SUSTAINABLE HEALTH DIALOGUE

Multi-Dimensional Approach to Ensuring Safe Blood Transfusion

30 January 2019

India International Centre, New Delhi

chase|india

Foreword

India's National Blood Policy (2002) recognises transfusions of blood and blood components as foundational to efficient medical care. Blood transfusions are critical for both basic and advanced medical procedures and surgeries, and are also necessitated due to blood disorders and diseases. An efficient blood system is all the more essential for India on account of its burgeoning trauma and surgical burden, coupled with high prevalence of haemoglobinopathies and communicable diseases. Achievement of the Sustainable Development Goal 3 of Good Health and Well-being also relies on the availability of adequate and safe blood, especially in the context of maternal and child health indicators, as obstetric complications are common in India and often require blood transfusions.

Despite it being a critical, life-saving pillar of any healthcare system, the existing policy framework governing blood has proven to be inadequate, and consequently, Indian blood scenario faces challenges of acute shortage, wastage, unsafe transfusions leading to transmission of infections, lack of standardization, reliance on old methods and technologies, among others.

Even today, many patients requiring transfusions in India do not have timely access to safe, quality blood. There are glaring inconsistencies in the processes and quality at blood banks across the country. There is also an acute shortage of blood collection — almost 15% below the WHO recommended norm to meet the basic needs of a population. This WHO norm doesn't account for the burgeoning blood needs of India's health system, which is more advanced than other developing nations. National AIDS Control Organization (NACO) estimated the total blood need in India for 2017 at 2,65,00,000 units, which means 62.3 donations per 1000 eligible population in a year are needed. This would need a commensurate effort to promote voluntary non-remunerated blood donation and patching the gaps within the existing blood system in order to minimize wastage. Almost 10-11% of the blood collected between 2014 and 2017 was wasted on account on logistical and process inefficiencies and due to reactivity for Transfusion Transmitted Infections (TTI).

In a nutshell, the blood safety system in the country needs overhaul and convergence between different relevant stakeholders from the medical community and the government is key to achieving that. To initiate dialogue towards this much-needed reform, Chase India organised a closed-door multi-stakeholder roundtable on 30 January 2019 at the India International Centre, New Delhi, to discuss key challenges and prepare a roadmap to reform the Indian blood system to ensure adequate access to safe blood for all. The participants for this discussion were as follows:

1. Dr. Shobini Rajan, Director, National Blood Transfusion Council
2. Dr. K Madan Gopal, Senior Consultant (Health), NITI Aayog
3. Dr. Reba Chabbra, Deputy Director of Quality Control and Diagnostics, National Institute of Biologicals
4. Dr. Paul Ness, Director, Division of Transfusion Medicine and Professor of Pathology, Johns Hopkins University and Hospital
5. Dr. Zarin S. Bharucha, Chairperson, Federation of Bombay Blood Banks
6. Dr. Joy Mammen, Professor, Department of Transfusion Medicine and Haematology, Christian Medical College, Vellore
7. Dr. Sangeeta Pathak, Secretary General, Indian Society of Blood Transfusion and Immunohaematology (ISBTI)
8. Dr. Aparna Singh Shah, Regional Adviser, Health Laboratory Services and Blood Safety, WHO-SEARO
9. Dr. P R Sodani, Pro-President and Dean (Training), and Director, Center for Health Economics, IIHMR University, Jaipur
10. Dr. Poonam Coshic, Faculty In-Charge, Blood Bank, AIIMS

The discussion was moderated by Ms. Surya Sadasivan, Practice Lead - Healthcare at Chase India.

Background of the discussion

To set a context of the discussion and draw attention to on-ground realities and the issues facing the Indian blood ecosystem, a joint case study was presented by Dr. Madan Gopal, Senior Consultant (Health) from NITI Aayog and Mr. Roland Biset, Vice President, Global Sales Development, Terumo BCT. The case study highlighted findings and key learnings from a pilot assessment undertaken by Terumo BCT with NITI Aayog's support, in a blood bank in Sonbhadra, an Aspirational District in Uttar Pradesh, with the objective of understanding addressable gaps in the blood transfusion system in order to increase access to adequate and safe blood, particularly for transfusion during pregnancies, in the district.

The Sonbhadra assessment revealed a dismal state of affairs in the district blood bank, with multiple challenges in adequacy, safety, quality and sustainability of blood supply. For instance, the overall blood collection in the blood bank was found to be only about 0.25% of the local population, which falls drastically short of even the WHO-recommended 1% to meet the population's basic needs. Of the total blood collection, nearly 80% was from replacement donors. Despite this, limited to no resources were allocated to Donor Management, and only an average of one donation camp was arranged per month.

Blood wastage and safety concerns were found to be high, owing to issues in collection, handling and transportation, including air entry into the blood bank, broken fridge in the storage centre and transportation of blood on ice. In addition, only whole blood was available in the blood bank and there was no provision for componentization or leukoreduction. The blood bank did not have any documented Standard Operating Procedures or Quality Manual and deviations from standard procedures can pose a risk to blood safety. Trainings for blood bank staff were rare, and there were limited checks to ensure implementation of training in practice.

The findings of the Sonbhadra assessment largely corroborated the overall blood transfusion challenges highlighted in Chase India's discussion paper, and the issue areas were deliberated upon in detail during the course of the half day discussion.

To give it more structure, the discussion was broken down into three separate but interlinked sessions on Blood Availability, Safety and Affordability. In each of the three sessions, the participants shared their recommendations on addressing key challenges in the area and this was followed by interactive discussion within the group. In the Way Forward session, each participant highlighted the priority actions necessary to redress the blood transfusion situation in India.

The following section captures the key challenges and recommendations that were highlighted by the participants during the discussion.

Challenges and Recommendations

Fragmentation and Lack of Centralization

Given the unorganized and disintegrated nature of India's blood transfusion services, there is a lack of consistency in terms of catchment, demand and supply, expertise and technology, and consequently the availability and quality of blood. Some western countries have institutionalized a centralized blood transfusion service that serves as a network connecting blood collection centers distributed across the region to enable demand-supply inconsistencies to be balanced out and also allows for blood banks to share capital-intensive resources for economic efficiency. Lack of centralization hampers adoption of uniform standards and practices, and each blood bank operates in virtual isolation.

> *"I understand there are issues that are going to make it difficult to have a centralized unique blood system in India, but ultimately that has to be the goal […] A centralized transfusion programme is needed to maximise all of the opportunities. Patients and quality are being compromised because of lack of a centralized transfusion system."*
>
> *Dr. Paul Ness*
> *Director, Division of Transfusion Medicine and Professor of Pathology*
> *Johns Hopkins University and Hospital*

However, India's large size, different ownership patterns of blood banks (government, private and civil society), and lack of adequate infrastructure for storage and transport of blood, together with the fact that health is governed at state-level, are all factors that impede complete centralization in India. The participants highlighted that in India, transfusion services are fragmented across the public, private and charitable sector, with each catering to a given catchment area and sometimes competing against one another. These lack collaboration and effective coordination amongst each other and are majorly clustered in urban and peri-urban regions. It was recognized that fragmentation of this nature and lack of a proper network of communication and collaboration creates challenge in ensuring availability and access to safe blood.

Moreover, the proliferating number of blood banks was highlighted as a major concern. A few participants shed light on how no other region world-over has as many blood banks as India does – 3,023 to be precise. Due to the high number, it is difficult to staff and manage these many blood banks. It is seen that State Blood Transfusion Councils give No Objection Certificates without assessing the need for it. While most participants did recognize the need to control the number of blood banks, a few pointed out the barriers in place. They highlighted that even though the existing policy framework recognizes the need to avoid clustering of blood banks, the government lacks control over the private and the charitable sector and in turn, the ability to address it.

India, therefore, needs models that better reflect our realities. For instance, the National AIDS Control Programme (NACP) had mentioned under its fold

the 'Metro Blood Bank', which envisioned setting up four centers of excellence in Delhi, Chennai, Kolkata and Mumbai collecting over 1 lakh units through 100% voluntary donation along with complete component separation. However, this decade-old proposal is yet to see the light of the day.

Partial centralization or a hub-and-spoke model might be well-adaptable to India. In this model, different satellite centres are connected to a regional hub that houses advanced technologies and highly trained manpower. Though there are different variations of the model that can adapted to the geographical and demographic context of a particular region, the most basic model calls for centralization of blood collection and processing at the hub in a state and transporting blood and blood components to different geographically dispersed storage centres, supported by efficient demand mapping and inventory management. This can help in curbing wastage of extra blood collected at blood banks, especially now that bulk-transfers between blood banks have been allowed by the National Blood Transfusion Council. Consolidation of advanced testing and processing will result in economies of scale, consequently bringing about cost reduction and also quality through standardization. An interconnected network of blood banks and storage centres will help address challenges of access.

Other views that were discussed included introducing a rating system for blood banks and subsequently allowing market forces to take their course, resulting in closure of low quality blood banks.

Recommendation 1:

Development of pilot hub-and-spoke projects, including centralization of collection, component separation, processing and advanced testing, in some regions to study impact of centralization on timely availability, efficient delivery, and quality of blood.

Recommendation 2:

Better coordination between existing blood banks, through use of connected databases, will need to be supported by improvement in on-ground logistical connectivity to bridge the demand-supply gap of blood.

Recommendation 3:

State Blood Transfusion Centers should assess the need for additional blood service capacity before granting NOCs to new blood banks in a region. While the proliferation of private and charitable blood banks cannot be controlled directly, it is important to create awareness about demand-supply metrics, so as to discourage unnecessary blood banks from cropping up in over-serviced regions.

Lack of Process Integrity and Uniformity

The existing licensing requirements for blood banks issued by the Central Drugs Standard Control Organisation (CDSCO) mandates that written Standard Operating Procedures (SOPs) shall be maintained by all licensees and shall include all steps to be followed in the collection, processing, compatibility testing, storage and sale or distribution of blood as well as preparation of blood components. While there are model transfusion manuals by the WHO and DGHS, it is ultimately upto the individual blood bank to develop and institute its own SOP. This in turn leads to inconsistencies in process across blood banks, and difficulties in proper monitoring and supervision.

At the same time, procedures need to be developed outside of the blood bank in tandem with physician bodies for rational and optimal prescription of blood transfusions, both from the perspective of patient safety and efficient use of the available blood. The WHO Handbook on Clinical Use of Blood can serve as a guiding document for this purpose. The Indian blood banking system must aspire to achieve compliance to international standards and skilling must be accorded in line with WHO guidelines. Efforts must also be made to reduce blood wastage and ensure optimal use by emphasising on the criteria laid out in the NBTC Clinical Use of Blood Guidelines, 2003.

> *"Complacency set within blood banks is worrisome. Sometimes, we don't even test all the units for TTI […] We need to build capacity right from collection of the blood to management of the blood and also see if the blood being supplied to the recipient is free from any reactions."*
>
> *Dr. K Madan Gopal*
> *Senior Consultant (Health)*
> *NITI Aayog*

Supervision and effective enforcement is further constrained by the large number of blood banks and the traditional manner in which inspections are conducted by licensing authorities. Inspections are usually conducted before the grant or renewal of licenses, however what is important is maintaining consistent and periodic supervision through yearly inspections. In the United States, the FDA has surprise drop-in inspections annually at the very least, which gives an impetus to the blood bank staff to maintain quality and safety standards all throughout the year and not just around the time of the intended inspection. Inspections are also balked by the limited human resources at the disposal of the enforcement authorities. Ideally, inspection teams consisting of trained personnel including representatives from the Drug Controller Organization, the SBTC, and where needed, pharmacists and other experts, should be tasked for conducting investigations in different allocated regions.

Lack of adherence to standard protocol and processes often poses grave risks to safety of blood. For instance, transportation of blood on ice can result in wastage and improper transportation of testing kits can reduce their efficacy, greatly endangering public health by increasing the chances of transfusion of infected blood. Discrepancies in labelling of blood bags can also give rise to adverse reactions and donor-receiver mismatch.

Recommendation 4:

Development of Common National Standards for blood banks, transfusion centres and storage centres through comprehensive stakeholder consultations. These standards should be followed by all blood centres and should cover the entire blood supply chain, including storage and transportation. Some standards have already been developed and are being reviewed, and should be finalized in an expedited manner with inputs from all relevant stakeholders.

Recommendation 5:

Institutionalization of proper capacity building measures for blood bank staff to implement process uniformity and adherence to SOPs. Periodic refresher trainings and supervision could help ensure adoption of written standards into practice.

Recommendation 6:

Institutionalization of proper inspection guidelines by the CDSCO to be followed by all state drug controllers for periodic planned and unplanned inspections of all blood centres within their administrative control, along with a clearly defined mandate and structure of the inspection teams (including subject matter experts). This may also require capacity building within the Drug Controller Departments to effectively and efficiently conduct inspections.

Recommendation 7:

WHO Guidelines on Blood Safety, especially on Appropriate Clinical use of Blood and Blood Products, can be translated into regional languages and incorporated into training material.

Insufficient Collection through Voluntary Non-Remunerated Blood Donation (VNRBD)

While NACO estimates show that around 71% of blood collection is voluntary, in reality this figure includes a large number of replacement donations made by the patient's relatives and friends. There was general consensus within the participants that replacement donors cannot be phased out until the voluntary donations greatly pick up.

Replacement donations are more likely to carry infections due to lack of awareness about and commensurate social taboo around transfusion transmitted infections like syphilis and HIV. Therefore, promoting voluntary non-remunerated and repeat donors from low risk population is key to ensuring safer blood and might even reduce the need for testing. However, this isn't possible without securing a larger cultural change and encouraging altruistic behaviour.

A few participants claimed that systematic constraints are deeply ingrained even within the structural setup of blood banks, which eventually translates into a lack of effort on their part to seek VNRBD once the captive number is achieved through replacement donations.

> *"The way we are brought up in our families and society, we are not taught to donate blood either in school or in family. If you talk to young people, they say no one asked us to donate […] Encouragement and awareness need to be taken up at a very high level. All of us starting from our homes need to start with it. We can't depend on the government for everything.."*
>
> *Dr. Sangeeta Pathak*
> *Secretary General*
> *Indian Society of Blood Transfusion and Immunohaematology*

While low education and awareness levels restrain donation, it is noticed that even for the educated and informed persons, blood donation is not a regular activity. A resounding observation during the discussions was that people tend not to donate because "nobody asked them to donate". It is important that school curricula encourages young adults to donate blood and dispels myths about blood donation. Public and/or community based awareness tools like social media, billboards, televised advertisements, workshops etc. all need a coordinated effort to change public perceptions.

Even though blood donation camps are important to supplement the bleak blood collection, the overall goal is to have a registered set of voluntary donors in the periphery of each blood bank who can be called upon to donate at the time of need. It is also important to maintain prudence in organisation of donation camps as it noticed that on some key days, many civil society organisations conduct large donation camps and collect large quantities of blood without accounting for the demand at that time, which leads to wastage due to expiry of the shelf life of blood

> *"Model of altruism is very different in our country […] Altruism is restricted to those within my circle of contact. We do not bother about any unknown face who needs blood at a hospital, because that's not part of our culture. We need to undertake a cultural change and talk about how we approach the concept of giving. The tragedy is that there is not a single bill board talking about how safe it is to donate blood."*
>
> *Dr. Joy Mammen*
> *Professor, Department of Transfusion Medicine and Haematology*
> *Christian Medical College, Vellore*

and blood components. Moreover, sometimes blood collected at donation camps is not able to reach a processing facility in time for component separation.

A few of the participants recommended considering the idea of changing the legal age from 18 years to 17 years as that could drastically increase the donor population, while another participant suggested increasing the quantity of blood taken during routine collection from the present 375ml to 500ml. However, there was no consensus among participants on these ideas, owing to various implementation challenges and the fact that the overall age of consent in the nation is 18 years.

Recommendation 8:

Promotion of voluntary non-remunerated blood donation and eventual phasing out of replacement donations through a coordinated national blood donation campaign by the Ministry of Health and Family Welfare, supplemented by region-specific local campaigns in appropriate vernaculars. This should involve a massive Information, Education and Communication (IEC) element focussing on community awareness.

Recommendation 9:

Preparation of a yearly calendar by the State Blood Transfusion Councils to map appropriate days for blood donation camps to be organised in different regions keeping in mind the disease burden and specific requirements of that state/region in order to promote optimal utilization of blood. Blood banks, too, should be encouraged to plan their donation camps in advance.

Recommendation 10:

Exploration of new avenues for blood collection like workplace donation, mobile collection units, and collection in schools and colleges (for parents and students over 18 years). Sensitization on the need for regular blood donations should be made a part of school curriculum.

Recommendation 11:

Promotion of the use of technology in donor recruitment, counselling, care and sustainable engagement with regular donors. For instance, social media can be used to spread awareness and mobile-based apps can be created to keep track of donors, and share updates on blood donation camps.

Recommendation 12:

Emphasising conversion of replacement donors to repeat voluntary donors. This will require maintaining updated data of donors and engaging with them regularly.

Recommendation 13:

Reducing reliance on whole blood through appropriate Patient Blood Management guidelines, capacity building and supervision. Ideally, separate camps should also be organised for voluntary apheresis, wherever the technology is available.

Safety Concerns due to Inconsistency in Testing and Haemovigilance

Nearly 1.5% of blood units collected are wasted due to reactivity for TTIs and still many times patients are transfused with infected blood. This might happen unknowingly due to absence of proper donor screening and testing as well as inadequate infrastructure for leukodepletion or pathogen reduction. However, in some cases, the blood bank is forced to transfuse infected blood knowingly due to limited availability and thereafter, treat the patient with antibiotics.

Donor screening and counselling are the first step of filtration in the blood safety value chain. Even though the NBTC has issued guidelines for donor selection and referral, it is noticed that there are gaps in adherence at the blood bank level. It is important that principles and processes suggested by these guidelines are reflected in the SOPs developed by individual blood banks. Donor counselling is important to inform the donor about their infection status and refer them for appropriate treatment.

Quality and efficiency of testing and processing can be improved by fostering regionalization through establishment of zonal centres under the hub-and-spoke model with advanced testing methods and techniques along with facilities for pathogen reduction and leukodepletion that may be difficult to equip all blood banks with owing to the cost element involved. The United States now has almost 100% leukoreduction and many European nations also have committed to having universal pathogen reduction in order to ensure that all transfusable blood is safe. This could be achieved in India in a cost-effective manner through partial centralization.

At the same time, focus on the quality of testing and processing equipment is integral to ensuring safe blood. Thus, ensuring that all blood banks use best quality and most advanced testing kits (like Fourth Generation ELISA) can further help strengthen the blood safety ecosystem. Constant assessments and audits of equipment quality and encouraging blood banks to get voluntary accreditations can supplement this effort.

Each blood bank should also operationalize an internal quality control and monitoring system for reporting of adverse reactions. This information can be further linked to a regional or national database for proper haemovigilance. The National Institute of Biologicals administers the Haemovigilance Programme of India through two electronic softwares (haemo-vigil for recipient haemovigilance and donor-vigil for donor haemovigilance), but this programme has limited outreach so far and all blood banks should

> *"Right now, the Haemovigilance Programme of India is voluntary in nature – with only 800 blood banks reporting adverse events as compared to the 2700 licensed blood banks in India. The moment it becomes mandatory, the reporting centers would increase manifold for a safer blood system."*
>
> *Dr. Reba Chabbra*
> *Deputy Director of Quality Control and Diagnostics*
> *National Institute of Biologicals*

> *"Donor counseling plays a very important part in blood safety. Once we find out that a person is reactive to TTIs, we counsel the donor and send them to further testing to the concerned department. Getting into all details is a time-consuming process and we are grateful to NBTC for providing us with counselors but the numbers are still inadequate."*
>
> *Dr. Poonam Coshic*
> *Faculty In-Charge, Blood Bank*
> *AIIMS New Delhi*

be encouraged to enroll on this platform for better effective supervision of adverse reactions.

While most blood banks use testing that is sensitive enough to catch TTI positives, they aren't as specific as ones existing in diagnostic labs, thereby sometimes giving rise to false positives. Therefore, the testing process needs to be adequately sensitive. However, when referred to concerned departments, it might create a conflict by giving a negative result due to lack of sensitive testing. There is a clear need for harmonizing good quality testing kits and moving to fourth generation ELISA kits. A few participants also mentioned how it is also important to make sure that the donor's privacy is protected and their willingness to respond needs to be addressed through appropriate counseling during the screening process to avoid ineligible or TTI infected donors from donating out of peer pressure or lack of information.

Recommendation 14:

Creation of zonal testing and processing centres under the hub-and-spoke model, with the overall objective of increasing the proportion of blood units undergoing leukoreduction or pathogen reduction over time. Cost-intensive testing technology, like NAT, can be partially centralized.

Recommendation 15:

Encouraging blood banks to develop internal haemovigilance and quality control systems within their SOPs and enlisting on the electronic haemovigilance platforms developed by the National Institute of Biologicals. For promoting internal haemovigilance, guidelines for establishment of hospital transfusion committees may be issued.

Recommendation 16:

Blood bank staff should be adequately trained for screening and donor counselling and adherence to process should be of foremost importance.

Recommendation 17:

Experience from other countries like Singapore, where NIC numbers are used to track blood donors, shows that maintaining proper nationally coordinated electronic records of all blood donors using existing unique identification (eg. Aadhar) can reduce the risk of adverse infection reactions. A similar database can be instituted to store donor data, and keep track of their donation status.

Lack of Accurate Demand Calculation

Absence of district-level demand mapping and consequent inventory management is a substantial reason for lack of timely access in a situation where less than 1% of the population donates blood but blood-intensive ailments are rising steadily. For instance, some districts have rates of High-Risk Pregnancies (HRPs) as high as 30% and in other regions low haemoglobin necessitates urgent transfusions. At the same time, seasonal variations also have a large impact on the burden of communicable and vector-borne diseases that may call for greater blood availability. Issues like these even forces the blood bank staff to donate blood in times of emergencies.

Recommendation 18:

Periodic National, state and district level demand calculation should be done through an electronic data management system.

Lack of Skilled and Trained Human Resource

Issues concerning lack of efficiency and requisite skills on part of the human resource working in blood banks and engaged in blood transfusion services were brought up by most participants.

Proliferation of multiple small blood banks creates an artificial dearth of skilled manpower. The frequency of refresher training often varies, and is not prioritized. This is especially true for smaller blood banks, where the staff is small and cost of training becomes high in comparison. Some of the participants also claimed complacency on part of the blood bank staff for not incorporating their training into practice, while others attributed it to lack of proper supervisory support. Available training modules are not incorporated well and medical officials and support staff are not specifically trained properly to undertake quality assessment and monitoring by themselves. Lack of coordination as well as the large number of blood banks in the country were also highlighted as causes for poor human resources management.

It was recognized that it is imperative to undertake reforms that place special emphasis on training and capacity building for quality assurance.

Recommendation 19:

Regular refresher trainings for blood bank staff should be scheduled and adequate supervisory control should be provided to ensure that the training content is adopted into practice.

Cost to Patients

Despite paid donations being banned, there still exists a grey market for blood and blood components. In addition, instances of blood banks overcharging for blood are still common, despite there being Guidelines for Processing Charges for Blood and Blood Components by NBTC. This is fuelled by inadequate supply and access to blood, and the lack of a strong regulatory framework to penalise erring banks. It was noted that the NBTC guidelines for processing charges are comprehensive, taking into account all costs incurred by blood banks in obtaining blood/components, however, periodic revision of the charges was recommended.

Some participants also highlighted the need to reduce the cost incurred by the providers and at the same time ensure blood services are affordable. One of the participants suggested a Single Reimbursement System, where only the Government is responsible for reimbursement, that is, blood banks issue blood to the patients but bill the government. However, there was no consensus on this.

> *"We have to figure out how to reduce the cost to the client but equally important is to consider how to reduce cost to providers – blood is not free as long as somebody is paying for it, be it the government or anybody else. Sustainability demands that both capital and recurrent cost to the government are considered and a certain proportion of recurrent cost can be charged to the user."*
>
> *Dr. P R Sodani*
> *Pro-President and Dean (Training)*
> *IIHMR University, Jaipur*

It was found that charges for blood were nominal in India compared to the US, and participants also discussed the possibility of blood banks applying user charges. However, these charges cannot be applied for everybody and there will be a need to exclude below poverty line patients from these additional charges.

Recommendation 20:

Periodic revision of NBTC's Guidelines for Processing Charges for Blood and Blood Components will ensure that blood banks do not incur loss or scrimp on quality in order to keep costs low.

Recommendation 21:

Periodic inspections can help keep a check on prices charged by blood banks. However, there is need for strengthening of regulatory framework to ensure that action can be taken against blood banks found to be overcharging.

Absence of Effective Regulatory Framework and Convergence

The need for a revamp of the existing regulatory system emerged as one of the most resounding recommendations. One of the prominent issues that was noted was multiple stakeholders having responsibility in matters related to blood. The National Health Mission and National AIDS Control Organization support BTS, while a Hemovigilance program is also there in National Institute of Biologicals. Further, the Directorate General of Health Services is responsible for technical matters. The licensing for blood banks is, however, under the purview of the Central Drugs Standard Control Organisation (CDSCO). There is need for a clearer structure, with proper allocation of responsibilities and backed by regulatory mechanisms to support enforcement.

> *"There are various stakeholders looking into different aspects related to blood. This brings to mind a picture of the elephant being seen by six blind people. One is seeing the tail, another the feet and each describing a different picture of the elephant. Nobody is looking at it in total."*
>
> *Dr. Shobini Rajan*
> *Director*
> *National Blood Transfusion Council*

The CDSCO is ill-equipped to issue and renew licenses for blood banks in a time-sensitive manner, and the backlog for licensing is immense. This activity, and also periodic inspections that should ideally be undertaken, requires considerable manpower, and the role would be better placed with a body with technical expertise in the area of blood and operation of blood banks.

Presently, the NBTC lacks statutory backing and there is no separate legislation for blood, even though both the WHO and the 1996 Judgment of the Supreme Court (Common Cause v. Union of India and Ors.). The guidelines issued by the NBTC are merely 'guiding' in nature and the states can take a decision on adopting them or not. The blood banks, too, are not bound by the guidelines, and besides the mandatory requirements for licensing, there is barely

> *"Though NBTC guidelines are applicable uniformly throughout India, these are not supported by legislation. Flouting of the NBTC guidelines also does not make a blood bank lose its license. Legislation is critical for establishing a Nationally Coordinated Blood Transfusion Service. Unless we legislate the policy, nothing is going to happen."*
>
> *Dr. Zarin S. Bharucha*
> *Chairperson*
> *Federation of Bombay Blood Banks*

any scope to control blood bank operation. This also limits what corrective or punitive action can be taken for activities such as unfair processing charges for blood, inadequate testing, etc.

It also emerged that guidelines and regulations have not kept pace with developments, which slows down adoption of newer technology and practices. For instance, processing charges for blood and blood components were last revised in 2014, and the charges have not been increased despite increase in overhead costs, manpower cost, among others. This has put pressure on blood banks to control cost and often results in compromising of quality standards. In some cases, it also encourages blood banks to flout pricing guidelines and overcharge patients.

Recommendation 22:

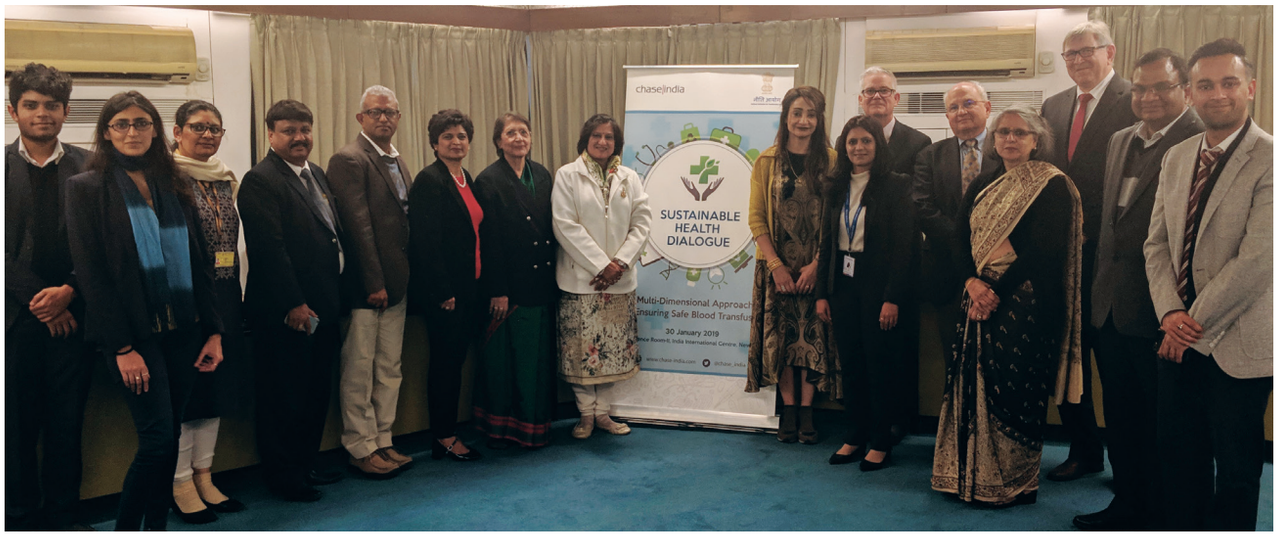
A separate legislation for blood is necessary to institutionalize standardized practices and address concerns of quality and access. This needs to be brought about on priority. All participants agreed that there is a need to introduce a national legislation to establish a Nationally-Coordinated Blood Transfusion System and fill the gaps in the regulatory framework by giving legal backing to NBTC/NACO.

Recommendation 23:

There should be one nodal body in-charge of blood related matters, and the body should have access to adequate funds and manpower to undertake its duties. Ideally, the NBTC, with its expertise in the area of blood, should be given this role. Participants recommended that legislation should effectively transform the mandate of NBTC by giving it the status of a regulatory vertical at the centre or state level and the authority to pool its own resources, impose penalties and undertake capacity building to ensure betterment of transfusion services. This would involve taking it out the ambit of the NACO and restructuring it within the Ministry of Health and Family Welfare.

Recommendation 24:

Guidelines and regulations should be revised periodically, taking into consideration emerging technologies and increasing costs.



Way Forward

The Indian blood transfusion system today faces a myriad of challenges, ranging from shortage, wastage, quality issues, and lack of standardization, to access and availability of blood. As blood transfusions are often life-saving interventions, a weak blood system has the potential to cripple a country's entire public health infrastructure.

Through the deliberations at the roundtable, it was increasingly clear that the gaps in the blood transfusion system cannot be addressed in isolation.

> *There was consensus amongst the policy makers and experts present during the discussion that bringing in a dedicated, comprehensive legislative framework for blood will undoubtedly have to be the first step towards reforming the blood system.*

The legislation, in addition to setting standards for the licensing and operation of blood banks, processing of blood and components, standardizing procedures, will also need to consolidate responsibilities for policy making and enforcement within one nodal body, such as the NBTC, and empower it with the resources to effectively undertake its duties.

While the National Blood Policy 2007 laid a roadmap for achieving an adequate, safe and sustainable supply of blood to meet the country's demand, and since then, several guidelines have been introduced to address various aspects of blood, including donor screening, selection and referrals, processing charges, promoting voluntary non-remunerated blood donation, etc., without regulatory backing, the policy and guidelines have remained toothless and unenforceable.

It is imperative that a forward-looking, solution-oriented dialogue be initiated for the framing of a National Blood Legislation. This can be done by setting up of an Expert Group or a Task Force comprising of policy makers, subject matter experts and legal experts, to deliberate on the particulars to be included in the legislation.

A legislation could also pave the way towards successful partial centralization of the blood transfusion infrastructure in India, by mandating coordination and connectivity amongst blood banks, bringing about process and operational standardization. This would help address issues of access, availability and quality of blood.

While a legislation is in the works, awareness building and sensitization activities can be initiated by the Central and State Governments to encourage citizens to donate blood. Fostering a culture of altruism and social good will require grass-root level efforts to dispel myths regarding blood donation and promote blood donation as a valuable contribution to the society. Private organisations and civil societies can be urged to organise awareness campaigns and blood donation camps to highlight the need for blood donation.

Details of Participants

Case Study Presentation

Dr. K Madan Gopal
Senior Consultant (Health), NITI Aayog

Dr. Gopal is a public health and development professional with over 25 years of experience in basic health services, public health administration, healthcare reforms, polio eradication, and other health policy research areas. He has served in many leadership and management positions in both government and international agencies.

Mr. Roland Biset
Vice-President, Blood Center Segment, Terumo BCT

Mr. Biset has over 25 years of experience in blood transfusion, medical device and healthcare service sectors in different capacities including product development, leadership, and business management. Mr. Biset is a holder of several patents in the domain of automation.

Discussion Group

Dr. Shobini Rajan
Director, National Blood Transfusion Council

Dr. Rajan is the Assistant Director General (Blood Safety) at the Ministry of Health and Family Welfare. She previously served as a Deputy Director in the Ministry of Health and Family Welfare where she looked after the management of the STI component of National AIDS Control Programme. Presently, she has been working on re-structuring of blood transfusion services of India and strengthening the NBTC.

Dr. K Madan Gopal
Senior Consultant (Health), NITI Aayog

Dr. Gopal is a public health and development professional with over 25 years of experience in basic health services, public health administration, healthcare reforms, polio eradication, and other health policy research areas. He has served in many leadership and management positions in both government and international agencies.

Dr. Reba Chhabra
Scientist Grade-I, National Institute of Biologicals

A leading scientist, Dr. Chhabra serves as the Deputy Director of Quality Control and Diagnostics at the National Institute of Biologicals, Ministry of Health and Family Welfare. She has been a pioneer contributor in the field of quality control and evaluation of immunodiagnostic kits over 25 years. She is an eminent resource person for NACO activities relating to HIV external quality assessments and strengthening quality management systems.

Dr. Joy Mammen
Associate Professor, Department of Transfusion Medicine and Immunohematology at the Christian Medical College, Vellore.

Dr. Mammen has been a fellow in Pathology Informatics at the Henry Ford Hospital, Detroit, USA. He is a specialist in laboratory hematology quality assurance, clinical laboratory, laboratory informatics and holds various research publications to his credit.

Dr. Sangeetha Pathak
Secretary General, Indian Society of Blood Transfusion and Immunohematology

Dr. Pathak is the Head of Tranfusion Services at Max Super Speciality Hospitals, New Delhi. With more than 19 years of experience, she has headed various blood banks in the past, including that of Indian Red Cross Society and Rajiv Gandhi Cancer Institute. She is also a certified NABH assessor for blood banks.

Dr. Zarin Bharucha
Chairperson, Federation of Bombay Blood Banks

Dr. Bharucha is a expert transfusion consultant with over five decades of experience in transfusion medicine. Apart from chairing the sub-committee tasked with the development of the National Blood Policy, she was integral to the development of the Standards for Blood Banks and Blood Transfusion as the Coordinator of the Technical Resource Group. She has worked with the WHO extensively in drafting Model SOPs for Blood Transfusion Services and has served on the WHO Expert Advisory Panel on Blood Transfusion Medicine, besides being integral to many WHO assignments in other developing nations. In the past, her guidance has been integral in development of many blood banks, and initiating hepatitis and HCV antibody testing in blood donors for the first time in India.

Prof. (Dr.) PR Sodani
Pro-President and Dean-Training
Director, Centre for Health Economics IIHMR University, Jaipur

Prof. (Dr.) Sodani has more than two decades of experience in research, teaching, training, consultancy and management, working in health systems and health economics. He is also the associate editor of the Journal of Health Management and has worked on multiple assignments for Johns Hopkins University, World Bank, WHO, Bill and Melinda Gates Foundation, UNFPA, UNICEF, and other development partners.

Dr. Poonam Coshic
Chief Medical Officer in-charge, AIIMS Blood Bank

Dr. Coshic has previously done extensive work on computerization of blood banks and has served as the technical expert for the procurement of blood bank equipments under the National AIDS Control Programme. She has conducted pioneering research on NAT, platelet pooling, adverse transfusion reactions and apheresis.

Dr. Aparna Singh Shah
Regional Adviser, Health Laboratory Services and Blood Safety, WHO-SEARO

Dr. Shah is the an expert adviser for Blood Safety and Laboratory Services at the WHO - South East Asia Regional Office, where she is responsible for providing technical support for strengthening public health laboratories, antimicrobial resistance detection, biosafety in laboratories and lab networking, as well as supporting blood transfusion services and blood safety. A specialist in in infectious disease and vaccine research, she was previously a a consultant to the International Vaccine Institute, South Korea.

Dr. Paul Ness
Associate Director of the Transfusion Medicine Division, Johns Hopkins Hospital

Dr. Ness is a Professor of Pathology, Medicine, and Oncology at The Johns Hopkins University School of Medicine in Baltimore, Maryland. He has previously served as the President of the American Association of Blood Banks and is the co-editor of two comprehensive texts in transfusion medicine, The Scientific Basis of Transfusion Medicine and Blood Banking and Transfusion Medicine, Basic Principles and Practice. He has also served as a consultant for transfusion medicine activities in developing countries in Africa, China, Thailand, India, and Vietnam.

Team Chase

Ms. Surya Sadasivan, (Moderator)
Practice Lead - Healthcare, Chase India

Ms. Sadasivan has over 12 years of experience in policy advocacy and communications. She has strong expertise in devising result-oriented advocacy campaigns and driving thought leadership programmes, especially on social impact issues. She has deep understanding of a range of policy issues pertaining to healthcare, food and beverages, nutrition, among others. Chase India is India's leading public policy research and advisory firm, and as Practice Lead - Healthcare, Surya has been instrumental in engaging with policy makers, influencers and experts to create and sustain policy discussions on health issues of pressing concern. In addition to blood safety, she is personally committed to campaigns on antimicrobial resistance and mental health.

Ms. Sugandha Mahajan
Manager – Healthcare, Chase India

Sugandha has 9 years of experience in policy advocacy, corporate strategy, marketing and brand communication. At Chase India, she has been instrumental in devising and implementing public advocacy strategies and stakeholder engagement in the area of healthcare. Her expertise lies in initiating and driving multi-stakeholder discussions and consultations on diverse topics, ranging from antimicrobial resistance to blood safety.

Mr. Abhinav Verma
Jr. Associate – Healthcare, Chase India

Abhinav is a young lawyer, with a specialization in international law, who presently supports the healthcare practice at Chase India. His professional and volunteer experiences include work with senior lawyers at the Supreme Court, UN in India, and NITI Aayog.

About Chase India

Chase India is India's leading public policy research and advisory firm with growing practices in healthcare, technology and environment. Chase India organizes policy discussions under its flagship platform the Earth Dialogue that brings together experts from the field of sustainability, environment and climate change to discuss issues of pressing concern. In its past editions, the Earth Dialogue has featured participation from senior officials and experts like Mr. CK Mishra, Secretary, Ministry of Environment, Forests and Climate Change, Mr. Amit Narang, Joint Secretary, Ministry of External Affairs, and Ms. Natalie Toms, Counsellor, British High Commission, amongst others. Chase India's other panel discussions have featured key speakers like Mr. Alok Kumar, Advisor, NITI Aayog, Mr. Rakesh Srivastava, Secretary, Ministry of Women and Child Development, and others. Chase India also recently organized a session on the 'Future of FinTech' in collaboration with the British High Commission.

About Sustainable Health Dialogue

Chase India has been working and conducting policy research on contemporary issues in healthcare and has supported ad-hoc discussion-based events in healthcare. Inspired by that success, Chase India has now established the Sustainable Health Dialogues, a series of policy discussions primarily focusing on developing India's capabilities for achieving SDG-3 (Good Health and Well Being). Sustainable Health Dialogues is a series of multi-stakeholder policy discussions with key persons from medicine, public health research, policymakers and legislators, regulators and industry, in a variety of different formats including roundtable sessions, workshops, panel discussions and task-forces, to deliberate on narrowly-focused topical areas of relevance to the Indian health system.

Disclaimer

CONTACT:

Manash K Neog
Director
manash@chase-india.com

Surya Sadasivan
Practice Lead – Healthcare
surya@chase-india.com

chase|india