What to report to the Commission

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The legal context

- Article 8 of Directive 2005/61/EC: the Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse events and reactions received by the competent authority.

- First reporting to the Commission: 30 June 2008, concerning information collected during the complete year 2007

- For reporting the formats in Part D of Annex II and Part C of Annex III of Directive 2005/61/EC have to be used.

The SAR reporting format

PART D

Annual notification format for serious adverse reactions

Reporting establishment

Reporting period

This Table refers to [ ] Whole blood [ ] Red blood cells [ ] Platelets [ ] Plasma [ ] Other *(use separate table for each component)*	Number of units issued (total number of units issued with a given number of blood components)
	Number of recipients transfused (total number of recipients transfused with a given number of blood components) *(if available)*
	Number of units transfused (the total number of blood components (units) transfused over the reporting period) *(if available)*

	Total number reported	Number of serious adverse reactions with imputability level 0 to 3 after confirmation (see Annex IIA)				
	Number of deaths	not assessable	Level 0	Level 1	Level 2	Level 3

Immunological Haemolysis	Due to ABO incompatibility	Total					
		Deaths					
	Due to other allo-antibody	Total					
		Deaths					
Non-immunological haemolysis		Total					
		Deaths					
Transfusion-transmitted bacterial infection		Total					
		Deaths					
Anaphylaxis/hypersensitivity		Total					
		Deaths					
Transfusion related acute lung injury		Total					
		Deaths					
Transfusion-transmitted viral infection	HBV	Total					
		Deaths					
	HCV	Total					
		Deaths					
	HIV-1/2	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					
Transfusion-transmitted parasitical infection	Malaria	Total					
		Deaths					
	Other *(specify)*	Total					
		Deaths					

The SAE reporting format

PART C

Annual Notification Format for Serious Adverse Events

Reporting establishment	
Reporting period	1 January-31 December *(year)*
Total number of blood and blood components processed:	

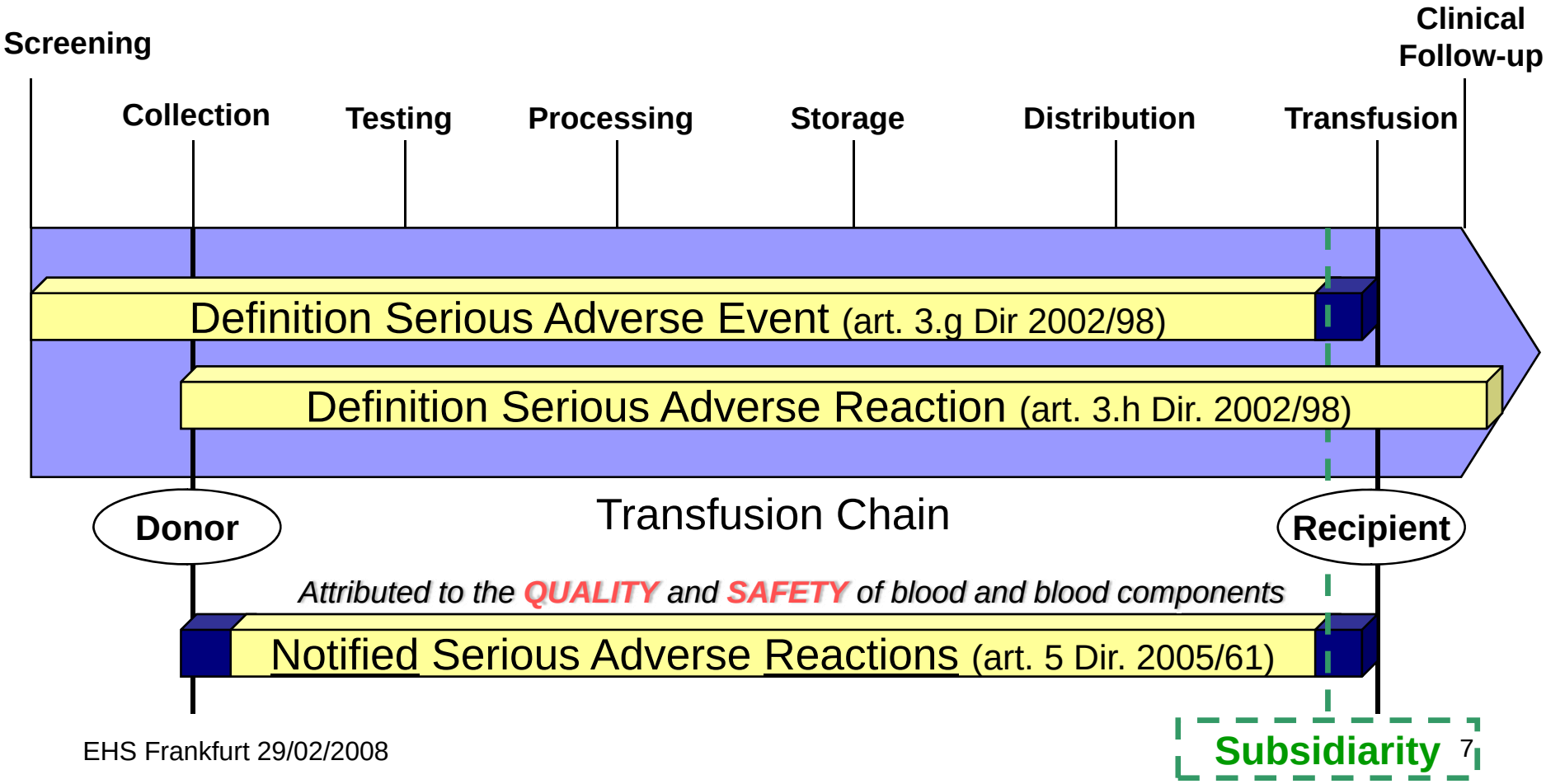
Serious adverse event, affecting quality and safety of blood component due to a deviation in:	Total number	Specification			
		Product defect	Equipment failure	Human error	Other *(specify)*
Whole blood collection					
Apheresis collection					
Testing of donations					
Processing					
Storage					
Distribution					
Materials					
Others *(specify)*					

Common approach

- Need to clear up as much as possible questions IN ADVANCE to the first collection (learning exercise during the coming years).
- MS agreed with the Commission's proposal for a common approach (scope and definitions) regarding the information to report.
- During the last meeting of competent authorities a working group on SAR and SAE was created.
- Finalisation of the common approach by the Commission June 2008.

Scope

SAR and SAE
Scope of the Blood Directive



Reportable SAR and SAE

- Donor reactions (complications): not included. Reporting on a voluntary basis.
- SAR attributable to Q/S blood: ABO haemolytic reaction not due to Q or S of the blood: not covered?
- SAE reported by hospital blood banks (HBB): covered?
- Secondary blood storage areas (isolated fridges) in hospitals covered?
- SAE occurring after issue of blood (at bedside): not covered?
- SAE related to compatibility testing: erroneous blood sample, error in testing blood sample, mislabeling?: covered if SAE concerns blood and error made before issue.

Definitions

Denominators

This Table refers to [ ] Whole blood [ ] Red blood cells [ ] Platelets [ ] Plasma [ ] Other *(use separate table for each component)*	Number of units issued (total number of units issued with a given number of blood components)
	Number of recipients transfused (total number of recipients transfused with a given number of blood components) *(if available)*
	Number of units transfused (the total number of blood components (units) transfused over the reporting period) *(if available)*

Nr of units issued:

- overall volume of units which is circulated from the HBB.
- total nr of units sent out definitively from the HBB.

Nr of recipients transfused:

- transfused with at least one unit during the reported year.
- at least one unit during a given hospitalisation period.
- absolute nr of transfusions done in a hospital.

Serious adverse reactions
(working document)

Directive 2005/61/EC categories	Reportable reactions
Immunological Haemolysis Due to ABO incompatibility	•Acute haemolytic transfusion reaction (AHTR) due to ABO-incompatibility (ISBT definition)
Immunological Haemolysis Due to other allo-antibody	•Acute haemolytic transfusion reaction (AHTR) due to irregular antibodies (ISBT definition) •Delayed haemolytic Transfusion Reaction (DHTR) due to irregular antibodies (ISBT definition)
Non-immunological haemolysis	Haemolytic Transfusion Reaction (HTR) due to physical, chemical or biological (but non-immune) reasons
Anaphylaxis / Hypersensitivity	■Severe allergic reaction (ISBT definition)
Transfusion Related Acute Lung Injury (TRALI)	TRALI (ISBT definition)
Transfusion transmitted bacterial infection	T-t BI (SHOT definition)
Transfusion-transmitted viral Infection (Others)	T-t viral infection (SHOT definition)
Transfusion-transmitted parasitical infection (Others)	T-t parasitical infection (SHOT definition)
Post-transfusion purpura	PTP Post Transfusion Purpura (ISBT definition)
Graft versus host disease	Transfusion associated Graft versus host disease (TA-GVHD) (ISBT definition)
Other serious reactions *(Specify)*	■Febrile non haemolytic Transfusion Reactions (FNHTR) (ISBT definition) ■Severe reaction due to Transfusion associated Dyspnea (TAD) (ISBT Definition) •Severe reaction due to Hypotensive Transfusion Reaction (ISBT Definition) •Severe reaction due to Unclassified complication of transfusion (UCT) (ISBT Definition) •Severe reaction due to Transfusion associated circulatory overload (TACO) (ISBT definition), as well as cases occurring after 6 hours if clinically confirmed •Transfusion transmitted prion infecttion •Others

Serious adverse reactions

Definitions:

- As a starting point: available ISBT definitions should be used as references. These definitions may be subject o further refinement in 2008.
- For TTI: SHOT definitions (ISBT definitions not available).

Some questions:

- Non-immunological haemolysis: a reaction to the blood itself?
- Transfusion associated circulatory overload (TACO): not related to the Q or S of the blood.
- ABO haemolytic reaction not due to Q or S of the blood?
- SAR of low imputability?

Serious adverse events

Table with examples of events and how they should be classified according to the proposed format

Text 2

When·*,·this·means·that·the·event·can·fall·within·several·specification·categories¶

Serious·adverse·event,·affecting·quality·and·safety·of·blood·component·due·to·a·deviation·in:	**Specification**			
	Product·defect	Equipment·failure:·	Human·error	Other·(specify)
DEFINITIONS	Serious·Adverse·Event·which·is·mainly·linked·to·a·defect·of·the·blood·or·blood·components.· **Product·defect**:·blood·or·blood·component·which·does·not·meet·the·quality·and·safety·requirements·set·in·annex·V·of·the·Directive·2004/33/EC,·or·which·contain·(remaining)·contaminating·agents·despite·screening,·testing·and·processing·were·undertaken·properly.	Serious·Adverse·Event·which·is·mainly·linked·to·a·failure·of·the·equipment. **Equipment**:·any·material·used·at·any·stage·from·the·collection·to·the·distribution·of·blood·and·blood·components,·such·as·whole·blood·collection·machines,·blood·bags,·aphaeresis·kits·and·machines,·production·sets,·reagents,·test·kits,·bags·for·platelets·or·plasma·storage,·filters·for·leukocyte·reduction,·labelling·machines,·IT·systems,·etc.	Serious·Adverse·Event·which·is·mainly·linked·to·a·mistake/error·of·Human·nature. **Human·error**:·An·inappropriate·or·undesirable·human·decision·or·behaviour·that·reduces,·or·has·the·potential·for·reducing,·effectiveness,·quality,·safety,·or·system·performance.·It·can·be·e.g.·an·omission:·(forgetting·to·do·something,·or·just·leaving·it·out),·a·commission·(performing·an·act·incorrectly),·a·problem·in·sequence·(right·action,·wrong·order)·or·timing·(too·fast·or·too·slow).	Any·Serious·Adverse·Event·which·cannot·be·classified·in·the·already·listed·specifications.
Whole·blood·collection		→Problem·linked·to·the·collection·set·with·a·risk·for·the·quality·and·safety·of·blood·and·blood·components,·such·as·defect,·contamination,·peeling·of·labels. →Failure·of·linking·procedure·due·to·error·in·IT·system.· →Donor·record·review·incomplete·or·incorrect.·*	**Donor·selection** →Donor·not·compliant·with·inclusion·criteria·but·accepted·anyhow →Donor·record·review·incomplete·or·incorrect.·* **Blood·collection** →*Excessive·volume·collected·(e.g.·>·20%·total·blood·volume).·* →Erroneous·donor·data.·*	**Blood·collection** →Erroneous·donor·data.·*

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Serious adverse events

- SAE linked to a failure of the equipment: reportable? If they cause a SAE? If they do not: = device failure (med.dev.vigilance).
- False negative test result despite correct procedures followed: hemo/med.dev.vigilance.
- Release of a component that did not fulfill the release requirements: release not defined in EU Dir.
- Seroconversion?
- Quid reporting of SAE that would arise in hospital blood banks.
- Reportable: not detected by the QS and blood distributed?

Conclusion

- Common approach regarding information to report.
- Collection during the coming years: considered as a learning by experience exercise.