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AND VITALITY WITH
SOMEONE IN NEED



Effectiveness of the donor questionnaire to ensure **donor** safety

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International Hemovigilance Seminar
Montreal, April 2012



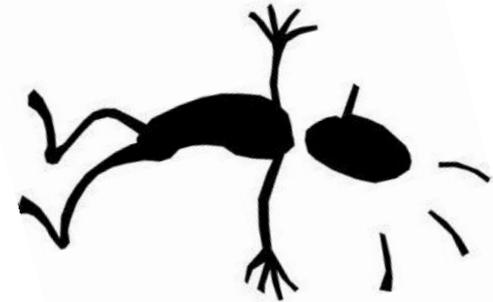
Canadian Blood Services
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Outline

- Donor adverse events
- Donor health assessment
- Why should we reconsider criteria
 - magnitude of problem
 - variability in practice
- Shift to evidence-based criteria

Donor adverse events

- Acute - at time of donation, or shortly after donation
 - local arm complications
 - - vasovagal reactions (faints) ←
- Long-term - cumulative
 - iron depletion

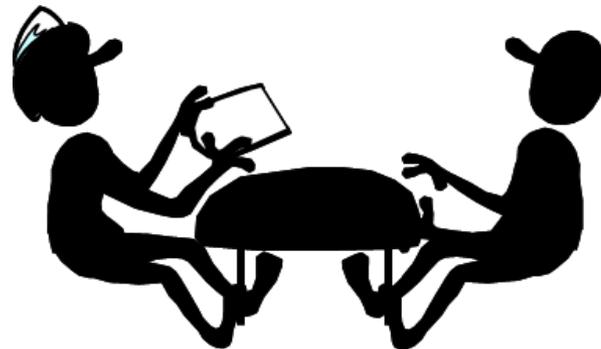


Vasovagal reactions

- Range of symptoms from feeling weak → loss of consciousness
- 2 main mechanisms
 - physiologic – effect of volume loss
 - psychologic – change in vagal tone
- Mild reactions occur in 2-5% of donors
- Loss of consciousness occurs in ≤ 0.5 in 1,000 donations

Donor health assessment

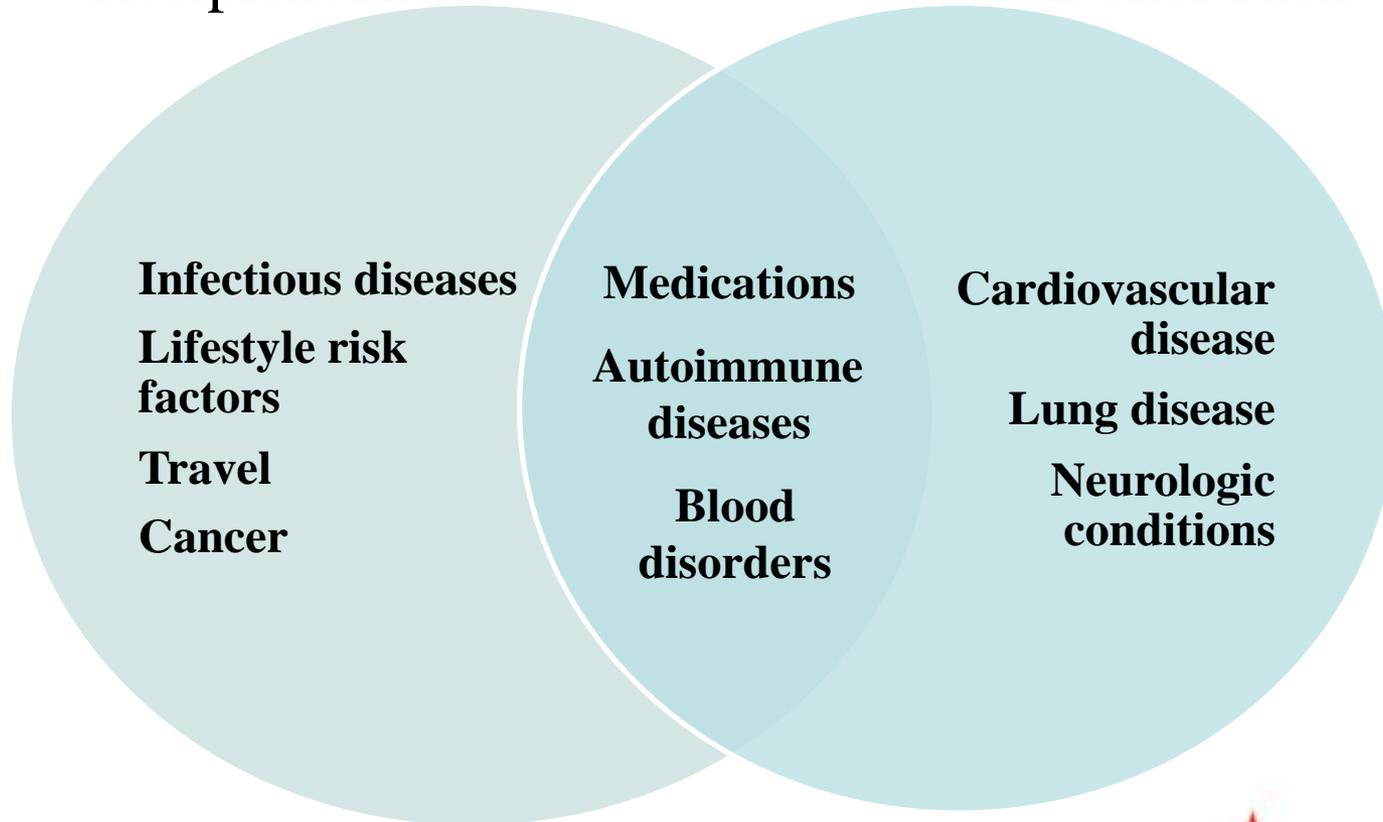
- General criteria: age, height, weight
(estimated blood volume)
- Miniphysical: blood pressure, pulse, temperature
- Hemoglobin estimation
- Health assessment questionnaire and criteria ←



Health assessment

Recipient Risk

Donor Risk



Health assessment

- Medications
 - antihypertensives
 - anti-arrhythmics
 - insulin
- Cardiovascular disease
 - history of myocardial infarction
 - history of angina
 - mitral valve prolapse
 - atrial arrhythmia



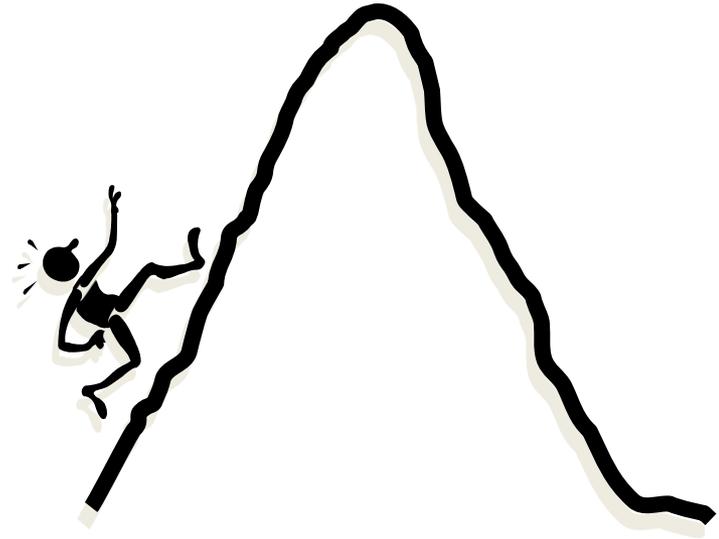
Health assessment

- Neurologic conditions
 - epilepsy on medications
- Endocrine disorders
 - diabetes on insulin
- Autoimmune disorders
 - rheumatoid arthritis

Health assessment, donor concerns

- Reduced ability to compensate for volume loss
 - anti-hypertensive medications
- Increased negative consequences of vasovagal reaction and hypoperfusion
 - ischemic heart disease
- overlap of symptoms of vasovagal reaction, underlying disease
 - hypoglycemic episode in diabetic
- General weakening of individual with a chronic condition
 - rheumatoid arthritis

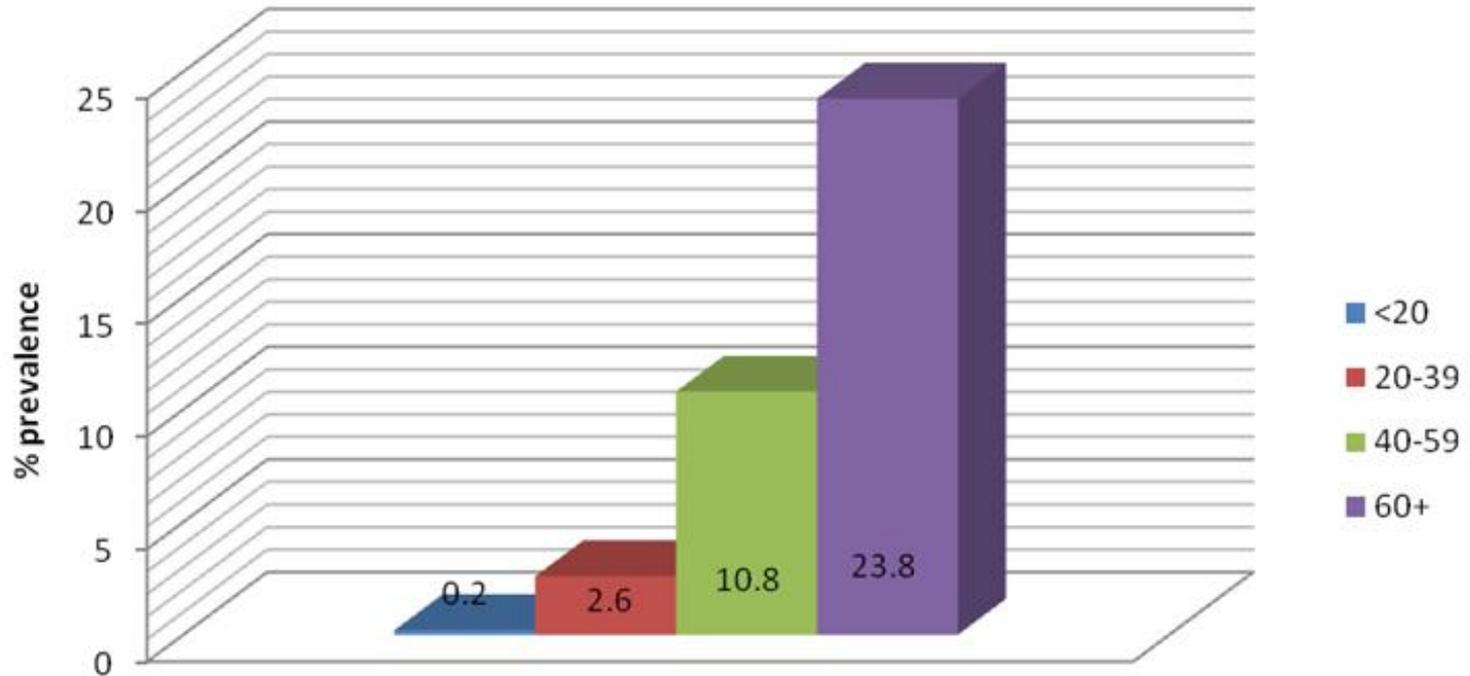
Why should we reconsider?



Magnitude of the problem

- Aging population in general
 - aging of donor base in particular
- Earlier diagnosis and treatment of chronic disorders
 - hypertension, diabetes
- Epidemic of obesity, related conditions
 - type 2 diabetes

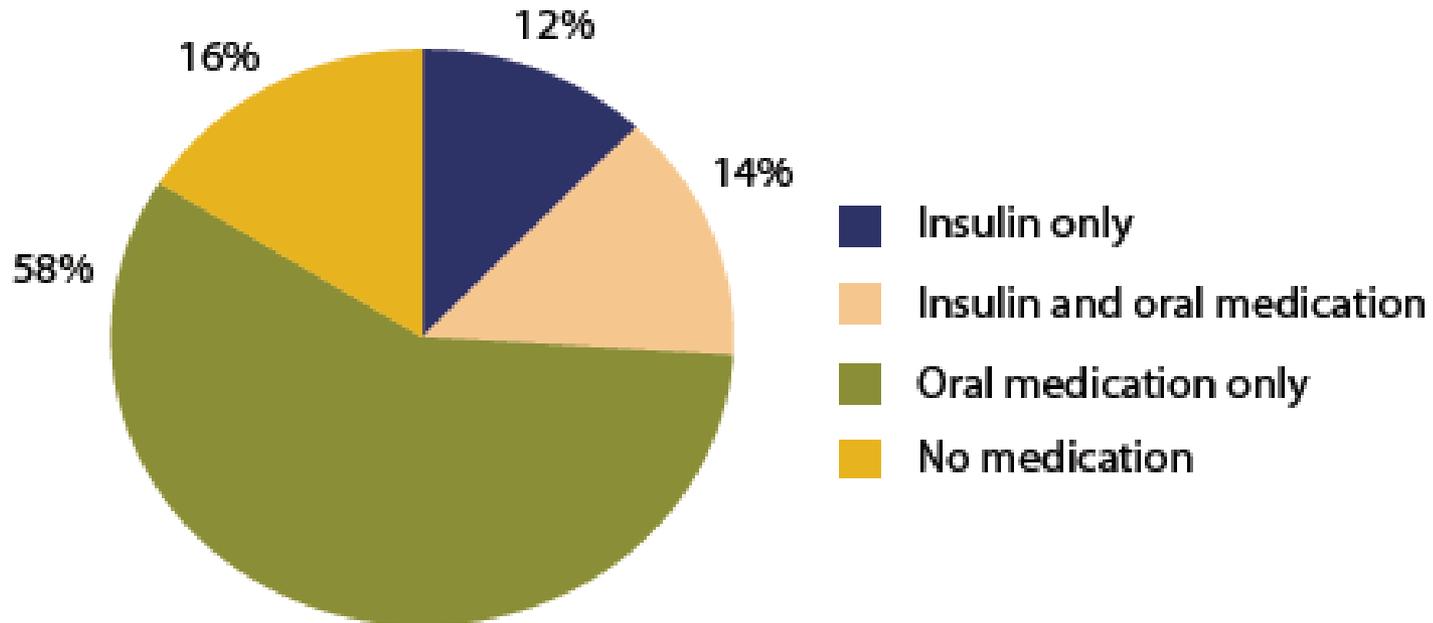
Prevalence of type 2 diabetes, US



Prevalence of Diabetes by Age

CDC, 2011, Diabetes fact sheet

Diabetic adults receiving treatment, US, 2007-2009



Source: 2007–2009 National Health Interview Survey

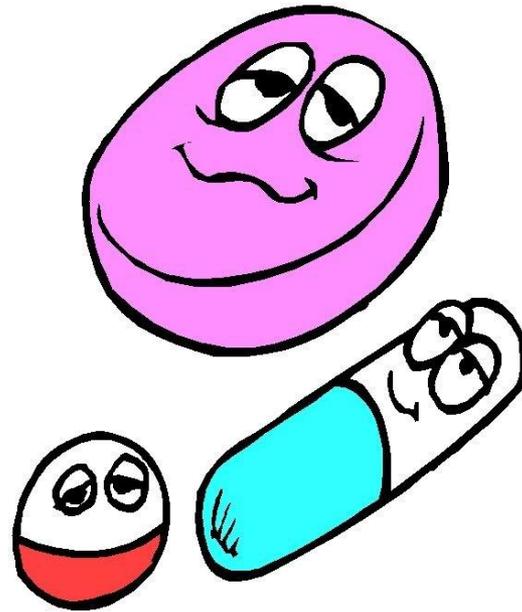
CDC, 2011, Diabetes fact sheet

Top 5 reasons for physician visits in Canada, 2009

REASON	VISITS
Hypertension	20,657,890
Routine General Medical Exam	10,491,640
Diabetes	9,746,500
Depression	8,580,910
Anxiety	6,366,280

Source: IMS Health, *Canadian Disease and Therapeutic Index* (CDTI, December 2009 data month)

Variability in practice



International selection practices

Medical Condition	% US ABC centers or ARC	CBS	Australian Red Cross Blood Services	EU Directive 2004/33/EC
MI	<ul style="list-style-type: none"> • 50% accept \leq 6 mo • 30% accept \geq 1 y • 6% permanent deferral 	Permanent deferral	Permanent deferral	Permanent deferral
CNS disease	Accept > 6 mo if medically treated , no new symptoms (ARC)	Permanent deferral, unless reversible underlying condition	Permanent deferral	Permanent deferral
DM	Accept if healthy and well (ARC)	Defer if on insulin†	Well controlled on diet/oral medication, accept Well controlled on insulin, accept with MD approval	Defer if on insulin

†Submission to change to accept for type 2 DM, well controlled on insulin

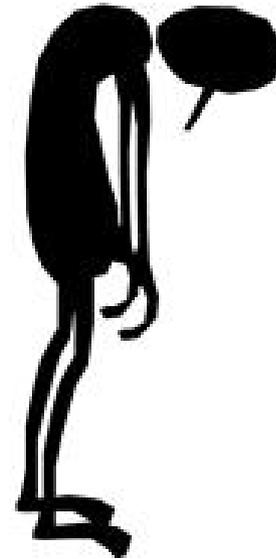
Eder et al. Transfus Med Rev 2009 (23): 205

Shift to evidence-based criteria

- Criteria for medical conditions based on “common sense”
- Variability in practice demonstrates lack of underlying scientific evidence
- Donors question rationale for deferral when they develop a new medical condition, especially if they are eligible in another jurisdiction

How do we get evidence?

- Impossible to do a randomized, controlled trial
- Difficult to isolate effect of an individual criterion
- Difficult to prove that there will be “zero risk increase”



Evidence to assess criteria

- Analysis of risk factors for adverse donor events, current criteria
- Analysis of adverse events in autologous donors, less restrictive criteria
- Surveillance of complication rates before and after changes
- International comparisons

DONOR BIOVIGILANCE!



Major risk factors for vasovagal reactions

- 1st time donor
- Younger age
- Low estimated blood volume
- Female gender

Wiltbank, et al. Transfusion 2008; 48:1799

Eder, et al. Transfusion 2011; 51:1522

Most likely to have a severe reaction



Autologous donors

- Slightly higher adverse reaction rate in autologous donors vs allogeneic donors
- Autologous donation generally safe, even in elderly patients/donors awaiting bypass grafting, with multiple comorbidities
- Adverse reactions are not more common in donors on antihypertensives, with diabetes

Post-implementation monitoring

- In 2005, ARC changed criteria to accept donors with a history of angina or MI who were stable and asymptomatic for 6 months after event
- Deferrals for ischemic heart disease and lung conditions decreased from 20.87 to 10.27 per 10,000 presentations in 2004 vs 2006
- Adverse event rate did not increase

Zou, et al. Transfusion 2007; 47:1990

Safety of blood donation from individuals with treated hypertension or non-insulin dependent type 2 diabetes – a systematic review

D. Stainsby,¹ S. Brunskill,² C. E. Chapman,¹ C. Dorée² & S. Stanworth²

¹*NHS Blood and Transplant Newcastle Blood Centre, Newcastle upon Tyne, UK*

²*NHS Blood and Transplant Systematic Reviews Initiative, Oxford Blood Centre, Oxford, UK*



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Review of studies, treated hypertension, type 2 diabetes

- *“No identified study indicated that raised baseline blood pressure level, treated hypertension or diabetes was predictive of increased adverse reactions in blood donors but the level of overall evidence was limited. This is the first attempt to systematically review a donor area as part of an approach to change longstanding practice recommendations, and may have implications for other recommendations for changes in donor acceptance criteria.”*

Stainsby, et al. Vox Sang 2010; 98:431

Conclusions

- Many criteria are designed to protect the blood donor
- These criteria may lead to increasing donor deferrals in the future
- Variability in practice points to a lack of evidence behind many criteria
- Donor biovigilance can assist in development of evidence-based criteria