

# Patient-centered medicine in hospitals: Determination of medical Accidents

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## Abstract

The concept of patient-centered medicine was first proposed by E. Balint in 1969 and has been widely disseminated worldwide. The Ministry of Health, Labor, and Welfare in Japan aims to implement patient-centered medicine in all hospitals to improve the quality of medical care. In cases of medical deaths due to problems, all hospital administration doctors should provide the patient's family with a full and exact interpretation. However, some hospital administration doctors do not do this because an honest explanation might damage the hospital's reputation. The Ministry of Health, Labor, and Welfare should amend who may request an investigation of the medical accident and request specialist physicians from the medical quality and safety committee of a relevant professional society to determine if the case constitutes a medical accident. If medical safety research organizations seek the full truth behind medical accidents, hospital members will learn to improve their medical care for patients in line with the mission of patient-centered medicine. Overall, the quality of medical care for patients will improve if the medical system becomes more patient-centered.

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## The essence of medical care

Healthcare is a crucial social welfare service provided around the clock to patients worldwide. The coronavirus disease 2019 (COVID-19) has had a particularly major social impact since 2020, infecting many people worldwide and causing numerous deaths. Certain political measures were necessary to deal with COVID-19 infections, and each country has responded accordingly. The essence of medical care suggests medical professionals provide the best care for infected patients, and many medical institutions help patients by providing the highest level of medical care possible, such as by administering drugs, oxygen, and other treatments. In this way, medical care is performed for the patient, and medical professionals are required to provide the best for their patients.

Patient-Centered Medicine (PCM) was first described by Enid Balint [1] in London in 1969, later conceptualized as a medical method in the 1980s, and has since spread globally. Stewart et al. of Canada have been describing models and methods of PCM since 1986. First, they note that to practice PCM, the healthcare provider must administer care that empowers patients and share information in a personal relationship. This means relinquishing the control that has traditionally been held by healthcare providers. Second, Stewart, et al. [2] highlight the need for medical personnel to harmonize their relationships with their patients and to integrate the concepts of body and mind.

The spirit of PCM is spreading worldwide, and in Japan, government institutions in charge of healthcare policy are giving the concept serious consideration. In 1987, the Ministry of Education, Culture, Sports, Science and Technology (MEXT) held a colloquium on medicine and medical care in the 21st century. In a lecture titled "Development of medical professionals who can protect life and health in the 21st century," the speaker underscored the need for "medical professionals to be patient-centered and patient-oriented" and observed that the public image of physicians requires that they be "personable

and warm; have a deep reverence for human life; interact with patients and their families with sensitivity to their feelings; and provide patient-oriented medical care" [3].

On October 3, 2016, the Ministry of Health, Labor, and Welfare (MHLW) declared at the "Study group for a vision of work structure for medical professionals based on a new form of medical care" that medical care should respect patients' way of life and become a patient-centered system for delivering medical care. The report, released by the study group on April 6, 2017, states, "The era in which medical care is conducted by medical professionals alone has come to an end; collaboration with patients and citizens is now indispensable. In the medical field, which is entrusted with the lives and health of patients and citizens, medical professionals are striving daily to produce better medical outcomes by devoting their physical and mental energies to the ever-increasing demands and uncertainties inherent in medical care" [4].

In July 2001, Tokyo Municipal Hospital created a Patients' Bill of Rights, which stipulates that "Patients have the right to receive medical care while maintaining their human dignity, based on the philosophy of [PCM]. Medical care is a collaborative effort between patients and medical providers based on a relationship of mutual trust in which patients' active participation is necessary" [5].

PCM provides the best possible medical care for patients afflicted by illness with the hope of improving their condition and bringing them to a state of health. In the 20th century, the Japanese medical

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system was based on physicians treating and instructing patients from a superior position in order to cure their illnesses. However, in terms of whether physicians can be fully aware of a patient's circumstances, there is no way that physicians can be cognizant of all aspects of the patient's life, including physical and mental conditions; this implies that medical care was once centered around physicians' ideas. In the 21st century, the social position of patients in healthcare is higher than ever.

Physicians must surely be aware that the physician-patient relationship requires the patient to impart all relevant information and for the physician to respond accordingly, but physicians are not providing enough for their patients. The medical community has sought to advance medical care to a higher level through academic developments. When medical care works as intended, physicians are properly focused on their patients, but when serious problems arise in medical care, physicians tend to focus on the medical side of an issue and often consider patients a lower priority.

The word *patient* rarely appears in the philosophies of Japanese academic societies. Although the term *medical safety* is used, *PCM* is almost completely absent from the philosophies of academic societies. In 2012, the Japanese Society of Cardiovascular Surgery announced the following as its mission statement to promote PCM:

The Japanese Society for Cardiovascular Surgery is dedicated to promoting health and well-being through patient care of the highest quality, offered with an attitude of heartfelt caring for every individual human being, with a deep regard for ethics, and with an international outlook, working in collaboration with patients.

This may be the first time that the Japanese medical society has made reference to patients in its philosophy. In other countries, the phrase *patient safety* is widely used, suggesting that patients are taken into consideration. Japanese medical societies also want to administer the best medical practice to patients, but since they provide serious and complex medical care, they only discuss "improving the quality of care" and do not include the word "patient" to avoid putting themselves at a disadvantage. Patients should be included in the foundation of academic medical societies, and the philosophy of PCM should always be considered.

Recently, the Japanese Society of Cardiovascular Surgery used the phrase "improving the quality of medical care for patients" when considering "improving the quality of medical care" in the context of workplace reform. This is because the society's membership believes it is important that

the essence of medical care be in the service of patients. Since it can be difficult to think objectively about patients in the language of medical care alone, medical professionals should recognize the long-held spirit of PCM to ensure that the psychological framework for medical treatment is always patient-centered at both the personal and societal levels and include *patient* in the philosophies of medical institutions. In the future, it is expected that Japanese medical societies will shift toward PCM.

### The medical system according to MHLW

MHLW aims to make the provision of PCM a basic principle of medical care. To this end, through the Medical Care Act, the Enforcement Regulations of the Medical Care Act, and the Health Policy Bureau Notification, MHLW has made the social system and structure of medical care widely known. Because issues may arise with MHLW's approach to health care, especially the important components regarding the patient, it will be examined in the following sections.

### Medical Care Article 6-10

When a medical accident (meaning a death or a stillbirth caused or suspected to be caused by medical care provided by medical care professionals working in the relevant hospital and determined by an Order of MHLW to be a death or a stillbirth, which the relevant administrators did not expect) has occurred, the administrator of a hospital must immediately report the date, time, place and circumstances of the relevant medical accident and other particulars specified by an Order of MHLW to the Medical Accident Investigation and Support Center.

Prior to submitting a report pursuant to the provisions of the preceding paragraph, the administrator of the hospital must explain matters as specified by an Order of MHLW to the bereaved family of a person killed in a medical accident, the parents of a stillborn fetus resulting from a medical accident, as well as other persons ("bereaved families") specified by an Order of MHLW. However, when there is no bereaved family, or the whereabouts of the bereaved family are unknown, this requirement does not apply.

**"Issues with the enforcement of the ministerial ordinance, partially revising the ordinance for Enforcement Regulations of the Medical Care Act," Director, General Affairs Division, Medical Policy Bureau, MHLW, reported June 24, 2016**

### Medical Accident Investigation and Support Center:

To improve the response to consultations from bereaved families, and because such consultations are important data for internal investigations conducted by hospitals when the Medical Accident Investigation and Support Center receives a consultation from a bereaved family, it shall refer the bereaved family to a medical care safety support center and, upon request from the bereaved family, shall communicate the details of the consultation to the hospital administrators.

### The hospital administrator:

If the bereaved family submits that a medical accident may have occurred, and it is determined that the incident does not constitute a medical accident, the reason for the decision should be explained to the bereaved family in an easy-to-understand manner. To distinguish between general medical accidents and reportable medical accidents as defined by the Medical Care Act, those based on this system will be referred to as "medical accidents" hereafter.

### Response to the Medical Accident Investigation and Support Center

To ensure that PCM is fundamentally provided as safely as possible, MHLW has stipulated that hospitals consult with the Medical Accident Investigation and Support Center in the event of an issue with medical care to clarify the matters of medical accidents. Furthermore, MHLW has established various measures to improve the quality of medical care. The Medical Accident Investigation and Support Center has also been diligently improving the quality of medical care by identifying issues in medical accidents and publicizing measures to prevent a recurrence, which has increased confidence nationwide. Medical care can never be 100% perfect, and staff at medical facilities must strive to learn from every error that occurs. It is impossible for any facility to have zero medical accidents, and if one occurs, MHLW expects the facility to report to the Medical Accident Investigation and Support Center, request an investigation, and adopt improvement measures. In practice, however, according to the center's medical incident reports over the

past six years, 60% of hospitals with 400 to 499 beds (230 facilities), 44% of hospitals with 500 to 599 beds (73 facilities), 34% of hospitals with 600 to 699 beds (38 facilities), 36% of hospitals with 700 to 799 beds (17 facilities), 33% of hospitals with 800 to 899 beds (230 facilities), and 15% of hospitals with 900 or more beds (8 facilities) have not reported incidents. In total, 48% of hospitals with 400 or more beds have not reported an incident to the Medical Accident Investigation and Support Center in the past six years. Moreover, 11 of the 87 Advanced Treatment Hospitals (12.6%) have never reported a medical accident [6].

MHLW believes that PCM is fundamentally important and requests that hospital administrators report medical accidents that occur at their hospitals to the Medical Accident Investigation and Support Center. In this system, the final decision of whether a case was a “medical accident” is made at the discretion of the hospital administrator alone. As mentioned above, many large hospitals in Japan have not reported accidents to the Medical Accident Investigation and Support Center.

Regarding this issue, the Patients Liaison Council on Medical Safety (representative: Hiroyuki Nagai), a coalition of families of patients who died after receiving medical treatment, submitted a written request to MHLW in December 2020, requesting that the Medical Accident Investigation and Support Center conduct accident investigations upon the request of patients’ families.

Professional societies also cooperate in investigations at the Medical Accident Investigation and Support Center, and the hope is that the quality of medical care will improve by drawing on the center’s analyses of medical issues to adopt measures to prevent accidents from reoccurring.

Currently, however, the definition of a *medical accident* is, as stated above, a death or stillbirth that is unexpected by the administrator of the hospital under Article 6-10 of the Medical Care Act. It must be understood that if an incident is deemed not a medical accident without accounting for whether the actual treatment of a patient constituted reasonable medical care, the level of quality of medical care in society will decline considerably. The ideal situation would be to ask a specialist physician from the medical safety committee of a professional society of relevant medical care to judge whether the case constitutes a “medical accident.” Furthermore, Article 6-10 of the Medical Care Act may need amending to ensure the provision of PCM.

## Handling medical accidents in hospitals

Drawing on a recent case, this section brings a PCM perspective to an examination of how medical institutions respond to accidents and the medical accident investigation system. The cardiac surgery-related death that occurred at Hospital A was not recognized as a medical accident. The bereaved family requested a report through the medical accident investigation system, but no investigation committee was established under the system. The medical facility involved in the case provided medical and autopsy records to the bereaved family, who had doubts about the explanation of the medical treatment and decided to contact me. Based on the data provided and my perspective as a cardiac surgeon, I discuss the cause of death and challenges for the medical accident investigation system.

In 20XY, surgery for mitral valve incompetence was conducted on a man in his early 70s in the cardiovascular surgery department of Hospital A by means of Minimally Invasive Cardiac Surgery (MICS). The patient was scheduled for mitral valve repair, but the procedure was changed to cardiac valve replacement midway through the surgery, and the aortic cross-clamping lasted nearly five hours.

The patient suffered an intraoperative myocardial infarction and immediate postoperative severe heart failure. Since it was difficult for Hospital A to treat the patient, he was transferred to a university hospital where he received advanced treatment, but he died of multiple organ failure about two months later; an autopsy was performed at the university hospital.

## Details of mitral valve surgery

Extracorporeal circulation (via a heart-lung machine) is used in most cases of cardiovascular surgery. When used, every hospital tells patients and their families before surgery that the mortality rate is non-zero even with the mildest condition, an atrial septal defect, which has a mortality rate of 0.5%. A slightly more complex procedure than this, mitral valve repair has a mortality rate of about 1.5%, as recorded by the Japan Cardiovascular Surgery Database Organization (JCVSD). Since the patient was well enough to perform swimming exercises the morning of admission and was in generally good condition, the mortality rate was only mentioned briefly, and the medical

personnel believed that the patient would be discharged in good health. However, the mitral valve repair was unsuccessful, and the procedure was changed to a mitral valve replacement. Aortic cross-clamping lasted 4 hours and 51 minutes, and the patient was in critical condition afterward. According to the JCVSD, a mitral valve replacement has a mortality rate of about 6%, but this was not explained to the patient before the procedure. Given that the details of the procedure were not explained, the surgery was extended beyond what had been planned in terms of length and scope. Furthermore, as complications did occur, Hospital A’s judgment that this was not a “medical accident” is highly questionable.

## Cardioplegia infusion

In cardiac surgery, the timing of extracorporeal circulation to block off the ascending aorta and to administer cardioplegia is of paramount importance. The mitral valve incompetence, in this case, was not a severe condition, and while mitral valve repair was likely the original surgical goal, it seems the surgeons were unable to control the valvular regurgitation of blood. Subsequently, the surgery was changed to artificial valve replacement, leading to an extremely long period of cardiac arrest (myocardial ischemia) due to aortic cross-clamping. A textbook edited by the Japanese Society of Cardiovascular Surgery states that during aortic cross-clamping, “cardioplegia must be administered every 20–25 minutes (up to 30 minutes is allowed) even if cardiac arrest is maintained” [7]. In this

case, cardioplegia was administered 8 times during the 4 hours and 51 minutes of aortic cross-clamping, but only twice within 30 minutes: once at 29 minutes and once at 16 minutes just before aortic cross-clamping was released. Cardioplegia was again administered at extremely long intervals: twice within 37 minutes and once after 39 minutes, 41 minutes, 44 minutes, and 46 minutes, respectively, indicating that cardioplegia was insufficient.

## The autopsy at the university hospital

The autopsy findings noted “gross extensive myocardial damage from the posterior to lateral walls of the left ventricle, with hemorrhage from the intima in certain areas. The anterior wall and septum of the anterior wall were relatively preserved. Histologically, there is extensive myocardial necrosis across a wide area from the posterior to lateral walls of the left ventricle, the septum of the posterior wall, and in the posterior wall of the right ventricle.”

Considering the above findings in terms of perioperative problems, in addition to the long aortic cross-clamping time and long dosage interval between cardioplegia administrations, it is known that air can easily enter the aortic root during mitral valve surgery. Thus, it can be surmised that the myocardium became necrotic because cardioplegia was not properly administered to the myocardium.

In the case of mitral valve surgery, the ascending aorta is blocked with forceps; cardioplegia (about 500 ml in a few minutes) is infused through a thin tube placed on the cardiac side of the aorta (aortic root) while in a state of cardiac arrest the left atrium is incised, as shown in Fig. 1. As mitral valve surgery proceeds, air enters the left atrium, the left ventricle, and even the aortic root. With the patient supine on the operating table, the front of the body is in an elevated position during the procedure, so air accumulates not only in the left atrium and left ventricle but also in the uppermost area, the aortic root. Normally, cardioplegia is infused at 20–25-minute intervals, at which time the air accumulated in the aortic root must be eliminated from the device and tube for infusion of the cardioplegia. If cardioplegia is infused while the air remains in the aortic root, the air enters the right coronary artery in front of the aortic root (the highest point), blocking the flow of cardioplegia, or enters the right coronary artery basin of the myocardium. Air further enters the intramyocardial veins from the arteries and then enters the entire myocardium of the right and left ventricles on the back (posterior) of the heart, making myocardial preservation impossible. The left coronary artery, posterior to the aortic root, may receive a small amount of air, but if it is nearly filled with

cardioplegia, this can protect the myocardial anterior walls near the left anterior descending coronary artery. The circumflex branch of the left coronary artery extends to the posterior myocardium. If air enters the myocardial posterior wall from the right coronary artery and permeates as far as the veins, a large amount of air will enter the myocardium around the posterior wall, making it impossible to adequately infuse cardioplegia from the circumflex of the left coronary artery into the myocardium.

The autopsy findings confirmed that the consequence of the inappropriate administration of cardioplegia on the myocardium during surgery was that while the anterior myocardium did not become necrotic, the posterior and lateral walls of the left and right ventricles became severely necrotic. Because surgery was performed as MICS, which results in a narrower operating field than in conventional cardiac surgery, the aortic root could not be adequately seen. Moreover, as a result of neglecting the duty of care to remove air from the aortic root, extensive myocardial necrosis from air embolization of the coronary artery is assumed to have occurred, which extended to the left and right ventricular posterior walls as well as the ventricular septum. Mitral valve surgery has a long history, and removing air from the aortic root is known to be a reliable procedure for myocardial preservation among cardiac surgeons. This must be considered, even in MICS. If this precaution was not fully implemented at Hospital A, the judgment that this case did not constitute a “medical accident” is far removed from PCM and does not conform to the basic tenets of MHLW Figure 1.

### Outside expert physicians requested by the hospital administrator

Hospital A obtained opinions from three outside expert physicians who found no major issues with the surgical technique. The names, affiliations, and other details pertaining to these three physicians were not disclosed by Hospital A, and the details of their investigation are unknown. External physicians who make such judgments should

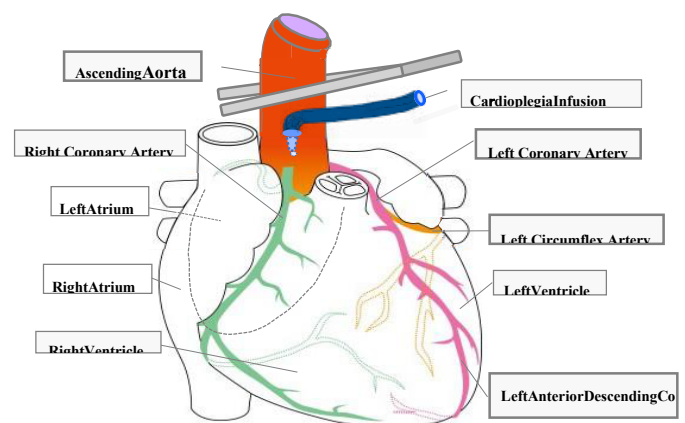
naturally be members of the Japanese Society of Cardiovascular Surgery and specialists certified by the society. The society’s Board of Directors has serious concerns about possible issues with the surgical technique in this case, but the opinion of the three physicians considered external experts was that the surgery was problem-free. Measures should be considered in the future to enable investigation of the causes of such discrepancies in judgment.

### Hospital’s response to the family

Regarding the myocardial infarction that occurred during surgery, Hospital A sent the following letter to the patient’s family: Concerning the fact that the surgery in question led to this kind of outcome, it has been established that the outcome of the surgery was foreseeable, and that this case does not constitute a medical accident that the hospital is obligated to report to the Medical Accident Investigation and Support Center...The opinions of three outside expert physicians were sought. Based on the results of their investigation, it was concluded that the indication of surgery and the choice of operative procedure in this case were appropriate, and that the execution of the operating procedure was within set standards.

According to the above response, Hospital A determined that the surgery that caused the myocardial infarction was conducted within set standards and, therefore, was not a “medical accident.” As such, there was no need to engage the Japan Medical Safety Research Organization to review the issue. However, the patient’s family felt that Hospital A’s explanation regarding the details of the surgery was insufficient and that the patient may have died due to insufficient medical care. As such, they have serious doubts regarding the judgment that this was not a “medical accident.” Despite MHLW wanting medical institutions to provide patients with fully understandable explanations regarding medical care, if Hospital A determined that the medical care that caused this myocardial infarction was not a medical accident and did not provide an adequate explanation to the patient’s family, it may constitute a troubling situation that runs contrary to the philosophy of PCM. The hospital administrator’s response may ignore PCM, despite the high probability of a medical accident in this case. MHLW should alter the current provision, which stipulates that decisions on medical accidents are made solely by the administrators of relevant hospitals when patients or their families express a concern that a medical accident may have occurred and request

specialist physicians from the medical quality and safety committee of a relevant professional society to determine if the case constitutes



**Figure 1.** The relationship between myocardial protection and the left and right coronary arteries during cardiac mitral valve surgery



a medical accident. If it is then judged that a medical accident has occurred, the Medical Accident and Safety Investigation Center should lead the investigation.

## The future of a patient-centered healthcare system

### PCM

Improving the quality of medical care is critical for the medical community. Furthermore, I believe we should pursue the improvement of the quality of medical care for patients considering the concept of PCM. Some of the medical community currently has a self-centered philosophy, but without a fundamentally patient-centered perspective of medicine, there can be no improvements in the quality of care. The development of medical care that is patient-centered and for the patient, rather than based on the self-centeredness of the medical staff—whether in medical school education, university hospitals, or general hospitals—will further improve the future quality of medical care to the benefit of both patients and medical staff.

### Determination of a medical accident

While it is desirable for hospitals themselves to determine whether a medical accident has occurred and to request an investigation by the Japan Medical Safety Research Organization, 48% of hospitals with 400 or more beds have not reported medical accidents to the Medical Accident Investigation and Support Center in the past six years. This may be because hospital administrators often consider only the interests of their own hospitals and therefore do not judge cases as medical accidents to avoid damaging the reputation of their facilities. There should also be an external system that issues an alert when a hospital administrator determines that a case was not an accident.

In particular, Article 6-10 of the Medical Care Act defines a medical accident as an unexpected death or stillbirth. However, the question of the expectation of death is difficult, and it is important for practicing physicians to have a scientific and rational standard for determining medical accidents as a basic aspect of medical treatment. Therefore, it would be better to change this law to improve the quality of medical care for patients.

Determining whether a “medical accident” has occurred solely within the hospital in question might not improve the quality of medical care or assist in PCM; it may be a major mistake. Thus, even if the hospital administrator determines a case not to be a medical accident, if the family disagrees, they should contact the committee on medical quality and safety of the relevant professional society and request a judgment from a specialist physician there. If it is determined that the case was not a medical accident, it is sufficient to explain this in detail to the patient or the family. If a medical accident is deemed to have occurred, however, it is important to accurately inform the Medical Accident Investigation and Support Center of the medical condition and to have the center decide on the matter to achieve better medical care. In this way, PCM will spread and facilitate the improvement of the quality of medical care nationwide. It is MHLW’s job to promote PCM nationwide rather than ignore patients and their families, and it is vital that all physicians give their best to this end. I hope that the Japanese medical community has a good understanding of PCM, which the international medical community values deeply, and strives to build a medical system that contributes to the well-being of everyone.

### References

1. Balint E (1969) The possibilities of patient-centered medicine. *J R Coll Gen Pract* 17: 269-276. [[Crossref](#)]
2. Stewart M, Brown JB, Wayne WW, Ian RM, Carol LM, et al. (1995) Patient-centered medicine, transforming the clinical method. *BMJ* 311: 1580. [[Crossref](#)]
3. *Medicine and Medical Care for the 21 Century (1987) Expected Medical Doctor Image*. MEXT, Ministry of Education, Culture, Sports, Science and Technology. Japan 9: 7 [[Crossref](#)]
4. *Report of Working Style Vision Conference of Doctors and Nurses for New Medical Treatment*. MHLW, Ministry of Health, Labor and Welfare. Japan 2016.10.3, 2017.4.6 [[Crossref](#)]
5. *Patient Right Qualification by Ethics Committee in Tokyo Metropolitan Hospital Organization*. 2001.7.6 [[Crossref](#)]
6. 2021 Year Report of Japan Medical Safety Research Organization 2022.3. [[Crossref](#)]
7. *Standard Textbook of Cardioplegia in the Japanese Society of Cardiovascular Surgery*. Bunkodo ISBN 978-4-8306-1928-1. [[Crossref](#)]