Steps towards the Development of National Health Data Standards in Developing Countries: An Exploratory Qualitative Study in Saudi Arabia

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Abstract—The proliferation of health data standards today is somewhat overlapping and conflicting, resulting in market confusion and leading to increasing proprietary interests. The government role and support in standardization for health data are thought to be crucial in order to establish credible standards for the next decade, to maximize interoperability across the health sector, and to decrease the risks associated with the implementation of non-standard systems. The normative literature missed out the exploration of the different steps required to be undertaken by the government towards the development of national health data standards. Based on the lessons learned from a qualitative study investigating the different issues to the adoption of health data standards in the major tertiary hospitals in Saudi Arabia and the opinions and feedback from different experts in the areas of data exchange and standards and medical informatics in Saudi Arabia and UK, a list of steps required towards the development of national health data standards was constructed. Main steps are the existence of: a national formal reference for health data standards, an agreed national strategic direction for medical data exchange, a national medical information management plan and a national accreditation body, and more important is the change management at the national and organizational level. The outcome of this study can be used by academics and practitioners to develop the planning of health data standards, and in particular those in developing countries.

Keywords—Interoperability, Case Study, Health Data Standards, Medical Data Exchange, Saudi Arabia.

I. INTRODUCTION

OWING to interoperability barriers between health information systems, there are potential limitations facing health sectors with regards to acquiring the benefits of those systems and, in particular those associated with the safety, quality and cost of medical services [1]. However, the level of interoperability that allows a "mix-and-match" environment requires a high degree of consensus on the health data standards [2]. Even though health data standards are expected to be the basis for interoperability solutions [3], the level of adoption of those standards remains frustratingly low [2], [4]-[11]. The normative literature exposed that the proliferation of

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standards is somewhat overlapping and conflicting, resulting in market confusion and leading to increasing proprietary interests [2]. In addition, standardization for health data is an authoritative field in which the mechanisms of the marketplace do not work. For example, health data standards developed for a particular market (e.g. the North American market) cannot, in general, be applied in other markets (e.g. the European market) without modification owing to the differences between countries regarding medical policies and procedures [12].

Many countries have launched some national initiatives to taking the lead of developing the required national health data standards [6]. The role of the national initiatives is to establish credible standards for the next decade, to maximize interoperability across the health sector, and to decrease the risks associated with the implementation of non-standard systems [13]. However, prior studies missed out the exploration of different steps and activities required for the development of national health data standards. The purpose of this study is to investigate the issues to the adoption of health data standards in the main tertiary hospitals in Saudi Arabia and based on the lessons learned from the case hospitals and the feedback from different expert in the area of data exchange and standards and medical informatics in Saudi Arabia and UK to develop a list of steps towards the development of national health data standards. The outcome of this study addressed the gap in knowledge and also provides those who are planning to the development of national health data standards with suitable strategy and guidelines. The remainder of the paper is structured as follows. First, the authors provide a background to the health data standard and the healthcare systems in Saudi Arabia. Then, the research methodology is described followed by the results and discussion. The authors conclude by presenting the main recommendations and steps developed in this study towards building in blocks the national health data standards.

II. HEALTH DATA STANDARDS

The use of such standards is based on the idea of developing agreed specifications or standards for data exchange. These will not depend on any proprietary systems but must be universally understood and accepted for data exchange [14]. The creation of interoperability depends upon two important concepts, syntax and semantics [15]. Syntax interoperability refers to the structure of the message content, which is the

equivalent of the rules for spelling and grammar. These must be agreed and standardized in both the sending and receiving sites. In contrast, semantic interoperability conveys the meaning of the sent message, the equivalent of a dictionary and thesaurus. However, without semantic interoperability, data can be exchanged but there is no assurance that it can be processed in a meaningful way at its destination [15].

Different types of health data standards have been reported in the normative literature. For example, Park and Hardiker [16] stated that current attempts to standardize the capture, representation and communication of medical data in such a way as to represent their meaning, rely upon three layers of artifacts. These are generic reference models for representing medical data (e.g. HL7 CDA and the EHR Reference Information Model), agreed definitions regarding the structure of clinical data (e.g. openEHR archetypes and HL7 templates) and clinical terminology systems (e.g. LOINC and SNOMED-CT).

Kim [15] described six types of health data standards including messaging, terminology, document, conceptual, application and architecture standards. Messaging standards specify the message format, data elements and structure to allow transactions to flow consistently between different systems (e.g. HL7 and DICOM). Terminology standards provide specific codes and terms for clinical concepts such as diagnosis and diseases (e.g. ICD and SNOMED). Document standards specify the types of information that are included in a clinical note and how it can be located (e.g. CCR and CDA). Conceptual standards allow information to be transported through the systems without losing meaning and/or context (e.g. EHR). Application standards determine the way medical procedures are processed and how systems interact (e.g. CCOW). Architecture standards define how medical data are stored and distributed (e.g. PHIN).

III. HEALTHCARE SYSTEM IN SAUDI ARABIA

The delivery and management of health services to communities and regions in Saudi Arabia is a truly complex task. Saudi Arabia spans a large geographical area with fragmented healthcare systems whose quality of care varies considerably between its diverse and scattered regions. The Ministry of Health (MoH) is the main government agency entrusted with the provision of preventive, curative and rehabilitative medical services. Its functions include strategic planning, formulating specific health policies, supervising all health service delivery programs, and monitoring and controlling all other health-related activities. However, health services' inception in Saudi Arabia took place 60 years ago, more specifically in 1950, when the first campaign against malaria was launched. Following this, the healthcare system in the Kingdom grew steadily until 1980 when there was a period of rapid of expansion in every sector in Saudi Arabia due to the increase in economic wealth [17]. In the early 1980s, the concept of primary healthcare became popular and the structure of the health sector started to become clear.

Currently, the MoH runs a three-tier healthcare system which includes primary, secondary and tertiary levels; these correspond to health centers, general hospitals and specialist hospitals respectively. Under the umbrella of the MoH, there are 20 health regions and the programs, plans and policies of the MoH are executed through this hierarchy [17]. In addition to the MoH, there are two other healthcare providers: the private health sector and other governmental public healthcare bodies (e.g. Army Force Hospitals, National Guard Hospitals and University Hospitals). While the MoH provides 58% of healthcare services, the remaining portion is shared between other governmental bodies (23%) and the private sector (19%) [18].

In the context of the adoption of medical IT systems, the health sector in Saudi Arabia is still lagging behind such developed or developing countries in terms of the utilization of advanced applications. Each healthcare provider is at a different stage in terms of the implementation of medical IT systems [18]. The majority of MoH hospitals and private clinics and hospitals lack an adequate and proper IT infrastructure due to the lack of professionals and adequate budget. Only few governmental care bodies are equipped with the most recent and advanced systems. Unfortunately, the number of these hospitals is still small, they are located in major cities, and moreover, they are overloaded with patients [18].

IV. METHODS

A multiple-case study methodology was conducted to investigate the issues to the adoption of health data standards in Saudi Arabian tertiary hospitals. Six maintertiary hospitals in the capital city, Riyadh, were chosen; these include the National Guard hospital, King Faisal Specialist Hospital and Research Centre (KFSH&RC), King Fhad Medical City (KFMC), the Security Forces' Hospital (SFH), Armed Forces' Hospital (RAF) and King Khalid University Hospital (KKUH). Those tertiary hospitals were chosen because they are considered among others as the more advanced ones in Saudi Arabia in terms of the quality of patient care and the IT infrastructures [18]. They are also considered to be the main stakeholders involved in the pilot project run by the Saudi Council of Health Services concerning the exchange of medical information. Therefore, such health data standards were expected to be adopted in these hospitals, given the authors the opportunity to investigate the issues to their adoption.

Different data collection methods were used in this study including semi-structured interviews and an analysis of existing documentation. As the focus of this study was on the adoption decision of health data standards and those people who are in charge in their adoption process in the case hospitals, The mangers of the IT departments where conducted initially to identify the targeted informants in each case. The number of participants totaled 33 persons, eight of these are from NGHA, seven are from KFSH&RC, four are from KFMC, four are from SFH, four are from RAFH and six are from RUHs. The participants were managers or senior officials constituting a mixture of different departments of the subject hospitals.

The 33 participants were conducted in person face-to-face to ensure that an appropriate expert had the opportunity to participate in the study, give feedback and tell his/her unique story relating to the adoption process of health data standards in his/her hospital. The semi-structured interviews lasted approximately one hour. The interviews were recorded using a digital Dictaphone. The IT departments of the cases hospitals also provided the authors with some valuable documents relating to the IT and information infrastructures and integration issues and different documents with regard to the policies, strategic plans and general information concerning the hospitals.

Four phases were passed to generate the list steps required for the development of national health data standards. In the first phase, the QSR NVivo 8 software was used to thematically analysis the qualitative data collected from the case hospitals. The empirical data were reviewed and analyzed several times by each one of the authors in order to enhance the validity and reliability of the results and to generate all the possible and initial issues to the adoption of health data standards in Saudi Arabian tertiary hospitals. Next, a brainstorming session was facilitated by the authors to elicit the key lessons learned from the case hospitals and the main issues to health data standards adoption. The outcome of this phase is an initial list of different recommendation and steps for the development of national health data standards. In the third phase, the authors re-focused the revision of the initial list at a broader level. This required reporting the initial list to five key experts in the field of health informatics in Saudi Arabia to review this initial list and give their feedback. The five key experts agreed upon the initial list and they only advised to have two main lists of recommendations and steps at both the national and organizational level. In the last phase, the list was refined once again through three experts in the area of data exchange and standards and medical informatics in UK. The experts suggested breaking down some steps to small once to facilitate their understanding. Once this comment was addressed, the final list was reviewed again by the three experts who agreed on the changes and the final list of the steps required for the development of national health data standards.

V. ISSUES AND LESSONS LEARNED

The results from the data analysis revealed that only a few health data standards have been adopted by the case tertiary hospitals in Saudi Arabia. These include ICD, SNOMED, CPT, HL7 and DICOM. A synopsis of lessons learned and the key issues, derived from the empirical data, is given below:

- Health Data Standards' Drivers:

Although some health data standards (e.g. HL7 and DICOM) have been imposed because these are the market standards, meaning that tertiary hospitals had no other option but to adopt these in order to retain market compatibility and support, the current standards were also adopted for other reasons. From a managerial perspective, health data standards were adopted by the tertiary hospitals to support the data analysis that is required for decision support systems, to acquire accreditation from certain leading international medical commissions, and to be able to benchmark themselves against other leading international hospitals. From a technical point of view, the main benefit of adopting health data standards is the increase of interoperability between the different systems while, for educational purposes, most of the case hospitals run education programs and are affiliated to a medical research group. As a result, the terminology standards, such as ICD, SNOMED and CPT, were imposed in order to facilitate searching and the provision of programs with accurate cases, reports and statistics. From a government perspective, the tertiary hospitals are required to report some medical information annually to the MoH and to the Saudi Oncology Centre in order to produce medical statistics and reports, such as mortality data, concerning the health situation in Saudi Arabia in general.

- The Lack of National Reference:

Although several government entities and commissions speak about the standards, no one has taken the lead in developing and promoting them in Saudi Arabia. Accordingly, everyone tertiary hospital is at a different stage in terms of adopting health data standards. The terminology standards are in limited profile use and so most of the data are built somehow based on a proprietary format structure; thus, exchanging medical data semantically among healthcare providers in Saudi Arabia is impossible. Obtaining meaningful also insights into the medical information, through the provision of accurate statistics and reports, is limited due to the insufficiency of the data. Consequently, producing medical statistics and reports, such as mortality data, concerning the health situation in Saudi Arabia in general is a real concern.

- The Lack of National Plan For Medical Data Exchange:

Owing to this issue, the tertiary hospitals preferred to invest in their IT infrastructure, in areas such as networks, platforms and other advanced clinical information systems, rather than focusing on health data standards from which they could not gain benefits directly. This is also because the medical information exchange among the healthcare providers in Saudi Arabia is a project that is impossible to achieve at the present time for many reasons. For example, healthcare providers in Saudi Arabia run a variety or range of different formats of information infrastructure that are difficult to manage and integrate. In addition, the national healthcare system in Saudi Arabia is not sufficiently well organized to allow data exchange amongst healthcare providers. There are substantial variations in the management and provision of medical services in Saudi Arabia. Every healthcare provider has its own policy and procedures that usually depend on the hospital's qualifications. A clear national policy is still lacking with regard to how medical services are, for example, managed, operated, structured and provided to patients. The national Healthcare varies between geographic areas. This has led to duplications in funding, wasted resources, and a lack of coordination in terms of managerial control.

- The Lack of Official National Plan for the Management of Medical Information:

No official plan for the management of medical information has been established at the national level; nor has any committee been assigned to deal with this issue. Saudi Arabia is still lack a medical information management plan at the level of how data are, for example, predefined, characterized, structured, stored, exchanged, integrated, accessed and governed. Due to the absence of an information plan, many concerns were raised, such as the privacy and confidentiality of patients' information. For example, with the absence of specific health privacy legislation governing hospitals in Saudi Arabia, every tertiary hospital has pursued a self-regulatory approach and has modeled its policies on internationally recognized privacy principles for the protection of personal information.

- Shortage of National Professionals:

Owing to the shortage of professionals in Saudi Arabia who can understand or cope with health data standards, the tertiary hospitals seek advice from reliable international sources, such as consultants and/or partners. Standardization for health data is a very complex field which requires many informed, interdisciplinary, experienced professionals and researchers. Saudi Arabia is newcomer in this area and the current education and training cannot meet the need.

- Less Engagement of Clinicians:

There was less engagement on the part of clinicians in applying the terminology standards on a routine, daily basis. This issue was due to a number of reasons, such as Saudi physicians not having undertaken any education programs with regard to health data standards and their applications in the medical environment. Therefore, they are unaware of the benefits that standards could bring to their hospitals; they also think that using health data standards on a daily basis just amounts to extra work so they do not want to accept them because they are already over-loaded. In addition, the public hospitals in Saudi Arabia still lack adequate policies and procedures that would offer some sort of incentive (and/or inflict certain punitive measures) to ensure the application of health data standards in hospitals on a daily basis by the medical staff.

- Less Utilization of Advanced Systems:

Various advanced systems are currently being used in the hospitals for different purposes in a less than effective way because of the nature of the proprietary format of the hospitals' data structure. For example, some tertiary hospitals have started a data warehouse project in some form or another. However, the hospitals are still lacking certain benefits that the system could offer owing to the inconsistency, the nature of the structure and the proprietary format of the data. In addition, some other systems (e.g. CPOE and Business intelligence) were found to have completely or partially failed to be implemented owing to the lack of appropriate health data standards.

- Capability and Compatibility Issues:

Concern was expressed with regard to the IT infrastructure in the hospitals. With the absence of national reference of health data standards, the government adopts such standards without involving the hospitals and checking their capabilities. For example, the ICD-10 Australian Modification (AM) was failed to be implemented by the majority of the tertiary hospitals due to capability and compatibility issues. Such capability and compatibility mean that the new system should operate within the resources that are currently available in terms of technical issues, such as platforms and networks, and human aspects, such as knowledge and skills. The hospitals have made substantial investments in terms of infrastructures. The hospitals will not discard capital and/or equipment as a result of the requirements for adopting the new standards.

VI. DISCUSSION

In the literature, the issues within the lessons learned were validated. For example, the interoperable infrastructures available to hospitals create a vast potential for quality improvement since they allow them to measure their performance through the use of international standards and definitions, and thereafter benchmark their care against others [19]-[21]. In addition, the accreditation has one of the strongest relationships with interoperable infrastructures since it facilitates the documentation and generated performance measures with such respected medical care agencies [22], [23]. The interoperable infrastructures were also seen by previous studies to be essential to support researchers in the biomedical and clinical fields with large numbers of patients, as well as to provide access to longitudinal clinical information [2], [19], [24].

Moreover, a large body of the literature concerning the integration between medical information systems indicated that the purpose of health data standards is to reduce the complexity of interface design and to facilitate information exchange among various health information systems [2], [5], [7], [25]. The governmental perspective was also seen by the related studies in the literature as the bottleneck to the adoption of health data standards in every nation. The existence of national regulator and national strategy concerning integration across health domains, together with the development of a minimal set of data standards, was seen to be crucial and in particular in those developing countries to reduce some of the challenges facing the delivery of medical services [9], [26]. However, the senior managers explained that the lack of the government actions and role in Saudi Arabia were seen as one of the main issues to the adoption of health data standards.

Equally important is the assessment of readiness for major change management at the national and organizational level. For example, health data standards require many levels of interaction and management of both personnel and systems, representing major organizational change [27]. If hospital staff were more knowledgeable about standards, there would be fewer advocator obstacles and lesser user resistance against

them [5]. In addition, the engagement of clinical expertise in the process of developing health data standards is crucial because clinical experts create scenarios for the content of standards, giving them actors, roles and interactions through which the required data structures and data exchanges are predefined and derived [2].

VII. STEPS TOWARDS THE DEVELOPMENT OF NATIONAL STANDARDS

Based on the empirical evidence and the lessons learned from the case tertiary hospitals in Saudi Arabia and the opinions from different experts in the area of data exchange and standards and health informatics in Saudi Arabia and UK, a list of such recommendations and steps required to be undertaken by the Saudi government for the development of national health data standards was constructed. These steps are also thought to be useful for every nation, and in particular those in developing countries. The list of such steps is divided into two main levels including the national and organizational level. The following explains these steps.

A. At the National Level

Various initiatives should be undertaken by governments at the national level in order to promote the standardization efforts for health data and the adoption of those standards in health sectors. These are:

- National Regulator:

The existence of a national formal reference for health data standards is essential to lead the development of such standards in the country and to promote their adoption. Different activities should be carried out by the national regulator for health data standards, these include:

1) The national regulator should be involved in the existing international standardization initiatives, rather than focusing its resources on developing its own standards and then customizing international ones according to local needs as this is the most appropriate approach and cost effective solution for the development of national health data standards.

2) The engagement of clinical expertise in the process of developing health data standards is also vital in order to create scenarios for the content of standards, giving them actors, roles and interactions through which the required data structures and data exchanges can be predefined and derived.

3) An advisory group, which should monitor the activities of the international standardization industry, will also be required to report back to national groups once the effectiveness of the new standards or versions become apparent.

4) The concept of trying to define and develop all the standards in advance is not a solution to the current interoperability issues. Instead, the most appropriate solution, offering the ability to produce effective and acceptable standards quickly, is the implementation of "just-in-time" standards and building in blocks.

5) The national regulator should monitor and govern the national market so that every system is certified before it can be marketed.

6) The national regulator should cooperate and coordinate with the Ministry of Higher Education, as well as different national universities, to redesign the curricula of medical colleges and to establish a new education program of health informatics in order to overcome the shortage of national professionals.

- National Medical Data Exchange Plan:

An agreed national strategic direction between the different medical entities must be established to control and govern the activities and issues associated with medical data exchange and, as part of this plan, the National Shared Electronic Health Record (EHR) must be taken into account in this stage. Parts of this plan are:

1) It should examine the capabilities of the market and of the hospitals in setting and defining the necessary standards, policies and information specifications required to enable medical data exchange.

2) A continuous evaluation process is necessary as there is a need to demonstrate the usefulness of the existing standards, or to find other solutions, or to demonstrate the impact of health data standards on clinical information systems, or for the hospitals in general.

3) An on-going process of analysis and debate between related national groups will be required, not only to enhance data exchange and aggregation, but also to generate the broad feedback needed to improve the standards, to identify the precise requirements of the health sector, and to clarify the suitability of each option for those requirements.

4) A program to offer some sorts of incentive (and/or inflict certain punitive measures) must be established to ensure the application of health data standards in the hospitals.

- National Plan for Medical Information Management:

There is a need for a national medical information management plan at the level of how data are, for example, predefined, characterized, structured, stored, exchanged, integrated, accessed and governed. However, this plan requires:

1) The significant involvement, engagement and commitment of the hospitals' managements and clinical communities in order to place continued emphasis on developing the information infrastructure by increasing the depth and breadth of electronic clinical content.

2) The national health communities to have a privacy-sensitive culture based on professional ethics and strict safeguards regarding medical data.

3) The development of specific health privacy legislation governing hospitals to ensure that a high value is placed on the confidentiality of patients' information. Security and protection of patient information are not only demanded by the patient himself, but in most countries they are also required by law. Aspects of patient data

security and protection need to be considered carefully for every such activity in medical data exchange.

- Change Management at National Level:

A dedicated program for change management must be established at a national level to ensure the national healthcare sector is redesigned to operate as an integrated, coherent system with clear policies and workflow mechanisms which would allow data to be exchanged seamlessly between the different entities within the sector. Other important issues that this program should encompass are:

1) It should ensure that highly collaborative approaches are employed by healthcare providers to regulate successfully the rate of change required for promoting the adoption of health data standards.

2) It must stress on the important role of insurance companies in the development of sustainable national health information network infrastructure.

3) It must recognize the importance of engaging clinicians in the development of a highly standardized medical information infrastructure. So, clinical leadership, collaboration, effective communication, and commitment to education, training and awareness-raising sessions, are critical success factors in maintaining the application of health data standards on a daily basis.

4) There is a need to offer incentives and forms of compensation to encourage medical staff to use terminology standards in their daily routine tasks.

- National Accreditation:

A national accreditation program should be initiated to encourage healthcare providers to apply the standards on a daily basis. This program should be developed based on international guidelines, while channels of communication should be opened with those considered to be well recognized international institutions for them to work hand-in-hand in accrediting the national healthcare providers. The national healthcare providers should also be rigorously evaluated and followed up in order to assess to what extent they are conforming to the standards in practical settings, not theoretical ones, to pinpoint and investigate barriers, and to implement means for continuous improvement.

B. At an Organizational Level

Certain steps should be taken into account at the organizational level to maximize the success of the healthcare providers in adopting and adhering to health data standards, these are:

- Top Management Awareness:

The healthcare providers' authorities must acknowledge the role of health data standards in the development of sustainable medical information infrastructure. They must also acknowledge that the success of health data standards implementation is never merely a matter of smoothing out technical issues. It is rather a complex balance between different types of requirement involving organizational, cultural and managerial aspects.

- An Adequate Policies and Procedures:

Clear policies and procedures with regard to the adoption of clinical information systems must be developed. The policies and procedures are a set of guidelines that should be defined precisely; these should be developed for all the different activities required when a request is made to purchase a new system and should be followed rigorously until the system is used on a regular basis. This would help healthcare providers to ensure that the new systems are conformed to the national standards including health data standards. These policies and procedures must stress the importance of the involvement of both top management and medical staff in the adoption process to increase the likelihood of the system's adoption, adherence and success.

- Change Management:

A dedicated change management program must be established at the organizational level to ensure that a highly collaborative approach is undertaken by the healthcare providers' authorities, different departments and related groups in order to regulate successfully the rate of change and ensure organizational change objectives are fully realized. These include:

1) The commitment of top management in supporting the implementation is a key factor in the success of the adoption of every health data standards.

2) The dedicated change management program should examine the implementation of technical metrics, measures of acceptance, and the use of health data standards by staff and physicians.

3) Healthcare providers must recognize the importance of engaging clinicians in the development of the highly standardized medical information infrastructure. Thus, clinical leadership, collaboration, effective communication, and commitment to education, training and awareness-raising sessions, are critical success factors in maintaining the application of health data standards.

4) The dedicated change management program should assess how the organizational structure is designed and should examine what changes are necessary to increase success in adopting the health data standards in such healthcare providers.

5) It is necessary to have health informatics personnel and those with medical backgrounds to work closely with IT experts since medical information systems require not only technical people but also a mixture of those with business or care backgrounds in order to ensure that the needs and requirements of the stakeholders are addressed.

6) The dedicated change management program should redefine how business processes operate and flow, how the systems are integrated, how the data are predefined and saved, and how the documentation is structured and located. This will bring about significant and potentially overwhelming changes to the flow of work and day-to-day operations.

7) The dedicated change management program must be managed carefully and with sensitivity as it will have a

considerable impact in the form of change for employees and medical staff.

VIII. CONCLUSION

The government role and support are seen to crucial for the development of standardization for national health data. The normative literature missed out the exploration of different steps required to be undertaken by the governments in order to build in blocks towards the development of national health data standards. In addressing this gap in knowledge, a qualitative, multiple-case study method was conducted to investigate the issues to the adoption of health data standards in six main tertiary hospitals in Saudi Arabia. Based on the lessons learned from the case tertiary hospitals and the opinions of different experts in the area of data exchange and standards and health informatics in Saudi Arabia and UK, a list of different recommendations and steps for the development of national standardization efforts for health data was constructed. This list is to aid healthcare authorities and in particular those in developing countries, while planning for the development of national health data standards.

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