HELPLESS PATIENTS, HAPLESS DOCTORS- The dilemma of blood banking in peripheral hospitals

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It was May 2011. In a tiny, remote village near Robertsganj in Uttar Pradesh State, a girl of seven years had met with an accident and was bleeding profusely. The village folk were unaware of first aid measures but managed to bring her in a tractor after a delay of two hours, to a small hospital at Robertsganj. When the doctors present there examined the patient, they realized that a transfusion of blood was essential in order to save the girl; otherwise the girl will surely die within few hours! But, alas! As per the latest amendment in the Drugs and Cosmetics Act doctors are prohibited from transfusing blood from another person (after cross-matching) unless the blood is obtained from a registered blood bank. The nearest blood bank, at that time was at Banaras, 90 Kms away. To get there one would have to travel at least a minimum three hours (one way) over very bumpy roads! The availability of blood was the next question! In the mid of the night, would there be a doctor in a small Government Hospital ready to do the job in that odd hour! The girl was slowly dying before the eyes of the doctors! They are qualified and experienced in their profession to cross-match and transfuse that blood; but this has been made illegal after 1999 and punishable with a minimum one year of imprisonment or up to three years!

The situation was deteriorating by the minute and pricked the conscience of the doctor. A human being was dying in front of the doctor, even though she could possibly be saved if only the doctor ventured to transfuse the blood. A hard decision had to be taken- there were two options; either to save the girl and go to jail; or keep quiet and turn the other side till life slowly ebbed from the body. This small medical team chose the first option. The girl was saved; now she is a grown up teenage girl; but criminal action was initiated and two persons were imprisoned. The case is still going at the Robertsganj Chief Judicial Magistrate’s Court!(1)

It would be important to mention about two deaths even after a new blood bank became operational now at Robertsganj – simply because of lack of timely supply from blood banks!

A patient arrived at Jiwan Jyoti Christian Hospital at 8.00 p.m. on 12th January 2012 with post partum haemorrhage following a live delivery at the nearby Government Hospital. Her B.P was not recordable on admission and she was severely anaemic. She was bleeding and in shock – the surgeon needed to do an emergency explorative laparotomy for which blood was essential. It took the relatives four long hours to obtain one unit of blood with difficulty from the (new) Robertsganj blood bank because it was night time. They managed to bring the blood at midnight but it was too late. The patient died.

A woman had C-section on 16th March 2011 at a rural hospital. After surgery the patient developed Disseminated Intravascular Coagulation and went into shock needing an urgent blood transfusion. Due to her unstable condition, she could not be shifted to another place where the blood bank was situated. Sadly, she expired at 1.35 a.m. on 18th March 2011.

These are just two examples; but thousands die because of the new amendment which virtually prevents medical professional from transfusing blood from another person after cross-matching.

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**OPINION – Blood banking in peripheral hospitals**

**What is the new amendment:**

Prior to 1999 (i) blood transfusion could either be made available through services of blood banks (ii) OR can be taken from a donor and after doing proper tests (cross-matching), directly transfused to the patient without “banking” or “storing”. The second method is called **Unbanked Direct Blood Transfusion** (UDBT). This procedure has saved thousands of dying patients in rural areas by quick, immediate and timely transfusion.

But, the Union of India, brought an amendment in the Drugs and Cosmetics (2nd amendment) Rules, 1999 which changed the definition of blood. It mandated that even mere collection of blood requires a “license for blood bank”. That means a doctor can collect blood from a third person only if his hospital has a license to have “a full-fledged blood bank”. Generally, blood cannot be collected ordinarily just like any other product in a bag; but only in special “collection bags”, which are chemically treated to preserve the blood and prevent clotting. This bag can be obtained only from manufacturers and after the amendment, the chemists were directed not to supply “collection bags” to donors doing UDBT.

**What is the consequence:**

The amendment should have been brought only after all the States had adequate number of blood banks- both in the city and rural areas alike.

But at present only cities and metros have adequate number of blood banks whereas in rural areas there are no blood banks. The decision to bring the amendment was brought by decision makers from metropolitan cities like Delhi, Mumbai without taking into consideration the remote and rural areas. The following facts may explain the situation more clearly:

- **(a)** Minister of State Mr. Shripad Yesso Naik informed in the Indian Parliament that 81 districts in the country are without even one functioning blood bank.
- **(b)** The “blood storage centers” brought in alternative for blood banks can be adjudged by the volume of blood they are distributing. They are functioning very badly because the volume of blood is very negligible. In emergencies, they simply say “no blood”; they close their doors leaving the patient in lurch.
- **(c)** In the District of Dhule in the State of Maharashtra, there were 5 blood banks. All of them were located in the District Town having a population of 3 lakhs, leaving the remaining 26 lakh population of the district with no Blood Bank.
- **(d)** Depending on the Distance of peripheral town, the time taken to procure blood from Authorized Blood Banks varied from 6 hours to 15 hours or even more at nights – resulting in valuable life leaving the human body at the rural hospital itself where qualified medical professionals are present; but who could not save the life as their hands are tied by this amendment.
- **(e)** In the year 1988, according to a study, Blood Banks had collected a total of 5500 units of blood out of which only **300 units** were sent to periphery where 26 lakhs of people were residing.

**Qualified medical professionals may be present but cannot save a life as their hands are tied by this amendment.**
OPINION – Blood banking in peripheral hospitals

(f) A study in the same district reveals:

(i) Out of 40 clinicians (doctors including surgeons, gynecologists and physicians) working in peripheral centers, 39 were still doing UDBT to save the patients (though illegally, risking penalization by law-enforcing authorities).

(ii) A study across the country done in October 1999 reveals that all doctors who practice UDBT continue to save women after deliveries and road accident victims within the golden hour.

(iii) A study at the rural Sivakasi town in Tamil Nadu State gives the figure that out of 18 doctors, 9 were practicing UDBT even in 2003 and a few such doctors are under prosecuting process even now by the State Chief Drugs Controller U/S 18(1) of the Drugs and Cosmetics Act, 1940.

(iv) It is an irony that while acting in good faith, a medical professional has to see valuable human life leaving the body because of non-availability of blood, even when blood is readily available from the victims’ relatives who are with them and are willing to donate. The law however, prohibits this and the doctors try to procure blood from blood banks that are 100 Km away. The patient may die but Doctors become law-abiding citizens!

(v) 74% of Indian population live in rural areas whereas blood bank availability is 10% to 15% only – because rural hospitals cannot spend money in maintaining a blood bank and obtain a license (yes, even this requires money!).

(vi) 25% deaths related to child birth and pregnancy are due to bleeding (haemorrhage) and many women die during child birth due to bleeding.

(vii) Death due to road accidents mainly occurring away from bigger towns moving vehicles and in rural areas doubled in the last six years.

(viii) Surgeons, Obstetricians and other qualified clinicians even when available in rural areas, are greatly handicapped because they cannot give their professional service without availability of blood.

What about other advanced countries?

In the U.S.A, Medical Practitioners who are permitted by law to prescribe and/or administer drugs are empowered to transfuse blood (after cross-matching) because, blood and blood products are declared as drugs as per law. In other words, a registered Medical Practitioner who is authorized to prescribe a drug can also transfuse blood to a needy patient.

The law states that, “Practitioners… are licensed by law to prescribe or administer drugs and who manufacture blood products solely for use in the course of their professional practice.” (Title 21 – Food and Drugs – Chapter: 1 – Food and Drug Administration - Subchapter: F – Biologists PART 607 , Sub Part – D - Exemptions (b))

The Hon’ble Supreme Court of India in its land mark judgement recently in Save life Foundation & Anr. Vs. Union of India & Anr in Writ Petition No. 235 of 2012 has observed the following facts in respect of good Samaritans who are willing to give a helping hand to the Road Accident victims. While heavily coming to protect such persons the Hon’ble Court observed:

(i) In England and Wales, the Parliament has enacted the Social Action, Responsibility and Heroism Act, 2015, which provides for certain factors to be considered by the Court while hearing an action for negligence or breach of duty. Section 2 of the Act provides that “the court must consider whether the respondent was acting for the benefit of society or any of its members” (Para – 4) “whether the respondent was acting heroically by intervening in an emergency to assist an individual in danger” (Page 3, Para-4).
In Iceland, Section 51-D of Civil Law (Miscellaneous Provisions) Act, 2011 provides “that a good Samaritan will not be in negligence for any act done in emergency to help person in serious and imminent danger”.

“Accident case requires fastest care and rescue which could be provided by those closest to the scene of the accident” Para- 5.

The letter further states that research shows that a number of the accident victims can be saved if they receive immediate attention” - (para 6), “whereas injured gradually bleeds to death” – (para 7).

What is happening in armed forces?

UDBT is legal in Armed Forces.

The Armed Forces in a remote area of combative operations felt the need of UDBT or else, they may lose their most trained and loyal war veterans. They cannot afford to wait for Blood Bank facilities – mostly because of urgency and availability issues in remote outposts. The Union Cabinet has decided to exempt all the provisions of Chapter IV of the Drugs and Cosmetics Act, 1940 and rules framed under (Sub-section 30 in 4.1.2001).

Conclusion:

The public at large, all the voluntary organizations in the country, the medical associations of India and all similar organizations should join in one voice to pressurise the officials and authorities including the members of Parliament and Ministers to take immediate remedial measures to save millions of poor illiterate in the rural villages especially the underprivileged women who are mostly affected by the enforcement of this amendment.

This will also give relief to thousands of medical professionals who are serving in the rural areas who have sacrificed their personal pleasure in serving the rural community, from unwanted litigations just because they act like a good Samaritans in good faith.

Doctors prosecuted in a criminal case because of this amendment have to stand side by side in the Magistrate Court in the place ear-marked for an accused person like a pick pocket or a murderer. A civilized society by no stretch of the imagination should place a respected, service-minded doctor, who has saved valuable lives, on the same level as a criminal offender, simply because of violating certain rules while acting in good faith.

References:
2. Trends in Maternal Mortality: 1990 to 2010
3. Drugs and Cosmetics (2nd Amendment) Rules, 1999 published on 05 April 1999 vide GSR 245(E) dt.5.4.1999
4. 1st Amendment of Drugs and Cosmetics Rules, 1945 published on 4 January 2001 vide GSR 6(e).

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