

vessels after closure of the wound. If the bleeding does not stop over time, the abdomen needs to be reopened.

- 3 . Postoperative infection : After operation, antibiotics are given to prevent bacterial infections inside and outside of the abdomen. But infection may be caused by a bacterial species which happens to be resistant to the antibiotic given or on special occasions. In those cases, the medicine will be switched to effective one and necessary treatment such as sterilization will be conducted.
- 4 . Poor union of wound : In patients with diabetes, very thick subcutaneous fat, or postoperative infection, union of wound may be poor. Those patients will take a little longer time before healing of the wound.
- 5 . Intestinal palsy : If the digestive tract, which was immobilized by anesthesia during operation, does not recover its motion well, it may take several days before the patient can take meals.
- 6 . Intraperitoneal adhesion, bowel obstruction : Many people who underwent laparotomy have adhesion of the intestine or wound in the abdomen. Most of them remain free of symptoms and harmless, but on rare occasions the intestine gets stuck in the adhesion site to cause bowel obstruction. If conservative (medical) management does not take effect, surgical treatment (operation) becomes necessary.
- 7 . Thrombosis, thrombotic embolism : Intrapelvic operation, in pregnant women or those patients who have long been in bed or liable to thrombosis, may cause, during or after operation, Thrombosis in a thick vein in lower extremities or the pelvis that may cause thrombophlebitis or, on rare occasions, severe pulmonary embolism.

(Such adverse reactions or complications very rarely, about one out of several thousands cases, lead to critical condition, but the risk is not zero.)

• Risk factors particular to you :

- 1) Hemorrhage (rare)
- 2) Infection (rare)
- 3) Adhesions (not uncommon)
- 4) Recurrence (rare)
- 5) Emergency recovery open surgery (very rare)
- 6) Accidental adjacent/target organ injuries (very rare)
- 7) Perforation (during D&C or endoscopic surgeries (very rare), this requires open repair
- 8) Blood clot formation after prolonged bed rest (uncommon)

I was given the above information and understood it. Thus I consent to have the operation.

Date:

Address:

Telephone No.:

Name of the patient:

Name of the attendant:

(Relationship with the patient:)

Blood transfusion therapy

Record of informed consent

Aiiku Hospital, Maternal & Child Health Center

This document is to explain about transfusion therapy to the patient who needs or may come to need a transfusion (including patients whose autologous blood are pooled).

Transfusion therapy is a therapy to supplement blood components (red blood cells, platelets, protein components, coagulation factors, etc.) when they decrease in number or function.

While blood transfusion has become remarkably safe recent years, it will be difficult to completely exclude side effects or complications associated with it. Non-use of blood transfusion, on the other hand, may lead to a threat to life or serious residual disabilities. When we judge a blood transfusion necessary, we explain it to a patient and the family. However, in case of emergency, the explanation will be performed after the transfusion therapy.

● You need transfusion therapy for the following reasons:

- Massive bleeding (at delivery / operation / _____)
- Decrease in coagulation factors (massive bleeding / abnormal blood clotting due to hypertension disorders of pregnancy / congenital clotting factor deficiency / _____)
- Thrombocytopenia • Others _____

● When blood transfusion is not given, it may lead to (_____)

● Planned volume of blood transfusion and type of blood preparation to be used:

- Red blood cells _____ units • Fresh frozen plasma _____ units
- Platelets _____ units • Others (_____) _____ units

● For each type of blood preparation, expected effects of blood transfusion and risk with non-use are as follows :

• Red blood cells

Red blood cells carry oxygen taken up at the lung all through the body. Depletion of red blood cells causes lack of oxygen and dysfunction of organs, and prolongation of such condition may leave disorders in the body system.

• Fresh frozen plasma

Plasma is the light yellow fluid which remains after cellular components such as red blood cells, leukocytes, and platelets are removed from the blood. Plasma contains various proteins and blood coagulation factors in it. In some pathological conditions, such as massive bleeding, blood coagulation factors are consumed excessively, which makes bleeding less controllable. Fresh frozen plasma is given on such occasions or when such conditions may arise.

• Platelets

Platelets cooperate with blood coagulation factors to close bleeding wounds or prevent leakage of blood by reinforcing the vascular wall. Lack of platelets due to massive bleeding or diseases such as thrombocytopenia may cause bleeding without any injuries or less controllable bleeding from a wound. Platelet preparation is used to treat such conditions. In patients who do not have sufficient platelets inherently, a platelet preparation will be given in advance of the delivery.

● Side effects, complications, and risk associated with transfusion therapy

*Figures in parentheses denote approximate incidences when blood from five donors is transfused (quoted from a report of the Informed Consent Subcommittee, The Japan Society of Blood Transfusion)

- Post-transfusion infections { Hepatitis C and B (1/ 1,000,000)
HIV (<1/ 10,000,000)
Other infections [Yersinia, malaria, HTLV-1 virus, parvovirus, Creutzfeldt-Jakob disease, and others] (from unknown incidence to <1/ 1,000,000)

In addition to hepatitis screening and HIV antigen/antibody screening conducted in blood donors, nucleic-acid amplification testing to detect trace amounts of viruses have shortened the negative test period in the early phase

infection (window period). As a result, the incidences of posttransfusion infections decreased fairly but it is impossible to completely eliminate them. Infections with unknown pathogenic agents may also arise.

- Allogeneic response

{	Hives, fever (1/ 10 - 1/ 100)
	Anaphylactic shock (1/ 10,000): with breathing difficulty, erythema, and blood pressure fall
	Hemolysis (1/ 1,000 of mild cases to 1/ 10,000 of severe cases)

※Immune reaction caused by anyone else's components taken into the body.

- Graft-versus-host disease [GVHD]

The complication has not been confirmed in Japan since 2000 as irradiated blood became widely used. It is a complication in which any donor leukocytes contained in a transfusion preparation attack and destroy the patient's body tissues. Irradiation inactivates those leukocytes. Fever, erythema, hepatic disorder, diarrhea, pancytopenia, and bone marrow aplasia develop after one to two weeks, and the condition follows fatal course. Once developed, there is no effective therapy for it at present. Transfusion of blood from relatives is avoided because it increases the risk of this complication.

- Transfusion-related acute lung injury [TRALI] (309 cases, including suspected cases were reported since 2004 to 2012 in Japan.)

It is breathing difficulty accompanied by lung edema which develops during or within 6 hours after blood transfusion. This condition is presumed to develop as antigen-antibody reaction, in which anti-leukocyte antibodies in blood preparations damage the peripheral blood vessels of the lung, though the detailed mechanism is unknown. Once developed, respiratory management with a respirator is necessary to control the condition.

- To avoid blood transfusion

When a bleeding necessitating blood transfusion is expected and there is sufficient time, the patient's own blood may be withdrawn and pooled. By the own blood transfusion, the side effects and the complications mentioned in the previous section are logically avoided. However, blood cannot be withdrawn in cases with, for example, anemia, and the withdrawing during pregnancy would be harmful for both the mothers and the fetuses. The preserved blood cannot be used in cases of bacterial contamination or clotting, which occur on rare occasions.

- Therapies, alternative to transfusion therapy

Usually alternative therapies, if available, are used before considering the blood transfusion therapy. Examples of alternative therapies: Fluid replacement therapy, vasopressor therapy, anti-inflammatory treatment with corticosteroid, iron preparation.

- Care after blood transfusion

Tests to see liver functions, anemia, and post-transfusion infections are conducted one and three months after transfusion.

- Emergency response

Please understand that the minimum necessary volume of blood may be transfused at a doctor's discretion when blood transfusion seems urgently necessary. In emergency situations, we do not have time enough to obtain prior consent from the patient or the family. In such cases, your retrospective approval would be requested.

- Retention of Records and Disclosure of Information

Aiiku Hospital retains the records of your name and address, the preparation's name and lot No. (Production number), and the date of administration for twenty years. If any events should occur requiring action to prevent occurrence or expansion of health hazards due to the use of blood transfusion, we may present the records to the preparation's manufacturer and/or Japanese administrative agencies.

Date: _____

Patient's signature _____

Aiiku Hospital, Maternal & Child Health Center

Plasma preparations are products prepared from plasma component, blood residue after removal of cell components. The preparations are used only when their benefits are thought to outweigh risks.

● Types of plasma preparations

• Dried and concentrated human anti-thrombin

Deficiency of anti-thrombin makes the body prone to develop clots to cause embolism or other disorders, thus threatening life. Anti-thrombin preparations work to normalize the regulating mechanism of clot formation or resolution.

• Fibrinogen preparations

In some conditions such as massive bleeding, sepsis, and systemic thromboembolism, the coagulation factors are consumed extensively and the clotting system falls into malfunction. The condition is called disseminated intravascular coagulation (DIC). Fibrinogen, which is one of the coagulation factors, usually decreases after acute DIC develops. In that condition, only fibrinogen preparations can resolve the bleeding tendency. Please understand that the Japanese health insurance does not cover the fibrinogen preparations therapy in acute DIC cases.

• Albumin preparations

The main function of albumin is to maintain the osmotic value level within the plasma and thus to prevent water in plasma from permeating out of vessels. In some conditions such as massive bleeding, plasma protein level drops to a low level, which brings in pulmonary edema, pleural effusion, and ascites. Albumin preparations are used to improve those symptoms.

• Immunoglobulin preparations

Immunoglobulin preparations are known to have an effect of improving or preventing infections. They are also effective in regulating immunity and improving Kawasaki disease, idiopathic thrombocytopenic purpura, Guillain-Barre syndrome, and chronic inflammatory demyelinating polyradiculoneuropathy.

※Anti-D human immunoglobulin is used when blood type incompatibility is expected between the fetus with Rh (+) and the mother with Rh (-).

• Fibrinogen preparations (factor XIII with fibrinogen, fibrinogen combination products, etc.)

An adhesive made of coagulation factor in blood, which is applied to operative wound (not to be administered intravenously). The agent prevents leakage of blood, fluid, or gas from the site of surgical suture or juncture.

• Other plasma preparations may be used to compensate for deficiencies in respective blood components and improve the clinical condition (such as an adhesive patch to stop bleeding on the surface of an organ).

● Adverse effects

• Infection

The preparations are made from blood which has been checked for viruses and heat-treated to inactivate viruses. No viral infections such as HIV infection or hepatitis due to those preparations have so far been confirmed. However, as they are made from blood, possibility of infection cannot be completely excluded.

Also undeniable is a risk of infection with unknown pathogens such as abnormal prions --presumably causative of the new type of Creutzfeldt-Jakob disease--which cannot be removed with the current technique.

Since it is difficult to completely inactivate or remove viruses such as human parvovirus B19 (pathogen for infectious erythema), we will cautiously follow the course after administration.

• Allergic reaction

Hives, anaphylactic reaction, fever, decrease in blood pressure, difficulty in breathing, etc.

● Emergency procedures

On life-threatening occasions, we will place utmost priority on life saving. Please understand that information in this leaflet may be given after administration of a plasma preparation in those cases.

● Possible risks associated with non-use of plasma preparations

• Pulmonary embolism (respiratory arrest) due to blood clot or embolism, multi organ failure;

• Respiration failure due to pulmonary edema;

• Excess strain on the cardiovascular system due to decreased circulating plasma volume; etc.

--All of the above conditions may threaten life.

● Retention of Records and Disclosure of Information

Aiiku Hospital retains the records of your name and address, the preparation's name and lot No. (production number), and the date of administration for twenty years. If any events should occur requiring action to prevent occurrence or expansion of health hazards due to the use of blood transfusion, we may present the records to the preparation's manufacturer and/or Japanese administrative agencies.

Doctor who gave the information: Hideki Sakamoto

Nurse/midwife in charge: _____

Date: _____

We have been fully informed about the necessity and risks of the transfusion and plasma preparations therapies. We have understood and consent to the therapies, related treatments and tests.

Date: _____

Patient's signature _____

(Family member's signature _____, patient's _____)

<Aiiku Hospital has adopted the following plasma fraction preparations.>

To be used	Product name	Blood Donation-derived	Non-blood Donation-derived	Source county
<input type="checkbox"/>	Neuart I.V. 1500 units (Antithrombin)	○		Japan
<input type="checkbox"/>	Anthrobin P 1500 for Injection (Antithrombin)	○		Japan
<input type="checkbox"/>	TachoSil Tissue Sealing sheet 9.5cm×4.8cm (Fibrinogen)		○	US, Germany, Austria
<input type="checkbox"/>	Fibrinogen HT I.V. 1g -BENESIS (Fibrinogen)	○		Japan
<input type="checkbox"/>	Beriplast P Combi-Set Tissue adhesion (3mL) (Factor XIII with fibrinogen)		○	US, Germany, Austria
<input type="checkbox"/>	BOLHEAL (3mL) (Factor XIII with fibrinogen)	○		Japan
<input type="checkbox"/>	Albumin 5% I.V. 12.5g/250mL -BENESIS (Albumin)	○		Japan
<input type="checkbox"/>	Venoglobulin IH 5% I.V. 0.5g/10mL (Immunoglobulin)	○		Japan
<input type="checkbox"/>	Anti-D GLOBULIN for I.M. injection 1000 「NICHYAKU」 (Immunoglobulin)		○	US
<input type="checkbox"/>	Anti-HBs Human Immune Globulin I.M. 200 units/1mL “Nisseki” (Immunoglobulin)	○		Japan
<input type="checkbox"/>	Neuart I.V. 500 units (Antithrombin)	○		Japan
<input type="checkbox"/>	Anthrobin P 500 for Injection (Antithrombin)	○		Japan
<input type="checkbox"/>	Kogenate-FS BIO-SET 500 IU (Factor VIII: genetical recombination)		○	US
<input type="checkbox"/>	Fibrogammin P I.V. (Factor XIII)		○	US, Germany, Austria
<input type="checkbox"/>	Beriplast P Combi-Set Tissue adhesion (1mL) (Factor XIII with fibrinogen)		○	US, Germany, Austria
<input type="checkbox"/>	BOLHEAL (1mL) (Factor XIII with fibrinogen)	○		Japan
<input type="checkbox"/>	Venoglobulin IH 5% I.V. 2.5g/50mL (Immunoglobulin)	○		Japan
<input type="checkbox"/>	Anti-HBs Human Immune Globulin I.M. 1000 units/5mL “Nisseki” (Immunoglobulin)	○		Japan
<input type="checkbox"/>	Sekijuji albumin 20% I.V. 4g/20mL (Albumin)	○		Japan

Information and Consent Form about Anesthesia (for Surgery/Treatment)

Department of Anesthesiology, Aiiiku Hospital

Method of anesthesia (planned)

General anesthesia

General anesthesia is means with which the patient is made asleep with medication.

It includes various kinds including from mild one which causes vaguely sleepy feeling to deep one which causes deep sleep followed by complete mechanical ventilation. Your anesthesiologist selects the safest method for each patient.

In cases of deep general anesthesia where breathing is completely controlled, air is sent mechanically through an instrument (through which a tube is inserted into the trachea or a mask is put into the mouth) inserted by the anesthesiologist to enable ventilation, that is artificial respiration.

(Possible complications/adverse reactions)

Nausea/vomiting, Hoarse voice for a few days (following tube insertion through the trachea),
Tooth damage, Pneumonia, Pulmonary atelectasis (partial collapse of the lung),
Pneumothorax (perforation of the lung), Lung edema, Heart failure,
Malignant hyperpyrexia (unusually high fever, very rare)

Spinal anesthesia

Spinal anesthesia is a means to temporarily immobilize the lower body, without making the patient sleepy.

The procedure consists of insertion of a needle through the space of the backbone (lumbar spine) and injection of medicine(s) into the spinal subarachnoid space around the spinal cord. Soon after injection, the lower body from the navel downward becomes virtually immovable (it becomes movable again a few hours after the surgery).

The immovable part of the body feels no pain, though there is sensation of being touched.

(Possible complications/adverse reactions)

Headache (it heals in about a week in most cases), Hypotension, Nausea/vomiting,
Temporary decrease in sensation/muscle weakness in the lower extremity,
Nerve injury (on very rare occasions, paralysis may persist long),
Epidural hematoma (accumulation of blood), Epidural abscess (collection of pus)

Epidural anesthesia

Epidural anesthesia is used in many cases to alleviate postoperative pain.

In some cases, operation may be performed only with epidural anesthesia (when the anesthesiologist judges that the procedure is safest).

For epidural anesthesia, a needle is inserted through the space of the backbone (spine) and a very thin tube named catheter is inserted into the epidural space near the spinal cord. Medicine(s) is injected through the catheter to eliminate the pain.

The catheter is left there for several days after operation. You can sleep on your back even with the indwelling catheter.

(Possible complications/adverse reactions)

Headache (it heals in about a week in most cases), Hypotension, Nausea/vomiting,

Temporary decrease in sensation/muscle weakness in the lower extremity,

Nerve injury (on very rare occasions, paralysis may persist long),

Epidural hematoma (accumulation of blood), Epidural abscess (collection of pus)

Other methods of anesthesia:

None planned

Finally,

If an unexpected complication/adverse reaction should develop in association with anesthesia or allergy, we would provide the best possible therapy.

I gave information as described above including advantages and possible adverse reactions for respective methods.

Date of giving information: ____ / ____ / ____ (hour) ____ : ____, By Dr. Hideki SAKAMOTO

I was given the above information, asked any questions, and understood what was told.

I thus give consent to receiving the anesthesia.

Date: ____ / ____ / ____, Patient's signature: _____

Signature of family member: _____ Relationship: _____