

Implementation of the EUD

Workshop 1

EHN Dublin February 2007

Aim of the workshop

- Hear about implementation in
 - Netherlands
 - France
 - UK
- Focus on the haemovigilance aspects
 - benefits
 - problems and how to overcome them

Some background

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

Aims of questionnaire

- Understand relationship between Competent Authorities and existing haemovigilance systems
- Look at interpretation of the terms 'Serious Adverse Reactions' and 'Serious Adverse events'
 - are we all reporting the same things??
 - what will we learn from the EU data?

4 sets of questions

- 1 Previous experience of the CA
- 2 How will haemovigilance be organised?
- 3 Adverse reaction scenarios
- 4 Adverse event scenarios

Q1 The Competent Authority

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

- A

Y	10
N	3

Q2 Haemovigilance system

- Was there a national hv system in place before implementation of the EUD?

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It will be/has been replaced by a new system 0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

Summary

- 10/13 competent authorities have previous experience
- All existing hv systems are being retained
 - 8 will receive reports on behalf of the CA
 - 3 will work in parallel
 - 1 is still to be determined

Serious adverse reactions

- There is unanimous agreement that ?TRALI and AHTRs are reportable
- Reporting of febrile reactions is
 - required by 7 countries
 - not required by 4 countries
 - discretionary in 3
 - 1 has a scoring system
 - 2 rely on reporter assessment (1 gives guidance)
- Donor SARs are reportable in 11/13

Serious adverse events

- No unanimous agreement!
- Majority (9/13) are reporting errors from hospital blood banks and clinical areas

For discussion

- How do we learn from these data?
 - Case verification?
 - Comparing like with like

