Telecardiology – Technical Innovations and Challegenes in Clinical Practice

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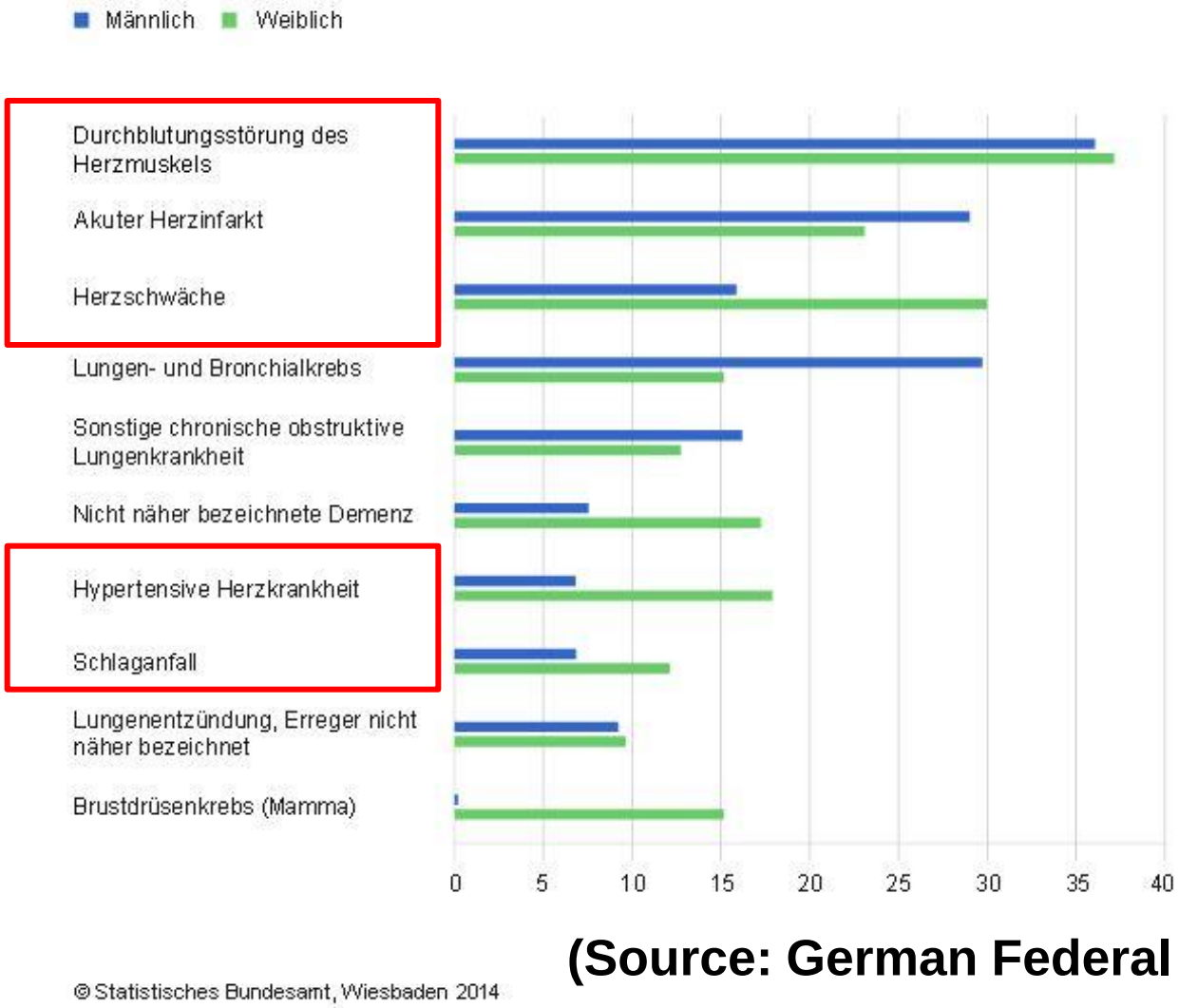
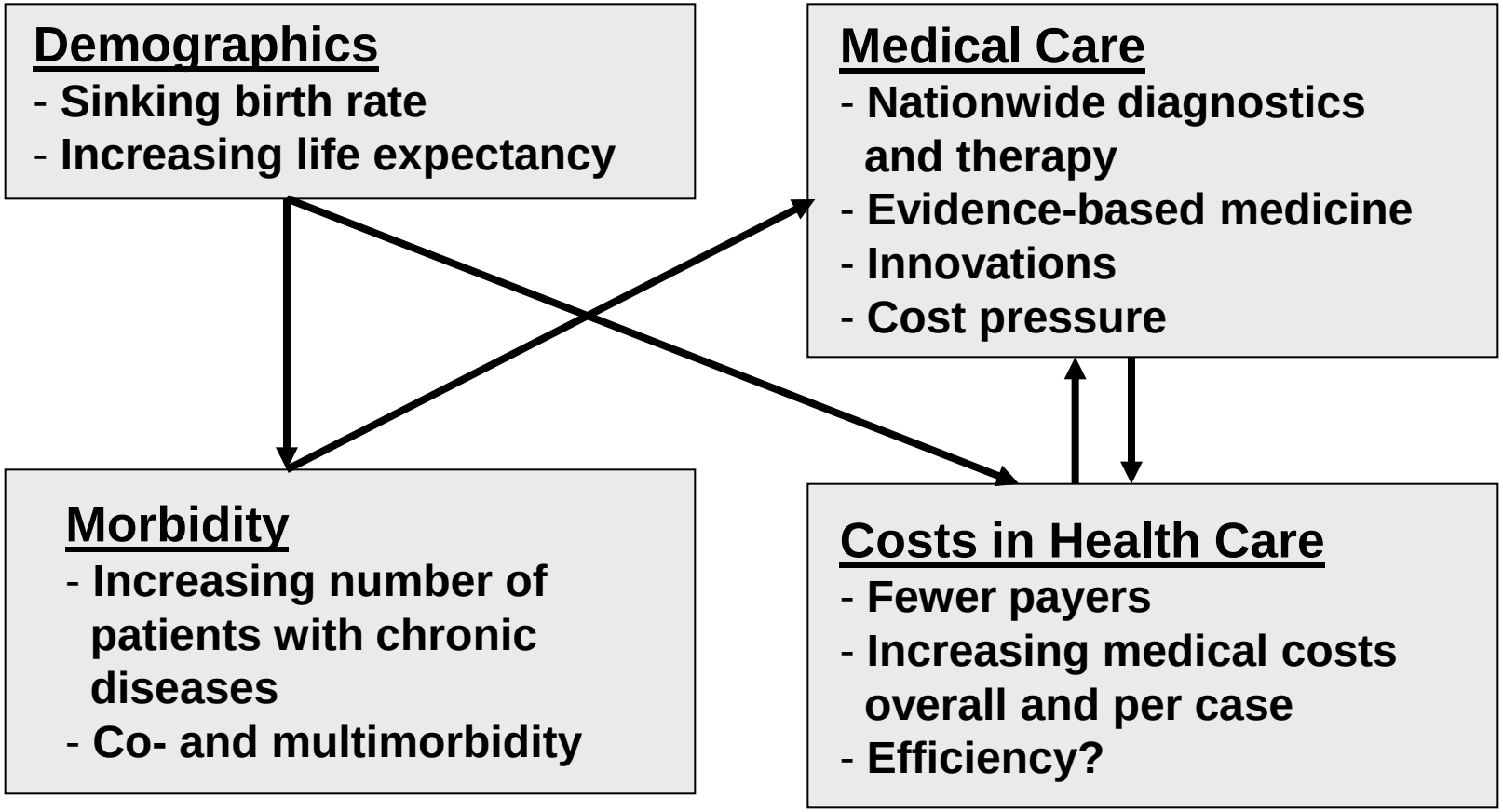
June 24, 2015

Causes of Death in Germany in 2013



(Source: German Federal Statistical Office)

Problems in the German Health System

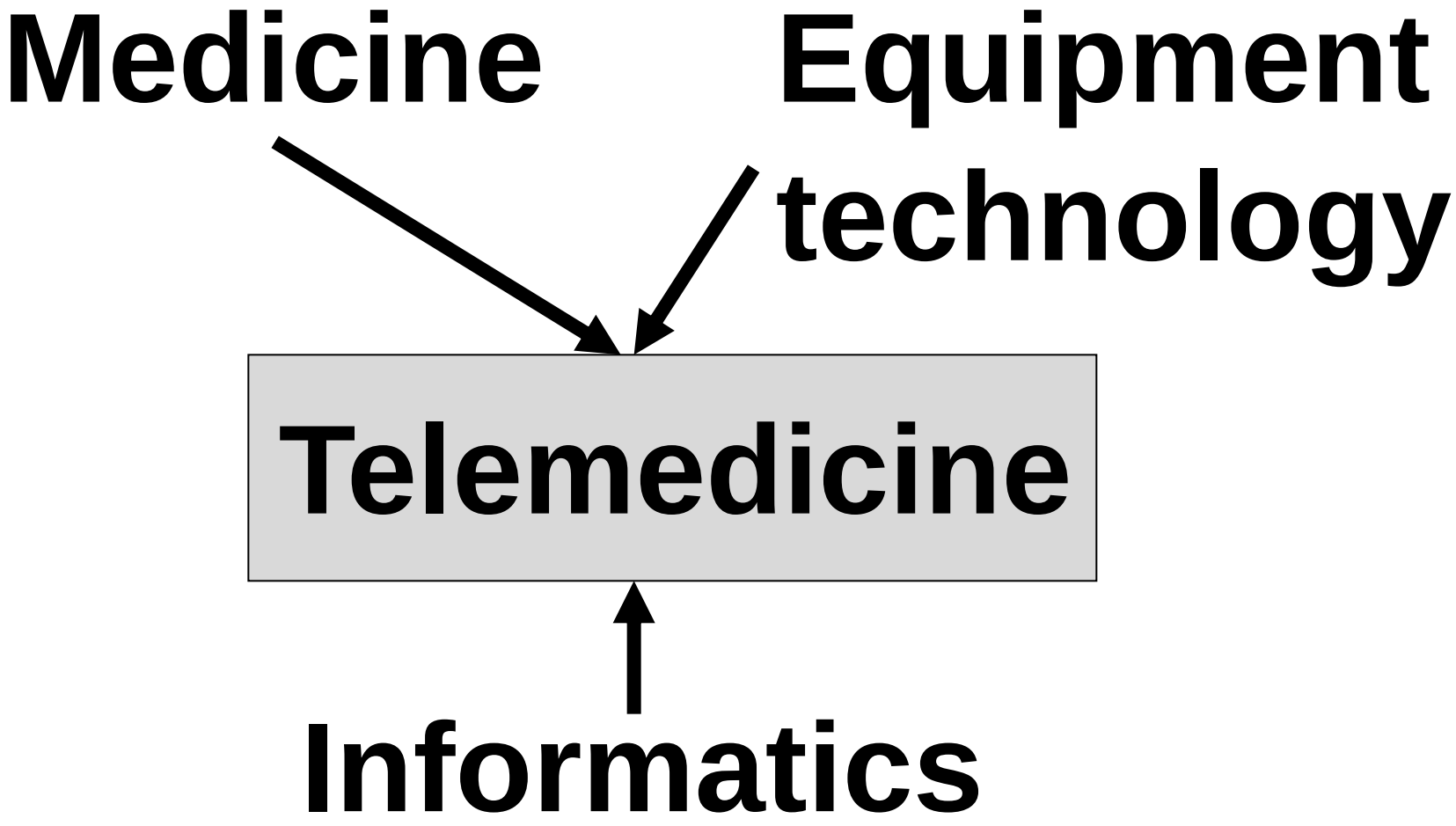


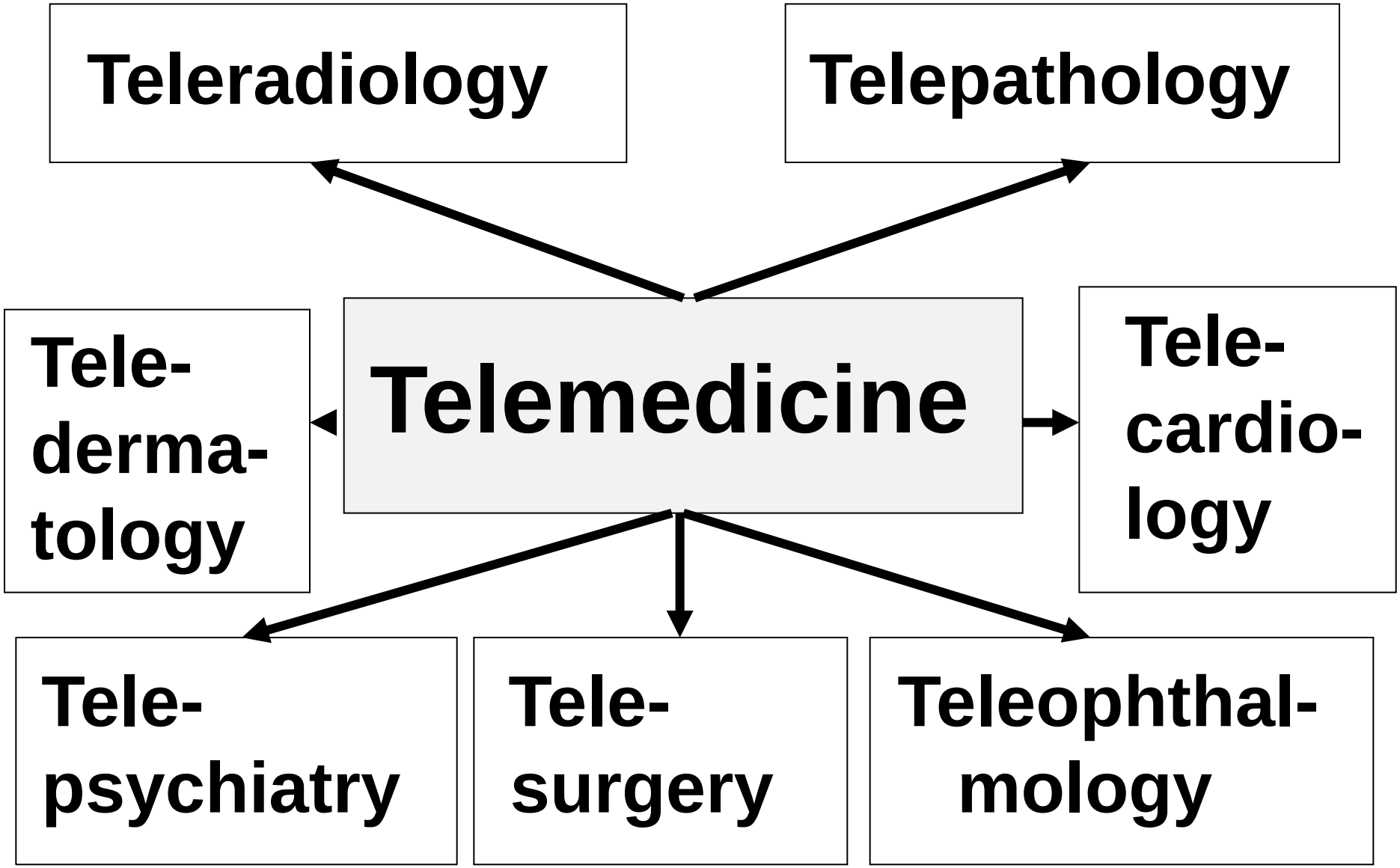
(A. Müller, T.M. Helms und J. Schweizer, 2008)

Telemedicine

- Collective term for the use of multimedia communication und information techno-logy in health care
- Use of different types of technology to provide individual medical services while simultaneously overcoming the spatial separation of physician and patient

(adapted from U. Tebbe, 2003)


Medicine
Equipment technology
Telemedicine
Informatics


Teleradiology
Telepathology
Tele-
derma-
tology
Telemedicine
Tele-
cardio-
logy
Tele-
psychiatry
Tele-
surgery
Teleophthal-
mology

Telemedicine in Cardiology: Challenges

- Demographics (patients, physicians)
- Epidemiology (e.g., heart failure)
- Structures for providing medical care (family doctor / inpatient / outpatient)
- New types of innovative diagnostics and therapy (e.g., CRT systems, coagulation inhibitors, new technological developments)
- Guideline-compliant diagnostics and therapy
- Medication compliance
- Cost development
- Financing (diagnosis-related group (DRG) system, remuneration eligibility of outpatient services)

Pacemaker | **ICD** | **CRT Device**

Complexity

Device function →

Holter monitoring →

Heart rhythm (IEGM) →

Shock delivery →

Heart failure management →

Implantable Loop Recorder
Insertable Cardiac Monitor (ICM)

Detection of arrhythmia

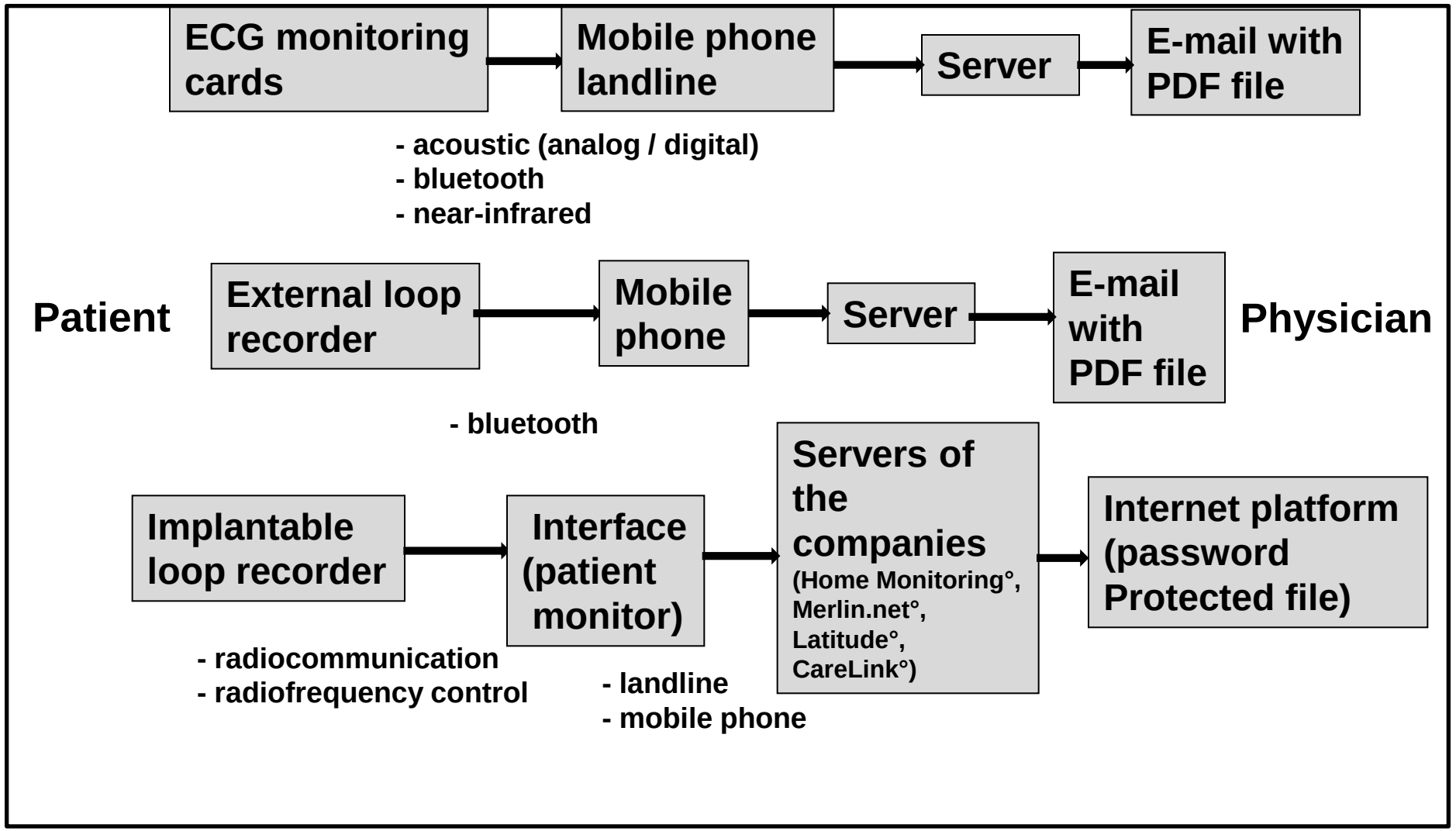
Telemedicine in Cardiology: Opportunities

- Improving the care situation of patients
- Technological development (mobile diagnostic systems, information technology)
- Electronic health records (EHR), networking etc.
- New structures in the health care system (sector-spanning health care)

Applications in Telecardiology

- Detection of arrhythmia
- Management of patients with congestive heart failure
- Telemedical management of patients with cardiovascular implantable electronic devices (CIED)

Tele-ECG Recording



Telemedical transmission

Via Bluetooth

Mobile phone

Server

Internet
(PDF file)

External loop recorder loop 3300 BT
(Vitaphone°, Mannheim)

Reliability of an external loop recorder for automatic recognition and transtelephonic ECG transmission of atrial fibrillation

Axel Müller*, Wilfried Scharner†, Tilo Borchardt†, Wolfgang Och* and Harald Korb‡

*Department of Internal Medicine I, Chemnitz Clinic gGmbH, Chemnitz; †Vitasystems GmbH, Chemnitz; ‡Vitaphone GmbH, Mannheim, Germany

Summary

In order to test a newly developed algorithm for detecting atrial fibrillation in clinical practice, we carried out parallel recordings using a conventional 24-h electrocardiogram (ECG) monitor and telemonitoring with an external loop recorder. Recordings were made in 24 patients with persistent atrial fibrillation and in another 24 patients with sinus rhythm. Atrial fibrillation was detected immediately in 23 of 24 patients with persistent atrial fibrillation and 20 min after fitting the single-channel loop recorder in the 24th patient (sensitivity 100%). On average, 3.1 false positives (i.e. detection of an episode, including the end or beginning of atrial fibrillation) were transmitted per patient. The sensitivity of the algorithms for automatically detecting bradycardiac and tachycardiac atrial fibrillation was also high. In 12 of 24 patients with sinus rhythm, false-positive tele-ECGs were transmitted. These were caused by supraventricular or ventricular extrasystoles and by sinus arrhythmias or sinoatrial (SA) blocks. The external loop recorder was very effective at detecting paroxysmal atrial fibrillation. Possible indications for the clinical use of this recorder include, in addition to diagnosis, monitoring patients for atrial fibrillation recurrence after cardioversion or catheter ablation.

(Journal of Telemedicine and Telecare 2009)

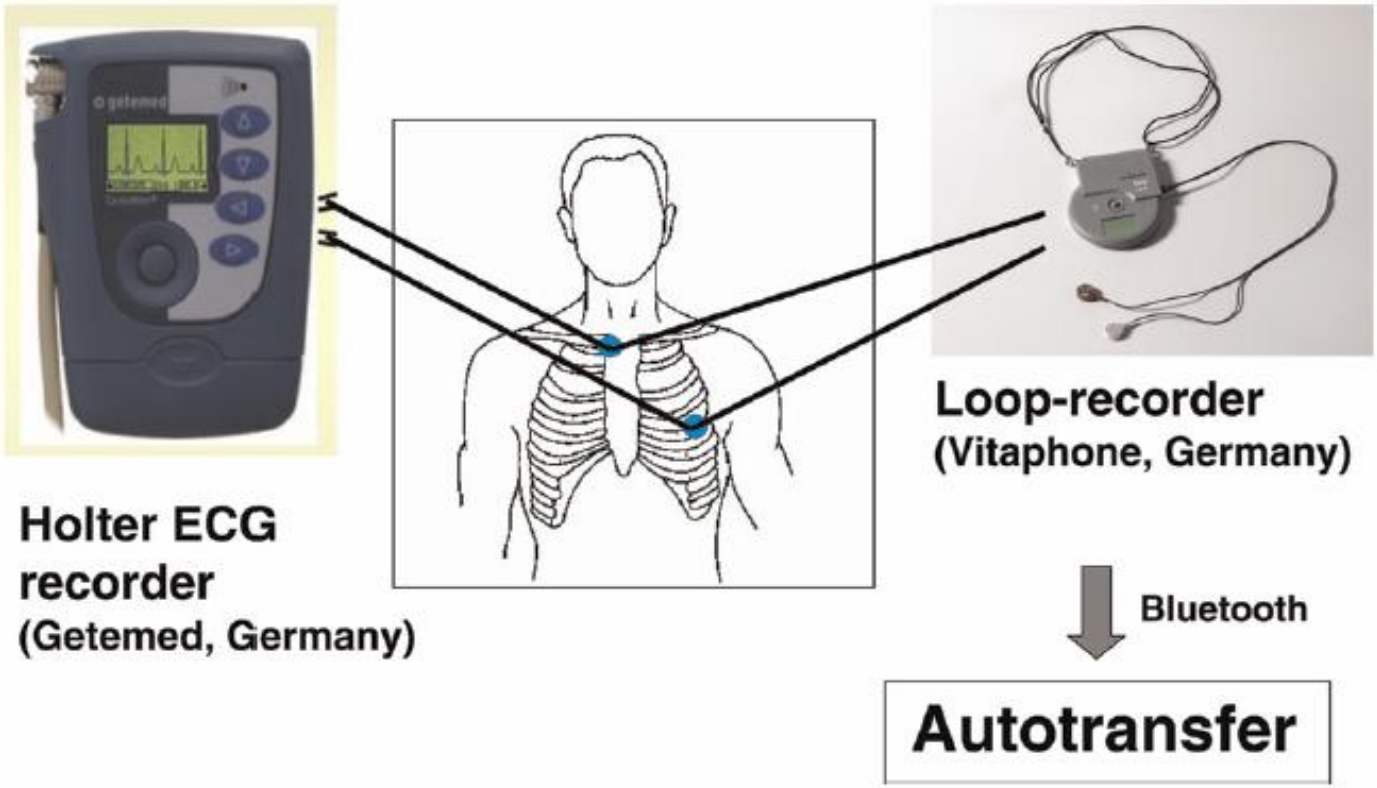


Figure 4 Test arrangement for the simultaneous recording of an ECG with a 24-h ECG (CardioMem CM 3000, Getemed) and with the loop recorder using a T-electrode connector

(A. Müller et al., 2009)

Table 3 Sensitivity and specificity of the initial automatic recognition of atrial fibrillation with the loop recorder for 48 patients with sinus rhythmic or permanent fibrillation

	Patients with permanent atrial fibrillation ($n = 24$)	Patients with sinus rhythm ($n = 24$)
Sinus rhythm or atrial fibrillation correctly detected	24	12
Sinus rhythm or atrial fibrillation incorrectly detected	0	12

(A. Müller et al., 2009)

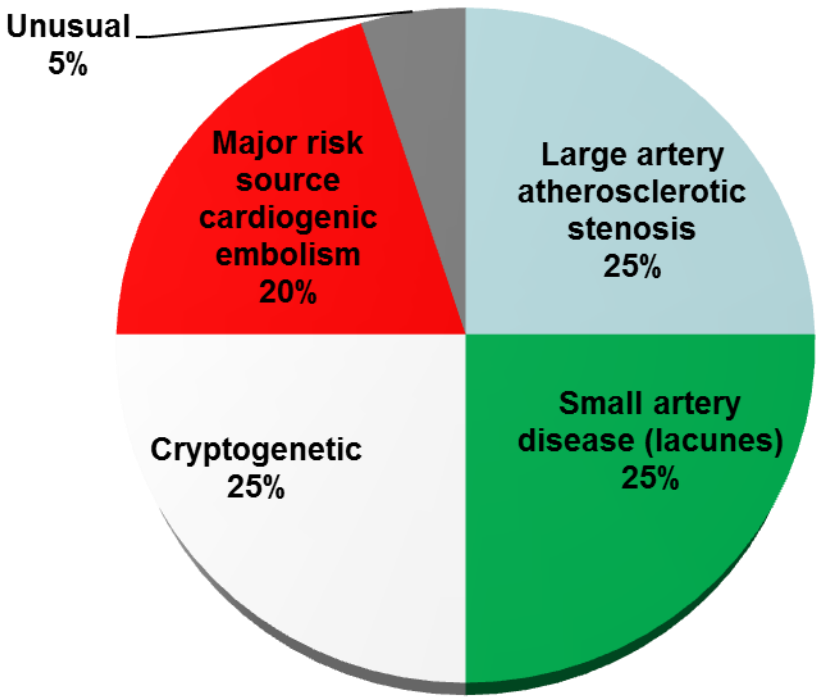
Detection of Atrial Fibrillation

Atrial fibrillation is the most common cardiac arrythmia and a significant risk factor for stroke and associated with increased mortality and higher health costs.

Using telemedical ECG monitoring cards, the PAFAC study showed that renewed occurrence of atrial fibrillation was asymptomatic in about 70% of patients after cardioversion.
(T. Fetsch et al., European Heart Journal (2004) 25:1385-1394)

In the SOPAT study of patients with paroxysmal atrial fibrillation, only 46% of documented episodes with atrial fibrillation were associated with specific symptoms during episodes.
(M. Patten et al., European Heart Journal (2004) 25:1395-1404)

Distribution of Ischaemic Stroke Subtypes in North American and European Studies



(adapted from R.G. Hart et al., 2014)

Applications in Telecardiology

- Detection of arrhythmia
- Management of patients with congestive heart failure
- Telemedical management of patients with cardiovascular implantable electronic devices (CIED)

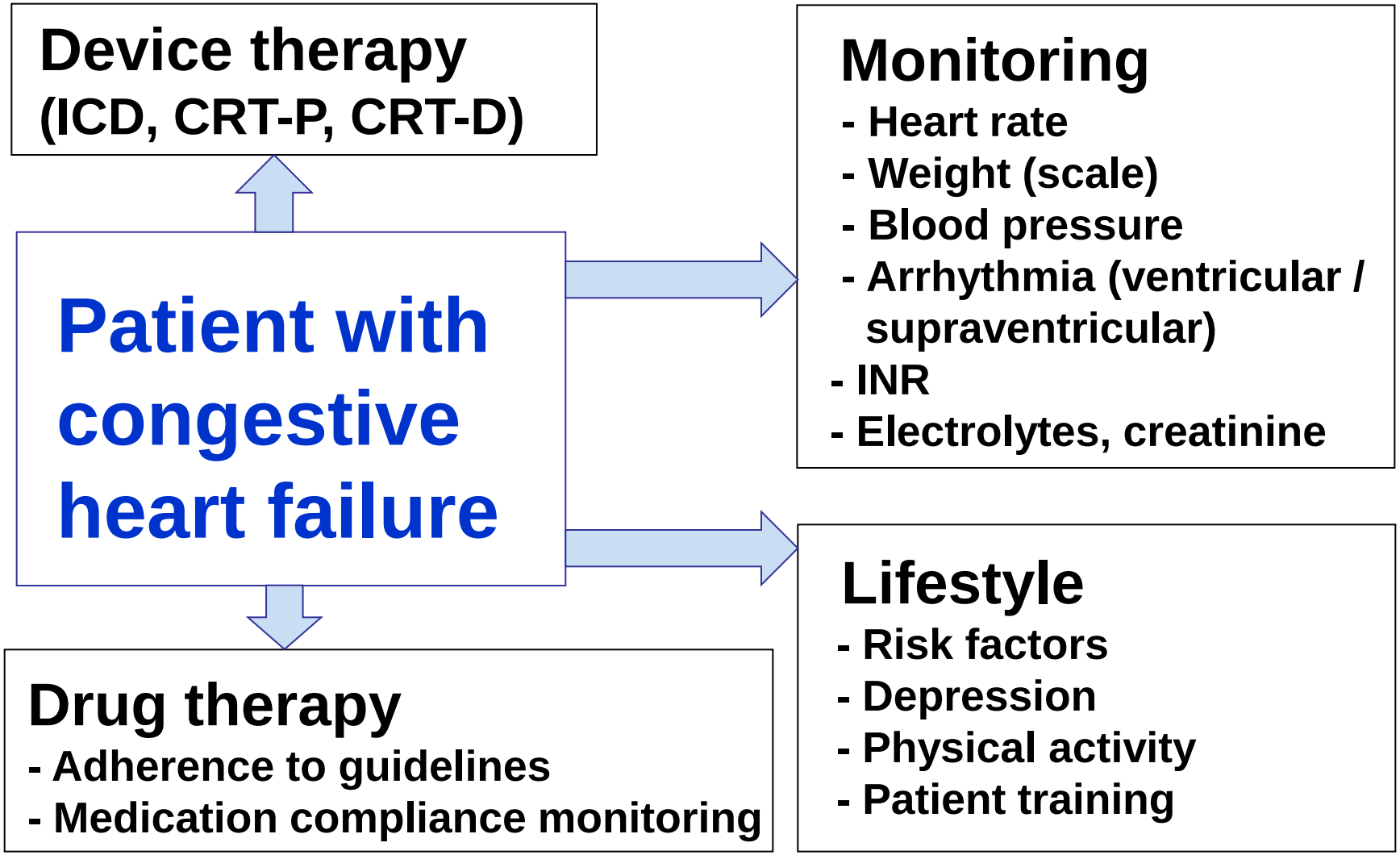
Heart Failure (Definition)

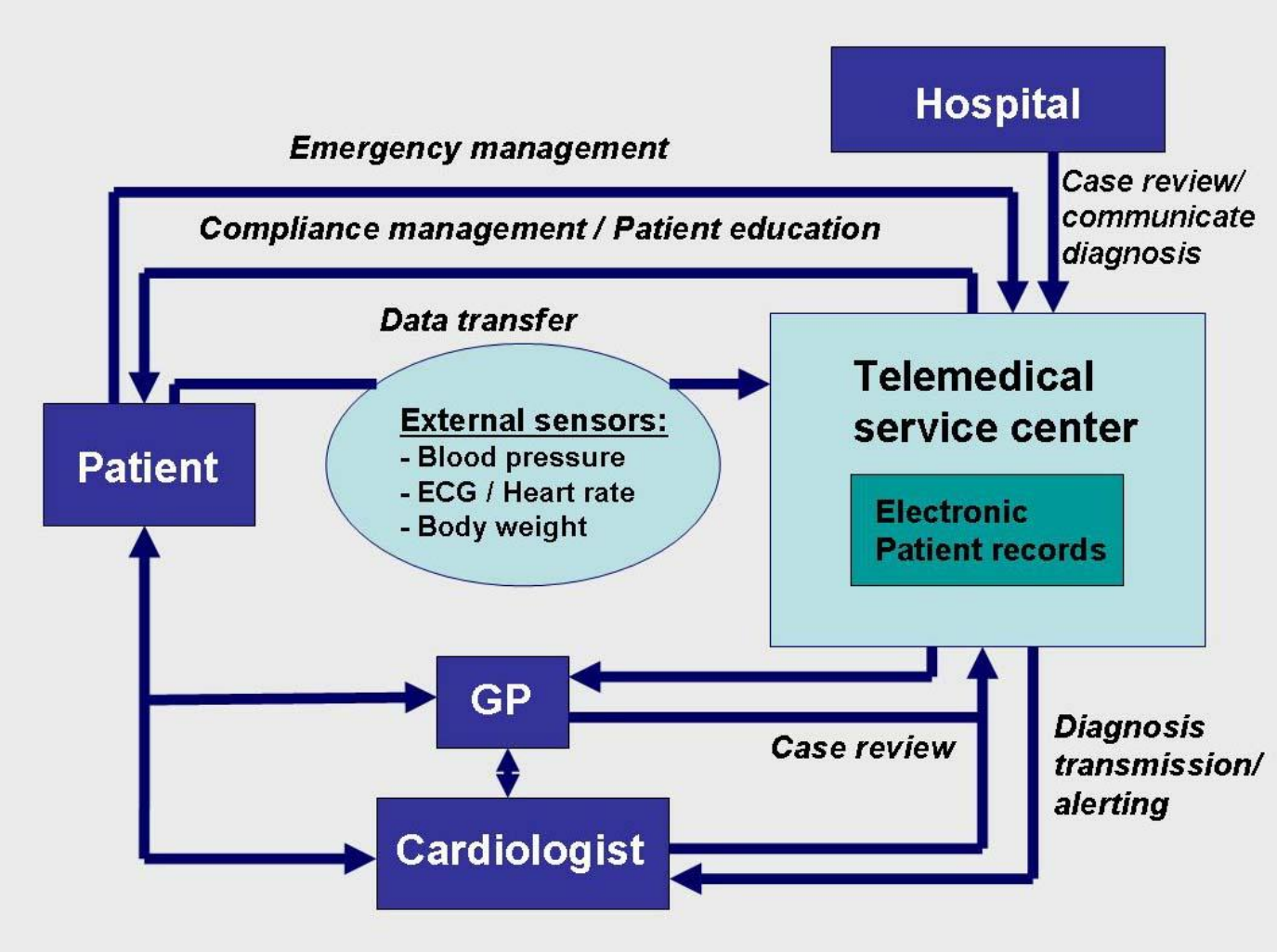
is characterized by the incapacity to provide a sufficient amount of blood to meet the metabolic and circulatory needs of tissue or by the fact that this can only be achieved at abnormally elevated end-diastolic pressures

(M. Fuchs und H. Drexler, 2000)

Management of Patients with Congestive Heart Failure: Goals

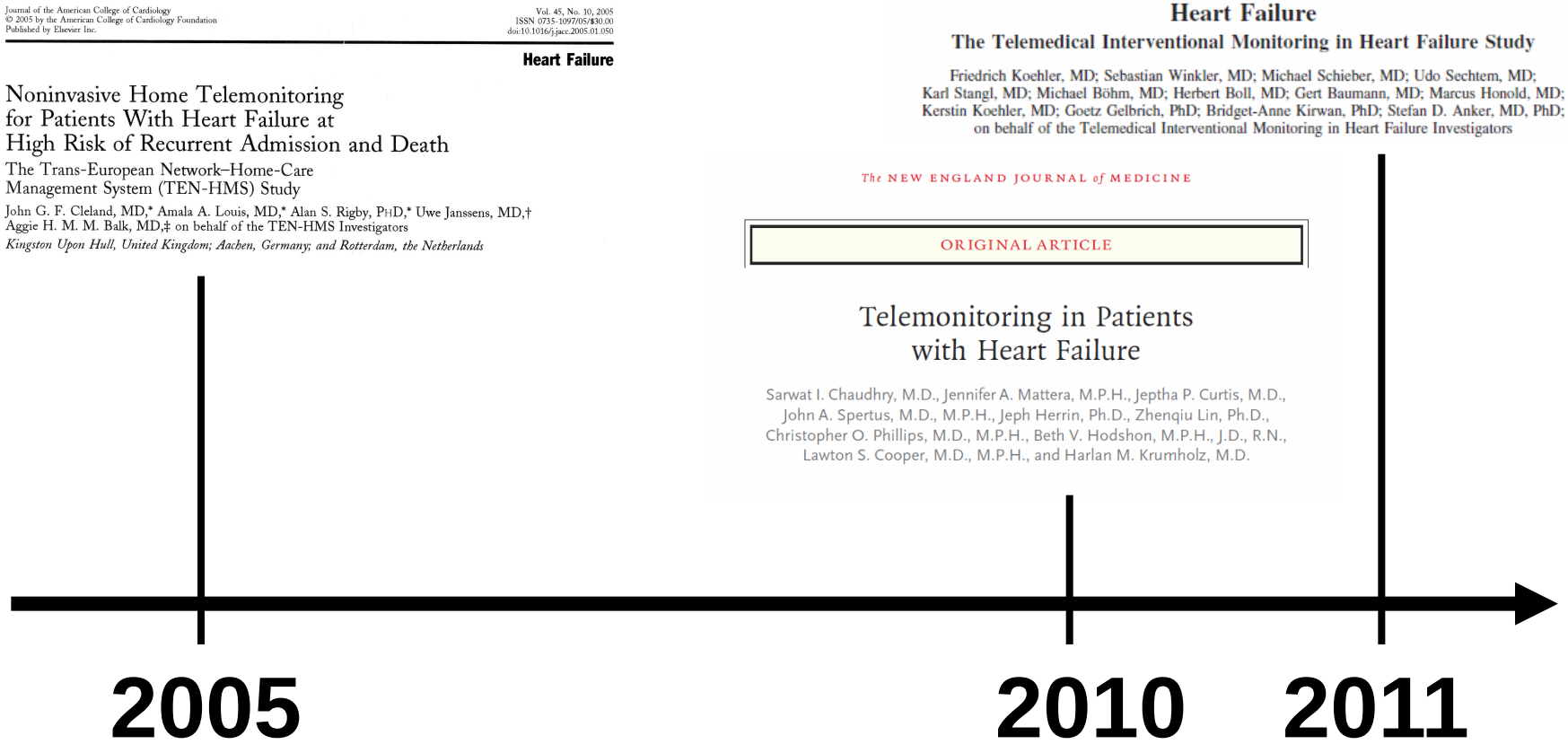
- Avoid cardiac decompensation and hospitalization
- Improve the quality of life
- Optimize the follow-up intervals
- Improve patient compliance (medication compliance, lifestyle)
- Improve the survival rate
- Cost efficiency


Device therapy
(ICD, CRT-P, CRT-D)
Patient with congestive heart failure
Monitoring
- Heart rate
- Weight (scale)
- Blood pressure
- Arrhythmia (ventricular / supraventricular)
- INR
- Electrolytes, creatinine
Drug therapy
- Adherence to guidelines
- Medication compliance monitoring
Lifestyle
- Risk factors
- Depression
- Physical activity
- Patient training



Telemonitoring in patients with congestive heart failure

Telemonitoring in Patients with Congestive Heart Failure



Trans-European Network-Home-Care Management System (TEN-HMS) Study

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doi:10.1016/j.jacc.2005.01.050

Heart Failure

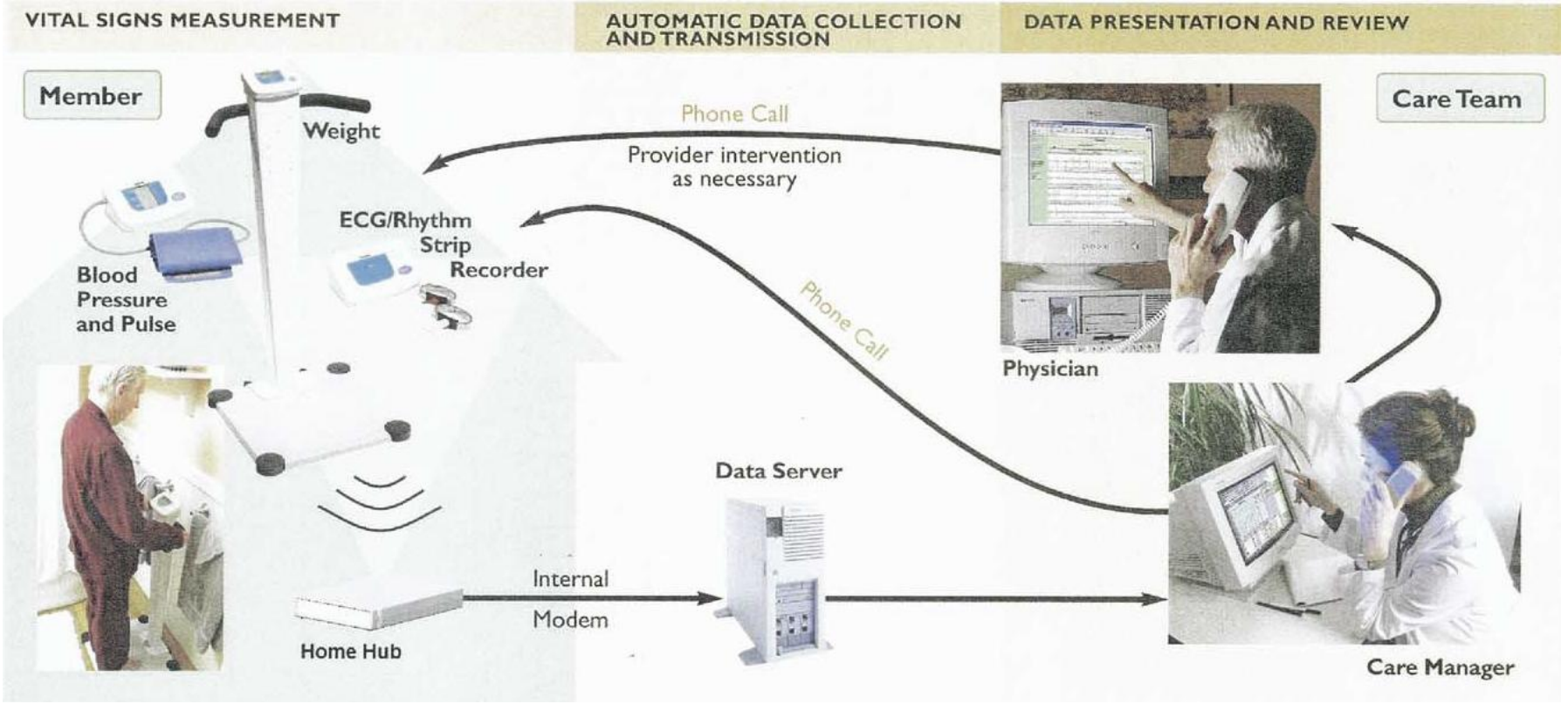
Noninvasive Home Telemonitoring for Patients With Heart Failure at High Risk of Recurrent Admission and Death

The Trans-European Network–Home-Care Management System (TEN-HMS) Study

John G. F. Cleland, MD,* Amala A. Louis, MD,* Alan S. Rigby, PHD,* Uwe Janssens, MD,†
Aggie H. M. M. Balk, MD,‡ on behalf of the TEN-HMS Investigators

Kingston Upon Hull, United Kingdom; Aachen, Germany; and Rotterdam, the Netherlands

Telemonitoring System in the TEN–HMS Study



(J. Cleland et al., 2005)

Patients with Home Telemonitoring (HTM)

Twice daily

*** Patient's weight**
*** Blood pressure**
*** Heart rate**
*** Rhythm analysis**

Intervention

- Weight change of > 2 kg
- Resting heart rate < 50 beats /min or > 80 beats / min
- Systolic blood pressure < 90 or > 140 mm Hg
- Newly diagnosed arrhythmia

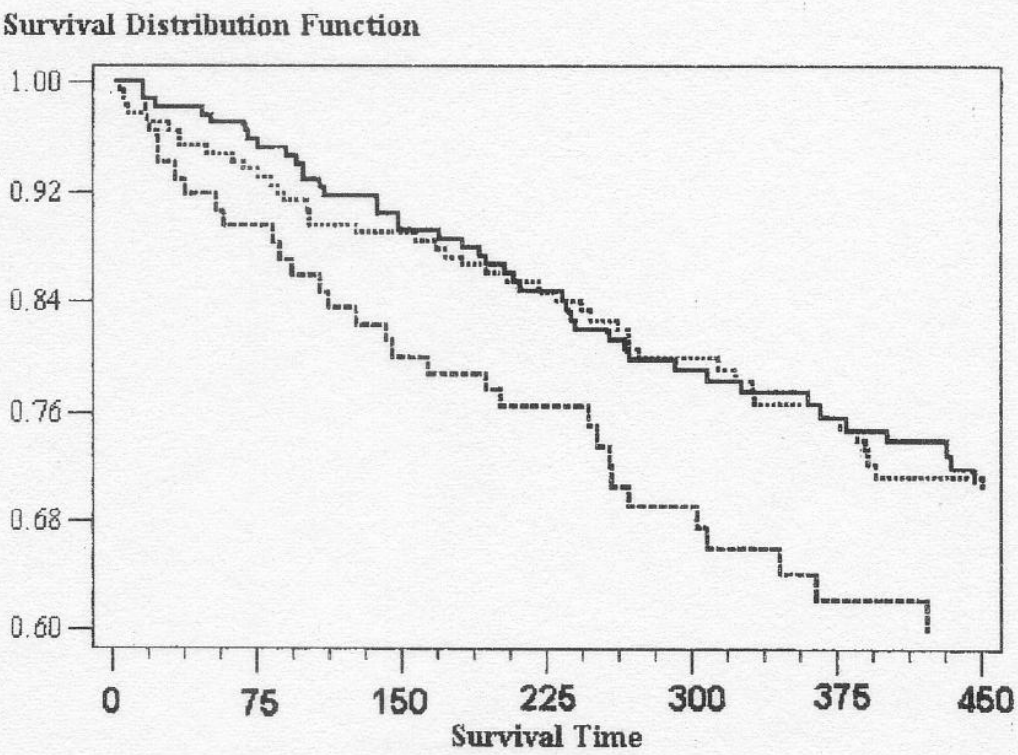
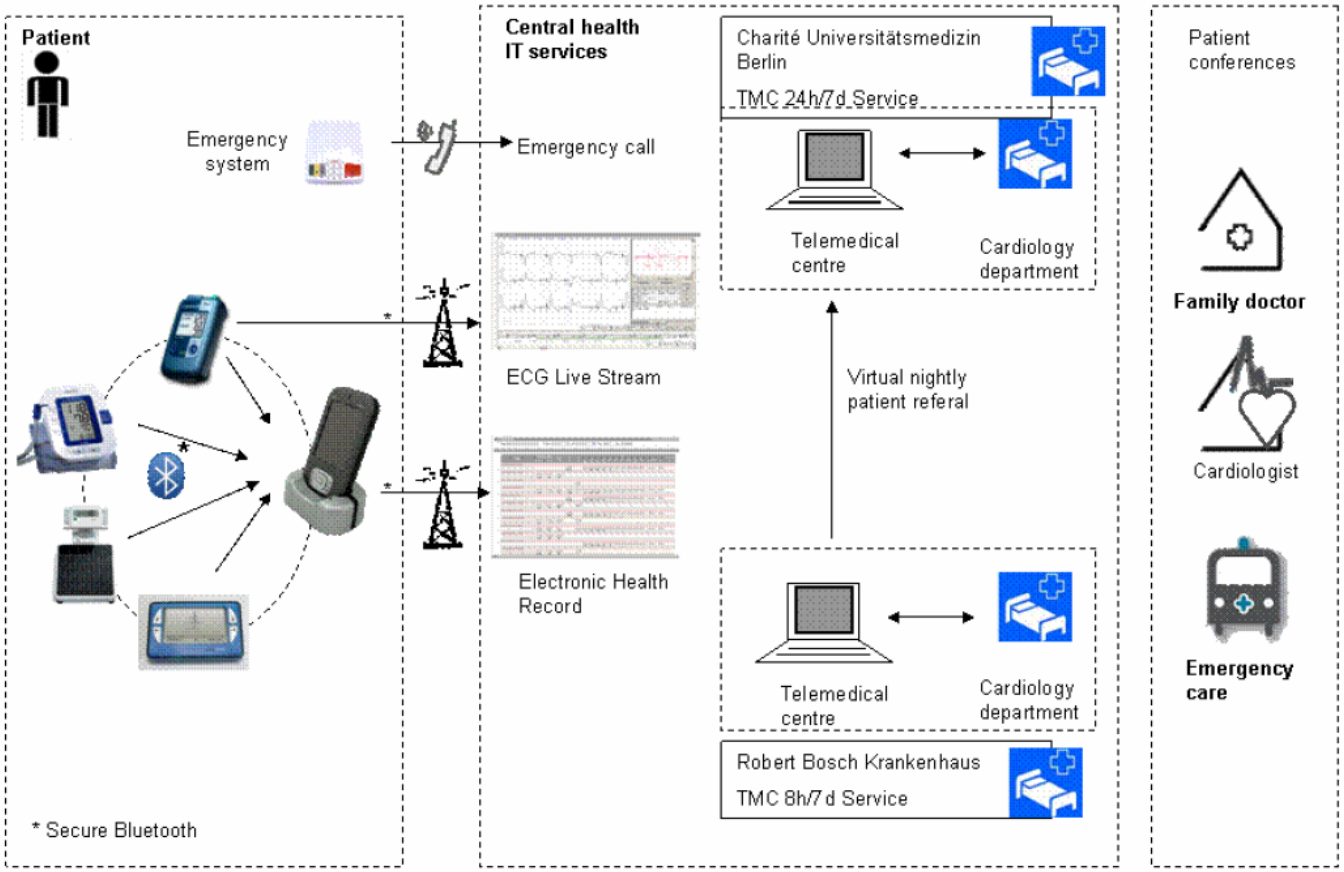


Figure 3. Mortality in each of the randomized groups. A difference was found between usual care and either nurse telephone support or home telemonitoring (chi-squared test: p = 0.0397). The absolute difference in mortality at one year was 16% to 18%. **Dashed line** = usual care; **dotted line** = nurse support; **solid line** = telemonitoring.

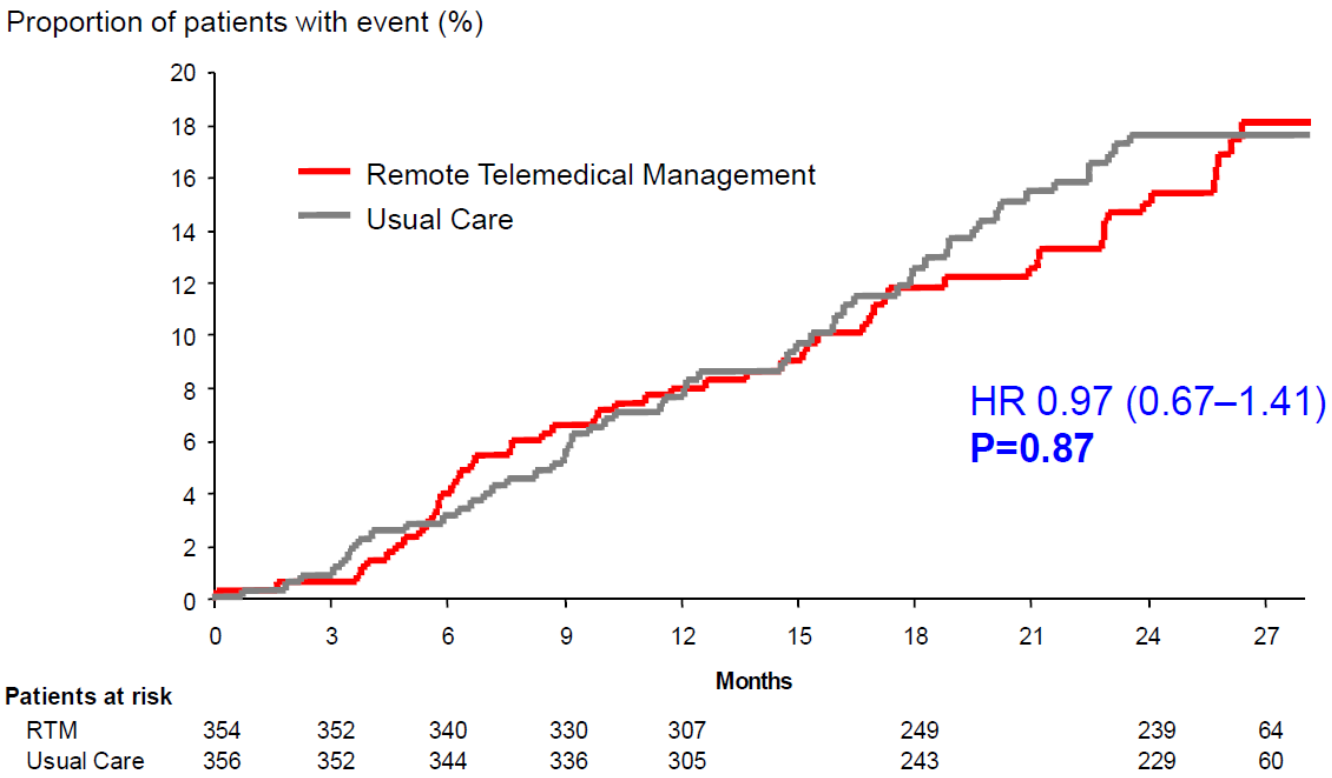
(J. Cleland et al., 2005)

The Remote Telemedical System used in TIM-HF



Telemedical Interventional Monitoring in Heart Failure (TIM-HF) Study (F. Köhler et al., 2011)

Primary Endpoint: All-cause mortality



TIM-HF Study (F. Köhler et al., 2011)

TIM-HF Study: Baseline Data

	RTM (N=354)	Usual Care (N=356)
Age (years)	67	67
Gender (% male)	81	82
Ischemic etiology (%)	57	55
ICD (%)	46	45
LVEF (%)*	27±6	27±6
Diabetes (%)	40	39
ACEi/ARB (%)	97	94
Beta-Blocker (%)	92	93
Diuretic (%)	94	94
Aldosterone antagonist (%)	65	63

(F. Köhler et al.,2010)

TIM-HF Study: Analysis of Subgroups

		RTM (N=354)	Usual Care (N=356)	P Value for interact.
Age	≥70 years	40.8 (7.2)	53.4 (7.1)	0.38
	<70 years	26.5 (6.3)	27.3 (6.4)	
Gender	Male	34.9 (5.3)	39.9 (5.3)	0.77
	Female	24.1 (10.8)	34.2 (11.2)	
NYHA	Class II	22.8 (6.7)	26.9 (6.7)	0.75
	Class III	42.6 (6.7)	51.1 (6.7)	
LVEF	LVEF ≥27%	21.3 (6.6)	35.2 (6.6)	0.23
	LVEF<27%	44.9 (6.8)	42.7 (6.8)	
Prior HF decompensation	Yes	30.1 (5.2)	44.5 (5.2)	0.005
	No	47.5 (12.1)	11.0 (11.6)	
ICD + prior HF decompensation	Yes	29.4 (7.9)	54.7 (8.1)	0.04
	No	34.7 (6.0)	30.6 (5.9)	
PHQ-9 depression score <10	Yes	49.4 (10.1)	29.1 (10.2)	0.03
	No	27.8 (5.5)	42.0 (5.5)	

(F. Köhler et al., 2010)

Fontane

DIE FONTANE-STUDIE TIM-HF II

Das Zentrum für kardiovaskuläre Telemedizin der Charité (TMZ) führt von 2013 bis 2015 eine klinische Studie bei 1.500 Patienten mit chronischer Herzinsuffizienz durch.

In die Studie sollen 500 Patienten aus Berlin und 1.000 Patienten aus ländlichen Regionen aufgenommen werden.
Das Forschungsprojekt wird vom Bundesministerium für Bildung und Forschung gefördert.

STUDIENZIEL

Es soll geprüft werden, ob die tägliche Messung von Gewicht, Blutdruck und EKG durch den Patienten zu Hause und die sofortige ärztliche Auswertung der Messwerte im TMZ Krankenhausaufenthalte vermeidet, Todesfälle verhindert und die Lebensqualität des Patienten verbessert.

In die Studie können Patienten mit

- fortgeschrittener chronischer Herzinsuffizienz (Herzschwäche) sowie
- einem Krankenhausaufenthalt innerhalb der letzten 12 Monate vor Studienbeginn aufgrund von Wassereinlagerungen im Körper

aufgenommen werden.

STUDIENABLAUF

Die Patienten werden von ihrem Hausarzt oder Kardiologen bei Eignung auf eine Studienteilnahme angesprochen. Wenn der Patient teilnehmen möchte, wird für ihn ein Termin beim Kardiologen vereinbart.

Dort wird die Basisvisite für die Studie durchgeführt. Dabei werden alle Patienten nach dem Zufallsprinzip entweder in die Gruppe, die telemedizinische Messgeräte erhält (Telemedizingruppe) oder in die Gruppe ohne telemedizinische Messgeräte (Kontrollgruppe) eingeteilt. Weder der Arzt noch der Patient können Einfluss auf diese Einteilung nehmen. Der Patient erfährt sofort, in welche Gruppe er gelost wurde.

In dieser Visite wird der Patient außerdem untersucht und es werden ein Herzultraschall, ein EKG sowie eine Blutentnahme durchgeführt.

Unabhängig von der Gruppeneinteilung werden alle Patienten regelmäßig alle 3 Monate beim behandelnden Hausarzt bzw. Kardiologen untersucht. Nach 12 Monaten ist die Studie beendet.

Für die Teilnahme erhalten alle Patienten eine einmalige Aufwandsentschädigung von 40 Euro.

DIE TELEMEDIZINISCHEN MESSGERÄTE

Die Patienten der Telemedizingruppe erhalten eine Waage, ein kleines EKG-Gerät, ein Blutdruckmessgerät, eine Sendestation sowie ein Hilferufhandy. Die Bedienung der Geräte ist sehr einfach.

Die Geräte werden den Patienten ins Haus gebracht und aufgebaut. Eine Pflegekraft des TMZ weist jeden Patienten ausführlich in die Gerätebenutzung ein und schult ihn im Umgang mit seiner Herzschwäche.

Im Regelfall ist nur eine morgendliche Messung von Gewicht, Blutdruck und EKG erforderlich. Der Messzyklus dauert ca. 5 Minuten. Über die Sendestation werden die Messwerte per Mobilfunk an das TMZ übertragen.

Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial

*William T Abraham, Philip B Adamson, Robert C Bourge, Mark F Aaron, Maria Rosa Costanzo, Lynne W Stevenson, Warren Strickland, Suresh Neelagaru, Nirav Raval, Steven Krueger, Stanislav Weiner, David Shavelle, Bradley Jeffries, Jay S Yadav, for the CHAMPION Trial Study Group**

Summary

Background Results of previous studies support the hypothesis that implantable haemodynamic monitoring systems might reduce rates of hospitalisation in patients with heart failure. We undertook a single-blind trial to assess this approach.

Methods Patients with New York Heart Association (NYHA) class III heart failure, irrespective of the left ventricular ejection fraction, and a previous hospital admission for heart failure were enrolled in 64 centres in the USA. They were randomly assigned by use of a centralised electronic system to management with a wireless implantable haemodynamic monitoring (W-IHM) system (treatment group) or to a control group for at least 6 months. Only patients were masked to their assignment group. In the treatment group, clinicians used daily measurement of pulmonary artery pressures in addition to standard of care versus standard of care alone in the control group. The primary efficacy endpoint was the rate of heart-failure-related hospitalisations at 6 months. The safety endpoints assessed at 6 months were freedom from device-related or system-related complications (DSRC) and freedom from pressure-sensor failures. All analyses were by intention to treat. This trial is registered with ClinicalTrials.gov, number NCT00531661.

Findings In 6 months, 83 heart-failure-related hospitalisations were reported in the treatment group (n=270) compared with 120 in the control group (n=280; rate 0·31 *vs* 0·44, hazard ratio [HR] 0·70, 95% CI 0·60–0·84, p<0·0001). During the entire follow-up (mean 15 months [SD 7]), the treatment group had a 39% reduction in heart-failure-related hospitalisation compared with the control group (153 *vs* 253, HR 0·64, 95% CI 0·55–0·75; p<0·0001). Eight patients had DSRC and overall freedom from DSRC was 98·6% (97·3–99·4) compared with a prespecified performance criterion of 80% (p<0·0001); and overall freedom from pressure-sensor failures was 100% (99·3–100·0).

Interpretation Our results are consistent with, and extend, previous findings by definitively showing a significant and large reduction in hospitalisation for patients with NYHA class III heart failure who were managed with a wireless implantable haemodynamic monitoring system. The addition of information about pulmonary artery pressure to clinical signs and symptoms allows for improved heart failure management.

(Lancet 2011;377:658-666)

CHAMPION Trial

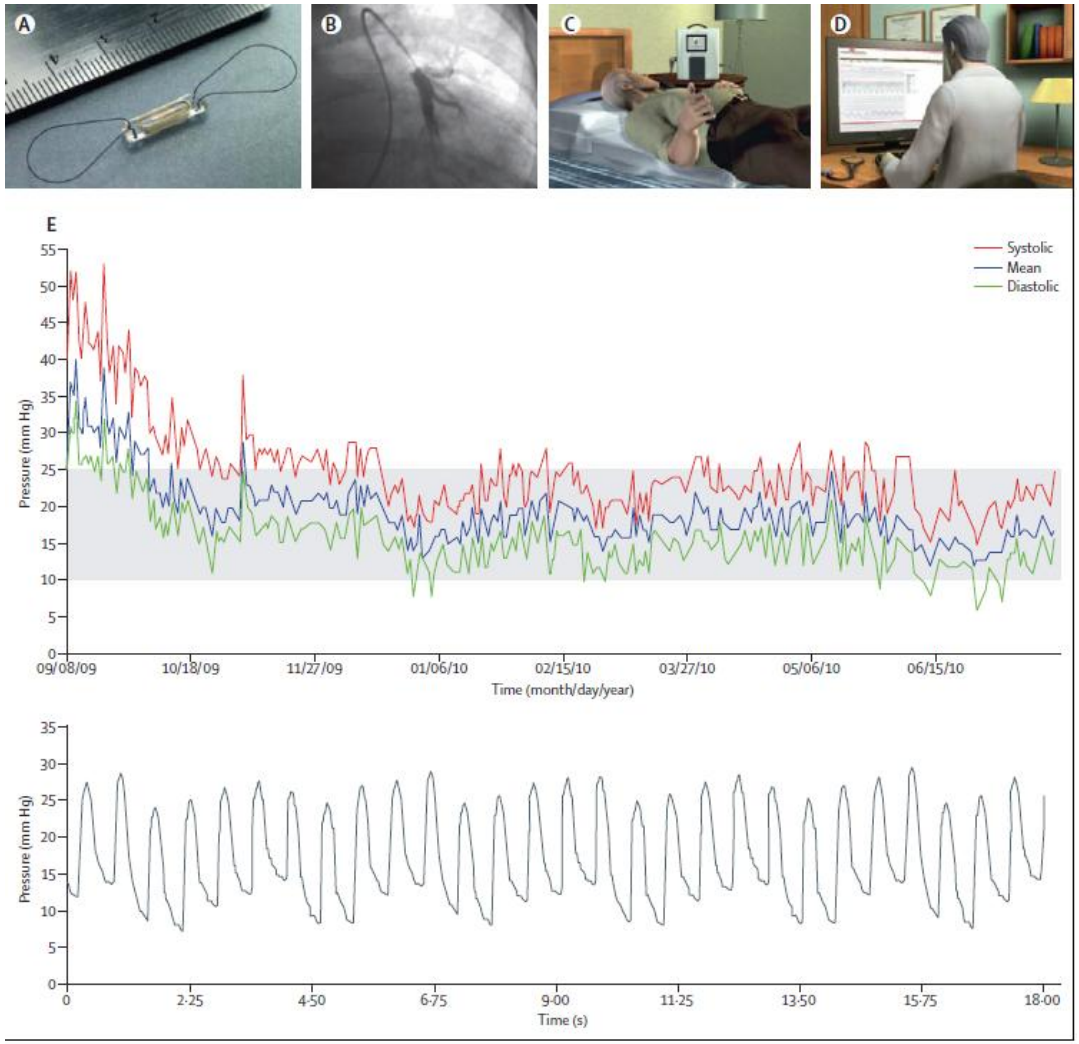
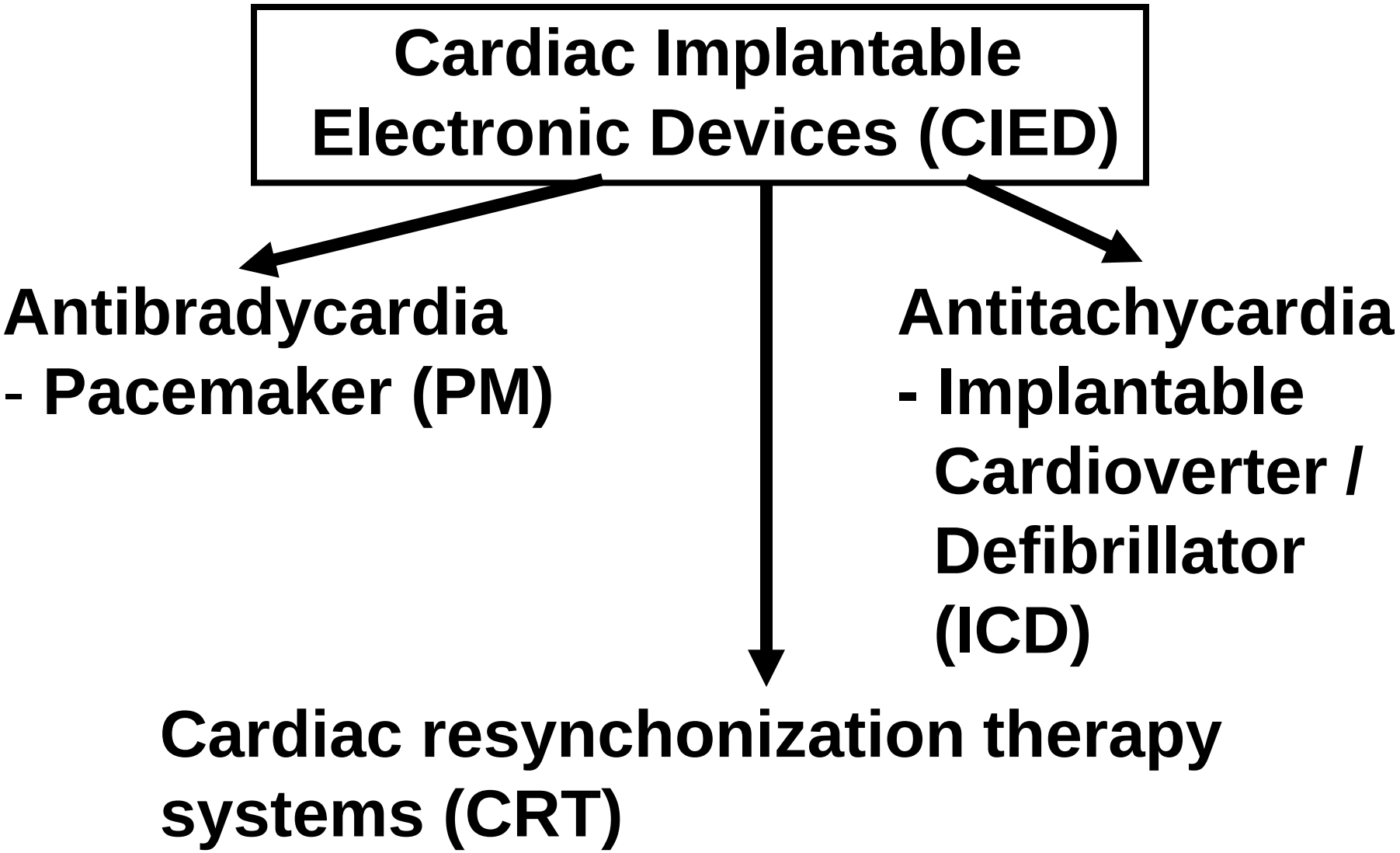


Figure 1: **Implantable haemodynamic monitoring system**
(A) CardioMEMS sensor or transmitter. (B) Transcatheter is implanted into a distal branch of the descending pulmonary artery. (C) Patient is instructed to take daily pressure readings from home using the home electronics. (D) Information transmitted from the monitoring system to the database is immediately available to the investigators for review. (E) Transmitted information consists of pressure trend information and individual pulmonary artery pressure waveforms.

(Lancet 2011;377:658-666)

Applications in Telecardiology

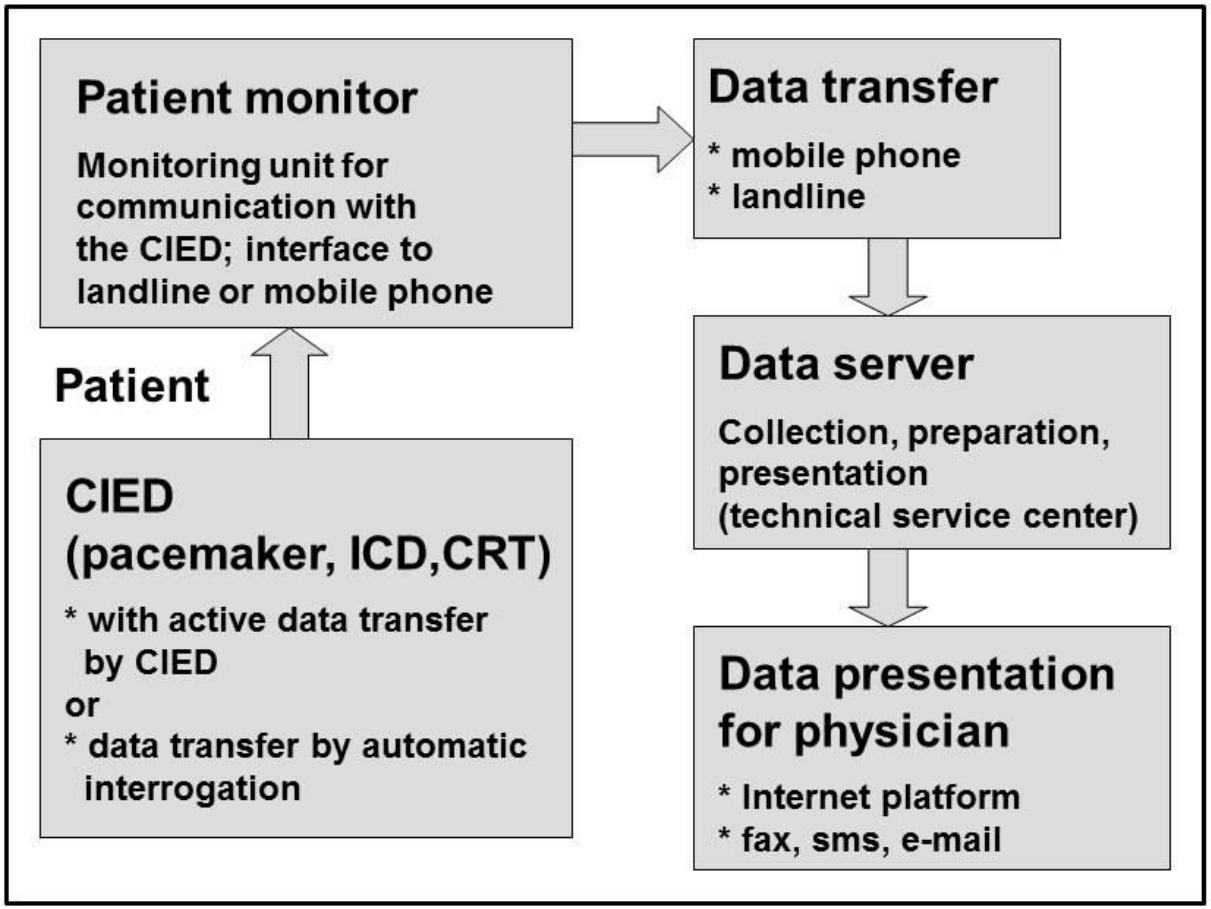
- Detection of arrhythmia
- Management of patients with congestive heart failure
- Telemedical management in patients with cardiovascular implantable electronic devices (CIED)


Cardiac Implantable Electronic Devices (CIED)
Antibradycardia
- Pacemaker (PM)
Antitachycardia
- Implantable Cardioverter / Defibrillator (ICD)
Cardiac resynchonization therapy systems (CRT)

Telemedical Device Management in Patients with Pacemakers, ICDs and CRT Devices

- Increase in the number of implants (follow-up, means and costs of shipping)
- Complex systems (e.g., CRT systems) offering new diagnostic opportunities (e.g., measuring impedance)
- Serious events (shock)
- Individualized control intervals
- Patients with serious primary diseases or comorbidity
- Patient safety

Telemonitoring in Patients with CIEDs



(A. Müller et al., 2015)

Home Monitoring° (BIOTRONIK)

Antenna in the header

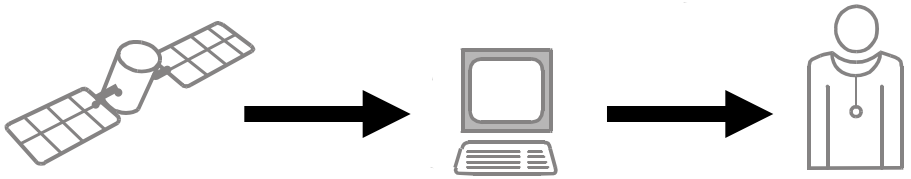
- **Data transmission in 403 MHz frequency for implants**
- **The same size as implants without the Home Monitoring feature**
- **Telecommunication and medical certification available**
- **Minor shortening of battery life time through Home Monitoring (< approximately 1 month)**

KLINIKUM CHEMNITZ gGmbH

Home Monitoring° (BIOTRONIK)

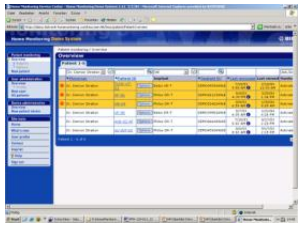
CardioMessenger°

BIOTRONIK
Service Center



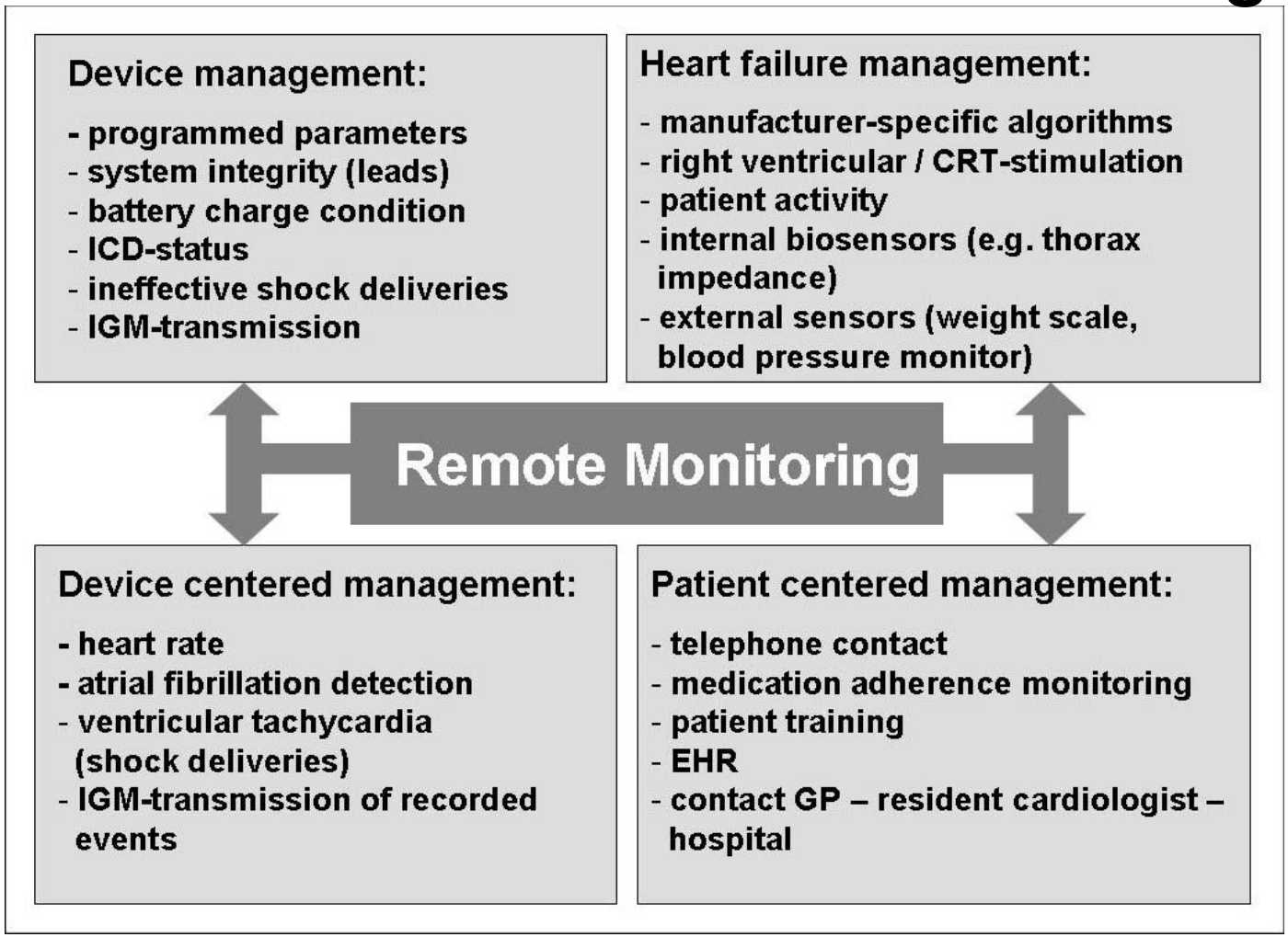
Transmission via mobile phone or landline

Data presentation via Internet, SMS or telefax



Pacemaker, ICD or CRT device with Home Monitoring° (Source: BIOTRONIK)

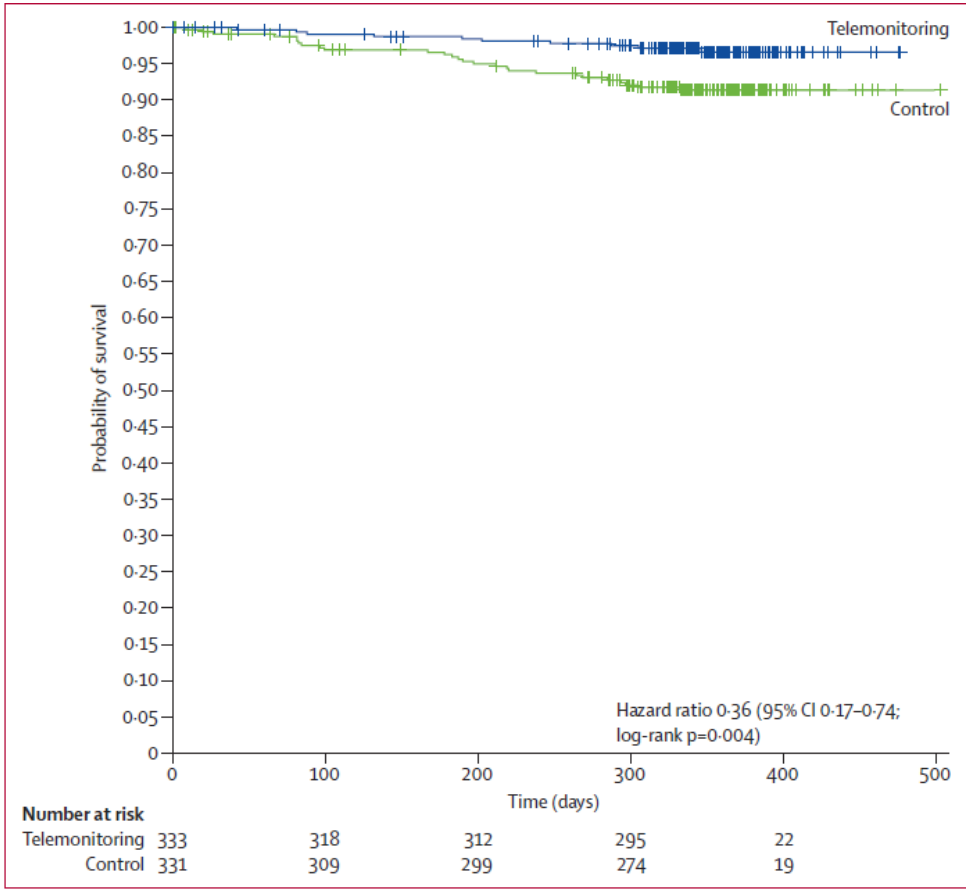
Device-based Remote Monitoring



(A. Müller et al., 2011)

Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial

*Gerhard Hindricks, Milos Taborsky, Michael Glikson, Ullus Heinrich, Burghard Schumacher, Amos Katz, Johannes Brachmann, Thorsten Lewalter, Andreas Goette, Michael Block, Josef Kautzner, Stefan Sack, Daniela Husser, Christopher Piorkowski, Peter Søgaard, for the IN-TIME study group**



Mortality

1. Timely recognition of ventricular and atrialen tachyarrhythmia

2. Timely recognition of suboptimal device functioning

3. Patient interview to understand the clinical situation and note any noncompliance regarding medication

(G. Hindricks et al., 2014)

Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial

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	Observation sent to investigational site	Patient contact by investigational site	Further action by investigational site*
Ventricular tachyarrhythmia or shock†	42 (56)	24 (38)	15 (22)
Atrial tachyarrhythmia‡	65 (109)	53 (70)	18 (24)
CRT <80% over 48 h§	35 (91)	28 (63)	15 (26)
Ventricular extrasystole frequency >110 per hour or increasing trend over 7 days	46 (54)	34 (39)	7 (7)
Decreasing trend of patient activity over 7 days	1 (1)	1 (1)	0 (0)
Abnormal IEGM or sensing safety notification¶	34 (51)	20 (25)	14 (15)
Pacing or impedance safety notification‖	26 (43)	13 (14)	5 (5)
Gap in data transmission of >3 days	241 (818)	174 (401)	4 (4)
Total	280 (1225)	238 (641)	63 (99)
Mean per patient-year	4·0	2·1	0·3
Median per patient-year (IQR)	3·0 (1·1–5·7)	1·1 (0·0–3·0)	0·0 (0·0–0·0)

Data are number of patients (number of events) unless stated otherwise. Observations were forwarded by the central monitoring unit to investigational sites. CRT=Cardiac resynchronisation treatment. IEGM=intracardiac electrogram. *A scheduled clinical follow-up or a suggested patient visit to their family doctor. †Could include inappropriate detections. ‡The first onset of atrial fibrillation for >30 s, a long atrial arrhythmia episode (≥6 h) with high ventricular rate (>120 beats per minute), or high atrial arrhythmia daily burden (≥50%) on 7 consecutive days. §Percentage of biventricular pacing needed for effective cardiac resynchronisation treatment. ¶Abnormal IEGM:T-wave oversensing, far-field atrial sensing of ventricular activity, or other suspected sensing problem; sensing safety notification: low sensing amplitude or insufficient safety margin on any lead. ‖Pacing safety notification: low safety margin for stimulation on right or left ventricular lead; impedance safety notification: out-of-range impedance of any lead.

Table 3: **Results of telemonitoring and clinical reactions**

Events and Clinical Reactions

“The effects of telemonitoring depend on the reaction of health-care professionals to the transmitted data.”

(G. Hindricks et al., 2014)

2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Remote Management of Arrhythmias and Device

Recommendations	Class [a]	Level [b]	Ref. [c]
Device-based remote monitoring should be considered in order to provide earlier detection of clinical problems (e.g. ventricular tachyarrhythmias, atrial fibrillation) and technical issues (e.g. lead fracture, insulation defect).	IIa	A	174–176

[a]Class of recommendation.
[b]Level of evidence.
[c]Reference(s) supporting recommendation(s).

(Eur Heart J 2013;34:2281-2329)

Empfehlungen

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Empfehlungen zum Telemonitoring bei Patienten mit implantierten Herzschrittmachern, Defibrillatoren und kardialen Resynchronisationssystemen

(Kardiologe 2013;7:181-193)

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EHRA SURVEY

Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association

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Barriers to the Implementation of Remote Monitoring of CIEDs

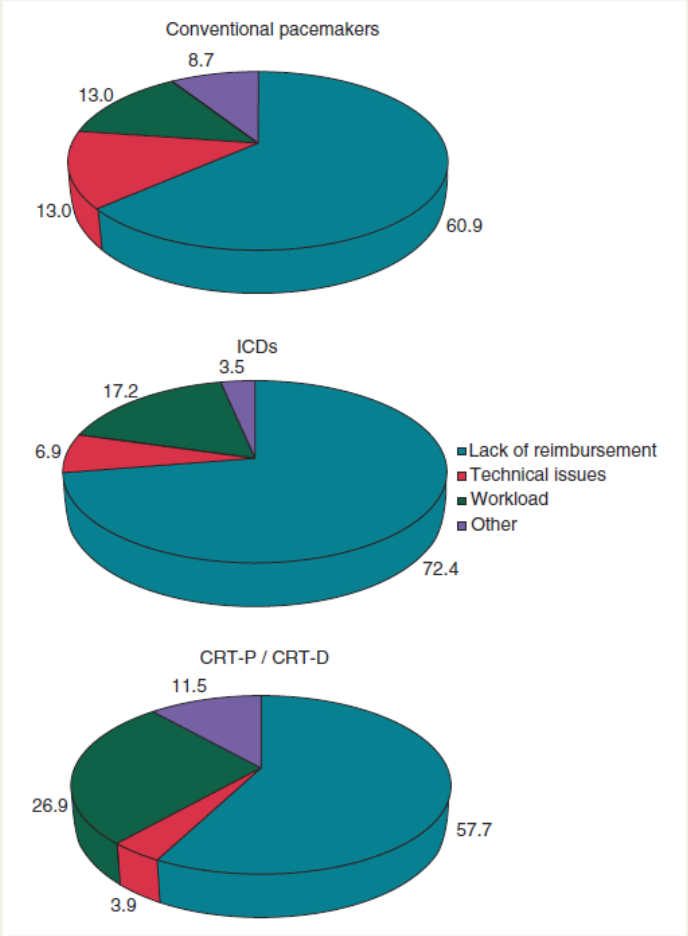

Figure 5 Barriers to the implementation of remote monitoring of CIEDs. Data are expressed as percentage of centres. ICD, implantable cardioverter defibrillators; CRT-P, cardiac resynchronization therapy pacing; CRT-D, cardiac resynchronization therapy defibrillation.

Table I Reimbursement of in-clinic and remote CIED device checks in different European countries

	Available reimbursement tariff for in-clinic device check	Available reimbursement tariff for remote device check	Sufficient reimbursement for procurement of hardware and services for remote device check
Austria	X	No	No
Belgium	X	No	No
Czech Republic	X	X	X
Denmark	X	X	No
Finland	X	X	X
France	X	No	Price premium for ICD and PM devices with RM
Germany	X	X	No
Italy	X	No	No
Norway	X	No	No
Portugal	X	X	No
Spain	N/A	N/A	N/A
Sweden	X	X	No
Switzerland	X	No	No
The Netherlands	X	No	No
UK	X	X (locally negotiated)	No

CIED, cardiac implantable electrical device; ICD, cardioverter-defibrillator; PM, pacemaker; RM, remote monitoring.

(G.H. Mairesse et al., 2015, G. Boriani, 2015)

Barriers to the Cardiological Use of Telemonitoring in a Clinical Setting

- The data provided is still considered to be insufficient
- Proof of the medical and economic utility in daily work
- Different interests of the parties involved (out-patient / in-patient / cost bearers)
- Difficult establishment of compatible infrastructures in clinics and doctors' offices
- Data protection and legal factors
- Problems of acceptance by physicians – data management
- Poor status of patient information
- Problems in sector-spanning health care
- Unsettled situation regarding costs and remuneration

(adapted from K. Rybak, 2012)

German Law for Safe Digital Communication and Applications in Health Care (the “E-Health Act”)

Goal:

Accelerating digitalization in health care and making it difficult to obstruct

Key Points

- Online validation and update of master data using the electronic health insurance card
- Electronic letter of discharge
- Medication prescriptions (medication plan)
- Emergency data set
- Telemedical services (teleradiology)