Hemovigilance in Hospital’s Blood Bank

Dr Azita Chegini
History of transfusions

• The first blood transfusions were attempts to transfusion humans with animal blood
• The 18th century, it forbade
• The 19th century, Henri Leacock and James Blundell pioneered inter human transfusion as a life saving therapy
• After the discovery of the ABO blood groups by Landsteiner, blood transfusion became less dangerous but certainly still not without risk
THE TRANSFUSION OF BLOOD—AN OPERATION AT THE "HÔPITAL DE LA PITIE," AT PARIS. [See Page 302.]
Introducing hemovigilance

• The word “hemovigilance” comes from the French and is derived from Greek haema meaning blood and the latin vigilans meaning watchful

• Pharmacovigilance (1970)

• 1980-1990s HIV

• In France in 1994 was the start of hemovigilance
Safer practice notice

Right patient, right blood

Blood transfusions involve a complex sequence of activities and, to ensure that the right patient receives the right blood, there must be strict checking points in place at each stage.

An initiative has been launched that offers a range of long and short-term strategies to ensure blood transfusions are carried out safely. The National Patient Safety Agency (NPSA), the Chief Medical Officer’s National Blood Transfusion Committee (NBTC) and Serious Hazards of Transfusion (SHOT) have collaborated to develop and evaluate these strategies.  

Administering the wrong blood type (ABO incompatibility) is the most frequent outcome of error during transfusions. Most of these incidents are due to the failure of the final identity checks carried out between the patient (at the patient’s side) and the blood to be transfused.

SHOT data have shown that between 1996 and 2004, five patients died as a direct result of being given ABO incompatible blood. ABO incompatibility has contributed to the deaths of a further nine patients and caused major morbidity in another 21.
IHN

• IHN = International Hemovigilance Network
• A set of surveillance procedures covering the whole transfusion chain
• From the collection blood to the follow-up of recipients
• Unexpected or Undesirable effects resulting from transfusion
• Prevent their occurrence or recurrence
Quality system

- Biovigilance
- Calibration
- Control of change
- Control of procedures
- Documentation
- Near miss
- Control of process
- Competence
Blood safety/ Transfusion safety

SAFE BLOOD COMPONENT
Hemovigilance

- Total Health Care Vigilance
- Pharmacovigilance
- Vigilance on medical devices

An Adverse Event
ارتباط بين واکنش جانبی وحادثه وحادثه قريب الوقوع

Adverse reaction
واکنش جانبی

Incident
حادثه (رخداد)

Near-miss
حادثه قريب الوقوع

Rene R.Pde veries, Jean claude faber. Hemovigilance Textbook 2012 p7-9
Figure 1
Total reports and total deaths definitely due to transfusion between 1996 and 2009

Key
- Orange: Number of reports
- Blue: Number of deaths
- Purple: Trend
Delayed 17%
Acute 10%
Infections 1%
Incorrect component 72%
Incorrect component

- Blood Bank: 28%
- Collection & Administration: 43%
- Prescription, Sampling & Request: 27%
- Other: 2%
Cumulative numbers of cases reviewed 1996-2010 n = 8117

*IBCT, incorrect blood component transfused; I&U, inappropriate, unnecessary and under/delayed transfusions; HSE, handling and storage errors; ATR, acute transfusion reactions; HTR, haemolytic transfusion reactions; TRALI, transfusion-related acute lung injury; TACO, transfusion associated circulatory overload; TAD, transfusion associated dyspnoea; PTP, post transfusion purpura; TA GvHD, transfusion associated graft versus host disease; TTI, transfusion-transmitted infection.
Modern Hemovigilance

Recipient  Process  Donor

AE  ER  NM  ID  AE

Recipients  Processes / Products  Donors

collection / analysis of data

continuous improvement of transfusion safety
The local transfusion safety and hemovigilance committee
Management, HO, prescribers, nurses, regional coordinator

- organization of transfusion
- transfusion procedures
- transfusion reactions
- traceability
- training

information
| نوع واکنش | آیا حادثه بدلیل اختلال در روند تزریق خون است؟ | آیا حادثه بدلیل کیفیت فراورده است؟ | بخشنامه | ناسازگاری و احساس تنش | ناسازگاری و احساس تنش | هموپلیزایامونولوژیک به دنبال NvesAZهار | هموپلیزایامونولوژیک به دنبال دیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| 1 | خیر | خیر | هموپلیزایامونولوژیک به دنبال NvesAZهار | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
| 2 | بله | بله | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
| 3 | روند تزریق خون نظرات بر خیال بانک خون وزنجهره سرما و حمل ونقل | بله | خیر | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
| 4 | پدیده وسیع هویت اهداکننده | استفاده از کیسه جانبی | احتمالا بدلیل عدم ارزیابی نکات فنی کیسه خون و فراورده قبل از تزریق است | بله | خیر | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
| 5 | انتخاب اهداکننده سالم | آزمایشات خون اهداکننده | خیر | بله | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |
| 6 | انتخاب اهداکننده سالم | آزمایشات خون اهداکننده | خیر | بله | هموپلیزایامونولوژیک به دنبال Dیگر Dیگر الروانی بادیها |

*注：此表格内容为假设性的语言翻译，实际内容可能有所不同。*
<table>
<thead>
<tr>
<th>قابل پیشگیری توسط</th>
<th>آیا حادثه بدلیل اختلالی درون‌داده‌های خون است؟</th>
<th>آیا حادثه بدلیل کیفیت فرآورده است؟</th>
<th>نوع واکنش</th>
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<tr>
<td>غیرقابل پیش‌بینی و غیرقابل احتمال</td>
<td>خیر</td>
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<td>ممکن است با گرفتن از FFP از هدایت‌گذاران مردک‌هاشیابد</td>
<td>خیر</td>
<td>خیر</td>
<td>تخمین حاده به دنبال تزریق خون در اتصال TRALI</td>
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<td>استفاده از محصولات از اشعه دیده برای بیماران در معترض خطر</td>
<td>بله</td>
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<td>بیماران پیوندهای میزبان GVHD</td>
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<td>پرهزی از تزریق حجم زیاد خون</td>
<td>بله</td>
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<td>شیوع آن ممکن است با فراورده کم‌کوشیت کاهش یابد</td>
<td>خیر</td>
<td>خیر</td>
<td>واکنش تب زای غیرهمولیتیک FNHTR</td>
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Pick up Blood and other products
The Procedure

Check the blood bag identification number, ABO blood group, and Rh compatibility.

Also, compare the patient’s blood bank identification number, if present, with the number on the blood bag.
Blood group serology-compatibility

- National guidelines for pre-transfusion testing
- Protocols for ABO-Rh
- Ab-screening
- Group and screen
- Crossmatching
- Sample validity
- Selection of RBC and non_RBC products
- Emergency transfusion
- Quality control
Recommendations

• Pregnancy
• Selection of blood & products in neonatal and infants
• Autologous transfusion
Guidance on identification

- Standardization of patient identification
- Standard Blood sampling
- Sample collection
- Labeling
- Compatibility tests
- Records
- Ensure quality and safety in blood group serology and compatibility
Patient Identification

- Must confirm recipient’s ID from bracelet ON the patient
  - Full patient name and hospital number
  - Name of physician

Sample Identification

• The sample should also have the full patient name, hospital number, and physician

• Date and time of collection, phlebotomist’s initials

• All of this should be on the request form and the sample
Specimen Tubes

Pink Top - EDTA

Red Top – no additives
sampling
Aim of transfusion laboratory

- Right test
- Right sample
- Right results
Quality assurance

- Personnel
- Records
- Reagents
- Equipment
- Storage requirements
- Transport
- Computer validation
Incorrect blood component transfused

- IBCT

- Analysis of data by category
- Transfused with reaction
- Transfused without reaction
- Component not transfused (near miss)
Site of primary error

• Blood unit (wrong donor group label, wrong recipient identification on unit)
• Patient sample (wrong name of tube, including wrong patient collected)
• Transfusion (ABO-incompatible transfusion, wrong patient but ABO-compatible, wrong product type plasma versus platelet)
Provide sample collection information
What- When- How

Provide appropriate containers and supplies

Assess all samples - preexamination

Define a good labeling system
Errors associated with blood group serology

• Technical failure in testing

• Inadequate procedures
  - misidentification of patient or donor sample
  - Transcription errors
  - Misinterpretation of results

• Combination of factors with the original error being perpetuated or compounded by the lack of adequate checking procedures
# Field Data Collection Form

### General patient information
- Name:
- Address:
- Country:
- City/town/village:

### Tracking record number
- Date of Birth (dd/mm/yyyy):
- Sex: M [ ] F [ ]
- Nationality:
- Occupation:

### Date of onset of illness (dd/mm/yyyy):

### Clinical specimens

<table>
<thead>
<tr>
<th>Unique ID No.</th>
<th>Type</th>
<th>Date of collection</th>
<th>Clinical diagnosis</th>
<th>Health status when specimens collected</th>
<th>Remarks</th>
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### Post-mortem specimens
- Date of death (dd/mm/yyyy): ___ / ___ / ___

<table>
<thead>
<tr>
<th>Unique ID No.</th>
<th>Type</th>
<th>Date of collection</th>
<th>Clinical diagnosis</th>
<th>Health status when specimens collected</th>
<th>Remarks</th>
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</table>

### Name of person completing form:

### Institutional affiliation:

### Contact details:

### Date (dd/mm/yyyy): ___ / ___ / ___
• The first step in the process of obtaining the sample is the request for testing.
• The laboratory must make available a test request form that specifies all the information that will be needed for proper handling and reporting.
• Essential information for the test request form includes:
  • patient identification;
  • tests requested;
  • time and date of the sample collection;
  • source of the sample, when appropriate;
  • clinical data, when indicated;
  • contact information for the health care provider requesting the test.
Sample collection requirements

- Sample collection and preservation will vary, depending on the test and the type of sample to be collected. The laboratory must carefully define a sample collection process for all tests it performs. The following should be considered when preparing instructions:
  - **Patient preparation**—Some tests require that the patient be fasting. There may also be special timing issues for tests such as blood glucose, drug levels, and hormone tests.
  - **Patient identification**—The person collecting the sample must accurately identify the patient. This might be done by questioning the patient, by questioning an accompanying family member, or by the use of an identifying wrist band or other device.
  - **Type of sample required**—Blood tests might require serum, plasma, or whole blood. Other tests might require urine or saliva. Microbiology testing deals with a variety of sample types, so specific information as to what is required for the test is needed.
  - **Type of container**—The container for the sample is often very important, as it will affect volume and any needed additives such as anti-coagulants and preservatives. If the container does not control volume, for example as with Vacutainer® tubes, this will need to be clearly specified. Some microbiology samples will require specific transport media to preserve microorganisms.
  - **Sample labeling**—All requirements for labeling of the sample at the time of collection will need to be explained in detail in the instructions for collection.
  - **Special handling**—Some samples may require special handling, such as immediate refrigeration, protection from light, or prompt delivery to the laboratory. Any important safety precautions should be explained.
Sample labeling

- Each sample should be clearly labeled with:
  - the patient’s first and last name;
  - a unique identification number – this might be a hospital number or a number assigned by the laboratory;
  - Sample Management
    - the test that has been requested;
    - the time and date of collection;
    - the initials of the person collecting the sample.
potential outcomes of collection errors

• Proper sample collection is an important element for good laboratory practice.
• Improper collection of samples can lead to poor outcomes, such as:
  • delays in reporting test results
  • unnecessary re-draws/re-tests
  • decreased customer satisfaction
  • increased costs
  • incorrect diagnosis / treatment
  • injury
  • death.
• The laboratory should keep a register (log) of all incoming samples. A master register may be kept, or each specialty laboratory may keep its own sample register.

• Assign the sample a laboratory identification number – write the number on the sample and the requisition form. If computers are used for reports, enter the information into the computer.
Handle all samples as if infectious
Best Dressed Tube

- Wrinkled
- Turtleneck
- The Wrap Around
- Cinched Belt
- Twisted Shirt
- Flying Ace Scarf
- Topsy Turvy Label

Instructions:
- Place label directly under cap
- NAME at the TOP
- Barcode straight
- Collector’s USER ID
- Hospital Gown Look is IN!
- Leave visible window to see blood
Exploring the iceberg of errors in laboratory medicine

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Pre-analytic phase
Post-analytic phase

ABSTRACT

The last few decades have seen a significant decrease in the rates of analytical errors in clinical laboratories, and currently available evidence demonstrates that the pre- and post-analytical steps of the total testing process (TTP) are more error-prone than the analytical phase. In particular, most errors are identified in pre- and post-analytic steps outside the walls of the laboratory, and beyond its control. However, in a patient-centered approach to the delivery of health care services, there is the need to investigate any possible defect in the total testing process that may have a negative impact on the patient. In fact, in the interests of patients, any direct or indirect negative consequence related to a laboratory test must be considered, irrespective of which step is involved and whether the error is caused by a laboratory professional (e.g., calibration or testing error) or by a non-laboratory operator (e.g., inappropriate test request, error in patient identification and/or blood collection). Data on diagnostic errors in primary care and in the emergency department setting demonstrate that inappropriate test requesting and incorrect interpretation account for a large percentage of total errors whatever: the discipline involved, be it radiology, pathology or laboratory medicine. Patient misidentification and problems in communicating results, which affect the delivery of all diagnostic services, are widely recognized as the main goals for quality improvement. Therefore, some common problems affect diagnostic errors, although specific faults characterising errors in laboratory medicine should lead to preventive and corrective actions if evidence-based quality indicators are developed, implemented and monitored. The lesson we have learned is that each practice must examine its own total testing process to discover its weaknesses and identify appropriate remedies.

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Overview of Sample Management

• Sample management is a part of process control, one of the essentials of a quality management system.

• The quality of the work a laboratory produces is only as good as the quality of the samples it uses for testing.

• The laboratory must be proactive in ensuring that the samples it receives meet all of the requirements needed to produce accurate test results.
Sample management components

- Written policies for sample management must be established and reflected in the Laboratory Handbook. Components to be addressed include:
  - information needed on requisitions or forms
  - handling urgent requests
  - collection, labeling, preservation and transport
  - safety practices (leaking or broken containers, contaminated forms, other biohazards)
  - evaluating, processing, and tracking samples
  - storage, retention, and disposal.
Getting the history

• Look at recipient’s records for any prior unexpected antibodies
• Previous transfusion reactions
The audit cycle:

1. Identify the audit topic
2. Set the standard
3. Design the method
4. Collect the data
5. Analyse the data
   - Was the standard met?
6. Implement change
Error management

• Up to half of all serious transfusion reactions are preventable
• With appropriate measurements
• Electronic system (barcode)
• Automated laboratory equipment
• Process control
• HTC
## AUDIT IN TEHRAN’S HOSPITAL

<table>
<thead>
<tr>
<th>blood bank</th>
<th>Improvement</th>
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<tbody>
<tr>
<td>Refrigerator</td>
<td>88.9%</td>
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<tr>
<td>Freezer</td>
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</tr>
<tr>
<td>Shaker incubator</td>
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<tr>
<td>Calibration</td>
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Audit in hospital blood banks

<table>
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<th>1385</th>
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<tbody>
<tr>
<td>100%</td>
<td></td>
<td>44.4%</td>
<td>Cross match</td>
</tr>
<tr>
<td>22.2%</td>
<td></td>
<td>5.5%</td>
<td>Ab-screening</td>
</tr>
<tr>
<td>Blood grouping</td>
<td>Percentage change</td>
<td></td>
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<tr>
<td>----------------------------------------</td>
<td>-------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Slide to tube test</td>
<td>44.4%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tube to slide test</td>
<td>11.1%</td>
<td></td>
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</tr>
<tr>
<td>Tube to tube (without change)</td>
<td>27.8%</td>
<td></td>
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<tr>
<td>Slide to slide (without change)</td>
<td>16.7%</td>
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Thank you for your attention.