Quality Management System - Korean Red Cross Blood Services

Submitted by: Korean Red Cross
Quality Management System

Korean Red Cross Blood Services

Blood Services in Korea
Structure of Korean Blood Services

Government

- Ministry of Health and Welfare (MoHW)
- Ministry of Food & Drug Safety (MFDS)

Korea Center for Disease Control and Prevention (KCDC)

Blood Management Committee

KRC Blood Services: 15 blood centers & others

Hospital Blood Centers

93.2% of blood donations were collected by Korean Red Cross (2014)

Roles and Responsibilities - Government

<table>
<thead>
<tr>
<th>Institutions</th>
<th>Roles and Responsibilities</th>
<th>Dept.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ministry of Health and Welfare (MoHW)</td>
<td>- Overall blood demand and supply management</td>
<td>Division of Bioethics Policy</td>
</tr>
<tr>
<td></td>
<td>- Permission of the establishment of blood center</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Decision of the price of blood products</td>
<td></td>
</tr>
<tr>
<td>Ministry of Food &amp; Drug Safety (MFDS)</td>
<td>- Overall collection and supply management of pharmaceutical product</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Overall plasma fractionation management</td>
<td></td>
</tr>
<tr>
<td>Korea Centers for Disease Control and Prevention (KCDC)</td>
<td>- Evaluation of blood establishments</td>
<td>Division of Human Blood Safety Surveillance</td>
</tr>
<tr>
<td></td>
<td>- Investigation of transfusion-transmitted infections</td>
<td></td>
</tr>
</tbody>
</table>
Statistics

- National Blood Donation Rate: 6.06%
- 100% of VNRBD
- Number of Blood Donations

<table>
<thead>
<tr>
<th>Year</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
<th>Jan-Sep 2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>2,722,609</td>
<td>2,914,483</td>
<td>3,053,424</td>
<td>2,290,476</td>
</tr>
<tr>
<td>RC(%)</td>
<td>2,542,495(93.4)</td>
<td>2,708,173(92.9)</td>
<td>2,844,538(93.2)</td>
<td>2,137,636(93.3)</td>
</tr>
</tbody>
</table>

- Number of Blood Supply

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of Units Supplied</th>
<th>For Transfusion</th>
<th>For Fractionation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Sub-Total</td>
<td>%</td>
<td>Sub-Total</td>
</tr>
<tr>
<td>Jan-Sep 2015</td>
<td>4,637,226</td>
<td>2,989,906</td>
<td>64.5</td>
</tr>
<tr>
<td>2014</td>
<td>6,272,253</td>
<td>4,099,483</td>
<td>65.4</td>
</tr>
<tr>
<td>2013</td>
<td>6,186,007</td>
<td>4,242,147</td>
<td>68.6</td>
</tr>
</tbody>
</table>

KRC Organizational Chart

(Updated Jan. 2015)
### Roles and Responsibilities - KRC

<table>
<thead>
<tr>
<th>Institutions</th>
<th>Role and responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood Service Headquarters</td>
<td></td>
</tr>
</tbody>
</table>
- Administration of overall blood services  
- Establishment of general policy & strategies  
- Supervision of institutions  
- Delegated tasks from the Minister of Health and Welfare |
| Blood Center (15) |  
- Blood collection, processing & supply |
| Blood Laboratory Centers (3) |  
- Screening tests  
- Research related to blood testing |
| Blood Fractionation Center (1) |  
- Manufacturing fractionated plasma product (albumin, etc)  
- Monitoring imported plasma, importing medicine  
- Inventory hold of source plasma for 100days for Look-Back  
- Blood sample storage (10 years) |
| Blood Transfusion Research Institute (1) |  
- Academic research related to blood and blood transfusion  
- Re-entry test for registered deferred donor  
- Evaluation of blood screening test reagent and QC  
- Administration of hematopoietic stem cell donor recruitment services  
- HLA testing |

### What Korean Blood Services Does

- Manufacturing and supplying blood products for transfusion  
  *(Self-sufficiency based on Voluntary Non Remunerated Blood Donation)*
- Manufacturing and supplying blood products for fractionation  
  *(Self Supply rate 79.9% in 2014)*
- Importing plasma derived medicinal products (12 kinds including tetanus)
- Donor recruitment of hematopoietic stem cell transplantation
- Management of blood donor information
Quality Management System - KRC Blood Services-

Quality Management System

- Organization Management
- Training
- Assessment Inspection
- Facilities Equipments Materials Management
- Standards & Documentation
Overview

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organization management</td>
<td>• Defined organizational structure</td>
</tr>
<tr>
<td></td>
<td>• Quality manager in every blood center</td>
</tr>
<tr>
<td></td>
<td>• Quality section in every blood center</td>
</tr>
<tr>
<td>Documentation &amp; Standards</td>
<td>• Compliance with national policy</td>
</tr>
<tr>
<td></td>
<td>– Blood Management Act and etc</td>
</tr>
<tr>
<td></td>
<td>• Accredited ISO 9001:2000 certification in every center</td>
</tr>
<tr>
<td></td>
<td>• Managed standard operating procedures</td>
</tr>
<tr>
<td></td>
<td>• IT-based blood donor management system</td>
</tr>
<tr>
<td>Training</td>
<td>• Training policy and plan</td>
</tr>
<tr>
<td></td>
<td>• organized training courses for the staff</td>
</tr>
<tr>
<td></td>
<td>- 23 courses for 597 trainee in 2015</td>
</tr>
<tr>
<td>Assessment &amp; Inspection</td>
<td>• National management (evaluation from KCDC, deviation)</td>
</tr>
<tr>
<td></td>
<td>• Red Cross management (audit from KRC HQs, inspection from KRC Blood Service HQs, internal inspection)</td>
</tr>
<tr>
<td></td>
<td>• Audit from parliamentary annually</td>
</tr>
<tr>
<td>Facilities, Equipments &amp;</td>
<td>• Qualification</td>
</tr>
<tr>
<td>Materials Management</td>
<td>• Internal quality control (Reagents, materials, etc)</td>
</tr>
<tr>
<td></td>
<td>• IT-based quality control</td>
</tr>
</tbody>
</table>

Documentation

National Blood Policy (Blood Management Act, Ordinance, Regulations, etc)

- Standards
  - Clearly state work standards

- Blood Management Guidelines
  - List items that the HQs and institutions need to follow

- Standard Operating Procedures (SOP)
  - State standardized procedures need to follow

- Internal / Work Procedures
  - State more details regarding SOP by each institution
Documentation
- Blood Management Guidelines
  • Category: General, Safety, Quality, Component Preparation, Supply, Donor Recruitment, Promotion, Collection, Testing, and Research
  • Review: being reviewed regularly (At least once a year)
  • Revision: KRC Blood Services HQs

Documentation
- Standard Operating Procedures (SOP)
  • Category: Blood center quality management system, donor selection, collection, apheresis collection, manufacturing blood components, labeling, transportation and stock, warehousing and supply, information exchange, documentation and records, Donor Recruitment, and promotion
  • Review: being reviewed regularly
  • Revision: SOP legislation & revision committee
IT Based Quality Management System

- Blood Information Management System

- Established in 2002 and launched in 2003 by Korean Red Cross
- The core integrated management system of all information generated thorough the whole processes of blood service, from donor recruitment to blood distribution, at national level in real time information processing
- Including the information from non-KRC blood centers on the legal authority of ‘Blood Management Act’
- Blood Information Sharing System (BISS) is developed to communicate with hospital blood banks

Integration of BIMS and BISS
Flow of IT based Quality management

- Pre Check
- Management of Donation organizations (History and etc)
- Electronic Donor Interview System
- Automated Donor Eligibility system
- Wristband
- Matching test(Donor’s wrist band, Samples, Blood)
- Management of donors’ History on apheresis donation
- Statistical Quality Control
- Real time Delta / Panic check
- Assay validation
- Real time monitoring on testing state
- Measure of Blood Volume
- Cross check the information on malaria, blood type, collection site and etc
- Temperature monitoring

Information Sharing System

- Based on the authority of ‘Blood Management Acts’, any organization should cooperate when its acquired information is requested by Ministry of Health and Welfare in order to provide blood services for blood safety
- Integrated into KRC BIMS to assist safety monitoring through the whole process from donor selection process to blood issuing
- Accessed only when the individual on the data actually attempts or has participated in blood donation in order to protect privacy
- Valid only during the corresponding deferral period

- Prescription and medication information
  (Acitretin, Dutasteride, Finasteride, Isotretinoin, Hepatitis B immune globulin)
  Source: HIRA, MoND

- Patient Information on HIV (available until 2012), vCJD, Malaria, Brucellosis, Babesiosis
  Source: KCDC
Assessment & Inspection
- External Inspection

• Blood Management Review & Evaluation (Korea CDC)
  According to the Blood Management Act No.1, Section.3
  - Target institution : blood center that has received permission of establishment from the Minister of Ministry of Health and Welfare
  - Periodic evaluation : every other year  (Non-scheduled evaluation : if needed)
  - Review and evaluation items: propriety of blood collection process, accuracy of blood testing, safety of manufacturing /storage/supply and quality management of blood products
• Laboratory Assessment : KCDC, Clinical Laboratory Accreditation program of the Korean Society for Laboratory Medicine
• External Quality Management (Proficiency Test) : Korean Association of Quality Assurance for Clinical Laboratory, CAP(USA), NRL(Australia)

- Internal Inspection

• Purpose : To improve the quality of blood services by checking compliance with laws, guidelines, and SOP
• Scope : overall blood management including planning, promotion, donor selection, collection, transportation, storage, preparation and supply, data management with IT, and document management
• Check Point
  ○ External/internal evaluation and implementation of corrective action
  ○ Implementation of follow-up action and announcement after check point
  ○ Implementation of operation details and decision by blood safety management committee
  ○ Management of validation working party by each institution
  ○ Compliance with laws, guidelines, and SOP
  ○ Checking the document and workplace related to blood safety and quality management
Assessment & Inspection

- Internal Inspection

• Period : Annually (biannually until 2014)
• Subject : Quality Management team in HQs
• Inspection Results
  - In 2014, HQs performed internal inspections at 9 blood centers
  - Requested 113 corrective measures and 107 recommendations for improvement of operations
  - Most frequent requests are related to equipment maintenance, calibration, group blood donation, quality managements
  - In the first half of 2015, 49 corrective measures and 71 recommendations for the improvement in 7 blood centers’ inspection

Challenge

• GMP Introduction
• Introduction of automated manufacturing blood components
• Eliminating Human Error
Thank You!