Donor Adverse Events

Common terminology
Frequency
Risk factors

Hold still, Mrs. Brown, while I draw your blood

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Canadian Blood Services
IHN Seminar, Paris
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Outline

- Donor adverse events
- Why are they important
- Definitions of adverse events
- Frequency and risk factors, vasovagal reactions

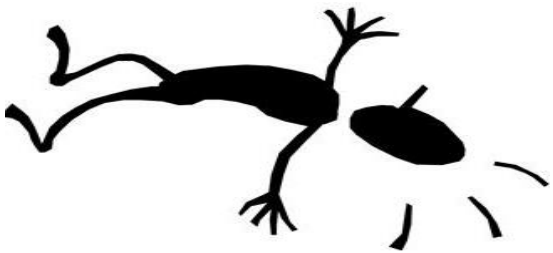
Donor adverse events

Acute

- at time of or shortly after donation
- local arm complications
- vasovagal reactions (faints)

Long term

- cumulative
- iron depletion
- possible osteopenia



Why are they important?

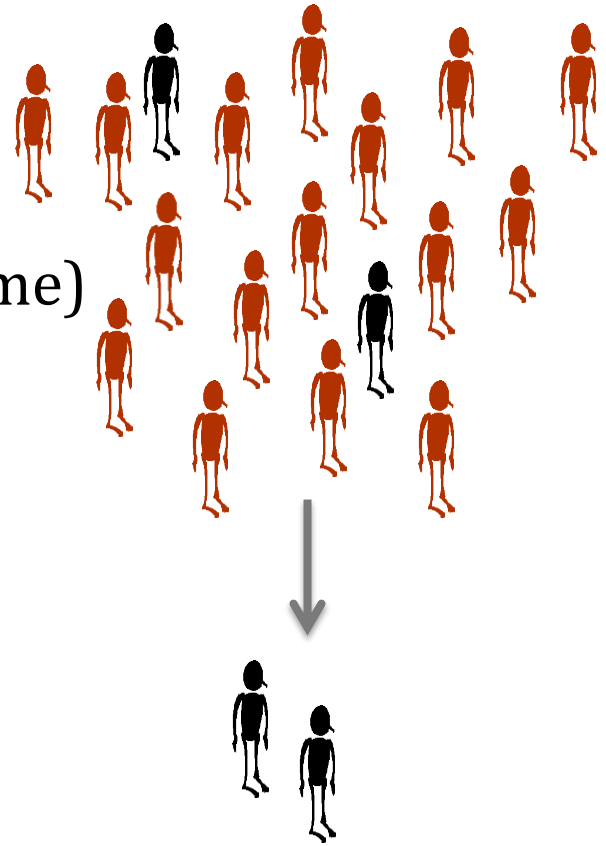
- Donor morbidity, extremely rarely, mortality
  - nerve injury
  - delayed vasovagal reactions most likely to lead to injury

- Decrease donor satisfaction
  - negative impact on return rate, particularly in donors early in donation career

- Should inform donor eligibility and assessment policies

Eligibility criteria

- Age
- Size (weight, estimated blood volume)
- Blood pressure, pulse
- Medications
- Heart disease
- Diabetes
- …



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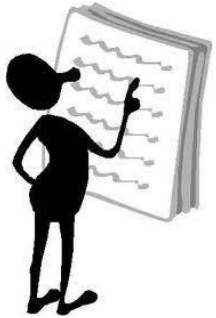

Mitigating actions

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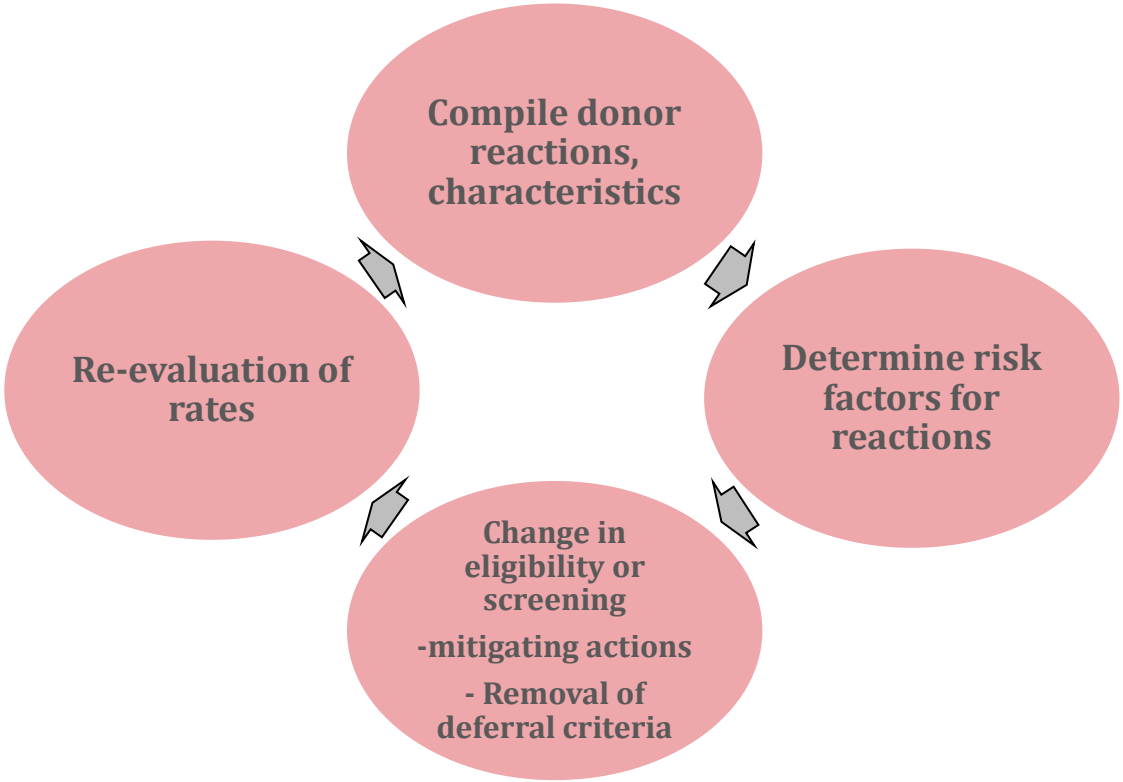
Donor haemovigilance



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Standard definitions

- Needed to establish baseline rates, evaluate risk factors, assess impact of changes, permit comparisons
- ISBT Working Party on Haemovigilance formed a revision subcommittee to review 2008 ISBT Standard definitions, AABB classification and related software, national systems
- Some members also part of IHN,
  AABB haemovigilance working group

Vasovagal reactions

ISBT 2008	AABB
• Mild - no objective symptoms	• List of 12 symptoms related to pre-faint
• Moderate – objective symptoms pulse, BP, loss of consciousness (LOC)	• ± LOC, duration of LOC separates mild, moderate, severe
• Severe – hospitalization, significant incapacity	• Injury separate attribute

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Aims

1. Provide simple definitions

   ↓

   easy to apply in a standard way

2. Minimal requirements for basic surveillance

   ↓

   international comparisons

3. *Additional optional attributes*

   ↓

   process improvements, research

Complications related to blood donation

A. Local Symptoms

i. Blood outside vessel
   - Haematoma
   - Arterial puncture
   - *Delayed bleeding*

ii. Arm pain
   - Nerve injury/irritation
   - *Duration < or > 12 months*
   - *Other arm pain*

A. Local Symptoms

iii. Localized infection/inflammation of vein or soft tissue
- *Superficial thrombophlebitis*
- *Cellulitis*

iv. Other major blood vessel injury
- DVT
- Arteriovenous fistula
- Compartment syndrome
- Brachial artery pseudoaneurysm

B. Generalized Symptoms – vasovagal reactions

- No loss of consciousness
- Loss of consciousness
  < 60 sec, no complications
  > 60 sec, ± complications
- *With or without injury*
- *On or off collection site*

C. Related to apheresis

- Citrate reactions
- Haemolysis
- Air embolism
- *Infiltration*

D. Allergic

- Local
- Generalized

E. Other serious complications

- MI
- Cardiac Arrest
- Other cardiac
- TIA
- CVA
- Death

F. Other

Numerator and denominator data

Numerator data about each complication	Denominator data about all donors
Type of donation a) Whole blood i. *allogeneic* ii. *autologous* b) Apheresis i. RBC ± *plasma* ± *platelets* ii. platelets ± *plasma* iii. *plasma only* Gender of donor First-time vs. repeat donor *Age group (16-18, 19-22, 23-29, 30-69, ≥ 70)* Type of complication	**Total donations (proceed to phlebotomy)/year** a) Whole blood i. *allogeneic* ii. *autologous* b) Apheresis i. RBC ± *plasma* ± *platelets* ii. *platelets* ± *plasma* iii. *plasma only* Gender of donors in each donation category First-time vs. repeat donors in each category *Age group (16-18, 19-22, 23-29, 30-69, ≥ 70)* *Total number of donors/yr. by type of donation, gender, first-time vs. repeat, age group*

Revised definitions

- Definitions have received wide endorsement
- Available as a leaflet
- We hope that their adoption will improve monitoring of donor adverse reactions and ultimately enhance donor safety
- isbtweb.org/working-parties/haemovigilance definitions
- Vox Sanguinis 2016;110(2):185-8

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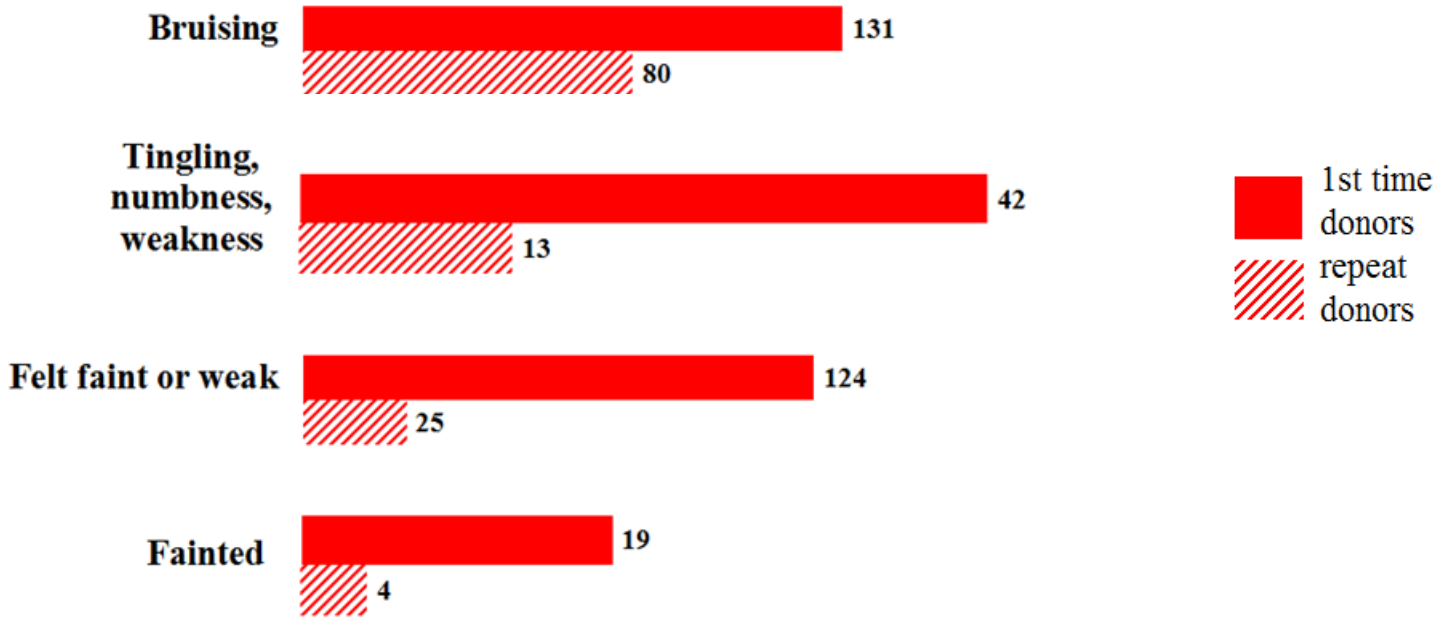
Long term effects – iron depletion

- Difficult to fit in haemovigilance scheme
  - not solely due to donation
  - iron levels (ferritin) not routinely measured
  - many possible mitigating strategies
- Important part of donor safety
- Can follow donation frequency, hemoglobin levels, hemoglobin deferrals over time

Frequency of donor adverse events

- Published studies
  - ~ 2-5% mild vasovagal reactions
  - ~ 4 in 1,000 syncope
  - ~ 6 in 10,000 injury
- Frequency is much higher in post-donation surveys and if donors are routinely asked about symptoms at time of next donation

Symptoms per 1,000 donors



Transfusion 2013(53):1979

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Risk factors, vasovagal reactions

- Mechanisms include a direct effect of acute hypovolemia, changes in vasovagal tone and orthostatic blood pressure, psychologic stress
- Large, observational studies done at ARC and Blood Systems demonstrated risk factors for vasovagal reactions
- Similar risk factors found for delayed vasovagal reactions

Risk factors, vasovagal reactions

Risk factor	Risk of reactions, adjusted odds ratio	Comments
First donation	1.95-2.80	
Age 16-18 17-20 19-24	 3.89 2.75-4.01 2.37	 Older donors (>65) examined in some studies and not at higher risk
Female gender	1.20-2.52	May be particular important risk factor for delayed reactions
Weight 110-120 lbs. (50-54 kg)	2.11-2.52	May not be independent of EBV
EBV[1] <3500 ml	2.45-2.88	In some studies continuous variable, with EBV >5000 ml having lowest rate
Fear of donation	2.6	Donors reporting fear on a predonation survey 2.6 times more likely to experience presyncopal reactions

Mitigating strategies

- Both ARC and Blood Systems observed a decrease in vasovagal reaction rates after implementing several measures, often simultaneously:
  - selection of donors with EBV ≥ 3.5 litres
  - pre-donation water
  - muscle tensing exercises, legs and buttocks (AMT)
- Compliance is an issue for H_2O and AMT
- Difficult to determine efficacy of specific intervention, particularly on syncope and injury

Mitigating strategies

- Interesting studies by C. France et al on importance of donor's psychological state, particularly young, first time donors
- Enhanced education about fear, pain, potential complications with specific instructions about preventative measures may reduce reactions
- Determination of subset of donors with higher fear factor who are at greatest risk of a reaction

Conclusions

- Donor haemogivilance plays an important role in the safety of blood donation
- Standard definitions of adverse reactions are a basic element in establishing reaction rates, risk factors
- There is incomplete understanding of the pathophysiology of vasovagal reactions
- Observational and before and after studies have shown efficacy of some measures
- Further studies needed on other mitigating strategies and their actual impact, particularly in reduction of syncopal reactions and donor injury

Thank you