T-21016/78/2018-eHealth
Government of India
Ministry of Health & Family Welfare
eHealth Section
*****

Nirman Bhawan, New Delhi
Dated 15th July, 2019

NOTICE

Subject: **Placing the report on National Digital Health Blueprint (NDHB) in public domain for comments/ views regarding.**

NITI Aayog released a proposal in July, 2018 for the National Health Stack (NHS). NITI Aayog has brought out that the National Health Stack is designed to provide the foundational components that will be required in health IT programs in India.

2. The components of the National Health Stack as proposed by NITI Aayog needed further examination. A Committee was constituted under the chairmanship of Shri J. Satyanarayana former Secretary, MeitY and Chairman of Unique Identification Authority of India (UIDAI) to create a frame work and implementation plan for National Health Stack.

3. After series of meetings and brainstorming sessions, the committee has prepared the report and named it "National Digital Health Blueprint (NDHB)". The report was submitted to MoHFW on 24th April 2019. Accordingly, National Digital Health Blueprint (NDHB) report is being placed in public domain with a view to elicit comments/ views of the stakeholders, including the general public.

4. The comments/ views may be forwarded to Deputy Director (eHealth), Ministry of Health and Family Welfare, Room no. 753 A, Nirman Bhawan, New Delhi-110011 or emailed at amit.k89@gov.in on or before 04th August, 2019.

15/7/19

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National Digital Health Blueprint

Ministry of Health & Family Welfare
Government of India
April 2019

Preface

 The National Health Policy 2017 (NHP 2017) envisages the goal of attainment of the highest level of health and well-being for ALL at ALL ages, through increasing access, improving quality and lowering the cost of healthcare delivery. The key principles of NHP 17 include universality, citizen-centricity, quality of care and accountability for performance. The policy lays significant emphasis on leveraging digital technologies for enhancing the efficiency and effectiveness of delivery of all the healthcare services. While recognizing the deficiencies that exist in the current health care systems the policy recommends a paradigm shift from the existing silos systems to a holistic and comprehensive health eco-system, founded on the latest digital architectures and technologies.

While the efforts in deploying technology for healthcare have been continuous and widespread, the benefits have been highly localized and fragmented. The citizen cannot access his health records speedily nor store them conveniently. In the absence of an integrated system, the service providers undertake diagnostic tests afresh and create isolated medical records enhancing the burden on the citizen significantly. Health service providers in the public and private sectors do not have an aggregated and complete view of the data for providing efficient health services to the citizens. Governments, Central and State alike, do not have reliable and complete data for policy analysis and evidence-based interventions.

The need of the hour is to elevate the existing systems from providing disparate electronic services to integrated digital services. We need to clearly adopt the principles of Enterprise Architecture, if we must leverage the digital technologies to achieve the vision of NHP 2017. While setting specific goals for the health sector in alignment with SDG's to be achieved over the next 5 years in vital areas such as life expectancy, IMR, MMR, TFR, immunization, malnutrition and disease control, the NHP 2017 has also prescribed such specific goals for adoption of digital technologies. These include creation of district-level electronic databases, establishing registries for all diseases of public importance and most significantly, 'establishing Federated National Health Information Architecture, to roll-out and link systems across public and private health providers at State and National levels consistent with Metadata and Data Standards (MDDS) & Electronic Health Record (EHR)'. The policy also envisages leveraging 'the potential of digital health for 2-way systemic

linkages between primary, secondary and tertiary care to ensure continuity of care'.

Against the above background, the Committee constituted by the Health Ministry to create an implementation framework for the National Health Stack (NHS) proposed by NITI Aayog, has come up with **the National Digital Health Blueprint**, after surveying the global best practices in adoption of digital technologies holistically. The blueprint is not merely an 'architectural document'. It has specific details of the building blocks required to fulfil the vision of NHP 2017 as also the institutional mechanism and an Action Plan for realizing Digital Health in a comprehensive and holistic manner. The key features of the blueprint include a Federated Architecture, a set of architectural principles, a 5-layered system of architectural building blocks, Unique Health Id (UHID), privacy and consent management, national portability, EHR, applicable standards and regulations, health analytics and above all, multiple access channels like call centre, Digital Health India portal and MyHealth App.

The mandate of the **National Digital Health Mission** recommended in this report is a balanced combination of designing, developing and realizing certain pure-play Technology Building Blocks and the essential Domain (Health) Building Blocks.

The National Digital Health Blueprint keeps the overall vision of NHP 2017 in perspective and recommends a pragmatic agenda to start with, adopting the principle of **'Think Big, Start Small, Scale Fast'**. It forms the foundation on which the edifice of an entire National Digital Health Eco-system can be built in a phased manner.

I wish to acknowledge the contribution made by all the members of the Committee and several other experts who have enriched the discussions.

J Satyanarayana
Chairman of the Committee

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Abbreviations

ASHA	Accredited Social Health Activist
BIS	Bureau of Indian Standards
CBHI	Central Bureau of Health Intelligence
CHI	Centre for Health Informatics
EHR	Electronic Health Record
FHIR	Fast Healthcare Interoperability Resources
GSTN	Goods and Services Tax Network
HIE	Health Information Exchange
HL7	Health Level-7
HMIS	Health Management Information System
ICD	International Classification of Diseases
ICMR	Indian Council of Medical Research
ICT	Information and communications technology
IDSP	Integrated Disease Surveillance Programme
InDEA	India Enterprise Architecture
IRDA	Insurance Regulatory and Development Authority
LOINC	Logical Observation Identifiers Names and Codes
MCH	Maternal & Child Health
MDDS	Meta Data & Data Standards
NCDC	National Centre for Disease Control
NDHB	National Digital Health Blueprint
NDHE	National Digital Health Ecosystem
NDHM	National Digital Health Mission
NHA	National Health Agency
NHP	National Health Portal
NHRR	National Health Resource Repository
NHS	National health Stack
NIC	National Informatics Centre
NIHFW	National Institute of Health & Family Welfare
NIN	National Identification Number
NPCB	National Programme for Control of Blindness
NPCI	National Payments Corporation of India
NSDL	National Securities Depository Limited
PHI	Patient Health Identifier
PHR	Personal Health Record
PMJAY	Pradhan Mantri Jan Arogya Yojana
SDG	Sustainable Development Goals
SNOMED CT	Systematized Nomenclature of Medicine-Clinical Terms
UHID	Unique Health Identifier
UIDAI	Unique Identification Authority of India

Executive Summary

The National Health Policy 2017 had defined the vision of 'health and wellbeing for all at all ages'. **Continuum of Care** is a concept strongly advocated by the Policy. These lofty ideals are sought to be achieved by refactoring the existing schemes and introducing several new schemes including some digital initiatives. **Citizen-centricity, quality of care, better access, universal health coverage, and inclusiveness** are some of the key principles on which the Policy is founded. All these aspirations can be realized principally by leveraging the power of the digital technologies. In the context of India, with its size and diversity, this mammoth task requires that a **holistic, comprehensive and interoperable digital architecture** is crafted and adopted by all the stakeholders. In the absence of such architecture, the use of technology in the health sector continues to grow in an uneven manner and in silos.

Eco-System, not System!

In the above context, the Committee constituted by the Ministry of Health and Family Welfare recognized the need for creating a framework for the evolution of **a National Digital Health Eco-system (NDHE)** – an *Eco-system and NOT a System*! The result is the **National Digital Health Blueprint (NDHB)**, which is more than an architectural document, as it provides specific guidance on its implementation as well. NDHB recognizes the need to establish a specialized organization, called **National Digital Health Mission (NDHM)** that can drive the implementation of the Blueprint, and promote and facilitate the evolution of NDHE.

The Blueprint keeps the overall vision of NHP 2017 in perspective and recommends a pragmatic agenda to start with, adopting the principle of **'Think Big, Start Small, Scale Fast'**. To this end, it has been designed as a layered framework, with the **Vision** and a set of **Principles** at the core, surrounded by the other layers relating to Digital Health **Infrastructure**, Digital Health **Data Hubs**, **Building Blocks**, **Standards** & **Regulations**, and an **Institutional Framework** for its implementation. The document also contains a high-level Action Plan.

The **Objectives** of NDHB are aligned to the Vision of NHP2017 and the SDG's relating to the health sector. These include:

a. Establishing and managing the core digital health data and the infrastructure required for its seamless exchange;
b. Promoting the adoption of open standards by all the actors in the National Digital Health Eco-system, for developing several digital health systems that span across the sector from wellness to disease management;

c. Creating a system of Personal Health Records, based on international standards, and easily accessible to the citizens and to the service providers, based on citizen-consent;

d. Following the best principles of cooperative federalism while working with the States and Union Territories for the realization of the Vision;

e. Promoting Health Data Analytics and Medical Research;

f. Enhancing the efficiency and effectiveness of Governance at all levels;

g. Ensuring Quality of Healthcare.

h. Leveraging the Information Systems already existing in the health sector.

NDHB Principles

An eco-system cannot be *built* – it must *evolve*. Given this, **a set of Principles - rather than specifications** - have been recommended to enable the evolution of the NDHE. The key principles of the Blueprint include, *from the domain perspective*, Universal Health Coverage, Inclusiveness, Security and Privacy by Design, Education and Empowerment of the citizens, and *from the technology perspective*, Building Blocks, Interoperability, a set of Registries as Single Sources of Truth, Open Standards, Open APIs and above all, **a minimalistic approach**.

Building Blocks of NDHB

In the context of the evolution of a digital eco-system, as is the case of NDHE, **building blocks** are reusable frameworks or artefacts that most stakeholder groups need to rely upon for designing, developing and delivering their services. The Blueprint identifies the **Minimum Viable Set of Building Blocks** required for the NDHE to evolve and describes their capabilities at a high-level. It is for the NDHM, as an organization, to arrange for the design, development and establishment of the Building Blocks. Conformance to the NDHB Principles on the one side and to the NDHB Standards & Regulations on the other side, are critical for an efficient design and development of the Building Blocks.

Building Blocks constitute the core of NDHB.

While the Blueprint has identified **23 Building Blocks**, a few of the critical capabilities of NDHE, addressed by appropriate combinations of the Building Blocks, are explained briefly along with a schematic of the Blueprint.as:

1. **Identification**: Unique identification of Persons, Facilities, Diseases and Devices is a key requirement and challenge as well in NDHE. The Blueprint handles this requirement through 2 Building Blocks, namely, **Personal Health Identifier (PHI)**, and **Health Master Directories & Registries**. The uniqueness in identification of Persons (citizens) required as an essential attribute of PHI is sought to be achieved through a combination of Aadhaar-based

Identification/ Authentication for schemes notified under Section 7 of the Aadhaar Act, and through other *specified* types of identifiers in respect of the rest. **However, the Committee recommends that the design of the PHI may be finalized by the MoHFW, in consultation with MeitY and UIDAI duly taking into consideration the regulatory, technological and operational aspects**. PHI in tandem with Health Locker will facilitate the creation and maintenance of **Personal Health Records**.

2. **Citizen to be in Control**: The need for maintaining the confidentiality, security and privacy of the health records cannot be over-emphasized. These regulatory requirements are built into the design of NDHE *a priori*, rather than being retrofitted. The Blueprint achieves these complex and mandatory requirements through a combination of a few Building Blocks, namely, **Consent Manager, Anonymizer and Privacy Operations Centre**. Besides these Building Blocks, application-specific features and relevant International standards defined in the Blueprint fortify the privacy regime.

3. **Service Access/ Delivery**: Omni-channel access/ delivery are an important capability required in NDHE. This is achieved by a combination of Web (**India Health Portal**), Mobile (**MyHealth App**) and **Call Centres** besides **Social Media Platforms**. The Command, Control and Communication Centre enable real-time monitoring and real-time interventions needed in the NDHE. Given the significant spread of smartphones and the prospects of its further growth, The Blueprint emphasizes the '**Mobile First**' principle for majority of stakeholder-facing services.

4. **Interoperability**: The most important contribution of the Blueprint is its advocacy of Interoperability, which is a pre-requisite for development of integrated digital health services and continuum of care but also for the autonomous development of innovative value-added services by entrepreneurs. Two Building Blocks, namely, the **Health Information Exchange** and the **National Health Informatics Standards** enable and promote the interoperability of various building blocks.

A significant effort requiring high-level expertise is involved in the preparation of the detailed designs for 17 of the 23 Building Blocks (excluding the building block of Standards [already specified in The Blueprint] and those relating to the Application Layer). A high-level approach for the same has been included in Chapter 2.

National Digital Health Blueprint (NDHB) Applications & Digital Services

The Application Layer of the Blueprint is merely a placeholder in so far as it identifies the **thematic areas** for development and deployment of **applications** but refrains from listing them. Such an approach has been adopted not only because of the large number and variety, but also because the applications must evolve in an innovative way that cannot be defined upfront. It is necessary here to underline the importance of leveraging some applications in the health sector that have evolved and matured over the last few years. Taking the legacy applications on board to the NDHE requires that each application is rigorously assessed w.r.t it's conformance to the standards, using a set of criteria like that defined by the Digital Service Standard.

The value of the Blueprint can be realized mainly in terms of the impact the Digital Health Services make on the various stakeholder groups. The Blueprint provides an illustrative, but by no means exhaustive list of **Digital Health Services**, to indicate the nature of qualitative difference its implementation can make. Needless to say that the portfolio of services must be validated and updated through a series of consultations with the stakeholder groups.

Standards

National Health Informatics Standards form the cornerstones of the foundation of NDHB. The health sector must adopt the international standards in a large number of areas. However, The Blueprint has adopted a pragmatic approach and recommended only the minimum viable set of standards, to make it easier for the eco-system players to adopt the same. FHIR Release 4 (in a highly condensed form), SNOMED CT and LOINC are among the standards recommended.

Institutional Framework

A Blueprint is only as good as its implementation. An appropriate **Implementation Framework** is suggested in Chapter 4. A new entity, **National Digital Health Mission (NDHM),** is recommended to be established as a purely government organization with complete functional autonomy adopting some features of some of the existing **National Information Utilities** like UIDAI and GSTN. The role and functions of NDHM and an appropriate organizational structure have been recommended. A high-level Action Plan has been recommended in Chapter 5 that can guide the implementation of NDHB.

CHAPTER 1

CONTEXT & SCOPE OF NATIONAL DIGITAL HEALTH BLUEPRINT

VISION

To create a National Digital Health Eco-system that supports Universal Health Coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, through provision of a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensuring the security, confidentiality and privacy of health-related personal information."

CHAPTER 1
CONTEXT & SCOPE OF
NATIONAL DIGITAL HEALTH BLUEPRINT

1.1 The Context

Healthcare has always been central to all development efforts be it a national or global agenda. Government of India envisages as its goal the attainment of the highest possible level of health and well-being for all at all ages and intends to provide universal access to good quality health care services without anyone having to face financial hardship as is enunciated in National Health Policy, 2017. The most promising approach adopted by National Health Policy towards this goal is extensive deployment of Digital Tools/Technology to enhance health system performance. Government is committed to Universal Health Coverage for all citizens; to make healthcare affordable, accessible, and equitable, and Digital Health technology has a huge potential for supporting Universal Health Coverage (UHC).

Ministry of Health and Family Welfare (MoHFW) has prioritized the utilization of Digital Health to ensure effective "service delivery" and "citizen empowerment" so as to bring significant improvements in the public healthcare delivery.

To improve efficiency in healthcare delivery, extend healthcare to rural areas and provide better quality services at low cost, certain eHealth initiatives using ICT (Information and Communication Technologies) were undertaken by MOHFW across the country with the following objectives:

- To ensure availability of services on wider scale
- To address the human resource gap by efficient & optimum utilization of the human resources existing in the health sector
- To provide healthcare services in remote & inaccessible areas through telemedicine
- To Improve patient safety by access to medical records and help reduce healthcare cost
- To monitor geographically dispersed tasks for meaningful field level interactions through effective use of MIS
- To help in evidence based planning and decision making, and
- To improve efficiency in imparting training and in capacity building

A few of the ongoing initiatives in Digital Health being implemented by MoHFW include Reproductive Child Healthcare (RCH), Integrated Disease Surveillance Program (IDSP), eHospital, e-Shushrut, Electronic Vaccine Intelligence Network (eVIN), National Health Portal (NHP), National Identification Number (NIN), Online Registration System (ORS), Mera Aspatal (Patient Feedback System) and National Medical College Network (NMCN). These initiatives are operational at a substantially mature level and are already generating enormous amount of data in the health

sector. Since health is a State subject, States are supported under National Health Mission (NHM) for services like Telemedicine, Tele-Radiology, Tele-Oncology, Tele-Ophthalmology and Hospital Information System (HIS).

The Government of India approved the National Health Policy 2017 (NHP 2017) with the vision of providing Universal Health Care. As a sequel to the NHP 2017, , the Union Budget for the fiscal year 2018–19 announced the Ayushman Bharat Yojana, a program designed to address health holistically through a two-pronged approach

- To set up **1.5 Lakh Health and Wellness Centres** for comprehensive primary healthcare, offering preventive and promotive healthcare accessible to all, and

- A flagship scheme **Pradhan Mantri-Jan Arogya Yojna (PMJAY)** to provide healthcare cover to over 10 Crore poor and vulnerable families up to Rs 5 Lakh per family per year for secondary and tertiary care requiring hospitalization.

Through Ayushman Bharat, the Government of India has taken steps to lay the foundation of a 21st Century Health System. It is expected that the provision of services through public and private sector under Ayushman Bharat will generate enormous amounts of health data, mostly in the digital space. To ensure that we can leverage the cutting-edge digital technologies, it is crucial to focus on creating an appropriate architecture and data structures which are both pan-India. With the current system of fragmented data capture by multiple stakeholders without any standardization, there is a serious risk of compartmentalization of Digital Health assets.

The aforesaid challenge also presents us with an opportunity to build a state-of-the-art **National Digital Health Eco-system (NDHE)** that can enable us to leapfrog many of the traps that bedevil health information systems even in developed economies.

Towards this end, NITI Aayog had proposed a conceptual framework for creation of a **National Health Stack** - a set of core building blocks to be "built as a common public good" that helps avoid duplication of efforts and achieve convergence among the IT systems of the diverse stake holders such as the Governments, the Payers, the Providers and the Citizens. Even at the conceptualization stage, it was recognized that the issue of data safety, privacy and confidentiality will be critical for the success of the NHS and consequently, the need has arisen for a mechanism to incorporate these elements *ab-initio* into the architecture.

The Ministry of Health & Family Welfare constituted a Committee chaired by Shri J. Satyanarayana, the then Chairman, Unique Identification Authority of India (UIDAI) to create an implementation framework for the proposed National Health Stack. The composition of the Committee is shown in **Annexure I**.

Given the vastness of the Health Domain and the complexities involved in designing architecture for National Digital Health Eco-system, the Committee constituted 4 Sub-Groups to deal with 4 distinct aspects of the mandate of the Committee. These relate to

i.   Scope of NDHB, Overarching Principles and Target Digital Services
ii.   Building Blocks of NDHB, including Universal Health Id
iii.   Standards and Regulations, and
iv.   Institutional Framework

The composition of the Sub-Groups and Terms of Reference are given in **Annexure II**.

Based on the efforts of the 4 Sub-Groups, the Committee prepared the National Digital Health Blueprint (NDHB) as a document that would act as an authoritative reference in guiding all future efforts for creation of NDHE. It is envisaged that the Blueprint will shape the path for a digitally inclusive healthcare system to be established in our country. The nomenclature of "National Digital Health Blueprint" is considered more appropriate as the document is a balanced combination of Architectural Principles, Building Blocks and an Implementation Framework as well, which together, provide an immediate setting for action in multiple dimensions and at multiple levels.

1.2 Vision of National Digital Health Blueprint (NDHB)

To complement the overall vision of Government to create an enabling digital health ecosystem and prioritization of Digital Health by Government as enunciated in the national level programs, the following Vision Statement is recommended to be adopted for National Digital Health Blueprint:

"To create a National Digital Health Eco-system that supports Universal Health Coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, through provision of a wide-range of data, information and infrastructure services, duly leveraging open, interoperable, standards-based digital systems, and ensuring the security, confidentiality and privacy of health-related personal information."

The Vision of NDHM encapsulates the goals of NHP 2017 and aims to leapfrog to the digital age by providing a wide range of digital health services.

1.3 Objectives of National Digital Health Blueprint (NDHB)

The following specific objectives need to be achieved if the Vision of NDHM is to be realized:

a. To establish state-of-the-art digital health systems, for managing the core digital health data, and the infrastructure required for its seamless exchange;

b. To establish National and Regional Registries to create Single Source of Truth in respect of Clinical Establishments, Healthcare Professionals, Health Workers and Pharmacies;

c. To enforce adoption of open standards by all the actors in the National Digital Health Eco-system;

d. To create a system of Personal Health Records, based on international standards, easily accessible to the citizens and to the healthcare professionals and services providers, based on citizen-consent;

e. To promote development of enterprise-class health application systems with a special focus on addressing the Sustainable Development Goals related to the health sector;

f. To adopt the best principles of cooperative federalism while working with the States and Union Territories for the realization of the Vision;

g. To ensure that the healthcare institutions and professionals in the private sector participate actively in the building of the NDHE, through a combination of prescription and incentivization;

h. To ensure National Portability in the provision of health services;

i. To promote the use of Clinical Decision Support (CDS) Systems by health professionals and practitioners;

j. To promote a better management of the health sector leveraging Health Data Analytics and Medical Research;

k. To provide for enhancing the efficiency and effectiveness of Governance at all levels through digital tools in the area of Performance Management.

l. To support effective steps being taken for ensuring Quality of Healthcare.

m. To leverage the Information Systems existing in the health sector, by ensuring that they conform to the defined standards and integrate with the proposed NDHE.

1.4 Overview of National Digital Health Blueprint

The National Digital Health Eco-system is large, complex, heterogeneous, sensitive and critical at the same time. Evolution of such an eco-system can and should happen by a combination of two distinct approaches, namely, establishment/ creation of Core Information Systems on a minimalist basis, and promotion of a set of Principles and Standards by all the eco-system players. The Blueprint adopts this twin approach precisely.

The NDHB has been conceptualized as a layered structure depicted in **Figure 1.1** and described later.

a. At the core of the Blueprint are its **Vision** and a set of **Principles** that should guide all the eco-system players. While the Vision has already been stated in Section 1.2 and supplemented by the objectives in Section 1.3, the Blueprint Principles are enumerated in the following Section.
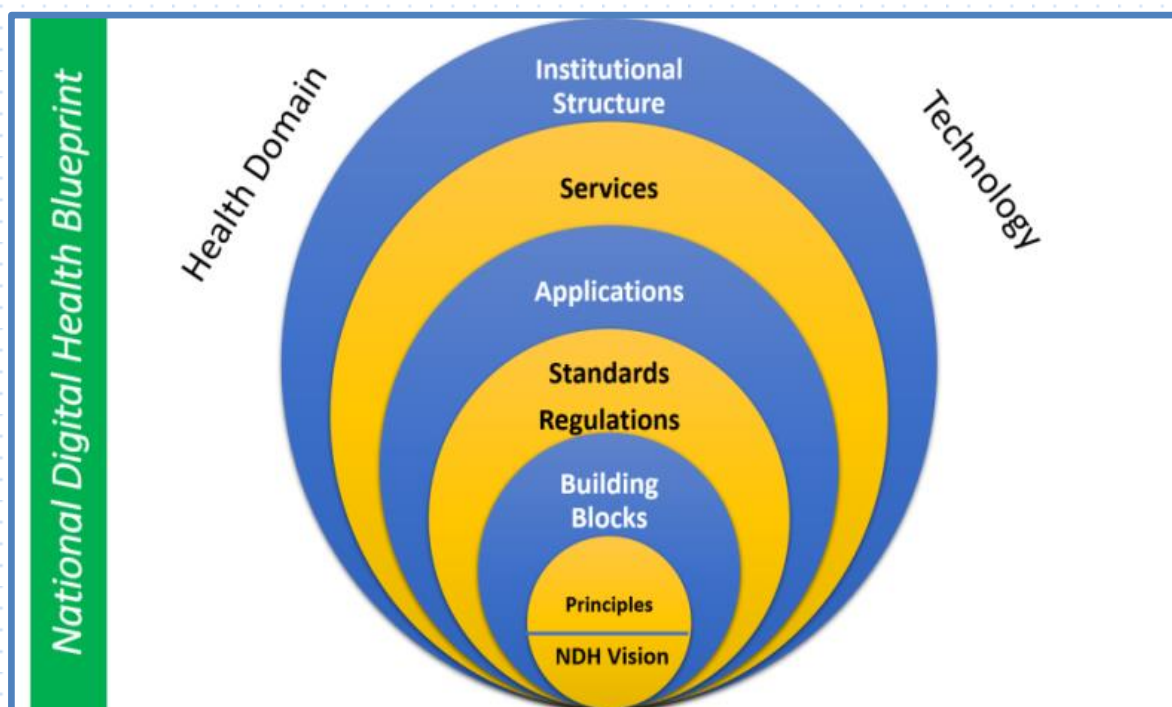

Figure 1.1 Layered approach to conceptualizing the blueprint

b. The **Building Blocks** are defined in Chapter 2. While the Core Building Blocks will be established centrally by NDHB, the remaining would have to be created in an interoperable manner by the eco-system players.

c. Chapter 3 defines the minimum set of **Standards** to be adopted by all the eco-system players. It also touches upon the **Regulations** to be enforced in the health domain.

d. The applications and services layers are substantially in the realm of the Providers of Healthcare Services, Wellness Services and Support Services. However, it shall be the endeavor of the NDHB to design, develop and put in place certain **Core and Reusable Applications and Services**, which are commonly used across the country and across the health domain.

e. Chapter 4 recommends an **Institutional Framework** appropriate for facilitating the establishment of the National Digital Health Eco-system in terms of all the components.

f. Chapter 5 provides a high-level Action Plan that envisages implementing the NDHB in 3 phases.

g. It may be noted that each of the layers has components that fall under both the areas, namely **Health Domain** and **Pure-play Technology.**

1.5 Core Principles of National Digital Health Blueprint

As alluded to earlier, an eco-system cannot be built, nor can it evolve on a prescriptive approach. Hence the Blueprint proposes to be evolved on the basis of a set of commonly believed Principles, which again, pertain to the Business (i.e the Health Domain) and to Technology. The Governments, Central and State, must play the role of facilitators, enablers and advocates of these Principles to speed up the evolution of the National Digital Health Eco-system.

While identifying and defining the principles, the following core requirements and architectural priorities have been kept in view:

a. **Unique and Reliable Identification** of persons, relations, professionals, providers, facilities, and payers across the whole eco-system.
b. **Trustworthiness** of the information created by the entities in the eco-system
c. **Capability for creation of a longitudinal health record** for every individual from information held in diverse systems
d. **Managing the consents** for collection and/or use of personal/ health data, to ensure privacy and confidentiality.
e. Adopting and aligning with **IndEA principles**, given the enterprise nature of NDHE.

The **Principles of NDHB** are stated and briefly explained **Table 1.1** and as a bird-eye view in **Figure 1.2**.

Business Principles (Health Domain Principles)
NDHB will be wellness-centric and wellness-driven.
Special focus will be laid on the building blocks and applications relating to Health Education, awareness, screening, early detection and AYUSH. Wellness centres and mobile screening teams will be strengthened through access to real-time Personal Health Records. Citizens will be encouraged to follow a well-designed referral system
NDHB shall educate and empower citizens to avail a wide range of health and wellness services
Mass awareness and education will be promoted through use of appropriate a MEDucation Platform and a portfolio of Health Apps targeting citizens of different age-groups and access to toll-free medical advice. Personalization and localization will facilitate higher uptake of the education and awareness services.
NDHB systems shall be designed to be inclusive.
Specialized systems will be designed to reach out to the "unconnected", digitally illiterate, remote, hilly and tribal areas. Telemedicine will focus on reaching out to such groups to provide them with services of experts.
NDHB shall ensure security and privacy by design.
A National Policy on Security of Health Systems and Privacy of Personal Health Records will be developed. All the building blocks that require handling personal health records will be designed to comply with such policy ab-initio

NDHB shall be designed to measure performance and display accountability of all providers of service.

Real-time monitoring of the Service Levels and health sector KPIs will be the key driver to measure and publish performance of all health institutions and professionals. Real-time dashboards, data analytics and visualization tools will support the Performance Management.

NDHB shall have a national footprint and shall enable seamless portability across the country.

Personal Health Identifier with its supporting blocks, including adoption of Health Information Standards will play a pivotal role in the national portability. A system of incentives will be put in place for early adoption.

The eco-system of NDHB shall be built basing on the principle, "Think Big, Start Small, Scale Fast"

While the "Big Picture" of NDHB will be comprehensive containing all the Building Blocks required to fulfil the Vision, NDHB will adopt a combination of strategies like taking a minimalistic approach for designing each Block, prioritizing and sequencing of the development/ launch of the building blocks, and designing a technology architecture that can scale horizontally and vertically.

Technology Principles

NDHB shall be developed adopting India Enterprise Architecture Framework (IndEA)

The artefacts prescribed by the IndEA Standard will be prioritized and sequenced. The design of the building blocks of NDHB will adopt and conform to IndEA by default. Other national and international standards will be adopted in areas not covered by IndEA.

NDHB may, when appropriate, adopt the Agile IndEA Framework, which combines the Vision of IndEA with the Speed of Agile methodologies of development.

All the building blocks and components of NDHB shall conform to open standards, be interoperable and based on Open Source Software products and open source development.

The policy of MeitY, GoI on Open Standards and Open Source Software shall be adopted in designing of the building blocks of the Blueprint and in all procurements relating to its implementation. Interoperability will be inherent to all the building blocks.

Federated Architecture shall be adopted in all aspects of NDHB.

Only the identified Core Building Blocks will be developed and maintained centrally. All other building blocks shall be designed to be operated in a federated model that factors regional, state-level and institution-level platforms and systems to function independently but in an interoperable manner.

NDHB shall be an Open API-based Ecosystem

All the building Blocks will be architected adopting the Open API Policy notified by MeitY, GOI. Security and Privacy will be built into the design and development of the APIs, which should be audited for security and privacy before deployment.

All major legacy systems shall be assessed for conformance to NDHB principles and leveraged to the extent feasible.

Compliance of legacy systems to the Blueprint principles and IndEA Principles will be assessed through an appropriately designed Assessment Tool. Only those legacy systems that cross the bar will be allowed to operate within the eco-system.

All the components, building blocks, registries and artefacts of NDHB shall be designed adopting a minimalistic approach.

Easy, early and collective adoption of the Blueprint by majority shall be critical to its success. Hence every component of the Blueprint shall be designed to be minimalistic.

All the registries and other master databases of NDHB shall be built as Single Source of Truth on different aspects and backed by strong data governance.

Rigid validations shall be applied to all mandatory 'fields', clear ownership and responsibilities shall be defined for all core databases and strong, dedicated data governance structures shall be established at the State and Central levels.
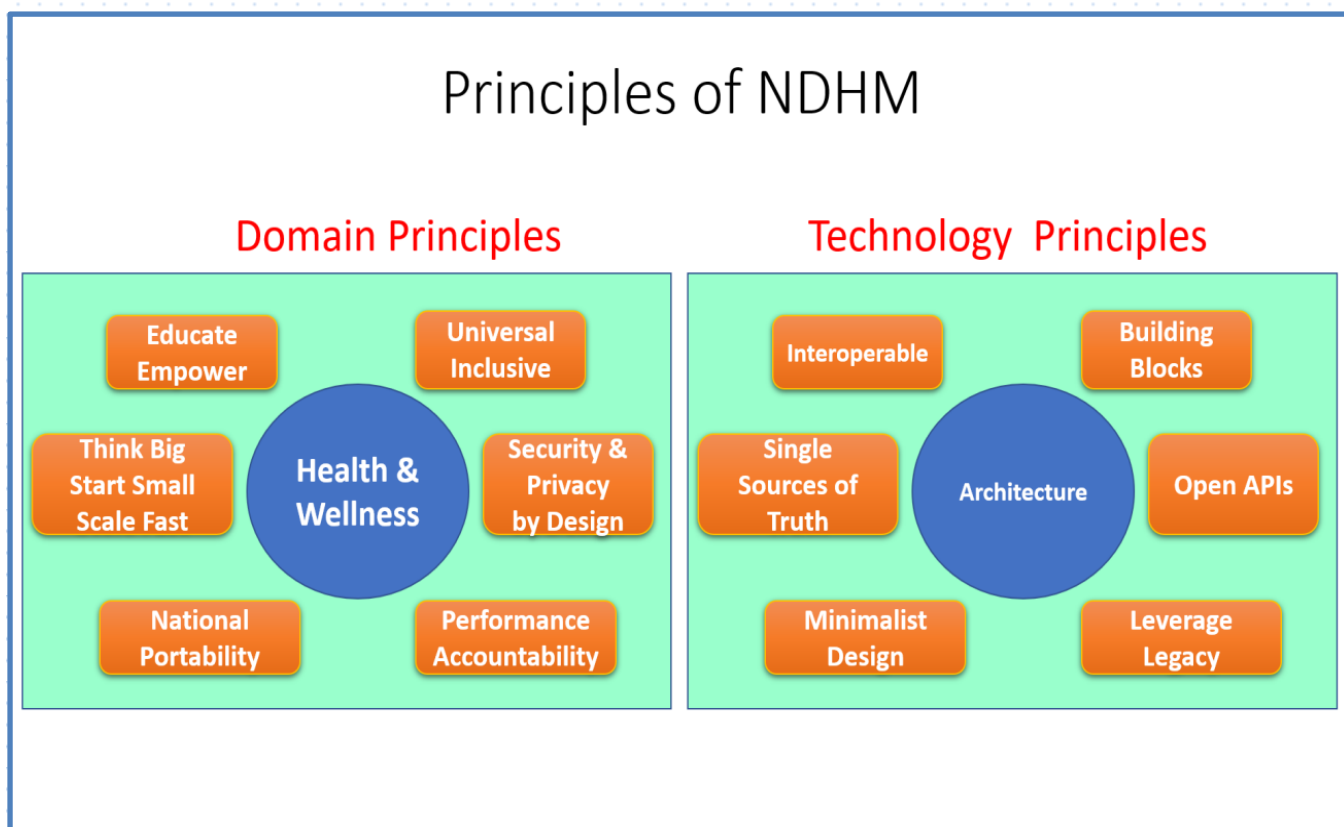
Table 1.1 Principles of NDHB
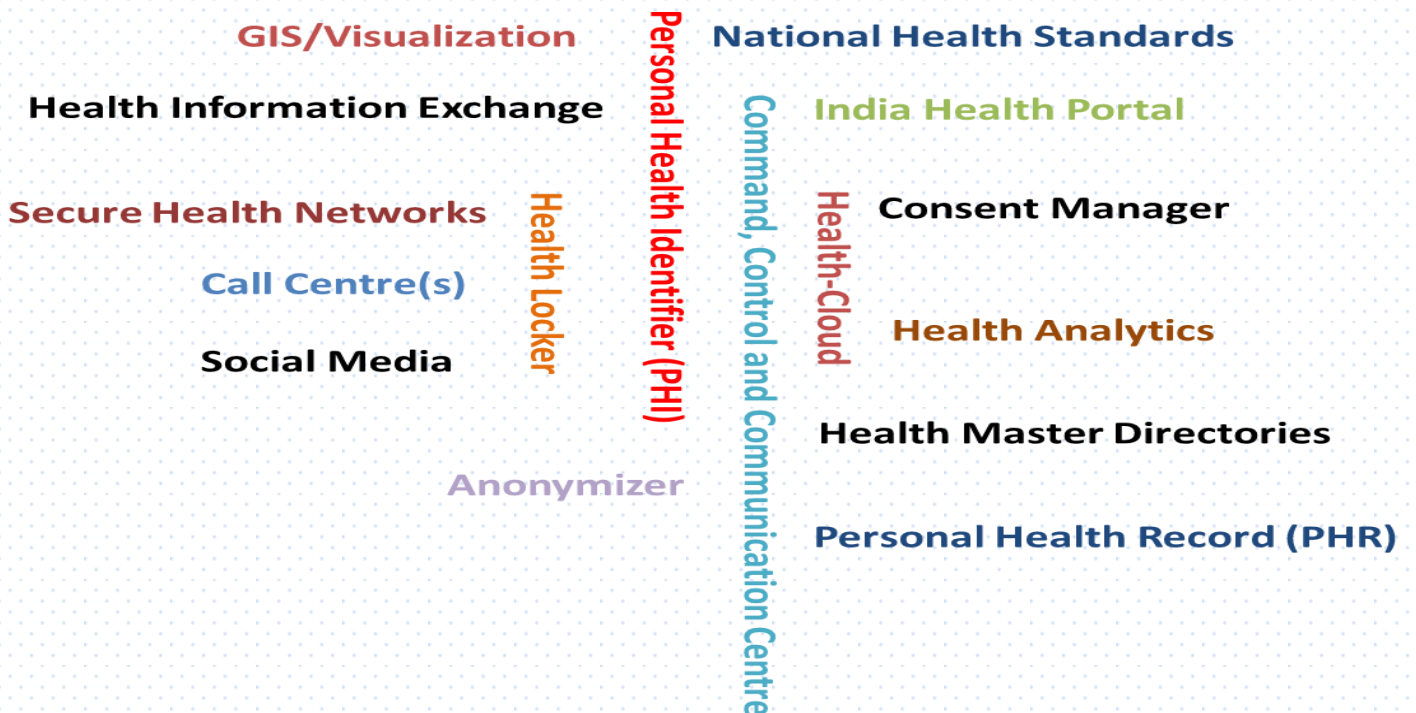

Figure 1.2 Bird's eye view of the NDHB Principles

CHAPTER 2

IDENTIFICATION &
DEFINITION OF BUILDING
BLOCKS

Security and Privacy Operations Centre (SOC)

GIS/Visualization

Personal Health Identifier (PHI)

National Health Standards

Health Information Exchange

Command, Control and Communication Centre

India Health Portal

Secure Health Networks

Health Locker

Health-Cloud

Consent Manager

Call Centre(s)

Social Media

Health Analytics

Health Master Directories

Anonymizer

Personal Health Record (PHR)

CHAPTER 2
IDENTIFICATION & DEFINITION OF BUILDING BLOCKS

2.1 Introduction

Digital technologies are playing a pervasive role in the delivery of Healthcare today. The National Digital Health Blueprint (NDHB) provides an approach to establish foundational IT components that will enable the Health ecosystem to streamline information flows across players in the ecosystem while keeping citizens, their privacy and confidentiality of data at the forefront. A good design can help accelerate the adoption and improve delivery of health services across both the public and private sectors. NDHB identifies key building blocks by looking at the most common requirements of the overall health ecosystem.

To establish a comprehensive National Digital Health Blueprint (NDHB), it is pertinent to identify the key actors in healthcare systems, which are given below:

- **Person** – Patient, Family Member, Beneficiary
- **Care Professional** – Doctors, Nurses, Lab Technicians, ASHA workers etc.
- **Care Provider** – Hospital, Clinic, Diagnostic Centre
- **Payer** – Insurer, Health Plan, Charity
- **Governing Bodies** – Ministry, Professional bodies, Regulator
- **Research Bodies** – Researcher, Statistician, Analyst
- **Pharmaceuticals** – Drug, Device Manufacturers and Supply Chain players

2.2 Identifying the Building Blocks

In architectural parlance, a building block is a package of functionality defined to meet business needs. Building blocks have to interoperate with other building blocks. A good choice of building blocks can lead to improvements in legacy system integration, interoperability, and flexibility in the creation of new systems and applications. Wherever interoperability is required, it is important that the interfaces to a building block are published and reasonably stable. A building block is intentionally designed to be cross-functional allowing its generic functionality to be applied to different contexts. Each Building Block must have the following characteristics:

- Provide a standalone, useful, reusable and implementable capability in the health domain
- Cross-functional across the value chain by design
- Applicable to multiple use cases in healthcare
- Interoperable with other building blocks
- Use shared digital infrastructure (to the extent feasible)
- Standards-based and
- Designed for scale

Each Building Block must have a clear "Business Owner" and "Technology Owner". The business owner is responsible for defining the rules and policies essential to effectively manage the building block. The technology owner would be responsible for managing the business requirements and technical implementation of these requirements efficiently.

Building Blocks once identified shall be implemented using workflow-based modules and must interface with other building blocks using open APIs. The Building Block of Personal Health Identifier (PHI) will be centre-piece for integration with all the other components of health ecosystem and for maintaining the Personal Health Record (PHR).

Identification of new blocks is an ongoing activity and more blocks would come up over time.

2.3 National Digital Health Blueprint (NDHB)

Based on the study of the existing health systems, discussions with stakeholders and analysis, the following key Building Blocks have been identified across 5+2 layered architecture:
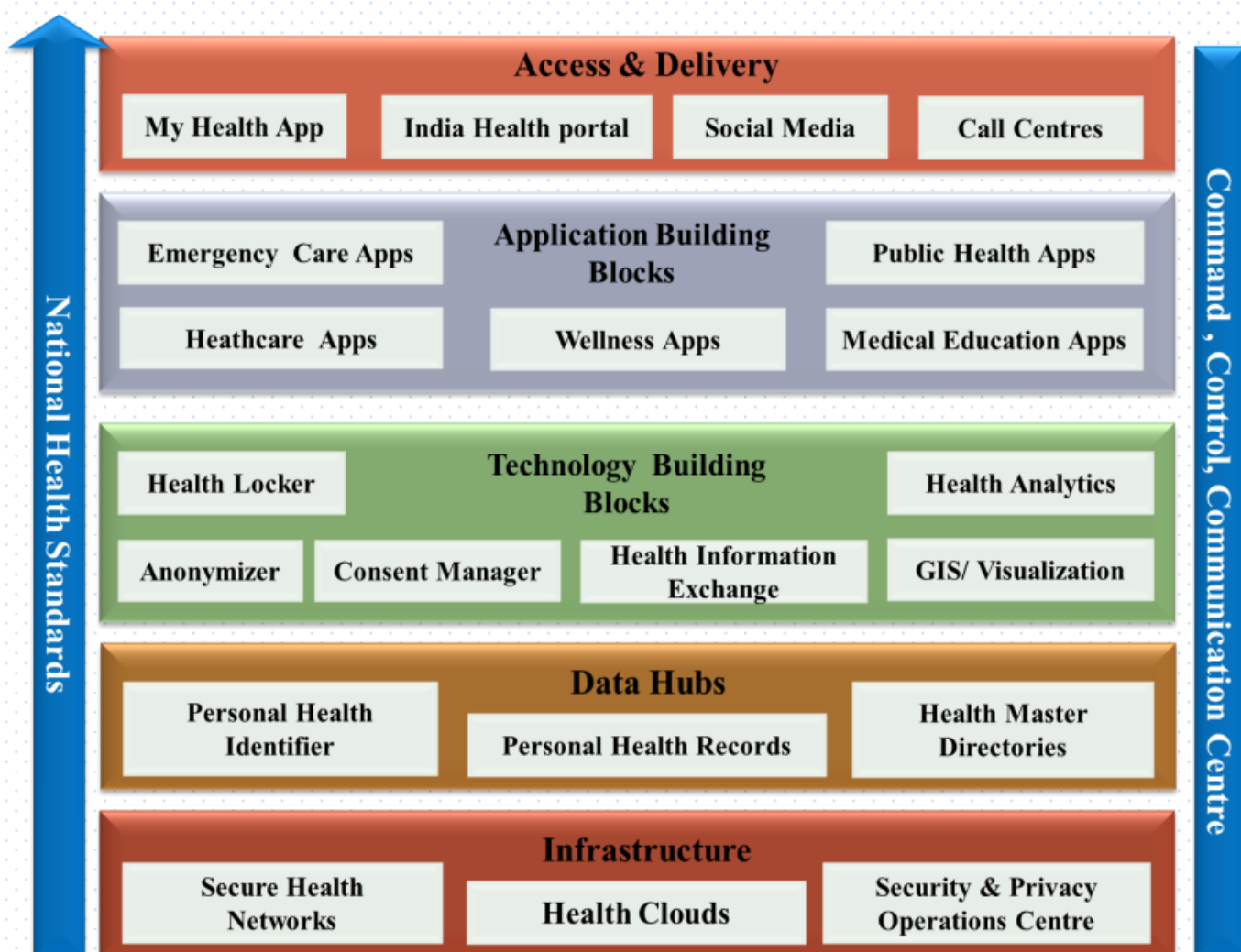

Figure 2.1 National Digital Health Blueprint (NDHB)

i. Infrastructure (Layer-1)

Privacy by design being a key principle of the National Digital Health Blueprint, an Infrastructure layer needs to be established for management of the key data services in a compliant manner. The objective of the Infrastructure layer is to ensure that health data and it's traversal is always secure and adheres to all privacy requirements. The Government Community Cloud infrastructure as defined by MeitY should be adopted for implementation of building blocks in Layer 2 and Layer 3. A hybrid cloud environment is recommended for other layers.

Secure Health Networks

Blueprint should be built to work on public networks by default. Wherever access to sensitive or aggregated data is involved, secure connectivity like MPLS or VPN may be used. For specific applications like Tele-health, Tele-radiology that require strong data links to systems like PACS low latency, high bandwidth network systems may be specially designed

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Health-Cloud (H-Cloud)

The Health-Cloud builds on the MeitY initiative of Government Community Cloud (GCC) with stronger security and privacy policies and infrastructure. Key data hub management services of the Blueprint must be deployed on the H-Cloud.

Security and Privacy Operations Centre (SOC)

All events on the Health-Cloud and the Health Network need to be under 24x7 security surveillance ensuring every data byte is highly secure. This is achieved through a Security Operations Centre (SOC). The Committee recommends the establishment of a dedicated **Privacy Operations Centre (POC)** to help drive compliance on the privacy requirements, adherence to which is a must in the health sector. The POC will monitor all access to private data, review consent artefacts, audit services for privacy compliance, evangelize the privacy principles on which the Blueprint is being built and bring trust and strategic control in the usage of health data in the ecosystem.

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ii. Data Hubs (Layer-2)

Data Hubs provide the fundamental building blocks that manage the key entities and standardized master data required for any health ecosystem transaction. This layer also identifies the minimum and critical transactional data blocks required for successful implementation of the other building blocks.

a) **Personal Health Identifier (PHI):** It is important to standardize how a person is identified at any point providing healthcare. This is the only way to ensure medical records created for the person can be issued to the correct individual or obtain consented access. As part of the issue of the PHI, the system must collect

Demographic and Location information, Family / Relationship information and contact details. Ability to update contact information easily is the key as India has a large churn in mobile numbers. The relevant FHIR specification for persons MUST be followed.

b) **Personal Health Record (PHR)** generates and aggregates health records for a person and puts the information in the control of the person to share it with consent. While there are several approaches to implementing a PHR system, keeping in line with the principles of NDHB, a federated system with multiple market players working on a national interoperable standard for sharing of health data is preferred. Health care providers are expected to identify the individual (through PHI) and insert a medical record into the person's PHR after providing care. The content in the PHR will need to allow for evolution, from basic content with very little metadata to a strongly structured content that meets the standards specified in Chapter 3. In addition, the PHR shall capture the data relating to ONLY the significant medical and health episodes and events of types to be identified and notified. This requirement addresses the issues like data overload, 'Physician Fatigue', and important health data getting buried under inconsequential data and thereby getting missed out. **Annexure V** points out the mistakes to be avoided in designing PHR/ EHR. The design of the DigiLocker system, which has multiple issuers and users who can exchange data with consent and strong non-repudiation methods, should be adopted with appropriate modifications and enhancements for implementing the PHR

c) **Health Master Directories** hold the master data of various entities, which will play a key role in the health ecosystem. Directories must be built with strong ownership and governance mechanism and must adhere to the principle of being the "single source of truth". Directories must be designed to be easily accessed and used from multiple users of the NDHB. Directories related to professionals must enable Identity and Access Management (IAM) for health applications that adopt the Blueprint. Health Applications must be able to verify a doctor using the registry and allow them to access their health application and to add / view records for which they are specifically authorized.

Health Registries: **Table 2.1** shows the key directories to be established in the first phase of the NDHB

Facilities Directory	The Facility Directory will consist of one record and a unique identifier for each Health facility in the country – Hospitals, Clinics, Diagnostic centres, Pharmacies etc.
Doctors Directory	The Doctor directory will consist of one record for each doctor who has registered with the medical council after completion of their

	education. The directory must be designed to be kept up-to-date as doctors gain skills via fellowships and map them to the facilities they are associated with.
Nurses & Paramedical Directory	The Nurses directory will essentially include the medical support staff including Nurses, ANMs etc. and will also consist of one record for each paramedical staff that is awarded a certification by the Paramedical board, Ophthalmic Technicians, Operation Theatre technicians, etc.
Health Workers Directory	This directory will consist of Health Workers like ASHA who act as the extended work force enabling door to door healthcare related services
Allied Professionals Directory	This directory contains the other key roles in the healthcare industry including Masters in Hospital Administration, Health IT, Disease Coders, Pradhan Mantri Arogya Mitras, etc.
Health Registries	
Disease Registry	Contains one record for each incidence of the disease in the population. The National Cancer Registry is an example. Disease registries must be established for all non-communicable diseases (NCDs) especially those being covered by the NCD Screening programme of MoHFW
Blood / Organ Donor Registries	Contains PHI for people wanting to be blood / organ donors or recipients in waiting. There are several registry initiatives in this area. The Government must seek to establish National registries that are trusted and have wide participation.

Table 2.1 Key directories in the first phase of the NDHB

Health Masters/ Health Data Dictionary: There are several master data requirements in healthcare including names of drugs, diseases, lab tests, procedures, etc. The Content and Interoperability section in Chapter 3 outlines the various standards / code sets to be adopted. The Blueprint must enable easy access to developers to incorporate Master Data into their applications.

iii. Technology Building Blocks (Layer-3)

Operationalization of the Master Data directories provides standardized operating data for any health transaction to happen via the Blueprint. For the Blueprint to meet its key objectives, it defines six key building blocks for data and access management; that need to adhere to by all implementation agencies to align their existing

applications to generate or access health related information. These are described in **Table 2.2.**

Anonymizer	The Anonymizer takes data from the Health Locker and/or other health data sets, removes all personally identifiable information to protect privacy and provides the anonymized data to the seeker. Tools available can anonymize both structured and un-structured data. At the same time, Anonymizer enables the Government or authorized agencies may need to access the health records of the citizens especially in some identified cases like monitoring of notified diseases etc., to take effective decisions to promote wellness in the country and to ensure that healthcare is provided in a timely fashion, as needed. There are 2 levels of delinking the personally identifiable information from the related health record(s), namely, De-Identification and Anonymization. De-identification process is reversible, whereby re-identification by the competent authority is possible after the processing of de-identified data has been completed by the processing agency. Anonymization, on the other hand, is a one-way process, whereby the data once anonymized, cannot be related to any person subsequently. It is necessary to identify the use cases where each of these 2 processes has to be used, depending upon the degree of privacy required in each use case. Though combined as a single Building Block, Anonymizer shall have all the capabilities required, namely, Anonymization, De-Identification and Re-Identification besides encryption and decryption as needed.
Consent Manager	Health records are personal for an individual and every access to each record requires explicit consent of the individual. The electronic consent framework specifications notified by MeitY should be used to develop the information sharing processes within the Blueprint. The goal of the Consent Management Framework and the Consent Manager should be to ensure that the citizen/ patient as the Data Principal, is in complete control of what data is collected, and how/with whom it is shared and for what purpose, and how it is processed. The Framework should apply not only to the data collected at each touch pint and each encounter but to the data relating to the entire Personal Health Record, both longitudinal (over a period of time) and vertical (relating to an

	episode).
Health Locker	The Health Locker is a standards-based interoperability specification that can be implemented by multiple players to enable the creation of a Personal Health Record ecosystem. When a medical record needs to be issued, only a reference link is shared with the locker ecosystem. Small clinics / hospitals are expected to subscribe to the authorized repository providers who can integrate with the Health Locker to be able to participate in this ecosystem. The health locker enables creation of a longitudinal health record from the various links it stores and provide the PHR to the providers who need the same. The PHR is created only on consent from the user. The design will need to factor uptime / network, storage and security considerations.
Health Information Exchange	All actors in the health ecosystem would in some way or the other be generating or accessing health information, using one or more access applications. The exchange of information needs to be enabled as real-time data exchange by implementation of Open APIs and other data exchange mechanisms. From a flow perspective each access application to submit or retrieve/ access any information from/ via the Blueprint, needs to be registered with the Health Information Exchange (HIE), which would be responsible for authentication and authorization of all data exchange requests and, if authorized, then for routing the request to the providing applications. The design of this component should support implementation of multi-channel solutions by participating applications, to ensure cross channel capabilities and a seamless user experience and for enabling an open market ecosystem to come up.
Health Analytics	This building block has the objective of providing Decision Support to the stakeholders on a wide variety of Themes, by analysing the aggregated datasets to be accessed from the providers. The Blueprint design must ensure that analytics data is created / collected at source when the medical record is being prepared to be issued to the PHR. Analytics data can be aggregated using either a subscription model or a push model where the data is sent mandatorily to one or more government-controlled analytics systems. Policies for access to the aggregated health data need to be setup. While the Building Block of Health Analytics can have very large scope in terms the number and nature of Themes for analysis, the

following initial set of themes is recommended with the corresponding benefits, as shown below

Theme	Decision Support Goal(s) (Illustrative)
Quality of Care	• Quality of Infrastructure • Quality of treatment • Effectiveness of follow up • Hospital-acquired Infections
Quality of Data	• Accuracy of Data • Completeness of Data • Appropriateness of Data • Conformance to Standards
Wellness	• Need for Screening • Early Detection • Preventive Interventions
Public Health	• Targeted Interventions in NCD's • Identification of endemic areas • Identification of endemic groups • Disease Surveillance
Fraud Detection	• Fraud Classification • Fraud Detection • Fraud Prevention through systemic improvem
Policy	• Policy Formulation Support

GIS/Visualization	This building block provides GIS / Visualization services that can be used by the application layer to answer queries like – Which is the nearest hospital with this specialty? Or plotting of disease incidence in a geographic area etc. The building block must take data sets from the health analytics system and produce outputs that can be consumed by the application layers. The GIS services will help in regional planning and monitoring of health services.

Table 2.2 Technology building blocks

iv. Application Building Blocks (Layer-4)

The three layers described earlier (Layers 1-3) are expected to provide open APIs that can be used by a wide variety of applications across the health sector – both by public and private providers. Applications across Emergency care, Healthcare, Wellness, Medical Education and Public Health are expected to benefit from the National Digital Health Blueprint.

Several existing applications need to be modified to comply with the National Digital Health Blueprint. These include:

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Government Managed Health Applications

e.g.: Reproductive and Child Health (RCH), NIKSHAY (Online TB Patients monitoring application), e-Raktkosh, Health Management Information System (HMIS), National Programme for Control of Blindness (NPCB), Ayushman Bharat, Hospital Information System (HIS), Integrated Disease Surveillance Program (IDSP) etc. **Telemedicine** should be given a high priority given the **low Doctor-Population ratio**, especially in the rural

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Private Sector Health Applications

e.g.: Hospital Management System applications, claims applications etc. being currently used by service providers. Open Source Products may be promoted for the sharing of **real-time patient data** among the members of the medical/ surgical/ nursing teams, especially **to ensure timely interventions in tertiary care**.

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Wellness, specialized applications shall be developed in the areas of Screening (especially of Students and Women), early detection and referrals.

New applications in the healthcare ecosystem will benefit from adoption of the Blueprint as it will speed up development and ensure interoperability at a national level.

v. Access & Delivery (Layer-5)

Since, Healthcare and Wellness related services primarily contact driven; in addition to the blocks requiring specific IT intervention the Blueprint also identifies the varied access and service delivery points that need to be the physical/ virtual points of access for the actors of the ecosystem. These are shown in **Table 2.3.**

Call Centre(s)	Provide telephonic support to all actors of the ecosystem, principally the citizens.
India Health Portal	A multi-lingual national portal enabling access to digital health services and data
Social Media	For emergency management, health awareness / education and community-based services like Blood/ Organ Donations.
MyHealth Apps	A wide range of Apps can be built by open market, including Start-ups and existing Health IT companies of all scales besides Government organizations. The end user thus has the choice of selecting the app that suits their needs best.

Table 2.3 Access & service delivery points

Given the prospects of a near universal coverage of all families in the country with Smart Phones, all the digital services are to be designed to be delivered through Smart Phones adopting the **Mobile First** Principle.

The Smart Phones should the preferred medium / channel for dissemination of appropriate content, information, alerts and updates to the **large force of health workers**, predominantly, the ASHA workers, given that a significant thrust has to be given to the MCH and NCD programs and related field activities.

Smart Phones can also be the preferred channel for **online education** of citizens and the field force.

Specific efforts shall be made to launch **voice-based services** using appropriate tools customized to work in spoken Indian Languages, **in collaboration with the OEMs**.

In addition to the above 5 horizontal layers, the Blueprint also identifies the following two vertical layers cutting across all the horizontal layers:

vi.   National Health Standards (Vertical Layer -1)
Governance, Strategic Control, Data Security, Privacy and Compliance to Standards would be one of the key verticals that cut across all building blocks of the Blueprint. Chapter 3 specifies the various standards to be adopted in these areas.

vii.   Command, Control and Communication Centre (Vertical Layer -2)
The goal of the Integrated Command, Control and Communication Centre (CCCC) is to provide a single point contact in to manage public health emergencies. The CCCC consists of a response team and also has the ability to constantly monitor disease surveillance and outbreak response. The large amounts of health data coming into the NDHB should be used to monitor for various diseases working closely with the existing programs of MoHFW and the States. The CCCC consuming information from all other components (internal as well as external), will run analytics on that information and generate alerts and visualizations as required. It shall also deploy Artificial Intelligence and Machine learning technologies.

2.4 Structure of Disease Registries for NCD
Registries can provide health care professionals and researchers with first-hand information about people with certain diseases, both individually and as a group, and over time, to increase our understanding of that disease. Broadly disease registries are based on information gathered in Screening and in the Hospitals.

Screening based registries are concerned with recording information about diseases for population at large for different age groups based on well-defined parameters

and invoke referrals. Hospital based registries are concerned with recording of information on the patients seen in a particular hospital.

National Cancer Registry being maintained by ICMR and the other Disease Registries currently maintained in India are not interoperable and not integrated with Hospital Management Information System (HMIS). Disease registries need to be standardized following the National Digital Health Blueprint to make them integrated and interoperable. **Table 2.4** depicts generic structure of recommended registries.

Type	refers to type of registry viz. Screening or Hospital based
Purpose	refers to the purpose of maintaining the registry
Size	refers to the number and complexity of data points, the frequency of data collection, and the enrolment of investigators and patients
Person Identifier	includes all parameters given under Person Health Identifier (PHI)
Family Identifier	includes detailed information about family members from PHI
Locational Parameters	includes location to which patient belongs, facility where person has been screened and/or referred to
Screening Parameters	include the disease specific parameters to be recorded
References/Pointers	defines the pointers to diagnosis, referrals, treatment, education, adherence to using Personal health Record (PHR)

Table 2.4 Generic structure of registries

2.5 Harmonizing Current Facility Registry Initiatives

There is a strong need to uniquely identify health facilities and ensure that any health data is correctly tagged with the facility id to ensure traceability, accountability and reliability of the health information. The Government needs to create a strong facility registry for use by several actors in the ecosystem.

After a comparative analysis of the ongoing initiatives for creation of facility registries (details in **Annexure III**), the Committee recommends the following.

Recommendations:

a. National Health Resources Repository (NHRR) complimented with National Identification Number (NIN) shall be utilized as the main facility registry
b. Incentive driven governance mechanisms need to be designed to ensure facility registry is kept updated and made available for integration with Health Systems

c. The format of the Facility Identifier being used by NHRR may be reviewed and enhanced considering the need for it to interoperate with other identifiers like NIN and ROHINI.

d. The format and structure of the identifier should be designed such that it does not allow deciphering of any information offline.

2.6 Approach to Personal Health Identifier (PHI)

In the health domain, the need for Personal Health Identifier (PHI) has been recognized for the purposes of uniquely identifying persons, authenticating them and threading their medical records across multiple systems and stakeholders.

PHI contains demographic details like Name, Father's / Mother's/ Spouse's Name, Date of Birth/Age, Gender, Mobile Number, Authentication Route, Email Address, Location, Family ID and Photograph, in line with the **Person Resource** defined by FHIR (please refer to Chapter 3 for relevant details of FHIR).

In India, Aadhaar provides for uniquely identifying and authenticating a citizen, amongst a very large population set of more than 134 crore people. Aadhaar has achieved the same by collecting, verifying demographic details of residents and de-duplicating using the biometric details of the residents. Aadhaar offers various authentication methods such as demographic, mobile OTP based, biometric as well as offline signed XML packet based.

Uniqueness is a key attribute of PHI, and the algorithm that issues a PHI must try to return the same identifier for the individual in all scenarios. While Aadhaar assures uniqueness of identity and provides an online mechanism for authentication, it cannot be used in every health context as per the applicable Regulations. The design of PHI, therefore, must allow multiple identifiers (chosen from the specified types of identifiers) for designing the structure and processes relating to PHI.

Considering the regulatory, technological and operational implications, the Committee suggests the following preliminary and tentative mechanism for identification and authentication of persons in the health ecosystem:

Health Programs notified by the MoHFW under Section 7 of the Aadhaar Act	Aadhaar eKYC / Virtual Aadhaar Id KYC / offline Aadhaar xml KYC / Scanning Aadhaar QR Code /Any other specified type of ID
All other Programs	Scanning Aadhaar QR Code/ offline Aadhaar xml KYC/ Any other specified ID

However, the Committee recommends that the design of the PHI may be finalized by the MoHFW, in consultation with MeitY and UIDAI duly taking into consideration the regulatory, technological and operational aspects.

As an identity system, PHI can opt for one of the three system archetypes – centralized, federated and decentralized. A comparative analysis of the three archetypes is shown **Annexure IV.** It is recommended that the centralized approach is adopted for the following benefits:

- It is easier for a single organization to provide and manage identifiers across the country maintaining uniqueness.
- When supported with adequate institutional mechanisms and checks, it evokes higher trust and authenticity.

CHAPTER 3

STANDARDS &
REGULATIONS

CONSENT

PATIENT SAFETY
& QUALITY OF
SERVICES

CONTENT &
INTEROPERABILITY

PRIVACY &
SECURITY
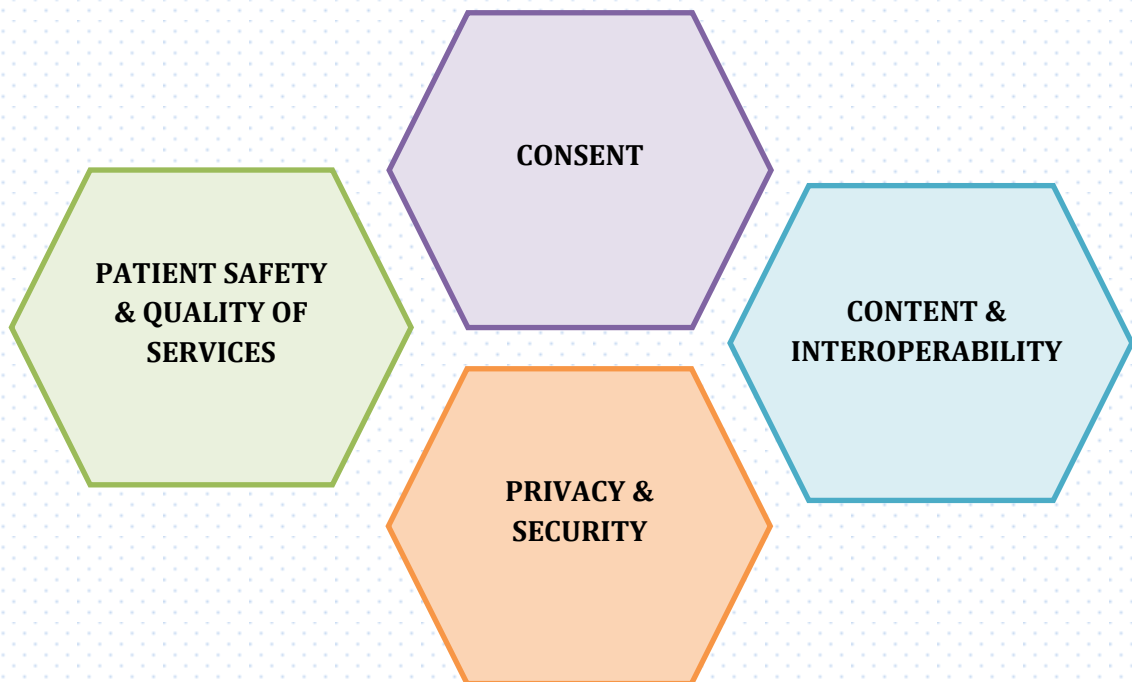
CHAPTER 3
STANDARDS & REGULATIONS

3.1 Objectives of Standards and Regulations

The National Digital Health Blueprint envisages the evolution of an entire eco-system in the health sector to provide a wide range of services to the stakeholders in a digitally-enabled manner. Creation of such an eco-system, in a heterogeneous and multi-level environment that obtains in India, can happen only through a multi-pronged approach by the efforts of a large number of actors acting in sync. The Building Blocks of NDHB defined in Chapter 2 need to work in unison in an interoperable manner if all the digital services have to be realized for the benefit of all the stakeholders, especially the citizens. Such a seamless and boundary less interoperability is possible ONLY IF all the building blocks and the digital systems are built using the defined standards.

The objective of this Chapter is to define the standards required for ensuring interoperability within the National Digital Health Eco-system. Adoption and implementation of standards in the health domain is a relatively slow process, as observed from the experiences of some of the countries that embarked on the same. Given this, it is proposed to recommend a set of **Minimum Viable Standards** in the initial stages.

Given the sensitivity of personal and health-related data, appropriate recommendations are made in respect of the Regulations to be complied with by the actors in the digital health eco-system.

3.2 Framework & Scope of Standards

The Scope of National Digital Health initiative, the digital services envisaged by it, the guiding principles and the Building Blocks required to create the eco-system have been identified and defined in the earlier Chapters. The Scope of the Standards is defined keeping the foregoing in view.

Table 3.1 depicts the areas chosen to define the Standards for the NDHB.

Consent	The consent from patient need to be covered from two aspects – consent for data capture and consent for data use.
Content &Interoperability	Standards related to exchange of healthcare data.
Privacy & Security	Standards related to data privacy (through access control) and Security of data at-rest and at-motion. Also, aspects such as data immutability and non-repudiation with audit trail.

Patient Safety & Data Quality	Standards related to ensuring patient safety while collecting data and quality of data captured.

<div align="center">Table 3.1 Areas chosen to define Standards for NDHB</div>

Appropriate recommendations are also made on the aspects relating to adoption and implementation of the Standards.

RECOMMENDED STANDARDS

3.3 Standard for Consent Management

The consent of the citizen plays a major role in ensuring that collection of data is done in a manner consistent with legal rights of the patient. It is also important to ensure that once collected, the data captured is used and disclosed (in an identifiable or anonymized shape) in a manner appropriate in law and preserving the citizen-directed constraints. Towards these the standard shown in **Table 3.2** is recommended for designing systems and workflows required for Consent Management:

Purpose	Recommended Standard
Consent Management	ISO/TS 17975:2015 Health Informatics - Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information
Consent Framework	Electronic Consent Framework (Technology Specifications v1.1) with its subsequent revision(s) published by MeitY, GoI.

<div align="center">Table 3.2 Recommended standards for Consent Management</div>

The above standard should be implemented in a way consistent with the applicable laws such as Information Technology Act 2000 (and its amendments), various directions and rules of Medical Council of India and State Medical Councils regarding patient consent and protecting patient privacy.

3.4 Standards for Content & Interoperability

Data content plays a major role in availability of appropriate medical information to be used in healthcare, policy formulation and health analytics. The National Digital Health Eco-system (NDHE) seeks to link/consolidate the health records generated in various national programs of the Central and State Governments, besides the records generated by the private hospitals, labs and other service providers. The interoperability standards should support the major clinical artefacts used globally. The standards should additionally support extensions to it for any national needs such as country specific clinical data elements, fields, records and value sets.

Interoperability in the context of digital health, is of two types, namely, **Technical Interoperability** and **Semantic & Syntactic Interoperability**. This section defines the minimum requirements of interoperability of both the types.

a. Technical Interoperability

Technical Interoperability is substantially defined in IndEA. Hence its requirements are mentioned briefly here.

- The Interoperability Standards defined by **IndEA Framework** shall be adopted by all systems comprising the NDHE. This should be preferably be a mandatory requirement for registration of the entities involved.
- NDHE seeks to connect varied systems developed in different technologies and on different platforms. The standards should therefore support integration of all such systems. This reduces complexity and change management of all the implementers.
- The standards should be agnostic to the underlying infrastructure relating to compute, storage and networking. Implementers should be able to incorporate the standard on top of their existing solutions.
- The Blueprint recommends a **Federated Architecture** for collecting and storing of health information. While certain core datasets like the various Registries, would be managed centrally, bulk of the information relating to citizen/ patient health records would be maintained and managed in a distributed model, at regional centres or at the sites of the Service Providers. **The Central Repository of NDHB shall support only records conforming to standardized formats of content**.

b. Semantic & Syntactic Interoperability (Content)

Apart from technical interoperability required for seamless exchange of clinical records, semantic interoperability standards shall be adopted for health-related terminology and formats.

The **Fast Healthcare Interoperability Resources** (FHIR) R4 Specification is the latest Standard for exchanging healthcare information electronically. It is built upon the HL7 series of Standards and is considerably rationalized and simplified. Adoption of FHIR ensures that the electronic health records are **available, discoverable, understandable**, and also **structured and standardized** to support automated Clinical Decision Support (CDS).

The building blocks of FHIR are **Resources**. FHIR specification defines a set of 13 modules with **143 resources**, and the infrastructure for handling the resources.

The following recommendations are made in respect of adoption of semantic interoperability.

- **FHIR Release 4 should be adopted** with any future errata(s) for all health-related information sharing/ exchange.

- For quick implementation a small but necessary set of health record artefacts shall be taken up first.
- Other artifacts may be taken up in *phased manner* to ensure early roll-out, easy adherence by implementers (source of data/record), and to enable spreading of the associated costs over a period of time.

A set of 8 essential and minimum class of health record artefacts SHOULD be notified for data capture in NDHB. The list of health record artefacts prioritized and mapped to the suggested corresponding FHIR resources is shown in **Table 3.3**. Depending on health record artefact requirement, other relevant FHIR Resources (not explicitly mentioned here) may also be used.

Sr. No.	Information Record Purpose	Corresponding Resources in FHIR	
		Category	FHIR Resource
1	Patient Demographics Care Provider Details	Administration	Patient Practitioner Person
2	History, Problem & Diagnosis	Summary	Family Member History Condition Clinical Impression
3	Vitals, Results, Assessments (incl. Pregnancy, Death), Wellness parameters	Diagnostic	Observation Diagnostic Report
4	Adverse Event, Alert	Summary	Adverse Event Allergy Intolerance
5	Medication / Wellness Lifestyle / Diet / Vision	Medications	Medication Request Immunization
		Care	Nutrition Order Vision Prescription Care Plan Goal
6	Procedure	Care	Procedure Procedure Request
7	Admission / Discharge / Transfer / Referral	Administration	Appointment Encounter Episode of Care Referral Request
8	Insurance	Financial	Eligibility Request Eligibility Response Claim Claim Response

Table 3.3 Health record artifacts mapped to FHIR resources

c. Content & Interoperability Standards

Apart from standards for content, it is necessary to define the standards required in the major areas of healthcare, namely, diagnostic content, terminology and codes for statistics and laboratory tests. These Standards are specified in **Table 3.4**.

Purpose	Recommended Standard
Structured Clinical Information Exchange	**FHIR Release 4** (subject to section 3.4.2) (with any future errata(s))
Still Images / Documents Audio / Video	Still Image: JPEG Document/ Scan: PDF A-2 Audio: MP3 / OGG Video: MP4 / MOV (embedded as Binary Content in relevant FHIR resource)
Diagnostic Images (Radiology including CT, MRI, PET, Nuclear Medicine / US / Pathology), Waveforms (e.g. ECG)	DICOM PS3.0-2015c (embedded as Binary Content in relevant FHIR resource)
Terminology/ Vocabulary	**SNOMED CT** (for all clinical terminology requirements in health records)
Coding System	**WHO ICD-10** (for statistical classification of diseases and related health problems) **LOINC** (for observation, measurement, test-panels, test items and units)

Table 3.4 Content & Interoperability Standards

3.5 Standards for Privacy & Security

Preservation of privacy of patient's healthcare is an important consideration that needs to be incorporated in the overall design and implementation of the Blueprint. The standards and various operational requirements for privacy and data security, are specified in **Table 3.5**.

Purpose	Recommended Standards
Security	Digital Certificate, TLS / SSL, SHA-256, AES-256
Access Control	ISO 22600:2014 Health informatics - Privilege Management and Access Control (Part 1 through 3)

Table 3.5 Privacy & Security Standards

In addition, it is important to ensure that data is **reliable and verifiable**. Provisions and guidelines related to the following should be incorporated in operational aspects of the Blueprint:

Immutability	Record once created cannot be deleted or modified without following due process
Versioning	Any record created may be 'amended' with new version number of same records with any changes (previous records to be marked inactive) with only highest version considered active.
Non-Repudiation	All created records must be traceable to its creator unambiguously.
Audit Log	All creation, amendments, access of records should be audit logged in manner that it is verifiable and reliable
Patient Control:	Patient should be able to access/view own health records anytime, and control access by others.

In regards of above, provisions, guidelines, standards prescribed in *EHR Standards for India 2016* should be incorporated.

3.6 Standards for Patient Safety & Data Quality

Quality in Health Care Services and Safety of Electrical-Medical equipment are of utmost importance in NDH. The following recommendations are made in this regard.

- Electrical-Medical Equipment used in the NDHE should be safe to patient and to the para-medical personnel against safety hazards like Electric shock, Harmful Radiation, Excessive Temperature, Implosion, Mechanical instability and Fire. Bureau of Indian Standard has published 38 standards in this area. These standards are either an adoption or technical equivalent of the related IEC standard. The work on some additional standards is ongoing in IEC/TC 62. At present, the certification against these safety standards is not mandatory in India. Keeping importance of safety of such equipment, **safety certification of the equipment may be made mandatory for participation in NDHE**.

3.7 Cost consideration of Standards

Most of proposed standards except FHIR are already part of EHR Standards for India 2016 notification. All proposed standards are open specifications from respective Standards Bodies and are internationally supported. The ISO/BIS standards are readily available. Use of SNOMED CT is free as India is already a member country.

The cost of implementation of standards will be spread on two sides; Repositories must support all the proposed standards, and source repositories will have to implement the content interoperability, terminology/codes, and transmission standards.

As noted above, acquisition of standards is mostly free/cheap due to standards being open or available through ISO / BIS, and as India is a member of standards body. The

implementation can be facilitated by a standards support agency to be created by MoH&FW and MeitY. The actual cost of implementation (development & deployment) in existing application will be minimal considering that most of the standards are already notified by MoH&FW, and vendors are in process of incorporating them into their healthcare applications.

3.8 Enablers of NDHB

Other than standards, various architectural, design and operational recommendations are shown in **Table 3.6** to ensure cohesiveness of the Blueprint:

MDDS & EHR Standards for India 2016	Meta Data and Data Standards solve the problems of common data dictionary at the semantic level. The EHR Standards for India 2016 is overarching set of recommendations for creating, interoperating and using health record systems within an enterprise and external ecosystem at various levels. Inter-operability at the technical level would require specific integration solutions. Inter-operability at the institutional level would require a dialogue between public health organizations, to understand information needs, as well as barriers to better quality and use of information. Solving the semantic and technical barriers brings inter-operability much closer.
Hub & Spoke Model	As there are glaring incongruities between health systems at various levels of governance and delivery, the Hub and Spoke Model may play a vital role in designing the components of NDHB, especially referring to the Health Data Storage and Operations management. The clinical establishments particularly in rural areas where sufficient Infrastructure (Servers, storage and bandwidth) is lacking, face a problem. In such cases, Health Data may be stored in a bigger facility equipped with necessary infrastructure. In this model, all the smaller clinical establishments will act as a Spoke and the location where this data is stored will act as a Hub. In such a model, Hubs will also act as Spokes for larger Hubs maintained at State, Regional or National level .
eSign	eSign is an online electronic signature service which can be integrated with service delivery applications via an API to enable the user to digitally sign a document. Considering the requirements of health data like non-repudiation and trusted access / transfer for various medical workflows such as advices or referrals NDHB can leverage the eSign services in a cost-effective manner.

Table 3.6 Architectural, design and operational recommendations

3.9 Recommended further work on Standards

While an attempt has been made in this Chapter to deal with the core and minimal standards required in the initial phases of implementing the Blueprint, further work of creating appropriate policies is needed in the following areas:

- Structure of Core Health Records for AYUSH and Wellness related information and Indexes to be maintained centrally.
- Policy for digitization of legacy or non-standardized (free-text/paper) health record.
- Policy for storing heavy records (PET/MRI/CT)
- Policy for making the PHR System citizen-controlled.
- Policy for emergency access to the records
- Policy for use of records for research (anonymization & De-identification) and analytics
- Policy for record retention and archival
- National Safety Certification Infrastructure for Electrical-Medical Equipment.

CHAPTER 4

INSTITUTIONAL FRAMEWORK

Governance

Implementation

CHAPTER 4
INSTITUTIONAL FRAMEWORK

4.1 Back ground

An ambitious initiative like NDHB can materialize only if the right institutional framework is put in place. The following factors are to be considered in suggesting the right Organizational Structure:

- Evaluation of capabilities of existing organizations handling large scale Health IT systems to be considered as potential candidates for implementing the Blueprint
- Identification of the gaps between the existing capabilities in the identified organizations and that required for the Blueprint and analysing whether such an organization could be re-organized and strengthened to carry out the task.
- Whether we would require an entirely new organizational entity to drive this initiative.
- Learning from International Experiences of creating similar institutions
- Designing a Governance and Operational structure that could accommodate the concerns of a wide variety of stake holders and yet be operationally nimble enough to adapt to a complex business environment and ever-changing technological ecosystem.

An evaluation was done of the existing organizations such as CHI and CBHI housed within the Ministry of Health and Family Welfare, Government of India, and handling health data. A comparative analysis has also been done of all the national organizations handling large data besides reviewing the international experience in creating Electronic Health Record (EHR) structures specifically looking at the South Korean model of EHR structure. It is observed that the establishment of any new organization will need to possess, by design, attributes like

- financial independence,
- ability to get the right personnel and retain them,
- staying ahead of the technology curve ,
- speed and productivity in implementation,
- promoting ownership on the part of the user community within the new structure and the institutions supporting them,
- cost and time effectiveness.

At the outset, it is proposed that the entity to be charged with the responsibility of implementing NDHB be called 'National Digital Health Mission' (NDHM), to connote the missionary approach required for its successful implementation.

In a nutshell, it is important to underscore that the success of NDHM is dependent on its wide adoption by both Centre and State, public as well as private entities. Its adoption rests heavily upon the clear definition of the role and responsibilities of NDHM. To establish a clear mandate for the NDHM the following key components, roles and responsibilities are envisaged:

The key components of the National Digital Health Mission are shown in **Table 4.1**

National Health Electronic Registries	to create a single source of truth for and manage master health data of the nation;
A Federated Personal Health Records (PHR) Framework	to solve twin challenges of access to their own health data by patients and to healthcare service providers for treatment, and availability of health data for medical research - critical for advancing our understanding of human health;
A National Health Analytics Platform	to bring a holistic view combining information on multiple health initiatives and feed into smart policy making, for instance, through improved predictive analytics;
Other Horizontal Components	Including, and not restricted to, Unique Digital Health ID, Health Data Dictionaries and Supply Chain Management for Drugs, payment gateways. Shared across all health programs.

Table 4.1 Key components of NDHM

The role of the NDHM will be to provide information and data to different components of the health eco-system to work together and also provide the technological infrastructure for collection and storage of core/ master data through the various registries.

The responsibilities of the NDHM will include:

- Providing the technology platform for collection of core health data from the providers and patients
- Provide a platform for interoperability of health care data through a unique identifier for the provider and patient across the health system
- improving the quality of health data collection, storage and dissemination for purposes of research and policy decisions

- publishing national indicators for health, to measure quality of care and progress against policy initiatives and SDG Goals
- Capacity building on health informatics, safety and security

4.2 Essential Elements of the National Digital Health Mission (NDHM)

The Institutional Framework of the NDHM will have to operate at two levels, namely the Governance level and the Implementation level.

The Governance architecture of NDHM should comprise of the following elements for it to be a successful enterprise.

- Clear and well-defined leadership structure with reasonable autonomy
- Clear demarcation of roles and responsibilities
- Separation of policy, regulatory and operational functions
- Decentralized leadership and decision making
- Robust and transparent processes and systems

The implementation architecture of NDHM must incorporate key elements such as a clear leadership structure, convergence between core ministries and departments, citizen-centric approach and services, conductive policies, legal and regulatory frameworks, appropriate technology architecture, information management and security, infrastructure expansion, planning, monitoring and evaluation in a comprehensive manner.

4.3 Global Experiences

Over the past two decades there have been several Digital Health initiatives that were launched globally to improve the quality of health care and bring down the healthcare costs. While some countries like the United States are ahead of the curve in terms of the availability of Information and Communication Technology (ICT) infrastructure, other countries are in the process of reforming their respective health care sector and using IT as a key component of the process.

In **England**, the National Health Services-Digital (NHS Digital) is the national provider of information, data and IT systems for commissioners, analysts and clinicians in health and social care. It provides digital services for the NHS, including the management of large health informatics programmes. They deliver national systems through in-house teams, and by contracting private suppliers. These services include managing patient data, the NHS Spine, which allows the secure sharing of information between different parts of the NHS, and forms the basis of the Electronic Prescription Service, Summary Care Record and Electronic Referral Service.

In **South Korea** the Ministry of Health and Welfare (MOHW) created an organization to maintain EHR. Several advisory committees were created for providing policy directions and expert opinions. Two centres were created for carrying out system development and the related researches: Implementation Center for Development and Research, and Development Center for EHR. South Korea has been successful in developing their digital health infrastructure due to reliable and cost-effective IT platform, user-friendly application systems, standards, law, budgets, and strong support from various stakeholder groups such as the Korean Medical Association and citizens' groups.

The experiences of NHS Digital in England and the South Korean Model are particularly relevant for India and what we intend to achieve through the proposed NDHM.

4.4 Indian Scenario: Comparative Analysis of existing Organizations

India has made remarkable progress in the Information & Communication Technology (ICT) space over the past two decades. The IT revolution in India has also had a positive impact on the public sector Governance Architecture in India which led to some transformational initiatives like Unique Identification Number (UID-Aadhaar) for almost all the residents of India, IT enabled platform for GST, IT systems integration in banking sector and IT-enabled public service delivery.

While India has pockets of IT excellence within the Public Sector the application of IT enabled systems has not been uniformly adopted across the entire Governance System. The IT initiatives in the Health Sector in particular, have been fragmented and compartmentalized hindering the realization of the full potential of ICT.

To develop a robust Institutional Framework for the National Digital Health Infrastructure it is imperative to understand and analyze the institutional framework of existing organizations that have been successful in implementing IT-enabled services for the citizens. A detailed analysis of 8 existing organizations implementing IT enabled services (namely, NSDL, UIDAI, GSTN, NIHFW, NPCI, NIC, CHI and NHA) (Annexure: V) has been done along 3 different dimensions, namely
   a) Nature of legal entity, ownership, mandate and services provided
   b) Suitability of the organization/ its Model w.r.t the needs of NDHM
   c) Pros and Cons of choosing an existing institution Vs Creating a New Institution.

Following the analysis of the organizations it is concluded that none of the organizations in its current form can take on the responsibilities of such large-scale implementation of the specialized task of realizing NDHM. However, it is instructive to pick up some specific features of these organizations, which are relevant and essentially required for implementation of NDHB.

4.5 Recommended Institutional Framework of NDHM

Given the federal nature of Indian government and the fact that (a) Health is a State subject, and (b) it is necessary to incorporate private sector (both service providers and insurance), it is felt that an Institutional Framework which is a hybrid of GSTN, UIDAI and NPCI should be considered. The following factors weighed with the Committee in this regard:

a. Study of international Institutional Frameworks is suggestive of separation of regulatory and implementation bodies. While regulatory body takes care of policy making and policy administration, the implementation body should stay close to market for voluntary adoption; build best technical solutions and processes around products (building blocks), with security and privacy being of great importance.

b. The model Institution should have a legal backing with right level of focused leadership, to allow the necessary independence for hiring the best technical staff at market rates, manage human resources, access to enough funds and ability to co-opt the private players.

Following the analysis of existing Indian organizations and reviewing the international case studies, it is proposed that **the National Digital Health Mission should be set up as a new organization**. The following further suggestions are made:

a. To avoid duplication of activities the existing organizations handling electronic records and with similar functions should be subsumed in the new organization.

b. It is essential that both the Central and State Governments be the joint owners or stakeholders in this new organization.

c. A combination of the GSTN and UIDAI models of institutional structure is suitable for National Digital Health Mission.

d. Given the sensitivity of health data involved, Government should have complete ownership of the proposed institution with flexibility to attract private sector talent at appropriate levels of implementation, with adequate safeguards.

e. The Structure of the Organization should include two separate arms - one for regulation and the other for operational management as shown in **Figure 4.1**
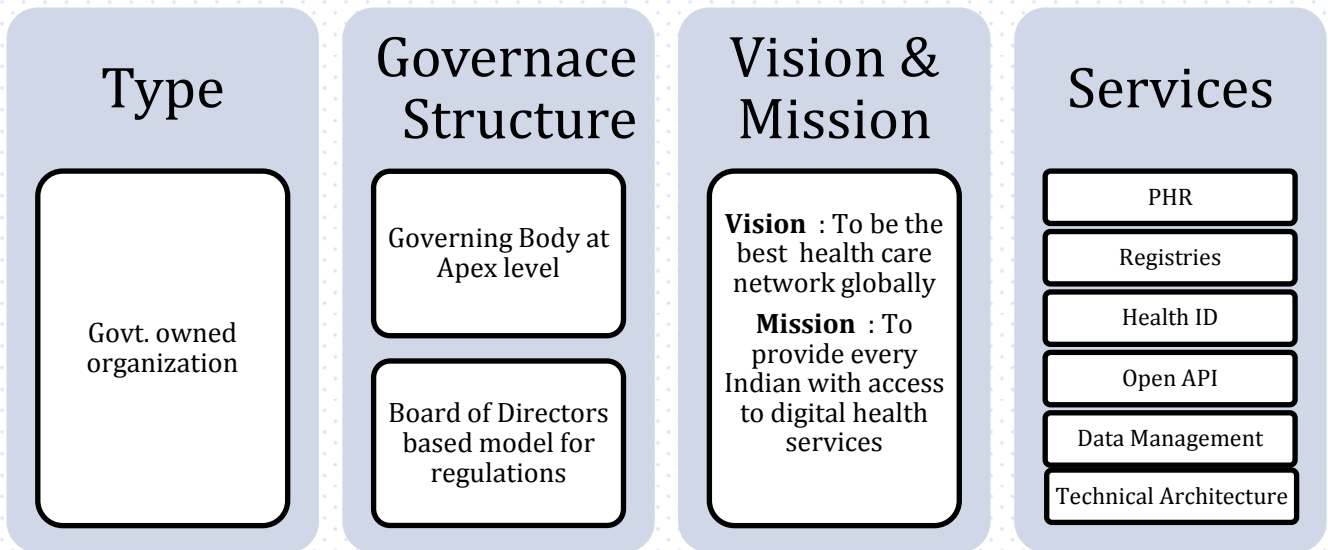
Figure 4.1 Vision and Mission of NDHM Organization

4.6 Roles and Responsibilities within the Institutional Framework

The roles and responsibilities at various levels of **NDHM** are suggested in **Table 4.2**

Level	Roles	Responsibilities
Apex Level	• Policy formulation and regulation related to National Digital Health Mission • Supervising the function of the entire National Digital Health Mission • Providing guidance to the National Digital Health Mission at the highest level	• Provide policy direction
Board of Directors	• Administrative leadership to the National Digital Health Mission • Develop policy direction for National Digital Health Mission • Develop models for self-financing of National Digital Health Mission	• Develop financing mechanism for sustainability of National Digital Health Mission
CEO	• Implement policies and decision approved by the Board of Governors at ground level • Identify models for funding Operation • Coordinate with MoHFW and the States/UTs • Engage with private sector to ensure their participation in the National Digital Health Mission • Resolve technical and operation issues at ground level • Policy administration	• CEO to have overall execution responsibility of the National Digital Health Blueprint • Ensure private sector participation in National Digital Health Mission

Operations	• Manage Day to Day Operation at the ground level • Capacity building of Health Informatics • Ensure smooth implementation of National Digital Health Infrastructure	• Overseeing all the activities of operation including implementation, training, support and modifications

Table 4.2 Roles and Responsibilities

The administration/implementation of the NDHM will rest on the CEO and will involve coordinating with different ministries/departments of the Government of India and State Governments. Hence it is proposed that the CEO should be of the rank of either a Secretary or Additional Secretary to the Government of India. The decision related to active engagement of private sector will be managed at the level of CEO to ensure up to date technology up gradation and effective administration/implementation of the National Digital Health Infrastructure.

4.7 Core Digital Services to be offered by National Digital Health Mission

The value of a Mission such as NDHM will be realized through the services it offers to the Stakeholders. NDHM will be shaped as the Technology Arm of the Health Sector of India. As such the focus of NDHM shall be primarily on the Technical Services it offers to the various organizations comprising the NDHE, in the public, private and NGO Sectors. However, given the nature of NDHB, it is necessary for the Mission to provide certain generic/ common services relating to the health domain, to avoid duplicative efforts by multiple States/ organizations.

While an exhaustive list of the digital services to be offered by NDHM will call for a stakeholder consultation and detailed deliberations, the Committee thought it fit to provide an illustrative list of the Digital Services of NDHM. The list is shown in **Annexure VI**.

4.8 Financing Model

National Digital Health Infrastructure is a public good. Its funding model must reflect this. In the earlier years, it must have budgetary support from the Government of India to get the National Digital Health Infrastructure built and operational.

A study was conducted to understand key cost components associated with the set up and running of organizations such as GSTN, UIDAI, NHA etc. to assist in the estimation of budgets required to support successful formation and running of the National Digital Health Mission.
It was observed that Development cost (Capital cost), People and Property (operating costs) formed the major cost components of such organizations. For the NDHM to be successful it will be important to undertake outreach activities with public and privates sector players. The NDHM will have to co-opt market players like

MedTech companies, NGOs, Foundations working in Health space as it builds the public utilities in the form of Registries, PHR, Health ID and Health Information Exchange etc. The outreach organization will have to have strong presence in all the states to ensure adoption of public utilities both by the state govt. as well as the Health ecosystem players.

If the new organization raises a part of its funding through a transaction fee, it drives a service orientation within the organization. However, it must be done without the risk of diluting the public good nature of the Institution. This can be done by using the concept of toll pricing model where no profit-making is allowed.

4.9 Recommendation in summary

The suggested model for the Implementation of the National Digital Health Mission (NDHM) is as shown in **Table 4.3**

Type	A new organization with a Governing Council and Board of Directors
Ownership	Government Owned body
Services	Health ID; PHR; Registries: Open API for insurance and Health Fiduciary (AA model)
Vision and Mission	**Vision**: To be the best health care network in the world **Mission:** To provide every Indian with access to digital health services

Table 4.3 Suggested model for NDHM

The recommendations are as follows:

1. NDHM should be a completely **government owned body** to ensure appropriate control within Govt. (Centre and States) as well as independence to deliver technology infrastructure within stipulated time frames and a business development orientation to co-opt the private players in the health eco-system.

2. The Institutional structure must include an organization with **two different arms** - one to handle the policy and regulations and the other for operations and service delivery.

3. Focus on **providing concrete value** to all players in the health ecosystem (Centre and State, private and public, service providers, insurance and citizens) through reduction in transaction costs, availability of infrastructure as public good and simple processes for easy adoption are more likely to bear desired results.

4. Setting up a **new organization** to implement the National Digital Health Blueprint.
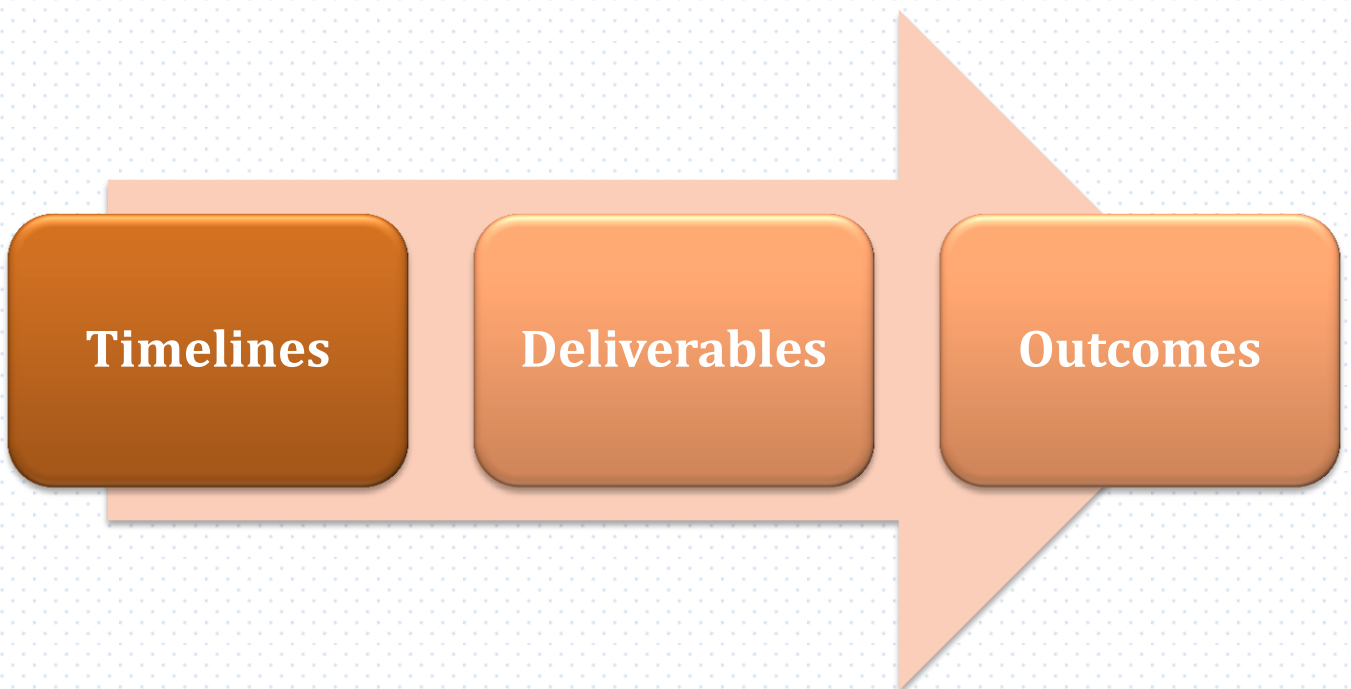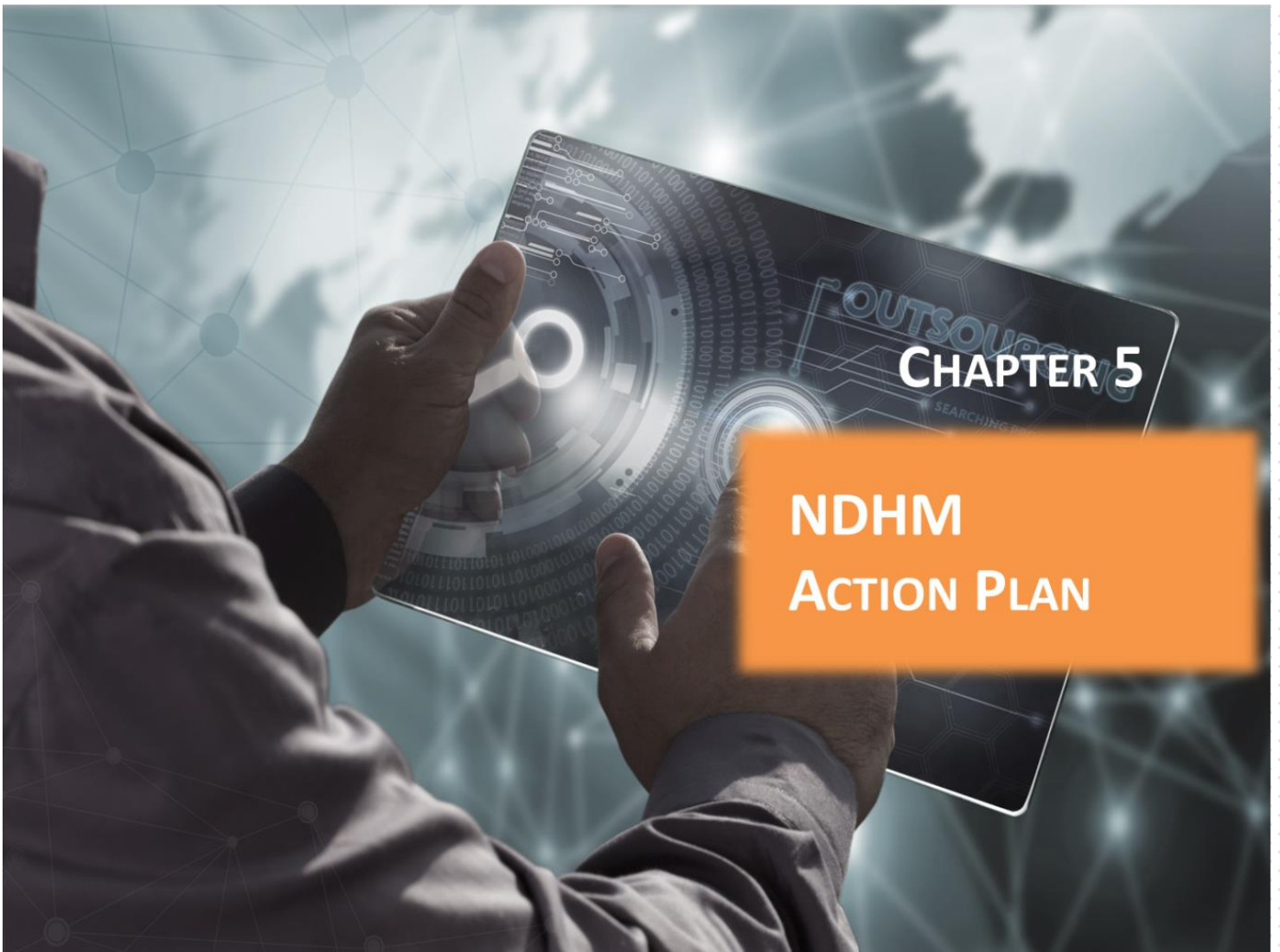
Timelines **Deliverables** **Outcomes**

CHAPTER 5
NDHM ACTION PLAN

5.1 Purpose of NDHM Action Plan

Any blueprint is as good as the systematic way in which is planned and implemented. Preparation of a high-level action plan is therefore considered to be an essential part of the National Digital Health Blueprint. The action plan outlined in this Chapter seeks to serve the following purposes:

a) The Action Plan enables crystallization and definition of the **Scope** and **Outcomes** of the initiative and to identify the **Methods** to be deployed for the implementation of the Blueprint;

b) It provides the approach to **Prioritization** of various activities required to fulfil the vision and objectives of the initiatives;

c) It paves the way for the establishment of the **Institutional Structure** at the earliest;

d) It identifies the **Core Building Blocks** of the Blueprint and guides the action to put them in place in a logical sequence;

e) It forms the rallying post around which can be created a widespread **awareness** of NDHB;

f) It speeds up the process of creation of the critical mass of **capacities** and **capabilities** required for a smooth implementation of NDHB.

This Chapter outlines the approach to address the above purposes effectively.

5.2 Scope of NDHM

The NDHB described in the previous chapters indicates, at different places, the contours of the **Scope of work** to be done if a digital health eco-system is to be established in the country. It is necessary to identify, collate and analyze all these work items to know the precise scope of NDHM. The following requirements culled from the previous chapters help us define the Scope more precisely:

a) Health and Well-being for ALL;
b) Health and Well-being at ALL Ages;
c) Universal Health Coverage;
d) Citizen-centric Services;
e) Quality of Care;
f) Accountability for Performance;
g) Efficiency and Effectiveness in delivery of services;
h) Creation of a holistic and comprehensive health eco-system.

The Action Plan must be designed to ensure that the scope as above is well-served.

5.3 Expected Outcomes

It is essential that clear **outcomes** are laid down for a major initiative like the NDHM, so that all the stakeholders can work towards achieving a common set of goals. The outcomes listed here are again culled from the previous chapters and collated for a holistic view. The various artefacts and deliverables of NDHM should be designed and developed in such a manner as to enable us to move in the direction of the outcomes.

a) All citizens should be able to access their Electronic Health Records in a convenient manner, preferably **within 5 clicks**;

b) Citizens need to undergo any diagnostic test **ONCE ONLY**, during the course of an episode, despite taking treatment from different health service providers;

c) Citizens should get **Integrated Health Services** at a single point, though multiple agencies/ departments/ services providers are involved;

d) NDHM shall assure **Continuum of Care** to the citizens, across primary, secondary and tertiary care and across public and private service providers;

e) A framework for **Unified Communication Centre** will be prepared to facilitate voice-based services and outreach;

f) NDHM shall support **national portability** for healthcare services;

g) **Privacy** of personal and health data, and **consent-based access** of EHRs will be the inviolable norm that shall be complied by all systems and stakeholders;

h) NDHM will be aligned to the **SDG's** related to health;

i) NDHM will enable **evidence-based interventions** in the area of public health;

j) Above all, the analytical capabilities of NDHM will support **data-driven decision-making and policy analysis**.

5.4 Methods & Instruments recommended by NDHB

Adoption of methods established in the health and IT domains would enable a systematic implementation of the blueprint. The following methods have been recommended by NDHB:

a) Federated Architecture

b) Universal Health Id (UHID)

c) Electronic Health Records (EHR)

d) Metadata & Data Standards (MDDS)

e) Health Informatics Standards

f) Registries for NCDs

g) Directories of Providers, Professionals and Para-medicals

h) Legislation and Regulations on Data Management, with focus on Privacy and Security

i) Data Analytics

Parallel streams of activities need to be initiated on all the above items.

5.5 'Deliverables' and Timelines

The essence of an action plan is the list of actions or deliverables, and the timelines and responsibilities for the same. The Action Plan turns the Blueprint into an actionable document through these deliverables. A list of 'deliverables' is given in the Table 5.1. The following explanatory notes enable a correct appreciation of the Action Plan

a) The deliverables are classified into 3 categories, namely,

    i.   Physical Deliverables (9 items)
    ii.   Digital Deliverables and (15 items, with 8 sub-items)
    iii. Artefact Deliverables. (12 items)

b) The deliverables in each category are again prioritized as Immediate (within 6 months), Short-term (within 1 year) and Medium-term (within 18 months).

c) Responsibilities are not spelt out. These can be firmed up largely after an organizational structure is put in place by the Ministry. As alluded to in Chapter 4, some of the early deliverables need to be worked upon by an 'interim organization', so as not to delay the implementation phase.

d) There are 15 Actionable Items in the immediate category, 12 in Short-term and 9 in Medium-term – 36 items in all. It is critical to identify and position appropriate resources to work on the various deliverables.

Timelines	Physical Deliverables	Digital Deliverables	Artefact Deliverables
Immediate (0-6 months)	1. Design, Procure **H-Cloud** 2. Establish **Secure Health Network** for accessing Core and Critical Health Data 3. Establish **Health Information Exchange (HIE)** for interoperability and integration.	1. Design and establish Personal Health Identifier **(PHI)** 2. Design and establish **Electronic Health Record (EHR)** system 3. Design and Develop **Core APIs** 4. Design, develop and establish **Consent Manager** 5. Establish **MyHealth App** 6. Design, develop and populate **Health Directories** (Master data of professionals, institutions)	1. Develop **Federated Enterprise Architecture,** adopting Agile IndEA Framework 2. Develop approach to working with **States/UTs** 3. Develop approach to working with **private sector** (health & IT service providers) 4. Assessment of Legacy Systems for conformance to NDHB 5. Design Organization Structure for NDHM 6. Design and implement a **Plan for Adoption of Health Informatics Standards**, including a system of incentives for adoption.

Timelines	Physical Deliverables	Digital Deliverables	Artefact Deliverables
Short-term (6-12 Months)	4. Establish **SOC**, **NOC** and Privacy Operations Centre (**POC**) 5. Establish special connectivity and IT Infrastructure for identified **Remote Areas**. 6. Establish **Telemedicine Infrastructure**	7. Establish **National Health Portal** 8. Design and establish **Health Locker** 9. Design and Develop **Health Analytics** system 10. Design and Develop **Anonymizer** 11. Integrate **PMJAY** with NDHM 12. Establish **NCD Registries**	7. Design and notify **NDHM Security Policy** 8. Design and notify **NDHM Privacy Policy** 9. Design Performance Management System and SLAs
Medium Term (12-18 Months)	7. Establish **GIS/ Visualization Platform(s)** 8. Establish **Health Call Centre**(s) 9. Establish **C4** (Command, Control & Communication Centre).	13. Design, develop and launch **Common Applications** including • Hospital Info Sys • Emergency Mgt Sys • E-Pharma • Wellness Centres Mgt • Ayush • Screening • MEDucation • CDS(Clinical Decision Support System) 14. Localization Tools 15. Design and Develop **Health Schemes Mgt** system(s)	10. Design and implement **Capacity Building Plan** 11. Design and implement **Plan for Clinical Audit.** 12. Architecture for Integration with CRS of **Registration of Births & Deaths**

Table 5.1 NDHM Action Plan for 2019-20

NDHM Action Plan

Physical Assets (IT)

Immediate (0-6 months)
- H-Cloud
- Health Info Exchange
- Secure Health Network

Short-Term (6-12 months)
- SOC, NOC, PrivacyOpCentre
- Telemedicine Infra
- Remote Area Connectivity

Medium Tr (12-18 months)
- GIS Platform
- Unified Call Centre
- C4 Centre

Digital Assets

- PHI, EHR
- Portal, Apps
- Health Directories

- Health Locker
- Health Analytics
- NCD Registries

- Common Applications
- Localization
- Schemes Mgt System

Artefacts

- Federated Architecture
- Org Structure of NDHM
- Adoption of Standards

- Security Policy
- Privacy Policy
- Perf Mgt/ SLAs

- Capacity Building Plan
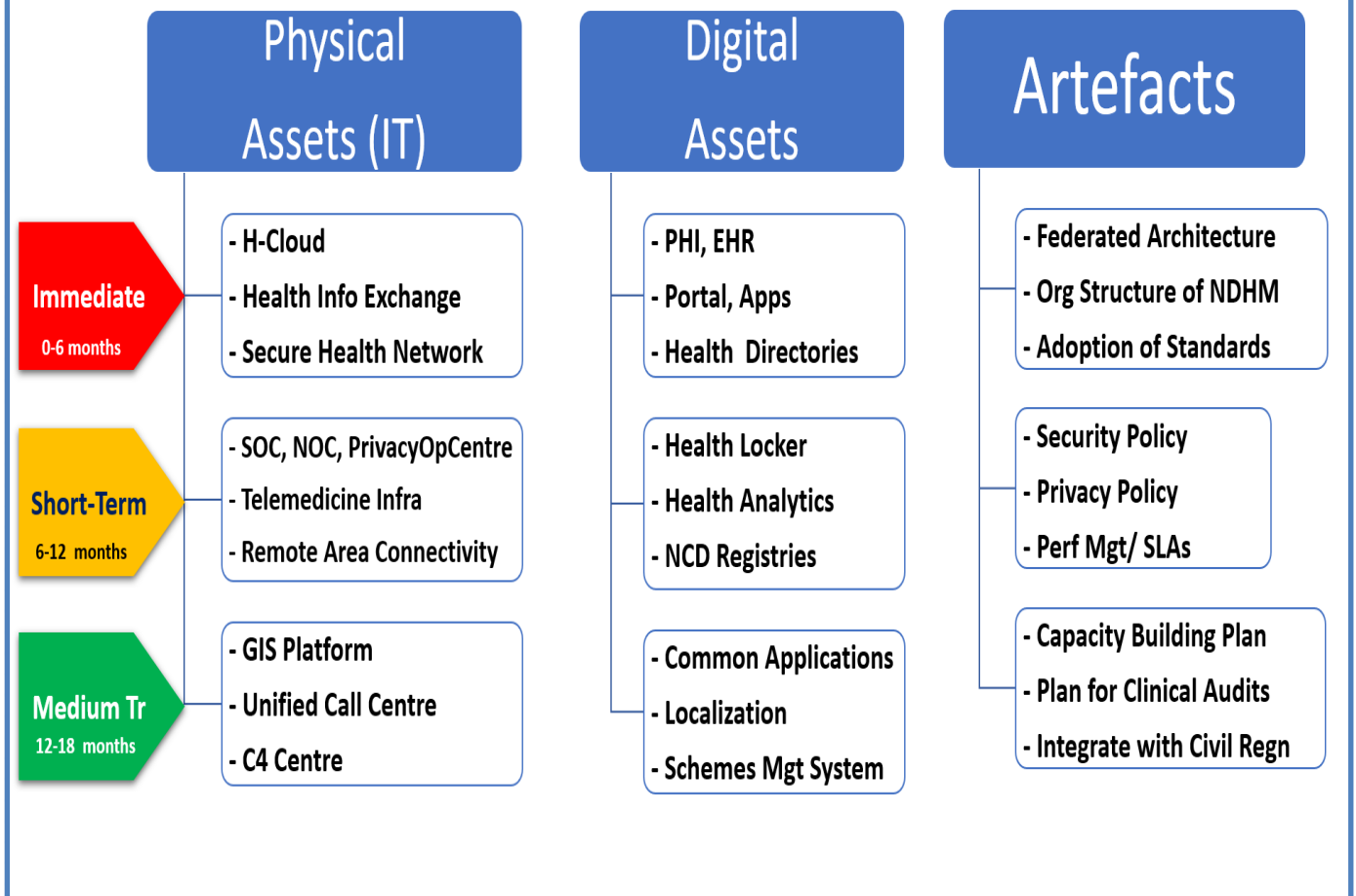- Plan for Clinical Audits
- Integrate with Civil Regn

Figure 5.1 Suggested Acton Plan for NDHM

Composition of the Committee on NHS

The Ministry of Health & Family Welfare, through its Office Memorandum T-21 016178/2018 eHealth dated 12th November 2018, constituted a Committee on NHS, with the following composition:

1. Shri J. Satyanarayana, (Former)Chairman, UIDAI & former Secretary, MeitY - Chairman

2. Shri Sanjeeva Kumar, Addl. Secretary, MoHFW - Member

3. Special Chief Secretary(Health), Government of Andhra Pradesh - Member

4. Additional Chief Secretary(Health), Government of Madhya Pradesh - Member

5. Mr. M. S. Rao, lAS, President & CEO, NeGD - Member

6. Shri Alok Kumar, Advisor(Health), NITl Ayog - Member

7. Shri Lav Agarwal, Joint Secretary(eHealth), MoHFW - Member

8. Nominee of Secretary, MeitY - Member

9. Nominee of CEO, NHA, MoHFW - Member

10. Dr. Neeta Verma, DG, NIC - Member

11. Shri Gaur Sunder, Joint Director, CDAC, Pune -Member

12. Director(eHealth), MoHFW -Convener

13. Dr Pallab Saha, Chief Architect, The Open Group (Co-opted by the Chairman)

14. Dr Manoj Singh, Professor, AIIMS (Co-opted by the Chairman)

Composition & ToRs of the Sub-Groups formed by the Committee

Sub-Groups	Chairman	Members	Deliverables
Scope, Principles & Services	Shri Lav Agarwal, JS (eHealth)-MoHFW	1. Dr. Sachin Mittal, Director MoHFW 2. Sh. Ankit Tripathi, Addl. Director -CHI, 3. Smt. Madhu Raikwar, Director, CBHI, MoHFW	1. List domain areas of high priority and of high impact, with a focus on Wellness; 2. Revise objectives of NHS so as to balance domain requirements with technology interventions;
Building Blocks & UHID	Dr. Neeta Verma, DG, NIC	1. Mr. Kiran Anandampillai, Representative-PMJAY 2. Dr. Pallab Saha, The Open Group	1. Identify and Define the Building Blocks for Domain and IT; 2. Structure of registries for NCDs like Cancer, Diabetes etc. ; 3. Harmonization and consolidation of Id's – Unique Health ID, NIN, NHRR; 4. Recommendation on the need for another ID, like UHID
Standards & Regulations	Mr. Jaideep Mishra JS, MeitY	1. Mr. Gaur Sunder , CDAC Pune 2. Mr. Manoj Singh, AIIMS	1. Minimum Standards required for adoption of EHR in a phased manner, including standards relating to wellness; 2. Feasibility of defining Indian standards in Health domain;
Institutional Framework	Shri Alok Kumar , Advisor(Health) NITI Aayog	1. Smt. Kavita Bhatia, MeitY 2. Dr. Sachin Mittal, Director MoHFW 3. Sh. Ankit Tripathi, Addl. Director -CHI, MoHFW	1. Reforms required in current structures; 2. Reforms required in current major schemes; 3. Institutional framework for the development and implementation of NHS.

Comparative Analysis of 4 Initiatives on Facility Registries

	NIN	ROHINI	NHRR	PMJAY
Background	Initiative by MoHFW to create a registry of Hospitals in the country	Insurers came together to create this DB to eliminate fake hospitals in insurance claims	Initiative by MoHFW to use a survey methodology to list every health facility in the country	Initiative to capture detailed info from secondary and tertiary care hospitals for empanelment
Process Owner	CHI	IRDA	CBHI	NHA
Coverage	250 K **public** facilities from sub centres upwards	15K **private** facilities who are active in health insurance	Public and Private facilities including clinics, diagnostic centers (Going on - Likely to be > 10 lakhs)	14K public and private facilities empanelled under PMJAY
Basic Info	YES	YES	YES	YES
Detailed Info	NO	NO	YES	YES
Process to Update	YES	YES	Under Development	YES
Incentive for facilities to participate	NO	YES	NO	YES
Trusted Data	Verified by District Administration	Verified by Insurer / TPA	Respondent based	Verified by District Administration

Comparative Analysis of 3 Archetypes for PHI

	Centralized	Federated	Decentralized
Definition	A single organization establishes and manages the identifiers	Different stand-alone entities, each with its own trust anchor, establish trust-based interactions with each other.	Multiple entities contribute to a decentralized digital identity; user controls sharing of identity data
Level of Adoption & Trust	Adoption dependent on value; trust dependent on system owner and identity proofing	Adoption dependent on establishing trust relationship; trust dependent on identity proofing	Trust dependent on trust anchors and attestations
Strengths	Can be built with specific purpose in mind; potential for organizational vetting of identity data	Users can access a wider range of services; efficiency for organizations	Increased user control and reduced amount of information collected and stored by organizations
Challenges	Generally low user control; centralized risk and liability; potential for abuse	Generally low user control; high technical and legal complexity	Governance model, acceptance and participation is complex; evolving landscape; complex liability

Mistakes to be avoided in Designing EHR

Mistakes to be avoided in designing EHR

Incorrect Identification

- Linking with WRONG EHR
- Administration of wrong medicine/ procedure

Incorrect Med History

- Missing entries/ episodes in EHR
- Critical info gets buried in mass of routine info

Bad UX/ UI

- More clicks than patient contacts
- Long drop-down lists
- Increased 'electronic paperwork'
- Physician Burnout
- Alert Fatigue
- Lack of interoperability between critical systems

Incorrect Lab/Diag results

- Tests ordered do not reach Lab
- Systems do not track Lab results

Incorrect Drug Info

- Lack of Allergy Info
- Prescriptions without start/ end dates
- Not using Standard Drug Codes

Status of 8 Existing IT-driven Organizations

Institution/ Organization	Type	Ownership	Services	Mandate
NSDL	For Profit Organization	Equity stake of multiple banks public and private and National Stock Exchange	NSDL provides various services in the capital market like, clearing members, stock exchanges, banks and issuers of securities	To Serve the nation with Technology, Trust and Reach and ensure that every Indian became a prudent investor
UIDAI	Statutory	Ministry of Electronics and Information Technology (MeitY)	Unique Identification numbers (UID), named as "Aadhaar", to all residents of India	To provide good governance, efficient, transparent and targeted delivery of subsidies and benefits to residents of India through assigning of unique identity numbers
GSTN	Not for Profit Organization	The central and state governments own 49% equity and Balance 51% equity is with non-Government financial institutions	The GST System Project is a unique and complex IT initiative that implements a uniform tax regime across the country	To become a trusted National Information Utility (NIU) which provides reliable, efficient and robust IT Backbone for the smooth functioning of the Goods & Services Tax regime
NIHFW	Autonomous organizati	Ministry of Health and Family	NIHFW is housing the National Health Portal	The National Health Portals mandate is

Institution/ Organization	Type	Ownership	Services	Mandate
	on, under the Ministry of Health and Family Welfare, Governme nt of India	Welfare		collecting, verifying and disseminating health and health care delivery services related information to all citizens of India
NPCI	Not for Profit Organizati on	Consortium of 56 Banks public and private	Payment Gateway Services	To touch every Indian with one or other payment services
NIC	Associated Office of Ministry of Electronics and Informatio n Technolog y (MiETY)	Ministry of Electronics and Information Technology	IT services to the Government of India. Some key services managed by NIC for the Ministry of Health and Family Welfare and CHI include RCH, Mother Child Tracking System (MCTS), Online Registration System (ORS), Beneficiary Identification system (BIS) etc.	Provide the Technology Backbone to all Govt. Departments
CHI	Society	Ministry of Health and Family welfare	RCH/ NHM, Training Unit HIV/ Surveillance Unit, Health Policy Unit Public Health Education & Research Consortium (PHERC)	To act as think tank, catalyst & innovator for management of public health and related health & family welfare programmes

Institution/ Organization	Type	Ownership	Services	Mandate
NHA	Authority	Chaired by Health Minister, Has cross functional team for Health Sector	Implementing Running of PMJAY	To develop IT components important to Health Sector

Illustrative List of Digital Services to be provided by NDHM

S. No	Name of the Digital Service provided
	Citizen/Patient Services
1	Single, Secure Health Id to all citizens
2	Personal Health Record
3	Single (National) Health Portal
4	App Store
5	Specialized Services for Remote Areas/ Disadvantaged Groups
6	NDHM Call Centre
7	Digital Referrals & Consultations
8	Online Appointments
7	e-Prescription Service
8	Digital Child Health
9	National "Opt-out" (for privacy)
	Services by / for Healthcare Providers/ Professionals
10	Summary Care Record
11	Open Platform to access Emergency Services
12	Technology for Practitioner (GP) Transformation
13	Digital Referrals, Case Transfers
14	Clinical Decision Support (CDS)
15	Digital Pharmacy & pharmacy Supply Chain
16	Hospital Digitization (HIS)
17	Digital Diagnostics
	Technical Services
18	Architecture & Interoperability
19	Health Information Exchange
20	Standards
21	Health Network
22	Data & Cyber Security
23	Information Governance