Legal, Ethical & Patient Rights

Presented by
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Medical Officer, LifeSouth Community Blood Centers, Gainesville, FL
And
President, SABM
Learning Objectives

- Learn the legal and ethical underpinnings of the principles of informed consent
- Understand the process of obtaining informed consent and who is responsible for doing so
- Evaluate institutional compliance with CMS, AMA, TJC, AABB, state laws
Informed Consent: The Trilemma

- Physicians with gaps in knowledge about transfusion therapy
- Patients with little knowledge and poor understanding of the complexities of healthcare
- Physicians and patients with suboptimal motivation to disclose and receive information
- Has heightened public concern about transfusion risks in recent past been replaced by complacency?
Patient Transfusion Safety: From brain to vein AND from vein to vein

Physician and Patient

Decision to Transfuse AND Informed choice “consent”

Donor Qualified

Blood collected

Donation testing (Testing may be sent out)

Compatibility procedures

Blood component available

Component is Issued to patient

Patient Transfused; followup

Physician

Obtain Patient blood samples and send to blood bank/lab

Patient usually admitted to hospital – ID attached

Lab
Legal cases supporting patient’s right to ‘consent’ to treatment


“every human being of adult years and sound mind has a right to determine what shall be done to his own body.”
1972  Cobbs v. Grant, 8 Cal. 3d 229, 240, 243, 502 P.2d 1, 104 Cal.Rptr. 505 (Cal. 1972)

“…as an integral part of the physician’s overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each.”
Legal Protection of Patient Rights

- Competent patients have the right to refuse treatment
- Incompetent patients have same rights as competent ones
- State opposition is virtually nonexistent for competent patients; very weak for incompetent patients whose prognosis for recovery is slim
- Decision-making should occur in the clinical setting (not courts)

(continued)
Patient rights (cont.)

- Making decisions for incompetent patients:
  - Surrogate decision makers should
    - effectuate patient’s preference as stated prior to patient losing decision-making capacity (Subjective standard)
    - If patient’s preferences are not known, based on best information available, approximate what the patient would have wanted (Substituted judgment standard)
    - If no information, make a decision that is in the patient’s best interests (Best interest standard)
Fundamental Principles of Clinical/Medical Ethics*

- Autonomy – patient’s perspective
- Veracity – truth-telling
- Beneficence – MD’s doing good
- Non-maleficence – doing no harm
- Justice – being fair

*Perlin TM. The Ethical Basis for Informed Consent, in Stowell CP, Sazama K, eds. Informed Consent in Blood Transfusion and Cellular Therapies. Patients, Donors, and Research Subjects, AABB Pres, Bethesda, MD, 2007, p. 9, from Table 1-3.
Requirements for Informed Consent: AMA

- Code of Medical Ethics and Current Opinions 8.08
  - patient’s right of self-decision can only be effectively exercised if the patient possesses enough information to make an intelligent choice.
  - present facts accurately and make recommendations in accord with accepted medical practice
  - rejects paternalistic view that the physician may remain silent because providing information might prompt the patient to forgo needed therapy.
Requirements for Informed Consent: CMS

- The patient has the right to make decisions about their care
  - Informed of health status, involved in care planning, treatment, and able to request or refuse treatment
- Hospitals must utilize processes that assure patients are given the information and disclosures needed to make an informed decision about treatment
- Hospitals must develop policies and procedures that assure patient’s right to request or refuse a treatment
  - Demonstrate that Hospital complies with these policies
Informed consent document (well-designed)
- Name of practitioner obtaining informed consent
- Listing of the material risks that were discussed with patient

Placed in medical record prior to treatment or intervention

Disclosures
- Statement that the procedure or treatment, including the anticipated benefits, material risks, and alternative therapies, was explained to the patient
  - Material risks could include risks with a high degree of likelihood but a low degree of severity, as well as those with a very low degree of likelihood but high degree of severity.
The Joint Commission (TJC) Requirements

- Three elements of performance RI2.40
  - The hospital policies must describe:
    - What procedures require informed consent
    - The process used to obtain informed consent
    - How informed consent is to be documented in the medical record
  - Informed consent must then be obtained and documented in the medical chart pursuant to hospital policies
A complete informed consent process includes a discussion of:

- Nature of the underlying diagnosis, proposed care, treatment, intervention, or procedure
- Potential risks, benefits, and side effects, and potential problems related to recuperation
- Likelihood of achieving the goals
- Alternatives
- Relative risks, benefits, and side effects related to the alternatives, which includes the results of not receiving the care or treatment
- Any limitation on the confidentiality learned from the patient

Documentation of these elements must be in the form, progress note, or elsewhere in medical record
AABB Requirements*

- Standard 5.19.1 **Recipient Consent**
  The blood bank or transfusion service medical director shall participate in the development of policies, processes, and procedures regarding recipient consent for transfusion.
  - 5.19.1.1
    - At a minimum, elements of consent shall include all of the following:
      - A description of the risks, benefits, and treatment alternatives (including nontreatment).
      - The opportunity to ask questions.
      - The right to accept or refuse transfusion.

- Standard 5.19.6 The patient’s medical record shall include: transfusion order, documentation of patient consent, …

*Standards for Blood Banks and Transfusion Services, 26th edition, AABB. Eff. 11/1/2009
Paul Gann Blood Safety Act*

- Reasonable possibility of transfusion, physicians must inform patients about the negative and positive aspects of autologous blood, and directed and non-directed homologous blood from volunteers.
- Must allow adequate time for predonation absent emergency or medical contraindications.
  - Patient may waive.
- Standardized written document.
- Document in the medical record that the standardized written summary was given to the patient.

*California law.
A decision to undergo medical treatment after receiving adequate disclosure of relevant information.*

Elements of Informed Choice

- Patient is informed about
  - Reason for transfusion
  - Risks of transfusion/no transfusion
  - Benefits of transfusion
  - Alternatives to transfusion

- Patient considers choices and
  - has time to “digest” information and
  - may ask and receive answers to questions

- PATIENT DECIDES – “Yes” OR “No”

- Patient’s choice: AGREE or DECLINE/REFUSE should be documented in writing

Adapted from Stowell CP, Table 3-1. Elements of Informed Consent, p. 63
When to transfuse RBCs

MEDICAL EVALUATION

- Patient’s clinical condition
  - Current -- measured by vital signs
  - Evidence of active bleeding
  - Predictable -- e.g., cancer treatment
  
  with reference to

- Patient’s laboratory test results
  - Hemoglobin OR hematocrit

PATIENT’s PREFERENCES
## Guidelines for When to Transfuse

<table>
<thead>
<tr>
<th>COUNTRY</th>
<th>Type of Guidance</th>
<th>Component(s)/Indication</th>
<th>Year</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>USA</td>
<td>Guidelines</td>
<td>Anemia in lymphoid malignancies</td>
<td>2007</td>
<td>Henry DH. Drugs 2007;67:175-194</td>
</tr>
</tbody>
</table>
Appropriate Blood Use

Figure 2. Survival Analysis by Transfusion Status Among Propensity-Matched Patients

Vincent JL, Baron J-F, Reinhart K, Gattinoni L, et al. Anemia and blood transfusion in critically Ill patients. JAMA 2002;288:1499-1507. Figure 2, p. 1505
Benefits/Risks of RBC transfusion

- Benefits of RBC transfusion:
  - To increase oxygen carrying capacity to tissues

- Risks of RBC transfusion – most likely:
  - Immunosuppression/other adverse
  - Infections
  - Alloantibody formation

- Benefits/Risks of NO RBC transfusion
Fig. 2. Estimates of the current risk per unit of blood transfusion.

The vertical bars represent log risk estimates (1-10, 1-100, etc.). The dashed edges to lighter shaded horizontal bars signify that the upper and lower estimates of risk are uncertain.
Do you have to disclose every known risk?

Canadians conclude that risk of prion transmission is material and must be included.*

“Material” risk is defined as [any] risk that a reasonable person, under such circumstances, would want to know.

## Alternatives to RBC Transfusion

<table>
<thead>
<tr>
<th>Alternatives to standard transfusion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhibitors of thrombolysis (EACA or tranexamic acid) and aprotinin</td>
</tr>
<tr>
<td>Use of growth factors such as erythropoietin</td>
</tr>
<tr>
<td>Autologous donation (preoperative autologous blood donation, acute normovolaemic haemodilution, cell salvage)</td>
</tr>
<tr>
<td>Use of haemostatics such as thrombin, fibrin sealant or recombinant factor VIIa</td>
</tr>
<tr>
<td>None (improving transfusion practice so only transfuse when appropriate)</td>
</tr>
</tbody>
</table>

EACA, Epsilon-Amino Caproic Acid.

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**Acceptability of blood and blood substitutes**


*From the "Risk Analysis, Social Processes and Health (RASP) group, School of Psychology, University of Nottingham, Nottingham, UK, 2Scottish National Blood Transfusion Service, Edinburgh, UK, 3Sanquin Blood Supply, Corporate Staff, c/o Department of Research and Education, Plesmanlaan 1a, Leiden, The Netherlands, and 4School of Biology, University of Nottingham, Nottingham, UK.*

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2008 | **Journal of Internal Medicine** 263; 244–255 | 245
## Table 3 Molecular and clinical characteristics of oxygen therapeutics

<table>
<thead>
<tr>
<th>Product</th>
<th>Oxygen therapeutic constituent</th>
<th>Technology</th>
<th>Trial status</th>
<th>Reported (side) effects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fluosol</td>
<td>PFC</td>
<td>100–300 nm emulsion</td>
<td>Discontinued 1993</td>
<td>Inflammatory response</td>
</tr>
<tr>
<td>Perfloran</td>
<td>PFC</td>
<td>100–300 nm emulsion</td>
<td>Licensed in Russia</td>
<td></td>
</tr>
<tr>
<td>Oxygenet</td>
<td>PFC</td>
<td>&lt;200 nm emulsion</td>
<td>Phase III recruiting</td>
<td>Red cell use reduced</td>
</tr>
<tr>
<td>Oxyceyte</td>
<td>PFC</td>
<td>100–300 nm emulsion</td>
<td>Entering phase II in brain trauma</td>
<td>NA</td>
</tr>
<tr>
<td>Hemopure (HBOC 201)</td>
<td>Bovine haemoglobin</td>
<td>Glutaraldehyde polymer (250 kDa)</td>
<td>Licensed in South Africa; FDA on hold phase III</td>
<td>Hypertension, stroke, MI, heart failure, hypoxaemia</td>
</tr>
<tr>
<td>OxyVita</td>
<td>Bovine haemoglobin</td>
<td>‘Zero-linked’ haemoglobin</td>
<td>No clinical trial (yet)</td>
<td>NA</td>
</tr>
<tr>
<td>Hemassist</td>
<td>Human haemoglobin</td>
<td>Diaspirin cross-linked tetramer</td>
<td>Reduced RBC use</td>
<td>Increased mortality</td>
</tr>
<tr>
<td>PolyHeme</td>
<td>Human haemoglobin</td>
<td>Glutaraldehyde polymer (150 kDa)</td>
<td>‘In-ambulance’ trauma</td>
<td>Increased blood pressure</td>
</tr>
<tr>
<td>Hemolink</td>
<td>Human haemoglobin</td>
<td>120–180 kDa raffinose polymer</td>
<td>Discontinued</td>
<td>MI</td>
</tr>
<tr>
<td>Hemospans</td>
<td>Human haemoglobin</td>
<td>95 kDa PEG</td>
<td>Phase III recruiting</td>
<td>Mild elevation hepatic enzymes</td>
</tr>
<tr>
<td>Recombinant</td>
<td>Recombinant haemoglobin</td>
<td>64 and 320 kDa (with PEG)</td>
<td>Discontinued</td>
<td>Febrile reactions and hypertension</td>
</tr>
</tbody>
</table>

NA, not applicable; MI, myocardial infarction; PEG, polyethylene glycol.
Caveat: Lack of General Acceptance of Oxygen Therapeutics – Risk concerns

Fig. 3 Acceptance of different products by UK and Dutch general public and blood donors.

Fig. 4 Perceived risk for different products by blood donors and the general public.

Acceptability of blood and blood substitutes

- E. Ferguson¹, C. Prowse³, E. Townsend¹, A. Spence¹, J. A. van Hilten³ & K. Lowe⁶

From the ¹Risk Analysis Social Processes and Health (RASPH) Group, School of Psychology, University of Nottingham, Nottingham, UK; ²Scottish National Blood Transfusion Service, Edinburgh, UK; ³Sanquin Blood Supply, Corporate Staff, c/o Department of Research and Education, Plesmanlaan 1, Leiden, The Netherlands, and ⁴School of Biology, University of Nottingham, Nottingham, UK.

2008 Journal of Internal Medicine 263; 244–255
Informed Consent or Informed Choice?

- “Consent” implies that there is no choice or option.
  - Merriam-Webster’s on-line dictionary definition: to give assent or approval: **agree <consent to being tested>**

- “Choice” conveys the possibility of several options, one of which will be selected.
  - Merriam-Webster’s on-line dictionary definition: to select freely and after consideration
Informed **Choice**: Two options

1. **Agree or accept; to consent**
   - Commonly understood

2. **Decline or refuse**
   - *Decline = to reject politely or courteously*
     - Consider “declining a dinner invitation”
   - *Refuse = emphasizes firmness, at times rudeness*
     - Consider “refusing to obey an order”

*Howarth G. Changes in policy of refusal of blood by Jehovah’s Witnesses. BMJ 2001;322:1123-4*
Informed “Consent” is a *Process with Documentation*

- **Communicative process between physician and patient**
  - A full and frank discussion
  - A *process*, not a static document or piece of paper

- **Documentation**
  - Misplaced reliance upon institutional forms
  - Flawed and incomplete or inaccurate information
  - Does not address necessary elements of informed consent
  - Confusing language and endless lists
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common vascular</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>NG intubation</td>
<td>0%</td>
<td>100%</td>
</tr>
<tr>
<td>Foley Cath</td>
<td>20%</td>
<td>80%</td>
</tr>
<tr>
<td>Blood transfusion</td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td>Endoscopy</td>
<td>80%</td>
<td>20%</td>
</tr>
<tr>
<td>Centeses</td>
<td>30%</td>
<td>70%</td>
</tr>
</tbody>
</table>

Surgeon’s Responses:
Responsibility for informed consent for transfusion during surgery

How NOT to Obtain Transfusion Consent

FILE IN PATIENT’S MEDICAL RECORD

INFORMED CONSENT FOR SURGERY/INVASIVE PROCEDURES AND/OR INFUSION OF BLOOD OR BLOOD COMPONENTS

Discussion took place with: ________________________________

On: ___________ Date ___________ Time ____________________

On: ___________ Date ___________ Time ____________________

Patient or Representative’s Name:

Mentally

Awake & Alert Yes  Sedated No  Compromised No

Procedure(s) Proposed: 1. Radical Retropubic Prostatectomy (RRP)

2. Bilateral Pelvic Lymph Node Dissection (BPLND)

Physician: ________________________________ Attending Physician: ________________________________ MD

With the above named individual(s), I discussed the major:

1) Indications for the procedure(s): Adenocarcinoma of the Prostate (Prostate Cancer)

Clinical Stage: _______ Serum PSA: _____ ng/mL Nuclear Bone Scan: Negative

The patient’s “History & Physical” laboratory/pathology findings, and all relevant information were reviewed by the urology team and discussed at the GU Pathology clinical conference prior to recommending treatment.

2) Benefits of the procedure(s): 1. To surgically remove your prostate gland and the adjacent related structures (spermatic vessels and ejaculatory ducts). 2. To surgically remove the lymph glands on each side in your pelvis where the cancer may spread.

The benefits in doing these procedures are to potentially cure you from your prostate cancer and to obtain tissue specimens for pathological staging (for prognosis and possible future treatment).

3) Risks included death, cardiac arrest, brain damage, disfiguring scar, paraplegia or quadriplegia, paralysis or partial paralysis, loss of or loss of function of any limb or organ, severe loss of blood, allergic reaction and infection.

Other risks: bleeding, blood transfusion infection, abscess, lymphocele (lymph fluid collection), thrombosis (clots) in limbs or lungs, anesthesia risks, impotence (no erection of the penis and no sexual intercourse), inability to ejaculate (no semen), infertility, urinary incontinence (no urine control), rectal injury, recto-urethral fistula (abnormal connection between rectum and urinary tract), need for colostomy bag (stool bag), urethral and bladder neck injury and strictures (scars), urinary obstruction (blockage), need for further surgical procedures and other treatment, cancer persistence, recurrence or worsening, inability to complete the procedure, UNSATISFACTORY RESULTS AND DEATH.

4) Alternatives: External Radiation Therapy, Brachytherapy (radiation seeds in prostate), Hormone therapy (Elimination of your male hormone ‘Testosterone’), Watchful Waiting (Observation), Others.

5) Prognosis if procedure is rejected: _____ Good _____ Fair _____ Poor  XX Unknown because: It depends on the final pathology stage and the biological behavior of your prostate cancer in the future.

6) Is the use of blood or blood components expected for this procedure?  Yes  XX  No ___

If the use of blood or blood components becomes necessary, do you consent to the use of these products?

To be initiated by the Patient:  Yes _________  No _________

Patient Identification

This form replaces VA-SC-522

OP 4703112 (508) 10-95  MRC# 95-005

Consent is good for 30 days

Fig. 1. Example of standardized consent form for radical RP shows 1 page of 2-page document. Form underwent further revisions and refinements, including increasing font size from 10 to 11 points.
## Jehovah’s Witnesses Preferences

<table>
<thead>
<tr>
<th>Not acceptable</th>
<th>Acceptable</th>
<th>“Matters of Conscience”</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood, including autologous</td>
<td>Crystalloids</td>
<td>Albumin</td>
</tr>
<tr>
<td>Red cells</td>
<td>Synthetic colloids, including dextrans, Hetastarch, gelatins (Haemaccel, Gelofusine)</td>
<td>Immunoglobulin</td>
</tr>
<tr>
<td>Platelets</td>
<td>Recombinant products such as G-CSF, Epo, coagulation factors</td>
<td>Vaccines</td>
</tr>
<tr>
<td>White cells</td>
<td></td>
<td>Haemodilution</td>
</tr>
<tr>
<td>Plasma (FFP)</td>
<td></td>
<td>Coagulation factors (non-recombinant)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intraoperative cell salvage</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Organ transplantation</td>
</tr>
</tbody>
</table>
**TABLE 1. Points to remember when caring for patients who refuse transfusion**

- Keep in mind that blood is not always needed.
- Remember that transfusion carries risks as well as benefits.
- Seek to understand the patient and develop good rapport.
- Access available resources.
- Limit blood draws and consider alternatives to blood products.
- Explore the treatment possibilities and decide together on a course of action.
- Ensure confidentiality.
- Document carefully.
- Make contingency plans in advance.
Consenting to blood: what do patients remember?

T. Chan,*† K. Eckert,* P. Venesoen,* K. Leslie*†† and I. Chin-Yee*†††* London Health Sciences Centre, †University of Western Ontario, and ‡Canadian Blood Services, London, Ontario, Canada

Transfusion Medicine, 2005, 15, 461–466

Fig. 1. Respondents’ perception of feeling better informed and more comfortable with their decision to accept blood on the basis of responses to the survey question ‘Did you receive the pamphlet entitled You may need a blood transfusion?’.
Consenting to blood: what do patients remember?

T. Chan,*‡ K. Eckert,* P. Venesoem,* K. Leslie*† and I. Chin-Yee*†‡ • London Health Sciences Centre,
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Transfusion Medicine, 2005, 15, 461–466
### TABLE 1. LAC + USC Healthcare Network Non-OR blood transfusion process assessment tool

<table>
<thead>
<tr>
<th>Blood transfusion process</th>
<th>Not compliant</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Informed consent</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. If elective transfusion, was consent to nonsurgical blood transfusion signed?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. If elective transfusion, did the patient receive Paul Gann Blood Safety Act brochure?</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Physician order</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. A written physician order exists.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. The doctor's order includes blood product name, number of units, and administration rate.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood product request (Call Card)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. Blood Call Card shows patient's name and identification number, blood product ordered, and two signatures verifying the information.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Patient preparation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. Patient was premedicated if ordered by doctor.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. Vital signs were checked within 30 min before transfusion.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood product issuance</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. Patient name and identification number on call card and Blood Product Record form match.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>9. The correct blood product was issued.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pretransfusion identification checks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10. The patient was wearing an ID band at the start of transfusion.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11. Patient ID was checked at the bedside by matching the patient's statement of his/her own name with the information on ID band.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Patient name and identification number on Blood Product Record form and ID band match.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>13. Patient name and identification number on unit label and ID band match.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14. Unit numbers, blood types, etc., on the unit label match the same items on the Blood Product Record form.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>15. Items 10-14 were checked at the bedside by two licensed personnel (RN, LVN, MD).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>16. Two licensed personnel (in Item #15) signed the Blood Product Record form.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Blood administering</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>17. Vital signs were checked within 15 min after start or after 50 cc transfused.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18. Lactated Ringer's solution, 5 percent dextrose, or hypotonic sodium chloride are not added to blood or simultaneously administered via the same IV line.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>19. Blood product was transfused at ordered rate.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Posttransfusion checks</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20. Vital signs were checked after completion of infusion.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>21. All areas were filled out on Blood Product Record form.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**A comprehensive assessment program to improve blood-administering practices using the FOCUS–PDCA model**

Sunita Saxena, Lois Ramer, and Ira A. Shulman

**TRANSFUSION 2004;44:1350-1356.**
A comprehensive assessment program to improve blood-administering practices using the FOCUS–PDCA model

Sunita Saxena, Lois Bamer, and Ira A. Shulman

TRANSFUSION 2004;44:1350-1356.
A comprehensive assessment program to improve blood-administering practices using the FOCUS–PDCA model

Sunjita Saxena, Lois Ranier, and Ira A. Shulman

TRANSFUSION 2004;44:1350-1356.
INFORMED CHOICE: Transfusion or No Transfusion?

- IF NO EMERGENCY:
  - Patient needs to know as much as possible about the medical reason for the proposed transfusion; the risks, benefits, and alternatives of blood and of alternatives
  - Patient should make a choice (uncoerced)
  - Documentation is expected

- Patients have the right to refuse transfusion