

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 (4th 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
- ⁵ 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

41 IRC-BCs in Sumatera island
263.453 bags (13% Total donation)

20 IRC-BCs in Kalimantan island
107.728 bags (4,5% Total donation)

20 IRC-BCs in Sulawesi island
81.927 bag (4% Total donation)

DKI Jakarta IRC-BC
282.653 bags (14% Total donation)

8 IRC-BCs in Maluku & Papua islands
20.455 bag (1% Total donation)

IRC central BC
10.000 bags (0,5% Total donation)

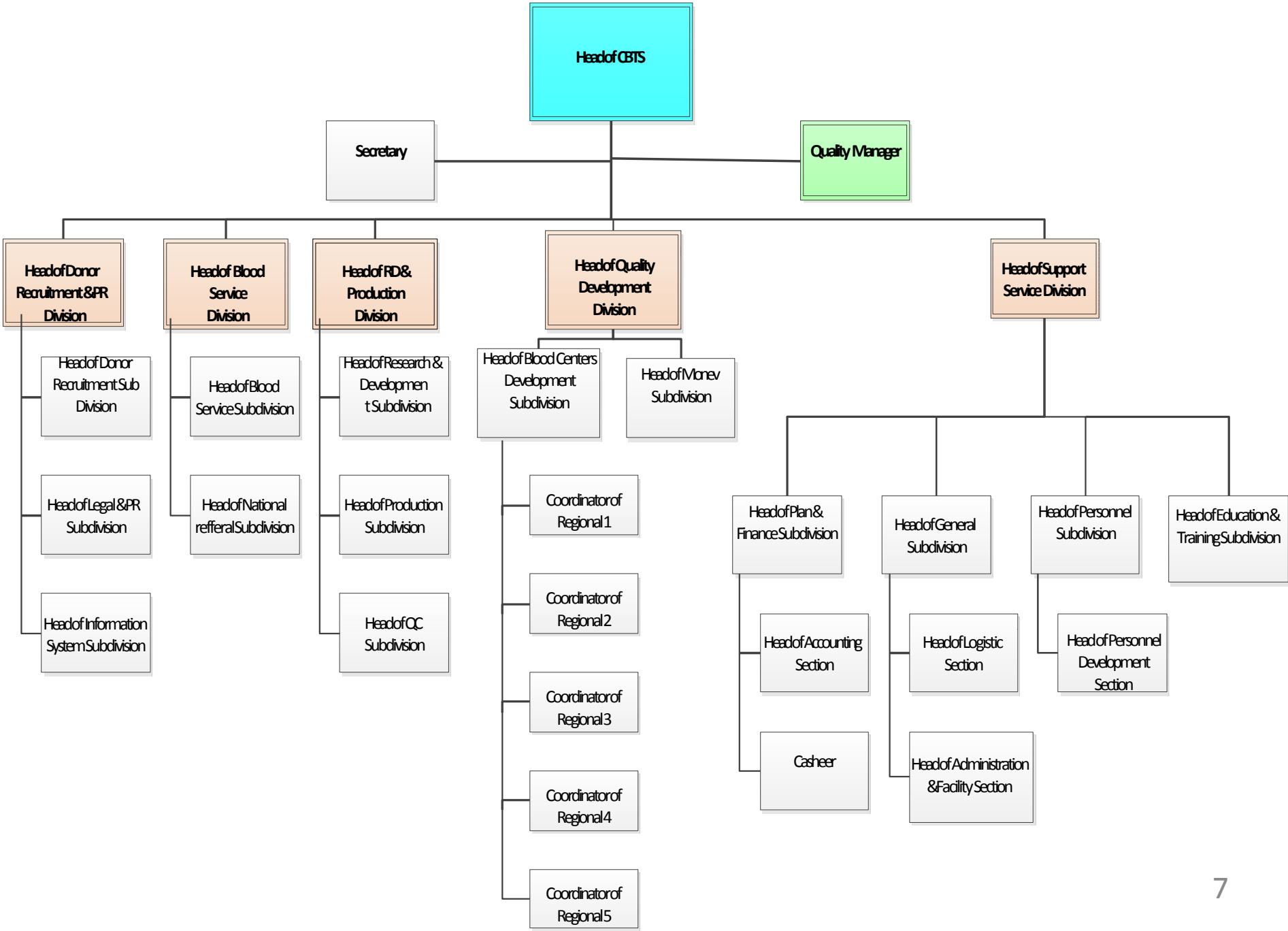
37 IRC-BCs in East Java
421.510 bags (20% Total donation)

23 IRC-BCs in Banten & West Java
389.011 bags (19% Total donation)

38 IRC-BCs in central Java & DIY
431.281 (21% Total donation)

15 IRC-BCs in Bali, NTB, NTT islands
68.031 bas (3% Total donation)





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)

- Purwasukasidebo (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

Prop 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

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

- 4 UTD Tipe Utama

- 24 UTD Tipe Madya

- 13 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 SELF ASSESSMENT

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

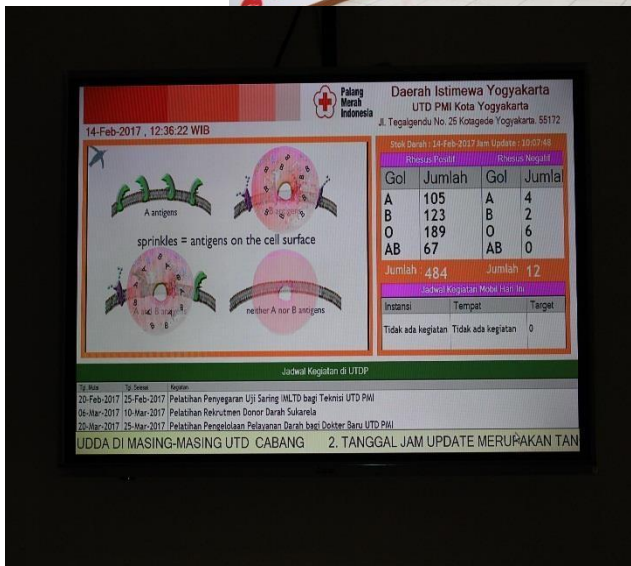
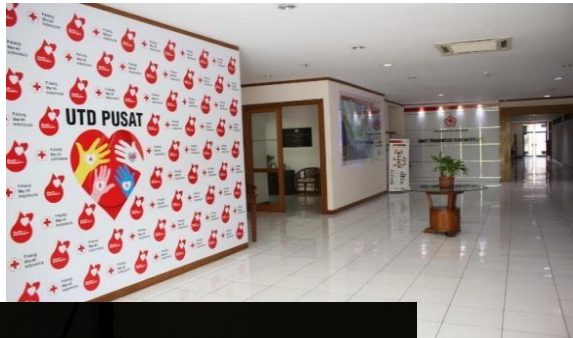
CHALLENGES

- 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

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THANK YOU