Cleveland Clinic

Quality Management

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History of Regulation in Blood Bank

- In the years before the HIV epidemic, blood banks were perceived as organizations that provided a community service
- Increased occurrence of HIV and increased public scrutiny resulted in stricter FDA regulations
- FDA regulatory oversight has resulted in an increased effort to provide a safe, high-quality product at low cost

Overview

- Primary goal is transfusion of a safe unit of blood.
- To achieve quality must have:
  - Well constructed SOPs.
  - Well trained personnel who carefully adhere to SOPs.
  - Comprehensive guidelines in compliance with Joint Commission, FDA, AABB and CAP.

Agencies Regulating Blood Banks

- FDA- regulate collection and manufacturing
- AABB- regulate standard of care for transfusion recipients
- CAP- inspections, proficiency testing
- CMS- standards for lab and testing
- CLIA- regulatory standards applying to all hospital testing (operated by centers for Medicare and Medicaid)

FDA

- Blood Transfusion Safety
  - Donor screening (collection, preparation, processing)
  - Blood testing
  - Donor lists
  - Quarantine
  - Problems and deficiencies

FDA and CBER

- Regulate biological products for human use
- FDA monitors
  - collection of blood and blood components
  - Manufacture of blood products
- CBER must be notified of any transfusion-related fatalities within 7 days

Terms

- **Quality control-** management of the testing process itself.
  - Monitoring of equipment and instruments
  - Determining that reagents are reacting appropriately.

- **Quality Assurance-** entire process of providing patient care, from the time the physician orders the test until treatment of patient based on results of test.
  - Were appropriate lab tests ordered to determine the need for transfusion.
  - Did the transfusion service perform appropriate testing of patient specimen and preparation of the appropriate component
  - Was the transfusion administered properly.
  - Did the patient obtain the anticipated benefit.

Examples of QC and QA

QC Activities	QA Activities
Collection equipment QC (apheresis equipment, blood-weighting scales)	Number of donor forms with incomplete or incorrect information
Red blood cell hematocrit	Number and types of unusable blood components
Platelet counts in platelet units	Number of and reasons for invalid tests
Residual leukocyte counts in red cells	Number and source of improper requests for blood components
Bacterial contamination of platelets	
Reagent antisera and red cells	Number of times wrong ABO was issued
Heating equipment	Number/source/reasons for unacceptable specimens
Water baths	
Centrifuges	Number and type of transfusion complications
Cell Washers	
Refrigerators, freezers, incubators	Number of and reasons for turnaround time failures
Shipping containers	

Quality Control

- Reagents must be tested for QC daily
- Exception: phenotyping reagents must be done daily or as needed
- Instruments: run QC daily
  - Daily, weekly, monthly maintenance performed according to manufacturer

Blood Product Temperature Control

- Equipment (refrigerators, incubators, freezers) must be within acceptable range for blood product
- Monitor temperature every 24 hours
- Out of temperature: remove products in given time

How long can products be out of storage?

- Red blood cells: 30 minutes
- Thawed plasma: 30 minutes
- Platelets: 8 hours in hospital or 30 hours in transport (due to necessity of agitation)
- Thawed cryoprecipitate: Room temp until expiration 6 hours
- If platelets or cryo are placed in refrigeration these must be discarded

Good Manufacturing Practices (cGMPs)

- cGMPs are legal requirements established by the FDA
- These regulations specify what *needs* to be done without specifying *how* it needs to be done
- The cGMPs are only a part of the overall quality assurance (QA) program

BOX 15-1

Good Manufacturing Practices

- Write SOPs
- Follow SOPs
- Record and document all work performed
- Qualify personnel by training and education
- Design and build proper facilities and equipment
- Clean by following a housekeeping schedule
- Validate equipment, personnel, processes, etc.
- Perform preventive maintenance on facilities and equipment
- Control for quality
- Audit for compliance with all of the above

SOPs, Standard operating procedures.

Proof of Competency Requirements

- The following agencies have established requirements for proof of competency for personnel testing, twice the first year of employment and annually thereafter:
  - The Center for Medicare and Medicaid Services
  - AABB
  - CLIA
- Corrective actions needed for unacceptability

Proficiency Testing

- A required component of QA program
- Used to ensure that test methods and equipment are working correctly
- Ensures that staff members are following procedures
- Assigning external proficiency testing samples on a rotating basis.
- Generally CAP surveys are used
- Corrective action is implemented and monitored for improvement when results are not acceptable

Patient Blood Management (PBM)

- Active programs to limit and prevent inappropriate or unnecessary transfusion while promoting strategies to reduce overall transfusion requirements of patients
- Goals:
  - 1. Enhanced Safety
  - 2. Quality Improvement
  - 3. Patient-Focused Care
  - 4. Resource Conservation
  - 5. Waste reduction/cost control

Tools to Achieve PBM Goals

1. **Transfusion Safety Officer** – coordinates/participates in PBM program
2. **Transfusion Guidelines** – statements relevant to transfusion therapy to assist clinicians and patients in making decisions related to transfusion
3. **Blood Order Sets** – standardized method to clarify indications which can aid in compliance during physician order entry
4. **Decision support algorithms** – additional questions or warnings that appear during blood order entry to alert practitioner of unnecessary transfusion

Tool to Achieve PGM Goals

5. **Utilization Auditing and Reviews**

- Required by Joint Commission
- Used to assess the blood ordering and transfusion practices of the medical staff.
- Do not want to waste units or expose a patient to the risks of transfusion when it was unnecessary
- Number of emergency releases.
- Calculate statistics by physician.
- Review of records to determine if transfusion was justified.
- If audit reveals unjustified transfusions, transfusion physician is notified and asked to respond.

Tools to Achieve PBM Goals

6. **Patient Focused Care**
   - Optimize erythropoiesis
   - Minimize blood loss and bleeding
   - Optimize physiological reserve of anemia

7. Education – Should occur regularly
   - Phone calls about specific cases
   - Small group discussions on current guidelines
   - Formal lectures at grand rounds
   - Resident education