

Thailand Experience in Implementing Haemovigilance

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General Country Information



- Area:
 - 514,000 square kilometers lie in the middle of mainland Southeast Asia.
 - WHO SEAR countries:
 - 11 Member States: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, **Thailand**, Timor-Leste.
- Economy*:
 - Income level: Upper middle income
 - GDP = 373.3 bil.USD [2012^F]
 - GDP per capita = 5497.3 bil.USD [2012^F]
- Population: 2011
 - 65.9 million
 - Density 132.1/km²
 - F = 51%, M = 49%
 - Age eligible donor [17-60yr] about 65%

Age yr	0-14	15-59	>60
Total 100	19.5%	67.5%	13.0%

* NESDB Economic Outlook, May 2012; Bank of Thailand's Monthly Report 31 May 2012, for April 2012. Division of Economic Information
Department of International Economic Affairs

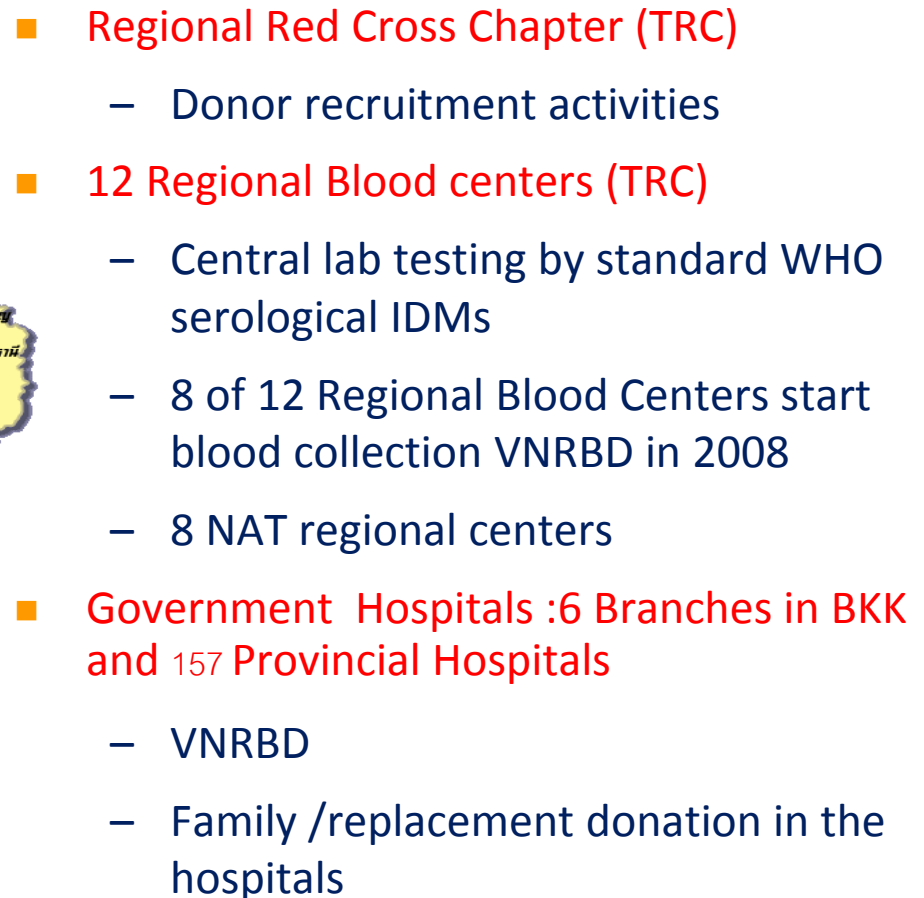


Blood Services in Thailand



National Blood Center , Head Quarter
Bangkok

- **National Blood Center BKK (TRC)**
 - VNRBD
 - Core Area :
 - running the National Blood Program as designated by the Royal Thai Government to the Thai Red Cross National Blood Centre.
 - Vision :
 - Procuring adequate and quality blood supply according to international standards at the excellent regional level.





Blood Services in Thailand

- 65,900,000 population
- Around 1,800,000 WB collection per year for the whole country
- Over all 2% of AE population donated blood
- 100% testing by mandatory WHO serological IDMs
- Nearly 80% NAT testing [project to 100% by Policy]
- >90% blood components preparation
- No paid blood donation
- No private blood collection center



Phuket Regional Blood Center
at Phuket Province



Blood donation



Blood components prep



Mobile blood drive



Standard Reagents preparation



Donor blood testing lab



Plasma fractionation plant



Inventory and distribution



HLA Stem cell/Cord blood lab





Whole country Blood collection

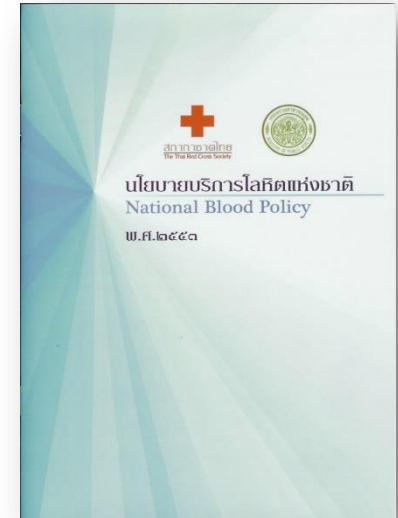
	Fiscal yr 2011			Fiscal yr 2012		
	VNRBD	F/R	total	VNRBD	F/R	total
NBC +RBC	571,185	0	571,185	588,753	0	588,753
Hospitals BB	111,428	11,221	122,759	108,857	12,186	121,043
Whole country Blood collection	1,766,537 93.64%	120,046 6.36%	<u>1,886,583</u>	1,806,559 93.24%	131,005 6.73%	<u>1,937,564</u>
Delivered to hospitals patients	7,784,234 94.6%			1,836,169 94.8%		
Infectious	44,117 2.3%			41,821 2.2%		
Expire and discard from other causes	59,295 3.3%			59,574 3.1%		



National Blood Policy 2010

Correlation to Haemovigilance

- Purpose 3
 - To provide **safe blood for patients** in accordance with the principles of the World Health Organization by recruiting blood donations from a low-risk group of population, screening blood donors, testing all units of blood with **standard and conducting a compatibility test for ensuring the safe transfusion**
- Purpose 4
 - To provide the effective blood services in every process at all levels
- Purpose 5
 - To appropriately utilize blood with common procedure and standard





National Blood Policy 2010: Purpose 3

- To provide safe blood for patients in accordance with the principles of the World Health Organization by recruiting the blood from a low-risk group of population, screening blood donors, testing all units of blood with standard and conducting a compatibility test for ensuring the safe transfusion
 - Indicator: The ratio of infectious patients from a transfusion and the ratio of the patients who receives wrong blood group
 - The hospitals are responsible for reporting the complication through the blood donation and the complication through the blood transfusion at the blood service center as the country database;



National Blood Policy 2010: Purpose 4

- To provide the effective blood services in every process at all levels
 - Indicator: The percentage of the blood services units accredited by the quality assurance system
 - The National Blood Center, in cooperation with professional organizations and experts, is responsible for setting the standard, guidelines and the manual including arranging the training courses and the assessment for ensuring all processes of blood services with quality as follows:
 - » Recruiting and Drawing
 - » Laboratory Testing
 - » Components Segregating
 - » Storing
 - » Distributing and Transferring



National Blood Policy 2010: Purpose 5

- To appropriately utilize the blood with common procedure and standard
 - Indicator: The ratio of compatibility test against the actual blood usage and the ratio of using the blood components
 - Setting the information technology system for all blood services units in order to monitoring against the blood usage indicator in all hospitals



Development of blood screening

1966
National Blood
Center
Thai red cross
Society

1969-1972
Blood Group
Direct/Reverse
antibodies
screening,
Rh grouping Syphilis
VDRL, HBsAg CIEP

1986
Home made HBsAg RPHA
reagent test for all units of
donated blood

1987
anti-HIV test
for all units of
donated blood

1994
HBsAg ELISA

1991
anti-HCV ABBOTT EIA 1st
Gen to 2nd Gen for all units

- Anti-HIV EIA 3rd Gen
/WELLCOME
- HIV-p24Ag
ABBOTT/COULTER
- Donor self screening
questionnaires

1996
Anti-HCV and
HBsAg
Chemiluminescent
PRISM

1997
Anti-HIV
Chemilumin
escent
PRISM

2001
ABO, Rh, RBC
antibody
screening
PK7200
3 machines
AHG from
tube test to
solid phase
microplate



By 2002

Donor self screening
questionnaires

Syphilis VDRL

HIV-p24Ag ABBOTT/COULTER

Anti-HCV and HBsAg Anti-HIV Chemiluminescent PRISM

ABO, Rh, RBC antibody screening AHG PK7200 /
3 machines [home-made reagents]

lab results from PRISM Interfacing to
computerized system AS400



2003-2008

2003

- Syphilis TPHA PK7200
- HIV, HCV NAT test TMA (Chiron)
- and HBV PCR Cobas Amplicor pilot project study
- lab results from PRISM, PK7200 and NAT Interfacing to computerized system AS400

2005

- Move to new building

2006

- NAT: HIV, HCV, HBV TMA TIGRIS for all units

2007

- HIV-Ag/Ab PRISM Combo

2008

- NAT: HIV, HCV, HBV Real time PCR pool6 s201 for all units of donated blood in NBC



2009-2012

2009

- ABO, Rh, Ab screening and Syphilis test on PK7300

2010

- National Blood Policy 2010 3rd ed indicated NAT test for 100% of units of donated blood of the whole country
- Guideline for Syphilis test
- Confirmation test for Syphilis by TPPA

2011

- Donor Selection Guideline 5th ed
- Physician Handbook on Appropriate Use of Blood and Blood Components
- Syphilis, HBsAg, Anti-HCV and HIV-Ag/Ab Architect i6000
- Evaluation of Architect HBsAg Qualitative II compare to current system

2012

- Standards for Blood bank and Transfusion Services 3rd ed
- NAT: HIV, HCV, HBV TMA TIGRIS for individual urgent samples
- HBsAg: Architect Qualitative II and Neutralization assay by Architect i6000

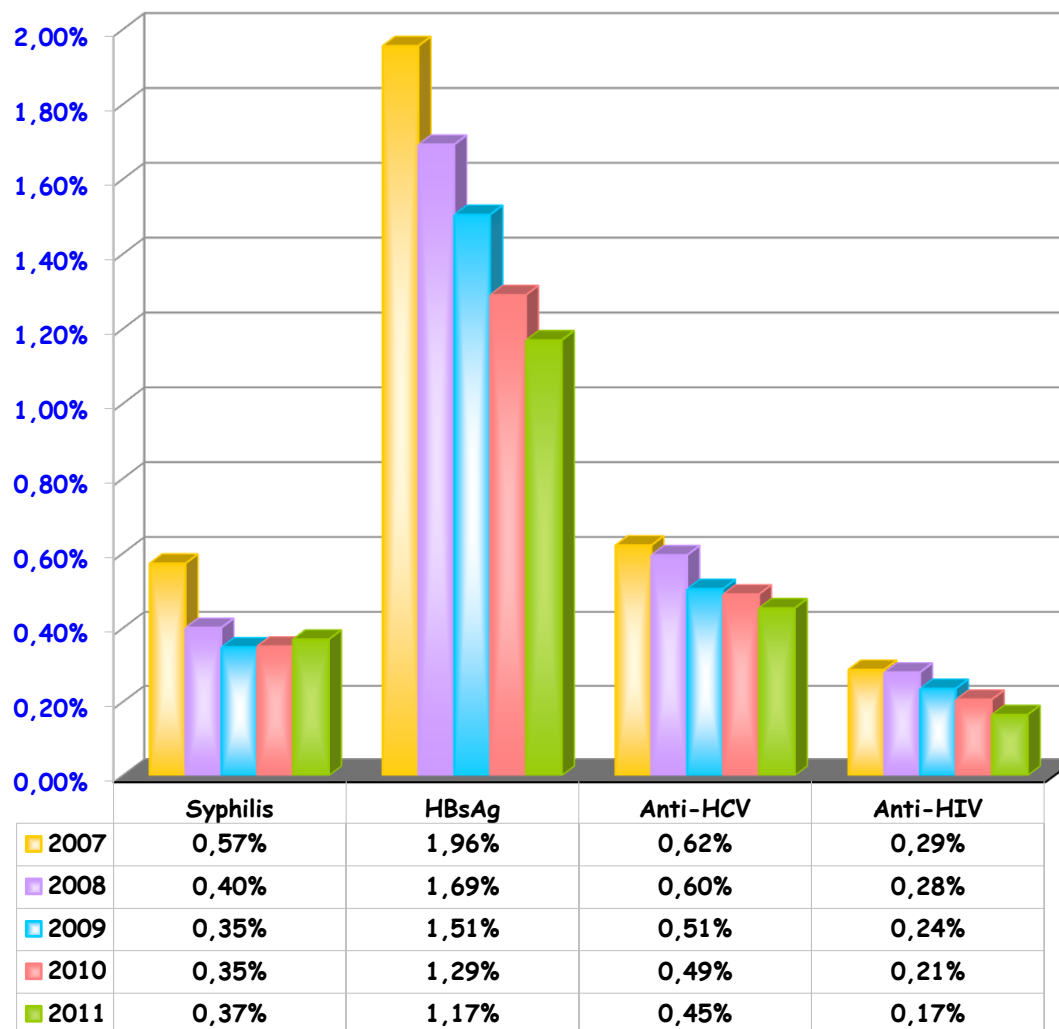


Research and Study

1. Performance Evaluation Blood bank Elecsys HBsAg II Elecsys Anti-HCV II Elecsys HIV combi PT on Elecsys e.
2. Performance Evaluation of Cobas Taq Screen MPX Test version 2.0
3. Study on Prevalence of HTLV I&II among blood donors in Thailand
4. Comparison of the Syphilis Serology Test between Elecsys Syphilis on Elecsys cobas e and Architect Syphilis TP on Architect i6000 for Blood Donor Screening

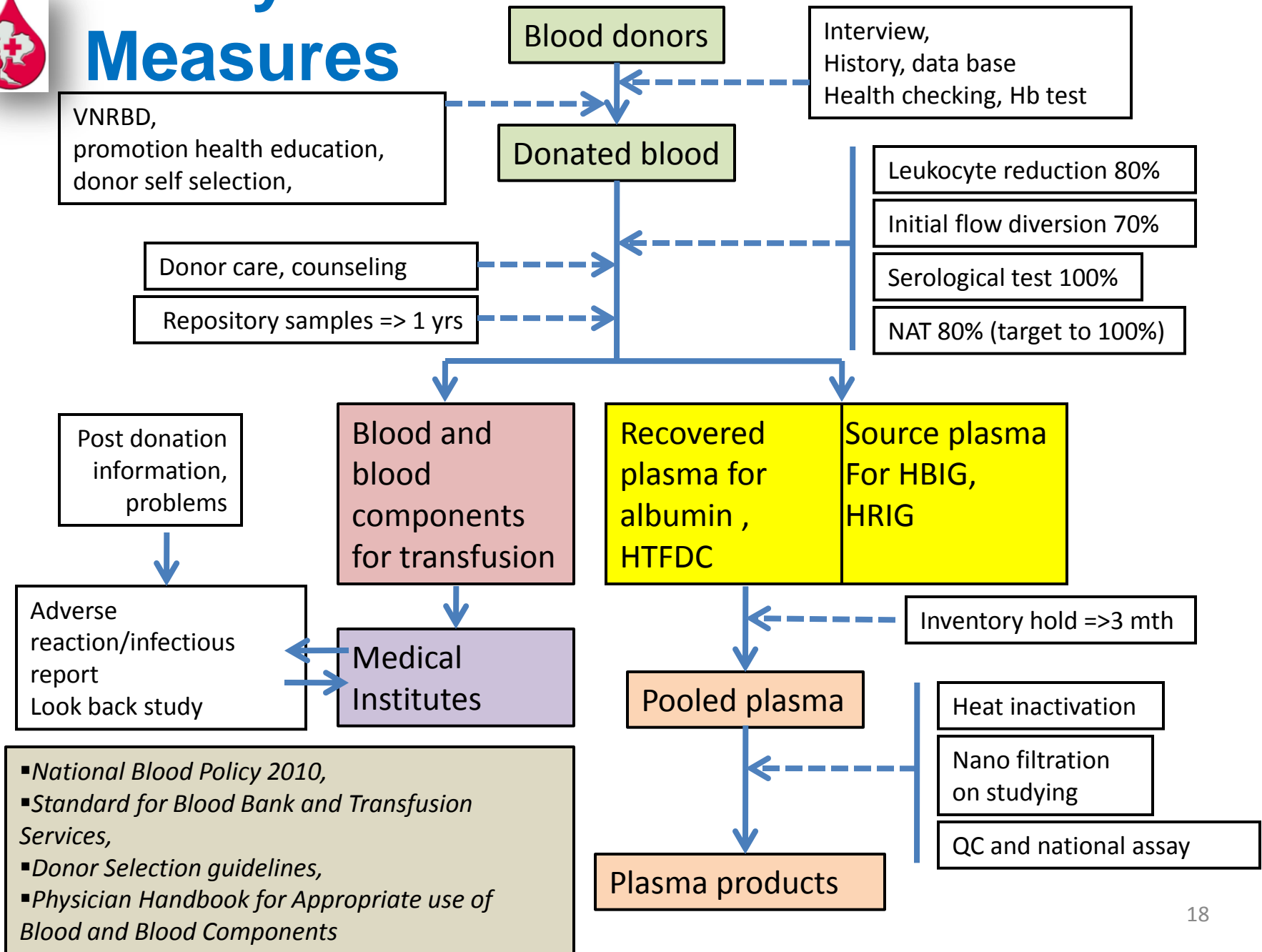


% of positive TTI in blood collections : Whole country 2007 - 2011





Safety Measures





National Blood Center Haemovigilance system

- 2001-2008
- Initiated by NBC
- Reported incidence since 2001-2008
- Reporting system: voluntary filled out questionnaires
 - with response rate of 20-40%,
 - data was annually collected and analyzed
- Scope: mainly on adverse effect of the blood recipients
- Reporting categories
 - Tx of ABO incompatible
 - Acute hemolysis
 - Dead
 - DHTR
 - Near miss incidence
 - Tx of TTI positive unit by error
 - Post Tx infection
- The program was discontinued



SUMMARY OF SHOT 2001 – 2004

P.Chiewsilp et.al. National Blood Center TRCs

[X1,000]	2001	2002	2003	2004
HIV	1:1,000	0	0	1:1400
HCV	1:500	0	1:970	0
HBsAg	1:200	0	0	0
Malaria	1:1,500	1:500	0	0
CMV	1:700	0	0	0
Bacteria	0	1:143	0	0

- Post transfusion infection by blood in window period.
(all units were negative for anti-HIV, HIV-Ag, anti-HCV and HBsAg)
- Total units transfused (WB and blood components)= 1,416,520



SUMMARY OF SHOT 2005 – 2008

P.Chiewsilp et.al. National Blood Center TRCs

[X1,000]	2005	2006	2007	2008
HIV	1:1,100	0	1:400	1:400
HCV	0	0	0	1:1,240
HBsAg	0	0	1:11	0
syphilis	0	0	0	0
malaria	0	0	0	0
CMV	0	0	0	0
Bacteria	0	0	1:11	0

- Post transfusion infection by blood in window period.
(all units were negative for anti-HIV, HIV-Ag, anti-HCV and HBsAg)



SUMMARY OF SHOT 2005 – 2008

P.Chiewsilp et.al. National Blood Center TRCs

[X1,000]	2005	2006	2007	2008
Tx of ABO incompat	1:50	1:77	1:50	1:80
Acute hemolysis	1:33	1:33	1:10	1:16
Dead	0	0	1:670	0
DHTR	1:5	1:66	1:6.5	1:10
Near misTx	1:2	1:0.9	1:2	1:2



Donor vigilance Aug-Nov 2011

P.Chiewsilp et.al. National Blood Center TRCs



Characteristics of Blood Donors

- Responders:
 - Total 2,789/12,000 = 23.24%
- Female 1479
 - = 12.33%
 - Age 17-65 yrs
- Male 1310
 - = 10.92%
 - Age 18-65 yrs
- Donation times
 - = 1-389

[including hemapheresis]



COMPLICATIONS RELATED TO WHOLE BLOOD DONATION AT NBC 22 AUG- 30 Nov,2011

Total donors =2789	N	%
Weakness	222	7.96
VVR	134	4.80
Injury to vessel (hematoma)	251	9.0
Nerve injury	40	1.43
Allergy	24	0.86
Total	671	24.06

Donor vigilance Aug-Nov 2011

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COMPLICATIONS RELATED TO WHOLE BLOOD DONATION AT NBC 22 AUG- 30 Nov,2011

VVR	Total Donors	VVR	%
Females	1479	106	3.80
Males	1310	28	1.00
Total	2789	134	4.80
M:F = 1:3.79			

Donor vigilance Aug-Nov 2011

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VVR OCCURRENCE IN BLOOD DONORS

Time of Donation	VVR	No. of total donor	%
1	24	161	0.86
2-5	40	422	1.43
6-10	22	453	0.79
11-20	22	612	0.79
21-30	10	341	0.35
31-40	6	228	0.22
41-60	3	283	0.11
61+	7	289	0.25
Total	134	2789	4.80

VVR

Total donors = 2789	N	%	NBC record = 87784	%
During donation	14	0.50	67	0.08
Immediately after donation	26	0.93	900	1.03
Before leaving Donation site	40	1.43	967	1.1
After leaving donation site	94	3.37	-	-
Total	134	4.80	967	1.1

OCCURRENCE OF VVR IN FEMALE AND MALE DONORS IN DIFFERENT AGE GROUP

Age group Yr.	VVR Female	%	VVR Male	%
17-20	4	0.14	1	0.04
21-30	32	1.15	9	0.32
31-40	35	1.25	8	0.29
41-50	22	0.79	5	0.18
51-60	13	0.47	5	0.18
61-70	-	-	-	-
Total	106	3.8	28	1.01

Donor vigilance Aug-Nov 2011

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Injury to vessel (Hematoma)	N	%
During donation	19	0.68
Immediately after donation	41	1.47
Before leaving	60	2.15
After leaving	191	6.85
Total	251	9.0

Injury to Nerve	N	%
During donation	13	0.47
Immediately after donation	8	0.29
Before leaving	21	0.75
After leaving	19	0.68
Total	40	1.43

Allergy	N	%
During donation	3	0.11
Immediately after donation	2	0.07
Before leaving	5	0.18
After leaving	19	0.68
Total	24	0.86

Donor vigilance Aug-Nov 2011

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PREVIOUS HISTORY OF DONOR REACTION IN REPEAT DONORS

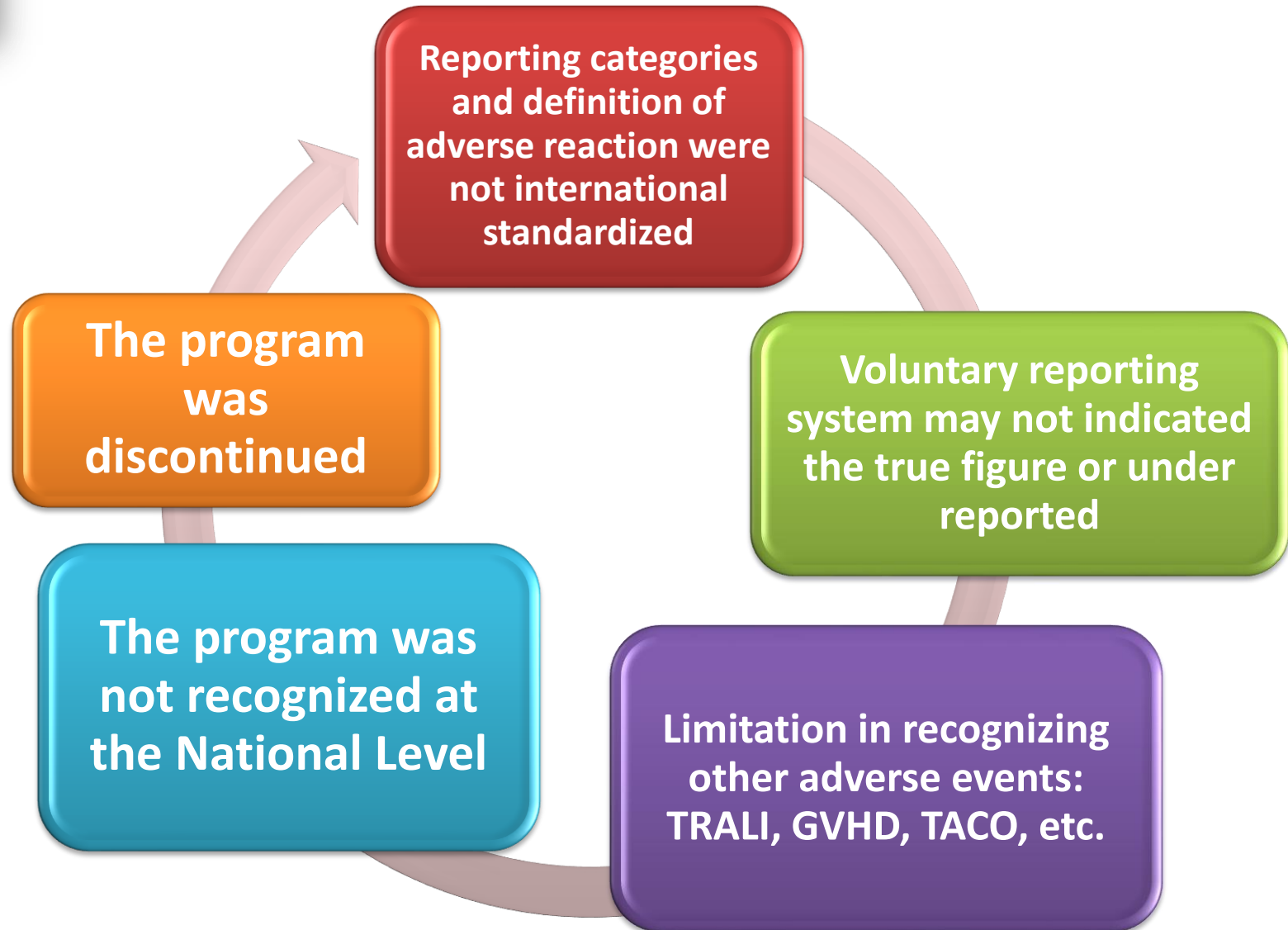
Total repeat donors= 2628	Yes (N %)	No (N %)
Previous history of donor reaction	693 (26.37%)	1935 (73.63%)

Willingness for further donation	N	%
Willing to donate blood every 3 months	2262	81.10
Will donate blood occasionally	386	13.84
No more	5	0.18
Not indicated	136	4.88
Total	2789	100

Donor vigilance Aug-Nov 2011
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Observation and recommendation





Forcing to re-try HV

ISBT

- Working party
- 2008
- 2011
- IHN

WHO

- 2007 Ottawa
Canada: The
strategies between
2008 and 2015

APBN

Thai National Blood Policy 2010

- ☐ Establish haemovigilance systems for improved blood safety
- ☐ Provide guidelines, tools and technical support for the establishment of national haemovigilance systems.
- ☐ Foster and support the creation of a Global Haemovigilance, Surveillance and Alert Network



Workshop on Haemovigilance

March 2011 Richmond Hotel, Nonthaburi



- National Blood Center TRC
- Dr. P. Flanagan, NZ Blood Service, Auckland
- 23 Members from: NBC, Hospital Blood bank Directors, Universities, Physicians
- International Standards and network for HV
- NZ model, Thai HV experience
- Group work



Key to achieve National HV

core group

- workshop attendees are core group of Thai HV

Leader team

- Leader team should be identified as soon as possible.

information

- Inform the organization involved

Definition

- Definition of events to report in HPV should be set up. And able to benchmark and be captured in international level so ISBT definitions should be that one to follow.

HV committee

- HVP Sub committee: members to be considered later.

National HV

- achieve



International perspectives on HV: WHO

Draft Aide-Memoire for Ministry of Health (MOH)

HV initially focussed on patients receiving a blood transfusion (recipients).

It now extends across the entire blood chain to include those donating whole blood and blood components (donors).

HV is defined as a set of surveillance procedures covering the entire blood chain

The Ministry of Health (MOH) should provide effective leadership and governance in developing a national HV system that is fully integrated into the blood system and the health-care system in the country and make available necessary financial and other resources.



Core components of a national HV system



Haemovigilance unit/s at national, provincial, state and/or regional level,

for central coordination, programme management, monitoring, evaluation

improvement through corrective/preventive actions in the blood system throughout the country

Blood transfusion service/s or blood centres

involved in blood and plasma collection, testing, processing, storage

and distribution of blood and blood products

Hospitals where blood transfusion is performed

through its blood banks, clinical wards, transfusion committees in charge for the timely provision of compatible blood,

appropriate use of blood products and its safe administration.

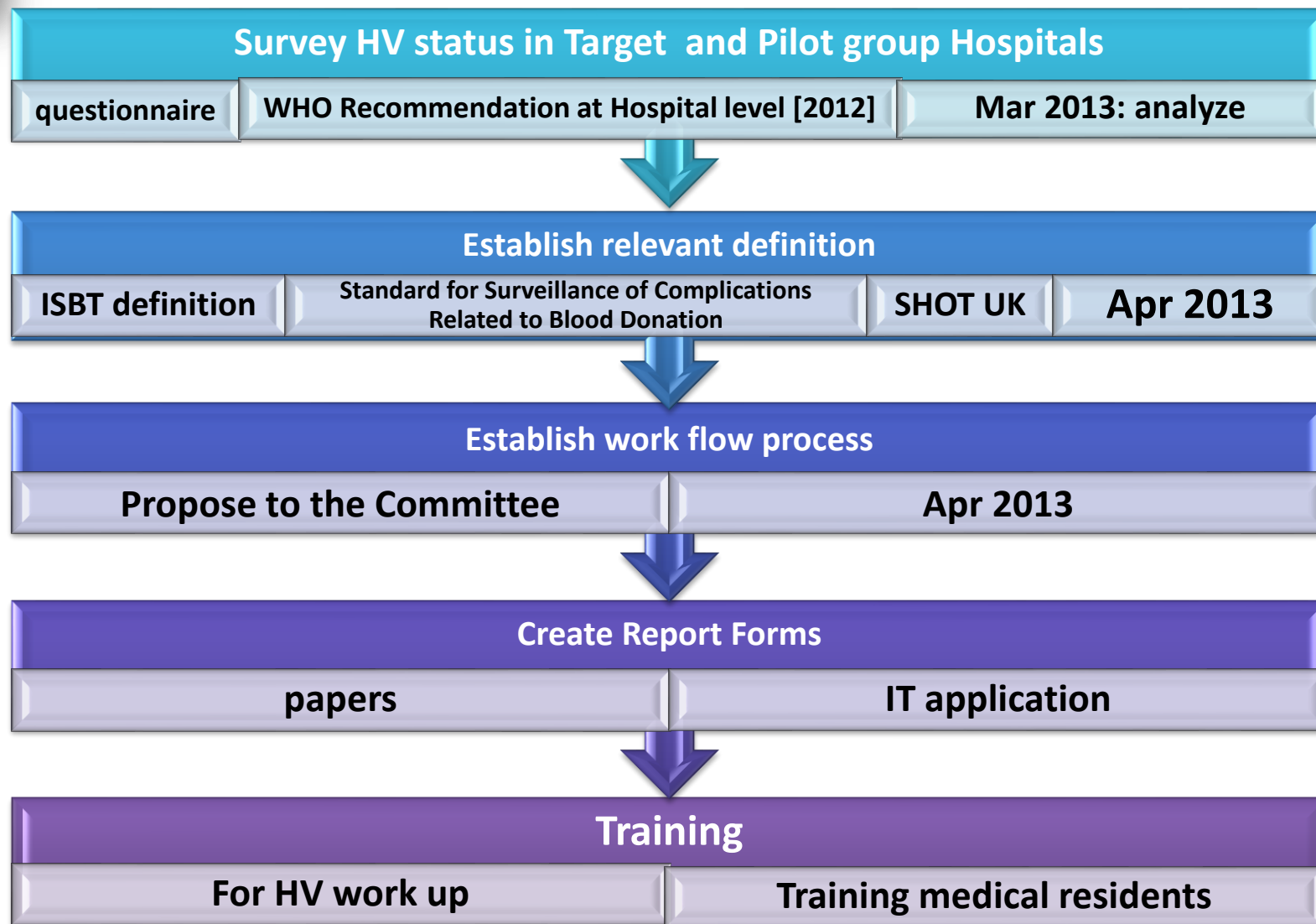


2012: HV Committee



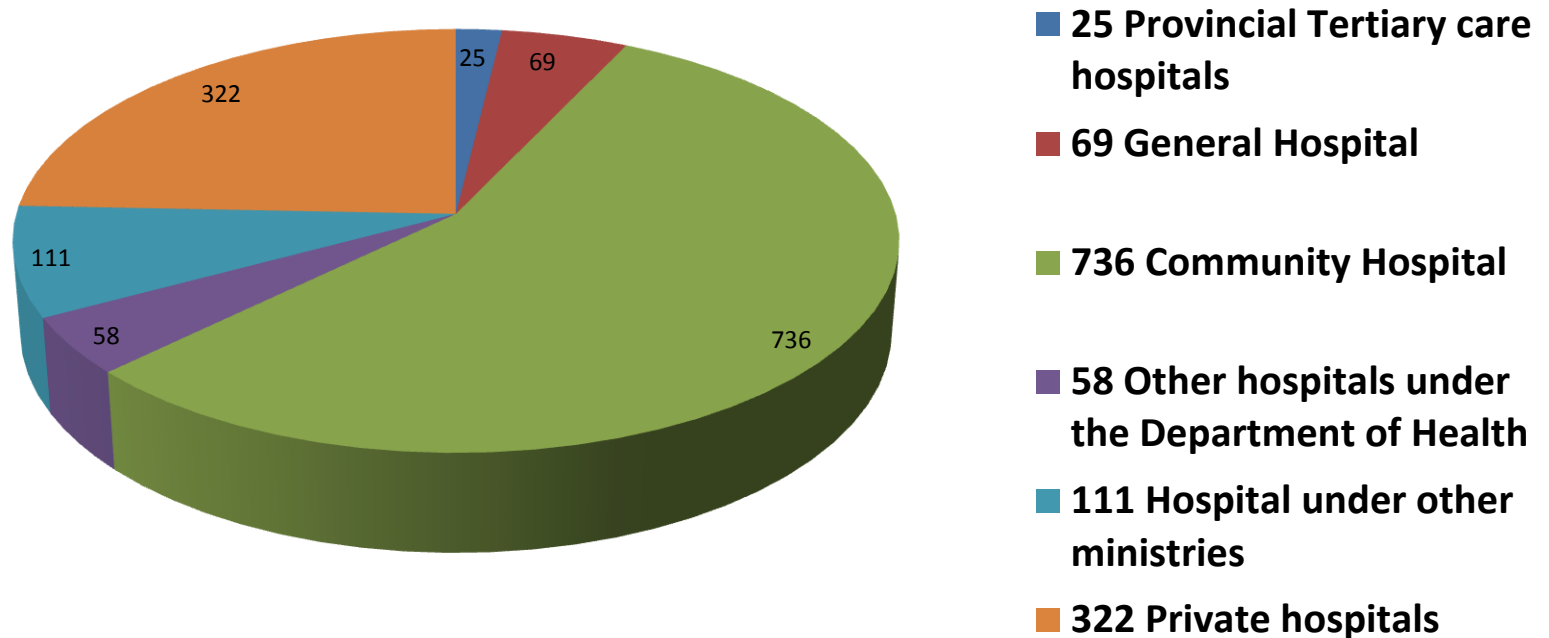


Action plan for HV





Proportion and number of hospitals in the country





Plan Capture data target groups

Phase 1)

1st – 2nd yr

- Medical Institutes
- 25 Provincial Tertiary care Hospitals
- Hospitals under Department of Medical Service

Phase 2)

3rd yr-4th

- General Hospitals over 300 beds

Phase 3)

After 5 yrs

- All General Hospitals



Thank you



- *Dr J.C. Faber*
- *Dr Neelam Dhingra*
- *Dr P. Flanagan*
- *IHS Sponsor*
- *WHO consultation Members HV Seminar in Dubai*
- *National Blood Center staff*
- *Dr Soisaang Phikulsod*
- *Dr Phimol Chiewsilp*
- *Thank you for your attention*