REGULATING IRANIAN MEDICAL INSTITUTES: TOWARDS CRIMINAL POLICY FOR A CLEAR REGULATORY MODEL

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Abstract- Regulation has been considered as a tool of performance improvement and an instrument of social justice. Iranian criminal legislator didn't specify criminal policy for a clear regulatory model in Iranian medical law. Lack of clarity and stability of medical regulation in Iranian medical institutes paves the way for some institutes to commit crimes against patients' rights and make their situation even worse. As such, this is going to increase the dark number of crimes committed and to simultaneously create a safe heaven for offenders to continue committing their crimes. To make the matters worse, most of Iranian medical institutes are reluctant to abide by criminal provisions. The authors try to discuss different criminal policies for medical regulation in Iranian statutes. After introducing Iranian health system with its main three sections, the authors explain the necessity of a clear regulatory model then discuss regulating managers and personnel, clinical governance, internal and external regulatory models with legislative approaches. The authors also conclude that crimes against patients' rights sometimes increase due to diversified regulatory models and new measures including severe criminal sanctions should be considered in Iranian Acts. Finally, the hybrid regulatory model is suggested to use as an appropriate regulatory model with the most benefits and the least disadvantages.

Key words- Iranian criminal statutes, criminal policy, medical institutes, medical regulation, clinical governance, internal and external regulation, hybrid regulatory model

Introduction

Medical regulation is now center stage in the politics of the National Health Service (NHS) and the profession can expect to be subject to the full range of devices of the disposal of this particular political theatre. As yet much remains unclear about the performance we are about to witness. The actors are all present but their scripts are different, the sequence of events is but dimly understood and the several stage managers are issuing countervailing directions to the players who will listen. The scriptwriters agreed that the final scene should unveil a new system of medical regulation to be greeted by suitably appreciative applause from the audience but there is little agreement on what that system should look like or who should control it [1].

"Regulation is the imposition of external constraints upon the behavior of an individual or an organization. As such, it is the exercise of authority by some entity over those individuals or organizations, forcing a change from their preferred behavior" [2]. Regulation can be understood as primarily a way of dealing with two types of failure: government failure and market failure. "In the arena of health care, regulation is usually aimed at ensuring good service quality and patient safety, containing cost, improving performance and accountability of providers,

efficiency and equity" [3]. Kelly [4] believes that the perceived need for regulation of the medical profession finds its roots in both the intrinsic nature of medical practice and the history of medicine. Fang [3] maintains that formal regulatory institutions are the institutions which have been set up by the government and granted power by specific laws to manage health care and other markets or to oversee the behavior of those organizations.

Peters and Muraleedharan [5] stated that the health sector is already widely dispersed and increasingly complex, making the logistics of traditional regulation ever more challenging. Moreover, other studies confirm that medical regulation, like most professional regulation, is an increasingly challenging task [6]. A study shows that regulation of prices, quality and quantity of health services is not easily achievable. This can be considered as a challenge which public health faces. The same study adds this type of regulation requires a high level of research capacity and is heavily data-driven, which can be a drain on regulatory capability [7]. The argument based on which the authors of this article confirm that the existing medical regulations in Iran cannot meet patients' rights and expectations is not that they consider health care system something unique and different than other

social goods, but they argue that criminal policy for a regulatory model has not yet been recognized by Iranian criminal legislator. Accordingly, the authors are trying to propose a model which can be fit with the now existing criminal policy in Iranian medical institutes.

Recent years have seen increased concerns about the overall quality and quantity of healthcare delivered in given areas [8]. The limited effect of regulating or overseeing the behaviors of health facilities is manifesting itself in rapidly rising medical costs, over-prescription of drugs and tests by providers, declining equity in public health care, widespread dissatisfaction with health workers by the public, increasing conflicts between health departments and their clients [3]. As the quote at the beginning of the present article described the situation, it seems that a clear and transparent regulatory framework is needed. The scant criminal provisions which can be interpreted for regulation are so obscure that indicate a lot of criminal gaps in existing criminal policy for medical institutes. Accordingly, this paves the way for the lack of regulators' criminal responsibility. Neither does the emphasis on clarity and transparency mean that these features are not important in other systems, nor does it mean that these features will have different roles and effects while applied to other systems.

Regarding the above-mentioned difficulties, the authors of this article believe that most of these problems with public health care system have been arisen from the lack of criminal policy for a transparent and accountable regulatory model. Also, this writing tries to pave the way to increase the quality of public health services through discussing issues related to medical regulation, and to introduce a framework based on which, the trust to public health cannot be demolished or it could be revived if some hurt inflicted on it. Accordingly, this article analyzes different and challenging criminal aspects of medical regulation in Iranian medical institutes. The authors also compare and contrast different regulatory models and provide medical and legal researchers with criminal and medico-legal aspects of such models. Moreover, the authors agree with Peters and Muraleedharan [5] who believe that the new mechanisms should be designed to build up trust between providers and patients, reduce information asymmetries, and reflect the rising role of consumers and brands in the market.

Method

The method of the present study is based on the literature review. Books, research and review articles were collected from different databases such as PubMed and ISI Web of Knowledge. After studying the literature and pondering on different criminal aspects of medical regulation, the authors introduced Iranian health system and discussed different ways to regulate medical institutes, health care systems, National Health Service organizations, public health, personnel, managers, clinical governance and different regulatory models with their medical and criminal aspects. The authors mainly intended to provide medical and legal researchers,

physicians and managers with necessary information with regard to medical regulation to establish a regulatory framework to prevent waning public trust to Iranian health care system which, the authors think, is the corner-stone of every health care system.

An introduction to Iranian health system

Different sections

Iranian Health System consists of three following sections each of which meets the needs of the system from one aspect: (1) Acts and legal provisions; (2) providing and distributing medicine; (3) financial system.

1. Acts and legal provisions— Iranian parliament (Islamic National Council) which, is constituted of agents from different provinces, is criminal legislator in Iran. The bills the parliament votes for will be approved and changed to Acts. The parliament is supervised by Iranian judicial system (judiciary) and the members of parliament are selected based on opinion polls for a four-year period. The parliament approved numerous Acts concerning Iranian health system. Followings are more important Acts: (a) The Act for Regulating Health Expenses 1980. According to this Act, Ministry of Health is obliged to regulate health expenses fairly and to enforce related guidelines; (b) The Act for Obligatory Registering Cancerous Diseases 1981. All laboratories and the therapeutic centers are obliged to register and report all cancerous diseases to study them epidemiologically and to prevent their prevalence as far as possible; (c) The Act to Constitute the Ministry of Health and Medical Education 1985; (d) The Act to Constitute Iranian Forensic Medicine Organization 1990; (e) The Act for Family Planning and population Control 1993; (f) The Act for Common Therapeutic Services Insurance 1994.

2. Providing and distributing medicine — Pharmacists should know about issues concerning management, economy, pharmaceutical Acts, and medical ethics. Pharmacist should also be able to answer pharmaceutical questions posed by physicians and patients. She/he should also have the capability to formulate prescribed medicine. The quality of medicines should be guaranteed based on criminal sanctions and moral codes. All the processes to provide medicine should be regulated and those involved in preparing medicine should be supervised. There are some challenges in this area which are as follows: (a) Discrimination is applied when dealing with imported and exported pharmaceutical products concerning quality control; (b) Industry of providing medicine is not familiar with new technologies and there is not a concentrated organization or institute to transfer new industrial technologies; (c) There are some objections in pricing system including lack of stability in profits in providing and distributing; (d) There is low efficiency of apparatuses and industrial machinery to produce medicine; (e) There are no strict criminal sanctions for those who are not honest in their propaganda to sell

medicine; (f) There is a destructive competition between producing companies located in Iran and those abroad; (g) Most of companies which produce medicine do not afford to pay their expenses due to instable bank policies and international sanctions; (h) There are some monetary problems in industries which produce medicine, and (i) There are some instable commercial regulations and practices.

3. Financial system— Financial system includes related and continuous activities to provide financial services in Iranian health system. Resources which have financial origins include individuals, industrial and commercial institutes, government and foreign financial assistances. Expenses are provided by the government, insurance companies, and private sectors in Iranian health system. Financial system faces some challenges including followings: (a) Financial resources are not fairly distributed and mechanisms to attract financial resources are not efficient; (b) There is not a homogeneous cooperation conducted by different social groups; (c) There is not a specific and normal pricing system for services delivered; (d) Cooperation in providing expenses are not crystal clear and do not follow a scientific, logical and legal paradigm; (e) Inflation rate is not homogeneous with credits considered for the health system.

B) Why a clear regulatory model?

A clear regulatory model seems necessary in Iranian health system because of the following basic challenges which the system faces: (1) Basically, Iranian statutes have not presented a united and coherent regulatory model. This makes one unable to recognize the features related to the status of regulation in Iranian health system. The authors of the present article believe that the basic challenge is the lack of criminal policy for a regulatory model which is originated from Iranian criminal legislator's viewpoints. Accordingly, the authors try to study the pros and cons of different regulatory models and propose a solution to all existing dilemmas in regulating Iranian medical institutes. The aim is to pave the way for Iranian criminal legislator to establish criminal policy for a regulatory model in Iranian health system. Unfortunately, regulating a medical institute which contains MD specialists does not play a role of a mechanism to preserve patients' rights but instead, it will protect the benefits of that institute and will ignore patients.

The consequence arisen from the lack of a united regulatory system in Iranian medical institutes is that the regulations, if any, have been incoherent and diversified and exposed to subjective measures rather than objective ones. In other words, in such situation, regulators don't consider themselves responsible for regulations. Furthermore, without a clear and transparent regulatory model, medical institutes will take the most advantages of an obscure situation and commit crimes against patients' rights. As such, the regulator will abuse his/her regulatory authorities and will use them as tools

to apply undue limitations for medical institutes rather than mechanisms to increase the efficacy of those institutes. Unfortunately, the status of patients' rights is grave in Iran due to the lack of criminal policy for a transparent and clear regulatory model.

Criminal sanctions in medical law: on paper or in practice?

A study shows that with regard to enforcement strategies (methods used to persuade, influence, or force regulated organizations to make changes to comply with regulatory requirements or directions), criminal sanctions are a valuable tool of an independent agency (fine, suspension of activity) to deter practices that are legally or ethically condemned [9]. Based on another study, the legal problem with the practice of multiple systems of medicine along with a plethora of unqualified practitioners has caused considerable concern in the courts [5]. The same study recites that courts have recently ruled strongly against the practice of medicine by those without qualifications in the type of medicine they are practicing.

Regulating personnel

Kelly [4] believes that the history of medicine presents reasons to support the idea of regulation of physicians. The medical profession, like most others, has a long history of mistakes, misjudgments and misguided initiatives that were ostensibly undertaken in the best interests of clients, but had outcomes that were at significant variance with this goal. Moreover, during recent years many studies have dealt with nature and frequency of errors in medical practice, further underlining the need of performance management systems and regulation of professional standards and practice [10, 11]. Medical practice is sufficiently complex and variable that a certain level of error is highly likely even when the best safeguards possible have been put into place [12]. No doubt, the reasons of necessity to apply criminal policy for a regulatory model in Iranian medical institutes do not limit to just one factor or feature. Therefore, it has not been argued that the mistakes and errors which have been committed in medicine are the only reason which justifies criminal policy for a regulatory model, but the emphasis on medical mistakes originates from the fact that patients' rights have been ignored in Iran due to the lack of criminal policy for a clear and specific regulatory model in medical institutes. Junior doctors increasingly find themselves acting unsupervised in both elective and emergency situations whilst at the same time having to rely on a narrower band of experience and skills than their pre-form predecessors [13].

Regulating Managers

Historically, there has not been a multi-departmental approach to health planning. This resulted in the awkward situation where a hospital general manager had to manage a complex hospital institution through considerable change with limited knowledge and skills [14]. Studies indicated that planning in hospitals and in

other health institutions had no strategic character [15, 16, 17]. Manager reacts to the challenges which they face by modifying and improving hospital management structures and upgrading managerial skills [18]. Therefore, hospital management teams have to deal with strategic management tools [19, 20]. Managers may acquire knowledge through management education/training, action learning, job assignments, on-the-job experience, and feedback-intensive programs [21]. As such, Longenecker and Ariss [22] believe that the management education/training is one of the most important sources of competitive advantage in any organization. Accordingly, some hospitals spend significant amounts of resources to educate their manager [23].

Expected educational benefits are the development and improvement of current managerial skills, encouragement to think differently about business, and producing new or better ideas and practices that can be applied in the organizations [22, 24]. A study revealed that communication between managers and employees was essential for achieving a participative approach, good teamwork, and high performance in a health organization specially, medical organization in public health sector [25]. It is believed that the success of any training depends on whether the managers are good learners [26] or just interested in management as well as how the management education/training is done [27].

Clinical governance: vision or reality?

Definitions and concepts

Clinical governance is a framework through which National Health Service organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish [28]. Studies show that policies to deal with poor practitioner performance [29] and to learn effectively from adverse events and errors [30] have been added to clinical governance structures to improve the safety of the clinical environment. Clinical governance was introduced when quality had been more explicitly addressed than ever before. In the UK, "the National Institute for Clinical Excellence has a key role in appraising new technology (such as drugs and medical devices), providing guidance on the appropriate use of treatment interventions and procedures, and developing clinical guidelines for the management of specific diseases" [30]. Palmer [31] believes that a comprehensive program of quality improvement activities – including clinical audit is a key to clinical governance.

Aims and scopes

Clinical governance was introduced in 1988 in the white paper entitled: "A First Class Service: Quality in the New NHS". Four following aspects of quality were developed in the above-mentioned document: professional performance, resource use (efficiency), risk management and user satisfaction [32]. Furthermore, guidance on implementation of clinical governance was issued by the

NHS Executive in 1999. The issued document identified four principal components for achieving excellence in practice which are: (a) clear lines of responsibility and accountability for overall quality of clinical care; (b) a comprehensive program of quality improvement activities (e.g. audit, continuing professional development, research and development); (c) clear policies aimed at managing risks, and (d) procedures for identification of poor performance [33]. The national Audit Office [34] stated that the clinical governance review process had had many beneficial impacts including that clinical quality was more mainstream; there was greater accountability for clinical performance; and there were more transparent and collaborative ways of working.

A survey [35] reported three review areas or pillars for clinical governance: (a) Patient, carer, service user and public involvement: how patients, carers, service users and the public have a say in decision making about health service delivery, policy and planning; (b) Risk management: the systems to understand monitor and minimize the risks to patients and staff and to learn from mistakes; (c) Clinical audit: the regular systematic review of procedures against defined standards leading to action to address any identified problems. Based on research, state regulation can take myriad forms ranging from licensing certain practices to prohibiting others, and providing a mixture of "carrots" and "sticks" in order to influence behavior [36]. It is proved that the series of high profile failures in standards of National Health Service care in Britain caused deep public and professional concern and threatened to undermine confidence in public health [37]. The authors of the present article will discuss three following regulatory models, compare and contrast them, and explain the approaches applied with regard to them. Finally, they will present a suggested model with the most benefits and the least disadvantages.

Regulatory models: plans for quality

Internal regulatory model

In self-regulation or internal regulatory model, the members of a regulating board are selected from the physicians and experts who work in the same medical institutes. It is believed that self-regulation in any system — be it medicine or parliament — is built on trust and if a gap grows between those who are regulating themselves and the public they serve – that's when the threat to self-regulation comes [38]. In the internal regulatory model, the prevailing approach of the regulatory process is based on the regulator's expertise knowledge. The quality of health care depends on the existing and facilities and measures in a medical institute. It seems that selecting members of the regulating board from physicians and experts of the same medical institutes helps to provide scientific and exact reports about the governing situations.

Benefits and privileges

Some factors can be considered as privileges of internal regulatory model: expert knowledge; awareness of

medical standards and criminal provisions; periodic selection of members of regulating board; unpredictable visits, and permanent regulation.

(a) Expert knowledge— Expert knowledge or specialization as a center of gravity in this regulatory model hinders authorities and personnel to abuse the regulating board members' inexperience. In the above model, members of regulating board are aware of specialized medical standards and criminal provisions of each department. "...It is ... appropriate for the profession itself to respond to clinical governance by showing that self-regulation can work locally as well as nationally" [39]. Authors of this writing emphasize that medical regulation may protect patients' rights against possible trespasses in medical institutes and it merely means that they try to present a regulatory model based on a protection-based approach concerning patients' rights. Undoubtedly, each medical regulation may pose some limitation on patients' rights and simultaneously secure them. Hence, limitations on patients' rights are not denied but it is important to interpret such limitations through a protection-based approach. Such limitations may secure patients' rights in one hand, and may increase the efficacy of medical institutes on the other.

Legislative approach— If Iranian criminal legislator recognized internal regulation, she/he would expressly state it in Iranian statutes. In the article, the authors emphasize on including the phrase "using expert knowledge when selecting members of the regulating board". Hence, Iranian criminal legislator should maintain that expert knowledge in regulation is rendered as an imperative law. Imperative law is a rule in the form of a command; a rule of action imposed on people by some authority that enforces obedience [40]. As such, if personnel deviate from such a rule and it results in committing crimes against patients' rights, they will face criminal sanctions. No doubt, moral codes in medicine are of great importance but attention should be paid to the existing criminal policy which is going on in Iran. In a country with high standards of medical regulation, moral codes may be very useful but such codes have not even been recognized by Iranian criminal legislator and their status has decrease to some guidelines whose ignorance will not have any criminal sanctions for the person or medical institutes who ignore them. Furthermore, no patient can refer to moral codes in court to oblige anyone to respond concerning his/her trespass to the patients' rights.

(b) Permanent regulation — Permanent regulation with the emphasis on emergency situations is another benefit of internal regulatory model. According to this model, some members of regulating board take their positions in therapeutic centers or medical institutes. Therefore, they are obliged to implement regulatory measures knowingly. Furthermore, permanent presence of regulators ensures preserving patients' rights and meeting their needs. Permanent regulation is necessary in emergency

situations because it is possible that the patients refer to medical institutes in each hour when their situations are grave. A permanent and continuous regulation can secure dealing with treatment issues concerning reception, preserving the patient's rights and meeting his/her needs.

Legislative approach— It seems that Iranian criminal legislator should assign a permanent regulation in emergency situations where regulators' presence is necessary to preserve patients' rights. In addition, the criminal legislator should consider a lawful bind to regulate medical institutes in unpredictable time. There is no doubt that in such a situation, regulators will not perform their duties arbitrarily and in a discretionary manner; that is, they conduct their duties objectively and based on legitimate provision and ignore all personal opinions and biases. Nevertheless, specifying emergency situations in their strict senses will limit regulators' autonomy and will prevent them making their own decisions. Here the authors would suggest objective test (i.e. objectivity) but this does not deny subjective test (i.e. subjectivity) when regulating. Rater it means that in the existing criminal policy of Iranian health system, objective test is considered as a priority because it secures patients' rights against undue personal preferences. Subjective test is also of great importance when a patient's specific and unique situation is going to be dealt with.

Disadvantages and objections

There are also some objections in internal regulatory model: Leaving personnel's duties and regulatory tasks to one person, in some occasions, which results in weakening regulatory aspects of duties; probability of conspiracy; taking duties easy due to some relations, and increasing dark number of crimes committed against patients. Dark number is unknown number of crimes which are committed but neither detected nor reported to the police or judicial authorities. It will also make a safe heaven for offenders to continue committing their crimes.

(a) Overlap of regulators' duties and those of personnel — In fact, effective and efficient regulatory duties necessitate that the experts who are working in a medical institute do not regulate a specialized department in the same institute. The combination of personnel's duties and regulatory tasks will result in weakening regulatory aspect of such duties. When both of these two groups of duties are left to one person to conduct, she/he may deviate from achieving them. Accordingly, such a person may not regulate his/her colleague's duties. As a result, the colleagues will commit crimes against patients' rights which, in turn, will be neglected. Basically, regulators, who are selected from the personal of the same medical institute or from other institute, may have a good relation with the personal. Such a relation is useful for a good regulation but the conflict of interest should be reached to a low possible rate.

(b) Probability of conspiracy — Since members of the regulating board are selected from the experts of the same medical institute, conspiracy may come into existence. Regulators who regulate according to internal regulatory model, and cooperate with the personnel, usually conduct their duties negligently. This arises from the presence and professional cooperation of regulators at the same medical centre. The authors of this article do not believe that in internal regulatory model, in emergency situation, preventing conspiracy is more important than protecting patients' rights rather they believe that preventing conspiracy is just one way to protect patients' rights. Therefore, what is important here is to apply a regulatory model which decreases the probability of conspiracy to a great extent. In emergency departments where specialized medical services are delivered, the most effective model is internal regulatory model.

3. Special regulatory mechanism — Special regulatory mechanism is a rather new mechanism applied to regulate special departments in medical institutes. The nature of medical activities in the following departments makes it necessary to deliver special therapeutic and hygienic services: I.C.U.; C.C.U.; the departments for HIV-infected patients and drug addicts, and special institutes for the physically or mentally disabled people and the elderly. Hence, regulators in these departments are suggested to conduct their duties according to the internal regulatory model. Such specialized departments require that their regulators be selected from the same departments. Otherwise, the regulators' lack of expert knowledge and their continuous contraventions will remain as a dark number. According to a pathological criterion, these special patients are vulnerable. Vulnerable (person or adult) is described as a person or an adult who is physically or mentally disabled; especially, one dependent on institutional services [40].

External regulatory model

External regulatory model has the following features: selecting members of regulating board from other medical institutes; existing legal framework, centralized regulatory activities, pursuit of public good; autonomy and independency of regulating board, and ignoring professional relations. In external regulatory model or independent regulation, members of the regulating board are selected from one medical institute but regulate another one. External regulatory model is based on the principle of separating the regulator and the decision maker and pays a lot of attention to the autonomy of regulating board with respect to the departments which are under its regulation. In fact, regulators try to regulate the authorities of the departments based on the regulating board's autonomy. Also, regulatory mechanism doesn't deal with the professional relations as it does in internal regulatory model. The center of gravity in external regulatory model is based on the preservation of the principle of autonomy and independence.

1. Process-based regulatory mechanism- In this mechanism, the following factors should be taken into consideration: the processes from acceptance to release from hospital or institutes; meeting patients' needs appropriately; justifications for acceptance, rejection and determination of long appointments; applying objectivity in reports; times of a patient's referral to a medical institute; reporting the amount, quality and quantity of existing facilities; regulating expenses received from patients; reporting appropriateness of received expenses and delivered health care services; periodic but unpredictable control of activities conducted in a medical institute, and justifications concerning accepting patients as inpatients or outpatients. Here the emphasis is on the process through which a patient should pass from the moment of referral to the hospital or medical institute till payment of expenses and release. Regulators are also obliged to regulate the determination of long dates for medical appointments in medical centers and institutes according to the provisions of a medical system.

The first criterion is the times a patient refers to a medical institute. Therefore, rejecting a patient or determining long dates for medical appointments is not merely a base to breach that criterion. It should be noted that accepting emergency cases should not be included in the reports as the times of acceptance. The second criterion is the amount of existing facilities in the institute both qualitatively and quantitatively. Hence, the kind and length of medical appointments should be based on the existing facilities through the reports. Accordingly, medical institutes are obliged to justify the necessity of determining long medical appointments to patients.

Like in every country, in Iran, criminal law protects high values of the society. Moreover, moral codes are not enough to secure patients' rights in Iran because some behaviors result in committing crimes against patients' rights and inflicting harm on patients, and the only way to prevent them is to enact criminal sanctions. Criminal protections are deterrent so that not only will they prevent the offender repeating such a behavior, but also they will teach other medical institutes a lesson not to commit crimes against patients' rights. Criminalizing some behaviors which result in committing crimes against patients' rights would remind every Iranian citizen of high status which patients' rights enjoy. To the authors of this article, criminalization and considering criminal sanctions can be considered as the last resort but they are necessary based on the existing criminal policy in Iranian health system. Criminalization is a process through which the criminal legislator determines some punishments for some behaviors which from then on, will be called crimes.

Regulators are obliged to regulate the expenses the hospitals or medical institutes receive from patients when patients receive medical treatments from hospitals or medical institutes. A regulator, who is an expert in accountancy and is a member of the regulating board, should refer to the accountancy department of the hospital or medical institute and oblige the personnel to justify the received expenses. Also, the authors of the

present article suggest that regulators oblige medical institutes to prepare a monthly report in respect of the logical and plausible appropriateness of received expenses and delivered health care services. Such a report will be delivered to the regulating board to make the process-based regulating legitimate. Periodic but unpredictable visits to medical institutes and drugstores will be conducted to ensure that therapeutic and pharmaceutical services are delivered continuously and appropriately. Moreover, regulators ask the department which is in charge of confining patients to bed to deliver the list of inpatients and outpatients.

2. Institute-based regulatory mechanism- Followings should be borne in mind thought this mechanism: achieving a balance between the number of personnel and that of patients; controlling personnel's shifts, expertise and licenses, and controlling the quality and quantity of medical equipments. Institute-based regulatory mechanism concentrates on the personnel in therapeutic centers, how to replace their shifts, employment, the amount of the personnel's expertise for each department, and the quality of medical treatments and medicines. Regulators evaluate the number of personnel in each department to ensure that there is a proportion between the number of personnel and that of patients, and the duties to be conducted in the same department. Regulating board regulates necessary licenses which the institute should receive according to provisions of the Medical System Organization of each country. The board also nullifies the licenses which don't enjoy legal terms and conditions. Such a duty will be achieved through an administrative process, but not a judicial proceeding which is usually a long and tiring process. Ensuring that the activities of medical institute are lawful, and taking regulatory measures in employment are also included in the above-mentioned regulatory mechanism.

Illegitimate replacing shifts of personnel are controlled to decrease the possibility of conspiracy. Accidental and periodic regulatory measures are taken due to the increase of such contraventions. In the case of an insurance contract, the commitments of the institute which deliver the therapeutic services and those of the insurer as the provider of these services will be included. An insurance contract makes an insurer to estimate the expenses which the patients should pay to medical institutes and know if there are any unlawful expenses. Contracting for health services between governments and non-state providers is an approach that has gained popularity as a way to stimulate improvements in health service utilization and quality in low income countries [41].

Hybrid regulatory model

This suggested model will enjoy several features which are mainly extracted from internal and external regulatory models: distinction between specialized and general departments; increasing the efficiency of medical institute; securing patients' rights; expert knowledge as a

determining factor to select members of regulating board; round-the-clock regulation; distinction between regulator and decision-makers, and protecting patients' rights and human dignity. It seems that regulatory measures should be taken based on municipal Acts of each country, and according to the separation of different departments located in medical institutes to provide a coherent and lawful policy. A distinction is also made between specialized departments which are responsible for delivering specialized health care services and general departments in institutes. Hence, the criminal legislator should consider the necessary conditions for a department to be called a specialized or a general department.

Iranian criminal legislator can consider a regulatory model appropriate with a department and she/he can provide an effective and useful regulatory model. In other words, in the hybrid regulatory model, the governing principle and exceptions are considered according to Iranian medical law. External regulatory model is usually identified as a governing model in special cases in hospitals or therapeutic centers. Internal regulatory model in specialized departments in hospitals can be applied with two characteristics: first, the expert knowledge of physicians and attending doctors (AD) in order to become a member of regulating board and second, continuous and round-the-clock regulation. On the contrary, external regulation is applied in general departments because the expert knowledge is somehow of less importance in such departments. In the latter case, the principle of the separation of a regulator from a decision-maker is taken into consideration to guarantee the impartiality of regulation process.

Moreover, there will be no internal communication which causes the conspiracy of regulators and personnel, and finally, medical contraventions will be considered. In fact, coexistence of both external and internal regulatory models has one advantage: In practice, both expert knowledge and Iranian medical custom in medical institutes are taken into consideration. Two above-mentioned models have also one common feature with hybrid regulatory model: In addition to meeting patients' needs, preserving their rights, and providing them with health care facilities, Iranian health care authorities apply the process-based and special regulatory mechanisms in Iranian medical institutes.

Criminal protections for patients' rights in hybrid regulatory model

In order to provide criminal protection for patients' rights, a coherent and legitimate criminal policy should be considered at the first instance. An appropriate criminal policy which can establish its protective mission with regard to crimes against patients' rights is suggested to contain the three following criteria: First, it should provide protective measures to secure and observe patients' rights in medical institutes so that criminal reaction against offenders committing crimes against patients' rights is used as the last resort. In other words, criminal combat against such offenders is merely going to start

when protective measures lack enough efficiency to reduce the rate of committing crimes. Second, criminalization in this area should provide criminal protection for right to treatment and quality of patients' treatment as unavoidable values and push forward criminal justice system towards criminalizing behaviors depriving patients from therapeutic and health services.

Third, criminal protection which Iranian criminal legislator considered with regard to crimes against patients' rights should be based on zero-tolerance paradigm. That is, when combating such crimes, criminal justice is suggested to resort to deterrent punishments. Moreover, when stipulating punishments Iranian criminal legislator should consider certainty and promptness in enforcing punishments as important features. In addition, punishments should be considered based on legal nature of medical institutes because traditional punishments in their strict sense such as imprisonment and flogging are not basically enforceable concerning medical institutes. Hence, resorting to a criminal policy in its wide sense, Iranian criminal legislator should consider punishments with most deterrent effect such as temporary or permanent cessation of work for medical institutes, nullifying permit, confiscating properties which should have been put into patients' access but have been used for personal interests. Punishments not based on legal nature of medical institutes have neither preventive aspect nor do they teach other institutes a lesson not to commit crimes against patients' rights.

As such, criminal policy makers should accept this fact that stipulating every effective and useful criminal policy in respect of crimes against patients' rights is merely possible through coincidence of criminal law and medical law. Such a coincidence will make Iranian criminal legislator pay attention to teachings of a hybrid regulatory model in three following domains: prevention, criminalization and considering punishments for crimes against patients' rights. In doing so and in the light of criminal gaps and shortcomings of internal and external regulatory models, Iranian criminal legislator should try to push forward criminalization towards a situation where Iranian medical institutes will not be able to resort to this argument or better to say "justification" that "we have taken advantage of criminal gaps in patients' rights rather than committing crimes against patients' rights".

Discussion and Conclusion

In many countries regulation is both a tool of performance improvement as well as an instrument of social justice. Different issues are evaluated in medical regulation including "...the nature of the regulating organization, regulatory goals and objectives, scope of the regulation, regulatory model (i.e. deterrence or compliance), methods used to communicate direction to regulated organizations, methods of detection, and methods of enforcement" [42]. The skills managers perceive as important and need improvement are decision making, risk-taking, and benchmarking and only after they have solved such problems do they become more open-minded about skills such as communication

skills, effective listening and system thinking [43, 44]. Personnel may also be regulated through training programs. They are taught to deliver health care information to patients. This will, in turn, result in fortifying public health sector. There is clearly a need for a more sophisticated model of medical regulation that recognizes the distinctive and complementary contributions to be made by individual clinicians, the profession collectively, employers, commissioners and the public [45].

Authors of this writing believe that it is high time to use experiences gained in other countries in addition to capacities of municipal Iranian Acts to end all disagreements, dispersions, and diversities of Acts in Iranian medical regulation. Furthermore, it seems that municipal Acts should be led to equalize regulatory provisions in medical institutes through providing a comprehensive and a unified plan. Doubtless, patients' rights will not be preserved and guaranteed unless experiences gained are taken into consideration, and grounds and capabilities of municipal Acts specially those of the Medical System Organization, guidelines and directives of the Ministry of Health and Social Welfare Organizations are paid attention to pragmatically rather than just theoretically.

Although regulating medical institutes is not a new subject in Iranian medical law, there is a reluctance to include such regulation in medical activities arena. It seems that some of medical institutes are reluctant to abide by criminal provisions. Also, they prefer to deliver their medical services and to treat their patients in a discretionary way and under no regulation. Some of such institutes commit crimes against patients' rights when delivering health care services and during the treatment process due to the lack of a specific regulatory model in Iranian medical law. In fact, wandering around different and ambiguous medical regulations, Iranian criminal legislator failed to observe patients' rights. Clearly, observing patients' rights depends on illustration of a specific regulatory model at the first instance. Criminal sanctions should also be specified for the situations where crimes against patients' rights are committed. Hybrid regulatory model is now suggested as a more appropriate model than others. This model will surely secure patients' rights to a great extent in Iranian medical institutes. Hopefully, through putting this model into practice, Iranian public health can observe patients' rights and provide their needs in all aspects. Surely, Iranian public health authorities, who are doing their best to upgrade Iranian health system, will consider such an important issue into consideration. The authors also suggest that the outcomes of the researches will be more valid if experts of different fields conduct researches concerning different groups of people who are involved in providing health care services rather than personnel and managers.

Criminal policy Iranian criminal legislator is suggested to take should be the one based on which patients feel secure from committing crimes against their rights in medical institutes under the protection of criminal law.

Also, patients need to be sure that criminal law will not treat with offenders negligently. It seems an undeniable fact that a criminal policy which is merely based on dogmatic approaches of criminal law, ignores teachings of medical law and denies a need to use the outcomes of an interdisciplinary study will not lead to preserving and securing patients' rights. Such a criminal policy will surely have no result but to wane patients' status in criminal justice system.

Conflict of Interest

Authors declare that they have no conflict of interest.

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References

- [1] Salter B. (2001) *Soc Sci & Med*, 52(6), 871-871.
- [2] Saltman R.B. (2002) *Soc Sci & Med*, 54(11), 1677-1678.
- [3] Fang J. (2008) *Soc Sci & Med*, 66(4), 952-960.
- [4] Kelly B.D. (2010) *Ir J Med Sci*, 179(1), 3-3.
- [5] Peters D.H. and Muraleedharan V.R. (2008) *Soc Sci & Med*, 66(10), 2133-2141.
- [6] Mallin C.A. (2004) *Corporate governance*. Oxford: Oxford University Press.
- [7] Bennett S. and Muraleedharan V.R. (2000) *Econ Pol Wkly*, 35(1/2), 59-67.
- [8] Davis M. (2000) *Medical self-regulation: crisis and change (medical law and ethics)*, Aldershot: Ashgate Publishing Limited.
- [9] Nunes R., Rego G. and Brandao C. (2007) *Health Care Anal*, 15(3), 169-77.
- [10] Gawande A. (2007) *Better: a surgeon's notes on performance*, New York: Metropolitan Books.
- [11] Groopman J.E. (2007) *How doctors think*. New York: Houghton Mifflin.
- [12] Gawande A. (2002) *Complications: a surgeon's notes on an imperfect science*, New York: Picador.
- [13] Collins C. (1999) *Brit Med J*, 318(7185), 682-3.
- [14] Zorica T.S., Bjegović V., Marinković J., Milicević M.S. and Vasić V. (2010) *Health Pol'y*, 96(1), 80-90.
- [15] Miljanović S.M. and Janković S. (2006) *J Public Health*, 14(4), 246-56.
- [16] Tosić O. (2002) *The Lancet*, 360(9327), 149.
- [17] Nelson B.D., Dierberg K., Šćepanović M., Mitrović M., Vuksanović M., Milić L. and VanRooyen M.J. (2005) *BMC Health Serv Res*, 5(1), 14.
- [18] Gregory D., Baigelman W. and Wilson I.B. (2003) *Health Serv Res*, 38(3), 905-18.
- [19] García C.M. and De Val Pardo I. (2004) *Health Pol'y*, 67(1), 1-13.
- [20] Alkhafaji A.F. (2003) *Strategic management: formulation, implementation, and control in a dynamic environment*, Binghamton, NY: Haworth.
- [21] Collins D.B. (2002) *Hum Resource Dev Rev*, 1(1), 91-110.
- [22] Longenecker C.O. and Ariss S.S. (2002) *J Mgmt Dev*, 21(9), 640-54.
- [23] Atwal A. and Caldwell K. (2006) *Int'l J Nurs Prac*, 12(6), 359-65.
- [24] White M. and Mackenzie-Davey K. (2003) *Career Dev Int'l*, 8(5), 228-34.
- [25] Savič B.S. and Pagon M. (2008) *Croat Med J*, 49(3), 334-43.
- [26] François P., Vinck D., Labarere J., Reverdy T. and Peyrin J.C. (2005) *Qual Saf Health Care*, 14(3), 234-9.
- [27] Hunt J.W. and Baruch Y. (2003) *J Mgmt Dev*, 22(8), 729-30.
- [28] Scally G. and Donaldson L.J. (1998) *Brit Med J*, 317(7150), 61-5.
- [29] Department of Health. (1999) *Supporting doctors, protecting patients: a consultation paper on preventing, recognizing and dealing with poor clinical performance of doctors in the NHS in England*. London: DoH.
- [30] Department of Health. (2000) *An organization with a memory: report of an expert group on learning from adverse events in the NHS*. London: Stationery Office.
- [31] Palmer C. (2002) *Adv Psychiatr Treat*, 8, 470-6.
- [32] NHS Confederation Great Britain. (1998) *A first class service: quality in the new NHS (briefing)*, London: NHS Confederation.
- [33] NHS Executive. (1999) *Clinical governance - quality in the new NHS HSC*, London: NHS Confederation.
- [34] National Audit Office. (2003) *Achieving improvements through clinical governance: a progress report on implementation*, London: NHS Trusts Stationery Office.
- [35] Jones R. and Jerkins F. (2006) *Managing and leading in the allied health professions (allied health professions - essential guides)*, London: Blackwell Publishers.
- [36] Parkin M. (2007) *Economics*, (8th Ed.). London: Addison Wesley-Pearson.
- [37] Halligan A. and Donaldson L. (2001) *Brit Med J*, 322(7299), 1413-7.
- [38] Smith R. (1995) *Brit Med J*, 310(6993), 1515-8.
- [39] British Medical Association, Central Consultants and Specialists Committee. (1998a) *Appraisal for senior hospital doctors*. London: CCSC, BMA.
- [40] Garner B.A. (2004) *Black's law dictionary*, London: Oxford University Press.
- [41] Loevinsohn B. and Harding A. (2005) *The Lancet*, 366(9486), 676-81.
- [42] Walshe K. (2004) *Int J Qual Health Care*, 16(3), 265-6.
- [43] Anderson P. and Pulich M. (2002) *Health Care Manager*, 2(2), 1-11.
- [44] Hancock H., Capbell S., Bignell P. and Kilgour J. (2005) *Int J Health Care Qual Assur Inc Leadersh Health Serv*, 18(2-3), 179-92.
- [45] Irvine D. (1999) *The Lancet*, 353(9159), 1174-9.

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