



Tâm-Tri-Đầu-Trước-Đầu

STATUS OF QUALITY IN BLOOD SUPPLY ACTIVITIES IN VIETNAM

IPFA 4th ASIA WORKSHOP ON PLASMA QUALITY AND SUPPLY
HANOI, VIETNAM, 6-7 th MARCH 2019

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General introduction

Legal documents

- Circular guiding on blood transfusion activities, decree No. 26/2013/TT-BYT, approved date on September 16, 2013: Providing regulations on blood transfusion activities and quality standards of blood products.
- Circular regulating good manufacturing practices for producing medicines and medicine materials, decree No. 35/2018 / TT-BYT, approved date on November 22, 2018. Appendix 2: Principles on good manufacturing practices for production bio-medicine derived from human blood and plasma (Translated from WHO guideline on good manufacturing practices for blood establishments).
- There is no law on blood.
- There is no regulatory on National Blood Organisation.

Blood collection centers in Vietnam in 2018

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- 1 National blood center
(National institute of hematology and blood transfusion)
- 4 Regional blood centers
(HCMC BTHH, Cho Ray, Can Tho HBTH, Hue)
- 1 Blood donation center
(HCM voluntary blood donation center)
- 10 Provincial blood centers
- > 49 small blood establishments



Collection of whole blood in Vietnam in 2018

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Blood centers	Number of BC	Number of WB	Collection rate (%)	Rate of VNBD (%)
National BC	1	323,615	22.81	98.11
Regional BCs	4	498,946	35.16	99.99
HCMC Blood donation center	1	170,096	11.99	100.00
Provincial BC	10	177,261	12.49	96.47
Other BEs	> 49	249,014	17.55	93.92
Whole country	> 65	1,418,932	100	98.06

National Blood Center

Tâm - Trí - Đức được nâng





National Blood Center

Tâm Trĩ - Đĩa Đĩa Vàng

- ❑ Establishment: Decision No. 4164/QĐ-BYT of Ministry of Health, date 18/09/2017. Under National Institute of Hematology and Blood Transfusion.
- ❑ Key activities: blood donors recruitment; collection blood; screening blood; preparation blood components; storage and distribution blood components.
- ❑ Collect blood from 18 provinces/cities, and supply blood and blood components to 156 hospitals in 26 provinces/cities.
- ❑ Provide external quality assurance scheme for:
 - Screening HBsAg, anti HCV, HIV-1,2 ag/ab: started in 2009 (11 cycles); 1 time/ year; 55 participants
 - Screening NAT: started in 2017 (2 cycles); 1 time/ year; 12 participants⁸

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Application quality management system

National BC and Regional
BCs (5 BCs)

- 3 BCs: cetificated ISO 9001, ISO 15189 and started applying GMP
- 2 BCs: started applying QMS (assign quality staff, develop documents, ...)

Provincial BCs
(10 BCs)

Blood establishments
(>49 BEs)

- Few BCs : assign quality staff, develop documents...
- Almost have not implemented QMS

QMS at 3 centers has achieved ISO certificate - Positive results

- Leadership highly commit to quality and support resources;
- Establish Quality Management Department, assign quality manager;
- Clearly define organizational structure, responsibilities, authorities;
- Yearly establish quality objectives and quality plan;
- Establish documentation: Quality policy, quality manual, processes, procedures, forms;

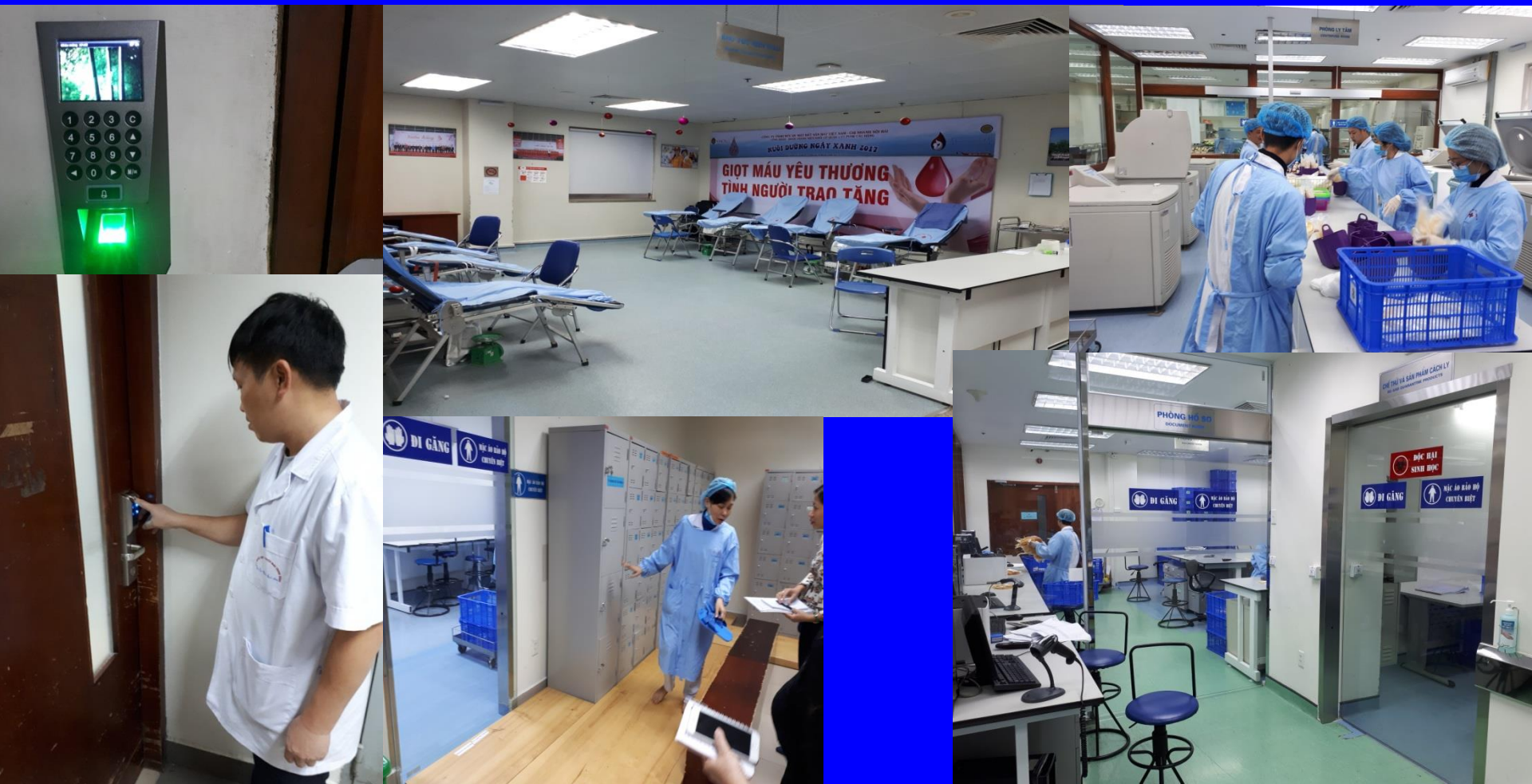
QMS at 3 centers has achieved ISO certificate -

Positive results (cont.)

- Leadership conduct regularly management review of QMS;
- Conduct internal and external quality audit;
- Control of nonconformities and carry out corrective action, preventive action;
- Initially implement risk management;
- Receive, address customer's complaint and recall products;

QMS at 3 centers has achieved ISO certificate - Positive results (cont.)

- Facilities: well designed and arranged to fit the work flow; Prevent unauthorized persons; production areas are separated from each other; be cleaned and control environmental conditions.



QMS at 3 centers has achieved ISO certificate - Positive results (cont.)

- Personnel: Job description, initial training, continuous training, evaluate competency ;
- Traceability: Blood components, equipments, critical materials;
- Equipments: have procedure, are maintained. Cold equipments are monitored, calibrated regularly;
- Materials: test reagents are verified performance before use in examination; well storage;



QMS at 3 centers has achieved ISO certificate - Positive results (cont.)

- Information system: control whole production processes.



QMS at 3 centers has achieved ISO certificate –

Negative issues need improvement

- Validation: Processes, system, test method.
- Qualification: equipments, critical materials, blood collection sites.
- Change control.
- Risk management for all processes, procedures.
- Training on GMP for all personnel.

QMS at other blood establishments

- Very few blood establishments have started implementing quality management: Assign quality staff, develop documentation, ...
- Almost blood establishments have not implemented quality management

Status of quality in blood supply activities in Vietnam

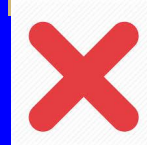
Unsafe risks cause by workflow arrangement

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- The work flow in the specialized departments does not guarantee a one-way
- Management of quarantined blood components: overlap between many departments .
- Determine ABO, Rh blood group outside of laboratory.
- Crossmatch laboratory has to do manufacturing activities: collection blood bags on duty time, managing of quarantined blood components, preparing some blood components in urgent cases.

Unsafe risks to blood donors

- Lack of qualification for blood donation sites before collection.
- Lack of scale; or scales were not checked accuracy.
- No checking Hb before donating blood.
- Risk of contamination: Donors stand around testing site; no changing gloves.
- Ensuring of donors information security.



Donor identification

- Lack of checking the identification documents (ID card, photo papers).
- No asking to verify blood donors at critical steps (examination, selection, barcode labeling, blood collection).

Process of taking blood and sampling

Tâm Trí - Điều dưỡng

- High risk of confusion (test tubes, records): one technician takes blood from 2 blood donors at same time.
- The process of taking blood or sampling does not guarantee a closed system for blood bags.
- The volume of samples taken is insufficient and uneven.



Testing of blood donations

Mandatory tests for blood donations:

- ABO, Rh
- Screening irregular antibodies
- Screening HBV, HCV, HIV: by EIA/ CLIA/ ECLIA and NAT technique
- Syphilis
- CMV (in cases of transplantation)

Testing of blood donations (cont.)

Serology screening for HBV, HCV, HIV

Technique:

- ELISA: 47 blood establishments
- CLIA/ ECLIA: 26 blood establishments

Many types of reagents:

- HBsAg: 16 types
- Anti HCV: 19 types
- HIV 1,2: 20 types

- There is no system for evaluating quality of tests at the national level.
- There is no similarity in quality of testing.

Testing of blood donations (cont.)

NAT testing

- ❑ 12 laboratories
- ❑ 29 blood establishments send samples for testing
- ❑ Total: 41 blood centers/ blood establishments have screened by NAT technique

Rate of blood donations are screened by NAT: 92%



Blood components preparation

- Lack of control of collection duration, storage condition before preparation
- Difference in preparation method between BCs/ BEs
- Many BCs/ BEs do not monitor quality of prepared blood components.
- Some BEs prepare blood components in open system, unclean environment.



Blood components preparation (cont.)

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Labeling

- Many BEs don't have standard label for blood components
- No control of labeling process
- Irrespective of blood products: safe, quarantined, discarded



Managing of quarantined blood components

- Many BEs do not have a separated area to keep quarantined, discarded blood components.
- In some BEs, there are no labels to distinguish the difference between safe, quarantined, discarded blood components.
- Some BEs put together in the same storage device: safe, quarantined, discarded blood components.



Distribution of blood components

Tâm - Trí - Đức được sống

Centralization for blood supply: 02 Blood centers

- ❑ National Blood Center (Hanoi): transport directly to 156 hospitals in 26 provinces/ cities.
- ❑ Can Tho Blood Center: transport directly to 41 hospitals in 26 provinces/ cities.

In whole country, > 35% blood components were transported directly to hospital



Challenges and improvements in the future

Challenges

☐ Legal system is incomplete

- Blood donation law
- National blood policy
- Regulations on blood transfusion network system
- Regulations on inspection and licensing
- Regulations on assessment and licensing of screening tests

☐ Many blood centers have been established but have not been invested in construction and equipped with appropriate facilities. Many blood establishments are still lack of manpower.

Challenges (cont.)

- ❑ Unadequate blood components for treatments
- ❑ Blood establishments lack knowledge and experience in quality management and GMP.

Improvements in the future

□ In the near future:

- Disseminate GMP standards issued by the Ministry of Health.
- Train on quality management and GMP to blood establishments
- Develop GMP checklist => Gap analysis => develop action plan for implementation GMP
- Seek support of organizations to implement GMP.
- Support to blood establishments for implementation quality management.

Improvements in the future (cont.)

□ In long-term:

- Propose legal documents on blood transfusion.
- Propose to governmental organization to invest in the construction of provincial blood centers.
- Advise the Ministry of Health to organize the inspection and licensing of blood establishments based on GMP standards.
- Reorganize the blood transfusion system towards centralization on testing, production and supply of blood products.

