ETHICS in Transfusion Medicine

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In medical practice, some questions are much easier to answer than others. **Consensus** on the right way to act in the situation helps us, answering some of the questions. **Absence of consensus** or a situation where all alternatives have drawbacks leads to dilemma.
What ethics is and how it helps?

- **Medical ethics** is a system of moral principles that apply values and judgments to the practice of medicine.

- Encompassing - practical application in clinical settings & work.
Ethical judgments & Principles

Ethical judgments involve a dual test:

- “Are the means acceptable?”
- AND
- “Are the ends worthwhile?”

Diagram:

- ETHICS
- Morals
- The Law
- Fairness
- Values
- Equality
Fundamental principles

1. **Autonomy** also called *principle of human dignity*.
   i. Not to interfere with decisions of competent adults.
   ii. Duty to empower others for whom we’re responsible.

2. **Beneficence**: obligation to bring about good in all our actions.

3. **Non-maleficence**: obligation not to harm others.

4. **Justice**: obligation to provide others with whatever they are owed or deserve.
Overlapping Ethical and Legal issues.

- Many ethical issues can be questioned in a legal trial.
- Without spelt out regulations, ethical issues can become basis for decision making in a legal judgment.
Application of these principles in situations may be problematic, because physicians, patients or their family members may disagree about The right way to act in a situation !!!
Need for ethics in Transfusion Medicine..?

- Transfusion Medicine involves a number of ethical issues because blood comes from human beings and is a precious resource with a limited shelf life.

- Moral responsibility towards both donors and patients.
Ethical Issues in Transfusion Medicine

1. Blood donation
2. Laboratory practices
3. Blood transfusion in Patients
4. Research ethics
Code of ethics in Transfusion Medicine

- **1980**: International Society of Blood Transfusion endorsed its first formal code of ethics.
- **2000**: Revised code of ethics for donation and transfusion
Code of ethics in Transfusion Medicine

1. Blood donation (for any specific component including hematopoietic tissues)

   • Voluntary and non-remunerated, no coercion.
   • Replacement Donor
   • Autologous Donor
   • Apheresis Donor
2. Informed consent

• Donation
• Use of blood by the transfusion service.
• Testing of samples
• Notification for TTI results
3. Blood donor safety:
   - Risks associated with the procedure, protection of donor's safety.
   - Procedures relating to the administration of any substance to a donor (apheresis).

4. Anonymity:
   - Anonymity between donor & recipient (except in special situations)
   - Confidentiality of donor information
5. **Pre-donation Donor Counseling:** to make donor understand his/her ethical responsibility towards the recipient and himself/herself.

**A. Counsellor interviewing/examining**

- One-to-one counselling to maintain **Privacy** of the donor.
- Interview language: understandable
- Polite and empathetic.
B. The donor should understand

- Safety of the donated blood.
- Risks of donating infected blood.
- Other health hazard if he/she is suffering from any disease or is taking medication.
- Consent form has to be duly signed.
6. **Blood Donation Criteria**

- Based on regularly revised medical selection criteria
- No discrimination of any kind.
- Donor selection and deferral should be based on scientific backgrounds.
Donor Deferral: Good Intentions with Unwanted Adverse Effects

- Feelings of Rejection.
- Confrontation with “Old” Diseases.
- Confrontation with Unrealized Risks.
- Feelings of Discrimination.
- Confrontation with (Unexpected) Information.

7. **Blood collection**

- Under responsibility of a qualified, registered medical practitioner.

- Donation & haemapheresis to comply with defined & accepted standards

- Donor should know the amount of blood that is withdrawn.
7. Blood collection

- Skilled phlebotomy (single painless prick).
- Monitoring for adverse events during donation.
- 10-15 minutes rest after donation.
POST DONATION

- Refreshments.
- Post donation instructions.
- Appropriate steps & contact no.
- Written feedback from the donor.
POST DONATION

- Escorting the donors.
- Sending off the donor with a sense of gratitude.
- Attempt to retain the donor as regular repeat voluntary donor and apheresis donor.
WE ARE THERE FOR YOU!

24/7

Contact Us:
- Phone
- Email
- WhatsApp
8. **Blood Bank Motive:** Profit motive should not be the basis for establishment & running of BTS.

9. **Access to Blood:** Blood is a public resource and access should not be restricted.

10. **Blood Components:** patients should receive only those particular components that are clinically appropriate & afford optimal safety.
11. **Harm**
   - Donors and recipients should be informed if they have been harmed.

12. **Patients Consent**
   - Risks and benefits of blood transfusion and/or alternative therapies.
   - Patient’s right to accept or refuse.
   - If unable to give consent, basis for transfusion must be in his/her best interests.
13. **Transfusion therapy**
   - Under responsibility of RMP.
   - Genuine clinical need should be the basis for transfusion

14. **Wastage**: Wastage should be avoided in order to safeguard the interests of all potential recipients & donor.

15. **Prescription of Blood**: No financial incentive to prescribe blood transfusion
Controversies: Code of ethics

Certain issues with long drawn controversy, from different perspectives and have been discussed in the following review article

Some reflections on the Code of Ethics of the International Society of Blood Transfusion

Albert Farrugia¹, Corrado Del Bò²

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Blood Transfusion 2015; 13: 551-8
Ethical issues related to Transfusion Laboratory
Ethical issues related to Transfusion Laboratory

1. Collection of sufficient information
   - Legitimate purpose.
   - To enable correct performance of the test and result interpretation.
   - Safety of the staff and other.

2. Blood samples
   - Appropriateness for the type of the sample.
Ethical issues related to the Transfusion Laboratory

3. Performance of the tests

- Carried out as per the SOPs, determined by professional organizations or regulatory bodies.
- Standard quality reagent.
- Proficient staff.
- Without delay.
Ethical issues related to the Transfusion Laboratory

4. Reporting of the results
   - Accurate
   - Procedure detailing
   - Timely manner

5. Storage and retention of records.

6. Access to medical records.

Very Important for RTI & Medico-Legal cases
Some commonly encountered practical issues
Notification of reactive donors

- Consent for notification prior to donation.
- How to inform, in appropriate and timely manner.
- Content of notification.
- Retesting and confirmation of the screening results required or not.
- High risk group donors / test seekers.
Issues during counseling following notification

- Screening test results.
- Confirmatory testing.
- Referral to appropriate specialty.
- Managing the distressed/anxious donor.
- Information to the spouse?
Voluntary Donation Camp

• Avoid overcrowding at camp site.
• Escort facility for donors.
• Signature of donor in questionnaire cum consent form.
• Privacy of donors while screening and post donation counseling as well.
• Basic amenities for donors viz. the drinking water, the toilet.
• Never hand-over blood bags to the donor
Blood Donation - Camp

For camp organisers

✓ Not to put undue pressure for donating blood.
✓ Not to pressurize medical personnel for bleeding the donor.
✓ Avoiding sudden rush for donation.
✓ Gifts should not be used to attract donors.
Ethical issues surrounding Autologous & Directed donation

Generally deemed to be safe but are they really safe..?

- **Autologous donation:**
  - Presence of underlying bacterial infection.
  - Patient's cardiovascular status.
  - Increased probability of over transfusion.
  - Increased chance of wastage.

- **Directed donation:** under peer pressure the donor may hide the presence of disease or risk behaviours.
Issues during Pre-transfusion testing

- Switch over of groups.
- Prioritizing.
- Age of blood component issued.
- Methods of testing/ time during urgency.
- Replacement.

Policies and processes or procedures should exist for optimum utilization of the resource, avoiding wastage.
Bed side transfusion practices

- When is transfusion indicated? Not indicated?
- When can other modalities be used?
- When can a patient decline transfusion?
- Can a physician refuse to treat the patient if he/she declines the transfusion?
Ethics in transfusion to the patient

**Clinical Appropriateness**

- Clinical indications based on an evaluation of the benefit and prevention of harm to the life and health of the patient deriving from the use of blood and blood components
- Can be expressed as the “proportionality” of care
Ethical Challenge: To transfuse or not?

- Physicians who order transfusions are required to
  - Be knowledgeable about the indications for transfusion of components
  - Inform patients about the risks, benefits and alternatives to transfusion and let the patient decide
  - Know the alternatives and be prepared to act on the patient's choice
Ethical Challenge: To transfuse or not?

- When “should” transfusions be given?
- Indications for **transfusion/no transfusion** are changing
  - Role of consensus guidelines
  - Published studies
- **A multi-disciplinary, patient-centered approach to minimizing transfusions**
  - Transfuse blood only when necessary
  - Minimize blood use
Ethical Challenge: What to tell the patient?

- Informed Consent: an emblematic expression of the relationship between the person providing health care and the person receiving this care
Ethical Challenge: What to tell the patient?

The patient should know

- The reason for any transfusion
- The risks, benefits and any alternatives to being transfused
- Also the risks and benefits of the alternatives
- The patient should ask questions and receive adequate answers to them
- The patient should choose to accept/reject the transfusion
Ethics and Apheresis (Therapeutic)

Apheresis seems as an innocuous process, but its apparent simplicity is misleading.

**Ethical concerns**

1. Consent
2. Risk assessment
   - Autologous
   - Allogeneic donors
3. Conflict of interest
   - Donors are often coerced.
   - Donor is a child or may be incompetent.
4. Procedure: **blood bank vs. ward**
Research ethics basics

- Research involving humans is **privilege, not a right!!!**
- Those who conduct research involving humans must meet norms for ethical research.
- The onus is on those who conduct, house or sponsor research to show these norms are met.
My friends, as a result of our experimentation, we have just lost a dear and valued colleague...

On the other hand, we have just gained a publication.
Three central questions

1. Does the research meet relevant scholarly/scientific standards?
   • Bad science is bad ethics
   • Is the science honestly done and accurately reported?

2. Will the likely net benefits of the research outweigh overall harms?

3. Does the research respect the rights of the research subject:
   • Protection from undue harm
   • Informed consent?
Norms for clinical research

1. Socially valuable research
2. Scientifically sound research
3. Fair subject selection
4. Favourable risk-benefit ratio
5. Independent review by an REB
6. Informed consent
7. Respect for actual and potential research subjects in the conduct of research

Emmanuel et al. JAMA 2000
The Role of Decision Analysis in Transfusion Medicine

- Decision analysis employs a variety of mathematical modelling methods to predict the outcomes of alternative approaches to a problem.

- Parallels that of other healthcare fields.

- But the implications of its outcomes are somewhat different because of the peculiarities of the current situation of transfusion medicine.
Take home message

A doctor being in the position of trust & power has a duty to act in the patient’s interest.

Treat all people equally, fairly, and impartially.

we must not forget

“Our specialty is very visible to the lay public and highly subject to regulatory, public opinion and legal constraints”
THERE IS NO RIGHT WAY TO DO A WRONG THING.

THANK YOU