

Sankalp-CIMS Center for Paediatric Bone Marrow Transplantation Inaugurated in Ahmedabad



A new hope, a new silver lining has surfaced for little children suffering from the pain and burden of thalassemia. A new Bone Marrow Transplant unit (BMT) with an exclusive focus towards treating children with thalassemia has been jointly established by Sankalp India Foundation, Bangalore, Care Institute of Medical Sciences (CIMS Hospital), Cure2Children, Italy at Ahmedabad. This unit is part of a unique network of BMT centres in the country and first of its kind in Gujarat, with an exclusive focus on thalassemia.

The centre was officially inaugurated on 6th May 2017 by Ms Jasmine Majethia, who is a thalassemia champion and a member of the advisory board of Sankalp India Foundation. We are grateful to the sponsors: Amit Iyer Memorial Foundation, Jai Shiv Shakti Health and Education Trust, Ghelani Charitable Trust and Kalpatru Trust, whose generous financial contributions will give several children a new ray of hope.



While Dr Milan Chag spoke of the CIMS vision of the program, Mr Lalith Parmar took the audience through the Sankalp BMT program and its contribution to thalassemia cure. Dr Lawrence Faulkner and Dr Deepa Trivedi spoke about how the BMTs to be performed at this centre are going to be beneficial to the children not only in terms of curing them of the burden of thalassemia in an immediate sense, but also in terms of long term benefits of using less intense yet effective treatment regimen. Mr S V Iyer, member advisory board of Sankalp stressed on the need to develop a culture of mandatory screening for women in their first pregnancies so as to avoid future birth of thalassemics in our country.

Sankalp India Foundation will be managing and operating the entire unit. Sankalp will take care of the

financial, socio-economic and patient management aspects at the centre. Sankalp has also forged relationships with several other partners to be able to set up the unit at minimal cost and yet offer quality care.

“This joint program is a conglomeration of three organizations, who believe that no child with thalassemia, if eligible for transplants should be denied the same, either due to lack funds or facilities. We have ensured that working on a NOT FOR PROFIT does not mean compromised care” says Lalith Parmar, President, Sankalp India Foundation.



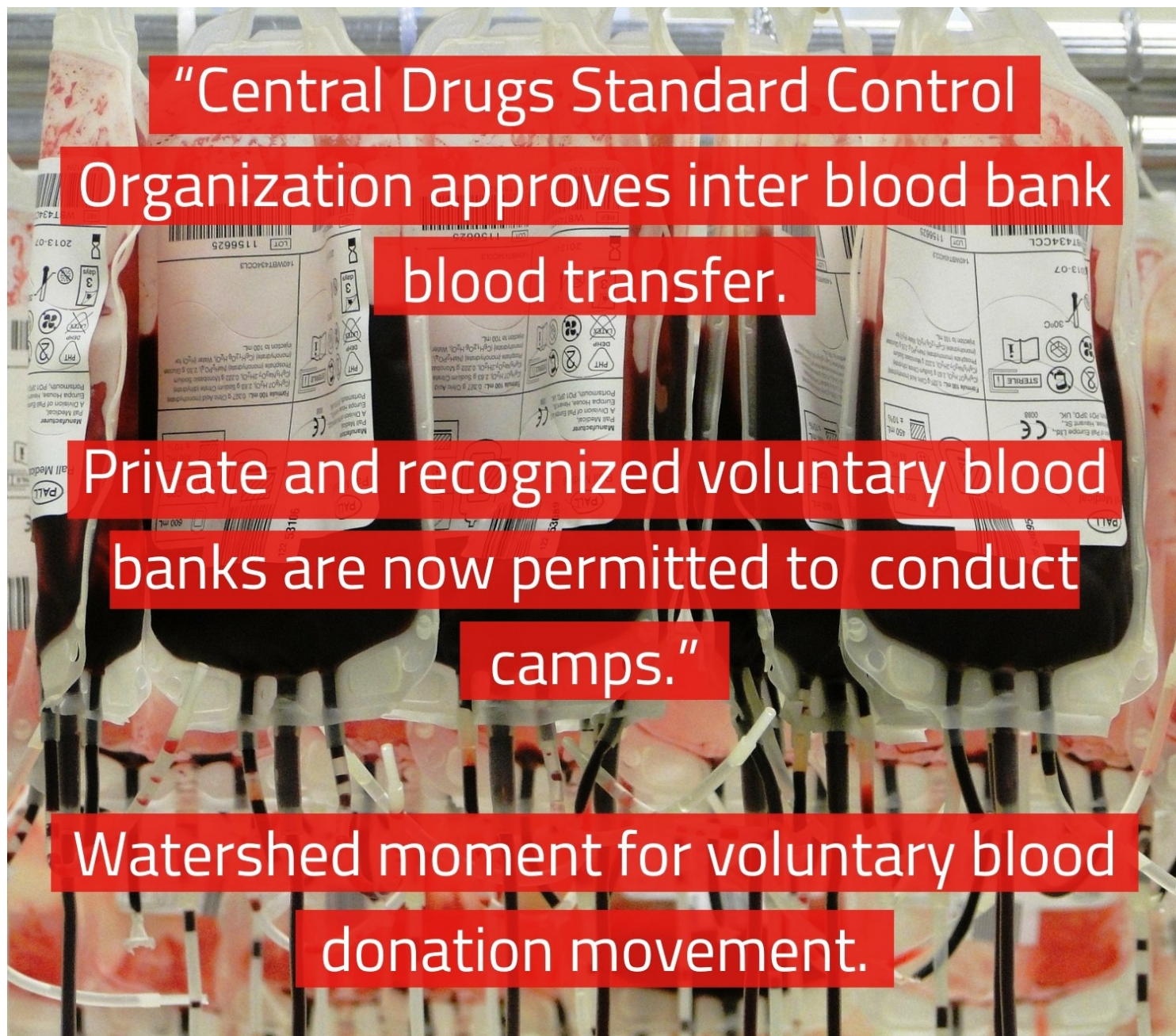
The world's first dedicated software platform for Bone marrow transplant, BMTPlus, developed by Sankalp's technology partner – Jagriti InnoHealth Platforms Pvt Ltd is being used as the platform where patient's daily treatment routines are tracked by all concerned. CIMS Hospital has always been active in creating not only world class medical centre of excellence but making high end treatment facility for childhood diseases affordable to all.

'By taking such a unique non profit initiative by starting paediatric Bone marrow transplant unit, we extend our hands

towards this noble cause" says Dr. Amit Chitaliya , Director Of Paediatric Critical Care Services- CIMS Hospital.

The first set of patients have already been admitted and are on their treatment course. It is being planned that over the next one year more than 20 children will have been cured. It is also expected that in due course of time patients from several other centres in the country may be benefitted by the services offered by the centre.

Drugs and Cosmetics Rules amended: Inter blood bank transfers permitted; Permission for camps liberalised



In Volume 6 Issue 4 (April 2016), Sankalp Patrika had reported that "Bulk transfer of blood between blood banks of all sectors permitted by NBTC". This one decision cleared a large number of roadblocks in the path of proper utilisation of blood. In spite of the decision from National Blood Transfusion Council, and endorsement of the decision by several state blood

transfusion councils, several blood banks were reluctant to utilise the new provisions as the Central Drugs Standard Control Organization, the regulator of blood banks in India was silent on the issue. We are pleased to inform our readers that government has amended the amend the Drugs and Cosmetics Rules, 1945 on April 3rd 2017 with the gazette notification

number, permitting the transfer of blood from one blood bank.

A serious roadblock in the direction of enabling 100% voluntary blood donation has been the hospital based blood banks which continue to seek replacement blood donations. These blood banks very rightly, blamed the fact that many of them were not permitted to organise

blood donation camps leaving them with an option other than seek walk in blood donors. In a remarkable decision, within the same order, the government has permitted both private hospital based blood banks and a licensed blood bank run by registered voluntary or charitable organisations recognised by the respective blood transfusion council to organise blood donation camps.

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REGD. NO. D. L.-33004/99



भारत का राजपत्र The Gazette of India

असाधारण

EXTRAORDINARY

भाग II—खण्ड 3—उप-खण्ड (i)

PART II—Section 3—Sub-section (i)

प्राधिकार से प्रकाशित

PUBLISHED BY AUTHORITY

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नई दिल्ली, सोमवार, अप्रैल 3, 2017/चैत्र 13, 1939

No. 261]

NEW DELHI, MONDAY, APRIL 3, 2017/CHAITRA 13, 1939

MINISTRY OF HEALTH AND FAMILY WELFARE

(Department of Health and Family Welfare)

NOTIFICATION

New Delhi, the 3rd April, 2017

G.S.R. 328(E).— Whereas the draft of certain rules further to amend the Drugs and Cosmetics Rules, 1945 was published as required by sections 12 and 33 of the Drugs and Cosmetics Act, 1940 (23 of 1940) in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), dated the 2nd February, 2017 vide notification of the Government of India in the Ministry of Health and Family Welfare, number G.S.R. 101(E), dated the 2nd February, 2017 for inviting objections and suggestions from all persons likely to be affected thereby before the expiry of a period of forty-five days from the date on which copies of the Official Gazette containing the said notification was made available to the public;

And whereas the copies of the said Gazette were made available to the public on 2nd February, 2017;

And, whereas, objections and suggestions received from the public on the said rules have been considered by the Central Government.

Both these decisions are nothing short of a watershed moment in the path to achieving the national goal of 100% non-remunerative voluntary blood donation by the year 2020. With the government taking note of and allowing two significant demands of the blood banking community, the impetus is now on the blood banks to use these provisions to strengthen their mission to make available voluntarily donated blood for all patients. Together with the voluntary organisations, it is their responsibility now to do enough to reach out to

the community and motivate adequate number of voluntary blood donors.

We would like to congratulate and thank the Government of India, the Central Drugs Standard Control Organization and the National Blood Transfusion Council for these decisions.

Now, therefore, in exercise of the powers conferred by sections 12 and 33 of the said Act, the Central Government, after consultation with the Drugs Technical Advisory Board, hereby makes the following rules further to amend the Drugs and Cosmetics Rules, 1945, namely:-

1. (1) These rules may be called Drugs and Cosmetics (Eighth Amendment) Rules, 2017.
(2) They shall come into force on the date of their publication in the Official Gazette.
2. In the Drugs and Cosmetics Rules, 1945, (hereinafter referred to as the said rules) in rule 122 P, after item (xiii), the following items shall be inserted, namely:-
“(xiv) The whole human blood and blood components may be transferred, under prescribed storage conditions, to another blood bank which have facilities to store and monitor blood distribution.
(xv) The recipient blood banks shall not further transfer units obtained from another blood bank except to another blood storage centre or a patient.”
3. In the said rules, in Schedule F, in Part XII B under the heading “II. BLOOD DONATION CAMPS”, after item (c), the following items shall be inserted, namely:-
“(d) a licensed blood bank run by registered voluntary or charitable organization recognised by State or Union territory Blood Transfusion Council; or
(e) a private hospital blood bank.”
4. In Schedule K to the said rules, in item 5(B), under the column relating to extent and conditions of exemption, condition (2) shall be omitted.

[F. No. X.11035/290/2015-DFQC]
K. L. SHARMA, Jt. Secy.

Note.- The principal rules were published in the Gazette of India vide notification No. F. 28-10/45-H (1) dated 21st December 1945 and last amended vide notification number G.S.R. 303 (E) dated 30th March, 2017.

SARVESH KUMAR
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Above: Friends at Cargill found a novel way to invite people to donate blood. They organised a flag march through their office both letting people know that the blood donation camp was happening and encouraging them to come forward to donate blood.

Below: After a wait for 2 long years and intense medical efforts to prepare her for transplantation, finally Joshitha from Hyderabad was cured of thalassemia. The little one is doing very well.















"It may seem a strange principle to enunciate as the very first requirement in a hospital that it should do the sick no harm."

- Florence Nightingale

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	301	402	 10	 1.8	 9.0	 98%
Project Samraksha	365	454	 2	 2.8	 9.0	 100%
KLE Belgaum	214	213	 3	 3.0	 10.0	 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	5	2
Total	2742	56	43





Bombay blood group network

	Total bombay blood group requests	Number of units organised off the shelf	Number of units donated
Last month	13	4	4
This year (cumulative)	13	4	4
Last year	71	18	21

April 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	17	1219	1103	 3.4%	 15.4%
This year	17	1219	1103	 3.4%	 15.4%

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

Aegis
AMD
Artech
Azim Premji University
Bangalore University

Cargill
HSBC
Jawaharlal Nenru Center for Advance
Scientific Research
Marvell
Microchip

Qualcomm
Sankalp Semiconductors
Seagate
Star Bazaar

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	398	87%	32%
This year (cumulative)	398	87%	32%
Last year	6348	84%	27%

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

Minimising and monitoring the transfusion transmitted infections in thalassemia patients

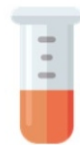
Recently, there was a news of 35 patients who were undergoing regular management for thalassemia in Civil Hospital Jalandhar being detected with Hepatitis C. This is not the first time such news has come out in open. This news comes as a shock. Can something be done?

Often, post the breaking of a news of large number of patients getting TTIs, there is a fair amount of short term media attention, public debate, blame game and worst of all fear and distrust among the stake-holders. However, such revelations only point to the failure of a proper strategy to prevent and handle such occurrences. At the end of the day, it is very questionable what end benefit do such expose bring. Without the ability to pinpoint the real reasons, often the culprit humans, procedures or equipment go undetected. Instead, the process tends to wrap itself up with demands for more expensive and complicated tests and adoptions of newer technologies. On a longer run, this is harmful to the system.

Without going into the details of this one episode, we are sharing some simple steps which could be followed by organisations involved in care and management of thalassemia to minimise and monitor transfusion transmitted infections(TTI). We hope and believe that these steps will help strengthen the overall care and management for thalassemia all over the country.



Source blood from limited blood banks



Screen transfusion transmitted infections every 3 months



Keep track of the overall rate of reactions



Immunize wherever possible



Keeping staff safe is paramount

Source blood from limited blood banks

We should ensure that blood for the children who are undergoing thalassemia management is sourced from limited number of blood banks preferably a single one. Those blood banks which rely heavily or totally on voluntary blood donors and those which are known and reputed to be rigorous in their adherence to the guidelines for blood transfusions medicines tend to be safer sources for blood.

The events of the child receiving blood from other blood banks should be kept as low as possible. Such transfusions could be dangerous because we still have some blood banks operational which have very poor track record of pursuing quality and safety. Additionally, if the patients receive blood from multiple

blood banks, the chances are that in the unfortunate event of a TTI being detected in future, connecting the dots backwards to the source of infection becomes impossible. Each unit transfused should be carefully recorded with the blood bag number, date of collection and name of the source blood bank for each patient in a reliable and traceable manner.

Screen for transfusion transmitted infections every 3 months

This is in-line with the recommendations for chronically transfused patients. Testing the patient for HIV, Hepatitis-B and Hepatitis-C every 3 months leads to early identification of the TTIs. When a new patient joins the centre, they should be screened for TTI so as to differentiate between infections acquired after joining the centre and those which the patient came with.

If a child has acquired an infection, the institution could proactively look at the transfusion history and try to establish a potential source. It is scientifically impossible to point to a single source with certainty, but such an exercise helps limit the potential sources to selected few and provide valuable insights. If repeated pattern is seen, with children acquiring TTI in spite of sourcing blood from selected blood bank exclusively, it indicates the need to review the donor recruitment and blood screening strategy.

Keep track of the overall rate of TTIs

Keeping track of the overall TTI rate is a very powerful strategy. It makes it possible to benchmark the rate of infections with peers a time tested and effective way to identify abnormal situations effectively. This also allows picking up changes in the TTI rates soon after

some change has contributed to it. Sometimes, recent changes like change in the test kits, technology for screening, change in operator etc. could be linked to increased rate of reactions giving valuable insights into the root cause of the issue.

Immunize wherever possible

Hepatitis-B is one of the infections against which immunisation is now universally available in India. It's very essential that the centre ensures that all patients who are receiving regular transfusions are immunised adequately.

Keeping staff safe is paramount

A very compelling reason to ensure regular monitoring of TTI in chronically transfused patient is the safety of the staff members. Just because patients suffering from inherited blood disorders like thalassemia do not present themselves as sick children (if well managed and taken proper care of), the staff should not become negligent towards personal safety.

Every procedure should be done in-line with the guidelines to prevent exposure to patient's blood. If there is accidental exposure to patient's blood like it happens in case of needle stick injuries, immediately the guidelines for post-exposure prophylaxis should be followed. The staff must be kept aware of the patient's TTI status. However, the need to ensure that the patients do not feel stigmatized and singled out cannot be over stressed. Proper sensitization of the team on handling patient with TTI and regular training on the same is essential.

We hope this is helpful. More suggestions are invited.

Drug promises to reduce maternal mortality by a third



Tranexamic acid could significantly reduce deaths due to post-partum haemorrhage.

Maternal mortality continues to be a significant challenge across the developing countries and particularly relevant to India. Post-partum haemorrhage is the leading cause of maternal death. Tranexamic acid is a widely available and inexpensive drug which is routinely used for trauma patients to reduce death due to bleeding.

Outcome of a large trial was published in the highly reputed "The Lancet" journal[1] which assessed the impact of early administration of tranexamic acid to women with post-partum haemorrhage on mortality, hysterectomy and other relevant outcomes. The study concluded that giving

this tranexamic acid significantly reduces maternal deaths and if given within the first 3 hours of start of bleeding may reduce up-to a third of all related deaths.

Tranexamic acid belongs to a class of drugs called antifibrinolytic. It works by preventing blood clots from breaking down too quickly. This helps to reduce excessive bleeding[2].

The study conducted between March 2010, and April, 2016 involved 20 060 women aged 16 years and older with a post-partum haemorrhage after a vaginal birth or caesarean section done in 193 hospitals in 21 countries. Half the women were given tranexamic acid

while the other half were given a placebo. Death in the tranexamic acid group significantly reduced to 1.5% as compared to 1.9% in the placebo group. The impact was more pronounced in the women who received the intervention within 3 hours of childbirth (1.2% in the tranexamin group versus 1.9% in the placebo group). No other adverse effects were observed in the tranexamic acid group.

The authors concluded "The administration of tranexamic acid to women with post-partum haemorrhage reduces deaths due to bleeding and laparotomy to control bleeding with no evidence of any adverse effects or complications. When given soon after delivery, tranexamic acid reduces death due to bleeding by nearly one third."

To establish the role of tranexamic acid in PPH was an active research question even for WHO[3]. Though the drug was already part of the recommendations, with the current study, the recommendations have backing of a strong evidence. In addition, the current study puts tranexamic acid as a candidate for the frontline management rather than to be used as in more difficult cases such as persistent bleeding.

Neither does the "FOGSI guidelines on Prevention of Post Partum Hemorrhage (PPH) - Consensus Statement for Prevention of PPH (2014)" nor does the Maternal Health Division nor the "Guidelines for Pregnancy Care and Management of Common Obstetric Complications by Medical Officers" by the Department of Family Welfare Ministry of Health & Family Welfare Government of India (2005) mention the use of tranexamic acid. Considering the availability of high quality evidence in favour of the drug, it is the right time to evaluate the role of the drug in management of PPH in Indian settings and if found

useful, expedite the process of universal adoption.

There are several reasons why the findings of this study are very significant. This drug costs as low as Rs. 180 in market and is routinely used for management of trauma. We are already struggling to make enough safe blood available through the length and breadth of the country. Though the authors have not explored the impact of tranexamic acid on reducing the overall blood requirement, by reducing bleeding, tranexamic acid is likely to lead to reduced number of blood transfusions.

While the country takes the strides forward to increase the availability of voluntarily donated blood, we must embrace all means possible to safely reduce the requirement of allogenic blood. As is often said in blood transfusion medicine 'no transfusion is safe the risks can only be minimised', we need to get into an aggressive mode to consider and adopt all available means to lead to conservative and rational use of blood.

References:

1. WOMAN Trial Collaborators. Effect of early tranexamic acid administration on mortality, hysterectomy, and other morbidities in women with post-partum haemorrhage (WOMAN): an international, randomised, double-blind, placebo-controlled trial. *Lancet Lond Engl*. 2017 Apr 26;
2. Tranexamic acid [Internet]. Drugs.com; Available from : <https://www.drugs.com/cdi/tranexamic-acid.html>
3. WHO recommendations for the prevention and treatment of postpartum haemorrhage. [Internet]. Available from : http://apps.who.int/iris/bitstream/10665/75411/1/9789241548502_eng.pdf

Annual Report 2016-17 released

We are happy to share that we have been able to summarise the work done by the Sankalp family in 2016-17 in our annual report. the report can be downloaded from the following URL:

<http://www.sankalpindia.net/drupal/annualreport2016-17>

We welcome any suggestions and feedback which could be shared at sankalp.admin@gmail.com

The picture on the front page is that of the first few kids who got transplanted at our center. Just one of them is a donor and rest were patients. Can you guess which one? We thought the best picture for the cover was the one which showed what can be achieved with persistent hard work. These children have returned to fully normal lives.

Please do keep supporting and participating in our mission to give life a better chance.

Annual Report 2016-17



Sankalp India Foundation®

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#460, "GOKULA", 8th Main, 4th Block, Koramangala, Bangalore 560034, India

Did you know:

**Only 7% of all blood donors
in India are women.**

Can something be done?



PLAN NOW TO AVOID SUMMER SHORTAGE

This alarm is being sounded for all in blood banking. It is being sounded to the authorities, the blood banks and to all the organisations involved in promotion of voluntary blood donation.

It's the right time to draw up a comprehensive plan to ensure that regular blood donation drives are organised starting May right through till July, traditionally the period of shortage of blood.

This summer - let us ensure that there is no shortage of blood!

ALL THE BEST!

**SAY NO TO
BLOOD SHORTAGE**

YOU too can make a difference.

Plan to organize a blood donation drive.

Call 9480044444
to know more.

We are offering free HLA Typing

At Sankalp India Foundation, We firmly believe that each child must be given an option for complete cure irrespective of their financial status. The HLA test is the first step which determines whether the sibling can be a matched donor to the child suffering from thalassemia. The cost of HLA typing in India is around Rs. 10,000/- per child making it inaccessible to most families.

There is good news. Currently, we are offering free HLA typing to those children with thalassemia who have a healthy sibling donor in association with Cure2Children Foundation, Italy. We are happy invite the families to make use of this opportunity. Please spread the word



about the availability of this option for the families. The families can call our central help-line number 9480044444 for further information and appointment.

"Perform all work carefully, guided by compassion."

- Ved Vyasa (The Bhagwat Gita)

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 propagate 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: