The „Blood Donor BIOBANK“

the first successful combination of blood donation and biobanking for medical research¹

¹ Zoglmeier et al., TRANSFUSION 2011, 51(5): 1121-1122

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SWISSTRANSFUSION 2011, Fribourg/CH
Outline

- Biobanking and blood donation
- Why the Bavarian Red Cross Blood Donor Service?
- Ethical and data protection issues
- Financing concepts
- Examples of research projects
- Successes and challenges
Why biobanking?

- Increased focus on personalised medicine, early diagnosis / prevention in order to reduce costs of health care system
- Improved methods for biomarker analysis, high throughput assays/multiplexes
- Growing demand for biological samples obtained under standardised conditions for biomarker research
- High quality biobank may replace clinical study and save time and money
Value of biobanks

The value of a biobank depends on:

- the number of samples and data
- the quality of sample processing/storage and data
- the IT infrastructure
- continuous investments
- long-term compliance of participants
- the design of biobank and study
Two types of biobanks

Disease biobank
Enrollment, sample and data collection
Monitor changes in life-style and health status

Prospective biobank
Enrollment, sample and data collection
5 year follow-up
10 year follow-up
15 year follow-up

Vortrag Dr. Weinauer, Swisstransfusion
2011, Fribourg, CH
Prospective biobanks

**Pros:**
- Covers many different diseases
- Large numbers of reliable controls
- Suitable for epidemiological studies
- Prospective, tailored data collection, life style monitoring
- Serial and pre-diagnostic samples from individual biobank participants

**Cons:**
- Sufficient numbers of participants required
- Not predictable when and how many participants become ill
- High degree of compliance / long-term commitment required
- High infrastructure, administration and storage costs
Why a blood donor service?

- Existing infrastructure for:
  - Large volume operation
  - Sample and data storage
  - Sample traceability
  - Networking capability
- Large pool of blood donors
- Standards for the manufacture of pharmaceutical blood products:
  - experienced, trained employees
  - CLIA/GMP standards
  - QM system (SOPs, audits,..)
Blood banks in Germany

- Red Cross blood banks are responsible for 80% of the German blood supply
- 8 blood banks collect 4.5 mio blood units of approximately 2 mio blood donors per year
- Legal requirement for a **5-year storage** of plasma samples for backtracking **since 1998**
- The Bavarian Red Cross (BRK) Blood Donor Service is the only Red Cross blood bank with a **central production and storage facility**
The BRK Blood Donor Service

- Pharmaceutical company founded in 1953
- 5 institutes for transfusion medicine and 1 central production and storage site
- 20 blood drive sessions a day, 5 days a week
- > 33,000 laboratory tests daily
- > 700 employees
- > 250 medical doctors
- > 18,000 honorary helpers
- **500,000 blood units p.a.** collected from **400,000 blood donors**
Central storage facility

- Sample storage at -42°C in one of the world’s largest, fully automated biorepositories in Wiesentheid
- Built for storage of pharmaceutic plasma
- 2011: ~ 4 mio. samples stored (900,000 samples with informed consent)
- 2011: New -80°C storage facility for the long term-storage of selected samples implemented
Standardised and qualified processes

- All blood donations are uniformly processed and stored in the central production site in Wiesentheid
- Proven, highly standardised processes, as implemented for pharmaceutical production of blood products
- DIN EN ISO 9001 certified quality management of all departments since 2008
- Qualified personnel, years of experience
Large pool of blood donors

1,000 blood donors with diseases available in the “Blood Donor BIOBANK” per annum

2,000 blood donors with diseases

250,000 regular blood donors

400,000 active blood donors
Blood donors are representative of the general Bavarian population\(^1\)
Exceptions: ↓ smoking, ↓ asthma, ↓ heart attack

\(^1\)The BSD health study: a pilot study to examine the comparability of Bavarian blood donors with the Bavarian general population by a comparison with KORA S4. Müller et al., Gesundheitswesen 2009; 71:481-8
Pre-diagnostic blood samples
approx. 4500 “Blood Donor BIOBANK” participants with diseases:

- cancer (prostate, breast, skin, gastrointestinal tract)
- cardiac diseases
- diabetes
- vascular diseases
- stroke
- CNS diseases
- autoimmune, gastrointestinal, respiratory diseases
Resources of the „Blood Donor BIOBANK“

- Serial, pre-diagnostic plasma samples for biomarker research, especially for slowly progressing / chronic diseases
- Data for epidemiologic studies
- Highly compliant donor pool for fast recruitment of study participants
- Established, powerful infrastructure for the conduction of prospective studies, screening and prevention campaigns
Ethical and legal issues

Issues relating to all biobanks:

- Protection of personal data
- Information and informed consent of participants
- Purpose for sample use, quality of research
- Transfer of ownership
- Communication of study results

Special issues of blood donation and biobanking:

- Separation of blood donation and biobank participation
- Potential damage of trust
- Extension of the medical scope of blood donation
Ethics vote

Responsible national ethics committee: Ethics review board of the “Bayerische Landesärztekammer”

- Positive ethics vote allowing general informed consent
- Additional review of research projects to ensure proper use of samples and data
Informed consent

Key documents: **Participant information** and **informed consent** form

- Documents are read and signed at home, no pressure to participate
- IC allows general use of samples and data for research
- Genetic analyses excluded
- Initial disease information by biobank participant
- For further (study-specific) medical data blood donors are re-contacted
- No individual communication of study results

(German documents can be downloaded at www.biobank.de)
Data protection concept was established following guidelines for biobanks established by TMF¹:

Separation of personal and medical data!

Practical implementation:

- personal and medical data stored in separate databases on separate servers
- pseudonymisation of data in research database (using 2 codes)
- access strictly limited to qualified, dedicated personnel
- supervision by internal data protection officer

¹ Telematikplattform für Medizinische Forschungsnetze
Prerequisite for use of samples

- Backtracking tests (e.g., infection state)
- Other uses (e.g., research)
- Participants’ information
- Written informed consent

- Ethics vote
- Data protection
- Pseudonymisation
- o.k.
The Bavarian Red Cross Blood Donor Service is a not-for-profit organisation, but investments are required to ensure biobank quality and sustainability:

- „Fee-for-service“: BIOBANK provides samples and data for a customer
- Funding: collaboration projects between BIOBANK and research institutes / companies
- Licensing contracts
Projects

- Since 2006 about 20 research projects using „Blood Donor BIOBANK“ samples have been performed
- Project partners: small and large pharmaceutical and diagnostic companies, academic research institutes
- Main indications:
  - cancer, cardio- and cerebrovascular diseases, diabetes
Selected projects

- Colon cancer: identification of a panel of new, early biomarkers using mass spectrometry/multiplex assays
- Stroke: evaluation of the prognostic value of previously identified biomarkers
- Coronary disease: evaluation of the prognostic value of previously identified biomarkers
Two studies were performed to screen blood donors for their risk to develop type 2 diabetes:

2005: 10,000 blood donors (recruited within 2 weeks)
2008: 61,000 blood donors (recruited within 2 months)

- Benefit for blood donors: early diagnosis, preventive measures
- Benefit for BIOBANK: increase number of biobank-participants, samples and data from early diabetic patients
- Participation rate: approx. 80%
Example of a combined epidemiological/diagnostic study

- **Blood Donor Service**: screening, providing samples and data
- **Research companies**: analysis of samples and data
- **Academic institutes**: scientific advice, data analysis
m^4 excellence cluster

- „Blood Donor BIOBANK“ is part of the Munich excellence cluster „m^4 - personalised medicine“
- Funded by the BMBF (Bundesministerium für Bildung und Forschung)
- Aim of our project: Implementation of an additional -80°C storage facility for categorised long-term storage of selected samples; improvement of infrastructure; networking
- m^4 - Biobank alliance: posters No. 812 and 813
History

2001
Start of sample collection

2003
Preparatory phase BIOBANK

2006
Official launch BIOBANK
2,5 mio samples

2011
Approx. 4 mio samples
70,000 biobank participants
20 research projects
New -80°C storage facility
Achievements

- Several successful projects conducted
- Large screening studies performed within short time
- New biomarkers identified, proving sample quality
- m^4 funding allows improvement of infrastructure
- Growing demand for biobank samples observed
Remaining challenges

- Despite existing infrastructure major investments
- There is less money spent on diagnostic than on pharmaceutic development
- Limitation to plasma samples
- Identification of diseased blood donors
- Validation of medical data
Thank you for your attention!