MINISTRY OF HEALTH & SOCIAL SOLIDARITY
HELLENIC CENTER FOR DISEASE CONTROL & PREVENTION (KEELPNO)
HELLENIC COORDINATING HAEMOVIGILANCE CENTRE (SKAE)

SUMMARY REPORT

EPIDEMIOLOGICAL SURVEILLANCE
OF TRANSFUSION TRANSMITTED INFECTIONS (TTIs)
(1996-2007)

SURVEILLANCE OF ADVERSE REACTIONS (ARs-TR)
AND ADVERSE EVENTS (AEs-TR)
ASSOCIATED WITH BLOOD TRANSFUSION
(1997-2007)

SURVEILLANCE OF ADVERSE REACTIONS (ARs-DN)
AND ADVERSE EVENTS (AEs-DN) DURING OR AFTER DONATION
(2003-2007)

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Ministry of Health & Social Solidarity

PREFACE

I am very pleased to introduce the latest summary report of Coordinating Haemovigilance Network’s (SKAE) extensive activities in the fields of haemovigilance, blood safety and quality.

On behalf of Hellenic Center for Disease Control and Prevention (KEELPNO) - which is the competent authority for public health issues and works for the prevention and elimination of all known and emerging diseases threatening public health - I would like to congratulate SKAE and all colleagues in the Blood Transfusion Services and the Clinical Departments of our hospitals for their dedication to the cause of haemovigilance and blood safety.

The contribution of SKAE, together with its regional and local network, to the national effort to upgrade blood transfusion medicine in Hellas places it in a special position of excellence. I look forward to its continued work towards fulfilling the task of improving the quality of life of all those in need of blood transfusion.

Ioannis Pierrooutsakos
President of the Hellenic Center for Disease Control and Prevention (KEELPNO)
PROLOGUE

This summary report of the major activities in the twelve years of operation of the Coordinating Haemovigilance Centre (SKAE) of the Hellenic Center for Disease Control and Prevention (KEELPNO) is dedicated to all those colleagues who have worked hard to fulfil the tasks of haemovigilance for the collection and analysis of information concerning the risks of blood donation and blood transfusion.

Their voluntary involvement in the development of a national haemovigilance network in order to establish a reliable database on undesirable and unexpected transfusion-associated reactions and events in recipients of blood components and in blood donors, is an important contribution towards the continuous improvement of the quality and the safety of blood and blood components.

As early as 1996, SKAE became a member of the European Haemovigilance Network (EHN) and has followed its guidelines in developing a holistic haemovigilance system based on voluntary participation, on education and on a continuous dialogue amongst blood services, the clinical sections in hospitals and all those involved in the process of blood donation and transfusion therapy, underlining the important role of hospital transfusion committees in the application of good operating practices for quality assurance.

The Recommendations of the Council of Europe for the establishment of organised surveillance procedures related to serious adverse or unexpected events or reactions in donors and recipients and the epidemiological follow-up of donors have been incorporated into SKAE’s working methods with the ultimate goal of preventing the occurrence of adverse events and reactions.

In recent years, the implementation of the European Directives 2002/98/EC, 2005/61/EC and 2005/62/EC into national legislation (Law 3402/2005 and Presidential Decree 25/2008) has shown the significant role of SKAE as a support mechanism to the national authorities for blood transfusion and public health, through the collection, analysis and notification of the serious adverse reactions and adverse events associated with transfusion, as required by these Directives. Furthermore, SKAE is working for the identification and study of “near-miss” events as well as the uneventful transfusion errors and other “submerged” risks of transfusion.

Alert reporting, crisis management and continuous education are also major tasks of SKAE. In this way, we hope that the joint efforts of the laboratory and the clinical settings of transfusion will help towards the elimination of the hazardous aspects of transfusion.

Constantina Politis
Head of SKAE
## CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preface</td>
<td>3</td>
</tr>
<tr>
<td>Prologue</td>
<td>5</td>
</tr>
<tr>
<td>Haemovigilance in Greece</td>
<td>8</td>
</tr>
<tr>
<td>Working Methods</td>
<td>9-11</td>
</tr>
<tr>
<td>The National Haemovigilance Network</td>
<td>12</td>
</tr>
<tr>
<td>Surveillance of Transfusion Transmitted Infections (TTIs) 1996-2007</td>
<td>13-23</td>
</tr>
<tr>
<td>Surveillance of Adverse Events Associated with Blood Transfusion 2006-2007</td>
<td>31-33</td>
</tr>
<tr>
<td>Surveillance of Adverse Reactions and Adverse Events During or After Blood Donation 2003-2007</td>
<td>35-37</td>
</tr>
<tr>
<td>Staff and Associates of SKAE</td>
<td>39</td>
</tr>
<tr>
<td>Work Plan</td>
<td>40</td>
</tr>
</tbody>
</table>
HAEMOVIGILANCE IN GREECE

The Coordinating Haemovigilance Centre (known as SKAE) was founded by the Hellenic Center for Infectious Diseases Control (KEEL, now KEELPNO) in November 1995. It was established for reasons in line with European efforts to promote the strictest possible standards for quality in blood donation and transfusion medicine, and particularly to limit the risks that arise in this area of public health, thus to improve the safety of the blood transfusion chain from donor to patient.

BASIC FUNCTIONS OF SKAE

• Surveillance of transfusion transmitted infections in blood donors and in blood donations

• Traceability of blood components
  − Tracing and retrieval of potentially infectious donations
  − Look back programme

• Surveillance of adverse reactions and adverse events in blood donors during or after donation

• Surveillance of adverse reactions and adverse events associated with the transfusion of blood and blood components

• Reporting to the competent authorities for blood transfusion (EKEA) and public health (KEELPNO)

• Recommending preventive and corrective measures

• Informing the medical community about adverse events and reactions associated with blood donation and transfusion

• Warning blood services and clinical departments about adverse events and reactions that could involve more than a single recipient

• Crisis management

• Education - Publications
SKAE has been collecting and analysing information via a regional haemovigilance network of six bases in Southern Greece, Eastern Greece, Northern Greece, Western Greece, Thessaly and Crete on the following activities.

**TRANSFUSION TRANSMITTED INFECTIONS (TTIs).**

**Use of a uniform questionnaire.**

Collection of data on:
- Infectious markers in blood donors
- Infections in tested units of whole blood and aphaeresis products
- Laboratory methods for blood screening; implementation of quality control programmes
- Quality parameters and Standard Operating Procedures (SOPs)
- Quality management indices

Analysis of data in relation to:
- Participation of blood services
- Number of tested blood units
- Number of blood donors (demographic characteristics, first time, repeat, regular)
- Profile of the seropositive donor
- Testing of blood and blood components
- Serological screening for infectious agents (HBsAg, anti-HIV 1/2, anti-HCV, Syphilis and anti-HTLV I/II)
- Molecular screening with NAT (HCV-RNA, HIV-RNA, HBV-DNA)
- Estimation of residual risk for TTIs

Other activities:
- Tracing and retrieval of potential infectious donations and look back programme
- Recording seropositive donors
- Geographical mapping of infections
- Conducting cost-effectiveness studies of measures for preventing TTIs

**ADVERSE REACTIONS ASSOCIATED WITH THE TRANSFUSION OF BLOOD AND BLOOD COMPONENTS.**

Use of standard forms for individual reports and aggregate hospital data (along the lines of Directive 2005/61/EC, the Recommendations of the Council of Europe and EHN standards).

**ISBT definitions of adverse reactions**

- Collection of data by:
  - type of reaction (immunological haemolysis due to ABO incompatibility, due to other alloantibody, non-immunological haemolysis, anaphylaxis, allergic, TRALI, febrile non-haemolytic, TR-GvHD, other, transfusion transmitted bacterial infection, transfusion transmitted viral infection, other infection)
- degree of severity: non-severe (grade 1), severe (grade 2), life-threatening (grade 3), death (grade 4)
- level of imputability (not assessable, 0, 1, 2, 3)
- degree of morbidity
- clinical outcome
- leukodepletion (with buffy coat, without buffy coat, prestorage leukodepletion, bedside leukodepletion, other)
- washing of RBCs
- irradiation

• Analysis of data
  - rates of total adverse reactions and serious adverse reactions in relation to the total number of products issued for transfusion
  - rates of total adverse reactions and serious adverse reactions in relation to the type of product (whole blood, RBC’s, platelets, plasma) and processing

INCORRECT BLOOD COMPONENT TRANSFUSED (IBCT)

Use of standard form for aggregate data

Definition of SHOT

• Analysis of data by category:
  - transfused with reaction
  - transfused without reaction
  - component not transfused (near miss)
  - site of primary error (blood unit-wrong label, patient sample-wrong patient collected/wrong name of tube, compatibility-testing errors/ wrong label and transfusion-wrong patient/ wrong product/ ABO incompatibility)

ADVERSE EVENTS ASSOCIATED WITH THE TRANSFUSION OF BLOOD AND BLOOD COMPONENTS


• Collection of data:
  - Serious Adverse Events - EU
  - Near – Misses
  - Uneventful Transfusion Errors

• Analysis of data by:
  - Deviation in procedure affecting the quality and safety of blood component (whole blood collection, aphaeresis collection, testing, processing, distribution, materials and other)
  - Specification (product defect, equipment failure, human error and other)
SURVEILLANCE OF ADVERSE REACTIONS AND ADVERSE EVENTS IN BLOOD DONORS DURING OR AFTER BLOOD DONATION.

Use of uniform questionnaire in line with ISBT/EHN instructions
Definitions of the ISBT/EHN Working Group on Complications related to Blood Donation (DOCO)

- Collection and analysis of data by:
  - category (loss of consciousness due to hypovolemia, vasovagal reactions, seizures, stroke, allergic reaction, citrate reaction, cardiovascular accident, needle injuries, arterial puncture, nerve damage, haematoma, falls, fractures, difficult vein, other)
  - severity
  - incidence per 1,000 blood donors

OTHER ACTIVITIES

- Blood logistics and management of blood supply
- Quality management indices
- Education and training
- Publications
Notification of the serious adverse reactions and adverse events are required by the national Law 3402/2005. Further to these requirements, SKAE requests for the notification of all adverse reactions and adverse events associated with transfusion and donation. For this purpose, a national haemovigilance network is developed. Haemovigilance data are collected by haemovigilance officers, usually the medical director of the blood bank or an experienced clinician or in some cases the senior nurse of the blood service. The responsibility for haemovigilance matters lies with the hospital blood transfusion committee and the haemovigilance officer.

Adverse reactions and adverse events observed in patients in the clinic or in the operating theatre are reported to the local hospital blood bank (TODIA), and are investigated at hospital level following a common protocol. They are notified to the Regional Haemovigilance Network (PEDIA) and finally to the Coordinating Haemovigilance Centre (SKAE).

SKAE is responsible for the collection and analysis of the annual aggregate data from hospitals. The haemovigilance database is coded and protected. SKAE reports to the National Blood Centre (EKEA) and to the Hellenic Center for Disease Control and Prevention (KEELPNO).
SURVEILLANCE OF TRANSFUSION TRANSMITTED INFECTIONS (TTIs) 1996-2007
National data
Prevalence of total infectious markers in 6,052,933 tested blood units

<table>
<thead>
<tr>
<th>Infectious Marker</th>
<th>Period</th>
<th>Mean annual change</th>
</tr>
</thead>
<tbody>
<tr>
<td>HBsAg</td>
<td>1996-2007</td>
<td>-0.024*</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>1996-2007</td>
<td>-0.008*</td>
</tr>
<tr>
<td>Anti-HIV</td>
<td>1996-2007</td>
<td>+0.0002*</td>
</tr>
<tr>
<td>Syphilis</td>
<td>1998-2007</td>
<td>+0.006*</td>
</tr>
<tr>
<td>Anti-HTLV</td>
<td>2003-2007</td>
<td>-0.0007*</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td></td>
<td><strong>-0.034</strong></td>
</tr>
</tbody>
</table>

* Statistically significant change, though not stable

Source: Department of Hospital Units Development, Ministry of Health

Analysis by SKAE
National data. Frequency of five infectious markers in 6,052,933 tested blood units

Source: Department of Hospital Units Development, Ministry of Health
Geographical mapping
Prevalence of infectious markers per 1,000 blood donations
1/1/2000 – 31/12/2005

HBsAg

Anti-HCV

Anti-HIV

Syphilis

Reference: SKAE
SURVEILLANCE OF TRANSFUSION TRANSMITTED INFECTIONS (TTIs)

BY SKAE

1996-2007
Participation in SKAE - Tested blood units

Cummulative seroepidemiological data 1997-2007

<table>
<thead>
<tr>
<th>Infectious Marker</th>
<th>Initial Testing</th>
<th>Confirmatory Testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Reactive</td>
<td>Reactive</td>
</tr>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>HBsAg</td>
<td>9,242</td>
<td>100</td>
</tr>
<tr>
<td>Anti-HIV</td>
<td>2,324</td>
<td>100</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>6,815</td>
<td>100</td>
</tr>
<tr>
<td>Syphilis</td>
<td>1,839</td>
<td>100</td>
</tr>
<tr>
<td>Anti-HTLV*</td>
<td>786</td>
<td>100</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>21,006</strong></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

* Testing Period 2000-2007

Seropositive blood donors 2005-2007

<table>
<thead>
<tr>
<th>Infectious Marker</th>
<th>First time donors</th>
<th>Repeat donors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>Rate per 100,000</td>
</tr>
<tr>
<td>Anti-HIV</td>
<td>101</td>
<td>55</td>
</tr>
<tr>
<td>HBsAg</td>
<td>4,040</td>
<td>2,184</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>767</td>
<td>415</td>
</tr>
<tr>
<td>Anti-HTLV</td>
<td>16</td>
<td>8.7</td>
</tr>
<tr>
<td>Syphilis</td>
<td>184</td>
<td>99</td>
</tr>
</tbody>
</table>
### Seropositive blood donors 2005-2007

#### HIV Seropositive donors by transmission group

<table>
<thead>
<tr>
<th>Transmission group</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Heterosexuals</td>
<td>5</td>
<td>4</td>
<td>2</td>
<td>3</td>
<td>7</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>%</td>
<td>42</td>
<td>19</td>
<td>19</td>
<td>36</td>
<td>41.2</td>
<td>15</td>
<td>39</td>
</tr>
<tr>
<td>Men who have sex with men (MSM)</td>
<td>4</td>
<td>11</td>
<td>52</td>
<td>43</td>
<td>60</td>
<td>43</td>
<td>107</td>
</tr>
<tr>
<td>%</td>
<td>33</td>
<td>52</td>
<td>52</td>
<td>52</td>
<td>52</td>
<td>49</td>
<td>53</td>
</tr>
<tr>
<td>Undetermined</td>
<td>3</td>
<td>25</td>
<td>2</td>
<td>9.5</td>
<td>1</td>
<td>1</td>
<td>15</td>
</tr>
<tr>
<td>%</td>
<td>25</td>
<td>52</td>
<td>52</td>
<td>52</td>
<td>52</td>
<td>17</td>
<td>5.5</td>
</tr>
<tr>
<td>Sexual contact with multi-transfused patients</td>
<td>0</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>5</td>
<td>25</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.4</td>
</tr>
<tr>
<td>Other</td>
<td>0</td>
<td>0</td>
<td>3</td>
<td>14.5</td>
<td>9</td>
<td>24.5</td>
<td>12</td>
</tr>
<tr>
<td>%</td>
<td>0</td>
<td>0</td>
<td>14.5</td>
<td>9</td>
<td>24.5</td>
<td>12</td>
<td>2.9</td>
</tr>
<tr>
<td>Total</td>
<td>12</td>
<td>113</td>
<td>220</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>220</td>
</tr>
</tbody>
</table>

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#### Infectious Marker

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Anti-HIV</td>
<td>101</td>
<td>55</td>
<td>81</td>
<td>81</td>
<td>73</td>
<td>64</td>
<td>220</td>
</tr>
<tr>
<td>Rate per 100,000</td>
<td>55</td>
<td>27</td>
<td>40.5</td>
<td>40.5</td>
<td>36</td>
<td>32</td>
<td>100</td>
</tr>
<tr>
<td>HBsAg</td>
<td>4,040</td>
<td>2,184</td>
<td>1,004</td>
<td>1,004</td>
<td>1,004</td>
<td>1,004</td>
<td>1,004</td>
</tr>
<tr>
<td>Rate per 100,000</td>
<td>200</td>
<td>109</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
<td>50</td>
</tr>
<tr>
<td>Anti-HCV</td>
<td>767</td>
<td>415</td>
<td>182</td>
<td>182</td>
<td>182</td>
<td>182</td>
<td>182</td>
</tr>
<tr>
<td>Rate per 100,000</td>
<td>384</td>
<td>207</td>
<td>91</td>
<td>91</td>
<td>91</td>
<td>91</td>
<td>91</td>
</tr>
<tr>
<td>Anti-HTLV</td>
<td>16</td>
<td>8.7</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Rate per 100,000</td>
<td>8.7</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
<td>4.5</td>
</tr>
<tr>
<td>Syphilis</td>
<td>184</td>
<td>99</td>
<td>69</td>
<td>69</td>
<td>69</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td>Rate per 100,000</td>
<td>9.2</td>
<td>5</td>
<td>3.4</td>
<td>3.4</td>
<td>3.4</td>
<td>3.4</td>
<td>3.4</td>
</tr>
</tbody>
</table>

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![Bar chart showing HIV Seropositive donors by transmission group from 2002 to 2007.](chart.png)
The profile of the seropositive donor 1996-2007

**Gender**

- Male: 84%
- Female: 16%

**Age (years)**

- HIV: 18-40
- HBV: 25-45
- HCV: 30-49
- Syphilis: 25-44

**Donor**

- 79% 1st time
- 21% Repeat
<table>
<thead>
<tr>
<th>Infection</th>
<th>Tested blood units</th>
<th>NAT Positive only</th>
<th>n</th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>355,214</td>
<td>HIV-RNA (+)</td>
<td>2</td>
<td>1:177,607</td>
</tr>
<tr>
<td>HCV</td>
<td>355,214</td>
<td>HCV-RNA (+)</td>
<td>2</td>
<td>1:177,607</td>
</tr>
<tr>
<td>HBV</td>
<td>332,138</td>
<td>HBV-DNA (+)</td>
<td>48</td>
<td>1:6,919</td>
</tr>
</tbody>
</table>

93.5% of blood units were tested for all three infectious markers with ID-NAT
6.5% of blood units were tested for HIV-RNA in pools of 6 and for HCV-RNA in pools of 24
Laboratory Methods

For quality assurance, only validated tests that had been licensed or evaluated and considered suitable by the responsible health authorities are used. Blood screening methodology is relatively uniform following the Guide of the Council of Europe. Screening test for infectious markers are performed in accordance with the instructions recommended by the manufacturer of reagents and test kits.

For confirmatory testing an algorithm recommended by the Guide of the Council of Europe is applied. For specific cases with indeterminate results from serological and the molecular testing of blood, blood centers cooperate with the National Reference Centre for HIV/AIDS and Hepatitis.

Internal day-to-day quality control covering both reagents and techniques is conducted in 85% of the blood services and 60% of the blood centers participate in external quality control programmes.

<table>
<thead>
<tr>
<th>Written Instructions – Protocols 2007</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Data from 60 Blood Services</strong></td>
</tr>
<tr>
<td>---------------------------------------</td>
</tr>
<tr>
<td><strong>n</strong></td>
</tr>
<tr>
<td>---------------------------------------</td>
</tr>
<tr>
<td>Standard Operating Procedures</td>
</tr>
<tr>
<td>Equipment validation, calibration &amp; maintenance</td>
</tr>
<tr>
<td>Records for reagents and consumables</td>
</tr>
<tr>
<td>Records of results</td>
</tr>
<tr>
<td>Quality control charts</td>
</tr>
</tbody>
</table>
The participation of blood services in SKAE’s epidemiological surveillance of transfusion-transmitted infections in 1996-2007 was very high, especially from 2003, the year of preparation for the Olympic Games.

The prevalence of any of the infections in mandatory screening declined in 1996-2001, was steady in 2002-2004 and subsequently fell again except in 2005

In particular, HBsAg, anti-HCV and anti-HTLV declined throughout the period 1996 – 2007. In contrast, the prevalences of HIV and syphilis after the initial steep decline (1996-1999) and stationary period up to 2002, have tended to increase in the last five years

- HIV infection increased in 2004 and has subsequently remained at a high level except in 2006
- The prevalence of syphilis has been relatively high in the last three years
- HBV infection shows a steady decrease except in 2005. Because HBsAg seropositivity represents 70% of all infections, this trend strongly influences the overall results
- Like HBV, HCV shows a declining trend
- HTLV has low prevalence and is tending to decrease

NAT testing started in 2003 in a few Blood Centres and was extended in stages to the end of 2007. In that year, NAT detected 2 cases of HIV, 2 of HCV and 48 of HBV that were negative in serological assays.

These findings are especially important for blood safety and public health, demonstrating the high prevalence of HIV infection (1:177,607 blood units) and occult hepatitis B (1:6,919) in the donor population and the level of residual risk of infection with serological screening.

Seroprevalence of all infections is particularly high in first-time donors compared to repeat and regular donors. The prevalence of HIV infection increased significantly in 2005-2006-2007 in first-time donors but not in repeaters. On the other hand, HBsAg and HCV changed in a similar way in both categories, syphilis increased in repeat donors only and HTLV showed no changes. These data and the unchanging profile of the seropositive donor throughout the surveillance period, show the need for improved methods of donor recruitment and retention.

Improvements were noted in 2007 in laboratory screening methods and in basic preconditions for quality – written guides and protocols, records of equipment maintenance, reagents, samples and results. However, there is still a deficiency in exterior quality control and obtaining accreditation.

In conclusion, despite progress, the prevalence of infections remains relatively high especially regarding HIV and occult hepatitis B.

The notable progress in the application of NAT screening for HCV-RNA, HIV-RNA and HBV DNA has already led to important advances in assuring quality of blood for transfusion. Further organizational and quality improvements in the blood services and continuous education are called for.
SURVEILLANCE
OF ADVERSE REACTIONS ASSOCIATED
WITH BLOOD TRANSFUSION
1997-2007
Reporting Hospitals (% of total) 1997 - 2007

Frequency of adverse reactions by blood product 1997-2007

Information on 3,952,120 blood products
Total adverse reactions n=3,981

Red Cells: 82%
FFP: 10%
Platelets: 8%
# Adverse reactions associated with the transfusion of 4,349,628 blood products 1997-2007

<table>
<thead>
<tr>
<th>Year</th>
<th>1997 - 2000</th>
<th>2001</th>
<th>2002</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood</td>
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<td></td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>components</td>
<td>components</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Issued</td>
<td>508,190</td>
<td>334,882</td>
<td>296,396</td>
<td>371,456</td>
<td>674,100</td>
<td>727,920</td>
<td>697,812</td>
<td>738,872</td>
<td>4,349,628</td>
</tr>
<tr>
<td></td>
<td>18*</td>
<td>47*</td>
<td>38*</td>
<td>42*</td>
<td>82*</td>
<td>85*</td>
<td>70*</td>
<td>69*</td>
<td>46*</td>
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</table>

<table>
<thead>
<tr>
<th></th>
<th><strong>Adverse Reactions</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Total Reactions</strong></td>
</tr>
<tr>
<td></td>
<td>330</td>
</tr>
<tr>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>212</td>
</tr>
<tr>
<td></td>
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<td></td>
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<tr>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td>861</td>
</tr>
<tr>
<td></td>
<td>100</td>
</tr>
<tr>
<td></td>
<td><strong>4,329</strong></td>
</tr>
<tr>
<td></td>
<td><strong>100</strong></td>
</tr>
</tbody>
</table>

|                  | **Serious Reactions** |
|                  | 49                    |
|                  | 15                    |
|                  | 23                    |
|                  | 11                    |
|                  | 21                    |
|                  | 6.7                   |
|                  | 21                    |
|                  | 5                     |
|                  | 44                    |
|                  | 6.5                   |
|                  | 31                    |
|                  | 4.7                   |
|                  | 59                    |
|                  | 6.8                   |
|                  | 52                    |
|                  | 6.04                  |
|                  | **300**               |
|                  | **6.93**              |

|                  | **Fatalities**         |
|                  | 1                      |
|                  | 2                      |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 1                      |
|                  | 2.3                    |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | **2**                  |
|                  | **0.67**               |

|                  | **IBCT**               |
|                  | 1                      |
|                  | 2                      |
|                  | 2                      |
|                  | 8.7                    |
|                  | 1                      |
|                  | 4.8                    |
|                  | 1                      |
|                  | 4.8                    |
|                  | 3                      |
|                  | 6.8                    |
|                  | 4                      |
|                  | 12.9                   |
|                  | 6                      |
|                  | 10.2                   |
|                  | 6                      |
|                  | 11.54                  |
|                  | **24**                 |
|                  | **8.00**               |

|                  | **TRALI**              |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 0                      |
|                  | 1                      |
|                  | 4.8                    |
|                  | 4                      |
|                  | 9                      |
|                  | 1                      |
|                  | 3.2                    |
|                  | 8                      |
|                  | 13.5                   |
|                  | 2                      |
|                  | 3.85                   |
|                  | **16**                 |
|                  | **5.33**               |

* % of the total components issued

** One fatality attributed to Incorrect blood component transfused (ABO incompatibility) and another to hyperagglutination syndrome
<table>
<thead>
<tr>
<th>Type</th>
<th>Serious reactions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Incompatibility ABO</td>
<td>n = 25, % = 8.33</td>
</tr>
<tr>
<td>Incompatibility due to other alloantibody</td>
<td>n = 55, % = 18.33</td>
</tr>
<tr>
<td>Haemolysis related to transfusion of platelets</td>
<td>n = 1, % = 0.33</td>
</tr>
<tr>
<td>Anaphylactic</td>
<td>n = 89, % = 29.67</td>
</tr>
<tr>
<td>TRALI</td>
<td>n = 16, % = 5.33</td>
</tr>
<tr>
<td>Other</td>
<td>n = 86, % = 28.67</td>
</tr>
<tr>
<td>Infectious</td>
<td>n = 28, % = 9.33</td>
</tr>
<tr>
<td>Total</td>
<td>n = 300, % = 100.00</td>
</tr>
</tbody>
</table>

**Rates of adverse reactions 1997 - 2007**

- **Serious reactions**
  - 1: 14,499 blood components
  - 7%

- **Non-Severe**
  - 1: 1,080 blood components
  - 93%

- **All reactions**
  - 1: 1,005 blood components
Total Adverse Reactions 2007

<table>
<thead>
<tr>
<th>Type</th>
<th>Total</th>
<th></th>
<th>Serious</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n       %</td>
<td>n</td>
<td>%</td>
<td></td>
</tr>
<tr>
<td>Immunological haemolysis due to ABO incompatibility</td>
<td>11 1.28</td>
<td>6</td>
<td>11.54</td>
<td></td>
</tr>
<tr>
<td>Immunological haemolysis due to other alloantibody</td>
<td>14 1.63</td>
<td>11</td>
<td>21.15</td>
<td></td>
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<tr>
<td>Non immunological haemolysis</td>
<td>2 0.23</td>
<td>1</td>
<td>1.92</td>
<td></td>
</tr>
<tr>
<td>Anaphylactic</td>
<td>33 3.83</td>
<td>17</td>
<td>32.70</td>
<td></td>
</tr>
<tr>
<td>Allergic</td>
<td>329 38.21</td>
<td>33</td>
<td>3.83</td>
<td></td>
</tr>
<tr>
<td>TRALI</td>
<td>3 0.35</td>
<td>2</td>
<td>3.85</td>
<td></td>
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<tr>
<td>GVHD</td>
<td>0 0.00</td>
<td>0</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Febrile non-haemolitic</td>
<td>380 44.13</td>
<td>33</td>
<td>3.83</td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>86 9.99</td>
<td>14</td>
<td>26.92</td>
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</tr>
<tr>
<td>Bacterial</td>
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<td>1</td>
<td>1.92</td>
<td></td>
</tr>
<tr>
<td>Viral</td>
<td>0 0.00</td>
<td>0</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Other infectious</td>
<td>0 0.00</td>
<td>0</td>
<td>0.00</td>
<td></td>
</tr>
<tr>
<td>Total</td>
<td>861 100.00</td>
<td>52</td>
<td>100.00</td>
<td></td>
</tr>
</tbody>
</table>

Serious Adverse Reactions 2007 - Imputability levels

- Certain (Level 3) 23%
- Likely Probable (Level 2) 35%
- Excluded/Unlikely/Possible (Levels 0-1) 42%
- N/A 0%

The clinical outcome of all 52 serious adverse reactions was satisfactory. There was complete recovery in 51 cases. Minor sequelae were reported in one renal patient receiving chronic haemodialysis who suffered acute haemolysis following transfusion of incorrect blood component (ABO incompatibility).
CONCLUSIONS

SKAE collects data on all adverse reactions, not just the serious ones, from a very large number of hospitals.

Serious adverse reactions are rare. Two deaths in 4,849,628 blood products transfused have been recorded, one from immunological haemolysis due to ABO incompatibility because of incorrect blood component transfused and another attributed to hyperagglutination syndrome. The frequency of transfusion of wrong blood to the wrong patient in 1997-2007 was 1:115,500 red cells units and arose mostly because of premarked sampling tubes and failure to verify identity in the ward or operating theatre.

A number of cases were attributed to immunological haemolysis due to other allo-antibodies (anti-C, anti-C\̃, anti-e, anti-Kell, JK\̃, anti-Duffy\̃, anti-Lewis\̃ and unclassified allo-antibodies), while a large proportion of anaphylactoid reactions were reported.

The infectious risk of transfusion corresponds to 10% of total adverse reactions. Two transmissions of HIV (from one donor) owing to donation during the window period were recorded as well as transmission of malaria in a further three patients. Twenty four cases of bacterial infections (mostly staphylococcal) were associated with the transfusion of plasma and platelets.

Data on non-severe ARs show a relatively high frequency of febrile non-haemolytic and allergic reactions, especially in thalassaemic patients. This calls for adherence to GOPs for leukodepletion and washing red blood concentrates which are chiefly transfused into these patients.

Increased reporting of TRALI and acute haemolysis associated with transfusion of platelets may be due to improved cooperation between blood services and clinical departments regarding haemovigilance. GvHD and post-transfusion purpura were not observed.

While recording has improved, difficulties remain in rating imputability and in classifying severe and non-severe reactions according to the European Directives 2002/98/EC and 2005/61/EC.

RECOMMENDATIONS

- The Hospital Blood Transfusion Committee is responsible for the application of safety measures in blood sampling, ordering, patient identification and the continual supervision of the patient by experienced mediconursing staff in the course of transfusion
- Every patient should receive a barcode on admission, which will be used for identification in all medical procedures including blood transfusion
- Computerized record-keeping in blood services and clinical departments is basic for the safety of blood transfusion and the avoidance of adverse reactions in transfusion
- The transfusion of male plasma is recommended for avoidance of TRALI, and of platelets from donors of the same blood group for avoidance of haemolysis
- Universal application of pre-storage leukodepletion is recommended for reducing reactions related to residual white cells in blood products
- Inactivation of plasma and platelets is recommended for avoidance of the transmission of bacterial and viral infections
- Continuous education of staff in good clinical and laboratory practices throughout the donation-transfusion chain will be an invaluable service to patients in need of transfusion
SURVEILLANCE
OF ADVERSE EVENTS ASSOCIATED
WITH BLOOD TRANSFUSION
2006-2007
Serious adverse events, near miss events and uneventful transfusion errors were reported by 60 blood services who collected, tested, processed, stored and distributed a total of 917,994 blood components during the period 2006-2007.

### ADVERSE EVENTS 2006-2007

#### DATA ASSOCIATED WITH 917,994 BLOOD COMPONENTS

<table>
<thead>
<tr>
<th>Serious adverse events, which may affect quality and safety of blood component due to a deviation in:</th>
<th>Product defect</th>
<th>Equipment failure</th>
<th>Human error</th>
<th>Other</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Whole blood collection</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
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<td>0</td>
</tr>
<tr>
<td>Testing</td>
<td>1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Processing</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<td>0</td>
</tr>
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<td>Storage</td>
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<td>2</td>
<td>0</td>
<td>4</td>
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<tr>
<td>Distribution</td>
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</tr>
<tr>
<td>Others</td>
<td>0</td>
<td>0</td>
<td>2</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>1</td>
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<td>6</td>
<td>2</td>
<td>11</td>
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<table>
<thead>
<tr>
<th>“Near-miss” Events</th>
<th>Product defect</th>
<th>Equipment failure</th>
<th>Human error</th>
<th>Other</th>
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<td>8</td>
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<td>0</td>
<td>13</td>
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<td>1,537</td>
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<td>6</td>
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<td>25</td>
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<td>Others</td>
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<td>13</td>
<td>32</td>
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<tr>
<td><strong>Total</strong></td>
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<td>78</td>
<td>88</td>
<td>1,919</td>
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<table>
<thead>
<tr>
<th>Uneventful transfusion errors</th>
<th>Product defect</th>
<th>Equipment failure</th>
<th>Human error</th>
<th>Other</th>
<th>Total</th>
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<td>0</td>
<td>0</td>
<td>12</td>
</tr>
<tr>
<td>Aphaeresis collections</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Testing</td>
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<td>9</td>
<td>15</td>
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<tr>
<td><strong>Total</strong></td>
<td>12</td>
<td>2</td>
<td>9</td>
<td>9</td>
<td>32</td>
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</tbody>
</table>
CONCLUSION

Serious AEs were 1:62,931 units of blood components in 2006-2007. Near misses were 1:402 (product defect 8.6%, equipment failure 3.4%, human error 3.8%, other causes 84.2%). Uneventful transfusion errors were 1:28,687 blood components (37.5% product defect, 6.5% equipment failure, 28% human error and 28% other).

Serious AEs and uneventful transfusion errors were rare and associated mainly with human error. Near misses were associated mainly with whole blood collection and processing.

Better reporting methods are recommended and further study of the factors associated with serious AEs as well as uneventful transfusion errors and near miss events.
SURVEILLANCE OF ADVERSE REACTIONS AND ADVERSE EVENTS DURING OR AFTER BLOOD DONATION 2003-2007
An important part of a haemovigilance system is the epidemiological surveillance of adverse reactions, injuries and accidents to blood donors during and after donation. The care of donors is a duty of blood services and assures quality of blood and blood products for transfusion. SKAE participates in the pilot epidemiological surveillance organized by the European Haemovigilance Network (EHN), which, along with the Council of Europe and the International Society for Blood Transfusion (ISBT), is working for common protocols for recording data. Four Blood Centres participated in 2003 and 2004, and 40% of all blood services thereafter.

In total, 2,409 adverse reactions were recorded (1 in 246 donors), 99% of them vagotonic. Serious reactions were 11.5% of the total (1:2,084 donors). Four reactions were due to citrate and one, with imputability not assessed, to cardio-vascular accident.

Serious adverse events were 239 in a total of 3,599 reports, with a rate of 1:2,476 donors. The majority (65%) were haematomas. The surveillance shows that vasovagal reactions and haematomas are quite common, although serious incidents in donation are rare.

Improved conditions for blood donation are recommended, especially in mobile units, with continuous education of staff in preventing and responding to adverse reactions and events. The handling of vasovagal reactions in particular should be improved and care should be taken to avoid injury by the needle.

Continuous nursing and medical supervision during donation and management of complications (especially haematoma, vagovasal reactions and nerve injury) will contribute greatly to safeguarding the well-being of our donors and ensure their willingness to be retained as regular donors.
## Adverse Reactions and Adverse Events in Donors During or After Blood Donation

<table>
<thead>
<tr>
<th>Year</th>
<th>Blood Donors</th>
<th>2003</th>
<th>2004</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>All</td>
<td>Serious</td>
<td>All</td>
<td>Serious</td>
<td>All</td>
<td>Serious</td>
</tr>
<tr>
<td></td>
<td></td>
<td>62,218</td>
<td>61,686</td>
<td>105,617</td>
<td>119,200</td>
<td>243,109</td>
<td>591,830</td>
</tr>
</tbody>
</table>

### Adverse Reactions

- **Loss of consciousness due to:**
  - Hypovolemia: 24, 18, 22, 22, 133, 28, 93, 35, 36, 0 (Total: 308, Serious: 103)
  - Vasovagal reactions: 180, 0, 225, 10, 323, 13, 412, 12, 785, 3 (Total: 1,925, Serious: 38)
  - Seizures: 22, 11, 18, 18, 38, 30, 41, 31, 45, 45 (Total: 164, Serious: 135)
  - Stroke: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 4, Serious: 0)
  - Due to allergic reaction: 2, 2, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 4, Serious: 4)
  - Due to citrate: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 3, Serious: 3)
  - Due to cardio-vascular accident (CVA, MI): 1, 1, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 1, Serious: 1)

**Total:** 229, 32, 265, 50, 494, 71, 550, 78, 871, 53 (Total: 2,409, Serious: 284)

Incidence: 1000 blood units
- (3.5:1000) (0.58:1000) (4:1000) (0.6:1000) (4.6:1000) (0.44:1000) (2:1000) (0.7:1000) (3.5:1000) (0.44:1000)

### Adverse Events in Blood Donors

- **Needle injuries**
  - Arterial Puncture: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 7, Serious: 7)
  - Nerve damage: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 3, Serious: 3)
  - Haemotoma: 186, 37, 197, 44, 155, 38, 172, 35, 126, 0 (Total: 836, Serious: 154)
  - Falls: 25, 19, 109, 16, 19, 8, 24, 18, 3, 3 (Total: 180, Serious: 64)
  - Fractures: 0, 0, 0, 0, 0, 0, 0, 0, 0, 0 (Total: 0, Serious: 0)
  - Others (difficult vein): 38, 0, 56, 0, 0, 0, 48, 7, 19, 1 (Total: 161, Serious: 8)

**Total:** 249, 56, 362, 60, 174, 46, 247, 63, 158, 14 (Total: 1,190, Serious: 239)

Incidence: 1000 blood units
- (4:1000) (0.9:1000) (6:1000) (1:1000) (0.7:1000) (0.44:1000) (2:1000) (0.5:1000) (0.64:1000) (0.06:1000) (2:1000) (0.4:1000)

### Grand Total

- 467, 88, 514, 100, 668, 117, 797, 141, 1029, 67 (Total: 3,599, Serious: 523)

Incidence: 1000 blood units
- (8:1000) (1.4:1000) (8.3:1000) (1.6:1000) (6.4:1000) (11:1000) (6.7:1000) (1.2:1000) (4.2:1000) (0.3:1000) (6:1000) (0.9:1000)
COORDINATING HAEMOVIGILANCE CENTRE (SKAE)

Head and National Coordinator
Constantina Politis
Associate Professor of Medicine,
Scientific Advisor to KEELPNO,
President of the Blood Transfusion Committee, National Blood Centre (EKEA)

Staff
Coordinating Technician Marina Asariotou
Data Analysis & Benchmarking Officer Spyros Koumarianos
Marketing & Communication Officer Dionysios Stasinopoulos
Administrative Supervisor Aikaterini Pyrgioti
Data Entry Athanasios Kallos

Regional Haemovigilance Network

Chairs
Southern Greece Dr. Olga Marantidou
Director of Blood Transfusion Service
General Hospital Athens, “Asklepeio”

Northern Greece Dr. Leonidas Papayiannis
Deputy Director of Blood Transfusion Centre
General Hospital “Ippokrateio” Thessaloniki

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WORK PLAN

2009-2013
- Look back programme for HIV, HBV, HCV
- Biovigilance
- Training

2005-2008
- Vigilance for all adverse reactions and adverse events, materials, reagents and medical devices
  - Training

2000-2004
- National Haemovigilance Network
- Participation in the European Haemovigilance Network Alert System
- National Network of Microbiological Reference Laboratories for the investigation of infectious adverse events
- Participation in the Olympic Games vigilance plan
  - Training

1998-1999
- Regional Haemovigilance Network
- Serious adverse events associated with blood transfusion
- Cooperation with European Haemovigilance Network
  - Training

1996-1997
- Epidemiological surveillance of viral infections in blood donors (syphilis, HBV, HCV, HIV)
  - Geographical mapping of viral infections
  - Performance of laboratory tests for injection
  - Internal quality control of screening for viral infections
  - Training