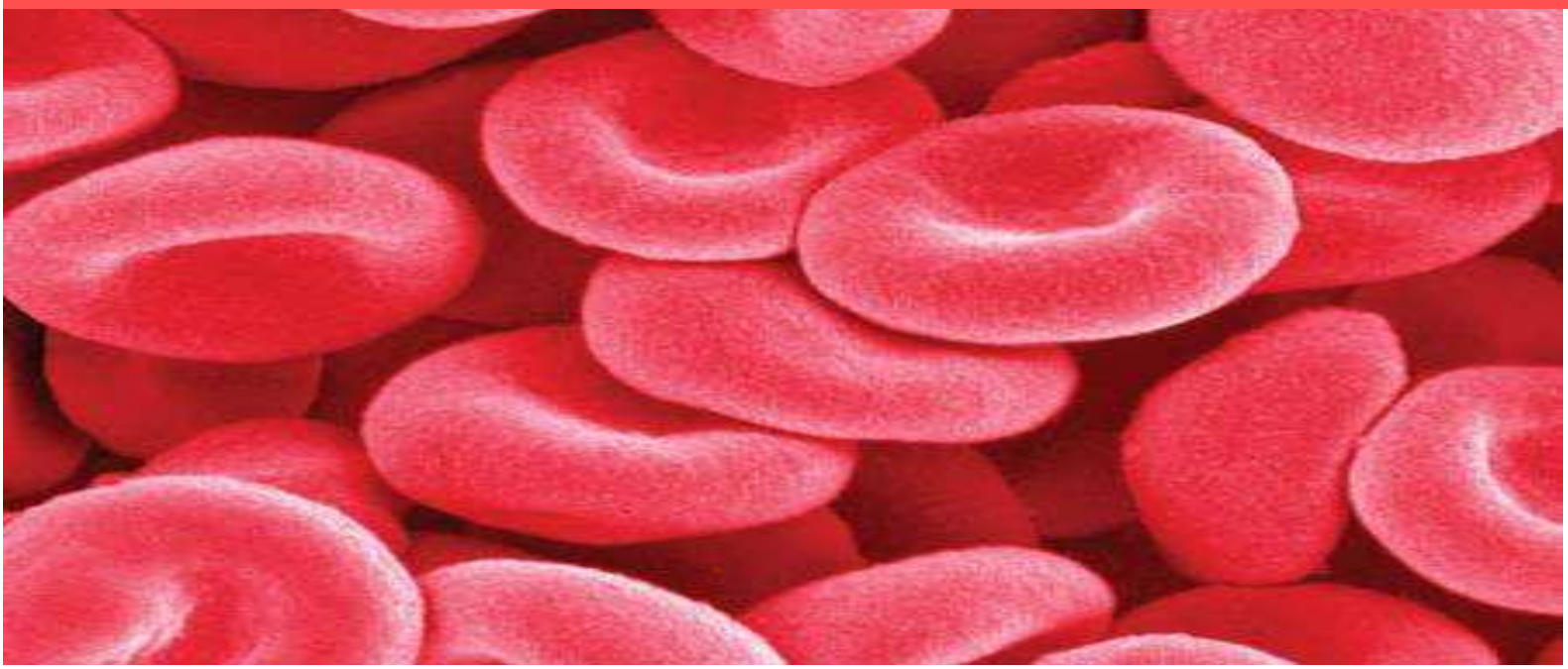
Department of Health Care Services Standards

HAEMOVIGILANCE

Annual Report 2008 MALTA



Contents

CONTENTS

Contents

EXECUTIVE SUMMARY

FOREWORD

It is with a sense of achievement to remark that this is the second national annual report as regards Haemovigilance following the establishment of the National Haemovigilance Unit within my Department for Health Care Services Standards, under the Directorate for Public Health Regulation.

Firstly it needs to be stated clearly that this report confirms again and in a reaffirming manner that blood transfusion in Malta is very safe.

On looking back, 2007 was a year when as a newly setup Department we were busy laying the foundations whilst as evident from the trends illustrated in this 2008 report several important developments in the area of haemovigilance have been instigated during this last year, to set firmly the developmental trajectory in the appropriate direction.

During this year, the National Haemovigilance Unit has been instrumental in re-engineering and streamlining the reporting system for the efficient monitoring of the quality and safety of blood.

The National Haemovigilance reporting system is becoming a learning platform for error reporting including the reporting of near misses. It is hoped that the experience gained in this area can be utilised in other areas of healthcare that affect also patient safety.

It is pertinent again to note the references cited in this report of the numerous networking and collaborative initiatives between Malta and other European countries, an illustrative case being in the licensing process of the National Blood Transfusion Services. This is an exemplary case of the potential proffered by Malta's membership within the European Union being actively exploited.

My thanks again as in the previous year are due to Dr. Miriam Vella who compiled this report and who is responsible for the newly established Haemovigilance Unit within my Department of Health Care Services Standards. This work would not have been possible without the valid contributions by the blood establishment, the blood banks and hospitals and the Medicines Authority and their help in collecting data.

Dr. Richard Zammit

Director Health Care Services Standards

EXECUTIVE SUMMARY

EXECUTIVE SUMMARY

During this year, several important advances were made in the field of haemovigilance in Malta. The national haemovigilance system was re-engineered and new reporting forms were made available in electronic and interactive PDF formats for greater ease of reporting.

These developments occurred in parallel with other developments within healthcare facilities where blood transfusion is being carried out, mainly the development of a Hospital Transfusion Committee within the main state hospital (Mater Dei Hospital), creation of forms for reporting at ward level and activities related to strengthening of the systems that ensure traceability of blood. The national haemovigilance office obtained a grant from the European Haemovigilance Network. The grant was then directed to the service provider and was utilised by Mater Dei Hospital to train a Haemovigilance Nurse.

This is the second annual haemovigilance report to be issued in Malta. This report again confirms that blood transfusion in Malta is very safe. The information collected includes reports on all adverse reactions in blood recipients and donors and all adverse events related to blood transfusion during the year 2008. During 2008, a total of 17 adverse reactions were reported. Most reactions that were reported were febrile non-haemolytic reactions and allergic reactions. There were no cases of transfusion-transmitted infections. There were no deaths related to blood transfusion.

During 2008, a total of 14,810 units of whole blood were collected and a total of 320 aphaeresis collections were performed. A total of 19532 units of blood components were distributed. The rate of transfusion reactions for all the reported reactions was thus 87 reactions per 100, 000 units of blood components distributed. The rate of serious adverse reactions that are reportable to the European Commission is considerably less (10 reactions per 100,000 units of blood components distributed). These figures are comparable with the rate of transfusion reactions during the previous year (2007) where the rate of serious adverse reactions that were reportable to the European Commission was 5 reactions per 100,000 units of blood components distributed and the rate for all the reported reactions was 148 reactions per 100, 000 units of blood components distributed and.

List of Abbreviations

LIST OF ABBREVIATIONS

AHTR	Acute haemolytic transfusion reaction
ALG	Antilymphocyte globulin
ALI	Acute lung injury
ARDS	Acute respiratory distress syndrome
ATR	Acute transfusion reaction
CA	Competent Authority
CMV	Cytomegalovirus
CRP	C-reactive protein
DAT	Direct antiglobulin test
DGPHR	Director General for Public Health Regulation
DHCSS	Director for Health Care Services Standards
DHTR	Delayed haemolytic transfusion reaction
DIC	Disseminated intravascular coagulation
DNA	Deoxyribonucleic acid
DSTR	Delayed Serologic Transfusion Reaction
DTR	Delayed transfusion reaction
ESR	Erythrocyte sedimentation rate
FBC	Full blood count
FFP	Fresh frozen plasma
HAV	Hepatitis A virus
HBc	Hepatitis B core antigen
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HHV-8	Human herpes virus-8
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
Ig	Immunoglobulin
INR	International normalised ratio
LDH	Lactate dehydrogenase
MA	Medicines Authority
NBTS	National Blood Transfusion Service

List of Abbreviations

PC-BC	Buffy coat-derived platelets
PCR	Polymerase chain reaction
PLTaph	Apheresis platelets
PTP	Post-transfusion purpura
RNA	Ribonucleic acid
SAE	Serious adverse event
SAR	Serious adverse reaction
SOB	Shortness of breath
SOP	Standard operating procedure
TACO	Transfusion-associated circulatory overload
TA-GVHD	Transfusion-associated Graft-versus-host disease
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenic purpura
vCJD	Variant Creutzfeldt Jakob disease

INTRODUCTION – BLOOD QUALITY AND SAFETY

The treatment of patients with blood and blood products has become an important issue in quality care medicine. Blood transfusions are often taken place as part of the treatment of a great number of hereditary and acquired diseases, are prescribed by almost all medical specialties, but imply potential dangers like immunological reactions and viral infections.
Safe transfusion practice results from shared responsibility of blood donors, blood centres, hospital transfusion services, attending physicians and regulatory agencies.

A blood supply of high quality requires vigilance of adverse events – haemovigilance. With the Haemovigilance system, all adverse events and incidents involving blood components, covering the whole chain from donor to patient is systematically being monitored. The goal is to analyse the data, discover areas where improvements are necessary and possible, to understand root causes of avoidable events and prevent their recurrence thus improving the safety of transfusion therapy.

All the information provided by haemovigilance may contribute to improving the safety of blood transfusion by:

- providing the medical community with a reliable source of information about untoward effects of blood transfusion.

- indicating corrective measures required to prevent the recurrence of some accidents or dysfunctions in the transfusion process.

- warning hospitals and blood transfusion services about adverse events that could involve more individuals than a single recipient, including:

  - those related to the transmission of infectious diseases;
  - those related to blood bags, solutions or blood processing.

Council of Europe: The "guide"14th edition[1]

[1] Council of Europe. Guide to the preparation, use and quality assurance of blood components - 14th edition (2008)

HAEMOVIGILANCE

Haemovigilance means a set of organized surveillance procedures relating to serious adverse or unexpected events or reactions in
• donors, or
• recipients and
• the epidemiological follow-up of donors

Directive 2002/98 of the European Parliament and of the Council "lays down standards, of quality and safety for the collection and testing of human blood and blood components, whatever their intended purpose, and for their processing, storage and distribution when intended for transfusion so as to ensure a high level of human health protection"

In order to prevent the transmission of diseases by blood and blood components, and to ensure an equivalent level of quality and safety Directive 2002/98 calls for the establishment of specific technical requirements dealing with traceability, a Community procedure for notifying serious adverse reactions and events and the notification format. To this end, Member States shall ensure that a **haemovigilance system** is established to improve the safety of donation and transfusion

The aim of Haemovigilance: The prevention of similar or equivalent events or reactions from occurring thereby, improving the security of transfusion by adequate measures

Commission Directive 2005/61/EC implements Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events

Traceability of Blood Components
Traceability, which is a pre-requisite for haemovigilance may be defined as the ability to trace each individual unit, blood, or blood components derived thereof from the donor to its final destination, whether this is a patient, a manufacturer of medicinal products or disposal, and vice versa. Traceability can provide information on

- The number of patients that have been transfused,
- The number of blood units or components that have been used,
- The number of blood donors that have provided the transfused components.
- The incidence of adverse events/reactions

Traceability
Member States shall take all necessary measures in order to ensure that blood and blood components collected, tested, processed, stored, released and / or distributed on their territory can be traced from donor to recipient and vice versa. Blood establishments shall implement a system for identification of each single blood donation and each single blood unit and components therefore enabling full traceability to the donor, the transfusion and the recipient.

The system must unmistakably identify each unique donation and type of blood component.
Data needed for full traceability shall be kept at least 30 years. (Directive 2002/98/EC, Article 14).

Records of data on traceability

By blood establishments

- Blood establishment identification
- Blood donor identification
- Blood unit identification
- Individual blood component identification
- Date of collection (year/month/day)
- Facilities to which blood units or blood components are distributed, or subsequent disposition

By facilities (hospitals, clinics, manufacturers and biomedical research institutions to which blood or blood components may be delivered):

- Blood component supplier identification
- Issued blood component identification
- Transfused recipient identification
- For blood units not transfused, confirmation of subsequent disposition
- Date of transfusion or disposition (year/month/day)
- Lot of the component, if relevant

Information systems should be available to facilitate rapid traceability

Prerequisites for implementation of a haemovigilance network

- Reporting and analysis of adverse reactions/events requires cooperation between the reporting physician from the clinical department and the transfusionist of the blood bank/blood establishment.
- Standardization of reporting requires an active training policy initiated inside the network(use of common report forms, training programme and agreed definition of the different types of adverse reaction/events)

LEGAL BACKGROUND

European Legislation

The Amsterdam Treaty of 1997 gave the European Union a mandate to pass laws on the quality and safety of blood, human tissues and cells and human organs used in medical treatment (Article 152 of the EC Treaty). The Commission put forward its first legislative proposals in late 2000 and the Blood Directive was passed by the European Parliament and Council in January 2003.

Directive 2002/98/EC[2]

- setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

The purpose of the EU Blood Directive is:
"*To ensure that blood and its components are of comparable quality and safety throughout the blood transfusion chain in all Member States, bearing in mind the freedom of movement of citizens within Community territory."*

Directive 2004/33/EC[3]

- implementing Directive 2002/98/EC…as regards certain technical requirements for blood and blood components

Two further technical Directives were adopted by the European Commission on the 30th September 2005

Directive 2005/61/EC[4] – implementing Directive 2002/98/EC as regards traceability requirements and notification of serious adverse reactions and events.

Directive 2005/62/EC[5] - implementing Directive 2002/98/EC as regards Community standards and specifications relating to a quality system for blood establishments.

Responsibility of Member States
Notification of serious adverse reactions

[2] DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 January 2003. Setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC.
http://www.emea.europa.eu/pdfs/human/pmf/2002-98-EC.pdf
[3] COMMISSION DIRECTIVE 2004/33/EC of 22 March 2004 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components.
http://www.emea.europa.eu/pdfs/human/pmf/2004-33-EC.pdf
[4] COMMISSION DIRECTIVE 2005/61/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards traceability requirements and notification of serious adverse reactions and events.
http://www.emea.europa.eu/pdfs/human/pmf/2005-61-EC.pdf
[5] COMMISSION DIRECTIVE 2005/62/EC of 30 September 2005 implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments.
http://www.emea.europa.eu/pdfs/human/pmf/2005-62-EC.pdf

Legal Background

Member states shall ensure that reporting establishments
(a) Notify to the competent authority all relevant information about serious adverse reactions of imputability level 2 or 3, attributable to the quality and safety of blood and blood components;
(b) Notify the competent authority of any case of transmission of infectious agents by blood and blood components as soon as known;
(c) Describe the actions taken with respect to other implicated blood components that have been distributed for transfusion or for use as plasma for fractionation;
(d) Evaluate suspected serious adverse reactions according to the imputability levels
(e) Complete the serious adverse reaction notification, upon conclusion of the investigation
(f) Submit complete report on serious adverse reactions to the competent authority on an annual basis. ***Directive 2005/61/EC, Article 5***

Notification of serious adverse events

Member States shall ensure that reporting establishments
(a) Evaluate serious adverse events to identify preventable causes within the process
(b) Complete the serious adverse event notification, upon conclusion of the investigation
(c) Submit a complete serious adverse events report to the competent authority on an annual basis ***Directive 2005/61/EC, Article 6***

Maltese Legislation

The **HUMAN BLOOD AND TRANSPLANTS ACT (ACT IV of 2006)**[6] regulating the collection and testing of human blood and blood components and establishing standards of quality and safety for human tissues and cells intended for human transplants was enacted on the 15th September, 2006.

L.N. 272 of 2006 HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006) Blood (Quality and Safety) Regulations, 2006[7]**.**
These regulations implement the requirements of the following EU Directives:
Directive 2002/98/EC
Directive 2004/33/EC

L.N. 273 of 2006, HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006) Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations, 2006[8]**.**
These regulations transpose Directive 2005/61/EC

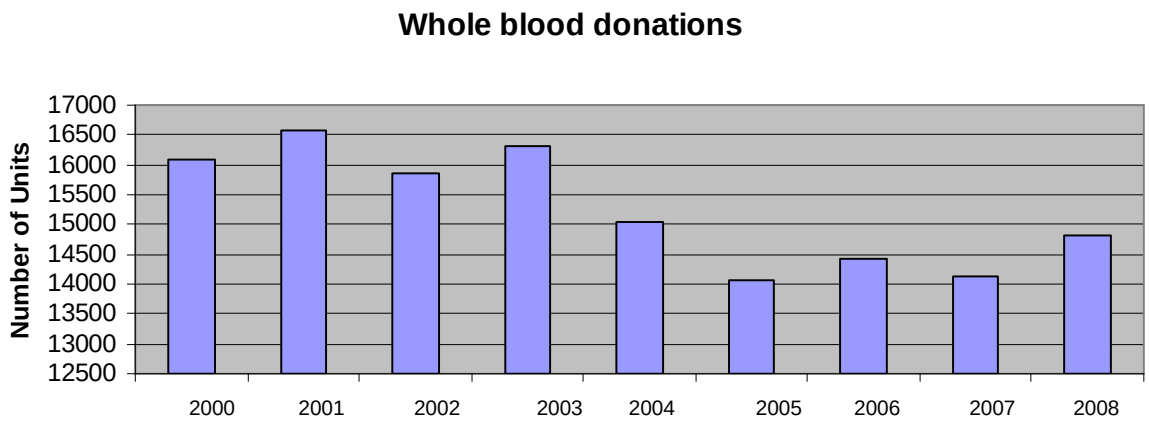
[6] The HUMAN BLOOD AND TRANSPLANTS ACT (ACT IV of 2006). Available online at:: http://docs.justice.gov.mt/lom/Legislation/English/Leg/VOL_15/Chapt483.pdf
[7] L.N. 272 of 2006 HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006) Blood (Quality and Safety) Regulations, 2006. http://www.doi.gov.mt/EN/legalnotices/2006/11/LN272.pdf
[8] L.N. 273 of 2006, HUMAN BLOOD AND TRANSPLANTS ACT, 2006 (ACT NO. IV OF 2006) Traceability Requirements and Notification of Serious Adverse Reactions and Events Regulations, 2006. http://www.doi.gov.mt/EN/legalnotices/2006/11/LN273.pdf

AN OVERVIEW OF BLOOD TRANSFUSION AND TRANSFUSION SERVICES IN MALTA

The Maltese islands have a population of around 404, 962 people[9]. Malta is self sufficient in blood and blood products. The blood products are obtained from voluntary and unpaid donations given by the Maltese. The Malta National Blood Transfusion Service (NBTS) is the sole supplier of blood and blood products and is responsible for provision of blood, blood products and related services to hospitals throughout the country. In addition to this only one central blood establishment (processing unit), there are two fixed collection centres and one mobile unit. The present NBTS is housed in G' Mangia at the footprints of St. Lukes' Hospital. The DHCSS has collaborated with the Malta Medicines Authority and the licensing of this establishment is now in an advanced stage. The inspection was also made possible through collaborative networking with the Irish Medicines Board In addition, the department has engaged in collaborative networking for developing standards and criteria for the inspection of blood establishments through the EUBIS (European Blood Inspection System). A new blood establishment is planned to be built in Attard.

The National Blood Transfusion Service report gives the following statistics[10];
Figure 1 gives the whole activity at the Donation Department including the Mobile Blood Donation Unit and Gozo General Hospital (GGH) for the last 9 years. Blood donation had declined drastically in 2004 and 2005. There is no evident reason for this drop in donor activity. One reason that might have contributed to this drop in activity is the recommendation to defer permanently donors who lived in UK from 1980-1996 in relation to the vCJD risk. Another contributing factor is the reluctance of employers to release employees from work to donate blood. The donation activity is increasing slowly.

Figure 1, below, gives an overview of the actual whole blood donation in the past 9 years:



[9] EUROSTAT
[10] Malta National Blood Transfusion Services Annual Report 2008

Year

Figure 1: Whole blood donations

Processing of Blood Products during 2008

Table 1 below show the amounts of blood products processed during 2008 and 2007 for comparative analysis.

	2007	2008
Whole Blood	13626	14406
Cryoprecipitate	1051	1066
Single Donor Platelets	319	296
Pooled Platelets	761	873
Single Donor Red Cells	1	1
Filtered F.F.P.	7508	6274
Fresh Frozen Plasma	6118	8132

Table 1: Blood products processed during 2008.

The blood was issued to the various hospitals and clinics in the following way.

Product	Gozo General Hospital	Mater Dei Hospital	Private hospitals
Whole blood (leucopoor)	0	13	0
Red blood cells	772	12644	573
Platelets	1	1306	1
Filtered FFP	194	3239	18
Filtered cryoprecipitate	140	631	0
Total units of blood components issued	19532		

Table 2: Issues per hospital during 2008 separated by Product

THE ORGANISATIONAL STRUCTURE FOR HAEMOVIGILANCE

Haemovigilance and the Competent Authority
The *EU Blood Safety Directive* introduces a legal requirement for serious adverse reactions (SAR) and serious adverse events (SAE) occurring within EU Member States to be reported to the relevant *Competent Authority*. The Competent Authority in Malta is the Director General for Public Health Regulation (DGPHR).

The Directorate for Heath Care Services Standards (DHCSS)
The Directorate for Heath Care Services Standards (DHCSS) within the Division of the DGPHR is responsible for ensuring Quality of Care and Patient Safety through regulation. http://www.sahha.gov.mt/pages.aspx?page=973. This department was officially established on the 18th September 2007, with the appointment of the Director. This is a new Department within the Division of the Director General Public Health Regulation. The licensing process which was previously within the remit of the Department of Institutional Health, is now part of the responsibility of DHCSS. The DHCSS is actively involved in establishing the structures and systems that are essential to satisfy the EU legal obligations emergent from the transposition into the Maltese legal framework of the EU Blood and Blood Components Directive as well as the Tissues and Cells Directive. The enforcement obligations under the regulations will be discharged by the DHCSS to monitor compliance with the regulations and in liaising with the Medicines Authority to carry out inspections of blood establishments.

The DHCSS, through the newly established National Haemovigilance Unit within it has taken the lead in the setting up of the haemovigilance system for the reporting and investigation of serious adverse events and reactions according to the specified EU Directives. During 2008, the national haemovigilance system was re-engineered and new reporting forms were made available in electronic and interactive pdf formats for greater ease of reporting. All the forms were uploaded on the Department's website.
It is planned that haemovigilance will be incorporated in a national adverse events reporting system as part of a national patient safety initiative.

The Haemovigilance Unit
The functions of the Haemovigilance unit are:

1. To consolidate the mechanism for the reporting and recording of Serious Adverse Reactions and Events related to blood transfusion.
2. To standardise the existing haemovigilance data and documentation in a way that it is harmonised with EU directive data requirements and to identify which data collection should be mandatory
3. To act as a national body that collects data and statistics on haemovigilance

4. To issue feed back statistics and reports to blood establishments, hospital blood banks, private and government blood banks and facilities where transfusions are performed in order to continuously improve quality and safety of the processes, the blood components and the related services
5. To issue various guidelines including:
   - Guidelines on haemovigilance (haemovigilance handbook)
   - Guidelines on the minimum standards for investigation of transfusion related adverse reactions (checklist of investigations to support the differential diagnosis and assessment of transfusion related adverse reactions).
6. To define rules and time-frames for rapid reporting
7. To promote haemovigilance awareness education nationally, targeting all members within the transfusion chain.
8. To be part of the EU Commission rapid alert system involving all the Competent Authorities of the EU Member States.

Future Tasks of the Haemovigilance Unit

Future tasks of the Haemovigilance Unit will be:

• To continue publishing reports

• To advise on all matters of Haemovigilance and blood safety, reviewing new policies and supporting with the interpretation of Haemovigilance data.

• To consolidate a network of the responsible persons for Haemovigilance of the blood establishment, national blood transfusion services, hospital blood banks, private and public clinics and hospitals. Once established, we shall be able to communicate effectively and provide information and feedback on all issues concerning Haemovigilance more effectively. The Haemovigilance Unit will assist in defining the minimum requirements necessary to address the requirements of Articles 14 and 15 (Traceability and Haemovigilance) of the Blood Directive, in particular in defining areas for addition to ISO 15189 (a standard for medical laboratories to which hospital blood banks are required to be accredited).

The Re-Engineering of the Haemovigilance system during 2008

Before the establishment of the National Haemovigilance Unit, reports on SARs and SAEs were being collected by the Medicines Authority. For an interim period after the Haemovigilance Unit was set up, the Medicines Authority continued collecting the reports which were then forwarded to the newly established Unit (Figure 3). During 2008, this system of reporting was simplified to make it less bureaucratic and more user-friendly and reports started being collected directly by the Haemovigilance Unit. New reporting forms were constructed, with the possibility of online reporting through interactive pdf forms. The electronic forms are available on the Haemovigilance website at: http://www.sahha.gov.mt/pages.aspx?page=974

In the area of Haemovigilance, the year 2008 was marked by the transition from the planning to the implementation phase.

Organisational Structure

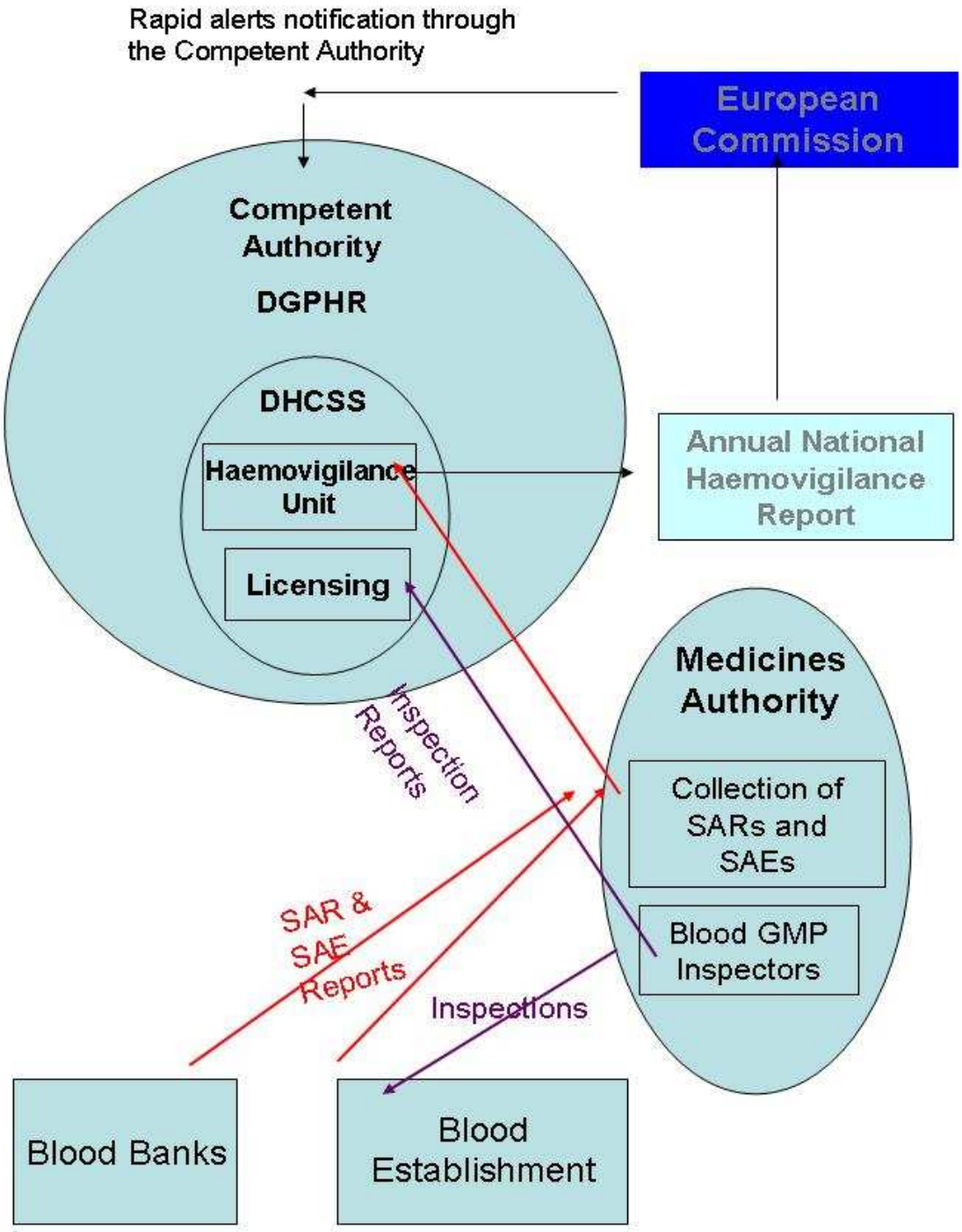


Figure 2 : Previous Organisational structure and Arrangements for reporting of SARs and SAEs

Organisational Structure

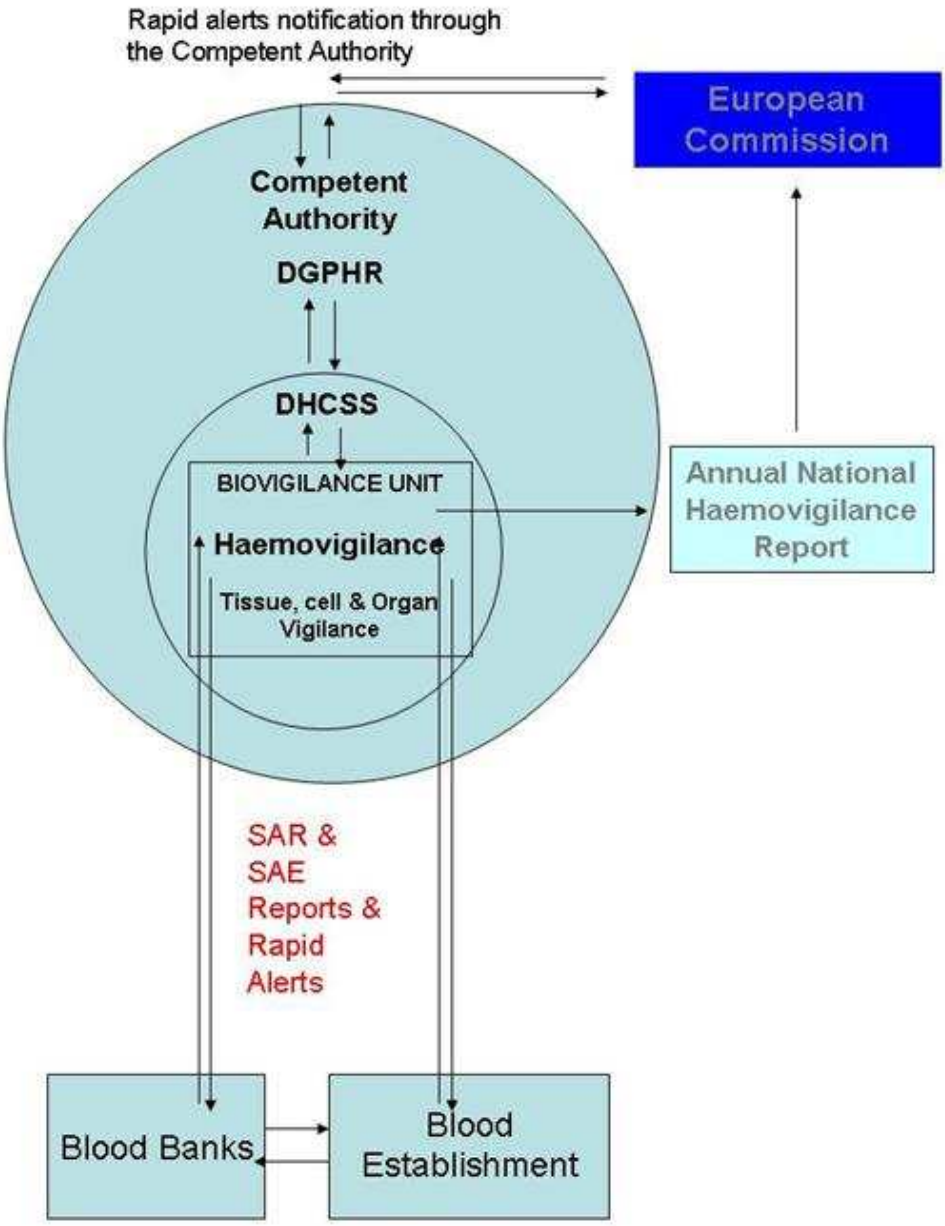


Figure 3 : New Organisational structure and Arrangements for reporting of SARs and SAEs

Serious Adverse Reactions

SERIOUS ADVERSE REACTIONS

Definition
A Serious Adverse Reaction is defined as '*an unintended response in a donor or in a patient that is associated with the collection, or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity*'

Classification of Serious Adverse Reactions
Serious Adverse Reactions can be classified as:
• Immunological haemolysis due to ABO incompatibility
• Immunological haemolysis due to other allo-antibody
• Non-immunological haemolysis
• Transfusion-transmitted bacterial infection
• Anaphylaxis / hypersensitivity
• Transfusion related acute lung injury (TRALI)
• Transfusion-transmitted viral infection (HBV)
• Transfusion-transmitted viral infection (HCV)
• Transfusion-transmitted viral infection (HIV-1/2)
• Transfusion-transmitted viral infection, other (specify)
• Transfusion-transmitted parasitical infection (Malaria)
• Transfusion-transmitted parasitical infection, other (specify)
• Post-transfusion purpura
• Graft-versus host disease
• Other serious reaction(s) – specify (e.g. transfusion associated circulatory overload)

Other serious reactions can include:
• Transfusion Associated Circulatory Overload (TACO)
• Febrile Non Haemolytic Transfusion Reactions (FNHTR): increase >1℃ and > 38℃. Febrile non-haemolytic transfusion reactions are the most common reactions. A reaction should only be classified as FNHTR after other causes have been excluded. Chills and rigors without fever are also classified as FNHTR.
• Allergic Transfusion Reaction: characterised by urticaria over >2/3 body affected or together with other symptoms. If urticaria is the only symptom, it must only be reported if more than two thirds of the body surface are affected. A line is drawn between allergic transfusion reaction and anaphylactic transfusion reactions when severe Hypotension is present in addition to cutaneous symptoms, shortness of breath, wheezing or tachycardia.
• Bacterial contamination
• Incorrect blood product transfused

Serious Adverse Reactions

Imputability Level
"Imputability" means the likelihood that a serious adverse reaction in a recipient can be attributed to the blood or blood component transfused or that a serious adverse reaction in a donor can be attributed to the donation process.

A useful tool[11] for determining the Imputability level is shown below:

Clinical features during/after transfusion		= + 1
Add	Time course appropriate for suspected reaction	= + 1
	Appropriate findings in investigation	= + 1
	Other causes excluded	= + 1
	Demonstration of probable alternative explanation	= - 1

Table 3a: Computation of the score

SCORE	Imputablity level	Definition of Imputablity Level
4	3	Certain
3	2	Probable
2	1	Possible
1	0	Unlikely
Another cause has been conclusively demonstrated	0	Excluded

Table 3b: Conversion of score into Imputablity Level

Tables 3a and 3b: Tool used for determining the Imputability level

The guidelines for the definition and description of the imputability levels are shown in Table 4 below and can be cross-referenced to the imputablity level and the relative definition in Table 3b above:

Imputablity Level	Definition	Description
N/A	Not assessable	When there is insufficient data for imputability assessment.
0	Excluded	When there is conclusive evidence beyond reasonable doubt for attributing the adverse

[11] TRIP (Transfusion Reactions in Patients)

		reaction to causes other than the blood or blood components.
	Unlikely	When the evidence is clearly in favour of attributing the adverse reaction to causes other than the blood or blood components.
1	Possible	When the evidence is indeterminate for attributing the adverse reaction either to the blood or blood component or to alternative causes.
2	Likely / probable	When the evidence is clearly in favour of attributing the adverse reaction to the blood or blood component.
3	Certain	When there is conclusive evidence beyond reasonable doubt for attributing the adverse reaction to the blood or blood component.

Table 4 : Imputability levels for Serious Adverse Reactions

Severity of a Reaction

Assessment of the severity of a reaction is separate from the rating of imputability. The guidelines for the definition of the severity levels are shown in Table 3 below:

Grade	Definition
Grade 0	No morbidity (no symptoms); Applicable when a reaction is detected only through laboratory investigation.
Grade 1	Minor morbidity, not life-threatening.
Grade 2	Moderate to serious morbidity, may or may not be life-threatening; also any case necessitating hospitalisation, where illness and/or hospitalisation is prolonged and/or where chronic invalidity or functional impairment ensues.
Grade 3	Serious morbidity with immediate threat to life.
Grade 4	Death as outcome after a transfusion reaction.

Table 5 : Severity levels for Adverse Reactions

Donor Complications

DONOR COMPLICATIONS

Haemovigilance is a continuous surveillance of all the procedures in the transfusion chain from the blood donor to the recipient of the blood components, in order to improve the safety of both. The intention is to collect and evaluate information on unexpected or undesirable events. The aim is to prevent the risk and/or to reduce the severity. In contrast to the importance of donor blood for the supply of raw material to the production of blood components, haemovigilance was from its beginning in the mid nineties mostly dealing with registration of complications in transfused patients and not so much in blood donors.

In Malta, the NBTS keeps a record of complications related to blood donation. Complications related to blood transfusion are classified according to the International Society of Blood Transfusion and European Haemovigilance Network Guidelines below:

COMPLICATIONS RELATED TO BLOOD DONATION

100 Local Reactions Related to Needle Insertion	
Code	Category
110	Vessel injuries
111	Haematoma
112	Arterial puncture
113	Thrombophlebitis
120	Nerve injuries
121	Injury of a nerve
122	Injury of a nerve by a haematoma
130	Other complications (related to needle insertion)
131	Tendon injury
132	Allergic reaction (local)
133	Infection (local)

Donor Complications

200 General Reactions	
210	Vasovagal reactions
211	Immediate type
212	Delayed type

300 Rare, Important Complications	
310	Related to vessel injury
311	Brachial artery pseudo aneurysm
312	Arterio-venous fistula
313	Compartment syndrome
314	Axillary vein thrombosis
320	Accidents
321	Accidents related to vasovagal syncope
322	Other kinds of accidents
330	Cardiovascular reactions
331	Angina pectoris
332	Myocardial infarct
333	Acute neurological condition (TIA, stroke)
340	Related to apheresis procedures
341	Diffuse allergic reaction
342	Anaphylaxis
343	Haemolysis
344	Air Embolus
350	Death
360	Other

Table 6:: Donor Complications.
(International Society of Blood Transfusion and European Haemovigilance Network Version 2007[12])

[12] ISBT/EHN. Complications related to Blood Donation. Version 2007.
http://www.isbt-web.org/members_only/files/society/DOCO%20Standard%202007%20%20List%20and%20Descriptions%20FINAL.pdf

Serious Adverse Events

SERIOUS ADVERSE EVENTS

Definition:
'any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity.'

Examples of these serious adverse events are failures to detect an infectious agent, errors in ABO typing, wrong labelling of blood components or blood samples.

Reporting requirements
'Blood establishments shall notify… any serious adverse events related to the collection, testing, processing, storage and distribution of blood or blood components by the blood establishment which may have an influence on their quality and safety, and; the person responsible for the management of a hospital blood bank shall notify… any serious adverse events related to the testing, storage and distribution of blood or blood components by the hospital blood bank which may have an influence on their quality and safety.'

NEAR MISSES
Near misses are a subgroup of adverse events, defined as any error which if undetected, could result in determination of a wrong blood group or un-detection of a red cell antibody, or collection, issue or administration of an incorrect, inappropriate or unsuitable component but was recognised before transfusion took place.

UNEVENTFUL TRANSFUSION ERRORS
Uneventful transfusion errors are another sub-group of adverse events defined as any incorrect, inappropriate or unsuitable component transfusion which causes no harm to the recipient.

REPORTING OF EVENTS
Open reporting without fear is a prerequisite for the full functioning of the system for reporting events. The philosophy of an 'open and blame free culture' emphasises the need for healthcare professionals and organisations to explore the underlying reasons for errors within a supportive environment, with the ultimate aim of improving patient care and safety. A punitive blame culture is destructive and counterproductive.

DEFINITIONS OF TRANSFUSION REACTIONS

ACUTE TRANSFUSION REACTIONS

These include reactions occurring at any time up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions due to incorrect component being transfused, haemolytic reactions, transfusion-related acute lung injury (TRALI), transfusion-associated circulatory overload (TACO) or those due to bacterial contamination of the component.

The reportable reactions under this category include:
Isolated febrile reactions – These are defined by a rise in temperature of more than 1^0C with or without minor rigors and chills during or in the first two hours after transfusion.

Minor allergic reactions – In minor allergic reactions, there are skin manifestations or symptoms with or without a rash. These include allergic phenomena such as itching, redness or urticaria but without respiratory, cardiovascular or gastrointestinal features, arising from a few minutes of starting transfusion till a few hours after its completion.

Severe allergic reactions –These are severe allergic reactions with risk to life occurring within 24 hours of transfusion, characterised by bronchospasm causing hypoxia, or angioedema causing respiratory distress.

Anaphylactic/anaphylactoid reactions – They are characterised by hypotension with one or more of: urticaria, rash, dyspnoea, angioedema, stridor, wheeze, pruritus, within 24 hrs of transfusion. These include rapidly developing reactions occurring within a few seconds to soon after the end of transfusion, with features such as inspiratory and expiratory stridor, fall in blood pressure >20mm Hg systolic and/or diastolic, nausea, vomiting or diarrhea, backache, and skin rash.

Hypotension – a drop in systolic and/or diastolic pressure of >30mm Hg occurring within one hour of completing transfusion, provided all other adverse reactions have been excluded together with underlying conditions that could explain hypotension.

Febrile reactions with other symptoms/signs – in these, there is a rise in temperature of more than 1^0C, with no features of an allergic reaction, but with one or more of myalgia, nausea, change in blood pressure or hypoxia.

ACUTE HAEMOLYTIC TRANSFUSION REACTIONS

Acute Haemolytic Transfusion Reactions are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion; confirmed by a fall in haemoglobin (Hb), rise in lactate dehydrogenase (LDH), positive Direct anti-globulin test (DAT) and positive cross-match.

Definitions of Transfusion Reactions

DELAYED HAEMOLYTIC TRANSFUSION REACTIONS

These are symptoms/signs of increased destruction of red blood cells occurring any time from 24 hours to 28 days after a transfusion: confirmed by one or more of: a fall in Hb or failure of increment, rise in bilirubin, positive DAT and positive cross-match not detectable pre-transfusion.

Simple serological reactions (development of antibody without positive DAT or evidence of haemolysis) are excluded. If new antibodies are found without biochemical confirmation of haemolysis, these are reported as “new allo-antibodies”.

TRALI

There are symptoms/signs of acute lung injury such as dyspnoea and hypoxia, occurring within 6 hours of transfusion, with bilateral fine patchy shadowing on chest X-ray.

TRANSFUSION-ASSOCIATED CIRCULATORY OVERLOAD (TACO)

This is defined by:

Any 4 of the following occurring within 6 hours of transfusion:

- Acute respiratory distress
- Tachycardia
- Increased blood pressure
- Acute or worsening pulmonary oedema
- Evidence of positive fluid balance
- Chest X-ray would be consistent with TACO

INCORRECT BLOOD COMPONENT TRANSFUSED

This would include all reported episodes where a patient was transfused with a blood component or plasma product that did not meet the appropriate requirements or that was intended for another patient.

This category currently includes:

- ‘Wrong blood’ events where a patient received a blood component intended for a different patient, or of an incorrect group, including components of an incorrect group given to BMT/SCT or solid organ transplant patients.
- Transfusion of blood of inappropriate specification or that did not meet the patient’s special requirements.
- Inappropriate or unnecessary transfusions.
- ‘Unsafe’ transfusion where there were handling or storage errors.

Definitions of Transfusion Reactions

DEVELOPMENT OF NEW ANTIBODY AGAINST BLOOD CELL ANTIGENS

These reactions are characterised by the demonstration of clinically significant antibodies against blood cells (irregular antibodies, HLA antibodies or HPA antibodies) after a transfusion, which were previously absent.

POST TRANSFUSION BACTERAEMIA/SEPSIS

Clinical features of bacteraemia/sepsis during, soon after or a longer time after a transfusion, with a relevant positive blood culture in the patient and sometimes with confirmation of a causal link with a transfused blood component.

POST TRANSFUSION VIRAL INFECTION

Any viral infection which can be related to a transfused blood component, with typing of the virus and demonstration of identical strains in the recipient and the donor or (related) blood component and with no other likely source of infection.

POST TRANSFUSION PURURA

Serious self-limiting thrombocytopaenia possibly with bleeding manifestations 1-24 days after transfusion of a red cell or platelet concentrate. Thrombocytopenia arising 5-12 days following transfusion of red cells associated with the presence in the patient of allo-antibodies directed against the HPA (Human Platelet Antigen) system.

TRANSFUSION-ASSOCIATED GRAFT VERSUS HOST DISEASE

- Characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days after transfusion. The condition is due to engraftment and clonal expansion of viable donor lymphocytes in a susceptible host.
- All cases where diagnosis is supported by skin/bone marrow biopsy appearance or confirmed by the identification of donor-derived cells, chromosomes or DNA in the patient’s blood and/or affected tissues.
- Cases with very high index of clinical suspicion.

STATISTICS- REPORTS OF ADVERSE REACTIONS AND EVENTS RELATED TO BLOOD TRANSFUSION FOR 2008

COVERAGE OF HAEMOVIGILANCE DATA IN THIS REPORT

This report is the first Maltese Annual National Haemovigilance Report. The report gives nation-wide coverage of adverse reactions and events related to blood transfusion. Reports are received by the National Haemovigilance Office. Reports on serious adverse reactions and events were received by the haemovigilance unit within the Directorate for Health Care Services Standards. These forms can be downloaded from the Department of Health Care Services Standards' website at:
http://www.sahha.gov.mt/pages.aspx?page=974
Neither the patient nor the donor is identifiable; however, the person who is reporting is identifiable, so that further information can be obtained if necessary. Any data that can lead to the identification of the donor, the patient, the blood bank, hospital or clinic is removed.
The statistics used in this report are based on the reports of all adverse reactions and events that threaten the recipient's health status and quality of life, regardless of their level of severity or the extent of harm actually caused (if any). Haemovigilance cannot be restricted only to serious adverse reactions and to those serious adverse events related to the quality and safety of the transfused blood products, as imposed by the EU Directives 2002/98/EC and 2005/61/EC (and also recommended by the relevant Guide of the Council of Europe). The reporting goes beyond the EU requirements in respect of its inclusion of errors and mistakes in the clinical area.
All levels of imputability are included i.e.: 1, 2 and 3 (possible, likely and certain, respectively), including reports of reactions with Imputability defined as unlikely or un-assessable.
The reports that were included were reports on all the reactions and events that were reported to the Competent Authority between the 1st January 2008 and the 31st January 2008. One of the reports was related to a reaction that had occurred late in December 2007 but was reported in January 2008.

Definitions

Common definitions used comply with the definitions of serious adverse reactions and serious adverse events and classifications of EU Directives 2002/98/EC and 2005/61/EC as well as the Council of Europe's "Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components" (European Committee (Partial Agreement) on Blood Transfusion, 14th edition, EDQM 2008).[13]

[13] "Guide to the Preparation, Use and Quality Assurance of Blood and Blood Components" (European Committee (Partial Agreement) on Blood Transfusion, 14th edition, EDQM 2008).

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

ISBT/EHN definitions were used for donor complications and for transfusion reactions, and the SHOT's definition was used for "incorrect blood component transfused".
Classification of adverse reactions was performed using the proposed standard definitions published by the International Society of Blood Transfusion (ISBT) 2006. Where no such definitions were available, the definitions published by SHOT were used.

During 2008, 17 blood safety reports were registered by the National Haemovigilance Office. The reports were reports on all the adverse reactions (most of which were febrile non-haemolytic transfusion reactions and allergic reactions). The total number of blood components distributed during the year 2008 is shown in table 7:

Component	**Number of Units Distributed**	
	2007	2008
Whole blood	0	13
Red blood cells	13560	13989
Platelets	994	1308
Fresh frozen plasma	3970	3451
Cryoprecipitate	1073	771
Total	19597	19532

Table 7: Units of blood components distributed by the blood establishment during 2008 (last column) compared with those distributed during 2007.

Transfusion Reactions Reported to the National Haemovigilance Office during 2008	
Type of Reaction	Number of Cases Reported
Acute haemolytic transfusion reaction	2
Delayed Haemolytic transfusion reaction	0
Delayed Serologic Transfusion reaction	0
Febrile Non Haemolytic Transfusion Reaction	10
Allergic Reaction	4
Anaphylactic Reaction	0
TRALI	0
Graft versus Host Disease	0
Transfusion transmitted Bacterial Infection	0
Transfusion transmitted Viral Infection	0
Transfusion Associated Circulatory Overload	0
Incorrect blood component transfused	0
Other reactions Transfusion-associated hypotension	1
TOTAL	17

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

Table 8: Transfusion Reactions Reported to the National Haemovigilance Office during 2008

Types of Transfusion Reactions

During the year 1 January to 31 December 2008, 17 adverse reactions were reported. The table below shows the number of reactions categorised by type of reaction and the number of reactions expressed as a percentage of the total reactions reported.

Reaction type	Number of Cases Reported	Percentage
Immunological haemolysis due to ABO incompatibility	1	5.9
Immunological haemolysis due to other allo-antibody	1	5.9
Hypersensitivity	4	23.5
Febrile non-haemolytic transfusion reaction (FNHTR)	10	58.8
Hypotension	1	5.9
Total	17	100

Table 9 : Types of Transfusion Reactions Reported to the National Haemovigilance Office during 2008 and percentage of each type as a proportion of the total reactions reported.

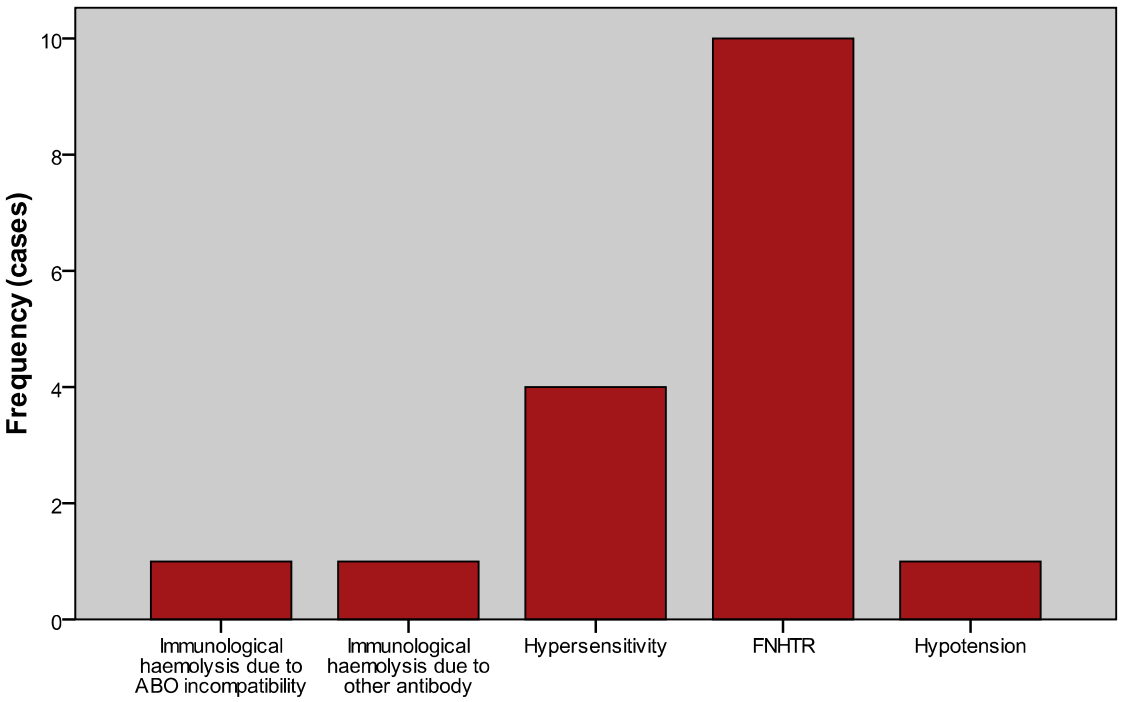


Figure 4: Types of Transfusion Reactions Reported to the National Haemovigilance Office during 2008 and number of cases

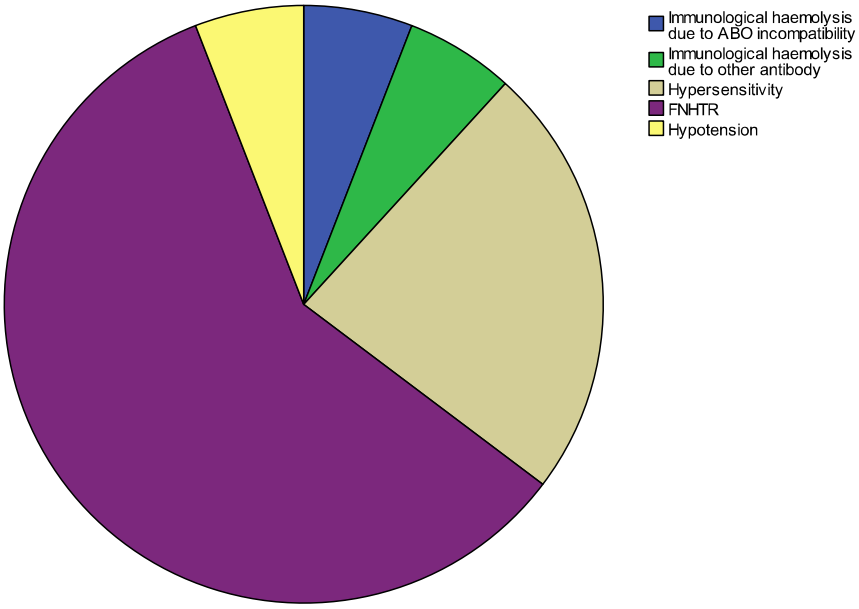


Figure 5 : Types of Transfusion Reactions Reported to the National Haemovigilance Office during 2008 and percentage of each type out of the total reactions reported.

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

Transfusion Reactions by Gender

The reported transfusion reactions occurred in the following gender distribution:

Gender	Number of Cases Reported	Percentage
Males	7	41
Females	10	59
Total	17	100

Table 10 : Distribution of adverse reactions according to gender

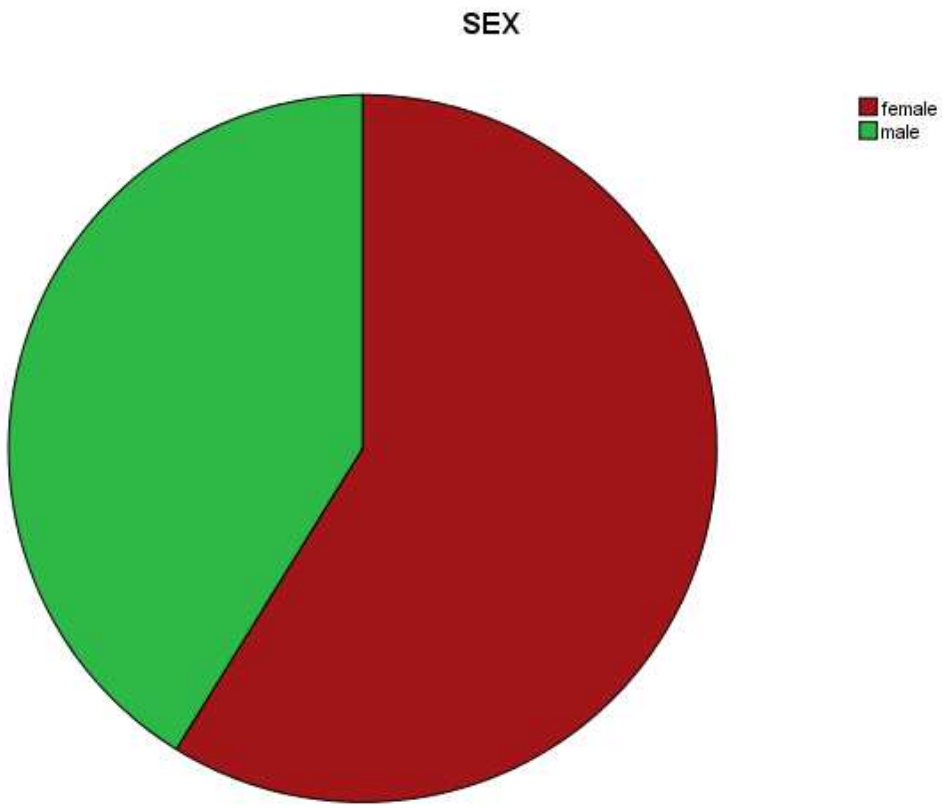


Figure 6 : Distribution of adverse reactions according to gender

Fifty nine percent (59%) of the reported reactions occurred in females.

Transfusion reactions by Age Group

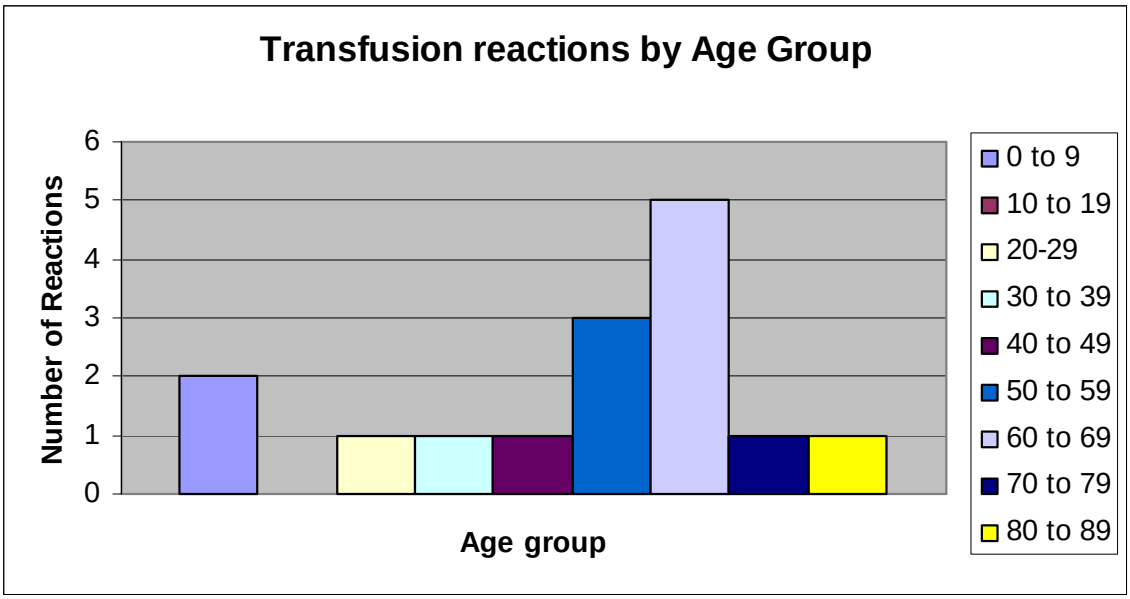


Figure 7: Frequency of adverse reactions related to blood transfusion according to age group

The age distribution of the recipients is weighted towards the older end of the spectrum, with a mean of 54.2 years. This probably is a reflection of the age profile of patients receiving blood products.

Minimum	Maximum	Mean	Standard deviation
0.13	82	54.2	25.4

Table 11 : Minimum, maximum and mean age of patients suffering from transfusion reactions

Distribution of Blood Components Causing Transfusion Reaction

All the reported reactions were caused by red blood cells.

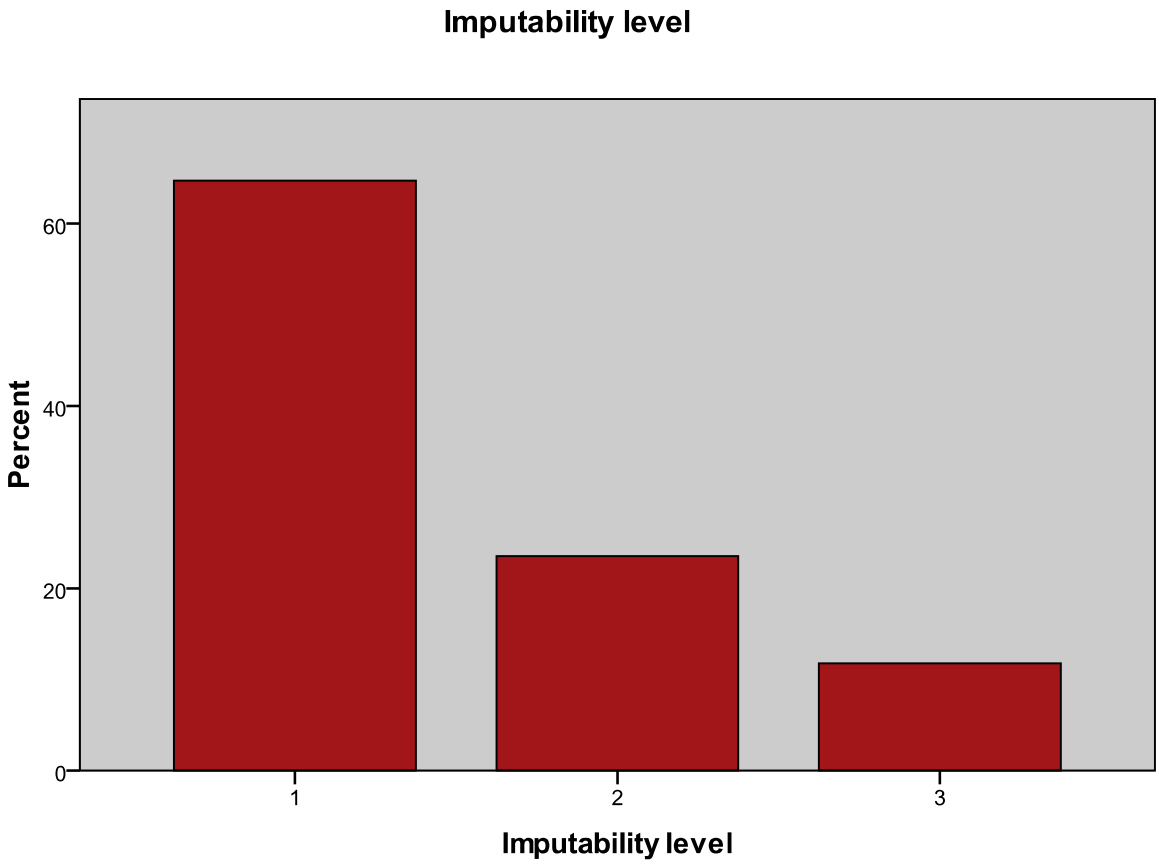


Figure 8 : Imputability levels of the reported adverse reactions

INDIVIDUAL TYPES OF TRANSFUSION REACTIONS

FEBRILE NON-HAEMOLYTIC TRANSFUSION REACTIONS (FNHTR)

Febrile Non-Haemolytic Transfusion Reactions have been the most frequent adverse reactions that have been reported. Out of a reported total of 10 cases, 5 were men and 5 were women. All the 10 febrile non-haemolytic reactions were caused by red blood cells.

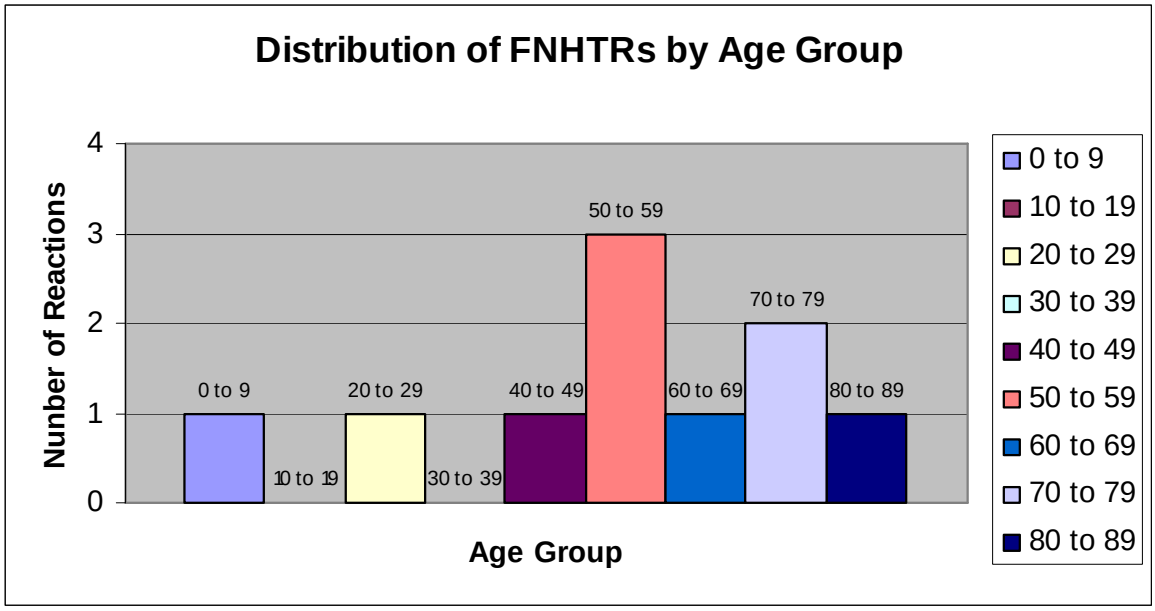


Figure 9 : Distribution of FNHTRs by age

ALLERGIC REACTIONS

Definition
Allergic reactions are categorised according to the nature and severity of the symptoms observed in the recipient as:

- Allergic reactions

These are characterised by one or more of the following: rash, allergic dyspnoea (stridor, cyanosis, wheezing), angioedema, generalised pruritis or urticaria, without hypotension during or within 24 hours of transfusion.

- Anaphylactoid / Anaphylactic reactions

These are allergic reactions with hypotension (drop in systolic blood pressure by ≥ 30 mm Hg) during or within 24 hours of transfusion.

Allergic reactions are the second most numerous category of events after NHFTR, accounting for 4 out of 17 (23.5%) of all reported reactions compared to 27% during 2007.

TRANSFUSION TRANSMITTED INFECTION (TTI)

As in previous years there were no instances of bacterial, viral or parasitic infections have been reported.

OTHER REACTIONS

REACTION TYPE AND NUMBER OF REACTIONS	BLOOD PRODUCT	Number of cases	IMPUTABILITY
Transfusion associated hypotension 1 cases	Red cell concentrate	1	2
Allergic reaction 4 cases	Red cell concentrate Red cell concentrate	3 1	2 1

Table 12: Other serious adverse reactions: Transfusion product, number of reactions caused by a particular blood component and imputability.

No cases of TRALI, TACO, post-transfusion purpura or graft versus host reactions have been reported.

The Timing Blood Transfusion and of Observed Reactions

The majority of blood transfusions (77%) were started between 8am and 8pm. Only 18% of transfusions were started after 8pm. It is generally a good practice to start blood transfusion during the day when reactions are observed more easily. Such practice of initiating transfusions when reactions can be observed more easily can serve as a mitigating factor.

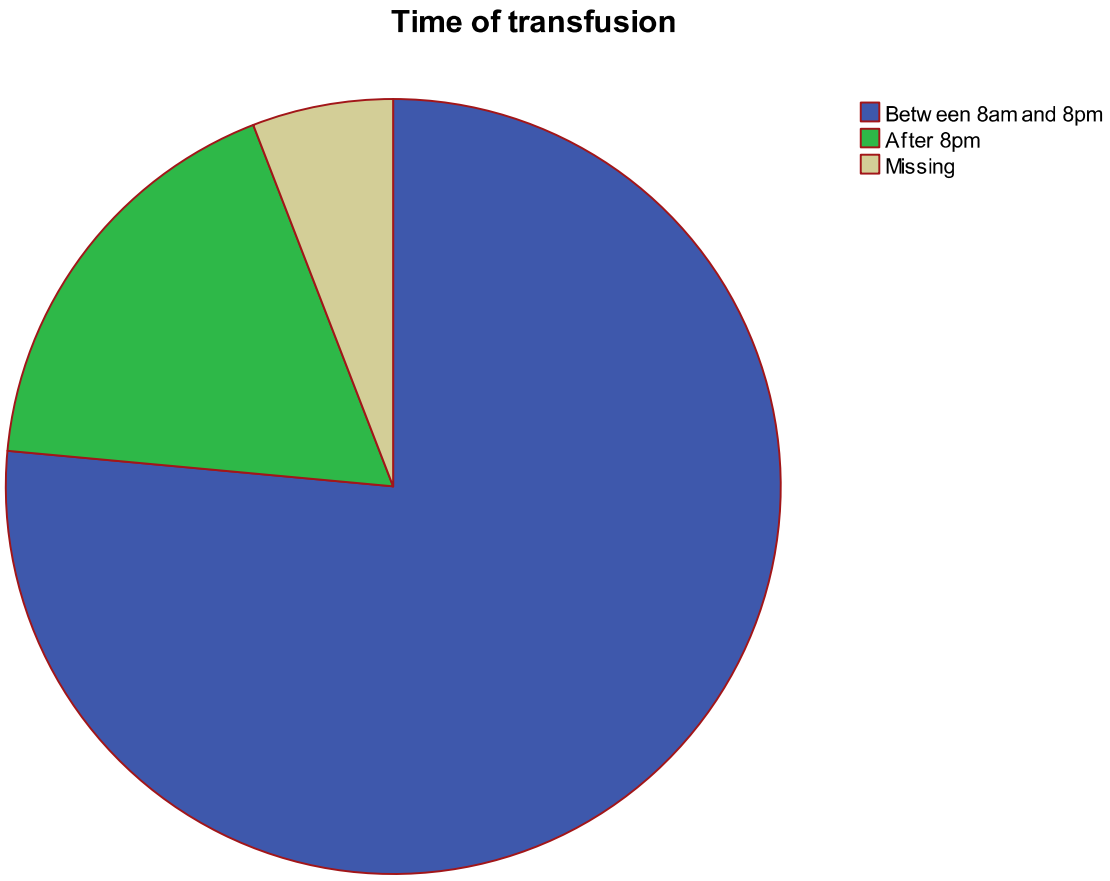


Figure 10: Time transfusion was started

The Timing of Reactions

Most reactions (65%) occurred during the day (between 8am and 8pm). The remaining occurred during the night. The shortest time of development of a reaction after starting a blood transfusion was 3 minutes, the longest time for development of a reaction was 8 hours, with a mean start of transfusion- to reaction time of 122 minutes. This emphasises the importance of nursing monitoring during transfusion.

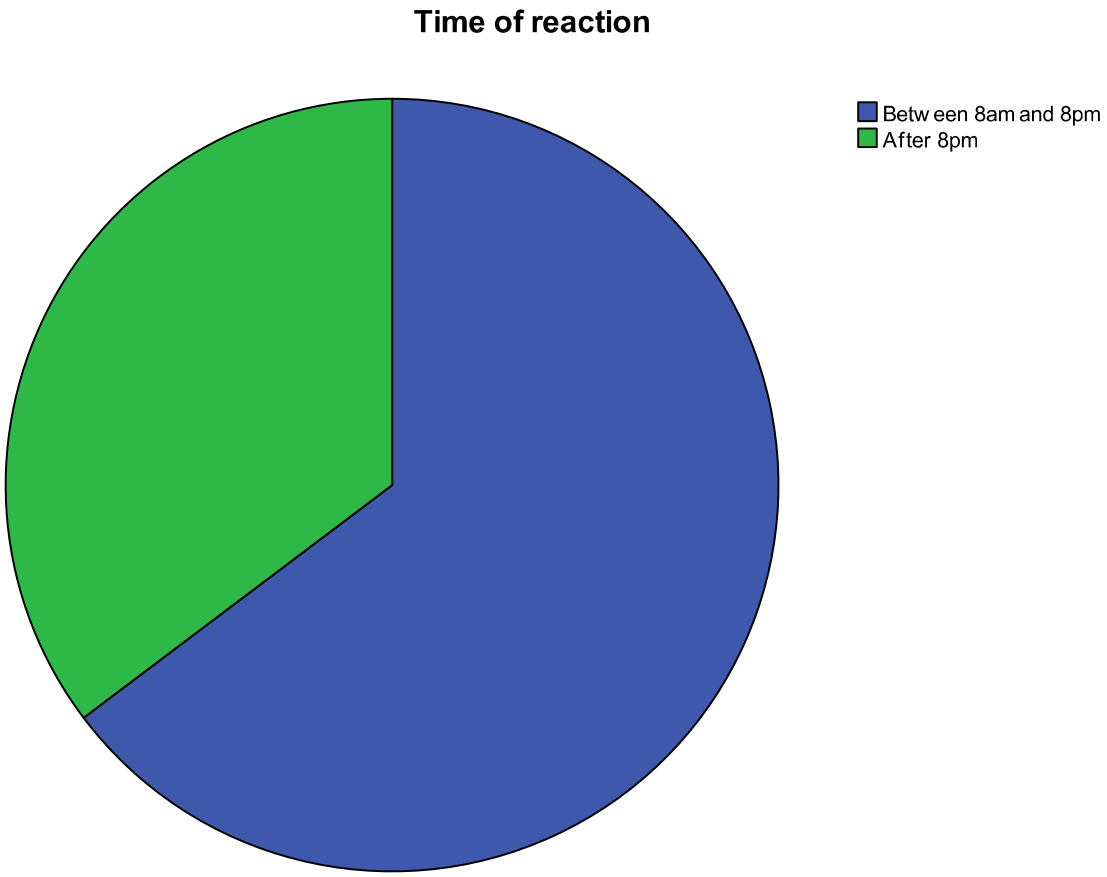


Figure 11: Time at which Reaction was noted

Amount of blood transfused when reaction was noted

In 52.9% of cases less than ½ of the unit had been transfused when the reaction was noted.

Amount of blood transfused	Number of cases	Percentage of cases
Less than ¼ unit	4	23.5
Less than ½ unit	5	29.4
Less than ¾ unit	3	17.6
More than ¾ unit	3	17.6
Missing information	2	11.8

Table 13: Amount of blood transfused at the time reaction was noted

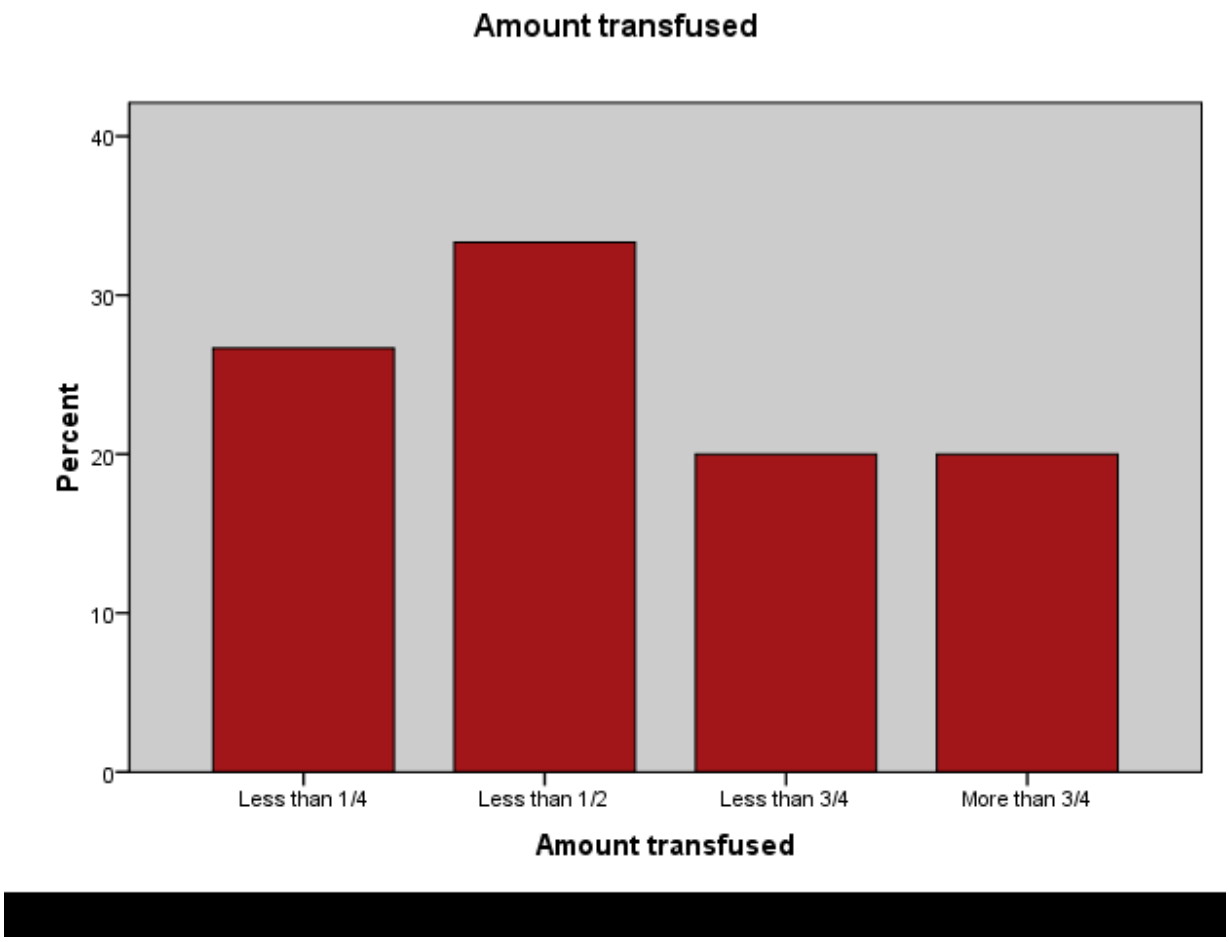


Figure 12: Amount of blood transfused (in units) when the reaction was noted

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

SERIOUS ADVERSE REACTIONS AND EVENTS NOTIFIABLE TO THE EUROPEAN COMMISSION

The following tables contain information on the serious adverse reactions and serious adverse events (grade 2 or higher) that are reportable to the European Commission as provided ion Directives 2002/98/EC and 2005/61/EC.

Annual notification format for serious adverse reactions

Reporting period – 1st JANUARY 2008 – 31st DECEMBER 2008

(Date of discovering the reaction)

This Table refers to **Red blood cells**	Number of units issued (total number of units issued with a given number of blood components) **13989 UNITS DISTRIBUTED**
	Number of recipients transfused (total number of recipients transfused with a given number of blood components) Not available
	Number of units transfused (the total number of blood components (units) transfused over the reporting period) Not available

2	Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)
0	Number of deaths	

			Not assessable	Level 0	Level 1		Level 2		Level 3	
					1a*	1b*	2a*	2b*	3a*	3b*
Immunological Haemolysis	Due to ABO incompatibility	Total	0	0	0	0	0	0	**1**	0
		Deaths	0	0	0	0	0	0	0	0
	Due to other allo-antibody	Total	0	0	0	0	0	0	0	**1**
		Deaths	0	0	0	0	0	0	0	0
Non-immunological haemolysis		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted bacterial infection		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

Anaphylaxis/ Hypersensitivity		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion related acute lung injury		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted viral Infection	HBV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HCV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HIV-1/2	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted parasitical infection	Malaria	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Post-transfusion purpura		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Graft versus host disease		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Other serious reactions (specify)		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0

*a Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component

*b Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component. SARs linked to SAE at the BE/HBB are captured under “b” classification systematically, as being due to “quality and safety of blood component”.

Table 14: Serious adverse reactions related to transfusion of red blood cells

This Table refers to **Platelets**	Number of units issued (total number of units issued with a given number of blood components) **119 UNITS APHARAESIS PLATELETS DISTRIBUTED** **1189 UNITS POOLED PLATELETS DISTRIBUTED** **TOTAL – 1308 UNITS PLATELETS DISTRIBUTED**

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

		Number of recipients transfused (total number of recipients transfused with a given number of blood components) Not available								
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) Not available								
0		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)							
0		Number of deaths								
			Not assessable	Level 0	Level 1		Level 2		Level 3	
					1a*	1b*	2a*	2b*	3a*	3b*
Immunological Haemolysis	Due to ABO incompatibility	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Due to other allo-antibody	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Non-immunological haemolysis		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted bacterial infection		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Anaphylaxis/ Hypersensitivity		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion related acute lung injury		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted viral Infection	HBV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HCV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HIV-1/2	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted parasitical	Malaria	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other	Total	0	0	0	0	0	0	0	0

infection	(specify)	Deaths	0	0	0	0	0	0	0	0
Post-transfusion purpura		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Graft versus host disease		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Other serious reactions (specify)		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0

*a Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component
*b Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component. SARs linked to SAE at the BE/HBB are captured under “b” classification systematically, as being due to “quality and safety of blood component”.

Table 15: Serious adverse reactions related to transfusion of platelets.

This Table refers to **Plasma**		Number of units issued (total number of units issued with a given number of blood components) **3451 UNITS FILTERED FFP DISTRIBUTED**							
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) Not available							
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) Not available							
0		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)						
0		Number of deaths							
			Not assessable	Level 0	Level 1		Level 2		Level 3	
					1a*	1b*	2a*	2b*	3a*	3b*
Immunological Haemolysis	Due to ABO incompatibility	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Due to other	Total	0	0	0	0	0	0	0	0

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

	allo-antibody	Deaths	0	0	0	0	0	0	0	0
Non-immunological haemolysis		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted bacterial infection		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Anaphylaxis/ Hypersensitivity		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion related acute lung injury		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted viral Infection	HBV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HCV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HIV-1/2	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted parasitical infection	Malaria	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Post-transfusion purpura		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Graft versus host disease		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Other serious reactions (specify)		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0

*a Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component

*b Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component. SARs linked to SAE at the BE/HBB are captured under “b” classification systematically, as being due to “quality and safety of blood component”.

Table 16: Serious adverse reactions related to transfusion of plasma.

This Table refers to **Other Components: Filtered Cryoprecipitate**		Number of units issued (total number of units issued with a given number of blood components) **771 UNITS FILTERED CRYOPRECIPITATE DISTRIBUTED**								
		Number of recipients transfused (total number of recipients transfused with a given number of blood components) Not available								
		Number of units transfused (the total number of blood components (units) transfused over the reporting period) Not available								
0		Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)							
0		Number of deaths								
			Not assessable	Level 0	Level 1		Level 2		Level 3	
					1a*	1b*	2a*	2b*	3a*	3b*
Immunological Haemolysis	Due to ABO incompatibility	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Due to other allo-antibody	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Non-immunological haemolysis		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted bacterial infection		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Anaphylaxis/ Hypersensitivity		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion related acute lung injury		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted viral Infection	HBV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HCV	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	HIV-1/2	Total	0	0	0	0	0	0	0	0

Statistics - Reports of Adverse Reactions and Events Related to Blood Transfusion for 2008

		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Transfusion-transmitted parasitical infection	Malaria	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
	Other (specify)	Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Post-transfusion purpura		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Graft versus host disease		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0
Other serious reactions (specify)		Total	0	0	0	0	0	0	0	0
		Deaths	0	0	0	0	0	0	0	0

*a Number of confirmed reports of serious adverse reactions related to blood or blood components which are not attributable to the quality and safety of the blood/blood component

*b Number of confirmed reports of serious adverse reactions related to blood or blood components which are attributable to the quality and safety of the blood/blood component. SARs linked to SAE at the BE/HBB are captured under “b” classification systematically, as being due to “quality and safety of blood component”.

Table 17: Serious adverse reactions related to transfusion of cryoprecipitate.

Summary

The above statistics show that blood transfusion in Malta is very safe. The rate of transfusion reactions for all the reported reactions is 87 reactions per 100, 000 units of blood components distributed. The rate of serious adverse reactions that are reportable to the European Commission is considerably less (10 reactions per 100,000 units of blood components distributed).

Annual Notification Format for Serious Adverse Events

Reporting period

1 January-31 December 2008

Total number of blood and blood components processed:

Serious adverse event, affecting quality and safety of blood component due to a deviation in:	**Total number**	**Specification**			
		Product defect	Equipment failure	Human error	Other (specify)
Whole blood collection	0	0	0	0	0
Aphaeresis collection	0	0	0	0	0
Testing of donations	0	0	0	0	0
Processing	0	0	0	0	0
Storage	0	0	0	0	0
Distribution	0	0	0	0	0
Materials	0	0	0	0	0
Others (specify)	0	0	0	0	0

Table 18: Serious adverse events related to blood transfusion

During 2008, there were no reported serious adverse events in patients that were related to the quality and safety of blood.

Non-Compliances Captured by the Quality System

The blood establishment kept a record of any non-compliances and shortcomings that the quality system detected and of the corrective actions taken. These included records of the blood products that were discarded and the reason.

Product	Reason for discarding	Year and number of units discarded	
		2007	2008
Whole Blood	Punctured	10	12
	Insufficient	461	338
	Over Weight	7	9
	Blood Clots	19	19
Pooled Platelets	Punctured	1	4
	Blood Clots	2	1
Single Donor Platelets	Punctured	0	0
Single Donor Red Cells	Punctured	2	0

Table 19: Discarded Blood Products for 2007 and 2008 Divided by Product and Reason for Discarding the Product

In addition, systems are in place to capture data on Serious Adverse Events related to clinical/bedside errors and errors categorised as Incorrect Blood Transfused. These systems capture data on incidents that include patient sampling errors such as wrong blood in tube and wrong name on tube and bedside errors of misidentification.
One near miss was reported during 2008. Trends are observed of these incidents so that if there is any clustering appropriate investigations are carried out in a timely manner.

DONOR COMPLICATIONS OBSERVED DURING 2008

The tables below (tables 20 and 21) give an overview of the incidents that donors giving blood during 2008 suffered during or after donation.

For the year 2006 there were 298 adverse reactions reported out of 14408 donations (2.6%) while there were 327 reported adverse reactions out of 14125 donations (2.3%) in 2007. During 2008, there were 222 reported adverse reactions for 14810 whole blood donations. (1.5%)

There is little difference in gender, and the most common complication during the donation is fainting without losing consciousness, consequently donation has to be stopped.

Incidents Reports (Donor Complications)		
National Blood Transfusion Services	**Mobile Blood Donation Unit**	**Gozo General Hospital**
138	39	45
Male	Female	Total
107	115	222

Table 20: Number of Donor Reactions and Donation Sites where they occurred

Donor Complications Observed during 2008

Complication	Number of cases
Haematoma	2
Painful Arm	1
During Donation Fainting without unconsciousness	102
During Donation Fainting with unconsciousness	9
During Donation Convulsion and Fits	10
After Donation Fainting without unconsciousness	74
After Donation Fainting with unconsciousness	13
After Donation Convulsion and Fits	3
During Venepuncture, Fainting without consciousness	3
During Venepunture Fainting with Unconsciousness	3
Irregular pulse	2
Total	222

Table 21: Types of Donor Complications Observed

The graph below gives an overview of the total number of adverse reactions and gender of donors suffering from the complications for the year 2006, 2007 and 2008.

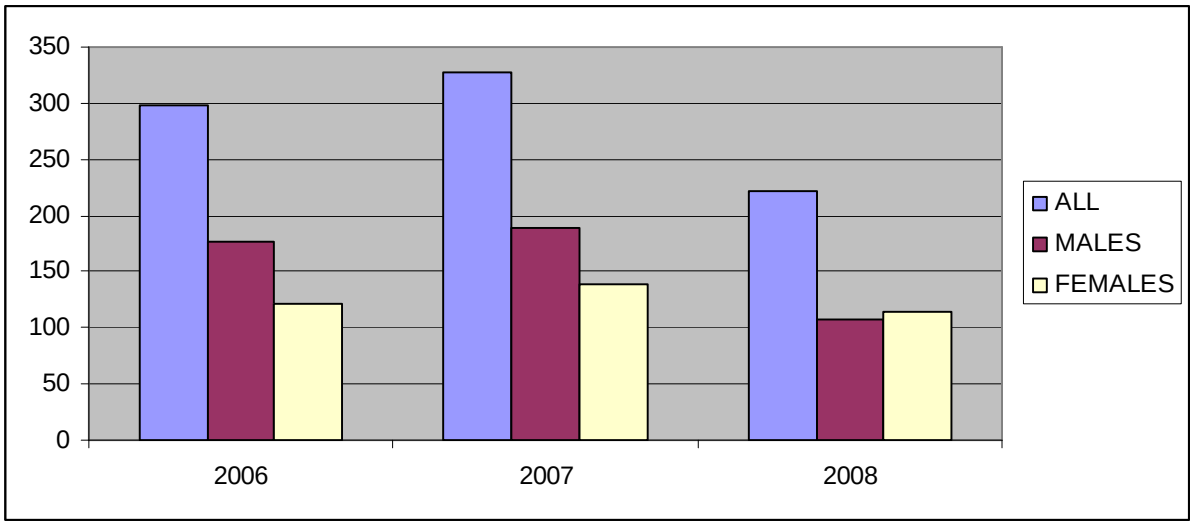


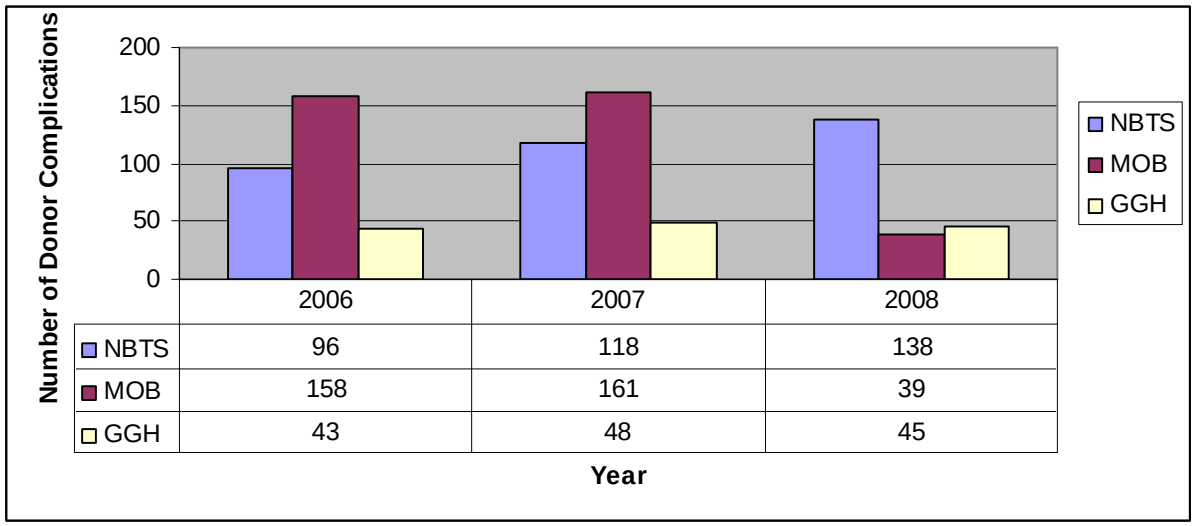
Figure 13: Number of adverse reactions and gender (2006, 2007 and 2008)

Donor Complications Observed during 2008

Complication	Number of donors experiencing complication (Year 2008)	Frequency
Haematoma	2	1: 7405
Painful Arm	1	1: 14810
During Donation Fainting without unconsciousness	102	1: 145
During Donation Fainting with unconsciousness	9	1: 1645
During Donation Convulsion and Fits	10	1: 1481
After Donation Fainting without unconsciousness	74	1: 200
After Donation Fainting with unconsciousness	13	1: 1139
After Donation Convulsion and Fits	3	1: 4937
During Venupuncture, Fainting without consciousness	3	1: 4937
During Venupunture Fainting with Unconsciousness	3	1: 4937
Irregular pulse	2	1: 7405
Total	222	1: 67

Table 22: Types of complications experienced by donors and frequency (year 2008)

Site where adverse reactions took place



	2006	2007	2008
NBTS	96	118	138
MOB	158	161	39
GGH	43	48	45

Figure 14: Number of donor complications and site where they occurred (2006, 2007 and 2008)

Recommendations

RECOMMENDATIONS

Two main issues emerge from the report:

1. Febrile non-haemolytic reactions and allergic reactions were the commonest types of adverse reactions related to blood transfusion in Malta during 2008. In view of the relative frequency of their occurrence, it is important that there are standard protocols for the investigation of such reactions and also protocols for their management and prophylaxis of the few preventable allergic reactions.
2. During 2008, there were two cases of acute haemolytic reactions, one due to ABO incompatibility and one due to other allo-antibodies. Acute haemolytic transfusion reactions (AHTRs) are a potentially fatal complication of incompatible blood transfusion. Delayed HTRs (DHTRs) generally are milder and characterized by anaemia and hyperbilirubinemia following red cell transfusion. Errors in sample and patient identification account for the majority of both reactions and thus these errors are largely preventable.

Haemolytic Reactions and Transfusion Errors

Haemolytic transfusion reactions (HTRs) typically occur when immunologic incompatibility between transfused donor red blood cells (RBCs) and recipient allo-antibodies produces accelerated destruction of transfused cells. Transfusion of ABO-incompatible RBCs to a recipient with the corresponding preformed antibodies is the most common aetiology.

Incidence. Blood product deviations in transfusion medicine are not uncommon. Fortunately, most do not produce a clinically unfavorable outcome. Approximately two-thirds of incorrectly transfused units will be ABO-compatible by chance alone. In one study, only half of the patients known to have received ABO-incompatible RBCs had clinical AHTR.

Haemolytic Transfusion Reactions and Error[14]

1 in 19,000 red cell units are administered erroneously; 1 in 1.8 million result in fatality. Most result from administration of properly labelled blood to an unintended recipient. As little as 30 mL of incompatible blood can be fatal.

Causes of AHTR

There are multiple causes of AHTRs. Process error-often clerical-associated with ABO-incompatible RBC transfusion is the most common. Sample or patient misidentification at any step in the transfusion process-from phlebotomy, through laboratory handling and testing, to blood issuance and administration-can result in the inadvertent transfusion of incompatible blood. The most commonly reported error is the administration of properly labelled blood to an unintended recipient as a result of failure to accurately identify the blood unit and recipient.
The most common causes of errors or deviations that are responsible for acute haemolytic reactions are listed below:

14

Recommendations

Product Deviations Associated with Haemolytic Transfusion Reactions
Collection of blood from the incorrect patient
Incorrect labelling of blood samples
Misidentification of the sample at the blood bank
Issuance of the wrong unit from the blood bank
Transfusion of blood to the incorrect patient

Contributing Factors
Failure to follow SOPs
Pre-printed sample labels
Patients with similar or identical names
Sequential patient identifiers
Verbal and stat orders
Simultaneous specimen processing from more than one patient
Manual issuance of blood
Overriding computer error messages
Insufficient segregation of units in refrigerators

Recommendations-Prevention of Transfusion errors related to Misidentification or Mislabelling
Humans will make errors at low levels despite their best efforts to avoid them. Repetitive or mentally unchallenging activities, such as sample and patient identification, are particularly prone to error. The chances of such errors can be substantially decreased by:
1. The use of double checks to address these issues, e.g., requiring two individuals to verify unit and patient identification.
2. In the laboratory, process control-a systematic effort to achieve standardization and maintain operational control-is used to limit unintended variation. This is achieved by:

(a) Defining how a process is to be performed in an SOP, validating the process, providing effective training to individuals involved in the process, and monitoring the process through audits and variance investigation.

(b) As most transfusion-related errors occur outside the blood bank, process controls should be extended to include the sample collection and administration arms of the transfusion process. The Haemovigilance / Blood Transfusion Nurse who was trained during 2008 was instrumental in monitoring of the administration of blood and in coming out with recommendations to promote safe practices during the transfusion process.

THE NATIONAL HAEMOVIGILANCE OFFICE AND HAEMOVIGILANCE-RELATED ACTIVITIES DURING 2008/2009

HAEMOVIGILANCE-RELATED ACTIVITIES DURING 2008/2009

During the year 2008, Malta participated in the following activities related to haemovigilance:

1. The System for Reporting of Serious Adverse Reactions and Events was re-engineered so that reports will now be passed directly to the National Haemovigilance unit within the Directorate for Health Care Services Standards under the Directorate General of Public Health Regulation. The reporting forms were also changed and electronic versions are now available online on the Department's website. Interactive PDF report forms were also designed to facilitate the reporting process.

2. Between the 28th February and 1st March 2008, the officer responsible for national haemovigilance attended the 10th European Haemovigilance Seminar (EHS) of the European Haemovigilance Network (EHN), held in Frankfurt, Germany.

3. Malta applied for a start-up grant from the European Haemovigilance Network to establish a haemovigilance system for Malta. The EHN Board granted 5,000 euro, a grant that was utilised to train a nurse in the area of Haemovigilance.

4. The Rapid Alert System for Reporting was strengthened by means of the establishment of a protocol for the use of this system. This system had previously worked well for the Chikungunya outbreak, During the year 2008, the system, as linked to the European Commission's alerting mechanism was used to alert local stakeholders and to provide updates about the outbreak of West Nile Virus and to disseminate the alert related to the transmission of vCJD through the use of plasma products.

THE WAY FORWARD

The following future activities are planned:

- It is important that as learning organisations we learn from such incidents. The Haemovigilance Unit aims to utilise.the reports from such incidents to conduct a root cause analysis to arrive at the basis of occurrence of these incidents and issue recommendations for the prevention of similar ones..

- To organise educational activities to increase awareness on the importance of haemovigilance amongst all professionals involved in the transfusion chain.

To improve networking between the National Haemovigilance Unit, the blood establishment and blood banks and institutions (both public and private) where blood transfusion is being performed and work closely with the newly established Mater Dei Hospital Transfusion Committee to collate, verify and obtain more information on reports of adverse reactions and events.

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I am extremely grateful to Dr. Stefan Laspina, Consultant in clinical transfusion, Mater Dei Hospital for the data provided on transfusion reactions and the investigation of such reactions and the support given in reviewing this report.

My sincere gratitude goes to Ms Dorianne Borg, Haemovigilance and Blood Transfusion Nurse who was indispensable in the collection of reports on adverse reactions and events related to blood transfusion and her enthusiasm and commitment to the promotion of safe practices in blood transfusion.

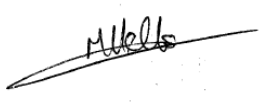
I acknowledge the ongoing support and efforts of the NBTS Medical Director, Dr. Alex Aquilina and the staff of the Malta NBTS. Their efforts in the continued recruitment of blood donors, who consistently and voluntarily give blood donations and in the processing and distribution of blood and blood components to the highest safety standards are the basic foundations of the national haemovigilance scheme.
Special thanks go to Dr. Aquilina for the continuous support and for having provided data without which this report could not have been possible. In particular, data on transfusion services in Malta and data on donor complications are wholly his contribution.

I acknowledge the continued support of Dr. Patricia Vella Bonanno, the Chief Executive Officer of the Malta Medicines Authority and her staff. In particular, the expertise and support of Dr. John Joseph Borg, Director of Post-licensing, the staff of the Pharmacovigilance Department and especially Ms Suzanne Mifsud is acknowledged.

The input of Transfusion Medical Scientists was also of central importance to this haemovigilance report.

I am very grateful to the European Haemovigilance Network for the grant awarded to Malta as a start-up grant for establishing the national haemovigilance system.

I thank all professionals involved in the transfusion chain for their continued efforts in heightening awareness and in developing mechanisms to increase transfusion vigilance and staff awareness in hospitals to reporting such incidents.



Dr. Miriam Vella

Annex 1: Serious Adverse Reactions Report Form

HAEMOVIGILANCE UNIT
DEPARTMENT OF HEALTH CARE SERVICES STANDARDS
PUBLIC HEALTH REGULATION DIVISION
Palazzo Castellania, 15, Merchants Street,
Valletta, VLT 2000
Tel:22992356 Fax: 22992656
Email: dhcss.mhec@gov.mt

BLOOD SERIOUS ADVERSE REACTION (SAR) REPORT FORM

Report Identification Number (given by reporting establishment) _____

RECIPIENT DETAILS *(Please tick or record details accordingly)*
INITIALS _____ SEX ☐ MALE ☐ FEMALE AGE (at time of SAR) _____

TYPE OF BLOOD/BLOOD COMPONENTS *(Please tick accordingly)*	**Batch number of blood/blood component**
☐ Whole blood	
☐ Red Blood Cells	
☐ Platelets (aphareseis)	
☐ Platelets (pooled)	
☐ Plasma	
☐ Albumin	
☐ Immunoglobulin	
☐ Autologous component	
☐ Other *(please specify)*	

DETAILS OF SERIOUS ADVERSE REACTION (SAR)

Date of Transfusion *(DD/MM/YYYY)*: / /	**Time of Transfusion:** a.m. / p.m.
Date of SAR *(DD/MM/YYYY)*: / /	**Time of SAR:** a.m. / p.m.
Amount transfused: ml	☐ <¼ ☐ <½ ☐ <¾ ☐ >¾ *(please tick accordingly)*

CLINICAL DETAILS

Baseline observations prior to Reaction	Temperature	_____°C	Pulse	_____/min	BP _____/_____mm Hg

NATURE OF REACTION

Parameters during/after reaction	Temperature peak _____°C	Pulse peak or trough _____/min	BP peak or trough _____/_____mm Hg

CLINICAL SIGNS OF REACTION

Fever ☐	Pulmonary oedema ☐	Purpura ☐
Hypothermia ☐	Urticaria/itching/rash ☐	Haemorrhage ☐
Nausea/vomiting ☐	Haemoglobinuria ☐	Tachycardia/arrhythmia ☐
Chest pain ☐	Jaundice ☐	Bradycardia ☐
Dyspnoea	Loin pain	High blood pressure

Annex 1: Serious Adverse Reactions Report Form

☐	☐	☐
Stridor/wheeze ☐	Kidney failure/falling urine output ☐	Hypotension (low blood pressure) ☐
Hypoxia (falling pO_2) ☐	Fits/seizures ☐	Shock ☐
Other symptoms ☐		

Type of SAR *(please tick accordingly)***:**	**Type of SAR** *(please tick accordingly)***:**
Immunological haemolysis due to ABO incompatibility ☐	Transfusion-transmitted parasitical infection (Malaria) ☐
Immunological haemolysis due to other allo-antibody (Acute) ☐	Transfusion-transmitted parasitical infection, Other *please specify)* ☐
Immunological haemolysis due to other allo-antibody (Delayed > 24 hours) ☐	Graft versus host disease ☐
Non-immunological haemolysis ☐	Febrile non-haemolytic transfusion reactions (FNHTR) ☐
Post-transfusion bacterial infection ☐	Post-transfusion Purpura (PTP) ☐
Transfusion-transmitted viral infection (HBV) ☐	TRALI (Transfusion Related Acute Lung Injury) ☐
Transfusion-transmitted viral infection (HCV) ☐	Transfusion Associated Circulatory Overload (TACO) ☐
Transfusion-transmitted viral infection (HIV-1/2) ☐	Transfusion Associated Dyspnoea ☐
Transfusion-transmitted viral infection, Other *(please specify)* ☐	Hypotensive transfusion reaction ☐
Other SARs (please specify) ☐	

Imputability of Serious Adverse Reaction	Excluded -0 ☐	Unlikely- 0 ☐	Possible -1 ☐
	Likely/Probable – 2 ☐	Certain – 3 ☐	Not assessable – NA ☐

SEVERITY GRADING

0. No morbidity. No symptoms. Reaction detected only through laboratory investigation	☐
1. Minor morbidity. Not life threatening	☐
2. Moderate to serious morbidity. May or may not be life threatening. Illness or hospitalisation is prolonged and/or results in chronic invalidity or impairment	☐
3. Serious morbidity with immediate threat to life	☐
4. Death as outcome	☐

REPORTING ESTABLISHMENT

Type *(please circle)***:** hospital blood bank, blood establishment, hospital, clinic, manufacturer, bio-medical research institution
Report made by (Name):

Annex 1: Serious Adverse Reactions Report Form

Address:
Telephone/Mobile:
E-mail address:

Signature _____ **Date of Report** _____

An electronic version of the SAR report form can be downloaded from: http://www.sahha.gov.mt/pages.aspx?page=974	***SUPPLY OF SAR REPORT FORM IS REQUIRED*** ☐

IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT: _____
(For office use only)

Annex 1: Serious Adverse Reactions Report Form

BLOOD SERIOUS ADVERSE REACTION (SAR) REPORT FORM

Report Blood Reaction Number (given by reporting authority)

Recipient details

Initials

Age

Sex

Type of Blood/Blood Components

Batch number of blood/blood component

Details of Serious Adverse Reaction (SAR)

Date of Transfusion | Time of Transfusion

Date of reaction | Time of reaction

Amount transfused (in ml)

Amount of unit transfused

Clinical details

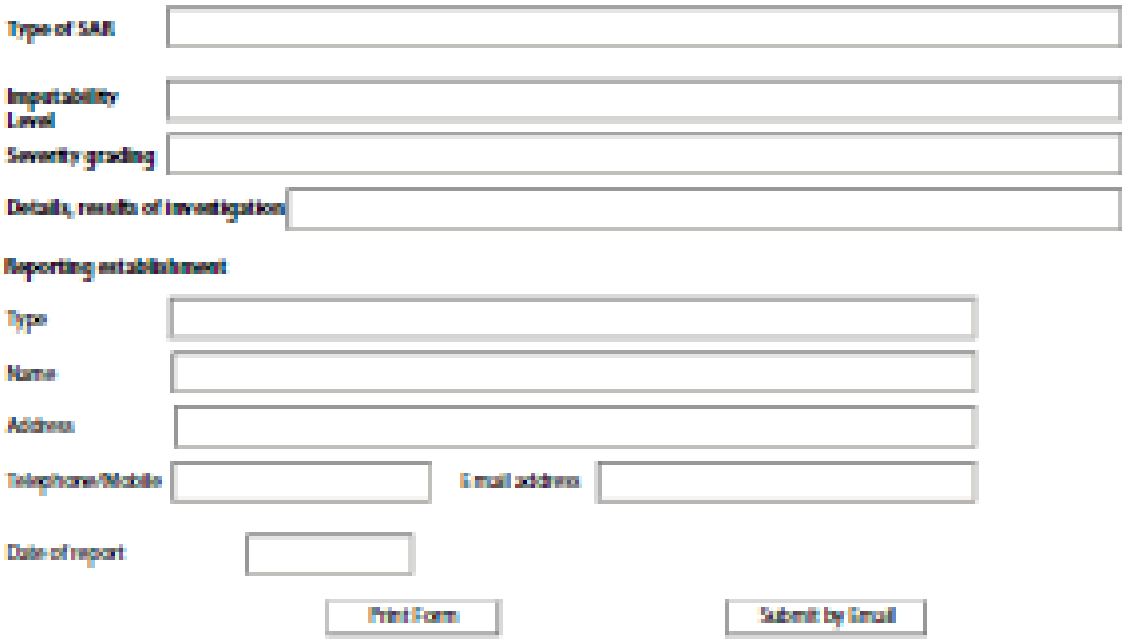
Baseline observations prior to transfusion	Temperature degrees C		Pulse / min		BP Systolic (mm Hg)		BP Diastolic (mm Hg)	
Parameters during/ after reaction	Temperature degrees C		Pulse / min		BP Systolic (mm Hg)		BP Diastolic (mm Hg)	

Clinical Signs/Symptoms of Reaction

- ☐ Fever
- ☐ Hypothermia
- ☐ Nausea/Vomiting
- ☐ Chest pain
- ☐ Dyspnoea
- ☐ Stridor/wheeze
- ☐ Hypoxia
- ☐ Other symptoms
- ☐ Pulmonary oedema
- ☐ Urticaria/Itching/rash
- ☐ Haemoglobinuria
- ☐ Jaundice
- ☐ Loin pain
- ☐ Kidney failure/low urine output
- ☐ Fits/seizures
- ☐ Purpura
- ☐ Haemorrhage
- ☐ Tachycardia/arrythmia
- ☐ Bradycardia
- ☐ Elevated Blood Pressure
- ☐ Hypotension
- ☐ Shock

Please specify

Annex 2: Serious Adverse Reactions Report Form (Interactive PDF)



Annex 4: Serious Adverse Events Report Form (Interactive PDF)

HAEMOVIGILANCE UNIT
DEPARTMENT OF HEALTH CARE SERVICES STANDARDS
PUBLIC HEALTH REGULATION DIVISION
Palazzo Castellania, 15, Merchants Street,
Valletta, VLT 2000
Tel:22992356 Fax: 22992656
Email: dhcss.mhec@gov.mt

BLOOD SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Report Identification Number (given by reporting establishment) _____

DETAILS OF SERIOUS ADVERSE EVENT

Date of SAE (DD/MM/YYYY):				
Serious Adverse Event (SAE) which may affect the quality and safety of blood component due to a deviation in:	**Specification**			
	Product defect	**Equipment Failure**	**Human error**	**Other (please specify)**
Whole blood collection	☐	☐	☐	☐
Apheresis collection	☐	☐	☐	☐
Testing of donations	☐	☐	☐	☐
Processing	☐	☐	☐	☐
Storage	☐	☐	☐	☐
Distribution	☐	☐	☐	☐
Materials	☐	☐	☐	☐
Other	☐	☐	☐	☐

REPORTING ESTABLISHMENT

Type *(please circle)***:** hospital blood bank, blood establishment, hospital, clinic, manufacturer, bio-medical research institution
Report made by (Name):
Address:
Telephone/Mobile:
E-mail address:

Signature _____ **Date of Report** _____

An electronic version of the SAR report form can be downloaded from: http://www.sahha.gov.mt/pages.aspx?page=974	***SUPPLY OF SAR REPORT FORM IS REQUIRED*** ☐

IDENTIFICATION NUMBER OF REPORTING ESTABLISHMENT: _____
(For office use only)

Annex 4: Serious Adverse Events Report Form (Interactive PDF)

HAEMOVIGILANCE UNIT
DEPARTMENT OF HEALTH CARE SERVICES STANDARDS
PUBLIC HEALTH REGULATION DIVISION
Palazzo Castellania, 15, Merchants Street,
Valletta, VLT 2000
Tel:22992356 Fax: 22992656
Email: dhcs.mhec@gov.mt

Department of Health Care Services Standards

BLOOD SERIOUS ADVERSE EVENT (SAE) REPORT FORM

Report Identification Number (given by reporting establishment)
Text Field

Details of Serious Adverse Event (SAE)

Date of Serious Adverse Event

Serious adverse event which may affect the quality and safety of a blood component due to a deviation in:

Whole blood collection

Apharesis collection

Testing of Donations

Processing

Storage

Distribution

Materials

Others

Reporting establishment

Date of report

Type

Name

Address

Telephone/Mobile

E mail address

Print Form

Submit by Email

All data collected is processed in accordance with the Human Blood and Transplants Act 2006 (Act IV 2006) and the Data Protection Act 2001. Data is required for administrative purposes in the interest of Public Health.

Further information

Requests for further information should be addressed to the National Haemovigilance Co-ordinator:

Dr. Miriam Vella
Department for Health Care Services Standards
Palazzo Castellania
15, Merchants Street, Valletta
VLT 2000, Malta.
Tel: +00356 22992356
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