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The Role of Health Data Standards in Developing Countries

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Abstract: Healthcare organizations have recognized that there are potential limitations with their clinical information systems. Interoperability barriers between different systems have resulted in medical information being collected by different people or systems which has made it difficult to understand, compare and exchange. There are many health data standards to try and overcome these issues, but in many developing countries these have not been adopted. This paper investigates health data standards and their roles in Saudi tertiary hospitals and provides insights into the issues, and recommendations which can be used by academics and practitioners to develop the planning of health data standards.

Keywords. Adoption, Interoperability, Medical Data Exchange, Saudi Arabia, Standardization

Introduction

After several years of running clinical information systems, healthcare organizations have recognized that there are potential limitations with regards to acquiring the benefits of those systems and, in particular, reducing the cost of medical services; this is because of interoperability barriers between different systems.¹ As a result, medical information is collected by different people or systems at different times and is difficult to understand, compare and exchange.²⁻³ However, the level of interoperability required to reduce these problems requires a high degree of consensus on the standards that will allow a “mix-and-match” environment.⁴⁻⁵ Although health data standards are expected to be the basis for medical data exchange, the level of adoption of health data standards remains frustratingly low among the vendors of clinical information systems and healthcare organizations.^{4,6} This is because the proliferation of standards is somewhat overlapping and conflicting, resulting in market confusion and leading users and vendors to implement no standards at all while they are waiting for the situation to resolve itself.⁷ In addition, health data standards are an authoritative field in which the mechanisms of the marketplace do not work; therefore, standardization for health data for every country must be undertaken by governments.^{2,8} The role of the government 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.⁹

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Many countries have launched some national initiatives to foster the adoption of clinical information systems and related standards. For example, Deutsch et al. (2010) studied national electronic health record programs run in England, Germany, Canada, Denmark and Australia, together with their most commonly documented critical aspects.¹⁰ According to the study; the standardization of health data was regarded as the core issue in those countries. Zhang et al. (2007) investigated the current status of standardization for health data in China.² For example, one national project has been undertaken to produce a set of data standards which are required for the hospital information systems. Many of the data items are from references to international standards, such as ICD-10, LOINC, HL7 and DICOM. Many barriers regarding the standardization process are reported in Zhang et al.'s study; these include technical, cultural, financial and language problems, as well as ethical and legal concerns.²

However, the current status of health data standards in many developing countries is still vague due to the absence of government actions and plans, and the lack of related studies. Therefore, the purpose of this paper is to investigate health data standards and their roles in Saudi tertiary hospitals. In doing so, the paper provides a background of healthcare systems in Saudi Arabia. In the next section the types of health data standard are highlighted and then the research design is described and the findings are discussed. The paper concludes by providing recommendations and the main findings from the study.

Healthcare Systems in Saudi Arabia

Health services' inception in Saudi Arabia took place 60 years ago, more specifically in 1950, when the Ministry of Health (MoH) was established and 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 expansion in every sector in Saudi Arabia due to the increase in economic wealth.¹¹ 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.¹¹ 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.¹¹ 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).³ While the MoH provides 58% of healthcare services, the remaining portion is shared between other governmental bodies (23%) and the private sector (19%).³ Today, the total number of hospitals in Saudi Arabia is 387. The total number of beds in all hospitals is 53519, with the number of beds in the MoH hospitals being 31420, corresponding to 58.7% of the total number of beds in the Kingdom. There are 2.2 beds per 1000 persons, equating to one bed for 453 people. The total number of physicians in the Kingdom, including dentists, is 47919; 21.6% of these are Saudi. The number of dentists totals 6049 (excluding those working in the private clinics) and 21.1% of these (i.e. 1275 dentists) are Saudi. The total number of pharmacists is 15043 (excluding those working in the private sector); 1875 pharmacists (12.5%) are Saudi while 99% of the pharmacists working in private pharmacies are non-Saudi. The total number of nurses is 93735, 28.8% of whom are Saudi.¹²

Health Data Standards

Various professional groups, and both public and private organizations, have established different types of health data standards, each serving a particular purpose. From an institutional perspective, four types of standard may be distinguished.⁴ Official standards are developed in an obligatory way because of government regulations (e.g. by-laws). Voluntary standards are developed based on requests from interested industrial parties. Industry standards are proprietary standards developed by one single company or group of companies. Open standards are characterized by the fact that everyone can participate in the development process without being a member of a specific group or institution. According to Kim (2005), the development of an interoperable system depends on two important concepts: syntax and semantics.¹³ Syntax interoperability is the structure of the message content which must be agreed and standardized in the sites that both send and receive. In contrast, semantic interoperability conveys the meaning of the sent messages; this is the equivalent of a dictionary and thesaurus. Without semantic interoperability, data can still be exchanged but there is no assurance that they can be processed in a meaningful way at their destination.¹³

The proliferation of health data standards today addresses both types of interoperability and different categories of health data standards have been reported in the normative literature. For example, Spooner and Classen (2009) explained three types of health data standards: Terminology standards ensure that the definitions of terms employed by users are consistent; Messaging standards specify the communications between electronic health record systems and registry systems; and Functional standards specify the rules that support correctly timed and properly administrated decision making.¹⁴ Kim (2005) described six types of health data standards: messaging (e.g. HL7 and DICOM), terminology (e.g. ICD, LOINC and DICOM), document (e.g. CCR and CDA), conceptual (HL7 v3 RIM), application (e.g. CCOW) and architecture (e.g. PHIN) standards.¹³ Messaging standards specify the message format, data elements and structure to allow transactions to flow consistently between different systems. Terminology standards provide specific codes and terms for clinical concepts such as diagnosis and diseases. Document standards specify the types of information that are included in a clinical note and how it can be located. Conceptual standards allow information to be transported through the systems without losing meaning and/or context. Application standards determine the way medical procedures are processed and how systems interact. Architecture standards define how medical data are stored and distributed.

Research Design

An interpretive, qualitative approach was employed in this study as the aim was to understand how health data standards are utilized in Saudi healthcare context. An interpretive paradigm gives the authors the opportunity to explore and better understand this phenomenon in an organizational setting.¹⁵ In addition, the authors considered a qualitative approach to be more appropriate in the context of this study as it is naturally associated with the epistemological assumptions of the interpretive paradigm and can be used to examine in depth a complex phenomenon in its natural setting.¹⁶

1. Methodology

A multiple-case study methodology was selected to examine the roles of health data standards in Saudi tertiary hospitals in depth. Six healthcare organizations were chosen to carry out this study. These organizations affiliate several different hospitals located in different major regions and cities such as Riyadh, Jeddah and Dammam. The six healthcare organizations were chosen since they are considered among other hospitals (e.g. those affiliated by the MoH and the private sector) as the more advanced hospitals in Saudi Arabia in terms of the quality of patient care and the IT infrastructures.⁸ Therefore, such health data standards were expected to be adopted in those hospitals. For reasons of confidentiality, the authors refer to these organizations by coded names such as ORG_A, ORG_B, ORG_C, ORG_D, ORG_E and ORG_F. Table 1 shows some information with regards to the case organizations in terms of general information and the current adopted health data standards.

Table 1: A description of each case including information on general, technological and standards.

		Healthcare Organizations					
		ORG_A	ORG_B	ORG_C	ORG_D	ORG_E	ORG_F
General Info	No. of Hospitals	5	3	4	1	3	2
	No. of Beds	2650	1129	1095	500	1034	1500
	No. of Physicians	2324	1275	852	447	1120	856
	No. of Nurses	4685	3062	2694	760	1665	1736
	Medical Universities?	Yes	No	No	No	No	Yes
	Education Centers?	Yes	Yes	Yes	Yes	Yes	Yes
	Research Centers?	Yes	Yes	No	No	Yes	Yes
Standards Info	ICD	10 AM	10 AM	10 AM	9 CM	9 CM	9 CM
	SNOMED	CT	CT	No	II	II	II
	CPT	No	Yes	No	No	No	No
	HL7	v2.3	v2.3	v2.3	v2.2	v2.2	v2.2
	DICOM	3.0	3.0	3.0	3.0	3.0	3.0

2. Participants

The intention of this study is to evaluate those standards being used in the case organizations in terms of the adoption process and particularly at the decision-making stage. The authors intended to focus on the target stakeholders whilst interviewing whoever was available as long as the person met the necessary study criteria as

informants. The purposive sampling method was used to identify the participants. A purposive sample was derived to identify all those people who were in charge in terms of the decision-making stage of the adoption process of health data standards. The IT departments of the selected healthcare organizations were contacted in order to identify the targeted informants. In addition, the chain referral or snowball sampling method was also used to identify other informants. This is because there are other people who are or used to be in charge in the decision-making stage and they are not affiliated to the IT department. A snowball sample was obtained by asking participants to suggest someone else who was appropriate for the study. However, through the snowball sampling process, some people and interviews were neglected based on the authors' knowledge and judgment as those people were found to be not appropriate for this study. A total of 33 senior managers were identified to be the main informants for this study as they agreed to participate in this research.

3. Data Collection and Analysis

Various data collection methods were used in this study including unstructured and semi-structured interviews and an analysis of existing documentation. Multiple data methods were used in order to overcome bias, which is considered to be dangerous in qualitative research, through data triangulation.¹⁷ The 33 senior managers were interviewed using unstructured and semi-structured interviews; these were recorded using a digital Dictaphone. All the interviews were conducted in person to ensure that an appropriate expert had the opportunity to participate in the research, give feedback and tell his/her unique story. The authors ensured that each interviewee felt perfectly free to talk openly when being recorded and gave their full consent without pressure to be recorded on tape. In addition, the authors took into consideration ethical issues when conducting the interviews. These included gaining informed consent and making assurances of confidentiality and anonymity. Table 2 gives a snapshot of some questions used in the interviews to evaluate at the decision-making stage the adoption process of health data standards in the case healthcare organizations. A hybrid approach of thematic and cross-case analysis was adopted to analyze the collected data. Different Computer Assisted Qualitative Data Analysis Software (CAQDAS) applications could have been used for analysis. However, QSR NVivo 8 software was employed since the final choice of software is often based on a combination of practical considerations and personal preference, which are usually based on subjective ease-of-use considerations.

Table 2: A snapshot of some questions used and asked during the interviews with participants.

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| <ol style="list-style-type: none">1. Could you specify the name of health data standards that are adopted in your organization?2. What were the main business problems and motivations the organization faced before adopting these standards?3. Who initiated the idea of adopting health data standards?4. What are your rules in the adoption and implementation process?5. Were there any concerns about the current IT infrastructure before adopting these standards?6. How are the selected standards being supported?7. What were the impacts of the adoption of these standards?8. Have any activities (e.g. promotion and awareness-raising and resource allocation) been carried out by the government to encourage and support the uptake of health data standards? Have you carried out any consultations with regard to health data standards? |
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The Current Health Data Standards

The health data standards, shown in Table 1, are described in more detail below and provide some reasoning regarding why the health data standards in each case organization were adopted.

1. ICD

ICD-9 Clinical Modification (CM) was the official system used in Saudi hospitals to classify and assign codes to health conditions and related information for in-patients. In 2005, the MoH announced the conversion to ICD-10 Australian Modification (AM) based on a Royal Decree. Since that time, only three healthcare organizations, ORG_A, ORG_B and ORG_C, have converted to this standard due to the lack of ICD-10 AM coders and owing to technical concerns. In addition, the cases which adopted the ICD-10 AM, have not integrated it into the hospital information system (HIS) owing to compatibility issues, and so, the applications of this version in those cases are based on standalone systems. One executive explained: *“the application of ICD-10 AM does not meet the hospital’s expectations since what we are looking for is to have it integrated into the hospital’s HIS system with the code finder system to enable physicians to assign automatically the proper codes for the treated cases.”* Nevertheless, ICD is being used in Saudi hospitals for different functions such as statistics, reports and benchmarking, and research.

2. SNOMED

SNOMED: Five healthcare organizations have adopted SNOMED including ORG_A, ORG_B, ORG_D, ORG_E and ORG_F. SNOMED has been adopted as a part of the lab information system as the cases follow and adopt the best of breed systems according to the availability of adequate budgets. So, if the cases need to use SNOMED in regular basis, they should update the SNOMED dictionary regularly and pay the license fees, as one lab information manager said: *“SNOMED falls within the lab information system so we should update the dictionary and pay the license fees if we want to use it on a regular basis.”* The data revealed that SNOMED is being used in a limited way in the lab departments of the case organizations. SNOMED’s main function is to register the cancer cases that are reported annually to the Saudi Oncology Centre.

3. CPT

Only ORG_B has adopted CPT to report medical services and procedures performed by the hospital for analytical, administrative and financial purposes. For examples, CPT is being used to measure the hospital’s performance and compare it, through international key performance indicators (KPIs) that have been introduced worldwide, to other leading international healthcare organizations. In addition, ORG_B provides medical services that are charged for so their medical services should be CPT coded in

order to facilitate the management of financial issues and to integrate their services with the insurance companies. However, CPT initially began 30 years ago when ORG_B was operated by an American medical group. In 2007, ORG_B developed its own customized CPT version to meet the hospitals' demands and needs, as one director said: *"we wanted to make sure that every medical service introduced by the hospitals was properly coded and so we developed our own CPT version with an American group to be able to benchmark with others and produce accurate reports and statistics."* This new version is a comprehensively coded medical services and procedures dictionary which was developed for different reasons such as for measuring productivity, providing statistics, benchmarking, research and billing.

4. HL7

All the studied cases have implemented HL7 with different versions. While some adopted HL7 v2.3, others are still using v2.2. This depends on the capabilities of the HIS systems. HL7 is mainly used to facilitate integration between clinical information systems. Every new system must conform to HL7 in order to integrate with the hospital HIS. In addition, each hospital has implemented the HL7 integration engine to exchange data seamlessly between the different systems, as one executive said: *"the ultimate goal is to make the messages across the systems uniform and, even more complicated, across the regions and hospitals, through the integration engine that will provide us with total ownership solutions and easy integration between the solutions."*

5. DICOM

All the studied hospitals have implemented the latest version of DICOM, which is DICOM 3.0. This is because the PACS system has recently been adopted in Saudi hospitals and the new PACS systems are DICOM 3.0 compliant. Since DICOM 3.0 has been chosen to be the communication protocol for integrating the different image systems into the PACS system, every image system is suitable as long as it conforms to DICOM 3.0.

The Role of the Current Health Data Standards

By analyzing the data collected from the study, the authors identified four reasoning perspectives that have led to the decision to adopt health data standards; these reasons are managerial, technical, educational and governmental. The following describes each perspective.

1. Managerial Perspective

The authors have identified various reasons behind the adoption of health data standards by the case healthcare organizations from a managerial perspective. These reasons are grouped into analytical, accreditation and performance factors. With

regards analytical purpose, data analysis is required for decision support systems; success or failure depends on the quality of data and how well the data are structured and predefined, as one manager stated: *“if we want to run reports across the systems, it will be difficult, if not impossible, if the systems do not conform to certain standards. We need accurate reports to support decision making.”* Concerning the second reason, one of the main initiatives taken by the top management in case organizations is the acquisition of certain accreditation from some leading international medical commissions, as one participant explained: *“the initiative of following certain standards comes sometimes from the management as one of the hospital’s aims is to be accredited by some international commissions.”* Being accredited means that the case hospitals not only provide high-quality medical services based on best practices, but also is internationally recognized as a highly standardized medical care bodies. In relation to the third reason, the case organizations have realized the importance of having a data warehouse system. This requires highly integrated systems and well-structured data to improve the hospitals’ performance; it also reflects on the quality of medical services and patients’ satisfaction. Moreover, having a well-structured data warehouse system helps the hospitals to measure their performance based on unbiased statistics and reports which are also in accordance with international KPIs.

2. Technical Perspectives

The main technical benefit for the case organizations of adopting clinical information systems based on standards is the increase of interoperability between the systems. In other words, standards normalize the communication between different clinical information systems, thus facilitating integration and data exchange between the systems. For example, one executive said: *“standards make the interface between the systems easier and this, in turn, facilitates the communication and integration between the systems.”* However, by enhancing interoperability between the systems, many technical benefits to the hospitals were reported such as increasing the scalability, portability, maintainability, consistency, uniformity, linearity, stability, accessibility, availability and efficiency of systems.

3. Educational Perspective

The majority of the studied cases provide excellent medical education and academic opportunities to conduct research, as well as opportunities to participate in industry and community service programs in the health field. For example, ORG_A and ORG_B have international medical research centers which aim to provide a specialized scientific environment that can support clinical research to help in promoting exceptional healthcare and the continuous development of diagnostic approaches and methods for the treatment and the prevention of diseases in Saudi Arabia. Since the research groups rely on the quality of the data provided by the hospitals, the case organizations are currently investing in the development of a standardized data warehouse in order to have robust information infrastructures to support education and research. One manager exposed: *“we need data to support our education system because we are an academic center with a research center and medical university.”*

4. Governmental Perspective

The case organizations are pushed by some government bodies, such as the MoH, the Saudi Oncology Centre and the Saudi Council of Cooperative Health Insurance, to adhere to certain standards such as ICD and SNOMED. This is because, for example, they are required to report some medical information annually to the MoH and Saudi Oncology Centre in order for those to produce medical statistics and reports, such as mortality data, concerning the health situation in Saudi Arabia in general. In addition, some tertiary hospitals have recently carried out treatment and provided medication for which patients pay direct. Therefore, they need to adhere to the standards of the Saudi Council of Cooperative Health Insurance in order to be linked with the health insurance companies. One manager said: *“in the absence of regulations, standards are driven based on need. However, ICD-10 AM is government-initiated and CPT is for billing and insurance purposes.”*

Discussion

The participants exposed that although several government entities and commissions talk about the standards, no one has taken the lead to develop and promote them in Saudi Arabia. Accordingly, few health data standards, including some messaging standards and terminology standards, were applied by the case healthcare organizations. The data revealed that the terminology standards are in limited profile use in the case organizations and so most of the data were built somehow based on a proprietary format structure; thus, exchanging medical data semantically among the hospitals or related medical groups in Saudi Arabia would be a future concern. In addition, obtaining meaningful insights into the medical information, through the provision of accurate statistics and reports, was limited due to the insufficiency of the data. The empirical evidence showed that every case healthcare organization is at a different stage in terms of adopting health data standards; they are therefore often based on the organization's needs and expectations such as from managerial, technical, educational and governmental reasons.

In the literature, these reasons were validated. For example, the interoperable infrastructures available to healthcare organizations create a vast potential for quality improvement since they allow such organizations to measure their performance through the use of international standards and definitions, and thereafter benchmark their care against other healthcare systems.¹⁸⁻¹⁹ 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.²⁰⁻²¹ 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.^{4,14,22} 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 which validates the technical integration reasoning perspective.^{2,4,23-24} The governmental reasoning perspective was also seen by the related studies in the literature as the bottleneck to the adoption of health data standards in every nation. However, the senior managers explained that the lack of the

government actions and role in Saudi Arabia were seen to have a negative impact on the adoption of health data standards. 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.²⁵

Healthcare systems in developing countries vary immensely between regions and geographic areas. This variation results in inequities and uneven development infrastructures which make the integration between the fragmented areas and systems more complicated.²⁵⁻²⁶ In addition and with the lack of national regulator, managing medical information and data exchange in the healthcare sector were an issue in those countries. For example, Greenhalgh et al. (2010) stated that information governance controls, access to information and gaining patients' consent were barriers to the development of a shared national electronic health records.²⁷ Similarly, Zhang et al. (2007) found that legal and ethical concerns (privacy and security) were barriers to the development of standardization for health data in China.²

Equally important for the existing of national regulator 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.²⁸ If hospital staff were more knowledgeable about standards, there would be fewer advocator obstacles and lesser user resistance against them.²³ 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.⁴ Nevertheless, Table 4 provides a set of recommendations to foster the adoption of health data standards, and so, facilitating the future direction of medical data exchange between healthcare providers in Saudi Arabia. These recommendations have been developed through the related literature and the participants.

Table 4: A set of recommendations to help in fostering the adoption of health data standards

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| <ul style="list-style-type: none">■ There is a need for the existence of a national formal reference for health data standards to lead the development and the promoting of the adoption of the standards in the country. It should also become involved in the existing international standardization initiatives, and then customizing international ones according to local needs. In addition, it should monitor and govern the national market so that every system will be certified before it can be marketed. Moreover, the formal body should cooperate and coordinate with the Ministry of Higher Education and different national universities to redesign the curriculums of medical colleges and to establish a new education program of health informatics to overcome the shortage of national professionals in the area of medical informatics.■ There is a need for an agreed national strategic direction regarding medical data exchange between the different medical entities. Part of this plan is to examine the hospitals capabilities and to set and define the standards, policies and information specifications which are required to enable medical data exchange. In addition, 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 for when there is need to show the impact of health data standards on clinical information systems or for the hospitals in general.■ There is a need for change management programs at both national and organizational level. The dedicated programs must insure the national healthcare sector is redesigned to operate as an integrated, coherent system with clear policies and workflow mechanisms. In addition those |
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programs should ensure that highly collaborative approaches are undertaken by the hospitals to regulate successfully the rate of change required for promoting the adoption of health data standards. This is because there is a need to examine technical implementation metrics, measures of acceptance, and the use of health data standards by staff and physicians.

- There is a need for medical information management plan, at the level of how data are, for example, predefined, characterized, structured, stored, exchanged, integrated, accessed and governed, at both national and organizational level. This step is the first part toward the development of national health information network. However, this plan requires the significant involvement, engagement and commitment of the hospitals' managements and the clinical community. This is because there is concern about the privacy and confidentiality of patients' information since there is no specific health privacy legislation governing hospitals in Saudi Arabia.

Conclusion

Due to the lack of national action regarding the adoption of health data standards, little is known of their current status in Saudi healthcare organizations. In addressing this gap in the research, an interpretive, qualitative, multiple-case study method was used to investigate the application and roles of health data standards in Saudi tertiary hospitals. An analysis of the qualitative data that were collected revealed that Saudi hospitals are currently at different levels of adoption of such standards. Various terminology and messaging standards have been adopted including ICD, SNOMED, CPT, HL7 and DICOM. The data also revealed that the hospitals have adopted standards from several perspectives, including for managerial, technical, educational and governmental reasons. The original nature of this work makes a contribution to the body of knowledge in the field of health informatics since academics and practitioners, who are devoted to the on-going use of health data standards, still lack a significant body of evidence with regard to the applications and roles of health data standards in developing countries. In addition, this work provides those with an interest of planning of health data standards in the developing world countries with a set of recommendations in order to promote the adoption of health data standards. This work also provides health authorities with a deeper understanding of the current status of health data standards in Saudi Arabia and an analysis of the benefits and roles of health data standards. However, the authors suggest that further studies should be conducted into the barriers that face the adoption of health data standards in hospitals in order to define a holistic approach, based on best practice solutions, to provide recommendations to aid healthcare authorities in developing their informatics systems.

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