CHARITÉ
UNIVERSITÄTSMEDIZIN BERLIN

Telemedicine in the Prevention and Monitoring of Heart Disease

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26. April 2012

Fontane
Gesundheitsregion der Zukunft
Nordbrandenburg

GEFÖRDERT VOM
Bundesministerium
für Bildung
und Forschung

LAND
BRANDENBURG

EUROPÄISCHE UNION
Europäischer Fonds für
Regionale Entwicklung

Charité-Universitätsmedizin Berlin

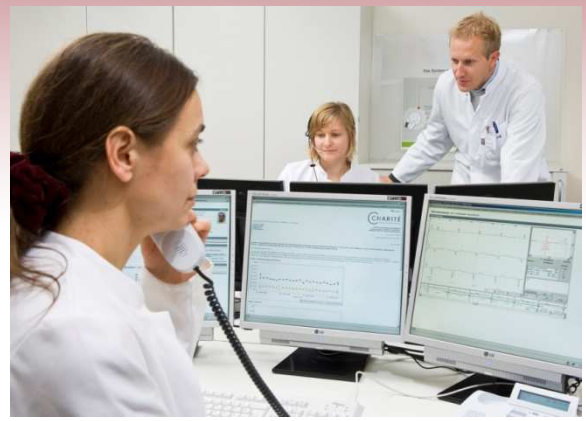
Facts

- Founded in 1710
- 11 Nobel laureates
- 12.922 employees
- 7.112 students
- 103 departments

- Turn-over 2009: 1.2 Billion €
- Scientific budget 2009: 127 Million €

Charité- Centre for Cardiovascular Telemedicine

- Division of the Department of Cardiology (Prof. Dr. med. Gert Baumann)
- Founded: 1st April 2008
- 11 Employees (4 doctors, 3 nurses, 1 study nurse, 2 scientists, 1 student)



Main areas

- Telemedical care of patients
- Education
- Research Projects
  - Partnership for the Heart (PfH) (BMWi, 2005-2011, 16.0 Mio €)
  - Health Region of the Future Northbrandenburg - Fontane (BMBF, 2009-2014, 20.0 Mio €)
  - Nanoelectronics for Mobile AAL-Systems (BMBF/EU, 2010-2013, 0.5 Mio €)

Definition: Telecardiology

Telecardiology = Telemedicine in Cardiology

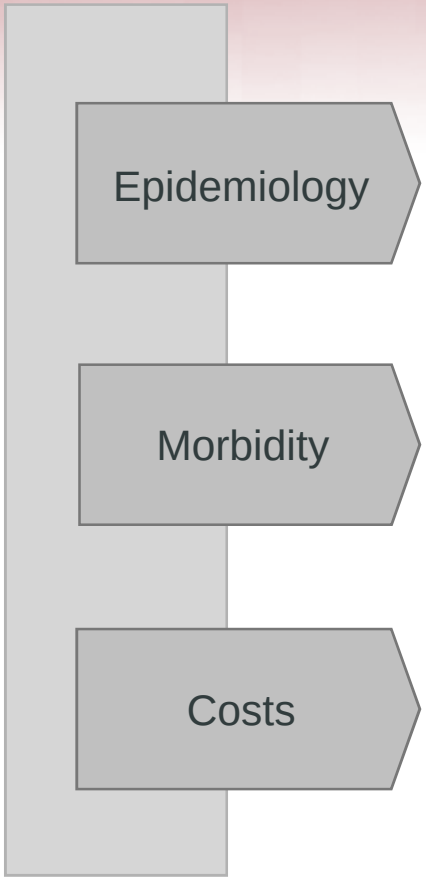
Remote patient monitoring, diagnostics and therapy using modern information and communication technologies (ICT)

Basic Scenarios in Telemedicine

a) „doc2doc“ systems, connectivity between health care providers

b) „doc2patient“ systems, connectivity between doctor and patient (remote patient monitoring)

Chronic Heart Failure – a Demographic Burden



- **Incidence approx. 1.2 million patients** (every tenth German citizen over 65 years)
- Approx. 200.000 new cases per year
- Approx. 9% Mortality in class NYHA II/III per year

- **Major cause of hospitalization** (approx. 375.000/year)
- Non-cardiovascular co-morbidity (renal failure, COPD; depression)
- **200.000 patients with 375.000 Hi-hospitalizations**

- Therapy costs – 3 billion €/year
- Approx. 85 % of the costs for hospital stay

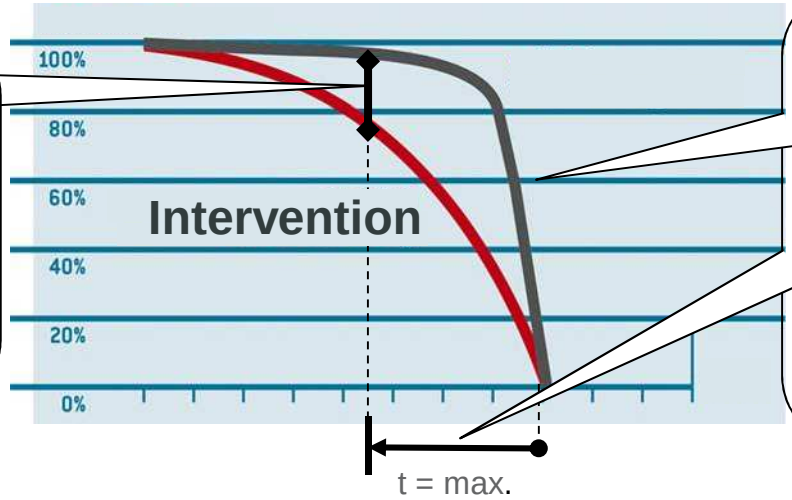
Benefits of Remote Patient Monitoring in CHF?

Gap between objective deterioration and subjective perception of cardiac function

„I feel healthy“

≠

„I am healthy“



- Intervention before significant deterioration (emergency)
- Time to Intervention (hours)

Standards for Remote Patient Monitoring

- Remote patient management as part of established health care structures
- Professional standards for telemedical staff
- Telemedical Homecare Devices – robust and easy to handle even for elderly people
- High standard in patients' data and privacy protection
- Data transfer of vital parameters via mobile technology (e.g. „EDGE"-Protocol)

Research and Development Project: „Partnership for the Heart“ (2005-2011)

- Development of a Remote Patient Monitoring System including mobile sensor platform and electronic patient record for cooperated telemedical care of chronic heart failure patients
- Clinical Trial: *Telemedical Interventional Monitoring in Heart Failure* (TIM-HF, NCT00543881)
- Funded by the Federal Ministry of Economics and Technology (Project number: 01MG531)

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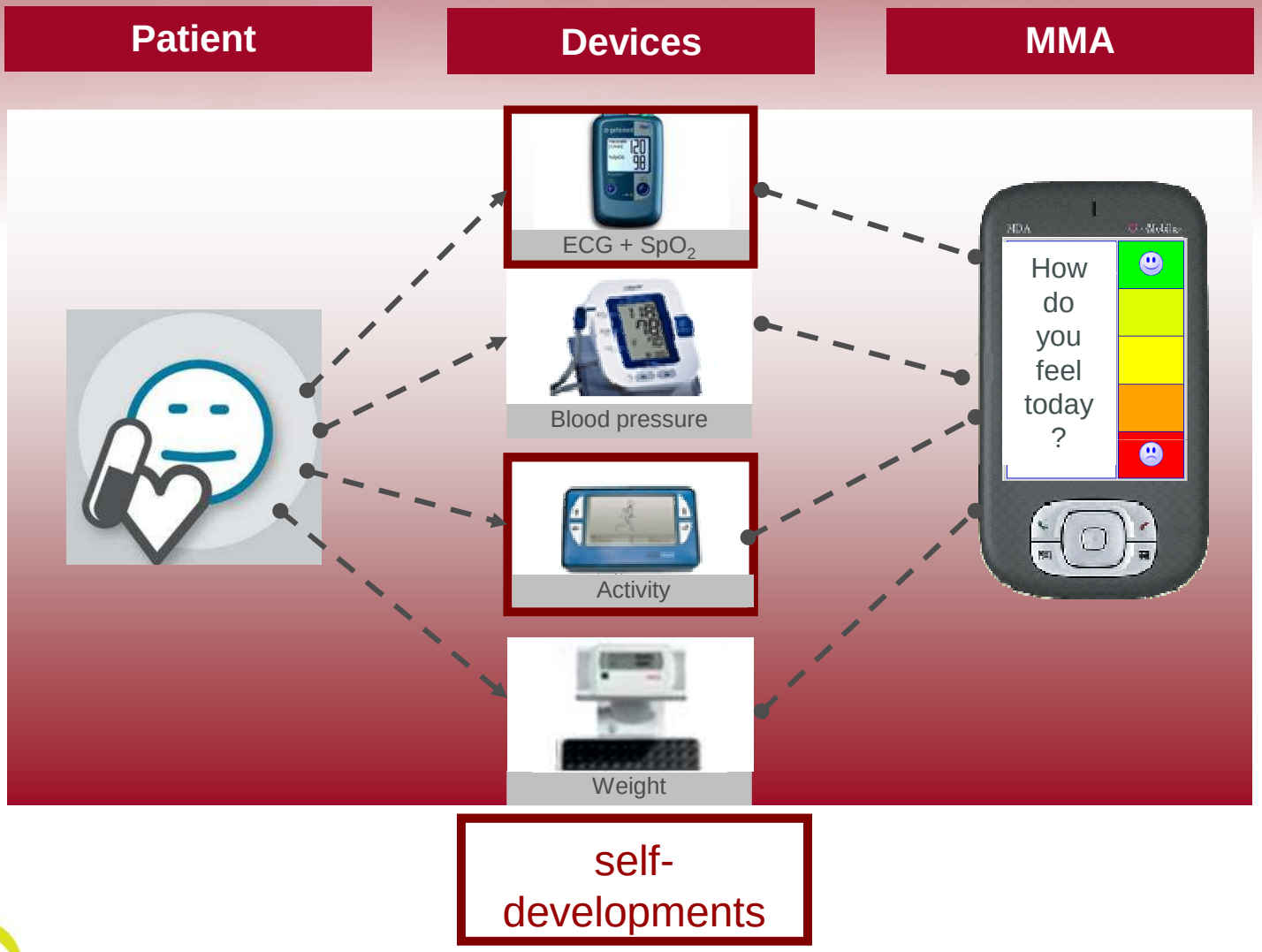
Federal Ministry of Economics and Technology

Patient's Home Devices



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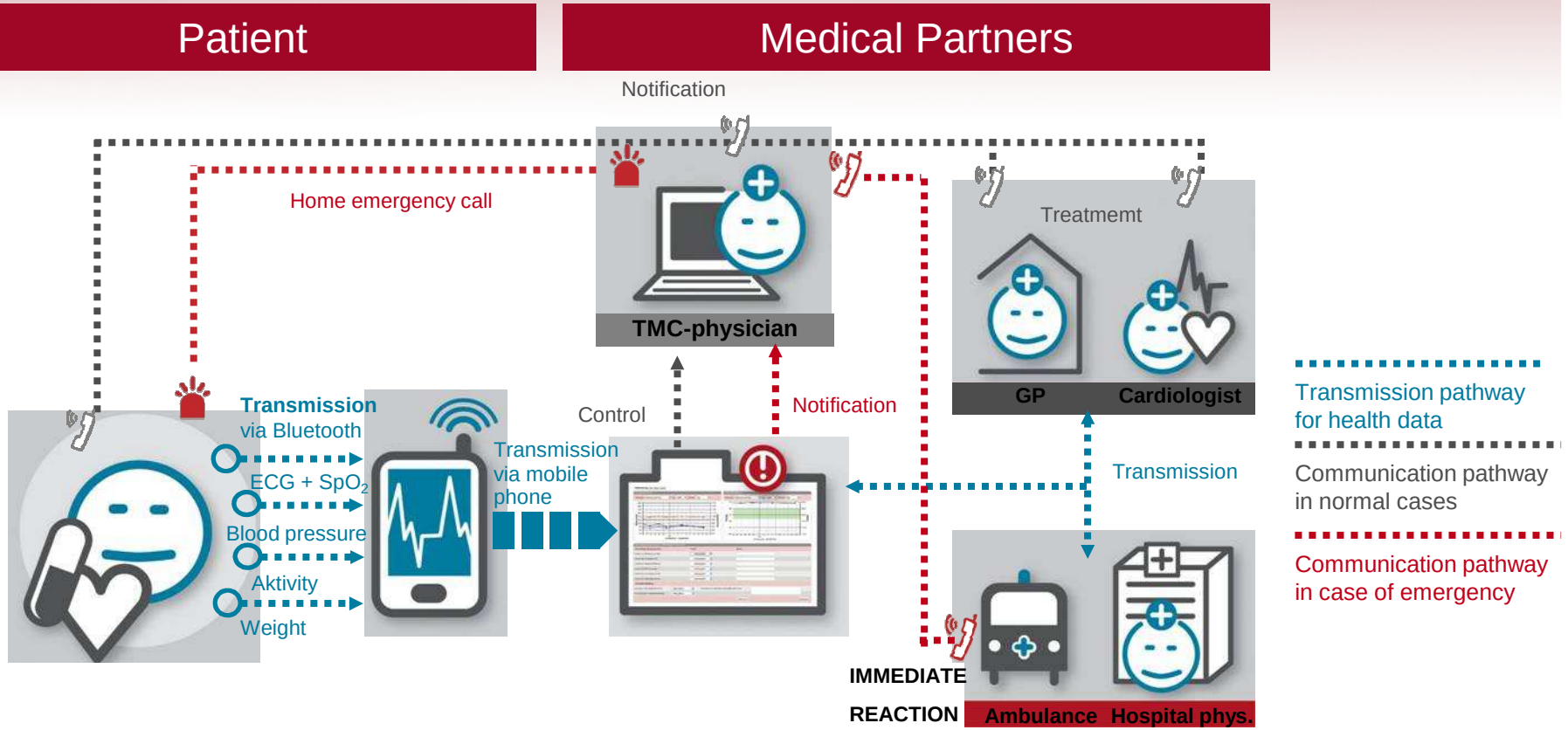
Jehn M, Koehler F.
Am Heart J 2009; 157(2):292-98

Architecture of the „PfH-System“



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Koehler et al., Eur J Heart Fail (2010)
12 (12): 1354-1362

Telemedical Interventional Monitoring in Heart Failure (TIM-HF) – NCT00543881

Objectives

- superiority of additional remote patient monitoring in stable patients with chronic heart failure compared to “usual care only” in terms of:
  - mortality
  - hospitalization
  - quality of Life
  - cost effectiveness
- in a long-term setting

Trial Design

- randomized, prospective, controlled open, parallel, multicenter
- 710 patients (1:1)
- remote patient monitoring for at least 12 months (max. 28 months)
- guideline based therapy

Inclusion criteria

- ejection fraction below 35%
- advanced CHF (NYHA II-III)
- hospitalization (cardiac decompensation) within 24 months prior to the study

Endpoints

Primary endpoint

- overall mortality

Secondary endpoints

- hospitalization due to HF or death
- days alive and out of hospital
- cardiovascular mortality
- cardiovascular hospitalization
- patients' quality of life
- cost effectiveness

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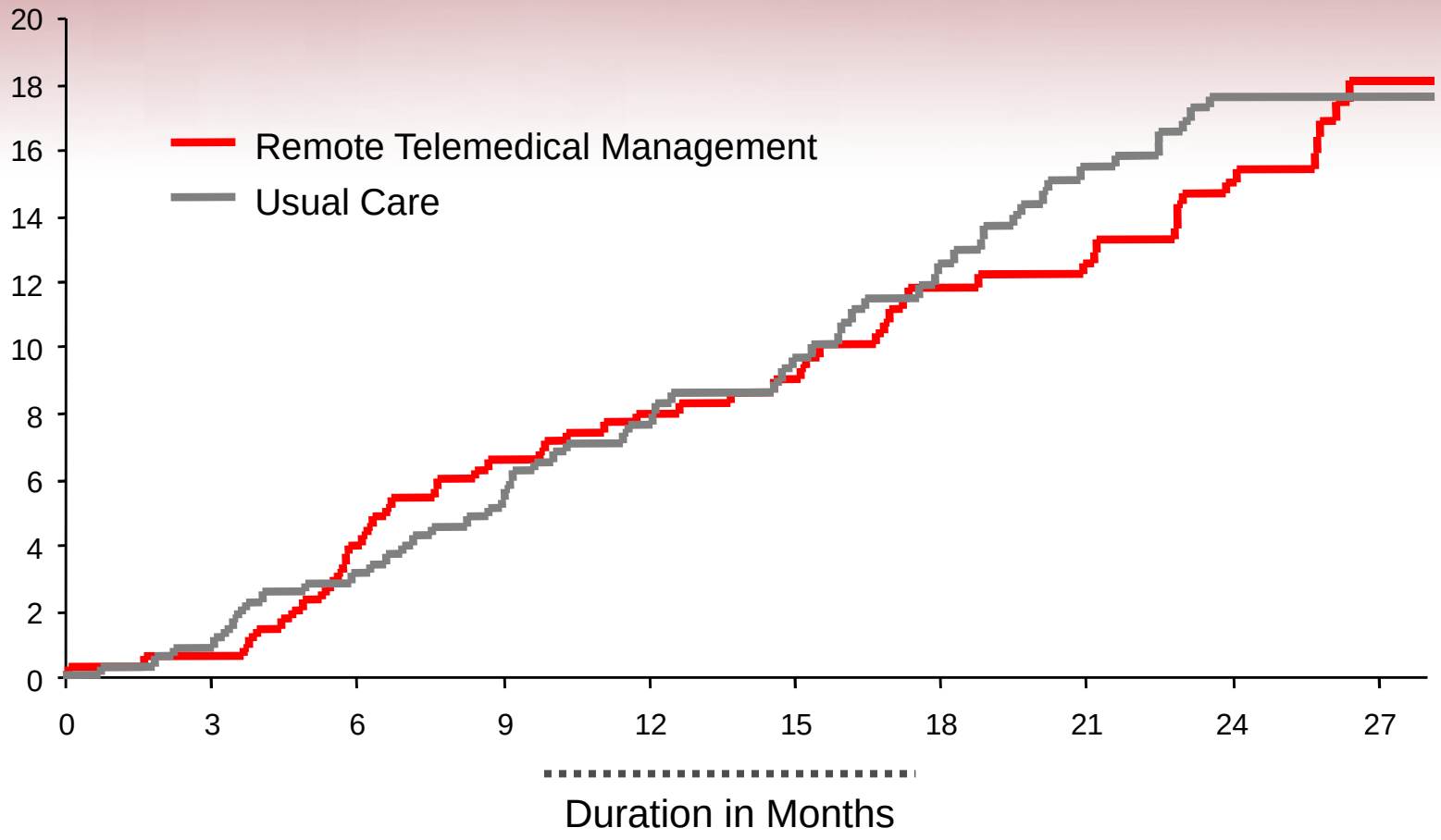
Primary Endpoint: Total Mortality



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Koehler et al., Circulation
2011 May 3;123(17):1873-1880

Responders to Telemonitoring: Patients at Risk

		RTM Events	UC Events	Hazard Ratio (95% CI)	P within group	P interaction
CV mortality						
HF Hospitalization + LVEF ≥ 25 % + PHQ<10	Yes 333 (47%)	12	25	0.48 (0.24-0.95)	0.035	0.024
	No 387 (53%)	28	21	1.32 (0.75-2.32)	0.34	

		Days	Days		P within group	P interaction
Days lost due to death or HF hospitalizaton						
HF Hospitalization + LVEF ≥ 25 % + PHQ<10	Yes 333 (47%)	22.0 (7.0)	43.5 (6.9)		0.03	0.03
	No 387 (53%)	42.0 (6.5)	34.6 (6.6)		0.42	

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Koehler et al. Int J Cardiol. 2011 Oct 7. [Epub ahead of print]

TIM-HF Benefits of Telemedicine
(Subgroup Analysis)

- **Patient profile of responders to telemedicine**
  - after a HF-hospitalization;
  - without depressive symptoms;
  - cardiac function not too weak (LVEF > 25%)

- **333 (47%) of the 710 TIM-HF patients**

- **Results for the risk group**
  - ~ 50% lower cardiovascular mortality due to telemedicine
  - ~ 50% reduction in the number of days lost due to cardiovascular mortality and HF hospitalization

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Koehler et al. Int J Cardiol. 2011 Oct 7. [Epub ahead of print]

Implications on Health Economy

- **HF-Epidemiology in Germany:**
  - 1.2 million HF-patients in GER (NYHA stages I - IV NYHA)
  - 200.000 HF-patients causing approx. 375.000 HF-hospitalizations per year
- **Prevalence for telemedicine in heart failure patients:**
  - approx. 150.000 telemedicine patients per year in GER
  - reduction of HF-hospitalizations by 20%
  - (health economics is currently under analysis)
  - annual constant savings potential of € 150 million (5% of the total treatment cost)

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Trends in Telemedicine

- Tool for rural territories (regionalization)
- Individualized patient monitoring (diabetes, COPD, depression)
- Mobility and telemonitoring
- Ambient assisted living (AAL)

Telemedicine for rural areas (regionalization)

North Brandenburg – Fontane-Project

- „Health Region of the Future“-Project founded by the German Federal Ministry of Education and Research

- Objective: Improvement of health care for cardiovascular disease in underdeveloped rural areas using:
  - broad application of modern IT-systems (telemedicine)
  - biomarker guided diagnostics and therapy

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Federal Ministry of Education and Research

Fontane-Project 2009-2014
(Heart-Failure Project)

Trial-Acronym: TIM-HF II

Region: Berlin/Brandenburg; parts from Saxony-Anhalt / Western Pomerania / East Saxony

Study-Population: 1.500 HF-Patients

Sites: 300 GPs / 25 Cardiologists

Telemedical Centers: Berlin

Primary Endpoint:

Days lost due to death or HF-hospitalization

Secondary Endpoint:

Lack of inferiority between telemedically assisted HF-Care in rural areas compared to guideline based therapy in metropolitan areas in terms of hospitalization and death

Fontane-Project
(Pregnancy-Project)

Acronym: TelePreg I

Region: Berlin/Brandenburg

Study-Population: 200 pregnant patients with hypertension

Site: Charité

Telemedical Centre: Berlin

Primary Endpoint:

„Telemedical assisted, guideline based care in pregnant patients with hypertension is superior to usual care in terms of “days lost to hospitalization or early delivery“

Comparison of TIM-HF I (PfH) and TIM-HF II (Fontane)

	TIM –HF I	TIM-HF II
Patients	HI (cardiologists) n= 710	HI+ co-morbidities (GP) n= 1.500
Type of study	RCT	RCT
Study phase	II	III (IV)
Telemedical system	III. Generation	IV. Generation
Intervention	Telemonitoring + emergency	Biomarker-guided therapy + telemonitoring + emergency + Implant data
Primary endpoint	Mortality	Days lost due to HF hospitalization or death
Secondary endpoint	Days lost due to HF hospitalization or death	Non-Inferiority of HF-telecare in rural compared to metropolitan areas
Study duration	2008 – 2010	2012 – 2014
Sponsor	BMWi	BMBF

Conclusion

- Remote Patient Management is a innovative technology to combat the challenge of the demographic burden
- Remote Patient Management will be a facet for physicians in the near future
- 1/6 of the HF-population needs telemedicine as a „bridge to stability“ (after HF-hospitalisation)
- Remote Patient Management has to be organized within the regions (1 Tele-Centre per German State = approx. 4 Mio. inhabitants)
- The outcome of Telemedicine in rural areas is currently under investigation
- Telemedicine has a potential to save costs in future health care