

Random testing for blood components QC and Comparison of Practice (CoP)

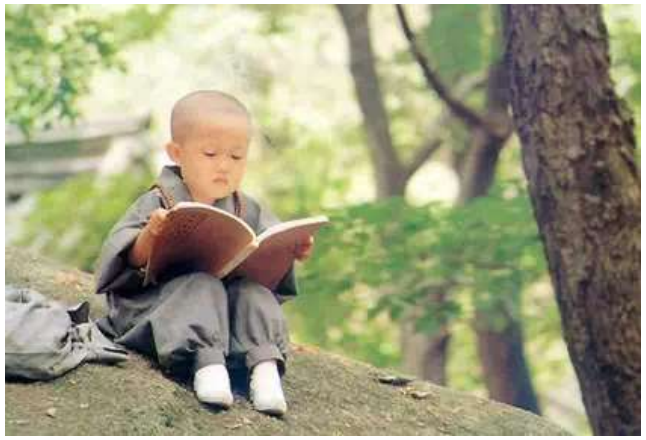
Yan QIU

Beijing Red Cross Blood Center, China

IPFA Asia Pacific Workshop on Plasma Quality and Supply

March8 -9, 2016 Taipei, Taiwan

Overview



- Asia Pacific Blood Network (APBN) CoP and Beijing Red Cross Blood Center (BRCBC)
- CoP in mainland China
- Recommendations for use of random testing for blood components QC for CoP

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APBN background

Asia Pacific Blood Network
Connecting Blood Communities

- Established in 2006
- A network of non-profitable blood operators in the Asia Pacific region who are committed to voluntary non-remunerated blood donation
- Respects different domestic contexts
- Mutually support member policy development and practice improvement





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APBN membership

Population: 262 million 12.8 million collections



- Beijing Red Cross Blood Centre
- Australian Red Cross Blood Service(Headquarters)
- Hong Kong Red Cross Blood Transfusion Service
- Japanese Red Cross Society Blood Service
- Macao Health Bureau
- New Zealand Blood Service
- Blood Services Group, Health Sciences Authority, Singapore
- Republic of Korea National Red Cross Blood Service
- Taiwan Blood Services Foundation
- National Blood Centre Thai Red Cross Society

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Knowledge exchange

APBN Activities

Comparison of practice & Performance improvement

Policy collaboration

Horizon scanning





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APBN CoP

- Data collection since 2006 and annual report with Data confidentiality
- Define the measures very precise with calculated formula and standardised the units to cover the areas of difference (small whole blood collection volumes, a-platelets, etc.)
- Collects performance measure data across the blood service chain
  - Patients
  - Hospital
  - Donors
  - Blood service business (staff, efficiency, productivity, inventory and financial)
- Measures examples follow



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APBN 2008 CoP Measures

STRATEGIC AREAS	STRATEGIC AREAS	MEASURE	No. of Q #
PATIENT(101)	PI To reduce the residual risk of transfusion(64)	Haemovigilance Program	6(1-6)
		TRALI	18(7-24)
		Bacterial contamination	9(25-33)
		Viral Marker Rates	23(34-56)
		Leucodepletion	2(57-58)
		vCJD Management Strategies	3(59-61)
		Pathogen Inactivation	3(62-64)
	P2 To Ensure the Appropriate Use of Blood(37)	Clinical Issue Rates	17(65-81)
		Demand Trend	20(82-101)
HOSPITAL(1)	H1 Customer (hospital) Satisfaction	Customer Satisfaction survey	1(102)
DONORS(37)	D1 Donor Satisfaction & Commitment		5(103-107)
	D2 Donor Other		11(108-118)
	D3 Participation Rate		11(119-129)
	D4 Donor Age		5(130-134)
	D5 Collection Method		2(135-136)
	D6 Donor Medical	Donor Adverse Events	3(137-139)
ORGANISATIONAL (46)	O1 To optimize the use of resources		29(140-168)
		Product Unit Price to Hospitals	8(169-176)
		Average Annual Product Price Trends	5(177-181)
		Cost per Capita	5(181-185)

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APBN 2009 CoP Measures

STRATEGIC AREAS	STRATEGIC AREAS	MEASURE	No. of Q #
PATIENT(87)	PI To reduce the residual risk of transfusion(71)	Haemovigilance Program	6(1-6)
		TRALI	13(7-19)
		Bacterial contamination	13(20-32)
		Viral Marker Rates	29(33-61)
		Leucodepletion	6(62-67)
		vCJD Management Strategies	3(68-70)
		Pathogen Inactivation	1(71)
	P2 To Ensure the Appropriate Use of Blood(16)	Clinical Issue Rates	16(72-87)
HOSPITAL(1)	H1 Customer (hospital) Satisfaction	Customer Satisfaction survey	1(88)
DONORS(49)	D1 Donor Satisfaction & Commitment		5(89-93)
	D2 To attract and retain sufficient donors		41(94-134)
	D3 To provide excellent donor care		3(135-137)
ORGANISATIONAL (103)	O1 To optimise the use of resources	Staff	17(138-154)
		Productivity	48(155-202)
		Inventory	14(203-216)
		Financial	24(217-240)

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APBN 2015 CoP Measures

STRATEGIC AREAS	STRATEGIC AREAS	MEASURE	No. of Q #
PATIENT(11)	PI To reduce the residual risk of transfusion		4（1-4）
	P2 To Ensure the Appropriate Use of Blood	Clinical Issue Rates	7(5-11)
DONORS(26)	D1 Donor Satisfaction & Commitment	Donor Satisfaction & Commitment	1(12)
	D2 To attract and retain sufficient donors		24(13-36)
	D3 To provide excellent donor care	Donor Care / Adverse events	1(37)
ORGANISATION (81)	O1 To optimise the use of resources		80(38-117)
		OX Other	1(118)

Derived measures

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BRCBC representation of mainland China in APBN

- Initial discussions 2008
- Beijing joined APBN in 2009
- Beijing has provided CoP data from 2008

APBN Biannual Meeting

18-19 November 2009
Nagoya, Japan

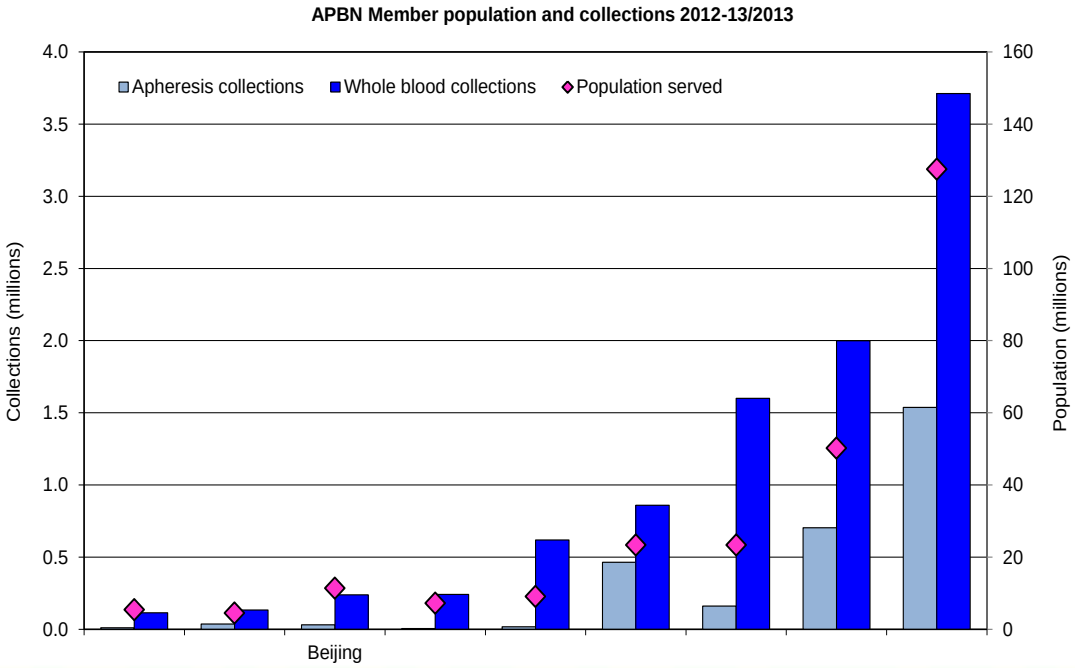


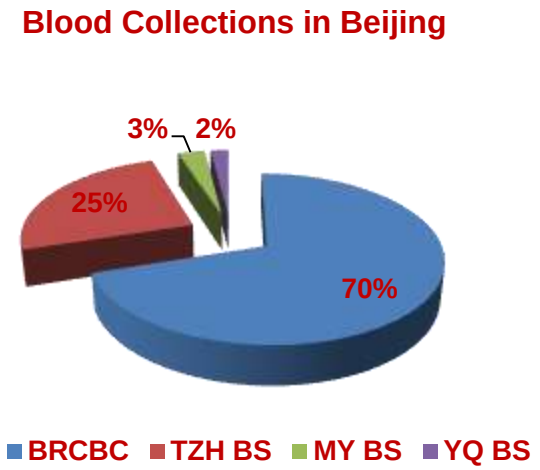
Dr Liu Jiang (left) receives the APBN Membership Certificate on behalf of the Beijing Red Cross Blood Center from Dr Che-Kit Lin (APBN Chair)

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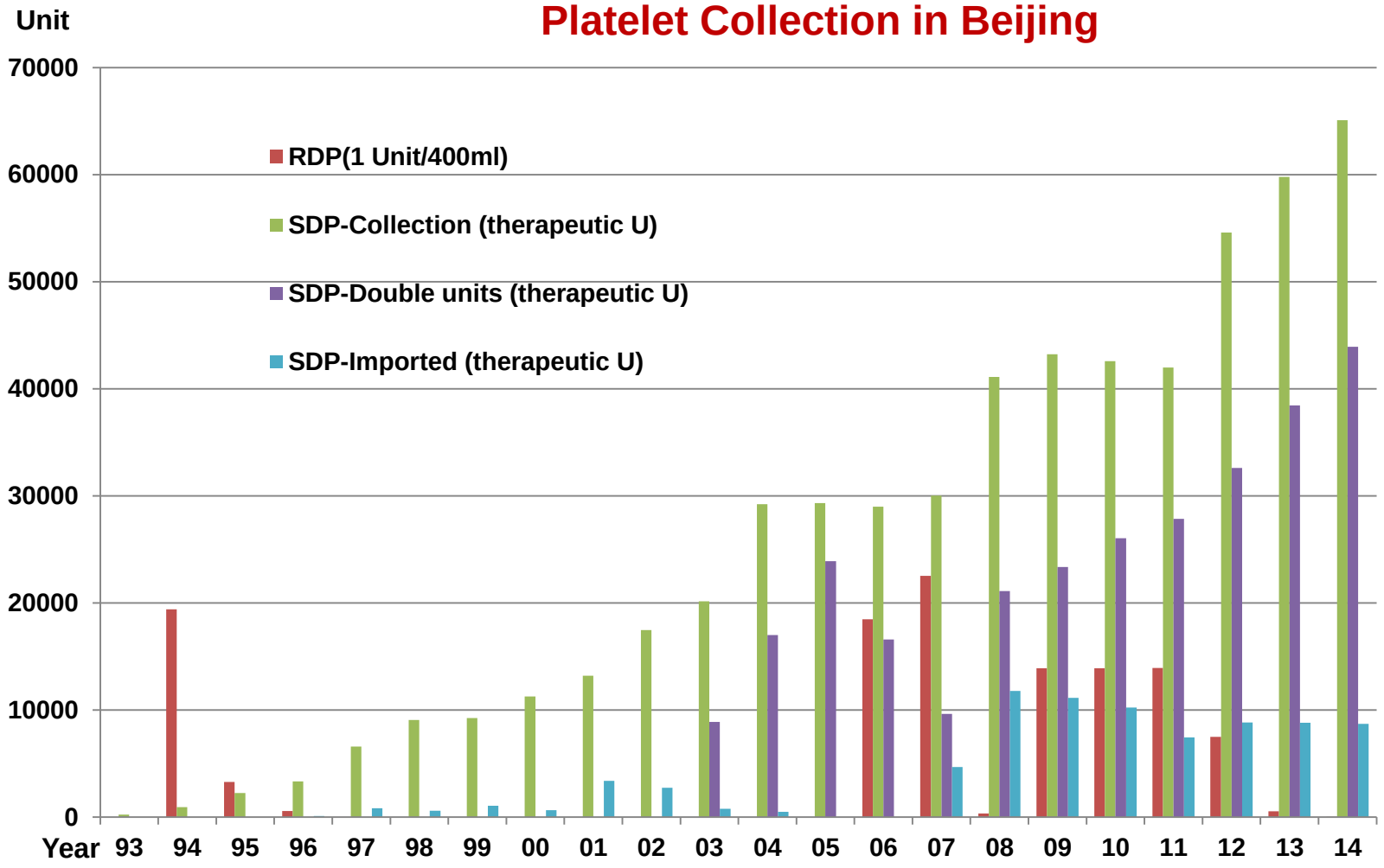
Health Care in Beijing

- Up to 2014 there are 10,244 health service organizations ,655 hospitals ,107,000 sickbeds, 216,000 health professionals including 81,000 registered doctors and 91,000 nurses in Beijing.
- In 2014 medical institutions totally diagnosed and treated 21.7 millions persons.
- The incidence of Class A and B infectious diseases was 17.6/ mil, mortality is 0.079/mil .
- Infant mortality is 2.33‰， maternal mortality is 0.719/mil.

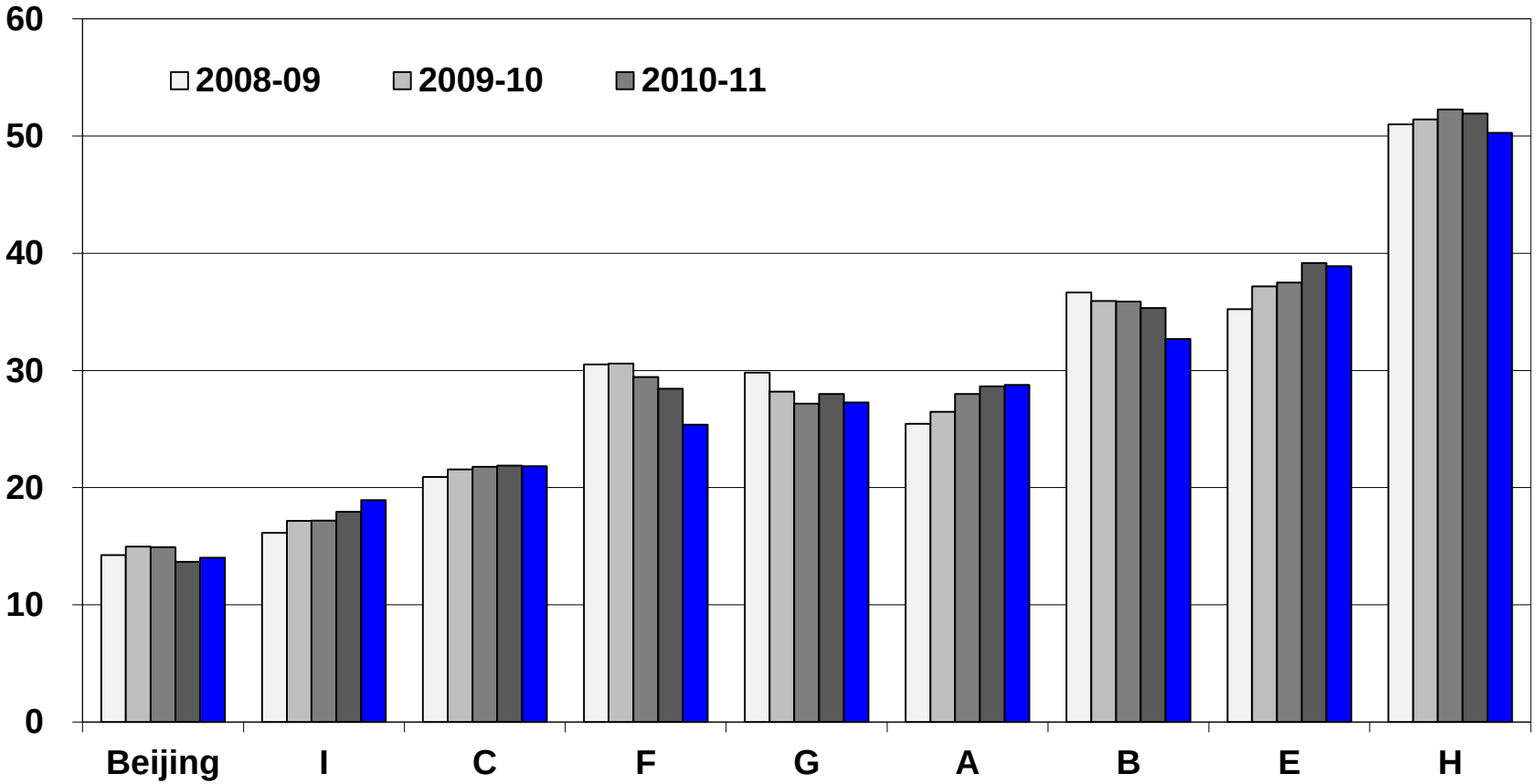




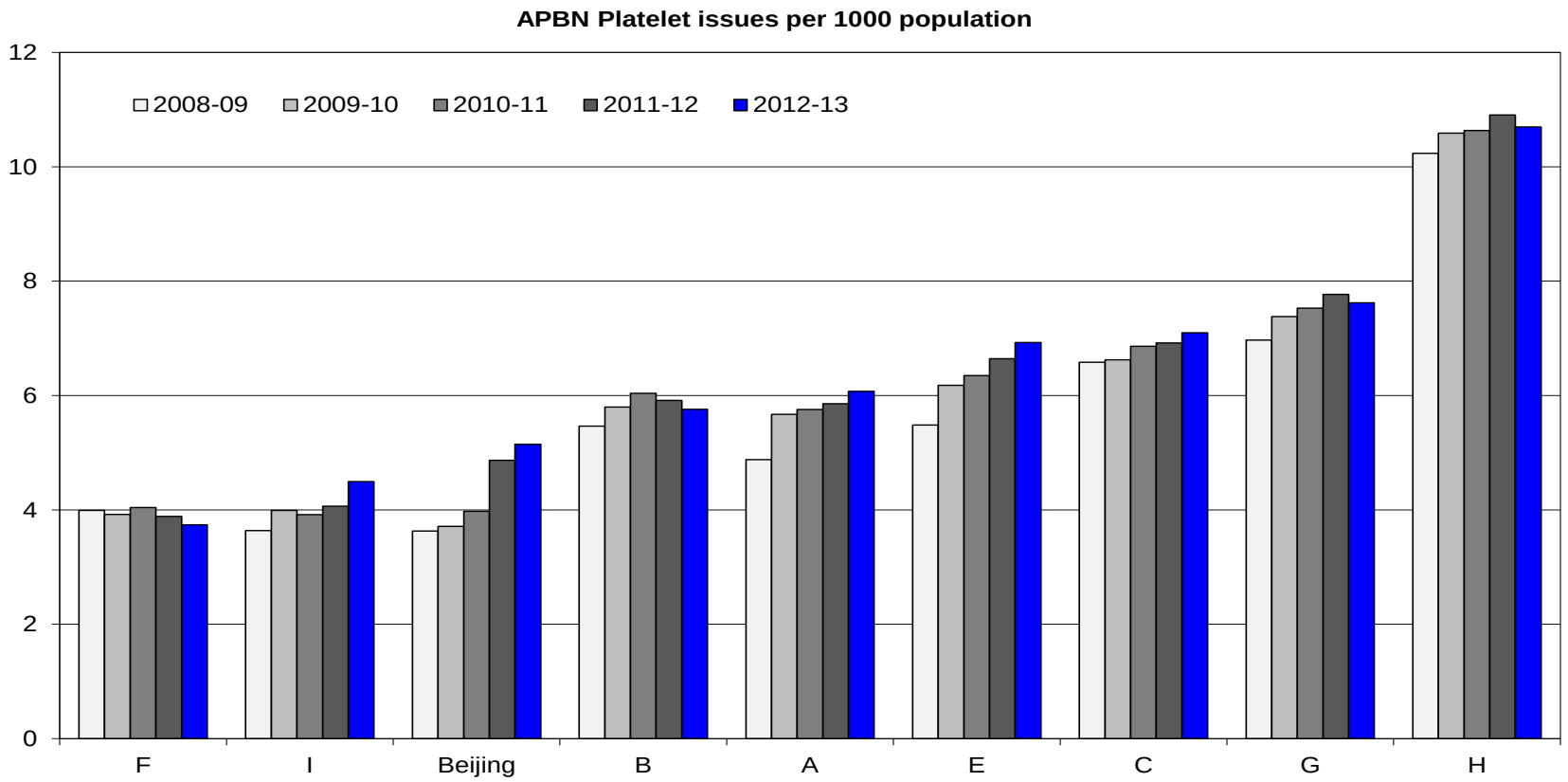
Platelet Collection in Beijing



Combined red cells and whole blood issues per 1000 population (standardised to 470 mL)



APBN Platelet Issues per 1000 Population



CoP in mainland China

- 2010 CoP in Mainland China
- CoP restarted in 2015
- Current status CoP in mainland



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2010 CoP in Mainland China

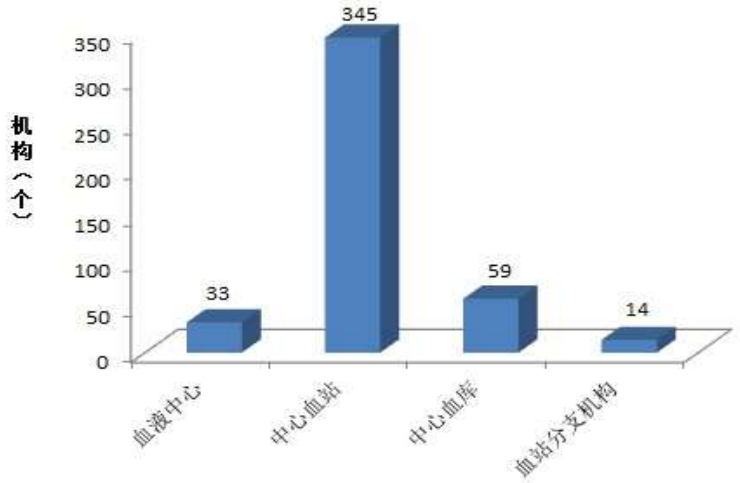
类别 STRATEGIC AREAS	指标 MEASURE	指标数 NO.of Q
社会指标(7) Donation	Donation base data	7(1-7)
管理指标(39) Organization Management	Productive rate	4(8-11)
	Predonation test and blood screening test	16(12-27)
	Staff	12(28-39)
	成分血再加工 Blood Products Processing	3(42-40)
	财政管理 Financial Management	4(43-46)
经济指标(31) Finance		31(47-77)

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Project Restart

- APBN recommended that BRCBC developed the CoP discussion forum to extend CoP in Mainland China with liaison to APBN, use APBN CoP scorecard.
- Declare the opening of CoP as a part work of CSBT during the Joint Workshop of APBN and CSBT in Nov. 2014.
- CSBT CoP WP has been organized within Administration Committee of CSBT with 29 members all around the mainland, China.
  - ✓ Scale of Blood services
  - ✓ Function of Blood services





451 blood services in China

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Project Update

- BRCBC working group of CoP has been set up in April, 2015 to to pilot CoP in mainland China.
- The first workshop has been held in Beijing May, 2015 and Reviewed and approved the working regulations and confidentiality agreement.
- Signed confidentiality agreement
- On Dec.15-18, 2015 CSBT CoP WP held second workshop in Beijing and introduce APBN 2008 CoP.





Project Update

- Set up a wechat



该微信群二维码将在2015年12月24日失效

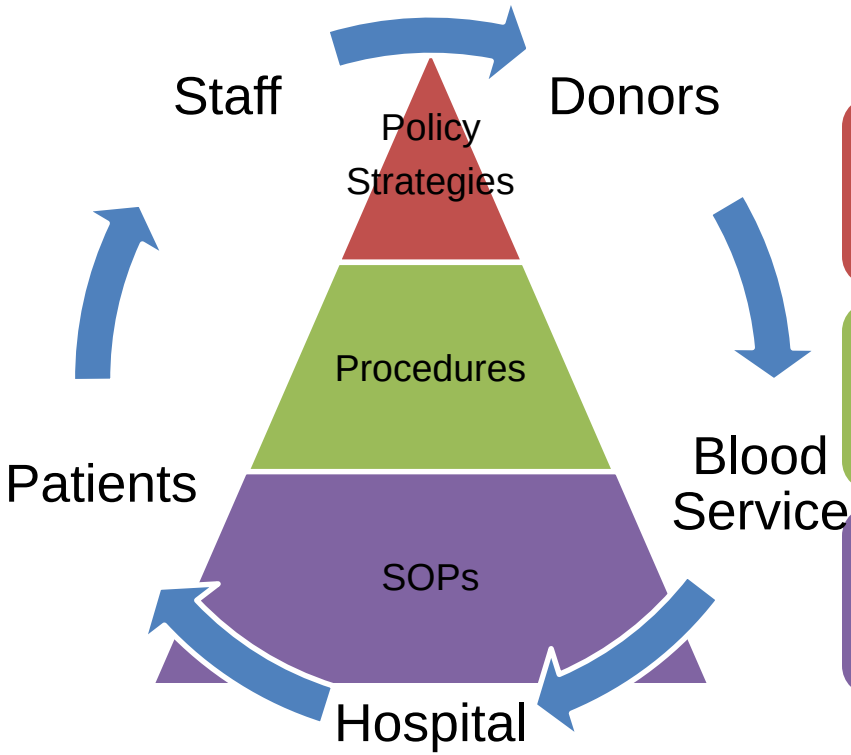
- The information management system development will be completed in April 2016
- The first data input has initiate in March,2016



- CSBT CoP WP meeting will be held in April, 2016 participants to review and discuss the first CoP data and identify performance improvement opportunities

Why use of random testing for blood components QC in mainland CoP ?

About 30%measures cannot be used by the blood services in China especially for patient and hospital



APBN CoP measures focus on

- organisational efficiency and cost effectiveness (staff, productivity, and financial)
- sufficient and sustainable donor panel, inventory
- ?

BLOOD PRODUCT

- Labile Blood Product
  - Whole blood
  - Blood components
    - Red cell components
      - Concentrate
      - With Additive Solution
      - Leukocyte Reduced
      - Washed
      - Frozen and Deglycerolized
    - Plts Concentrate
    - Cryoprecipitated Antihemophilic Factor
    - Fresh Frozen Plasma
    - Aphaeresis Blood Components
      - Plts
      - Plts Leukocytes Reduced
      - Granulocytes
      - FFP
    - Irradiated Blood Component
- Hematopoietic stem cell
  - Peripheral bloods stem cell
  - Bone marrow stem cell
  - Umbilical cord blood stem cell

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✓Regulations for Donations

- ✓ Health examination criteria of blood donors: GB 18467-2001
- ✓ Whole blood and components donor selection requirements: GB 18467-2011

- ➢ Requirements for whole blood and blood components quality: GB 18469-2001
- ➢ Quality requirements for whole blood and blood components: GB 18469-2012

➢Random Test for Quality Control in China





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Specificities for WB

Measures	aaBB	EU	China（2001）	China（2012)
Volume	labelled±10%（excluding anti-coagulant）	450ml±50ml（excluding anti-coagulant）	250ml/unit±10%（ACD-B） 228ml/unit±10%（CPD、CPDA-1）	Labelled±10%
Hemolysis		End of shelf-life< 0.8%	FHb≦0.29g/L(ACD-B) ≦0.26g/L(CPD) ≦0.72g/L(CPDA-1)	End of shelf-life < 0.8%
HB		≧45g/U		≧20g/200ml ≧30g/300ml ≧40g/400ml
Hct	≧0.38		≧0.30(ACD-B) ≧0.38(CPD,CDA-1)	
pH			6.6—7.0(ACD－B) 6.7—7.2(CPD) 6.8—7.4(CPDA-1)	
K+、Na+ Free HB			Depend on anti-coagulant	

Specificities for RBC additive solution

Measures	aaBB	EU	China（2001）	China（2012)
Volume	300~400ml	Depend on the system	labelled±10%	Labelled±10%
Hemolysis		End of shelf-life < 0.8%		End of shelf-life < 0.8%
HB		≧45g/U		≧20g/200ml ≧30g/300ml ≧40g/400ml
Hct	0.55-0.65	0.50-0.70	0.50-0.65	0.55-0.65

Specificities for Leukocytes Reduced RBC

Measures	aaBB	Britain	EU	China（2001）	China（2012)
Volume		280ml ±10%	Depend on the system	labelled±10%	labelled±10%
Hemolysis		End of shelf-life< 0.8%	End of shelf-life< 0.8%		End of shelf-life < 0.8%
HB	Recovery rate≧85%	≧40g/U	≧40g/U		≧18g/200mlWB ≧27g/300mlWB ≧36g/400mlWB
Hct				0.45~0.60	0.45~0.65
WBC Residual	≦5.0×10^6 /U	≦5.0×10^6 /U	≦1.0×10^6 /U	≤2.5×10^6 /U CMV ≤2.5×10^8 /U NHFR	≤2.5×10^6/200mLWB ≤3.8×10^6/300mLWB ≤5.0×10^6/400mLWB

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Specificities for Deglycerolized Red Blood Cells

Measures	aaBB	Britain	EU	China（2001）	China（2012)
Volume		Depend on the system	≥185ml	200ml±10%/U	200mL±20mL 300mL±30mL 400mL±40mL
Free-HB		≤2.0g/U	≤0.2g/U	≤1.0g/L	≤1.0g/L
HB recovery rate	≥80%	≥36g/U ≈80%	≥36g/U ≈80%	≥80% （ ≈16g ）	≥16g/200ml≈80% ≥24g/300ml≈80% ≥32g/400ml≈80%
Hct			0.65~0.75		
Residual plt				≤1%	
Residual WBC		≦5.0×10^6 /U		≤1%	≤2×10^7/200mL ≤3×10^7/300mL ≤4×10^7/400mL
Hemolysis				≤50%	
Residual glycerol				≤10g/L	≤10g/L

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Specificities for RDP

Measures	aaBB	Britain	EU	China（2001）	China（2012)
Volume	40~70ml/U	Depend on the system	>40ml	25~30ml/200 50~70ml/400	25~38ml/200 38~57ml/300 50~76ml/400
Plt count	≧5.5×10^{10}/U	≧2.4×10^{10}/pooling	≧6.0×10^{10}/U	≧2.0×10^{10} /U	≧2.0×10^{10}/200 ≧3.0×10^{10}/300 ≧4.0×10^{10}/400
pH Value	>6.2	6.4~7.4	6.4~7.4	6.0~7.4	6.4~7.4
Residual WBC	≦8.3×10^{6} /U	≦5.0×10^{6} /pooling	≦2.0×10^{8} /U-PRP ≦0.5×10^{8} /U-BC ≦1.0×10^{6} /pooling		
Residual RBC				≦1.0×10^{9} /U	≤1.0×10^{9}/200mL ≤2.0×10^{9}/300mL ≤3.0×10^{9}/400mL

Specificities for SDP

Measures	aaBB	Britain	EU	China（2001）	China（2012)
Volume		Depend on the system		125~200ml（1day） 250~300ml（5days）	125~200ml（1day） 250~300ml（5days）
Plt Count	≧3.0×10^{10}/U	≧2.4×10^{11} /U	≧2.0×10^{11}/U	≧2.5×10^{11} /U	≧2.5×10^{11} /U
pH	>6.2	6.4~7.4	6.4~7.4	6.0~7.4	6.4~7.4
WBC residual	≦5.0×10^{6} /U	≦5.0×10^{6} /U	≦3.0×10^{8} /U ≦1.0×10^{6} /U	≦5.0×10^{8} /U ≦5.0×10^{6} /U	≦5.0×10^{8} /U ≦5.0×10^{6} /U
RBC residual				≦8.0×10^{9} /U	≦8.0×10^{9} /U

Specificities for FFP

Measures	aaBB	EU	China（2001）	China（2012)
Volume	Depend on the system	labelled±10%	labelled±10%	labelled±10%
F VIII	≧0.70IU/ml	≧0.70IU/ml	≧0.70IU/ml	≧0.70IU/ml
Plasma protein	≧50g/L		≧50g/L	≧50g/L
Residual PLT	≦3.0×10^9 /L	≦5.0×10^9 /L		
Residual WBC	≦5.0×10^6/L	≦0.1×10^9 /L		
Residual RBC	≦6.0×10^9/L	≦6.0×10^9/L		

Statistic result of SDP QC Data from BRCBC

	Volume	pH	Plt	WBC	RBC
unit	ml		x 10^{11}/bag	×10^{8}/bag	×10^{9}/bag
n	464	308	464	464	464
limits	250-300	6.2-7.4	>2.5	<5.0	<8.0
Mean	272.2	7.04	2.7	1.2	5.670
SD	21.9	0.21	0.7	1.8	5.040
VC %	8.0	3.0	24.1	150.4	88.9
min	209	6.34	0.7	0.0	0.000
max	340	7.40	5.9	13.1	26.200



Summary

- ✓ CoP is a tool helping to identifies good practice opportunities by selecting benchmark
- ✓ Promote performance improvement, practice achievement and exchange knowledge within members
- ✓ An empirical non-parametric benchmarking method is not enough for assessing the organization on all level.
- ✓ Quantity benchmarking can help monitor the blood product quality and optimize the produce process.

Your comment is appreciated

THANK YOU

