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Does The Gann Act in California Require Informed Consent for Transfusion?

A California hospital was recently inspected by JCAHO because of interest in their use of restraints. However, reportedly, the **inspector opined that the hospital was out of compliance with state law, including the Gann Act, because they did not require each patient to 'sign' a consent prior to each and every transfusion episode.** The hospital policy was to give potential transfusion recipients a custom-made educational sheet about transfusion risks, options, etc., and to place an attestation stamp in the chart (to be signed by the physician), that transfusion risks, benefits, and alternatives were discussed - and to require this once per hospitalization. What do others in California do?

The following ideas have been submitted in response to the posed question. These opinions are paraphrased and are being presented without attribution. They do not represent an official opinion or position of the CBBS.

1. **One panelist** commented about a facility that had a JCAHO inspection in April. That particular facility protocol stated that "Consent must be obtained once per surgical procedure, or once per year for nonsurgical patients, or until there is a change in the risks or benefits of treatment." This was further clarified by stating "once per surgical procedure for surgical patients, once per admission for non-surgical inpatients, and once per year for outpatients." Apparently this protocol did not pose any problems for either the facility being inspected or for the JCAHO inspectors.
2. **A second panelist** commented that based on having worked with the California Committee which, at the time, created the "standardized written summary, and based on a recent review of the Gann Act (Calif. Health and Safety Code, Division 2, Chap. 4.5, Section 1645) , Section 1645 (b) states "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 statement does NOT indicate that the "patient" must sign nor does it indicate for EACH transfusion episode. It was in the context of this Act that the "standardized written summary" became the pamphlet that the Department of Health distributes. The panelist commented that the use of "customized" hospital educational sheets (in place of the State approved pamphlet) may not be sufficient.
3. **A third panelist** stated that the Paul Gann Safety Act requires that whenever there is a reasonable possibility that a blood transfusion may be necessary for an inpatient or an outpatient as a result of a medical or surgical procedure, the physician or surgeon who makes the determination that the reasonable possibility exists, must do the following:
 - A. Inform the patient, by means of the State Department of Health Services standardized written summary of the positive and negative aspects of receiving autologous, blood, and directed and non-directed homologous donations from volunteers, including relatives, friends and blood bank donors.
 - B. The physician and surgeon shall note on the patient's medical record that the standardized written summary was given to that patient.
 - C. Allow adequate time before surgery for blood pre-donation to take place except in a life-threatening emergency or where there are medical contraindications.

No guidance is given by the Gann Act as to how often it is necessary to repeat the procedure in patients who require multiple transfusions. At the panelist's institution, this question was considered by the Transfusion Committee and by the Medical Staff Executive Committee and the hospital's legal staff. The hospital policy that was adopted requires that Gann Act requirements

be satisfied once per surgical procedure, once per admission for medical patients and once per year for outpatients unless there is a change in the risks or benefits of treatment. As far as I am aware, the frequency of compliance with the Gann Act has never been tested in court. The panelist suggests that hospitals adopt their own policy after consideration by appropriate committees and by medicolegal staff. The panelist expects that most medicolegal experts would consider that placing a stamp in the chart to be signed by the physician that transfusion risks, benefits and alternatives were discussed with the patient is adequate indication of informed consent. However, informed consent generally requires an indication by the patient that they have received the information, that they understand and give consent. The panelist's own view is that it is safer to have the patient sign something indicating that they understand and give consent for transfusion. Otherwise, the patient may state later that a discussion of risks, benefits, etc never took place and it would be impossible to prove that it did. (Great care should be taken in obtaining informed consent for transfusion. Lack of informed consent and lack of a justifiable indication for transfusion are two major points of vulnerability for medicolegal action when something goes wrong.)

The procedure at the panelist's hospital is to use an Informed Consent for Transfusion form which includes all of the information required by the Gann act and includes the most recent data about the approximate chance per unit of blood of transmission of the various blood-borne infectious agents as well as the chance of serious and even fatal transfusion reactions. Both the physician and the patient sign the form thus satisfying the Gann Act requirements as well as satisfying the need for good documentation of informed consent by having the patient's signature.

ADDENDA Jan. 29, 2008

4. **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.

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

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