Healthcare Technology, Standards & Policy Updates (Europe & India)

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Outline

- About Project SESEI
- e-Health, Role of Standards & Technology in Healthcare
- Policy and Standardization work around Healthcare (e-Health)
  - Europe & India
- Conclusion

Project SESEI

Project is a permanent presence in India

SESEI (**S**econded **E**uropean **S**tandardization **E**xpert in **I**ndia) ***is a local face for the European standardization community in India: Dinesh Chand Sharma***

Why SESEI: India is a major trade partners for Europe, Increasing role of standards to gain market access and Evolving & complex nature of regulatory and standardization landscapes, Sharing best practices, work together

Sector: ICT: M2M/IoT, Security, 5G, NFV/SDN, e-Accesibility, eHealth, eCALL ! **Electrical equipment including Consumer Electronics**: Smart Grid, Smart Meter, LVDC, Micro- Grid, Lift Escalator **! Mobility**: Connected Cars, ITS, e-Mobility, Railways ! **Smart Cities**: Mobility, Waste, Energy, ICT ! **Energy Efficiency & Circular Economy etc.**

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e-Health, Role of Standards & Technology in Healthcare

What is e-Health?

"WHO defines eHealth as the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research"

e-Health and Standards

Standards

- Create necessary interoperability among healthcare systems.
- prevent single vendor lock-in.
- reduce costs by enabling market competition and eliminating the need for expensive and customized solutions.
- ensure widespread adoption.
- address specific concerns about privacy, security, and patient identification.

Role of Technology in Healthcare (IoT)

ICT Technologies like artificial intelligence (AI) and the Internet of Things (IoT) have penetrated almost every aspect of healthcare

IoT:

- IoT devices can provide the required health information remotely and lessen the need for direct patient-physician interaction.
- IoT devices can be used to derive valuable insights from the data from ECG, temp monitors, glucometer etc.
- It can also help in integrating data collected from tests instantly, monitor the condition of the patient, and then relay that information to the doctors and staff in real time, thereby improving the efficiency of the overall healthcare system.
- In healthcare surveillance, IoT can also help in early detection of health problems.
- Finally in a world of connected everything – IoT through different distributed & connected devices can gather, analyze and communicate real-time medical information to open, private or hybrid clouds, making it possible to collect, store and analyze big data streams, and activate context dependent alarms.

Role of Technology in Healthcare (AI)

ICT Technologies like artificial intelligence (AI) and the Internet of Things (IoT) have penetrated almost every aspect of healthcare

Artificial Intelligence (AI)

- Data management of health records is one of the most widely used applications of AI and automation.
- AI can also be deployed to perform certain repetitive tasks like analyzing laboratory tests, X-rays, CT scans and other medical data entries.
- AI-based apps can also be used to provide medical consultation based on personal medical history and intelligence gathered through analytics.
- Drug creation can also be supported by AI-powered programs which can significantly lower the costs of developing pharmaceuticals.
- Precision medicine is another application of AI wherein AI-powered - body scans can spot cancer and vascular diseases early and predict the health issues people might face because of their genetics.

Policy Initiatives: e-Health (Europe)

e-Health action plan 2012-2020

- **eHealth Action Plan 2012-2020** provides a roadmap to:
  - ✓ empower patients and healthcare workers,
  - ✓ link up devices and technologies, and
  - ✓ invest in research towards the personalized medicine of the future

- **Operational objectives:**
  - ✓ Achieve wider interoperability in e-Health services
  - ✓ Support Research, Development and Innovation
  - ✓ Facilitate uptake and ensuring wider deployment
  - ✓ Promote international cooperation

- Action Plan emphasizes cross-border activities and encourages national/regional authorities, healthcare & Socialcare professionals, industry, patients, service providers, researchers and EU Institutions to work together closely

For more details, please click here

eHealth Network - EU4Digital

- eHealth Network established in February 2017
  - Connects the health systems in EU and 6 Eastern partner countries of Armenia, Azerbaijan, Belarus, Georgia, Moldova and Ukraine, was officially.

- The strategic goal of the Network is to:
  - Facilitate the adoption of EU eHealth guidelines and standards within EU and Eastern partner countries' including norms, regulation and practices by accomplishing three specific objectives:
    - ✓ Establishment of a platform for partnership building, regular exchanges of information, dissemination of "knowledge and expertise" on the issues related to eHealth.
    - ✓ Development of common "guiding documents and recommendations" for harmonizing eHealth policies and standards, formulation of joint projects and regional initiatives, provision of expert support on demand for partner countries.
    - ✓ Capacity building of eHealth institutions, communities and professionals.

Digital Single Market: Transformation of Health and Care

- In line with Digital Single Market (DSM) strategy, EC on 25 April 2018 adopted 'Communication on enabling the digital transformation of health care in the Digital Single Market for empowering citizens and building a healthier society'.

- **Three Priorities:**
  - ✓ Citizens across borders secure access to their personal health data
  - ✓ Personalized medicine through shared European data infrastructure
  - ✓ Citizen empowerment with digital tools for feedback and person centric care

For more details, please click here

EU4Health programme

- European Commission EU4Health programme was launched in response to COVID-19(2021-27)
- It aims to make contributions to the recovery response by strengthening the resilience of health systems while promoting medical innovation and digital transformation in the healthcare.
- The programme aims to boost the EU's preparedness for major cross border health threats by creating:
  - Reserves of medical supplies for crises.
  - Reserve of healthcare staff and experts that can be mobilized to respond to crises across the EU.
  - Increased surveillance of health threats.
  - Strengthen health systems so that they can face epidemics as well as long-term challenges.
  - Disease prevention and health promotion in ageing population.
  - Digital transformation of health systems.
  - Access to health care for vulnerable groups.
  - Make medicines and medical devices available and affordable,
  - Advocate the prudent and efficient use of antimicrobials as well as promote medical and pharmaceutical innovation and its greener manufacturing.
- The programme aims to invest €5.1bn in EU countries for health organizations and NGOs to boost innovation and build the resilience of health systems. For more info click here

EC Mandate M/403

Standardization mandate M/403 was issued in March'2007 and addressed to the European Standards Organizations CEN-CENELEC-ETSI and is in the field of ICT applied to the domain of eHealth.

Mandate aimed to provide a consistent set of standards to address the needs of the rapidly-evolving field of eHealth for the benefits of future healthcare provision

Standardization (Europe)

European Committee for Standardization (CEN)

- CEN/TC 251 'Health informatics' is responsible for standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems and to enable modularity.
  - ✓ This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality.
- **CEN/TC 251 has two working Groups:**
  - CEN/TC 251/WG 1: Enterprise and Information - concerned with standards and specifications for the safe and secure use of information within the eHealth domain, as well as its governance and management.
  - CEN/TC 251/WG 2: Technology and Applications - concerned with standards and specifications in the field of Health Information and Communications Technology (Health ICT), including safety and security aspects, to achieve compatibility and interoperability between independent systems.
- Published more than **110 standards**

European Telecommunications Standards Institute (ETSI)

- **ETSI TC eHEALTH** is responsible for coordinating ETSI's activities in the eHealth domain
- **ETSI TC eHEALTH covers:**
  - ✓ Collect and define Health ICT related requirements from relevant stakeholders, and input these requirements to the concerned ETSI Technical Bodies
  - ✓ Identify gaps, where existing ETSI standards do not fulfil the Health ICT requirements, and suggest further standardization activities to fill these gaps
  - ✓ Develop Health ICT related deliverables in all areas not covered by existing system and horizontal Technical Bodies or other SDOs
  - ✓ Co-ordinate Health ICT related activities with oneM2M, 3GPP and other ETSI Technical Bodies (including SmartM2M, SmartBAN, CYBER, DECT, HF, ITS, USER etc.) to avoid duplication of effort and deliverables
  - ✓ Co-ordinate activity with other European and international standards making bodies to avoid duplication of effort and deliverables
  - ✓ Represent ETSI positions externally on Health ICT-related issues
- **List of Published Standards covering COVID, use cases, architecture etc. are available here**

Policy Initiatives: e-Health (India)

National Health Policy, 2017

- **National Health Policy (NHP), 2017 builds on the progress made since the last National Health Policy of 2002, which had replaced National Health Policy of 1983**
- The primary aim of the National Health Policy, 2017, is to Inform, clarify, strengthen and prioritize the role of the Government in shaping health systems in all its dimensions:
  - ✓ Investments in health, organization of healthcare services, prevention of diseases and promotion of good health through cross sectoral actions, access to technologies, developing human resources, encouraging medical pluralism, building knowledge base, developing better financial protection strategies, strengthening regulation and health assurance.
- **Objectives**
  - ✓ Progressively achieve Universal Health Coverage
  - ✓ Reinforcing trust in Public Health Care System
  - ✓ Align the growth of private health care sector with public health goals
  - ✓ Specific Quantitative Goals and Objectives covering Health Status and Programme Impact, Health Systems Performance, strengthening etc.

National Health Stack (NHS) 2018

- Niti Aayog released National Health Stack (NHS) Strategy and Approach in July 2018
- NHS is digital infrastructure built with the aim of making the health insurance system more transparent and robust, while factoring in the uniqueness of India's health sector, and the political realities of federalism.
- There are five components of NHS:
  - ✓ **A Coverage and Claims Platform** that would serve as the building blocks for large health protection schemes and allow the horizontal and vertical expansion of schemes like Ayushman Bharat by states and enable a robust system of fraud detection.
  - ✓ **An electronic National Health Registry** that would serve as a single source of health data for the nation.
  - ✓ **A federated Personal Health Records (PHR)** framework that would serve the twin purposes of access to their own health data by patients, and the availability of health data for medical research - critical for advancing the understanding of human health.
  - ✓ **A National Health Analytics Platform** that would provide a holistic view combining information on multiple health initiatives, and feed into smart policymaking, for instance, through improved predictive analytics
  - ✓ **Other horizontal components** includes but not limited to a unique digital health ID, health data dictionaries, supply chain management for drugs, payment gateways etc. to be shared across all health programs.

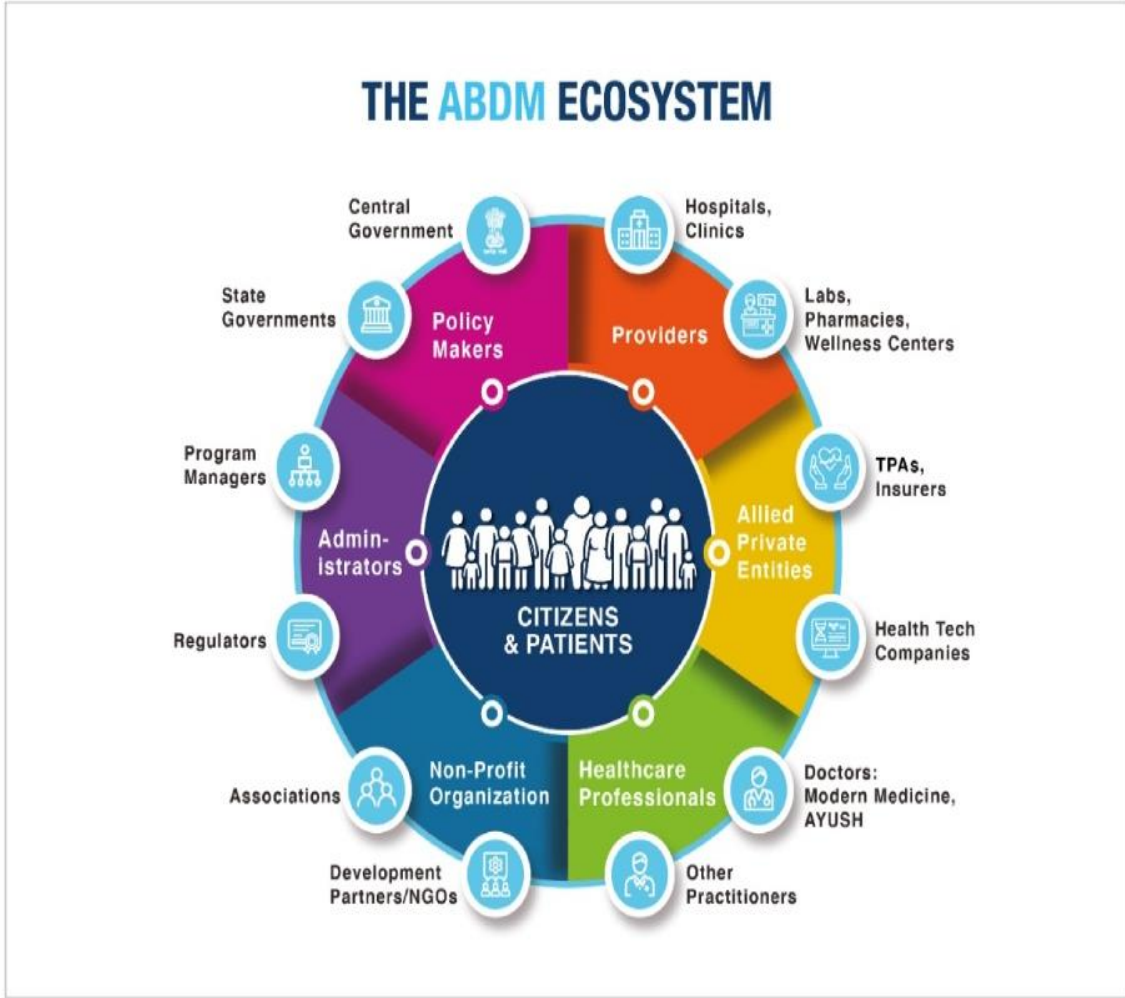
National Digital Health Blueprint (NDHB) 2019

- National Digital Health Blueprint (NHDB) is an extension of National Health Policy of 2017 (NHP 2017) that was formulated to provide universal healthcare to all citizens of India based on digital technologies for achieving higher efficiency and effectiveness.
- **Objectives of NDHB include:**
  - Establishing and managing the core digital health data and the infrastructure required for its seamless exchange.
  - Promoting the adoption of open standards by all the actors in the National Digital Health Ecosystem (NDHE) for developing several digital health systems that span across the sector from wellness to disease management.
  - Creating a system of Personal Health Records, based on international standards, which is easily accessible to the citizens and to the service providers, based on citizen-consent.
  - Promoting Health Data Analytics and Medical Research.
  - Enhancing the efficiency and effectiveness of Governance at all levels.
  - Ensuring Quality of Healthcare.
  - Leveraging the Information Systems already existing in the health sector.
  - Follow the best principles of cooperative federalism while working with the States and Union Territories for the realization of the Vision.

Download Final Report on National Digital Health Blueprint (NDHB)

Ayushman Bharat Digital Mission (ABDM)

- In September 2021, Government launched Ayushman Bharat Digital Mission (ABDM) with an aim to develop the backbone necessary to support the integrated digital health infrastructure in the country.
  - ✓ It shall bridge the existing gap amongst different stakeholders of Healthcare ecosystem through digital highways.
- ABDM to create a seamless online platform "through the provision of a wide-range of data, information and infrastructure services, duly leveraging open, interoperable standards based digital systems" while ensuring the security, confidentiality and privacy of health-related personal information.
- National Health Authority (NHA) is entrusted with the role of designing strategy, building technological infrastructure and the implementation of ABDM
- A unique health ID for every patient, healthcare professionals and health facility is being created under this initiative.



National Health Portal (NHP)

- Ministry of Health and Family Welfare (NIHFW) has set up National Health Portal (NHP) in pursuance to the decisions of the National Knowledge Commission, to provide health care related information to the citizens of India and to serve it as a single point of access for consolidated health information
  - ✓ NIHFW has established "center for health informatics to be the secretariate" for managing activities Of NHP

- **Goal:** Gateway to authentic health information of all citizens

- **Vision:** Aims to establish a single point access for authenticated health information for citizens, students, healthcare professionals and researchers.

- **Mission:** Achieve the vision by collecting, verifying and disseminating health and health care services to all its citizen of India

Integrated Health Information Program (IHIP)

- To strengthen the disease surveillance in the country by establishing a decentralized State based surveillance system for epidemic prone diseases to detect the early warning signals, so that timely and effective public health actions can be initiated at the Districts, State and National level.

- To provide interoperability of various implemented Electronics Health Record (EHR) systems

- To enable better continuity of care, secure and confidential health data/records management, better diagnosis of diseases, reduction in patient re-visits and even prevention of medical errors, better affordability, optimal information exchange, better decision support system etc.

Read more>>

Standardization: e-Health (India)

Standardization

Ministry of Health & Family Welfare (MoH&FW):

- ✓ In Sep 2010, MoH&FW constituted an experts committee for Development of Standards on Electronic Health Record (EHR)
- ✓ In Dec. 2016, MoHFW notified EHR Standards Version 2016 (revised version of EHR standards 2013) with an intent to bring standardization and homogeneity, inter-operability to capture, storage, transmission & use of healthcare information across various Health IT systems.

>>EHR standards 2016 are available here

- ✓ In March 2020 MoHFW has also released its Telemedicine Practice Guidelines

National e-Health Authority (NeHA): established in 2015 as a promotional, regulatory and standards-setting organization in Health Sector

- ✓ To formulate "National eHealth Policy and Strategy" for coordinated eHealth adoption
- ✓ To formulate and manage all health informatics standards for India
- ✓ To lay down data management, privacy and security policies, guidelines and health records of patients in accordance with statutory provisions

>>Read more about NeHA

Bureau of Indian Standards (BIS):

- Medical Equipment and Hospital Planning Department is responsible for Standardization in the field of medical equipment. Department has published around 1470 standards. For more information, please click here

CEN CENELEC ETSI European Commission EFTA SESEI Seconded European Standardisation Expert in India
Enabling Europe-India Cooperation on Standards

Conclusion

- Number of hospitals and doctors especially in rural India are not adequate.
- Technology would make critical healthcare much more accessible to the common man as it would provide affordable, effective and quicker solutions.
- For providing the effective health services, role of technology integration is must, which means e-health , m-health and telemedicine solutions are required to be implemented.
- Spread of cell phones, falling internet data rates and affordable healthcare facilities can lead to significant penetration of eHealth into rural india - villages.
- Technologies like IoT, Artificial Intelligence (AI), and 3D Printing already have a huge impact on the healthcare sector.
- A standardized e-health ecosystem is necessary to leverage the potential of digitization and much needed economies of scale in healthcare sector

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