



Blood Biobanking – Chances and Risks

The Bavarian Red Cross "Blood Donor Biobank"

EORTC-NCI-ASCO Meeting - November 2007





Outline

- Types of biobanking
- Why blood biobanking?
- Why blood banks?
- Why the Bavarian Red Cross Blood Bank?
- The "Blood Donor Biobank"
- Chances and risks of blood biobanking





Different Types of Biobanks

- Genetic biobanks collect biological samples from the general population or particular subsets of individuals
- Disease biobanks collect samples from patients suffering from selected conditions
- Prospective banking of normal and pathological samples(leftover samples) collected during routine clinical pathology diagnostic procedures
- Prospective banking of samples collected from healthy volunteers





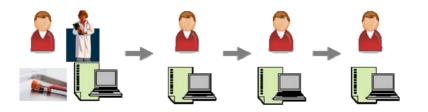
Two Models of Biobanking

Collection of patient material

Collection of samples from healthy volunteers



Enrollment sample and data collection



| Enroliment | 5 yrs follow up | 10 yrs follow up | 15 yrs follow up |
|-----------------|--|------------------|------------------|
| sample and data | Change in life style or health status? | | |
| collection | | | |





Pitfalls Prospective Biobanks

- Reasonable number of participants required
- Time until a healthy individual becomes ill is not forseeable
- High degree of compliance required
- High infrastructure, administration and storage costs





Why Blood Biobanking?

- Easy to access convenient for donor (higher degree of compliance)
- Easy to collect convenient for doctor/study nurse
- Easy to transport and to store convenient for biobank operator
- Easy to analyse convenient for researcher





Why Blood Banks?

Blood banks are biobanks

• Collection and storage of biological material and associated data

Existing infrastructure for

- Large volume operation
- Sample traceability
- Sample storage
- Networking capability

Well established standards for the manufacture of pharmaceutical blood products (experienced employees, GMP facilities, SOPs, regular audits)





Why the Bavarian Red Cross Blood Bank?

Red Cross Blood Banks

- The Red Cross collects one third of the 75 Mio blood donations that are collected annually worldwide
- In more than 20 countries (e.g. Australia, Japan, Belgium, Finnland, Switzerland) blood supply is solely organised by the national Red Cross
- In 35 countries the national Red Cross is responsible for the predominant part of the blood supply (US, Austria, Germany)

The situation in Germany

- Red Cross Blood Banks are responsible for 80% of the blood supply
- 8 blood banks collect 4,5 Mio blood units of approximately 2 Mio blood donors

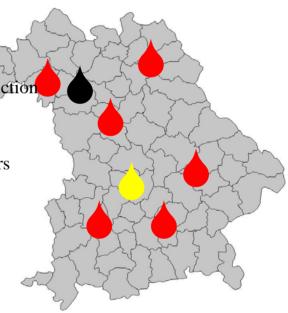




Why the Bavarian Red Cross Blood Bank?

The Bavarian Red Cross Blood Bank

- Pharmaceutical company founded in 1953
- 6 institutes for transfusion medicine, 1 central production site and 1 plasma centre
- 20 blood drive sessions a day, 5 days a week
- 500000 blood units p.a. collected from 400000 donors
- > 33000 laboratory tests daily
- > 700 Employees
- > 250 Medical doctors
- > 18000 honorary helpers







Reasons for a biobank at the Bavarian Red Cross blood bank

- Well characterised and large donor collective
- Over 4 Mio plasma samples stored in a fully automated and access controlled storage facility at -42°C
- Experienced in the conduction of epidemiological and diagnostic studies according to ICH GCP and other international and national guidelines
- Donors are willing to participate in research studies





Over 4 Mio samples stored at -42°C

Legally required plasma sample of every blood donation for potential follow up analysis

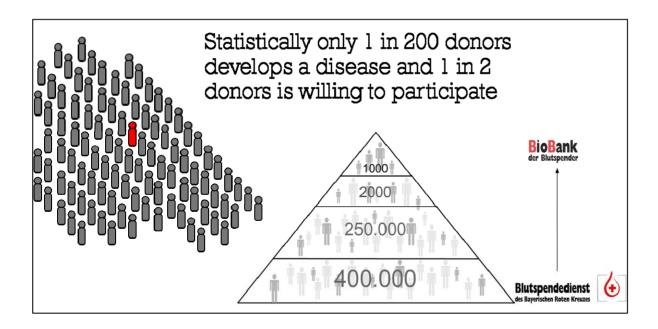






Large donor population

400000 registered blood donors

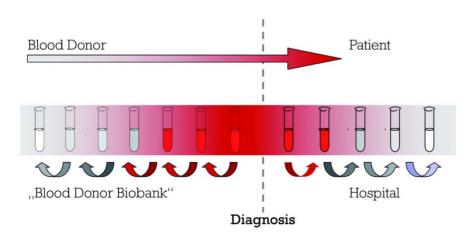






Available samples

- Multiple plasma samples of one donor
- Plasma samples taken every 6 months on average over a period of 7 years
- Samples taken <u>before</u> the diagnosis of a disease

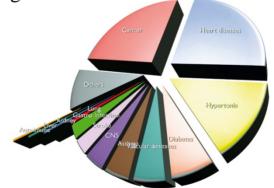






Approval by the responsible ethics committee and data protection boardWritten informed consent of more than10000 donors

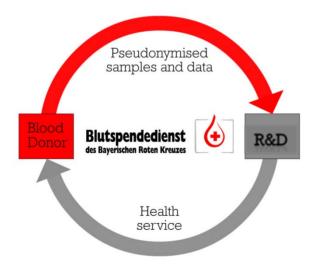
- 5000 healthy and active blood donors
- 5000 former blood donors diagnosed with a severe disease
 - Cancer
 - Heart disease
 - Diabetes
 - Cardio vascular
 - Stroke
 - CNS
 - Autoimmune, Asthma
- Over 100000 plasma samples for research projects







Our idea is to contribute to the identification of predictive biomarkers by providing samples collected before the diagnosis of a disease







Blood Biobanking- Chances and Risks

Chances

- Accessibility allows regular sample collection
- Blood is routinely collected at blood donation sessions, hospitals, doctor surgeries
- Blood collection is easy to standardise
- Low collection, shipment and storage costs
- Allows screening procedures

Risks

- Only circulating biomarkers can be identified/analysed
- Multiple operators , no standardised procedures





Thank You

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