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CALIFORNIA BLOOD BANK SOCIETY

"We help save lives of people who need blood"

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Informed Consent for Transfusion of Blood Components and/or Plasma Derivatives

Several members have asked about informed consent for **transfusion therapy**, including consent for the use of whole blood, RBC's, platelets, and FFP. In addition, members have asked about their policies for obtaining informed consent for **plasma derivatives** such as Rh Immune Globulin (RHIG), PLAS-Plus, Factor Concentrates and albumin. The e-network was asked to comment about the **duration** consent can remain in effect, the method of documentation, and the **use of translators** for individuals who do not speak English as their primary language. Members were also requested to **share experiences** with regulatory (FDA, state) or accrediting (AABB, CAP, JCAHO) organizations that caused their facilities to be **cited** for inadequate consenting policies/procedures, and if so, what successful corrective actions were employed? For an **example** of how a California hospital addressed such a citation, see this [earlier e-*Network* issue](#) (on the Gann Act).

Here is the input submitted for the e-network to review:

1. **Response #1** was submitted by a **physician** who describes himself as a veteran of many years in a hospital transfusion service setting, and a person who is often consulted on ethical, legal, and accrediting matters. Here is what he had to say. "**The bases for any accrediting organization's requirement for transfusion informed consent are two-fold.** The first is a view of blood transfusion as a unique form of therapy with unique risks, and perceived risks, thus requiring specific consent. The second is the fundamental nature of consent, which has three key elements to the "informed" aspect. They are readily understood descriptions of benefits, risks, and alternatives. Accrediting organizations may specify blood consent, as part of a checklist, but the rationale is often elsewhere, either in a policy statement or in an overall delineation of patient rights, which usually will delineate these three elements. In the case of transfusion all three elements are usually intertwined with the primary underlying therapy, such as surgery, or marrow transplantation, or chemotherapy. To say that a separate consent must be obtained for each unit of blood leads to requiring consent for each administration of other therapies, such as having separate consent for each dose of Cytoxan in a course of chemotherapy. Similarly, consent might be given for a specific number of units intra-operatively, but this theory would require an added spousal consent during surgery, if the anticipated number of units is exceeded. The practical and ethically **correct approach to obtaining new consent for transfusions, is to obtain new consent when one of the benefits, risks, and alternatives CHANGE, and/or it is possible the patient's views on the overall treatment program to have changed.** If there is no change then a single consent should suffice, such as for a particular surgery with multiple transfusions, including postoperatively, similarly for a course of chemotherapy. A patient who subsequently requires a different surgery, may now have a different benefit/risk ratio with regard to transfusion as part of the second surgery. The same for a patient who has had a marrow transplant with consent, but now requires transfusion support for chemotherapy, when the malignancy recurs. In each of these scenarios, renewed consent for transfusion may be part of the consent for the new treatment or procedure. While a patient's views on accepting transfusion may change, this is almost always in the context of a new therapy. The above patient requiring chemotherapy for relapse after marrow transplantation may reject transfusion as part of rejecting ALL further therapy. A simple approach is defining for the patient the overall treatment (including transfusion) for an admission, and have a single consent for that admission. For uniformity, there is **an advantage to giving a patient an information sheet with a description of the risks.** The document's receipt can be acknowledged in the consent. For most admissions, this would be adequate. **Unexpected**

changes might require added consent, analogous to an unanticipated surgery. For outpatients, a single consent might apply for a course of therapy. **For chronically transfused patients**, my bias would be to renew consent at least yearly, since there are risk changes over time, such as iron overload. The foregoing is an individual opinion. No one can guarantee what an individual inspector/surveyor/agent might say. However my opinion is rooted in accepted ethical principles of informed consent, and a cited deficiency might be appealed. If cited, the inspector/surveyor/agent should be asked to show you the entire accreditation policy on transfusion. This will generally disclose that there is not a specific requirement for consent with each unit. I have not touched the other aspects of consent, such as ensuring the patient/family understand the information given, and have adequate time for questions and reflection. **Lastly, a hospital having a rule/policy of consent for every blood unit during a course of treatment, is likely to fail in applying such a policy, and will be cited.** Compliance would be difficult, and many accrediting/licensing agencies will hold you to YOUR rules, even if stricter than theirs. The usual inspector's approach for a given topic is to look at federal, state, accrediting body, and inspected institution's rules, and use the strictest to judge compliance."

2. **Response #2** was submitted by a **transfusion medicine specialist in California**. He commented that the population of the U.S. was becoming quite ethnically diverse, and that there appeared to be an increasing number of people who did not speak or comprehend the English language very well. This was leading in his own hospital to require the **interpreter/translator** for obtaining consent for transfusion. In fact, on the day that this particular e-network discussion was broadcast to the forum, he had a meeting with his hospital medical director, and a key discussion point was how to comply with JCAHO standards when obtaining consent for surgical procedures, when a patient is not English-speaking.
3. **Response #3** was submitted by an e-network member who works at the **University of Michigan** Health System Department of Pathology. She wants to refer the e-network forum readers to their [web site](#) and to their "Real Player" presentation on informed consent. Also, at the above link can be found their Blood Transfusion Policies, and in chapter 6 of those blood transfusion policies is a written text of their informed consent policy.

ADDENDA Aug. 19, 2001

4. **Response #4** was submitted by a member of the **AABB Ethics Committee** who says that this e-network forum discussion may be referred to at a session on Informed Consent at the forthcoming **AABB Annual Meeting** in San Antonio. The session will be on Monday, October 15th at 10:30am, presented by the AABB Ethics committee. One talk will address ethical concepts and will be presented by a noted outside ethicist, Dr. Jonathan Moreno from the University of Virginia. Two shorter talks on consent in tissue banking and cord/stem cell banking will be given, and questions will be encouraged.

ADDENDA Aug. 23, 2001

5. **Response #5** was submitted by the chair of a Transfusion Committee of a multi-hospital and multi-clinical health care network in **Southern California**, who reports that she discussed the issue of obtaining consent for blood transfusion with a member of the JCAHO's Standards Interpretation Group (SIG). The **JCAHO was asked for clarification of standard RI1.2.1** (see below for the wording of this standard) and for a response to the following questions.
 1. When a patient is likely to receive multiple transfusions, such as for surgery or a course of chemotherapy, **should a separate consent be obtained for each unit?**
JCAHO's response: **No**, separate consent is not necessarily needed for each transfusion during chemotherapy.
 2. Is there a standard that explains **how frequently** the consent for transfusion should be obtained when multiple transfusions are anticipated during a course of therapy?
JCAHO's response: No, our standards **do not specify frequency** for obtaining consents for transfusions.
 3. If there are no standards on the frequency of obtaining consent for transfusions, can the institution **develop its own policy** on this issue?
JCAHO's response: **Yes**, your organization may develop its own policy. **Below is this JCAHO Standard.**

JCAHO Standard RI.1.2.1 Informed consent is obtained.

Intent of RI.1.2.1

Staff members **clearly explain** any proposed treatments or procedures to the patient and, when appropriate, the family. The explanation includes:

- potential benefits and drawbacks;
- potential problems related to recuperation;
- the likelihood of success;
- the possible results of nontreatment; and
- any significant alternatives.

Staff members also inform the patient of the name of the physician or other practitioner who has primary responsibility for the patient's care; the identity and professional status of individuals responsible for authorizing and performing procedures or treatments; any professional relationship to another health care provider or institution that might suggest a conflict of interest; their relationship to educational institutions involved in the patient's care; any business relationships between individuals treating the patient, or between the organization and any other health care, service, or educational institutions involved in the patient's care.

Example of Implementation for RI.1.2.1

The medical staff, in collaboration with others, develops a **formal process** to guide and support the following:

- **Documenting the disclosure process** (for example, discussions with the patient relative to the specific benefits and drawbacks of the treatment or procedure, including impact on daily living activities and alternate therapies, when available);
- Availability of **translation services** when appropriate;
- Availability of appropriate **audiovisual aids**;
- A method to assess and document evidence of **patient understanding**; and
- Documents of **patient consent** for procedures.

ADDENDA Aug. 24, 2001

6. **Response #6** comes from the **Editor**, who reports that at the USC University Hospital and at the Kenneth Norris Cancer Hospital, whenever it seems likely that a patient will need a blood transfusion, the physician is to **discuss** this matter with the patient beforehand and obtain the patient's consent (emergency transfusions excepted). The discussion will include the risks and benefits of transfusion, the alternatives to transfusion, and the possibility of directed donations and of autologous transfusions, where this is feasible and available. This discussion will be **documented in the patient's medical record** and will recount the substance of the discussion with the patient. In order to assure that availability of blood products for all scheduled surgery, the Blood Bank must be notified in advance of surgery and specimen sent for compatibility testing (type/screen or type/crossmatch) at least 12 hours prior to surgery if the need for blood is anticipated, emergency cases excepted.

ADDENDA Jan. 29, 2008

7. **Editors' Note: Senate Bill 102** was introduced by Senator Carole Migden in January 2007. The bill was approved by the Governor in July 2007 and **has been chaptered**. The previous version of the Paul Gann Blood Safety Act required that a physician inform the patient of the positive and negative aspects of receiving autologous blood and directed and nondirected homologous blood from volunteers, whenever there was a reasonable possibility that a blood transfusion may be necessary as a result of a medical procedure, and by means of a standardized written summary that is published by the Medical Board of California. The new version of the law **expands the list of individuals who may provide the written summary to include doctors of podiatric medicine**. Furthermore, the new law **permits that the information be given** directly by the physician or doctor of podiatric medicine, or **indirectly via a nurse practitioner, certified nurse midwife, or physician assistant**, who is authorized to order a blood transfusion. Click [HERE](#) for full text of the chaptered bill.

ADDENDA April 9, 2008

8. **A colleague located at a healthcare system in Georgia** would like to know if other hospitals currently obtain **informed consent for IVIG and albumin**? If so, how is the consent **documented**? Is a form used which is similar to that used to document consent for blood

products, or is a different form used? The inquiring colleague acknowledges that **her hospital does NOT** obtain informed consent for IVIG, albumin, and other derivatives of human plasma or recombinant products such as rFVIIa, rFVIII and rFIX.

Please submit comments to the [e-Network Forum](#).

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