## **Remote monitoring: how to remove** barriers and implement advances



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Genève

## **Conflicts of interest**

• Biotronik, Boston Scientific, Medtronic, Sorin, St-Jude

- research grants, speaker honoraria, consulting fees, institutional fellowship support

## **Remote device management**

- Incentives
- Workload and workflow
- Reimbursement

# Remote device management: definitions



- *Remote follow-up*: full remote device interrogation at scheduled intervals
- *Remote monitoring*: unscheduled transmission of pre-defined alert events
- Patient-initiated follow-up: non-scheduled interrogations as a result of a patient experiencing a real or perceived clinical event

Dubner Europace (2012) 14, 278-

#### Remote Monitoring of Implantable Cardioverter-Defibrillators

#### A Systematic Review and Meta-Analysis of Clinical Outcomes

Nirmalatiban Parthiban,"† Adrian Esterman, PhD, Rajiv Mahajan, MD, PhD," Darragh J. Twomey, MBBS," Rajeev K. Pathak, MBBS," Dennis H. Lau, MBBS, PhD," Kurt C. Roberts-Thomson, MBBS, PhD,"

Glenn D. Young, MBBS,\* Prashanthan Sanders, MBBS, PHD,\* Anand







#### Remote monitoring: a cost or an investment?

Haran Burri<sup>1</sup>, Hein Heidbüchel<sup>2</sup>, Werner Jung<sup>3</sup>, and Pedro Brugada<sup>4</sup>

<sup>1</sup>Cardiology Service, University Hospital of Geneva, Switzerland; <sup>2</sup>Cardiology-Electrophysiology service, University Hospital Gasthuisberg, Leuven, Belgium; <sup>3</sup>Schwarzwalid-Baar Klinikum, Academic Hospital of the University of Freiburg, Germany; and <sup>9</sup>Heart Rhythm Management Center, UZ Brussel Vrije Universiteit Brussel, Brussel, Belgium

	Accessibility	Quality	Efficiency
**********************			
Patients	Increased, especially if remote	Better care received Quality of life Reduced mortality and morbidity <sup>a</sup>	Less travel Less time spent
Medical personnel	Increased access to patient data	Better care given Increased satisfaction	Quicker follow-up Fewer missed visits Increased flexibility Less administrative work
Hospital	Networking of patient data	Reputation Increased satisfaction of personnel	More efficient use of hospital resources
Device manufacturer	Data centralization	Product quality control	Increased (avoids participation in in-office follow-up)
Insurance company	Data on healthcare use	Better patient care	Management of healthcare system
State	Increased access of patient care	Better public service	Management of healthcare system

# 2013 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

The Task Force on cardiac pacing and resynchronization therapy of the European Society of Cardiology (ESC). Developed in collaboration with the European Heart Rhythm Association (EHRA).

Recommendations	Class*	Level <sup>®</sup>	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).	lla		174-176

HRS Exp and mon devices	AS Expert Consensus Statement on remote interrogation d monitoring for cardiovascular implantable electronic Heart Rhythm 2015 Jul;12(7):e69-100		Level of Evidence
	A strategy of remote CIED monitoring and interrogation, combined with at least annual IPE, is recommended over a calendar-based schedule of in-person CIED evaluation alone (when technically feasible).	Ţ	٨
	All patients with CIEDs should be offered RM as part of the standard follow-up management strategy.	1	A
	Before implementing RM, it is recommended that each patient be educated about the nature of RM, their responsibilities and expectations, potential benefits, and limitations. The occurrence of this discussion should be documented in the medical record.	1	E
	It is recommended that all CIEDs be checked through direct patient contact 2–12 weeks postimplantation.	I	E
	It may be beneficial to initiate RM within the 2 weeks of CIED implantation.	IIa	C
	All patients with an implantable loop recorder with wireless data transfer capability should be enrolled in an RM program, given the daily availability of diagnostic data.	I	E
	Device and Disease Management	Class of Recommendation	Level of Evidence
	RM should be performed for surveillance of lead function and battery conservation.	I	A
	Patients with a CIED component that has been recalled or is on advisory should be enrolled in RM to enable early detection of actionable events.	1	E
	RM is useful to reduce the incidence of inappropriate ICD shocks.	I	B-R
	RM is useful for the early detection and quantification of atrial fibrillation.	I	( A.
	The effectiveness of RM for thoracic impedance alone or combined with other diagnostics to manage congestive heart failure is currently uncertain.	Пр	c



Europace (2012) 14, 278-293 doi:10.1093/europace/eur303

#### ISHNE/EHRA CONSENSUS PAPER

Half- -----

OFFICIAL COMMUNICATIONS

Cardiovascular Medicine 2011;14(2):58-60

#### ISHNE/EHRA expert of monitoring of cardiova electronic devices (CII

Sergio Dubner<sup>1</sup>°, Angelo Auricchio<sup>2</sup>, J Peter Stone<sup>5</sup>, Josep Brugada<sup>6</sup>, Ryszard Paulus Kirchhof<sup>9,10</sup>, Günter Breithardt Mehmet K. Aktas<sup>11</sup>, Michal Chudzik<sup>13</sup>,

HRS Expert Consensus S

#### Richtlinien für die Fernüberwachung (Remote Monitoring) implantierter Geräte zur Diagnostik und Therapie von Rhythmusstörungen und Herzinsuffizienz<sup>1, 2</sup>

Jürg Fuhrer, Istvan Babotai, Urs Bauersfeld (†), Haran Burri, Hans Gloor, Jürg Schläpfer, Christian Sticherling, Peter Zwicky

für die Arbeitsgruppe Herzschrittmacher und Elektrophysiologie der Schweizerischen Gesellschaft für Kardiologie

#### and monitoring for cardiovascular implantable electronic

#### devices

David Slotwiner, MD, FHRS, FACC (Chair),<sup>1</sup> George Annas, JD, MPH,<sup>4</sup> Marianne I Nestor O. Galizio, MD,<sup>7\*</sup> Taya V. Glot Charles J. Love, MD, CCDS, FHRS, F/ Suneet Mittal, MD, FHRS,<sup>12</sup> Loredan Merritt H. Raitt, MD, FHRS,<sup>15</sup> Renat Mark H. Schoenfeld, MD, CCDS, FHR Julie Shea, MS, RNCS, FHRS, CCDS,<sup>1</sup> Atul Verma, MD, FHRS, FRCPC,<sup>5</sup> Che

Neth Heart J (2012) 20:53-65 DOI 10.1007/s12471-011-0239-5

SPECIAL ARTICLE

#### Remote monitoring and follow-up of cardiovascular implantable electronic devices in the Netherlands

An expert consensus report of the Netherlands Society of Cardiology

C. C. de Cock + J. Elders + N. M. van Hemel + K. van den Broek + L. van Erven + B. de Mol + J. Talmon + D. A. M. J. Theuns + W. de Voogt

## **Remote device management**

- Incentives
- Workload and workflow
- Reimbursement

## **Remote monitoring: workload**

#### 117 patients with Home Monitoring

Time spent in web connection: - Nurse: 59 min/week

- Physician: 12 min/week



Ricci et al. Europace (2008) 10, 164-170



#### Workload and usefulness of daily, centralized home monitoring for patients treated with **CIEDs:** results of the MoniC (Model Project Monitor Centre) prospective multicentre study

Thomas Vogtmann<sup>1,8\*</sup>, Sascha Stiller<sup>2</sup>, Andrea Marek<sup>1</sup>, Stefanie Kespohl<sup>3</sup>, Michael Gomer<sup>4</sup>, Volker Kühlkamp<sup>5</sup>, Göran Zach<sup>6</sup>, Steffen Löscher<sup>7</sup>, and Gert Baumann<sup>1</sup>

#### 1 nurse + 1 supporting physician 62 PM and 59 ICD patients

#### nine satellite clinics



Table 3 Screening and communication workload at the monitor centre<sup>a</sup>

Activity	Telemonitoring nurse (min)	Physician (min)
Basic screening		
Analysis of event reports <sup>b</sup>	25.7	0.7
Communication of selected events to SC	4.3 @	0.4 (phone)
Total	30.0	1.1
Extended screening		
Scheduled analysis of online data trends	34.7	0.3
Communication of abnormal trends to SC	2.2 @	0.0
Total	36.9	0.3
Transmission-gaps related communication	2.8 (phone, @)	0.0

SC, satellite clinics: (2), email communication.

"Normalized per working day for 100 patients monitored, assuming each week has 5 working days.

"Event reports were customized in a way to cover almost all types of arrhythmia and technical events, to maximize the input information for the monitor centre.



### **Ressource utilization**







200











Heidbuchel EHJ 2015 14;36(3):158-69



Europace (2011) 13, 1166-1173 doi:10.1093/europace/eur026 CLINICAL RESEARCH

Sudden Death and ICDs

#### Healthcare personnel resource burden related to in-clinic follow-up of cardiovascular implantable electronic devices: a European Heart Rhythm Association and Eucomed joint survey

Giuseppe Boriani<sup>1+</sup>, Angelo Auricchio<sup>2</sup>, Catherine Klersy<sup>3</sup>, Paulus Kirchhof<sup>4</sup>, Josep Brugada<sup>5</sup>, John Morgan<sup>6</sup>, and Panos Vardas<sup>7</sup>



Visit	n	Actual time, mean (SD)	P-value
			0.007
Type of wat			0.007
Scheduled	397	16.2 (9.2)	
Unscheduled	29	19.3 (8.3)	
Device			< 0.001
PG	183	14.0 (7.5)	
ICD .	156	17.7 (10.0)	
CRT	84	19.1 (9.6)	
Reprogramming			< 0.001
No	294	15.3 (8.7)	
Yes	127	19.3 (9.7)	
Country			0.07
CH	64	24.3 (10.0)	
France	31	22.7 (8.7)	
Germany	81	14.4 (7.3)	
Greece	34	15.8 (9.4)	
kaly	94	12.9 (7.2)	
Spain	68	19.9 (8.6)	
UK	54	16.3 (7.8)	

Remote monitoring of cardiac implantable electronic devices in Europe: results of the European Heart Rhythm Association survey

Antonio Hernández-Madrid<sup>1</sup><sup>\*</sup>, Thorsten Lewalter<sup>2</sup>, Alessandro Proclemer<sup>3</sup>, Laurent Pison<sup>4</sup>, Gregory Y.H. Lip<sup>5</sup>, and Carina Blomstrom-Lundqvist<sup>6</sup>, conducted by the Scientific Initiatives Committee, European He<u>art Rhythm Association</u>

Europace (2014) 16, 129-132

- Survey of 54 centres belonging to the EHRA EP research network (83% University, 11% private)
- 76% use remote device management
- 57% nurse review
- 25% no specific workflow

## **Frequency of checks on alerts**





Mairesse, Europace (2015) 17, 814-818

# Remote, Wireless, Ambulatory Monitoring<br/>of Implantable Pacemakers, Cardioverter Defibrillators,<br/>and Cardiac Resynchronization Therapy Systems:<br/>Analysis of a Worldwide Database<br/>ARNAUD LAZARUS, M.D.From the InParys Clinical Research Group, Paris, FrancePACE 2007; 30:S2–S12

n=11,624 patients implanted worldwide with Biotronik PM, ICD or CRT-D

3,004,763 automatic wireless transmissions

Monitoring of 10.5 ±9 months (1-49 months)



#### Remote Monitoring Reduces Healthcare Utilization and Improves Quality of Care in Heart Failure Patients with Implantable Defibrillators: The EVOLVO (Evolution of Management Strategies of Heart Failure Patients with Implantable Defibrillators) Study

Maurizio Landolina, Giovanni B. Perego, Maurizio Lunati, Antonio Curnis, Giuseppe Guenzati, Alessandro Vicentini, Gianfranco Parati, Gabriella Borghi, Paolo Zanaboni, Sergio Valsecchi and

Maurizio Marzegalli

Circulation 2012 19;125(24):2985-92.

Table 2. Number (annualized rate per patient year) of healthcare utilizations for HF, arrhythmias or ICD-related events, by arm.

Clinical Event	Remote Arm	Standard Arm
Total healthcare utilizations	559 (4.40)	726 (5.76)#
<ul> <li>protocol-defined clinic visits</li> </ul>	283 (2.23)	451 (3.60)#
- non-urgent in-office visits	144 (1.13)	109 (0.87)
- urgent in-office visits (*)	50 (0.39)	79 (0.63)#
<ul> <li>emergency room visits (*)</li> </ul>	25 (0.19)	38 (0.30)
- hospitalizations requiring at least 1 overnight stay	57 (0.45)	49 (0.39)
Alert Condition		
Total alert conditions	315 (2.50)	256 (2.39)
- OptiVol Alert	274 (2.17)	231 (2.16)
- AT/AF burden at least 6 hours	13 (0.10)	17 (0.16)
- Ventricular rate at least 100 beats/min during AT/AF	22 (A)	3.8 1997
episodes lasting ≥6 hours	8 (0.06)	4(0.04)
- Shock delivered	9 (0.07)	2 (0.02)
- Lead impedances out of range	8 (0.06)	0 (0)
- VF detection/therapy off	1 (0.01)	2 (0.02)
- Low battery	2 (0.02)	0 (0)

\*: primary endpoint; #: significant difference in the rate of events (p<0.001).



#### Combined Heart Failure Device Diagnostics Identify Patients at Higher Risk of Subsequent Heart Failure Hospitalizations

Results From PARTNERS HF (Program to Access and Review Trending Information and Evaluate Correlation to Symptoms in Patients With Heart Failure) Study

David J. Whellan, MD, MHS,\* Kevin T. Ousdigian, MSEE, MSIE,† Sana M. Al-Khatib, MD, MHS, Wenji Pu, PHD,† Shantanu Sarkar, PHD,† Charles B. Porter, MD,§ Behzad B. Pavri, MD,\* Christopher M. O'Connor, MD,‡ for the PARTNERS Study Investigators

J Am Coll Cardiol 2010;55:1803–10

#### 694 CRT patients



Figure 3 Evaluations With a Subsequent HF Hospitalization Due to Sign/Symptoms of Pulmonary Congestion Optivol >100Ωdays

or any 2 of: Optivol ≥60 Ωdays AF duration≥6h AF with V rate≥90bpm Daily activity <1h/d Night HR > 85bpm HRV <60ms % CRT pacing <90% ICD shock

#### Algorithms



30-day HF hospitalization

#### Development of a Method to Risk Stratify Patients With Heart Failure for 30-Day Readmission Using Implantable Device Diagnostics

David J. Whellan, MD<sup>a,\*</sup>, Shantanu Sarkar, PhD<sup>b</sup>, Jodi Koehler, MS<sup>b</sup>, Roy S. Small, MD<sup>c</sup>, Andrew Boyle, MD<sup>d</sup>, Eduardo N. Warman, PhD<sup>b</sup>, and William T. Abraham, MD<sup>e</sup>









#### Heart Failure Management Report - Last 90 Day Zoom

Device: Consulta"\* CRT-D D234TRK

Seria Number PUD022200H

Date of interrogation: 15-Sep-2010 09:53:15

Heart Failure Risk

Last 90 Day Zoom (16-Jun-2010 to 15-Sep-2010)

Heart Failure Risk Status on 15-Sep-2010 is Medium\*



#### A novel algorithm to assess risk of heart failure exacerbation using ICD diagnostics: Validation from RAFT @

Lorne J. Gula, MD, MS, FRCPC, FHRS, George A. Wells, PhD, Raymond Yee, MD, FRCPC, FHRS, Jodi Koehler, MS, Shantanu Sarkar, PhD, Vinod Sharma, PhD, Allan C. Skanes, MD, FRCPC, FHRS, John L. Sapp, MD, FRCPC, FHRS, Damian P. Redfearn, MD, FRCPC, Jaimie Manlucu, MD, FRCPC, Anthony S.L. Tang, MD, FRCPC, FHRS

Heart Rhythm2014;11:1626–1631

#### 1224 pts from RAFT ICD or CRT-D (61%)

#### Table 2 ID-determined risk of HF exacerbation/admission





#### FLEISCHHACKER MEDI = CONNECT

Data transfer





**OneView**<sup>-</sup>CRM





## **Remote device management**

- Incentives
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- Reimbursement

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. Mairesse<sup>1</sup>, Frieder Braunschweig<sup>2</sup>, Katherine Klersy<sup>3</sup>, Martin R. Cowie<sup>4</sup>, and Francisco Leyva<sup>5+</sup> Europace (2015) 17, 814–818

Electronic survey from 43 centres in 15 European countries



	Costs	Financial incentive
Patients	No extra cost*	Less costs (travel etc.)
Medical personnel	No extra cost*	Possibility to increase total number of follow-ups
Hospital	Transmitter *	Shorter hospital stay (for same DRG)?
Device Company	Transmitter (~2,600 Euros for mobile system, based on 2010 UK list prices ( <i>CEP 1069</i> ) Telecom Database servicing Helpline Scientific studies	Marketing value
Insurance company	Transmitter* Costs of alerts	Fewer cost-intensive clinical events?
State	Transmitter*	Cost control Fewer cost-intensive clinical events?

\*Depends on reimbursement

Burri et al. *Europace* 2011; 13: 44–48



Europace (2013) **15**, 1601–1608 doi:10.1093/europace/eut070

#### Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator and resynchronization devices in the UK

Haran Burri<sup>1\*†</sup>, Christian Sticherling<sup>2†</sup>, David Wright<sup>3</sup>, Koji Makino<sup>4</sup>, Antje Smala<sup>5</sup>, and Dominic Tilden<sup>4</sup>

#### Markov model

Conservative analysis assumes:

- No ↓ hospital admission, stroke
- No ↑ in FU before ERI
- No travel costs
- No increase in efficiency



## Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study

Laurence Guédon-Moreau<sup>1\*</sup>, Dominique Lacroix<sup>1</sup>, Nicolas Sadoul<sup>2</sup>, Jacques Clémenty<sup>3</sup>, Claude Kouakam<sup>1</sup>, Jean-Sylvain Hermida<sup>4</sup>, Etienne Aliot<sup>2</sup>, and Salem Kacet<sup>1</sup>, on behalf

of the ECOST trial Investigators

Europace 2014 Aug;16(8):1181-8

#### N=310

RM : 1 in-office FU/yr Control: 2 in-office FU/yr

Data: actual billing documents issued by the French health insurance system

400"Adding the ICD to the non-hospital costs, P < 0.001Total costs incurred per patient-year the savings were  $\in$ 494 (P < 0.005) or when 350 €323 + 206 the monitoring system (€ 1000) was 25% included, € 315 (P < 0.05) per patient-year 300 €242 ± 180 250 -€290 ± 212 No provision for reimbursement of 200 RFU costs, but should easily be €215 ± 185 absorbed by the cost saving 150 -100 50 €28 ± 40 €33 ± 48 Costs reimbursed by the healthcare insurance Active group Control group Costs supported by the patients

## - EuroEco





#### **Provider costs**



#### Country dependent variations Provider perspective

## - EuroEco



#### Heidbuchel EHJ 2015 14;36(3):158-69

#### Country dependent variations Payer perspective



~ EuroEco

Even in countries with remote monitoring reimbursement (UK and Germany), total costs for insurers over 2 years of follow-up do not increase. Remote monitoring for patients with implanted defibrillators

Technology evaluation and broader regulatory framework



Belgian Health Care Knowledge Centre

September 2010

KCE reports 136C

INGARD VINCE, SERGE STROOBANDT, SOFHE GERKENS, CHRS DE LAET

"As long as benefits for the patient or the healthcare system are not clearly demonstrated, regular reimbursement for remote monitoring should remain out of scope. Even conditional reimbursement of remote monitoring irrespective of the medical application, should only be considered once there are sufficient indications of efficacy and safety.... »



http://www.kce.fgov.be



Ont Health Technol Assess Ser. 2012;12(1) Internet-Based Device-Assisted Remote Monitoring of Cardiovascular Implantable Electronic Devices: An Evidence-Based Analysis



G Pron, I. Ieraci, K Kaulback, Medical Advisory Secretariat, Health Quality Ontario.

Visits per Patient-year (over 15 months)	Standard Care	Remote Monitoring
Average total in-office visits per patient year	3.07	1.92
Average scheduled in-office visits per patient year	2.12	0.51
Average remote-monitoring visits per patient year		1.41
Average costs		
Average cost per in-office visit	\$140.45	
Average cost per remote-monitoring visit		\$105.85
Total costs		
Total cost (over 15 months)	\$1,364,161.00	\$853,022.00
Annualized costs	\$1,091,329.00	\$682,418.00
Annual cost per patient	\$262.12	\$163.91
Annual incremental cost of remote monitoring		-\$408,911.00
Annual incremental cost per patient		-\$98.22.00



#### COMMISSION NATIONALE D'EVALUATION DES DISPOSITIFS MEDICAUX ET DES TECHNOLOGIES DE SANTE

AVIS DE LA CNEDIMTS 09 juillet 2013



# Reimbursement of remote device management in Europe



Moving towards good practice in the reimbursement of CIED telemonitoring



http://www.eucomed.org/uploads/Modules/Publications/whitepaper\_reimbursementciedtelemonitoring.pdf

## **Adoption of remote management**

Many incentives

better patient care, guidelines, improved efficiency, higher income...

- Many hurdles reimbursement, costs, workload, paradigm shift
- Improve workflow nurse triage, integrated diagnostics, automated data transfer
- Implication control of the second seco



Hôpitaux Universitaires Genève

## Thank you !