

## Informed consent for anesthesia: survey of current practices in Japan

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### Abstract

Anesthesia requires informed consent because it is an invasive procedure with certain risks. However, the state of informed consent for anesthesia in Japan remains unclear. The purpose of this survey was to examine the state of informed consent for anesthesia in Japan. A questionnaire was sent to all hospitals certified by the Japanese Society of Anesthesiologists ( $n = 854$ ). The questionnaire consisted of four sections: explanation of the anesthesia, method of documentation, consent for anesthesia, and other information such as the hospital's size. A total of 504 (59.0%) questionnaires were completed and returned. At 96.7% of hospitals, an anesthesiologist would explain the scheduled anesthesia. Most departments provide an explanation of dental damage, malignant hyperthermia, and nausea/vomiting. Explanation of anesthesia was standardized at 59.0% of hospitals. A written description was handed out to patients routinely at 61.3% of hospitals. Although consent for anesthesia was obtained at more than 90% of departments, only 59.9% of departments would keep records of having obtained consent. This survey found that the explanation of anesthesia varied among hospitals and was not standardized in Japan. Further attention is needed on how to improve the documentation of informed consent.

**Key words** Informed consent · Anesthesia · Consent form

### Introduction

In recent years, the need for informed consent in clinical medicine has been recognized in nations worldwide, including Japan. In the United States, discussion of informed consent first appeared in courts at the beginning of the twentieth century; and by the 1950s a legal definition of informed consent had been established [1,2]. According to this definition, physicians are required to

obtain informed consent from their patients prior to providing treatment. If medical treatment were to be provided without informed consent, reparation for injury can be claimed even in the absence of a medical mistake [3].

Informed consent has also been established as a legal concept in Japan. Today, many courts in Japan declare that informed consent is required when providing a medical treatment that entails high or unforeseen risks. Likewise, anesthesia requires informed consent because it is an invasive procedure with high risks. Informed consent for anesthesia must be distinguished from surgery-specific informed consent and needs to be obtained by an anesthesiologist [3]. Despite this essentiality, the state of informed consent for anesthesia in Japan remains unclear. The present survey examined the state of informed consent for anesthesia at hospitals certified by the Japanese Society of Anesthesiologists and highlights the present issues of concern.

### Methods

This study's sample included all hospitals certified by the Japanese Society of Anesthesiologists (hereafter referred to as certified hospitals). A total of 854 hospitals were certified when the present survey was conducted in September 2003.

Questionnaires were self-administered, and answers were multiple choice. Questionnaires were addressed to each hospital's chief of the anesthetic department and mailed with a cover letter by regular mail with a stamped return envelope enclosed. Respondents were asked to reply within 2 weeks. Results were calculated as percentages with Microsoft Excel. Questions consisted of the following: (1) explanation of anesthesia; (2) method of recording the details of what was explained to the patient; (3) consent to undergo anesthesia; and (4) others.

## Results

A total of 504 questionnaires were completed and returned (59.0%). Three questionnaires were returned blank; two of these were due to there being no attending anesthesiologists. Sample characteristics are shown in Table 1.

**Table 1.** Sample characteristics

Hospital	No.
Type	
University	80 (15.9%)
Public	233 (46.2%)
Other	191 (37.9%)
Size (beds)	
≤199	14 (2.8%)
200–499	268 (53.2%)
≥500	221 (43.8%)
Unknown	1 (0.2%)

At 96.7% of hospitals, an anesthesiologist explained about the scheduled anesthesia (Table 2). However, the explanation of anesthesia was standardized at only 59.0% of hospitals. The details of the explanation are summarized in Table 3.

Table 4 shows answers to the types of complications explained. Most departments provided an explanation of dental damage, malignant hyperthermia, nausea, and vomiting. Only a quarter of departments informed patients about the risk of death.

The responses to questions on documentation of the explanation are shown in Table 5. Nearly half of the departments (47.5%) used a written form in all cases. Consent for anesthesia was obtained in 90.9% of departments. Only 59.9% of departments kept records of having obtained consent (Table 6).

**Table 2.** Questions concerning the explanation of anesthesia

Question	Responded/total responses <sup>a</sup>
Does an anesthesiologist explain?	
Yes, in all cases	398/504 (79.0%)
Yes, only in cases of a scheduled surgery	89/504 (17.7%)
No	13/504 (2.6%)
Is the explanation consistent among anesthesiologists?	
Yes	289/490 (59.0%)
No	201/490 (41.0%)
Is the attending physician knowledgeable of the explanation?	
Yes, we reached a consensus	88/488 (18.0%)
Yes, if he/she looks at the patient's chart	155/488 (31.8%)
No	63/488 (12.9%)
Uncertain	177/488 (36.3%)

<sup>a</sup>The total number of responses differed among questions

**Table 3.** Explanation of anesthesia

Parameter	Explain as a principle (%)
Scheduled method of anesthesia	100.0
Type of complication	85.3
Incidence of complication	38.7
Alternative methods of anesthesia	65.0
Type of complication	41.8
Incidence of complication	15.9
Insertion of arterial catheter	37.1
Type of complication	14.1
Incidence of complication	3.9
Insertion of central venous catheter	38.7
Type of complication	20.2
Incidence of complication	5.7
Anesthesiologist	
Name of attending anesthesiologist	59.9
Held licenses, years of clinical experience	2.4

## Discussion

Anesthesia is an invasive procedure with a certain level of risk and thus requires specific informed consent. This

**Table 4.** Explanation of risks

Risk	Explain as a principle (%)
Aspiration pneumonia	51.1
Malignant hyperthermia	56.4
Dental damage	91.4
Epidural hematoma	33.2
Cerebral infarction	22.4
Myocardial infarction	25.9
Nausea/vomiting	53.8
Pulmonary thromboembolism	31.1
Anaphylactic shock	37.5
Death	24.6

Other responses included postdural puncture headache, sore throat, hoarseness, and peripheral nerve injury

study identified the state of informed consent for anesthesia in Japan.

To establish informed consent in Japan, medical providers need to explain to the patient: (1) the patient's current condition; (2) the objectives and nature of the scheduled medical treatment; (3) any inherent risks of that treatment; (4) alternative therapies and their inherent risks; and (5) the patient's prognosis in the absence of treatment [2]. Although these conditions may not necessarily all apply to anesthesia, anesthesiologists need to keep in mind the principle of informed consent.

Our results indicate that anesthesiologists explain anesthesia for patients undergoing scheduled surgery at approximately 97% of certified hospitals. Conventionally, the nature and risks of anesthesia have been included with general information on surgery. However, White and Baldwin argued that an anesthesiologist who is familiar with the risks of anesthesia should explain the procedure to the patient [3].

**Table 5.** Questions on recording what was explained to the patient

Question	Responded/total responses <sup>a</sup>
Is a written description handed out to patients?	
Yes, in all cases	233/491 (47.5%)
Yes, only in cases of a scheduled procedure	68/491 (13.8%)
Only to patients who ask for one	26/491 (5.3%)
No	162/491 (33.0%)
Are contents of the explanation recorded? (Please select all applicable answer choices.)	
Noted on the patient's chart	97/488 (19.9%)
A copy is attached to the patient's chart	180/488 (36.9%)
"Explanation provided" is noted	86/488 (17.6%)
Not noted	159/488 (32.6%)
When did your hospital first use a written explanation?	
During the last year	64/318 (20.1%)
1-3 years ago	99/318 (31.1%)
>3 years ago	155/318 (48.7%)

<sup>a</sup>The total number of responses differed among questions

**Table 6.** Questions on consent

Question	Responded/total responses <sup>a</sup>
Is consent obtained?	
Yes, and it is recorded	296/494 (59.9%)
Yes, but it is not recorded	153/494 (31.0%)
No	43/494 (8.7%)
Is a consent form used?	
Yes	219/493 (44.4%)
Presently in the process of developing one	128/493 (26.0%)
No plan to develop one exists to date	146/493 (29.6%)
What is the length of time between explanation and signature giving consent?	
Immediately after explanation	278/470 (59.1%)
Within 1 day	98/470 (20.9%)
2-7 Days	81/470 (17.2%)
>7 Days	13/470 (2.8%)

<sup>a</sup>The total number of responses differed among questions

Fewer than 40% of hospitals explained the invasive techniques accompanying anesthesia, including insertion of a central venous catheter (CVC) or an arterial catheter. Fewer than 20% of hospitals provided an explanation of the complications inherent to each procedure. In light of the recent increase in publicity of malpractice cases related to CVCs, it may be important to have the patient understand the associated risks prior to the procedure. According to the ASA closed claims database, claims for central catheter injuries had a higher severity of injury, with an increased proportion of death (47%) than other claims in the database (29%) [4]. The Australian and New Zealand College of Anaesthetists (ANZCA) recommends obtaining informed consent for anesthesia and related procedures [5]. We agree that adequate explanation and consent are needed for both anesthesia itself and related invasive procedures.

According to Japanese case law, medical providers are required to explain all possible risks except those with a low incidence [2]. Despite this obligation, few departments explain severe complications to patients. This may be related to the medical providers' concern that such information could instill anxiety in patients. In this regard, Jenkins and Baker claimed that, in the current medicolegal climate, patients should rarely have detailed information about the risks of anesthesia or surgery withheld on the grounds that they are likely to suffer adversely from such information [6]. Waisel and Truog suggested that the patient should determine the level chosen after initial statements about the more common risks [1]. Osuna et al. reported that 75% of patients who undergo surgery claimed not to have been informed about the risks of anesthesia. They argued that correct information not only increases patient satisfaction and the quality of the health service offered to society but also influences the number of operations carried out with no subsequent claims of malpractice even in the case of complications [7].

Inconsistency in the explanations by the anesthesiologist and the surgeon can instill a sense of distrust in the patient. Consistency within an anesthetic department is also important. Watkins et al. reported that 27% of anesthetic departments in the United Kingdom had no departmental policy for consent to anesthesia. They pointed out that inconsistencies might provide grounds for legal challenge [8]. Similarly in Japan, anesthetic departments need to standardize their explanation and promote better communication between anesthesiologists and surgeons.

Our results show that one-third (32.6%) of departments did not note anything about the explanation of anesthesia on a patient's chart. According to "Information and Consent for Anaesthesia," the guidelines published by the Association of Anaesthetists of Great

Britain and Ireland (AAGBI), the anesthesiologist should make a record of the anesthetic techniques that have been discussed with and agreed to by the patient and should list the material risks that have been explained [9].

The use of a written explanation form could be useful for standardization of contents and documentation. Such a form could also facilitate better patient understanding and possibly shorten the time needed to explain anesthesia to the patient. We surmise that the use of written forms will continue to increase in coming years.

The use of a written consent form for anesthesia varies internationally among nations. In New Zealand, 68% of anesthesiologists in Auckland obtain signed anesthesia-specific consent for all public hospital patients [10]. In the United Kingdom, the Department of Health recommends that written consent be obtained for general anesthesia. However, according to Watkins et al., only 4.5% of those anesthetic departments used separate anesthetic consent forms. They reported that 70% of departments surveyed documented oral consent on the anesthetic chart, and 72% of departments thought separate anesthetic consent forms were unnecessary [8]. On the contrary, White and Baldwin argued that anesthesiologists should obtain separate, written consent for anesthesia. They suggested that a standardized consent form for anesthesia may prove invaluable when retrospectively defending a claim of negligence founded around information disclosure by recording exactly the risks and consequences of interventions discussed by the anesthesiologist and the patient [3]. Our study shows that 44% of departments in Japan use consent forms specific to anesthesia. Given the many departments that are currently in the process of introducing this approach, we estimate that up to 70% of hospitals will use a written consent form in the near future.

The objective of informed consent is to have the patient understand the procedure by providing a sufficient explanation and answering any questions and, then, based on that understanding, have the patient decide. To have the patient understand, a certain degree of time between explanation and consent is necessary. In this survey, however, more than half of the hospitals have the patient sign immediately after providing an explanation. This may be related to the system of preanesthetic rounds and a shortage of anesthesiologists in Japan. We recommend allowing more time to the patient to consider the implications of giving consent.

This study has a number of limitations. First, our sample was limited to certified hospitals and may not reflect the situation at all hospitals in Japan. At noncertified hospitals, it may be common for the surgeon to explain anesthesia to the patient and to use the

same consent form used for surgery. Second, not all patients undergoing surgery at certified hospitals are in the care of an anesthesiologist. Respondents of this survey answered that physicians who were not anesthesiologists would conduct general anesthesia at 16.8% of hospitals and spinal anesthesia at 60.9% of hospitals. Accordingly, our results do not indicate how informed consent was obtained by nonanesthesiologists.

## Conclusions

The present study found that explanation of anesthesia to patients varied among hospitals and was not standardized in Japan. Documentation of what is explained to the patient remains inadequate. Further attention is needed on how to resolve these insufficiencies. We estimate that the use of written explanation forms and consent forms will continue to spread in Japan, making anesthetic explanation standardized and preventing lawsuits.

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