

Confidentiality challenges surrounding plasma therapy during the COVID-19 pandemic: a case discussion in Iran

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Abstract

Maintaining confidentiality, both in national and international codes of ethics, is considered an important principle in healthcare and the medical profession for both patients and physicians. This case-report article focused on a real case. Based on the request of the Iranian Blood Transfusion Organization (IBTO) for plasma donation from recovered COVID-19 patients, we asked the names and personal information of those patients from hospitals affiliated with Iran University of Medical Sciences (IUMS) and arranged for the subjects to be referred to the Medical Ethics Department of IUMS for consultation during the COVID-19 pandemic. Various ethical and legal aspects of this case were discussed in a special meeting, and practical solutions were then provided considering the limits of confidentiality and conditions for ethical access to patients' information during a pandemic.

Since plasma therapy is not a definitive cure for COVID-19 and considering the ethical and legal points presented in this article, it is not recommended to announce the names of patients in the early stages. Given the potential impacts of the procedure and the possibility of patients being cured, however, their consent should be obtained in different situations and, if necessary, providing information to patients or educating them should be considered.

Keywords: Confidentiality; Confidentiality breach; COVID-19; Plasma therapy.

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Case Introduction

To conduct research and provide treatment using plasma therapy, the Iranian Blood Transfusion Organization (IBTO) requested the names and personal information of the recovered COVID-19 patients from hospitals affiliated with IUMS. The IBTO also asked the ethics authorities of the university to propose the best ethical way to obtain information, given the existing laws and instructions and the current conditions and needs. Moreover, hospital authorities consulted the medical ethics experts in IUMS about the ethical aspects of the request.

Introduction

In the medical and health-care system, patient confidentiality and privacy of personal data is among the fundamentals of therapeutic relationships and professional ethics. Confidentiality of medical information, a significant aspect of the doctor-patient relationship, has a long history in medical ethics from the Hippocratic Oath to the current codes of professional conduct (1). Muhammad ibn Zakariya al-Razi, an Iranian physician, also stated in his treatise that doctors, as confidants, must keep patients' secrets. In Iran (as in other parts of the world), at the time of graduation from medical schools, medical students take an oath and declare, "I swear by God almighty, the Holy Quran and my conscience that I will never reveal

patients' secrets" (2). Furthermore, maintaining confidentiality is a prominent ethical virtue emphasized in Islamic ethics. According to Imam Sajjad (PBH) and Imam Sadegh (PBH), failure to maintain confidentiality is a moral vice that can violate others' rights, and breach of confidentiality can adversely affect all human interactions (3). The four common principles of medical ethics are beneficence, non-maleficence, respect for autonomy, and justice, and the obligation to maintain patient confidentiality is justified by the first three principles (4, 5). Respect for autonomy means that patients should be free to make decisions about their issues and problems, including choosing a confidant to keep their personal secrets. With regard to confidentiality, the principle of non-maleficence requires physicians to avoid disclosing patients' information. Furthermore, breach of confidentiality can damage the doctor-patient relationship and patients' trust in doctors, as well as the society's faith in the medical and health-care community over time. The principle of beneficence seeks to provide maximum benefit to patients. Hence, patients should be able to disclose all relevant information to their doctors with confidence so that the doctors can use the patients' entire information and history to correctly diagnose and treat their condition. Therefore, patients as well as the medical and health-care community should have protection against the consequences of

disclosure of confidential information. According to the abovementioned principles, the necessity of maintaining confidentiality is obvious to physicians, and they should make their maximum effort in this regard. Preservation of human dignity is a significant ethical principle that should be considered in all human actions and behaviors. Furthermore, due to the special nature of the doctor-patient relationship (patients need to trust their doctors to express their pain and suffering), doctors are required to be highly sensitive to confidentiality as a fundamental principle in doctor-patient interactions.

The Concept of “Secret” in the Medical and Health-care Field

In health-care providers' interactions with patients, the following information is considered as secret: (i) all Information revealed by patients to doctors for correct diagnosis and treatment, and (ii) information that health-care providers accidentally obtain while delivering patient care (6). During the diagnosis or treatment process, information from patients' private life, including their physical and mental states, is provided to the medical and health-care team members. Part of this information is so private that even people close to the patient are not aware of it, despite knowing the patient or cohabiting with him/her for many years. However, physicians have access to this information because of their professional circumstances (7). If such information is disclosed or made public, a group of individuals may face

stigma or discrimination. Therefore, various philosophical reasons make maintaining confidentiality imperative in the medical and health-care system including respecting patient's autonomy and avoiding damage to the doctor-patient relationship, which is founded on trust.

Confidentiality forum, Legal Perspective and International Laws

In most guidelines and codes of medical ethics, confidentiality is highlighted, and in some countries, enacted as laws such as the Health Insurance Portability and Accountability Act of 1996 (HIPAA) (8).

In the United Kingdom, breach of confidentiality is only permitted with the patient's consent, in response to court orders, or in case of certain public interest requirements. In the United States (9), regulations allow hospitals to provide the patient's information to insurance companies and relevant organizations without the patient's written permission if that information is directly related to health service provision. The Personal Information Protection and Electronic Documents Act (PIPEDA) in Canada and the European Union Privacy Directive in European countries support data privacy and protection (10 - 12).

The Laws in Iran

Article 648 of the Islamic penal code stipulates, “Health-care staff are confidants and secret keepers. With the exception of legal cases, if personal secrets are disclosed,

the liable staff member is sentenced to the stated punishment". According to article 106 of the penal code, doctors are responsible for keeping patients' secrets due to the nature of their profession. In cases other than those required by the law, if doctors violate confidentiality, they are sentenced to lashes, imprisonment and fines. Article 19 of the law regarding the prevention of communicable and infectious diseases, approved in 1941 and amended in 1968, obliges doctors to inform the Ministry of Health and Medical Education immediately when observing one of the following infectious diseases: cholera, plague, yellow fever, typhoid, exanthematous typhus, smallpox, scarlet fever, rubella, diphtheria, dysentery, malaria, polio and plague. In addition, if pertussis, leprosy, rubella, tuberculosis, pneumonia, trachoma, typhoid dermatitis, chickenpox, viral hepatitis or food poisoning is found in densely-populated centers (e.g., schools, factories, etc.), the doctor in charge must report it to the local health department (13).

According to article 3 of the law on the prevention of infectious and sexually transmitted diseases, approved in 1941, all physicians who treat sexually transmitted diseases are required to store relevant information and keep such information safe (13). According to article 1 of the law on compulsory registration and reporting of cancer, approved in 1984, to study and research epidemiological cancer diseases, if relevant institutions, in sampling from the human body for diagnosis and treatment, encounter cancer or suspected cases, they

must send the test results confidentially to the Ministry of Health's designated centers (14). Furthermore, in articles 76 to 80 of section 7 of the General Guide to the Professional Ethics of Medical Professionals and Affiliates of the Medical Council of the Islamic Republic of Iran, the necessity of maintaining confidentiality is highlighted, and disclosure of information is subject to the request of a court or a written legal article (15).

Ethical Conflicts in Maintaining Confidentiality

As mentioned above, the aim of confidentiality is to maintain patient's autonomy and respect for human dignity; it also is in line with the principles of bioethics: autonomy, non-maleficence, beneficence, and justice.

However, what approach should we take if fulfilling one principle is at the cost of dismissing other principles, or if fulfilling any of these principles for one patient leads to other people losing them? For example, when benefiting a patient is in conflict with benefiting a larger group of people or maximizing profits for others, or preventing harm to a patient is in conflict with protecting another person or a group of people in the community from harm. As another instance, respect for autonomy or dignity of one patient may be in conflict with respect for autonomy or dignity of others. Such questions indicate that confidentiality is not absolute and has exceptions that need to be addressed per case (16).

Therefore, since medical confidentiality is not absolute, doctors are allowed and even obliged to disclose patients' private health information under several conditions: (i) in case of patient's awareness and consent to release information; (ii) to prevent harm to the patient or others (e.g., when one's health or life is danger); and, (iii) to meet legal requirements or in response to court orders (17). For breach of confidentiality, the following conditions must be met: (i) the danger must be definite, serious and imminent; (ii) disclosure is the only way to prevent harm to the third person; (iii) the damage caused by disclosure is insignificant and tolerable; and, (iv) disclosure must only be made to the responsible authorities or people at risk and in the minimum amount required (18).

Method

The reported case was considered as an ethical challenge. In a two-hour group meeting of the medical faculty of IUMS, various aspects of the reported case were thoroughly discussed, and different viewpoints were expressed. Using the gathered data based on the ethical decision-making model and the four principles of bioethics, practical and logical solutions were presented for the raised problems considering the current conditions of the society during the COVID-19 pandemic.

Discussion

In the reported case, respect for human autonomy and dignity require that people have the right to control and manage their personal information. Furthermore, respecting patient's autonomy is an ethical principle in health, treatment and care. Hence, if patients do not wish to disclose personal information, medical and health officials are not allowed to breach confidentiality unless under several conditions:

- (i) *Legal requirements*: The clauses and legal provisions in Iran do not apply to the reported case, that is, COVID-19 cannot be regarded in accordance with the existing legal prose. It should also be noted that from a legal standpoint, disclosure of information is allowed only to the relevant official mentioned.
- (ii) *Patient's consent*: Because prior consent to participation in research had not been obtained in the reported case, disclosure of information was not possible without obtaining the recovered patients' consent and their willingness to volunteer for participation.
- (iii) *Danger of harm to a third person*: Currently, COVID-19 does not have a standard and definitive cure, and various studies are still evaluating treatment options. Therefore, plasma therapy is considered neither a standard and definitive treatment nor the only method to save patients' lives according to the

available scientific documents. Therefore, recovered COVID-19 patients' refusal to donate their plasma would not pose a definite danger to other patients' lives. Consequently, in the reported case, abandoning the act (not saving lives) does not cause definite harm to patients, and hence the recovered COVID-19 patients cannot be forced to donate plasma.

Despite the abovementioned arguments, scientific research may prove in the near future that plasma therapy is definitely effective in treating COVID-19; in fact, some articles have mentioned that it may be, as it has been used to improve patients' survival rate in the case of SARS, the 2009 influenza A (H1N1) pandemic, the avian influenza A (H5N1) pandemic, Ebola, MERS, and other viral infections (19 - 24).

Hence, given the sanctity of life and the exigency of saving lives, considering the potential benefits of plasma therapy is a sensible choice. From an ethical perspective, it should be discussed whether human beings have a duty to take a course of action that will probably benefit others. According to various moral schools of thought, both minimalistic and maximalistic, no human being should have to bring a probable benefit to others. Instead, they unanimously emphasize not harming others. For example, for patients with rare blood types in dire need of blood, hospitals cannot receive information from the IBTO without donors' initial consent, and they usually adopt other solutions. In such cases, a request to donate

is made to the patients' family members who have the same blood type, or to the IBTO's blood donors who expressed their consent to be contacted in special circumstances.

Islam emphasizes human life preservation so strictly that in Shiite jurisprudence, if survival is exclusively dependent on committing an act that is not allowed (haram), that act becomes obligatory (25). With similar emphasis, if human life is dependent on usurpation of another person's property, usurpation will be permissible and even obligatory. For example, food, medicine or sutures can be taken by force from those who own them and do not need them, but refuse to give them to persons in need (26). However, such actions are allowed if they are the only way to save human life, are definitely effective in saving life, and do not harm the owners' lives. In the reported case, the plasma method has not yet been proven effective in treatment of COVID-19, and in terms of effectiveness is equal to other suggested methods, and no more.

In this case, as mentioned before, disclosing patients' private health information and transforming data to IBTO are not recommended based on ethical, legal and Islamic principles.

Conclusion

During the COVID-19 pandemic, the Iranian Blood Transfusion Organization (IBTO) requested the information of the recovered COVID-19 patients from several

hospitals for plasma therapy and related research. Based on the above ethical arguments and legal considerations, providing such information to the relevant organization is not recommended. However, during the COVID-19 crisis, the interest of the society should also be considered. To manage the ethical challenges during the COVID-19 pandemic, practical solutions and provisions should be sought to achieve maximum benefit and dismiss potential loss, which mainly revolve around different methods of obtaining consent.

Although plasma therapy is still in the research phase and is not a definitive cure for COVID-19, ongoing studies may prove its effectiveness in the near future. Therefore, various practical solutions can be proposed to resolve the abovementioned issues. Clearly, it is necessary to find solutions that will provide the conditions for acquiring sufficient volunteers to donate plasma without disclosing patients' secrets. Some of these solutions are briefly mentioned in Table 1, and can be divided into two groups. The first group aims to provide therapists with the necessary information or training to justify the importance of confidentiality and patient information management methods; the second group comprises policy-making for public culture, media education, and the definition of an appropriate consent process. For example, plasma therapy can be discussed before admitting patients to the hospital or even before their release from the

hospital to obtain their informed consent for research. If the initial consent has not been obtained, calling for volunteers or advertisements in various forms and communities could be used to raise awareness and attract participation. Such measures would both prevent the risk of losing the trust of individuals due to breach of confidentiality and encourage participation of the recovered COVID-19 individuals to save other patients' lives.

Finally, regarding the advisory action taken by the relevant organization with the relevant ethics experts, the following solutions have been suggested to resolve the issue.

The Proposed Operational Solutions:

- Informed consent regarding plasma donation should be obtained from patients upon arrival or discharge from the hospital.
- Necessary information should be given to hospital patients to contact IBTO themselves.
- Hospitals can directly contact patients to obtain permission regarding plasma donation.
- Voluntary participation in plasma donation programs should be announced publicly in central hospitals.

A public call for voluntary participation of recovered patients in plasma donation programs should be announced and advertised.

Table 1- Proposed solutions for maintaining confidentiality during the COVID-19 pandemic

Policy making and management	Education and raising awareness
<ul style="list-style-type: none">• Developing culture at the macro level of the society and raising awareness• Calling for volunteers and advertisement in various forms and communities• Developing a suitable protocol to obtain informed consent upon patients' diagnosis and admission• Offering education through mass media to raise public awareness and understanding of the benefits of plasma donation for the community	<ul style="list-style-type: none">• Educating the medical and health-care staff about patient information management• Raising awareness regarding the consequences of mismanaging patient information• Teaching physicians and patients how to manage patient information and maintain confidentiality in interactions with the mass media• Raising the ethical sensitivity of physicians, especially regarding the consequences of inappropriate information disclosure for the profession• Raising awareness regarding the benefits of maintaining patient confidentiality both to patients and the community

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Conflict of Interests

None.

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