Definitions, SAE in blood establishments

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Serious adverse event: definition

EU Directive 2002/98/EC

Any untoward occurrence associated with the collection, testing, processing, storage and distribution, of blood and 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.

Reportable: SAE which may affect the Q or S of blood (components).

(Donors not included)

Some possible definitions of a reportable SAE

1. Any untoward occurrence (error, quality deviation or accident) from collection to distribution, that may lead to harm of the patient?
2. The release of a blood component, that did not fulfill the Q and S requirements?
3. The distribution of a blood component, that did not fulfill the Q and S requirements?
4. The use of a blood component, that did not fulfill the Q and S requirements?
5. An event that could have (had) implications for other patients due to a procedural or a technical problem?
6. An event that might put the live of a donor in danger?
7. An event that could have (had) implications for other donors due to a procedural or a technical problem?
8. Or combinations of these?

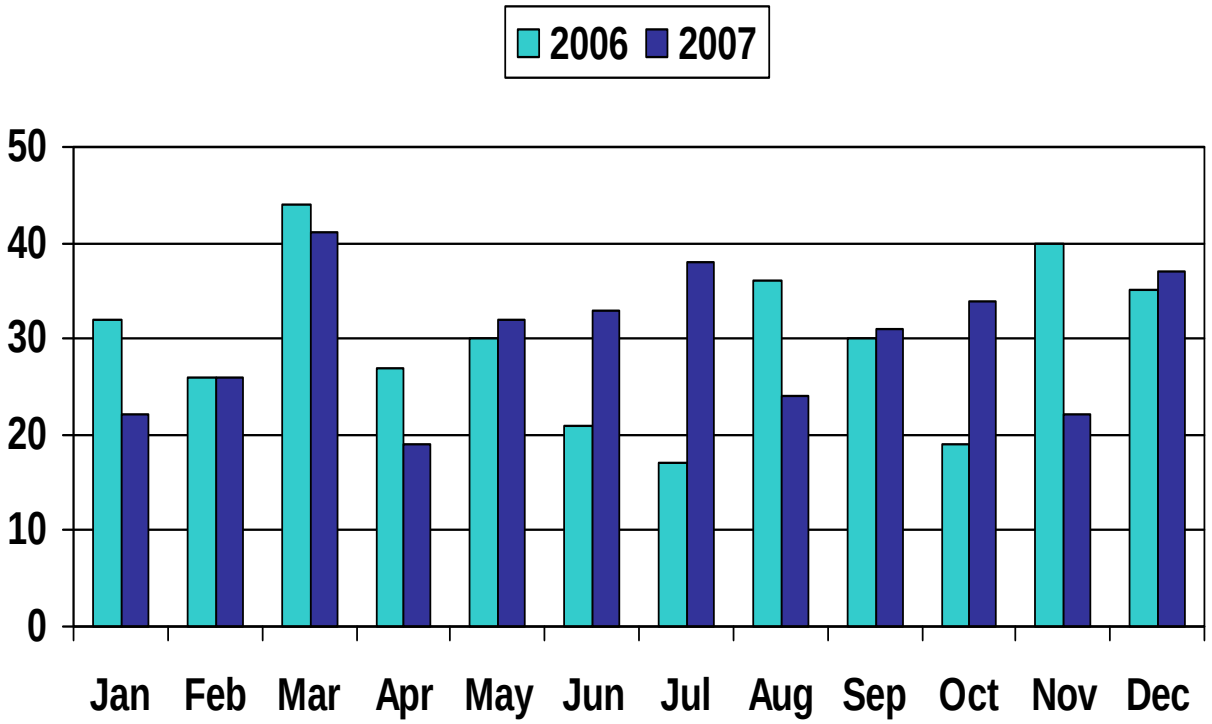
Two year reporting in Belgium using the following definitions for SAE

1. The distribution of a blood component, that did not fulfill the Q and S requirements (but was not used).
2. The use of a blood component, that did not fulfill the Q and S requirements.
3. An event that could have (had) implications for other patients due to a procedural problem of the release proces.
4. An event that might put the live of a donor in danger.

The SAE's were classified on where these occurred and their type

1. Donor suitability
2. Blood collection
3. Laboratory testing
4. Blood processing
5. Labeling
6. Storage
7. Release
8. Distribution
9. Material (includes informatics).
10. Other

Reporting of serious adverse events
(nr/month)



Type of serious adverse events

SAE type	2006*	2007*
1. Use of BC	276 (83.6 %)	228 (71.5 %)
2. Near miss	57 (16.4 %)	78 (26.0 %)
3. Release process	0	0
4. Donor in danger	0	11 (2.5 %)
Total	330 (100 %) **(49.3/100.000 donations)****	319 (100 %) **(47.6/100.000 donations)****

* After exclusion of non-serious adverse events

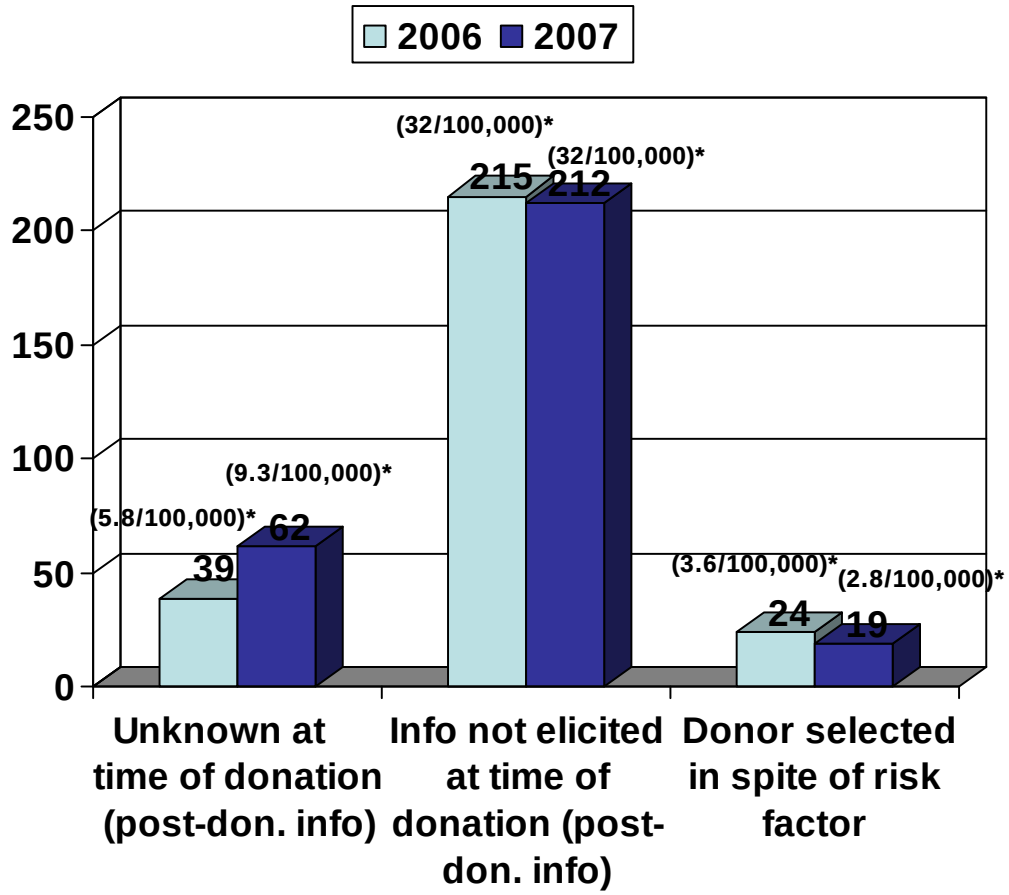
** 670.000 donations

Type of errors or quality deviations, that led to the events, based on where these occurred

Activity	Number of errors or quality deviations (type)	
1. Donor suitability	278 (NM 44)	263 (NM 60; DON 5)
2. Blood collection	0	11 (NM 3; DON 6)
3. Laboratory testing	1	0
4. Blood processing	0	2 (NM 1)
5. Labeling	4 (NM 4)	5 (NM 5)
6. Storage	0	0
7. Release	0	2
8. Distribution	9 (NM 9)	8 (NM 5)
9. Material (incl. informat.)	0	0
10. Other	38 (31 bact. scr. +)	28 (23 bact. scr. +)

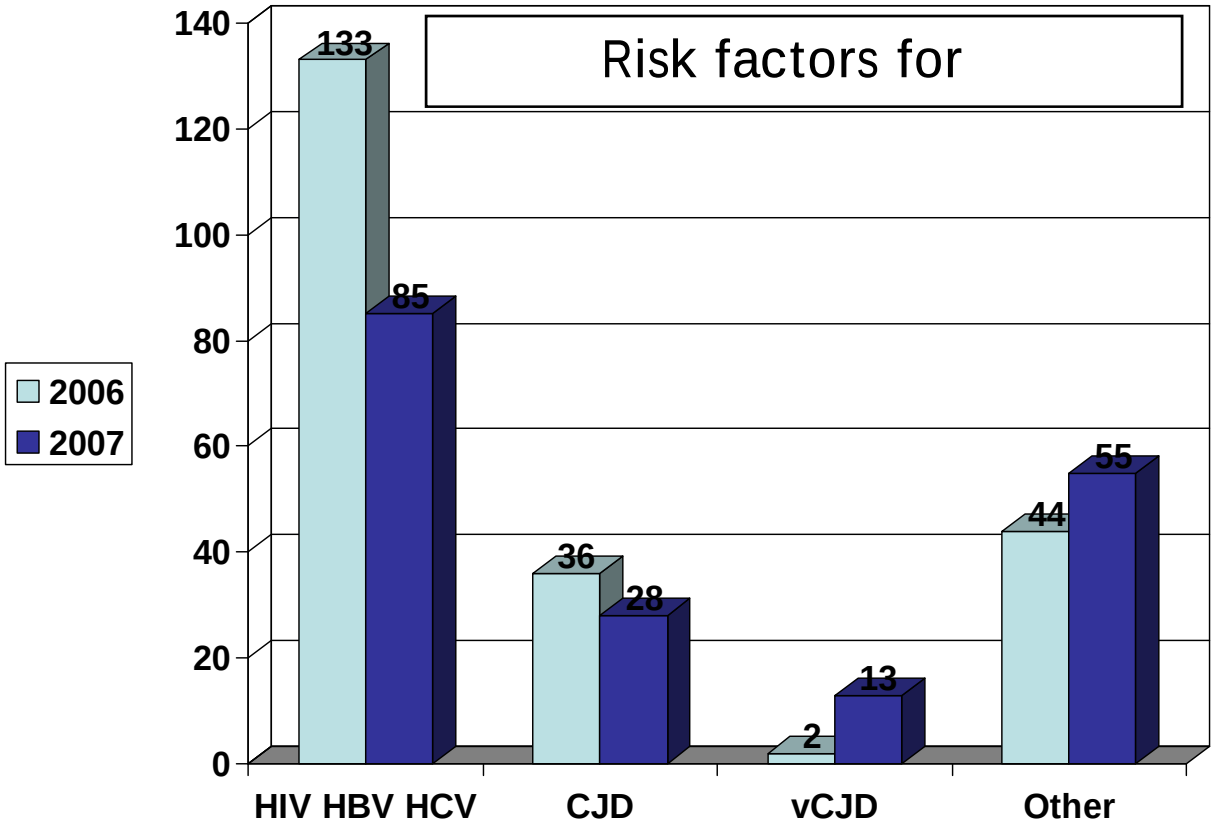
NM: NEAR MISS. DON: donor in danger;

1.Donor suitability: risk factor at time of donation

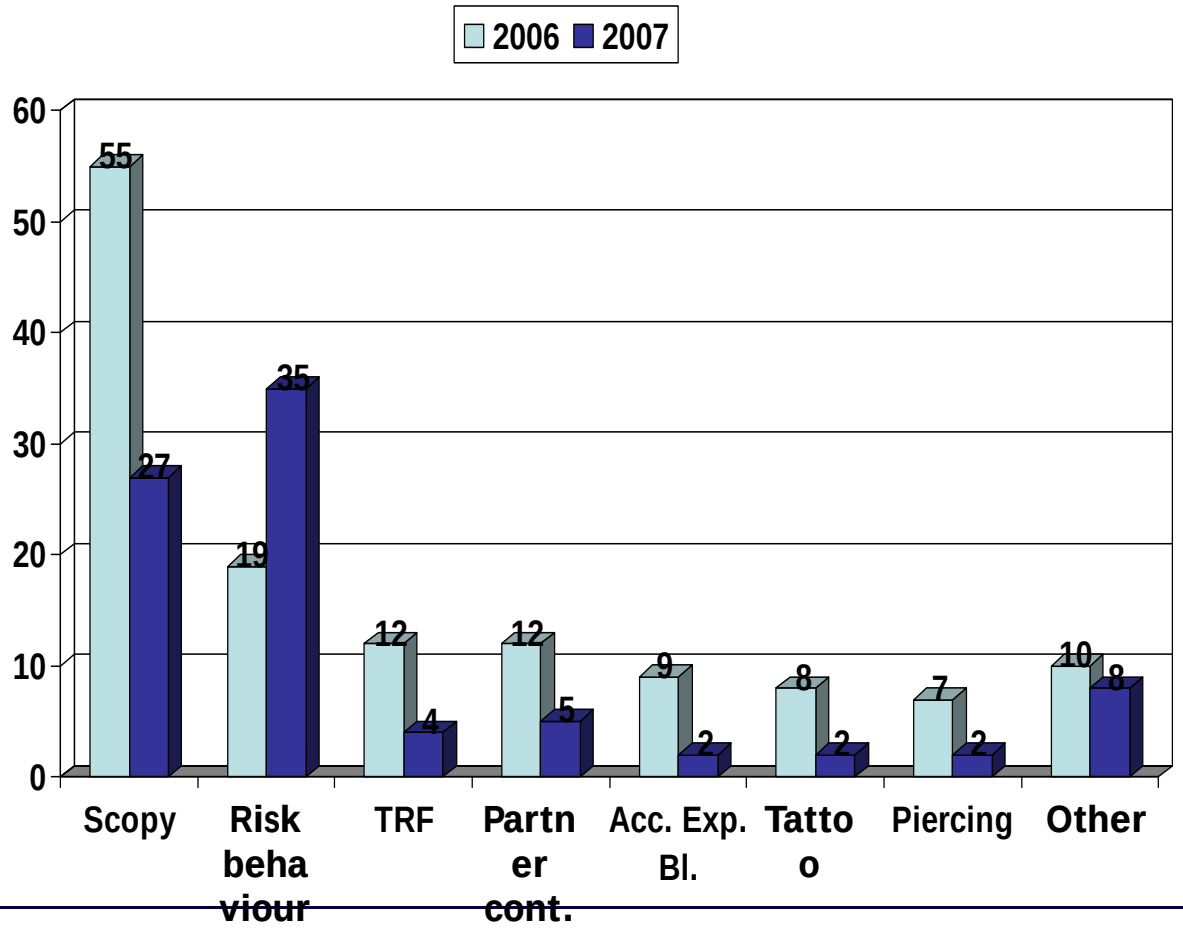


*670,000 donations/year

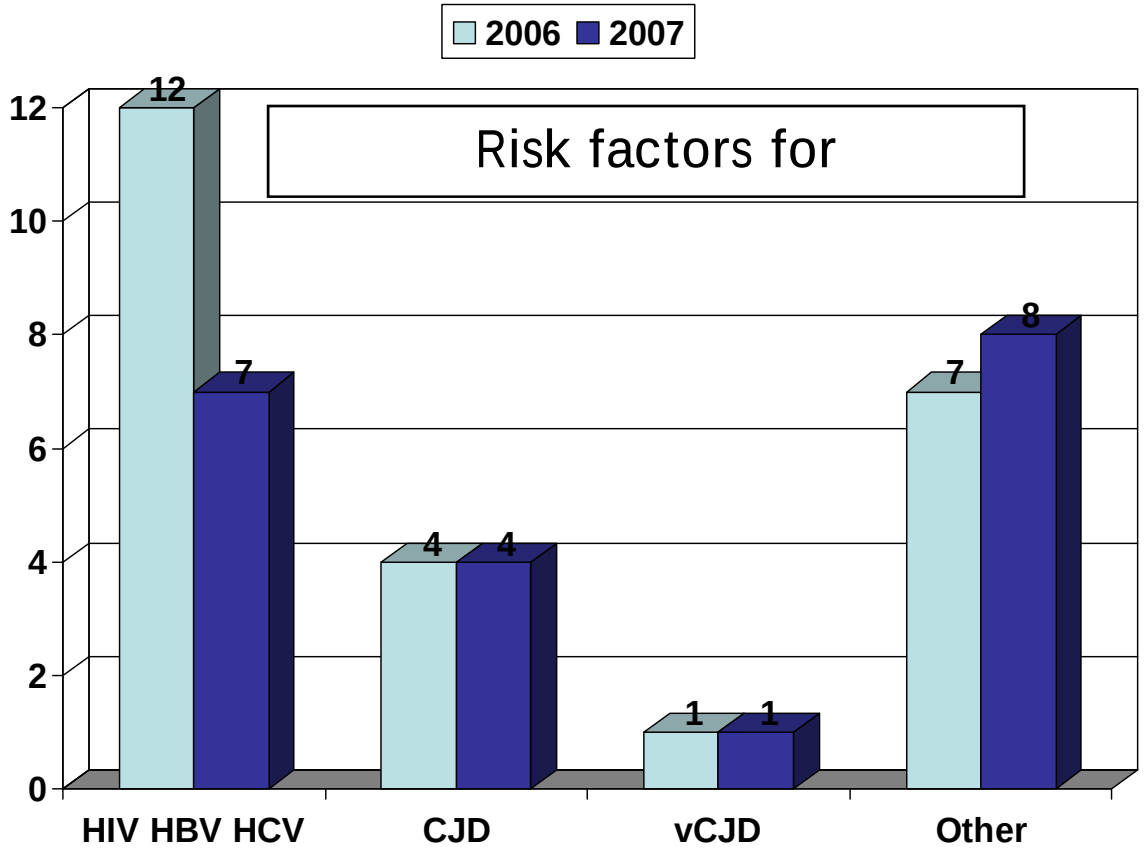
1.2. Post-donation information that was known by the donor but was not elicited at the time of the donor screening.



1.2. The donor notifies post donation a risk factor for AIDS/HBV/HCV.



1.3. Donor selection: The donor did not fulfill the relevant donor selection criteria but was accepted in spite of this.



Events that might put the live of a donor in danger

1. Donor suitability
   - **Epilepsy** **2**
   - **Ablatio for arrythmia** **1**
   - **Coagulation disorder** **1**
   - **Cerebral thrombosis** **1**
2. Blood collection

- Whole blood collection:
  - **Excessive volume collected** **3**
  - **Whole blood collected instead of a blood sample** **1**
- Plasmapheresis:
  - **Confusion of citrate and NaCl solutions** **2**

Total **11**

Conclusion:

Reportable SAE should be:

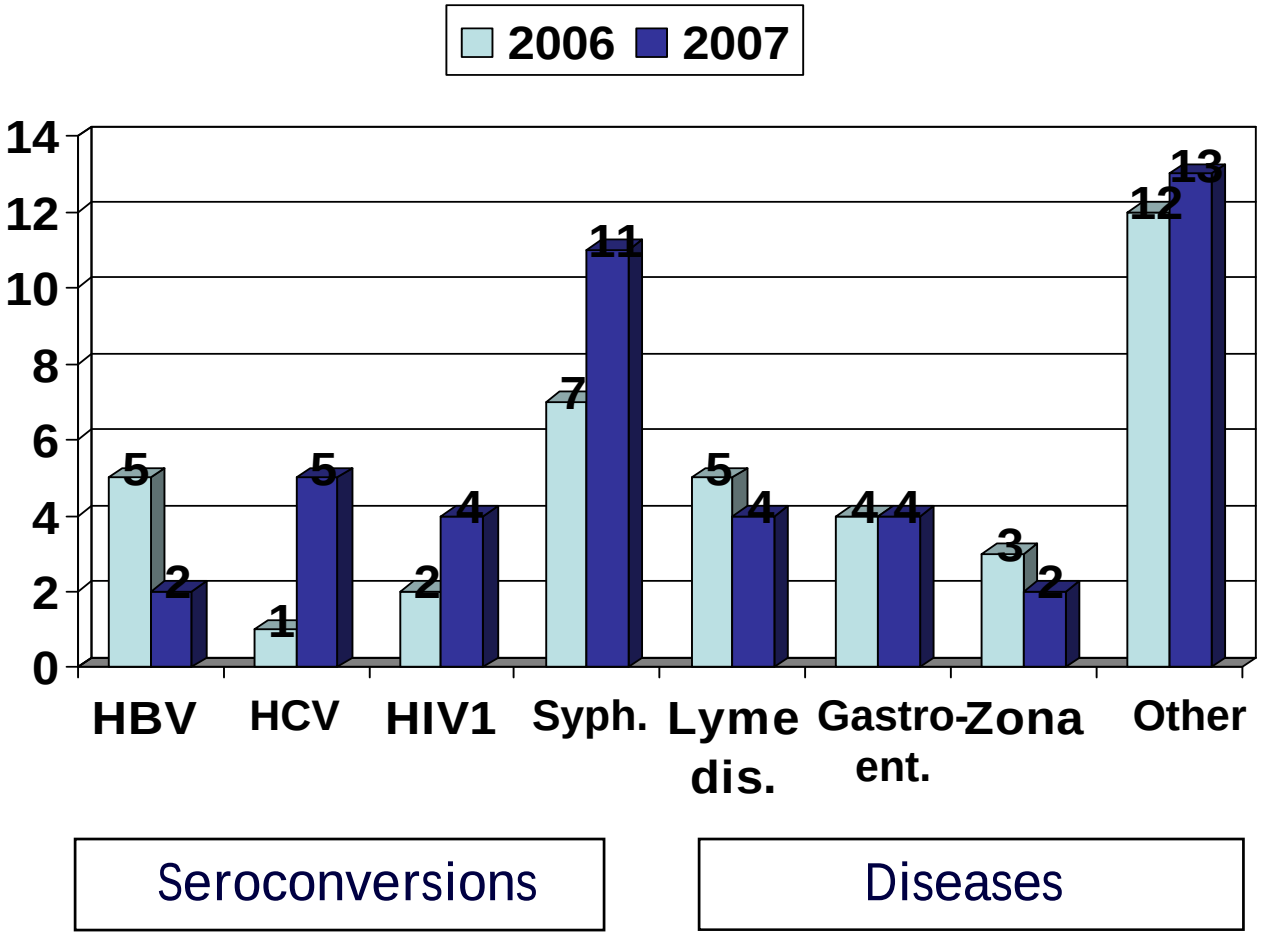
- *clearly defined.*
- *limited to the ones that slip through the barriers.*
- *standardised.*

Results of two year reporting indicate that standardised definitions of reportable SAE:

- *make possible stable reporting.*
- *provide an estimation of non-conformity of distributed BC.*
- *allow comparison of data.*
- *help to evaluate effect of modified procedures/training.*

THANK YOU

1.1. Post-donation information unknown at the time of the donor screening



Administration of components not fulfilling donation criteria

Risk factor at time of donation	Donations			Time between donation and info about risk factor
	Year.	Total Number	Used %	Median (range)
1. Unknown at time of donation (post-donation info)	2006	24	33 %	4.5 d (1 d – 3 mo)
	2007	33	43 %	7 d (1 d – 2 mo)
2. Not elicited at time of donation (post-donation info)	2006	215	95 %	3 mo (3 d – 12 y)
	2007	212	94 %	3 mo (2 d – 10 y)
3. Donor selected in spite of risk factor	2006	24	92 %	4 mo (5d – 6 y)
	2007	19	90 %	3 mo (1d – 11y)