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The Healthcare System in Saudi Arabia and its Challenges: The Case of Diabetes Care Pathway

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Abstract. The advances of Information Technology (IT) play an important role globally in improving quality and capacity of healthcare sector. IT helps the health professions in managing resources and increasing productivity effectively. Although the conversion from paper to electronic patient records (EPR) conveys many benefits for both caregivers and caretakers, but also has brought many challenges in different aspects. Hospitals have implemented EPR to different degrees. They have used a set of standards in order to insure that data is accurately and consistently processed. Even though, the standardization of how data are captured, exchanged and used includes a set of complications that should be discovered to provide better health data quality for patients with multiple healthcare providers. Therefore, through an analysis of the EPR systems utilization in Saudi Arabia and the diabetes care pathway, three factors have been determined. These factors affect the workflow of the implementation and utilization of health information system (HIS) in terms of capturing, sharing and using its data efficiently.

Keywords. HIS, EPR, information sharing, social factors, standards, health information management, diabetes care pathway, health informatics, data capturing, data sharing, Saudi Arabia.

1. Introduction

The technology investment in health sector has importance in the management of healthcare services delivery in the developing countries. It is necessary to enhance the utilization as well as the implementation of HIS through standardizing the medical data in order to have a better data quality and more reliable system. As such, a stronger health information infrastructure is essential.

The developing countries such as the countries of the Gulf Cooperation Council (GCC) are new investors in the field of heath informatics. Health informatics can be defined as a multidisciplinary field used to improve the processing and managing of healthcare by providing an advanced technology to provide sophisticated medical services [3, 70, 71].

Due to the development of technology field, healthcare in Saudi Arabia has gradually shifted from a traditional paper approach to the use of electronic patient record systems. The term *electronic patient record* (EPR) has been defined by the *National Health Service* (NHS) as 'an electronic record of periodic healthcare of a single individual, provided mainly by one institution'. Adopting an EPR strategy has its advantages and disadvantages in supporting the health system [4]. Many benefits have been achieved by implementing EPR systems like improving the quality of healthcare performance, decrease disparity in health between countries and providing more effective care due to a reduction in error rates such as transcription errors [5].

However, the move from a paper-based system to EPR systems is also challenging because of the complexity of managing the health information system alongside the wide range of stakeholders involved in the healthcare pathways.

EPR systems have been implemented in various Saudi hospitals without first ensuring integration and coordination between those systems. The diversity among systems reflects the need for a universal standard classification system that can enhance the quality of transferred information, improve its structure and provide international data integration with reliable management. Such a universal standard classification system also promotes the analysis and research of morbidity data in timely manner, and reduces potential medical errors [6].

Thus, a profound study of the HIS and EPR in the Health sector of Saudi Arabia forms the basis for this paper. A narrower case study has been adopted to give a full focus for the Diabetes Care Pathway specifically.

The prevalence of type 1 diabetes among Saudi Arabia's children has been ranked as the third-highest in the world with a rate of 31.4 per 100,000 children [2].

In terms of type 1 diabetes, primary care and secondary care for diabetic patients are provided by multidisciplinary teams. Therefore, many health professionals are involved in creating, sharing or accessing the EPRs [7]. This can lead to difficulty in designing a standard national or regional network for health records.

Therefore, this case study provides an overview of the healthcare system in Saudi Arabia alongside the use of HIS and EPR. The adopted research methodology is discussed and analyzed. The diabetes care pathway for type 1 is provided. Its main challenges including data capturing, data sharing as well as the human factors are explained in depth. The deliverables of this preliminary study can be used by corresponding

authorities in Saudi Arabia to overcome the pre-mentioned challenges and produce an effective health information system.

2. Research Methodology

According to Creswell [72], Research methodology is defined as a formal guideline for solving a problem professionally or a systematic way to solving a problem via a novel design for the suggested solutions.

There are different types of research approaches; these include qualitative approach, quantitative approach and mixed approach, which is a mixture of qualitative methods and quantitative methods.

In this case study, a combination of three methods have been adopted due to the nature of this research questions that need the use of multiple methods in order to provide the suitable answers. Multiple methods offer great features in terms of the flexibility of overcoming the research complications, the strengths of using multiple approaches and the capability to answer more broader questions [72, 73].

As such, a literature review, qualitative and quantitative research methods have been used.

The study was carried out in Central and Eastern regions hospitals of Saudi Arabia. Several visits and observations were conducted which helped in obtaining a clear understanding and a full picture about the key issues of current HIS in terms of its implementation and utilization .

The data collection methods contain multiple types that direct the study in a proper manner to explore the opinions of both caregivers and caretakers about the current health system challenges specifically in the case of diabetes care pathway. Those methods include the review of reliable sources of information (organisational website, research papers, reports, etc) besides conducting surveys, group discussions and interviews with the partners, end-users and key stakeholders, if possible.

After applying those various techniques, a comprehensive analysis alongside a delicate assessment have been performed in order to draw a clear outline. This has facilitated defining the key challenges surrounding the implementation and utilization phases of the HIS that cover data capturing, data sharing and human factors.

2.1 Research Methods Discussion

Health informatics is an emerging field in the developing countries. The number of research studies is still few compared with the developed countries [3].

In this study, different issues have been discussed using the pre-mentioned research methods to determining those key challenges. Narrowing the case study to a specific care pathway is to ensure collecting accurate and reliable data in a timely manner instead of distracting the researcher concentration to the whole domain.

Thus, the research methods as well as research questions are mapped together to clarify the reasons behind adapting the current classification of challenges.

The following table gives a sample of the questions used in determining the case study criteria.

Table 1: Mapping the research questions to the research methods

Research Question	Literature Review	Interviews and Surveys
1- What are the key challenges with the electronic patient record system EPRs in regard to data collection and reporting methods among healthcare providers?	Review the literature on the current health information systems in the developing world to investigate the challenges behind health data collection methods.	Asking HIS experts, health professions and other stakeholders from the selected hospitals to define the limitation that they face, such as: • Limitation of efficient health data processing and capturing tools. • Lack of accuracy and consistency in reporting health data. • Fragmentation of health information system due to the multidisciplinary teams that are involved in the different care pathways.
2- What are the main factors that affect data quality and consistency in the current HIS?	Review the literature on the current health information systems in the developing world to investigate the current level of data quality and consistency in HIS.	A set of issues has been covered through this question, such as: • Lack of reliable communication infrastructure among health facilities. • Not all the code sets are complete. Ex: example, ICD-9-CM diagnosis codes do not include detailed classifications of asthma that affect treatment decisions. While ICD-10-CM codes do include them.

		• The enhancement to some code sets diminish the full interoperability between health information systems. • The quality of the original documentation due to the many numbers of people who enter data with different levels of training.
3- Who controls the data and how can we get access to it?	Review the literature on the current health information systems in the developing world to determine the proper access level of system users.	Stakeholder, admins, technicians, physicians and all other caregivers types with different access level to ensure privacy and confidentiality of patient data. • Ex: some HIS systems do not allow researchers access, while others allow access to different contents of HIS.
4- What are the privacy and confidentiality issues that must be considered?	Review the literature on the current health information systems in the developing world to determine the main issues of HIS in terms of privacy and confidentiality.	The question leads to the fact that the technology solutions are moving faster than the privacy and security solutions, which is a critical problematic. Examples of those issues (but not limited to): • Un-updated or inappropriate policies. • The use of different EPR systems. • Data access level specifications. • Insufficient awareness programs. • System reliability factors.

Consequently, combining literature review with quantitative and qualitative methods address the research questions and expand researcher's knowledge effectively. In case of literature review, the state of art is considered through using the latest published articles besides reliable resources.

The survey and interview results present a realistic picture of the current status of HIS systems across some Saudi Arabia's hospitals. They reflect the current problems that are more likely to happen and their circumstances.

3. Healthcare System in Saudi Arabia and Electronic Patient Records (EPR)

The Ministry of Health (MOH) in Saudi Arabia is considered by the government as the main provider of healthcare services in Saudi Arabia. The MOH is responsible for a total of 244 hospitals and 2,037 centres of primary healthcare (PHC).

The healthcare services of the MOH are classified into three levels: primary, secondary and tertiary. Primary care services such as preventive and curative care are provided by PHC centres; if a case requires more sophisticated care, then it is referred to public hospitals for the secondary level of care, while cases that need more complex levels of care are transferred to central or specialised hospitals (the tertiary level of healthcare)[7].

Due to the hybrid approach that has been used in the Saudi health sector, healthcare processes might include recording information both electronically and on paper.

4. The Case of Diabetes Care Pathway in Saudi Arabia

Multidisciplinary teams are involved in providing the required healthcare to type 1 diabetic. The composition of the healthcare team might include physical, psychological and sometimes acute illness care, as diabetes mellitus type 1 can be a complex health condition. Thus, multiple systems will be used by practice physicians, diabetes specialists, nurses and other medical staff from different organisations to capture and share data [8, 9].

In Saudi Arabia, A patient begins the treatment process through three stages. The processes of admission, treatment and discharge include recording information both electronically and on paper due to the hybrid approach that has been used in the Saudi health sector [10].

4.1 First stage: Diagnosis

This stage starts at the PHC centre where the patient's record is.

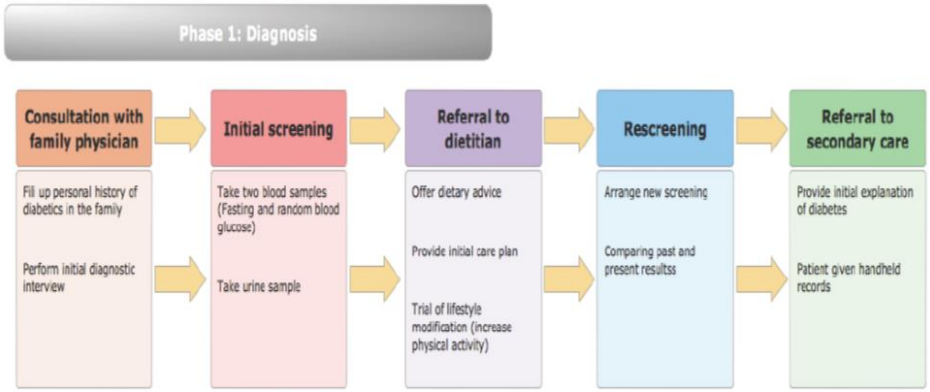

Figure 1. First Phase

4.2 Second stage: Treatment and complications management

In this stage, the patient will be referred to several consultants to screen for complications.

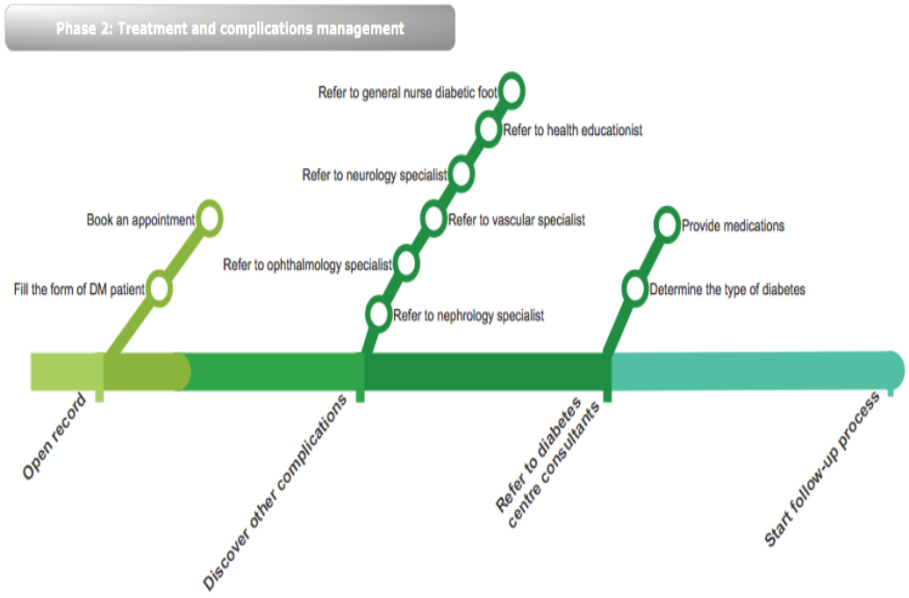

Figure 2. Second Phase

4.3 Third stage: Maintenance

In this stage, the patient will visit the diabetes centre periodically and will continue to see the consultants once every two or three months.

Even though the hospital is a single organisation, sharing the captured information is considered a critical challenge. In the last two stages, a wide range of people are involved with different knowledge bases, needs and systems, leading to the use of different standards and outcomes formats. The diabetic care pathway example reflects the use of a "best of breed" approach rather than an "all-in-one" approach [11].

An all-in-one approach is based on one super system to perform all healthcare services, while a best of breed approach includes different specialised systems. The best of breed approach overcomes the challenges of replacing the infrastructure with a completely new system; such replacement is time-consuming, costly and affects the healthcare workflow due to staff training needs. Each part of a best of breed system is intended to meet its professionals' requirements and reflect their needs in terms of usability and design [12]. This is more efficient and less disruptive, and is commonly used by health sector systems [13].

However, making the separate parts of a best of breed system work together professionally with their myriad functions is quite challenging in terms of ensuring interoperability between hospitals and PHC systems. Moreover, there are still types of information that are preserved on paper and cannot be accessed outside the organisation [12, 13, 14, 15].

As such, the procedures of capturing, managing and sharing the data of diabetic patients among varied systems cross organisation boundaries and become more complex. The perfect access between the organization parts can be accomplished by using consistent standards to ensure the compatibility and integrity of morbidity data [7]. This pathway includes many challenges that need to be overcome; these are explored individually in the following sections.

5. Challenges:

5.1 Data Capturing Challenges

Electronic records acquire an exaggerated level of trust from the medical staff in diagnosing the patient's health status, alongside designing efficient care and treatment plans.

Both hospital staff and patients have benefited from the move to electronic patient records systems (EPRs), but EPRs have also posed many challenges in capturing data accurately and sufficiently in the utilization phase. Despite the fact that EPR features contribute to preventing errors, they present also new risks that become more challenging with large and networked EPR systems. Data entry errors, incomplete details, improper format and illegible data are the most frequently seen limitations of data health quality with EPRs. Those challenges create hurdles to the process of retrieving and producing the required information for analysis and research purpose. Further exploration of these issues follows [16, 17]:

5.2 Data Quality and Lack of Standards

The activities and processes of the diabetes care pathway are not simple and straightforward. Many clinical systems with different needs are involved in this pathway, which use various coding systems and data structures for classifying identical clinical concepts [18]. Even though there are high expectations by the health services' users for the efficiency of EPR systems, many challenges have been encountered.

Firstly, there are common errors in terms of the quality of data collection, such as data entry errors, data omissions, data conflict, incomplete data and data ambiguity. These errors might result from poor training and awareness for medical staff; this can lead to improperly capturing information [19]. Additionally, there is a challenge of providing efficient communication of the patient's complete medical details due to a lack of interoperability between various systems [18].

Consequently, there is an urgent need for adopting standard clinical terminologies and classifications to present classified and coded medical data. Those standardised data provide the same coding for the same disease; this addresses the problem of inconsistent format, data conflict and data-entry errors as much as possible [20].

Health data standards depend on the use of clinical coding, which plays an important role in addressing the data capturing and sharing

issues. Clinical coding has been defined by NHS as the translation of the clinician's description of the patient's health status, which includes his or her 'problem, diagnosis and treatment', to be presented in electronically coded format. This provides data in a tabulated form to be stored and used for national and international statistics, analysis and research with appropriate management [21]. In the healthcare sector, many different classification systems with varied editions have been created to be used in coding morbidity data. The most widespread of these are: ICD codes, OPCS4, ICPC, read codes and free text [22, 23, 24].

To clarify the concept of standards, some authors have defined the three types of health data standards: Firstly, the terminology standards are meant to guarantee the consistency of terms definitions when they are employed by multiple users. Secondly, messaging standards are intended to determine the communications among registry systems and electronic health record systems. Finally, functional standards provide efficient decision-making in a timely manner and proper management using specific rules [25].

Additionally, health data standards have been classified into six types: messaging (e.g. HL7 and DICOM), document (e.g. CCR and CDA), application (e.g. CCOW), conceptual (HL7 v3 RIM), terminology (e.g. ICD, LOINC and DICOM) and architecture (e.g. PHIN) standards. For the purpose of clarification, messaging standards are used to support integration and consistency for proper data flow between various systems by assigning the format, data elements and structure of messages. The terminology standards are intended for clinical concepts to produce consistent codes and terms for diagnoses, health problems, etc. Document standards determine information types in the clinical notes and the way to locate them. Conceptual standards prevent the transferred information among the systems from losing its meaning or context. Application standards define the main processes of medical procedures and the systems interaction. Architecture standards determine the process of storing and disseminating the medical data [26].

In terms of data collection, terminology standards are the target to be investigated.

- *International classification of disease*

International classification of disease (ICD) is one of the most popular classification systems for mortality and morbidity data in the world; it was developed by the World Health Organisation (WHO). ICD is based on a complex structure with precise details, which makes it preferable in hospitals. ICD has many versions that have been adopted in Saudi hospitals. ICD-9 Clinical modification (CM) was officially used in Saudi

hospitals until 2005, when the MOH decreed a transition to the latest version of ICD, which is ICD-10 [27].

However, ICD-10 has some shortcoming in covering detailed clinical requirements and specifications. Consequently, the developed countries have added specific modifications to the codes and issued their own versions to support their specific applications and needs. Australia (ICD-10-AM), Canada (ICD-10-CA), Thailand (ICD-10-TM), United States (ICD-10-CM), Germany (ICD-10-GM) and others have been authorised by the WHO to published their own versions [28].

Australian modification (AM) has been adopted by some Saudi hospitals, while others are still using the ICD-9 edition. The lack of ICD-10 AM coders and its technical issues have led to incomplete integration of it through the hospital information systems. The use of ICD-10 applications has been restricted to standalone systems due to compatibility problems [27].

In fact, the difference among those versions might affect the goal of ideal communication to support statistics, research and analysis internationally. Therefore, it is essential to state the difference between these versions. First of all, it is worth noting that the modifications to the original ICD-10 classification have been regulated by the WHO. Before any alteration, a country intending to modify the system must request prior permission from the WHO, which holds the copyrights to ICD-10. Additionally, all modifications to ICD-10 must satisfy the conventions of the WHO for the ICD, by adhering to some restrictions. The restrictions prevent the modification of 3- and 4-character codes in the content, meaning and the codes titles. This is an attempt to mitigate any potential compatibility problems that could affect the evaluation of morbidity data globally [29]. The varied versions of extended ICD-10 result in a set of problems that pose considerable challenges in tracking these modifications by WHO in order to accomplish efficient communication for comparing, studying and exchanging morbidity data internationally [6, 28].

Four challenges are introduced for evaluation by Jetté, N et al. and Manchikanti, L et al. Firstly, the WHO version of ICD-10 doesn't contain the new added codes of country-specific modifications. For example, the Thailand edition of ICD-10 has 36,586 codes compared with 12,420 codes in the original edition. Thus, the modified versions have increased their new entry codes significantly compared to the original ICD-10. Secondly, changes in the main structure of the ICD-10 classification versions complicate the process of comparing morbidity data globally, especially at the sub-digit level. Many changes have been applied to various

categories at the digit level; these involve the 4th and 5th digits alongside the additions in the United States (ICD-10-CM) and Canadian (ICD-10-CA) versions for the 6th level. Those changes lead to inconsistency and difference in defining codes at the subcategory level among versions [6, 29]. For example, the code M41.51 refers to 'septicemia due to pseudomonas' in the Canadian modification, while in the Australian modification it refers to 'sepsis due to Escherichia coli' and 'septicemia due to Escherichia coli' in the German version. Moreover, the difference might appear differently at the main category level. For example, the American modification defines 'E09' as 'drug- or chemical-induced diabetes', while it has been defined as 'impaired glucose regulation' in the Australian modification. Furthermore, the original version of ICD-10 does not include the 'E09' code [6, 29].

Thirdly, the main condition or primary diagnosis might be defined differently on the various ICD-10 clinical modifications, leading to great challenges in exchanging morbidity and diagnosis data internationally. The WHO ICD-10 identified the 'main condition' or 'Principle diagnosis' as 'the condition diagnosed at the end of the episode of healthcare, primarily responsible for the patient's need for treatment or investigation. If there is more than one such condition, the one held responsible for the greatest use of resources should be selected'. This definition has been accepted by Canada while Thailand, Germany, Australia and United States have made different definitions for their diagnosis. Therefore, the difference in main condition definitions results in disease miscoding at the primary diagnosis phase, followed by misdiagnosis of patient health conditions by the physician in the secondary diagnosis phase due to the problems of miscoding. A serious consequence might occur when a patient is misdiagnosed and gets the wrong treatment.

The fourth challenge, beside the predefined problems, is language issues, which also impact healthcare communication globally. The WHO has introduced six official languages of ICD-10 (Arabic, Chinese, English, French, Russian and Spanish). On other hand, some countries with multi-racial backgrounds need more than one language version of ICD-10 to cover their domestically used languages. Additionally, some countries' languages have not been covered by ICD-10 versions. Accordingly, a number of ICD-10 translations have been published, increasing the count to more than 42 language versions. Thus, the use of a wide variety of languages results in complicating the consistency among the various translations of ICD-10 [6, 29].

Within the scope of ICD-10, a meeting was conducted by the WHO Collaborating Centres in order to develop a metadatabase, which is being

referred to as ICD-10-XM. This product will be suitable for the countries without their own clinical modifications, in addition to helping to preserve comparability among existing ICD-10 modifications.

The ICD-10-XM metadatabase is expected to involve different versions of ICD-10 countries' modifications, eliminating the need for costly software for conversion mapping. ICD-10-XM can be considered as a platform for ICD that helps in reaching ideal convergence between modifications versions. Moreover, it will help in reviewing and updating the upcoming ICD-11, which is expected to improve the international comparability of morbidity data. ICD-11 will be released in 2015 [28, 29, 30].

Although ICD-10 is perfect for use in secondary care due to its very detailed structure and elements, it is not suitable and reliable for primary care use. According to investigation by Wockenfuss et al., ICD-10 provides moderate reliability and some coding errors when used in the primary care sector [31].

ICD-10 does not deal with many non-disease conditions, psychological and social issues that are processed within a general practice. Primary care needs systems provide small and easy terminologies. ICPC (international classification of primary care) is one of the most famous classification systems; it is intended for the primary care sector. WONCA (World Organization of Family Doctors) has developed many versions of the ICPC that are widely used in Europe and Australia as well as in Saudi Arabia. The Saudi Society of Family and Community Medicine (SSFCM) is one of WONCA's International Classification Committee Members [32]. ICPC-2 has exceeded the ICD-10 in processing administrative tasks and care procedures such as referrals, tests etc. [33].

Thus, data collection and encoding in primary healthcare centres are conducted using the latest version of ICP (ICPC-2) [34]. Coding with ICPC has its shortcoming in providing effective communication and comprehensive clinical codes due to missing some diagnoses. As with ICD-10 modifications, some countries have added more diagnostic codes as well as more than one diagnosis text option per code. According to one study, the evaluation of the ICPC-2 framework leads to the observation that the English version of the code L82 ('congenital anomaly musculoskeletal') corresponds to 82 options in the Norwegian version. With respect to multi-language support, the ICPC provides translations for 22 languages, resulting in some challenges in term of consistency [35].

In term of ICPC defects, there are some issues that need to be considered. Firstly, a lack of high level granularity results in the need for

supported systems to be used in clinical care as with ICD-10. For example, the code F99 refers to other diseases of eye, which is counted as a barrier to efficient interpretation of coded data. Secondly, the objective results, which are presented during physical examination or investigations, are not involved in ICPC-2 codes [36].

Thirdly, the development of ICPC-2 supports the easy transformation of codes among primary and secondary care systems. However, there are still some issues need to be considered in the case of conversion between ICD and ICPC. One of these issues is the difference in the level of diagnostic comprehensiveness of health conditions where ICPC connects to ICD. It is a considerable challenge to map the correct disease codes and diagnosis between the primary and secondary healthcare systems. Some ICPC-2 codes that cover some specific problems might be converted to a general code in ICD-10, and vice versa. For example, 'other diseases' in ICD has been mapped to a code of a specific social problem in ICPC-2. Further, ICD codes may refer to some common diseases in hospitals that are rarely used in general practice. Additionally, there is inefficient mapping between ICPC and ICD-10 to provide the feature of one-to-one code matches, leading to an increased number of misinterpretations of coding and diagnosis. For example, 'P74' refers to anxiety disorder in an ICPC-2 code, which is cross-referenced to four codes of ICD-10 [36, 37].

Another perspective to be considered is the issue of upgrading the codes of the classification system. This refers to the inability to remove the predefined concept codes from the system. This problem continues to increase if there is no efficient management mechanism. The mechanism must preserve the old concept codes and their descriptions to be used only with the outdated data and at same time not to be used in capturing new data. The continued use of those codes leads to incorrect results. In the UK, the Read Code classification system version 2 (Read v2) was mainly used in the primary healthcare sector beside minority use of Clinical Terms Version 3 (CTV3). Read v2 has the previously mentioned problem, publishing 43% of its codes that are no longer used but still represent 20% of new clinical codes, leading to serious problems in clinical reporting and analysis [38, 39].

Read v2 classification has its drawbacks in providing high-level performance for general practitioners' workflow. It provides five levels of details strictly based on a fixed single hierarchy, which leads to restricted structure. The concepts in Read v2 are inferred directly from specific concept codes and must have only one parent. For example: any concept beginning with C10 refers to a form of diabetes mellitus; C10E indicates type 1 diabetes mellitus. Additionally, the vast majority of codes in Read

v2 exist at the last (5th) level and have no children. This means that all the forked cases that are children of a code are represented at the same level as siblings. For example, ophthalmic complications of type 1 diabetes are coded in parallel with the parent as follows:

- C10E1 refers to type 1 diabetes with ophthalmic complications.
- C10EF refers to type 1 diabetes with diabetic cataract.
- C10E7 refers to type 1 diabetes with retinopathy.

There are also inconsistency problems that arise in Read v2 code. Read v2's concepts can be re-used with completely different meanings, as has happened in England and Scotland. For example, the code '9NDA' in Scotland refers to 'immunology report received', while in England it refers to 'Social Services report received'. This conflict leads to great challenges when data are collected, analysed and exchanged internally and externally [38,39].

5.2.1 Lack of Efficient and Effective Design

According to Jensen et al. (2010), one of the main challenges in capturing data via EPR that is not meeting the needs of all physicians and medical staff. EPR allows physicians to express their own diagnosis, ideas and opinions in a limited space. Moreover, the structure of records might be not suitable or preferable for a physician and cannot be restructured.

Therefore, there is a lack of efficient EPR design in terms of its structure and contents. Additionally, collecting the health information of patients is considered a challenge due to the sensitivity and importance of a patient's information, which complicates the process of grouping them [10].

Much research suggests that EPR can be associated with the use of paper to provide more space as well as a reasonable level of flexibility for physicians and staff.

5.3 Data Sharing Challenges

Transferring electronic patient records between primary and secondary healthcare is considered as one of the most serious challenges. In the UK, 10% of patients move between general practitioners yearly, which requires transferring the 'EPR' to help in providing high-quality care for patients [40]. As seen, medical information collected by different people or systems makes the process of exchange significantly difficult. Further,

the increasing number of classification systems requires specific conversion tools to ease the transfer process among them [41].

Due to this situation, hospitals, doctors, pharmacists, laboratories and patients need to be connected with each other to mitigate any potentially harmful errors and to present accurate care. Those transferred records should resemble ‘native’ record entries to be easily processable and retrievable for analysis. When a patient record is transmitted, data privacy, integrity and authenticity must be taken into consideration. Thus, there is an urgent need for information exchange standards that provide interoperability between those systems in a secure manner [42]. Interoperability has been defined as: ‘Interoperability is integrated connectivity. Interoperability enables data and information generated by one system to be accessed and re-used in a meaningful way by another system, whether or not the latter system is based on different technologies’ [43].

5.3.1 Standardisation Barrier

The healthcare sector tries to solve data-sharing issues from different aspects. In the UK, there was an attempt at centralised implementation of standard healthcare applications under the National Programme for IT (NPfIT), which has not continued as planned. As Health Secretary, Andrew Lansley said, ‘Labour's IT programme let down the NHS and wasted taxpayers' money by imposing a top-down IT system on the local NHS, which didn't fit their needs’ [44]. Thus, NHS has changed its policy of ‘replace all’ to ‘connect all’, which allows the use of existing applications with the ability to improve their integration for interoperability purposes. From dream to reality, the NHS has introduced the Interoperability Toolkit (ITK) in 2009. ITK is not software or a product to be downloaded but a group of standards, frameworks and implementation guides for making health systems interoperability possible. ITK aims to reduce the risks of losing data quality, present consistency for system integration and greatly decrease the integration costs and complexity among the individual applications with bespoke interfaces or different standard interfaces across local health communities [45].

The ITK is an attempt to provide a unified specification as well as recommended technologies to ensure interoperability and consistency for a wide range of healthcare members [46]. The specifications of ITK include:

1. Core service definitions: the applicable services that are defined through ITK.
2. Transmission specifications: the ITK main methods for messages transport, such as web services and Data Transfer Services (DTS). These methods include the contributions of elements like web standards-based protocols with a flexible security layer that protects data in transmission from becoming compromised.
3. Architecture specifications: The specifications of expected technical framework of ITK-accredited applications.
4. Distribution specifications: The specifications of information dissemination by defining the criteria of the routing transmission and its payloads details.

To reach a high level of standardisation, ITK includes an accreditation scheme that involves a set of its specifications and policies for the health market [47].

- *Messaging standards of health data*

For the purpose of development, it is essential to adopt standards between health organisation networks that provide interoperability and sharing in an effective manner. ITK adopts many standards such web services standards, transport protocols like simple object access protocol (SOAP) and different versions of Health Level 7 (HL7) [27, 47].

The latter has been officially adopted by all Saudi hospitals with versions v2.2 or v2.3, according to the capability of the hospital information system. Health Level 7 (HL7) is considered the most common messaging standard in terms of healthcare interoperability [48]. HL7 is the global authority on standards, which ensures interoperability for health information technology with over 55 member countries. It is a non-profit organisation that was founded in 1987 and has been accredited by the American National Standards Institute (ANSI). Its role has been to introduce a comprehensive framework and related standards to enhance the sharing, integration, transfer and retrieval of electronic patient records [48].

The main aim of HL7 is to design qualified standards to enhance semantic interoperability among all platforms. This lead to the expansion of the scope of HL7 standards to cover the representation of clinical documents like discharge summaries and progress notes. Those document standards contribute to the present HL7 Clinical Document Architecture (CDA), which was approved by ANSI in November 2000.

Thus, HL7 is used essentially to accelerate data integration within clinical information systems. Any new system must satisfy the HL7 requirements in order to be compatible with hospital EPRs. Therefore, each hospital is able to exchange data smoothly by applying the HL7 integration engine throughout its EPRs [27, 49].

The HL7 standards have two broad versions, which are version 2 (V2) and version 3 (V3). V2, which was published in 1987, is the most-used one, with its many editions. V2.7 is the latest modification, which was released early in 2011. The newer version, V3 was first published in late 2005 and constitutes only a small portion of real-world usage [50, 51].

Standardised and demonstrable format has been assigned to HL7 messages. Therefore, understanding message format and syntax of HL7 is essential to accommodating the exchange of workflow. In version 2, each message consists of a set of segments. An abstract message syntax table will be assigned to describe the overall structure and message contents; these definitions are applied in order of occurrence of each segment. Additionally, V2 determines whether the segments are optional and can be repeated or mandatory and might not be repeated. Messages are sent as a response to trigger events. The message type and a trigger event will compose the message name. For example, a general acknowledgment message is symbolised as ACK [52].

However, there are many challenges have been encountered in V2; these can be listed as follows:

1. Lack of consistent data model for application.
2. Privation of modal methodologies to regulate the data elements of messages. This leads to inconsistency and difficulties in recognising the relation between message elements.
3. Shortcoming in defining application and user roles accurately and making these the vendor's choice. This leads to a huge variation in definitions, where clinical functions are assigned to messages when two different applications use the standards of HL7 V2.
4. Not comprehensive enough to cover international needs [53].

In the early 2000s, the HL7 standards community decided to handle the challenges of HL7 V2. The new HL7 V3 standard aims to ensure internationalisation of HL7, allowing it to be used globally and meet multiple needs effectively. V3 provides a consistent data model, clear definition of roles makes it less expensive to build long-term interfaces and provides fewer options in message elements. Those strict standards

and models ensure easier interfaces and efficient exchange of messages [53].

According to one [54] study, the unambiguousness of data and its syntax alongside semantic features when data is exchanged is considered the most critical issue to be handled in V3.

This refers to computable semantic interoperability, or CSI. Consequently, the main core of V3 is based on 'Four pillars of computable semantic interoperability', which are:

1. Common model to cover different domains and interests, which is known as the 'Reference Information Model'.
2. Framework includes clear definitions of the semantics of message elements while a message is transferred, based on robust data type specifications to prevent ambiguity.
3. Strong infrastructure for specifying and binding values for message elements using concept-based terminology.
4. Well-designed methodologies to define the process of data interchange structures.

However, the four pillars have not covered other critical data-sharing issues such as security, auditing or terminology management services, which are left to be supported by the vendor or IT expertise [54]. Additionally, HL7 V3 is not compatible with V2, which means that applications with existing V2 interfaces cannot communicate with interfaces of V3 without considerable modification. Thus, applications must support both versions currently; this is considered the main challenge of V3 [53, 54]

Within the scope of HL7 overall challenges, supporting the need for local-variant users is still a critical issue. Therefore, the existing HL7 general framework, which requires local customisation or profiling in the deployment is vulnerable to the continued risk that each vendor will customise HL7 differently, compromising the interoperability goal of healthcare systems [55, 56].

In the UK, there was an attempt to solve the customising and communicating issues by developing HL7 UK, which is a dependent organisation to HL7. It has been founded to satisfy the UK's health sector needs by reporting any UK-specific needs that are not met by original HL7 standards. HL7 UK is used as a single contact point for all HL7 versions in the UK. It also provides a 'forum' to discuss interoperability standards,

effective implementation guidelines and secure information flow issues by healthcare professionals [57].

Despite the challenges of HL7, it supports the patient care pathway by allowing the use of multiple resources for population care. The care pathway involves many health information systems that need to be connected together through a comprehensive framework using the standards of HL7 for exchanging and integrating electronic health precisely.

5.3.2 Privacy and Security Issues

One of the main challenges in data sharing is system security for the patient's record information. According to one [10] study, most electronic information systems are not adequately secure for patients' sensitive information. Sharing patients' data between multiple systems allows access to patient records from various locations, resulting in exposing the data to security vulnerabilities and privacy threats.

Some studies present some major challenges of privacy, which include:

1. Patient resistance to sharing particular information and data to a third party for statistics as an example.
2. The use of different EPR systems might override privacy and security rules in certain circumstances.
3. Security concerns and threats throughout the transmission process of medical data and information, and ensuring the ability to share such information safely.
4. Access issues due to an organisation's mechanism for granting access rights to prevent any unauthorised access.
5. Human factors risks in breaching the privacy and confidentiality of medical data due to insufficient awareness or misunderstanding of patients.

As such, there is a substantial need to protect shared messages among systems, to prevent any potential damage to healthcare stakeholders. All healthcare sector members have to ensure the confidentiality, integrity, privacy and security of healthcare information. Therefore, policies and controls must be identified for data while it is in storage or travelling out of the healthcare system, and periodic auditing is needed to ensure the implementation of these policies and controls. Many standards have been

developed as guidelines for securing data-sharing; EPR systems must conform to these standards, the foremost of which are:

1. The European legal framework 95/46/EC, which aims to ensure concordance among European countries' regulations in terms of personal data protection.
2. The European project Secure Environment for Information Systems in Medicine (SEISMED), which is intended to provide guidelines for security management, taking into consideration the main elements of processing healthcare data through various legislation within the EU.
3. The British Medical Association (BMA) security policy, which is designed to identify access control on medical records in a manageable way.
4. The Health Insurance Portability and Accountability Act (HIPAA) law established in the US to develop security standards for health information systems to protect patient's rights and privacy and enhance the transformation of electronic information. HIPAA regulations are categorised into four types of standards: a) Privacy, b)Security, c) Identifiers, and d) Transactions and Code Sets [10, 58].

These safeguard regulations categories are considered as a global framework. They ensure a high-security environment by defining clear guidelines, stating the inquiries and observations and influencing the development of secure sharing networks [58].

To sum up, secure transmission can be more effective if it depends on awareness courses, security protocols and efficient training.

5.4 Human Factors Challenges

Human factors represent the central element in the creation and use of electronic patient systems and services. Human factors are responsible for ensuring the efficient use of electronic system services. Staff must meet many requirements, such as learning new skills, gaining experiences and raising their educational level.

Those requirements might include training on computer and web technologies or efficient management and leadership skills necessary for developing workflow and job roles [59].

However, many challenges have posed barriers to medical staff and physicians in using electronic systems, in terms of understanding the

functions and capabilities of EPR system technologies, besides being aware of the related legal, finance and ethical issues [59].

5.4.1 Employees' Resistance to Change

The evolution from traditional patient records to electronic patient records, or even from one classification system to a more modern one, involves critical requirements for employees in terms of changing attitudes, improving awareness, attending training courses and acquiring new skills and knowledge in order to become familiar with the shift to a new system.

One of the main limitations according to many studies is the high possibility of employees' resistance to changes. Medical staff and physicians might not be interested in obtaining new skills and qualifications when new systems or services are implemented [10]. They also worry about anticipated changes in their daily workflow, the possible disadvantages of new systems alongside increasing concerns about their new clinical missions [60].

This shift requires changes from employees in seeking information about new systems and learning new communication technology skills while they remain more comfortable with their old approach [10, 61].

5.4.2 Inadequate Training and Loss of Productivity

The medical staff and physicians are responsible for maintaining or transmitting health information, properly taking into account the main technical process to protect data integrity and confidentiality [58].Thus, it is the primary and secondary care communities that are subjected to the serious challenges of training their staff in the efficient use of EPRs.

Improving the medical staff, physician and IT-specialist performance requires continuous training necessitated by hiring new members, upgrading systems or updating applications. From the IT perspective, the IT staff should work with the EPR systems and medical application vendors in learning the system formalism to customise the system if required and to bridge the gap between technology and health services providers [60].

From the perspective of medical staff and physicians, the most common concerns are about the lack of training, technical skills and free time for training. The movement to a new health system is not possible without educating the health professionals in the essential knowledge about the system [61]. For example, the movement to the ICD-10 system, which includes 140,000 codes, requires intensive code training course for physicians and nurses [62].

From another view, some researchers have studied the effect of staff learning and training on a new system. Around 134 hours have been spent on non-clinical activities, at an estimated cost of $10,325 per physician, which might also impact the associated time for clinical responsibilities [63].

Another challenge of an EPR system is that inadequate training negatively impacts the clinical workflow by reducing time spent with patients and thus quality of care. Some studies show that some staff consider the training on electronic systems as a time-consuming and non-essential mission, resulting in improper use of the system and losses in productivity [64].

Researchers have observed an increased in re-work, modification and the amount of queries by physicians when documentation or training are not adequate to qualify them to the required level to use the system. Therefore, proper preparation is a key factor in reducing many of these negative outcomes and achieving a successful implementation. Furthermore, periodic evaluation will help management to remain updated on staff performance in order to implement better training plans [62].

5.4.3 System Usability

The attractive features of EPRs in terms of a regulated patient database, promoted communication between staff and improved capabilities have also posed some challenges. Usability issues are considered as a major obstacle that need to be considered [65]. The complexity of a system interface will negatively affect many patients' care in aspects such as the physician-patient interaction. It has been reported, for example, that in some classification systems – due to their excessively detailed options or lack of efficient definitions for each code – that they can be difficulties in finding the correct diagnostic code [64].

As such, systems ought to be flexible, effortless, user-friendly and easy to navigate [66]. The physicians, nurses and administrative staff are responsible for performing data entry, information retrieval and decision-making using EPR systems. The designers of EPR systems must therefore ensure that the system will be easily accepted and be operated efficiently to reach its fully capacity and capabilities [65].

6. Discussion and Analysis

Approximately 30 billion SR per year has been spent by the Saudi Government to support healthcare for diabetes [67]. The move towards electronic patient record systems has provided the opportunity for the healthcare sector to improve the quality of patient care. A best-of-breed approach has been prioritised for adoption due to its efficiency. This includes smaller and more local EPR systems, which are more reliable than one super system.

There is a reasonable complexity in the patient care pathway due to the increased number of different teams and organisations that are involved. Patients who have a long term health condition require extensive care pathways, and the processes of collecting, storing and interchanging data are complex [5, 69, 70, 71].

Accordingly, significant challenges have arisen in terms of providing comprehensive, reliable, compatible, correlating, accessible and timely patient information for each healthcare team, whether in primary or secondary care.

Moreover, there is a lack of roadmaps for policies and procedures to ensure the quality, interoperability, confidentiality and privacy of medical data across the different health sectors.

Addressing those issues is not easy and requires the adaption of multifunctional EPR system that enhances data quality capturing and guarantees interoperability among various systems.

This system can provide those features by implementing widely used and adopted standards such as ICD-10 for data capturing, and HL7 for data exchange within or beyond the organisation's boundaries.

However, it is preferred while using those standards to customize and modify them according to the Saudi's hospital needs taking into consideration also the international criteria.

In terms of data capturing, the development of a local set of international data standards is important. So that, all the patients' treatment procedures codes as well as diagnostic codes should cover the local cases. This guarantees the availability of complete medical information and knowledge at any point and time of care.

Regarding the data sharing, the interoperable infrastructures is strongly essential for the purpose of supporting the integration between the large number of primary and secondary healthcare providers. The interoperability feature will minimize the fragmentation issues and also

assist researchers in the biomedical fields in accessing a large numbers of patients' records.

In terms of human factors, engaging the system's clinical users and expertise during the implementation of an EPR system is essential to ensure its suitability for meeting all their needs. The medical staff should have sufficient knowledge and skills about the interface of health information system and its functions through sophisticated training courses. This helps to avoid their resistance to the new technologies, reduce the improper use, overcome the shortage of health informatics professionals and ensure system usability [69, 71].

In Saudi Arabia, there is a successful example of an effective EPR system at Saudi National Guard Health Affairs, which includes multiple primary and secondary healthcare centers around the kingdom.

NGHA's Clinical Information Management Systems department has introduced QuadraMed's Computerized Patient Record Systems, the main objective of which is to assure the integrity and accuracy of the integrated patient data. The system was awarded the prestigious Excellence Award at the 2010 Arab Health Awards in Dubai, UAE. The Excellence Award is granted to the healthcare provider that makes the most innovative use of EPR systems to mitigate potential errors, improve data quality and ensure interoperability in an effective manner [68, 69].

As such, this study defines the reasons of unsuccessful implementation and utilization of health information systems in order to improve the quality of data capturing and boost the exchange workflow between multidisciplinary health teams for better care pathways.

7. Conclusion

A profound study of the HIS and EPR in the Health sector of Saudi Arabia forms the basis for this paper. A narrower case study has been adapted to give a full focus for the Diabetes Care Pathway specifically.

The study was carried out in Central and Eastern regions hospitals of Saudi Arabia. Several visits and observations were conducted which helped in obtaining a clear understanding and a full picture about the key issues of current EPR in terms of its implementation and utilization.

The preliminary results of this study give an overview about the current status of healthcare system locally. It compares the outcomes of quantitative and qualitative research methods with the literature review of latest published articles in the field of EPR systems.

Thus, it indicates the reasons of unsuccessful implementation and utilization of EPR systems in Saudi Arabia. Accordingly, the key challenges are categorized into three main issues, which are data capturing, data sharing and human factors. Such a classification will lead to improve healthcare services via using reliable EPR systems alongside a professional management of those systems.

Consequently, tackling those issues requires a full understanding about the healthcare system shortages in terms of health informatics professionals, data capturing and sharing standards, privacy issues, policies and procedures.

To sum up, this study is in line with prior studies concerning developing countries. For the future, more investigations are recommended to support the research outcomes in terms of its validity besides enrich the knowledge in this area effectively.

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