MEDICO-LEGAL & ETHICAL ISSUES IN BLOOD TRANSFUSION SERVICES

The quality of blood safety in a country is determined by several factors main being acceptance of a civic, medical & ethical code, to guide actions around safe blood. The whole gamut of ordering, distribution, handling & administration of blood as well as the response to transfusion is covered in the moral & ethical code—the rights & responsibilities. Why are we so concerned about the ethical & ML aspects of BTS? Basically because it involves human endeavour— it is a question of saving human lives—taking advantage of the vulnerability of the person & his dire need at a moment when he is low.

We talk of ethics because it involves public. It is a voluntary act, it affects the life of an individual unknown—hence the general public & can have tremendous repercussions. No money is involved hence no rights to demand service.

The importance attached to ethical rules and the ease with which they may be converted into legislation varies with the legal system existing in the country. It is necessary to enact effective legislation to take action, to protect and promote health, of donors and recipients.

WHY IS LEGISLATION REQUIRED?
It is needed to protect both donors & recipients from nefarious practices. In several countries stringent rules are set for donors giving false history. In our country no such rules are in force. We depend on donor’s integrity to give proper history.

HISTORY
It was the initiative of NGOs in the country that compelled the Government to take Blood Transfusion Services seriously & issue legislative guidelines for setting up of blood banks. There were serious deficiencies & shortcomings in collections, storage & supply of blood & of course the scourge of HIV.

Common Cause an NGO in Delhi run by Mr. H.D. Shourie, after looking at the sorry state of affairs of BTS in the country, filed a PIL under article 32 of the constitution & appealed to the apex court to make the Government answerable & responsible towards this very vital area of medical services. It directed the Government to come up with a comprehensive plan to fortify blood transfusion services in India. Spell out its blood policy: (all India reporter - legal journal)

Ms. A.F. Ferguson were entrusted the job to study the BB system in the country, recommend policy, & prepare a scheme for modernization.

The judgment dated January 4, 1996 issued 18 directions, reported as AIR 1996 SC 929. The most crucial of these was to close down all commercial blood banks by January 1998 As per the directions, a National Blood Transfusion Council was to be set up with similar State Blood Transfusion Councils, in each state & union territories, which, would monitor & assist the working of all the blood banks in the country.

In April 1999 part XII-B was amended to schedule F of the Drugs and Cosmetic Act –1945 for functioning & operations of Blood bank & preparation of components and setting up of HRD as part of the plan.

With the fear of HIV coming into the BTS, NACO also issued comprehensive guidelines— which was a very welcome step.

Now as we all know, all blood centres are under the baton of the approving & licensing authorities and what Blood Transfusion Service is today is far away from what it was 20 years ago, a part of Pathology department set up in a remote corner.

The report came out with startling revelations.

Of 1018 BB, at that time, in the country, 203 were commercial, rest, government, private & NGOs. 19.5 lakhs units were collected, of which, 4.7 or 30% were from commercial Blood Banks, collecting blood from professional donors. No health checkup was done, blood trade flourished with beggars, rickshaw pullers selling blood 5-6 times a month. Testing & training of personnel lagging. Storage facilities abysmal, unhygienic environment. Government needs to spell out the health policy vis a vis blood transfusion.

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NATIONAL BLOOD POLICY -MISSION STATEMENT- OBJECTIVES OF THE POLICY

1. Govt. commitment to provide safe & adequate blood & Blood components
2. Make available adequate resources to develop BTS
3. Make available latest technology to BTS
4. Launch awareness programs for IEC for donor’s recruitment & retention
5. Encourage appropriate use of blood.
6. To strengthen manpower/ HRD
7. To encourage R & D in BTS
8. Take adequate regulatory & legislative steps to monitor/ evaluate BTS & eliminate profiteering in Blood Banks.

There are two main partners in safe blood transfusion: the donor, the recipient & between them the product, blood & facilitator i.e. the medical personnel & health system. All have rights & responsibilities assigned to them—medical, civic, ethical & moral rules & principles. We shall take them one by one.

- Donor Rights & Obligations
- Recipient-Rights & Obligations
- Authority-Rights & Obligations

FIRST THE UNIVERSAL RIGHTS:

- Confidentiality: not to disclose data on health & private life
- Medical secrecy: not to disclose data on personal life got through questionnaire.
- Non-discrimination: equitable treatment: race, caste sex, religions etc.
- Honest & clear information: accurate info on medical act & consequences.
- Free Informed consent: full consent to undergo the medical act & consequences.
- Human Dignity: moral & physical respect for patient/donor.

Nowhere is there any mention of the rights /responsibilities of the donor or recipient or Health care worker as to legal compensation or penal provisions. Individual has the right to access his report but is not required to be forced to receive the info—only if he opts to know the results.

SUPREME COURT RULING

The Question of doctor being prohibited from disclosing a blood donor’s HIV status, violates the right of privacy of the donor, arose in supreme court in 1996.

A doctor donated blood for a patient & was found to be HIV positive. He was to marry but marriage came off when hospital disclosed that he was positive for HIV. He sought remedy from National consumer disputes redressal commission under Consumer Protection act 1996. It dismissed the petition for interim relief & asked to seek remedy in civil court. Matter went to supreme court for appeal for violation of his right to privacy & said that the hospital must pay damages. He sought compensation for breach of duty to maintain confidentiality & consequential discrimination, loss in earnings & social ostracism.

The Supreme Court ruled, after much deliberation, that no breach of privacy had occurred especially, when rights of a third party were involved. It also said that under sections 269 & 270 of IPC any negligent act or malignant act, likely to spread infection, dangerous to life was a criminal offence. But in this case no infringement of the suspended right to marry had occurred & cannot be compensated by damages. There are always exceptions to these rights when larger public interest is involved. The fiancée in this case was saved in time from being infected.

Thus, such cases can be termed as exceptions to the general rules of confidentiality when the information is disclosed in court, under the orders of the presiding judge. The disclosures are in the best interests, in limited circumstances, in which public interest is involved. Thus, the right to confidentiality was not enforceable under these circumstances. In several cases the apex court has ruled that the right to privacy is not to be taken as an absolute right. It can be weighed with reference to the effects on other members of society or society in general. Even the Hippocratic oath is a code of professional conduct & code of ethics. It is not enforceable in court of law as it has no statutory force.

Soon, NGOs in AIDS field, filed a writ petition in Apex court challenging decision on grounds that no opportunity was given to bodies representing AIDS/HIV + infected persons. The court treated as application for clarification of their earlier judgment & nullified the conclusions of the earlier judgment. The vital issues about blood donors infected with HIV their legal rights & duties to themselves & others still remain to be settled.

PRE & POST DONATION COUNSELING

It is the right of the donor to be made aware of his infective status Thus post donation counseling is important for him to find remedy to his illness, either by referring to the concerned medical specialist or in case of HIV to the VCTCs set up by NACO. The BB has to guide them by providing Pre & post donation counseling in order:

- To benefit from prophylactic or therapeutic interventions
- To modify behaviour
- To limit the spread to 3rd party

DONOR’S RESPONSIBILITY

- Give blood without remuneration—refuse if financial reward given
- Honesty in giving personal information. Need to understand HIV infection and possibility of TTI transmission. He should understand seriousness of endangering blood supply
- Use only licensed blood centers for donating blood—official circuits

ISSUES RELATED TO DONOR ORGANIZERS— AWARENESS.

Donor organizers form the backbone of the Donation/Transfusion program in the country. Without their social commitment it would not be possible for most blood centers to be adequate with stocks as required However, sometimes they compromise on the documentation & medical history of the donor via a vis records of collection. This leads to maybe higher number of units collected at the cost of safety. Some of them feel that meticulous screening is meddlesome & unnecessary. They need to be educated on these aspects of donor/patient safety

Continued
II. RECIPIENTS’ RIGHTS

Blood is a public resource & to receive units of blood when needed is basic right of the recipient/public.

1. He/She must have unrestricted access to this vital fluid, in a professional environment.
2. He/She has the right to receive safe blood collected, stored supplied as per prescribed safety standards, & to receive blood a transfusion, if indicated by the treating physician.
3. He/She has the right to receive blood irrespective of caste, creed, nationality, socio-economic status & religion.
4. He/She must also be given option for alternatives such as components, pharmacological alternatives, autologous transfusion.

RECIPIENTS’ OBLIGATION

The recipient of Blood Transfusion must give correct information regarding his health before and after transfusion to the treating doctor. He must always use official circuits of Public health system for his blood/component requirements.

III. Responsibility of Blood Transfusion Centres /Authorities

The Blood providers which includes the hospitals & healthcare services also have responsibilities towards safe & beneficial transfusions of blood & components.

• Important being, erroneous notification of result leading to mental anguish & unnecessary litigation
• Proper documentation of compliance of procedure is important for blood bank’s defense in case of litigation.
• Insurance cover – compensation is restricted if donor suffers from any harm or loss.

LIABILITY OF BLOOD CENTRES

It is the responsibility of blood center, that it is legally liable for failing to make proper use of resources available, overlooking safety, efficiency and quality of blood through negligence. It also has Responsibility towards staff to provide safety by making available materials for universal precautions.

It is the Responsibility of the medical officer in charge of the Blood Centre, for blood donation, safety of donor, & recipient’s safety by complying with all criteria covered by legislation/guidelines. He must ensure correct transfusion practices as prescribed & institute measures for error prevention. He/she has to oversee that the equipment used is validated, reagents are of specific quality & techniques as per SOPs. Quality control of components prepared are essential to a safe transfusion & need to be maintained, waste disposal is as per rules, responsibility & Bio safety procedures towards staff are also his lookout. Good Quality systems are implemented to prevent errors & risk management.

IV. RESPONSIBILITY OF HEALTH AUTHORITIES

The health authorities, have the eventual responsibility to see that the BTS is run all over as per prescribed guidelines. This includes general awareness regarding safe blood/VNRBD(Voluntary non-remunerated blood donation) to eliminate commercialization and resist/protest against other ethical misconduct.

V. LEGISLATION GOVERNING BTS

Blood is considered as a manufactured product hence it comes under the provisions of the licensing authorities. Provision of required infrastructure including HR, Storage conditions/cold chain, management, quarantine storage and mandatory testing procedures are governed by the regulatory authorities.

VI. LEGAL REMEDIES

1. Civil remedy: Is provided for negligence, breach of duty, care/results in injury. Donor/patient can file suit for damages. The hospital authorities are also liable for the negligence of their employees.
2. Remedy under the consumer protection act 1986 for deficiency of service.
3. Criminal remedy: Under section 269-270 IPC Whoever negligently does any act which is likely to spread infection of disease dangerous to life, can be punished imprisonment 6 months/fine or both.
4. Malignant Act: Willful spread of infection, dangerous to life eg marriage to infected person, he/she is liable to 2 years imprisonment/fine or both.

ISBT Ethical code for Blood Donation-Transfusion covers all aspects of blood transfusion services

• Gen Assembly, ISBT July 12, 2000 stipulated the code for Transfusion Services
• Blood Donation totally voluntary & non-remunerated-
• No pressure on donor
• Patient informed of risk/benefit of blood transfusion--consent
• No profit motive to running a BTS
• Donor advised of risks of Bl donation
• Donor’s health & safety protected
• Anonymity between donor–recipient
• Donor informed of self-deferral risks
• Donor/recipient informed if harmed.
• Clinical need for transfusion assessed
• Wastage of scarce resource avoided.
• Blood public resource-unrestricted access.

HOWEVER IN OUR COUNTRY LAW IS SILENT ON:

1. Willful suppression of HIV status of an individual.
   Often blood is donated to find the donors HIV status. In Australia there are penal provisions for a donor willfully doing so.
   2. Punishment to professional donor.
      (Now legally prohibited)
   3. Whether to inform or not the donor, his HIV status.
   4. Is blood a purchasable commodity-hence MRP-yes or no?

The answer surely is No because it is never a saleable commodity. (Lately, processing charges for blood & blood components have been enforced)

5. No mention of penal provisions for aspects of Blood Transfusion Services

6. What happens to Health Care Worker during service if affected with TTIs.
   We the Blood Bankers need to find ways of getting round the system.
This year’s National Blood Donation Day was organized in a unique way by Terumo Penpol Pvt Ltd. ‘Save A Rupee, Spread A Smile’, KEBS and Vijaya Fans Association. Mr. Sabarinathan K S, MLA, who was the Chief Guest, gave an inspirational message to the crowd. Dr. C S B Nair, Consultant (R &D) of TPPL presided over the function. K S Sabarinath, Member of the Legislative Assembly, inaugurated the National Voluntary Blood Donation Day organised by Terumo Penpol at the Sreemoolam Club. In his address the young MLA said the message of blood donation should be promoted in rural and tribal areas as well. The blood donation was inaugurated by popular Radio Jockey Firoz by being the first to donate blood.

Sabarinath also spoke about non-communicable diseases and deficiency of Vitamin D in the current generation. He said with people spending more time indoors the general public’s health was getting affected. He also advised young girls to avoid becoming anemic.

Mr. K P Rajagopalan, General Secretary (KEBS) said about the shortage of blood and motivated the Students to donate blood.

K P Rajagopal, General Secretary, KEBS spoke about de-worming and the importance of blood donation. He urged the new generation to come forward for donating blood. Anand, a young member of the Vijay fan’s association who was present at the event told Yentha that he has been donating blood for the last three years. Nowadays he donates every 3 months.

PROMOTION THROUGH PRINT / ELECTRONIC MEDIA AND SOCIAL NETWORK

• Massive Promotion was done through the Print and Electronic media.

• Promotional Campaign was done through BIG FM Radio from 24th September – 1st October.

• Used e-mail and facebook for quick information update

• Yentha.com was the online Media Partner.

COMPETITIONS ORGANIZED TO PROMOTE VOLUNTARY BLOOD DONATION

• Slogan Competition for High School and Higher Secondary Students

• Quiz Contest for School Students

• Certificates and cash prize were distributed to the winners of Slogan competition and Quiz contest

BUDDY FOR LIFE CONTEST

• A buddy for life contest was also arranged for school students to promote voluntary blood donation. School Students were encouraged to recruit as many voluntary blood donors as possible in this contest. The school who has recruited the most donors from 15 July before October 1 was selected as the winner.

• Govt Higher Secondary School Anavoor emerged as the winner and the Buddy for life contest winner was honored

DISTRIBUTION OF IEC MATERIALS

VBD IEC materials in Malayalam were distributed to the General Public at Shopping Complexes, Railway Station and Bus Stand.

AWARENESS SESSION

• School Education Program -Awareness session at Schools -Distribution of IEC material to the students of 11th & 12th standards of Model School, John Cox Memorial Engineering College, Women’s College and University College

Continued
To celebrate National Blood Donation Day and to promote voluntary blood donation, TERUMO PENPOL IN HOUSE Band delivered a performance of music and dance to convey how giving blood can save lives, aiming to inspire more youngsters to donate their blood for love.

This event also forms the prelude to the next step in the movement, the collection of inspiring real life stories, titled “Ordinary People, Extraordinary Power”. We hope to influence more people to join in donating blood through stories about ordinary people donating blood to save others’ lives. From celebrities to any member of the public, whether donating blood or supporting others to donate blood, you can be a Little Red Hero! Everyone can save lives!

This message was reinforced at various colleges and public places through music and dance, executed by TPL Associates comprising of Shajudeen J S, V K Sreekumar, Arun Nath, Aneesh Babu and Children of Sreekumar, Shajudeen and Shahul Hameed in a show designed to deliver the idea that miracles can happen when the “power” of blood is injected into life.

Their aim is to encourage other young adults to donate their blood or their support to motivate others to donate blood. Many Students commented that they were touched and eager to join the program. Mixing entertainment and a relaxed atmosphere, the occasion brought together many Students from the city colleges involved in the program and also attracted wide attention, emboldening a new, younger generation to dedicate their love.

For many years we’ve been successfully calling for voluntary blood donations. We want to thank our celebrity friends, the regular donors of TPL, the volunteers and others who have worked so hard. Going forward, TERUMO PENPOL will redouble its efforts and, with the growing support and understanding in the community, we are confident more members of the public will join the volunteer’s database, to save more lives with their blood, donated for love!
Promotion of blood donation among CETians is considered as one of the major social services offered by NSS (National Service Scheme) CET Unit. Presently more than 1000 donations/year are held in various hospitals in Trivandrum city like RCC, Medical College Hospital, KIMS and SUT hospital. Now NSS CET has decided to precede one step forward in this area by formation of a blood cell. A center for 24 hr assistance for blood donation.

As College of Engineering Trivandrum is one institution where the student strength is more than 3000, it is the right place to implement such a blood cell. The blood cell CET is instituted as a center that will work 24 hours 365 days to provide maximum support for patients who are in search of blood donors. Public can contact the blood cell when they need blood donors and the blood cell will help them by finding blood donors from CET and public in a systematic manner using a database and a blood cell management software.

For the smooth function of the cell there will be a permanent phone number in the name of NSS programme officer, College of Engineering, Trivandrum. This number will be displayed in the major hospitals in Trivandrum. The 200 volunteers of NSS CET unit will take duty of blood cell in turn basis.

We hope blood cell can help patients in search of blood donors by arranging blood donors internally from CET if available, or from public by using online facility available for blood donation. More than this, it will act as a nodal point for promotion of blood donation in Trivandrum city.
Letters To The Editor

Great job as always
Dr. Nisha Nigil
Endocrinologist Hospital & Health Care Sudbury, Ontario, Canada

Thanks for sending latest (40th issue) Blood Line Journal. It is very useful journal for motivating a person for donating blood voluntarily. I suggest to incorporate some basic date of blood collection vis-a-vis blood groups of collected blood. I also request to publish an article on ‘BOMBAY GROUP’ & ‘GRAFT vs. HOST disease’ due to blood transfusion.

Sitansu Kumar Bahaduri, Nepal

I hope that the journal would be sent at my mail in future also.

Regards
Debabrata Ray, Secretary, Association of Voluntary Blood Donor organisations, West Bengal

Dear Ms. Baby,

Thank you for sending me the latest issue of Bloodline, which is also the 40th. Congratulations for your continued efforts in bringing out the journal regularly.

From this issue, I came to know of the interest people from various walks of life in Kerala show in donating blood. Thank you.

Kind regards
Dilip Varma, HR Consultant

This is all your hard work and efforts. Keep going!

Thanks
Deepa P, HR Manager, Technopark

Thanks for sending the journal madam. Always a great effort.

Regards
Anoop S K
QUEST Technologies

Student, State’s first unrelated bone marrow donor

Ajaykrishnan U., who donated bone marrow to a boy suffering from a blood disorder.

Twenty–year–old Ajaykrishnan U. has become the first person from the State and the third in the country to donate bone marrow to an unrelated person. He did this with the support of his family and over coming fears. "It was a shock initially to learn that my bone marrow was suited for the recipient," the final–year student of the College of Engineering, Thiruvananthapuram, told The Hindu. He and his friends learned about blood–stem donation during a college fest in March, 2015, while passing by a kiosk set up by HOPE (Hold on Pain Ends) team for DATRI Blood Stem Cell.

DATRI is a Donors’ Registry, a non–profit organisation founded in 2009, to help patients suffering from blood-related disorders. Realising that blood stem cell donation from an unrelated donor can save the life of patients suffering from blood cancer and other blood-related disorders, he registered as a donor. “It was to be some day in life, but never imagined that a call would come so soon,” he added.

“We were shocked and confused, but when we got to know about all procedures, my family and friends came out in support.” It was an informed decision and the procedure was safe and done by experts, he said. Ajaykrishnan was discharged from hospital on the third day and travelled back home from Chennai, where the procedure was done, on the fourth day. His father is an engineer and mother a housewife. His sister is an MBBS graduate. He donated blood–stem cells to a 12–year–old boy suffering from Aplastic Anaemia, a chronic blood disorder, said DATRI in a statement.

Two methods

According to DATRI, there are 1.60 lakh people registered as donors. There are two ways to donate blood stem cells. In peripheral blood stem cell (PBSC) donation, blood stem cells are collected from the circulating blood. This is a 4–5 hours outpatient procedure and similar to the more common platelet donation.

The second method is to donate bone marrow under general anaesthesia, where the marrow is drawn out from the hip bone in a 1–2 hours procedure. Ajaykrishnan went through this procedure.

There are certain non–malignant blood disorders that respond well to bone marrow stem cells compared to the peripheral blood stem cells. For more information on blood stem donation, log on to www.datri.org

ALBERTIAN INSTITUTE OF SCIENCE AND TECHNOLOGY, KALAMASSERY AND ROTARY CLUB OF COCHIN QUEEN CITY CONDUCTED BLOOD DONATION CAMP

NSS Technical cell AISAT and Rotary Club of Cochin Queen City in association with IMA Ernakulam Conducted a Blood Donation Camp on 10th September in AISAT Campus. The event was attended by a social cause was blessed by the presence of Rev.Dr.Clement Valluvassery, Manager AISAT, Rev.Fr. Alex Kurishuparambil, Associate Manager, AISAT and Rev.Fr.John Christopher, Assistant Manager, AISAT. Prof. Dr.K.E. George,Principal, AISAT welcomed the gathering. The Chief guest for the camp was Mr. Jijo Palathinkal, President of Rotary Cub member.

Prior to the camp, students and staff members were apprised of the benefits related to blood donation by the Volunteers of NSS Technical cell which serves the society in a variety of forms. More than 50 units of blood were collected through the camp.

The Camp started at 9.00 a.m. and went up to 1.30 p.m. in the afternoon. NSS Technical programme office Mr.Majo Davis supervised the entire camp. The team of doctors thanked principal and teachers for their co-operation.

This is an initiative by the AISAT community as a part of giving back to the society.
When unknown blood donors became one’s savior...

"Tobacco chewing is injurious to health & causes cancer"– a tagline we come across multiple times in our day to day life but ignore in the end. Same was the case with 29 years old Mr. Jaypalsingh Dhirubhai Darbar. He was admitted to Shubham Hospital and got operated for CA tongue and radical neck dissection.

Radical neck dissection is an operation used to remove cancerous tissues in the head and neck. Cancers of the head and neck (sometimes inaccurately called throat cancer) often spread to nearby tissues and into the lymph nodes. Removing these structures is one way of controlling the cancer. Out of the 600 hundred lymph nodes present in the body around 200 are in the neck. The purpose of Radical Neck dissection is to remove lymph nodes and other structures in the head and neck that are likely or proven to be malignant.

HOW PRATHAMA DONORS SAVED A LIFE:

“Jaypal’s case was an unusual case. He was operated for CA tongue and radical neck dissection but suffered from acute renal shutdown after the surgery. There was a drop in platelet count and haemoglobin level. We suspected that the patient is going into septicemia and DIC. The patient was unable to open the mouth so intubation became difficult. As a result, an emergency tracheotomy was done,” said Dr.Bhavin Mehta (Nephrologist), Jaypal’s treating doctor. He runs Shubham Hospital in Naranpura and is giving services to Siddvinayak Hospital at Maninagar.

Jaypal’s situation was critical and he had platelet count of 11,000 only. Low platelet count resulted in bleeding from tracheotomy site which gave rise to requirement of blood transfusion. “Immediately, we required blood components for Jaypal, as there was bleeding from tracheotomy site and his platelet count was very low. At that time we could only think of Prathama for quality blood products and we got desired blood components quickly,” said Dr.Bhavin. Adding to this Dr.Bhavin said that blood components acts like a magic in such cases. Jaypal’s hemoglobin level and platelet count raised subsequently and that too without any transfusion reaction which is very common when a large volume of blood was transfused. It was only because of the careful testing and cross matching of blood in Prathama using state of the art machinery to ensure best quality blood and blood components.

Jaypal was transfused with 13 units of cryoprecipitates and 4 units of red blood cells. He was fortunate enough that he got required blood components in time and that too without replacement. There are many blood banks in India but most of them work on replacement donation only. "We got all units of blood from Prathama easily and without replacing blood. When large amount of blood was needed, we were very tensed but Dr.Bhavin guided us and we got support from Prathama,” said Jaypal’s relative.

3550 BLOOD BOTTLE UNITS COLLECTED IN MEGA BLOOD DONATION CAMP IN RAJKOT

As many as 3550 bottle units of blood were collected at Mega blood donation camp in Rajkot organized at a car showroom on Gondal Road on outskirts of Rajkot. Mahipat sinh Jadeja Gondal, MLA organizes blood donation camp twice in a year in memory of his late brother Ramdev sinh Jadeja who had died in a road accident in 2001. They started organizing blood donation camps twice in a year. Blood can save people’s lives and our aim is that no blood banks should be in scarcity of blood. Jadeja has adopted over 250 patients suffering from Thallesemia, a genetic blood disorder and provide blood regularly to help them survive. Till now, more than 83,000 bottle of bloods have been collected by these blood donation camps.