Quality Management System in Hong Kong Red Cross Blood Transfusion Service – Organization Management and Standards

Submitted by: Hong Kong Red Cross
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For Year 2013 :-
- Blood Collection: 247,041 units
- Blood issued: 472,478 units

Mandatory tests
- ABO grouping, Rh(D) typing, Ab screening
- HBsAg; anti-HCV; anti-HTLV I & II;
  HIV Ag/Ab Combo; anti-syphilis Ab
- NAT: HBV, HCV & HIV
- Bacterial Culture
  ( For all platelet concentrate units)

Supplementary test
- Anti-CMV
Major Concerns of Blood Service

- **Blood safety**
  - Contaminated product (infected donors, plasma pool contamination)
  - Human, reagent or equipment error in testing and labeling (blood grouping, TTI screening, cross-match)

- **Blood quality**
  - Adulterated during production, storage and delivery

- **Sufficiency**
  - Shortage of supply affecting patients

- **Effective use of resources**
  - Misuse
  - Wastage

→ Need to implement a quality management system

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Hospital Authority
WHO - Key Elements of a Quality System

- Organisational management
- Standards
- Documentation
- Training
- Assessment
Organisational Management

- Committed to implement quality system in 1997
- Senior management team formed a core team after training to coordinate implementation in departments
- Established a Quality Department and appointed a Quality Manager directly reporting to the Chief Executive BTS
- Established clear organisation structure - accountability, authority, responsibility
- Promoted quality culture, motivated staff and enhanced awareness
- Mapped out processes and procedures, and identified critical control points
Implementation of ISO9002:1994 standards

- No regulatory body or standards for blood products in HK
- ISO9000 is generic for all organization providing goods and services
- Provides the structure of quality management covering all five key elements
- Third party audit
- Achieved certification in 1999
Implementation of Australian Code of Good Manufacturing Practice (cGMP)

- ISO9000 provides the backbone of quality system but does not specify standards

- cGMP specifies quality standards throughout the manufacturing process from raw material to final products

- The process control and audit system ensure safety & efficacy of products

- Integrated cGMP standards with ISO9000 into one quality management system
TGA cGMP Accreditation

- In October 2002, full compliance to the cGMP for Human Blood and Tissues was successfully assessed through a accreditation audit conducted by the Australian TGA.

- The scope covers blood collection, processing, storage and release for use of cellular products and plasma for clinical use and fractionation.
Implementation of ISO 14001:2004 Environmental Standards

- Incorporate eco-manufacturing practices
- Minimize resources wastage and negative impacts of manufacturing process on the environment
- Comply with applicable laws, regulations, and other environmental related requirements
ISO14001:2004 Certification

- In 2005, achieved certification of ISO14001:2004 standards integrated into the existing quality management system.
- The scope covered Donor Recruitment, Blood and Stem Cell Collection, Testing, Processing, Storage and Supply Services.
Implementation of OHSAS 18001:2007 Standards

- Promotes a safe & healthy working environment by
  - consistently identify & control health & safety risks
  - reduce the potential for accidents
  - aid legislative compliance
  - improve overall performance
Risk Management Concept

- **Hazard Identification**: Identify Hazards
- **Risk Estimation**: Estimate Frequency, Estimate Consequence, Estimate Risks
- **Decision Making**: Is it Safe?
  - Yes
  - No

**Mitigate Risks**
OHSAS18001:2007 Certification

- In February 2009, achieved certification of OHSAS18001:2007 standards integrated into existing quality management system
- Covered all work places including blood donor centres and mobile blood drives
Chronology of Quality Standards Implemented

- 5-S Practice (adopted in 2000)
- cGMP (Australia TGA, since 2002)
- ISO15189:2003 (start accreditation in 2007)
- ISO15189:2007 (accreditation from 2008 to 2012)
- OHSAS18001:2007 (certification in 2009)
- ISO9001:2008 (upgraded in 2009)
- ISO/IEC17043:2010 (start accreditation in 2012)
- NetCord-FACT Standards (start accreditation in 2013)
Maintenance of Quality System

Quality Management System (chart QMS 4a)

4. Quality Management System

5.6 Management review

5. Management Responsibilities

6. Resource Management

4.2.3 Control of documents

7. Product Realization

8. Measurement, Analysis and Improvement

8.2.2 Internal audit

8.5.2 Corrective action

8.5.3 Preventive action

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Corrective & Preventive Action

- are improvements to an organization's processes taken to eliminate causes of non-conformances or other undesirable situations
- the path towards improvement & effectiveness of Quality Management system
Audits

- Types of audits
  - Internal Audit: auditing by internal staff trained for this process
  - External Audit: standard auditing by an external certification body

- The aim is a continual process of review & assessment
  - to verify that the system is working as it is supposed to;
  - to find out where it can improve; and
  - to correct or prevent problems identified.
Management Review

- According to ISO requirements, “Top management shall review the organization’s management system, at planned intervals, to ensure its continuing suitability, adequacy & effectiveness.”
- is carried out by, or on behalf of, the management personnel having direct responsibility for the system.
- identifies consistency with & deviations from plans, or adequacies & inadequacies of management procedures.
- Once or twice per year, as required
Lean Six Sigma

Define → Measure → Improve → Analysis → Control → Define

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Objective

- to meet customer requirements by
  - improving efficiency
  - reducing waste
  - improving quality
- Completed 27 projects
Road ahead
- AABB Accreditation

- The Program strives to improve the safety of collecting, processing, testing, distributing &.administering blood, blood products & cellular therapy products through assessment of the quality & operational systems in place within the facility.
- Target completion: Early 2015
Road ahead

- ISO/IEC 27001

- Information technology -- Security techniques -- Information security management systems – Requirements

  specifies a management system that is intended to bring information security under explicit management control
Success Factors in Quality Management Development

- Commitment
  - Top Management
  - Staff

- Communication
  - Open communication at all levels

- Change in culture
  - Seek continued improvements
“Quality is not an act, it's a Habit”
Quality is a journey, not a destination
Thank you!