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A strategic roadmap to the successful implementation of digital health records in India

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ABSTRACT

Digital Health Records (DHR) implementation in India involves careful planning and consideration of legal frameworks, such as HIPAA or GDPR. The DHR is being implemented in India thanks to the Ayushman Bharat Health Stack, a technology platform. Interoperability Standards, data centres, connectivity, user consent, audit trails, and regular security audits are all critical for the effective implementation of DHR in India. Health Information Exchange (HIE) is essential for successfully integrating Digital Health Records in India. It involves creating a safe framework for the transmission of medical records, adopting internationally recognized protocols, adopting standardized medical terminologies, training healthcare providers, conducting public awareness campaigns, encouraging cooperation between the Government, healthcare providers, technology suppliers, and other stakeholders, setting standards, guidelines, and policies, launching small-scale pilot projects, launching a 2.0 scalability plan, monitoring and evaluating the DHR implementation's progress, and encouraging input from patients, healthcare professionals, and other stakeholders. The Union Cabinet approved the National Health Policy 2017 to create a digital health technology ecosystem, increasing access, improving quality, and lowering the cost of healthcare delivery. However, the pitfalls of the NHP 2017 included low enrolment of beneficiaries, low participation in reimbursement services, and the need for more data analytics. The GoI then came out with the Ayushman Bharat (2018-19) with the aim of 1.5 lac health and wellness centres and provision of financial protection of up to 5 lacs per year per family. To overcome these obstacles, the Ministry of Health and Family Welfare constituted a committee to develop an implementation framework for the National Health Stack. The National Digital Health Blueprint (NDHB) initiative establishes an efficient, accessible, affordable, and secure national digital health ecosystem. It aims to create a system of personal health records and a Federated health data storage system based on individual informed consent. The National Health Stack (NHS) is a holistic platform integrating health I.T. with joint efforts of ministries, State, and central Government. It focuses on e-learning platforms, teleradiology and diagnostic technology, prevention, and nutritional management.

Keywords: Digital Health, Electronic Health Records, Niti Aayog, ABDM, NDHM, ABHA.

1 INTRODUCTION

According to Dr Vinod K Paul, Member (Health), NITI Aayog, in today's time, a robust health system is only possible with a solid and resilient digital backbone. [4]

The Union Cabinet chaired by Prime Minister Shri Narendra Modi in its meeting on March 15 2017, had approved the National Health Policy 2017- creation of a digital health technology ecosystem aiming at developing an integrated health information system, increasing access, improving quality,

and lowering the cost of healthcare delivery. Importance of Sustainable Development Goals (SDGs), expand preventive, promotive, curative, palliative, and rehabilitative services.

The pitfalls of NHP 2017 were [20]

Low enrolment of entitled beneficiaries because of poor implementation and adverse incentives

Low participation by hospitals and nursing homes in reimbursement services due to low package rates, long payment times, and lack of transparency in the claim process

Low fraud detection resulting in fund leakage, long claim cycle time, and increase in rejected claims

All resulted in a need for more reliability among the healthcare providers and the patients.

The lack of adequate, timely universal data aggregation resulted in a lack of data analytics, which resulted in constraints on policymakers to evaluate and measure the outcomes and improvements in healthcare services.

The GoI then came out with the Ayushman Bharat (2018-19) with the aim of 1.5 lac health and wellness centres and provision of financial protection of up to 5 lacs per year per family for the deprived ten crores plus households [Pradhan Mantri-Rashtriya Swasthya Suraksha Mission (PM-RSSM)] [4]

To overcome the obstacles and drawbacks in the NHP 2017 to fulfil the healthcare goals, the Ministry of Health and Family Welfare constituted a committee headed by Shri J. Satyanarayana to develop an implementation framework for the National Health Stack. This committee produced the National Digital Health Blueprint (NDHB), laying out the building blocks and an action plan to comprehensively and holistically implement digital health. This initiative is referred to as National Digital Health Mission (NDHM). In September 2021, Prime Minister Modi announced the National Digital Health Mission (NDHM) with a budget of Rs 144 crores. It aims at developing an efficient, accessible, affordable, and secure national digital health ecosystem by adopting open APIs, interoperable standardized digital systems, and highly secured and confidential health data storage and portable sharing policies for its seamless exchange nationally. Besides this, it aims to create a system of personal health records and a Federated health data storage system based on individual informed consent by collaborating with States and Union Territories and following the international principles of Sustainable Development Goals for Health. [4]

National Health Stack (NHS) is a visionary digital framework, a holistic platform integrating health I.T. with joint efforts of ministries, State, and central Government. With its powerful artificial intelligence and machine learning technology, NHS is designed to reline the flow of healthcare resources, people, and information. This architecture will make Healthcare portable and universally accessible for all. NDHM hopes that having the health data of 1.3 billion Indians digitally stored will put the country at the forefront of medical research in the world. [4]

The National Health Stack [4] is a collection of cloud-based services accessible via simple open APIs compatible with global standards. NHS has been made with the prime focus on e-learning platforms, teleradiology and diagnostic technology, and prevention and nutritional management of infectious diseases. The critical components of the National Health Stalk are -National Health Electronic Registries, Coverage and Claims platform, Federated Personal Health Records (PHR) Framework, National Health Analytics Platform, and other horizontal Components.

1.1 BACKGROUND

Digital health technologies- from wearable sensors and portable diagnostic technologies to telemedicine tools and mobile healthcare apps—can transform the healthcare delivery system by empowering consumers to play an active role in their care and define what services are important to them [7][8]. A study by **C Ernsting et al. [9] 2017** found that 61.25% (2538/4144) of participants used smartphones. Among smartphone users, 20.53% (521/2538) used health apps. Smartphones have been routinely used for patient/professional interaction to deliver medical advice and treatment guidelines, perform diagnoses, and conduct patient follow-ups [10]. The adoption of these technologies has increased the acceptability of people towards online appointments and consultations, digital payments, paperless documentation, access to Digi locker, and digitalized signatures. Ayushman Bharat has used these advancing health I.T. facilities—Pradhan Mantri Jan Arogya Yojana (AB-PMJAY) to integrate and implement universal healthcare coverage by building a digital healthcare ecosystem. Emerging technologies such as artificial intelligence, the Internet of Things (IoT), Blockchain, and cloud computing provide additional opportunities for facilitating a more holistic digital health ecosystem that can increase equitable access to health services, improve health outcomes and reduce costs. [3]

Telehealth and e-health applications have integrated various clinicians, especially during the pandemic, to deliver the required patient-centric health services virtually. Telehealth allows virtual assessment of a patient's health condition through video calls or m- health applications avoiding in-person visits to clinicians. This not only saves time and money for both the patients and the clinicians but also provides safety against infectious diseases and hospital-acquired infections [11]

The Health data [3] can be classified as Personalized and Non-Personalized. The personalized health data contains personally identifiable health-related information of the concerned stakeholder. The non-personalized health data includes anonymized, aggregated data with no personally identifiable information. To store the healthcare data, three software are being used- **Electronic Medical Records (EMR), Electronic Health Records (EHR),** and **Personalized Health Records (PHR).** EMR is generally used in hospitals or clinical setups to store data related to patients' medical histories, diagnoses, treatment planning, the treatment undergone, and transaction details. EHRs contain records for a patient across multiple doctors. PHRs enable patients to compile, update and keep a copy of their

medical records, which can help them better manage their health. PHR also contains details and daily updates from personalized wearable health monitoring devices. The implementation of PHR will allow patients to securely store, access, and share their medical records after appropriate consent, whose framework, as per standards, will be specified by NDHB and adopted for consent management. Besides this, the National Digital Health Mission will increase the transparency of healthcare services and reimbursement procedures and allow patients to choose the services according to their will. This will also be helpful in fraud detection and delivering seamless Healthcare, a faster and more accurate continuum of care. Finally, data-driven healthcare services will benefit medical statisticians, researchers, and policymakers to perform analytics and predict the outcome of the current healthcare practices and decision-making to strengthen the implementation of health programs and policies. [3]

2 METHODOLOGY/FRAMEWORK

The design of the building blocks for NDHM [3] will adopt the Agile IndEA Framework notified by MeitY. All the building blocks and components will conform to open standards, be interoperable, and be based on open-source software products and open-source development. The data stored in these building blocks will follow the **federated health records exchange system**, enabling patient data to be held at the point of care or the closest possible location to where it was created. It allows scalability and flexibility over a centralized solution for managing health data. To participate in a federated health record system, the Health care providers, public hospitals, Community Health Centre and Health and Wellness Centre across India are expected to enrol in the **NDHM healthcare registry** and adopt software that enables them to become **Health Information Providers (HIPs)**, also known as **Health Data Fiduciaries**. The patient's data will be uploaded in EMR using appropriate Health Data standards (FHIR-R4, SNOMED-CT, LOINC, ICD10/11), and the HIPs will keep a digital copy. HIPs will be required to ask patients for a Health ID, educate and create Health I.D.s for patients, keep a link of the Health ID with the medical documents they produce, and issue the medical records only with the patient's consent. Various web interfaces and mobile applications have been generated to allow the patients to self-register themselves for getting Health I.D.s and to assess their records uploaded by HIPs in PHR. HIPs will also produce aggregated health data and anonymize patients' data, which can then feed the National Health Analytics architecture. HIPs are legalized to store the data for users for only a specific period. Users can only delete their data or a copy of their records in their Health Locker. Anonymized data of individuals will be kept and remain available for public health purposes, e.g., epidemiological or disease burden research. **Health information users (HIUs)** will be able to request the health records of a patient. The patient will provide them with the same after appropriate consent (Recommended standard- ISO/TS 17975:2015 Health Informatics).

The National Health Registries [4] form the base of the stock. It comprises of Provider Registry and Beneficiary Registry. The hospitals, clinics, diagnostic labs, and other establishments include the provider registry. These registries are managed by combined efforts of state and central governments, including the Ministry of Health and Family Welfare (MoHFW), ROHINI (e Registry of Hospitals in Network of Insurance), National Health Resource Repository (NHRR), and Central Bureau of Health Intelligence (CBHI). Beneficiary Registries generally involve patients who are provided with a unique health id that will be linked to an Aadhar number by a health data consent manager. The registered beneficiary can access their health records using their 14-digit Health id and share the same after giving proper consent. Two or more beneficiaries sharing blood relations can be connected by beneficiary-to-beneficiary linkages using the Health ID. The consent-driven PHR sharing is facilitated by Health Data Fiduciaries (HDF) using OTP sent to mobile or Aadhaar-based authentication after anonymizing the PHR data. The HDFs are authorized to determine the purpose and the means of processing personal data in the PHR. Government-organized health programs will also be integrated with these services and included in the patient's longitudinal health records.

Digital Health Stack comprises three technology stacks [19] – ABHA, UHI, and HCX. **ABHA stands for Ayushman Bharat Health Account**. The patients/customer, after signing in to the account, can access their medical records digitally. Hospitals, doctors, and diagnostic centres can use these accounts to upload patients' digital records in one place, which can be assessed directly by the patients. Since all the data is being uploaded from different sources to the ABHA/ABDM compliant software to upload the files, the entire data set of a customer is genuinely decentralized, hence adding to the privacy concerns of the individuals. **UHI, or Unified Healthcare Interface**, is an open network of Heath Information Users (HIUs) and Heath Information Providers (HIPs) which will allow the delivery of digital healthcare services by healthcare providers, including appointment booking, teleconsultation, and e-payments. **Health Claims Exchange or HCX** allows the smooth processing of these insurance claims. It seems similar to using the Internet and connecting through the mail, facilitating communication with the desired consistency, security, privacy, and durability. But, unlike the Internet or email, HCX is designed for exchanging only claims-related information among patients, insurance providers, regulators, and observers. In its initial version, HCX focused on the following information exchange- Getting provider/payor details, Eligibility check, Pre-auth request flow, Claims request flow, Payment notification, Payment acknowledgement, Search/fetch claims data for status checks and regulatory compliance.

NHS's **coverage and claims platform** [4] will provide the building blocks required to implement any large-scale health insurance program. It will enable public and private insurance companies to implement insurance schemes in an automated, data-driven manner through open APIs. It comprises three components- a **policy engine, a claims engine, and a fraud management service**.

The **Policy Engine** allows the patients and their families to define, select and store their health insurance and provides APIs to consume and update these policies. It has two key components- **Unified Multi-Policy View and Policy Markup Language (PML)**. PML is a machine-readable language designed for describing, updating, accessing, and communicating policies between software programs. The procedure is uploaded, validated, and digitally signed by the concerned insurance company providing the service. The policy engine activates the approach when the beneficiary can pay the premium to the company.

The **Claim Engine** manages how claims flow in health insurance schemes and ensure ease of filing and settling claims. The claimed engine automates the shares after the PML reads them. Once the beneficiary pays the premiums, the engine will notify the designated entities to ensure that the process is completed timely and that protocols adhere to the Service Level Agreements (SLAs). It also provides data points for Fraud detection and management. It also receives requests for audits on past claims from the **FMS (Fraud Management System)** and helps analyze and rectify the issues.

Fraud Management Service aims to reduce losses due to dishonest claims and ensure that the healthcare system covers the people who most need it—fraud Detection using big data analytics and machine intelligence to improvise the pace of delivery of services. The engines will **be incentivized** to report fraud events and will compete with each other in the process. This approach will boost the rates of true positives as well as the rate of true negatives in fraud detection. Once fraud is reported, pending any new claim, settlements are placed on hold until the copy raised gets verified and settled.

NDHM [3] is a collaborative initiative between many ministries/departments comprising of **Mission Steering Group** (Chaired by the Hon'ble Minister, H&FW), **Empowered Committee** (Chaired by the Secretary, Health) **MoHFW and MeitY** (responsible for Legal and Regulatory Framework), and **National Health Authority** (responsible for Implementation of NDHM). The Project Management Team, Development, and management teams have been putting their continuum efforts into building the foundation of digitalization in the country.

All the ministries work in a phased manner to successfully implement the mission.

Phase 1 will include working with the Union Territories on the registration of doctors and providing them unique I.D.s and provision of e-prescription and e-signature. Also, the registration of public and private hospitals in NDHM and their verification by NHA will be carried out under this phase. It also includes the development of a Health account and health id of patients linking the same to their Aadhar and uploading their health records in PHR by HIPs.

Phase 2 will take the pilot in additional States and expand the service bouquet. A Mission team will be authorized to manage and execution of NDHM at the State level. The states are asked to set predefined targets, and the performance of each State will be monitored at the level of the Mission Steering Group. Their progress will be included in the e-State Health Index by NITI Aayog. Notable

awards and recognition will be given as a reward to the best-performing stakeholder. The doctors and hospitals registered in the first phase will be verified via MCI/NMC/CCIM/CCH/DCI APIs. The qualifications and employment status of all the registered doctors will be updated on the software to increase the transparency of the healthcare services. Integrating all related state schemes and systems like eHospital, eSanjeevani, eSushrut, and DigiLocker will be carried out to provide unified healthcare services to the citizens and reduce the staff's burden.

Phase 3 will target nationwide implementation, operationalizing, and converging with all health schemes across India, along with the promotion, onboarding, and acceptance of NDHM across the country. The health data accumulated through the electronic software will be accessed using various visualization and analytical tools for developing policies for the prevention of diseases. Appropriate feedback and rating systems will be generated publically, and all procedures will be linked to health I.D.

Security, privacy, confidentiality, and autonomy of individuals play a crucial role in the success of digital interventions. "Zero Trust Architecture "is being followed by NDHM. All the protocols, rules, and regulations enlisted under e Personal Data Protection Bill and Non-personal Data Framework, as well as the I.T. Act 2000 and the Aadhaar Act 2016, have been wisely followed for rolling out the mission. Health I.T. companies have been appointed for 24x7 security surveillance through a Security Operations Centre (SOC). NDHM will also establish a Privacy Operations Centre (POC) to help drive compliance with the privacy requirements [4]

The aggregated health data in the database can then be used in the creation of dashboards, reports, and medical statistics, which can be used for disease surveillance, predicting epidemics, classifying and clustering population segments for proactive care, nutrition, health schemes, and national health infrastructures such as telemedicine, teleradiology, and the enhancement of process controls. This will help shift evaluation away from an annual exercise towards a real-time approach to help rapidly curate data collected through the insurance schemes and feed into agile, intelligent policy decisions [4]

2.1 LITERATURE REVIEW OF CURRENT SCENARIO

Edelweiss General Insurance has partnered with the Ministry of Health, Government of India, to help Indians generate their Ayushman Bharat Health Account (ABHA) number. It is a 14-digit number that allows users to share and access their health records digitally with registered healthcare providers. For this, the customers must go to the company's website and follow the steps on the ABHA microsite. [5]

Currently, the software Version - 0.6 (Baseline) has been used for HCX. It was released on September 08, 2021. It was built by 60+ volunteers from across the healthcare ecosystem (including

Insurers, Hospitals, TPAs, Insurance Technology players, and Think tanks) as a part of a transparent, collaborative, and open effort during July 2020-September 2021 and launched for public consultation on September 08, 2021.

In March 2022, about 374 private entities were empanelled with the NHS, according to a response from the NDHM to RTI queries filed by Srinivas Kodali, a researcher on open data. This number is expected to grow as hospital chains, diagnostic centres, Artificial Intelligence (A.I.) companies, health data management companies, and insurance companies join the NHS to develop applications and services catering to hospitals and users. According to Kamalavelan, the secretary of the Free Software Hardware Movement (FSHM), an advocacy group based out of Puducherry, as the data is becoming huge, more startups, MNCs and I.T. companies are coming forward to take the hold on managing, securing and analyzing the healthcare data with their 24*7 service delivery systems to the hospitals and healthcare setups. [12]

The increase in health data generation in Indian hospitals has increased the threat of breaching the data to foster health services abroad. An incident of a Ransom attack was reported in September 2022 at Jawaharlal Institute of Postgraduate Medical Education and Research (JIPMER) in Puducherry, crippling its teleconsultation services. This resulted in temporarily shutting the digital grid on which the hospital functioned as a precautionary measure. In 2018, a similar ransomware attack was reported at Mahatma Gandhi Mission Hospital in Mumbai. During the pandemic, in the stress of developing a vaccine, Indian Healthcare faced over seven million cyber-attacks, as reported by CyberPeace Foundation, a Jharkhand-based civil society organization. [12]

3 POLICY OPTIONS OR POLICY CONTEXT (PROS/CONS) IN CONTRAST TO DIFFERENT STAKEHOLDERS

3.1 BENEFITS TO THE PUBLIC [4]

In the current scenario, there is a change in how the policies are being made and healthcare services are being delivered. Previously, secondary and tertiary Healthcare was focused more. Still, citizen and wellness-centric policies are being made with a focus on primary healthcare practices and the prevention of diseases. The services provided by the NDHM will address solutions to the four challenges of Healthcare faced by the people of India— Availability, Accessibility, Affordability, and Acceptability. The instant adjudication, advanced fraud detection services, and on-time payment of claims will reduce out-of-pocket expenses by the public. As the cost of primary healthcare services is always less than that of advanced treatment carried out in secondary and tertiary Healthcare, this will result in reduced wage loss for the patients. Providing an Integrated Healthcare and Personalized Health Record system will decrease the unnecessary tests the patients undergo while shifting doctors or hospitals or if the patient's manual records get misplaced. The coverage and claim platform will allow

citizens to access and avail of their shares anytime. Providing proper and on-time service delivery by the incentivized service providers will make them available and accountable to the customers and hence increasing the accessibility of the customers to their insurance claims. The registered hospitals will increase the transparency of their services and make the infrastructure and services patient-centric to improve the patient's compliance and acceptability to the digitalized platform.

- A Value-based Purchasing feature, a reward-based program, incentivized payments, and public reporting for the quality of care. Eliminating or reducing healthcare errors, evidence-based care standards, and protocols, changing hospital processes, increasing transparency, recognizing hospitals that give high-quality care at a lower cost to government-funded healthcare program beneficiaries, the distinction between good and bad service providers

3.2 BENEFITS TO CENTRAL GOVERNMENT [4]

Portability for migrants places India at the forefront of medical research, with the most significant health databases with secured anonymized aggregated data, holistic view across health verticals, and a holistic view across health verticals, reducing the cost of Healthcare, fraud detection, and effective management of schemes and missions.

3.3 BENEFITS TO THE STATES [4]

Horizontal and vertical expansion of the scheme, Leverage RSSM funds, Avoid duplication of efforts, ease of adoption, and more advanced systems.

The digital stack, like UHI, has allowed many doctors to take time from their busy schedules and connect with patients in remote areas and villages to help them with their health issues. This has allowed clinicians to diversify their reach in the community by marketing and delivering their services online.

3.4 BENEFITS TO SERVICE PROVIDERS [4]

On-Time Payments for the Service Providers., Incentivized services- rewarded immediately for making legitimate claims, Improvising the services, enabling the distinction between good and bad service providers, standardized empanelment, pre-authorization, claims processes and streamlining operations resulting in administration ease, Analytics result in establishing scientific packages and pricing of procedures.

3.5 BENEFITS TO HEALTH INSURANCE PROVIDERS [4]

The claim engine will decrease the workload on the employee and also decrease the human errors occurring in the claim processing. It will also result in a dramatic reduction in fraud, an increase

in fraud detection and assessment, reduced cost of operations as a claim engine does the process. It will also allow access to data on the performance of service providers, regulate their performances, and streamline their work and services accordingly. It will help reduce the claims ratio and develop an ecosystem that can work toward the management of health rather than the management of disease. The data-driven services can help market expansion and meet the current demands and needs of the public.

3.6 DRAWBACKS

Although the mission includes the involvement of both public and private hospitals, the services can only be implemented in private hospitals, as public hospitals need more facilities. Even talking about private hospitals, not enough private hospitals have registered for the mission. The development of data-driven services requires considerable investment and cooperation by healthcare providers, which is unable to achieve in many hospitals even after providing incentives to private providers through the NDHM. Moreover, instead of building up the public hospitals' infrastructure and reducing the private sector's dependency, the Government is more focused on incentive-driven services to the top-performing healthcare providers. [14]

The data-driven startups and new technologies leave people out of the digital healthcare system. As rightly said by Kamalavelan. "Technology can always be useful, but problems arise when people, for whatever reason, cannot be part of the system." The aggregated health data have imposed risks on the privacy concerns of the LGBTQ+ community and young women who underwent abortions and thus resulting in personal problems for them in the future. [12] It will also result in a breach of highly confidential health records. Such privacy concerns led many persons with HIV to drop out of treatment programs when antiretroviral therapy centres began collecting Aadhaar details from patients.

The technology-based services have increased the demand for educated employees, especially data analytics and data scientists. Due to the reduced manual work, unskilled employees needing more knowledge to tackle technological advancements are continuously on the verge of losing their jobs. Also, there is an increase in employees' requirement for digital skill courses to increase their survival in the tech-driven world. According to a report, [18] the number of Indian workers who require digital skills for their jobs is expected to rise by 27.3 million over the next year, accounting for 7 per cent of India's workforce. Despite this, only 45 per cent of Indian employers have a training plan in place, which may jeopardize their competitiveness in productivity, innovation, and employee retention. The ability to use cloud-based tools, such as cloud developer tools, online collaboration, accounting, and customer relationship management (CRM) software, was also identified as the most in-demand skill required by employers by 2025, followed by technical support skills and cybersecurity skills. It also emphasizes the need for more advanced cloud computing skills, such as machine learning and cloud architecture design, which have emerged as the fifth and sixth most in-demand digital skills by Indian

employers by 2025. These skills are expected to be in high demand in various industries, including Healthcare, agriculture, fintech, and media & entertainment.

4 ANALYSIS OF FINDINGS OR EVIDENCE

Digitalization had already started prior pandemic in 2020. Still, the pandemic came out to be an accelerator of the trends that were going on, including clinical innovations, changes in customer preferences, changes in the policymaking for citizens' well-being, rapidly evolving technologies, and newer talent models [2]. In the face of ongoing trends, different stakeholders, including hospitals and healthcare companies, have been developing new business models to build the core of this transformational strategy.

A survey conducted by the Deloitte Center for Health Solutions [2] with different healthcare systems discussed the current State of the digital ecosystem. According to the study, achieving better patient experience has been the top desired outcome among 92% of healthcare systems for digital transformation. The participants of the surveys felt that digitalization is more challenging to achieve than they had thought. The most significant barriers to overcoming this digital transformation are investments in data interoperability, creating the right KPIs as top priorities in the next three years, and the quality and quantity of talent to support digital transformation initiatives. Besides this, the survey also proved leadership (80%) and management of implementation (68%) to be the key accelerators and culture (60%), communication ownership, and transparency (48%) the critical barriers to success.

5 PESTEL ANALYSIS

5.1 POLITICAL ANALYSIS

Most health insurance schemes and products in the Indian market are not designed for the missing middle. A modified, standardized product that builds on the **Arogya Sanjeevani hospitalization insurance product** – launched by IRDAI in April 2020 – can appeal to the missing middle. Arogya Sanjeevani has laid the foundation for a standardized health insurance product; it offers an essential benefits package standard across insurers. However, it has limited uptake due to high premiums and a two-to-four-year delay in covering several diseases/treatments. The Government needs to build consumer awareness of health insurance through IEC campaigns. Government can partially finance or provide health insurance. It can expand PMJAY coverage to the poorest segments of the missing middle population and leverage NHA's PMJAY infrastructure to offer a voluntary contributory enrolment [24]

MyGov.in, a platform for citizen engagement in governance, was launched by the Hon'ble Prime Minister on July 26 2014, as a medium to exchange ideas/ suggestions with Government. It will

facilitate 2-way communication between citizens and the Government to bring in good governance, but most of the citizens are still unaware of such platforms and policies [22]

As we are moving towards the era of digitalization, the responsibilities Indian government and the tech sectors are continuously being handed over to the private companies that are acting as a go-between between Indian Government and the tech sector. Steered by individuals having faith in technology-driven healthcare services and developing entrepreneurship solutions to save the Indian Government and its governance, the country is continuously marching toward technology-driven and market-based reforms to the health and wellness of its citizens. Privatization is resulting in the withdrawal of the Government's control on the crucial sector and concentration of healthcare resources in the hands of the tech-people, with only a few people having eligibility. It will support and benefit from the resources. [14]

According to National Sample Survey Office data in India, only 14% of rural and 18% of urban residents have some form of health insurance. The private sector delivers almost 60% of hospitalizations and 70% of outpatient services [16]. People are not interested in going for health insurance because of high premiums. The growing reliance of people on the private sector is also resulting in paying more than the amount covered by the government-funded AB-PMJAY. India's National Human Rights Commission has taken the position that denial of care by private service providers is outside its ambit, notwithstanding their enrolment into state-funded insurance schemes like AB-PMJAY. [14]

5.2 ECONOMIC ANALYSIS

With India's Government spending only 1.5% of GDP on Health, which is among the lowest in the world, the expenses of developing the technology, maintaining the database, maintaining and following cybersecurity policies, educating the community, and providing public based health care insurances to the people couldn't be possible. The investment in health and research must be enhanced for the implementation and progress of healthcare technologies.

War in Ukraine has caused supply disruptions worldwide, leading to global inflation [38]. India's poor and middle-class have been feeling the pinch of soaring inflation, with everything—petrol, food platter, and other subsequent products—becoming heavy on the pocket. Against that backdrop, if someone in the family falls ill, people must now dig into their life savings. In 2021, the country registered the highest medical inflation rate among Asian countries, according to the Indian Health Insurance report released by Motilal Oswal Financial Services Limited (MOFSL) in May. According to data from the Ministry of Statistics and program implementation, the cost of medical treatment in India increased by 7.21 per cent in April this year. Everything has been attracting a higher price, from medical procedures to medicines. [37]

5.3 SOCIAL ANALYSIS

Many people still need their Aadhar cards, or even if they have, there are errors. It will result in the exclusion of those people from vital health services. Numerous reports have been there, including allegations that a patient died of being deprived of health services during the pandemic because of the inability to provide Aadhar details demanded by the hospital. [14]

Medical professionals need to stay on their toes about new trends. Older doctors, who are more resistant to change and have a different perception of the benefits of the latest tools, do not directly use the EHR system and new technologies like medical devices. Healthcare professionals must be incentivized to promote new healthcare devices and digital technologies to monitor remote patients suffering from chronic diseases. The lack of promotion and support by medical professionals and lack of knowledge regarding the use and data security while dealing with digital health systems hampers the accessibility and the trust of the general public for such technologies.

5.4 TECHNOLOGICAL ANALYSIS

Technology is advancing quickly and changing the complexion of our daily lives. Digitalization has changed healthcare services globally. Digital Health technologies have changed Healthcare delivery systems wholly. A decade before, it started with the primary healthcare apps monitoring the miles travelled throughout a day, tracking the menstrual cycles and ovulation in females, and the heart rate and blood pressure of an athlete working on their cardio. Since then, many devices like this have been developed that can be worn as a 'wristwatch' or even transplanted under the skin. The sensors in these devices send messages to the Internet of Things (IoT) platform. IoT gathers all the information from the sensor, filters it, and transforms the data into valuable information by applying analytics. This information can then be stored in the cloud. It can be used to make recommendations and diagnose and predict possible diseases the patient might suffer before they become critical. Besides wearable devices, digital technologies have paved their way in daily lives through telehealth and e-health applications that have integrated various clinicians, especially during the pandemic, to deliver the required patient-centric health services virtually. Telehealth allows virtual assessment of a patient's health condition through video calls or m- health applications avoiding in-person visits to clinicians. This not only saves time and money for both the patients and the clinicians but also provides safety against infectious diseases and hospital-acquired infections.

A lot of money is being invested in finding new treatments for patients with life-threatening illnesses is a significant factor in the rise in medical costs in India, leading to medical inflation in India. Modern medical treatments and therapies for diseases like cancer, transplants, etc., are likewise more expensive as they are developed. These days, most of the equipment used in top-notch hospitals is imported from other nations, leading to increased medical costs [39]. In addition, additional investment

is required to train the staff on using implemented technologies. Foreign medical tourists frequently overspend on Healthcare due to their stronger currencies, which has directly contributed to an increase in service charges in Healthcare and a sharp increase in medical costs in India. [39]

5.5 ENVIRONMENTAL ANALYSIS

By reducing paper usage, hospital visits, and the use of developed technologies, digitalization would help shrink the healthcare sector's carbon footprint and improve its resilience to the effects of climate change and future pandemics. But besides reducing environmental harm, digitalization continuously adds threats to the background. In his study, Maddy Thompson mentioned three critical areas of interest: devices, data, and communication networks. The increase in medical device production has resulted in increased demand for raw materials and an increase in e-waste generation. Only 10% and 40% of electronic devices are recycled; the rest are sent to landfills, releasing toxic chemicals into the environment. Moreover, health data storage requires large servers which use vast amounts of electricity to run and keep cool, mainly when data is saved on cloud services. Sending, copying, and safely storing data on clouds takes approximately one million times more energy than saving directly to devices. [42] [43] [44]

Healthcare policymakers are aiming to design digital services that consume less energy, manufacture medical equipment with longer lifespans, moderate daily digital uses, act on reuse and recycling, reduce the data collected to those that are strictly necessary, etc. [41]

5.6 LEGAL ANALYSIS

- The current legal framework in India- Information Technology Act, 2000, Information Technology Rules 2011 protects the collection, disclosure, and transfer of sensitive personal data, which covers medical records and history within its ambit.
- Indian counterpart to HIPAA. DISHA and the Personal Data Protection Bill, 2019 ("**PDP Bill**"). DISHA lays down provisions that regulate the generation, collection, access, storage, transmission, and use of Digital Health Data ("**DHD**") and associated personally identifiable information ("**PII**").
- Addresses rules of processing of personal data where such data has been collected, disclosed, shared, or otherwise processed in India and processing of personal data by the State, any Indian company
- Individual rights to a physical, physiological, and mental health condition, sexual orientation, medical records, medical history, and biometric data. Applies to any Indian citizen or any person or body of persons incorporated or created under Indian law.

- The scope is wide enough to also apply to foreign companies processing personal data in connection with any business carried on in India, any systematic activity of offering goods or services to data principals within the territory of India, or in connection with any activity which involves profiling of data principals within the region of India. Work must be done to analyze and use the PII of the NRIs used by Indian and International companies.
- Penalties in case of breaching PII need to be made more robust. The companies/organizations need to be penalized according to the level of the insult to the law and the data breached.

6 BENCHMARKING CYBER SECURITY SYSTEM

- Concerning Citizens' Personal Identifiable data rather than focusing on only Health-related data as in General Data Privacy Regulation in Europe
- Providing provisions for Person of Contact (POC) and information governing their personal information and skills to tackle the breaching and cyber-attack on the Indian population. With timely, accurate data and the incorporation of medical device cybersecurity into their organizational emergency response plans, it has been easier for HDOs to assess and mitigate the impact of these incidents on their medical devices [28]. FDA, in collaboration with MITRE [27], updated the Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook. This Playbook outlines how hospitals, HOEs, and healthcare organizations prepare themselves for cybersecurity incidents and the framework for addressing the incidents relating to the same.
- Provision of data policies to the NRIs and the International businesses dealing with the patients' data.
- They are escalating the need to educate customers and employees about data protection threats and solutions.
- Penalizing healthcare companies and hospitals depend on the level of insult to cybersecurity caused due to legal negligence. As in the case of HIPPA, the organizations have **72 hours** to notify all data subjects of a security breach by email, phone, or public announcement. HIPAA has outlined different levels of penalties for non-compliance. This includes-

  Level1- Lack of Awareness – $100 to $50,000 per violation, up to $1.5M per year

  Level2- Lack of due diligence – $1,000 to $50,000 per violation, up to $1.5M per year

  Level3- Willfully default and neglect – $10,000 to $50,000 per violation, up to $1.5M per year

Level 4: Willfully neglect with no effort to correct – $50,000 per violation, up to $1.5M annually. Individuals involved may also face potential criminal charges: Unknowingly or with Reasonable Cause: up to 1 year.

False Pretences: up to 5 years and a $100,000 acceptable Fraud: up to 10 years and a $250,000 fine

- Rules for certification of the company for following cybersecurity protocols and annual risk assessment need to be framed.

GDPR Certification takes 6-36 weeks, depending on the company's structure. Once implemented, organizations must periodically complete internal GDPR assessments to demonstrate compliance. Also, the organizations must perform Data Protection Impact Assessment every three years or when data processing will likely result in a high risk to data subjects. HIPAA requires entities to conduct Risk Assessments annually to ensure HIPAA Compliance.

- NHS **uses next-generation firewall (NGFW)** and **web application firewall (WAF) protection** to protect internet traffic from digital and cloud-based threats. This system increases visibility which allows better management of risk. It enables identifying malicious content within encrypted traffic on behalf of the wider N.H. It provides capabilities to improve Data Security Protection Toolkit (DSPT) and Cyber Essentials Plus (CE+) assessment scores. The solution is compliant with CE+, DSPT, National Cyber Security Centre (NCSC) and I.T. Healthcare (ITHC) regimes and will remain compliant throughout the development of the service. [35]
- **Provision of measurement of cyber security risk to a software-** U.N. has **a Vulnerability Monitoring Service** which can scan the organization's I.P. address to help identify any cyber security risks. The scanning is done by a separate team, which prepares its assessment report. The information is provided to the organization within ten working days post-assessment. The report will also include suggested actions and a range of services to help with remediation. NHS also has a **cyber security rating service- BitSight**, which allows the organization to measure levels of cyber security risk. It helps in benchmarking various organizations' cyber security systems. It pinpoints and maps the vulnerabilities to the plans in a particular geographical area and provides reports emphasizing risks to the organization's management and the most appropriate action to improve security posture. **Cyber Assurance Services** are also provided to the organization that assesses and measures data security standards by completing an I.T. Health Check relating to cyber security. [35]

6.1 BENCHMARKING IN TERMS OF FRAMEWORK AND ORGANIZATIONAL STRUCTURE [25] [30]

- They are building an online and offline free platform to educate people about the current digital health policies and making digital health education compulsory in all private and Government institutions. The Learning Hub and the e-Learning for Healthcare (e-LfH) Hub are the two stand-alone educational platforms NHS provides for the health and care workforce to easily access a wide range of education and training resources, enabling users to contribute, search for, and access resources. [31] Technology Enhanced Learning (TEL) aims to support the health and social care workforce in the U.K. to use technologies and techniques to improve patient care.TEL identified the need for an easy-to-access, national learning solution for the health and social care workforce. In the future, the TEL team aims to transition the Learning Hub to a public beta phase, where the platform is open for use on the InternetInternet. [32]
- It is authorizing an organization- built by a public-private relationship to handle all the policies regarding digital health and technologies. USA's FDA built its daughter organization 'the Digital Health Center of Excellence (DHCoE)' which is a part of the planned evolution of the Digital Health Program in the Center for Devices and Radiological Health (CDRH) and will align and coordinate digital health work across the FDA. It empowers digital health stakeholders to advance health care by fostering responsible and high-quality digital health innovation.
- Development of a mechanism to address queries from digital health developers, including mobile app makers, to provide dedicated policy support and clarify published policies.
- Improving the international regulatory environment for digital health products
- India has followed **A 'carrot-and-stick approach** [26] that was followed by President Barak Obama in 2009 to change the face of Healthcare by providing provided financial incentives for providers to implement health information technologies and financial penalties for those who did not. This has increased the number of healthcare registries in India. However, still, incentives need to be enhanced for providing telehealth consultancy and following digital healthcare models for following up and monitoring remote patients undergoing rehabilitative care or suffering from chronic diseases to decrease the number of visits to the hospitals to enhance **volume- to value-based financial compensation** as followed by U.S. healthcare system. Healthcare providers and hospitals need to be incentivized to focus on preventive healthcare facilities rather than focusing only on secondary and tertiary Healthcare.

- Rather than forming individual segregated units, the market players must focus more on merging, acquisitions, technological collaborations, and product development to meet the unmet demand for digital healthcare platforms.
- Use regulatory levers, as by NHS in the U.K., to control healthcare delivery services, prioritize digitalization, identify essentials, and monitor and support compliance wherever appropriate. [29]
- We are setting national goals and framework for the best practices and ideology dealing with Digital Health. U.K. has a **What Good Looks Like (WGLL) framework.** WGLL is directed at all NHS leaders and sets out what good looks like at both a system and organizational level. The WGLL framework has seven success measures: Well led, ensure smart foundations, safe practice, support people, empower citizens, improve care, and healthy populations.
- Provision of an **Online Hub** of digital health tools and information regarding blueprints, standards, templates, real-life examples, and best practices. These tools can be used for repeatable and regular assessment of the digital framework, which can identify gaps, prioritize improvement areas and measure the organization's digital maturity.
- Use of digital communication tools to enable self-service pathways such as self-triage, referral, condition management, advice, and guidance
- To authorize a person as Head of the Department to look into the rules, regulations, and data security and management. In NHS, a CSO and DPO have been appointed and authorized for all the abovementioned duties.
- Extending the use and scope of EMR to diagnostic systems and electronic prescribing and medicines administration (EPMA) to ensure greater clinical functionality
- The data must be stored longitudinal to enable population segmentation, risk stratification, and population health management.
- To fulfil the required goals, multidisciplinary teams must be made rather than just incorporating a technical team and management for building digital health infrastructure, including clinical, operational, informatics, design, and technical expertise.
- The Government should ensure 'the simplification of the infrastructure by sharing and pooling resources and considering consolidation of spending, strategies, and contracts.
- Interoperability has three equally important aspects vital for success: good co-working relationships between staff; technology that makes co-working as easy as possible; and an enabling environment (in which funding, capacity, skills, education and governance are aligned). The Indian society is working on technological upliftment, but much work needs to be done to build co-working relationships and a working environment. [35]

- Compatible workflow and sufficient capacity across organizations for the digital transformation of healthcare services [35]

6.2 BENCHMARKING IN TERMS OF MEDICAL DEVICE EVALUATION

- Active surveillance to improve device availability and safety for patients through a cloud infrastructure approach has the potential to change how devices are evaluated, how they come to market, and how their performance is measured throughout the total product lifecycle (TPLC) from clinical entry to sunset
- I follow a risk-based approach to regulating digital health technology rather than the traditional system to moderate, higher-risk, hardware-based medical devices. The standard implementation of the premarket requirements may impede or delay patient access to critical evolutions of software technology, particularly those presenting a lower risk to patients.
- Avoiding focus on products that only promote general wellness and increasing focus on advanced technologies and applications that provide solutions to significant health problems
- It was fastening the medical device development process, pre and post-market studies, and its approval. FDA intends to develop a precertification program that could replace the need for a premarket submission for lower-risk devices and products. This allows a faster review of the marketing submission for such products without additional FDA review or with a more streamlined premarket review.
- FDA has framed a separate organization for medical device evaluation 'The National Evaluation System for Health Technology (NEST), to generate evidence across the total product lifecycle of medical devices by strategically and systematically leveraging real-world evidence and applying six advanced analytics to data tailored to the unique data needs and innovation cycles of medical devices.
- Setting up Clinical Assessment guidelines and standards to ensure clinical systems and tools meet clinical safety standards. The U.K.'s ICS has placed the following criteria to be followed by the organizations- the **Digital Technology and Assessment Criteria (DTAC)** and **DCB0129** and **DCB0160** [30]

7 SWOT ANALYSIS

7.1 STRENGTH

India has always been a consumer market. The improved technologies at an affordable cost can always have its stand in developing the future of Healthcare. With favourable demography, a culture

of entrepreneurialism, and an open economic environment, India is highly conducive to entrepreneurial activity. India has more than 1.2 billion individuals, 31% of which, i.e. 379 million, are between 18 and 35 (According to Census Report, 2011). A large number of youngsters are skilled and educated but need job opportunities. In this scenario, digitalization accompanied by globalization can be the best fit for the growth and progress of the citizens and the economy. [45]

7.2 WEAKNESS

India's Government spending on health at 1.5% of GDP is among the lowest in the world [15]. Persistently low Government spending on health has constrained the capacity and quality of healthcare services offered in the public system. [17]

India has a multi-therapeutic system involving Hemopathy, Ayurvedic, Unani, and Modern Allopathic Systems. Here, there is a need for more caution because the other streams of medicine – namely, Ayurveda, Yoga and Naturopathy, Siddha, Unani, and Homeopathy – follow entirely different principles from modern medicine. Therefore, cross-referrals may add to the complexity and confusion, ultimately harming the patient. [21]

Any new advancement and its adoption depend on the economic governance by the govt of the country. In U.K. and USA, the healthcare system is a three-tier system involving mandatory insurance that pays the companies for providing preventive Healthcare and promotion of qualitative healthcare practices that can reduce the overall cost of Healthcare and better health among the citizens. In India, the price of this advanced technology and devices will burden the middle- and low-class pocket and hence won't be affordable to them. Even the high class will be ready to invest in preventive care once the robust and compulsory healthcare measures compel them to go with it or the product is promoted by their healthcare provider.

In India, the patients, rather than following the chain or approaching the specialist doctors in terms of severity, try to directly come to the experienced doctors, even for typical colds and coughs. The older doctors, who are more resistant to change and have a different perception of the benefits of the new tools, do not directly use the EHR system and new technologies like medical devices. Hence reducing the reach of new technologies to the general public.

Access to analyst and data science workforce: using data from digital systems requires analytical skills and the support of specialist staff, including analysts and data scientists. However, there is a limited number of highly trained analyst professionals, so organizations compete to recruit and retain analysts.

8 OPPORTUNITIES

The COVID-19 pandemic has attracted market players to invest in digital health solutions and virtual care. As per the data published by OrthoLive, in 2019, 93% of healthcare professionals believed that mobile health applications could improve patients' health. Moreover, the increasing geriatric population, the rising prevalence of chronic disorders, and the growing trend of preventive Healthcare have driven several initiatives to be undertaken by the Government. According to the report of Rock Health, a full-service seed fund, investments in digital health have increased by 72% in 2020 from 2018. In addition, the growing industrial developmental activities, such as acquisitions and mergers, in the digital healthcare sector are also anticipated to accelerate market growth. For instance, acquisitions and mergers have increased to 145 in 2020 from 113 in 2019. One of the significant mergers in the telehealth industry was the merger of Livongo Health and Teladoc in 2020, worth USD 18.5 billion. [36]

Digitalization will increase opportunities for collaboration and globalization of Indian healthcare systems, resulting in improved skills acquirement and job opportunities for people nationally and internationally. It will also increase evidence-based research work and healthcare practices among providers and researchers. Globalization with attracting more foreign businesses and universities to collaborate with Indian universities and startups to drive Healthcare to great heights.

With the growing demand for functionally improved software platforms and the increasing application updating services, the developers provide support with the segment growth. Increasing activities of the service providers, such as training, installation, and education of the digital health platforms to hold their strong position in the market will boost the market growth [36]

Advanced medical technologies are increasing medical tourism in India, adding to GDP and job opportunities in the nation. Healthcare startups not only help patients gain access to quality healthcare but also create job opportunities. The sector will create 40 Mn jobs by 2030, according to Invest India. In 2018, the investment in Indian health tech amounted to a striking $ 571 million, according to Traxcn data. Further, there are about 3,225 health techs in India, according to Invest India. [40]

9 THREATS

Digitalization will increase the transparency of diseases, especially the genetic disorders they are suffering from. It will result in heavy premiums from the insurance companies and even rejection of their previous claims in which the patients had hidden their chronic health diseases [14].

Digitalizing the healthcare ecosystem and making it easier for insurance companies to pay the hospitals does not solve more urgent and severe problems like the need for healthcare facilities in rural areas. [14] It can even increase the demographic differences in the delivery of healthcare services; the

urban areas containing a rich supply of private hospitals will be more flourished with quality healthcare, and the rural areas will also have a backseat.

As rightly said by Gonsalves, a cyber expert, “The health data is a double-edged sword.” The health care data and its management can be a blessing in providing quality and affordable healthcare services to the community. Still, it can risk the nation's security if not stored correctly. The data can be breached or attacked by foreign players or even misused by the Government currently in the rule as there is an absence of checks and balances on the Government itself. [12] CloudSEK, an A.I. company, reported that the Indian healthcare sector was second in terms of the number of attacks, accounting for 7.7 per cent of the total attacks on the healthcare industry worldwide in 2021 and 29.7 per cent of all attacks in the Asia-Pacific region [48]. Currently, AIIMS Delhi faced a ransomware attack on November 23. The attack crippled the servers and e-hospital services at the country's premier public healthcare facility, causing significant inconvenience to patients [46]. The users needed help accessing a critical application that manages appointments, stores medical records, and hosts reports from diagnostic tests carried out by the facility. Doctors and patients at the institute continued to struggle to get their lab reports and long queues of patients and attendants waiting to get their messages. The database included “Personally Identifiable Information (PII) of patients and healthcare workers, and administrative records kept on blood donors, ambulances, vaccination, caregivers and employee login credentials were attacked, and the attackers asked for ransom to give the access back [48]. AIIMS incident has red-flagged the vulnerability of the government sector – all ministries have separate portals and are separately vulnerable – to cyber-attacks and hybrid warfare. [47]

9.1 CASE STUDIES AND BEST PRACTICES

Swasth Alliance [6], a not-for-profit social enterprise, was founded in 2009 to address healthcare delivery gaps by providing primary healthcare services to low-income populations in Mumbai through a network of health centres. It uses information technology (I.T.) for its clinical and administrative functions through an integrated cloud-based platform called Swasth Live. Swasth Live comprises Electronic Medical Records (EMR) and Enterprise Resource Planning (ERP). The EMR contains patients' medical records registered through their unique identification numbers. It includes their demographic and contact information, medical history, and details of consultation visits. The EMR allows Swasth to plan the best treatment plan, predict prognosis, and conduct follow-ups of the patients. The ERP facilitates supply-chain management of drugs and medical products/equipment, supporting H.R. and financial management operations. The data on clinical consultations recorded on the EMR is linked to inventories and finances on the ERP. The consolidated data facilitate better audits, avoid stock-outs, and checks potential leakages of medical supplies. During the pandemic, when social media was overflowing with information relating to Covid-19, and it was becoming hard to select

trustworthy resources, Swasth came out with a WhatsApp-based Swasth Selfcare/Homecare Bot — Sakhi. The Sakhi bot guided caregivers in charting the right treatment plan and helped patients with self-monitoring, setting reminders to check and record vitals, and creating a downloadable record. The bot was also linked to the portal providing data regarding the availability of health resources. To tackle the increasing oxygen demand, the organization collaborated with the suppliers of oxygen cylinders. Also, it developed Swasth Covid-19 Rescue Bot to match oxygen demands and supplies in real-time for various cities in India.

Besides working on Covid 19, the organization has started Swasth All Hands Calls. It's a fantastic platform where sessions are being conducted by various healthcare innovators, researchers, and policymakers on the third Monday of every month. In these sessions, people share and present their work in healthcare policy implementation and advancement. Swasth Alliance has collaborated with GoI in its ABDM to develop health stock for HCX. It worked with various stakeholders in the performance of baseline version 0.6 in 2021 and currently drafted software with version 0.7 to fulfil and overcome the challenges faced by the previous system.

The Organization for the Review of Care and Health Apps (ORCHA) is the world's leading independent digital health evaluation and distribution organization. It helps health and care organizations to deliver the right digital health apps, to the right people, at the right time. They conducted a survey which reveals that whilst 65% of the public is open to trying digital health technologies, only a fraction of tools is recommended by health or care professionals. The core work of this organization is reviewing health apps, and rating them on various parameters, to provide the public and medical professionals confidence in using these apps for Healthcare. ORCHA examines government organizations across Europe, the Middle East, and Australasia. In the U.K., ORCHA conducts reviews for NHS Digital and NHS providers in 70% of regions. NHS England is accelerating adoption across the NHS, placing ORCHA in its National Innovation Accelerator Programme. The organization also provides online training modules for frontline health and care professionals who want to use and recommend digital health tools but have yet to access the knowledge to do so safely. For this, the organization has developed the Digital Health Academy, the foundation-level modules of which are freely available at **Sorcha-academy.com** and on the Health Education England NHS Learning Hub (**learning Hub.nhs.uk**) at **learning hub.nhs.uk/Catalogue/ORCHA.** ORCHA has created the infrastructure of the online training portal and designed courses, drawing on experience gained reviewing more than 17,000 health apps and operating health app libraries in 70% of NHS regions. The team is anticipating training up to 50,000 healthcare staff in one year of the projects, with all 630,000 NHS health and care professionals having the opportunity to improve their skills by 2031. [33] [34]

Glooko, Inc. is a US-based company that aims at providing calorie and glucose monitoring services to patients for the remote management of chronic disorders. The key market players focus on mergers, acquisitions, technological collaborations, and product development to meet the unmet demand for digital healthcare platforms. For instance, in January 2021, U.S. Orthopedic Alliance (USOA) and Allscripts entered a strategic technology partnership to improve EHR implementation, create value-based care analytics, and transform clinical protocols nationwide. In October 2021, Deloitte and Vodafone partnered to launch Vodafone Virtual Center for digital health technology and simplify service access to patients & healthcare professionals. In March 2020, NextGen Healthcare launched the NextGen patient experience digital platform to modernize and improve the efficiency of routine interactions between providers & patients. [36]

9.2 IMPLEMENTATION AND NEXT STEPS

A separate Division and a new functionally and financially autonomous entity under NHA may be created to take care of the overall operationalization and management of NDHM.

NHS currently stores its data using cloud-based technologies. The next target is implementing a blockchain model and using the health id as a private key to encrypt and decrypt data shared between a sender and receiver. This system will govern the principle of patient anonymity in PHR data. [12]

The new software version, i.e., Version 0.7, was drafted for managing HCX stock in January 2022. This has been built to improvise the baseline version 0.6. This includes- Multi-party processing support through REDIRECT and FORWARD constructs, Initial support for digital encoding of policies using the Insurance Plan FHIR profile, New APIs to support the pre-determination cycle, Introduction of communication APIs to keep additional information exchange during various claim cycles - pre-determination, pre-auth, or claims, Introduction of status API to support fetching the status of a submitted request, Simplification of Protocol Headers - identifiers and level, Standardization of protocol errors and Restructuring, examples, and language modifications to enhance readability. [6]

NDHM, with the IRDAI NHA Joint Working Group, will be working on building a Health Claims Platform (HCP) for managing health claims. [13] An e-claim form, with a format derived from the FHIR-R4 standards, can be used for both public and private shares. The health providers (e.g. hospitals, labs, or primary care centres) will submit their e-Claims, and Payers (Insurers and TPAs) will receive e-claims via standard APIs on HCP. The platform will also be updated with standards for claim processing that can be used by insurance companies and fasten their process in delivering insurance services. An e- facility form will also be provided on the HCP. This form will contain details of specialities, infrastructure, and workforce available at a health facility and will help simplify the health provider empanelment process. The Healthcare Facility Registry will store and share e-facility forms with payers / TPAs on consent.

Assuring accountability to patients for services- Digital Healthcare has yet to consider systems of holding providers accountable to their patients for the quality and outcome of their services. Introducing measures for assuring accountability can go a long way in improving patients' trust in advanced technological healthcare facilities.

9.3 RECOMMENDATION/ ACTION POINTS

Digital Health Records (DHR) implementation in India involves thorough planning and consideration of several variables, including legal frameworks and ongoing activities. Let's compare the legislative frameworks of HIPAA (the United States), GDPR (the United Kingdom), ABDM, NDHM, and ABHA (India) while discussing a strategic roadmap for the effective implementation of DHR in India.

a. HIPAA (USA): In the U.S., the Health Insurance Portability and Accountability Act (HIPAA) guarantees the confidentiality and privacy of protected health information (PHI).

b. GDPR (U.K.): In the European Union, the General Data Protection Regulation protects personal data, mainly health information.

c. ABDM (India): The Aadhaar and Other Laws (Amendment) Bill 2021 governs how Aadhaar-related data is gathered, stored, and used in India.

d. National Digital Health Mission (India): This initiative intends to create a framework for the safe and reliable exchange of medical records in India.

e. ABHA (India): The DHR is being implemented in India thanks to the Ayushman Bharat Health Stack, a technology platform.

Building a dependable I.T. infrastructure will cost money, but it will be worth it when it comes to storing, transmitting, and retrieving massive amounts of health records.

b. Interoperability Standards: Standardize protocols and formats to facilitate seamless data interchange across various healthcare providers and systems.

c. Data Centres: To safeguard health records from theft or unauthorized access, establish secure data centres with suitable backup and disaster recovery systems.

d. Connectivity: To enable real-time access to medical records, increase internet connectivity across the nation, particularly in rural areas.

Implementing robust data encryption, access controls, and authentication systems will protect health records from unauthorized access or breaches. This is part of the data privacy and security category.

a. User Consent: Establish precise procedures for getting patients' informed consent before storing or disclosing their health information.

c. Audit Trails: Create audit trails to keep track of and keep an eye on who has access to health records. This will ensure accountability and help you spot any possible data breaches.

d. Regular Audits: Conduct regular security audits to find vulnerabilities and close any security and privacy breaches in the DHR system.

Health Information transmission (HIE): Create a safe framework for communicating medical records across healthcare providers to ensure interoperability and data standardization.

b. Adopt internationally recognized protocols for sharing health information, such as HL7, FHIR, and DICOM, to simplify interoperability.

b. Terminology Standards: To guarantee accuracy and consistency in health record reporting, promote the adoption of standardized medical terminologies (e.g., SNOMED CT, ICD-10).

Training and Awareness: a. Healthcare Provider Training: Educate healthcare workers on how to use DHR systems, protect their patients' personal information, and follow security best practices.

b. Conduct public awareness campaigns to inform people about the advantages of DHR, their rights regarding the privacy of their personal data, and how to access their health records safely.

Encourage cooperation between the Government, healthcare providers, technology suppliers, and other stakeholders to set standards, guidelines, and policies for the implementation of DHR. a. Government-Industry Collaboration.

a. Cross-Border Collaboration: Participate in knowledge exchange and teamwork with foreign counterparts, drawing on their implementation of DHR best practices and experiences.

Pilot Projects: Launch small-scale pilot projects in a few healthcare facilities or regions to test the DHR system's efficacy, discover problems, and make required adjustments.

2.0 Scalability Plan for the DHR system's progressive growth and scalability, considering variables including rising data volumes, the inclusion of new healthcare providers, and developing technology.

Continuous Evaluation and Improvement: a. Monitoring and Evaluation: Set up systems to continuously assess the DHR implementation's progress, pinpointing opportunities for improvement and resolving any new problems that may arise.

a. Feedback Loops: Encourage input from patients, healthcare professionals, and other stakeholders to include their thoughts and insights for improving the usability and functionality of the DHR system.

India can successfully integrate Digital Health Records by adhering to international regulatory frameworks and utilizing domestic initiatives like ABDM, NDHM, and ABHA. Throughout the deployment phase, it is essential to ensure data protection, security, interoperability, stakeholder participation, and continual development.

10 CONCLUSION

The Indian Govt needs to increase its focus on improving the general public's and healthcare providers' Awareness and skills regarding the use, benefits, and privacy concerns associated with digital health. Also, rather than developing a federated system, a unified system focusing on incentivizing the Health workers for qualitative care in reducing patient visits needs to be increased. Healthcare transparency, increased funding, a robust system for tackling threats and penalties, and accessibility of Healthcare to all citizens, whether visiting Govt or Private hospitals, need to be focused on. It is also essential that the Government take crucial steps to ensure that the PHR of Indians is treated equivalent to protecting their fundamental right to privacy.

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