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The Paul Gann Blood Safety Act - Documentation Questions

Dear CBBS e-network members. The following question has been posed for your consideration. Please e-mail your replies to the Editor at CBBS-network@mail.com

For hospitals in California, here is a question regarding compliance with the Paul Gann Act, California Health and Safety Code Section 1645(b). The Gann Act specifically requires that the patient's physician document ***on the patient's medical record*** that the patient was informed of his/her transfusion options. In preparing for a CALS Survey, the individual posing this question was told that the inspectors will want to see this documentation on the patient's ***hospital*** medical record, even though in all practicality the notification must take place as the patient is being scheduled for the procedure, in the physician's office. The institution of the individual posing this question currently has the patient signing that he/she has been informed as a part of consenting to transfusion, but the physician doesn't sign. What are other hospitals in California doing ?

AND before you all answer, here is the most **current version of the Paul Gann Safety Act**, as it appears in the California Health and Safety Code:

HEALTH AND SAFETY CODE SECTION 1645

- (a) Whenever there is a reasonable possibility, as determined by a physician and surgeon, that a blood transfusion may be necessary as a result of a medical or surgical procedure, the physician and surgeon, by means of a standardized written summary as most recently developed or revised by the State Department of Health Services pursuant to subdivision (e), shall inform the patient of the positive and negative aspects of receiving autologous blood and directed and nondirected homologous blood from volunteers. For purposes of this section, the term "autologous blood" includes, but is not limited to, predonation, intraoperative autologous transfusion, plasmapheresis, and hemodilution
- (b) 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.
- (c) Subdivisions (a) and (b) shall not apply when medical contraindications or a life-threatening emergency exists.
- (d) When there is no life-threatening emergency and there are no medical contraindications, the physician and surgeon shall allow adequate time prior to the procedure for predonation to occur. Notwithstanding this chapter, if a patient waives allowing adequate time prior to the procedure for predonation to occur, a physician and surgeon shall not incur any liability for his or her failure to allow adequate time prior to the procedure for predonation to occur.
- (e) The State Department of Health Services shall develop and annually review, and if necessary revise, a standardized written summary which explains the advantages, disadvantages, risks, and descriptions of autologous blood, and directed and nondirected homologous blood from volunteer donors. These blood options shall include, but not be limited to, the blood options described in subdivision (a). The summary shall be written so as to be easily understood by a lay person.
- (f) The Medical Board of California shall publish the standardized written summary prepared pursuant to subdivision (e) by the State Department of Health Services and shall distribute copies thereof, upon request, to physicians and surgeons. The Medical Board of California shall make the summary available for a fee not exceeding in the aggregate the actual costs to the State Department of Health Services and the Medical Board of California for developing,

updating, publishing and distributing the summary. Physicians and surgeons shall purchase the written summary from the Medical Board of California for, or purchase or otherwise receive the written summary from any other entity for, distribution to their patients as specified in subdivision (a). Clinics, health facilities, and blood collection centers may purchase the summary if they desire.

- (g) Any entity may reproduce the written summary prepared pursuant to subdivision (e) by the State Department of Health Services and distribute the written summary to physicians and surgeons.

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. **The first respondent** stated that this question has come up from a number of hospitals in Northern California recently. Apparently at least one hospital was asked to show documentation of informed consent in the hospital records. While this is different than the Gann information, their decision was that they **might as well have the physician document the Gann information in the hospital chart** as their way of showing they were requiring informed consent and they are auditing it. One hospital will hold up elective surgery unless the consent is documented on the hospital chart. Another hospital with a good internal LAN system is putting the forms for informed consent with the new Gann information sheet attached so a physician can print them out from the hospital system and give them to the patient. A few years ago, some of the hospitals were of the opinion that by becoming involved in the Gann process they took on extra liability. Now it seems their risk managers are telling them the liability is there either way and they are generally becoming involved in the documentation.
2. **A second respondent** stated that at his institution in Southern California, they **have a patient sign a form that says the doctor provided the informed consent** (which is usually signed and filed in the doctor's office).
3. **A third respondent** stated that the question raised is a difficult one as it is much easier to have the Gann Act documentation in the patient's outpatient chart than in the hospital chart. Unfortunately, inspectors will be unable to go through records in individual physician's offices and will assume that if it is not in the hospital records, it was not obtained. This is not totally unreasonable as the hospital has no way to be certain that the Gann Act was complied with unless the hospital sees some documentation. What this responder's institution does is to have the **physician sign the Gann Act materials in his/her office and send the signed form to their surgery scheduling office along with other forms unrelated to blood that are required to schedule a surgery. This office then sends to Gann Act form to the hospital's record room to be placed in the patient's inpatient chart.**
4. **A fourth respondent** stated that some of hospitals have developed a **form for documenting at the time of admission that the Paul Gann Safety Act provisions have been satisfied.** This respondent does not think that this documentation is being signed by a physician; rather, he thinks that most use a nurse. This responder believes that it can be argued that a hospital form is NOT necessary. The process and documentation should be in the physician's OFFICE chart, long before hospitalization. The respondent does not think it is up to the hospitals to see that a form or notation is made in the patient's record. If a patient comes in with autologous, directed donation, or other products mentioned in the Gann Law, that would be proof that the provisions have been satisfied. This responder does **encourage physicians to make a note in the hospital chart that "informed consent" for transfusion has been carried out.** A hospital chart note is preferred to a specific form, especially if there is a temptation for such a form to be filled out by a nurse (who is asked to fill it out and obtain the patient's signature). It is recommended that a **simple statement such** as "the risks and benefits of a blood transfusion have been explained to the patient, including all options, and the patient agrees (or doesn't agree)" followed by a signature. The "options" include autologous, directed, standard allogeneic, other products, or no transfusions.
5. Finally, a **fifth respondent** stated that in addition to Health and Safety Code Section 1645, the **JCAHO accreditation manual states** the following:

TX.5.2 Before obtaining consent, the risks, benefits, and potential complications associated with procedures are discussed with the patient and family.

TX.5.2.1 Alternative options are considered. Discussions with the patient and family about the need for, risk of, and alternatives to blood transfusion when blood or blood components may be needed are considered.

Examples of Evidence of Performance for TX 5.2.2 are interviews, policies and MEDICAL RECORDS.

This respondent commented that informed consent seemed to be a hot topic for the JCAHO last year and in fact his institution was cited for lack of compliance with this standard. Indeed an internal audit showed only 35% compliance.

In response to this citing, the respondent's institution recently implemented **a new transfusion informed consent policy**. In developing the new policy, the state form was revised to have the consent/signature area on the front along with instructions for nursing to follow (nursing has been made the informed consent gatekeeper). The standardized state form is on the back. The **physician statement** says "I have discussed with the patient the risks and benefits of blood transfusion and alternate therapies and the patient has been provided with a copy of the Paul Gann Blood Act 'A Patient's Guide to Blood Transfusion' ." The form is **two-part** so that one copy can be charted and one copy can be provided to the patient. A packet of forms and instructions were mailed to the offices of all of the high-use physicians. Any patient being admitted for surgery that has a type and cross or type and screen order is required to have a **signed consent form sent over with the admitting orders** (it is assumed that by ordering a type and screen or type and cross that the physician considers that there is a "reasonable possibility" of requiring blood). If a consent form is not received, the pre-admission screening department contacts the physician's office. On the nursing units, nurses will no longer hang a blood product in a non-emergency setting until they have found a signed form OR documentation in the H&P by the physician that informed consent has taken place. If they find physician documentation in the H&P they simply have the patient sign the form and blood is given. No further action is required. If no physician documentation exists on the chart, either by way of a signed consent or note in the H&P, the patient is asked if they have discussed risks and benefits with the physician. If the patient states they have already talked to the physician, the nurse has them sign the form and it is flagged for MD signature at a later time. If the patient states they have not talked to the physician, the physician is called. If the physician talks to the patient by phone, the patient signs and the form is again flagged for MD signature at a later time. There are boxes on the form for each of these scenarios for the nurse to check off. Informed consent must be **completed with each admission, or annually for ongoing, outpatient transfusions**. This institution will be re-auditing in November to measure the effectiveness of this newly implemented policy, and hopes to see some improvement.

If any other members would like to share their approach to complying with the Paul Gann Act, feel free to e-mail the Editor (below).

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

1. The **first additional comment** stated that "One of the responses seems to refer to the State Gann information form and documented informed consent almost interchangeably. It is important that the two are differentiated." Apparently, the new State approved Gann "A Patient's Guide to Blood Transfusion" specifically states that this information does not constitute informed consent. This new version has been approved by the Medical Board of California and will be available as soon as it is printed (and also on the CBBS web-site).
2. The **second additional comment** stated that no one can require that the use of the Paul Gann Safety Act be documented in the **hospital** chart. If an inspector challenges the physician, the doctor should reply, "Check my office charts" and invite the inspector to do so. The individual submitting this additional comment also stated that he/she had been pushing that use of the "Type and Screen" option, by definition, means that there is **not** a reasonable possibility of a transfusion being given so there is no need for following the provision of the Paul Gann Safety Act. When blood is set up using a "Type and Cross" on the other hand, there is a reasonable possibility and the provisions of the current Paul Gann Safety Act must be followed, if this is not an emergency.
3. The **Editor's institutions**, on the other hand, **does** use the Type and Screen as evidence of at

least a 1-10% possibility that a patient will need a transfusion, and that range of possibility is considered to be a 'reasonable' possibility.

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](#).

Ira A. Shulman, MD
CBBS e-Network Forum Editor & Moderator

W. Tait Stevens, MD
CBBS e-Network Forum Assistant Editor & Moderator

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Posted: June 5, 1999

Updated: June 14, 1999

Addenda: Jan. 29, 2008



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