

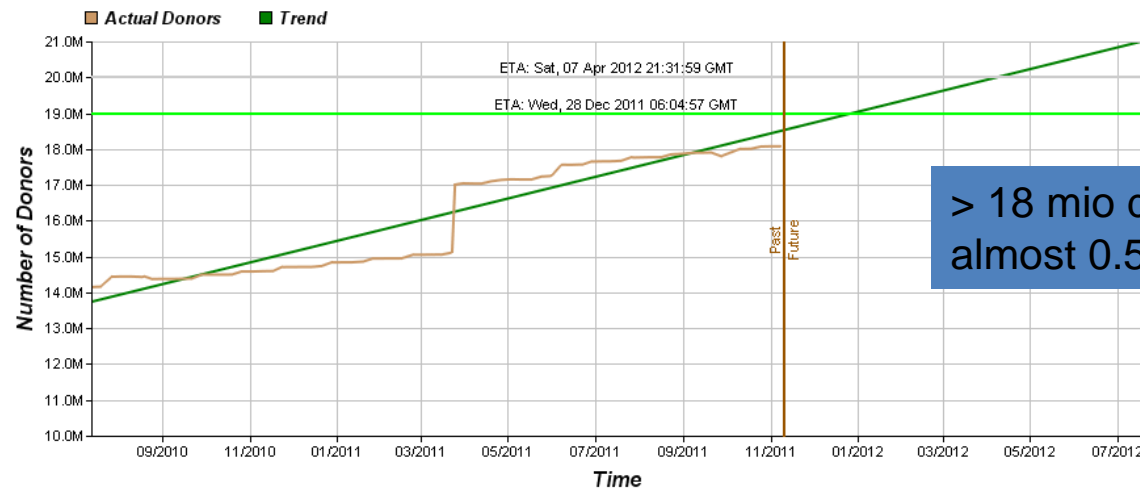
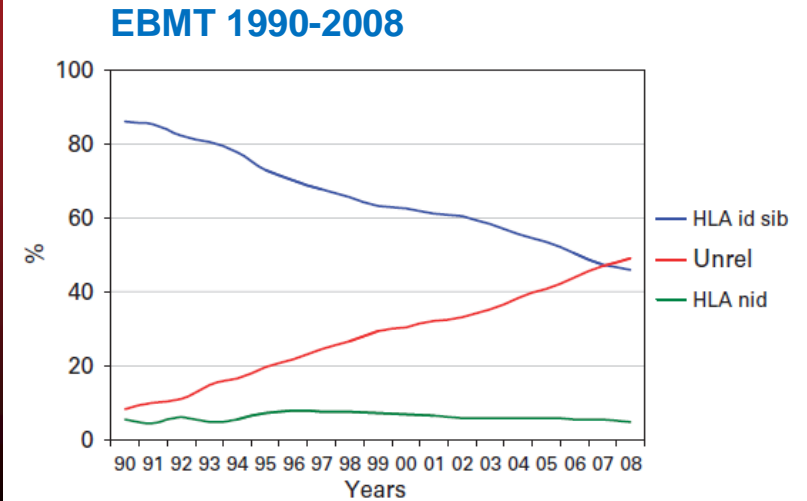
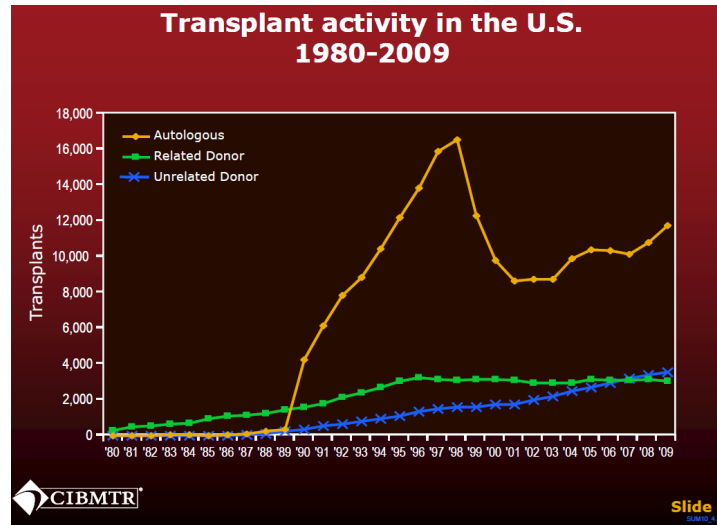
Donor outcome follow up a global challenge

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Background I

- for every allogeneic HSCT, you need a donor



> 18 mio donors
almost 0.5 mio CBU

Background II

- Donation is associated with rare severe adverse reactions
- Incidence?
 - Available safety data are mainly from unrelated donors (NMDP, DKMS, WMDA: www.worldmarrow.org)
 - Data on related donors are still scarce (JSHCT, RDSafe, Spain, Switzerland, Poland, single centers)
 - include many donor populations who are not represented in the URD group
- Why do we need a donor outcome follow up?
because of:
 - may already be mandatory by law
 - it's in the WHO guiding principles
 - donor selection, counselling, identification of risk factors
 - SAR may have detrimental effects on the willingness to donate

**donor outcome follow up
minimal dataset
1st donor outcome workshop**



Donor characteristics and procedure related data

Donor data:

- Donor ID
- Age at donation
- Sex
- Relationship to the recipient: twin, sibling, other family donor, unrelated donor

Harvest data

- Start date of the procedure
- Was the product collection completed? → yes/no
- Number of harvest/subsequent donation
- Were hematopoietic growth factors used (eg. GCSF)? → yes/no
- Were cell binding inhibitors used (eg. plerixafor)? → yes/no
- Was erythropoietin used? → yes/no
- Were other drugs used for mobilization (without further specification)? → yes/no

Product:

BM (including harvest of MSC), PBSC, both, unstimulated leucapheresis (eg. DLI), others

Adverse event reporting

Complications in temporal association with the donation procedure:

- report only severe adverse reactions (SAR)
 - definition of SAE is the same as in WMDA and includes:
 - Death (ICD code)
 - life-threatening event (ICD code)
 - require in-patient hospitalization or prolongation of existing hospitalization due to WHO grade 3 or 4 toxicity (ICD code)
 - persistent or significant disability/incapacity (ICD code)
- every SAR occurring in the interval between start of the donation procedure and day 30 after end of the procedure must be reported.
In most countries, these events have also to be reported to the authorities.

Long term follow up

- up to 10 years after completion of the last donation procedure
- minimal reporting after 1 year, 5 years and 10 years but annual or biannual reporting is recommended

3 items: survival status – malignancy – autoimmune disease

Donor survival status

- Date of last follow up or death
- Donor alive? - if no: cause of death (ICD code)

Malignancy

- Hematologic malignancy?
 - if yes: was diagnosis confirmed by medical data (ICD code)
- Non-hematologic malignancy?
 - if yes: was diagnosis confirmed by medical data (ICD code)

Autoimmune disease

- if yes: was diagnosis confirmed by medical data (ICD code)

the future

- donor outcome follow up for all donors
- may be performed practically in different ways, but with identical data sets
- introduction of new mobilizing agents (e.g. biosimilars, cell-binding inhibitors) need to be assessed carefully (separate funding?)
- reimbursement for allogeneic transplant must include the outcome follow up for two individuals: the patient and the donor, who makes the allogeneic HSCT possible