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sankalp patrika

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Let's give life a better chance

First meeting of the Sankalp-Cure2Children thalassemia BMT network, India organised

Bangalore 21-22 Jan 2017

The meeting was organized with the intention of developing synergy between the various centers involved in the transplantation for thalassemia as part of the Sankalp-Cure2Children Thalassemia BMT Network. The following organizations were represented in the meeting:

- Cure2Children Foundation, Italy
- Jagriti Innovations
- Kokilaben Dhirubhai Ambani Hospital, Mumbai
- Project Samraksha, Bangalore
- Sankalp-People Tree Centre for Pediatric Bone Marrow Transplantation, Bangalore
- Sankalp India Foundation, Bangalore
- SEAIT, Jaipur
- SRM Medical College, Chennai

Dr Prakash Satwani from the Columbia University-USA also joined the meeting.

Rich discussions and deliberations on various aspects related to bone marrow transplantation for thalassemia and Sickle Cell Disease happened over the two days. Clinical practices and outcomes were discussed. The discussions led to the following key decisions:

1. All centers agree on a coordinated FACT-JACIE-oriented continuing quality improvement program.
2. All centers agreed to have a common way to analyze and report outcomes (including costs and value delivery).
3. The plan for both retrospective and prospective multicenter studies was defined. Certain areas where there is a need to study the data were identified and the participants volunteered to work upon some of them.
4. Key areas where working parties need to work upon and develop clinical practice guidelines and standard operating procedures were identified.
5. The group agreed to meet regularly online on the Thalassemia group of Cure4Kids (St Jude-Memphis) held in Room A 9 to 10am Central European Time (GMT+1) every second Wednesday of the month.

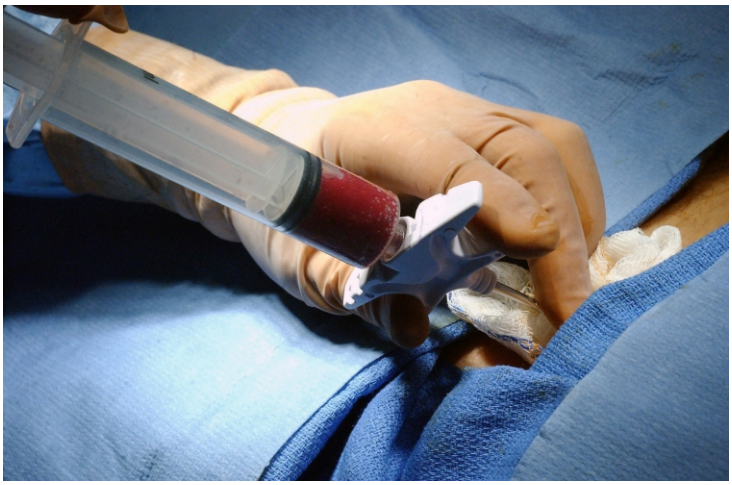
All the participants agreed that such meetings are very helpful. We thank each participant to have spared time from their busy schedule to come together for this meeting.

GRFS: as a true measure of outcome for BMT

Bone marrow transplantation is becoming an increasingly acceptable curative option for patients suffering from thalassemia. This coincides with improved access to care and management of thalassemia. There is a need for a measure to be available for the patient families, support organisations, government and donors to make a truly informed choice on whether or not the option of a bone marrow transplantation of a particular kind at a particular centre is the best option for the patient. Overall survival post transplant and disease free survival are the generally used measures.

In case of transplants for malignancies where the patient may not have good chance to survive without undergoing the transplant, measuring the overall and disease free survival alone may look sufficient. However, the context of thalassemia is different. The transplants for thalassemia are more directed at reducing the suffering resulting from chronic blood transfusion therapy, consequent complications, and with a treatment goal to restore the quality of life of the patient. If a patient ends up with a serious complication which makes the life of the patient worse than what it was with thalassemia – it cannot be called success in the context of thalassemias.

Graft versus host disease is a common complication associated with BMT. GVHD has been shown to have severe impairments to the quality of life of patients. The associated problems include fatigue, difficulty in breathing, gastrointestinal side effects, worries/anxiety and skin problems. A patient may get cured from the disease as such and yet land up with a much worse quality of life.



In this context the measure of overall survival and disease free survival are inadequate to assess what to expect post transplant. A more informative measure which is being considered is a GRFS[1-2] - the survival free of graft failure, chronic GVHD, or death. This measure is one step closer to showing how many patients reached an acceptable state of being cured after the transplantation. It allows assessment of how many patients truly benefitted from the transplant in the direction of meeting the treatment goal – to restore the quality of life.

Dr Prakash Satwani from the Columbia University retrospectively reviewed the transplant essential data submissions made to the Center for International Blood and Marrow Transplant Research database for patients who underwent transplant for Sickle Cell Disease in USA from 2000-2011[3]. It showed overall survival at 2 years of 90% (95% confidence intervals [CI] 85-95%). It was also noted that Chronic GVHD incidence was 31% (95% CI 23-38%) at 2yrs. Thus, the 2yr GRFS was 64% (95% CI 56-71%). This example leaves little doubt that since GRFS is a more indicative measure for the success of the transplantation procedure.

We as an organisation are working towards adopting GRFS in our reporting of transplantation outcomes for all our centres. We eagerly look forward to more centres sharing their treatment outcomes in a relevant manner. This may even help place emphasis on the most important thing – giving meaningful cure to each patient who is offered a bone marrow transplantation!

References:

1. Holtan SG, DeFor TE, Lazaryan A, et al. Composite end point of graft-versus-host disease-free, relapse-free survival after allogeneic hematopoietic cell transplantation. Blood. 2015;125(8):1333-1338. doi:10.1182/blood-2014-10-609032.

2. Solh M, Zhang X, Connor K, et al. Factors Predicting Graft-versus-Host Disease-Free, Relapse-Free Survival after Allogeneic Hematopoietic Cell Transplantation: Multivariable Analysis from a Single Center. Biol Blood Marrow Transplant J Am Soc Blood Marrow Transplant. 2016;22(8):1403-1409. doi:10.1016/j.bbmt.2016.04.006.

3. Satwani P, Brazauskas R, Arnold SD, et al. A Study of Predictors of Clinical Outcomes and Healthcare Utilization in Children with Sickle Cell Disease Undergoing Allogeneic Hematopoietic Cell Transplantation. Blood. 2015;126(23):528.

Our Princess Anushree goes back home - cured!

We read somewhere - 'Perseverance is not a long race; it is many short races one after the other.' Anushree personified it.

It was day 172 post transplant and day 190 after she was admitted to the transplant unit that our little princess - Anushree - walked out of the with her parents. Not only she, but each member of the team was eagerly waiting to see her get discharged - cured from the disease. In the last few months, the little one had seen several children come in and leave the unit cured - while she still combated one of the most gruelling post transplantation complications - graft versus host disease.

This little girl had made the team very nervous several times during her stay. In the Indian context, graft versus host disease of the grade that this little one had is often associated with mortality. Her donated bone marrow engrafted in her body well - but it went to the extreme of attacking her own body. The whole setup of transplantations was put to test as she faced one complication after another. There is something more about the spirit of this little girl. In-spite of the fact that she was weak and exhausted, being fed intravenously for a considerable time, battling the diarrhea, rashes

and fever each time we went to see her, she would lift her little hand to wave back at us. Each time she would smile. She would listen carefully to what the doctors and the nurses told and cooperated with the treatment plans.

Anushree's transplant adds strength to our conviction and our model for transplantations. Often, in most transplant centres in the country, the planning for the transplantation costs is done only to cover the duration of treatment. If there is a complication, the family is asked to bear the additional load. Fortunately, we believe that once the child has been taken up for the transplantation, the management of all transplant associated complications are the responsibility of the team. The family had a lot of things to worry about - but not money.

A few days before her anticipated discharged, when one of us visited her, with a gentle little smile she made a request. She reminded that she was promised the cutting of a cake when she get's discharged. And so it was. The entire pediatric team and the transplantation team got together for the little event. Taking slow steps across the room, our princess saw to it that each one got their share of cake to enjoy. We - were overjoyed! So were the parents!

While Anushree has got back home, the intense monitoring and care will continue. Our goal is not just to finish the transplantations - but to take the children to normal healthy life. To achieve this goal, we will walk the slow steps from now till complete recovery - together with her.

In-spite of facing a host of complications, the way this child was managed and taken care of through the course of the transplantation gives us immense pride and confidence in our team. The doctors, the nurses, the housekeeping and everyone else involved kept faith and fought the battle with the disease very well.

"Everyone is breakable, but not everyone is aware that it's a choice to stay broken"
- Stanley Behrman

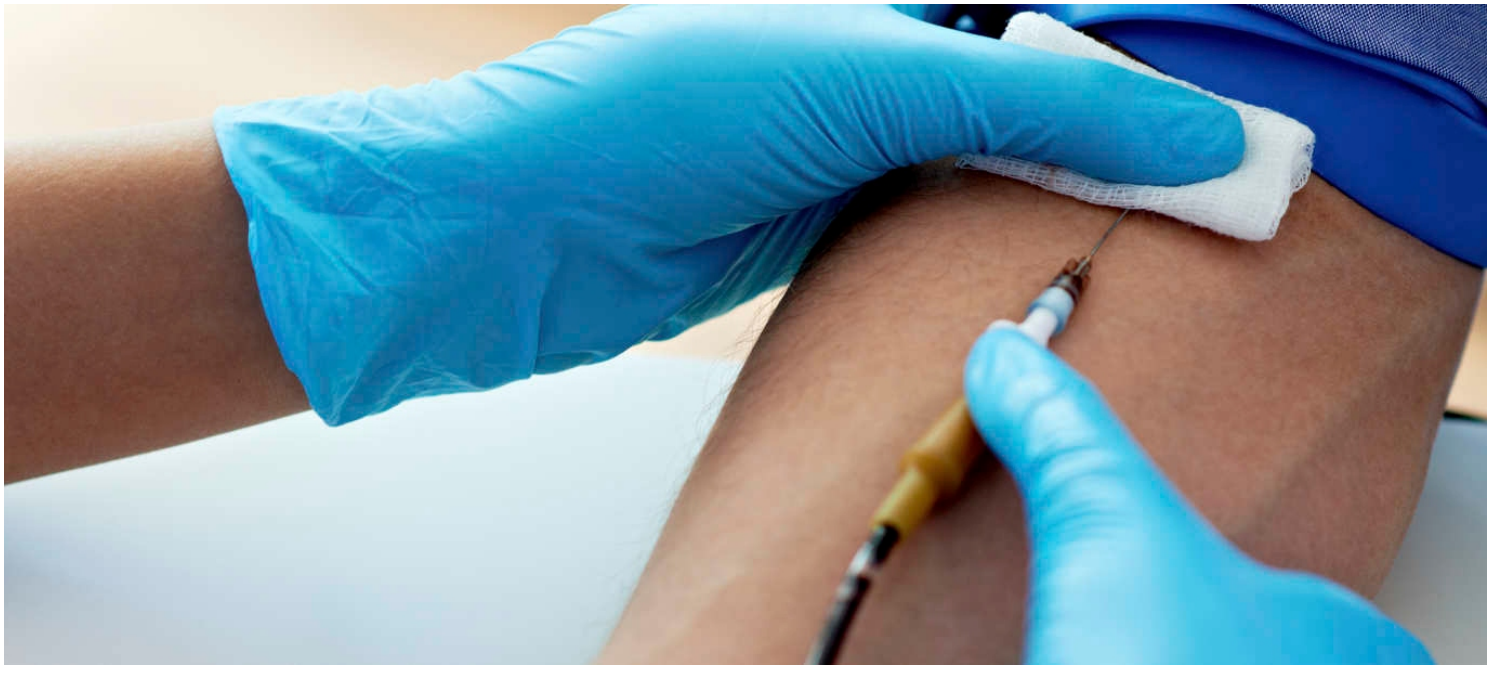
Should donor care in blood donation drives vary with seasonal blood stocks?

Performance analysis is very important as it fosters thought by encouraging us to look at areas of improvement. In 2015, Sankalp India Foundation published a write up in the Asian Journal of Transfusion Science (AJTS) on the non compliance of blood banks to agreed upon standards in blood donation drives. In 2016, we had the publication on adverse events and complication management in the same journal. The deeper intent of going through the exercise of compiling data for the publications was to devise a culture within the organisation to have internal analysis done at regular intervals. Be it thalassemia, BMT or our blood donation drives, we believe that from time to time we must analyze our results and take corrective actions.

There is no well documented definition of how to rate blood donation drives for quality. We have been dwelling upon this question for quite some time. Time and again we try to look at the blood donation drives from a variety of perspectives. What is done here is another such attempt. We looked at the following factors to understand if performance by teams in blood donation drives is influenced by the already available stock in blood banks:

i) non compliance to quality standards,
ii) rate of adverse complications,
iii) rate of deferrals
iv) the overall camps and collection.

The seasonal variation of blood in Karnataka is now a well established fact. While April to July and December to January can be considered as challenging months to sustain good stocks in blood banks, the period between August to November and February to March are much easier (At times there is also a heavy red cell overload in these months). We took this as an important element to be considered while we sit to measure the performance.



	No Shortage Period (February-March, August-November)	Shortage Period (December-January, April-July)	Significance(P)
Total number of camps *(n)*	144	198	
Rate of post donation complaications *Mean(SD)*	3.7%(0.03)	3.5%(0.03)	0.49
Rate of donor deferrals *Mean(SD)*	22.1% (0.11)	18.6%(0.10)	**0.003**
Rate of non-compliance in camps *Mean(SD)*	1.67(1.5)	1.3(1.36)	**0.013**
% of camps with NO non-compliance	22%	34%	**0.014**

An analysis of 336 blood donation drives organised by Sankalp India Foundation in the period between 1 January 2015 to 31 January 2017 in Karnataka (more than 95% of which was in Bangalore) was made to study the perceivable quality of blood donation drives throughout the year (with focus on the seasonal windows). The results are summarised above.

Unfortunately, the data shows that the quality offered to donors in blood donation drive varies according to available stocks.

A brief interpretation of the results can be made as follows:

1. The rate of adverse complications remain nearly the same This does not seem to have got affected with shortage.

2. The rate of deferrals is distinctly different in periods of high stock and low stock. During periods of good stock, nearly 3.5% more donors are deferred clearly throwing questions to ask if the deferrals were actually scientific.

3. The rate of non-compliance per blood donation drive is significantly higher in the time of year when there are good stocks. The percentage of blood donation drives having at-least one instance of non compliance is also higher in periods of good stock. This suggests that blood bank teams are choosing to be compliant to standards only when there is a pressure to get more units from voluntary blood donors.

Our findings suggest that more works remains to be done in the direction of ensuring that each voluntary blood donor is given the same quality of care all the time. Each donor must be given a fair and scientifically guided opportunity to donate. Each camp must be done with attempts to achieve highest standard of quality and safety. Both these parameters seem to be getting significantly affected by the demand supply equations and there is an urgent need to fix this.

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	325	411	11	1.8	9.8	98%
Project Samraksha	317	381	3	3.0	9.0	100%
KLE Belgaum	240	235	2	3.5	9.1	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	28	22
Total	2742	48	38

Bombay blood group network

	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	456	18%	23%
This year (cumulative)	5765	16%	26%
Last year	8392	89%	23%

January 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	7	576	499	4.0%	13.2%
This year	149	13895	11870	3.6%	15.2%

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

Blue Ocean
DHL
Robert Bosch
Silvan Innovation Labs
Tata Power
Volunteer for a Cause
Yaskawa

Disha Statewide Blood Helpline - 9480044444

	Total bombay blood group requests	Number of units organised off the shelf	Number of units donated
Last month	8	6	3
This year (cumulative)	56	17	18
Last year	68	30	50

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

We receive life guard vials: Deferoxamine therapy strengthened at our centers

Guns work - only when we have bullets.

Infusion pumps work - only when we have the medicine!

Last year, we had shared how extremely high ferritin levels are being controlled using a combination of deferasirox and deferoxamine at our centres. "A Novel approach to control very high ferritin levels - our experience - (Volume 6 Issue 8 September 2016 Pg 6-7)" Iron overload is the root cause of the complications associated with thalassemia. Even for those children who find a match and thus have a chance to get cured - bringing down the ferritin levels is the first step towards transplantation preparation. In-spite of having an effective approach, we were facing difficulties in iron control. Deferoxamine therapy may cost about Rs 6800 per month for a 25kg kid. Most families are unable to afford the drug.

In this context we requested Jasmeen Ben for her help. A few days later she called back to inform that Dr. C J Thakkar and Suman Ramesh Tulsiani Charitable Trust have kindly agreed to support Sankalp's Program for Thalassemia Cure with Deferoxamine. The missing link in the fight against high ferritin fell in place.

This medicine is given using infusion pumps - a costly piece of equipment. We have 10 of these in Bangalore and another 4 in Mumbai. Starting January 2017 we have kept all the infusion pumps busy targeting about 80% utilisation of the quipment week after week. With

the support we have got, we are able to make sure that each child gets adequate access to this therapy without the limitations of cost. Each vial is being used judiciously to ensure maximum benefit reaches the children.

The results of using short term therapy of Deferoxamine continue to be encouraging. We are moving to the next step of proving the efficacy of this therapy and publish our findings. Work on this is already underway. We truly believe that this therapy will continue to be the answer to the requirements of rapid control of serum ferritin.

Managing rare blood requests - an internal perspective

It is true that in an ideal world there would be enough blood units for all patients and more to spare. In the real world, things are different. Sometimes it could be seasonal variation in blood collection, disease outbreak, and sometimes it may be the relatively rare blood groups which are a reason for shortage. When it comes to calling a blood group rare, Sankalp India Foundation only calls blood groups which have the prevalence of 1 in thousands as rare. Bombay blood group in one such blood group for which time and again there is a situation where there are fewer units than patients.

We realised the need and value of special handling of such situations. Apart from getting blood from voluntary blood donors, there are a variety of things that can be done when a person is in need of blood.

- There are medicines available which could potentially reduce blood requirement. This could be as simple as iron supplementation or the use of erythropoietin – a component which promotes the natural production of red cells in blood.
- Sometimes there are surgical and medical techniques which could reduce loss.
- Autologous donation is an option for planned surgeries where the person may donate up-to 3 units of blood for use self-use immediately after the procedure.
- Finally, you have modern techniques like intra-operative cell salvage which involved cleaning the blood which is pouring out during a procedure and re-transfusing it to the patient.

In all, thanks to science and technology, there are several possible options together with blood donation which are there to attend to the need for blood. It is no surprise that the emergency team of Sankalp manages blood requests with half the number of units originally demanded by close collaboration with the medical team and use of alternatives.

Extremely judicious use of blood is essential to maintain the fine balance for rare blood types. If over provisioning is done for one patient, it may impact several other patients in the days to come. This was witnessed in case of a little girl whose heart surgery kept postponing for 18 months for 4 blood donors of Bombay negative blood group to come together at the same time and donate. Sometimes, hospitals seek to over provision for units with the intention of being on the safer side. Such situations are better managed when a pragmatic approach is taken including the alternatives to transfusions, the option of get blood units donated at a short time frame if needed and planning in detail for the worst case scenarios. There is a fine balance to be maintained between one patient's need and the greater good of everyone. When doctors or families refuse to take this view and would rather have "reserved" units off the shelf for their patients – blood wastage and suffering for other patients is unavoidable.

We are confident that at some time in future there will be a well defined organisation with the necessary authority, experience, training and capacity to help patients who face such tough situations as part of the larger healthcare setup public or otherwise. However, in the absence of this, the gap is being filled by voluntary organisation like ours. With the singular intention of ensuring that the needful is done to ensure

adequacy of blood for each patient, empowered with the collaboration with the experts in the field of blood transfusion medicine, equipped with scientific research, experience and most of all commitment and most importantly, the trust and perpetual support of both donors and clinicians we work tirelessly to coordinate with the various stakeholders to ensure that all of them come on the same page in the best interest of patients. Sometimes it is almost like we have several different patients and donors in one single family, also to which we belong, and we need to coordinate enough for everyone's need.

When we receive difficult blood requests, we prefer to engage with the clinicians. Another thing yet to be corrected in our system is the practice of involving the families in organising for blood. When an individual or a family member is asked to organise for blood – specially when the blood group is rare – things can become very difficult both for them and for those who may help. With the prospect of a loved one's life in danger and with patchy information available from various sources, the fear, prejudices, scepticism and the over cautiousness can make people say and do very strange things. Patients often become extremely emotional and if they make contact with potential donors things easily boil down to emotional blackmail. What starts with pleading has known to take the shape of stalking as sometimes even abusing should the potential donor refuse to donate. Leave alone the right to choose whether to donate or not, donors of rare blood groups often find their privacy breached by patients representatives who would have nothing short of what they want. In past, some donors have changed houses, contact numbers and refused to donate blood anymore purely to avoid such harassment.

Those who know us are aware that pressure, intimidation, and tantrums fail to influence our sense of rationality and commitment to do the best for each patient. This is not by chance – it is by training. We, as a team are well aware of what we stand against and we ensure that each of our person is groomed not to give way to inappropriate demands and behaviour. Nevertheless, while we do what is right, this harassment does cause ripples in the mind of the involved volunteers.

An important aspect of a volunteer's life and role at Sankalp is to completely separate from any appreciation or contempt. We have had to choose one between doing what is right and doing what involved people may want us to do. A volunteer who seeks appreciation from the families he strives to help may not be able to bear the insults, abuse and bad behaviour which they may need to tolerate in the hands of the other - and seamlessly do what needs to be done nevertheless. One may ask why should someone put up with bad behaviour. It is because, the problem at hand, the pursuit to guard the human life is much higher and important than the behaviour of the patient or his family. Should we change our way, when confronted with inappropriate behaviour, the risk to the life in question may increase. Everything can be managed - but a dead cannot be brought back to life. Therefore, complete disconnect from appreciation and contempt - and singular focus on doing the best - guided by the internal voice and higher goals is the way forward. And we, the volunteers, choose to keep walking!

Experience of a young doctor at our BMT unit

It was an incredible experience working in the Bone Marrow Transplant unit of People Tree Hospital - Sankalp collaboration. I absolutely fell in love with the meticulous nature and detailed organization in the system. It gives an opportunity to the physicians to remotely monitor patients with able assistance from the nurses.

I would like to mention a few incidents which have made a lasting impression on me.

Dr Lawrence Faulkner, being the medical director of Cure2Children is the most humble person I have met in my grown up years. His simplicity in approaching an issue or tackling through any critical scenario is inspiring.

There was a day when we were very busy working on a case and he enquired with the housekeeping person if she was free to make him a cup of coffee. He assured he would have it only if it was not coming in the way of her schedule. That level of humility is not something I am used to, coming from a medical college background in India; where hierarchy is followed and respected. That is a great quality to pick up and inculcate into practice.

There was a time when we were tackling a rather sick child during the process of transplant. She stayed sad for far too long and Dr Chetan Ginigeri, the paediatric intensives asked her about anything that could make her happy. The nine year old quickly responded with "chicken leg piece." And so she was served the very next meal.

I am only pointing out the incidences which struck a chord in my heart.

I would be frequently and constantly overwhelmed at the concern of the doctors and their elementariness; at the same time amazed at the micro management of events and their perseverance to give a new lease of life to a thalassemic child. It makes me feel proud to be a part of the doctor-fraternity. I consider my three month stint with BMT unit at People Tree Hospital-Sankalp a truly rewarding, perspective sculpting and a sublime experience.

Story of Vijju - Courage and determination personified

He may just pass on as just another man from the hinterland of Bihar when you first see him. Vijju's looks of-course don't give out the determined and courageous soul inside. He is the father of little Chetan - a child from Bhojpur, Bihar who suffers from thalassemia. He is a man who did not let limited financial means, travelling long distances and pressure from his family come in the way of ensuring that good treatment was available for his child.

Each month, the father and son embark upon a journey of 2000 km in general compartment of the train to come to our centre in Bangalore for treatment.

We hated to see the them travel all the way. A few years back we made arrangement for them to receive transfusion at a well known centre closer to their home. Two months later, they were back in Bangalore. After repeated attempts to organise the transfusions closer to home did not keep them from deciding to come back to Bangalore - the father had just 1 thing to say. He said that the child does not get transfusion associated reactions in our centre which happen every single time elsewhere.

Vijju has aged parents at home. He is the breadwinner for a family of 7. Each time he ventures out to bring the child to Bangalore - he faces the wrath of the family - which believes that he should have let go of the child long back. Chetan has a healthy sibling - why then should the family suffer to treat a child who they consider a burden? Vijju refused to give up to the pressure. We asked him if he could relocate to Bangalore. He was concerned about how his parents would be looked after if he made that decision.

Recently, Chetan's ferritin trend showed an upward movement. The child receives chelators free of cost and yet, for several reasons he was not chelated

adequately. We offered to give 4 weeks of deferoxamine together with deferasirox to them. After brief consideration, the father agreed.

All hell broke loose at home. The family thought that he is going just too far. The father suffered silently in agony. Just around the same time an email came with certain HLA reports. The volunteer involved was overjoyed. Chetan has a match - and therefore a chance for cure! The same message was shared with the treating staff and the father.

When we met the father, we expected to see him bubbling with joy. We found him staring at the buildings far away through the windows when we met - with a blank expression on his face. He was worried. He was concerned. The news of a match brought in the concerns about the money involved and the tense situation he would face in his social circle.

His exemplary determination was shaky. As we spoke to him for the next few minutes - counselling him about the risks, benefits, procedure, challenges and options, on the back of our mind we knew that at least for this one child, the society will come together behind us to not let money come in the way of cure.

Many times, the silent suffering that family members of the patients undergo is heartbreaking. It's a slow and painful fight against the horrible impact of thalassemia on the patients and families alike. Small, persistent, well thought out and committed steps, we hope, will be the best way forward for this child and all the others.

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.

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

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Mail: contact@sankalpindia.net
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