

Implementation of the EUD

How it is interpreted in practice

Feedback from Workshop 1

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What we heard

- Results of survey on interpretation
- Experience from 3 countries
 - Netherlands - Martin Schipperus
 - France - Cyril Caldani
 - UK - Clare Taylor
- Focus on haemovigilance aspects
 - benefits
 - challenges

Survey

- Questionnaire on implementation sent to contact persons in 18 countries
- 13/18 returned
- Results anonymised

4 sets of questions

- 1 About the Competent Authority
- 2 Role of existing haemovigilance schemes
- 3 Adverse reactions - reportable or not?
- 4 Adverse events - reportable or not?

Q1 The Competent Authority

- Has the CA in your country had previous experience in blood transfusion (e.g. as regulator or inspector)?

- | | |
|---|----|
| Y | 10 |
| N | 3 |

Q2 Haemovigilance system

- Was there a national haemovigilance system before implementation of the EUD?
- | | |
|---|----|
| Y | 12 |
| N | 1 |

Q2 How will the existing hv system work in future?

It will be further developed and will receive reports on behalf of the CA 8 (?+1)

It will be/has been replaced by a new system 0

It will work in parallel with the CA, with some integration 3 (?+1)

It will work entirely independently of the CA 0

No existing system 1

Q3 Which of the following **reactions** are reportable to the CA?

Scenario	Y	N
Acute dyspnoea and hypoxia within 6 hours of transfusion	13	0
Acute haemolysis caused by blood given to wrong patient	13	0
2° C rise in temp during transfusion, not due to sepsis or haemolysis	10 [*] *3 only if serious	4

Q3 Which of the following reactions are reportable to the CA?

Scenario	Y	N	?
Death of a donor at a blood collection session	10	2	1
Median nerve damage causing major incapacity in a blood donor	10	2	1

Q4 Which of the following events are reportable to the CA?

Scenario	Y	N	?
Donor sample mix-up at session resulting in loss of donations	5	7 +1V	
Notification of Hepatitis A by donor 2 weeks post-donation leading to recall	7	4	2
Issue by BE of a CMV positive platelet unit for a v small premature infant	4	7	2
Wrong ABO group determination in hospital blood bank	9	3 +1V	
Blood given to wrong patient by a nurse	9	4	

What will the EC do with our data?

- Different interpretations of scope of Directive
- How are cases verified?
- Are we comparing like with like



Some concepts

- **Competent authority**
 - who has the competence and who is the authority?
 - expertise to validate reports
- **Blame-free (?fair blame) culture**
 - protects the identity of the individual
 - how to reconcile with regulatory requirements

3 models of implementation

- Netherlands
 - TRIP receives all reports on behalf of CA
 - Reporter determines if EU reportable
 - Inspectorate can access all mandatory reports
- France
 - Afssaps is the Competent Authority
 - Scope extended to include donor reactions
 - Algorithm to determine SAEs
- UK
 - SHOT and MHRA working in parallel (?convergent)
 - Some areas of overlap
 - Common electronic reporting system (SABRE)

Benefits

- Strengthening of existing system (TRIP)
- Electronic reporting (SHOT)
- More timely reporting (TRIP)
- Can retain existing scope
- Potential to extend scope - donor hv(Afssaps)
- Potential to learn from each other
 - but will need a more consistent approach

Challenges

- Threat to 'blame free' culture
- Systems become more complex
- Lack of consistency of scope
 - first annual reports to EC?
- Interpretation (what is 'serious'?)
- Lack of understanding (reporters)
- Influence of lawyers

Principles

- Confidentiality - protect individuals
- Reporting
 - Keep it simple!!
 - User-friendly
- Retain professional emphasis
 - expert analysis of reports
 - recommendations for improvement
 - separation from inspectorate

Speculation

- What might the first EC reports look like?
- What will the EC do with the data?
- Is a consistent approach possible?
- How might EHN contribute?