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SUMMARY OF THE 2011 ANNUAL REPORTING OF SERIOUS ADVERSE EVENTS AND REACTIONS (SARE) FOR BLOOD AND BLOOD COMPONENTS (DATA COLLECTED FROM 01/01/2010 TO 31/12/2010)

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 2010 (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 2011 (for 2010 data) was version 2.1.

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 2011, version 2.1 of the Common Approach document was available to those reporting SARE 2010 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 2010 DATA COLLECTION

2.1. General comments

The first reporting exercises have shown that data collection is 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 over the years, the data presented here is considered partial and should therefore be interpreted with caution.

Responses were received from all EU27 Member States, Croatia, Liechtenstein and Norway. For most countries, the number of SARs/SAEs was reported, but in some cases the number of blood components issued and/or transfused was not included, raising questions about availability and accuracy of data.

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, 16,718,258 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 19 countries (AT, BE, BG, CZ, DK, ES, FR, IE, IT, LT, MT, NL, NO, PL, PT, RO, SE, SK, UK) reported this figure (for any blood component). The breakdown by component is shown below.

Figure 1: Units transfused per blood component ('Other' refers to 'more than one component', granulocytes, and cryoprecipitates).

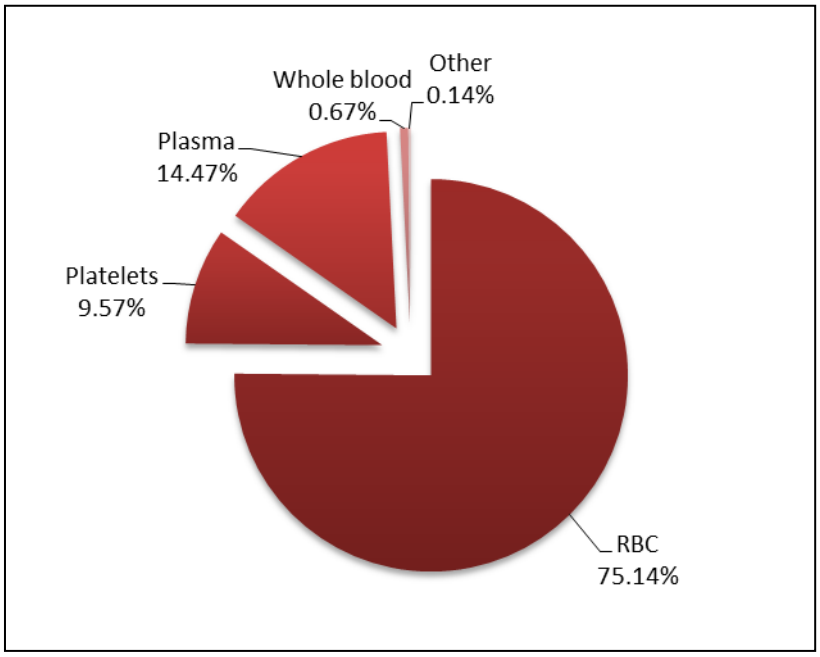
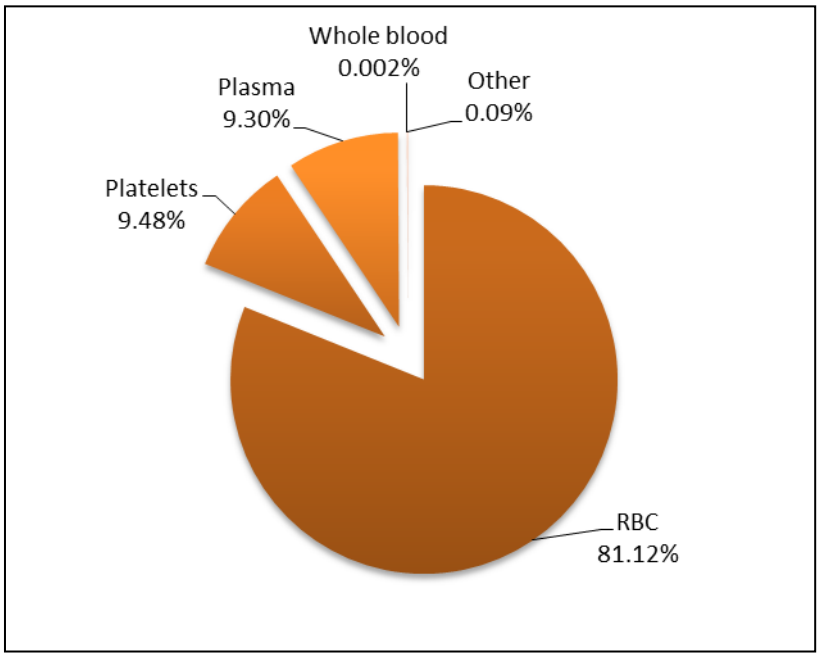
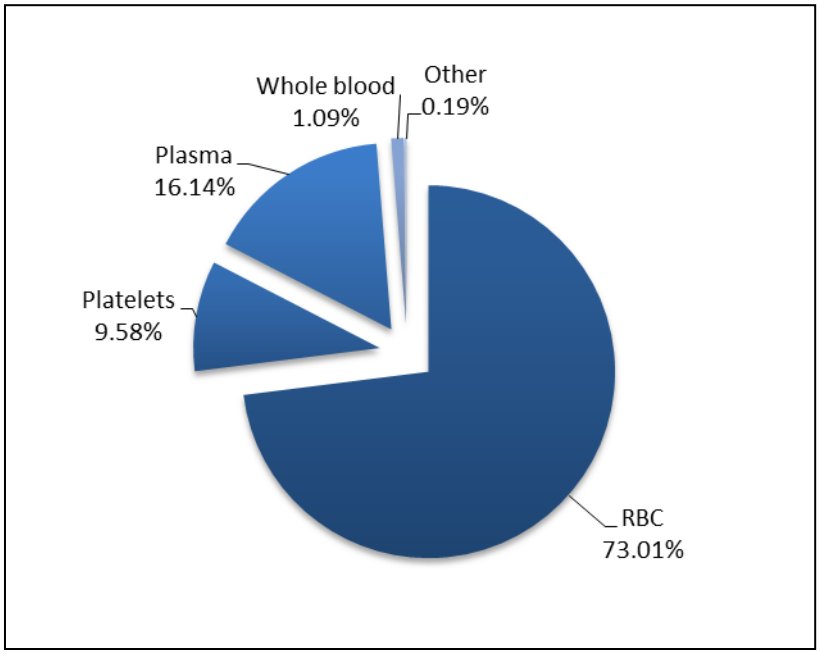


Figure 2: Recipients per blood component (BE, CZ, IE, MT, PT, and the UK provided per component data, totalling 707,732 recipients) ('Other' refers to 'more than one component', granulocytes, and cryoprecipitates).



According to the reports, 2,298,304 recipients (patients) were transfused in 2010. As mentioned above, these are partial figures, only eleven countries (BE, CZ, FR, IE, IT, LT, MT, PT, RO, SE, and UK) provided data on both units transfused and the number of recipients of blood. Eight countries only provided data about units of blood components transfused (AT, BG, DK, ES, NL, NO, PL, and SK). The eleven remaining countries (CY, DE, EE, EL, FI, HR, HU, LI, LU, LV, and SI) did not provide any data for units transfused or the number of recipients. The breakdown by component is shown above.

Figure 3: Units issued per blood component ('Other' refers to 'more than one component', granulocytes, and cryoprecipitates).



Twenty-four EU Member States (AT, BE, BG, CY, CZ, DE, DK, EL, ES, FI, FR, HU, IE, LT, LU, LV, MT, NL, PL, RO, SE, SI, SK, and UK), Croatia and Norway provided data regarding units of blood components issued in 2010. Overall, a total number of 22,817,166 units of blood were issued in 2010. The breakdown by component is shown above.

2.3. Serious Adverse Reactions (SARs)

2.3.1. Information by country

In 2010, a total of 1,259 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 7.5 SARs per 100,000 units transfused or conversely 13,279 units transfused per SAR (16,718,258 units were reported as transfused in 2010). This figure should, however, be interpreted with caution. This is an over-estimation of the number of SARs per units transfused, because not all countries provided data for units transfused, due to collection difficulties in some Member States.

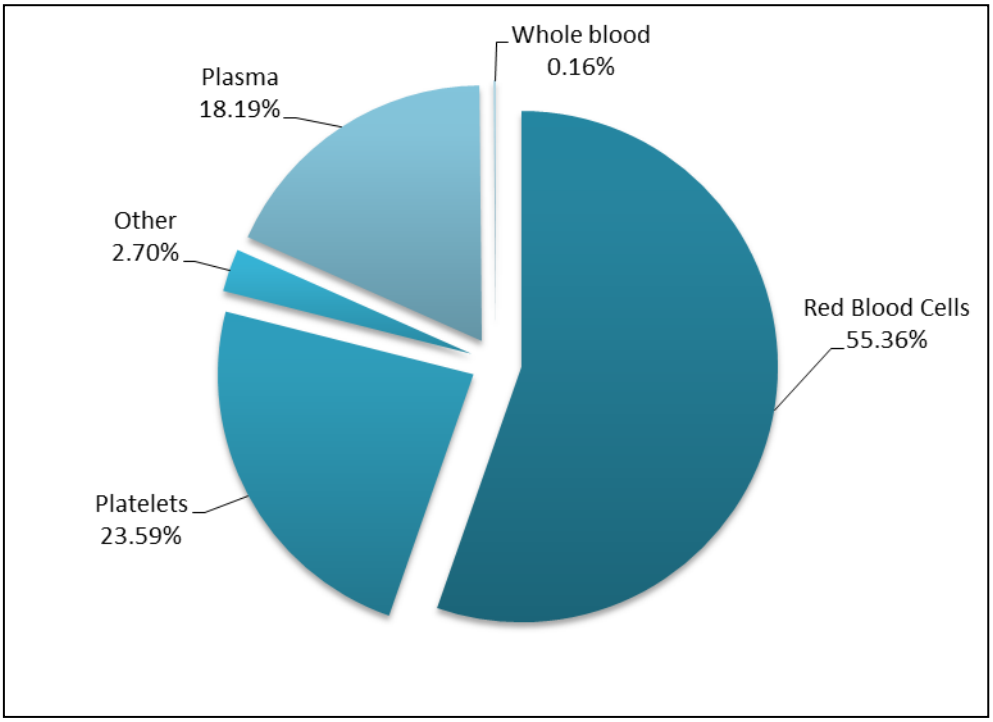
Seven countries (BG, CZ, EE, LI, LV, RO, and SK) did not report any SARs related to the quality and safety of blood products in 2010 (at imputability level 2-3). Where SARs and units transfused were reported, the number of units transfused per SAR (at imputability level 2-3) ranged from 1,725 to 175,330 across countries. These figures should, however, 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, as well as a lower number of SARs resulting from under-reporting.

2.3.2. Information by blood component

Of the 1,259 level 2-3 SARs reported:

- 697 SARs were related to **red blood cells**,
- 297 SARs were related to **platelets**,
- 229 SARs were related to **plasma**,
- 2 SARs were related to **whole blood**, and
- 34 SARs were related to '**other components**' (i.e. 'more than one component', granulocytes, or cryoprecipitates).

Figure 4: Percentage of SARs per blood component.

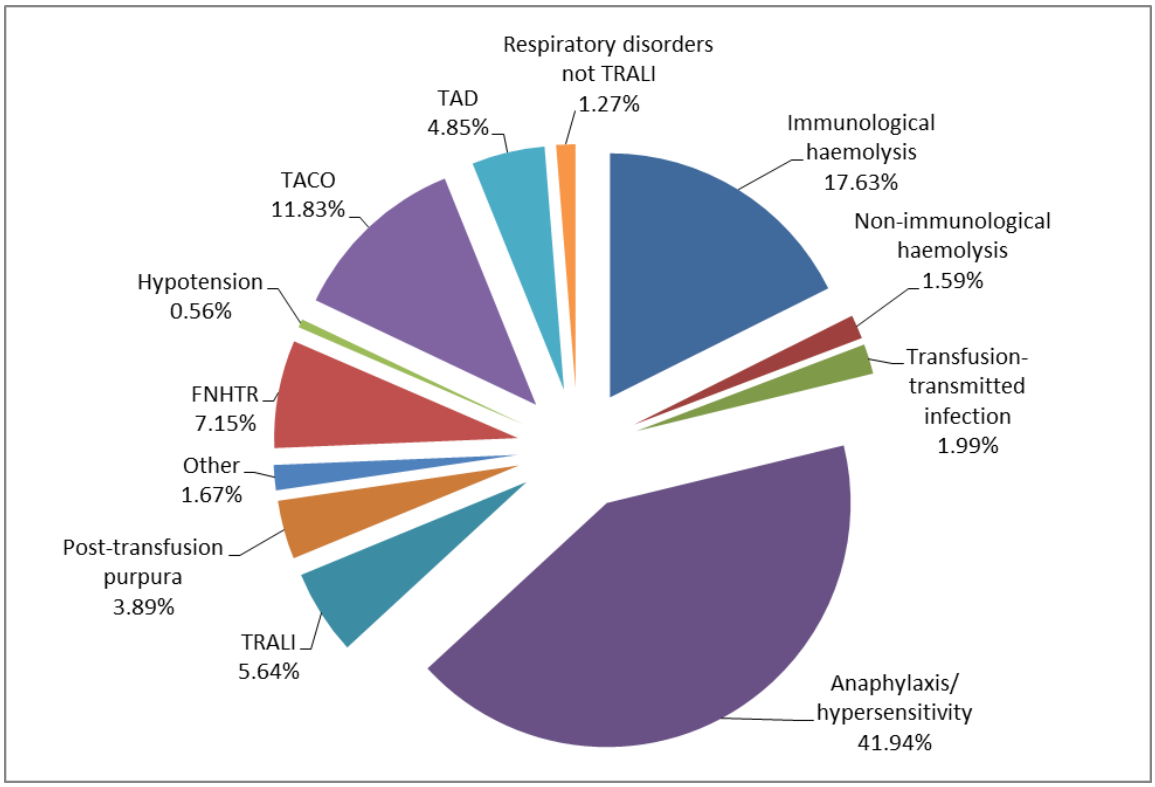


2.3.1. Information by category of SAR

The 1,259 SARs (level 2-3) reported were classified as follows:

- **Immunological haemolysis**: 222 cases (17.63% reported SARs), of which
    - 66 cases due to ABO antibody (5.24%), and
    - 156 cases due to other allo-antibodies (12.39%),
- **Non-immunological haemolysis**: 20 cases (1.59% reported SARs),
- **Anaphylaxis/hypersensitivity**: 528 cases (41.94% reported SARs),
- **Transfusion related acute lung injury** (TRALI): 71 cases (5.64% reported SARs),

Figure 5: Percentage of SARs per category.



- **Transmitted infections**: 25 cases (1.99% of reported SARs), of which:
    - 15 cases of bacterial infections (1.19%), and
    - 10 case of viral infection (0.79%), of which:
        - 6 cases Hepatitis B (0.477%), 2 cases Hepatitis C (0.159%), 1 case HIV (0.079%), and 1 case CMV (0.079%),

  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.

- **Post transfusion purpura**: 49 cases (3.89% reported SARs),
- **Other SARs**: 344 cases (27.32% of reported SARs). This category includes:
    - 90 cases of febrile non-haemolytic transfusion reaction (7.15%),
    - 7 cases of hypotension (0.56%),

- 149 cases of transfusion associated circulatory overload (TACO) (11.83%),
- 61 cases of transfusion associated dyspnea (TAD) (4.85%), and
- 16 cases of respiratory disorders other than TRALI (1.27%).

2.4. Serious Adverse Events (SAEs)

2.4.1. Information by country

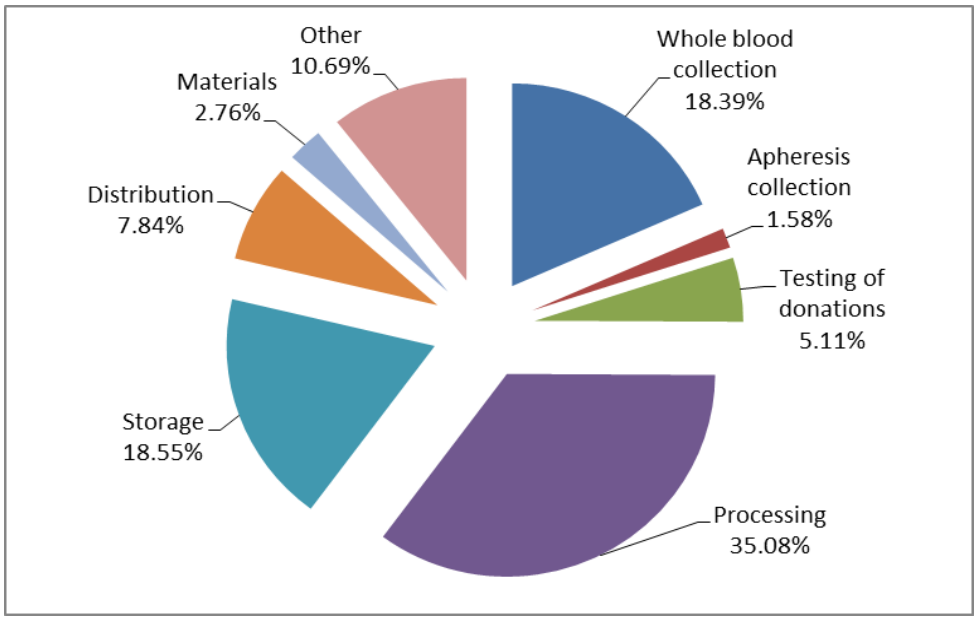
SAEs were reported by 25 Member States (AT, BE, BG, CY, CZ, DE, DK, EE, EL, ES, FI, FR, IE, IT, LT, LU, LV, MT, NL, PL, PT, RO, SE, SI, and UK), Croatia, Liechtenstein and Norway. The total number of SAEs reported for 2010 was 16,360 (some countries reported that no SAEs had occurred). It should be noted that many of these events may reflect difficulties for reporting establishments in distinguishing between adverse events and 'serious' adverse events.

2.4.2. Information on SAEs by activity step

The 16,360 SAEs reported were linked to the following activity steps:

- **Whole blood collection**: 3,009 SAEs (18.39%),
- **Apheresis collection**: 258 SAEs (1.58%),
- **Testing of donations**: 836 SAEs (5.11%),
- **Processing**: 5,739 SAEs (35.08%),
- **Storage**: 3,035 SAEs (18.55%),
- **Distribution**: 1,283 SAEs (7.84%),
- **Materials**: 451 SAEs (2.76%), and
- **Other activity steps**: 1,749 events (10.69% reported SAEs). This category includes unspecified events, microbial contamination, transport, and lab errors.

Figure 6. Serious adverse events by activity step.



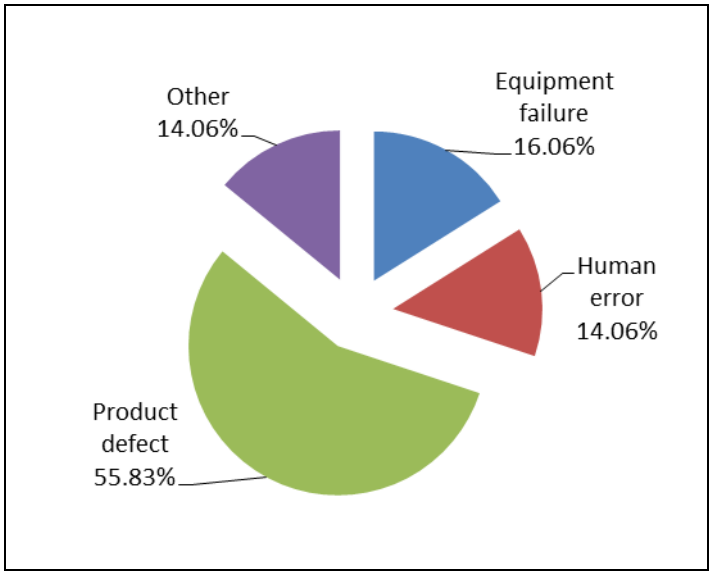
2.4.3. Information by SAE specification

The 16,360 SAEs were attributed to one of the following specifications:

- **Human Error**: 2,300 SAEs (14.06%)
- **Equipment failure**: 2,627 SAEs (16.06%)
- **Product defect:** 9,133 SAEs (55.83%)

  Other: 2,300 SAEs (14.06%), including 'power loss', 'expired components' and incomplete 'collection'.

Figure 7: Serious adverse events per specification.



3. TOWARDS IMPROVED REPORTING IN 2012

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, before the launch of the 2012 SARE reporting exercise.

The PDF reporting template for the 2012 reporting exercise (for data reported in 2011) was also revised and refined. Some of the changes included collection of data on completeness, dedicated sections for each blood component, and more specific SAE categories.

4. CONCLUSION

The number of SARs (at imputability level 2-3) reported for 2010 is low (1,259), especially when compared to the number of units of blood components transfused in the EU (7.5 SARs per 100,000 units transfused or 13,279 units transfused per SAR).

For SAEs, figures are higher (16,360), which is probably the result of difficulties for reporting establishments in distinguishing between all adverse events and 'serious' adverse events. This data should, however, be interpreted with caution as many countries have difficulties collecting accurate data for both SARs/SAEs and denominators (units issued, units transfused and recipients).

Although data collection has improved considerably, further work is still necessary to ensure that countries provide reliable, accurate and complete data. The European Commission and Member States are continuously working to improve data collection, and assist those countries which have difficulties in collecting reliable data.

Ultimately, improved data collection and reporting will allow countries to better understand and address safety and quality issues in the blood sector, helping to improve the safety of blood transfusion across the EU.