

Reasons for Deficiencies in Health Information Laws in Iran

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Abstract

Introduction: Laws, regulations, and guidelines are necessary external stimuli that influence the management of health data. They serve as external mechanisms for the reinforcement and quality improvement of health information. Despite their inevitable significance, such laws have not yet been sufficiently formulated in Iran. The current study explores reasons for inadequacies in the health information laws.

Methods: In this descriptive study, health-related laws and regulations from the United States, the United Kingdom, and Iran were first collected, using a review of the literature and available data. Then, bearing in mind the significant deficiencies in health information laws in Iran, the researchers asked a group of managers and policy makers in the healthcare field to complete a questionnaire to explore the reasons for such deficiencies. A test-retest method was used to determine the reliability of the questionnaire. Descriptive statistics and tables were then used to analyze the data.

Findings: Experts' opinion on reasons for deficiencies in health information laws and regulations in Iran are divided into four principal groups: cultural conditions of the community, the status of the health information system, characteristics of managers and policy makers in the healthcare field, and awareness level among public beneficiaries about laws.

Conclusions: The health departments or ministries in developed countries have brought about suitable changes in their affiliated organizations by developing external data enhancement mechanisms such as information-related laws and standards, and accreditation of healthcare organizations. At the same time, healthcare organizations, under obligations imposed by the external forces, try to elevate the quality of information. Therefore, this study suggests that raising healthcare managers' awareness of the importance of passing health information laws, as an effective external mechanism, is essential.

Keywords: health information–related laws, deficiencies in laws, healthcare field managers

Introduction

An efficacious and accurate system of registering and reporting medical information is fundamental to treatment, education, research, and supervision.¹ In addition, high-quality healthcare depends on comprehensive information in medical records.^{2,3} With an increase in the complexity of healthcare organizations and their tendency toward high-quality healthcare comes the need for timely, accurate, and comprehensive information.⁴ In addition, in recent years there has been an exponential increase in the importance of health information for follow-up care and for defense purposes in legal actions and administrative proceedings.⁵ The health information management field is strongly influenced by laws, guidelines, and standards that determine the content of medical or health records.⁶ Health laws and

regulations are at the heart of healthcare systems and legal systems, so any change in such laws or regulations will result in a number of significant consequences and challenges in the area of health information. Because laws can serve as tools to guarantee advances in healthcare and to achieve important economic and social aims, the effect of laws and regulations in the healthcare field is more prominent. At the same time, healthcare organizations attempt to meet the general standards established by accreditation organizations in order to achieve a higher level of quality and validity, such as by assuring and improving the quality of healthcare data.⁷ In other words, external stimuli such as laws, regulations, and guidelines influence a wide range of health information and its management techniques.⁸ In developed countries, laws and regulations to ensure the privacy and confidentiality of patients' records have been in effect for a long time.⁹ Given the role of laws as an external mechanism to reinforce information,¹⁰ together with significant deficiencies in health information laws in Iran as compared to developed countries such as the United States and the United Kingdom, the present study was undertaken to specify the reasons for such deficiencies in the field of health information in Iran.

Methods

A descriptive method was used in the present study. The research environment consisted of the Ministry of Health and Medical Education, the Medical Council Organization, and the Health Commission of the Islamic Consultative Assembly in Iran, along with Internet and library research.

To evaluate the present status of health information laws in Iran, as compared to common practices in other countries, this study focused on seven aspects: recording and keeping health information, observing health data privacy, respecting confidentiality, considering information security, retention of medical or health records, accessing healthcare information, and using medical or health records as legal documents. These aspects served as a basis to compare health information laws in Iran with those in two developed countries, the United States and the United Kingdom. First, the health-related laws and regulations from the United States, the United Kingdom, and Iran were collected, using a literature review and the available data. Then, the reasons behind the probable deficiencies in laws in the field of health information in Iran were studied through the use of a questionnaire.

The questionnaire was filled in by 24 participants from the Ministry of Health in Iran. They included the minister, the vice minister, and top managers with administrative experience at ministerial levels. The questionnaire included six open-ended questions on numerous issues, as follows:

1. In your opinion, what are the reasons for passing new laws in different fields of healthcare such as education, research, food, drugs, clinics, employment, and office work?
2. In your opinion, in what ways could the health information laws more effectively meet the goals and objectives of the Ministry of Health?
3. In your opinion, is it necessary to have high-quality health information, as an effective factor in promoting the health of society? If so, can the formulation of new health information laws promote the quality of health information?
4. In your opinion, what are the main reasons for the lack of sufficient laws in the health information field?
5. In your opinion, which specific problems, if any, are caused by insufficient laws in the health information field?
6. In your opinion, what is the significance of problems caused by insufficient laws in the health information field?

The data collected via the questionnaire were analyzed as follows. First, the answers to each question were carefully studied and were classified on the basis of their content. The frequency of each specific content area was then calculated, and responses were organized in tables. For example, if a respondent's answer dealt with cultural issues, it was included in a column in the table titled "cultural." Because of the nature of the open-ended questions, which allowed respondents to provide as many answers as they deemed necessary, the participants often provided more than one answer to each question; accordingly, the number of answers in each content area exceeded the number of participants. The validity of the data collection tool was determined by the content validity method, and to determine its reliability the test-retest method ($r = 0.85$) was used.

Findings

Literature Review

A literature review was used to determine the benefits of and reasons for passing laws related to various aspects of the health field in Iran. The laws in the field of health information in Iran, based on the documents available in law books and guidelines, include the following:

- Laws related to keeping patients' health information; these laws just deal with recording medical patients' files or providing an admission register and registering particulars of the patients.
- Laws to observe confidentiality and to ensure privacy of a patient's disease, which have been introduced in two disciplinary guidelines.
- Reports of cancer cases, mortalities, and certain communicable and noncommunicable diseases, which have been deemed necessary in one law and two guidelines.
- Access to information, which is permissible for inferior boards and the public prosecutor's office.

The laws above, taken from Iranian law books, are different from those of the United States because in the United States, 74 federal laws and regulations directly control the collection, use, and reporting of health information. When the laws are classified into the seven aspects mentioned above, the most numerous are the laws (39 laws according to the Department of Health and Human Services website) dealing with data privacy. In the United Kingdom, on the other hand, 56 laws are found in the seven main aspects, with the most numerous laws (33 laws according to the Department of Health website) dealing with the confidentiality of patient health information.

Questionnaire

Table 1 and Table 2 show the distribution of respondents' opinions regarding the reasons to pass laws in the field of health information and the benefits of such laws. Table 3 presents respondents' opinions of the role and impact of laws on health information to improve health and its information quality. According to Table 3, all of the respondents (which included the minister, the vice minister, and top managers with administrative experience at ministerial levels) agreed with the effect of related laws on health information quality. Their opinions on the reasons for deficiencies in such laws are shown in Table 4. Table 5 presents respondents' opinions regarding the main problems resulting from deficiencies in health information laws and regulations.

Discussion

The results of this study showed that the laws in the field of health information are very limited in Iran and that the existing laws are mostly extracted and inferred from the laws in other fields of health; indeed, there are no independent laws in the health information field. The results of this study are consistent with those of other studies related to health information.¹¹⁻¹⁷ One of the responsibilities of the Iranian Ministry of Health in the 4th National Development Plan is "to design and establish a comprehensive health information system for the citizens of Iran" in order to continuously improve the quality of healthcare and related services and improve the performance or productivity and use of health and therapeutic resources of the country.¹⁸ In a study to determine priorities in the development of

electronic health in Iran, the provision of laws and regulative infrastructures were considered the most important priorities among other factors, and it was concluded that there are no laws regarding data privacy in Iran.¹⁹ According to Act No. 60 on e-commerce (2004), the storage and processing of medical or healthcare data and the distribution of healthcare information require the ratification of laws or guidelines by the Ministry of Health.²⁰ However, preparation of these laws or guidelines has not been completed after seven years. As noted above, the most numerous laws in the field of health information in Iran are related to the retention of medical records, which is conducted on the basis of personal preferences because of the presence of clear contradictions in the laws and regulations; in addition, there is much confusion in this respect. On the other hand, the laws and guidelines on document retention have only referred to medical or health records in general. However, in the United States and the United Kingdom, lists specifying the minimum retention time of any medical or healthcare documents have been prepared.²¹⁻²⁵

In Iran, the laws and regulations for keeping healthcare information are mainly limited to registering patients' admissions and recording their medical files; they may sometimes include guidelines on how to establish clinics and healthcare institutions or health centers. These requirements are expressed in general terms without specifying the methods to document and keep healthcare data. In relation to the confidentiality issue, there are only two disciplinary guidelines maintaining that "the medical personnel should not disclose patient secrets and the type of the disease condition they have, unless obliged by the laws ratified by the Islamic Consultative Assembly." The only laws regarding permission to gain access to healthcare information are confined to two guidelines, according to which it is permissible to present healthcare information to inferior boards and the office of the public prosecutor; none of these guidelines have been ratified by the Islamic Consultative Assembly. In fact, such deficiencies are not limited to laws on observing confidentiality, respecting health data privacy, and keeping or documenting healthcare information; there is not even one law on disclosure of healthcare information that could result in the incorporation of external and internal health information disclosure policies into healthcare organizations.

Nonetheless, deficiencies in health information laws do not mean that health policy makers are unaware of the significance of formulating new laws. Those completing the questionnaire, as the data in Table 1 show, enumerated seven reasons for the significance of passing laws for the health fields, and their reasons are strong enough to warrant formulation of necessary laws on health information. However, top managers and policy makers in Iran have failed to pass the necessary laws. The reason may be that the managers in charge are unaware of the importance of high-quality information in assessing the quality of health services, improving patient care, increasing validity of health information systems, and promoting health research, as shown in Table 2. The consequence has been lack of proper attention to the need to make laws on health information.

Meanwhile, according to Act 28 of the Disciplinary Guidelines, on "trial of occupational wrongdoings of the medical personnel under the supervision of the Medical Council," the technical supervisors of medical organizations, including public, private, and welfare organizations, should observe the existing laws and regulations in the guidelines ratified by the Ministry of Health and the Medical Council. Likewise, they should follow scientific and occupational principles. In certain cases, also, some universities and medical centers use their own discretion to issue specific guidelines on healthcare information in line with their own needs, resulting in inconsistencies and lack of harmony in collection, reporting, or even retention of healthcare information. In addition, in some cases, insurance companies have specific requirements related to registration of certain information in medical or health records for reimbursement, which could complicate the existing inconsistencies.

The findings of the present study showed that, from the perspective of respondents to the research questionnaire, the reasons for deficiencies of laws in the field of healthcare information in Iran can be classified into four main groups:

1. The cultural conditions of the community
2. The status of the health information system
3. Managers and policy makers in the health field

4. Public beneficiaries of laws, such as healthcare providers and the general public

One of the most important reasons for deficiencies in laws in the health information field in Iran is the cultural background of the country. Managers' subjective decision making has resulted in a feeling that there is no need for any laws in this field. In other words, the cultural aspects of the community lead to the impression by the managers that there is no need or demand for such laws. On the other hand, lack of integrity in the health information systems has led to lack of a clear-cut definition for health information, lack of correct understanding of the benefits of quality healthcare information, and lack of awareness of a need for laws in this field. Other reasons include a deficiency in the awareness of top managers and policy makers about the role and importance of health information laws for the provision of community health; added to these reasons are the repeated change of managers at short intervals, appointment of less experienced managers to key positions, and lack of sufficient attention to information and informatics. In addition, deficiencies in management techniques, along with other reasons, have resulted in the absence of long-term plans in most fields, the lack of opportunity for top or middle managers to offer suggestions, and the lack of their participation in promoting health-services, which in turn are the result of various daily routines the managers have to deal with. Finally, low levels of knowledge among the public beneficiaries of such laws, especially among the individual members of society, has led to a lack of demand for their rights, which is one of the main reasons for deficiencies in the field of health information.

According to Table 3, top managers and policy makers in Iran's Ministry of Health mentioned that they know about the importance of high-quality information in promoting the health of society, and they also know about the effect of health information laws in enhancing information quality; however, in practice, they fail to adopt concrete measures to pass laws. This paradox indicates that their understanding has not been sufficiently internalized to persuade them to follow practical measures to pass new laws on health information.

Another reason for not passing sufficient laws, despite awareness of the need for such laws, is that health authorities are unaware of the effect of laws as an external force in shaping the behavior of healthcare organizations to ensure the production of high-quality information.

Conclusion

A society's health depends on the continuity of patient care. Nonetheless, to achieve the intended continuity, health authorities need to perform two important tasks: (1) keeping high-quality healthcare information in paper forms or electronic records and (2) developing effective links between healthcare organizations while integrating their functions.

The health ministries in developed countries, paying due attention to such issues, have brought about suitable changes in their affiliated organizations by developing external data enhancement mechanisms such as the formulation of information-related laws and standards, and accreditation of health care organizations. At the same time, healthcare organizations, under obligations imposed by the external forces, aim to elevate the quality of information by setting up proper internal mechanisms, such as information management committees or qualitative and quantitative analyses. Quality healthcare information serves as an important tool for auditing healthcare services. The reason is that successful auditing of health care services in these countries is at the stake of high quality health care information.

Therefore, in line with the objectives of this study, raising healthcare managers' awareness of the importance of passing new health information laws, as an effective external mechanism, is essential because such laws could elevate the quality of information, improve healthcare management, lay the infrastructure for electronic health records, bring about interoperability in health information systems, improve the quality of care delivery, and ultimately promote social health.

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Table 1

Frequency Distribution of Reasons to Pass Laws in Different Aspects of Health Information Based on the Opinions of 24 Top Managers and Policy Makers

Reasons for Passing Laws		Frequency	Percentage
1	Need for laws in designing missions and objectives	18	41
2	Systemic planning for community health	8	18.2
3	Problems arising due to deficiencies in laws and attempts to solve such problems	4	9.1
4	Prevention of problems and health risks in future	4	9.1
5	Establishing guarantees for implementation of control and surveillance	6	13.6
6	Establishing communication between different organizations in the field of health	2	4.5
7	Comparison of domestic laws with those in other countries to benefit from previous achievements	2	4.5

Table 2

Frequency Distribution of the Benefits of Laws in the Field of Health Information Based on Content-oriented Classification of the Opinions of 24 Top Managers and Policy Makers

Gross Benefits	Detailed Benefits	Frequency	Percentage
Community health	Planning for community health	30	29.5
	Identification of problems and threats to community health		
	Orienting infrastructures toward health, decreasing health problems and their high costs		
	Promotion of health services		
	Promotion of productivity and optimal use of human resources and equipment		
	Preparation of an appropriate situation for just distribution of resources		
general public	Awareness of individual rights	22	23.5
	Prevention of violation of individual rights		
	Provision of mental security for individuals in relation to submitting information		
Policy makers	Provision of IFA (Information for Act) for managers	18	17.6
	Clarification of the general aims of community health		
	Tracing problems and prioritizing health problems based on the severity and extent of the problem		
	Decision making based on documented evidence		
Health information system	Promotion of health information system	12	11.8
	Promotion of information quality		
	Internalization of the documentation culture		
Executives managers	Identification of measurable aims and executive strategies	8	7.8
Healthcare specialists	Identification of duties	6	5.9
	Scientific and practical promotion in order to be responsible in relation to duties		
Researchers	Promotion of the quality of medical research	4	3.9

Table 3

Frequency Distribution of Respondents' Opinions on Health Information Quality and the Need for Passing Relevant Laws

Question	Yes		No	
	Frequency	Percentage	Frequency	Percentage
Do you agree that high-quality health information could serve as an effective factor in promoting health?	24	100	0	0
Can the formulation of new laws on health information improve the quality of health information?	24	100	0	0

Table 4

Frequency Distribution of Reasons for Deficiencies in Laws in the Field of Health Information Based on Content-oriented Classification of the Opinions of 24 Top Managers and Policy Makers

General Reasons	Detailed Reasons	Frequency	Percentage
Characteristics of managers and policy makers in the health field	Lack of belief in a comprehensive information system for proper management	18	42.9
	Lack of proper understanding of responsibilities in both lawmakers and executives		
	Presence of a large number of people around the managers and inattention to subtle and important points		
	Short-term management periods and selection of inexperienced managers		
	Preoccupation of managers with repeated daily routines, leading to deviation from making necessary laws in different aspects		
	Unawareness of some managers of laws		
	Inadequate awareness of managers and lawmakers of the role of information in providing community health		
	Absence of long-term planning in majority of fields		
	Lack of opportunity for middle and low-level managers to give suggestions		
	Lack of any role for middle and low-level managers in promotion of healthcare services		
	Inattention to new international definitions of the principles of global trading		
	Absence of plan-oriented evaluation of needs		
	Absence of clarification of law-making authorities and centers in some departments, leading to parallel actions and interference		
Cultural conditions of the community	Lack of the culture for decision making based on evidence, statistics, and previous data	10	23.8
	Inadequate attention to data, information, and, on the whole, to software and brain ware		
	Insufficient attention to human dignity		
	Inadequate law-abiding qualities		
Status of health information system	Lack of integrity of the health information system	8	19.0
	Absence of a definite guardian for health information system		
	Absence of a clear definition of health information		
	Absence of a proper undertaking of information as an interdisciplinary component and a feeling that it does not need any laws		
Awareness level of public beneficiaries about laws	Lack of awareness resulting in no demands for rights	6	14.3
	Inadequate knowledge of the beneficiaries of laws in this respect		

Table 5

Frequency Distribution of Problems Arising from Deficiencies in Health Information Laws Based on Content-oriented Classification of the Opinions of 24 Top Managers and Policy Makers

General Problems	Detailed Problems	Frequency	Percentage
Health system	Absence of strategic planning to promote the health system	22	42.3
	Weaknesses in management and planning for health system		
	Lack of optimization of health promotion trend		
	Absence of a proper understanding of the country's health problems		
	Unjust distribution of resources		
	No participation in regional and international trading		
	Investment risks		
General public	The effect of physical, mental, and environmental well-being of the individual and community	14	26.9
	Lack of social justice in alleviating patient harms		
Health system managers	Absence of adequate evidence to act, resulting in decision making without evidence	8	15.4
	An increase in the risks of managing decisions		
	Absence of accurate information		
Health system personnel	Lack of a clear definition of subtle relationship between caregivers and those who are cared for	6	11.5
	Lack of a clear definition of the relationship between the personnel		
	Lack of clarity and transparency in executing affairs		
Researchers	Lack of high-quality clinical trials	2	3.8