Quality Systems for Blood Safety in Indonesia

Submitted by: Indonesian Red Cross Society
QUALITY SYSTEMS FOR BLOOD SAFETY IN INDONESIA

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CENTRAL BLOOD CENTER – INDONESIAN RED CROSS

OUTLINE

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

Indonesia:
- Population: 254m (4th 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

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
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

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

<table>
<thead>
<tr>
<th>Year</th>
<th>Donasi</th>
<th>Donasi Sukarela</th>
<th>Donasi Pengganti</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>1,742,151</td>
<td>1,644,398</td>
<td>297,753</td>
</tr>
<tr>
<td>2010</td>
<td>2,061,558</td>
<td>1,758,570</td>
<td>302,988</td>
</tr>
<tr>
<td>2011</td>
<td>2,191,226</td>
<td>1,903,702</td>
<td>287,424</td>
</tr>
<tr>
<td>2012</td>
<td>2,182,519</td>
<td>1,899,776</td>
<td>262,743</td>
</tr>
<tr>
<td>2013</td>
<td>2,568,993</td>
<td>2,280,754</td>
<td>288,239</td>
</tr>
<tr>
<td>2014</td>
<td>2,776,202</td>
<td>2,495,449</td>
<td>280,753</td>
</tr>
</tbody>
</table>

- Voluntary blood donation: 90%
- Replacement donation: 10%
- Celebrate WBBD every years
- Give Satya Lancana kebaktian Sosial for 2100x donation by President
BLOOD DONATION NUMBER

Total Donation of 211 IRC BCs (2014): 2,776,202 bags
> 6.3 M bags of blood components: fulfill 48% of blood needs nationally
29 IRC-BCs in Banten & West Java: 569,307 bags (20.5% Total donation)
41 IRC-BCs in central Java & DIY: 574,957 bags (20.7% Total donation)
37 IRC-BCs in East Java: 576,191 bags (20.3% Total donation)
20 IRC-BCs in Bali, NTB, NTT islands: 89,390 bags (3.2% Total donation)
6 IRC-BCs in Maluku & Papua islands: 30,914 bags (1.1% Total donation)
19 IRC-BCs in Sulawesi island: 97,411 bags (3.5% Total donation)
20 IRC-BCs in Kalimantan island: 153,171 bags (5.5% Total donation)
38 IRC-BCs in Sumatera island: 354,730 bags (12.8% Total donation)

BLOOD COLLECTION ACTIVITIES

Indonesian Red Cross have achieved to provide >100 Mobile Unit Bus for Blood Centers in the district areas (2011-2012)
Apheresis Donation: 2014 collect 5,844 Apheresis donation in several big blood centers
BLOOD COMPONENT PROCESSING

2,776,202 Unit of Whole Blood
- Nationally 1% is used as Whole Blood

PRC  +  Plasma (20%)

FFP 5%  +  TC 11.4%

ABO BLOOD GROUPING

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

RHEUS BLOOD GROUPING

- Rhesus Positive  : > 99.94%
- Rhesus Negative  : < 0.06%
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 ≥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 → increase closed system of blood transportation

TTI BLOOD SCREENING 2009 - 2014

Screening test method: 85% used EIA and 15% used Rapid Test
ID NAT was applied in 12 Big Blood Centers in 11 big cities since 2011. In 2014 screened around 30% (250,000 bags) of blood donation in 12 Big Blood Centers. Since 2015, Jakarta Chapter have increse 100% (300,000 bags)screened on ID NAT

<table>
<thead>
<tr>
<th>Year</th>
<th>% HIV</th>
<th>% Hepatitis C</th>
<th>% Hepatitis B</th>
<th>% Sifilis</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>0.04</td>
<td>0.58</td>
<td>1.94</td>
<td>0.62</td>
</tr>
<tr>
<td>2010</td>
<td>0.02</td>
<td>0.56</td>
<td>1.85</td>
<td>0.61</td>
</tr>
<tr>
<td>2011</td>
<td>0.02</td>
<td>0.55</td>
<td>1.63</td>
<td>0.73</td>
</tr>
<tr>
<td>2012</td>
<td>0.02</td>
<td>0.39</td>
<td>1.57</td>
<td>0.71</td>
</tr>
<tr>
<td>2013</td>
<td>0.03</td>
<td>0.4</td>
<td>1.56</td>
<td>0.77</td>
</tr>
<tr>
<td>2014</td>
<td>0.05</td>
<td>0.37</td>
<td>1.45</td>
<td>0.79</td>
</tr>
</tbody>
</table>
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.

5 REGIONAL AREA

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

(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

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 (SIMDONDAH) 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

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 and 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)

<table>
<thead>
<tr>
<th>Program, Infrastructure and Equipment</th>
<th>Remarks</th>
</tr>
</thead>
</table>
| • Strengthening Regional Blood Program
• Increasing awareness on blood donation in small cities
• Improving infrastructure (Implementation otomation, NAT, standart BCs building, Use of validated and calibrated instruments) |

<table>
<thead>
<tr>
<th>Program</th>
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<tbody>
<tr>
<td>National Policy for all BCs in Indonesia</td>
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</tbody>
</table>
| • Commitment from all relevant parties
• Establishing a National Blood Center
• National blood system, strategy and networking
  → develop a culture of quality
• Assurance of funding budget from government and local government |

<table>
<thead>
<tr>
<th>Standards</th>
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</table>
| • Develop a national quality policy
• Develop Blood Services Standard
• Develop GMP Guide for Blood Establishment |
Challenges to Improve of Quality System for Blood Safety in Indonesia (2)

<table>
<thead>
<tr>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Personnel</td>
</tr>
<tr>
<td>• Sufficient number of competent personnel</td>
</tr>
<tr>
<td>• 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)</td>
</tr>
<tr>
<td>• Training for Clinicians for rational use of blood</td>
</tr>
<tr>
<td>Documentation</td>
</tr>
<tr>
<td>• Implementation of Good Documentation System in all IRC BCs</td>
</tr>
<tr>
<td>• Implementation SIMDONDAR (MIS) in all IRC BCs</td>
</tr>
<tr>
<td>• Trace-back System → support in Haemovigilance System</td>
</tr>
<tr>
<td>Inspections and Audit</td>
</tr>
<tr>
<td>• Scheduled regularly from The authority bodies</td>
</tr>
<tr>
<td>• Continuous support from WHO (Achilles Project)</td>
</tr>
</tbody>
</table>

ACKNOWLEDGE

- CBCs IRC Staff
- Dr Linda Lukitari, Chairman for Blood Transfusion Services and Hospital Indonesian Red Cross
- Dr Yuyun SM Soedarmono MSc
- Medquest team
- Grifols team