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SUMMARY OF THE 2012 ANNUAL REPORTING OF SERIOUS ADVERSE EVENTS AND REACTIONS (SARE) FOR BLOOD AND BLOOD COMPONENTS (DATA COLLECTED FROM 01/01/2011 TO 31/12/2011)

Article 8 of Directive 2005/61/EC[1] provides that Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events (SARE) received by the competent authority using the formats in Part D of Annex II and C of Annex III.

This document intends to provide a summary report of the data collected during 2011 (from 1st January to 31st of December) received from the Member States, including preliminary conclusions.

1. DATA COLLECTION METHODOLOGY

The first SARE reporting exercise for blood and blood components was launched in 2008. Since then DG SANCO has worked together with groups of national experts to refine the SARE reporting exercise. More recently a Working Group on haemovigilance, whose members are nominated by the national Competent Authorities, has met on a yearly basis to discuss improvements to the SARE reporting tools. These are:

1) An electronic reporting template to be filled in by Member States with the data collected in the previous year (1st January to 31st December). Once completed by Member States this is sent in html format to a DG SANCO hosted database. The template used in 2012 (for 2011 data) was version 2.2.

2) A common approach document which, although it is not legally binding, provides guidance to Member States when filling out the electronic SARE reporting template as required by Directive 2005/61/EC. First published in 2008, the Common Approach has been regularly updated to clarify points of ambiguity and inconsistency. This has in turn resulted in a gradual increase of the quality of the data collected from the Member States. In 2012, version 3 of the Common Approach document was available to those reporting SARE 2011 data.

[1] Commission Directive 2005/61/EC 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 (OJ L 256,1,10, 2005, p.32).

2. MAIN FINDINGS OF THE 2011 DATA COLLECTION

2.1. General comments

Data collection is still a difficult task. Even though Member States have transposed and implemented the legal requirements of Directive 2005/61/EC, data collection methods vary at national level. Although data quality has improved, the data presented here is considered partial and should therefore be interpreted with caution.

For the 2012 exercise (data reported in 2011), a revised version of the 'Common approach for definition of reportable serious adverse events and reactions' was developed by the Commission, together with the Haemovigilance Working Group.

The PDF reporting template was also revised and refined. Some of the changes included collection of data on completeness, dedicated sections for each blood component (whole blood, red blood cells, plasma, and platelets), and more specific SAE categories.

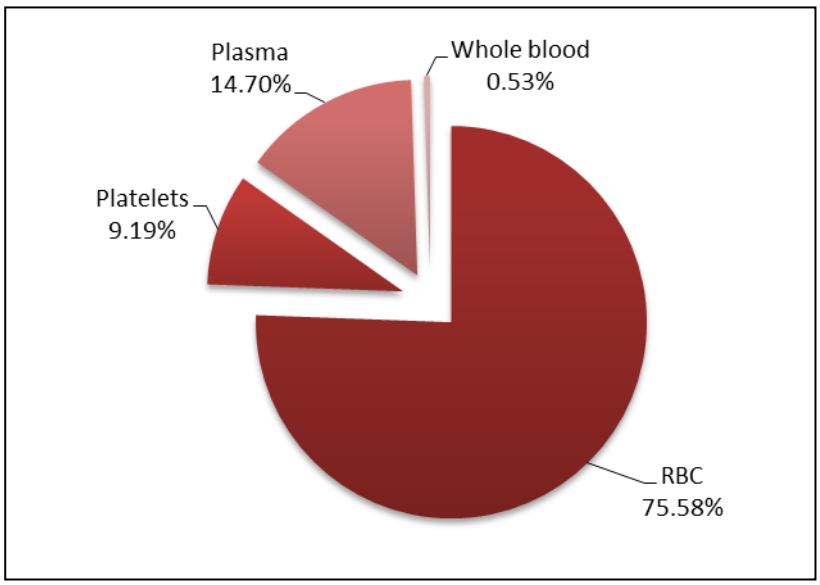
Responses were received from all EU27 Member States, Croatia, Liechtenstein and Norway. All countries reported SARs and most reported SAEs, but in many cases not all denominators were reported, raising questions about the availability/accuracy of data. The data was presented at the February 2013 meeting of the Haemovigilance Working Group and the April 2013 meeting of the competent authorities on blood and blood components.

2.2. Denominators

All Member States, as well as Croatia, Liechtenstein, and Norway submitted replies to the questionnaire, thereby complying with the annual report submission established by Article 8.

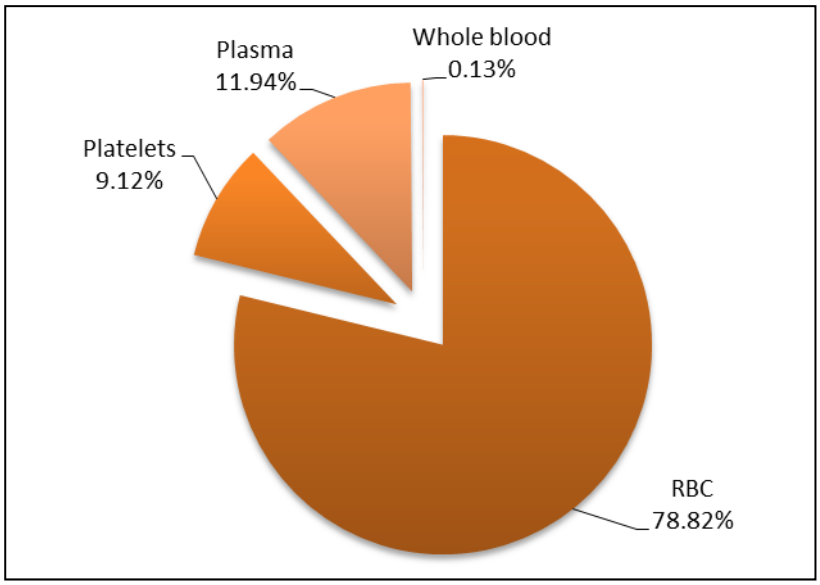
In total, 12,311,691 units of blood components were reported as transfused by facilities in EU and EEA countries. It should be noted that this is not the total number of units transfused, as only 17 countries (AT, BE, BG, CZ, DK, EE, EL, ES, IE, IT, LT, MT, NO, PT, RO, SE, and UK) reported this figure (for at least one blood component). The breakdown by component is shown below.

Figure 1: Units transfused per blood component.



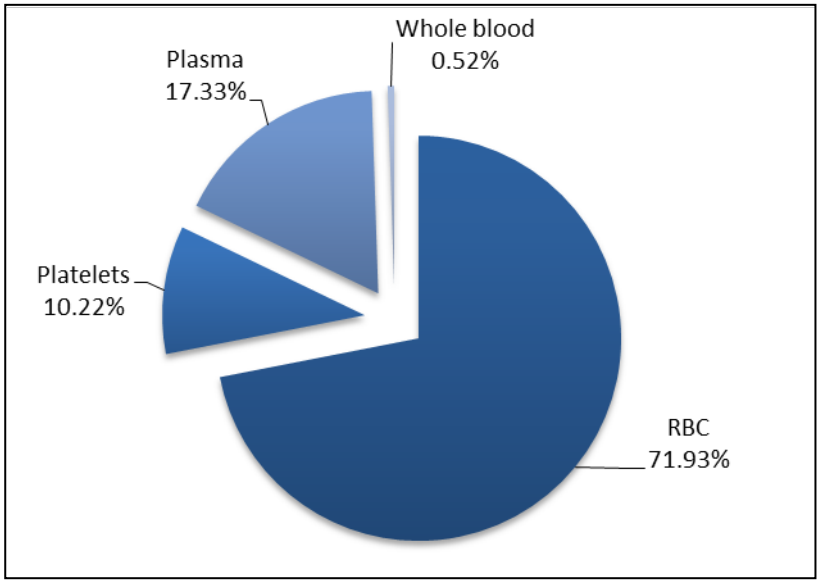
According to the reports, 2,964,839 recipients (patients) were transfused in 2011. As mentioned above, these are partial figures, only thirteen countries (BE, BG, CZ, EE, IE, IT, LT, MT, NO, PT, RO, SE, and UK) provided data on both units transfused and the number of recipients of blood. Four countries (AT, DK, EL, and ES) only provided data about units of blood components transfused, and three countries (CY, FR, and LV) provided information on recipients but not units transfused. The ten remaining countries (DE, FI, HR, HU, LI, LU, NL, PL, SI, and SK) did not provide any data for units transfused or the number of recipients. The breakdown by component is shown below.

Figure 2: Recipients per blood component (BE, CY, CZ, IE, IT, MT, NO, PT, SE and the UK provided per component data, totalling 2,046,215 recipients).



Twenty-six EU Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, SK, and UK), Liechtenstein, Croatia and Norway provided data regarding units of blood components issued in 2011. Overall, a total number of 24,821,809 units of blood were issued in 2011.

Figure 3: Units issued per blood component.



2.3. Serious Adverse Reactions (SARs)

2.3.1. Information by country

In 2011, a total of 1,574 SARs with a likely or certain attribution to the blood or blood component transfused (i.e. at imputability level 2-3) were reported by the 27 Member States, Croatia, Liechtenstein and Norway. This equates to 13 SARs per 100,000 units transfused or conversely 7,822 units transfused per SAR. This figure should, however, be interpreted with caution. This is most likely an over-estimation of the number of SARs per units transfused, as only 17 countries provided data for units transfused, but all reported the number of SARs.

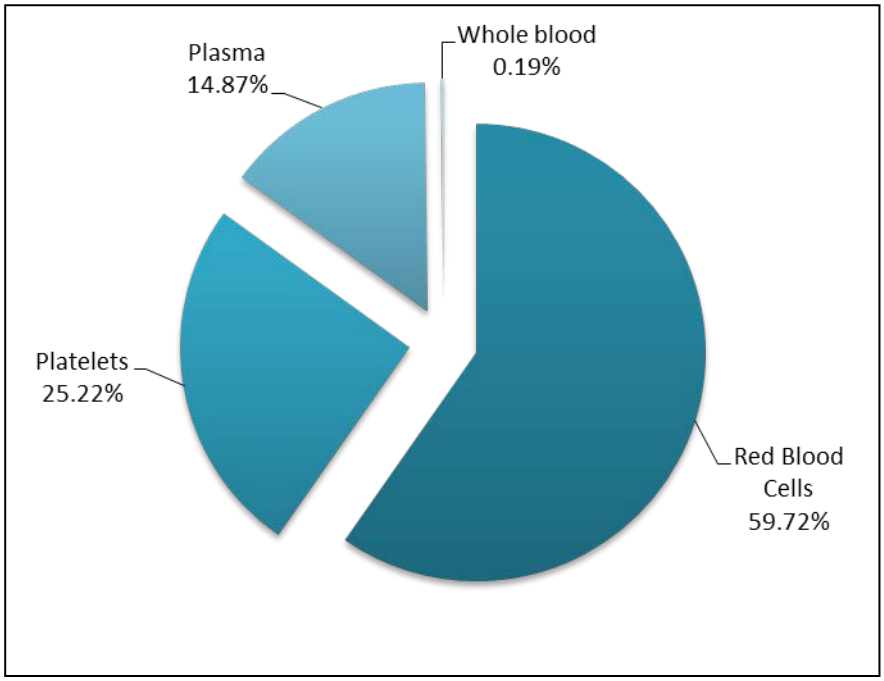
Four countries (LI, LU, LV, and SK) did not report any SARs (level 2-3) related to the quality and safety of blood and blood components in 2011. Where SARs and units transfused were reported, the number of units transfused per SAR (level 2-3) ranged from 1,042 to 588,235 across countries. These figures should also be interpreted with caution as many reports are still partial and differences between countries do not necessarily indicate a safer system. In fact, a higher number of SARs reported may indicate a more reliable and accurate reporting system, and a lower number of SARs may indicate under-reporting.

2.3.2. Information by blood component

Of the 1,574 level 2-3 SARs reported:

- 940 SARs were related to **red blood cells**,
- 397 SARs were related to **platelets**,
- 238 SARs were related to **plasma**,
- 3 SARs were related to **whole blood.**

Figure 4: Percentage of SARs per blood component.



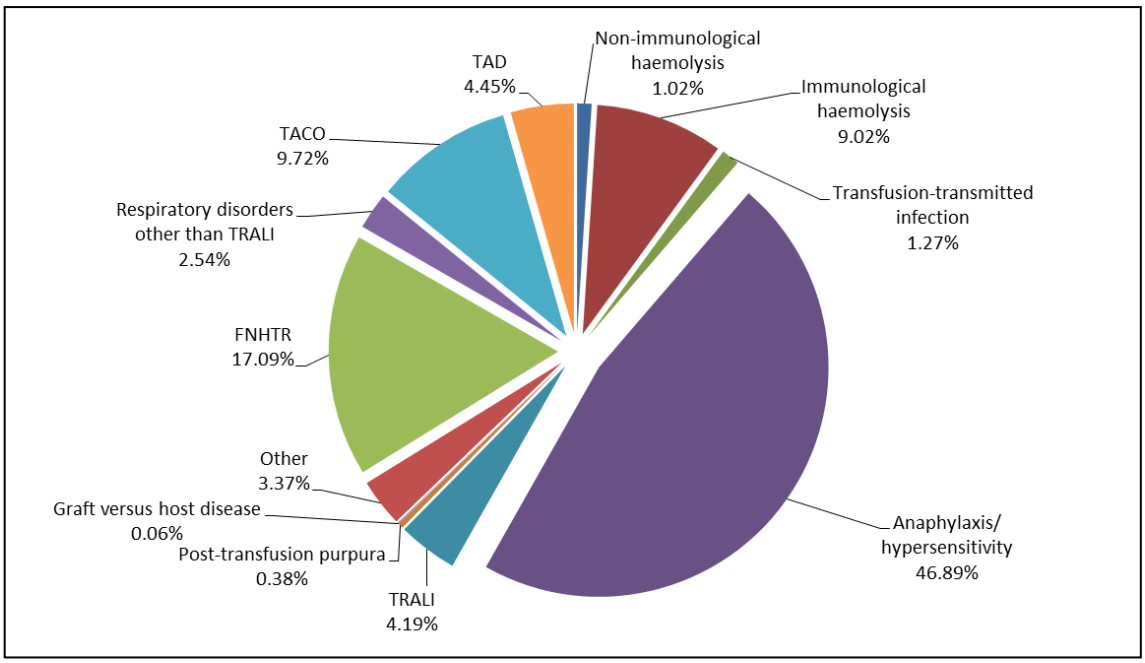
2.3.3. Information by category of SAR

The 1,574 SARs (level 2-3) reported were classified as follows:

- **Immunological haemolysis**: 142 cases (9.02% reported SARs), of which
    - 56 cases due to ABO antibody (3.56%), and
    - 86 cases due to other allo-antibodies (5.46%).
- **Non-immunological haemolysis**: 16 cases (1.02% reported SARs),
- **Anaphylaxis/hypersensitivity**: 738 cases (46.89% reported SARs),
- **Transfusion related acute lung injury** (TRALI): 66 cases (4.19% reported SARs),
- **Transmitted infections**: 20 cases (1.27% of reported SARs), of which:
    - 18 cases of bacterial infections (1.14%),
    - 1 case of viral infection (not specified) (0.06%), and
    - 1 case of parasitical infection (malaria) (0.06%),

    This number concerns infectious agents that were present in the final preparation and transfused to the patient. It should be noted that safety and quality measures from donation to transfusion eliminate the vast majority of infectious agents at earlier stages.

Figure 5: Percentage of SARs per category.



- **Post transfusion purpura**: 6 cases (0.38% reported SARs),
- **Graft versus host disease**: 1 case (0.06% reported SARs),
- **Other SARs**: 585 cases (37.17% of reported SARs). This category includes:
    - 269 cases of febrile non-haemolytic transfusion reaction (17.09%),
    - 7 cases of hypotension (0.56%),
    - 153 cases of transfusion associated circulatory overload (TACO) (9.72%),
    - 70 cases of transfusion associated dyspnea (TAD) (4.45%), and
    - 40 cases of respiratory disorders other than TRALI (2.54%).

2.4. Serious Adverse Events (SAEs)

2.4.1. Information by country

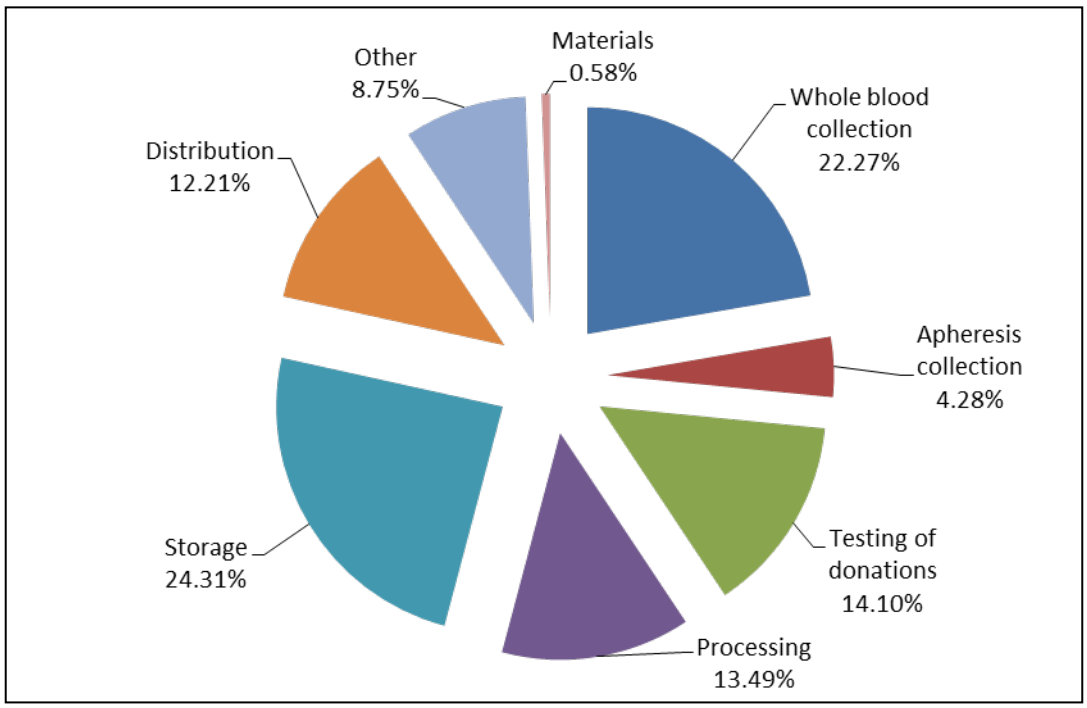
SAEs were reported by 22 Member States (AT, BE, BG, CZ, DK, EE, EL, ES, FI, FR, IE, IT, LT, LV, MT, NL, PL, RO, SE, SI, SK and UK), Croatia, Liechtenstein and Norway. The total number of SAEs reported for 2011 was 4,113 (some countries reported that no SAEs had occurred).

2.4.2. Information by type of SAE

The 4,113 SAEs reported were linked to the following activity steps:

- **Whole blood collection**: 916 SAEs (22.27%),
- **Apheresis collection**: 176 SAEs (4.28%),
- **Testing of donations**: 580 SAEs (14.10%),
- **Processing**: 555 SAEs (13.49%),
- **Storage**: 1,000 SAEs (24.31%),
- **Distribution**: 502 SAEs (12.21%),
- **Materials:** 24 SAEs (0.58%), and
- **Other activity steps:** 360 events (8.75% reported SAEs). This category includes 'unspecified events', 'compatibility testing', 'transport', and 'bacterial contamination'.

Figure 6: Serious adverse events by activity step.

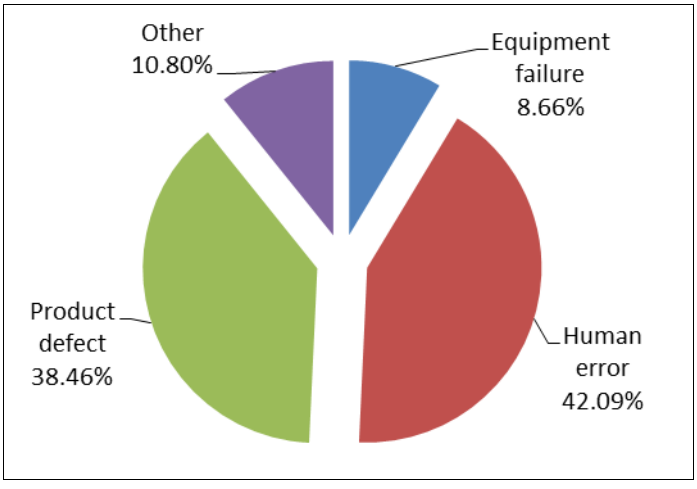


2.4.3. Information by specification of SAE

The 4,113 SAEs were attributed to one of the following specifications:

- **Human Error**: 1,731 SAEs (42.09%)
- **Equipment failure**: 356 SAEs (8.66%)
- **Product defect**: 1,582 SAEs (38.46%)
- **Other:** 444 SAEs (10.80%), including 'organisational errors' and 'classification problems'.

Figure 7: Serious adverse events per specification.



3. TOWARDS AN IMPROVED REPORTING IN 2013

A revised version of the 'Common approach for definition of reportable serious adverse events and reactions' has been developed by the Commission, together with the Haeomovigilance Working Group, before the launch of the 2013 SARE reporting exercise.

The PDF reporting template for the 2013 reporting exercise (for data reported in 2012) has also been revised and refined. Some of the changes include collection of data on denominator totals, the addition of a dedicated section for more than one blood component, and the removal of classification A/B for imputability levels 2-3.

4. CONCLUSION

The number of SARs (level 2-3) reported for 2011 seems to be low (1,574), especially when compared to the number of units of blood components transfused in the EU (13 SARs per 100,000 units transfused or 7,822 units transfused per SAR). This figure is however higher than that reported in 2010, but, considering that the data reported in 2010 and 2011 was partial, it is not possible to draw conclusions from year on year comparisons.

For SAEs, the reported figures also seem to be low (4,113), (16.5 SAEs per 100,000 units issued or 6,035 units issued per SAE) and are lower than previous years. This may indicate improvements in the classification of serious adverse events as well as improvements in data collection.

Although work to improve data collection and reliability is continuous, this exercise shows that improvements can be and have been made. Ultimately the collection of robust and reliable date will allow individual countries to better evaluate the safety of their national blood sectors and identify where quality issues occur, improving the safety and quality of blood in the EU.