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Guidelines for Managing Conscientious Objection to Blood Transfusion

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Running short title: Managing objections to blood transfusion

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ABSTRACT

Parents sometimes deny their children blood transfusion because of their religious beliefs. The Japanese Joint Committee on the Refusal of Blood Transfusion on Religious Grounds asserts that the health and life of every child under 15 years of age should be guarded by the collective efforts of health, welfare and advocacy institutions when a parent or guardian seeks to withhold transfusion therapy. Patients 18 years or older should receive treatment without transfusion after signing and submitting a "Certificate of Refusal Blood Transfusion and Exemption from Liability". For a patient younger than 18, but 15 years or older, essential transfusion can be performed if the patient or at least one guardian consents. Without patient or guardians consent, guidelines for patients 18 years or older shall apply. Healthcare providers should offer the best possible care that is consistent with a patient's age and competency.

Patients, or their legal guardians, may object to blood transfusion for various reasons. Reasons arising from misinformation or fear can be approached as with other medical interventions. Informed reasons arising from religious belief or personal conviction are legally and ethically challenging and warrant special consideration.

Concepts of human rights and personal autonomy have expanded in modern society where people with different value systems must co-exist. Jehovah's Witnesses, who number more than 200,000 active members in Japan and 6 million worldwide, embrace conservative values and avail themselves of modern medical care except transfusion of whole blood and the four major components of red blood cells, platelets, plasma and white blood cells¹⁾.

A Japanese national survey revealed that in 2003, 0.8% (4 of 541 cases) of deaths attributed to surgical bleeding were related to religious refusal of blood transfusion²⁾. Although competent adult have the right to refuse blood transfusion for themselves³⁾⁴⁾, laws or judicial precedents in Japan have not totally established whether parents have the right to refuse necessary medical care, including transfusion for their children, even though there are two cases in which such parental rights were clearly denied by lower courts⁵⁾⁶⁾. The US Supreme Court made this clear in 1944, "parents may be free to become martyrs themselves. But it does not follow they are free, in identical circumstances, to make martyrs of their children before they have reached the age of full and legal discretion ----" ⁷⁾.

With regard to patients who object to blood transfusion, in 1998 the Japan Society of Blood Transfusion (JSBT, currently the Japan

Society of Transfusion Medicine and Cell Therapy, JSTMCT) reported that patients 18 years of age or older should be allowed to submit a "Certificate of Refusal of Blood Transfusion and Exemption from Liability" as a personal human right⁸⁾. For patients under 12 years of age, transfusion therapy is deemed appropriate when necessary, even against the wishes of the parent or guardian. However, JSBT did not address the patients between 12 and 18 years of age, leaving these cases for hospitals to address independently, because clear guidance was lacking at the time⁸⁾.

An investigation of child fatalities in the USA between 1975 and 1995 revealed that when faith healing was used in lieu of conventional medical treatment a substantial number (>140 cases) of child fatalities and associated suffering could be prevented⁷⁾. Existing laws in 1998 may have been inadequate in the USA to protect children from this form of medical neglect⁹⁾.

UNICEF found that almost 3,500 children under the age of 15 die every year from child abuse and neglect in 27 developed countries¹⁰⁾. Japan appears to have a higher incidence of child maltreatment deaths (1.0/100,000 children/week) than Spain (0.1) and Italy (0.2), comparable to Germany (0.8), UK (0.9) and Canada (1.0), and lower than the United States (2.4) and Mexico (2.7). Some parents/guardians will seek healing through religion rather than medical care. Medical neglect evaluations should focus on the child's needs rather than the caregiver's motivations or justifications. Religious objections should not be granted fundamentally different status from other types of objections⁹⁾.

Because second-generation believers are born into and grow up in a religion chosen by their parents or guardians, these second-generation believers can, in principle, leave the religion of their upbringing and move to another one; young children in this category should be protected by society as a whole from caregivers who abuse and/or neglect them.

The Joint Committee guidelines, discussed below, are officially sanctioned by JSTMCT, Japanese Society of Anesthesiologists, Japan Pediatric Society, Japan Society of Obstetrics and Gynecology and Japan Surgical Society. They clearly define when to accommodate the wishes of competent patients and when to protect younger children in situations where there is an objection to blood transfusion.

BASIC POLICIES REGARDING THE ADMINISTRATION OF BLOOD TRANSFUSION

Patients likely to benefit from blood transfusion, or suffer without transfusion, should be considered as belonging to one of three age categories: 18 years or older, 15 to 17 years, and under 15 years (Figure 1). Age 18 marks the transition from childhood to adulthood in Article 4 of Japan's Child Welfare Law, and age 15 has been considered a threshold of competence in several Japanese legal sources, including Article 797 of Japan's Civil Code, as the age of valid consent to adoption without proxy; Article 961 of the Civil Code, in reference to testamentary capacity; and Japan's Organ Transplant Law, as the age of valid consent to donate organs. Patients should also be considered as competent to make medical decisions, or not, as assessed by more than one doctor, including the doctor in charge of the patient's care.

For patients 18 years or older and competent to make medical decisions

the following apply:

If the medical provider consents to treat without blood transfusion, the patient shall sign and submit a "Certificate of Refusal of Blood Transfusion and Exemption from Liability" (see appendix 1 - Note 1) to the medical provider.

If the medical provider cannot consent to treat without blood transfusion, the medical provider shall, at the earliest possible time, recommend transfer to the care of another provider.

For patients under 18 years or not competent to make medical decisions

the following apply:

Patients 15 years or older and competent to make medical decisions:

- a. When a legal guardian objects to blood transfusion but the patient wishes to receive it, the patient's informed consent shall be documented.
- b. When a legal guardian approves of blood transfusion, but the patient objects, the medical provider shall avoid transfusion to the greatest possible extent but may transfuse according to medical necessity. The guardian's informed consent shall be documented.
- c. When all legal guardians and the patient object to blood transfusion, guidelines for patients 18 years or older shall apply.

Patients under 15 years (see appendix 1 - Note 2) or not competent to make medical decisions, and a legal guardian objects to transfusion:

- d. When both legal guardians object to transfusion, the medical provider shall seek consent from the guardians and shall carry out treatment without blood transfusion to the greatest possible extent but may transfuse according to medical necessity. If consent is not granted, to the detriment of patient care, the medical provider shall report the situation as a case of child abuse to a governing authority. The governing authority shall place the child under protective custody and petition a family court to suspend the rights of guardianship. When the petition is granted, transfusion shall proceed according

to medical need with the consent of a court-appointed proxy guardian.

- e. When one legal guardian consents to blood transfusion but the other objects, the medical provider shall make an effort to obtain the consent of both guardians, but in the case of an emergency, shall administer blood transfusion with the consent of the guardian who consents to blood transfusion.

FLOWCHART OF CONSENT TO BLOOD TRANSFUSION AND CERTIFICATE FOR EXEMPTION FROM LIABILITY

Figure 1 represents a flow chart showing the procedures that a medical provider should follow in cases where objection to blood transfusion is asserted by a patient and/or legal guardian(s). Form 1 (see appendix 2) is a Certificate of Refusal of Blood Transfusion and Exemption from Liability.

BLOOD TRANSFUSION THERAPY AND INFORMED CONSENT

The Ministry of Health, Labor and Welfare released the "Guidelines for Performing Blood Transfusion Therapy" (revised version) and the "Guidelines for the Use of Blood Products" (revised version) in September 2005¹¹⁾. The responsibilities for medical professionals appear in these guidelines. Regarding the requirements on the effectiveness and safety of blood products and the proper use of said products, the guidelines specify that medical professionals shall provide appropriate and adequate explanation to patients and/or their

family members in an effort to obtain informed consent, and that a medical professional shall decide whether or not to perform blood transfusion therapy after adequately weighing the potential benefits against the risks. Transfusion shall be kept to the minimum required for the desired effect and excess transfusion shall be avoided. Every effort shall be made to relieve clinical symptoms while avoiding blood transfusion to the greatest possible extent, if suitable alternatives are available. In addition, the statement on explanations and informed consent specifies that the following items shall be adequately explained in a manner easily understood by the patient and/or his/her family members:

- (1) Need for blood transfusion therapy,
- (2) Type and amount of blood product to be used,
- (3) Risks involved in transfusion,
- (4) Remediation available to those who suffer side effects and infectious diseases arising from transfusion,
- (5) Availability of autologous blood transfusion,
- (6) Screening for infectious diseases and storage of specimens,
- (7) Retention of medical records and their use in retrospective surveys, and,
- (8) Other transfusion therapy precautions.

Upon informed consent of the patient and/or his/her family members, documentation of consent shall be executed. A copy shall be given to the patient and a copy shall be attached to the medical record (physically or electronically, as applicable). If consent of the patient or his/her family is not obtained, blood transfusion should

not, in principle, proceed.

ACTIONS TO BE TAKEN BY MEDICAL PROVIDERS

On the basis of judicial precedents, published guidelines set forth a way to allow blood transfusion under special circumstances, such as a situation that is life-threatening without transfusion, even if patient and/or guardian consent is not obtained. It is also feasible for medical institutions to adapt guidelines to particular circumstances after due diligence and with the approval of an ethics committee and/or other relevant body. In addition, it is desirable to have procedures in place to secure the consensus of more than one doctor, including the doctor in charge of a patient's care, to judge a patient's capacity to make medical decisions.

COMMENTARY ON THE GUIDELINES FOR MANAGING CONSCIENTIOUS OBJECTION TO BLOOD TRANSFUSION

JSBT (currently JSTMCT) published the "Report on Informed Consent in Blood Transfusion"⁸⁾ in 1998. Regarding objection to blood transfusion on the basis of one's religious beliefs, this Report states that such patients should be required to submit a "Certificate of Refusal of Blood Transfusion and Exemption from Liability" and/or to change hospitals according to the rights of self-determination in medical care. From judicial precedents described below, refusal of blood transfusion is regarded as a personal human right in the case of competent adult patients. However, for patients under 18 years of age, objection to blood transfusion has been a matter for hospitals to address independently.

More recently, however, local family courts have issued provisional orders to affirm petitions for the temporary suspension of parental rights and the appointment of a proxy guardian from the directors of child consultation offices in cases of surgery with high levels of urgency¹²⁾. Although intervention in parental rights must follow court proceedings, which generally take time, the judiciary has expressed understanding towards hospitals having difficulties in the case of surgery for children for whom parental consent is not obtained, and this can be said to have prompted local family courts to issue provisional orders pending final determination. Discussions on the revised Child Abuse Prevention Law, passed on May 25, 2007, included one on allowing children to be treated without parental consent under the stipulation that only the "custodial rights" by which children are

protected and supervised (see appendix 1 – Note 2) could be temporarily suspended. This was not included in the present revised law, but was incorporated in an appendix as the “temporary termination of parental rights” to be discussed in future revisions of the law.

The concept of medical neglect has contributed to an increase in such discussions. Medical neglect means not giving children the health care necessary or appropriate for them in light of medical standards and conventional wisdom. It includes not only parents not taking children to a hospital but also parents taking children to a hospital but not consenting to treatment. There is also the view that parental objection to blood transfusion for their children, e.g., on the basis of religious beliefs, is child endangerment and a form of child abuse¹³⁾. However, it cannot be denied that, depending on their age or stage of mental development, the children themselves may have internalized their parents' religious beliefs and established the refusal of blood transfusion as their own belief. It is therefore also difficult to make a sweeping judgment that all cases of the refusal of blood transfusion are cases of child abuse.

On the basis of the above-mentioned recent trend, Japanese Guidelines recognize a duty to provide the best treatment, including blood transfusion, to persons under 15 years of age, or otherwise lacking the capability to make medical decisions, by giving special consideration, while respecting the right of self-determination to the greatest extent possible. Regarding adults over 20 years of age who are incapable of making medical decisions, at present, the refusal of blood transfusion can only be left as a future issue to be addressed

in view of the relevant legal and social trends, since ethical, medical and legal standpoints are not yet fully established.

Assertion of people refusing blood transfusion on religious grounds and consideration of their psychological characteristics

People who refuse blood transfusion on the basis of their religion assume an attitude of being unequivocally against blood transfusion, asserting the superior value of not receiving blood transfusion over maintaining life, in accordance with their faith. However, it is assumed that they accept alternatives to blood transfusion and indeed, seek them out actively. From this viewpoint, the medical provider should explain the availability of alternative treatments and the likelihood of successful surgery without blood transfusion at the hospital concerned.

Consideration should also be given to differences in the mental characteristics between first-generation followers who themselves chose to follow the religion and second-generation followers who have been greatly influenced, through their parents, by the doctrine and the organization of the religious group since childhood. It is pointed out that the second-generation followers are likely to acquire their parents' faith on the basis of their upbringing, and their feelings of fear and guilt at disobeying both their faith and their parents may be stronger than those of first-generation followers. The possibility should therefore be taken into consideration that children still under the care of persons with parental rights may suffer a negative psychological effect from choosing blood transfusion treatment of

their own will or upon being administered such treatment against their will, which may affect their future faith or family relationships. The medical provider is responsible for encouraging the parents of children who were administered blood transfusion against their will to nurture their children with the same care and responsibility as before the treatment. Measures should also be taken to obtain understanding and support from the religious organization if possible. In addition, counseling by persons specializing in pediatric/adolescent psychiatry should be provided to the patients during and after hospitalization to minimize the negative emotions that may arise as a result of having received blood transfusion contrary to their faith or against the parents' will. If blood transfusion is given under the temporary termination of parental rights, the parental rights should be reinstated quickly after the blood transfusion and continuous support be given so that the persons with parental rights will fully nurture the children after transfusion.

Judicial precedents

Judicial decisions in which patients or their legal guardians objected to blood transfusion or treatment are described below. These are very important cases in understanding the right to refuse transfusion and health care neglect.

Case 1: A male patient in his 30s was hospitalized in University Hospital A for bone sarcoma surgery in 1984. The patient desired surgery without blood transfusion for religious reasons. His parents

filed a provisional disposition with the court to the effect that the hospital could be entrusted with operating on their son, the blood transfusion needed for it and other medical intervention. Oita District Court ruled it impossible to conclude that the refusal of blood transfusion was an illegal violation of parental rights because the patient was an adult of normal mental ability, including understanding and decision-making capacity, and dismissed the provisional disposition (see appendix 1 - Note 3) (December 2, 1985).

Case 2: A 10-year-old male patient was injured in a car accident in 1985. His parents refused blood transfusion, and the patient died at University Hospital B without receiving blood transfusion. Ultimately, only the driver was charged with an offence causing death, and was found guilty and fined 150,000 yen, although this criminal case was a summary order (see appendix 1 - Note 4; Kawasaki summary order, August 20, 1988).

Case 3: A 63-year-old female patient underwent surgical excision of a hepatic tumor at University Hospital C in 1992. The patient was given blood transfusion against her will. She claimed damages and the Supreme Court ruled that the right to refuse blood transfusion was a human right (see appendix 1 - Note 5; February 29, 2000).

Case 4: For an infant (born in 2005) in whom a brain abnormality had already been detected in the fetal stage, the doctor explained the need for surgery because leaving the infant without treatment was very likely to lead to serious psychomotor retardation or death. However, the infant's parents (persons with parental rights) did not consent to surgery on the basis of their religion. The hospital reported this

as child abuse to the child consultation office. The director of the child consultation office petitioned a family court to: effect the determination of the removal of parental rights; take preservative measures prior to determination to temporarily suspend parental rights until final determination; and appoint a doctor specializing in the patient's disease, a former university medical professor, as the surrogate to exercise parental rights during that period. The Kishiwada Branch of the Osaka Family Court affirmed this petition on February 15, 2005, and stated that it was necessary to temporarily terminate the father's and mother's exercise of parental rights, because the refusal of surgery, even on the basis of religion or personal conviction, was an immediate danger to the infant, with a high likelihood of impeding healthy development, which are fundamental to a child's welfare. Also, it was decided that since "waiting for the results of determination on the merits of this case risks being hazardous to life or causing serious impairment, proper treatment, including surgery, must be performed as quickly as possible." With regard to the surrogate guardian, the court-appointed doctor was considered a specialist in the said disease and "to have the ability to choose the most appropriate medical procedures" after carefully evaluating various conditions including the patient's medical condition, and the appropriateness and risks of surgery (see appendix 1 - Note 6).

Case 5: An infant with serious heart disease (born in 2006) required emergency surgery. However, the infant's parents (persons with parental rights) did not consent to surgery on the grounds of their

religion. The director of a child consultation office asked a family court to enforce adjudication of the removal of parental rights on the merits of this case and to take preservative measures to provisionally terminate the exercise of parental rights prior to final and conclusive determination and to select a suitable lawyer as legal guardian during that period. The Nagoya Family Court accepted this request in an adjudication on July 25, 2006, and stated that leaving the situation as it was would certainly have risked the infant's life and that the parent's refusal to consent to surgery was an abuse of parental rights in the absence of a rational reason (see appendix 1 - Note 6).

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Legend to Figure 1. Flowchart of consent and refusal of blood transfusion.

The flowchart shows that objection to blood transfusion shall be resolved according to the age and autonomous decision-making capability of the patient.

APPENDIX 1 (End Notes)

Note 1: A "Certificate of Refusal of Blood Transfusion and Exemption from Liability" (Form 1) is desirable. In an urgent case, however, a similar document completed by the patient himself/herself is also considered valid.

Note 2: Children or infants refer to persons less than 15 years of age in these guidelines.

Note 3: The decision of case 1 can be considered as having had considerable impact on the subsequent theoretical and practical development of the blood transfusion refusal issue in Japan.

Note 4: Case 2 suggests that even a patient's parents may face criminal charges, such as for abandonment of a vulnerable, dependent person or for causing death by misconduct (involuntary manslaughter). This may also apply to the doctor who treats such patients. Other questions arise: Was there any causal relationship between the driver's behavior and the child's death? Can parents be allowed to refuse blood transfusion to their children on the grounds of their own religious beliefs? Are parents not criminally responsible? Is the doctor who withheld blood transfusion not criminally responsible for the child's death? Asserting the parents' religious beliefs against the best interests of the child's life may also be considered an abuse of parental rights. The child should not be prevented from establishing his/her own religious beliefs in the future.

Note 5: The court decision for case 3 is more definitive than that for case 1 in that the refusal of blood transfusion was explicitly acknowledged as a human right. The hospital adopted the policy that

if patients refuse blood transfusion on the basis of their religion, their refusal of blood transfusion is to be respected to the greatest possible extent, but that blood transfusion shall be administered regardless of the consent of the patient and the family members if there is no other life-saving procedure than blood transfusion. The Supreme Court stated, "It is right for doctors engaged in the profession of managing human life and healthcare to perform appropriate surgery in accordance with medical standards to remove the liver tumor from the patient. However, if the patient expresses a definite intention to refuse medical treatment including blood transfusion on the grounds that receiving blood transfusion violates his/her religious beliefs, the right to make such a decision must be respected as a human right. Since the patient had a strong determination to refuse blood transfusion under all circumstances in accordance with his/her religious beliefs and entered Hospital C expecting to receive surgery without blood transfusion, the doctors should have explained that they would follow their hospital policy of giving transfusion if a situation arose during surgery in which no life-saving means other than blood transfusion was available, and should have left the decision on whether or not to undergo surgery to the patient, while continuing the patient's hospitalization. Furthermore, it is undeniable that the doctors deprived the patient of decision-making rights regarding whether or not to undergo surgery that was likely to involve blood transfusion, and that, from this point of view, the patient's human rights were violated and the doctors should be liable to compensate the patient who suffered emotional distress [partially omitted]."

Notes 6: Cases 4 and 5 are not cases of religious belief *per se*, but concern the temporary termination of parental rights and the appointment of surrogate guardians by preservative measures prior to determination because of the refusal of the parents to allow surgery. Case 4 in particular was the first case of this type of decision in Japan. Regarding these cases, it should be noted that the framework of child abuse prevention was employed in which, upon the receipt of the hospital's report of the parents' refusal to consent to surgery as a case of child abuse, the director of the child consultation office filed the petition to family court (Article 6 of the Child Abuse Prevention Law and Article 25 of the Child Welfare Law). This indicates that the irrational refusal of treatment should be taken to be medical neglect, even if arising from religious beliefs. It is also noted that the doctor and the lawyer were appointed as guardians in cases 4 and 5, respectively, during the temporary termination of parental rights. The system adopted in these determinations is such that the court does not directly enforce medical treatment of a child, but excludes irrational judgment by the persons with parental rights, and leaves medical care decisions to persons able to act rationally. It can be said, therefore, that case 4, which determined that a person able to choose the most appropriate medical treatment should be selected as the surrogate guardian, provided a decision which can serve as a beacon in the future. In general, it takes time to legally intervene in parental rights, but it was recently indicated that, in a very urgent case involving human life, the court can take preservative measures for the temporary termination of parental rights in a short time

(October 21, 2006, Osaka District Court).

Appendix 2 - Form 1

Certificate of Refusal of Blood Transfusion and Exemption from Medical Liability (example)

Regarding the treatment (surgery, etc.) of _____

Date of explanation:

Explained by:

Doctor in charge (signature) _____

Doctor in charge (signature) _____

Department: _____

Director of oooo Hospital

I have received an explanation of the possibility and/or need to receive transfusion of the following blood product(s) for the procedure described below:

(Specify the type and dosage of the blood product)

In accordance with my personal convictions, however, I request that blood

transfusion be withheld regardless of the risks or disadvantages that may arise.

I will not, in any way, hold responsible the medical professionals concerned, including the doctor in charge, any situation caused by my refusal of blood transfusion.

I refuse the following types of blood transfusion (circle all items that apply)
whole blood, red blood cells, white blood cells, platelets, blood plasma, autologous blood (preoperative blood storage / perioperative dilution / perioperative recovery / postoperative recovery), and blood plasma fraction products (albumin, immunoglobulin, blood coagulation factor, and other products (please specify) _____).

I have no objection to treatment involving fluid infusion or a plasma expander.

Date of signature

Name of patient (signature) _____

Name of proxy (signature) _____

Relationship with the patient _____

