Rural blood availability: regulations must meet ethics

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Abstract

Rural physicians have been practising the technique of emergency bleeding and transfusion called Unbanked Directed (to a specific recipient) Blood Transfusion (UDBT), which has been declared illegal, to meet the need for blood in rural and inaccessible areas. As a result, a crisis has emerged in the availability of blood. Is UDBT a second rate technology for the poor and the disadvantaged? And should we not rather advocate for rapid scaling up of the establishment of blood banks in all areas? We examine the ethical issues related to blood availability in the rural areas. We argue that a regulated and licensed UDBT passes muster on the ethical principles of beneficence, lack of maleficence, justice and Swaraj. Using this issue as a case in point, we further examine the idea of what constitutes appropriate or acceptable technology. While affirming that any technology has to pass muster on a litmus test of acceptability, we discuss the difference between "ideal" and "acceptable" (but less than ideal) technology. We argue there is a dynamic push and pull between the urge to regulate and restrict the use of skills by all versus the need to communitise technology. Regulated use of UDBT will allow blood to be available where it is needed most in the foreseeable future in India.

Background

One evening in September 2013, a 26-year-old woman came to the Jan Swasthya Sahyog health centre in hypovolaemic shock due to a bleeding placenta previa (1). While we were arranging for an emergency blood transfusion thanks to the kindness of two voluntary donors, we were informed that these were the last of our blood collection bags. The owners of shops selling medical devices would now sell blood bags only to those who had a licence for a blood bank, and this is not possible in our rural health centre. At almost the same time, news arrived about the arrest of a doctor in a mission hospital in Robertsgunj whose crime was practising this brand of emergency bleeding and transfusion called Unbanked Directed (to a specific recipient) Blood Transfusion (UDBT). We knew that a real crisis was at hand. There are difficulties in procuring blood in an emergency from a blood bank far away in the city, and the blood storage centre at our hospital can only partially meet our needs for blood transfusion since it is supplied poorly by the mother blood bank in the nearest town, even at the best of times. We and hundreds of secondary healthcare providers in marginalised India would no longer be able to bleed donors for transfusions in medical emergencies. Rural surgeons and the coalition of Christian health organisations which dot the entire countryside in India were alarmed, as were we.

Jan Swasthya Abhiyan wrote a petition to health administrators (2), asking for remedial action and the legalisation of unbanked emergency blood transfusion. Pressured by this and a few articles that came up in the lay press (1,3,4), the health administrators in the country were forced to take cognisance of this crisis. The reality of our health systems and their inability to ensure the availability of blood while following the regulations of blood banking could not be ignored. Worried that their departments of AIDS control (which, curiously, control all blood-related issues) and health were getting a bad name, and also realising that there was a mismatch between the need for and impracticality of the regulations, the administrators started working to thrash out more practical regulations.

While we were examining the technical issues related to unbanked blood donation, testing and transfusion, well-meaning friends in the medical profession and in the administration asked a genuine question: Were we not justifying the practice of an inferior technology? Why were we rather not advocating for rapid scaling up of the establishment of blood banks in all areas? Were we justifying the continuation of a second rate technology for the poor and the disadvantaged? This set us thinking. Here, we present our examination of the ethical issues related to the availability of blood in the rural areas.

Blood transfusion is a health technology required in hospitals that provide secondary or tertiary-level care. Using the example of blood transfusions as a case in point, we examine the idea of what constitutes appropriate or acceptable technology. While affirming that any technology has to pass muster on a litmus test of acceptability, we will try to discuss the difference between "ideal" and "acceptable"(but less than ideal) technology. Lastly, we will briefly discuss the dynamic push and pull between the urge to regulate and restrict the use of skills by all versus the need to "communitise" technology, using some examples in healthcare.

Since 1998, the rules have mandated that blood banks will be the essential structure for providing safe blood to people. This entails adequate infrastructure, skilled manpower, prescribed methods and materials for donation, testing, storage, and issue and transport of blood. A less elaborate infrastructure, consisting of blood storage centres, was allowed to be set up in 2001 as an infrastructural concession to women in labour in the rural hinterland. In these centres, some units of blood can be stored in a refrigerator and this blood can only be

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procured from what was aptly called the "mother" blood bank. Blood storage centres cannot bleed donors, nor test blood for potential transmissible infections. In the last 14 years, very few blood storage centres have been made operational and only a miniscule number of units of blood have been transacted through them. There are no published data on this, but we know from a perusal of government figures in Chhattisgarh that the number of blood units transacted in blood storage centres in the state is actually zero, except in our own blood storage centre. Similarly, a friend who is a public health activist working in eight districts of Bihar told us that there is not a single functional blood storage centre in those districts, even though each district headquarters has a functional blood bank.

We have tried to explore ways to improve the working of blood storage centres. The main reason for the poor supply of blood in storage centres is that the mother blood banks demand replacement for the blood before issuing it, and do not make efforts to get voluntary non-remunerated donation in any significant volumes. Thus, they have limited blood to offer to the rural blood storage centres, from where it is not possible to get replacement donors at all times of day or night. We have been trying to enhance the blood supplies of our mother blood bank by organising regular voluntary blood donation camps, as well as walking blood donor groups in the surrounding villages who would periodically donate blood in camps.

Unbanked directed blood transfusion

Drawing blood from voluntary donors when a sick person is in need of blood urgently, testing it for infections and compatibility, and then transfusing it to the person, of course without banking, is what many of us have continued to practise even post-1998. Described as Unbanked Directed (to a specific patient needing blood) Blood Transfusion (5), a term coined by Ravindranath Tongaonkar of the Association of Rural Surgeons of India, it is practised in many parts of the world where ready access to blood banks is a problem. While the American Red Cross (6) and the New York Blood Centre (7) welcome directed but banked donation, Medicins Sans Frontiers (8) recommends unbanked directed transfusions in situations in which blood banks are not available. It is ironic to note that the practice of UDBT is not recognised by any publication of the WHO, nor by the National AIDS Control Organisation (NACO), nor by any other developing country, even though it is highly probable that it is in widespread use. At present, the practice is illegal in India (9).

It is not our case to justify UDBT as a replacement for blood banks or advocate the dilution of efforts towards opening more functional blood banks or blood storage centres. We, however, submit that UDBT is a public health method that is likely to be needed in many areas of our country for several more years, till blood banks start functioning in every nook and corner of this vast country, and are able to supply blood for all needs. We also argue that UDBT meets the standard of care on technical grounds, even if it is not the ideal technology. Thus, it is ethical to practise it where there is no other option, such as access to functioning blood banks. In fact, it is an ideal solution in the current context of inaccessible blood banks, especially in emergency situations. Of course, we have to have regulations and monitoring to ensure that UDBT is not misused and does not remain undocumented or unstandardised. Legalising a regulated and standardised UDBT practice (10) is the way forward**.**

Meanwhile, NACO should also focus on raising standards while easing infrastructure norms for blood banks to make them as safe as possible, while making them more accessible to people in need. This may involve easing civil construction requirements, not insisting on air conditioning in all rooms and relaxing qualification norms that are difficult for the human resources to meet, to the extent that this does not compromise the quality of services.

Deconstructing the technology of blood transfusion

To understand the various issues that plague the debate on blood supply in the rural areas, let us deconstruct the entire process that culminates in a needy person getting a blood transfusion. Blood is necessary broadly in two situations – emergency situations, in which blood is required in the next four hours, and non-emergency situations, in which blood procurement can be planned, eg in an elective surgery. Here, we shall take up only the emergency need for blood.

We appreciate that there are many shades of grey between the extremes of emergency need within four hours and elective need for blood. Sometimes, blood of specific groups may not be available in a blood bank in enough quantities at a given time and specific donors may have to be called upon to donate on priority. With that caveat, UDBT, as we see it, does not have much of a role to play in non-emergency situations, and it cannot be justified.

In an emergency, first a clinician identifies the need. He/she ascertains whether blood is indeed essential for care, and whether it cannot be replaced by another therapy. Over the years, recommendations for the use of blood have progressively become fewer. Volunteers, who are deemed healthy after their blood is tested, are encouraged to donate blood. The donors are either those who donate regularly or those who are called upon to donate in an emergency to replace the units that may be used. There is a general acceptance that by 2020, 100% of blood will have to be procured from voluntary donors (11). Blood is collected from these donors in quality disposable blood bags. The blood is then tested for a standard list of known transmissible infections by competent technicians, using prescribed methods of assured quality. Next, the blood is either stored at an assured temperature of 2–8° Celsius for a maximum of 35 days, or if facilities are available (which is so only in a tiny fraction of the blood banks), it is fractionated into as many as four parts, each of which can potentially be used for different

recipients. When a demand comes from the clinic, the unit of blood is matched for compatibility with a sample of the recipient's blood, again according to prescribed minimum standards. The blood unit is then issued to the clinic, and if this clinic is more than half an hour away, the blood has to be transported to the clinic at a temperature between 2 and 8° Celsius. At the clinic, the blood unit's identity is verified against the specific recipient's identifiers and the blood is transfused in no more than four hours. Records of all these processes have to be kept. Reports are sent to regulatory bodies from licensed blood banks and blood storage centres.

The prescribed infrastructure for carrying out these steps is a blood bank, which has to take all the steps, except identify the need, match the identity of the unit and finally transfuse the blood. These are done by a clinical team comprising a doctor and a nurse. In contrast, the blood storage centres can only store a few units of blood procured from a blood bank and then issue it to the clinical team on demand, after cross-matching the blood unit against the recipient's blood for compatibility.

The ethics of UDBT

What can the centres that practise UDBT do? They test the potential donor for his/her blood group, test him/her for transmissible infections, hygienically draw blood, do cross-matching of the blood against the recipient's blood and then issue blood units to the clinical team for the specific patient. They neither store blood for future use, nor make components. The donor base is likely to be more than or just as voluntary as it would be in a blood bank. Many health centres, including ours, have a responsive walking blood donor pool in the community nearby, from whom healthy volunteers are called in quick time. As long as blood is not taken from a first-degree relative and is put through all the standard tests, unbanked blood is as good as banked blood. Obviously, storage is not necessary in situations in which UDBT is necessary. At present, components are not the standard prescription in most emergency medical and surgical situations (12). Once tested for compatibility and safety, the blood is available within an hour.

Of course, we assume that the physician and laboratory technicians are competent and trained. Thus, we recommend that the practice of UDBT be permissible only for those selected physicians and associated laboratory technicians who undergo training and certification, and are ready to operate under prescribed regulations which prevent undermining of safety and quality. Component preparation will not take place in UDBT, but that is not a concern in an emergency situation.

Several rural hospitals like ours often have a woman come in on a late evening or at night with severe postpartum haemorrhage. If uterine atony or retained placenta is a cause, while you administer other treatment to stop the bleeding, you often require 3 to 4 units of blood over the next 10–12 hours. We find our blood storage centres inadequate to meet this need and the blood banks are inaccessible. At such times, UDBT proves to be the only life-saving technology. By criminalising this technique without offering a viable alternative, the state has left a major void in public health.

What, then, is the main concern that well-meaning people have about efforts for the legalisation of UDBT, in addition to setting up more blood banks and blood storage centres? The concern is not about transmissible infections since the types of testing methods and their quality are similar across UDBT, blood storage centres and practically the majority of blood banks. It is not about components that the banks can supply because in any case, most blood banks do not provide components at present. Further, as mentioned above, in trauma, when blood is needed for treatment, blood components are increasingly not being recommended. The main fear is of misuse, which may lead to the potential transmission of infections such as HIV through inadequate checking by those who wish to break rules. It is for this reason that the authorities are in favour of strict regulation, even though this curtails access to this life-saving technology. The difference between blood banks is not so much in the medical aspects, but in administrative aspects such as the level of trust and in access, through regulatory threat as a tool.

There is no doubt that the regulation of blood has taken place through the institution of blood banks in the last 15–20 years. This is because blood is now available only through regulated blood banks. This translates into blood being available in places where blood banks are located or which they are likely to cater to, and these are cities and their peri-urban rural sites. In areas that are not served through blood banks, the result is a drying up of blood supplies.

Yet this demonstrates that if we really do want to regulate institutions and establishments like blood banks, we can do it. This has also demonstrated that it is possible to screen all units of blood. Not only this, we have blood components being available in 10%–15% of these regulated blood banks.

Why can we not extend this regulatory regime to include individual clinicians in middle-sized and small places in a wider expanse of rural India to make safe blood available by allowing the practice of regulated UDBT?

Those who work in the marginalised areas of India and in places where blood banks exist have a couple of questions – how often do clinicians in need of blood for their acutely sick patients ask donors to rush to their blood bank for a donation because enough blood of that group is not available in their bank? How often is blood that is less than six hours old after donation urgently issued for transfusion? We find these rather common occurrences. This would mean that these licensed blood banks are actually practising UDBT. So if a blood bank infrastructure can be allowed to practise UDBT, then why not allow it for a non-blood bank infrastructure, after the personnel receive the necessary training and licensing?

It must not be forgotten that there are obviously some emergency situations in which banked blood is not appropriate. Some examples are - in people who are bleeding excessively due to markedly diminished platelets, such as in dengue haemorrhagic fever; and diminished coagulation factors, such as in haemophilia. Also, if platelet components or fresh frozen plasma, respectively, are not available in the health facility, then fresh whole blood is a better choice than banked whole blood. In fact, fresh whole blood is clearly indicated for the treatment of disseminated intravascular coagulation.

Ethics of health technology – ideal versus appropriate?

Safe and accessible blood transfusion technology is necessary for ensuring blood security for all. Blood banking and UDBT are two types of blood transfusion technologies. They are examples of secondary-level care and are thus comparable, for example, to a caesarean section or appendectomy, administering spinal anaesthesia, or carrying out diagnostic ultrasonography. Should a caesarean section be carried out only by a degree-holding obstetrician in all places and others not be allowed to do so? Can a non-specialist be allowed to administer spinal or even inhalational anaesthesia? Should only qualified radiologists be allowed to perform ultrasonography? In an ideal world, some may answer these questions in the affirmative, but are there other ways? There are many things we do in healthcare in certain situations without specialised certification.

An appropriate healthcare technology should fulfil the needs of the majority, foster a humane and creative health service and make the best use of local resources (13). At the same time, it has to pass muster on the following: effectiveness, safety, availability and affordability. While all these attributes are important, effectiveness is the most important, followed by safety, followed by availability and affordability. Appropriate technology is not synonymous with either high-cost or low-cost unsophisticated technology. It certainly is not poor technology for poor people.

Of course, there may be more than one appropriate technology for a healthcare need. When an ideal technology that meets the four above-mentioned attributes maximally is not available, what should one do? When is it a matter of "making do" with a less than ideal (and yet appropriate) option? We say that regulated and certified UDBT is an acceptable, even if not ideal, technology for rural blood security in emergency medical situations.

Let us talk of parallels in which technology has been taken out of the confines of a rigidly delivered structure and has then been shown to work.

We would like to explore examples of healthcare technology that are presently appropriate yet not ideal, under five heads: personnel, equipment and appliances, infrastructure, diagnostic technology and treatment strategies.

Table 1

Where practised health technology is inferior to the ideal technology yet meets the criteria for appropriateness

Health personnel

1. Village health workers examining, testing and offering treatment for possible *P falciparum* malaria (14)*
2. An auxiliary nurse midwife conducting an institutional delivery in a sub-centre or primary health centre (15,16)
3. A trained nurse administering spinal anaesthesia to a woman in obstructed labour when an experienced doctor is doing a caesarean section (17)
4. Non-surgical specialists but MBBS degree-holding doctors with some training performing appendectomy for acute appendicitis.
5. General surgeons performing super specialty surgery
6. Mid-level health workers (18) performing various curative tasks

Equipment and appliances

1. Testing for anaemia using copper sulphate solution (19,20)
2. Using nylon mosquito bednet material for hernia mesh repair (21) instead of a marlex mesh

Clinical examination or diagnostic technology

1. Counting the respiratory rate for the diagnosis of pneumonia and not doing stethoscope-based or chest X-ray examination (22)
2. Using rapid kits for *P falciparum* malaria instead of blood smear examinations (23)
3. In the RNTCP, using sputum smear conversion to negative at the end of tuberculosis treatment to define cure, rather than performing sputum cultures and confirming no growth (24)
4. Using rapid kits for screening for HIV versus ELISA reader-based testing
5. Using ELISA reader-based testing versus nucleic acid amplification testing kits for Hepatitis B screening
6. Visual inspection by acetic acid application (VIA) and colposcopic biopsy versus PAP smear examination and biopsy for cervical cancer screening (25) versus VIA-aided "see and treat" method
7. Slide-based cross-matching versus tube-based cross-matching for compatibility testing of blood for transfusions

This is only an illustrative list and can be expanded. As a society, we have accepted many technologies that are not ideal, and are not substandard. They are still appropriate. Borrowing from a clinical ethics framework and paraphrasing what Laurie Baker proposed about science in India, we suggest the following litmus test for healthcare:

1. Does it solve the problem that it aims to (beneficence)?
2. Does it reduce inequality (justice)?
3. Does it cause any harm (non-maleficence)?
4. Does it foster autonomy?(swaraj)

Note ** All numbers in parenthesis refer to citations*

New technology will keep appearing to add to the existing technological choices. Many of these new technologies may be more sensitive or specific, but can we say that the older technology will be inferior? It is important to realise the importance of this. For example, in the case of blood transfusion technology, the arena for diagnostic tests for transfusion- transmissible infections is evolving fast. Does this mean that the ELISA for Hepatitis B surface antigen becomes

unacceptable once nucleic acid amplification technology is commercially available and also installed in some blood banks? Of course, with time, these judgements on such technology also evolve and do not remain constant.

NACO may be pleading non-maleficence as a reason for banning UDBT. We know there is no hard evidence to support the harm done by UDBT. In response to the petition filed by Common Cause in the Supreme Court of India in 1996, the Government of India had asked (26) one investigating agency, M/s Ferguson and Company, to file a status report for the blood banks in India. This report only talked about the abysmal quality of the blood banks. It was silent on the blood transfusions being practised as UDBT. This status report formed the basis of the 1998 amendments to the Drugs and Cosmetics Act. In the absence of any hard evidence, banning UDBT for use in emergency situations is against the tenets of beneficence, justice and autonomy. At any rate, UDBT certainly allows autonomy. Once trained and licensed, physician–laboratory technician teams in the rural hospitals can offer blood transfusions to people in need without being dependent on inaccessible health facilities. As we have suggested above, the standardisation of UDBT can ensure that a similar process of bleeding–testing–transfusing can be done without storage, hence completely annulling the concern regarding possible maleficence.

Licensing is an efficient mechanism to ensure standardisation and accountability. What stops us from developing a licensing system for UDBT? Monitoring more licensees would be a greater challenge for the regulators, but can still be done. Attacking the Achilles' heel of emergency blood transfusion – strangling the sale of blood bags – is clearly ill advised. That may take care of unregulated transfusions, but it does not take care of patients who need blood transfusion.

There is a need to review the impact of such regulation on blood security. How many fewer cases of transfusion-related illnesses have occurred and how many more deaths have taken place due to the non-availability of emergency blood transfusions? Is anyone counting these numbers? Not having this information is unacceptable and it makes one wonder whether the law made in 1998 can stand the test of morality.

Health technology: specialisation versus generalism

Blood banking is an example of a specialised technology. It demands special infrastructure, specialists are involved in it and the guidelines restrict the use of this technology to only licensed people. The entire debate on going for "only the blood bank" model versus a more inclusive model that includes licensed UDBT, besides blood banks, reflects a polarity of views in the discourse in public health. At one end, there is a desire to encourage specialisation and have more specialists do more and more of less and less. Further, these specialised people restrict the use of their specialised knowledge and skills by others. On the other hand is the desire to de-specialise and have more generalists and communitise knowledge and skills. We need rules either way, but these regulations have to meet ethics.

While we do need specialists, let us ask ourselves whether generalists have harmed public health. Is the path towards multi-skilling and communitising technology not desirable?

This may be a future debate – but one thing can be said for sure – specialists and specialisation certainly make the technology more expensive. Higher costs affect accessibility for the poor. Besides, the path towards specialisation naturally encourages more regulations. Certification and licensing are desirable since they are, arguably, a convenient and effective method of maintaining high standards as they restrict entry, but they encourage a feeling of high status and elite privileges in any profession. In the name of eliminating competition from unqualified amateurs or generalists who may provide a cheaper but allegedly substandard service, specialisation seriously restricts the number of active professionals working in society (27).

Conclusions

Unbanked directed blood transfusion, if used by trained and certified healthcare teams, meets the ethical standards necessary for any appropriate technology and is likely to play an important part in fulfilling the emergency need for blood in rural healthcare. When a litmus test of beneficence, non-maleficence, ability to foster justice and *swaraj* is applied to several health-related technologies, many of those being used at present will pass muster on appropriateness, even if they are not ideal. We contend that UDBT is an appropriate technology. Regulated use of UDBT will allow blood to be available when it is needed most, for example, when a mother who has just delivered an infant is bleeding profusely and needs blood transfusion to save her life in the late evening in a rural hospital. It will allow vital healthcare to be delivered at a decentralised level like a rural hospital or a community health centre, and avoid unnecessary dependence and referral to district hospitals or medical colleges.

It is also time we examined the risks of taking the path of specialisation and abandoning the generalism in healthcare.

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The urgent need for advance directives in India

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Abstract

Many individuals at the end of life are unable to convey their wishes regarding medical treatments. Advance directives (ADs) or living wills (LWs) allow them to crystallise their wishes in a written form so that these can be carried out if the relevant situation arises. In many countries, ADs are legally valid and enforceable; they reduce the use of life-sustaining treatments, which often merely prolong life without improving or even maintaining the quality of life. Such treatment puts a financial burden on the patient's family, often leading to penury. Resources are limited, the more so in countries like ours, and should be spent only when/where they can make a difference. The general public is not well versed in the advantages and disadvantages of life-sustaining treatments and needs to be educated on how to distinguish between them. A well-designed legislation for legalising ADs would help society at large. In addition to legalising ADs, some countries are contemplating making them compulsory. We could learn from them and empower our citizens by giving them the right to self-determination at the end of life.

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Introduction

An advance directive (AD) or living will (LW) is a document prepared by a person to instruct doctors and caregivers on