

10th European Haemovigilance Seminar (EHS)
February 28 Frankfurt/Main, Germany



EU BLOOD AND TISSUES DIRECTIVES

European Commission
Health and Consumer Protection Directorate General
Public Health and Risk Assessment Directorate
Health Measures Unit



Article 152 (4) (a)

4 ...Shall contribute to the achievement of the objectives referred to in this Articles through adopting:

(a) Measures setting high standards of quality and safety of organs and substances of human origin, blood and blood derivatives, these measures not prevent any member States from maintaining or introducing more stringent protective measures.



Legislation and policy on human substances

- Blood Directive (2002/98)
 - Three Commission Directives
 - Two Commission reports
- Tissues and Cells Directive (2004/23)
 - Two Commission Directives
 - Two Commission reports
- Open consultation on policy options on organ donation and transplantation (2006)
 - Communication in 2007

SoHO Committees/Groups

1. Regulatory Committee

- Working group on European Coding System
- Working group on Ethical related aspects

2. Meeting of Competent Authorities

- SAR/SAE reporting group

3. National Experts Technical Meetings

The blood and blood components Legal Framework

DIRECTIVE 2002/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 27 January 2003

setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC

Transposition deadline
8 February 2005

COMMISSION DIRECTIVE 2004/33/EC

of 22 March 2004

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards certain technical requirements for blood and blood components

(Text with EEA relevance)

Transposition deadline
8 February 2005

COMMISSION DIRECTIVE 2005/61/EC

of 30 September 2005

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

(Text with EEA relevance)

Transposition deadline
31 August 2006

COMMISSION DIRECTIVE 2005/62/EC

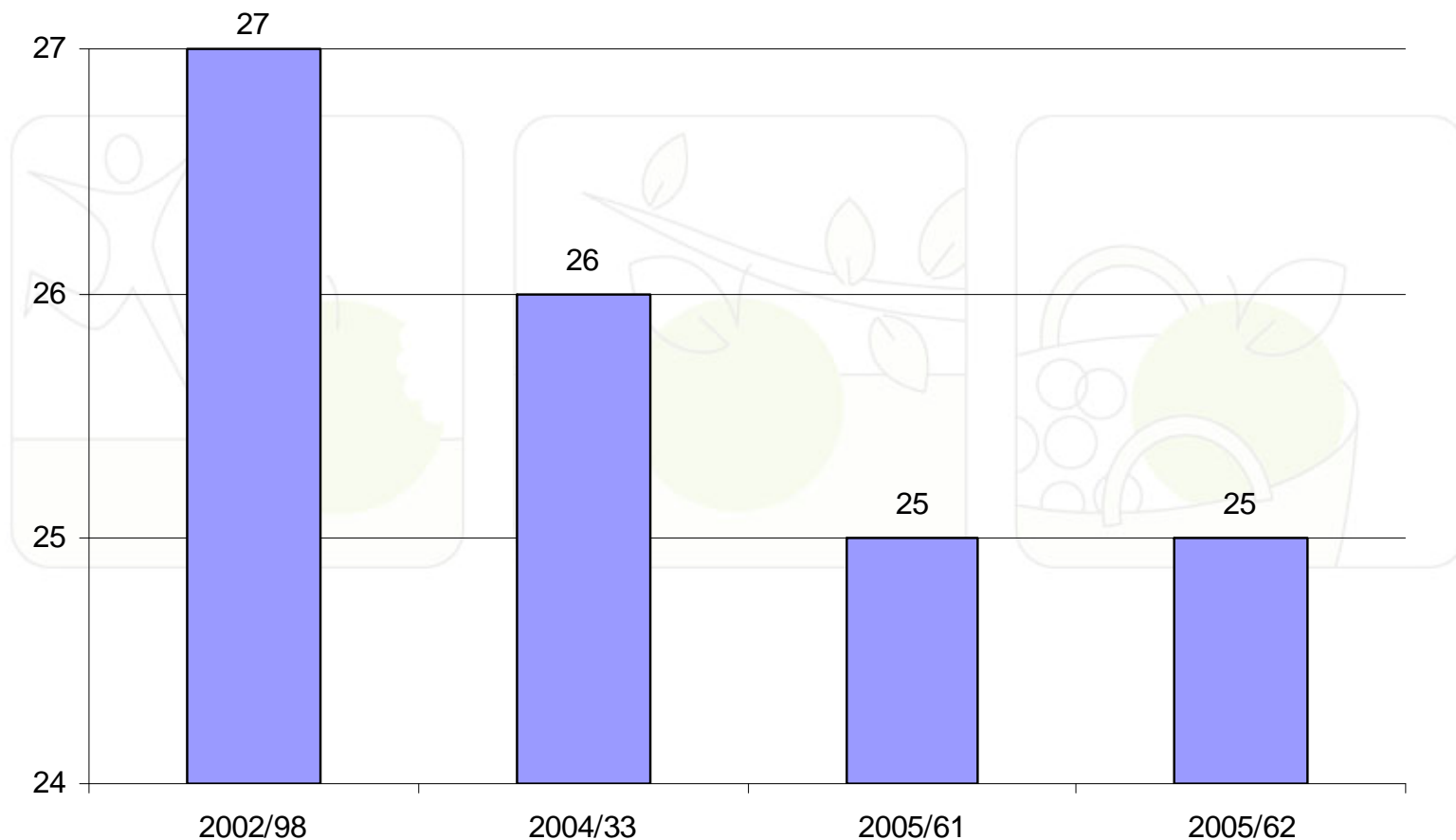
of 30 September 2005

implementing Directive 2002/98/EC of the European Parliament and of the Council as regards Community standards and specifications relating to a quality system for blood establishments

(Text with EEA relevance)

Transposition deadline
31 August 2007

TRANSPOSITION TO DATE (February 2008)



Notifications received by the Commission

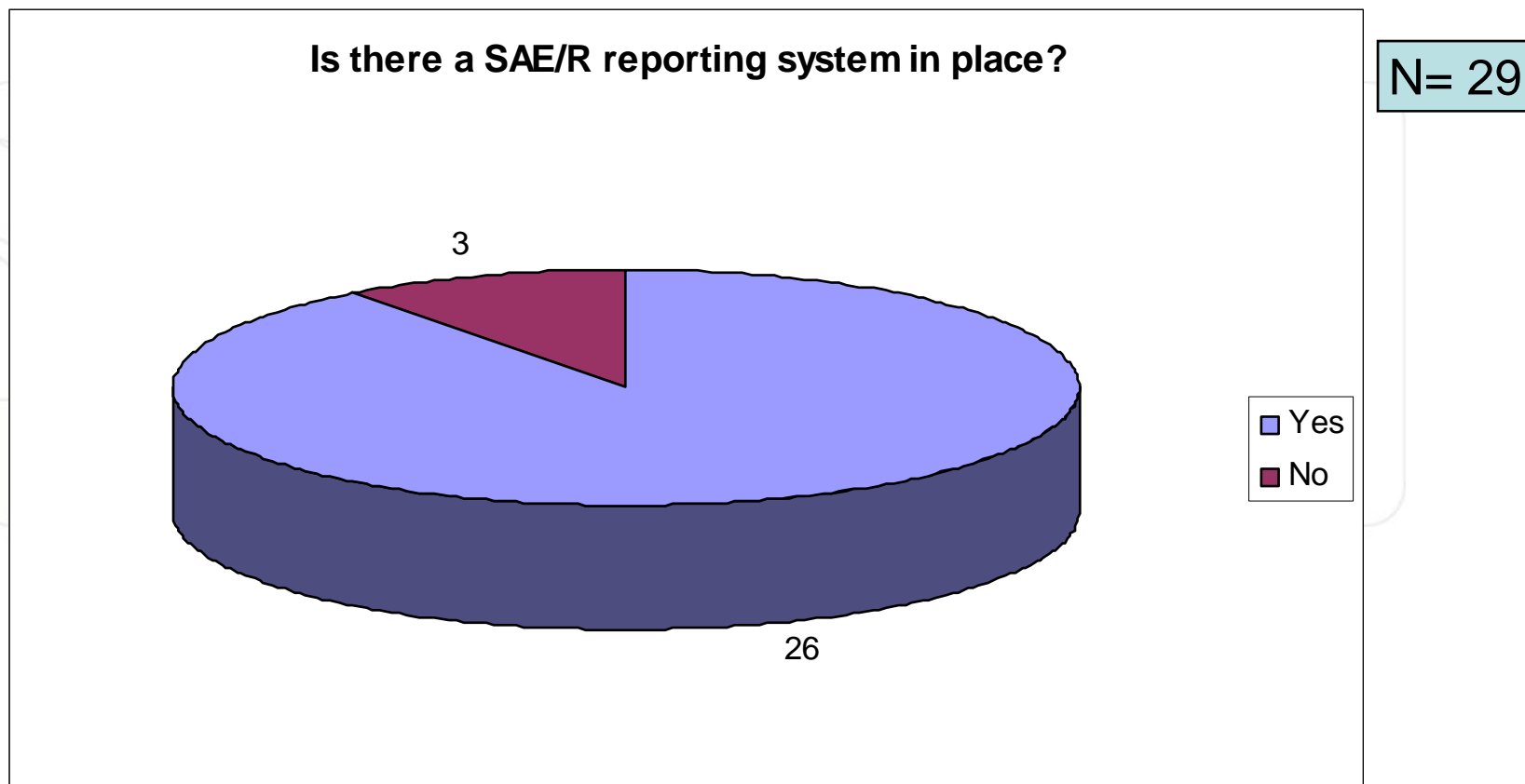
The Blood Legal Framework

- Competent authorities
- Accreditation, designation, authorisation, or licensing of blood establishments
- Quality systems/ Quality standards
- Inspection and control measures
- Traceability
- Import/export of blood/blood components
- Notification of Serious adverse events and reactions

THE LEGAL CONTEXT

- System in place in Member States on SAE/SAR reporting
- Article 8 of Directive 2005/61/EC: the Member States shall submit to the Commission an annual report,
- First reporting to the Commission: 30 June 2008, concerning information collected during the complete year 2007 (from 1st January to 31st of December)

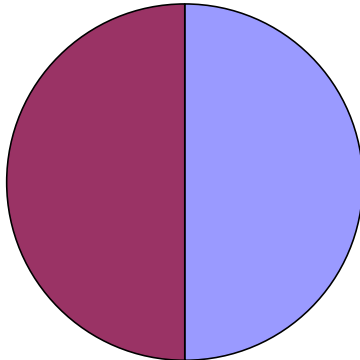
Serious Adverse Events and Reactions (October 2006)



Serious Adverse Events and Reactions (October 2006)

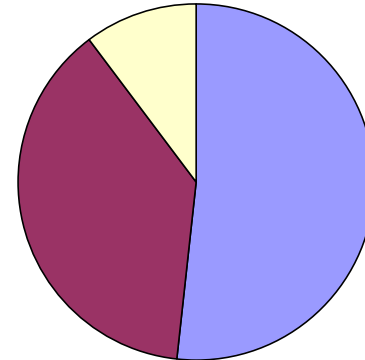
N= 29

Is there a link with pharmacovigilance systems?



■ Yes
■ No

Is there a link with medical devices vigilance?



■ Yes
■ No
■ N/A

Definitions of Serious Adverse **Events** Serious Adverse **Reactions**

SAE

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

might

lead to
death

SAR

Unintended **response** in donor or in patient associated with the collection or transfusion of blood and blood components that...

is

fatal

... (or/,) life-threatening, disabling (or/,) incapacitating (conditions for patients) or which results in, or prolongs, hospitalisation or morbidity.

Haemovigilance in the Blood Directive

What falls in?

Blood and blood components when intended for
TRANSFUSION

SAE

SAR

Attributed to the **QUALITY** and **SAFETY** of blood and blood components

COLLECTION, testing, processing, storage and **DISTRIBUTION**

Reporting establishment

Reporting period

This Table refers to <input type="checkbox"/> Whole blood <input type="checkbox"/> Red blood cells <input type="checkbox"/> Platelets <input type="checkbox"/> Plasma <input type="checkbox"/> 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 parasitological infection	Malaria	Total					
		Deaths					
	Other (specify)	Total					
		Deaths					

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)					

COMPETENT AUTHORITIES WORKING GROUP

- How to ensure that the reported information is exploitable?
- How to optimise the gathering exercise to avoid unnecessary burden at all stages?



Need to ensure that everyone is clear
on WHAT should be reported

What is the information to report to the Commission?

- Information gathered by the Competent Authorities according to the formats in Part D of Annex II and Part C of Annex III of Directive 2005/61/EC
- Feed back from stakeholders and Competent Authorities: lack of clarity, risk of mistake or misreporting, long internal discussions...

➡ Necessity to clear up as much questions as possible IN ADVANCE to the first collection... keeping in mind that we remain in a learning by experience exercise

Next steps?

- Written comments on the working document by 30 November
- Working group to outline the common approach – 19 December 2007
- Finalisation of the common approach by the Commission - early 2008

The Tissues and Cells Legal Framework

DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 31 March 2004

on setting standards of quality and safety for the donation, procurement, testing, processing,
preservation, storage and distribution of human tissues and cells

Transposition deadline
7 April 2006

COMMISSION DIRECTIVE 2006/17/EC

of 8 February 2006

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards
certain technical requirements for the donation, procurement and testing of human tissues and cells

(Text with EEA relevance)

Transposition deadline
1 November 2006

COMMISSION DIRECTIVE 2006/86/EC

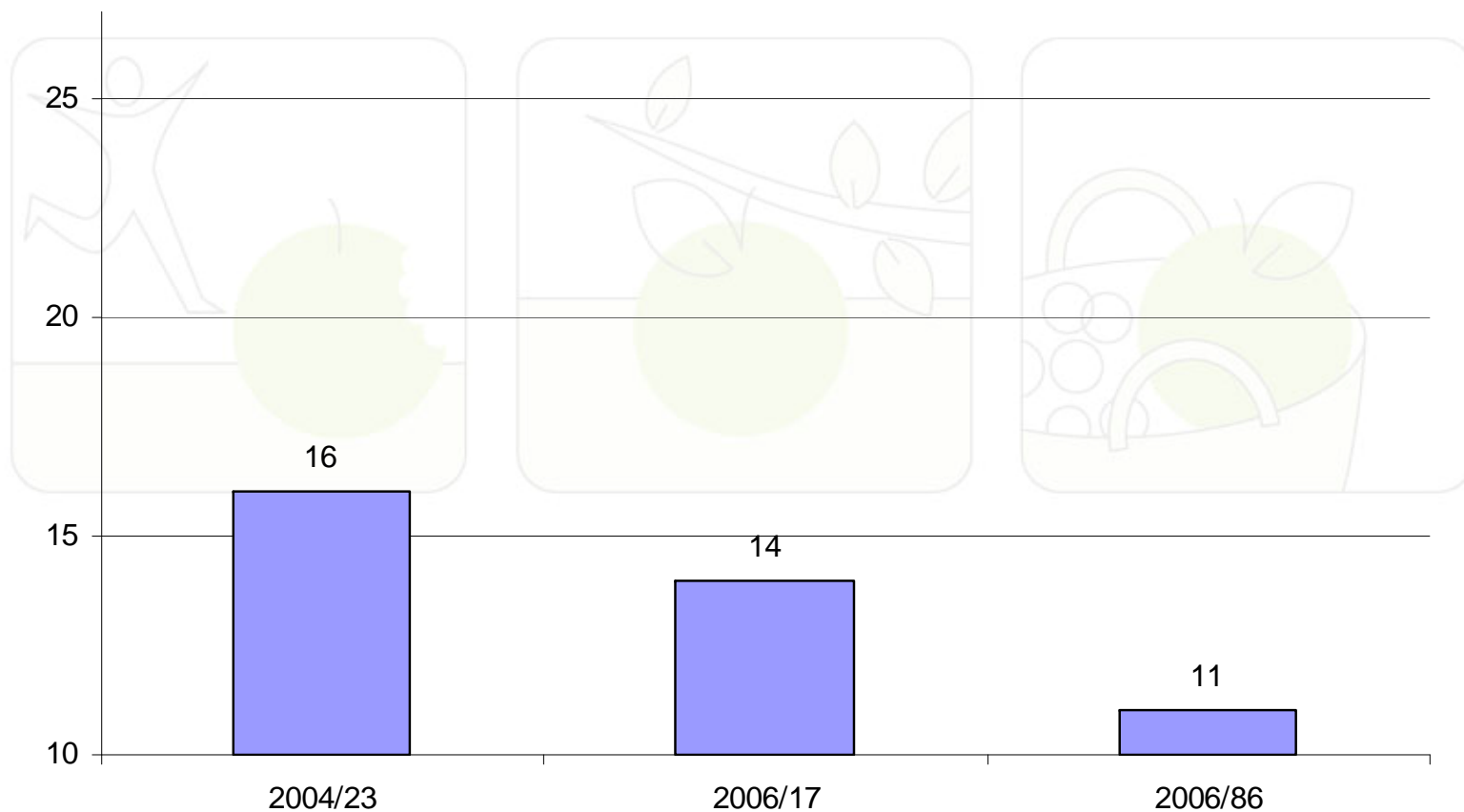
of 24 October 2006

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards
traceability requirements, notification of serious adverse reactions and events and certain
technical requirements for the coding, processing, preservation, storage and distribution of
human tissues and cells

(Text with EEA relevance)

Transposition deadline
1 September 2007

TRANSPOSITION TO DATE (February 2008)



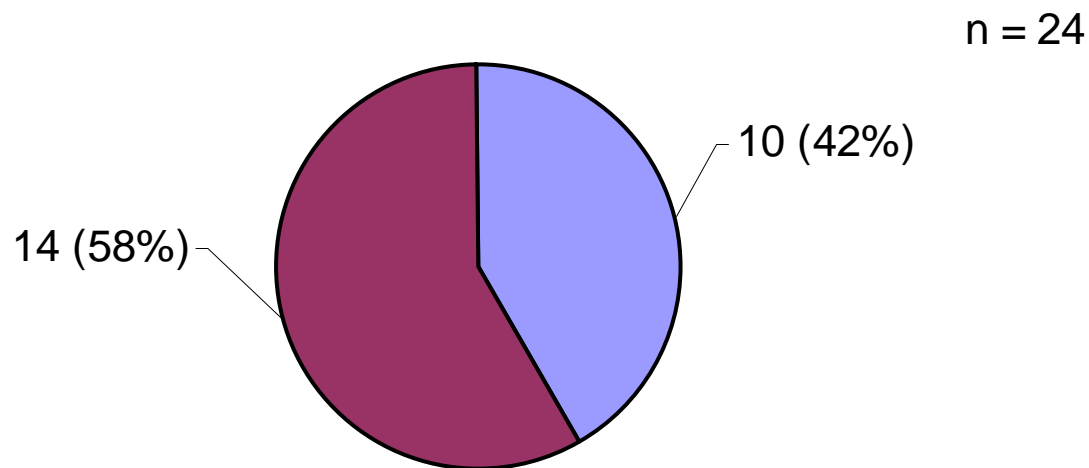
The Tissues and Cells Legal Framework

- Competent authorities
- Supervision of human tissues and cells procurement
- Accreditation, designation, authorisation, or licensing of tissue establishments and tissues and cells preparation processes
- Quality systems/ Quality standards
- Inspection and control measures
- Traceability/Coding system
- Import/export of human tissues and cells
- Register of Tissue establishment
- Notification of Serious adverse events and reactions

THE LEGAL CONTEXT

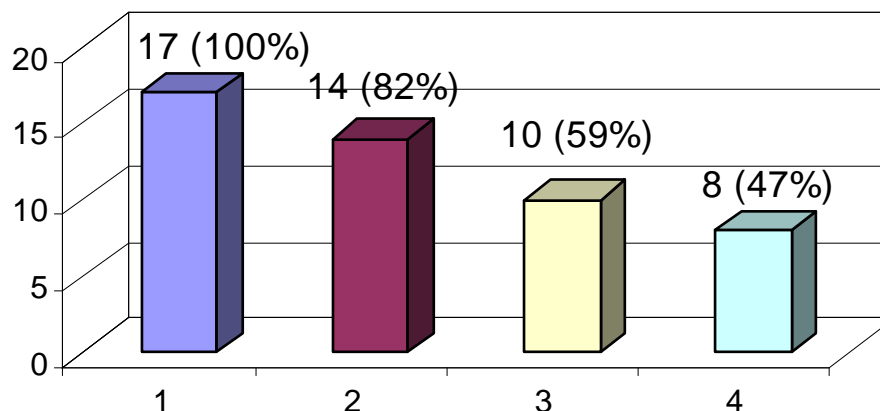
- System in place in Member States on SAE/SAR reporting
- Article 7 of Directive 2006/86/EC: the Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse events and reactions received by the competent authority
- First reporting to the Commission: 30 June 2008, concerning information collected during the complete year 2007 (from 1st September to 31st of December)

SAE/SAR (February 2006)



- Yes, reporting system for SAE/SAR is in place
- No, reporting system is not in place

Definition of SAR (February 2006)

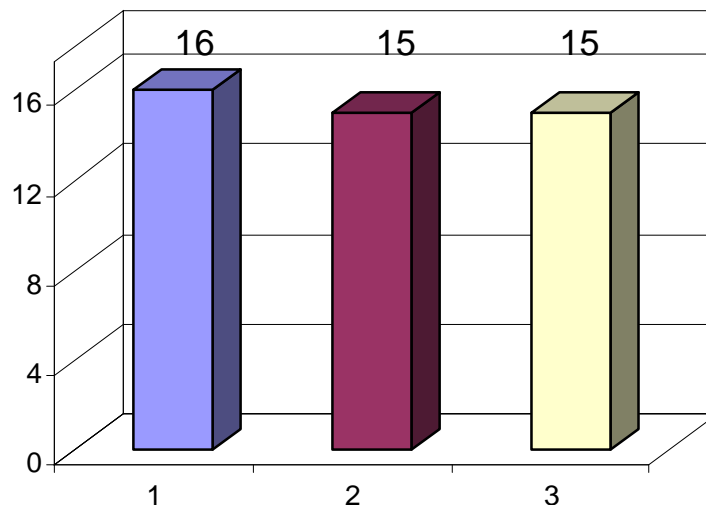


n = 17

1. Serious adverse reactions in the recipient which may be linked to the quality and safety of tissues/cells
2. Serious adverse reactions in the donor which may influence the quality and safety of tissues/cells
3. Serious adverse reactions that cannot be attributed to the quality and safety of tissues/cells
4. Serious adverse reactions in the donor that do not influence the quality and safety of tissues/cells

Additional definitions used in MS: adverse reaction which occurs with abnormal frequency; adverse reaction possibly linked to the ancillary product; disease transmission, serious infection; a) Perte accidentelle avant la greffe d'un greffon autologue (réactions indésirables graves chez le patient déjà conditionné pour la greffe) b) Mauvaise qualité d'un produit annexe découverte après la délivrance ou la distribution de ce produit Contamination bactérienne ou fongique d'un greffon découverte après la greffe

Definition of SAE (February 2006)



n = 16

1. The administration or the use of tissues/cells that did not fulfill the safety and quality requirements
2. A near miss: the distribution of tissues/cells that did not fulfil the safety or quality requirements at the time (but that was not administered or used)
3. The release of tissues/cells (even if not distributed), that did not fulfil the release requirements, due to a procedural problem of the release process

Additional definitions used in MS: An event that might put the life of a donor in danger, seropositivity,

European Union Standards and Training in the Inspection of Tissue Establishments: EUSTITE

In 2009 a system for the definition, classification and reporting of adverse reactions and events associated with safety and quality of tissues and cells applied to the human body will have been proposed by the project and established on a pilot basis. The system will have links to developing surveillance systems in the field outside the EU.

Thank you

