Towards a Holistic Digital Health Ecosystem in India

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ABSTRACT In an effort to facilitate the digitisation of the country's healthcare systems, India released a National Digital Health Blueprint in January 2020, which provides a detailed framework for a "Federated National Health Information System." This brief makes a case for expanding the scope of the blueprint to include digital therapeutics, digital diagnostics, and telemedicine. It proposes a "National Digital Health Blueprint 2.0," with diverse elements of a futuristic digital health ecosystem, representing the interplay of new science, new actors, and technological innovations. It recommends a list of policy levers and value principles that can help design a suitable policy framework. The ongoing Covid-19 pandemic has underlined the need for urgent action on this.

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INTRODUCTION

In 2015, the Government of India (GoI) launched the "Digital India" campaign: the mission to transform India into a knowledge economy, empowered with on-the-go access to information, governance and services. In the five years since, the country has become second-fastest digital adopter in the world.[1] With almost half a billion internet users, and more than 350 million smartphone users consuming 8.3 GB of data per month per subscriber, the Indian economy has the tremendous potential to unlock additional economic value of US$ 1 trillion through inclusive growth across all strata.

Indeed, India has become a force to reckon with in the field of technology. This is evident in the rapid pace of digital permeation, the remarkable achievements of the Indian Space Research Organisation (ISRO) in space technology, and the rise of the India-trained CEOs leading the most valuable technology companies in the world.

At the same time, however, India's healthcare scenario remains less than ideal. It is short by almost half of what the World Health Organization (WHO) recommends as the optimal number of doctors, nurses, medical technicians and healthcare facilities required to serve the population. Under excessive strain for decades, and without sufficient budget, India's health system is frail, inadequate and of inconsistent quality. It is overburdened by the arduous task of tackling infectious diseases (tuberculosis and neglected tropical diseases[a]) and the rising epidemic of

so-called lifestyle disorders as well (diabetes, stroke, and heart and neurological problems).

Therefore, policy analysts must note that in India, any estimate to quantify the growth in economic output ascribed to digitisation must be adjusted for the inherent negative pull on productivity due to the country's ailing health system. Without the digitisation of health infrastructure and delivery, India cannot accomplish its growth potential, as duly acknowledged by the GoI. In January 2020, policy action was initiated in this direction, with the release of the National Digital Health Blueprint (NDHB). The blueprint covers the architectural framework and infrastructure requirements to undertake the first essential step in integrating health data across public and private sectors.

Will the digitisation of health data maximise health outcomes or achieve the goal of "health for all"? The answer is a mixed one. Indeed, the digitisation of data (e.g. medical records or directories of healthcare staff and suppliers) is a colossal and complex task and forms the foundation of accessible, affordable and quality healthcare delivery. Yet, on its own, it will not move the needle significantly or fast enough to create any tangible impact on the ground. The current scope of India's Digital Health mission must therefore expand beyond mere digitisation of health data, to include various applied aspects of digital health. This brief proposes the drafting of an NDHB 2.0, in addition to the planned digitisation activity, which will carry an all-encompassing vision for a futuristic digital-health ecosystem, including telemedicine,

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a   Neglected tropical diseases: a diverse group of communicable diseases that prevail in tropical and subtropical conditions, such as dengue, leishmaniasis, and leprosy.

digital therapeutics and digital diagnostics, in its purview for actionable impact.

The Economist's Perspective of Health

"This is indeed India!" remarked Mark Twain in his travelogue,[2] flummoxed at the wide-ranging contrasts he witnessed in the Indian society at the cusp of the first and second industrial revolution. More than a century later, India continues to be a paradox. One of the fastest growing economies of the world, India is currently the fifth largest and is working towards vaulting to the top-three club by 2025. However, in the Healthcare Access and Quality (HAQ) Index, it is ranked a dismal 145 out of 195 countries.[3] Simply put, India's growth juggernaut is pulled by a labour force that is performing far below optimal productivity levels due to ill-health.

Optimistically, this paradox can present a scenario of hope, wherein India's real growth potential will be significantly greater if health systems were to be fixed on priority, with adequate financing and staffing. For example, if India leapfrogs into the top quartile of the HAQ Index in the next five years, to join the likes of China and the US, it will boost India's GDP exponentially. After all, the interdependence between human health conditions and macroeconomic fundamentals is well-established.[4] However, realists argue against a sudden radical surge in healthcare financing, at the risk of imposing an unfair burden on total spend of a nation grappling with several burning issues, all equally important as health. And, never the twain shall meet. The rational approach, therefore, is for India to go digital in how its population consumes, delivers and measures the impact of health services.

DIGITISED HEALTH IN DIGITAL INDIA

Powered by artificial intelligence (AI) or machine learning (ML), digital health solutions operate at the intersection of technologies spanning biotechnology, communication and network, computer science, and robotics. Adopting digital solutions across the care pathway of prevention, diagnosis as well as cure is the smartest route for India to inch closer to the "health for all" goal. There are three broad reasons for this:

1. Blending digital approaches into traditional healthcare models will create a three-in-one antidote to at once tackle the systemic problem-trio of access, affordability and quality.

2. A digital health system fits in with the overall strategic direction that India is taking to shape its new internal order, with missions such as Ayushman Bharat, Swachh Bharat, Digital India and Make in India, all aimed at developing a healthy and prosperous society.

3. Health-tech is a transformational phenomenon of the Fourth Industrial Revolution, with diverse ramifications both for the industry and the society, which is getting sicker and older, with a longer average lifespan. Consequently, there is opportunity for India to influence policymaking in global health and sharpen its competitiveness ranking in technology development. Unlike space-tech, where India has already reached the top echelons, the health-tech arena is in a germinal stage, with most countries on a level playing field.

The 2020 National Digital Health Blueprint (NDHB)

The Ministry of Health and Family Welfare of India (MoHFW) has already initiated policy action towards digitising healthcare. The NDHB, released in January 2020,[5] presents a detailed architectural framework of a "Federated National Health Information System." It proposes to link systems within private- and public-health provider organisations across primary-, secondary- and tertiary-care value chains. This aligns with the goal set by the National Health Policy of 2017, i.e. to create an integrated health information system for all stakeholders in the health system, to improve efficiency, transparency and citizen experience.[6]

The NDHB lays down sound design principles to execute the mammoth mission of creating a longitudinal database of electronic health records, which will serve as the single source of truth for health data per unique patient within India. Other datasets, such as state-wise directories of health-workers (doctors, nurses, paramedics) and health facilities, disease registries, inventory records and insurance-claim history will also form important constituents in the federated system. The data hub and key services will be hosted in the Health-Cloud (H-Cloud). For seamless data exchange, the system will be made interoperable.

The Blueprint also lists the standards for maintaining the privacy and security of the digitised health data. Project execution will be based on agile methodology, following the technology sandbox approach to create a massive data-management system. This will be leveraged for tracking population-wide health status to make real-time and customised system interventions, for performing predictive analytics to forecast community outbreaks and pandemic spread propensity by region, for running optimising algorithms to allocate scarce resources at district and state level, and more.

There are three important pre-conditions for the successful completion of the exercise that the NDHB proposes. These are: internet and telecommunications availability across the country, an extensive network of primary healthcare centres for service delivery, and trained health workforce. All three are works in progress in India and must continue to receive uninterrupted support from the government—both in spirit and funding.

An integrated national-health database will be an invaluable asset to run complex data analytics, which can be strongly leveraged for policy-design and implementation control. It will also allow automated and timely interventions within the health system, such as relaying targeted health messages within the population, managing stock-level notifications and warnings to manage health supplies inventory, and providing training content for medical research and education to create a strong foundation for innovation. Once operational, the database is expected to connect and expedite India's slow-moving fragmented health system. While this will not fix the system entirely, it is the first step towards making it efficient and future-ready.

The Brave New World of Digital Health

The NDHB does not fully capture the complex interplay of new institutions, definitions and trends that will come together to shape the

digital health ecosystem in future. Two overarching trends are leading a disruptive change in healthcare:

1. The rise of empowered patients; and

2. The philosophy and science of personalised medicine.

Ill-health or disease is no longer exclusively managed by health-workers. As the healthcare ecosystem expands, patients are surpassing their status as mere subjects. Increasingly, they are becoming empowered by wearables and devices to take control of their health. Moreover, the scope and definition of a person's health has evolved beyond medical records. Personalised medicine or individualised care is expanding the data profile of patients, to include additional characteristics in the categories of genomics, metabolomics and health-seeking behaviour. Patients' increased cognitive engagement with their own health outcomes has introduced behavioural elements into their health data profile.

If a human being were to be viewed as a data lake, the total data generated over their lifetime would be approximately 1,110 terabytes, of which genetic and clinical data will amount to 40 percent.[7] The remaining 60 percent will comprise health behaviours (captured by fitness and wellness apps) and social determinants of health (environmental factors, such as access to clean drinking water and air, determining one's susceptibility to communicable and non-communicable diseases). Large technology giants such as Apple, Google, Microsoft and Amazon have announced strategic projects in digital therapeutics and digital diagnostics, to create

data and software-driven products to prevent, manage or treat diseases. For example, Apple Watch is an FDA-approved Class-2 medical device for fall detection and heart-monitoring capabilities.[8] Recently, a mobile-based health management platform called BlueStar secured FDA approval for use and reimbursement as Type-1 diabetes therapy.[9]

In light of these developments, the 2020 NDHB can be considered the first version of India's Digital Health Blueprint. It promises to lay a solid groundwork (of ICT infrastructure, system software and a well-structured health database at the population level) to deploy direct-to-customer and direct-to-healthcare-centre digital-health solutions.

NATIONAL DIGITAL HEALTH BLUEPRINT 2.0

As the first version of the National Health Blueprint, i.e. the January 2020 NDHB, is rolled out, a structured effort should begin towards writing the next version. The NDHB 2.0 should be an all-encompassing vision document for a futuristic national digital-health ecosystem, aimed at preparing India to launch itself into the next century of healthcare provision, while ironing out the old issues that still persist.

The key to success lies in identifying contextual use cases for the adoption of digital-health solutions for problems unique to India. It is also essential to factor in WHO's guidance that digital-health interventions must be treated as supplements, not substitutes, for functioning health systems.[10] The NDHB 2.0 must include digital therapeutics, digital diagnostics and a priority

push for telemedicine towards tangible impact and action on the ground.

Telemedicine

Telemedicine is one of the original components of digital health and the National Health Policy lists it as an essential objective. However, it has yet to be properly nurtured in India. The ISRO's modest beginning with the Telemedicine Pilot Project in 2001 has since progressed slowly. In 20 years, it connected to only 45 remote and rural hospitals and 15 super-specialty hospitals.[11] The performance and uptake of these facilities have been dismal,[12] due to limited infrastructure and lack of regulation. The former is expected to be addressed in due time, as the NDHB specifies "inclusivity" to ensure the unconnected and the digitally illiterate are not left out. The latter, i.e. lack of regulation, needs urgent action.[b] Telemedicine must be brought under immediate policy deliberation to enable access to specialised medical consultation services across the country, as a workaround to ease out doctor shortages and excessive load on tertiary-care hospitals in Tier-1 and Tier-2 cities.

So far, the private sector has shied away from making large investments in telemedicine, due to lack of a clear policy and legislation. While a set of guidelines is available, it is neither comprehensive nor binding. There is no standardised format to qualify patient–physician interaction or to seek patient consent for privacy and confidentiality. Further, there is no accountability framework to tackle medico-legal negligence matters or malpractice liabilities.[13] The most pressing need is a clear policy and legislation for delivery and reimbursement of services, such as virtual consultations, digital prescriptions and virtual ICU management for critical care.

Digital Therapeutics and Diagnostics

The advent of digital therapeutics and diagnostics has begun to disrupt the 20th-century format of health products and services. Four intersecting forces of technology and research are at play in this regard:

1. Deep-tech in Human Biology: Including genomics, microbiome science, tumour immunology and brain science, deep-tech enables deeper understanding regarding the genesis of health, and how diseases arise and progress.

2. Genetic Engineering and Biotech Innovations: These include gene-editing, tissue engineering and molecular medicine, and facilitates the development of new-age therapies, which are precise and personalised.

3. ICT Advances: Information and communication advances such as 5G, internet of things, cloud computing and 3D printing, enable the consumption of healthcare services in a seamless continuum of care, with a mix of in-clinic and virtual care. Further, it allows patients to control their health in real time, with apps that constantly relay information and alert them to take immediate corrective action or make healthy lifestyle choices.

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b   At the time of writing, the GoI sanctioned a part of the long-pending telemedicine guidelines to cope with the ongoing Covid-19 pandemic outbreak, allowing a registered medical practitioner to offer Covid-19 treatment remotely by using telemedicine tools.

4. AI/ML, Blockchain, Predictive Analytics: These make clinical and diagnostics decision-making more robust, i.e. less error-prone, quicker, evidence-driven, and free of judgement and experience bias. It allows the practice of medicine to become more humane, wherein the doctor–patient interactions become empathetic and care-oriented, rather than time-pressed and transactional.

India must frame a concerted action plan to operate at various levels on the above-mentioned areas for health problems. AI-based decision support systems can drastically improve physician efficiency by reducing errors and standardising of medical judgements. This will, in turn, improve access and quality. Recently, Google tested and published results from its high-profile use case for eye health in India.[14] Its ML algorithm is designed to detect referable diabetic retinopathy in Indian patients, with an objective to expand access to 66 million out of 72 million diabetics in India, who are not currently screened for eye diseases. It is now being clinically evaluated at the Aravind Eye Hospital in Madurai, India.

While AI-based solutions can help India to be one of the leaders in the next technology-driven paradigm shift in digital health, they come with known risks and pitfalls. Therefore, a national policy must be put in place. Definite guidelines and a regulatory framework will also provide a fresh impetus to indigenous start-ups to explore ground-breaking ideas and attract investment. There has been a dramatic spurt in funding for health-tech start-ups in the last three years. Clarity on regulatory and legal risks will further drive this trend.

National Digital Health Blueprint 2.0: Policy Levers

Policy action for new-generation digital diagnostics and therapeutics must be aligned with the broader AI policy of India. The current version of India's AI policy lists "healthcare" as one of the most promising areas but classifies it as one of the most challenging in terms of defining the next steps. However, India is not alone in this predicament. Starting 2020, European Commission's newly appointed President, Germany's Ursula von der Leyen, has announced her intent to make digital health and AI Europe's priorities.[15] Leyen noted that the framework will be designed specifically for Europe and will be distinct from the US and Chinese models of integrating digital health.

The following is a list of proposed design principles that India can use for its policy for digital therapeutics and diagnostics:

1. Foster indigenous innovation in health-tech (public and private research institutions and start-ups) while maintaining technological sovereignty.

2. Prioritise use cases for India, keeping in mind the inherent infrastructure limitations and resource shortages.

3. Prioritise patient safety through regulatory frameworks for clinical validation of products/services falling under digital diagnostics and therapeutics category. Check for algorithmic bias due to inappropriate testing or training models or inappropriate medical and cultural representation of population in large training sets.

4. Foster trust in users (physicians and health workers) to accept and integrate new technology as non-autonomous decision support systems, backed with results of validation studies in clinical trials and real-world setting for a clear view of benefits, harm and utility.

5. Make transparency, data confidentiality, cyber security and ethics the underlying premise for innovation and real-world use. Formulate guidelines for health data of individuals to be used by medical software developers in transparent data-sharing agreements, wherein rights of patients are protected.

Digital health adoption will bring many changes in the functioning of the current system across the value chain. The benefits of public goods, products and services under this category must be maximised, with minimum disruption to the society. Policy design intervention should follow the set of nine values advocated by a report from the United Nation Secretary General's panel on digital cooperation, listed below:[16]

1. Inclusiveness: For equal opportunity of access to better health facilities and outcomes to all

2. Respect: Consideration for human dignity, privacy and law

3. Human-centeredness: Designed for human benefit with accountability for outcomes

4. Human flourishing: To promote social good with sustainable growth

5. Transparency: To refrain from information black-boxes

6. Collaboration: For interoperability to facilitate co-working and co-development

7. Accessibility: For simple, reliable and affordable healthcare for all

8. Sustainability: Following best practices for a zero-carbon, zero-waste economy

9. Harmony: For use by governments and businesses in good faith without exploiting or provoking conflicts

CONCLUSION

In today's interconnected world, health is no longer an internal matter for any one nation. Digital health is fast emerging as one of the most defining trends of this decade and will have a profound influence on geopolitical and socioeconomic realities in the future. India must play a more proactive role in influencing global policies and governing principles to navigate its way around new questions and conundrums arising from this disruptive trend.

The National Digital Health Blueprint is not a silver bullet for immediate relief, considering the limitations of the current state of India's healthcare, i.e. weary infrastructure and resource shortages. However, it will make India better-prepared to achieve sustainable development goals in an inclusive manner, and to face black swan events such as the ongoing Covid-19 onslaught. With a regulatory framework and an ecosystem to embrace digital therapeutics and diagnostics, along with telemedicine, the Blueprint will be a tremendous opportunity for India to leapfrog decades of failures in its health report. ORF

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