

# Experience from Indonesia of Quality Management / GMP programmes

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CENTRAL BLOOD CENTER – INDONESIAN RED CROSS

# OUTLINE



- Introduction
- Regulation
- Progress of blood services in Indonesia
- Management Blood Transfusion Program
- Challenges

# INTRODUCTION



Indonesia:

- Population: 254m (4<sup>th</sup> largest in world, between US and Brazil)
- Area 1.9m sq Km (similar to Mexico), located across the equator
- >17,000 Islands of which 69,000 are inhabited. Extent is similar to Canada



# INTRODUCTION

Administratively, Indonesia consists of 33 provinces and 420 districts.  
In 2018:

- 220 Indonesian Red Cross (IRC) Blood Centers
  - 3,2 million bags of blood donated
  - 4,2 million bags of WB and components
  - fulfill 90% of national needs
- 204 (164 active) Government Hospital Based Blood Centers
  - 123,000 bags of whole blood
  - Fulfill 3% of national needs
- Hospital transfusion services
  - Blood transfusion services in Hospital that only do pre-transfusion testing

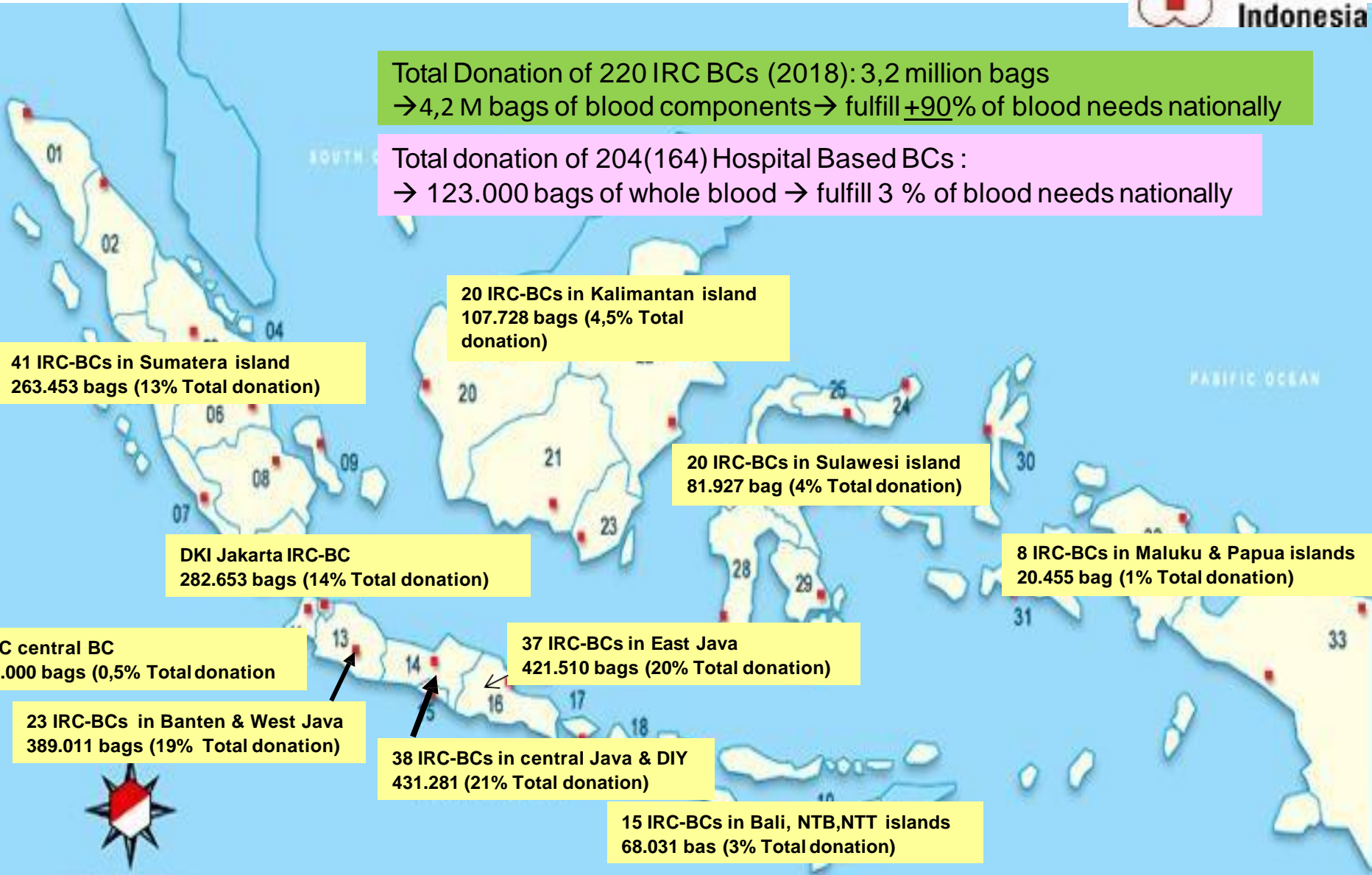
Progress regulation of blood services in Indonesia in three years later (2015-2017):

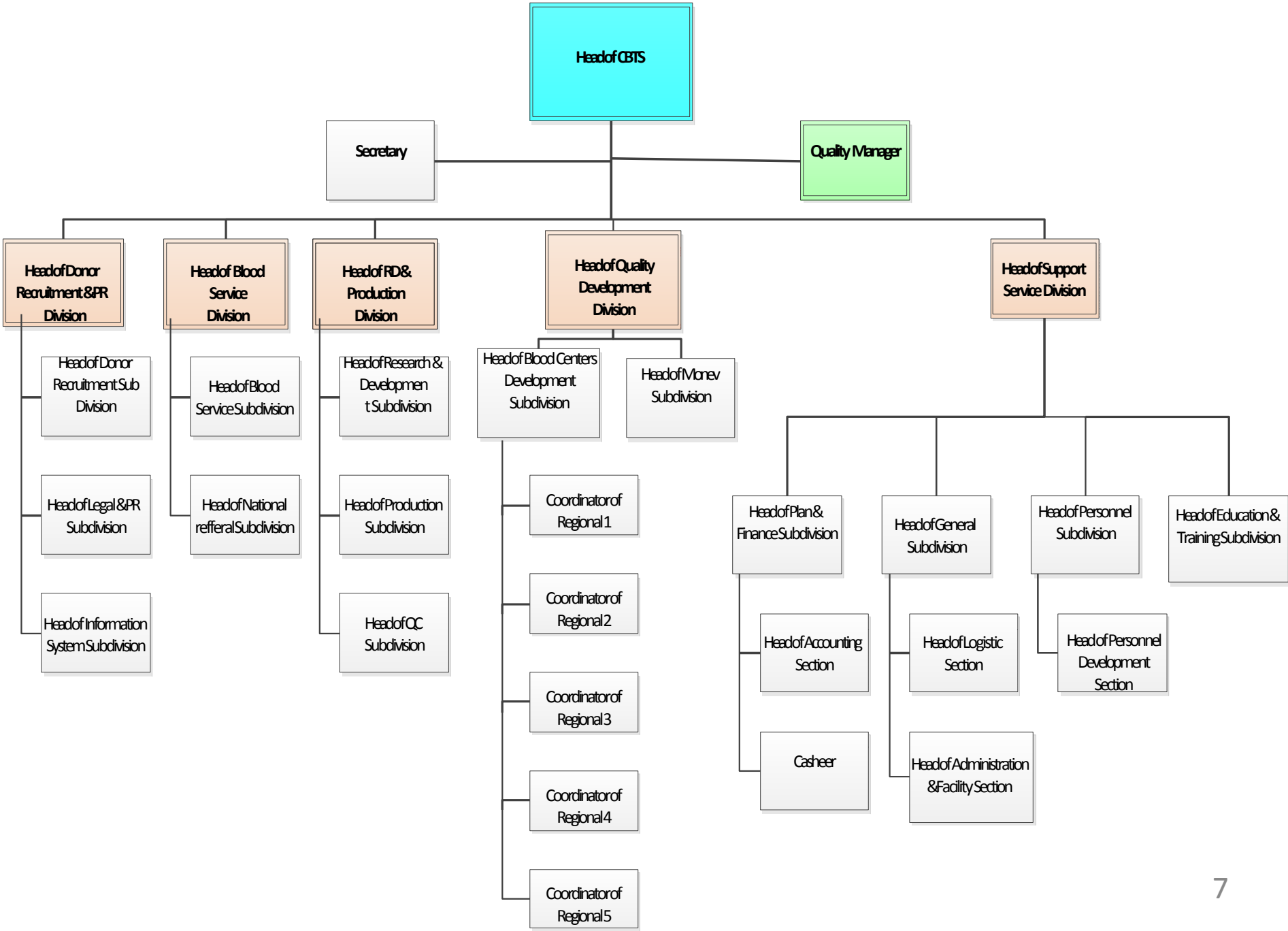
- Government Decree No. 36/2009 on Health
- Government Regulation No.7/2011 on Blood Services
- Minister of Health Regulation No. 83/2014 about BCs, HBB and networking
- Minister of Health Regulation No. 72/2015 about Fractionation
- Minister of Health Regulation No. 91/2015 about National guideline and standard on blood services
- IRC Internal Regulation on Blood Service No. 001 /KEP/PP PMI/I/2016
- Since 2016 IRC BCs was received an private assistances by GMP International Consultan for Implementation of Quality System and GMP for blood establishment for 8 BCs
- <sup>5</sup> National GMP Guide for Blood Establishment in 2017

# BLOOD DONATION NUMBER

Total Donation of 220 IRC BCs (2018): 3,2 million bags  
→ 4,2 M bags of blood components → fulfill +90% of blood needs nationally

Total donation of 204(164) Hospital Based BCs :  
→ 123.000 bags of whole blood → fulfill 3 % of blood needs nationally





# 5 REGIONAL AREA

No of Regional	Regional	IRC BCs	Main BCs	Middle BCs	Primary BCs
I	DKI Jakarta, Banten, Sumatera	45	5	13	15
II	West Java, Kalimantan	43	4	14	17
III	Central Java, Yogyakarta Province	41	4	24	13
IV	East Java, Bali, East and West Nusa Tenggara	54	4	25	19
V	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 )

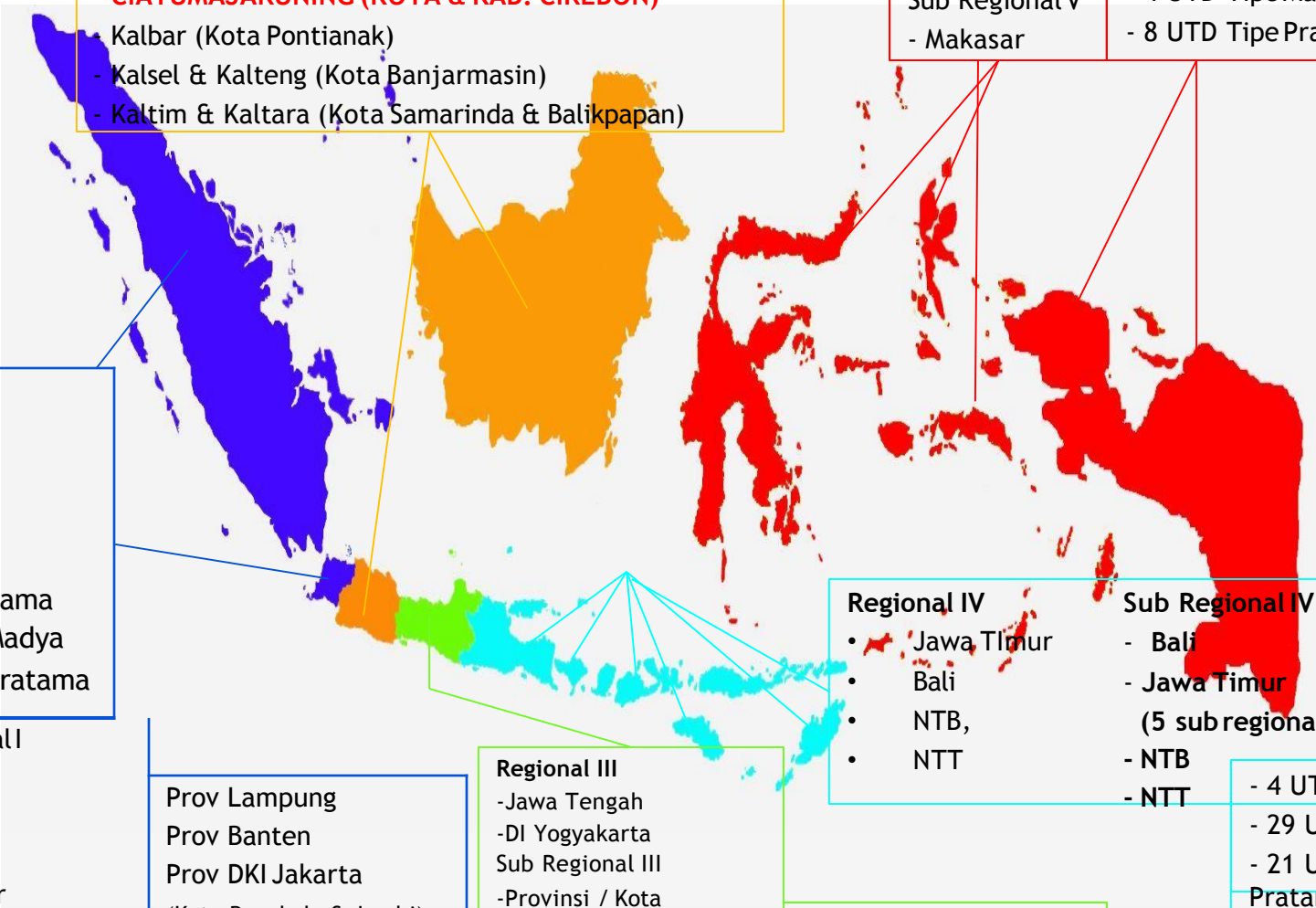


# DISTRIBUTION AREA REGIONAL

- Indonesia is very vast territory. To facilitate the development and monitoring of blood service activities throughout BCs IRC: for its development is divided into 5 regional areas, each region has Regional Responsible (PJ)
- **Regional divisions are among others considered:**
  - **Geography**
  - **Ease of transportation (land, air and sea)**
  - **Ability of every BCs**
  - **Facilities / infrastructure of each region (including problems in each region)**

- Regional II**
- Jawa Barat - 4 UTD Tipe Utama
  - Kalimantan - 16 UTD Tipe Madya
  - Sub Regional II** - 20 UTD Tipe Pratama
    - Cibasugabatik (Kota Bandung)
    - Purwasukasido (Kab. Bekasi)
    - **CIAYUMAJAKUNING (KOTA & KAB. CIREBON)**
    - Kalbar (Kota Pontianak)
    - Kalsel & Kalteng (Kota Banjarmasin)
    - Kaltim & Kaltara (Kota Samarinda & Balikpapan)

- Regional V**
- Sulawesi
  - Maluku
  - Papua Barat
  - Papua
- Sub Regional V**
- Makassar
- 1 UTD Tipe Utama
- 4 UTD Tipe Madya
- 8 UTD Tipe Pratama



- Regional I**
- Sumatera
  - Banten
  - DKI Jakarta
- 5 UTD Tipe Utama
- 15 UTD Tipe Madya
- 18 UTD Tipe Pratama

- SUB Regional I**
- Prop NAD
  - Prop Sumut
  - Prop Riau
  - Prop Sumbar
  - Prop Sumsel
  - R. Bangka Belitung

- Prov Lampung
- Prov Banten
- Prov DKI Jakarta
- (Kota Bengkulu & Jambi)

- Regional III**
- Jawa Tengah
  - DI Yogyakarta
  - Sub Regional III**
    - Provinsi / Kota Semarang
    - Kota Surakarta
    - Kabupaten Banyumas
    - Kota Yogyakarta

- 4 UTD Tipe Utama
- 24 UTD Tipe Madya
- 13 UTD Tipe Pratama

- Regional IV**
- Jawa Timur
  - Bali
  - NTB,
  - NTT
- Sub Regional IV**
- Bali
  - Jawa Timur
  - (5 sub regional)
  - NTB
  - NTT

- 4 UTD Tipe Utama
- 29 UTD Tipe Madya
- 21 UTD Tipe Pratama

# Progress of Quality Systems for blood safety in 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.**
  - Since 2016 have regular technical meeting and regional meeting → Recommendation

# Progress of **Quality Systems for blood safety** in 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 83 BCs (40%)

### **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

# CONSOLIDATION

By doing CONSOLIDATION NETWORK so the implementation of blood service more efficient and effective → **Because of all the BCs although its donations vary considerably to consolidate for inspection:**

- **Screening of IMLTD filter with better method and NAT**
- **Blood type confirmation and antibody screening test**
- **Processing of blood components / Apheresis**
- **Component product quality control**
- **Examination of bacterial contamination**
- **Centralized data → MASTER FILE DATA**
- **Reference**
- **Training**

# CONSOLIDATION

By consolidating, each BCs in the consolidated network will have:

- Have the same SPO, because the same inspection method
- Can do the training together
- Have the same documentation system, including donor registration
- **Competency Officer / HR is appropriate, with the same personnel system**
- Good infrastructure and complete facilities
- Sufficient blood supply



**SECURITY AND QUALITY BLOOD AND IMPROVE EMPLOYEES WELFARE**

# CONSOLIDATED OBJECTIVES

→ Improve the effectiveness of blood services, because:

- The product is more qualified, all BCs has its network donor data
- **GMP / CPOB is achieved for all consolidated BCs**
- **The residual plasma is utilized and there is no need to dispose of it**
- **The BCs network is more focused on improving the quality of blood supply so there will be no complaints of no blood or can not serve blood demand**  
→ NO MORE BCs THAT DOES NOT HAVE BLOOD SUPPLY
- **Appreciation of BCs employees involved in consolidation (salary, benefits, rules etc)**
- **NEED CONSOLIDATION AND NETWORKING SETTINGS**  
→ **COMMITMENT OF ALL PARTICIPANTS OF CONSOLIDATED EQUIPMENTS** → **MOU /Operational cooperation** → **IS A JOINT PROGRAM**
- **THERE ARE AN APPLICABLE CONSOLIDATED SYSTEMS**

# PROBLEMS

Some of the problems faced as to why consolidation is not yet applicable:

- **Geography → Should not be a problem**
  - **Insufficient blood supply**
  - **Lack of understanding related to quality and consolidation**
  - **Concerns related to employee finances and welfare**
  - **Human resources become less experienced**
  - **Etc**
- MAPPING BCs WITH SELFASSESSMENT



# HOPE

- It is expected that each region and then its sub-regionals each discuss plans related to improving the quality of its blood service, assisted by regional responsibility and Quality Development from CBC - IRC
- So that each sub-regional will have a plan / plan and timeline related to improving the safety and quality of blood service.
- Since the plan is derived from each sub-regional then it is expected that each sub-regional member BCs will succeed the plan / program.

# ACHIEVEMENTS AND CHALLENGES

## ACHIEVEMENTS:

- Clear regulation and guideline on technical aspect of blood services
- Increasing awareness of blood donation (30-50 people donated blood/day in a shopping mall/campus)
- Blood donation number increase  $\geq 10\%$  per-year
- 70% 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 NAT implementation
- MIS has been implemented in 30% to 50% of blood centers
- More hospital has Blood Bank Unit → increase closed system of blood transportation

# PROGRESS OF QUALITY SYSTEMS FOR BLOOD SAFETY IN INDONESIA



- Clear regulation and guideline on the technical aspect of blood services include for fractionation
- 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

# PROGRESS OF QUALITY SYSTEMS FOR BLOOD SAFETY IN INDONESIA

- MIS has been implemented in 40% of IRC BCs
- More hospital has Blood Bank Unit → increase closed system of blood transportation
- EQAS for TTI screening by CBC IRC (2014) for BTS IRC throughout Indonesia in order to see BTS IRC laboratory performance in conducting the TTI screening
- Since 1999, CBC participate in maintain the quality of the blood screening through of following the NRL EQAS program
- In 2017, CBC will follow NAT EQAS program, to perform quality of NAT testing in CBC

# ACHIEVEMENTS AND CHALLENGES

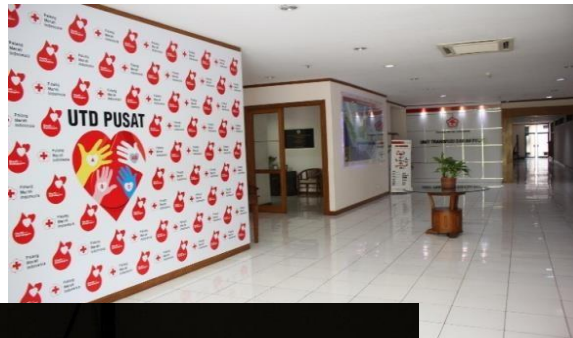
## CHALLENGES

- Community mobilization:
  - Increasing awareness on blood donation in small cities
- Pertaining to governance:
  - Role and financial aspect of National Blood Committee
  - Establishing a National Blood Center
- Programmatic:
  - National blood system, strategy and networking
- Financial:
  - Assurance of budget especially from the local government

# SUMMARY

- **The development of blood services is very rapid, BCs is challenged to improve the quality, effectiveness and efficiency of blood services**
- **To improve the effectiveness of blood services (quality and safety) can be done by establishing a network of consolidation and networking service quality improvement of blood supply**
- **Consolidation and networking arrangements need to be drawn by taking into account the inputs and needs of all BCs**
- **Consolidation and similarity of quality will affect GMP certification, employee welfare, regulatory unity, etc.**
- **Need to improve understanding and similarity of consolidated related notions**

# CENTRAL BLOOD CENTER – INDONESIAN RED CROSS



Palang Merah Indonesia

Daerah Istimewa Yogyakarta  
UTD PMI Kota Yogyakarta  
Jl. Tegayendro No. 25 Kotagede Yogyakarta, 55172

14-Feb-2017, 12:36:22 WIB

Stok Darah : 14-Feb-2017 jam Update : 10:07:43

Rhesus Positif		Rhesus Negatif	
Gol	Jumlah	Gol	Jumlah
A	105	A	4
B	123	B	2
O	189	O	6
AB	67	AB	0
Jumlah : 484		Jumlah : 12	

Jadwal Kegiatan Mobilisasi

Instansi	Tempat	Target
Tidak ada kegiatan	Tidak ada kegiatan	0

Jadwal Kegiatan di UTD

17.03.17 17.03.17 17.03.17

20-Feb-2017 15-Feb-2017 Pelatihan Penyelenggaraan Uji Saring MLTD bagi Teknisi UTD PMI  
 04-Mar-2017 19-Mar-2017 Pelatihan Rekrutmen Donor Darah Sukarela  
 20-Mar-2017 28-Mar-2017 Pelatihan Pengetahuan Pelayanan Darah bagi Dokter Saru UTD PMI

UDDA DI MADING-MADING UTD CABANG 2. TANGGAL JAM UPDATE MERUPAKAN TAN



THANK YOU