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sankalp patrika

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Let's give life a better chance

Fertility sparing cure from thalassemia - now possibile

blood advances™

REGULAR ARTICLE

blood advances

ATG vs thiotepa with busulfan and cyclophosphamide in matched-related bone marrow transplantation for thalassemia

Lawrence Faulkner,[1,2] Cornelio Uderzo,[1] Sadaf Khalid,[1] Priya Marwah,[3] Rajpreet Soni,[3] Naila Yaqub,[4] Samina Amanat,[4] Itrat Fatima,[4] Sarah Khan Gilani,[4] Tatheer Zahra,[4] Stalin Ramprakash,[2] Lallindra Gooneratne,[5] Ruwangi Dissanayake,[5] Senani Williams,[6] Wasantha Rathnayake,[6] Reshma Srinivas,[7] Amit Sedai,[7] Ankita Kumari,[7] Lailith Parmar,[7] Rakesh Dhanya,[7] and Rajat Kumar Agarwal[7]

[1]Cure2Children Foundation, Florence, Italy; [2]People Tree Hospitals, Bangalore, India; [3]South East Asia Institute for Thalassemia, Jaipur, India; [4]Children's Hospital Pakistan Institute of Medical Sciences, Islamabad, Pakistan; [5]Asiri Central Hospital, Colombo, Sri Lanka; [6]Nawaloka Hospital, Colombo, Sri Lanka; and [7]Sankalp India Foundation, Bangalore, India

Thalassemia is an inherited genetic blood disorder that does not allow the production of normal healthy red cells. Bone marrow transplantation from a HLA-matched sibling donor can be a safe option for definitive cure but the chemotherapy used to get rid of the diseased marrow may cause infertility.

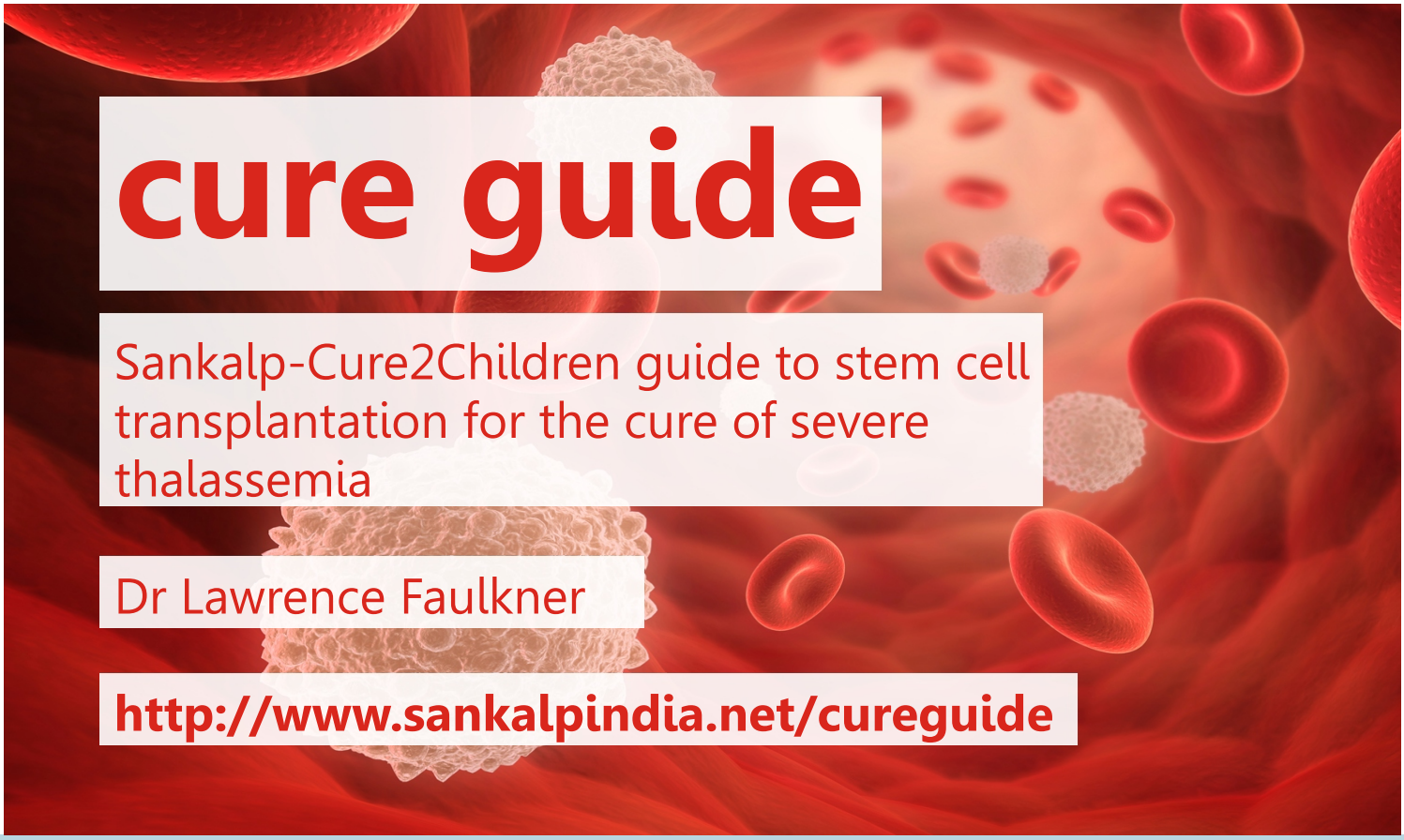
A recent study done in the Indian sub-continent and published in Blood Advances, the official online journal of the American Society of Haematology (ASH), shows that it is possible to achieve a high degree of success in bone marrow transplantation even if drug combinations that are more likely to preserve fertility are employed. This comes as great news for patients who may undergo bone marrow transplantation and increases hope for complete cure with good quality of life.

The study led by Dr Lawrence Faulkner, an Italian doctor who has dedicated his life to the cause of strengthening bone marrow transplantation in the developing world, designed and monitored the medical strategy for transplants done across 5 centres in South Asia namely South East Asia Institute for Thalassemia-Jaipur, Sankalp-People Tree Centre for Paediatric Bone Marrow Transplantation-Bangalore from India, Pakistan Institute of Medical Science- Islamabad from Pakistan, Central Asiri Hospitals-Colombo and

Nawaloka Hospitals-Colombo from Sri Lanka between January 2009 and July 2016. Transplant outcomes were compared between two preparative drug combinations including either Thiotepa or ATG. The study showed that children transplanted using ATG did at least as well as those using Thiotepa - a significant step forward in reducing transplant-associated toxicities.

"The ultimate goal of transplantation in thalassemia is to cure the disease and restore a normal health-related quality of life and avoid infertility, the most relevant long-term problem associated with transplantation. The fact that we already have a few of the little girls who are going into spontaneous puberty after transplant is very encouraging even if it will take a few more years to assess this more rigorously." says Dr Lawrence Faulkner, the Medical coordinator of Cure2Children Foundation and the Program Director, Sankalp-People Tree Centre for Paediatric BMT, Bangalore.

"This is good news in more than one ways. Not only is ATG fertility sparing, but it costs significantly less in comparison to Thiotepa. This study has long-term implications as it shows that curing children from thalassemia not only is becoming safer but also more accessible." – said Dr Stalin Ramprakash, Paediatric Hematologist Oncologist at Sankalp-People Tree Centre for Paediatric BMT, Bangalore.



"Don't let the fear of contradicting yourself, keep you from acknowledging what is right"
- Soami

"With more than 100,000 patients living with thalassemia in India and an additional 12,000 estimated to be born each year, the need to offer a reliable and widely accessible cure cannot be underestimated. Saving a child from a serious medical problem at the cost of compromising his/her fertility maybe hard to accept eventually. We are very happy that the team has been able to establish that the cure for thalassemia can be achieved with decreased long-term toxicities and return to a completely normal life ." - said Mr Lalith Parmar, President of Sankalp India Foundation, an organisation working for the care and cure of thalassemia.

Thalidomide in Thalassemia

Authors:

1. Dr Lawrence Faulkner, MD, Program Director, Sankalp-People Tree Centre for Pediatric BMT, Bangalore;Scientific Advisor - Cure2Children Foundation, Italy

2. Dr Vikramjit S Kanwar MRCP(UK) MBA FAAP, Chief, Division of Pediatric Hematology-Oncology, John and Anna Landis Endowed Chair for Pediatric Hematology-Oncology, Director, Melodies Center for Childhood Cancer and Blood Disorders, Professor, Department of Pediatrics, Albany Medical Center, New York

3. Dr Stalin Ramprasad, MD, Consultant Paediatric Haematology oncology and Bone marrow transplant Institution, Sankalp-People Tree Center for Paediatric BMT, People Tree Hospitals, Bangalore

4. Dr Deepa Trivedi, MD, Program Director, Sankalp-CIMS Centre for Paediatric BMT, Ahmedabad; Hemato-Oncology Clinic Vedant Institute of Medical Sciences Navrangpura,Ahmedabad

5. Dr Reshma Shrinivas, Medical Officer Incharge, Project Samraksha - Thalassemia Day Care Centre, Rashtrotthana Parishat, Bangalore

There has been an increase in the number of patients seeking to know the position of Sankalp - Cure2Children Network's position on the use of Thalidomide for treatment of thalassemia. The following is the position of Team Sankalp-Cure2Children as of date.

Fetal haemoglobin induction may reduce transfusion dependence

Patients with beta thalassemia are unable to make normal haemoglobin but can make fetal haemoglobin. Increasing this production of fetal haemoglobin using medications (HbF induction) is a recognised approach to reduce transfusion dependence as reported in a comprehensive review in the journal Blood in 2013 [1].
Role of thalidomide and safety concerns

Thalidomide is one drug that has been reported to increase fetal haemoglobin where reports have mentioned the use of drug in un-transfusable patients[2,3] or in settings where transfusions are difficult. The initial reports while acknowledging the role of the drug have pointed to the need for further scientific work [1,2,4] to determine safety and efficacy. There is no peer reviewed data even from pilot studies evaluating the safety of the drug for thalassemia. A recent report of stroke in a patient receiving thalidomide highlighted the risk of the drug [5], and thalidomide-associated birth defects are also well documented(https://www.ncbi.nlm.nih.gov/pubmed/?term=thalidomide+pregnancy).

Need for scientific work to establish safety and efficacy

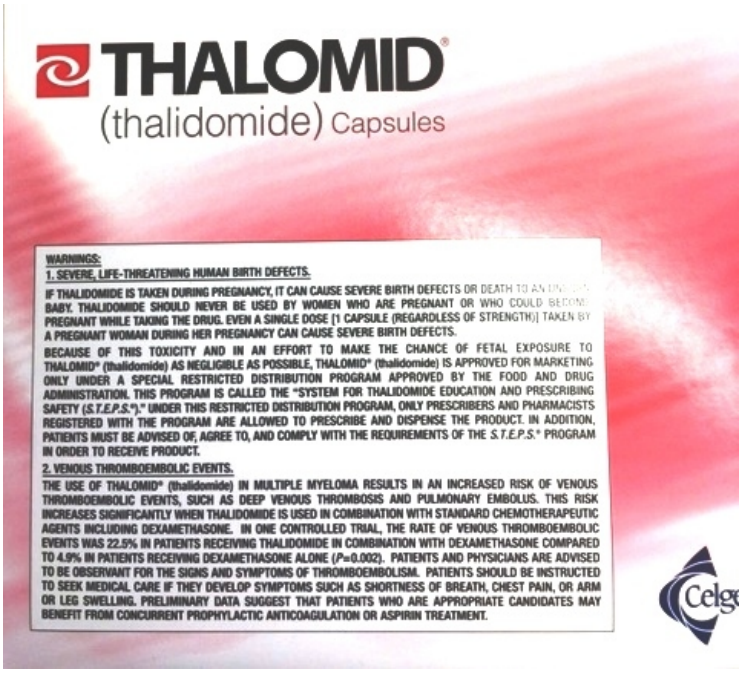
In a 2016 article from the journal Blood Lowrey et al. noted that HbF induction using 5-azacytidine and later hydroxyurea (HU) could provide clinical benefits to patients which led to HU becoming the first, and so far only, FDA-approved HbF-inducing agent. Hydroxyurea is not an idea drug because is not an ideal drug because blood counts of patients must be closely monitored and it is effective only in less than half of β-thalassemia patients. Continued research to identify HbF-inducing agents that demonstrate long-term safety, high response rates, and ease of use such that they can be applied to most patients, including those who lack access to modern medical facilities has led to many active agents being described, including thalidomide, and derivatives such as pomalidomide and lenalidomide but the known risks of pomalidomide include birth defects, blood clots and low blood counts and lenalidomide has been associated with increased risk of secondary cancers.[6]

Summary of the current situation

The current evidence and scientific data bring out the fact that while thalidomide and related drugs may induce fetal haemoglobin, their safety and efficacy remains unproven, and well described risks exist.

How could reports of any complication or death help other thalassemia patients?

If any doctor can relate a complication or death to the use of thalidomide, it is very important they file a report using the Adverse Drug Reporting Form of the Pharmacovigilance Program of India



(http://www.ipc.gov.in/PvPI/adr.html). In addition it would be ideal that they publish the case in a peer-reviewed journal to contribute further knowledge about this drug.

Our stand

In the absence of reliable evidence on safety, with known side effects and the need to monitor aggressively for complications, thalidomide and other related agents should not be used to treat thalassemia outside the confines of a clinical study. If used as second-line therapy in the absence of a clinical study, such "off label" treatment should not be offered without well documented informed consent that explains the standard care available, why it was felt necessary to use this drug and potential risks of such therapy.

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We are happy to share that our work related to the HLA typing requirement has been accepted for publication in the official journal of the American Society of Blood and Marrow Transplantation. We hope that the findings are useful to improve the safety of bone marrow transplantation.

Sankalp-CIMS Centre for Paediatric BMT is up and running and other news from Thalassemia Cure

Picture from a few months back. 3 of these 4 kids have been transplanted and cured while the fourth is getting ready to be admitted.

A few months back we announced the starting of Sankalp-CIMS centre for Paediatric BMT at CIMS Hospital, Ahmedabad. We are happy to share that the new centre continues to deliver upon the promise of excellence in transplantation for thalassemia. Typically, the first few months of a BMT unit are the most difficult period. We are glad to share that keeping in-line with the tradition of the Sankalp-Cure2Children Network for BMT, the first five children who have undergone transplantation are doing very well. Two kids are back home with their families while the other three are in the step down accommodation provided to the families in our program. The staff in our unit have no time to celebrate as they have the next group of kids in the unit eager to take all their time and attention.

It was heartening to see the Bangalore nursing team guiding this new team at Ahmedabad in running the unit efficiently in no time. Since both the centres use BMTPlus, our software platform for transplantations and the units share similar protocols and procedures, the two teams could work together seamlessly.

While the transplant unit is busy, still busier is the outpatient department for the pre-transplant preparation. As we have shown, with persistent and well directed efforts, it is possible to reduce the risk

with which the child proceeds for transplantations. Those children who have a match are undergoing a process of down-staging with regular monitoring – with the intention of reducing the risks prior to transplantation. This includes attempts to reduce the serum ferritin levels, control the liver and spleen enlargement and undertake thorough medical screening.

OPD at Mumbai

In order to aid the children who belong to Mumbai and are likely to get transplanted outside the city, we started a weekly follow-up clinic with the help of Dr Sangeeta Mudaliar and her team at B J Wadia Children's Hospital in Mumbai. Even this little initiative is up and running in full swing.

Visit to Dehradun

Following the invitation of Himalayan Thalassemia Society, Dehradun, we visited Haldwani and Dehradun for an HLA typing cum awareness event. The learning from the process of setting up of the several day care centres comes handy in such events as the problems faced by the children are more-or-less the same. Uttarakhand is unique in the sense that all blood products, chelating agents, labs and even filters are funded by the state government for all children undertaking treatment at public healthcare setups, while those in the private setup receive the blood products and chelators. And yet, most of the children continue to be poorly managed.

As we interact with more groups, our conviction that a single point, data driven strong day care centre is crucial to the delivery of care for thalassemia – at-least for those patients who are constrained by resources and education. We are working together with the team there in an attempt to find the way forward.

* * *

PERFORMANCE REPORT

Sankalp Program For Thalassemia Management

Centers	Total Patient Visits (patients)	Number of units of blood transfused (units)	How many day old blood units were transfused (days)	Time taken to process blood components (hours)	Pre-transfusion Hemoglobin (g/dl)	Share of blood units from attached blood bank (%)
			<7: Good 7-10: Average >10: Bad	<2: Good 2-3: Average >3: Bad	>9: Good 8-9: Average <8: Bad	>95%: Good 90-95%: Average <90%: Bad
Indira Gandhi Institute of Child Health	361	443	3	2.8	9.1	96%
Project Samraksha	373	447	3	3.0	9,1	100%
KLE Belgaum	237	229	2	2.0	8.8	100%

Sankalp Program For Thalassemia Cure

	Total HLA typings	Total number of children offered Bone Marrow Transplantation	Total number of children cured of Thalassemia by Bone Marrow Transplantation
This year	910	18	18
Total	2742	69	59

Bombay blood group network

	Total bombay blood group requests	Number of units organised off the shelf	Number of units donated
Last month	19	10	6
This year (cumulative)	43	17	11
Last year	71	18	21

June 2017

Rakta Kranti - The Blood Revolution

	Blood Donation Camps	Total Donors	Total Units Collected	Rate of Post Donation Complications	Rate of Donor Deferral
				<2%: Good 2-4%: Average >4%: Bad	<10%: Good 10-15%: Average >15%: Bad
This month	27	3546	2952	5.0%	16.8%
This year	64	6829	5888	4.1%	15.9%

Thanks to the following orgnisations for having supported us to ensure continued supply of safe blood to the needy

AIG
Bosch
CGI
Continental
Cox and Kings
Huawei
Inteva
Lido
Medi Assist
Red Hills High
Redington
Samsung
Societe Generale
VFC
Wipro
WNS

Disha Statewide Blood Helpline - 9480044444

	Total Blood requests on the statewide help-line	% of blood requests satisfied by existing blood bank stocks	% of blood requests from outside Bangalore
Last month	661	79%	21%
This year (cumulative)	1784	84%	25%
Last year	6348	84%	27%

For any queries or suggestions, please write to sankalp.admin@gmail.com

Demand for Replacement – a disease we continue to suffer from

This **World Blood Donor Day**

let us

#StopReplacement

Sign petition on change.org

In 2003, we saw a man die in an ICU. The family of the man was running from pillar to post looking for blood donors! The pain, agony and helplessness led to the formation of Sankalp India Foundation. For some time after that, we continued to see blood banks as institutions where blood should be provided when when there is a need. We continued to maintain donor lists! As we worked through the blood requests - we realised that by waiting to donate blood when people need, we were actually ensuring that the family goes through very anxious time. We realised that we had to rush donors to the blood bank. What if the same donor who donates in an emergency had donated as and when he/she was free? What if blood bank had plenty of blood available in the blood bank - so much that the blood bank need not have to ask for replacement or wait for donors? Trusting the innate goodness of all, we accepted our mistake, said a good bye to our databases and switched to voluntary blood donation program in a true sense.

It was only after some time that we realised that the

shortage of blood in the blood banks was often artificially created. Many blood banks did not intend to go for outdoor blood donation camps. There was a large group of blood banks who did not feel the need to go and participate in outdoor blood donation camps. A blood donation camp is reasonably time taking and effort intensive for the blood bank. They felt that by arm-twisting the families of the patients coming to their hospitals for replacement donation, they could continue to have a beeline of blood donors and avoid participation in blood camps.

"14 years on the fight is still on! We are ashamed that we still have more than half of the blood banks - almost every blood bank attached to a private hospital, who are unwilling to participate in outdoor blood donation camps. We are ashamed that they continue to harass families to bring in donors. So deep is the rot, such open is the show that it is almost advertised as a new form of philanthropic opportunity."

Do we really need to wait till a person pleads us to donate blood? Should blood banks not keep enough blood in stock all the time?

The answers are one sided and clear - blood banks need to take the responsibility of organising blood! If they can't, they must SHUT DOWN! However, the larger question is how long will it take for we the people to recognize this deep rooted rot in our blood banking tradition and take a stand against blood banks demanding families to provide replacements.
Please support the cause we fight for.

Please also express disagreement and oppose us with the power of arguments and logic as much as you like.
But, please do think.

One single intervention has the power not only to save lives, but also save blood and improve general well-being our our most special population - women and children.

Fighting iron deficiency anemia in schools and pregnancy are arguably the most simple and cost effective strategies to save lives and add value to it.

Call us to get involved.

"Success follows doing what you want to do. There is no other way to be successful."
- Malcolm Forbes

Managing Bombay blood group requests – how does the team do it?

One would often wonder how Sankalp's emergency team manages to handle a multitude of request of Bombay blood group day after day.

Just within June the organisation got 19 blood requests for Bombay group patients. These were requests for 34 units of blood with 26 requests indicating the need for immediate transfusion.

All the requests were attended to and addressed and yet we could manage all that with only about 8 donations. Here we share the experience summarised by our team for a brief period of 10 days within the month of June. This gives insight into how much work, planning and management goes into ensuring that each patient is kept safe in-spite of the very few donors and available units.

BombayBloodGroup.Org tracks all the blood units reported by blood banks, either which were donated for some other patient who no longer needs them or the units which were collected without prior knowledge that they are Bombay blood group. When there is a request for units, the team explores the option to move the units which are available on the shelf under temperature controlled condition first, before exploring the option to get the units donated. In June, within 10 days the following is the list of blood units which were moved around coordinated by the organisation:

- One unit which was collected from voluntary walk-in blood donor in Hosapete was moved to Davanagere
- One unit available in Ramnagara was moved for a patient in Mysore
- Two units were shifted from Bangalore to Hyderabad
- One more units was moved from Hosapete to Hyderabad

Beside finding the units off the shelf, when units were not available we got the donations done. Within 10 days we had

- Two donation in Bangalore
- Two donation in Durg-Chattisgarh
- One donation in Hyderabad

The team still had several open blood requests and the knowledge of one unit being available on the shelf in Mangalore.

There is a fine balance to be kept between having enough blood for patients and ensuring that the units available on shelf don't go waste. Additionally, the known Bombay blood group donors need to be guarded against emotional blackmail and undue stress oriented towards coercing them to donate blood. The team managing Bombay blood group requests puts in effort to ensure this fine balance is not disturbed.

We thank all the blood donors and the involved blood banks who walk the extra mile to ensure that Bombay blood group continues to be available for each patient in need.

Landmark month of June 2017 - 27 camps and 2952 units of blood

June 2017 was the a landmark month in Sankalp's quest to ensure that no one suffers due to shortage of blood. We had a whopping 27 camps with a total of 3546 willing donors and 2952 units of blood donated (at an average of nearly 100 units of blood collected each day), camps which happened during the summer shortage and the peak dengue period - the time of low blood donation camps and thereby severe shortage of blood in the city of Bangalore. Colleges, which contribute a significant portion of the blood units do not organise blood drives from April to June leading to shortage. Knowing the issue well in advance we invest in months of intense planning to ensure that blood supply to the city was maintained. This year has been a landmark as 22% of the blood units we collected in the whole of last year got collected in a single month. In one way we are quite lucky that world blood donors day falls in this period - on the 14th of June. That day in particular we had 3 huge blood donation drives involving 5 blood donation drives.

We would like to congratulate the donors and the corporate partners who participated in this mission to ensure safe blood off the shelf for each patient. Infact, we had 2 major organisations postponing their drives by a couple of months due to sudden internal issues. Should those drives also have been held, the number would have touched 3600+ units collected.

We believe in better distribution of blood

Our aim is to ensure more collection of voluntarily donated blood. However, we also believe that one blood bank in a day must not collect more than 150-180 units of blood. The aim is to find more quality

compliant and transparent blood banks willing to do the right things and ensure distribution of blood across the blood banks.

Therefore in the month of June we involved 6 teams from across the city - including 2 government, 1 voluntary and 3 hospital based blood banks to collect the 2952 units

Happy Donors – Happy Us

This month we built a stronger bond with our voluntary blood donor heroes. Along with the blood donation drives, this month we also went hard on our stop replacement campaign. In most of the blood donation drives, Sankalp team members carried posters and stickers asking people to support the stop replacement campaign. At the post donation areas where people sit down to have snacks and refreshments, they were explained about the menace of replacements and asked to support the campaign by signing up on change,org. The response shown by the donors was phenomenal. Many donors were able to relate to incidents in their own lives when hospitals had forced them to organise for blood and they used to run helter skelter in search of blood donors. Many donors took out their phones and immediately scanned the QR code or logged on to the link and signed up supporting the petition. Some of them even took photos of the same and promised to propagate the message. Incidentally, in one of the drives a donor in the enthusiasm of getting more people to support the campaign took the poster away with him leaving the volunteers and people running the drive wondering what happened to the poster.

One of these drives was held in the blood bank where our Samraksha day care centre is run. Volunteers who donated blood also spent quality time with the kids who had come for transfusions on that day - playing with them, singing , dancing with them and spending time in storytelling. Such blood donor heroes prove that the spirit of voluntary blood donation can inspire one to do more.

Deferrals continue to be a concern

The gaping 17% blood donor deferral rate continues to be a matter of concern. Even as we summarise the 1500+ reports of donor deferral which we have collected over the last few quarters, it remains clear that there is a need for a clear and detailed guideline indicating who can donate and who cannot. Currently, the assessment of suitability of the donor to donate blood continues to be vague and in some scenarios even lacking sound basis of evidence. While Sankalp has tried to address the same in our camps, leading to donor deferral coming down from about 20% to 15%, the need for national guidelines is clear. The key issue that while the Drug Controller and National AIDS Control organisation continue to talk about conditions for deferral, they do not explicitly discuss the acceptance and deferral criteria for each condition. For example, while the guidelines mention diabetes, hypertension and alcohol intake, all three conditions which have very high incidence in society, they fail to address the details within these conditions. WHO had published "Blood donor selection: guidelines on assessing donor suitability for blood donation" and this is supposed to be the initial document for countries to start develop their own context specific guidelines. Unfortunately, there has been little progress from the central agencies adopt these guidelines as well as modify them as per local context. We were in for a rude shock when the much awaited update from the

National Blood Transfusion Council on the issue turned out to be a lukewarm clarification of some of the condition rather than a comprehensive guidance document. In-fact we believe that our policy on deferrals, drafted in 2015 is a great reference on this topic, especially in the Indian context

Reducing inconvenience and injury to donors

Solving any problem starts with the admission of the existence of the problem and the 3-5% donors facing post donation complication is one such reality. As an organisation, we continue to face situations where potentially more could be done to reduce inconvenience to donors. The high attrition rates and the poor human resource management are problems preventing the Indian healthcare system from performing to its capacity. Thanks to the same issues, limiting donor inconvenience has been an exceptional challenge. We have worked closely with partner organisation to help them identify root cause and enable them to strengthen their strategy for prevention of complications. Nevertheless, the rate of control continues to be a challenge left to be addressed with June still witnessing 5% overall rate of complications.

This point has been brought up time and again. Blood banks must get well trained technicians and staff nurses for phlebotomy. One bad hematoma can cause serious mental damage to the donor. Some such donors in the fear and apprehension that they have developed an infection put in a note of complaint to their HRs. Mails with photographs of the site of phlebotomy are circulated internally causing panic. Sankalp has received atleast 2 major complaints in the month of June. Both the cases were duly investigated and the reason for the hematoma were nailed down. Wherever it was a problem associated with an untrained resource, it was taken up with respective authorities. Yet, significant efforts have been made to ensure that donors who face these complications do not feel discouraged to donate again in future. Therefore, each person who faces a complication is duly counseled and also given a handout listing the points to take care should they feel further discomfort. The brochure also gives our emergency contact number asking people to call back immediately if there is a situation which is bothering them. As per the rigorous protocol followed at Sankalp, the donors are reached out to on phone the next day to check if there were any further reasons to be concerned about. Only after the donor confirms that he/she has been doing well does our team feel satisfied.

Blood on shelves saves lives

Sankalp continues to strongly advocate that the good time to seek blood donors is not when there is a patient in need of blood inside a hospital. We continue to maintain that if the donors are approached in a proper manner, with safe environment to donate blood, with ease and convenience, we as a society are happy to contribute to save our brethren. We do not take pride in rushing donors to hospitals on urgency this which could mildly be put as emotional blackmail. Rather, we prefer to toil in blood donation camps ensuring that adequate number of blood units are available off the shelf for any patient in need. Fewer emergency calls, fewer donors being rushed, fewer patient families having to go through breath-stopping moments are the reward that each voluntary blood donor, their organisations and Team Sankalp gets for ushering in the era of voluntary blood donation.

Hi Sankalp!

Please get in touch for any of the following

Sankalp Emergency Team

- Seek assistance for arranging blood in extremely difficult situations
- Donate platelets voluntarily and help ensure platelets on shelf all the time.
- Learn about strategies and technologies for conservative and rational management of blood.

Bombay blood group network

- Register if you are a person with Bombay blood group
- Inform if you have Bombay blood group on your self
- Request if you need Bombay blood group

Statewide Blood Helpline

- Call 9480044444 when in need of blood anywhere in Karnataka

Rakta Kranti

- Organise blood donation camps
- Learn about organising safe and effective blood donation camps
- Form a Team Red - a team of volunteers who help propogate the message of blood donation
- Volunteer in our blood donation camps

Thalassemia Prevention

- Opt to get tested for thalassemia and other related hemoglobin disorders
- Organise a drive to get people around you tested
- Assistance for antenatal testing for parents who are at risk of getting a child with thalassemia

Thalassemia Management

- Support the treatment and management of a child suffering from thalassemia
- Refer a patient who is in need of help for thalassemia treatment at our centers
- Seek advice on management of thalassemia

Thalassemia Cure

- Refer a child suffering from thalassemia for free HLA typing
- Refer a child for Bone Marrow Transplant
- Donate towards Bone Marrow Transplant of a child
- Seek advice on options for cure for families with thalassemia

Contribute

- Make a donation - help us do more of what we do
- Volunteer - join us to make a difference!
- Share your experience and problems

From:

Call: 9480044444 |Visit: www.sankalpindia.net
Mail: contact@sankalpindia.net
Address: #460, "GOKULA", 8th Main, 4th Block, Koramangala, Bangalore - 560034

To:

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