MINISTRY OF HEALTH & FAMILY WELFARE

NATIONAL COMMITTEE ON META DATA AND DATA STANDARDS FOR HEALTH DOMAIN

PART I- OVERVIEW REPORT- HEALTH DOMAIN METADATA AND DATA STANDARDS

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Metadata of MDDS Health Domain

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		sector requires exchange of information across applications.	
		There is a need for commonly accepted data definitions for	
		the various data elements used in e-Governance systems in	
		Healthcare. Hence, standardization of data elements is the	
		prerequisite for systematic development of e-Governance	
		applications in health sector.	
		On same lines, Health Domain has made an effort to identify	
		and define data elements and the relevant code directories of	
		domain so that to bring uniformity in usage and context of	
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		All national and state level Public Health Administrators,	
		Health 11 program managers and system designers.	
		• Program managers of National Health Programs,	
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> Shri Lav Agarwal Chairperson Committee on Meta Data & Data Standards in Health Domain Ministry of Health & Family Welfare New Delhi

Terms of Reference of Health Domain Committee

- a) To identify generic data elements in the health domain, which are common across e-Governance applications within the domain as well as other domains involved in providing sectoral services delivery under e-governance.
- b) To study the global standards for standardising the metadata of identified generic data elements for adoption as Indian standards.
- c) To develop own standards / extension of global standards in Indian context, wherever required, around policy on open standards, and in synergy with other domain committees by following Institutional Mechanism for formulation of Domain specific MDDS formulation published by MeitY.
- d) Create and maintain repository of metadata of standardised generic standards, and include the same in central repository by having liaison with e-Gov standards Div, NIC.
- e) Ensure enforcement of standards in the applications being developed in health domain at central/ state Government level.
- f) To advise for identification of suitable test suits for conformance testing of the implementation.

Health Domain MDDS Committee Members

1.	Joint Secretary (e-Governance), MoHFW	Chairperson
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Executive Summary

Under the National e-Governance Plan (NeGP), several initiatives have been taken for the growth of e-Governance in the country. The success of e-Governance systems needs seamless sharing and exchange of data among the e-Governance applications within/across domains. Standards play a pivotal role here. Ministry of Electronics and Information Technology (MeitY) has set up an Institutional Mechanism for evolving/ adopting standards for e-Governance applications.

The Health Domain MDDS Committee is an initiative, constituted on Sept 2012, under the chairmanship of Joint Secretary (Policy) with the senior technical officer of NIC as its member secretary. The secretariat is located in the National Health System Resource Centre (NHSRC), entrusted with the task of extensive stakeholder consultations and recruiting appropriate technical agencies to support this work. The process included a study of existing systems and their interoperability issues and a study of global data and interoperability standards.

For identification of diseases, clinical procedures, laboratory and diagnostic tests and therapeutic interventions, standards referenced by MDDS committee include ICD-10, SNOMED-CT, LOINC, HL7 v2.x, HL7 v3 RIM, Canadian Classification of Health Intervention (CCI), WHO Morbidity and WHO Mortality list etc. MDDS also absorbed all recommendations made by the EHR Committee report (Dec-2016). Existing programmes and systems such as MCTS, IDSP, RNTCP, Drug Inventory & Distribution system of Rajasthan were also studied to identify relevant common data elements and metadata. One of the challenges that this committee has addressed is the establishment of a set of *"identifiers"*- i.e. standards for identifying the Facility, the Medical Provider, Patient, and all others handling healthcare data so that information across different locations can be exchanged easily and securely.

The Meta Data and Data Standards are developed following the guidelines set by the MeitY and are organised in four parts:

- Part I: The Overview
- ↓ Part II: Data Elements: Quick Reference
- **4** Part III: Code Directories: Quick Reference; Sample Values and their structure:
- ✤ Part IV: Metadata of Data Elements

The first of these parts is this report, whereas the other three parts are made available only as soft copy format on the MoHFW, NHM and NHSRC websites.

Part 1 provides an overview of Health Domain MDDS which will help reader in understanding other parts of Health MDDS. It talks about how MDDS is structured for domain vis-à-vis listing of data elements, their metadata, code directories (controlled values for some data elements) and their structure.

Part II lists different data elements of Health domain along with their commonly defined context-based data definitions, data formats and maximum sizes. Approximately 1000 data elements are identified for health domain and are grouped under logical entities such as Patient, Examination, Diagnosis, Mortality, Pharmacy etc. Grouping of data elements under these entities would make MDDS better manageable and easier to use.

In case of certain data elements, the values need to be controlled and are defined in advance for using them uniformly within/across domain applications. For such data elements, Code Directories are defined.

Part III lists down Code Directories where set of values are used from established sources. The structure of Code Directories is illustrated indicating source of Code Directory, ownership details, etc.

Part IV has metadata for each data element identified by MDDS.

In addition to the above, the document provides annexures with sample data sets for users of the Health Domain MDDS for drug inventories and blood banks. The system specific integration recommendations are also included in the annexure.

As the National Health Mission moves towards the goal of Universal Health Coverage, one of the key challenges is to provide the information architecture for the increasingly large and growing complexity of information needs of service users, healthcare providers, of hospital and health managers and for e-governance. Establishing nationwide interoperability, domain specific metadata and data standards and interoperability standards is one of the key steps in the endeavour to better manage this complexity.

Implementation of these standards requires an institutional measure in the form of a National Digital Health Authority charged with the management, promotion, adoption and compliance with these standards. Though MDDS is an essential pre-condition of interoperability it is not sufficient. Interoperability requires solutions at the semantic level, at the technical level and at the institutional level.

MDDS solves the problems at the semantic level. 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, but there would be still challenges to face. The MDDS publication is thus the first step of a long journey, not its destination.

Note to the Reader

The Health Domain MDDS has created Common Data Element which is meant for the use of Healthcare-IT Professionals involved in requirement analysis, system design, upgrade, reengineering or interoperability of Healthcare-IT applications. Though Healthcare terminology much of which is derived from Greek and Latin, is largely limited to code directories. Some key words could have a different meaning in general English as compared to its use in Healthcare Informatics. For Example- The keyword 'Provider' has a specific meaning in healthcare i.e. Service Provider e.g. Physician, Dentist, Nurse etc.; whereas the word provider in English can mean anything e.g. main bread winner or provider of a family. Therefore non-Healthcare-IT professional while reviewing this list of Common Data Elements, would find it advisable to refer to a standard Medical Dictionary e.g. Steadman's or keep a Healthcare-IT professional handy. We also provide a Glossary of terms for the uninitiated audience.

The Meta Data & Data Standards published by MeitY titled as 'Metadata and Data Standards – Demographic (Person Identification and Land Region Codification)¹ V1.1, Nov 2011' is referred by Health Domain for data elements specific to Person Identification, Land Region Codification and for other common data elements. Users are suggested to read Health Domain Metadata & Data Standards in addition to the above mentioned publication by MeitY. The above mentioned document should also be referred to know more about Metadata & Data Standards.

¹<u>http://egovstandards.gov.in/sites/default/files/MDDS_Demographic_Ver1.1.pdf</u>

1. Introduction

The Metadata and Data Standards is an initiative taken by Ministry of Communication and Technologies under National e-Governance Plan (NeGP). The intent was to promote the growth of e-Governance within the country by establishing interoperability across e-Governance applications for seamless sharing of data and services. Under the MDDS initiative domain specific committees have been constituted in priority areas. The Health Domain MDDS Committee was one such initiative, which was constituted on Sept 2012, under the chairmanship of Joint Secretary in pursuance of communication received from Secretary, Ministry of Electronics and Information Technology (MeitY) previously known as Ministry of Communication and Technology.

Post formation, the Committee had initial orientation meetings on Metadata and Data Standards development for health domain. After initial discussions, National Health System Resource Centre was constituted as secretariat for the committee. To help develop Meta Data & Data Standards, two agencies were brought on-board following a proper selection process based on their merit on Health informatics. The due diligence was thoroughly done to study the landscape of existing health domain by involving all relevant stakeholders and knowledge partners including Program Officers and System Managers of Central and State Health IT Systems. As part of terms of reference, a thorough study of global data and interoperability standards were taken into account.

Initially generic data elements were extracted from the existing health IT systems. However these existing systems were geared towards addressing specific program requirements which was falling short to address the vast scope of Health domain. The other challenge was that data elements of these systems were not aligned with global data standards. Efforts were made to adopt and modify global standards in such a way that these existing applications could easily be upgraded to MDDS standards.

The exercise yielded to approximate 1000 data elements which were regrouped and formatted into 39 entities for better assimilation and presentation. These data elements will serve as the common minimum data elements for development of IT applications for various sub domains of health care. This is intended to facilitate interoperability among all these applications.

2. Purpose of Health Domain MDDS

The adoption of Metadata and Data Standards across healthcare IT systems will enable easier, efficient exchange and processing of data. It will also remove ambiguities and inconsistencies in the use of data. Once the MDDS standards are adopted by all e-Governance applications in healthcare, the interoperability would be easier.

Inevitably the migration to these new Standards may appear at the outset to be costly and time-consuming to some parts of government. However this burden should be outweighed by reduced development costs through the use of the agreed schemas that use these Standards. It is also expected that new IT system in healthcare, as and when they come will use MDDS standard and will participate in information sharing and data exchange.

3. Structure of the MDDS Standard

The Metadata and Data Standards in Health Domain are developed following below mentioned guidelines set by MeitY.

- **a.** Metadata and Data Standards Demographic v1.1
- **b.** Operational Manuals for formulation of Domain specific MDDS
- c. Institutional Mechanism for formulation of Domain specific MDDS

As per the guidelines the MDDS Standards are broadly covered under three sections as given below.

- 1. Data Element Quick Reference (ref: Part-II)
- 2. Code Directory Quick Reference, Sample values and their structure (ref: Part-III)
- 3. Data Element Metadata (ref: Part-IV)

Data Elements common across all health domain applications are listed, defined and standardised in the Data Element Quick Reference document (Part II). This list gives brief description about the data elements in addition to the data format & size it follows. For easy readability the data elements are grouped in various entities. However these entities should be considered as logical grouping only and users are free to regroup these data elements as per their need. Under the quick reference document, each data element is classified into four categories to help identify following:-

- Data elements which can be used from health domain to other domains (Prospective Generic Across Domain (Viz.: PGAD))
- Data elements which are common within health domain (Prospective Generic Within Domain (Viz.: PGWD)),
- Data elements which are customised from already standardized generic data elements (Custom (Viz.: C))
- Data elements which are application specific in health domain (Application (Viz.: A)).

Health Domain MDDS has followed ISO/IEC 11179 standard for development of data elements, value sets and code directories. As per the conceptual design of data element in ISO/IEC 11179, each data element can have a single value or multiple values attached to it. The data element which has a single value will be complete in itself and if a data element has a limited list of values associated with it, then those values will be a part of value list for that data element. However if there is a long list of complex values for the data element, they have been put in relevant code directories. Values in the code directories can grow and mature with review and modification.

Code Directory Quick Reference document is ready reference to the code directories developed (Part III). This indicates name of code directory, source of code directory and the

ownership rights for each of the code directory. The metadata of each code directory is given in the Code Directory Meta Data and the sample values for each code directory are also populated in the Part III of the MDDS Standard. The sample value for each code directory is populated in the Part III. Some code directories (i.e. Inventory Store Master; Employee Master; Service Tariff; Package; OT Preference Card; Blood Bank Master; Ward; Bed; Authority; Supplier Master; Laboratory Master; Floor Master), which are highly implementation specific, no sample values are populated and it is expected that each implementer will populate the values in these code directories and help MDDS committee to enrich these code directories. In addition there are few code directories (i.e. Test Result Reference Range; Homeopathic Generic Drug; Non-Drug Item Brand; Homeopathic Brand Drug; Brand Drug; Manufacturer Master; Equipment Classification; Equipments; Ayurvedic Generic Drugs; Ayurvedic Brand Drugs; Unani Generic Drugs; Unani Brand Drugs) for which standard value set is presently not available. Domain specific Working Groups would be constituted to help populate these code directories. Work is presently going on for population of remaining 8 Code Directories (Facility Master; Facility Type; Ownership Authority; Facility Area Coverage; Facility Beds; Facility Human Resources Type; Administrative Linked or Referral Facility; Facility Services Master) which are part of the National Health Facility Registry initiative of MoHFW.

4. What is Common Data Element?

The Health Domain MDDS Committee provides a list of data elements that will serve as the common data elements [CDE] for any new application being developed in Health domain.

The need for the CDE arose because most of the Healthcare-IT applications are being developed without any standards by different agencies and vendors in public and private sector in India. Later it becomes difficult to connect the systems and make them talk to each other because they were never designed for that purpose.

Due to the inherent complexity of Health domain - It is difficult to create minimum set of data elements that every sub-domain must adhere. Each sub-domain's minimum data element may not be completely applicable to other sub-domains – meaning 'My minimum need not be your minimum'. For example the Lab Order data elements required at Primary care setting will be far less than the Lab Order data elements required at Secondary care and Tertiary care settings.

Therefore the health domain MDDS committee has come up with the Common Data Elements. CDE will provide most of the data elements required for any new Healthcare application to be built. However the users may add additional data elements above and beyond the CDE for their local needs. Using CDE the applications would be able to share information with each other. There are two ways to use CDE, either use CDE from the design phase of application development or make applications compliant with the CDE post implementation. The latter option is cost and efforts intensive and may be difficult to implement. It would be easy to use CDE from the design phase of application development.

While developing CDE the attempt was to be universal. However the healthcare is so vast that some specific data elements on the fringes may have been left out inadvertently. CDE is intended to be a living document and a designated Health Domain MDDS Committee will have the authority to add any new data elements, values or code directories that were left out at this stage or that may emerge as a result of natural evolution of the Healthcare domain. When new applications do not find the relevant data element or values for their use, they will have to use 'Free Text' data element or 'Other' Value from the code directory or value list. Though the usage of 'Free Text' data element or 'Other' Values will have to be discouraged in principle; however this usage of 'Free Text' data element or 'Other' Values has to be regularly monitored by the Health Domain MDDS Committee and used as valuable feedback for the next versions of the CDE.

Therefore CDE is intended to be a living document and a designated Health Domain MDDS Committee will have the authority to add any new data elements, values or code directories that were left out at this stage or that may emerge as a result of natural evolution of the Healthcare domain.

Why is Common Data Element required? Organizations often want to exchange data quickly and precisely between computer systems.

The need for the CDE arose because most of the Healthcare-IT applications are being developed without any standards by different agencies and vendors in public and private sector in India. Each application is developed for standalone use without much attention to semantic interoperability. Later when the thought of interoperability emerges – it becomes difficult to connect the systems and make them talk to each other because they were never designed for that purpose. Even if technical and organizational interoperability is done the semantic interoperability may remain a challenge. For example – all applications must have the same Facility master. When Application A sends the ANC data for Facility 123, the receiving Application B should understand ANC and uniquely identify Facility 123. Another example is if a hospital application sends the insurance reimbursement bill to insurance company/government, the recipient application should be able to understand and re-present the same meaning of bill information.

5. Health Domain MDDS: Conceptual Framework

The holy grail of Healthcare is the Provider – Patient relationship. The entire common data elements have been designed by keeping the Provider – Patient relationship in mind rather than either entity as the centre. The CDE has been designed based on the standard ISO/IEC 11179. This standard is a result of the following principles of semantic theory, combined with basic principles of data modelling.

- Conceptual Domain: The first principle from semantic theory is the thesaurus type relation between wider and more specific concepts; For Example- the wider concept 'Order' has a relationship with similar more specific concept Pharmacy Order And immunization order. Therefore the CDE has created Pharmacy Order and Immunization Order entity.
- Concept: The second principle from semantic theory is the relation between a concept and its representation. Different synonyms or closely related keywords can convey the same concept. For Example –The number of times the drug/medication has to be taken at what interval is a concept. 'Frequency of Drug' and 'Frequency of Medication' are different representations of the same concept.
- Data Element: The basic principle of data modelling is the combination of an Object class and an Attribute to form a more specific 'data element concept'. For example- the abstract concept 'Frequency of Medication' is combined with the object class 'Medication Order' and is associated with Attribute 'Frequency' to form the data element concept 'Medication Frequency'. The standard must select the most appropriate keyword as the representation of the concept. In the above case the
 - Object: is 'Medication Order' and,
 - Attribute: is 'Frequency'
- Value Domain: A value domain is the permitted range of values for a Concept. If the data element concept has a single value then it will remain as a single data element. If it has a limited set of values attached to it then it will have a value list. If the data element has a long list of values that are liable to change or be modified due to the business needs of the Health domain then it is advisable to create a Code Directory for those values. For Example- For data element concept 'Medication Frequency' the related Code Directory will have values: BID, TID, QID, HS, SOS, and Stat.



Figure 1: ISO/IEC 11179 Meta Model

Table:1 Example of Conceptual Design				
Example	Depicting the concept Health	Depicting the concept, Facility		
	Condition, Chickungunea.	Operational Status.		
Data Element	Health Condition Code	Facility Operational Status		
Object	Health Condition	Facility (Sub Centre)		
	(Chickungunea)			
Attribute	Code (ICD-10 Code)	Operational Status		
Value Domain	ICD-10 Code value for	Operational Status Value List		
	Chickungunea (A92.0)	(Functional)		

Many of these data elements have been drawn from standards such as -

- Continuity of care document [CCD]: CCD was developed by HL7 for portability of medical records.
- HL7 v2.x: String based standard for interoperability of Healthcare data, developed by HL7.org and adopted widely across the globe.
- HL7 v3 RIM: XML based standard for interoperability of Healthcare data, developed by HL7.org and adopted widely across the globe.
- EHR Standards: EHR Standards for India v2 released by MoHFW in Dec 2016.

Though the above said standards are our reference point but we have extended and modified them to apply to Indian setting. The associated Code Directories are drawn from standards such as –

- ICD-10 for Diagnosis and Classification: ICD is used to classify diseases and other health problems recorded on many types of health and vital records including death certificates.
- LOINC for Lab: LOINC is a universal code system to identify laboratory and clinical observations to facilitate exchange and storage of clinical results or vital signs for patient care and research
- Procedure & Radiology Codes (preferred primary terminology): SNOMED CT.
- WHO Morbidity list: The noun morbidity means "the quality of being un-healthful." The special tabulation list for morbidity published in ICD-10 volume 1 consists of 298 groups defined by their ICD-10 codes.
- WHO Mortality list: The noun mortality means "Death" The special tabulation list for mortality published in ICD-10 volume 1 consists of groups defined by their ICD-10 codes.
- WHO ICF: The International Classification of Functioning, Disability and Health (ICF) are used for defining functionality & disability.
- WHO Verbal Autopsy Standards: Is list of standards for causes of death with mapping to ICD-10 Codes.

6. Identifiers

For data exchange across applications, accurate identification of each person/ facility receiving or providing healthcare services, and also anyone accessing or using this information is extremely important. It is critical that a set of standards be established for identifying the Facility, the Medical Provider, Patient, and all others handling healthcare data so that information across different locations can be exchanged easily and securely.

An Identifier could be a number, image (e.g. Bar Code or Blackberry ID), Biometrics (e.g. finger print or retinal scan), Radio Frequency Identifier Tag (RFID), Smart Card or a combination of these. Considering that none of these identifier standards exist today in Public Health space- The Health Domain MDDS Committee proposes basic number based identifiers. The standard can be upgraded to include Alternate Identifiers such as Bar Codes, RFIDs, Digital Signature etc., as the healthcare industry matures. For now appropriate Data Elements have been created to capture information about these Alternate Identifiers.

With regards to the nomenclature of the Identifiers some qualifiers were followed to maintain the uniformity.

- a) Identifiers which were drawn from established sources were used as it is and no change is made in their names. e.g. Unique Identification Number (UID), PAN etc.
- b) Identifiers which are proposed to be used uniquely and uniformly across states are termed as "Numbers" e.g. Unique Facility Identification Number, Alternate Unique Identification Number etc.
- c) Identifiers where code directory or value list from established source is used are termed as 'Codes" e.g. Diagnosis Codes (ICD10 Codes) etc.
- d) Identifiers which were transaction specific are termed as "Identifiers or IDs". E.g. Employee ID, Document ID etc. However some of these can come from code directory master but are named as IDs because they are transaction identifiers to be populated at the time of implementation.
- I. **Facility Identifiers**: Facility Identity management is complex therefore a Facility Code Directory is created to give a structure to it. This Facility code directory will serve as a Master to which all the Applications will refer. Two set of identifiers are proposed to uniquely identify each facility-GUID & NIN.
 - **a. Global Unique Identifier (GUID)** This data element is a 16-bit number, which will be generated following a standardized algorithm by system. An example of a GUID in its standard form is 40e74fae-c0ab-11dfb090-0017f2300bf5. GUID will be used at the back-end to uniquely identify each facility. GUID will guarantee global uniqueness of each facility no matter where or by whom they are generated. All prospective systems need to follow standard algorithm in their backend to use GUID.

- **b.** Facility National Identification Number (NIN)-NIN is a 10 digit random number given for each facility (public & private) engaged in providing some form of health care services. NIN will be used at the front-end with some form of human readability. There are two ways to do this.
 - ✓ Give the facility a number with facility related information embedded in it (e.g. ABC-13-05-0001, where AB&C represents State, District & Block respectively and next two digits represent year of facility formation and next two digits represent type of facility and last four digits represent the facility itself). However this approach has certain challenges as facilities might upgrade or facility attributes change due to administrative, geographic or political realignments.
 - ✓ The other way of doing it is by giving a unique running number to each facility without making this number dependent on any other factor. Where the facility related information can be added as an attribute to the NIN.

The Health Domain MDDS Committee has adopted the later approach to uniquely identify each facility.

Why two identifiers for a facility?

Although each facility will also be given a sequential 10 digit integer number (NIN) and this is used as a unique facility identifier by all users, still the uniqueness of these codes will be dependent on database system which generate these numbers, which still does not necessarily guarantees to be always unique e.g. if the database is ported from one Database Management System (DBMS) to another, the unique sequential number (or auto increment primary keys of tables) will change. In order to avoid this problem GUID is proposed along with NIN.

Master Facility List (MFL): Using NIN & GUID, a Master Facility List will be created at the centre and put up in a public domain and this will be used as reference by all prospective applications built at state or national level. At the implementation level we propose a Health Information Exchange or Intelligent Gateway with a Facility Registry to match facility identifiers given by various healthcare applications.

Facility identification and associated attributes can be categories in four major groups.

a. *Facility Signature Domain*: Information which will help in identification of each facility with its attributes is grouped under signature domain. The associated attributes arefacility type, address, Geocode, facility access (difficult/ hard to reach) and region (rural/ urban) indicator, hierarchy of facility, facility operational status (functional/non-functional), linked facility for referral and facility ownership. The other most important information is the population covered by the facility. The population covered code directory will help provide a population based denominator to the facility. Each facility will be mapped with the census population of area which it covers to. E.g. Each Health Sub Centre will be mapped to the villages it is serving currently, through the Census

village data-base. Two or more HSCs which are sharing one village will use a proportionate population formula to get their piece of serving population from the census village data-base and to accommodate this Many-to- many relationships with HSC and villages would be required. This arrangement would further help in identification of areas covered by the PHCs and their serving population. In the urban areas each ward will be mapped with Urban PHC through Many to many relationship. Population based catchment area would be defined for the government facilities under public health systems. For private and other ministry run facilities no population catchment area would be assigned.

The principle of defining this linkage is that the denominator of the sub-unit aggregate would provide the denominator for the administrative hierarchy e.g. all sub-centres under one PHC are linked with it. Private and other ministry run health facilities data will not be aggregated with the block data. Data of these facilities will be aggregated at the district level.

- **b.** *Facility Services Domain*: Each facility in India provides a set of services as mandated by the respective administration. In addition a set of facilities also provide services of alternate system of medicine. E.g. Ayurvedic, Homeopathy etc. For Allopathic system of medicine list of services will come from LOINC & Procedure Codes. However in the case of alternate system only name of system of medicine would be applicable as the standard list of services from alternate system of medicine are not available. Code directory on 'Facility System of Medicine' and 'Facility service master' will help define services available in facilities.
- **c.** *Facility Human Resource Domain*: Code directory Facility Human Resources Type Master: Indicates the number of human resources available with the facility with their designations.
- d. Facility Infrastructure Domain:
 - i. Facility Bed Master: This will indicate number of beds available with facility.
 - ii. Facility Bed Type Master: This will indicate the type of beds available with the facility- sanctioned, functional and available.
- II. **People Identifiers**: These are the identifiers used to identify individual patients, relatives and various providers in the health system.
 - a. *Patient Identifiers*: Currently multiple patient identifiers are used across applications in health care space in India. There is also a massive program allocating unique identification number to individuals i.e. Aadhar Number. Aadhar number is 12 digit integer allocated by Unique Identification Authority of India (UIDAI). The Health Domain MDDS Committee proposes to use Aadhar Number as unique patient identifier. However in case patient does not have Aadhar Number a provision has been made for the use of Alternate ID, issued by any other competent authority e.g. Election ID, Driving License ID, Ration Card ID, PAN Card ID, BPL ID etc. Provision has also been made to identify unknown persons/dead bodies coming to emergency hospital wards in

case of emergency or Mass Casualty Incident (MCI) e.g. John Doe and Jane Doe (widely used placeholder for unidentified persons in emergency).

- b. *Healthcare Provider Identifiers:* Each provider would be given a unique identifier and for this purpose individual registration number from respective registration councils would be used. E.g. for Allopathic Doctors registration number given by MCI, for Ayurvedic Physicians registration number from Central Council of Indian Medicine, and for Nurses registration number given by Nursing council. Those providers who do not have any registration authority (i.e. physiotherapist, paramedic workers, and community health volunteers) individual person UID or alternate UID would be used for this purpose. Later on when a competent registration authority is put in place the number can be captured just like other Providers after appropriate values in relevant code directory has been updated.
- c. *Other People Identifiers* e.g. Identifiers for Patients relative and next of kin.
- III. **Disease Identifiers**: Each procedure and service is uniquely identified by a standard code.
 - a. *Diagnosis Identifiers:* e.g. ICD10 codes for diseases
 - b. *Output Identifiers*: e.g. WHO Morbidity and Mortality list based on ICD10 codes, and WHO ICF codes for functionality and disability.
- IV. **Clinical Event Identifiers**: This indicates Document Registry to match Encounter and Episode identifiers given by various healthcare applications.
 - a. *Encounter Identifiers* Every time the patient meets a provider it is documented as an Encounter with a new Encounter ID. Encounter identifiers would apply to clinical, lab, radiology encounters. Physical Examination done by the Provider is considered as an Encounter and documented as clinical notes with a specific Encounter Identifier.
 - b. *Episode Identifiers* A group of closely related encounters for the same patient will get an Episode ID.
- V. Drug and Inventory Identifiers: Each drug whether generic or brand is given a unique identifier. For generic names– drug list from National Formulary of India (NFI) is used as the code directory. For brand names the brand name code directory structure has been defined but it is left to the application to take the code directory values from appropriate source. However MoHFW is working on publishing Drug and Substances codes as national extension of SNOMED CT. It is advisable to prefer this code set for designing of respective application.
 - A. *Item Identifiers*: As discussed above, all items consumables, semi-durables, durables and equipment will also be given unique identifiers in the code directories.
- VI. Lab identifiers: For laboratory procedures LOINC codes are proposed for use as identifiers.
- VII. **Financial Identifiers**
 - a. Source of Payment Identifiers e.g. Insurance Provider Identifier.

b. *Billing Identifiers*: Identifiers for services, procedures and medications billing.

VIII. **Other identifiers**- For identifying each entity or event separately a unique ID is proposed i.e. Medical Registration board ID, ambulance service providers ID, ambulances ID, hospital departments ID etc.

7. Common Data Element Entities

Health Domain is very vast and to make it more readable, Health Domain MDDS Committee has created logical grouping of data elements named as entities, however this grouping should not be confused with data sets. Data sets are list of data elements required for certain program or application to function and should be created choosing relevant data elements from various entities e.g. Diabetes Data Set, Family Planning Data Set, Inpatient care Data Set. This grouping does not act as a binding to further development, regrouping or change in the Common Data Element list. Description of each entity is given below.

	Table-2: Description of Entities			
SN	Entity	Description		
1	Generic	Generic Entity contains data elements which can be applicable to various applications used in health domain. E.g. Time		
2	Person	Person is an individual with certain attributes associated with it. These relates to identity management of an individual in health care. E.g. Alternate Unique Identification Number(UID)		
3	Patient	A patient is any recipient of health care services. This entity list patient attributes as data elements. E.g. Patient Age		
4	Employee	An Employee is a person who is hired to provide health care services to a health delivery organisation in exchange for compensation under the ambit of a contract. Human Resource Management Related data elements are grouped under this entity. E.g. Employment Status, Employment Type.		
5	Healthcare Provider	A health care provider is any individual that provides preventive, curative, promotional or rehabilitative health care services to individuals, families or communities. Under this entity Individual health service provider related data elements are grouped together. E.g. Unique Individual Health Care Provider ID		
6	Source of Payment	Source of Payment in healthcare indicates who is paying for the service given to patient. This can be out of pocket by patient, insurance (public, private) or by provisioned through government budget, government reimbursement. Relevant data elements are grouped under this entity. E.g. Insurance Policy Type.		
7	Bill	A bill is a commercial document issued by a seller to a buyer, indicating the products, quantities, and agreed prices for products or services the seller has provided the buyer. This entity contains list of data elements which are related to billing for hospital purposes and for		

	Table-2: Description of Entities			
SN	Entity	Description		
		insurance purposes. E.g. Bill ID, Bill Type.		
8	Facility	Any institution which is engaged in the delivery of health care services to the individuals, families or communities. This entity contains list of data elements which are related to health facility identification and related attributes. E.g. Unique Facility ID, Facility Type Code.		
9	Episode	An episode of care consists of all clinically related services for one patient for a discrete diagnostic condition from the onset of symptoms until the treatment is complete [http://www.ncmedsoc.org/non_members/pai/PAI- FinalWorkbookforVideo.pdf] Thus, for every new problem or set of problems that a person visits his/her clinical care provider, it is considered a new episode. Within that episode the patient will have one to many encounters with his/her clinical care providers till the treatment for that episode is complete. Even before the resolution of an episode, the person may have a new episode that is considered as a distinctly separate event altogether. Thus, there may be none, one or several ongoing active episodes. All resolved episodes are considered inactive. Hence they become part of the patient's past history. A notable point here is that all chronic diseases are considered active and may never get resolved during the life-time of the person, e.g., diabetes mellitus, hypertension, etc.		
10	Encounter	A clinical encounter is defined by ASTM as "(1) an instance of direct provider/practitioner to patient interaction, regardless of the setting, between a patient and a practitioner vested with primary responsibility for diagnosing, evaluating or treating the patient's condition, or both, or providing social worker services. (2) A contact between a patient and a practitioner who has primary responsibility for assessing and treating the patient at a given contact, exercising independent judgment." Encounter serves as a focal point linking clinical, administrative and financial information. Encounters occur in many different settings ambulatory care, inpatient care, emergency care, home health care, field and virtual (telemedicine). [http://www.ncvhs.hhs.gov/040127p1.htm]		
11	Advance Directives	An advance directive is a set of written instructions that a person gives that specify what actions should be taken for their health, if they are no longer able to make decisions due to illness or incapacity. E.g. Advance Directive Type		
12	ADT	ADT refers to Admission, Discharge & Transfer of a patient in a health facility. E.g. Admission Date, Admission Type		
13	Emergency	Emergency care relates to the inpatient emergency care provided to the patient reaching to the emergency department of the health facility.		

	Table-2: Description of Entities			
SN	Entity	Description		
		E.g. Patient Status, Ambulatory Status		
14	Outreach	Outreach is an activity of providing services to populations who might not otherwise have access to those services. A key component of outreach is that the groups providing it are not stationary, but mobile; in other words they are meeting those in need of outreach services at the locations where those in need are in addition to delivering services, outreach has an educational role, raising the awareness of existing services. E.g. Outreach Service Provider, Outreach Service Type etc.		
15	Disaster Response	Disaster response is the health care response to the disaster and consist data elements which are part of rescue, first aid, triage, transport to the facility and deceased management. E.g. Mass Casualty Incident Type.		
16	Examination	Medical examination or clinical examination is the process by which a medical professional investigates the body of a patient for signs and symptoms of disease. Patient examination related data elements are grouped under this entity. E.g. Examination Type etc.		
17	Vital Signs	Vital signs are measures of various physiological statistics, often taken by health professionals, in order to assess the most basic body functions. i.e. Body Temperature, Blood Pressure. Relevant Data Elements are covered under this entity. E.g. Vital Sign Result Status		
18	Allergy	An allergy is a hypersensitivity disorder of the immune system. Allergic reactions occur when a person's immune system reacts to normally harmless substances in the environment. A substance that causes a reaction is called an allergen. Relevant Data Elements are grouped under this entity. E.g. Adverse Event Type.		
19	Clinical Notes	Clinical Note is documentation of patient conditions, by medical service provider - which helps to reach diagnosis, acts as communication between two providers for medical care and also acts as historical reference document in patient case file.E.g. treatment summary, discharge notes etc		
20	Diagnosis	Diagnosis is the process of reaching to a conclusion by determining which disease or condition is affecting human health. Health Conditions (Diseases) related data elements are placed under this entity. E.g. Health Condition Type		
21	Laboratory	Lab entity covers data elements related for ordering laboratory services. E.g. Lab Order Code		
22	Radiology	Radiology entity covers data elements related for ordering Radiology services. E.g. Radiology Procedure Code		
23	Pharmacy	Pharmacy entity covers data elements related for ordering Pharmacy services. E.g. Medication Frequency, Dose		

	Table-2: Description of Entities			
SN	Entity	Description		
24	Immunisation Order	Orders are indication for execution of certain tasks related to patient care, medication administration, disease prevention etc. Immunisation Order Entity covers data elements related for ordering Immunisation services. E.g. Immunization Administered Date, Immunisation product code		
25	Clinical Order	Orders are indication for execution of certain tasks related to patient care, medication administration, disease prevention etc. Clinical Order Entity covers data elements related for Clinical Orders. E.g. Order to admit date		
26	Procedure	A procedure (medical/non-medical) is a course of action intended to achieve a result in the care of person with health problems. In this entity health care procedure related data elements are listed. E.g. Procedure Code, Procedure Type		
27	Blood Bank	A blood bank is a bank of blood or blood components, gathered as a result of blood donation or collection, stored and preserved for later use in blood transfusion. The term "blood bank" typically refers to a division of a hospital where the storage of blood product occurs and where proper testing is performed. However, it sometimes refers to a collection center, and indeed some hospitals also perform collection. Relevant data elements are grouped under this entity. E.g. Blood Bank ID, Blood Group.		
28	Nursing	Nursing care is the care of individuals, families, and communities so they may attain, maintain, or recover optimal health and quality of life. In-patient nursing care related data elements are grouped under this entity. E.g. Bed Side Procedure Indicator		
29	OT	Operation Theatre is a facility within a hospital where surgical operations are carried out in a sterile environment. Relevant data elements are grouped under this section. E.g. Anaesthesia Type, Procedure Priority		
30	CSSD	Central Sterile Supply Department (CSSD) is essential department in the hospital and supports sterile supply, processing, distribution for various departments especially Operation Theatre. Relevant data elements such as Sterilization Test ID are grouped under this section.		
31	Inventory	Inventory management is primarily about managing supplies and stocks are required at different locations within a facility or within many locations of a supply network. This entity includes data elements required for inventory management for drug and non drug items in health facilities. E.g. Drug ID, Supplier Name etc.		
32	Remission	Remission is a condition of being healthy after an episode of disease. Relevant data elements are grouped under this entity. E.g. Remission		

	Table-2: Description of Entities			
SN	Entity	Description		
		Туре.		
33	Complications	Complication is an unfavourable evolution of a disease or a health condition or a therapy. Relevant Data Elements are grouped under this entity. E.g. Complication Code		
34	Relapse	Relapse is recurrence of past disease or condition. Relevant data elements are grouped under this entity. E.g. Relapse Type		
35	Morbidity	Morbidity is a diseased state, or poor health due to any cause in a person or in a population. Relevant data elements are grouped under this entity. E.g. Morbidity Code		
36	Disability	Disability is the consequence of an impairment that may be physical, cognitive, mental, sensory, emotional, developmental, or some combination of these. Relevant data elements are grouped under this entity. E.g. Disability Code.		
37	Mortality	Mortality refers to the death of an individual or incidence of Death in a population. Relevant data elements are grouped under this entity. E.g. Mortality Code.		
38	Ambulance	An ambulance is a vehicle for transportation of sick or injured people to, from or between places of treatment for an illness or injury and in some instances will also provide out of hospital medical care to the patient. Relevant data elements are grouped under this entity. E.g. Ambulance ID, Ambulance Distance Covered, Ambulance en route event.		
39	Indicator	Indicator entity is created as placeholder for the aggregate data elements and for reporting from population-based indicators. E.g. Infant Mortality Rate etc.		

8. Using MDDS Standards

- A. **Data Sets:** MDDS gives common data elements which are grouped in certain entities. The users who are involved in the designing of any new system may develop data sets out of these common data elements for their purposes. Data sets are list of data elements required for certain program or application to function and should be created by choosing relevant data elements from various entities. Each sub-domain, e.g. Disease Control Program, will not require all of the CDE therefore they must create their own minimum data sets from the CDE. The details of few sample data sets are given in the Annexure e.g. Drug Inventory, Diabetes Control, School Health Program Data Set etc.
- B. **Standards Adoption for historical systems:** Adoption of the Standards will vary by organisation and IT system. Some organisations will be early movers owing to their leadership and HR capacity to adopt the standard and undergo a rapid transformation,

whereas others will lag behind, and then there will be few those may completely resist the change.

- *Historical Applications:* Some of the resistance to change will be genuinely rooted in necessity to keep the past data and maintain the current operations. The leadership has to make a hard decision about the duration of status-quo pending an imminent upgrade. For such necessities point-to-point integration maybe considered in the interim e.g. MCTS-HMIS.
- *Upgraded Systems:* For this systems will have to map their data elements to the CDE so that they can send the data in a standard format for interoperability. Slow movers will update/upgrade the systems as per the standard wherever necessary e.g. non-compliant data elements, non-compliant modules, and periodicity of reporting, facility masters, and other masters. They have to fulfil the gaps between their data elements and related master, and those required as per MDDS CDE and Code Directories. Meanwhile the paper based records have to change their formats to match with upgraded systems and build capacity to feed patient data & aggregate data to upgraded systems. For Example MCTS has data elements such as Hb < 7 and Hb > 7; Whereas CDE has data elements such as Result Type, Result Status, Result Value and Result Reference Range. Over time MCTS will have to upgrade such that it can accept data inputs as per MDDS standard, aggregate it and convert it into outputs such as HB < 7 & HB > 7 without having entry of this as separate data elements. Institutional capacity will have to be built to support this change. Another Example Peripheral paper based records will have to change their formats as per MDDS to feed IDSP.
- *Clean Slate Systems*: New systems to be built on MDDS standards. These systems will be fully geared for Interoperability with all applications built on MDDS standard. Though they will also go through a maturation cycle to completely comply to the standard and in many ways may help the MDDS Health domain standard to grow. Meanwhile as paper based recording shifts to e-recording based on MDDS standards, it would be able to feed patient data & aggregate data to clean slate systems.

Given such a context, a Health Information Exchange using an Intelligent Gateway is a preferred interoperability solution for an imperfect world of Healthcare including, where Historical, Upgraded and clean slate applications, would all continue and converge.

	Table 3: Standards Roll-out across Systems				
	Enabling provider for	Reporting Aggregate	Recording Systems		
	Quality of care	Data			
Historical	Legacy System can	HMIS can take inputs	Paper based records fed		
Systems	function as it is. E.g.	from MCTS in the	into MCTS at block		
	MCTS can function as is	interim.	level.		
Upgraded	Modify Data Elements	HMIS can take inputs	All entries are granular		
Systems	and Masters as per	from Upgraded MCTS in	to patient level		
	MDDS standard. E.g.	the interim.	aggregate data. Build		
	MCTS upgraded as per		capacity to feed patient		
	CDE.		data.		
	Technical workarounds				
	for integration.				

Clean	Fully geared	for	Create	logical Agg	gregate	Recording	of data	in
Slate	Interoperability	with all	Data	Elements	[MIS]	EHR forma	it. Autom	iate
Systems	applications bu	uilt on	from	common	data	aggregation	as per lo	ocal
	MDDS standard.		elements.			reporting requirements		

C. **Prospective Applications:** Given the diversity of India, historical and clean state applications will coexist at any point of time since the existing applications cannot be retired overnight. For Example – TN and Delhi states have their own Drug Inventory and Distribution systems and over a course of time, they have familiarized themselves with the operation and usage of the system; Whereas Rajasthan, Maharashtra and Punjab are adopting the e-Aushadhi system being developed by CDAC. Also each of these e-Aushadhi implementations has a different code base owing to extreme differences in masters e.g. organisation hierarchy, drug procurement and distribution processes and implementation methodology. Even if CDAC upgrades e-Aushadhi to MDDS standards, there are other disparate drug inventory systems (e.g. systems functional in Tamil Nadu & West Bengal etc.) which may not be able to completely interoperate e-Aushadhi.

To make these disparate systems interoperable, following three options can be explored: Point-to-point, Broker based, and Exchange based patterns. However, point to point will be expensive to maintain, broker systems may not be able to lookup a registry to locate the source of data. This requires to setup a centralised data warehouse model for reporting, which is a costly proposition in terms of maintainability and feasibility. Exchange based pattern can be achieved by introducing an intelligent gateway to define concept, code mapping and transformations at dynamic run time for all historical applications and clean slate applications. This will lead to feasible interoperable solution.

9. Interoperability Solution

A. Different Models for Interoperability

There could be numerous ways of integrating disparate applications; however the approaches are logically grouped into the following main categories of application integration. Each one has its own pros and cons-

- a. *Point-to-point model*: This approach by design is too expensive to write and maintain because the resultant solution could end up with a spaghetti of approximately (X)n point-to-point connections for all States and UTs.
- b. *Broker Model*: This model has some know inherent design challenges e.g. generating a report on demand from a broker based model is not possible. The broker may not have a Registry lookup access to locate the source of the data. The solution may not know the location of data and cannot discover all applications. For Example If drug distribution related data is spread across three e-Aushadhi applications, the Non Intelligent Broker

will have challenges to access the data from these three systems. This challenge can be resolved if the logic of integration and data retrieval for all three applications is defined in the Broker in advance during the design phase. The data need and integrating logic are not static in nature in the given context so this design will always have a maintainability and feasibility issue.

In the broker based system the only option is to have a centralised data warehouse model for reporting. Given the size [~1.2 Billion] of India's population and the daily transactions e.g. drug distribution is sure to become a bottleneck for any centralised data warehouse model and will push it above and beyond its limit.

c. *Health Information Exchange Model*: The concept of intelligent broker and Registry architecture pattern appears to be better suited in the given context. This approach allows to dynamically locate the data records and the application locations. This will allow applications to serve requested data in a more optimal way. Also, this model allows connecting throughout an array of heterogeneous applications removing the need for complex point-to-point connectivity.

B. Recommended Model for Interoperability: Health Information Exchange

In a long run all public and private Health IT systems have to converge to a Health Information Exchange to realize the objective of Universal Health Coverage. This model addresses MDDS standards to ensure semantic interoperability across all applications, their data storage, privacy, security, integration, data retrieval, analysis and information usage.

This model envisages the creation of local, regional and state Health Information Exchanges [HIE] that feed the National Health Information Network [NHIN]. A centralised Health Information Exchange [HIE] has to emerge for every state that will be used for exchanging health information. All public and private Health IT applications will be integrated with the HIE exchange following a decentralized model leaving their respective data repositories intact within application data centres/premises and applications exchanging their data using constellation of intelligent gateways and centralized registries.

The HIE will have a data warehouse to analyse the consolidated public health data. A federated structure should be adopted where the data is pulled on-demand. Central data repository model is not a suggested route as it becomes unwieldy and too expensive over a period of time. By design, the HIE pulls up only a part of data that is required for consolidated data analysis or health record portability. The patient registry will have entries for the diseases being tracked and will also cater to population migrations where the portability of patient-based health record is important.

The HIE will support the centralized Metadata registry and register the standard Metadata specifications for all Health domain concepts. The data from Different integrating applications will be transformed to these standard concepts based on Metadata registry lookups inside the intelligent gateways before passing the data to the requesting application.

Intelligent Gateway will have the built in logic to discover the applications which will provide the requested data based on the type of request generated from a requesting application or person. The gateway will be able to locate the records from different application repositories, apply dynamic transformations, codes and concept translations, any data aggregation logic, based on the predefined rules in the Intelligent Gateway.

The HIE model will specify data analytics framework so that it can become flexible and capable of catering to local, District, State and National analysis and reporting requirements. This includes:

- a. National Data Warehouse Define a National level data warehouse in the NHIN to analyse the consolidated data and produce indicator based reports from source systems.
- b. Local Data Analytics -Define a local data mart in every State HIE. The exchange should provide online analytical processing [OLAP] for the users at all levels to generate their own reports needed for local action. The users should be able to save the report format and define the frequency at which the reports should be populated with data. This will significantly enhance acceptability, usability and adoption.

The HIE will provide the flexibility to allow inputs in consolidated [District-wise or facilitywise] as well as granular [patient-based] models. Based on readiness, HIE will allow the States to decide the mode of data entry – consolidated, facility-wise or patient-based; as long as the published architecture and standards for vocabulary, data, input/output, storage, integration, hardware and network are followed. The HIE model envisages all public health IT systems to follow integration based on known standards such as HL7, DICOM, XML etc.

Registries: - The heart of the HIE is a registry based model that has district and state level registries about disease, facility and patient. The registry may be indexed and searched by using unique identifiers. The registry will have metadata that points to the details in the source system. The indicators derived from the state disease registries should be rolled up to the central disease registry for reporting. However drill down should be available to get granular data on demand.



Figure 2: State Health Information Exchange [HIE]- Conceptual Architecture



Figure-3: National Health Information Network [NHIN]- Conceptual Architecture

C. Benefits of Health Information Exchange

I. Historical applications can never be done away due to their current wide-spread usage, substantially large database, user adoption and heavy investment. Using this model all existing Historical and Clean state applications can be integrated to form a unified Health Information Exchange based on a federated data model without any disruption or application design changes in existing historical applications.

- II. The semantic interoperability in different applications can be ensured using a centralized metadata registry using HIE based intelligent gateways having functions to register, discover, transform, notify, query and retrieve concepts and their meta data from centralized metadata registry. This model has already been successfully implemented in Canada Infoway.
- III. Integration with other domain applications is quite easy.
- IV. Lack of awareness in India towards the need of a HIE which is apprehended by many as a complex thing to achieve which is just a negative perception and need to be corrected by proper education of this model.



Figure 4: State Health Information Exchange – Proposed Architecture

10. Institutional Framework for MDDS implementation

As compared to other domains, information requirement in health domain changes more rapidly and today's information systems and standards slowly becomes obsolete if not updated on a regular basis. There has been a surge in public health IT systems development under National Health Mission as noted by various Common Review Mission (CRM) reports. However each system was developed to cater local requirements and have followed their own standards leading to a situation where systems were not being able to exchange data. This adversely affects use of information. In addition data from private sector was not available for generation of population-based analytics as required to assess universal health coverage.

There is great need to make systems interoperate at various levels for seamless flow of information. Mission Mode Project has also documented the challenges of IT silos in health care and suggested that systems should be able to speak to each other using standards of interoperability. All this necessitates an institutional structure to be in place for information sharing among various systems and between various providers (public & private), supported by frameworks for standards implementation, certification and management. Globally such work is managed by National level eHealth Authority or similar institution. In India constitution of National Digital Health Authority (NDHA) is under process and management of standards could very well be taken up by the NDHA. With respect to the health IT standards the authority will be required to formulate policies around standard, facilitate implementation of standards and actively manage standards. For management of standards following major functions would be required.

A. **Managing repository of standards:** Healthcare is a very diverse domain and to address standardization, it needs a large set of data standards. It is an error prone and difficult task to manage these standards manually and would require automated management of standards. DietY has a framework to address this purpose and it suffices the need of health domain as well.

B. Update & Upgrade Standards

- a. *Documenting specific standards request*: As an iterative process the standards management organisation has to work closely with the state public health departments and private health sector to document various standards requirements originating with new program and with new areas as they open up.
- b. **Organising standards consultations**: The organisation has to arrange specific standards consultations with participation from various stakeholders which will discuss and recommend updation in the standards list.
- c. *Decision making:* Once thorough deliberation is done on the prospective standards and legitimate feedbacks are absorbed, a decision should be made on the shape, size and form of standards. The decision can include the timelines and mode of releasing the standards and guidelines for implementation.
- d. *Notifying the standards*: All the competent stakeholders should be dully notified using the prevalent mode of communication by standards organization. The standards once notified should be available in public space for usage.

C. Ensuring Compliance to standards

a. *Certification*: Prospective health IT applications have to undergo auditing and testing to ensure compliance with the standards. This task should be done by a 'Standards Auditor Group' in which external empanelled experts should participate with internal consultants. If any incentive mechanism is put in place

for standards compliance, the applications which are not compliant can be disqualified for incentive schemes.

- b. *Accreditation*: Authority can accredit different health IT systems based on series of evaluations and audits ensuring compliance with the standards.
- c. *Voluntary association:* Currently private health sector is unregulated and does not participate in information sharing. Private sector may voluntarily come forward and adopt standards for recognition and certifications.
- D. Facilitate adoption/implementation:
 - a. *Incentive Mechanism*: The authority can provide incentives for system design, implementation and maintenance if they comply with the MDDS standards.
 - b. *Legislations*: To ensure that systems collaborate and participate in information sharing and exchange, a legal support needs to be in place in form of an 'act'.
 - c. *Others*: Other mechanism should be carved out in consultation with various stakeholders.



Figure 5: Standards Organization: Roles & Functions

Standard Development Processes: For standards development and updation, participation of various stakeholders is required. Health Informatics Standards Forum can provide a platform for various stakeholders from industry, academia & implementers to participate and provide suggestions and feedbacks on standards under the guidance of National Digital Health Authority. Industry, state-users can submit standards requests through the forum to the standard committees or authority, which in turn will facilitate updation of standards. Health Informatics Standards forum should have participation from academia, health IT agencies, public health organisation, hospitals, insurance firms and international experts. The forum should meet twice a year however based on the necessity additional meetings can be arranged.



Figure 6: Standard Development Process

Vast amount of work has been globally done for the health IT standards development by governments, private organisation and by international NGOs. However keeping pace with these developments is only possible when the authority works closely with these institutions through partnerships from inception. In addition the authority should have easy access to documented studies, research publications on health IT standards. The authority should also collaborate with the other sectors such as insurance, IT, hospitals etc. to understand their needs and demands.

11. Concluding Remarks

The benefit at the decision making level will be an enabler to look across the health domain silos such as RCH, Malaria, TB, HIV and help to bring more meaningful decisions to the table with respect to resource planning & optimisation.

After the MDDS standard compliance, the Field workers will not be burdened to report on multiple systems. The systems will have the flexibility to define its own data elements, forms, workflow, reporting frequency and report formats. That way it is easy to integrate the different implementations of the same architecture and aggregate the data at any level. Also it takes off the load from the field staff, as they have to report in one system. This will go a long way in improving the adoption of Health IT systems.

Abbreviations

ADT	Admit, Discharge & Transfer			
BPL	Below Poverty Line			
CCI	Canadian Classification of Health Interventions			
C-DAC	Centre for Development of Advanced Computing			
CDE	Common Data Element			
CSSD	Central Sterile Services Department			
MeitY	Ministry of Electronics and Information Technology			
EHR	Electronic Health Record			
GoI	Government of India			
HL7	Health Level Seven			
ICD	International Classification of Diseases			
ICF	International Classification of Functioning, Disability and Health			
ID	Identifier			
IDSP	Integrated Disease Surveillance Project			
IT	Information Technology			
LOINC	Logical Observation Identifiers Names and Codes			
MCI	Medical Council of India			
MCTS	Mother & Child Tracking System			
MoHFW	Ministry of Health & Family Welfare			
NHSRC	National Health Systems Resource Centre			
NIC	National Informatics Centre			
OT	Operation Theatre			
PAN	Permanent Account Number			
RNTCP	Revised National TB Control Programme			
SNOMED	Systematized Nomenclature of Medicine			
UID	Unique Identification Number			
UIDAI	Unique Identification Authority of India			
WHO	World Health Organization			

References

- 1. E-Governance Standards Accessed from <u>https://egovstandards.gov.in/</u> on 15th July 2013.
- 2. MDDS Demographics v1.1 Accessed from <u>https://egovstandards.gov.in/sites/default/files/Published_Standards/Metadata%20and%</u> 20Data%20Standards/MDDS_Demographic_Ver_1.1.pdf on 11th July 2013.
- 3. Website of Ministry of Health & Family Welfare (<u>http://mohfw.nic.in/</u>) Accessed on 20th July 2013.
- 4. Website of National Health Systems Resource Centre (<u>www.nhsrcindia.org</u>) Accessed on 1st August 2013.
- Website of Medical Council of India (<u>http://www.mciindia.org/</u>) Accessed on 17th August 2013.
- 6. Website of Rajasthan Medical Services Corporation (<u>http://www.rmsc.nic.in/</u>) Accessed on 15th August 2013.
- 7. Website of IRDA. Accessed from <u>www.irda.gov.in</u> on 21st September 2013.
- 8. Website of National Disaster Management Authority, Government of India (<u>http://ndma.gov.in/ndma/index.htm</u>) Accessed on 19th August 2013.
- 9. NRHM HMIS Web Portal, <u>www.nrhm-mis.nic.in</u> Accessed on 11August 2013.
- 10. NRHM Mother Child Tracking System, <u>www.nrhm-mcts.nic.in/MCH</u> Accessed on 18th September 2013.
- 11. Website of Integrated Disease Surveillance Project (IDSP), (<u>www.idsp.nic.in/</u>) Accessed on 9th September 2013.
- 12. Strategic Information Management System, National AIDS Control Organization (<u>www.naco-sims.nic.in</u>) Accessed on 12th September 2013.
- 13. Master Facility List Guidelines, WHO 2012 Accessed from <u>http://www.who.int/healthinfo/systems/WHO_CreatingMFL_draft.pdf</u> on 6th August 2013.
- 14. Master Facility List- Implementation Guide, Division of Health Information Systems Department of Standards and Regulatory Services Ministry of Medical Services, Kenya February 2010 <u>http://www.ehealth.or.ke/facilities/</u> Accessed on 11 August 2013.
- 15. HITSP Data Dictionary Component, Healthcare Information Technology Standards Panel. Jan 2010. Accessed from <u>http://wiki.siframework.org/file/view/HITSP V1.0 2010 C154 - Data Dictionary.pdf</u> on 8th August 2013.
- 16. International Statistical Classification of Diseases and Related Health Problems 10th Revision, WHO Accessed from <u>http://apps.who.int/classifications/icd10/browse/2010/en</u> on 20th July 2013.
- 17. Canadian Classification of Health Interventions (CCI Codes) Accessed from <u>http://www.cihi.ca/cihi-ext-portal/pdf/internet/cci_vol3_2009_en</u> on 18th July 2013.
- 18. International Classification of Functioning, Disability and Health (ICF), WHO 2001, Accessed from <u>http://apps.who.int/classifications/icfbrowser/</u> on 17th August 2013.
- 19. LOINC Standards Accessed from <u>https://loinc.org/</u> on 11th August 2013.
- 20. Website of Standards International Accessed from <u>http://www.standardsinternational.net/</u> on 26th August 2013.
- 21. Public Health Guide for Emergencies, Centre for Refugee & Disaster Response, John Hopkins Bloomberg School of Public Health, Accessed from <u>http://www.jhsph.edu/research/centers-and-institutes/center-for-refugee-and-disaster-</u>

response/publications_tools/

publications/_CRDR_ICRC_Public_Health_Guide_Book/Public_Health_Guide_for_Emer gencies__on 10th September 2013.

- 22. Additional Information Specification 0001: Ambulance Service Attachment Release 2.0, Based on HL7 CDA Standard Release 1.0, with supporting LOINC® Tables, CDA Ballot, August 2003 Accessed from <u>http://www.hl7.org/documentcenter/public/wg/ca/AMBULANCE%20Additional%20Inf</u> <u>ormation%20Specification%20(Jan%202012%20Draft%20Copy).doc</u> 8th September 2013.
- 23. Management of Dead Bodies after Disasters: A Field Manual For First Responders, Pan American Health Organization, Washington 2006. Accessed from <u>http://www.paho.org/disasters/</u> on 18th August 2013.
- 24. Data Against Natural Disasters: *Establishing Effective Systems for Relief, Recovery, and Reconstruction*. The World Bank, Washington DC 2008. Accessed from <u>www.ipcc-wg2.gov/njlite_download.php?id=6686</u> on 8th September 2013.
- 25. Impact of Public Health Emergencies on Modern Disaster Taxonomy, Planning, and Response, Frederick M. Gregg G, Special Focus 2008 Accessed from <u>http://www.ncbi.nlm.nih.gov/pubmed/18562943</u> on 9th September 2013.
- 26. Special tabulation lists for mortality and morbidity, ICD-10, WHO. <u>http://apps.who.int/classifications/icd10/browse/2010/en</u> on 20th July 2013.
- 27. Report on Medical Certification of Cause of Death 2008, Office of The Registrar General, India, Government of India, Accessed from <u>http://www.censusindia.gov.in/2011-Documents/mccd Report1/Report%20on%20Medical%20Certification%202.pdf</u> on 8th August 2013.
- 28. NSSO -71- the List of ailments with codes and working definitions. NSSO.
- 29. Verbal Autopsy Standards: Ascertaining and attributing causes of death, The 2012 WHO verbal autopsy instrument, WHO Accessed from http://www.who.int/healthinfo/statistics/verbalautopsystandards/en/ on 23 August 2013.
- 30. Institutional Mechanism for Formulation of Domain specific Metadata and Data Standards in e-Governance, eGSI-IM:02, Version 1.0, April 2012, Department of Electronics and Information technology Ministry of Communications and Information Technology Government of India, Accessed from <u>http://egovernance.gov.in/policy/institutional-mechanism</u> on 8th September 2013.
- 31. The Signature Domain and Geographic Coordinates: A Standardized Approach for Uniquely Identifying a Health Facility Health Facility Assessment Technical Working Group January 2007, WP-07-91, WHO. Accessed from <u>http://www.cpc.unc.edu/measure/publications/wp-07-91/at_download/document</u> on 11 September 2013.
- 32. United States of America Food and Drug Administration (FDA) Medication Physical Form <u>http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162038.</u> <u>htm</u> Accessed on 12th September 2013.
- 33. United States of America Food and Drug Administration (FDA) Pharmaceutical Unit of Measurement

http://www.fda.gov/forindustry/datastandards/structuredproductlabeling/ucm168397.ht <u>m</u> Accessed on 8th September 2013.

34. United States of America Food and Drug Administration (FDA) - Medication Package Type

<u>http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/ucm162034.</u> <u>htm</u> Accessed on 3rd September 2013.

- 35. United States of America Food and Drug Administration (FDA) Route of Administration <u>http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequireme</u> <u>nts/ElectronicSubmissions/DataStandardsManualmonographs/ucm071667.htm</u> Accessed on 3rd September 2013.
- 36. Rajasthan Medical Service Corporation for Equipments or Instruments <u>http://www.rmsc.nic.in/pdf/eel.pdf</u> Accessed on 18th August 2013.
- 37. API Textbook of Medicine Volume-I & II, Ninth Edition
- 38. National Formulary of India. Accessed from <u>http://www.cdsco.nic.in/NFI 2011.pdf</u> on 12th September 2013.
- 39. Website of Canada Health Infoway Accessed from <u>https://www.infoway-inforoute.com/</u> on 11th October 2013.
- 40. Metadata Online Registry METeOR, Australia Accessed from <u>http://meteor.aihw.gov.au/content/index.phtml/itemId/181162</u> on 12th October 2013.
- 41. Website of Society of Health Information Systems Program (<u>http://hispindia.org/</u>) Accessed on 28th August 2013.
- 42. DHIS 2 Software Accessed from <u>http://www.dhis2.org/downloads</u> on 13th September 2013.
- 43. iHRIS Software Accessed from <u>http://www.ihris.org/</u> on 13th September 2013.
- 44. National eHealth Transformation Authority, NEHTA http://www.nehta.gov.au/ Accessed on 18th October 2013.