DO ELECTRONIC HEALTH RECORDS STANDARDS HELP IMPLEMENTING PATIENT BILL OF RIGHTS IN HOSPITALS?

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ABSTRACT

Introduction: Patient bill of rights (PBR) calls for equal rights to access health services for all patients. It makes a foundation for preserving good relationships between patients, doctors and other healthcare staffs. Third Edition of national PBR was published in Iran in 2005. On the other hand, developing national wide Electronic Health Records (EHR) is now one of the strategic goals of Iran Ministry of Health and Medical Education. EHR as a basic repository for all related information provides access to the necessary data to organize, store and manage them. It also makes an additional support to the legal aspects of healthcare services, increases staff information about patient rights, and raises them to respect these rights. This article reviews how EHR standards can help to institutionalize the PBR. Methods: To do that, we have collected some important topics of PBR in Iran. Then we used some valid references on Electronic health record standards like ASTM, ISO, HL7 and CEN to review existing standards. The Main issues regarding patient rights derived from these standards were: privacy, confidentiality, and secrecy, access levels to patient information, medical care in emergency situations, patient autonomy and authentication (electronic signature). In each topic, the most relevant standard phrases are marked. Results: Developing EHR creates an opportunity to establish patient rights in its structure. To internalize them, there are some reliable EHR standards like ASTM and ISO 13606-1 that implementing them could be very fruitful. Key words: EHR, standard, patient bill of rights, Hospital.

1. INTRODUCTION

Increasing ethical challenges of medical care asks policy makers to think more and more about human rights, especially for patients as vulnerable ones with remarkable needs. (1) Meanwhile, Patient Bill of Rights (PBR) calls for equal rights to access health services for all patients. It also makes a foundation for preserving good relationships between patients, doctors and other healthcare staffs. Thus, many countries developed a national PBR to achieve higher degrees of patient satisfaction. Efforts for developing PBR started with the release of a universal declaration in 1947 and continued until 1973 when the first statement about PBR was published (2). The contents of these bills are nearly similar. They simply try to seek support about patient rights. Moreover, they increase staff’s information about patient rights and ask them to respect these rights (3).

In Iran, PBR was developed first in 2001 by the Ministry of Health. However, because of some shortages, it undertook some revisions in the topics and fields. The Last version of Iranian PBR was launched in 2009. Now this bill has some axes about: receiving optimal services, patient autonomy and decision making, respect for his/her privacy and confidentiality, and having access to an efficient complaint system (4). Other countries put some additional issues in their national PBR such as: receiving Care With high Quality, informed consent and authorization, having Peace, pain relief and Euthanasia (5). Although statements about patient rights could improve health care services, but they need to become practicable through the relevant standards in national programs of hospital assessment (6). ICT in the health system as an appropriate tool for system improving can reduce some deficiencies in the field. It has many benefits such as problem registration and promoting access to information and services, which could be performed better by implementing standards (7). According to American Institute of Medicine (IOM), applying standards is one of three factors that noticeably would help developing EHR (8). The most fundamental point in fostering EHR is harmony between standardization and organizations. These standards refer to the ability of information use, exchange and reuse. They also balance between different levels of e-learning through the world (9).

2. METHODS

This was a comparative study to show how EHR standards can help
to institutionalize the PBR in Iran. To do this, we carried out four steps, as following:

1. We evaluated all five main axes and 37 sub axes of national PBR (the third version).
2. Based on it, we formed a checklist with different items including all main issues about patient rights.
3. On the other hand, we searched for the most important non-profit organizations that produce international standards regarding HER and obtained their last version of standards from their official sites.
4. Then, we compared published standards with our checklist items based on their content, meaning, scope and objectives. For each item, we proposed the most relevant standard as far as possible.

3. FINDING

According to our surveys, the most important organizations (which are non-profit and affiliated with the Europe Union) that produce international standards regarding EHR are:

a) ASTM: “American Society for Testing and Materials” is a nonprofit society established by the National Institute of America in 1998 (10); b) ISO: “International Organization for Standardization” works on different standards (11); c) CEN: “Commission for European Normalization”; d) “Health Insurance Privacy and Portability Act” works as a responsive organization to develop national standards for transferring electronic health information (12); e) HL7: “Health Level Seven” is also a developer institution for valid standards (13).

Other findings are summarized in five tables below according to the five axes of patient bill of rights.

4. CONCLUSION

The results of this research showed that for most issues of Iranian national PBR, there are substantial standards in EHR. The most proposed axis was the second axis. Among standard organizations, the most consistent with PBR axes, is ASTM. It means that implementing ASTM standard may have a great influence on promoting PBR in a

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**Table 1. The patient has the right to receive appropriate health services.**

| Number of standard | Tittles | Axis |
|--------------------|--------|------|
| ISO CEN [EN 13606] | the content of information should include: Charter rights of patients on admission; | 2-1 |
| ASTM E1239-04 | | |
| ASTM E1215 | terms and predictable costs of hospital medical and non medical services and insurance regulations and the introduction of support systems at the time of admission; | 2-2 |
| ASTM E1714 | the names, ranks and responsibilities for professional medical care delivery team including: physicians, nurses, and students should be clear and their professional relationship with each other should be obtained | 2-3 |
| ASTM E2369 – 05e1 | diagnostic and therapeutic procedures and their benefits vs. their risks and their possible complications, and prognosis should be explained and help patients for effective decision-making; | 2-4 |
| HL7 v3 | how to access health care and the main members of the group during treatment | 2-5 |
| EN 13940-1-2007C | All measures of research nature should be clear | 2-6 |
| E.H.C.R | to provide all requirements for continuing treatment | 2-7 |
| ASTME 1998 – 98 | How the information is as follows: | 2-8 |
| ISO/TC 215[DS 18308 | providing timely and appropriate information to patients with conditions such as anxiety and pain, considering their personal characteristics such as language, education and understanding; | 2-9 |
| ASTM E2211 | When delay in starting treatment due to the information, may cause harm to the patient, do the necessary action, at the right time; | 2-10 |
| ASTM E2369 | despite the right information, refusal of patient should be respected, unless that makes his or others at serious risks; | 2-11 |
| ASTM E2017-99 | All patients can access their clinical records and files; | 2-12 |
| ISO/olis 18308 | | |
| CEN/TR 15299.2006 | | |

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ACTA INFORMED. 2013 MAR; 21(1): 20-22 / ORIGINAL PAPER
Table 5. Access to an effective complaint system

| Number of standard | Tittles                                                                 | Axis |
|--------------------|------------------------------------------------------------------------|------|
| P.H.R (HIPAA ASC X12N) | the patient has the right to claim to the authorities of the complaint, without fear of any impairment of health services quality | 5-1  |
| EN ISO 10781 | Any damage caused by failure of health service providers must be compensated as soon as possible | 5-2  |

health institute like a hospital.

A study in USA showed that nearly 68% of people are worried about leakage of their private information from their EHR. Besides, most doctors do not have enough knowledge about efficient control of their patients’ personal information (14).

Pagilari study revealed that the main problems in the implementing of an electronic health system could be: different communication language, culture, motivation, operational processes structure, privacy and security (15).

Another research showed that in most cases, there are no reliable laws to control the use and disclose of patient information in medical records, in Iran (16).

A research revealed that a developed complaint assessing was effective to meet the patient and their families’ expectations at Memorial Hospital, by which the patients can freely express and follow their complaints through verbal, written, e-mail and website mode (17).

Another research in 2003 showed that about 90% of workers in Canadian health organizations had to sign a confidentiality agreement about patient information in EHR (18). Developing national wide EHR was recently a strategic goal of the ministry of Health. Thus, increasing general access to personal health information would be unavoidable, and deploying relevant standards related to patient rights in EHR are highly recommended.

Conforming to this strategy, there is a good opportunity to promote the situation of PBR in our health care system.

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12. ISO/IEC 2382-8 1986-98 | only patient and the patient companions and individuals who are deemed to be authorized by law, are allowed to have access to patient information; | 4-3 |
| ISO/IEC 2382-8 | The patient has the right to choose diagnostic procedures, including examination by a trusted person. Children parents have right at all stages of treatment unless it is contrary to medical necessities. | 4-4 |
| ASTM E2147 -01[2009] | to observe the confidentiality of patients information is essential, except in cases where the law has exceptions | 4-4 |
| ASTM E3115 | in all stages of diagnostic and therapeutic care, patient privacy must be respected | 4-2 |
| EN 12251-2004 | Number of standard | Tittles |
| EN 13606-4:2007 | to decide freely in health services are as following: the choice of physician and other healthcare providers | 3-1 |
| ISO/CEN 10781:2009 | Choosing a physician as a consultant | 3-2 |
| ISO/ISO catalogue/catalogue tc/catalogue detail.html | participating freely in any search study, by ensuring that his decision would not affect the continuity of health services; | 3-3 |
| ISO/ISO catalogue/catalogue tc/catalogue detail.html | to accept or reject the recommended treatment, knowing possible complications arising from the acceptance or rejection, except in cases of suicide | 3-4 |
| ISO/ISO catalogue/catalogue tc/catalogue detail.html | the patient’s previous consideration about future treatment decisions are recorded in the patients files | 3-5 |
| ASTM E3115 | Selection criteria and decisions include the following: patient should be free in his decision, based on adequate and comprehensive information | 3-6 |
| ASTM E3115 | Sufficient time should be given to patients to make his decisions. | 3-7 |

Table 3. The patient autonomy and right to decide freely in health services should be respected

| Number of standard | Tittles |
|--------------------|--------|
| ASTM E2147 -01[2009] | to observe the confidentiality of patients information is essential, except in cases where the law has exceptions |
| ASTM E3115 | in all stages of diagnostic and therapeutic care, patient privacy must be respected |
| EN 12251-2004 | Number of standard |
| EN 13606-4:2007 | only patient and the patient companions and individuals who are deemed to be authorized by law, are allowed to have access to patient information; |
| ISO/IEC 2382-8 1986-98 | The patient has the right to choose diagnostic procedures, including examination by a trusted person. Children parents have right at all stages of treatment unless it is contrary to medical necessities. |
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