HAEMOVIGILANCE IN MALAYSIA: GUIDELINES FOR THE RATIONAL USE OF BLOOD PRODUCTS IN MALAYSIA

Dr Faraizah Abd Karim
HAEMOVIGILANCE (HV)

- Haem (‘Greek’ word) : blood
- Vigilance (‘Latin’ word) : paying particular attention to

- A set of surveillance procedures covering the ‘transfusion chain’
HAEMOVIGILANCE

“A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.”
HAEMOVIGILANCE

• A continuous process of data collection and analysis
• An integral part of Quality Management in a blood system
• Necessary for continual improvement of quality and safety of blood products and transfusion process
• Essential to identify and prevent occurrence and recurrence of adverse reactions and unwanted events
• Increase safety, efficacy and efficiency of blood transfusion
• Cover vein to vein
AIDE-MEMOIRE FOR NATIONAL HEALTH PROGRAMS

Developing a National Blood System

The Clinical Use of Blood

Safe Blood Components

Checklist

Leadership and governance
- National blood policy and strategic plan
- Legislative framework
- Standards
- Financial sustainability
- Risk assessment and management
- Experience of medical, scientific, financial and ethical issues
- Regulatory mechanism

Coordination and collaboration
- Efficient organizational structure
- Coordination of programs and organizations involved:
  - Voluntary blood donation
  - Provision of blood and blood products, including plasma derivatives
  - Coordination with hospitals and facilities involved in blood transfusion
  - Human resource management, including education, training and career development
- Surveillance and haemovigilance
- Procurement and supply systems
- Data collection and reporting
- Collaboration and partnerships
- Monitoring and evaluation

Provision of safe blood and blood products
- Adequate qualified, trained staff
- Suitable infrastructure and facilities
- Quality system
- Donor education, recruitment and retention
- Donor selection, blood collection and donor management
- Donor counselling and referral
- Blood processing and testing
- Waste management
- Blood storage and inventory management
- Blood cold chain and distribution
- Liaison with hospital transfusion services

Clinical transfusion in patient management
- Hospital standards and guidelines
- Education and training
- Estimation of blood requirements
- Blood storage and handling
- Blood stock management
- Patient's involvement in treatment
- Patient's product identification

Safety and quality systems
- Hospital transfusion committees
- Haemovigilance

Checklist

- Prerequisites
  - Well organized, nationally coordinated blood transfusion service
  - National blood policy and plan
  - Incorporating the clinical use of blood
  - National committee on the clinical use of blood
  - Quality system for the BTS, hospital blood banks and clinical departments
  - Adequate resources
- National guidelines
  - Clinical and laboratory indications for the use of blood, blood products and alternatives to transfusion
  - Information about available blood products and alternatives to transfusion
  - Standard blood request form
  - Guidance on the development of blood ordering schedule and standard operating procedures at hospital level
- Education and training
  - Training of clinicians, nurses and BTS/blood bank staff in:
    - Undergraduate and postgraduate programmes
    - In-service training
    - Continuing medical education
- Hospital transfusion committees
  - Effective implementation of national guidelines
  - Training of hospital staff
  - Hospital blood ordering schedule
  - Hospital standard operating procedures
  - Monitoring and evaluation at hospital level
- Monitoring and evaluation
  - Safety and adequacy of available blood and blood products and alternatives to transfusion
  - Traceability of blood and blood products
  - Compliance with national transfusion guidelines
  - Patterns of blood usage and clinical transfusion practice
  - Adverse events related to transfusion
BLOOD TRANSFUSION RISKS

- Despite rigorous screening blood components continue to pose a small risk of transmission of pathogens, including viruses, bacteria, and parasites.
- Currently unrecognized pathogens may also emerge in time.
- Some studies have suggested that allogeneic blood may have an immunomodulatory effect.
ESTIMATED RESIDUAL RISKS OF SOME TRANSFUSION-TRANSMISSIBLE VIRUSES

Virus Recent Risk Estimate Ranges
- HIV-1 1/1,467,000 units
- HCV 1/1,149,000 units
- HBV 1/280,000 – 1/357,000 units
- HTLV 1/1,208,000 units
NON-INFECTIONOUS COMPLICATIONS OF TRANSFUSION
IMMUNOLOGIC COMPLICATIONS, IMMEDIATE

- Hemolytic transfusion reaction
- Immune-mediated platelet destruction.
- Febrile nonhemolytic reaction.
- Allergic reactions as mild or self-limiting urticaria or wheezing.
- Anaphylactoid/anaphylactic reactions.
- Transfusion-related acute lung injury (TRALI)
IMMUNOLOGIC COMPLICATIONS, DELAYED

- Delayed hemolytic reactions occur in previously red-cell-alloimmunized patients in whom antigens on transfused red cells provoke anamnestic production of antibody.
- Alloimmunization to antigens of red cells, white cells, platelets, or plasma proteins may occur unpredictably after transfusion.
- Post transfusion purpura (PTP) is characterized by the development of dramatic, sudden, and self limited thrombocytopenia.
- Transfusion-associated graft-vs.-host disease (TA-GVHD).
METABOLIC AND PHYSIOLOGIC COMPLICATIONS

- Citrate— toxicity reflects a depression of ionized calcium caused by the large quantities of citrate anticoagulant. Because citrate is promptly metabolized by the liver, this complication is rare.

- Acidosis or alkalosis and hyper- or hypokalemia

- Transfusion Associated Circulatory Overload can accompany transfusion of any component at a rate more rapid than the recipient's cardiac output can accommodate.

- Iron overload is a long-term complication of repeated RBC transfusions
117 KKM hospitals – only 106 respond (90.6%)

1. Blood transfusion errors: 14 hospitals (13.2%)
   - No of cases not reported
   - No details except HKL/PDN

2. Seroconvert donors
   - 25 hospitals (23.6%) – 322 donors
   - Not reported to KKM

3. Seroconvert recipients
   - 6 hospitals (5.6%) – 10 cases

4. Transfusion reactions
   - 46 hospitals (43.4%) – 748 cases
Training; to recognise transfusion reaction; donor reaction, seroconvert, how & what to report
Reporting forms – general & specific form
Ensure all adverse events are reported
Recipient and donor haemovigilance programme
Resources to improve analysis, haemovigilance reports, access to these reports
HAEMOVIGILANCE PROGRAM IN MALAYSIA BACKGROUND

- Haemovigilance programme was initiated as a national programme in 2003 under the Ministry of Health (MOH).
- Since its inception in 2003 the Programme has evolved and has become an integral part of our transfusion service.
- Voluntary reporting
- A standardised form was created with inputs from all party involved: Physicians, surgeons, BTS.
- Data collection started in 2003
HAEMOVIGILANCE PROGRAM IN MALAYSIA

- Maintaining record and registry of seropositive donors for the whole country.
- Evaluate transfusion practices toward improvement

- Evaluate residual risk among population.

- Explore strategies in blood screening to improve safety of donated blood donation.

- Evaluate and dissemination of current information regarding transfusion transmitted diseases to public and health personnel.

- Recording of adverse events (immunologic and non-immunologic) in transfusion

- Coordinate audit and inspection

- Identify training needs.
HAEMOVIGILANCE PROGRAM IN MALAYSIA: IMPLEMENTATION PHASE

- Adverse Transfusion Events Forms were created in 2003
- Algorithm establish
- Things to report:
  - All adverse events: recipient and donors
  - Seroconvert donors and recipients
  - Monitoring incidence and prevalence infectious disease markers.
  - Reagents, blood bags, equipment etc
HAEMOVIGILANCE PROGRAM IN MALAYSIA

- National Blood Safety Meeting in MOH 2004
  - A hospital transfusion committee should be set up in all KKM hospitals to implement the national policy and guidelines as well as monitoring the transfusion practice.
  - Update existing guidelines
  - National Policy for Blood Transfusion service in Malaysia
IMPLEMENTATION PHASE

- To have Hospital Transfusion Committee & State Transfusion Committee
- Training (2004 -2007)
  - National Level
  - Regional
  - State
- Transfusion Practice guideline 2003 (2nd Ed)
Peraturan Peraturan
Untuk Kakitangan Kakitangan
Makmal Tabung Darah

National Blood Centre
Ministry of Health Malaysia

1st edition 2003

1980’s

Manuscript Guidelines for the Rational Use of Blood and Blood Products

Guidelines for the Rational Use of Blood and Blood Products

National Blood Centre
Ministry of Health Malaysia

2nd edition 2005

1980’s

1st edition 1994

2nd edition 2007
REPORTING FORMAT FOR ADVERSE TRANSFUSION EVENT

Report ALL adverse events related to transfusion of blood or blood products using this form. Completed forms should be sent to your blood bank for compilation. Where appropriate, treatment of reactions and investigations of event should be carried out using existing protocol.

Product implicated (4) in the appropriate box.

<table>
<thead>
<tr>
<th>Whole blood</th>
<th>Packed Red cells</th>
<th>Plasma (FFP)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Platelets</th>
<th>Cryoprecipitate</th>
<th>Others (specify)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Date of transfusion: ........................................ Time: ........................................

Type of adverse events: (4) in the appropriate box

<table>
<thead>
<tr>
<th>ADVERSE EVENT</th>
<th>(See overleaf for clinical features of reaction)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Incorrect blood or component transfused</td>
</tr>
<tr>
<td>2</td>
<td>Acute transfusion reaction (occurring within 24 hours)</td>
</tr>
<tr>
<td>2a</td>
<td>Mild (rash and itchiness)</td>
</tr>
<tr>
<td>2b</td>
<td>Moderate (fever, chills and rigors, ± above)</td>
</tr>
<tr>
<td>2c</td>
<td>Severe (with dyspnoea, low BP, chest pain, bronchospasm including anaphylaxis)</td>
</tr>
<tr>
<td>3</td>
<td>Delayed transfusion reaction (occurring more than 24 hours following transfusion)</td>
</tr>
<tr>
<td>4</td>
<td>Bacterial contamination</td>
</tr>
<tr>
<td>5</td>
<td>Post transfusion viral infection</td>
</tr>
<tr>
<td>6</td>
<td>Post transfusion purpura</td>
</tr>
<tr>
<td>7</td>
<td>Transfusion associated graft versus host disease (TA-GVHD)</td>
</tr>
<tr>
<td>8</td>
<td>Transfusion Related Acute Lung Injury (TRALI)</td>
</tr>
<tr>
<td>9</td>
<td>Others (describe reaction) eg: Pulmonary Oedema</td>
</tr>
<tr>
<td>10</td>
<td>Near misses</td>
</tr>
</tbody>
</table>

How would you consider this reaction?

Suspected and not confirmed □ Certain □

Patient Outcome:

No adverse outcome □ Morbidity due to event □ Death due to event □

Patient’s particulars:

Name: ........................................ I/C No: ........................................
Ward: ........................................ Age: ........................................ Race: ........................................ Sex: ........................................

Reported by:

Name: ........................................ Date of reporting: ........................................
Designation: ........................................ Tel. No: ........................................
Flowchart for reporting of adverse transfusion events

Adverse transfusion events

1. Investigate and treat

2. Report to Hospital transfusion committee

3. Report to State Transfusion committee

   (Reporting format for adverse transfusion events)

5. Report to KKM Transfusion committee

Note:
1. Every case of adverse reaction must be reported.
2. If the case of adverse reaction involved a seropositive donor, a look back and recall procedure must be carried out.
3. Identity card number (I/C), donation date must be submitted to Surveillance Unit, National Blood Centre.
# Recipient Surveillance Report

<table>
<thead>
<tr>
<th></th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>No of Hospital</strong></td>
<td>81 (66.4%)</td>
<td>105 (85.5%)</td>
<td>121 (100%)</td>
<td>121 (100%)</td>
</tr>
<tr>
<td><strong>Total Blood collected</strong></td>
<td>447,690</td>
<td>472,234</td>
<td>477,365</td>
<td>507,808</td>
</tr>
<tr>
<td><strong>Total blood transfused</strong></td>
<td>345,354</td>
<td>376,572</td>
<td>384,780</td>
<td>397,288</td>
</tr>
<tr>
<td><strong>No of adverse events</strong></td>
<td>1467</td>
<td>1281</td>
<td>1936</td>
<td>2268</td>
</tr>
</tbody>
</table>
**Adverse events 2004-2007**

IBCT: Incorrect blood component transfused
ATR: Acute Transfusion Reaction
ATR Mild: Acute Transfusion Reaction (Mild)
ATR Mod: Acute Transfusion Reaction (Moderate)
Purpura
ATR Sev: Acute Transfusion Reaction (Severe)
TA-GVHD: Transfusion associated graft versus host disease
TRALI: Transfusion Related Acute Lung Injury

BC: Bacterial Contamination
PVI: Post Viral infection
PTP: Post Transfusion Purpura
NM: “near misses”

DTR: Delayed Transfusion Reaction
TRALI: Transfusion Related Acute Lung Injury

Legend:
- Light blue: 2004
- Dark blue: 2005
- Yellow: 2006
- Light green: 2007
<table>
<thead>
<tr>
<th></th>
<th>Year 2004</th>
<th>Year 2005</th>
<th>Year 2006</th>
<th>Year 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participation</td>
<td>81 (66.4%)</td>
<td>106 (85.5%)</td>
<td>121 (100%)</td>
<td>121 (100%)</td>
</tr>
<tr>
<td>Total No. Transfusion</td>
<td>345,354</td>
<td>376,572</td>
<td>384,780</td>
<td>397,288</td>
</tr>
<tr>
<td>Total No. Recipient</td>
<td>221,287</td>
<td>220,673</td>
<td>253,968</td>
<td>270,258</td>
</tr>
<tr>
<td>No. of Incorrect</td>
<td>0.9%</td>
<td>0.54%</td>
<td>0.51%</td>
<td>0.3%</td>
</tr>
<tr>
<td>Blood Component Transfusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfusion Error Rate:</td>
<td>0.00376%</td>
<td>0.00185%</td>
<td>0.00259%</td>
<td>0.00176%</td>
</tr>
<tr>
<td>No. of IBCT / Total No.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Transfusion</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Near Miss</td>
<td></td>
<td></td>
<td>147</td>
<td>53</td>
</tr>
</tbody>
</table>
DEFICIENCIES:

1. Under reporting due to failure to recognize the transfusion reaction thus
   1. Inadequate management of events
   2. Failure to report,
2. There are many reports that incomplete and lack the details of events leading to the error.

3. Reasons for this deficiencies includes:
   1. Current reporting form does not asked for such details
   2. No standard guideline of essential details required should report being submitted
   3. Lack of thoroughness in the investigation of the event (no RCA)
   4. No adequate training
Continuous education implemented, there is marked improvement seen in the number and quality of reports.

Dedicated staff is required in each hospital to ensure all adverse events are reported.

Regular updates and feedbacks are important to sustain the programme and prevent fatigue in reporting.

Identify weaknesses in guidelines

National Policy for Blood Transfusion Service
POLICIES & GUIDELINES

1st edition 2008

2nd edition 2007

3rd edition 2008
ENSURE APPROPRIATENESS OF BLOOD TRANSFUSION

- Risk should be outweighed by the potential benefits.
- Alternative strategies to reduce the use of allogeneic blood should be considered.
- Patients should be informed that transfusion is part of the planned intervention.
- The patient’s consent should be obtained for the planned transfusion and recorded in the patient’s medical chart.
14.0 HAEMOVIGILANCE & LOOK BACK

• Any event or untowards incident occurring at any point during donation or during/after transfusion is to be monitored & documented appropriately.
• All adverse transfusion events & errors shall be reported according to existing procedures.
• All adverse transfusion events shall be investigated.
• All errors & adverse events shall be reported to the Haemovigilance Secretariat at NBC.

National Policy for BTS in Malaysia (1st edition 2008)
NUMBER OF REPORTS RECEIVED FROM 2004 – 2015

No. of reports submitted

No. of reports submitted
ADVERSE TRANSFUSION EVENTS MONITORED

- Incorrect Blood or Blood Components Transfused
- Acute Transfusion Reaction (*occurring within 24 hours*)
- Delayed Transfusion Reaction (*occurring more than 24 hours following transfusion*)
- Bacterial Contamination
- Post Transfusion Viral Infection
- Post Transfusion Purpura
- Transfusion Associated Graft Versus Host Disease (TA-GVHD)
- Transfusion Related Acute Lung Injury (TRALI)
- Others
- ‘Near Misses’
Source of Error in IBCT 2015

- Blood Bank Error: 50%
- Sampling & Labelling: 29.4%
- Administration of wrong blood: 20.6%
Near Miss Events from 2014-2016

<table>
<thead>
<tr>
<th>Year</th>
<th>Error in Ward</th>
<th>Blood Bank's Error</th>
</tr>
</thead>
<tbody>
<tr>
<td>2014</td>
<td>305</td>
<td>24</td>
</tr>
<tr>
<td>2015</td>
<td>146</td>
<td>15</td>
</tr>
<tr>
<td>2016</td>
<td>228</td>
<td>22</td>
</tr>
</tbody>
</table>
SHOT 2014 Annual Report
(Paula Bolton-Maggs, Debbi Pole)

Figure 4.2: Cumulative data for SHOT categories 1996/7-2014
n=14822

- UCT: Unclassifiable complications of transfusion
- PTP: Post-transfusion purpura
- TTI: Transfusion-transmitted infection
- TAD: Transfusion-associated dyspnoea
- CS: Cell salvage
- ATR: Acute transfusion reaction
- TAGvHD: Transfusion-associated graft vs host disease
- TRALI: Transfusion-related acute lung injury
- Allo: Alloimmunisation
- TACO: Transfusion-associated circulatory overload
- HTR: Haemolytic transfusion reaction
- ADU: Avoidable, delayed or undertransfusion
- HSE: Handling and storage errors
- Anti-D: Anti-D immunoglobulin errors
- IBCT: Incorrect blood component transfused

Legend:
- Cumulative to 2013
- 2014

Transfusion reactions which may not be preventable
Possibly or probably preventable by improved practice and monitoring
Adverse incidents due to mistakes
“WRONG BLOOD” EPISODES…

- International evidence shows that the bedside is the commonest site of failure in the transfusion process.
- Events reported to NHCC, the majority of failures were seen to occur in earlier steps in the process, namely at prescription sampling or requesting and in the blood bank or laboratory.
## Clinical Decision

<table>
<thead>
<tr>
<th>What can go wrong?</th>
<th>Why it goes wrong?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unnecessary transfusion or failure to give necessary transfusion</td>
<td>Inadequate clinical assessment</td>
</tr>
<tr>
<td>Wrong component or dose prescribed</td>
<td>Lack of transfusion knowledge or failure to follow guideline</td>
</tr>
<tr>
<td>Patient was not informed &amp; consent not obtain</td>
<td>Unaware of importance of information &amp; consent</td>
</tr>
</tbody>
</table>
**SPECIMEN COLLECTION**

What can go wrong?
- Patient was not identified correctly
- Pre transfusion specimen taken from wrong patient
- Request form/ sample tube was wrongly labeled

Why it goes wrong?
- Do not follow SOP for specimen collection
- Staff takes shortcut
ISSUING/DELIVERY OF BLOOD

What can go wrong?
- Wrong unit selected
- Blood delivered to wrong location
- Wrong storage

Why it goes wrong?
- Patient ID details not properly checked
- SOP was not followed
The Serious Hazard of Transfusion (SHOT) scheme showed that approximately 70% of IBCT event errors take place in clinical areas, the most frequent error being failure of the final patient ID check at the bedside.

(Serious Hazards of Transfusion (SHOT) 2007)
HOTSPOTS FOR ERRORS

Table I. Hotspots for errors in the transfusion process: multiple steps and many different professional groups.

<table>
<thead>
<tr>
<th>Location</th>
<th>Critical point</th>
<th>Health care professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donor centre or session</td>
<td>Identification of donor. Assessment of donor for safety of donation. Identification of donation.</td>
<td>Donation session staff</td>
</tr>
<tr>
<td>Blood centre</td>
<td>Processing and issue</td>
<td>Blood centre laboratory staff</td>
</tr>
<tr>
<td>Ward or outpatient clinic</td>
<td>Assessment of recipient and decision to transfuse</td>
<td>Medical and nursing staff</td>
</tr>
<tr>
<td>Ward</td>
<td>Prescription Request form</td>
<td>Medical staff</td>
</tr>
<tr>
<td></td>
<td>Sampling for pretransfusion testing</td>
<td>Medical and nursing staff</td>
</tr>
<tr>
<td></td>
<td>Transfer of sample to laboratory</td>
<td>Doctors, midwives, nurses, phlebotomists, Porters</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Reception, testing, allocation of component, labelling and issue</td>
<td>Medical laboratory assistants, Biomedical scientists</td>
</tr>
<tr>
<td>Blood transfusion laboratory or remote blood refrigerator</td>
<td>Collection from storage site</td>
<td>Porters, nursing staff</td>
</tr>
<tr>
<td>Ward, operating theatre, emergency department</td>
<td>Bedside administration checks</td>
<td>Nurses, midwives, doctors, operating department practitioners</td>
</tr>
<tr>
<td></td>
<td>Monitoring or adverse incidents</td>
<td></td>
</tr>
</tbody>
</table>

(Bolton-Maggs and Cohen 2013)
CAUSES OF TRANSFUSION ERROR

- Incorrect identification of patients
- Sampling and labelling errors
- Laboratory errors & clerical errors
- Improper storage and handling of blood
- Failure to perform final bedside check prior to blood administration
- Lack of patient monitoring during transfusion.
Source of IBCT in Blood Bank in 2015

- Technical: 64.7%
- Issuing: 23.5%
- Transcription: 11.8%
# Laboratory Error

<table>
<thead>
<tr>
<th>What can go wrong</th>
<th>Why it goes wrong</th>
</tr>
</thead>
<tbody>
<tr>
<td>Wrong ABO/ Rh grouping</td>
<td>Patient sample and request not checked for consistency and completeness</td>
</tr>
<tr>
<td>RBC alloantibodies not detected</td>
<td>Error in testing procedure or recording of result</td>
</tr>
<tr>
<td>Error in crossmatch &amp; wrong unit issued</td>
<td>Poor staff training or failure to comply with SOP</td>
</tr>
</tbody>
</table>

- Patient sample and request not checked for consistency and completeness
- Error in testing procedure or recording of result
- Poor staff training or failure to comply with SOP
LESSON LEARN

Why do error occurs?

- Attention lapses (being distracted/interrupted during a task)
- Deliberate non-compliance (taking short cuts and failing to follow SOP)
- Genuine errors (intention of carrying out correct procedure but failed)
- Misperceptions (what the task involves)
- Misplaced priorities (mixed messages over clinical priorities)
Encompasses a series of inter-connected steps including:

a) Prescription and ordering of blood products
b) Patient identification, collection & labelling of blood samples
c) Pretransfusion compatibility test and issue of blood
d) Collection and transportation of blood units
e) Handling of blood units in the clinical area
f) Blood administration
g) Monitoring of patients
h) Management of adverse transfusion events.

WHO Clinical Transfusion Process & Patient Safety, 2010
HOW DO WE PREVENT TRANSFUSION ERROR IN HOSPITAL?

- Policies and systems
- Hospital transfusion committees
- Personnel training
- Standardized procedures
- Haemovigilance systems
IMPORTANT POINTS TO REMEMBER

- Is the transfusion really necessary?
- Does the benefit outweigh the risk?
- Is there any appropriate alternative?
- Not all anaemic patients require transfusion.
- There is no universal transfusion trigger, each patient should be evaluated individually.
- Decision making:
  - Transfusion should not be based on laboratory result alone
  - Transfusion should be based on clinical assessment and evidence-based guidelines
- Discuss the risks, benefits and alternatives with the patient before informed consent is obtained.
- Documentation:
  - Reason for transfusion
  - Any adverse events associated with transfusion
  - Report all adverse events
- Ensure right blood for right patient by checking patient’s identity before blood sampling and transfusion. Do not transfuse if there is any discrepancy.
- Timely provision of blood saves lives.
- Monitor patient’s vital signs during and after transfusion.
Updated Adverse Event Reporting Form

APPENDIX II
Flowchart for reporting Transfusion-Related Adverse Events

1. Fill up Appendix I and send to Blood Bank with relevant investigations.
2. Blood Bank perform relevant laboratory investigations (MTC, etc).
3. BIO2001/04 2014 to be filled.
5. Blood Bank to verify and send report to:
   - Hospital Transfusion Committee (HTC)
   - National Adverse Event Coordinating Centre (NAECC)
   - State Transfusion Committee (STC)

SECTION A: PATIENT DETAILS

Name of Patient:
Age:
Gender:
Male:
Female:
Hand:
Department:

SECTION B: BREAKDOWN OF EVENTS

DEFINITION OF TERMS:
1. Adverse Event: Any error which has occurred but did not cause any significant adverse event as described below.
2. Blood Transfusion Reaction: Any error which has occurred and resulted in an adverse event.
3. Failure of Transfusion: Any error which has occurred and resulted in death.

SECTION A: EVENT OF TRANSfusion REACTION

1. Date of transfusion:
2. Time of transfusion:
3. Duration of transfusion:
4. Type of reaction:
5. Time of onset:
6. Time of resolution:
7. Description of reaction:
8. Conclusion:
9. Patient's condition:
10. Treatment:
11. Outcome:

SECTION B: BLOOD COMPONENTS IMPlicated IN THE ADVERSE EVENT (please check):

1. Whole Blood
2. FreshFrozen Plasma
3. Platelet Concentrates
4. Factor Concentrates
5. Other (please specify):

SECTION C: DETAILS OF ADVERSE EVENTS

1. Description of adverse event:
2. Treatment given:
3. Outcome:

SECTION D: LABORATORY TESTS

1. Test performed:
2. Result:
3. Other investigations (please specify):

SECTION E: INCIDENTS OCCURRING TO TRANSFUSION PROCESS (NOT OF ABOVE)

1. INCIDENTS OCCURRING TO TRANSFUSION PROCESS
   - Problem with equipment/technique
   - Medication error
   - Cross-matching error
   - Incorrect blood component
   - Other (please specify):

SECTION F: INCIDENCES OCCURRING TO TRANSFUSION PROCESS (NOT OF ABOVE)

1. CLASSIFICATION OF INCIDENCES OCCURRING TO TRANSFUSION PROCESSES
   - Type of incident:
   - Description:
   - Impact:
   - Action taken:

SECTION G: OTHER INCIDENTS OCCURRING TO TRANSFUSION PROCESS

1. Registration Error (including ID, ABO, Rh, etc):
2. Error in blood grouping in other hospitals
3. Other (please specify):

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March 13, 2013
National Transfusion Program
ADDITIONAL/SPECIFIC TOPICS IN GUIDELINES

- Patient Blood Management
- Autologous Blood transfusion
  - Autologous plasma eye drop
- Development and implementation of MSBOS
- Procedures for emergencies
  - Use of safe O bleed
  - Massive transfusion protocol
- Recommendation of Rh Negative blood
- Therapeutic Apheresis
- Management of anticoagulant associated bleeding
- Plasma derivatives Medicinal Products
ADDITIONAL/SPECIFIC TOPICS IN GUIDELINE

- Intra uterine transfusion
- Consent for blood transfusion
- Transfusion checklist
- Hospital blood banks
  - 2nd regrouping
  - 2nd fresh sample for blood grouping prior to release
INFORMED CONSENT

- There must be policy in place
- A decision for each health service organisation whether this is:
  - Specific to transfusion or more general
  - Signed by the patient or documented by the doctor
  - Perpetual (or one year) or for each transfusion

- Also gives the patient the opportunity to ask questions.
- Documenting informed decisions and information

This flexibility is to make the requirement achievable. There has been communicated a preference for consent to be specific, signed by the patient and undertaken either for each transfusion or regularly where there are high transfusion requirements.
REDUCE EXPOSURE TO ALLOGENEIC TRANSFUSION

- Autologous transfusion
- Surgical, anaesthetic and pharmacological approaches to reduce blood loss.
- Strategies for management of transfusion requirements in surgical patients:
  1. Pre-operative
  2. Intra-operative
  3. Post-operative
PRE-OPERATIVE MANAGEMENT

- Treatment of Pre-existing Anaemia
- Predeposit Autologous Donation
- Avoidance of Drugs that Increase Surgical Blood loss
INTRA-OPERATIVE MANAGEMENT

- Management of Blood Loss
- Management of Volume Replacement
- Reduction of Oxygen Demand
- Intra-operative Blood Salvage (IBS)
- Antifibrinolytic Agents
POST-OPERATIVE MANAGEMENT

- Post-operative Blood Salvage (PBS)
- Management of Volume Replacement & On-going Blood Loss
- Post-operative patients in ICU/HDU require close monitoring of haemodynamic status, oxygenation, pain relief, biochemical and haematological indices and on going blood loss.
- Red Cell Transfusion
THRESHOLDS FOR SPECIFIC SITUATIONS

- Red cell transfusion should be administered primarily to prevent or alleviate the signs and symptoms of morbidity due to inadequate tissue oxygen delivery.

- There is no single value of haemoglobin concentration that justifies the need for transfusion and the requirements of each patient should be based on their clinical status. It is generally accepted that a haemoglobin of 7.0 g/dL and above is tolerable for a healthy adult with no medical condition.

- Hb <7 g/dL during surgery associated with major blood loss or if evidence of impaired oxygen transport

- Hb <8g/dL; patients on a chronic transfusion regimen or during marrow suppressive therapy (for symptom control and appropriate growth)

- Hb <10g/dL; only for very select populations (eg. neonates)
SINGLE UNIT TRANSFUSION

WHAT
Transfuse one unit, then reassess the patient for clinical symptoms before transfusing another

- Every unit is a new clinical decision
- Base decision on patient symptoms, not only on haemoglobin level
EVERY ONE MATTERS

Transfuse One Unit

↓

Re-assess the patient

↓

Don’t increase the RISKS

if

NO BENEFIT
EMERGENCY O/SAFE O

- Life Threatening condition
  - Emergency Group O blood
  - Safe O

- Emergency
  - Immediate spin
  - Group Specific
  - Blood is released and full GXM continued
  - If positive informed and appropriate action taken

- Treating doctor - responsible
EMERGENCY SITUATION

- Local standard procedure - placement of blood in identified areas
  - Use of Emergency O/ Safe O
    - Clinician should state the reasons for a decision & document
  - Emergency cross-matched
    - continue thereafter with full crossmatched
    - Any positive finding or deviation need to communicated and act accordingly.

- Emergency requests should be accompanied by a phone call to person in the blood bank
- Liaison personnel need to be identified.
Massive Transfusion Protocol

Rapid blood loss of more than 150ml/min leading to circulatory failure and hemodynamic instability:

**ACTIVATE MTP**
BB Doctor on call: XXXXXXX
Blood bank/TMU: XXXXXXXX

**Information required by Blood Bank:**
- Name of senior clinician in charge who activates the MTP
- Patient’s details:
  - Name, I/C or passport and RN
  - Location
  - Cause of bleeding
- Name and contact details of MTP coordinator

**Sample required by laboratories (baseline & monitoring):**
- 10mls EDTA for GXM for every subsequent cycle required
- FBC and coagulation screen (PT, APTT, INR, fibrinogen) to haematology/hemostasis laboratory

**Notes:**
- Each hospital should have local procedure once MTP is activated.
- MTP blood coordinator roles and responsibilities to be defined
- Ensure the follow up of blood and blood components are managed effectively
- Case should be communicated effectively at all levels.

**Definition of massive transfusion:**
1. Transfusion of half of one blood volume in 3 hours, or more than one blood volume in 24 hours (adult blood volume is approximately 70mL/kg).
2. Transfusion of more than 40 mL of blood/kg in a child (blood volume of children older than neonates is approximately 80 mL/kg).

**Availability of blood and blood product for collection:**
- Safe O/group specific uncrossmatched (available onsite/Blood Bank) Immediate
- Urgent crossmatched blood 15 minutes
- Full crossmatched blood 45 minutes
- Fresh Frozen Plasma 30 minutes
- Cryoprecipitate 30 minutes
- Platelets Immediate

**Notify Blood Bank once MTP is stopped**
Steps taken for improvement

- Standardised procedures
  - Introduction on the requirement of second samples prior to transfusion or
  - 2nd Blood grouping
  - 2nd fresh sample for blood grouping prior to release
  - Posters and pamphlets in wards

- Training:
  - Transfusion safety
  - Patient safety

- Housemen training: Module in Blood transfusion
- Transfusion Nurse
- Advanced diploma MLT
- Transfusion Specialist

- Audits
TRANSFUSION NURSE LINK

- Promote safer more efficient use of blood via audit and liaison role
- Increase clinical staff awareness of transfusion via education
- Policy/procedure development and support
- Increase the support for clinical staff, the recipient and their families
<table>
<thead>
<tr>
<th>Location</th>
<th>Critical Point</th>
<th>Healthcare Professional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood donor centre or session</td>
<td>Identification of donor. Assessment of donor for safety of donation Identification of donation</td>
<td>Donation session staff</td>
</tr>
<tr>
<td>Blood centre</td>
<td>Processing and issue</td>
<td>Blood centre laboratory staff</td>
</tr>
<tr>
<td>Ward or outpatient clinic</td>
<td>Assessment of recipient and decision to transfuse</td>
<td>Medical and nursing staff</td>
</tr>
<tr>
<td>Ward</td>
<td>Prescription Request form</td>
<td>Medical staff and nursing staff</td>
</tr>
<tr>
<td>Ward or phlebotomy clinic</td>
<td>Sampling for pretransfusion testing Transfer of sample to laboratory</td>
<td>Doctors, midwives, nurses, phlebotomists Porters</td>
</tr>
<tr>
<td>Laboratory</td>
<td>Reception, testing, allocation of component, labelling and issue</td>
<td>Medical laboratory assistants, Biomedical scientists</td>
</tr>
<tr>
<td>Blood transfusion laboratory or remote blood refrigerator</td>
<td>Collection from storage site</td>
<td>Porters, nursing staff</td>
</tr>
<tr>
<td>Ward, operating theatre, emergency department</td>
<td>Bedside administration checks Monitoring or adverse incidents</td>
<td>Nurses, midwives, doctors, operating department practitioners</td>
</tr>
</tbody>
</table>
GOOD TRANSFUSION PRACTICE

1. Procedure in blood taking and for transfusion
2. Adherence to the protocol
3. Availability of the procedures
4. Patient transfusion records
Clinical decision
Contributory factors are similar in all areas of medical practice where humans are involved.
Slips, lapses, short cuts, distraction, and omission of essential steps leads to errors.
Human factors are widely recognized but how can this be changed.
Removal of manual steps
- Automated analysers
- Electronic system
- Barcode readers
End to end electronic control
Training and education is essential
Thank you