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DISCLOSURES: PATH-Foundation has received donations and/or has sponsoring relations with the following companies: Roche, Novartis, GlaxoSmithKline, Pfizer, AstraZeneca, Amgen and Pierre Fabre

Abstract

Purpose: PATH was founded by a German breast cancer advocacy group in 2002. It acts as an independent foundation. While there are other tumor banks around the world, the immediate benefit for the donating patient is not always clear. With PATH, we set out to prove that patients, physicians and researchers can join forces to operate a tumor bank at the highest ethical standards while collecting tumor specimen at highest and standardized quality. In addition, PATH has developed new data acquisition and management methods for disease and therapy process monitoring and follow-up.

Design: PATH Foundation is a non-profit organization. Seven certified German "breast centers" are currently our partners. The PATH concept is presented to patients in pre-OP discussion and they are given the opportunity to take part, by agreeing to an informed consent. The informational documents and consent form were developed in collaboration with Prof. Taupitz of Germany's National Board of Ethics. The whole PATH procedure causes no additional cost for the patient.

PATH tissuebank contains fresh frozen quality specimen stored in -152-°C freezers or liquid nitrogen (LN2) tanks. The first aliquot of each specimen is stored exclusively for the patient, the rest of the material is donated to PATH for research purposes. All cooperation partners (OB/Gyns and pathologists) commit to working strictly according to PATH's SOPs. Cooperation partners' compliance and the implementation of the SOPs is monitored in biannual visits and meetings. All important data is collected in PATH's own centrally managed MySQL database. Furthermore, PATH collects necessary follow-up data directly from the patient as well as from local tumor registries.

Objectives and Methods

Special credibility: "Driven and inspired by a passionate desire to live!"

Main objectives:

- tissue and serum storage for patients at no cost
- Support of clinical and genetic research

PATH tissue bank contains fresh frozen:

1. Tumor specimen,
2. Normal tissue samples,
3. Blood serum aliquots

Monitoring:

- Compliance and implementation of SOPs monitored by biannual visits and meetings with each cooperation partner
- annual joint revision and adjustment of the SOPs

Dimensions of data collection: All data are collected in PATH's centrally managed database

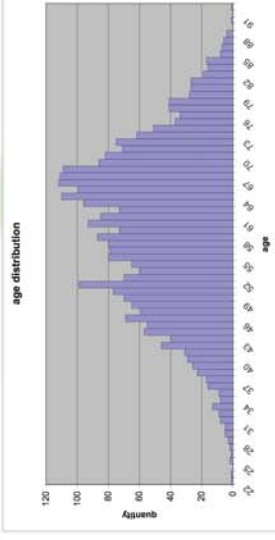
Collected data:

1. Patient-related data
2. Sample processing data (e.g. time of ischemia)
3. clinical and tumor associated data excerpted from gynecologists' or pathologists' medical or diagnostic report
4. Follow up data (disease and treatment history)

Advantages to patient:

- Patient can access her tissue sample whenever she wants to, e.g. to perform newly developed diagnostic tests having possible implications on her personal disease management
- No additional burden to surgery
- No cost to patient

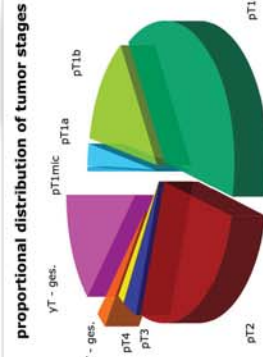
Results - collecting tumor specimen



Date of evaluation: 15.10.2009

Collective: 3070 well documented cases

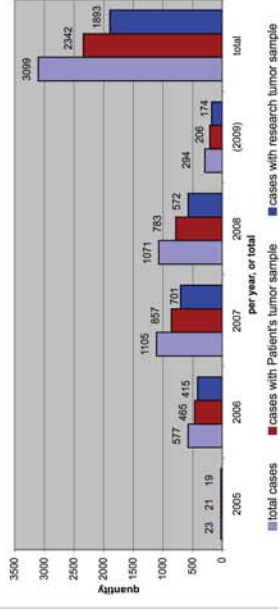
Average age: 60 years, median age: 61 years
50% of the cases btw. age 51 and 68 years



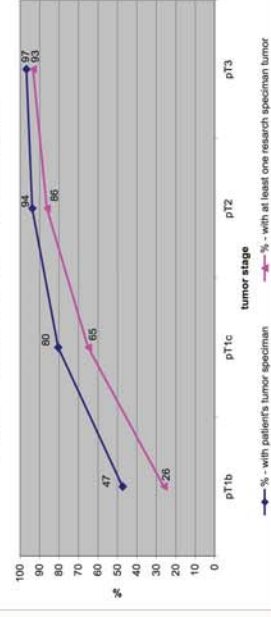
	total	%
pT1mic	15	0,5
pT1a	72	2,5
pT1b	362	13,1
pT1c	1095	37,7
pT2	777	26,7
pT3	90	3,1
pT4	38	1,3
rT-ges.	64	2,2
vT-ges.	374	12,9
total	2907	100,0

Quantities of specimen	
tumor, patient	2.342
blood serum, p.	2.918
normal tissue, p.	2.381
tumor, research	4.080
blood serum, r.	9.029
normal tissue, r.	4.075
total	24.825

total cases - cases with tumor reservation



Possibility of sample reservation in different tumor stages



Results - follow up

Follow up efforts started in March 2009. Patients are contacted regularly by a „patients newsletter“. For Follow up patients receive an additional personalized letter. They are informed about being contacted by phone soon plus asked to give additional informed consent to enable PATH to contact the actual treating physician to validate medical history.

Contacted patients by mail, so far (15.10.) 1251
Additional informed consent (permission to contact physician) 624 ~ 50%
Called and interviewed by phone 802 ~ 65%
No follow up, by now 449 ~ 35%

Average age of this group (youngest patient: 23 years; oldest patient: 88 years)
Events of death, total 32
(15 „breast cancer associated“; 17 indistinct)
Events of progression, total 44
(30 cases of metastases, 10 cases of local recurrence, 4 indistinct cases)

Our clinical partners

PATH Foundation's work and efforts won't be possible without the work of our partners! These are (OB/GYNs and pathologists):

- Klinikum **Kassel** (Prof. Dimpfl/Prof. Walter)
- Universitätsklinikum **Marburg-Gießen** (Prof. Wagner/Prof. Moll)
- Uniklinik and Johanner Krankenhaus **Bonn** (Prof. Göhring/Prof. Büttner)
- Johannes-Hospital **Dortmund** (PD Dr. Kunz/Pathologisches Institut Josefshaus)
- Brustzentrum Herne/Ruhruniversität **Bochum** (Prof. Tannapfel)
- Klinikum **Offenbach** (Prof. Jackisch/Dr. Braun)
- Uniklinikum/Krankenhaus St. Josef **Regensburg** (Prof. Ortman/Prof. Hofstädter)

Conclusion

Over the last 5 years PATH has gained broad experience in tumorbanking. Because of this expertise we are able to operate the biobank at the highest ethical and qualitative standards. With its follow-up efforts, PATH will be able to provide a great variety of research specimen with at least a **median follow-up time of 5 years in 2011!** So we will be able to support e.g. genome wide sequencing/association projects or biomarker discovery and validation projects with a great number of fresh frozen tissue samples as well as other specimen like serum or paraffin embedded tissue.

Giving away of samples:

Research groups submit a request (description of research project, biometric specifications, suspected outcome), project evaluation by PATH's advisory boards (scientific board, board of trustees), final decision by the board (patient majority)