions to control the disease and reduce economic losses for communities around the world. With novel pathogen characteristics and limited prior knowledge of the virus spread, ongoing data were the only reliable source used by decision makers to guide policies. However, empirical scientists faced immense challenges associated with the data, such as its collection, cleaning, sharing, ensuring its reliability, and disseminating of effective information to mass. India has its own share of major challenges in response to gathering information and timely designing data-driven control of COVID-19.<sup>1-3</sup>

A report by WHO estimates that approximately 15 million people have died due to COVID-19 since it emerged in 2019

(Adam, 2022), but it is difficult to quantify the true overall health burden associated with it. To account for the cost related to COVID-19, we must first identify how different populations are affected and provide evidence about the course of the virus for each subpopulations. Additionally, it is key to align the definitions used in the data sets to compare the health burden of the disease across disciplines and policies. With its large population and high density, India needs to have wide data coverage, which currently lacks the ability to comprehensively track health burden because of an inadequate surveillance system and often inconsistent definitions to collect data from different sources.

### *Ongoing Health Technology Research at Kalam Institute of Health Technology (KIHT) in India*

There is a key ground-level evidence we need to continuously gather to carry out research for today's health technology

assessment and be a global leader in effective use and distribution of medical technology and disease control. In India, KIHT is carrying out some cutting-edge research on health technology such as evaluating the economic value of screening tests (such as Positron Emission Tomography and Computed Tomography (PET/CT)) to diagnose the high prevalent cancers, the cost-effectiveness of Orphan drugs development for rare diseases, implications for rolling out mass rapid diagnostic kits for COVID-19, and identifying medical devices for whom, India can become major global production and distribution player. These are critical research for quantifying ground-level management of diseases as COVID pandemic impacted the complete health system. The broader types of empirical information needed to make effective and sustaining implications are explicitly spelled in Figures 1 and 2. However, challenges exist as there are limited empirical studies specific enough to capture the characteristics of India's different subpopulations and regions.

**Historical Health Problems and Learning for Post Pandemic Evidence Process**

Due to COVID-19, 2020 brought redefined “normal” for all of us and altered our world in ways we are only beginning to understand and comprehend. COVID-19 pandemic raised global concerns in almost all countries with sufficient to limited medical capacity.<sup>2-6</sup> In one study, the Years of Life Lost (YLLs) due to COVID was estimated as 4,072,325 in 30 high-incidence countries on July 14, 2020 (Oh *et al.*, 2020).<sup>2</sup>

Evidence-based modeling studies for optimizing strategies is required for healthcare problems (Akman *et al.* 2022).<sup>7</sup> Such studies will have scope in multiple dimensions (see Figure 1). It will reduce healthcare's cost, improve quality and reliability, and enhance the underlying data infrastructure of the healthcare system. One of the major challenges we face is how to develop interagency structures that break silos and focus on responding to complex community needs despite limited evidence.

In a book “Who Shall Live”, the author explored multiple healthcare challenges at that time and highlighted that evidence-based research is key to achieve a comprehensive and diverse understanding of the continuously evolving healthcare system (Fuchs, 2011). He used evidence to make a key distinction between the healthcare systems of the different states. For example, Fuchs explored using 1960s data from state

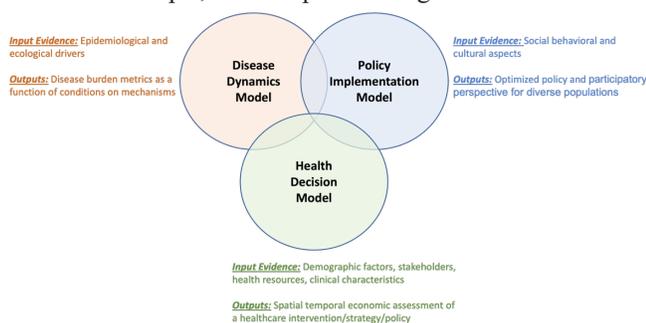
of Nevada and Utah in USA, why they had vastly different life expectancy despite similar health care use patterns. For a long time this remained a serious puzzle for health experts. It is found that health behaviors and social factors matter for longevity and quality of life. Even though the puzzle's solution is now well known, it was radical news at that time, especially to physicians. Fuchs continued to explore such questions in his book through many examples and provide evidence-based reasoning for various health care challenges through links between socioeconomics, health-related behaviors, and health. The essence of the book is still valid for today's time as it stressed that result need to be replicated and reconsidered in light of expanding data and statistical methods currently available to researchers.

**TURNING CRISIS INTO OPPORTUNITY WITH INNOVATION USING NOVEL EVIDENCE**

Healthcare industry in the US is around \$4.00 trillion market, whereas in India, it is around \$0.35 trillion market. In recent times, many companies such as Big Tech have invested massively in the healthcare system, but some large corporations have failed miserably. Some examples include Google Health division, Apple's Health Habit app, IBM's Watson AI and data analytics, and Amazon JP Morgan Chase Berkshire Hathaway's Haven Health, all are either disbanded or sold off. The question that comes in mind is why Big Tech failed in healthcare despite being heavily funded and resourced. Some of the reasons are mentioned below:

- Their functioning include basis of their early success only with small patients data sets,
- Marketing hype outpacing accountability,
- Missing domain expertise and lack of required understanding of the partnership model,
- Lack of compliance promises for secure and safe data sharing (e.g., rigorous following “The Health Insurance Portability and Accountability Act of 1996 (HIPAA)”, a US law that required the creation of national standards to protect sensitive patient health information from being disclosed without the patient's consent or knowledge), and
- Late realization that healthcare has a “dirty data” problem (that is, data is unstructured and inconsistent).

If we throw light during the last few years, it is not hard to see that health startup companies adapting fast to changing evidence and readily incorporating data from multiple dimensions in their product design are successful in the market. To name a few, Anacity, Biobot Analytics, Ekincare, etc. are some of the examples in this list. ANACITY is a technology solutions provider which provides ‘touch-free’ automated gated community management system as a product for the residential experience. This company automates multiple health safety features such as electronic temperature and mask checks, contactless delivery of mails, electronic booking of common area facilities such as gyms, pools, etc. to avoid overcrowding, automated SpO2 Readings, etc. to residents of its customers. In order to achieve this type of automation and features, it uses multiple data sets through smart tech, enhanced visualization,



**Figure 1:** Evidence and methods for different components in policy design

and top-of-the-line digital intelligence. Biobot Analytics aims to track COVID-19 by analyzing human waste from multiple sites and time points. While using this alternative data from wastewater systems can provide an early warning of an impending spike in COVID-19 cases, detect other pathogens potentially circulating in the population, and identify other substances of interest (like opioids). The challenge with the evidence for them includes making evidence consistent that is being gathered from different sites by different organizations and aligning them systematically over time. Ekincare, a health benefit platform company, provides people with the facility to save patients' medical documents securely and access those documents anytime from anywhere. This company also lets user understand their medical data in a simplified manner through graphical charts and visuals. Thus, addressing patients' needs in all predictive, preventive, and personalized ways while maintaining trust from patients and ethical considerations.

**INTO THE FUTURE**

**Future Health Problems**

Future health problems have changed over time. Big Tech companies are now becoming more like medical devices companies. For example, Google now has its health unit called Verily, and Apple is currently focusing on portable diagnostics technology. There is also immense progress in developing state of the art in surveillance and detection for many diseases. For example, in case of Cancer numerous discoveries has occurred: a blood test like "Galleri", which can reportedly detect 50 different types of cancer in early stages, and a "CAR-T cell therapy", a treatment that uses a patient's own immune cells or the immune cells from another person to help battle diseases thus provides 'immunological memory,' against cancer cell. However, novel diagnosis technology comes with other social consequences and risks such as early diagnosis allow anxiety to consume our culture. Hence, multidimensional evidence is required to find a balance and comprehensively maintain healthy communities.

On the other hand, only 5% of the roughly 7,000 rare diseases (mutations on a gene) have an approved drug, leaving thousands of conditions without a cure (Haendel *et al.*, 2020). The rare disease affects around 400 million people worldwide (Ferreira *et al.*, 2019). But the cure for some of these diseases are extremely expensive, thus, making it out of reach for major population, e.g., Zolgensma, used to treat spinal muscular atrophy, cost around \$2.1 million for a dose. Another field in which future health technology is growing is Biologics, which are medications isolated from a variety of natural sources and used to treat multiple medical conditions for which no other treatments are available. The treatments using biologics are typically extremely effective and have low side effects. However, unlike conventional drugs, most biologics are complex to produce and are expensive for population. Recently, a cheaper version of biologics, biosimilars, has also seen continuous growth with more competition with biologics. Thus, choosing evidence and methods for health technology assessments becomes extremely important to evaluate and compare novel and different types of therapeutic compounds across multiple scales.

**Health Technology Assessments**

An article by Kolchinsky and Rubin in 2021 claims that math used by some current health economists has been limited by available evidence and is short-term planned rather than comprehensive and its value more relevant (Kolchinsky *et al.*, 2021). Hence, such analysis of health technology assessment is undervalued as it includes values that can be only measured but fail to identify implications by ignoring other relevant factors for which data is limited or unavailable. For example, in estimating the value of rapid molecular test (RMT) for COVID, often modeling studies fail to capture the role of secondary cost from community transmission in case of a false negative result from the test. Additionally, the implication on other existing diseases with common symptoms due to the implementation of control policies for a disease based on its cost-effectiveness analysis is often ignored. The proper economic evaluation needs key but comprehensive list of categories.

Health		Productivity	
Costs Categories	Evidence sources	Cost categories	Evidence sources
Treatment cost to health system: <ul style="list-style-type: none"> <li>Salary of healthcare staff</li> <li>Daily maintenance of health standards</li> <li>Tests, medications and therapies</li> <li>Health insurance and pharmacy</li> </ul>	<ol style="list-style-type: none"> <li>Claims data</li> <li>Literature on Economics of healthcare</li> </ol>	Lost wages: <ul style="list-style-type: none"> <li>While in quarantine</li> <li>Due to treatment</li> <li>Missing work as a result of long-haul symptoms</li> </ul>	<ol style="list-style-type: none"> <li>Unemployment claims</li> <li>Consumer spending reports</li> </ol>
Long-term health impacts: <ul style="list-style-type: none"> <li>Early deaths due to disease</li> <li>Long haul disease implications</li> <li>Medical interruptions in other health conditions</li> </ul>	<ol style="list-style-type: none"> <li>Mortality data</li> <li>Studies on relative risk for and severity of specific conditions</li> </ol>	Ability to work: <ul style="list-style-type: none"> <li>Temporary or permanent disability</li> <li>Loss of opportunity</li> </ul>	<ol style="list-style-type: none"> <li>Disability network data</li> <li>Workforce reports</li> </ol>
Mental health related: <ul style="list-style-type: none"> <li>Social isolation</li> <li>Financial instability</li> <li>Fear of contagion or intervention</li> <li>Life insecurity</li> </ul>	<ol style="list-style-type: none"> <li>Depression and anxiety literature</li> <li>Social surveys</li> </ol>	Societal impacts: <ul style="list-style-type: none"> <li>Educational interruptions</li> <li>Business closures</li> </ul>	<ol style="list-style-type: none"> <li>Trends in community educational scores</li> <li>Income trends</li> <li>Community business reports such as Yelp</li> </ol>

**Figure 2:** An example of evidence needed for economic evaluation of COVID-19

For example, various components needed to economically evaluate COVID-19 are shown in Figure 2. The figure also shows required cost categories and sources of data for obtaining estimates for those categories.

## DISCUSSION

COVID has highlighted challenges related both to evidence gathering and handling, including ease of access to healthcare. It seems domain expertise and a complete understanding of the partnership model is must for modeling key future healthcare technology problems. In a developing country like India, where the capacity of health systems is limited, cutting-edge delivery of health technology through telemedicine and software as a service (SaaS) as a subscription model are needed.

In India, typical data-related challenges include deeper understanding of the customer persona and workforce, implementation of best data collection practices with complete transparency and accountability, and quick and fast scaling operations through inconsistent policies of regional boundaries. There must be easy importability of data from different platforms and sources. The data that are critical for the modeling cost to the health system include costs related to tests, medications and therapies to individual patients and healthcare providers, claims and reimbursement data, consumer spending and pharmacy use data, a disease-specific burden to society, and social costs of mental health and secondary trauma from early diagnosis.

There is a need for novel evidence-gathering approach that is multidimensional, integrated and has its value for all stakeholders. Big data methods are being increasingly used; however, we must stress strategic and collaborative ways of gathering evidence using a broad range of modeling and data methods. Siloed and fragmented data collection has hampered

existing health economics and outcome research, primarily because the implications from those studies have been either short-term or evaluate value for only selected populations and markets. Deeper understanding of these evidence-related challenges needs immediate attention and national to global evidence-generation are to be planned. We hope that future studies will focus on identifying evidence gaps and then strategically developing a cross-functional evidence-gathering process, keeping many of the issues mentioned here in mind.

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