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Health for All - Now!

Health is a Basic Human Right!

Comments by Jan Swasthya Abhiyan on the National Digital Health Blueprint Report

The National Digital Health Blueprint may represent an advance over earlier documents in that now much more of the important principles are articulated. For example concerns on data privacy and security occur in most chapters. Concerns like cooperative federalism, not a feature of many earlier articulations of national-e-health architectures are much more visible. But an examination of the text/detail raises the concern that there is still considerable work needed to link the broader objectives to design features that will address the bottlenecks known to exist, or to any overall implementation plan. Without such detailing, one would be concerned that the articulation of the principles is nothing more than using the politically correct buzzwords- rather than a serious engagement with the problems of digital health.

One major problem with this document is that there is absolutely no reference to existing body of work and experiences. There is cursory reference to UK and South Korean as part of global experiences and none at all on Indian experiences. It is very much an approach of starting from a clean slate, as if history does not matter.

The key vision is of starting from a clean slate a new system based on individual patient records which records almost every significant health encounter. This ignores the fact, that to a large extent what is working within government health sector is aggregated information based systems. The experience with starting up patient centric systems- like the Mother and Child Tracking Systems and others have been mixed- limited functionality limited largely to being able to collect the data. The evidence that such data has had the fidelity required for contribution to either management or quality of care is almost non-existent. Aggregate data has however evolved and is now largely available as a reasonably effective program management tool- especially at more decentralized levels (HMIS, NIKSHAY etc).

It would have been useful for the team to engage with why individual patient records have been so difficult. The document just mentions some of the challenges- in both annexures and in the text- but does not feel it necessary to go into how these would be addressed.

The interface between the patient records system and the aggregate health systems is more or less taken for granted- and even the transition only talks of testing for fidelity and then absorbing the legacy data. In practice what would happen is that these new crop of systems would become another burden on the providers since

they would not have the capacity to replace existing systems- and both would continue for indefinite time period.

This disconnect between the realities on the ground and the NDHB is further illustrated by the documents structure where it visualizes the Indian health care sector as more or less synonymous with Ayushman Bharat at its two components- Health and wellness centers and PMJAY. No doubt that would be the way it would appear from the Niti Aayog headquarters. But on the ground it is a mess of different types of government facilities ranging from sub-centres to medical colleges, and different types of private providers and facilities. All public players already subscribe to many forms of data collection, transmission and digitization. All private providers under PMJAY or publicly funded insurance schemes supply data on a sub-set of their patients. But for most of their patients they do not provide any data. The majority of private providers are not under any of these schemes and they provide no data whatsoever- not even the notification of diseases. The NDHB simply ignores this context. It assumes that every private provider would be able and willing/enforced to provide the necessary data in the necessary format and that every public provider would readily migrate to this new system which would be better for them than their existing ones. (Almost none of the existing systems have PHIs and PHRs and EHRs as central to their functioning).

The disconnect between ground realities and top-down prescriptions is also illustrated by what is said with respect to standards. Many new standards are sought to be enforced. For example, LOINC enforces standardization in laboratory tests. For this to work all laboratory testing equipment must be LOINC compliant. At present only large labs with huge investments can afford these fully automatic machines. Most of the tests at present are done in small labs and in small hospitals. If this is enforced, users will know what the test result was and what machine and which reagent was used to do the test. For this information, labs using older machines will have to throw them out and acquire costly new machines, ensure internet access etc. - the costs don't match the benefits. A study of why existing standards have not been adopted would have shown the need for an incremental and plural approach with adoption of standards which would vary with institutional capacity and readiness across the nation.

This LOINC is just an example. If basic protocols and practices in use today are not changed on the ground, computerization will not change outcomes. Yet digitization must begin with the world as it is. The Blueprint hopes to achieve a level of universal computerization as in the USA while keeping healthcare investment at the same low rate. This will not work. Also, in the USA and other developed countries, stakeholders spend enormous amounts of money upgrading their equipment and software to keep up with changing standards. In India, this will increase healthcare costs considerably. If this is not supported by increased government spending, it will lead to more costs for the poor and increasing amounts of destitution.

The document calls for open source and open standards but does not engage with why even central applications like the HMIS. Government has issues policies on use of open source software for all public systems, and all new software systems should

provide for open API (Application Program Interface) access. This policy is not operational, and even after 7-8 years of active trying, the national HMIS (which is built on proprietary platform) has not provided states with API access, causing great difficulties. It will be worthwhile for the government to do an inventory of software systems (including those of NIC and CDAC) and assess if the code is available on public repositories and if open API access is provided.

When it comes to governance, merely proposing a mission as almost a stand-alone institution, largely managed by bureaucrats, is unlikely to work. There is a requirement to link up with processes of research and education. There is a need to link therefore with academic and research institutions and the need for imaginative studies and evaluation and critical thinking during the process of design and implementation. Few bureaucrats have engaged with IT in the health sector long enough, or have the background in theory required, to be able to understand the specificities that block IT development and use in this domain- though it is well known that unlike sectors like finance and travel, IT applications struggle to make a mark in this sector. Time and again deadlines are set- as this document also does- but these are not reached. The section on governance requires an understanding of sustainable and institutional capacity development over a long term perspective. Currently the document mentions mostly government officials - secretaries, directors etc. - they are only going to work with tried and failed models of implementation - innovations are not going to come from them, they will only stifle them.

Further governance is reduced to another set of IT systems- anonymizers, consent manager etc. In practice these are primarily institutional questions. Who has the powers to anonymize, decide on degree of anonymity, authenticate requests, collect and interpret consent etc. How are these persons selected? What is the oversight into their functioning? What are the checks and balances? These are not addressed and in the absence of such information the ability to ensure privacy, confidentiality, security etc. is compromised. An IT system can at best block an unauthorized information user. But what if a bad request is duly authorized due to collusion, or weak gatekeepers.

With respect to core design and elements and principles- there are some key issues:

1. The document states that: "The Building Block of Personal Health Identifier (PHI) will be centre-piece for integration with all the other components of health ecosystem and for maintaining the Personal Health Record (PHR)." But the question is how does the PHI integrate all other systems? It can integrate a few and allow use of some others.
2. The term personal health record and electronic health records are used interchangeably. A glossary would have helped. It is important to separate two closely related concepts, irrespective of how these are named:
 - a. We should understand the term Personal health record to be one voluntarily created by the user and shared with anyone else only on his/her direction. They should reside in their control. Users would

require assistance to create it. The facility/provider/authority can access, read and write only into that part which is permitted by the person whose record it is. An individual can thus block off a provider from accessing data, that he/she does not want to provide, even if it is in their best interests. Even personal doctors would need explicit authorization from patient to access it. They can be stored in one of many sites, or even offline. However if the person wants the information transferred, building the PHR with data standards that would allow inter-operability would be useful.

- b. Electronic Health Records are systems created and records care done in a healthcare facility/health management organization as part of their providing care. Much like the hospital case sheet. It can allow multiple providers from multiple levels to read into it, provided both provider and patient allow it.
 - c. There must also the right to forget- to remove from the data-base that is inconvenient- though one has to think through the categories.
 - d. The EHR and even the PHI is not/should not be a tool for wellness care- preventive and promotive care. Though these would work in the PM-JAY part, they may not be feasible in the HWC part. Much simpler designs are required for this.
3. The concept of the health locker is unclear. Who maintains this? Who is in charge? For many terms a glossary and some more explanation is required. It appears from the context, that this where the PHIs and/or EHRs are stored. There is a strong case against such a locker stored at any level above the primary healthcare provider. Certainly not at state or national level. Since PHCs/HWCs/HSCs may not have the capacity, the district may be where it is possible now. Transfers of information from one district to another can be facilitated, for purposes of portability. However in the name of hub and spoke the control of the EHRs cannot be with the main hospital- and certainly not with a private hospital.
 4. The architecture discussed in the document is only around software. The data architecture needs to be explicitly defined, and the software solutions should be thought subsequently on how best they can meet the needs of the data architecture. Very broadly, data architecture represents what level and programme should receive what data and who governs this process. There should be some guiding principles to define this architecture, example: i) only collect data which contributes to indicators; ii) no level should receive data for more than 2 levels below (which implies no patient data should go above block or district).
 5. The Privacy Operations Center is a welcome concept and reflects an engagement with the issue of privacy. But in itself it may not be enough. As the blueprint repeatedly states: it should be written into the architecture. But the latter is not seen clearly in the document.
 6. What is the implication of calling the registries and patient identifier codes "the single window of truth"? This includes clinical establishments, healthcare providers, health workers and pharmacies. These are dynamic data. NDHB acknowledges that the need to be updated- but neither has any experience with doing so, nor experience with validating basic data. It is quite

possible, that there would be gaps in updating. Systems should be able to use multiple identifiers for linking up with providers. This could be the main path to establishing provider identity- or else it could lead to exclusions. These exclusions are likely to be in more difficult to access areas.

7. The stricture on open standards and open source applications are fine. But implementation on this has been non-existent. Even within the document itself SNOMED CT is recommended. SNOMED CT is open standard within India, only as long as India pays a hefty annual membership fee- but by the strict meaning of the term it is not an open standard. Similarly when talking of the building blocks it is essential to insist on open source applications.

8. The concept of building block requires some degree of elaboration. According to the document

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

This is rather simplistic. The rules and policies of the building block would need to be defined by the overall governance structure. Further these rules and policies are likely to change. Leaving each building block to different technology vendors is likely to create much avoidable confusion. Also some of these are very open blue-sky ideas. To think of operationalizing them in 6 to 12 months across the nation seriously under-estimates the tasks at hand. This is part of the culture of hype and techno-optimism that is commonplace in the IT world, but a government document could be more cautious and measured.

9. The report emphasizes that in the spirit of cooperative federalism it will allow states/districts/hospitals to have and operate their own systems as long as they are inter-operable with central systems – at least in that they can transfer the data legitimately required by the center/other providers. It is not clear whether every building block proposed is in conformity with this criterion.

10. Smart phones and indeed digital health have a useful contribution to make in health workers education and support. But this should be placed in the context of the overall training and support mechanisms. Smart phones and digital health will supplement but never fully substitute for more hands on training and support.

11. Blockchain technology is controversial. It requires enormous amounts of energy to run, is unregulated and has led to the banning of cryptocurrencies etc. However, there are benefits and companies such as Facebook are planning to start its own currency using this technology and many countries including China are planning to use it. For a sensitive application such as healthcare, it is prudent that such technology is used only after proper validation.

In conclusion: The recognition of the need to have a digital health architecture that is consistent with federalism is welcome and so are the articulation of many good principles and reports. However this architecture

as reflected in this draft blueprint is designed for an imagined health care system (consisting only of HWCs & PMJAY) which represents less than 5% of the health systems/providers that are actually on the ground. As recommended the blueprint is suggesting an imagined blue-sky solution where the new architecture consists of building blocks erected on a clean slate, incorporating earlier systems by tweaks as it goes along. And all of it would be completed within 12 to 18 months.

It could work- but more often than not, as global experience shows it does not- though in the process it could provide many lucrative contracts to India's IT majors. In a worst case scenario it could disrupt not only an ongoing incremental process of IT development that is ongoing, but also the organization of healthcare services at the district and sub-district levels- especially when new systems are being proposed as replacing all others. An approach where the biggest and newest software seeks to undermine or stop all others, even if they may be working well in their local settings is one reason- why some of these bold new 'disruptive' innovations- can be literally disruptive of progress being made, without offering any alternative. ¹

We therefore would call for an incremental approach that builds on the current situation and processes, with center providing technical support and guidance to multiple decentralized efforts. We set out some of the main features of such an alternative below:

An alternative, would be for the Center to:

- a) Specify what information it needs for public health management and policy at the center and with what periodicity, and allow states to deliver this the best way they can.
- b) Such information that state provide can be tested and validated for reliability. The state systems must also confirm to meta-data and data standards and other core standards required to ensure that the data they supply can be read without loss or distortion of content by central systems.
- c) States that do not have the capacity to build their systems can choose from a limited menu of application options.
- d) The main purpose of IT systems in the states and districts should be for decentralized management at that level. The center should limit itself to data that is actionable for the center- it need not be able to "see" every facility, let alone every individual.
- e) The IT systems that states choose would be in line with the maturity of their healthcare systems. Mature public health systems may aspire to give

¹ A recent example is the Integrated Health Information Portal (IHIP) which started as a system for IDSP but is now being considered to include 25 or so other programmes. It is reported that work on digitizing malaria control that was going well in several states was stopped in anticipation of IHIP; which firstly is not in sight, and secondly, it is not possible to incorporate the particular work practices and needs of different health programmes in one software).

patient specific data from each facility with considerable granularity whereas less mature systems can give aggregate numbers from a block or district level.

- f) Private Hospitals and healthcare providers that sign up for PM-JAY may be asked to file patient records- but small providers would need help. This is already operational
- g) It may be understood that the vast majority of private providers are not under PM-JAY and would therefore need to link up to portals where they will be able to provide certain aggregate information that would be required of them. They would neither be ready to provide patient specific information, nor can it be forced on them.
- h) The main purpose of PHI and EHRs is to enable continuity and quality of care at that levels and facilities/states may choose what works best for them. For purposes of portability a request for information from a different district/facility authenticated by the patient can be responded to by the facility/local district or state repository holding the data.
- i) A central repository is neither required nor manageable nor desirable. Though these repositories are justified in the name of universal coverage and reaching the poor, it will like most such systems provide little in the way of entitlements to the poor. However in the hands of a powerful state, it can be used to encroach on privacy harm select individuals who are perceived as hospital by the government of the day. Such large data banks have also commercial value and there is much data mercantilism- on which the entire document is silent. This silence is of great concern. There needs to be safeguards and guarantees against this.
- j) There is potential for use of data from centralized repositories (health lockers?) for research. But for these separate channels and mechanisms and authorities must be created. Research use need not and must not be conflated with use of PHIs in individual patient care. This is important to demarcate because much of the so called research could be data mining for market research for a wide range of users far removed from the purposes for which individual trusted providers with the data.
- k) Patient identifiers may be used but no patient can be refused care/excluded at any point because of a lack of ability to prove identify. The fact of sickness as Louis Pasteur pointed out, is the only identify that a provider/healthcare system requires. For continuity of care and quality of care there are number of identifiers to choose from. For specific data aggregation purposes- to avoid duplication there are multiple methods that can be used. There should not be an insistence on Aadhaar.
- l) The facility and provider register need to be developed as a dynamic tools which can be updated from time to time and allow alternative channels also for facilities and providers to notify their own existence and processes for claims.
- m) It will be important to propagate the meta data and data standards, EHR standards and other such standards as are necessary for transfer of information across systems and incentivize and support public systems in states and IT applications developers to understand and conform to these standards.

- n) The mechanisms of governance require much greater transparency, participation from civil society and academia and care in selecting persons for key positions than the document reflects.
- o) Government has issued policies on use of open source software for all public systems, and all new software systems should provide for open API access. However this policy is not operational, and even after 7-8 years of active trying, the national HMIS (which is built on proprietary platform) has not provided states with API access, causing great difficulties. Therefore it will be worthwhile for the government to do an inventory of software systems (including those of NIC and CDAC) and assess the code available on public repositories and if open API access is being provided.
- p) Instead of proposing new systems that are to replace all others, the focus therefore must be on data integration and interoperability and not software integration that usually leads to the biggest (and politically supported) software seeking to remove all others, even if they may be working well in their local settings.
- q) The WHO has been actively engaged in developing standard modules (for TB, Malaria, HIV, EPI, Mortality reporting etc.) on the free and open source DHIS2 platform and inviting and supporting countries to adapt it, together with guidance material, training guidelines etc. India should seek to work with these globally designed standards rather than having new systems developed by IT vendors who have limited understanding of the public health domain.

Finally, though it is appreciated that the government has called for a public consultation on this document, but the time given for responding is too short for an adequate preparation. We would like to submit these comments for discussion also in the meeting being held on the 6th. However, we request an opportunity at a later date where civil society and academic experts in this area can get to participate with adequate preparation.