Voluntary and Unpaid Donation of Blood and Blood Components 2014 Report

Blood Competent Authority Meeting – 24th April 2015

D4 Substances of Human Origin Team
Legal context

• Principle governing voluntary and unpaid donation (VUD) (art 20, Directive 2002/98/EC)

“Member States shall take the necessary measures to encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are in so far as possible provided from such donations“

• Member States shall report on the practice of VUD every three years (art 20-2, Dir. 2002/98/EC)
To allow for comparable replies, and only for the purpose of this survey, the Commission proposed the following definitions:

- **Compensation** means reparation strictly limited to making good the expenses and inconveniences related to the donation.

- **Incentive** means inducement/stimulus for donation with a view to seeking financial gain or comparable advantage.

- **National self-sufficiency** means fulfilling the needs of human blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country’s population.

- **National sufficiency** = fulfilling the needs of blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country and through regional/international cooperation.
2014 Report

• Reports submitted between May and September 2014 by 28 MS, Liechtenstein and Norway. Further information provided by MS up to December 2014.

• Report outline – four key areas:
  1. Legislative provisions/guidelines and policies
  2. Practices vis-à-vis donors and collectors
  3. Ensuring sufficient supply of blood, blood components and derivatives
  4. Organisation of collection and supply
1. Legislative provisions/guidelines governing the principles of VUD
   – Mandatory Nature and Enforcement

- 25 MS report that VUD is mandatory (although the national legal provisions in some of these only encourage it)
- 4 report that it is not mandatory
- 17 have defined penalties for infringements of VUD provisions – very variable – no case of a penalty being applied up to now
- 9 take additional measures (e.g. inspection of promotional material)
- In 2, VUD is respected also for imports.
1. Legislative provisions/guidelines governing the principles of VUD
   – Changing provisions and guidelines

• Since 2010, 5 MS have introduced binding national provisions on VUD
• 3 MS have regulated the forms or amounts of compensation
• 2 MS have established rules for promotion of VUD

• 3 MS plan to introduce guidelines promoting VUD
• Others are considering developing guidelines or other measures such as school education, recognition of donors and monitoring of cross-border donation
1. Legislative provisions/guidelines governing the principles of VUD
   – Replacement Donors

- 5 MS report being aware of the practice of replacement donation in their MS – varying from common to exceptional.

- Greece and Romania make concerted efforts to convert replacement donors to regular voluntary donors and see them as important contributors to the blood supply.

- 3 MS have policies that forbid or strongly discourage replacement donation
1. Legislative provisions/guidelines governing the principles of VUD – Trans-border donation

'Donating in a country where the donor is not living'

- 5 MS report being aware of individuals coming to their MS to donate.
- 6 MS are aware of residents going to another MS to donate (3 of these have local shortages – not necessarily connected to trans-border donation).
- 11 MS facilitate trans-border donation by providing donor questionnaires in English or in other languages
- 16 MS and Norway discourage donation by persons who are not resident by
  - Requirement for ID document from country of donation (9)
  - Requirement to have been living in the country of donation for some time (5)
  - Requirement to understand the language of the country of donation to a certain level (5 MS and NO)
- Mainly an individual practice although Hungary and Slovakia report organised groups travelling to Austria for plasma donation and Poland report young first time plasma donors travelling to Germany.
2. Practices vis-à-vis donors and collectors
   – Donors – compensation/incentive

• All MS and Liechtenstein and Norway report that donors are given some form of compensation or incentive.

• 13 have guiding principles (binding or non-binding) regarding the form or amount of compensation

• The most common practices are:
  – Provision of refreshments
  – Provision of small tokens such as pins, pens, t-shirts
  – Reimbursement of travel costs
  – Time off work in the public or private sector
2. Practices vis-à-vis donors

– Compensation

Other practices include:

• Food vouchers
• Physical check-up (beyond what is required for donation)
• Reimbursement of medical costs
• Compensation linked to loss of earnings
• Compensation for inconvenience associated with donation
• Fixed some of money (established nationally, irrespective of actual costs)
• Fixed some of money (established by BE, irrespective of actual costs)
• Other
2. Practices vis-à-vis donors

Value of compensation

- Fragmented data
- Highest values reported were between 25 and 30 euros
- Refreshments and tokens of values between 1 and 10 euros
- Food vouchers – usually worth 1 to 4 euros but a fixed value of 15 euros established in Romania
- Travel costs up to 27 euros where specified
2. Practices vis-à-vis donors

Value of compensation

10 MS reported practices involving transfer of money other than for reimbursement of travel or medical costs. These are compensation for loss of earnings or for inconvenience and in some cases are fixed.

In 3 MS, transfer of money is allowed. This includes for apheresis of plasma & platelets and in certain other circumstances:

- Emergency cases
- Rare blood group donation
- Apheresis of anti-D plasma
- Donation for vaccine, sera or immunoglobulins or for R&D and diagnostic purposes in medicine.
- Specific donation for a specific patient or special donor preparation or selection.
2. Practices vis-à-vis donors
Deciding the value of compensation

• In 15 MS, BEs or operators are involved in defining what is given to donors
• In 10 MS, this is decided by the National government
• Other bodies were also listed:
  — Insurance schemes (3 MS)
  — Regional or local government (2 MS)
  — Red Cross (1 MS and LI)
  — Board of local donors
  — A working group
  — Hospital Transfusion Committee
  — Blood donors association
• In many MS, these decisions are made jointly by more than one stakeholder.
2. Practices vis-à-vis donors
– Differing Perceptions among MS

<table>
<thead>
<tr>
<th>Practice</th>
<th>Number of Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>Refreshments: 27</td>
<td></td>
</tr>
<tr>
<td>Food voucher(s): 7</td>
<td></td>
</tr>
<tr>
<td>Small tokens: 24</td>
<td></td>
</tr>
<tr>
<td>Free physical check-up (beyond what is required for the donation): 4</td>
<td></td>
</tr>
<tr>
<td>Free or reimbursement of medical costs (e.g. additional medication, etc.): 5</td>
<td></td>
</tr>
<tr>
<td>Reimbursement of costs linked to travel (to and from place of donation): 13</td>
<td></td>
</tr>
<tr>
<td>Time off work - public sector: 16</td>
<td></td>
</tr>
<tr>
<td>Time off work - private sector: 13</td>
<td></td>
</tr>
<tr>
<td>Compensation linked to loss of earnings: 4</td>
<td></td>
</tr>
<tr>
<td>Compensation for the inconveniences related to donation: 5</td>
<td></td>
</tr>
<tr>
<td>Fixed sum of money, irrespective of actual costs, established at national level: 4</td>
<td></td>
</tr>
<tr>
<td>Fixed sum of money, irrespective of actual costs, established by BE: 4</td>
<td></td>
</tr>
<tr>
<td>Other forms: 1</td>
<td></td>
</tr>
</tbody>
</table>

Number of countries
2. Practices vis-à-vis collectors
Activities for which Member States provide financial incentives to blood establishments etc.

- Organising awareness campaigns
- Organising donor drives
- The actual recruitment of potential donors in a registry
- Donation and blood collection
- Processing of blood and components
- Storage and distribution of blood and components

Member States in brackets provide incentives only for activities related to whole blood.
4. Ensuring sufficient Supply of Components and Derivatives
- Shortages

8 MS report regular shortages

7 MS report seasonal shortages
- mostly associated with West Nile Virus

Sweden and Cyprus report collaboration between neighbouring BEs to manage the impact of shortages
3. Ensuring sufficient Supply of Components and Derivatives
- Policies promoting sufficiency and self-sufficiency

For the purpose of this report, the following definitions were provided:

**National self-sufficiency**: fulfilling the needs of human blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country's population.

**National sufficiency**: fulfilling the needs of human blood, blood components and plasma derivatives for medical application of the resident population by accessing resources from within the country and or through regional or international cooperation.
3. Ensuring sufficient Supply of Components and Derivatives

- Policies promoting sufficiency and self-sufficiency

- 25 MS have policies in place to promote self-sufficiency or sufficiency and one is preparing a policy

- Policies include the following approaches:
  - Increasing the blood supply by promoting donation
  - Export restrictions
  - Decreasing demand by promoting rational or efficient use
  - Centralisation to provide a national overview of stocks
  - Co-operation between BEs

- There is more focus on sufficiency for blood than for derivatives

- Policies are generally stable although some MS have recently increased their efforts in the plasma sector.
3. Ensuring sufficient Supply of Components and Derivatives
- Promotion of VUD - measures

Other includes training of BE staff and volunteers in promotion activities
3. Ensuring sufficient Supply of Components and Derivatives

- Promotion of VUD – target groups

<table>
<thead>
<tr>
<th>Category</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>Youth/young adults</td>
<td>19</td>
</tr>
<tr>
<td>Army recruits</td>
<td>6</td>
</tr>
<tr>
<td>Enterprises/work environments</td>
<td>4</td>
</tr>
<tr>
<td>Others</td>
<td>10</td>
</tr>
</tbody>
</table>
3. Ensuring sufficient Supply of Components and Derivatives
- Policies on clinical use

[Diagram showing number of countries having policies on the respective level for Blood and blood components and Plasma derivatives.]
3. Ensuring sufficient Supply of Components and Derivatives
   - Audits on clinical use

- 16 MS reported carrying out regular audits of blood and blood component use
- These audits are carried out at the level of hospitals and operators (14 MS) and at the national level (10 MS)
- 8 MS reported carrying out regular audits of plasma derivative use
- There is more focus on sufficiency for blood than for derivatives
- Policies are generally stable although some MS have recently increased their efforts in auditing the use of plasma.
3. Organisation of collection and supply

- Main collectors of blood and blood components

• 24 MS reported that the main blood collectors are public national establishments.

• Plasma is collected by the same establishments in 22 of these.

• Private national establishments (including not for profit organisations such as the Red Cross) are main suppliers of both whole blood and plasma in seven Member States (AT, BE, CZ, DE, FI, NL, SE) and of plasma in Latvia.

• Establishments from other Member States are the main suppliers for Ireland as regards solvent/detergent-treated plasma and for the United Kingdom as regards variant Creutzfeldt Jacob Disease negative plasma.
3. Organisation of collection and supply
   - Plasma Fractionation

- 12 MS have the capacity to fractionate plasma
- Plasma is fractionated by for-profit (8 MS), not-for-profit (2 MS) and public (2 MS) organisations
- 9 MS send the plasma for fractionation in another MS (mostly they send to Austria)
- 7 MS do not fractionate the plasma they collect (in UK and IE due to risk of v-CJD).
Possible next steps...

• Better harmonised interpretation and implementation of Article 20 in the Directive 2002/98/EC?
  – Issues that might be addressed:
    - measures to ensure transparency on donor compensation?
    - the type and value of the compensations for donors?
    - best practices to ensure sufficiency/self-sufficiency?
    - measures to reduce shortages?
    - verification of the implementation of the VUD principle?

• Reflection on how to ensure both respect for the VUD principle and an adequate supply of blood, blood components and plasma derivatives for the patients who need them across the EU.
Thank you!