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IMA Opinion on NDHM Ecosystem

The key principles of citizen centricity, quality of care, better access, universal health coverage and inclusiveness are defined in the National health policy 2017 and continuum of care is the concept strongly advised. The NDHB documents envisages a holistic, comprehensive and inter operable digital architecture is drafted and adopted by all the stake holders. The document also wish to create a national digital health ecosystem managed by a specialized organization called National Digital Health Mission. (NDHM).

NDHB document published by Government of India, comprises of an ambitious plan to bring a digital ecosystem comprising of digital health network under NATIONAL DIGITAL HEALTH MISSION.

We do not favour the content of the NDHB document, its roll out plan and the administrative mechanism. Our opinion is based on the following contentions.

India still lacks adequate health care infrastructure and man power. There is no standardisation of many streams of treatment adopted in our country. The Government is adopting strategies to allow untrained and partially trained individuals to practice medicine to address the manpower shortage. Infrastructure deficiencies have not been addressed to. Strategic purchasng through Ayushman Bharath (PMJY) has not made any impact due to lack of adequate fund allocation and non empanelment of tertiary care hospitals due to unrealistic package rates. Primary care has lost focus and the proclaimed Wellness centres are yet to make an impact. There is skewed distribution of medical training infrastructure. Primary care, strengthening of public Health infrastructure and HR as well as addressing the social determinants of Health are our priority.

Funding for such an ambitious plan is not appropriately described. any diversion of funds from NHM will further jeopardise the public funded health care, especially primary care. Hence there is a definite possibility of the plan to become a non starter if the investment in health care is not significantly increased. Out of pocket expenditure in health care will increase further in such a situation.

Privacy is of utmost concern. Privacy protection laws in India are weak and practically nonexistent. Privacy is being ensured through consent manager in NDHB. The consent in digital platform in a country where literacy is low is cause of concern. The consent mechanism described in the document is inadequate to address the concern.



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Accessibility of health documents to treating doctors is ill defined. Medical records are considered to be a document equally owned by the treating doctor, patient and the institution with right of accessibility to remain with all the three. The concepts of data ownership, erasure etc described in the document is in violation of this principle and is objectionable.

Data protection is another area of grave concern. Apart from the issue of privacy, management of analytical data by the agency is poorly defined in the document. The management of analytical data will be governed by data protection laws which is practically nonexistent at present.

The National Digital Health Mission, stemming from the National Health Policy of 2017, is purported to digitise the entire healthcare eco-system in India. The self-proclaimed guiding principle of the NDHM is “Security and Privacy by Design” for the protection of individuals’ data privacy. It is paramount to see whether the principle satisfies the test of Right to Privacy of the stakeholders under the Act, including, but not limited to, patients and their family members.

1. Before addressing that issue, it is prudent to understand whether the Union Government is vested with the requisite legislative powers to formulate a pan-India policy to establish the mechanism outlined by the NDHM. After all, the legislative powers of a state government stemming from Entry 6, List II under the 7th Schedule of the Constitution of India cannot be superseded by a policy fronted by the Union Government. Entry 6 in List II reads as follows: “Public health and sanitation: hospitals and dispensaries.” *Prima facie*, it appears that the proposed policy would not find shelter under the residual powers of the Parliament in the light of the aforesaid entry. It would also raise serious questions as to whether a legislation having far reaching implications on public health can be proposed as a policy.
2. Assuming that the Union Government is competent to bring forth the NDHM Policy into force, it appears to face hurdles in its implementation. The practice prevalent in the healthcare community *vis a vis* the confidentiality of a patient’s medical records is entrenched in the fundamental principle of doctor-patient confidentiality relationship. This principle finds legislative backing in the Indian Medical Council (Etiquette and Ethics) Regulations 2002. The relevant provisions from the Regulations read as follows:



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“1.2.1 The Principal objective of the medical profession is to render service to humanity with full respect for the dignity of profession and man. Physicians should merit the confidence of patients entrusted to their care, rendering to each a full measure of service and devotion. Physicians should try continuously to improve medical knowledge and skills and should make available to their patients and colleagues the benefits of their professional attainments. The physician should practice methods of healing founded on scientific basis and should not associate professionally with anyone who violates this principle. The honoured ideals of the medical profession imply that the responsibilities of the physician extend not only to individuals but also to society.”

“7.14 The registered medical practitioner shall not disclose the secrets of a patient that have been learnt in the exercise of his / her profession except –

- i) in a court of law under orders of the Presiding Judge;*
- ii) in circumstances where there is a serious and identified risk to a specific person and / or community; and*
- iii) notifiable diseases.*

In case of communicable / notifiable diseases, concerned public health authorities should be informed immediately.”

As evident from the aforesaid provisions, there is a duty cast upon the medical practitioner to maintain utmost secrecy of a patient's medical records in the course of his/her practice. The policy does not appear to account for these Regulations, although it attempts to salvage itself with a boilerplate clause offering itself to be read along with, and not in contradiction to, laws presently applicable in India. The Regulations make it clear that only under specified circumstances can the confidential medical information of a patient be divulged by the physician. This would then beg the question as to the ability and requirement of seeking the consent of a patient to share the medical information including health records with a party not specified in Regulation 7.14 of the Indian Medical Council (Etiquette and Ethics) Regulations 2002. This would further call into question the competence of the Union Government to propose a policy akin to the NDHM Policy in its present nature.



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3. We have taken the liberty to assume the definitions of various terms used hereafter in the context they are used in the proposed policy. Although the policy sets out “Privacy by Design” as its guiding principle, it does not explicitly recognize a data principal’s fundamental right to privacy, inasmuch as according a legislative recognition of the said right of the data principal. Merely because the participation of the data principal is made voluntary under the policy, the information including sensitive personal data does not cease to lose its ability to violate the data principal’s fundamental right to privacy. Personally identifiable information of the data principal, including but not limited to financial information such as bank account details, caste or tribe status, and religious or political beliefs or affiliation as categorized under “sensitive personal data” in para 4 (ee) of the policy make it paramount to recognize the fundamental right of privacy of the data principal, namely a patient who voluntarily consents to sharing the information. This is all the more important when seen from a point of practicality. For the sake of illustration, considering a scenario where a patient requiring critical and time sensitive healthcare, may not be in the right frame of mind to review the potential effect of granting express consent to the sharing of his/her health and medical information for the purposes of this policy. Subsequent attempts to review the consent initially provided could be an exercise in futility. This also puts the healthcare provider and other data fiduciaries at risk. This concern is amplified in situations where the information is made available to companies and other juristic entities with commercial interests. Naturally, the risk of information being shared with entities outside the territorial jurisdiction of India could seriously jeopardise the fundamental right to privacy of the data principal unless the policy accounts for such situations.
4. As per para 26.4 of the policy, data fiduciaries are given the option of adopting either an “opt-in” or “opt-out” mechanism to gain the consent of the data principal. The risk of a data principal unknowingly and unwittingly sharing their medical and health information and other sensitive data sought to be collected under this policy is substantially higher if the data fiduciary chooses the “opt-out” mechanism, where it is for the data principal to actively express revocation of consent to collect personally identifiable data. From a practical viewpoint , even an “opt-in” mechanism might not subserve the interests of the data



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principal, as illustrated previously, the data principal could very well inadvertently offer their consent and “opt-in” to share sensitive personal information. Therefore it cannot be said that the policy provides sufficient safeguards against attempts at infringing the fundamental right of privacy of data principal namely a patient or any person to whom the personal data relates. Furthermore, the policy makes a distinction between anonymization and de-identification. As per para 4(a), anonymization is an irreversible process whereas, as per para 4(l), de-identification does not claim to be an irreversible process. Therefore, there is a risk of data fiduciaries opting for de-identification instead of anonymization, for the purposes listed out in para 29 of the policy.

5. It must also be borne in mind that there are existing policies that provide for collection of relevant medical data for the broader purpose of medical research and analysis. In such circumstances, it appears that the NDHM policy poses higher risk to sensitive data protection in return for a repetitive policy exercise.

Therefore, it is our considered opinion that the NDHM policy does not satisfy the rigours of protecting the fundamental right to privacy under Article 21 of the Constitution of India. It is also our considered opinion that the policy strikes a discordant note with the existing rules and regulations pertaining to medical practice in India.

Concerns of the Medical profession

- The implementation of National EHR is a complex task and it requires serious well thought out planning backed with strong global healthcare informatics expertise. A badly designed national EHR system will not only be a pain for clinicians for but also could endanger patients as we have seen in other countries where the cost of redesign is significant.
- **For Single Doctor & Couple Doctors Establishments.**
 - a) Becomes an Insurance driven practice.
 - b) Accreditation based practice.
 - c) Purely technology driven practice, due to which doctors .
 - d) Leads to revenue model profession.



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- It is also stated that this blueprint is optional and the incentive will be given to the institutions that are joining this network but it can be made compulsory later.
- Another major concern is that India doesn't have appropriate laws regarding the data privacy and data protection. So even if any company or institution violates data protection and use this software for commercial or any other use with the present legislation they cannot be punished accordingly.
- Whether this ambitious policy is necessary for the patient or for the interest of the pharmaceutical companies or insurance companies is also a big question.
- Data error: Uniformity in data entry among all healthcare professionals is very difficult to achieve and can result in the wrong interpretation of the medical records.
- Data availability to the insurance companies to decide on the payments, can be misused by these companies for not paying to the clients.
- There is a high chance of leakage of the medical records data and the confidentiality can be breached under this policy. Therefore, privacy of the patient is a major concern where data can be shared with insurance or Pharmaceutical Companies.
- There will be an increased workload on the doctors because treatment details need to be uploaded on the database/ software by the doctors themselves.
- Digital health system will also lead to the mandatory evidence-based practice and there will be a counter effect on the patients especially the poor patients.
- (4q) Health facility ID -One more entity for registration of Hospitals and Clinics.
- (9.2) Consent is free and voluntary then how do we ensure that all details will be revealed to practicing physicians especially relevant past history and investigations (patient may hide H/o HIV, HbsAg, etc)
- (14 bi) Data principal can rectify personal data is defined in 4. ee. Then who is responsible if physician manages the patient as per any false entries done by patient or deletion of relevant past history?
- (14 b ii) Too much power of manipulating data has been given to data principal.



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Technical Comments of IMA

1. PHR, EMR & EHR

It is proposed that NDHB would ensure the interoperability of data, creation of standardized “EHR” and providing continuum of care. The NDHM Architecture has mentioned building only a “PHR”. However to achieve the key objectives of NDHM both EHR as well as PHR to be built as part of the minimum viable architecture. The concept of EHR, EMR and PHR should be as follows.

a. Electronic Medical Record (EMR)

An electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one health care organization.

b. Electronic Health Record (EHR)

An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one health care organization.

c. Personal Health Record (PHR)

An electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be drawn from multiple sources while being managed, shared, and controlled by the individual.

2. UHID

Unique identification of persons, facilities, diseases and devices is a key requirement as well as a challenge in the National Digital Health Ecosystem (NDHE).

The Blueprint handles this requirement through 2 building blocks, viz. Unique Health Identifier (UHID) and the Health Locker.

The ability to automate the process of matching records and maintaining cross reference index of identifiers for individuals and organizations is seen as a key enabler for efficient and accurate Unique Health Identifier (UHID). For a patient or an organization in particular, the ability to support standards-based applications and programs that allow it to be integrated to support Personal Health Record, is a key enabler of health information exchange. Appropriate technology like Integrating the Health Enterprise (IHE) based profiles for the patient, provider and facility registry will be useful.



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3. Access

The Electronic Health Record (EHR) has two key dimensions i.e. the physician view and patient view. The Health Locker addresses the ability to store PHR but how the doctors will be able to access patient's family history, allergies, vital signs etc. need to be mentioned in detail. In addition to the Health Locker there is a need to have unified portal for clinicians and citizens to access their health records.

4. Consent Manager

It is important that NDHM leverages well defined consent management frame work. There are several consent models used by HIEs and the consent management framework should be flexible to adopt varying needs of the citizens.

- No consent*- Patient health information at a participating healthcare organization is automatically included in and available through the HIE (NOTE: This is not recommended, and is rarely used.)
- Opt-out* - All or some pre-defined data sets are qualified to be included and available for exchange, after patients are given the opportunity to opt out in full.
- Opt-out with exceptions* - All or some pre-defined data sets are qualified to be included and available for exchange after patients are given the opportunity to:
- Opt-in* - No patient data sets are made available for electronic exchange until patients actively express whether they would like to make all, or a pre-defined set, of their information available.
- Opt-in with restrictions* - No patient data sets are made available for electronic exchange until patients actively give their consent to participate.

The NDHB document suggests opt-in model for voluntary citizen participation in the NDHM. Opt out model may have better compliance.

The technology based consent mechanism should be fool-proof from exploitation as the majority of beneficiaries are illiterate rural people. Ensuring that the EHR is prudently citizen controlled is a task which has to be meticulously undertaken.

5. Data Exchange & Health Information Exchange (HIE)

There should be appropriate regulations to define how the data and health information will be shared, between whom and to what extent.



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Preventing commercial exploitation of health data by Insurance companies, Medical devices manufactures, Pharmaceutical companies, corporate facilities etc. is of paramount importance.

An individual's personal health record can be assembled and stored locally by an authorised user (Hospital, Doctors) through the query mechanism provisioned in the eco-system. This may be with consent of the individual. How the data movement can be traced and acted on when an individual asks the data fiduciary to delete the health record/opt-out from the eco system to be defined.

6. AVAILABILITY

Ready to use HIS/EMR with minimum customisation to be made available in cloud with a reasonable subscription fee for use by individual, small and medium healthcare providers.

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