

On the Legal System of Medical Malpractice Management in China and Its Impact on Medical Ethics

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Abstract

The identification of medical malpractice requires sophisticated techniques. However its difficulty always exists in diminishing the disagreements between medical agents and patients, in settling medical disputes or dispute resolutions. Since 1980s, Chinese government is emphasizing more and more importance to adjust the legal relationship involved in medical malpractice by adopting legal means. Imperfect though, some administrative laws and regulations have been established.

This paper reviews the relative legislation process and discusses the legal problems existing in the field of medical malpractice management. It also addresses the issues and impact on medical ethical principles. It is pointed out that the perfection of legal system of medical malpractice treatment in China is not just an issue limited to medical system. It also depends on the further improvement of social security mechanism, judicial trial system, administrative system, moral and ethical concept in China.

Keyword: medical malpractice management

1. Introduction

In March 2001, a scholar wrote in the preface of a book introducing typical cases of

medical disputes in China: “After reading the 98 cases included in this book, readers will be saddened and astonished to tears. In these appalling cases, the ovary of a girl as young as 4 was removed by mistake; the arm of a professor as old as 60 had to be amputated. In these cases, a surgical needle was left in the body of the patient; a steel plate for fixation was broken. All these cases lead to either malfunction, disability or even death on the spot of the patient. Some other examples are a 6-year old boy was infected with AIDS after blood transfusion and a newborn baby was sent to wrong parents...” The scholar finally raised a question: who should be blamed for all these? In China, most medical establishments and medical practitioners are conscientious; the general public is satisfied with their proficiency and commitment. Although the happening of medical malpractice accounts for only a small percentage, it is still the case that due to the specific features of medical profession, the absence of sense of responsibility and medical ethics in medical personnel may bring irrecoverable loss to the patient in the event of malpractice. Besides, the identification of malpractice requires sophisticated techniques, which means the suffering patients and their families are usually in a position of disadvantage due to their lack of medical knowledge.

Disagreement between the medical establishment and the patient is ubiquitous

and the conciliation of medical disputes usually cannot be achieved easily.

Since the 1980s, Chinese government has been emphasizing more and more on taking legal means to handle the legal relationship in medical malpractice. Imperfect though, some administrative laws and regulations have been formulated. Taking the review of this process as a starting point, the paper then proceeds to a discussion over existing problems and the relative impacts on medical ethics.

2. Origination and development

Because of some well-known historical reasons, China, with a population of over 1 billion, still has many gaps to cover in legal system building. Following the reform and opening policy adopted in 1979, under the leadership of Deng Xiaoping, China started its course of ruling by law. At the very beginning, the legislation concerning medical malpractice was initiated by local governments instead of the central government. For example, the Standing Committee of Shanghai Municipal People's Congress enacted "Measures for the Management of Medical Malpractice" in 1984, which is the first law of medical malpractice management. One of the authors of this paper participated in the whole process, which provided him with a detailed knowledge of the background and process of legislation.

In the early 1980s, Shanghai witnessed an increasing number of medical disputes between regional hospitals and patients. With the intensification of disputes, there happened some severe incidents, in which the hospital was assaulted by patients' families and medical care personnel were beaten up. These incidents fall into two categories of different nature: 1. some medical care personnel were negligent and ill-mannered in their work, which led to medical accidents or errors and inflicted irrecoverable injury on the patients

and their families; 2. some patients and their families misunderstood the cure and treatment measures taken by the hospital because of their ignorance of and unfamiliarity with medical work.

Then Shanghai Ministry of Health drafted a bill, which was presented to the Education, Science and Health Committee of Shanghai Municipal People's Congress for discussion. As a bill drawn up by the medical administration, aiming at maintaining the smooth operation of medical agencies, it understated the importance of protecting the legitimate rights and interests of patients and their families. This kind of attitude is manifest in the regulation concerning medical records. Medical records provide important information in analyzing the case and identifying the possible existence of medical malpractice. Both situations once appeared in the past, in which the hospital counterfeited and altered medical records to shirk responsibility and the patients and their families fight against the hospital to get medical records. At that time there was a heated debate over whether the patient and his family were entitled to peruse medical records. Finally the draft submitted by Shanghai Ministry of Health prohibited the patient and his/her family from reading medical records. The authors deem that when there is a possible existence of medical malpractice, if the patient and his/her family are deprived of the right to refer to medical records, they are in effect deprived of the right to be informed of the facts concerning their immediate interests, which runs contrary to the spirit of China's constitution. Even when there is no medical malpractice happening, it does help dispel suspicion and facilitate settlement of dispute to allow the patient and his/her family to peruse medical records. Whether the patient and his/her family have the right to read the medical records or not is not important. The key point is the design of the legal system should guarantee the authenticity of the information

provided by medical records and prevent any institution or individual from counterfeiting, altering or damaging medical records. The authors' opinion was seconded by the experts attending the meeting of discussion and finally was included in the law.

On December 28, 1984, "Shanghai Interim Regulations on the Management of Medical Malpractice" was approved by the 12th Session of the Standing Committee of the 8th Shanghai Municipal People's Congress. The law, which was brought into effect as of May 1, 1985, was a regional law to be effective only in Shanghai, but it had a far-reaching significance in that it bridges a gap in the field of malpractice management in China.

The proper management of medical disputes, which concerns the immediate interests of both the medical establishment and the patient, is of vital importance to the stability of the society. Thus, the legislation of national level on malpractice management is of necessity. On June 29, 1987, the State Council decreed "Measures for Medical Malpractice Management", hereinafter referred to as the "Measures".

The "Measures" comprises 6 chapters and 29 clauses. The first chapter is the "General Provisions", which stipulates the objective of legislation and the definition and scope of medical malpractice. Medical malpractice happens when in the process of medical treatment and care, the medical provider's dereliction of treatment and care directly causes the patient's death, disability and dysfunction due to the injury of apparatus and organs. According to the "Measures", four kinds of situation are definitely excluded from medical malpractice: 1. a medical error which does not lead to the death, disability or dysfunction of the patient; 2. the unfavorable consequence that can not be predicted and prevented because of the particularities of the patient's disease or physical condition; 3. the occurrence of unavoidable complication; and 4. the unfavorable consequence arising

mainly from the absence of cooperation of the patient and his/her family.

The second chapter involves "Classification and Grading of Medical Malpractice", which divides malpractice into liability accidents and technical accidents. Liability accidents refer to the malpractice arising from activities of dereliction, such as acting against regulations or routine practices; Technical accidents refer to the malpractice caused by technical delinquency of the medical personnel. Based on the degree of direct injury to the patient, medical malpractice can be categorized into 3 degrees. First-degree malpractice covers the malpractice leading to the death of the patient. Second-degree refers to the malpractice causing severe disability or dysfunction of the patient. Third-degree malpractice is defined as that causing disability or dysfunction of the patient. The standards of medical appraisal concerning the degrees of malpractice are to be established by the Ministry of Health.

The third chapter introduces "Management Procedures of Medical Malpractice". The stipulations concerning medical records run as follows: the medical establishment involved in the medical malpractice or incident should assign a specific person to keep all kinds of source material, which must not be counterfeited, hidden or destroyed in any way. No regulation as to whether the patient and his/her family can peruse medical records or not is available in this part. However, in "Explanation on Several Issues of 'Measures for Medical Malpractice Management'" issued by China Ministry of Health on May 10, 1988, it is definitely provided that "the entrusted medical malpractice appraisal committee and the court or procuratorate hearing the complaint can peruse the original document when necessary after bringing forth the letter of reference. The work unit employing the patient, the patient, the patient's family and other relevant parties are not permitted to refer to the original document." The

“Explanation” deprived the patient and his/her family the right of perusing medical records, which is obviously unfair and is an infringement of the patient and his/her family’s right to be informed.

Chapter four is “the Appraisal of Medical Malpractice”. This chapter stipulates that every province should establish an appraisal committee of medical malpractice of provincial, regional and county level respectively. (Municipality directly under the Central Government should set up an appraisal committee of medical malpractice at the municipal and regional levels respectively). The committee should comprise authoritative medical practitioners of integrity who are at ranks higher than doctor-in-charge and nurse-in-charge, as well as several administrative personnel of health sector. The candidates of the committee will be nominated by health administration and submitted to the people’s government at the same level for approval. The committee is responsible for the technical appraisal of medical malpractice happening in medical establishments within the region. The conclusion of the committee at the level of the province, the autonomous region or the municipality directly under the Central Government is final and can serve as a basis to handle medical malpractice. Any relevant party, who contests the conclusion, may reapply to the appraisal committee of higher level for a review, or sue directly at a court within 15 days from the date of receiving the appraisal report.

Besides, the “Measures” stipulates the withdrawal of certain committee members and the distribution of appraisal expenses in chapter four.

Chapter five of the “Measures” relates to “Management of Medical Malpractice”, which prescribes the economic reparation and disciplinary measures against personnel with direct liability.

“Supplementary Provisions” are included in chapter six of the “Measures”,

which spell out the formulation of detailed rules, judicial explanation and the date of execution, etc.

The establishment and execution of the “Measures” is the termination of a stage in which the law of medical malpractice is absent in mainland China. But when the “Measures” was carried out, the emergence of many problems showed that the articles were too crude with an ambiguous explanation of many issues and were not effective in protecting the party suffering from malpractice. There were intense appeals to revise the “Measures” from both the medical establishment and the patient, as well as the court. Under this circumstance, a new law called “Regulations on Medical Malpractice Management” (hereinafter referred to as “Regulations”) was promulgated by the State Council in April 2002.

The “Regulations” includes 7 chapters and 63 clauses and was to be effective as of September 1, 2002. At the same date, the “Measures” was rescinded. Compared with the “Measures”, the “Regulations” includes many more clauses with several major amendments, which are listed as follows:

(1) The scope of medical malpractice is redefined. The “Measures” divides malpractice into liability accidents and technical accidents, while according to the “Regulations”, medical malpractice happens when in medical activities, the medical establishment and medical personnel perform against administrative laws and regulations, departmental rules, performance norms and conventions of medical treatment and care, and inflict bodily injury on the patient out of delinquency. According to the “Regulations”, the following 4 conditions shall be fulfilled to constitute a malpractice: 1) behavior against the norms of the industry; 2) delinquency of the relevant party (parties); 3) the fact of injury; and 4) causality between the behavior and the injury. No one condition is dispensable to identify a malpractice. The concept of a technical accident has no place

here.

(2) The grading of malpractice is changed from 3 degrees to 4 degrees. Besides revisions to the original three degrees, "leading to other consequences of obvious bodily injury to the patient" is added as the fourth degree.

(3) The patient and his/her family are returned the right to peruse medical records, which is denied in the "Measures". The "Regulations" states clearly that, the patient has the right to photocopy or duplicate his/her medical documents such as records in outpatient department, hospitalization records, temperature reports, doctor's instruction, laboratory test reports, medical imaging reports etc.

(4) It is definitely stipulated that medical establishment and personnel have the obligation to "inform truthfully". The "Measures" stipulates that, in medical activities, the medical establishment and personnel should honestly inform the patient of the state of illness, medical measures taken and relative medical risks, and reply to the patient's inquiry promptly. However, any unfavorable influence on the patient should be avoided.

(5) The appraisal agency of malpractice is brought into reform. The provision in the "Measures" that the appraisal committee of malpractice should be approved by the government is rescinded. In the "Regulations", it is stipulated that the local medical association (i.e. the medical association of municipal level if there is a region or the medical association of county level directly under the province, autonomous region or municipality directly under the Central Government) will be responsible for the first-time appraisal of malpractice and the medical association at the provincial level will organize the second-time appraisal. The Chinese Medical Association is to undertake the technical appraisal of malpractice with significant national influence that is difficult or complicated in identification, when it is

necessary.

(6) There are more detailed stipulations on the working procedures of malpractice appraisal.

(7) The items to be compensated and the standard of calculation in the case of malpractice are stipulated.

To lay a legal foundation on which the appraisal of malpractice can be based, the Ministry of Health also enacted "Interim Procedures of Medical Malpractice Appraisal" and "Malpractice Grading Standard (Provisional)" in July 2002.

3. Existing Problems

(1) The scope of medical malpractice is still ambiguous, which in fact hinders the realization of the patient's civil rights. One of the issues that aroused intense controversy in the execution of the original "Measures" is that the scope of malpractice is too limited, which fails to cover medical errors and thus the patient's civil rights cannot be fully realized. The experience of one patient serves as a ready example. A 13-year old girl underwent an operation of caeectomy because of acute typhlitis in a hospital in Shanghai. The operation was carried out smoothly and she left the hospital 2 days later. But on the third day, the girl suffered fierce bellyache, which was accompanied by high temperature. Her second visit to the hospital was not taken to heart by the doctor, who just prescribed some antipyretic and painkiller for her. But later the girl went to see the doctor again because of sustained high temperature. After the CT inspection, it was found that there was an unidentified tumor near her ovary. The girl's abdominal cavity was opened again and a parasitus was found near her cecum. In fact when the operation of caeectomy was performed, the inexperienced doctor didn't remove the parasitus. The parasitus, which was touched in the operation and then inflamed, conglutinated with the ovary. Finally the

second operation had to be performed and the girl's ovary was excised. According to the appraisal agency, there was no malpractice. But a different voice was uttered on the patient's side. They thought that since the patient was operated twice within a week for a usual illness of typhlitis and an organ originally in good condition was finally removed, the hospital at least had made medical errors. For example, before the operation, the patient was not treated with CT inspection. After the operation, the patient went to see the doctor several times but was not examined carefully, which allowed the condition to develop and delayed the best opportunity of cure. Since the "Measures" excluded the medical error from the medical malpractice, the patient couldn't claim reparation according to the law. The girl's parents have been brooding on that ever since. The argument of the hospital was that the treatment process of the doctor-in-charge conforms to the performance norms, and he should not be accused of malpractice for inexperience. There is a great disagreement between the two parties. With the adoption of the "Regulations", some experts believe it narrows down the scope of malpractice by excluding technical accidents. Some other experts deem that it enlarges the scope of malpractice by including medical errors. The fact that even the experts cannot agree with each other reflects the definition of malpractice in the "Regulations" is too theoretical and abstract to be properly adopted in judicial practice.

(2) The impartiality of malpractice appraisal is still being questioned. Malpractice cases are very sophisticated in techniques, the appraisal of which requires specific medical knowledge. It often happens that those people responsible for malpractice management are not well-informed in relevant knowledge. Thus the appraisal of the experts turns out to be of extreme importance and even may have decisive influence on the final judgment of the case. For many years, a

lot of problems exist in the appraisal of medical malpractice in China, including the problems of the appraisal agency, the member composition of the committee, the openness of appraisal process and the legal supervision of the appraisal, etc. Compared with the "Measures", many amendments have been brought to the "Regulations". But quite a few defects can still be identified after a careful study. The "Regulations" is different from the "Measures" in that the right of appraisal is delegated to the medical association, a kind of nongovernmental organization, while under the "Measures", appraisal from the experts is to be organized by governmental administration. Thus the old appraisal system, which is extremely unreasonable in that it is just like to ask "the father to appraise the son", is changed. The "Regulations" can be considered as a progress in this sense. But can the medical association really carry out the appraisal in an objective and impartial way? It is still a problem worried by many people and some of them considered the new system as "to ask the uncle to appraise the nephew". Theoretically speaking, a medical association is a pure nongovernmental organization, which operates on its own. But due to various reasons, in present China, the work of all kinds of association is still somehow interfered in by the government. Even if with the deepening of the reform of political system in China, the medical association may become a pure nongovernmental organization but its impartiality in malpractice appraisal is still questionable. According to the "Regulations", the experts participating in the appraisal are selected by the medical association at random. They are all locals and will of course know about the hospital and patient involved in the malpractice case after the appraisal is carried out. Since the health administration, hospital, medical association and medical experts are always interrelated with each other one way or another, the impartiality of the appraisal cannot be guaranteed. For example, the medical

practitioner subject to the appraisal may happen to be the committee member's teacher, student or classmate in the past. Besides, the committee member will consider the possibility of one day being appraised by one party involved, which will unavoidably affect the impartiality of the appraisal.

(3) The "Regulations" still has the tendency of sectoral protectionism. The "Regulations", which is laid down by the Ministry of Health and approved by the State Council, is an administrative law. Although the benefits of all parties will be taken into consideration when the sectoral administrative law is established, it is still difficult to prevent the administration in charge from prioritizing the interests of its own sector. That explains why sectoral protectionism can be detected in many administrative laws in China, which also inheres in the first regional law of malpractice management and is descended all the way to the "Regulations". Thus objectively speaking, some provisions of the "regulations" put the patient, who requires equal rights as one party of civil subject, in an unfavorable position.

4. Dilemmas with respect to medical ethics

(1) Because the "Regulations" is still defective in the design of malpractice appraisal system and fails to guarantee the impartiality of the appraisal, the public is having a more and more derogatory evaluation on the professional ethics and integrity of the medical sector.

(2) Medical care and treatment is a profession of high risk, and the "Regulations" emphasizes the observation of performance norms with the purpose of protecting the medical practitioner. If only the professional performance norms are followed, risks in the part of medical practitioners can be avoided. When the doctor is facing a choice between an active therapeutic plan and a passive one, he will usually choose the passive one to alleviate his risk, without considering that the

patient may lose an opportunity of survival or cure. A doctor with conscience may choose the former, but it may cost him a high price of administrative penalty, while the doctor who chooses to protect himself will suffer from the remorse of conscience.

(3) The present medical security system in China still needs to be improved, with the expenses of the hospital mainly covered by the fees patients pay for medical treatment and care. If a poor patient cannot afford the operation or expensive medicine he needs, should the hospital provide him treatment? If an active therapeutic plan is not adopted, the patient may lose his life. If the hospital tries its best to cure the patient, it may not get paid. Whether taking the passive treatment should be considered as malpractice remains an issue to be further discussed. At least we may say this kind of practice is against the traditional principle of medical ethics in China, which runs as "to heal the wounded and rescue the dying; to cure the sickness and save the patient".

5. Expectations

Of course, the existence of legal problems concerning medical malpractice and its relative impact on principles of medical ethics is not just an issue limited to the medical system. It actually reflects the inadaptability of the administrative system, the social security mechanism, the judicial trial system and moral and ethical concepts in a fast developing society. With the development of China's economy, the reforming of the medical security system, the improvement of legal system of medical treatment and the strengthening of the concept of medical ethics, which calls for the respect of life and human rights, the problems China's legal system of malpractice management is facing will be gradually solved in practice. For example, to protect the legitimate rights and interests of the patient, the system of the inversion of the burden of

proof has been adopted by the court in the trial of medical disputes cases, according to which some evidences must be produced by the defendant, i.e. the medical establishment. As a reform to the judicial trial system, it supplies a deficiency in administrative legislation and highlights the protection of the patient.

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