



**Asia-Pacific  
Economic Cooperation**

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## **Quality Systems for Blood Safety in Indonesia**

Submitted by: Indonesian Red Cross Society



**APEC**  
PHILIPPINES  
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# QUALITY SYSTEMS FOR BLOOD SAFETY IN INDONESIA

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## OUTLINE



- Introduction
- Regulation
- Progress of blood services in Indonesia
- Progress of Quality systems for blood safety in Indonesia
- Challenges

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## INTRODUCTION



### Indonesia:

- Population: 254m (4<sup>th</sup> largest in the world, between US and Brazil)
- Area 1.9m sq Km (similar to Mexico), located across the equator
- >17,000 Islands. Extent is similar to Canada



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## INTRODUCTION



Administratively, Indonesia consists of 33 provinces and 420 districts. In 2014:

- 211 Indonesian Red Cross (IRC) Blood Centers
- 204 (164 active) Government Hospital Based Blood Centers
- Hospital transfusion services

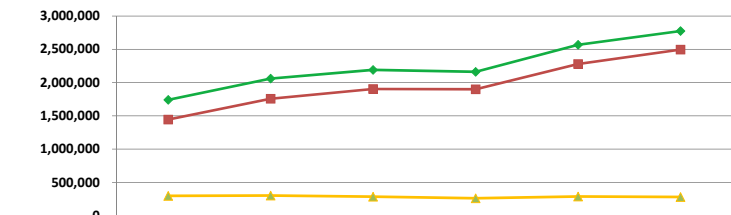
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## REGULATION ON BLOOD SERVICES

- Minister of Health Regulation No. 118/2007
- Government Decree No. 36/2009 on Health
- **Government Regulation No.7/2011 on Blood Services**
- **IRC Internal Regulation on Blood Service No. 002 /KEP/PP PMI/I/2011 (In revising due to MOH Regulation)**
- **Minister of Health Regulation No. 83/2014 about BCs, HBB and networking**
- National guideline and standard on blood services (in the process to set up → revising IRC Guideline and standard)
- National GMP Guide for Blood Establishment (in the process to set up)
- **“WHO Achilles Project” for plasma fractionation program**
- **Australian Red Cross guidance to reach of the GMP Standard**



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## DONATION NUMBER ACHIEVED BY IRC BLOOD CENTERS 2009 – 2014 ( increased 59%)

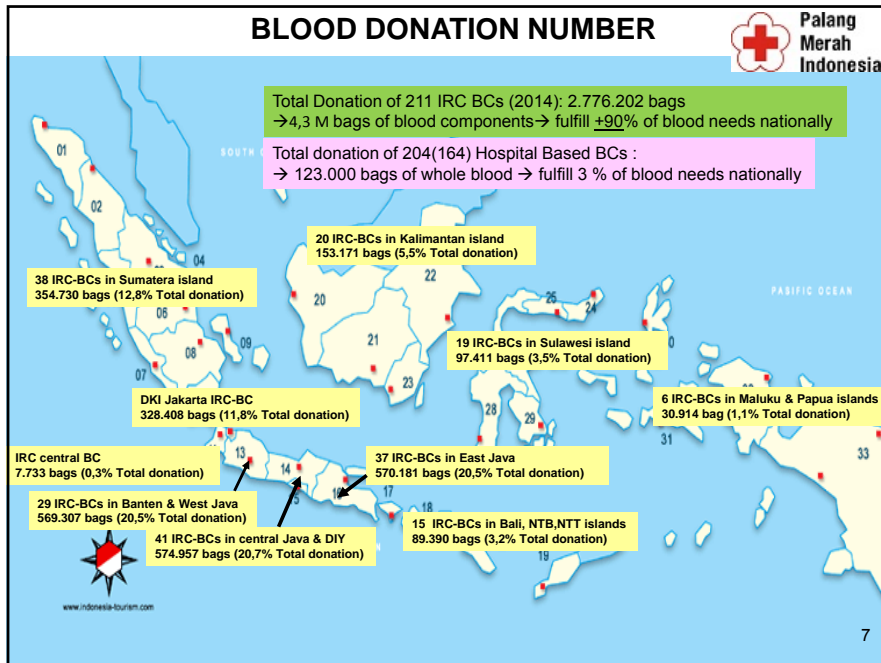


	2009	2010	2011	2012	2013	2014
Total Donasi	1,742,151	2,061,558	2,191,126	2,162,519	2,568,993	2,776,202
Donasi Sukarela	1,444,398	1,758,570	1,903,702	1,899,776	2,280,754	2,495,449
Donasi Pengganti	297,753	302,988	287,424	262,743	288,239	280,753

- Voluntary blood donation : 90%
- Replacement donation : 10%
- Celebrate WBDD every years
- Give Satya Lancana kebaktian Sosial for ≥100x donation by President

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### BLOOD COLLECTION ACTIVITIES


**Palang Merah Indonesia**

#### BLOOD COLLECTION CENTER IN SHOPPING MALL & CAMPUS

Indonesian Red Cross have achieved to provide >100 Mobile Unit Bus for Blood Centers in the district areas (2011-2012)


Aferesis Donation:  
 2014 collect 5.844  
 Aferesis donation in several big blood centers

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### BLOOD COMPONENT PROCESSING


2.776.202 Unit of Whole Blood  
- Nationally 16% is used as Whole Blood



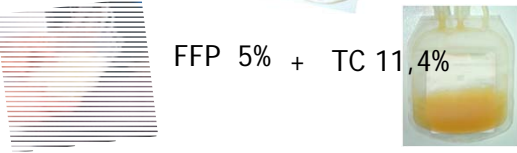
PRC



Plasma (20%)




(AHF) 0,6%



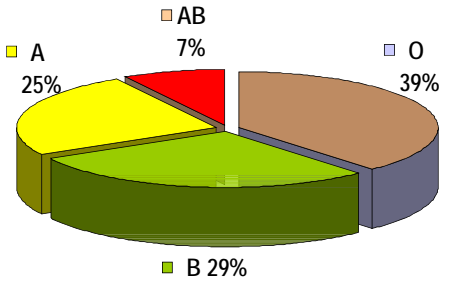
FFP 5% + TC 11,4%

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## ABO BLOOD GROUPING



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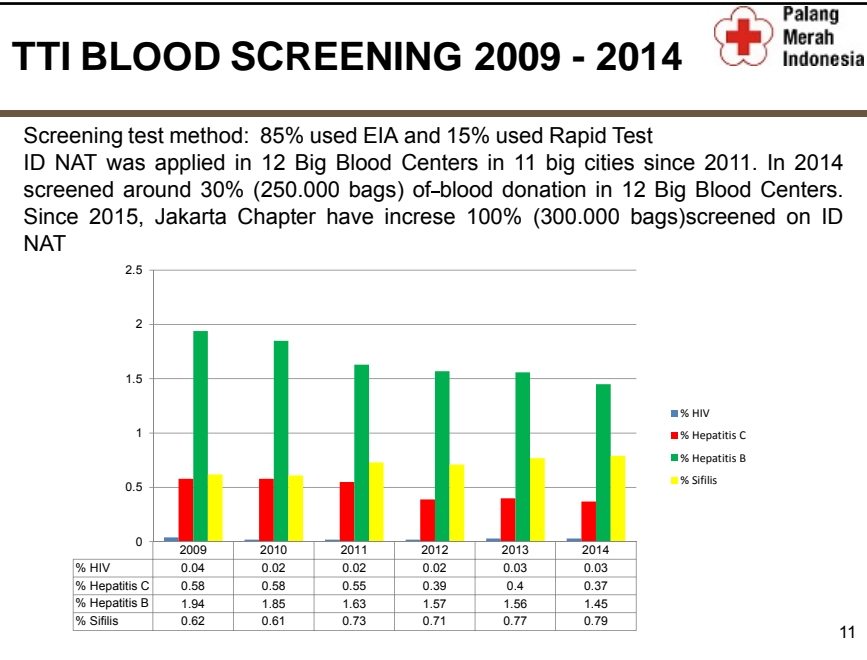
Group	Percentage
A	25%
B	29%
AB	7%
O	39%

### RHESUS BLOOD GROUPING


- Rhesus Positive : > 99,94%

- Rhesus Negative : < 0,06%

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- ### Summary Progress of Quality Systems for Blood Safety in Indonesia
- Clear regulation and guideline on the technical aspect of blood services
  - Increasing awareness of blood donation (30-50 peoples donated blood/day in shopping mall/campus/Bus MU)
  - Blood donation number increase  $\geq 10\%$  per-year
  - 84% of WB has been processed into component (PRC, TC, AHF, FFP, etc)
  - 100% of blood has been screened for TTIs
  - Safety of blood for multi transfused patients in 11 big cities was increased due to the NAT implementation
  - MIS has been implemented in 55 of BCs
  - More hospital has Blood Bank Unit  $\rightarrow$  increase closed system of blood transportation
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**Progress of Quality Systems for blood safety in Indonesia**  Palang Merah Indonesia

**FIVE ELEMENTS of QUALITY SYSTEM:**

**I. Organization Management**

- In 2015 IRC CBCs have developed a new structure of Quality Development for blood centers and perform self assessment IRC BCs Capacity mapping.
- **Since 2013 IRC BCs was received an assistances by the Australian Red Cross Blood Service for Implementation of Quality System and GMP for blood establishment**
- **QUALITY POLICY of CBCs:**
  - Central Blood Center Service is committed to quality and will meet the needs of its customers by providing effective services and safe blood products.
  - This will be achieved through the participation of all employees in the maintenance, continual improvement and harmonisation of systems and processes that are based on best practice.
  - As the National Blood Center Service for IRC, CBCs is committed to the establishment of a quality national blood service.
  - This will be **achieved by leading and supporting all BCs in the implementation of a quality system based on good manufacturing practice.**

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**5 REGIONAL AREA**  Palang Merah Indonesia

Regional	IRC BCs	Main BCs	Middle BCs	Primary BCs
DKI Jakarta, Banten, Sumatera	45	5	13	15
West Java, Kalimantan	43	4	14	17
Central Java, Yogyakarta Province	41	4	24	13
East Java, Bali, East and West Nusa Tenggara	54	4	25	19
Sulawesi, Maluku and Papua	27	1	4	5

(Not all of BC's has been reporting of self assessment result, just around 80% from the total of IRC BCs )



## Progress of Quality Systems for blood safety in Indonesia



Palang  
Merah  
Indonesia

### FIVE ELEMENTS of QUALITY SYSTEM:

#### II. Standard

MOH, CBCs IRC and National Agency of Food and Drug Control (BPOM-Indonesia) developed Blood Services Standard and GMP Guide for Blood establishment

#### III. Documentation

MIS (SIMDONDAR) has been implemented in 58 BCs (27%)

#### IV. Training

In 2015, CBCs conduct Quality System and GMP Training for IRC BCs, 1st phase for 12 Main IRC BCs, will continue to other main IRC BCs

#### V. Assessment

Assessment and Visitation in 5 Big Main BCs as the pilot project by NADF Control and CBCs for GMP Accreditation (supported from Archilles project WHO) → for preparation of plasma fractionation

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## Meeting Discussion of GMP between IRC, MOH, NADF, and Aus RC Consultant

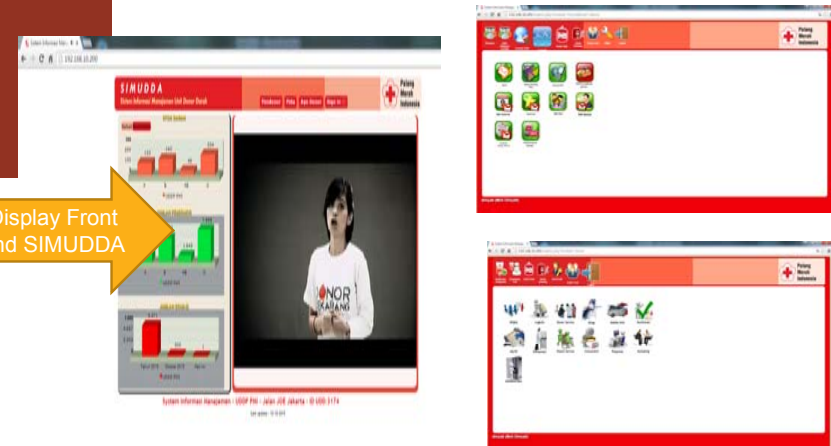


### Quality System and GMP Training for IRC BCs



### Display of IRC BCs MIS: SIMDONDAR

Display Front end SIMUDDA




**VISITATION WHO with NADF Control for ACCREDITATION of GMP in SURABAYA BCs IRC**



**Challenges to Improve of Quality System for Blood Safety in Indonesia (1)**




Program	Remarks
National Policy for all BCs in Indonesia	<ul style="list-style-type: none"> <li>• Commitment from all relevant parties</li> <li>• Establishing a National Blood Center</li> <li>• National blood system, strategy and networking → develop a culture of quality</li> <li>• Assurance of funding budget from goverment and local government</li> </ul>
Standards	<ul style="list-style-type: none"> <li>• Develop a national quality policy</li> <li>• Develop Blood Services Standard</li> <li>• Develop GMP Guide for Blood Establishment</li> </ul>
Program, Infrastructure and Equipment	<ul style="list-style-type: none"> <li>• Strengthening Regional Blood Program</li> <li>• Increasing awareness on blood donation in small cities</li> <li>• Improving infrastructure (Implementation otomation, NAT, standart BCs building, Use of validated and calibrated instruments)</li> </ul>

**Challenges to Improve of Quality System for Blood Safety in Indonesia (2)** 

	Remarks
Personnel	<ul style="list-style-type: none"> <li>• Sufficient number of competent personnel</li> <li>• Continues training to assure the required QS and GMP → need support from other country have Quality System in place (Austr Red Cross, Thai Red Cross, etc)</li> <li>• Training for Clinicians for rational use of blood</li> </ul>
Documentation	<ul style="list-style-type: none"> <li>• Implementation of Good Documentation System in all IRC BCs</li> <li>• Implementation SIMDONDAR (MIS) in all IRC BCs</li> <li>• Trace-back System → support in Haemovigilance System</li> </ul>
Inspections and Audit	<ul style="list-style-type: none"> <li>• Scheduled regularly from The authority bodies</li> <li>• Continuous support from WHO (Achilles Project)</li> </ul>

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**ACKNOWLEDGE** 

- CBCs IRC Staff
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