

Donor Adverse event reporting

The Donor Haemovigilance program

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Objectives

- Review the regulations and guidance on donor haemovigilance
- Review UK wide donor adverse event haemovigilance program
- Discuss what we are doing with reporting in the future

Donor Haemovigilance

- EU directive
 - 2002/98/EC: (18) It is important to introduce a set of organised surveillance procedures to collect and evaluate information on the adverse or unexpected events or reactions resulting from the collection of blood or blood components in order to prevent similar or equivalent events or reactions
 - 2005/61/EC: 3. Member States shall ensure that reporting establishments:
 - (a) evaluate serious adverse events to identify preventable causes within the process;
- BSQR 2005
 - Blood establishments shall notify the secretary of state of any serious adverse events related to the collection, testing.....of blood or blood components by the blood establishment which may have an influence on their quality and safety, and...

Council of Europe 15th ed

- Adverse events are any untoward occurrence associated with the collecting.....of blood & blood components that might lead to an adverse reaction in recipients or donors
- Serious events are those which might lead to death, or life threatening, disabling or incapacitating conditions for patients or donors or which might result in prolonged hospitalisation or morbidity
- Adverse reactions in a donor should be fully documented in donor records and serious events should also be documented in the quality system

Haemovigilance

- Definition (IHN):
A set of surveillance procedures covering the whole transfusion chain (from the collection of blood and its components to the follow-up of recipients), intended to collect and assess information on unexpected or undesirable effects resulting from the therapeutic use of labile blood products, and to prevent their occurrence or recurrence.

| | | | | |
|-----------------------------|------------------------------|--------------------------------------|------------------------------|-------------------------|
| Local symptoms | Blood outside vessels | | Haematoma | |
| | | | Arterial puncture | |
| | | | Delayed bleeding | |
| | Pain | Specified as | | Nerve irritation |
| | | | | Nerve injury |
| | | or not specified | Tendon injury | |
| | Others | | Painful arm | |
| | | | Thrombophlebitis | |
| | | Allergy (local) | | |
| | | | | |
| Generalised symptoms | Vasovagal reaction | | Immediate | |
| | | | Immediate with injury | |
| | | | Delayed | |
| | | | Delayed with injury | |
| | | | | |
| Related to apheresis | | Citrate reaction | | |
| | | Haemolysis | | |
| | | Generalised allergic reaction | | |
| | | Air embolism | | |
| Other | | | | |

UK Donor adverse event recording

- All known events in whole blood and component should be recorded
- Each of the UKBTSs have there own system
- Serious adverse events are recorded as quality incidents and investigated

Blood and Transplant

| IHN/EHN | NHSBT | SNBTS | NIBTS | WBS |
|--------------------------|-----------|-----------------------|------------------|-----------------------|
| Haematoma | BR0,1,2,3 | 111 Haematoma | | Haematoma 1,2,3 |
| Arterial puncture | MAP | 112 Arterial Puncture | | Art P 1,2,3 |
| Delayed bleeding | DRB | 141 Rebleed | | Re Bleed |
| Nerve irritation | NER | 121 Inj to Nerve | | Indirect NI 1,2,3 |
| Nerve injury | NER | 121 Inj to Nerve | | Direct NI1,2,3 |
| Tendon injury | | | | Inj T 1,2,3 |
| Painful arm | | | DR16 (apheresis) | |
| Thrombophlebitis | THP | | | Ax Th or Th'phlebitis |
| Allergy (local) | CAL | | | Allergic R 1,2,3 |

| IHN/EHN | NHSBT | SNBTS | NIBTS | WBS |
|--------------------------------------|----------|---------------------|--|--|
| VVR Immediate | VV1,2,3 | 210 VV immediate | Faint Mild, Mod, Severe | Immediate with or without comps |
| VVR Immediate with injury | VV3 | | | |
| VVR Delayed | DV1,2, 3 | 220 VV delayed | Delayed faint Mild, Mod, Severe | Delayed with or without comps |
| VVR Delayed with injury | DV3 | | | |

| IHN/EHN | NHSBT | SNBTS | NIBTS | WBS |
|--------------------------------------|---------|------------------------|--------|--------------|
| Citrate reaction | CIT | | A2 A/C | Cit reaction |
| Haemolysis | An SAED | | | Haemolysis |
| Generalised allergic reaction | | 341 Diffuse Allergic R | | G Allergic R |
| Air embolism | An SAED | | | Air embolism |
| Other | | Other | | |

Severe complications

Conditions which define a case as severe:

- Hospitalization: If it was attributable to the complication.
- Intervention: To preclude permanent damage or impairment of a body function
To prevent death (life- threatening)
- Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)
- Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

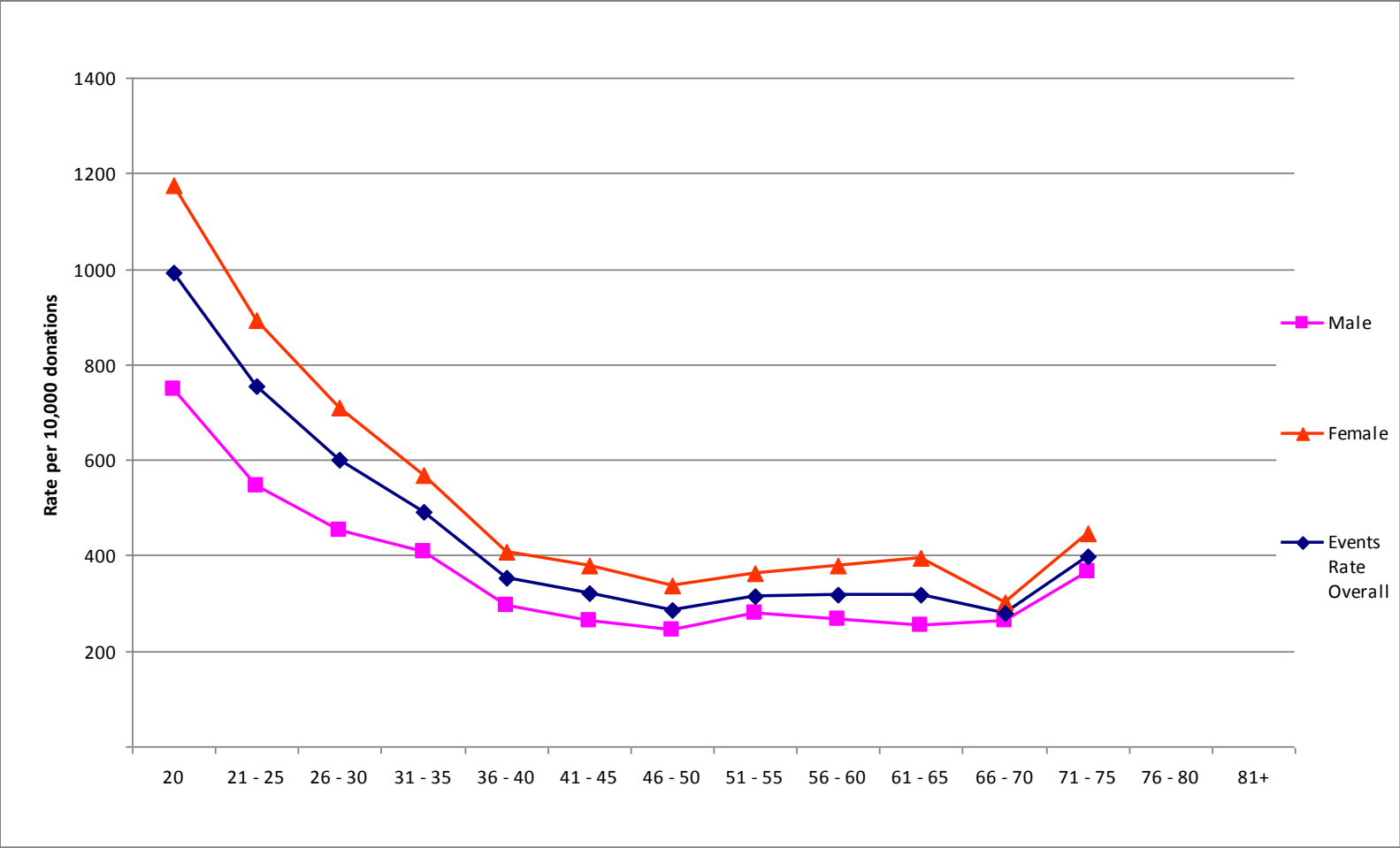
UK Severe Categories

- Death within 7 days of donation
- Hospital admission within 24hrs of donation
- Injury resulting in a fracture within 24 hrs
- Road Traffic Collision (RTC) within 24hrs of donation
- Acute Coronary Syndrome (ACS) diagnosed within 24hrs of donation
- Problems relating to needle insertion persisting for more than a year
- Anaphylaxis, haemolysis or air embolism (CD)

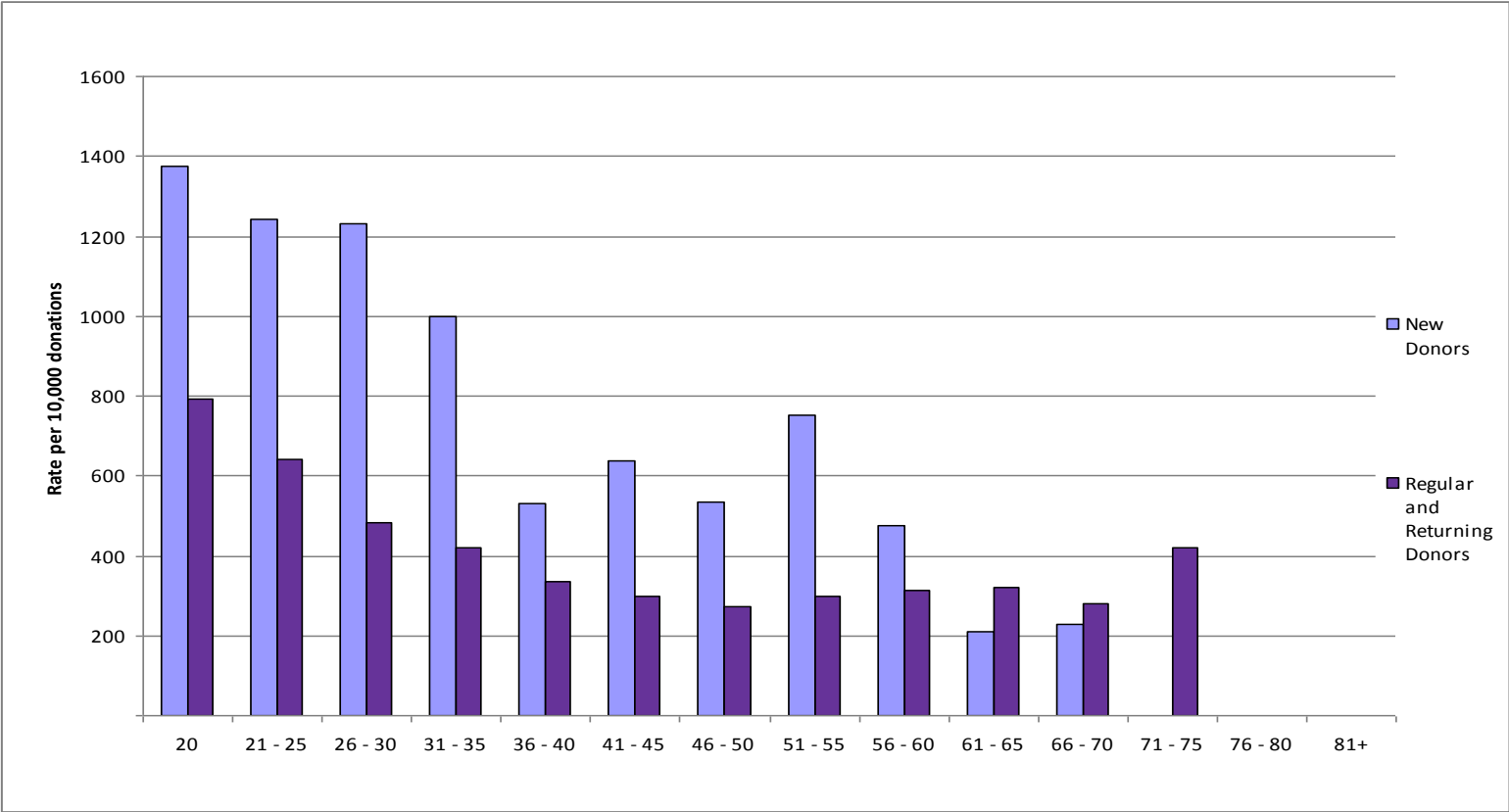
What is the size of the problem?

- Donor adverse events are common in all UKBTSs
- In NHSBT 7,313 were reported in January 2010 in 173,164 donations i.e. 4.2% of accepted donors have an event
- The commonest event is a faint or a pre faint (1.97% of donors)
- Other services pro rata

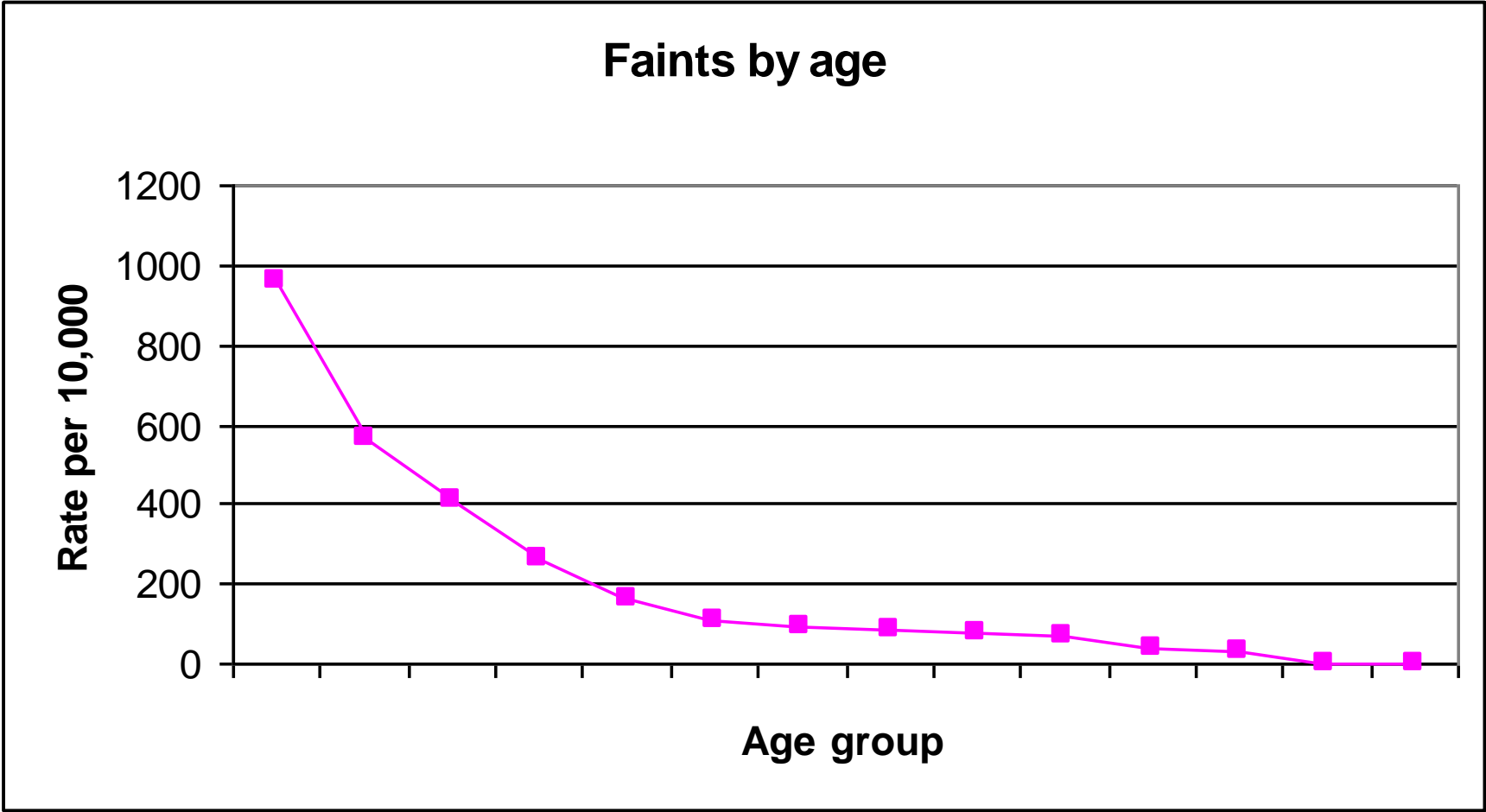
Female donors

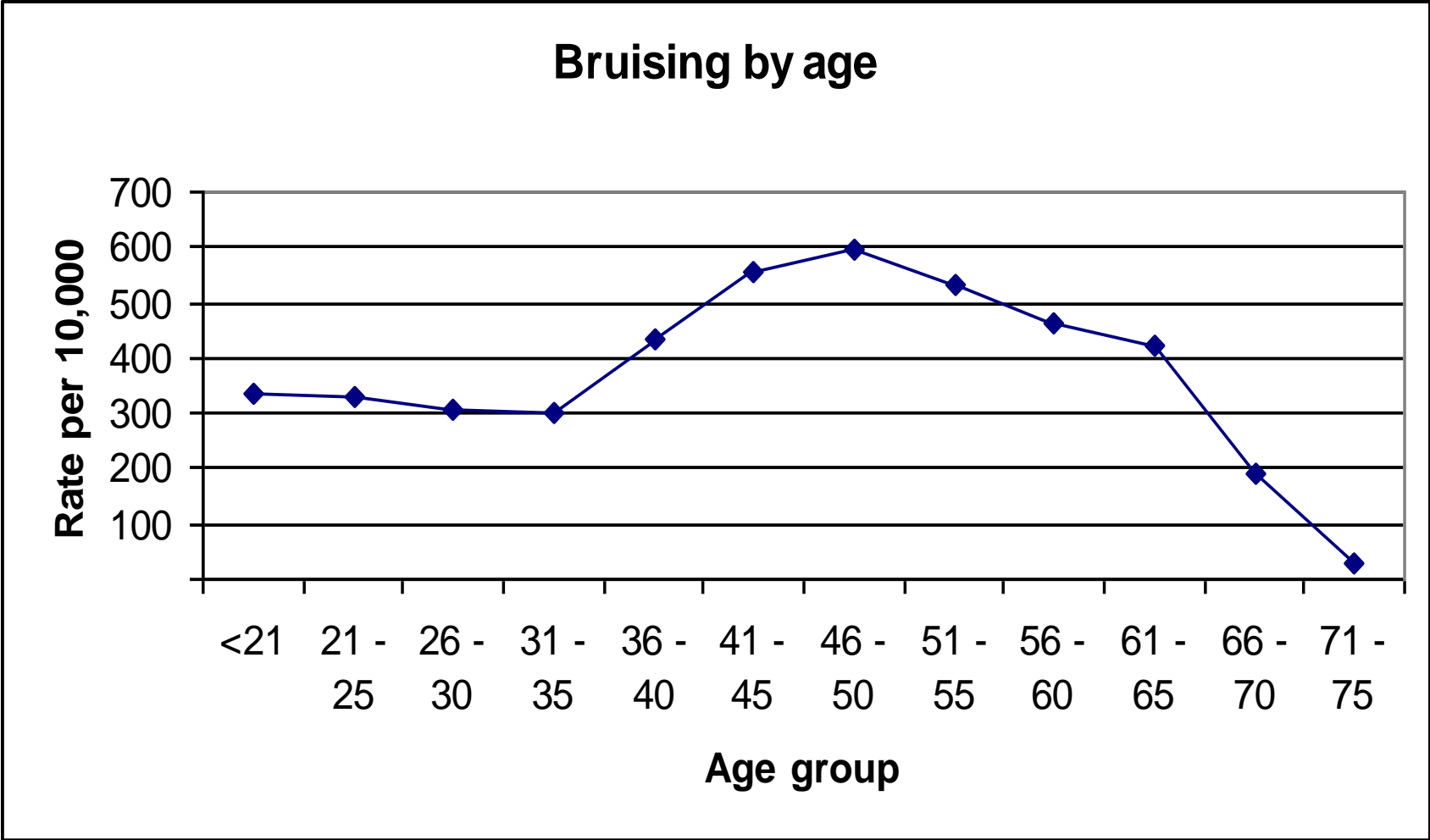


New Donors



A female first time donor under 20 has a 13% chance of an adverse event!





Grading of imputability

- The strength of relation between donation and complication is
 - Definite: when there is conclusive evidence beyond reasonable doubt for the relation*
 - Likely: when the evidence is clearly in favor of a relation*
 - Possible: when the evidence is indeterminate for attributing the complication to the donation or an alternative cause*
 - Unlikely: when the evidence is clearly in favor of attributing the complication to other causes
 - Excluded: when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

SAEDs reported over the last 4 years

| Category | 2006 | 2007 | 2008 | 2009 |
|---|-----------|-----------|-----------|--------------------------|
| Death within 7 days of donation | 0 | 1 | 1 | 2 2e |
| Hospital admission within 24hrs of donation | 6 | 2 | 2 | 11 6d, 2l ,2p ,1u |
| Injury resulting in a fracture within 24 hrs | 2 | 2 | 3 | 2 2d |
| Road traffic collision within 24hrs | 1 | 2 | 1 | 1 1l |
| ACS diagnosed within 24hrs of donation | 2 | 1 | 2 | 4 1l, 3e |
| Problems relating to needle insertion persisting for more than a year | 9 | 7 | 3 | 4 4p |
| Anaphylaxis, haemolysis or air embolism (CD) | 0 | 0 | 0 | 0 |
| Total | 20 | 15 | 12 | 24 18d, l or p |

Does it matter?

- Syncopal events reduce the likelihood of returning to donate.

Various studies have put the reduction in 1 year return rate at between 34% and 45% for all donors and 51%-72% in novice donors (Newman et al, France et al and Eder et al)

- NHSBT donors are 18% less likely to return within one year if has **any** adverse event, 35% if they felt faint & >50% if they actually fainted.
- Syncopal events are a significant cause of injury and litigation.

Plans

- Record numerical data on all adverse events on SHOT database
- Record full data on serious events on SHOT database
- Allow annual reporting
- Facilitate benchmarking

Any Questions?

Summary

- Severe donor adverse event reporting is mandated by the EU directive
- Other event recording recommended by Council of Europe
- All UKBTS have a system
- Plans to report via SHOT