Telecardiology – Technical Innovations and Challenges in Clinical Practice

Axel Müller

Clinic of Internal Medicine I
(Head of Department: Prof. Dr. med. J. Schweizer)
Klinikum Chemnitz gGmbH

June 24, 2015
Causes of Death in Germany in 2013

(Source: German Federal Statistical Office)

© Statistisches Bundesamt, Wiesbaden 2014
Problems in the German Health System

Demographics
- Sinking birth rate
- Increasing life expectancy

Medical Care
- Nationwide diagnostics and therapy
- Evidence-based medicine
- Innovations
- Cost pressure

Morbidity
- Increasing number of patients with chronic diseases
- Co- and multimorbidity

Costs in Health Care
- Fewer payers
- Increasing medical costs overall and per case
- Efficiency?

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

- Collective term for the use of multimedia communication und information technology 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)
Telemedicine

Informatics

Equipment technology

Medicine
Telemedicine

- Teleradiology
- Telepathology
- Tele-dermatology
- Tele-psychiatry
- Tele-surgery
- Teleophthalmology
- Tele-cardiology
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)
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

ECG monitoring cards → Mobile phone landline → Server → E-mail with PDF file

- acoustic (analog / digital)
- bluetooth
- near-infrared

External loop recorder → Mobile phone → Server → E-mail with PDF file

- bluetooth

Implantable loop recorder → Interface (patient monitor) → Servers of the companies (Home Monitoring°, Merlin.net°, Latitude°, CareLink°) → Internet platform (password Protected file)

- radiocommunication
- radiofrequency control

- landline
- mobile phone
External loop recorder
loop 3300 BT
(Vitaphone°, Mannheim)

Telemedical transmission

Via Bluetooth

Mobile phone

Server

Internet
(PDF file)
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; †Vitaminsystems 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 bradycardic 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.
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.
### 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

<table>
<thead>
<tr>
<th></th>
<th>Patients with permanent atrial fibrillation (n = 24)</th>
<th>Patients with sinus rhythm (n = 24)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sinus rhythm or atrial fibrillation correctly detected</td>
<td>24</td>
<td>12</td>
</tr>
<tr>
<td>Sinus rhythm or atrial fibrillation incorrectly detected</td>
<td>0</td>
<td>12</td>
</tr>
</tbody>
</table>
Detection of Atrial Fibrillation

Atrial fibrillation is the most common cardiac arrhythmia 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

- Major risk source cardiogenic embolism: 20%
- Large artery atherosclerotic stenosis: 25%
- Small artery disease (lacunes): 25%
- Cryptogenic: 25%
- Unusual: 5%

(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
Patient with congestive heart failure

Device therapy (ICD, CRT-P, CRT-D)

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

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 Janssen, MD;† Aggie H. M. Balk, MD;‡ on behalf of the TEN-HMS Investigators
Kingston Upon Hull, United Kingdom; Aachen, Germany; and Rotterdam, the Netherlands

Impact of Remote Telemedical Management on Mortality and Hospitalizations in Ambulatory Patients With Chronic Heart Failure
The Telemedical Interventional Monitoring in Heart Failure Study
Friedrich Koehler, MD; Sebastian Winkler, MD; Michael Schieber, MD; Udo Soehm, MD; Karl Stangl, MD; Michael Bolten, MD; Ulf Boll, MD; Geri Buntman, MD; Marcus Honold, MD; Kerstin Koehler, MD; Goetz Gelbrich, PhD; Bridget-Anne Kirwan, PhD; Stefan D. Anker, MD; on behalf of the Telemedical Interventional Monitoring in Heart Failure Investigators

Telemonitoring in Patients with 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)
Telemedical Interventional Monitoring in Heart Failure (TIM-HF) Study (F. Köhler et al., 2011)
Primary Endpoint: All-cause mortality

Proportion of patients with event (%)

- Remote Telemedical Management
- Usual Care

HR 0.97 (0.67–1.41)
P=0.87

TIM-HF Study (F. Köhler et al., 2011)
## TIM-HF Study: Baseline Data

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

(F. Köhler et al., 2010)
### TIM-HF Study: Analysis of Subgroups

<table>
<thead>
<tr>
<th></th>
<th>RTM (N=354)</th>
<th>Usual Care (N=356)</th>
<th>P Value for interact.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>≥70 years</td>
<td>40.8 (7.2)</td>
<td>53.4 (7.1)</td>
<td>0.38</td>
</tr>
<tr>
<td>&lt;70 years</td>
<td>26.5 (6.3)</td>
<td>27.3 (6.4)</td>
<td></td>
</tr>
<tr>
<td><strong>Gender</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>34.9 (5.3)</td>
<td>39.9 (5.3)</td>
<td>0.77</td>
</tr>
<tr>
<td>Female</td>
<td>24.1 (10.8)</td>
<td>34.2 (11.2)</td>
<td></td>
</tr>
<tr>
<td><strong>NYHA</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Class II</td>
<td>22.8 (6.7)</td>
<td>26.9 (6.7)</td>
<td>0.75</td>
</tr>
<tr>
<td>Class III</td>
<td>42.6 (6.7)</td>
<td>51.1 (6.7)</td>
<td></td>
</tr>
<tr>
<td><strong>LVEF</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LVEF ≥27%</td>
<td>21.3 (6.6)</td>
<td>35.2 (6.6)</td>
<td>0.23</td>
</tr>
<tr>
<td>LVEF &lt;27%</td>
<td>44.9 (6.8)</td>
<td>42.7 (6.8)</td>
<td></td>
</tr>
<tr>
<td><strong>Prior HF decompensation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>30.1 (5.2)</td>
<td>44.5 (5.2)</td>
<td>0.0005</td>
</tr>
<tr>
<td>No</td>
<td>47.5 (12.1)</td>
<td>11.0 (11.6)</td>
<td></td>
</tr>
<tr>
<td><strong>ICD + prior HF decompensation</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>29.4 (7.9)</td>
<td>54.7 (8.1)</td>
<td>0.04</td>
</tr>
<tr>
<td>No</td>
<td>34.7 (6.0)</td>
<td>30.6 (5.9)</td>
<td></td>
</tr>
<tr>
<td><strong>PHQ-9 depression score &lt;10</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Yes</td>
<td>49.4 (10.1)</td>
<td>29.1 (10.2)</td>
<td>0.03</td>
</tr>
<tr>
<td>No</td>
<td>27.8 (5.5)</td>
<td>42.0 (5.5)</td>
<td></td>
</tr>
</tbody>
</table>

*(F. Köhler et al., 2010)*
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 Krankenhausaufenthalt 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 (Telemedizinegruppe) 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 Herzentenshall, ein EKG sowie eine Blutentnahme durchgeführt.


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.


In 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 Nedagaru, 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 < 0·001). 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) Transcateter 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 resynchronization 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

Patient monitor
- Monitoring unit for communication with the CIED; interface to landline or mobile phone

Data transfer
- mobile phone
- landline

Data server
- Collection, preparation, presentation (technical service center)

Data presentation for physician
- Internet platform
- fax, sms, e-mail

CIED (pacemaker, ICD, CRT)
- with active data transfer by CIED
- data transfer by automatic interrogation

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

Transmission via mobile phone or landline

Data presentation via Internet, SMS or telefax

BIOTRONIK Service Center

BIOTRONIK°

CardioMessenger°
Device-based Remote Monitoring

**Device management:**
- programmed parameters
- system integrity (leads)
- battery charge condition
- ICD-status
- ineffective shock deliveries
- IGM-transmission

**Heart failure management:**
- manufacturer-specific algorithms
- right ventricular / CRT-stimulation
- patient activity
- internal biosensors (e.g. thorax impedance)
- external sensors (weight scale, blood pressure monitor)

**Device centered management:**
- heart rate
- atrial fibrillation detection
- ventricular tachycardia (shock deliveries)
- IGM-transmission of recorded events

**Patient centered management:**
- telephone contact
- medication adherence monitoring
- patient training
- EHR
- contact GP – resident cardiologist – hospital

(A. Müller et al., 2011)
1. Timely recognition of ventricular and atrial 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

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 Piorokowski, Peter Sogaard, for the IN-TIME study group

<table>
<thead>
<tr>
<th>Event</th>
<th>Observation sent to investigational site</th>
<th>Patient contact by investigational site</th>
<th>Further action by investigational site</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ventricular tachyarrhythmia or shock†</td>
<td>42 (56)</td>
<td>24 (38)</td>
<td>15 (22)</td>
</tr>
<tr>
<td>Atrial tachyarrhythmia†</td>
<td>65 (109)</td>
<td>53 (70)</td>
<td>18 (24)</td>
</tr>
<tr>
<td>CRT +80% over 48 h Fig. 2</td>
<td>35 (91)</td>
<td>28 (63)</td>
<td>15 (26)</td>
</tr>
<tr>
<td>Ventricular extrasystole frequency &gt;110 per hour or increasing trend over 7 days</td>
<td>46 (54)</td>
<td>34 (39)</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Decreasing trend of patient activity over 7 days</td>
<td>1 (1)</td>
<td>1 (1)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Abnormal EGM or sensing safety notification¶</td>
<td>34 (51)</td>
<td>20 (25)</td>
<td>14 (15)</td>
</tr>
<tr>
<td>Pacing or impedance safety notification¶</td>
<td>26 (43)</td>
<td>13 (14)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Gap in data transmission of &gt;3 days</td>
<td>241 (818)</td>
<td>174 (401)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Total</td>
<td>280 (1225)</td>
<td>238 (641)</td>
<td>63 (99)</td>
</tr>
<tr>
<td>Mean per patient-year</td>
<td>4 (0)</td>
<td>2 (1)</td>
<td>0 (3)</td>
</tr>
<tr>
<td>Median per patient-year (IQR)</td>
<td>3 (1-1-5.7)</td>
<td>1-1 (0.0-3.0)</td>
<td>0.0 (0.0-0.0)</td>
</tr>
</tbody>
</table>

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)
### Remote Management of Arrhythmias and Device

<table>
<thead>
<tr>
<th>Recommendations</th>
<th>Class&lt;sup&gt;a&lt;/sup&gt;</th>
<th>Level&lt;sup&gt;b&lt;/sup&gt;</th>
<th>Ref. &lt;sup&gt;c&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>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).</td>
<td>IIa</td>
<td>A</td>
<td>174–176</td>
</tr>
</tbody>
</table>

<sup>a</sup>Class of recommendation.

<sup>b</sup>Level of evidence.

<sup>c</sup>Reference(s) supporting recommendation(s).

(Eur Heart J 2013;34:2281-2329)
Empfehlungen zum Telemonitoring bei Patienten mit implantierten Herzschrittmachern, Defibrillatoren und kardialen Resynchronisationssystemen
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

Georges H. Mairesse¹, Frieder Braunschweig², Katherine Klersy³, Martin R. Cowie⁴, and Francisco Leyva⁵*

¹Cliniques du Sud Luxembourg, Arlon, Belgium; ²Karolinska University Hospital, Stockholm, Sweden; ³IRCCS Fondazione Policlinico S Matteo, Pavia, Italy; ⁴Imperial College London (Royal Brompton Hospital), London, UK; and ⁵Aston University Medical School, Queen Elizabeth Hospital, Birmingham, UK

Received 2 November 2014; accepted after revision 4 December 2014; online publish-ahead-of-print 20 February 2015
Barriers to the Implementation of Remote Monitoring of CIEDs

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

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

Table 1 Reimbursement of in-clinic and remote CIED device checks in different European countries

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

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