CLINICAL ETHICS

Does informed consent exempt Japanese doctors from reporting therapeutic deaths?

H Ikegaya, K Kawai, Y Kikuchi, K Yoshida

J Med Ethics 2006;32:114–116. doi: 10.1136/jme.2004.009480

See end of article for authors' affiliations

Correspondence to: Hiroshi Ikegaya, MD, PhD, Department of Forensic Medicine, Graduate School of Medicine, University of Tokyo, 7-3-1 Hongo, Bunkyo-ku, Tokyo 113-0033, Japan; ikegaya@m.u-tokyo.ac.jp

Received 26 May 2004
In revised form 11 May 2005
Accepted for publication 17 May 2005

The Japanese Medical Act section 21 states that doctors must report unnatural deaths to the police, even though the term "unnatural death" is not defined by law. However, many doctors are reluctant to report potential therapeutic deaths (PTDs). The Japanese Society of Legal Medicine has submitted guidelines for unnatural death, including PTD. These define a PTD as an unexpected death, the cause of which is unknown, but which is potentially related to medical practice. Such deaths are "reportable" to the coroner in the UK. In this study, we addressed the question of whether physicians would report each of eight hypothetical PTDs. Although the clinical societies (the Japan Society of Internal Medicine and the Japan Surgical Society) declare that doctors must report deaths due to gross negligence, 60% of the participants said that they would not report gross negligence involving an overdose in cases where they had obtained informed consent or had provided an explanation after the death occurred. This can be accounted for by the mistaken belief on the part of the participants that obtaining informed consent exempts Japanese physicians from the duty of reporting PTDs. The attitude of Japanese physicians is caused by the death investigation system, which is designed to discover whether a crime has been committed rather than focusing on the cause of death. Accordingly, the Japanese Government has decided to commission a pilot study from an independent organisation in which medical specialists will investigate PTDs in order to prevent deaths occurring as a result of gross negligence.

In Japan, doctors have a legal duty to report "unnatural deaths" to the police, according to the Medical Act section 21.^{1–2} In 1999, there was an accident in a public hospital in which a nurse gave the wrong injections to a patient but doctors did not report the resulting death. The litigation concerning this accident was focused on the legal duty of doctors to report such unnatural deaths. As a result, many clinical societies criticised the Japanese Society of Legal Medicine (JSLM) guidelines because such reports initiate a criminal investigation into the professional misconduct of those making the report.^{1–2} Additionally, the clinical societies declared that doctors should report such deaths when they judge that there has been gross negligence. By contrast, the JSLM has proposed that doctors should report "potential therapeutic deaths" (PTDs) irrespective of their judgement on gross negligence.^{3–5}

In Japan during 2003, of 248 criminal autopsies handled by the police, 192 cases were reported by doctors. The police cannot judge the necessity of an autopsy from a professional viewpoint. In a limited area of Japan, medical examiners investigate these deaths, determine whether an autopsy is necessary, and perform administrative autopsies.¹ However, about 90% of unnatural deaths are not examined by forensic specialists. In this situation, most PTDs remain unreported, and death certificates indicating natural deaths are accepted by lay municipal registrars.

In the UK, although there is no legal duty for doctors to report PTDs as unnatural deaths, it is widely accepted that they should refer these to the coroner.^{5–6} As most UK doctors recognise the merit and necessity of such disclosure, many PTDs are reported. The facts of these cases are disclosed by the coroners, thereby providing relief for both families and society in general.^{5–6} Coroners can also make proposals for the prevention of accidents. In Japan, the police and prosecutors who direct death investigations are not interested in such public health or medical issues, but in crime detection. Under such circumstances, many clinicians think that doctors do

not have to report these deaths if they have obtained informed consent of any kind.

The purpose of this study was to clarify whether informed consent or self-assessment regarding gross negligence affect doctors' attitudes to the reporting of PTDs.

MATERIAL AND METHODS

We sent a postal questionnaire to 466 board members of the Japan Society of Internal Medicine in May 2003. For eight hypothetical PTDs we asked whether respondents would report each one to the police. The cases were categorised according to the presence of gross negligence and whether information was given either before informed consent was obtained or after the adverse event had occurred (Table 1).

We also asked questions concerning the respondents' knowledge of the JSLM's definition of unnatural death, and on their opinions regarding autopsy and the investigation of deaths by a third party in order to reach an accurate diagnosis. The JSLM defines "unnatural deaths" as deaths excluding those for which clinicians can definitively diagnose intrinsic/natural death.

RESULTS

The response rate to the questionnaire was 58.8%. Of those who responded, 63.1% did not know the JSLM definition of "unnatural death".

As shown in Table 1, even when there is gross negligence involving an overdose of a drug, about 60% of these physicians would not report this to the police if they had obtained informed consent before administering the drug or even if they had explained the risk of death after the treatment (cases 1 and 2). If informed consent had not been obtained, 32.4% said they would report it (case 3).

Abbreviations: JSLM, Japanese Society of Legal Medicine; PTD, potential therapeutic death

Table 1 Doctor's action in the case of unexpected death during medical treatment (n = 274)

Case	Doctor's action*	
	Report (%)	No report (%)
Unnatural death due to the doctor's negligence		
1. Informed consent obtained prior to the medical treatment (Death due to an overdose of an anticancer drug; informed consent with information on the risk of death by adverse drug reaction)	32.8	61.7
2. Risk of death not sufficiently explained during the informed consent procedure (Death due to an overdose of an anticancer drug; informed consent with information on adverse drug reaction but not on risk of death)	36.5	58.8
3. Treated without informed consent (Death due to overdose of an anticancer drug without informed consent being obtained)	58.0†	32.4
Unnatural death without obvious negligence by the doctor		
4. Informed consent was obtained prior to the medical treatment (Unpreventable death due to a normal dose of an anticancer drug; informed consent on the risk of death by adverse drug reaction)	1.8	97.1
5. Death caused by risks not covered by the informed consent (Unpreventable death due to normal dose of an anticancer drug; informed consent on adverse drug reaction but not risk of death)	16.8	79.2
6. Death occurred while under the doctor's care (Fall from bed in hospital at night resulting in death)	37.2	49.8
7. Doctor had not examined the patient within 24 hours‡ (Death at home of a patient with a history of ischaemic heart disease; the patient's condition was stable one week previously when the doctor visited)	17.9	79.6
8. Death could be due to the doctor's slow response to start treatment (Death of a patient who fell on the hospital floor at night, but was left untreated until the next morning; despite emergency treatment, the patient died of acute subdural haematoma, but might have been saved by immediate treatment)	17.5	80.3

*Doctors have to report unnatural deaths to the police department (Japan's Medical Act section 21): all cases have to be reported under this law; †Statistically significant versus all other categories, $p < 0.05$; ‡In Japan, doctors must not write death certificates for persons who have not been examined within 24 hours of their death (Japan's Medical Act section 20).

In the absence of gross negligence, very few of these physicians would report deaths to the police: only 1.8% said they would do so if informed consent on the risk of death had been obtained (case 4), while 16.8% said they would report such deaths to the police if death had been caused by a risk not covered by the informed consent (case 5).

Deaths resulting from a fall in the hospital would be reported by only 37.2% of the doctors (case 6), even though there should be an administrative obligation to conduct an independent investigation in these cases. This is in line with the infrequency with which deaths in prison in Japan are reported or investigated.²

Article 20 of the Japanese Medical Act states that "A doctor must investigate a cadaver when he is required to write a death certificate unless he has attended the deceased within 24 hours before the death". However, the death at home of a patient with a history of ischaemic heart disease would be reported only by 17.9% of the participants, even when they had not attended the deceased within the previous 24 hours (case 7).

Notably, death due to delayed treatment for a subdural haematoma would be reported by only 17.5% of these doctors (case 8), reflecting their attitude of concealment of their own nonfeasance. On the other hand, 75.9% considered that autopsy investigations by a third party are needed to obtain a proper diagnosis in such cases, and 86.9% said that they thought that the investigation of such deaths is necessary.

DISCUSSION

The main finding is that about 60% of the Japanese doctors who participated in this study would not report PTDs due to a drug overdose when informed consent had been obtained. The question of whether informed consent was obtained before a mishap did not make any difference to the doctors' attitude, although, from a legal perspective, informed consent should be obtained before treatment. The clinical societies declared that they report cases to the police when they find gross negligence. However, about 60% of the doctors surveyed would not report these cases if informed consent

had been obtained, compared with 32.4% who would not report such cases even if informed consent had not been obtained. Thus, in Japan, the obtaining of informed consent doubled these doctors' underreporting of PTDs, though one in three of them would not report such deaths even without informed consent.

In the UK and other developed countries, informed consent would not affect doctors' attitudes towards reporting deaths, since reporting is demanded by law. Article 21 of the Japanese Medical Act defines a doctor's duty to report a therapeutic death; this was validated by the judgment of the Supreme Court (13 April, 2004) concerning a case involving an injection error. However, the clinical societies have criticised the guidelines of the JSLM, which recommend the reporting of PTDs irrespective of causality and the presence of gross negligence. In the UK, it appears that doctors are aware of the merits of reporting such cases in demonstrating their own fairness. As for deaths occurring shortly after the administration of drugs, both those who are bereaved and the general public would wonder if an overdose or a wrong drug had killed the patient, even if the doctor diagnosed anaphylactic shock and explained the death to the family as unpreventable. This would be a typical coroner's case in the UK, but it would rarely be reported by doctors in Japan.

Informed consent appears to have influenced Japanese doctors too deeply insofar as it has led them to believe that informed consent is a safeguard in their reporting of PTDs. Another reason for the underreporting is the failure of the Japanese death investigation system.¹ Because of the crime-blame structure of report and investigation, only 12% of total deaths are reported as unnatural and forensic autopsies are performed in 1.3% of cases, compared with about 32% and 23% respectively in the UK.¹ Police officers with no special medical background investigate doctors as crime suspects, in most cases without the attendance of forensic experts, whereas forensic pathologists who carry out autopsies are urged to make judgements on doctors' negligence despite a poor system of assistance from medical specialists. The most

serious drawback of the Japanese system is that the information from an investigation and autopsy is not disclosed to those who are bereaved or to the doctors concerned.¹⁻⁵

The benefits of a reporting system are to show fairness on the part of the doctors, to initiate investigation by medical and death investigation experts, and to take advantage of the information to prevent similar accidents and disputes/litigation. However, none of these benefits is achieved by the Japanese system. The appropriate disclosure of the causes of unexpected deaths, by means of an external hearing conducted by a death investigation specialist such as a coroner, is demanded and well understood in the UK. However, these merits are not understood by Japanese doctors or by Japanese society.

By contrast, we undertook a questionnaire study of ordinary Japanese citizens concerning hypothetical PTDs, which showed that both bereaved people and the public would demand the disclosure of the facts/truth if a person died in such circumstances. We also demonstrated that lay people cannot discriminate gross negligence from an inevitable mishap in a hypothetical case (K Kawai, H Ikegaya, M Nakajima, K Yoshida, unpublished observations), although doctors can easily distinguish between the two.⁷ It has also been reported that autopsy discloses clinical misdiagnosis in nearly half of those carried out in a university hospital in the USA.⁸ Moreover, analysis of 99 PTDs in the Appeals Court in the USA showed that autopsy has benefits for doctors even when they have been negligent.⁹

The most important duty of a medical specialist in this situation is accountability to the deceased's family and to the public. The only way of ensuring fairness and preventing accidents is for doctors to report unnatural deaths for public investigation. Accordingly, it is essential to reform the death investigation system for PTDs in Japan so that doctors will report all cases. In the summer of 2005, a pilot project of reporting deaths and performing autopsies focused on PTDs

will commence, in which autopsy operators and clinical specialists will cooperate to disclose the truth and audit medical practices.

In conclusion, obtaining a patient's informed consent or even giving an explanation to interested parties after a death is apparently seen by Japanese physicians as a safeguard that relieves them of the duty of reporting PTDs. This is because of their misunderstanding of the role of informed consent, and also because of the poor death investigation system in Japan. To improve the fairness and quality of medical practice we must reform the Japanese death investigation system, particularly with regard to PTDs.

Authors' affiliations

H Ikegaya, K Kawai, Y Kikuchi, K Yoshida, Department of Forensic Medicine, Graduate School of Medicine, University of Tokyo

Competing interests: none declared

REFERENCES

- 1 Yoshida K, Kuroki H, Takeichi H, Kawai K. Death during surgery in Japan. *Lancet* 2002;**360**:805.
- 2 Yoshida K, Kuroki H, Takeichi H, et al. Investigation of death in prison in Japan. *Lancet* 2003;**362**:921-2.
- 3 Yoshida K, Takeichi H, Kawai K. [Is a medical accident unnatural death?] *Japan Medical Journal* 2002;**4069**:57-62 (Japanese).
- 4 Yoshida K, Takeichi H, Kawai K, et al. [Proposal of new investigation system for medical accidents on the basis of the UK and USA systems.] *Japan Medical Journal* 2002;**4086**:57-61 (Japanese).
- 5 Yoshida K, Segami K, Takeichi H, et al. [A report of Los Angeles County Department of Medical Examiner.] *Japan Medical Journal* 2003;**4150**:59-64 (Japanese).
- 6 Powers MJ, Harris NH, eds. *Medical negligence*. London: Butterworth, 1990.
- 7 Leflar RB. Informed consent and patients' rights in Japan. *Houston Law Review* 1996;**33**:1-112.
- 8 Berigan TR, Deagle EA. Low-tech autopsies in the era of high-tech medicine. *JAMA* 1998;**280**:1273-4.
- 9 Bove KE, Iery C; Autopsy Committee, College of American Pathologists. The role of the autopsy in medical malpractice cases, I: A review of 99 appeals court decisions [Review]. *Arch Pathol Lab Med* 2002;**126**:1023-31.