# Donor safety and suitability for donation

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THE ROYAL MARSDEN

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# Talk overview

- Who is a suitable donor and how do we decide this?
  - At recruitment
  - At CT stage
  - At work-up/medical
- How do we keep donors safe during donation?

# Donation is very safe, but…

- No procedure is 100% safe
- No direct physical benefit to the donor
- Systems must be robust

- Donor health, assessed at three key stages:
    - Recruitment, CT, Medical

- There must be medical exclusions, but these may be:
  - Absolute or Qualified
  - Time dependent
  - Route specific

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# Types of Risk

- Risk to Recipient
  - TC responsibility
- Risk to Donor
  - Registry responsibility
  - Hard evidence generally does not exist
  - At best retrospective donor registry data, case reports and expert opinion
  - At worst, theoretical or just wild speculation etc…
  - “If in doubt, say NO”

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# Reducing risk: recruitment

- The best time to ‘exclude’ a donor is at recruitment
  - Unrelated: fixed criteria
  - Related: information giving BEFORE tissue typing

- Gives the community confidence in the donor pool
  - Reduce disappointments later
- Gives donors confidence their interests are being looked after

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Before completing the form please check below.

## YOU WILL NOT BE ABLE TO JOIN IF:

- **You are aged under 16 or over 30**
- **You weigh under 8st (51kg) or are severely overweight (a BMI of more than 35)**
- **You (or your partner) are, or think you are, HIV or Human T-cell lymphotropic virus (HTLV) positive or believe you may carry the Hepatitis B or C virus**
- **You don't live in the UK**
- **You have ever been injected with non-prescription drugs including body-building drugs (includes one off use)**
- **You have, or have EVER had, any of the following:**
  - Cancer
  - Coronary artery disease (blocked arteries in the heart, angina, heart attack), heart failure, bypass surgery or heart valve replacement
  - Stroke
  - Epilepsy (unless you have been free of seizures and off medications for epilepsy for the last three years)
  - Emphesema / COPD
  - Pulmonary embolism (blood clot on the lung)
  - Diabetes (unless controlled by diet alone)
  - Certain autoimmune diseases, including:
    - Ulcerative colitis or Crohns disease
    - Rheumatoid arthritis
    - Sarcoidosis
    - Multiple sclerosis
    - Systemic lupus erythematosus (SLE)
    - Ankylosing spondylitis
    - Any vasculitis
    - Pernicious anaemia
    - Myasthenia gravis
    - Guillain-Barre syndrome
  - Schizophrenia
  - Haemophilia or other bleeding disorder
  - Sickle cell disease (sickle cell trait is acceptable)
  - Thalassaemia (thalassaemia trait may be acceptable)
  - A severe allergy to latex or anaesthetic

**If you have a needle phobia, please speak to a member of staff.**

# WMDA medical guidelines:
http://www.worldmarrow.org/donorsuitability/index.php/Main_Page

- Attempt to harmonise practice
- Collect evidence
- Review regularly
- User friendly!

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Acupuncture, see Tattoo, body piercing and acupuncture

Alcohol intake

Alcoholism, see Alcohol intake

Allergy

Alopecia areata, see Single organ autoimmune disease

Anaemia

Anaphylaxis, see Allergy

Angina, see Coronary artery disease

Ankylosing spondylitis, see Back complaints

Antiphospholipid syndrome, see Thrombosis and Thrombophilia

Antithrombin III (ATIII) deficiency, see Thrombosis and Thrombophilia

Aortic regurgitation, see Valvular heart disease

Aortic stenosis, see Valvular heart disease

Arrhythmia

Arterial thrombosis, see Thrombosis and Thrombophilia

Asthma

Atrial fibrillation/flutter, see Arrhythmia

Atopy, see Allergy

# Alcohol intake



## Individual at risk

Donor / Recipient

## Guidance at RECRUITMENT

Unacceptable if current or recent history of alcohol abuse.

Unacceptable if history of alcoholic liver disease or cardiomyopathy.

Registries may wish to set an upper limit of safe alcohol consumption based on local recommendations.

## Guidance at CT/Work-up

Unacceptable if current or recent history of alcohol abuse.

Unacceptable if history of alcoholic liver disease or cardiomyopathy.

Registries may wish to set an upper limit of safe alcohol consumption based on local recommendations.

At the CT stage, registries may wish to request liver function tests in donors with a history of current or past alcohol abuse.

## Justification/References

Alcoholics or those with a heavy alcohol intake may be less reliable donors and there is a risk of donor attrition or withdrawal at a late stage. In addition, there is a possible risk of donation in those with alcohol-related organ damage, such as cirrhosis or cardiomyopathy.

G-CSF has been documented to cause transient rises in liver function tests, so should be used with caution in those with a history of liver disease related to alcohol.

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# Talk:Alcohol intake

## Comments from reviewers

alcohol unit should be explained

Only minimal description. I would say that liver function tests are routinely indicated. There is also a medical risk for the donor if there are alcohol-related complications, not only a reliance risk. See also my general comment on quantatively defined safety levels.

the cut-off '>40 units' per week seems me to be very high. In the NL we call someone a heavy drinker, if he, at least once per week, uses 6 or more units. 40 units per week means almost 6 units per day. I would assume such a person an alcoholic.

## Changes made after review 1

Removed reference to 'units'

Expanded justification section to include medical risks of alcohol with donation.

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# Work-up request

- Donor has already provided CT samples
- Reconfirmed interest
- Had 2 or more ‘formal’ medical screens

# Surviving the medical

- Full medical history
  - Travel history
  - Vaccines etc
  - Drugs/medication
  - High risk behaviour
  - Embarrassment/confidentiality
- Full examination

# Surviving the medical

- Blood tests
  - U&E, FBC, LFT
  - Blood group
  - Virology
- Additional tests
  - CXR
  - Ecg
  - Pregnancy test
  - ?bone marrow/ultrasound

# Medical reasons for failing the medical

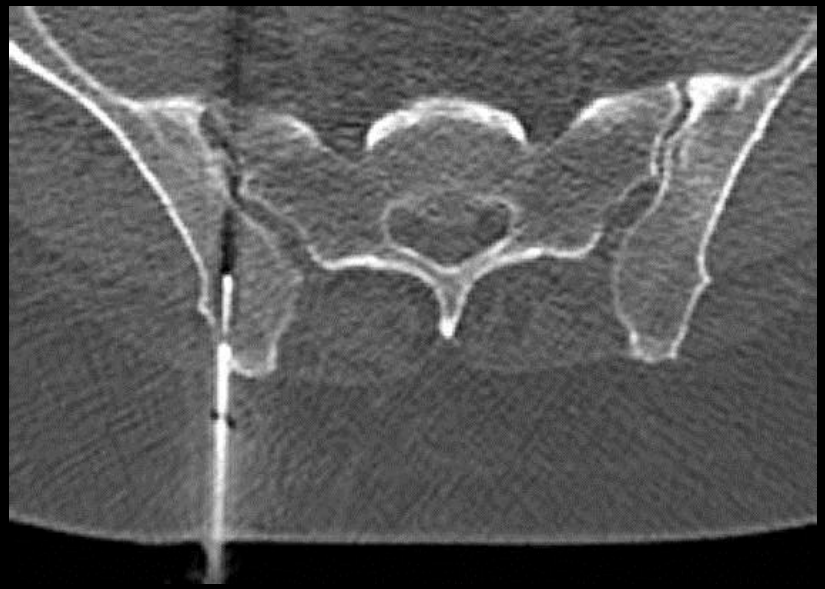
- Late donor deferrals for medical reasons are uncommon
- In general, they are related to occult medical conditions that could not have been picked up at an earlier stage:
  - blood pressure
  - abnormal laboratory indices
  - ECG
  - chest x-ray

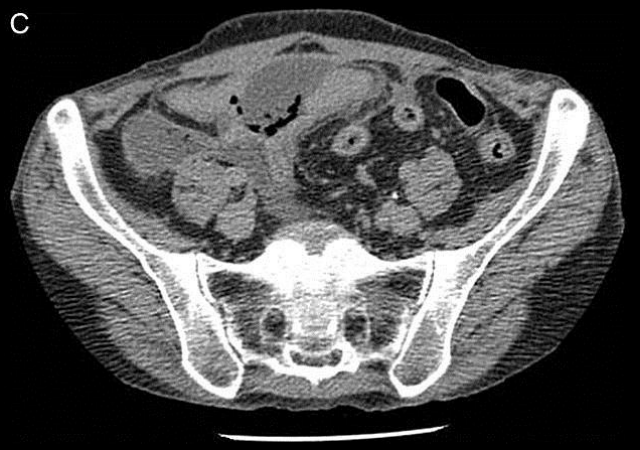
# Route of donation

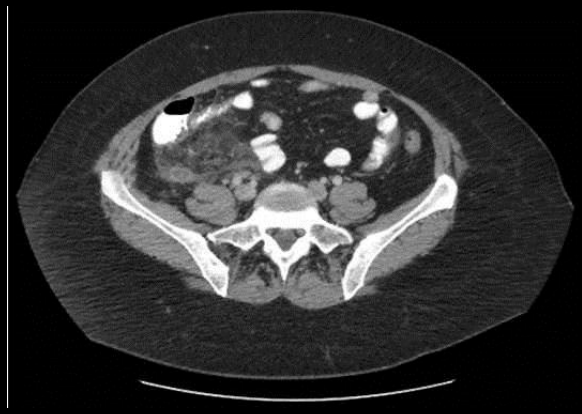
- Bone marrow vs PBSC
  - Medical
    - Back pain
    - Weight/BMI
    - Venous access
  - Donor choice

## Donor weight

- Bone marrow:
  - Risks of anaesthesia
  - Local injury
- PBSC:
  - Potential for more central lines





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# Bone marrow

- Autologous unit (??)
- Hospitalization
- General anaesthetic: formal review
- Anaemia
- Pain
- Time off work
- Slower recovery

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# PBSC: GCSF

- Administration of a drug
- Logistics
- Short term side effects
- Long term sequelae

# PBSC: Apheresis

- Short term side effects
- Good venous access
- Central venous catheters
  - Insertion of a CVC for PBSC collection should only be used in exceptional circumstances i.e. only when peripheral venous access is not deemed feasible after skilled assessment or cannot be obtained or has failed

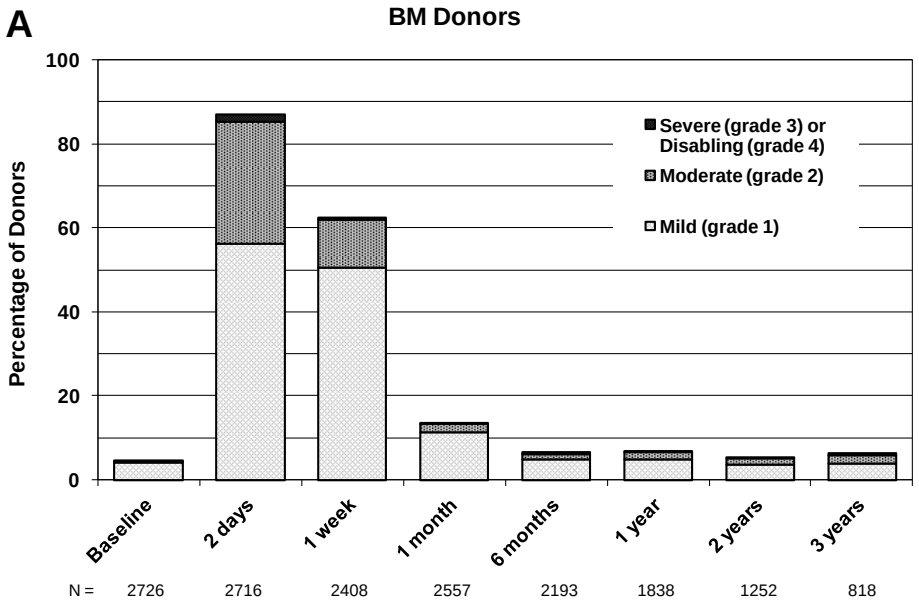
# Central venous catheters: policy

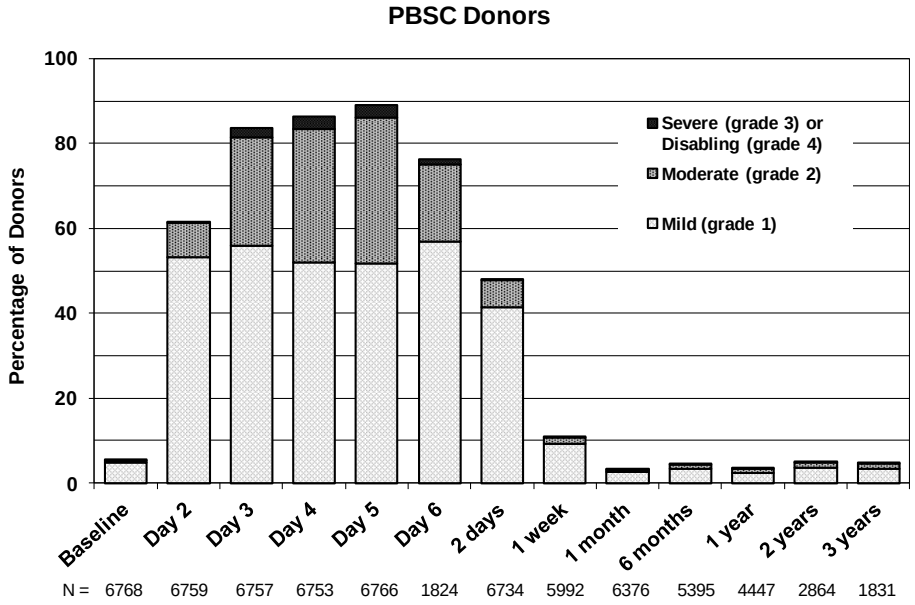
- Consenting procedures (and counselling) for CVC insertion, including who should take informed consent.
- Qualifications and expertise of the person(s) permitted to insert the CVC.
- Permissible sites for CVC insertion.
- The requirement for radiological guidance for all CVC inserted above the umbilicus, if locally available.
- The need for in-hospital care for all patients with CVCs, cared for by appropriately trained personnel.
- The requirement for reporting SAE/AEs.

# PBSC

- Second collection
- Failed collection (BM)
- Generally quick recovery

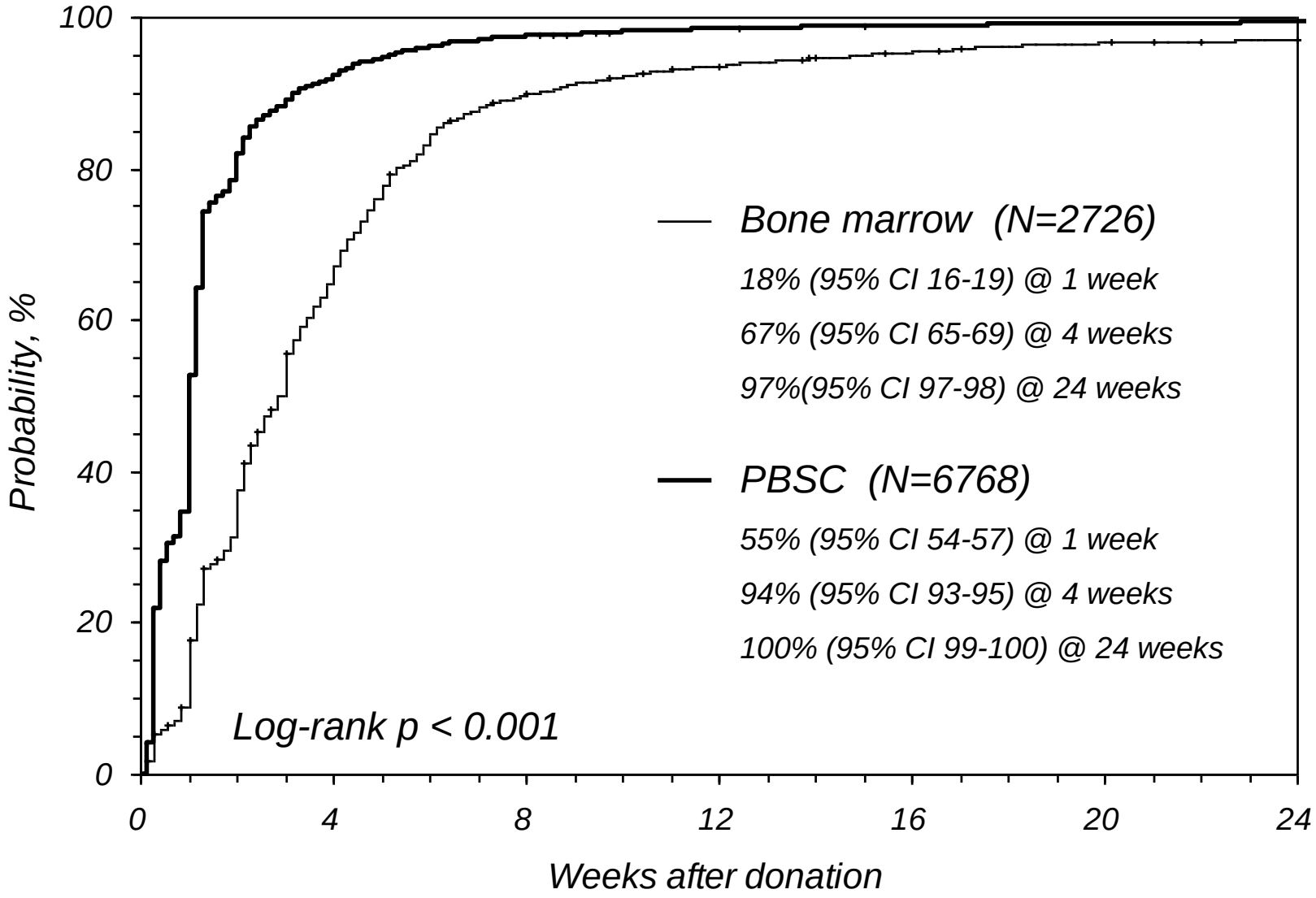
# Skeletal pain experienced by BM and PBSC donors at various time points peri-donation



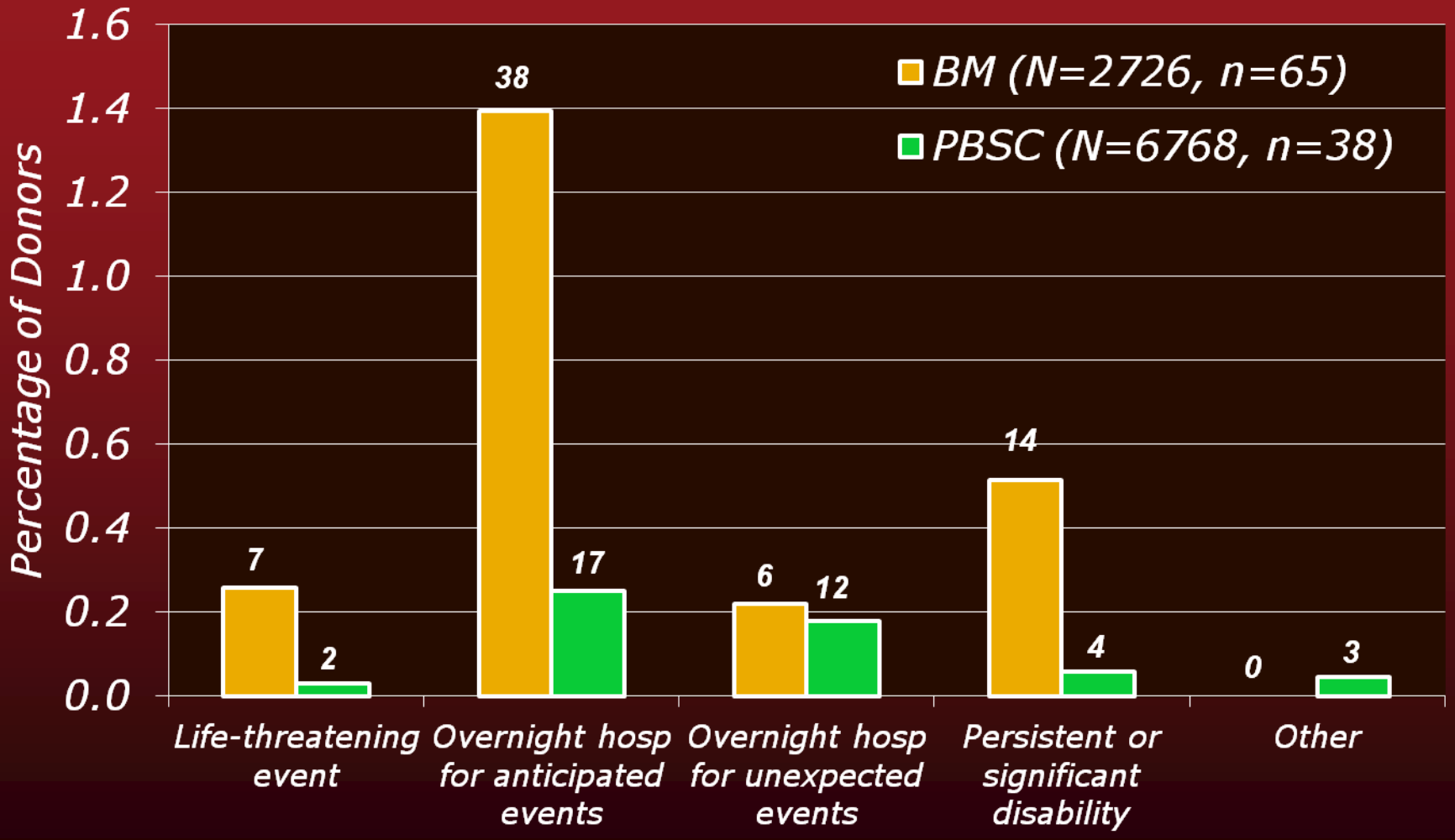

Pulsipher, et al, Blood 2012

# Probability of reported complete recovery from stem cell donation




Pulsipher, et al, Blood 2012

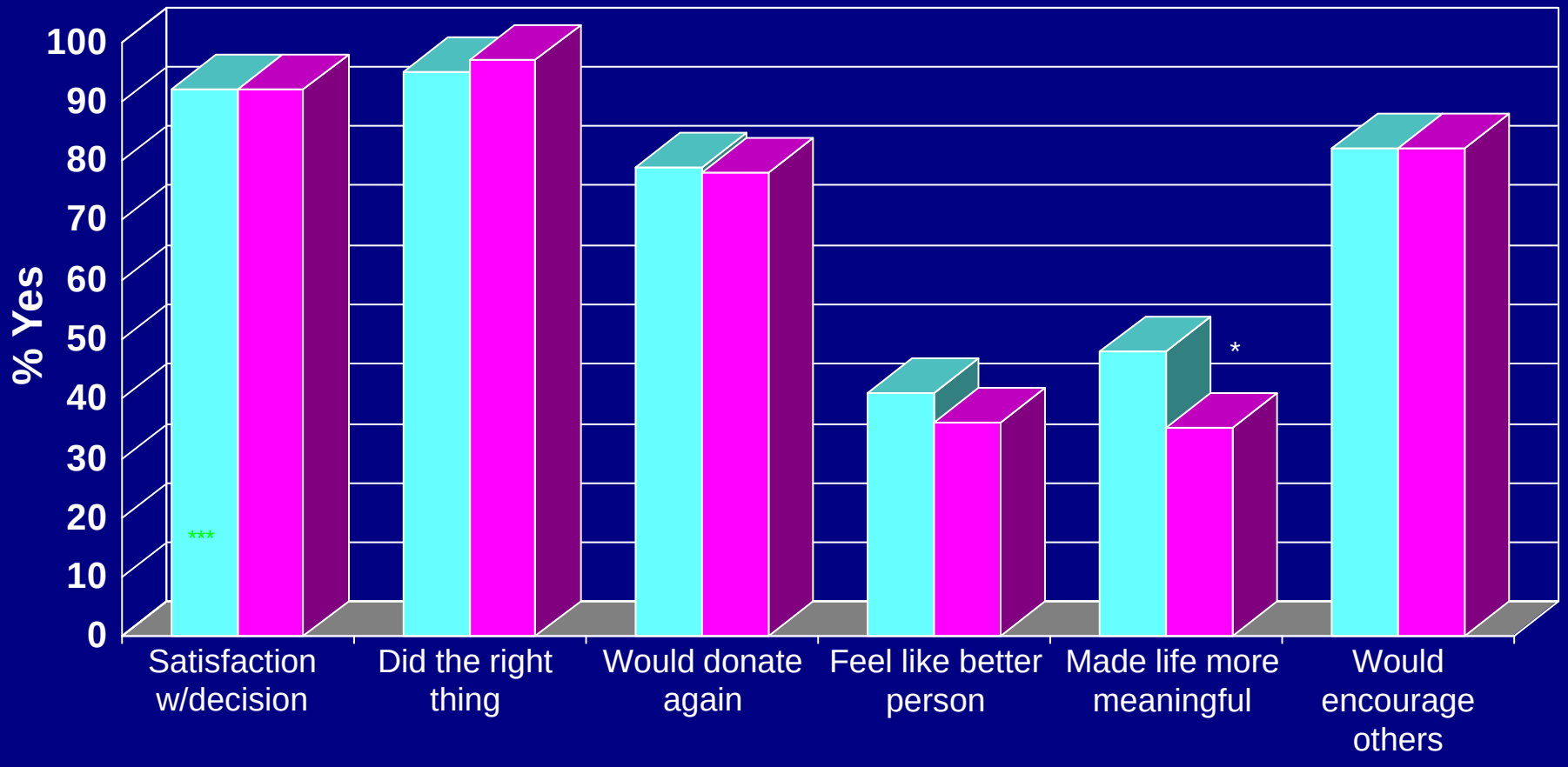
# Severe Adverse Events by Category




The number above the bar indicates the number of SAEs in that category.

Pulsipher, in press

# Donation Satisfaction




*p ≤ .05; **p ≤ .01; ***p ≤ .001

Galen Switzer, personal communication

# Conclusion

- Donation is generally safe and well tolerated
- Strict criteria must be followed for:
  - Exclusions
  - Medical examination
  - Harvest
  - GCSF and apheresis
- Lots of help available from national/international societies and organisations