Initiatives for establishment of plasma fractionation in Sri Lanka

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KERALA
Allinagaram
Madurai
Jaffna
Point Pedro
Bay of Bengal
Alleppey
Kambam
INDIA
Paramagudi
SRI LANKA
TAMIL NĀDU
Tenkāsi
Talaimannar
Nedunkeni
Mullaittivu
Tuticorin
Mannar
Trivandrum
Vavuniya
Thiruvananthapuram
Horowupotana
Trincomalee
Anuradhapura
Pūvār
Vijaya Nārāyanam
Kalpitiya
Puttalam
Kekirawa
Habarane
Nāgercoil
Dambulla
Gulf of Mannār
Batticaloa
Hettipola
Wariyapola
Wattegama
Kandy
Uhana
Kurunegala
Akkaraipattu
Pamunugama
Gampola
Badulla
Colombo
Hatton
Nayabedde
Ratnapura
Kotte
Balangoda
Mipagama
Embilipitiya
Ambalangoda
INDIAN OCEAN
Baddegama
Beliatta
Galle
Matara



Sri Lanka









Sri Lanka



- Land area of approximately 62,705 square kilometers (1/5th of UK)
- The mid year population for 2014 was 21 million
- Population density of 319/sqKm
  (USA 31/sqKm)
- Multi-ethnic and Multi-Religious population
- Blessed with a tropical climate, beautiful beaches, and extraordinary wild life
- Culturally rich with a written History of Over 2500yrs.

Sri Lanka - vital statistics

- **GNI per capita - US$ 3400 Rank 127**
  (Singapore – US$ 55,150)
  (Wikipedia 2014)

- **Population Growth Rate - 0.47%**
  (India – 1.46%)
  (list by United Nations)

- **Infant Mortality Rate (per 1000 live births) - 11**
  (India – 55)
  (United Nations Population Division)

- **Maternal Mortality Rate (per 100,000 live births) - 58**
  (Thailand – 110)

- **Life expectancy at birth - 72.4 years (overall)**
  (Sweden – 80.9 years)
  (List by UN 2005-2010)

- **Literacy rate - 95.6%**
  (India - 66 %)
  (United Nations Development Programe Report 2009)

MEDIUM HDI

Sri Lanka - Health Services

Free for All

- Total Health Expenditure US$ 632 Mn. (% of GDP 1.92)
- Per capita expenditure on health – US$ 31.58
- Expenditure on health 4.1% of total govt. expenditure
- As at December 2010 there were:
  - 1042 Government Hospitals
  - 13,720 Medical Officers
  - Total bed strength is 69,501
  - There were 115 private sector hospitals
- No. of Persons Per Medical Officer – 2500

The National Blood Transfusion Service Sri Lanka –NBTS

- Nationally coordinated service
- Operates under the Ministry of Health
- Established in late 1950s
- Presently is the sole supplier of blood and blood products to the entire patient population in the state sector and majority in the private sector

NBTS

- Once the National Blood Policy is legislated, NBTS will have the authority to directly monitor the activities of all the blood banks including those in the private sector and thereby maintain stringent quality standards all over the country

- The operational head quarters of the NBTS-

  National Blood Centre (NBC)-Colombo

- The 83 other hospital based blood banks of NBTS are managed through 16 Clusters

- Blood is collected in-house or from mobile drives; processed 100% into components; tested for transfusion transmitted infection (TTI) markers and issued by NBTS.

NBTS

- A foreign funded Hospital Based Blood Bank development project has been approved by the government

  Includes:

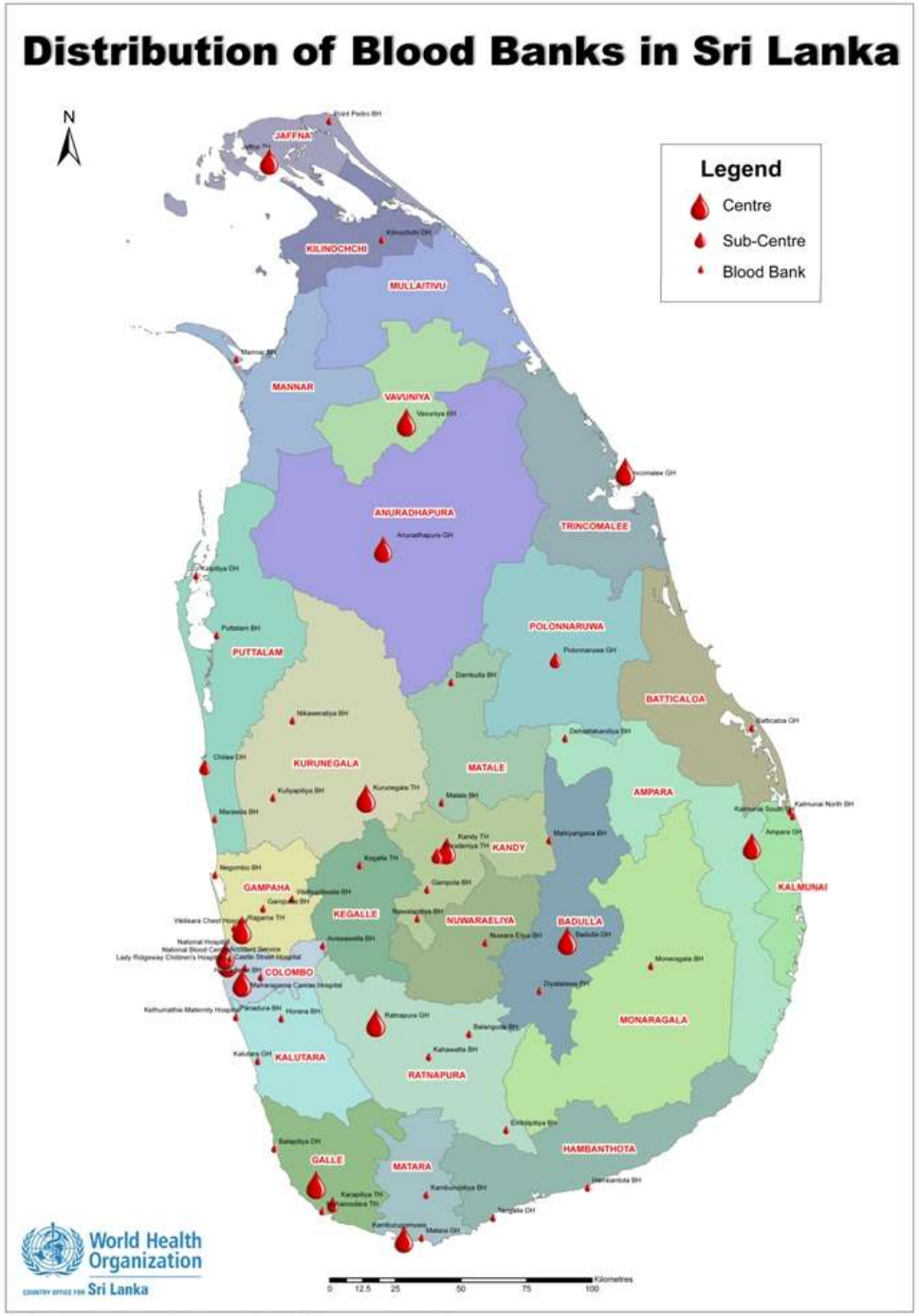
  - infrastructure for 19 regional blood centers
  - basic equipment for all hospital blood banks

- Another project for introduction of NAT testing, Cord Blood banking & Frozen Red Cells, is Almost Completed
- Development of Soft ware for blood collection
- Devolution of certain administrative powers by Cluster Management Concept

NBTS

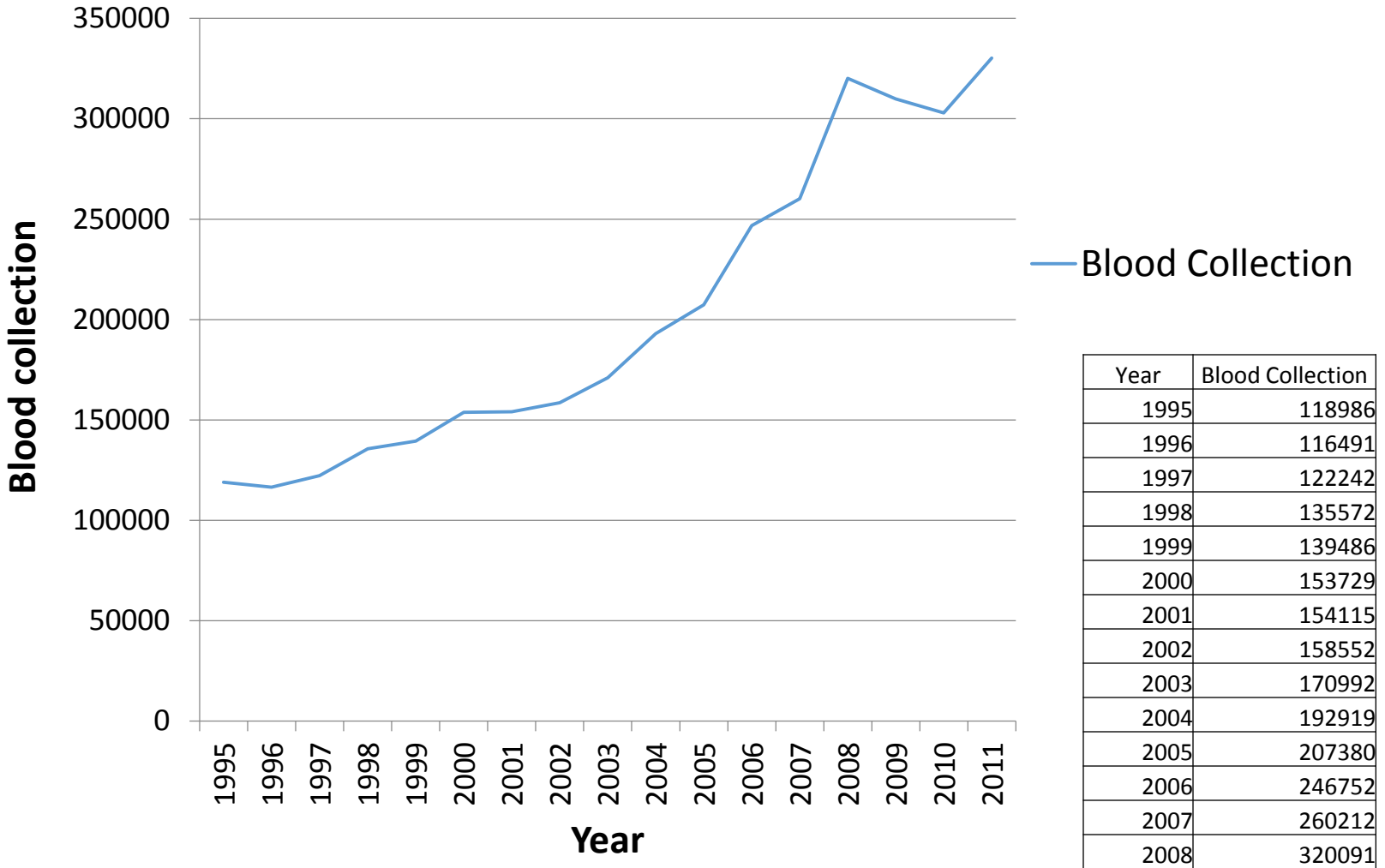
- Acceptance of Transfusion Medicine as a specialty by the Post Graduate Institute of Medicine
- Appointment of board certified Consultant Transfusion Physicians to all regional blood centers
- Establishment of the College of Transfusion Physicians in January 2011
- Blood Policy approved and Fractionation is included in that.
  - Relevant legislations already drafted and awaiting parliamentary approval

Distribution of Blood Banks in Sri Lanka



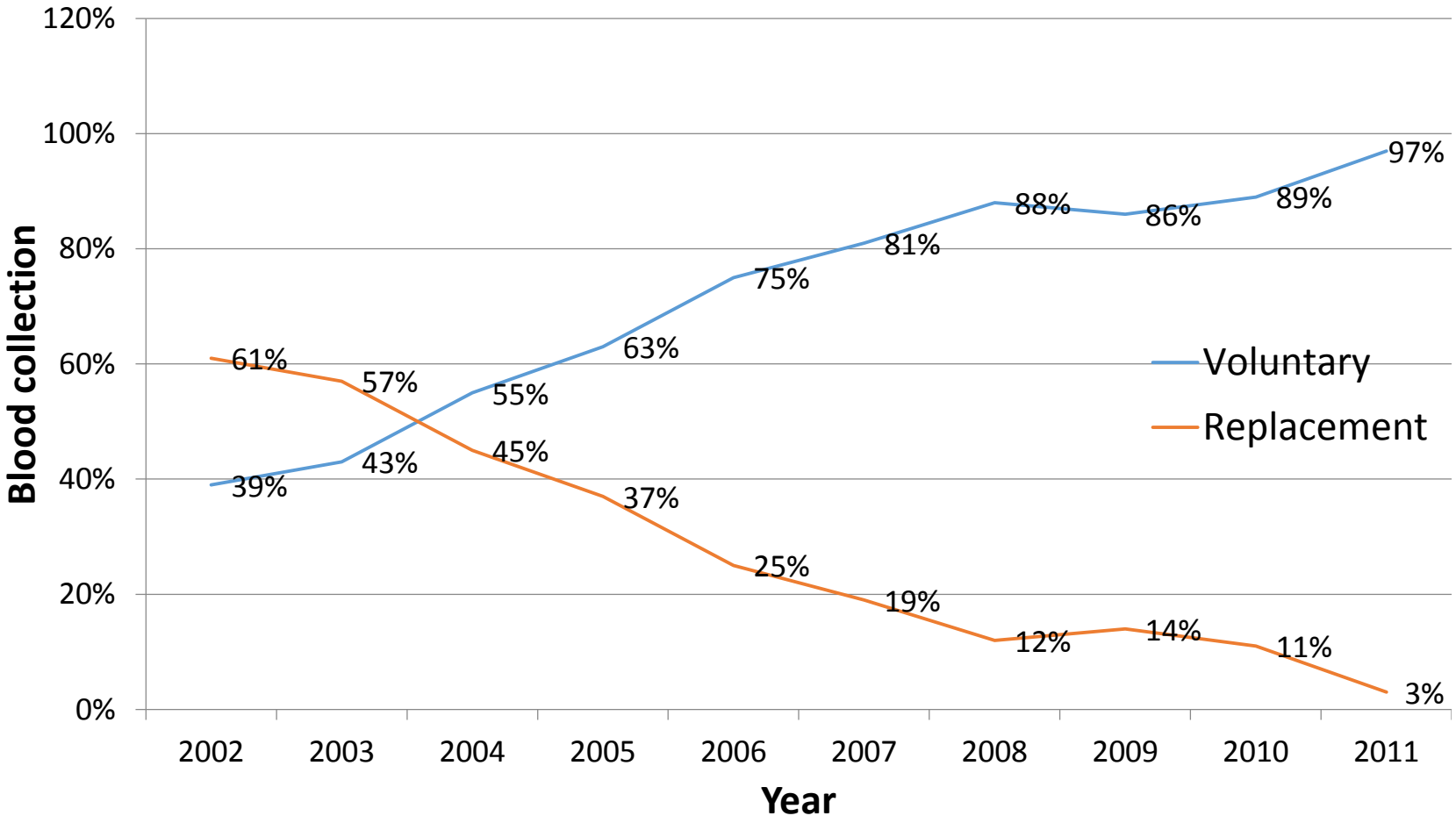
Note : The boundaries and names shown and the designations used on this map do not imply official endorsement or acceptance by the United Nations.

Annual Blood Collection-NBTS



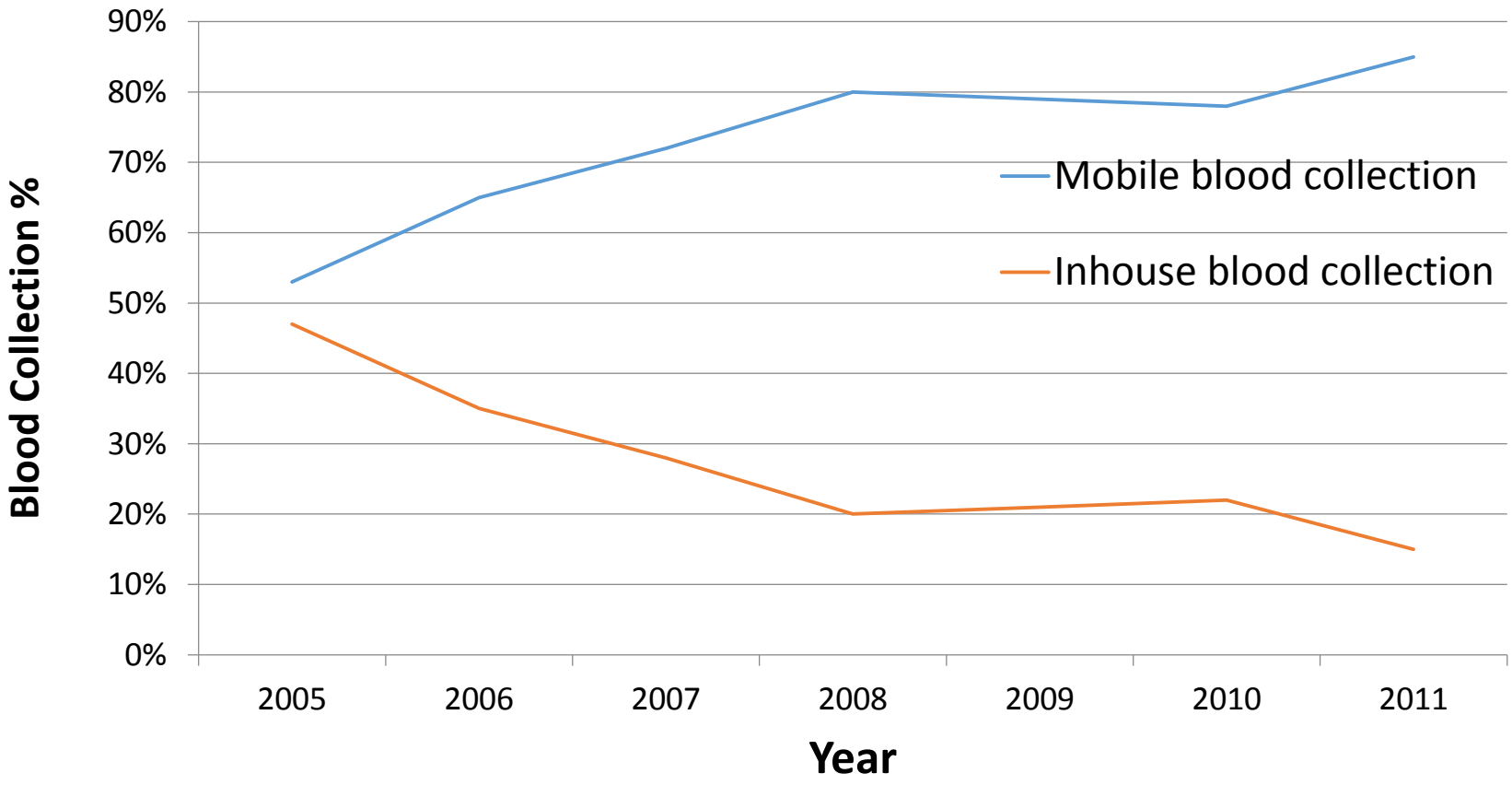
Year	Blood Collection
1995	118986
1996	116491
1997	122242
1998	135572
1999	139486
2000	153729
2001	154115
2002	158552
2003	170992
2004	192919
2005	207380
2006	246752
2007	260212
2008	320091
2009	309909
2010	302883
2011	330200

Blood collection voluntary and replacement- NBTS

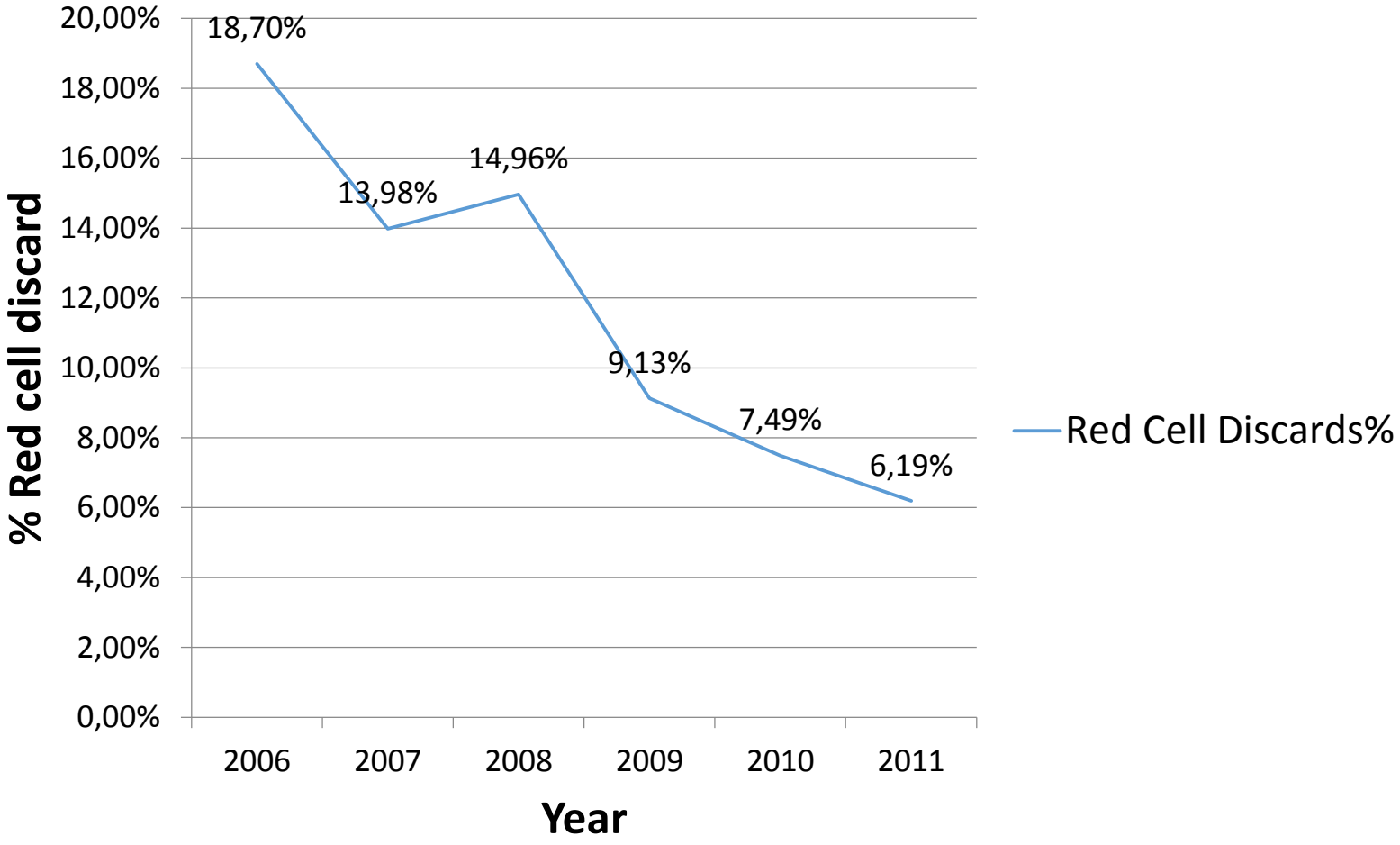


NOW 100% VOLUNTARY DONATIONS SINCE 2013

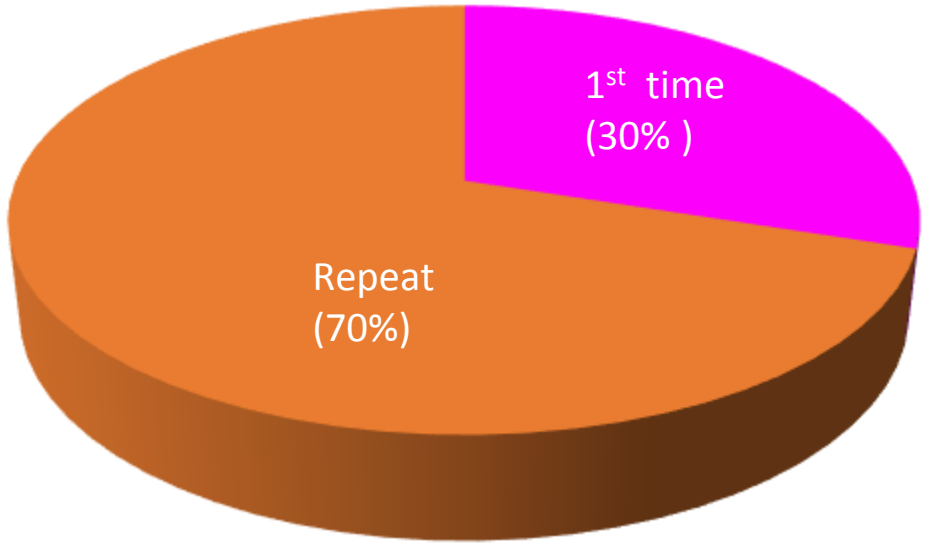
Annual mobile and inhouse blood collection -NBTS



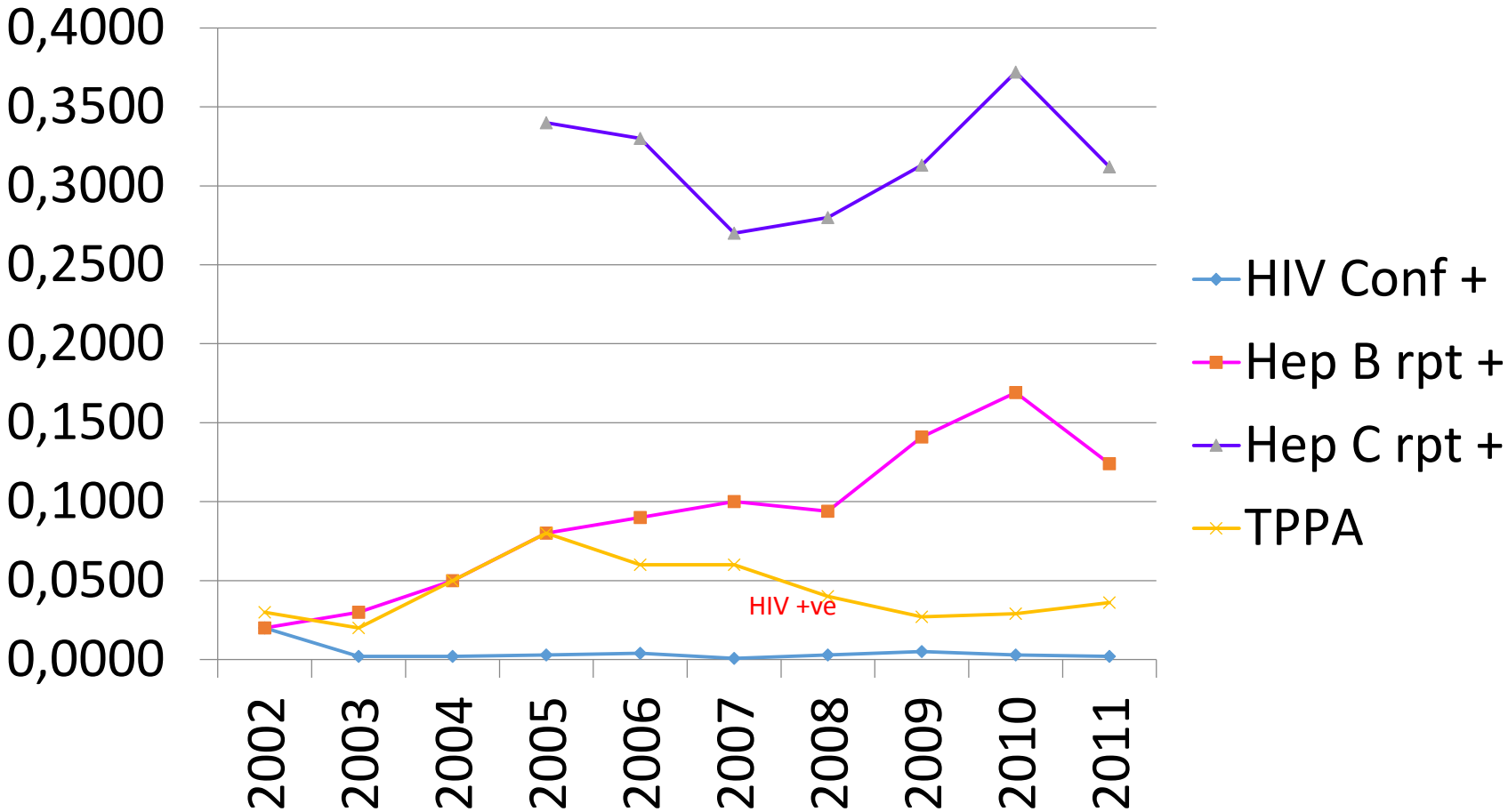
Red Cell Discards (due to past expiry)- NBTS



1st time and Repeat donations 2011



Prevalence of TTI among units collected (2002 – 2011)



NAT & PI INTRODUCED IN 2014

Achieving **ISO 15189** accreditation for NBTS laboratories



SLAB

SRI LANKA ACCREDITATION BOARD

Certificate of Accreditation

Sri Lanka Accreditation Board for Conformity Assessment
hereby declares that

The National Blood Centre
The National Blood Transfusion Service
Sri Lanka

having being found to comply with the accreditation criteria for medical/clinical laboratories as described in ISO 15189 :2007, has been accredited as a medical laboratory under the fields of testing in

Microbiology/ Serology &
Haematology/ Immunohaematology

and has been assigned the accreditation number

ML 012-01

This certificate is issued on 17th August 2011 and is valid until

16th August 2014

The accreditation was granted for the first time on 17th August 2011

The scope and conditions of accreditation are specified in the Schedule of Accreditation bearing the accreditation number appearing in this certificate.

Acting Director / CEO
Sri Lanka Accreditation Board for Conformity Assessment
Colombo, Sri Lanka

- Received ISBT award for best blood Transfusion Service 2011



Plasma Production

NBTS Statistics for past 5 years

(Number of Units)

Item	2007	2008	2009	2010	2011
blood collected	260212	320091	309909	302883	330200
plasma obtained	250215	297854	285020	279250	294910
plasma utilized	144089	157976	256078	183954	159847

(Volume in Litres)

Item	2007	2008	2009	2010	2011
Volume of blood collected (L)	117095.40	144040.95	139459.05	136297.35	148590.00
Volume of (FFP) plasma obtained(L)	50043.00	59570.80	57004.00	55850.00	58982.00
Volume of(FFP) plasma in Excess(L)	21225.20	27975.60	5788.40	19059.20	27012.60

EXPENDITURE FOR THE PLASMA PRODUCTS 2012

	item	**Amount (m)**	
01	Normal immunoglobulin for intravenous use BP, 5g - 69 vial	586	
02	Dried, Factor VIIA fraction 120 KIU (2.4 mg) vial	50	
03	Dried factor VIII Fraction BP	366	
04	Concentrated. monoclonal, Purified and Detergent treated Dried factor IX Fraction BP or Human Coagulation Factor IX ph Eur, 500IU	129	
05	Normal immunoglobulin for intravenous use Bp, 2.5g - 3.0g Vial	113	
06	Normal immunoglobulin for intravenous use BP. 1g vial	88	
07	Human albumin solution BP (ph Eur)	235	
08	Epoetin injection 200 IU Pre-filled syringe	45	
09	Epoetin injection 4,000IU – 5,000IU prefilled syringe Each pre-filled syringe to contain 4,000IU to 5000IU Of Epoetin (Recombinant Human Erythropoietin) in water for injection BP/USP for subcutaneous or Intravenous injection.	106	

TOTAL 1718 SLR Millions USD 12 MILLION

Forecast on Requirement

Name of the Item	2013 Current Indications	2014 Proposed Indication	Approximate vials per year	Strength(IU%)
Albumin Solution (human) 20%,50ml bottle	48,026	60,000	50,000	20%
Dried factor VIII Fraction,250 IU vial	45,571	40,000	40,000	250IU
Dried Factor IX Fraction 500 IU vial	5,425	4,200	5,000	500IU
Dried factor VII fraction 2mg (100 KIU) vial	665	500	450	2mg(100KIU)
Human immunoglobulin injection for IV use 5g - 6g vial	23,300	25,000	24,000	5g - 6g
Human Immunoglobulin Injection for IV use 2.5g - 3.0g in Vial	8,609	7,000	7,000	2.5g – 3.0g
Human immunoglobulin Injection for I.V.use 1g Vial	10,958	6,250	9,000	1g

Source – MSD of MOH

The below table is an overview of expenditure for plasma products in the year 2012.

Table 1 - Procurement Cost for Plasma Fractionated Products for Ministry of Health for the Y 2012

S/N	Cost Elements	Products				
		Factor VIIa	Factor VIII	Factor IX	Albumin	Ig- G
1	Requirement per year	900	45571	5425	48026	43000
2	Procurement Price USD / vial	1,800.00	66.48	182.00	22.34	100.00
3	Amount spent in Imports per year (USD)	1,620,000.00	3,029,560.08	987,350.00	1,072,900.84	4,300,000.00
	Total import Cost for MOH with SPMC Cost (USD)	12,110,792.01 (12 Million USD)				

The below table shows the approx. potential revenue opportunity if the manufacturing is done in Sri Lanka (100,000 L Plasma)

Table 2 – Total revenue potential (approx.) of the manufacturing in Sri Lanka

Products	Vial/L	Total Vials 100KL	Revenue
FVIII	0.8	80000	$5,318,400
FIX	0.5	250000	$25,000,000
IgG	1.6	160000	$3,574,400
Albumin	2.5		
FVIIa	0.15	15000	$27,000,000
Total revenue			$69,992,800

Asian plasma Situation

- Asia Fractionates Only six Million Plasma Liters
- Which is just (20%) of the Plasma Fractionated Worldwide
- This is for 60% of World Population
- Iran 2,071,031 units of Blood/yr
- Bangladesh 800000 units of Blood/yr
- China 21 million units of Blood/yr
- Bhutan 9375 units of Blood/yr
- India 9.5 million units of Blood/yr

JUSTIFICATION

- Stable Political Situation
- Good Health Care System
- Quality Blood Transfusion Service
- Government Commitment
- Board of Investment(BOI) Privileges
- Buy Back Guaranty by the Government
- Possibility of Obtaining Plasma from Neighboring Countries
- Supportive National Regulative Authority
- Good Rate of Return

Thank You