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Survey on Informed Consent for Transfusion

A transfusion medicine physician at a large tertiary care hospital in Southern California reports that they use a pre-printed form which the **patient** must sign, to document that informed consent for transfusion was obtained from the patient. Furthermore, the ordering **physician** is also required to sign an 'Attestation of Informed Consent', essentially stating that the patient was informed of the risks and benefits of transfusion. While not mandatory, the physician may also put a note in the chart that they had a discussion with the patient about transfusion, and that informed consent was obtained. The inquiring physician would like to know the current status of obtaining informed consent for transfusion at other hospitals, specifically if others are routinely obtaining informed consent for transfusion, and if so, by what mechanism (preprinted form, free text note in medical record, other). Please respond to this query even if you do not obtain informed consent for transfusion.

We encourage those who wish to indicate their policy to fill out this [short survey form](#) (PDF) and fax it to the Editor by Aug. 27 if possible. (Identity of contributors will be kept confidential.) Additional comments may be sent by email. Results of the survey will be posted here.

The following responses have been received.

1. **At the Editor's institutions** (LAC+USC Medical Center and USC Kenneth Norris Cancer Hospital) **preprinted forms** are available for use in documenting that informed consent for transfusion has been obtained. In addition, colleagues might find the information at these previously posted issues germane to this discussion.

- [Informed Consent for Transfusion of Blood Components and/or Plasma Derivatives](#)
- [Is an attending physician's countersignature required for transfusion consent forms?](#)

2. **A colleague in Tennessee** reports that her hospital uses **two different forms** to document informed consent for transfusion. One form is a stand-alone consent form for blood transfusions. The other form is their surgical consent form which has a sentence that addresses the possibility of receiving a blood transfusion. Their facility requires that the physician sign the consent form, as well as the patient. Their blood bank, at the request of the hospital quality department, began **auditing charts for physician compliance** with obtaining and signing the informed consents for transfusion. The responding blood banker reports that the results, after almost a year of audits, were **not encouraging**. Now, also at the request of the quality department, the "floor" must send either the original or a copy of the consent along with the request slip for the blood/product being requested. If the physician has not signed the consent, no products are issued, unless it is an emergency. The patient's nurse may call the physician and with another nurse as witness, sign the consent form. A system is in place to remind the physician to sign the consent form at the next opportunity.

ADDENDA Aug. 25, 2003

3. **A colleague at a hospital in Maryland** reports that they use **two pre-printed forms**. The first form has the risks and benefits and is for the patient to keep. The patient's nurse gives that to the patient prior to the transfusion. The other form is for the nurse to **document** that she gave the education material to the patient and for the physician to document that he/she also spoke with the patient.

4. **Dr. Breannan Moore** of the Mayo Clinic (attribution used with permission) reports that they have had **consistent problems with adequate documentation** of informed consent, but that they are now utilizing a new technology to resolve this problem. Dr. Moore reports that upon recently implementing **an electronic blood ordering system** (for inpatients) an obligatory check box was incorporated to indicate that informed consent for transfusion was obtained. At

present, with the exception of an emergency, no order to dispense blood for transfusion is filled unless the documentary box for informed consent is checked.

Each physician attempting to order blood is made aware that their order will not be filled by Transfusion Medicine unless the documentation box for informed consent is checked. The policy for the medical record at Mayo is that any and all invasive interventions should trigger a note indicating that the risks and benefits were discussed with the patient. The surgeons will frequently include a statement regarding transfusions in their clinical note about discussing the operative procedure. Mayo has yet to implement the electronic orders for **outpatient** transfusions, but hope to do so as soon as is practical.

The obvious question is how does the Mayo Transfusion Service know that informed consent has really been obtained versus the box merely being checked off without having obtained consent? Dr. Moore admits that they have yet to devise a good system for auditing the compliance of the ordering physicians, to be perfectly confident that they really did obtain informed consent and did not just check the mandatory box on the order. However, the physicians ARE MADE AWARE that falsifying documents is grounds for instant dismissal from the institution.

- 5. A colleague in Iowa** reports that their facility uses a **printed Consent To Transfusion of Blood or Blood Products form** which explains the procedure and general risks. This form is signed by the patient or legal representative acknowledging that the nature, risks and benefits have been explained to them and that all of their questions had been answered satisfactorily. By signing this form they consent to transfusion, if determined to be necessary by their physician. **This signed form is placed in the patient's chart.** The person (most usually **nursing**) giving the patient the information and talking with them signs the form as witness to consent. The patient is also given a patient education flyer about blood transfusion, which gives statistics, safety precautions, risks, disease transmission, alternatives/options available for non-emergent transfusion, etc. The patient can read and retain this information.
- 6. At a hospital in Pennsylvania** they use a pre-printed form which the patient must sign, to document that informed consent for transfusion was obtained from the patient. Furthermore, the ordering physician is also required to sign an 'Attestation of Informed Consent', essentially stating that the patient was informed of the risks and benefits of transfusion. While not mandatory, the physician may also put a note in the chart that they had a discussion with the patient about transfusion, and that informed consent was obtained.

ADDENDA Aug. 26, 2003

- 7. A colleague at a Children's Hospital in Northern California** reports that they have high compliance rate with consents for transfusion. **The nurse starting the transfusion has the responsibility for checking the chart** for documentation of consent, and will not start the transfusion without a consent, except in emergencies (usually trauma cases admitted through Emergency Dept.).

ADDENDA Aug. 28, 2003

- 8. At an institution in Southern California specializing in oncology care**, they routinely obtain informed consent for blood transfusion. Both the patient and physician sign the consent form, the original copy going to the patient chart and a copy to the patient. In addition, they use printed information from the California Department of Health Services entitled "A Patient's Guide to Blood Transfusion" which appears on the back of the informed consent form to consolidate the informed consent process and provision of the Paul Gann Blood Safety Act information into a single process. (**Editor's note:** *The 2006 State of California revision of "A Patient's Guide to Blood Transfusion" is available [here](#) in both English and Spanish.*)
- 9. A transfusion medicine physician in the Pacific Northwest** reports that at her large academic institution informed consent for transfusion has been required for more than 10 years. A **preprinted form** must be used and **two forms are available**. The first (their original form) has a transfusion consent **embedded in the consent for procedure**. In the case of surgeries the patient must specifically indicate if they are not including consent for transfusion along with their consent for the procedure; if they are not including consent, they are then required to complete other paperwork for "bloodless surgery" documenting what they will and will not accept. This form was originally also used for consenting the patient for transfusion only, but they found this confusing and created a **separate form for transfusions not associated with surgery**. These forms outline the risks of transfusion in very general terms. Housestaff are educated regarding risks and counseling of patients and many of them carry little pamphlets on transfusion that outline specific risks. **Nurses in this institution check for consent as the first step in their transfusion procedure.** Consents must be updated on an annual basis. The Pacific

Northwest physician follows compliance with the consent process as one of their QA indicators. Their soon to be rolled out computerized medical record will have this information available as part of an individualized transfusion profile.

ADDENDA Aug. 30, 2003

10. **A colleague at a medical center in Los Angeles** suggests that the form shown [here](#) (*PDF file*) is one example of documenting informed consent for transfusion.

ADDENDA Sept. 1, 2003

11. **A colleague in Los Angeles** wishes to call to the attention of the e-Network Forum that informed consent for transfusion may be of particular importance if the transfusion therapy is investigational. The information at *Newsday* (*link no longer available*) raised ethical issues surrounding failure to inform individuals about their involvement in 'research' studies.
12. **Editor's Note:** In addition to comments submitted directly to the e-Network Forum (which have been posted above), **nine institutions provided responses to the Questionnaire** found [here](#) (PDF file).

- **Question #1;** *Does your institution routinely obtain written informed consent for transfusion?*

All nine institutions indicated that they obtain written informed consent for transfusion.

- **Question #2;** *If YES to the above, do you also require the patient's physician to document that he/she has informed the patient of the risks/benefits and alternatives to transfusion?*

Eight of the nine institutions require that the patient's physician document that the patient has been informed of the risks/benefits and alternatives to transfusion. The one institution that does not require that a physician do this documentation reported (verbatim)? This is nursing's responsibility at our facility. Charts are audited quarterly for compliance. The transfusion tag attached to the unit has a reminder box to check for 'consent signed'. Patients are given a transfusion information flyer that contains more specific information. This is the patient's copy to read and keep and ask questions from. The consent form is charted and signed by the patient or legal representative and witnessed (usually by a nurse).?

- **Question #3;** *If YES to the above, how does the physician document this?*

Many facilities use more than one approach.

- On the same form as that signed by the patient: 8 of 8 facilities use this approach
- On a separate form that is placed in the medical record: 3 of 8 facilities use this approach
- By a note in his/her OFFICE patient's record: 2 of 8 facilities use this approach

ADDENDA Feb. 9, 2007

13. **A California colleague** reports that their hospital policy **requires a physician to cosign a patient's informed consent for transfusion**, and that the signed form must be placed into the medical record. In reality, this does not always occur. In a recent chart audit they discovered that one reason for a less than 100% compliance was that they were using two different transfusion consent forms in their system. One form had a line for the physician's signature and the other had a line for the patient's signature, but not for the physician's. This caused the hospital administration to take a look at the Paul Gann blood safety act law itself to see what was actually required. The verbiage in the Gann Act says that "the physician and surgeon shall note on the patient's medical record that the [standardized written summary](#) described in subdivision (e) was given to the patient". This does not say that the physician must sign, but it merely requires the physician make a notation. They are aware of the various discussions on the e-Network Forum about the Gann Act. However, they wonder **if other institutions still require a physician to sign the transfusion consent form, or if other healthcare providers can sign it**. This question is of interest in light of a [recently introduced California legislation](#) which if passed, would permit other healthcare providers to participate in this process.

ADDENDA March 15, 2007

14. **Editors' note:** The Paul Gann Blood Safety Act is actively being considered for amendment, as pointed out in the posting to this discussion of Feb. 9, 2007. However, an amended version of this proposed California legislation can be found [HERE](#).

ADDENDA March 23, 2007

15. **The medical director of a University Transfusion Service in Southern California** writes they also found non-reassuring results when auditing compliance transfusion consent. As a corrective action, they **now require physicians to check a box on their blood order sheet:**

- I have consented this patient for blood transfusion.
- I have verified this patient has been consented for a blood transfusion.
- Emergency Transfusion - consent cannot be obtained.

They have yet not audited compliance following implementation of the new forms.

ADDENDA Jan. 29, 2008

16. **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 Oct. 24, 2008

17. A **California colleague** wonders **if there are circumstances** when obtaining informed consent for transfusion that the possibility of **iron overload or toxicity is mentioned** to the patient as one of the **potential risks of transfusion?**

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

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