

Haemovigilance in Malta

Dr Stefan Laspina MD FRCPath

Maltese Islands

Population: 413,000



Hospitals

Public:

Mater Dei Hospital (Nov, 2007)

St.Luke's Hospital

Gozo Regional Hospital (8%)

Specialty Hospitals

Private Hospitals

Hospital Blood Banks

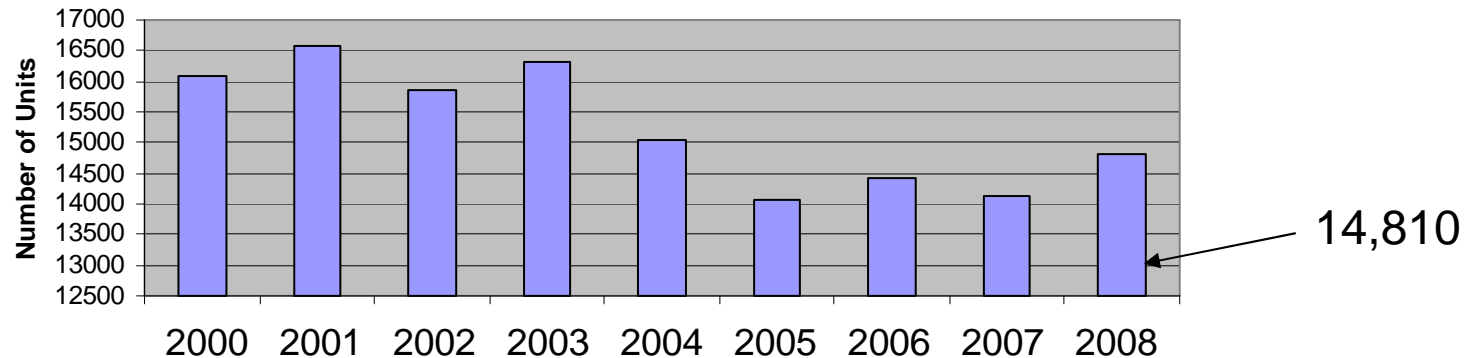
MDHBB: 91%

GGHBB: 6%

Private Hospitals: 3%

Blood Products

Whole blood donations



2007 19,597 Blood Components Issued

2008 19,532 Blood Components Issued

2008

Red Cell Concentrates: 13,989

Platelets: 1,308

FFP: 3,451

Cryoppt: 771



Acute Adverse Effects of Blood Transfusion Form

Patient Details						
ID Card Number						Patient Diagnosis
Patient's Name						
Ward						
Date of Birth	DAY	MONTH	YEAR			
Sex	Male <input type="checkbox"/>		Female <input type="checkbox"/>			
Date of Reaction	DAY	MONTH	YEAR			
Firm/Physician						
Symptomatology						
Were any drugs administered?	Y <input type="checkbox"/> N <input type="checkbox"/> (If Yes specify)					
Febrile Reaction (>1°C Increase)	<input type="checkbox"/>	Temp during event	°C	Temp before event	°C	
Rigors	<input type="checkbox"/>					
Hypotension	<input type="checkbox"/>	BP during event	mmHg	BP before event	mm Hg	
Shock	<input type="checkbox"/>					
Pain at Infusion Site	<input type="checkbox"/>					
Back Pain	<input type="checkbox"/>					
Haemoglobinuria	<input type="checkbox"/>					
Respiratory Symptoms	<input type="checkbox"/>	Describe				
Shortness of Breath/Wheezing	<input type="checkbox"/>					
Hypertension	<input type="checkbox"/>	BP during event	mm Hg	BP before event	mm Hg	
Rash	<input type="checkbox"/>	Describe				
Angio-oedema	<input type="checkbox"/>					
Brief Description of Incident/Comments						
Product Details						
Product Type	RCC <input type="checkbox"/>	Platelets <input type="checkbox"/>	Plasma <input type="checkbox"/>	Cryoprecipitate <input type="checkbox"/>		
Unit Number						
Amount Transfused	mls	<input type="checkbox"/> < ¼	<input type="checkbox"/> < ½	<input type="checkbox"/> < ¾	<input type="checkbox"/> > ¾ (please tick accordingly)	
Time Transfusion Started			Time Reaction Occurred			
Samples Required						
ALL	1 EDTA Sample + Return unit giving adverse reaction to HBB					
Respiratory Symptoms	1 Extra EDTA sample					
Hypotension/Shock/Increase in temperature by >2°	Patient Blood Cultures (To Bacteriology Laboratory)					
Doctor's Signature	Full Name		Registration Number			

PAT/1022/02.0

Data Protection Statement
The personal data on this form is required to provide health care services as necessary. It is processed in accordance with the Data Protection Act, and as permitted by law. Further information about the processing of personal data can be obtained on request.

Education & Training

- Scientists
 - IBMS (UK) accredited course
 - Pathology Department CPD
- Nurses
 - Nursing Officers & Dep. Nursing Officers
 - MUMN
 - Ward Contacts
 - Porter Staff
- Specialty Hospitals
 - Outreach program
- Medics
 - Foundation House Officers
 - Association Meetings

Staffing

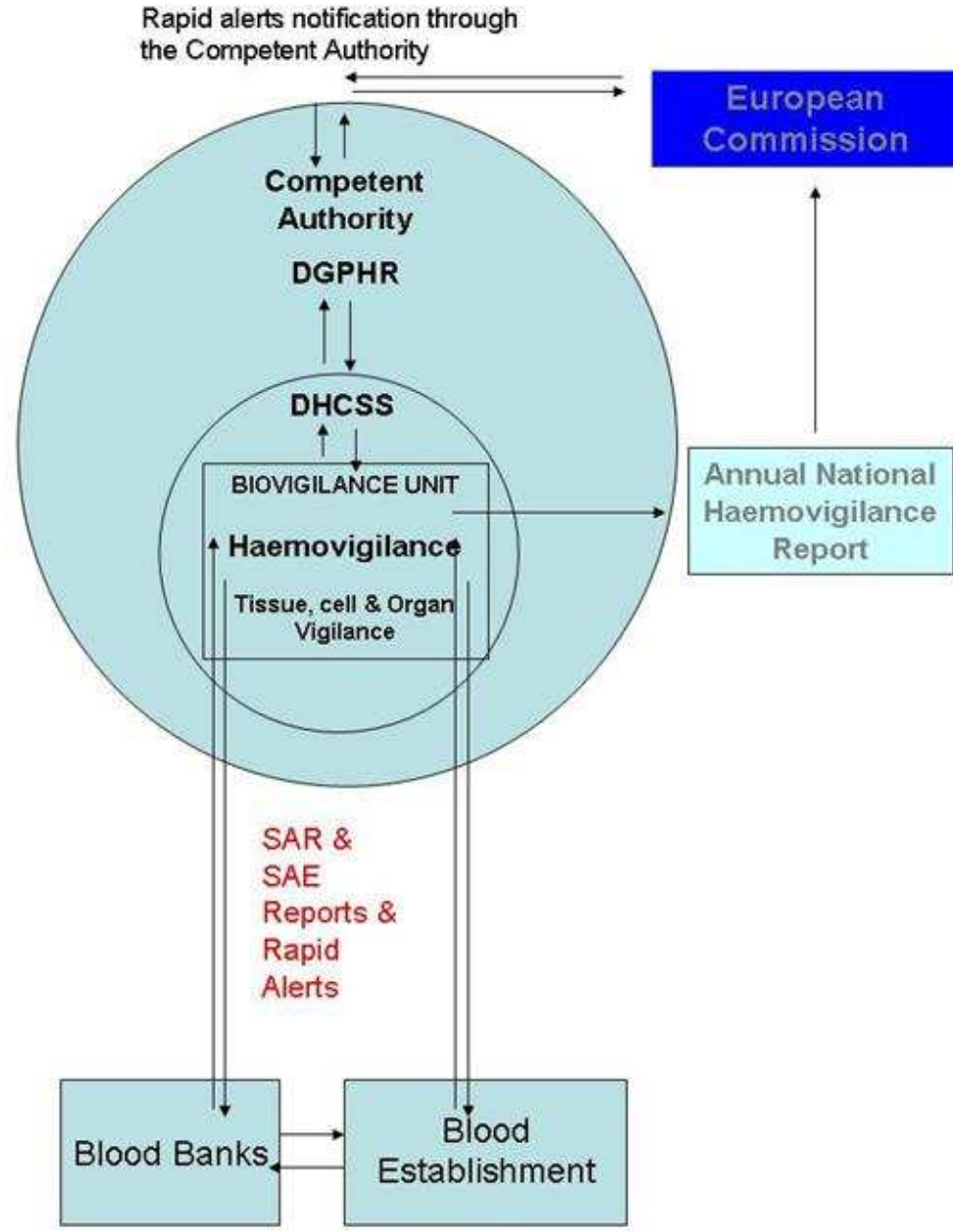
- Nurse
 - Haemovigilance Nurse – DCU (Grant from EHN / IHN) 2008
- Laboratory
 - 2006:
 - Lab Manager (Just been appointed)
 - 2 scientists – attachment with IBTS
 - 10 scientists all on day and night duties
 - 2 Receptionists – day only (no training)
 - 2009:
 - Lab Manager
 - 12 scientists: 8 on d/n duties, 4 on day duties
 - 4 trained Paramedic aides on d/n duties
- Medical
 - Trainee in TM

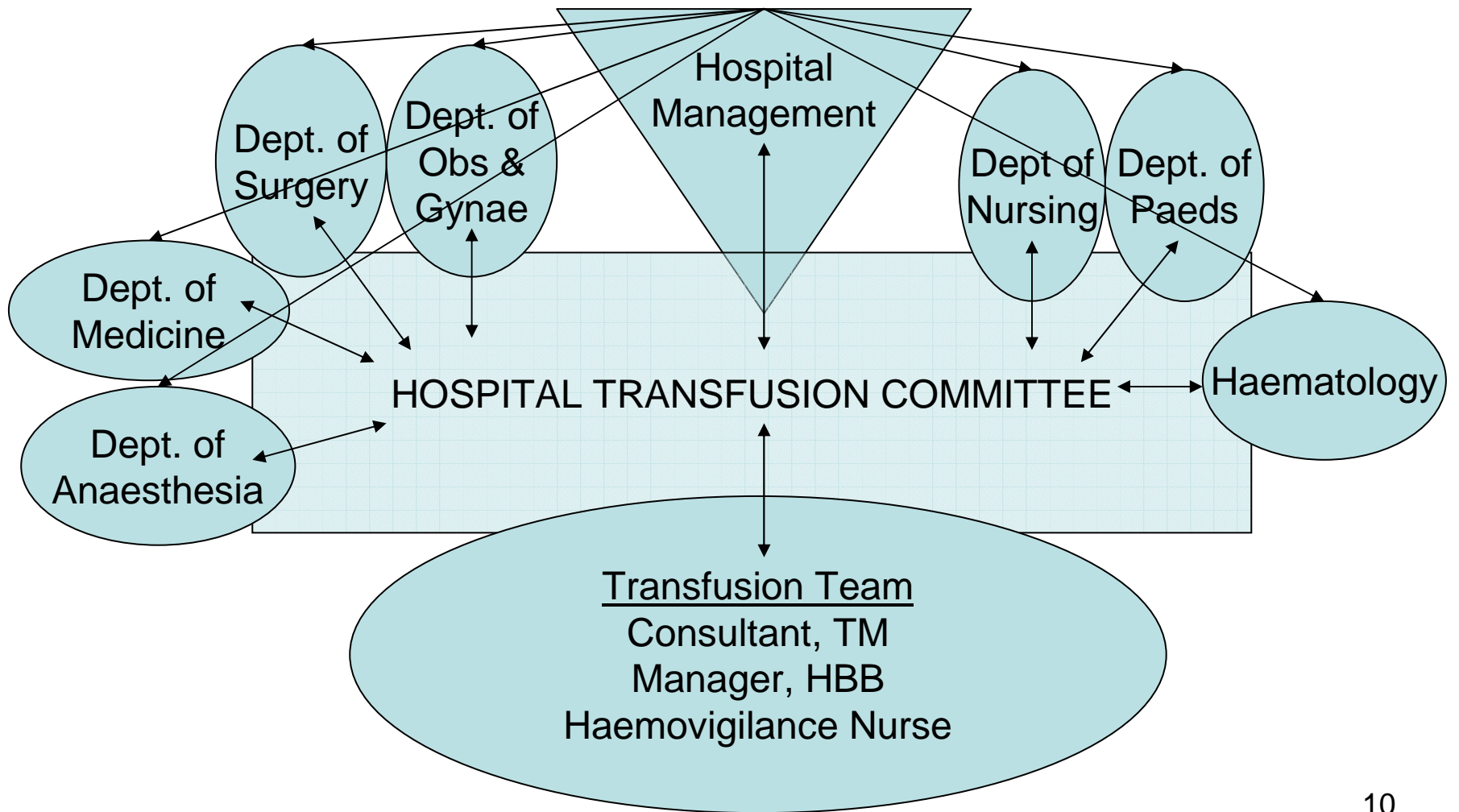
Laboratory

- Premises
- Type & Screen
- 24 hour cover Blood Bank Scientists
- Reference - Red Cell Serology
- Laboratory Information System (March 2009)
- Cold Chain
- Equipment Validation
- Quality & Management Team
- ISO 15189 – IIIrd Quarter 2010

Health Department

- Competent Authority vs Service Provider
- Directorate of Health Care Services Standards
 - Dr Richard Zammit
 - Dr Miriam Vella
- Twinning program with Netherlands on Haemovigilance
 - Jo Wiersum / Lisa Kok
 - Two day Workshop







HAEMOVIGILANCE

**Annual Report
2007
MALTA**

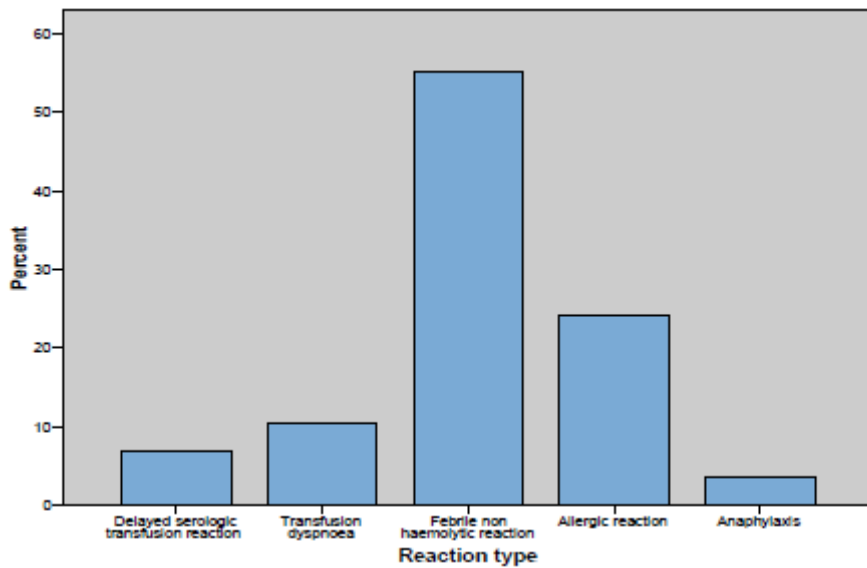


HAEMOVIGILANCE

**Annual Report
2008
MALTA**

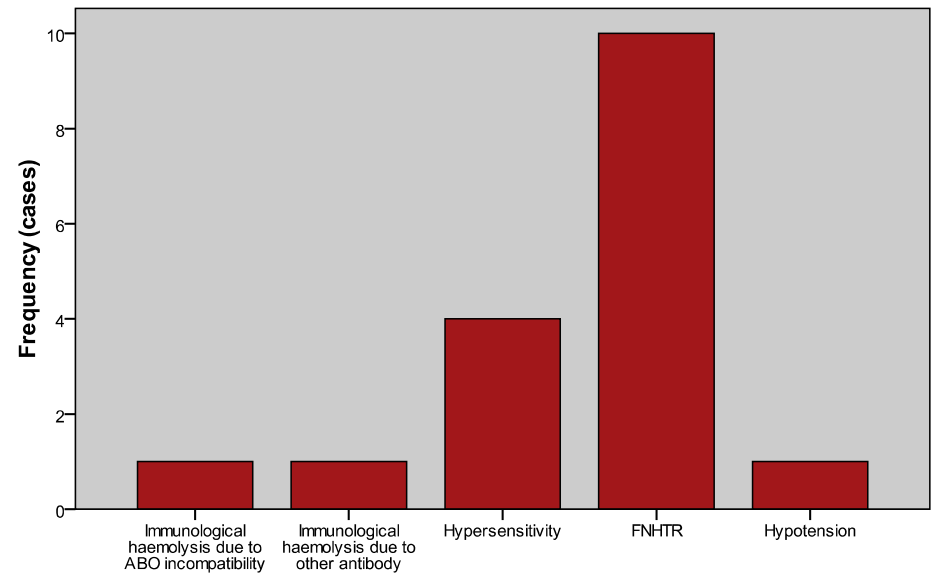


Incidents Reported



2007

N = 29



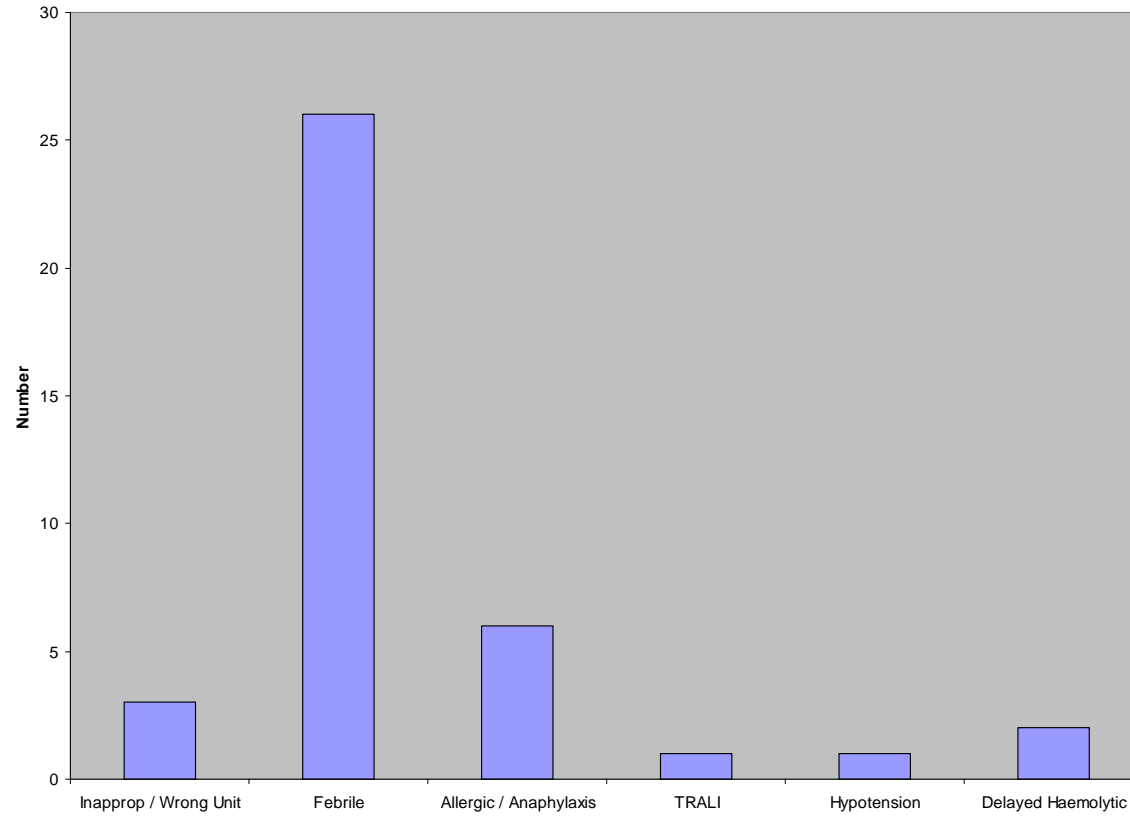
2008

N = 17

Reporting in haemovigilance systems

Country/ region	*Reports/ 1000 units	What is reportable	Type of system
UK	0.20	Serious reactions + IBCT	Voluntary
Canada	0.31	Serious reactions without IBCT	Voluntary
Ireland	1.22	Serious reactions + IBCT	Voluntary
France	2.83	All reactions	Mandatory
Netherlands	2.90	All reactions	Voluntary
Québec	7.07	All reactions	Voluntary
Malta 2007	1.48	All reactions	Voluntary
Malta 2008	0.87	All reactions	Voluntary

Incidents Reported



2009

N = 39 and counting

Near Miss Project (2009)

- 5 cases of wrong labelling on sample bottle
 - Identified through historical data on LIS
 - Mostly Foundation Year Medical Officers
 - All on-call
 - Phlebotomy Service
- Inappropriate product requested
 - Irradiated RCC
- Wrong product issued from lab
 - Scientist vs Paramedic Aide

Traceability

- A4 Receipt
 - Data populated via database
- 80 – 85 % Returns
- 15 - 20% Investigated
- 100% resolution
- Stored on LIS

Hospital Blood Bank – Transfusion Receipt			
Pathology Department			
Mater Dei Hospital – Ext: 6330			
ID Number:	_____	Ward/Dept.:	_____
Surname:	_____	Consultant:	_____
Name:	_____		
Sex:	_____	DOB:	_____

Specimen Number:	_____	Required:	_____
Received:	_____		
Reason for request:	_____		
Specimen Comment:	_____		

Unit Number	Blood Component Transfused? Yes / No	Full Name & Signature	Date & Time Transfused

Donor Events

Number of Whole Blood Donations in 2008 – 14,810

Number of Donor Adverse Events in 2008 – 222 (1.5%)

Haematoma	2
Painful arm	1
Mild Vasovagal	179
Faints	12
Delayed Faints	13
Convulsions	13
Irregular Pulse	2

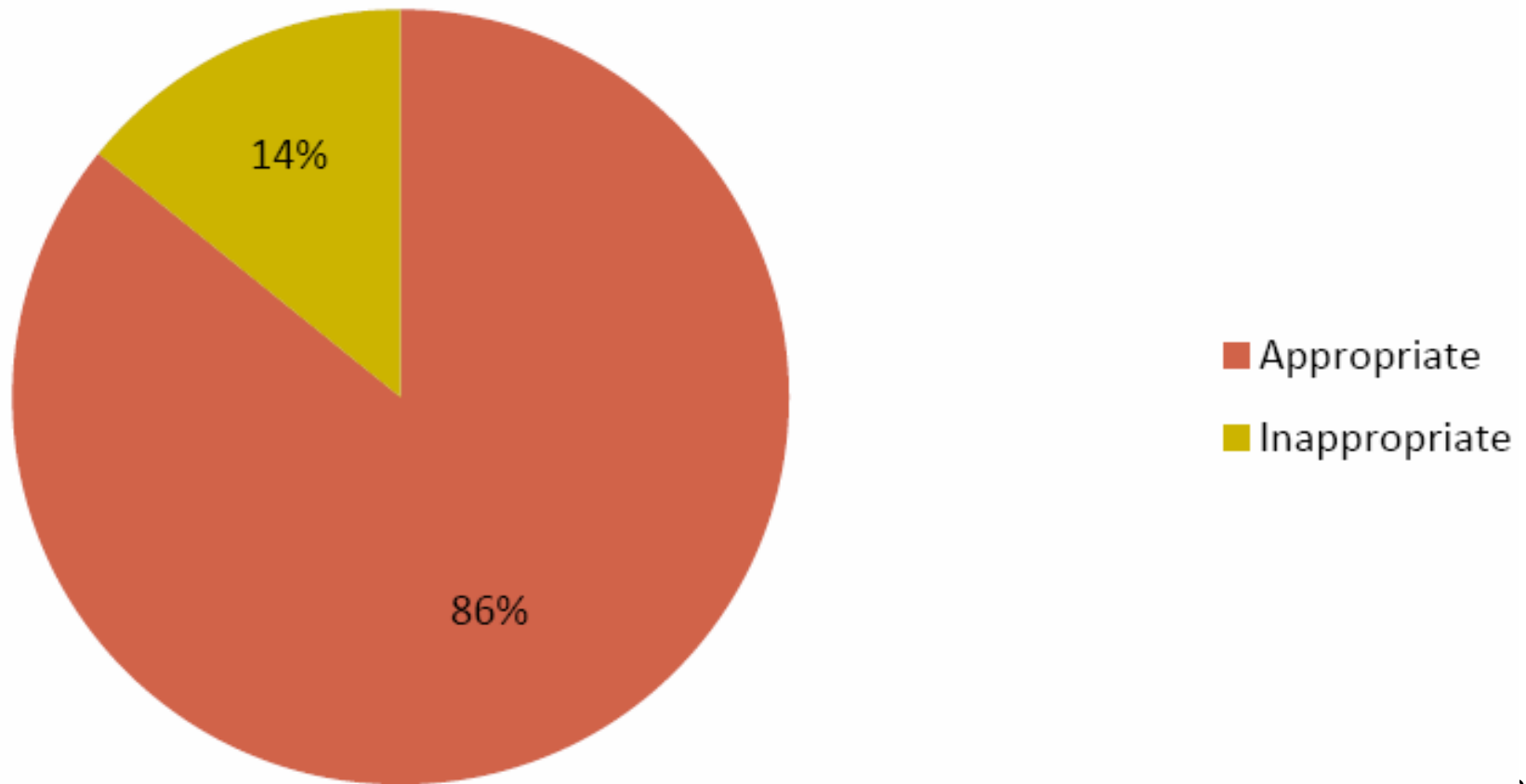
Red Cell Audit

- 400 consecutive requests
- 5 IVth year Med Students
 - Training Session
- Audit form – NI (with kind permission)
- After completion all forms were reviewed by the same person
- 13 requests could not be followed up
- 289 of the 387 requests resulted in a transfusion episode.

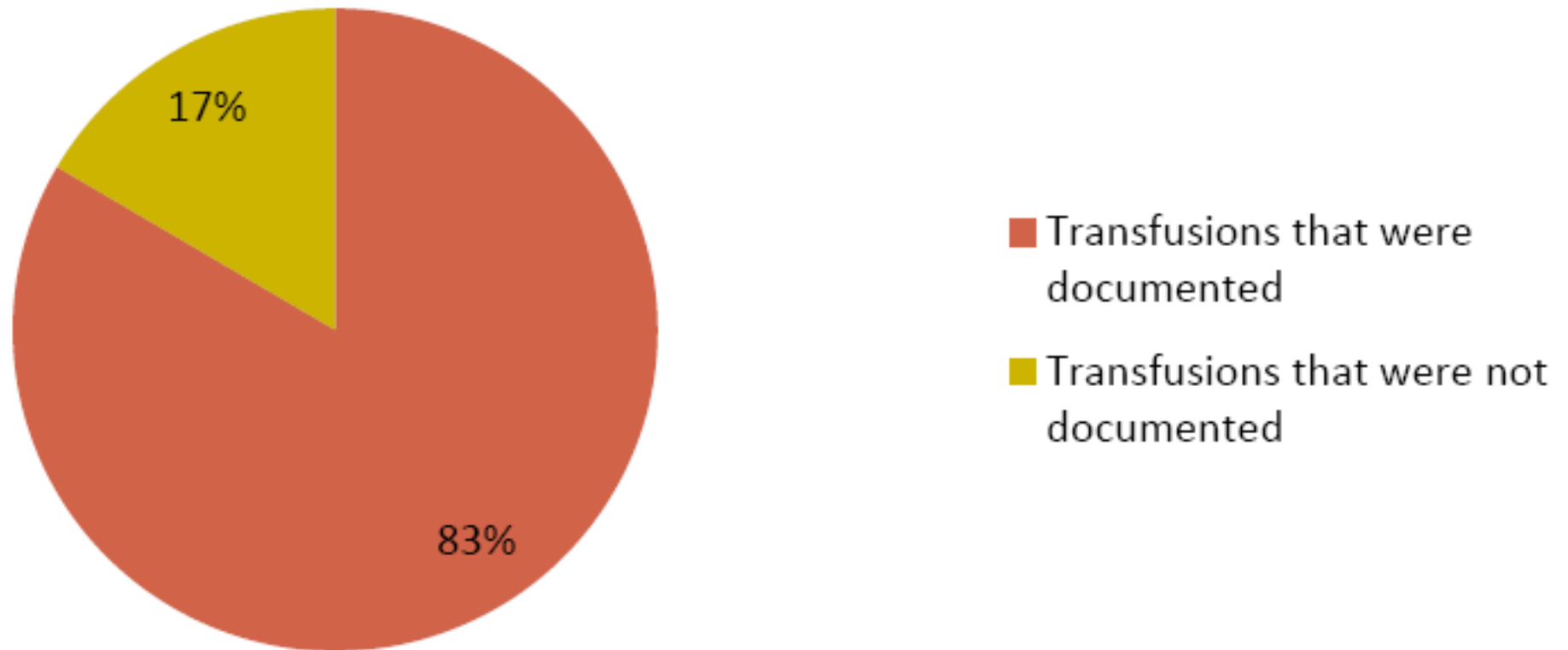
Red Cell Audit

[APPROPRIATENESS OF RED CELL TRANSFUSION] Mater Dei Hospital	[APPROPRIATENESS OF RED CELL TRANSFUSION] Mater Dei Hospital	[APPROPRIATENESS OF RED CELL TRANSFUSION] Mater Dei Hospital
<p>1. PATIENT CODE NUMBER: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/></p> <p><small>THIS NUMBER MUST BE AN INDIVIDUAL IDENTIFIER CODE NUMBER THAT IS GENERATED SO THAT THE CHART CAN BE TRACED AT A LATER DATE IF REQUIRED FOR PEER REVIEW. AT THE CONCLUSION OF THE AUDIT, THE MASTER RECORD WILL BE DESTROYED.</small></p> <p>2. GENDER: <input type="checkbox"/> MALE <input type="checkbox"/> FEMALE</p> <p>3. SPECIALTY: <input type="checkbox"/> SURGERY <input type="checkbox"/> MEDICINE</p> <p>4. PATIENT AGE: _____ YEARS</p> <p>5. REASON FOR ADMISSION: _____</p> <p>6. ADMISSION DATE: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p><small>(IN THE EPISODE IN WHICH THE PATIENT WAS TRANSFUSED)</small> DAY MONTH YEAR</p> <p>7. CO-MORBIDITY (TICK AS NECESSARY):</p> <p><input type="checkbox"/> CARDIAC <input type="checkbox"/> CEREBROVASCULAR <input type="checkbox"/> CURRENT CHEMOTHERAPY <small>(CURRENT OR PAST CARDIAC ISSUE) (CURRENT OR PAST CVA/TIA) (OR TREATMENT IN THE LAST 3 MONTHS)</small></p> <p><input type="checkbox"/> CURRENT RADIOTHERAPY <input type="checkbox"/> CURRENT MARROW FAILURE <input type="checkbox"/> OTHER: _____</p> <p>Pre-Optimisation</p> <p>8. HAEMOGLOBIN ON ADMISSION: <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p><small>(THIS SHOULD BE ONLY THE HAEMOGLOBIN RESULT FROM THE FULL BLOOD COUNT DONE ON THE DAY THE PATIENT WAS ADMITTED TO HOSPITAL, OR THE FIRST HAEMOGLOBIN RESULT DONE IN THE HOSPITAL)</small></p> <p>9. RED CELL MCV ON ADMISSION: <input type="text"/> <input type="text"/> MCV</p> <p><small>(OBTAIN FROM FIRST FULL BLOOD COUNT)</small></p> <p>EVALUATION OF MCV: <input type="checkbox"/> LOW <input type="checkbox"/> NORMAL <input type="checkbox"/> HIGH <small>(ACCORDING TO HOSPITAL REFERENCE RANGE)</small></p> <p>10. IF ANAEMIC ON ADMISSION (MALES <13.0 g/dl; FEMALES <11.5 g/dl) – was the patient on any of the following: <input type="checkbox"/> Iron Therapy <input type="checkbox"/> Folic Acid <input type="checkbox"/> Vitamin B12</p> <p><small>(IN B. ONLY ANSWER THE ABOVE IF THE PATIENT WAS ANAEMIC ON ADMISSION)</small></p> <p>SURGERY:</p> <p>11. DID THE PATIENT HAVE ANY SURGERY DURING THIS HOSPITAL ADMISSION? <input type="checkbox"/> YES <input type="checkbox"/> NO DATE OF SURGERY: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p><small>IF YES PROVIDE A BRIEF DESCRIPTION OF THE SURGERY: _____</small></p> <p>TRANSFUSION EPISODE:</p> <p>12. WHO DECIDED THAT THE PATIENT WAS TO HAVE THE BLOOD TRANSFUSION?</p> <p><input type="checkbox"/> UNKNOWN <input type="checkbox"/> CONSULTANT <input type="checkbox"/> SENIOR REGISTRAR <input type="checkbox"/> REGISTRAR <input type="checkbox"/> SHO <input type="checkbox"/> HOUSE OFFICER</p>	<p>13. DATE OF DOCUMENTED DECISION TO GIVE BLOOD: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p>DAY MONTH YEAR <input type="checkbox"/> NOT DOCUMENTED</p> <p>14. PRE-TRANSFUSION HAEMOGLOBIN: <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p>15. DATE OF ABOVE HAEMOGLOBIN RESULT: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p><small>(DATE OF RESULT TO Q. 14)</small> DAY MONTH YEAR</p> <p>16. WAS THE PATIENT ACTUALLY TRANSFUSED: <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>17. DATE OF TRANSFUSION: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p><small>(ACTUAL DATE THE PATIENT RECEIVED BLOOD)</small> DAY MONTH YEAR</p> <p>18. NUMBER OF DAYS SINCE LAST Hb CHECK: _____ DAYS</p> <p><small>(I.E. CALCULATE THE DIFFERENCE BETWEEN Q. 17 AND Q. 15)</small></p> <p>19. NUMBER OF UNITS TRANSFUSED AT THIS EPISODE: <input type="text"/> UNITS</p> <p><small>(IN B. ALL BLOOD TRANSFUSIONS CARRIED OUT BEFORE THE NEXT HAEMOGLOBIN CHECK, OR WITHIN A 24 HOUR PERIOD AFTER STARTING THE TRANSFUSION, PROVIDED THE HAEMOGLOBIN IS NOT CHECKED, IS TO BE REGARDED AS ONE EPISODE)</small></p> <p>20. PATIENT'S HAEMOGLOBIN AFTER THIS TRANSFUSION: <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p>21. DATE OF THIS HAEMOGLOBIN RESULT: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p>DAY MONTH YEAR</p> <p>22. PATIENT STATUS: <small>(TICK ONE OF THE FOLLOWING)</small> <input type="checkbox"/> DISCHARGED: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p><input type="checkbox"/> STILL INPATIENT <input type="checkbox"/> DEAD <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p>DAY MONTH YEAR</p> <p>23. WAS THE PATIENT FURTHER TRANSFUSED ON A SEPARATE DATE BEFORE DISCHARGE? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>24. TOTAL NUMBER OF UNITS TRANSFUSED DURING THIS HOSPITAL STAY: <input type="text"/> UNITS</p> <p>25. IF INPATIENT: LAST HAEMOGLOBIN BEFORE DISCHARGE: <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p>DATE OF THIS HAEMOGLOBIN RESULT: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p>DAY MONTH YEAR</p> <p>26. IF OUTPATIENT: FIRST AVAILABLE HAEMOGLOBIN POST TRANSFUSION <input type="text"/> <input type="text"/> <input type="text"/> g/dl</p> <p>DATE OF THIS HAEMOGLOBIN RESULT: <input type="text"/> / <input type="text"/> / <input type="text"/></p> <p>DAY MONTH YEAR</p>	<p>27. COMMENTS/DISCREPANCIES NOTED: _____</p> <p>28. TICK THE MOST APPROPRIATE DESCRIPTION OF THIS PATIENT:</p> <p>I. <input type="checkbox"/> THE PATIENT IS <65 AND HAS NO CARDIOVASCULAR/CEREBROVASCULAR PROBLEMS → THE TRANSFUSION THRESHOLD IS BELOW 7 g/dl</p> <p>II. <input type="checkbox"/> THE PATIENT IS >65 AND HAS NO CARDIOVASCULAR/CEREBROVASCULAR PROBLEMS → THE TRANSFUSION THRESHOLD IS BELOW 8 g/dl</p> <p>III. <input type="checkbox"/> THE PATIENT HAS KNOWN CARDIOVASCULAR/CEREBROVASCULAR HISTORY → THE TRANSFUSION THRESHOLD IS BELOW 9 g/dl</p> <p>IV. <input type="checkbox"/> THE PATIENT IS APPROPRIATELY SYMPTOMATIC* → THE TRANSFUSION THRESHOLD IS BELOW 10 g/dl</p> <p><small>(SYMPTOMS SUCH AS DYSPNOEA, ANGINA, PALPITATIONS, TACHYCARDIA, ORTHOSTATIC HYPOTENSION, AND SINCOPY THAT IS DOCUMENTED AND LIKELY TO BE DUE TO ANAEMIA. PATIENTS ALONE IS NOT AN APPROPRIATE SYMPTOM FOR TRANSFUSION)</small></p> <p>V. <input type="checkbox"/> IF THERE IS DOCUMENTED/OBVIOUS EVIDENCE OF ONGOING SIGNIFICANT BLEEDING AT TIME OF TRANSFUSION → THE TRANSFUSION THRESHOLD IS BELOW 10 g/dl</p> <p>VI. <input type="checkbox"/> IF THERE IS CURRENT OR RECENT (WITHIN 3 MONTHS) MARROW FAILURE OR CHEMOTHERAPY OR RADIOTHERAPY → THE TRANSFUSION THRESHOLD IS BELOW 10 g/dl</p> <p>EVALUATION:</p> <p>1. PLEASE INDICATE THE MOST APPROPRIATE DESCRIPTION OF THIS TRANSFUSION EPISODE:</p> <p><input type="checkbox"/> APPROPRIATE TRANSFUSION (TRANSFUSION OCCURRED WHEN HAEMOGLOBIN WAS BELOW THRESHOLD VALUE)</p> <p><input type="checkbox"/> INAPPROPRIATE TRANSFUSION (TRANSFUSION OCCURRED WHEN HAEMOGLOBIN WAS ABOVE THRESHOLD VALUE)</p> <p><input type="checkbox"/> POSSIBLY INAPPROPRIATE TRANSFUSION (ENSURE – FOR REVIEW)</p> <p>2. IN THE ABSENCE OF SIGNIFICANT ACTIVE BLEEDING (>50ml/hour AND NOT STOPPING), WAS THE PATIENT TRANSFUSED MORE THAN 2.0g/dl above their threshold value? <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>3. IF THE PATIENT WAS ADMITTED WITH ANAEMIA, WAS THERE APPROPRIATE IRON, FOLIC ACID, OR VITAMIN B12 THERAPY? (TO EVALUATE THIS LOOK AT THE MCV. IF MCV WAS LOW, THEN THE PATIENT SHOULD BE ON IRON THERAPY. IF MCV WAS HIGH THEN THE PATIENT SHOULD BE ON FOLIC ACID OR VITAMIN B12 THERAPY.) <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> ADMITTED ANAEMIC BUT WITH NORMAL MCV <input type="checkbox"/> NOT APPLICABLE</p> <p>4. IF THE PATIENT WAS IN HOSPITAL FOR MORE THAN 7 DAYS, WERE THEY CONTINUED/COMMENCED ON ANY ORAL OR IV IRON THERAPY IN HOSPITAL PRIOR TO THE TRANSFUSION? <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NOT APPLICABLE</p> <p><small>(TICK ONLY IF TRANSFUSED AFTER 8+ DAYS) (TICK IF TRANSFUSED WITHIN 7 DAYS OF ADMISSION)</small></p>
1	2	3

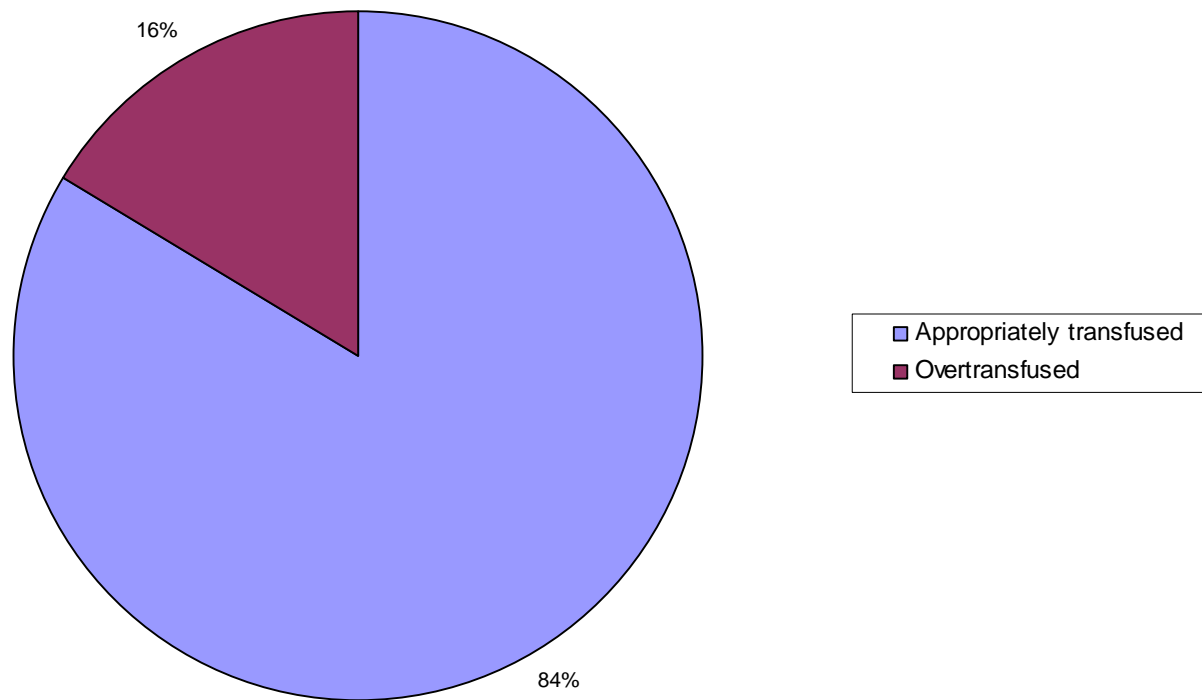
Appropriate vs Inappropriate



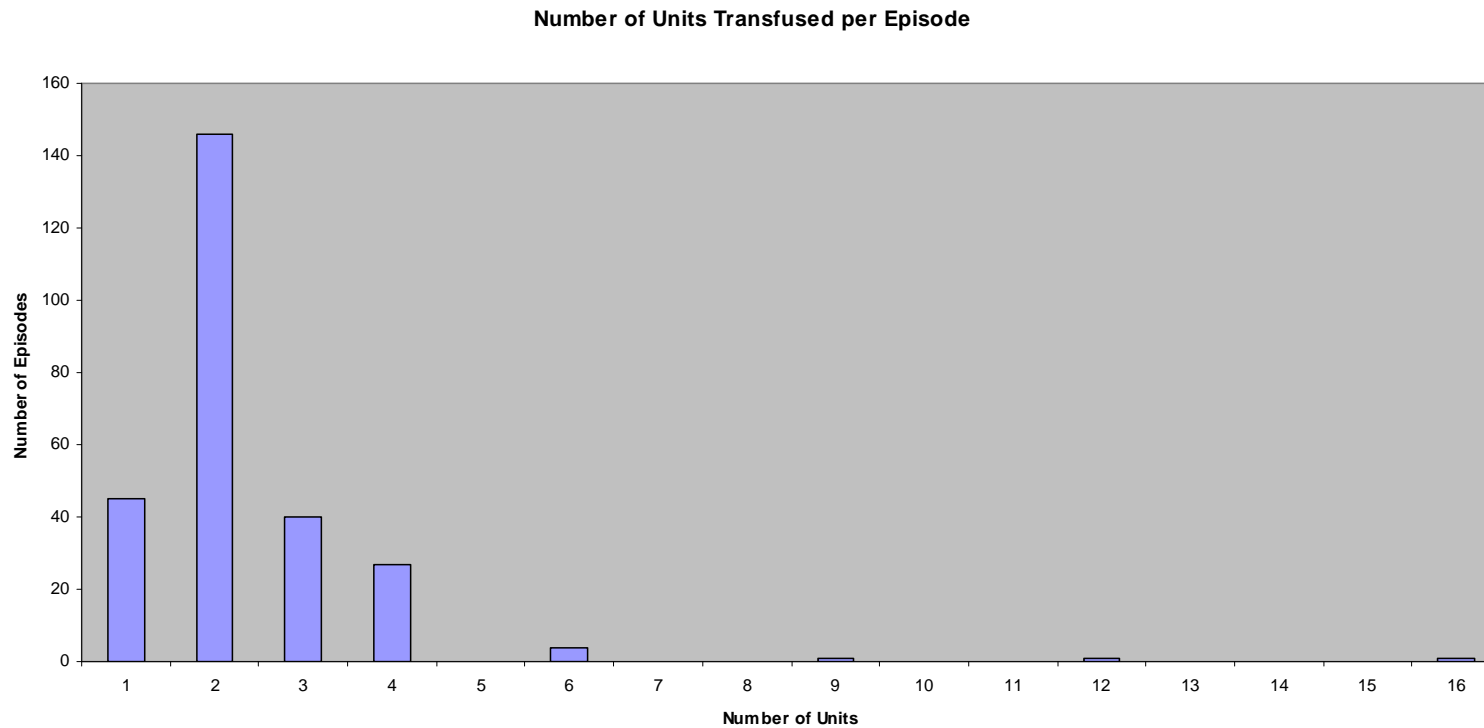
Documentation



Overtransfusion



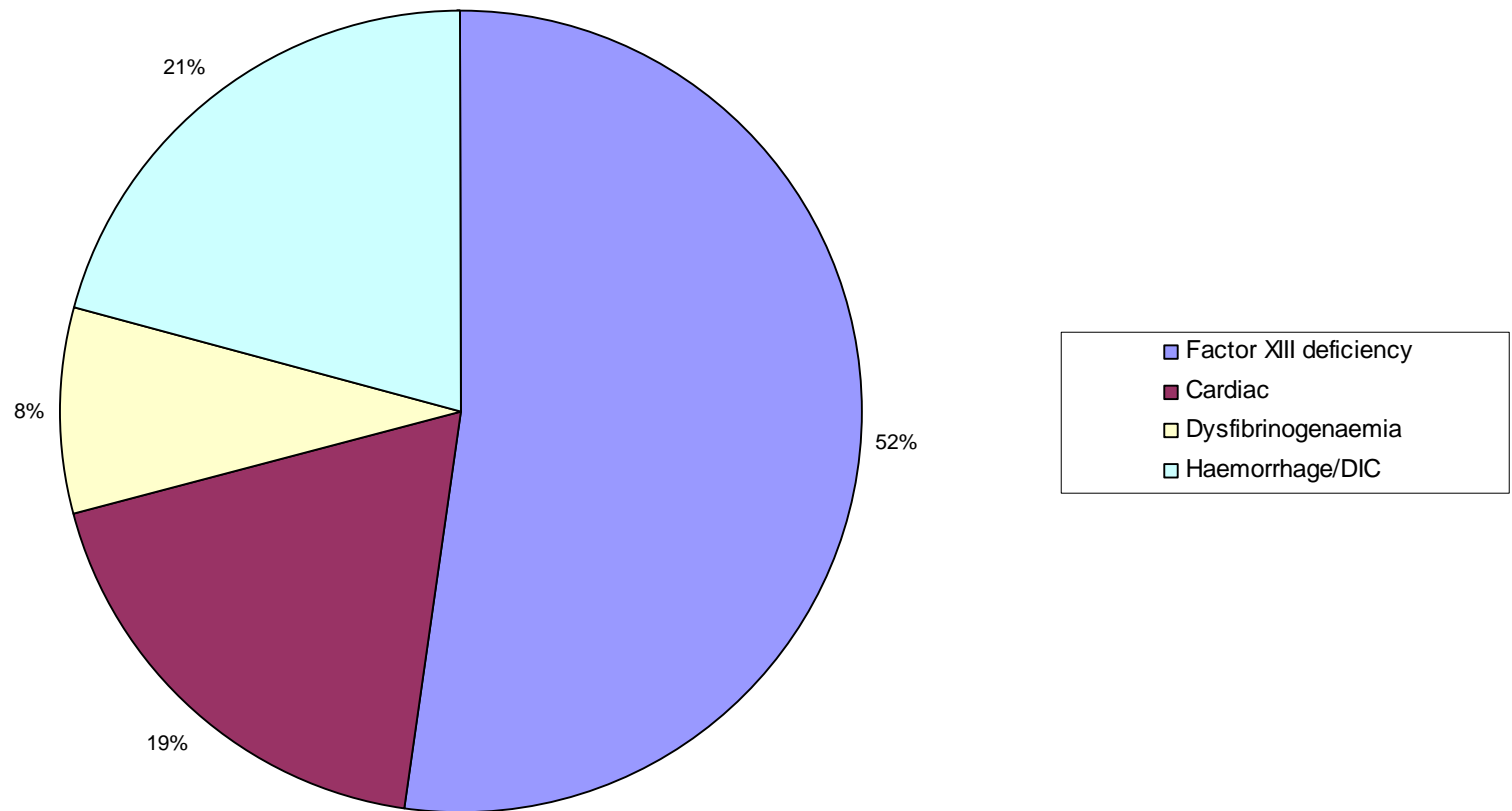
Number of Red Cell Units Transfused per Episode



Cryoprecipitate Audit

- Data collected over a 6 month period
- All cryo units transfused over that period
- Total number of requests: 48
- Total number of single units issued: 319
- ***No Fibrinogen assays were performed***

Reasons for Transfusion



Specific Requests

- Factor XIII Deficiency
 - 3 Families
- Dysfibrinogenaemia
 - 1 Patient
- Cardiac
 - CABG
 - AVR
 - Angioplasty
- Haemorrhage / DIC
 - GI Haemorrhage
 - Abdominal Surgery
 - Vascular (AAA) Surgery
 - Haematology

Future

- Guidelines
 - Mater Dei Hospital
 - Administration of Blood Components
 - Massive Haemorrhage – In preparation
 - Use of Red Cells / Platelets / FFP – Initial stages
- MDH Blood Bank
 - ISO 15189
- Biovigilance Unit
 - On-line reporting
- National Strategy
 - Team
 - Draft policy document

Haemovigilance

- Narrow definition
- Legal Obligations
- How are we helping our patients?

- Blood Use
- What is the real benefit?