

Managing Systems in Remote Monitoring A Complex Challenge Turned into an Important Clinical Tool

Mário Oliveira, MD, PhD, FESC, FHRS

Head of Pacing and Electrophysiology Laboratory Cardiology Department – Santa Marta Hospital Institute of Physiology, Faculty of Medicine of Lisbon



BIOSTEC 2014

7th International Joint Conference on Biomedical Engineering Systems and Technologies

CARDIAC ELECTRONIC IMPLANTABLE DEVICES - THE SUCCESS OF REMOTE MONITORING



PACEMAKERS ICDs CRTs >500.000 per year

Imagine relaxing in the comfort of your home. At the same time, your doctor is

getting important information from your cardiac device







• great differences in implanting rates among EHRA members

• the number of implants is increasing in almost all countries

Lubinski, et al, Europace 2011







✓ Clinical trials have consistently demonstrated the ability of ICDs and CRTs to reduce mortality in selected pts with moderate-to-severe LV systolic dysfunction and HF.

indications for CIEDs expanded dramatically

ICDs »» 149/million PMs »» 947/million CRT-P »» 26/million CRT-D »» 85/million

Eucomed 2009

total implants in 2009 in 'Europe 27' of 471 284 PMs and 74 151 ICDs!

Review of the ICD Registry



	2006	2007	2008	2009	2006-2009
Total implants (N, for each year and cumulative for 2006–2009)	92,897	120,668	131,086	141,374	486,025
Single chamber ICD (%)	23.4	21.9	20.5	18.9	20.9
Dual chamber ICD (%)	39.1	39.1	39.8	39.3	39.3
Biventricular ICD (%)	37.4	<u> 38</u> .9	<u>39.</u> 6	41.7	39.6
Adverse procedure-related event (%) (for new ICD implants only)	3.77	3.34	3.01	2.87	3.22
Death in laboratory	0.02	0.02	0.03	0.02	0.02
Cardiac perforation	0.09	0.08	0.09	0.06	0.08
Hematoma	1.18	0.96	0.8	0.71	0.89
Lead dislodgement	1.11	1.08	1.02	1.01	1.05
Hemo/pneumothorax	0.66	0.54	0.50	0.466	0.53
Transient ischemic attack/stroke	0.10	0.08	0.07	0.07	0.08
Other	0.61	0.58	0.50	0.53	0.57

Hammill C, et al. Heart Rhythm 2010:7:1340-1345

Year



in 2007 over 1.6 million CIDs were implanted in the USA and Europe, which would translate to > 5.5 million patient-encounters per year...

Heidbüchel, Europace 2008

78% PRIMARY PREVENTION

Congestive Heart Failure - scope of the problem

>22 million individuals worldwide

2% of European population

>500.000 new cases/year



WHAT IS THE PERCENTAGE OF HF PATIENTS CANDIDATES FOR CRT?

Euro Heart Failure Survey, 2007

Increase in the Use of Implantable Cardioverter-Defibrillators

- > follow-up visits are scheduled at 3 or 6-month intervals
- > additional unscheduled visits are often required to investigate symptoms, shocks, alarms
- > in "conventional" follow-up any device problem which occurs will not be identified quickly!



THERE IS A (REAL BIG) ROLE FOR REMOTE MONITORING

Wilkoff BL, Heart Rhythm. 2008;5(6):907–25 Hess PL, et al. Heart Rhythm 2013; 10(8):1127-33

Remote Monitoring:

Some implantable cardiac CIEDs have the capacity to have interrogation evaluations done outside of a medical facility, usually the patient's home. Remote monitoring has the potential to provide timelier and nearly identical information on CIED performance as a traditional in person interrogation. Some method for communication of information between the patient and the physician and/or CEAP responsible for CIED follow-up is an important component of remote monitoring.

Europaæ 2008;10:707-25.

- Everyone with an implantable device must have regular monitoring to make sure that it is working properly.
- Remote device monitoring allows us to check the device between follow-ups.
- Remote monitoring can support more timely comprehensive care for heart health.

Remote, Wireless, Ambulatory Monitoring of Implantable Pacemakers, Cardioverter Defibrillators, and Cardiac Resynchronization Therapy Systems: Analysis of a Worldwide Database

ARNAUD LAZARUS, M.D.

From the InParys Clinical Research Group, Paris, France

Study Objective: To describe the daily routine application of a new telemonitoring system in a large population of cardiac device recipients.

Conclusions: This broad clinical application of a new monitoring system strongly supports its capability to improve the care of cardiac device recipients, enhance their safety, and optimize the allocation of health resources. (PACE 2007; 30:S2–S12)

Conclusions: Home monitoring technology allowed optimization of medical treatment and device programming with low consumption of healthcare resources (Europace 2008; 10:164-170)

Home monitoring remote control of pacemaker and implantable cardioverter defibrillator patients in clinical practice: impact on medical management and health-care resource utilization

Renato Pietro Ricci*, Loredana Morichelli, and Massimo Santini

Department of Cardiovascular Disease, San Filippo Neri Hospital, Via Martinotti 20, 00135 Rome, Italy

How Does Remote Monitoring Work?

Remote monitoring allows you to send comprehensive device information to your clinic over a <u>standard phone</u> line.

Your clinic then reviews your device information on a <u>secure website</u>, allowing routine device follow-up or a special situation to be reviewed quickly and efficiently. All <u>remote monitoring systems</u> are slightly different and use slightly different technology.







hold the antenna over your heart device

Remote Monitoring Systems Implantable Cardiac Devices



generator interrogation (manual or automatic)
regular transmission of data (programmable)
time between transmissions (team decision)





stored and measured information about the lead(s), sensor(s), battery and the implanted pulse generator function, as well as data collected about the patient's <u>heart</u> rhythm, heart rate and rhythm treatment <u>settings</u>.



Who deal with the telemonitoring information?



healthcare team access to patient's clinical status

- manual transmissions
- automatic scheduled transmissions
- transmission of Care Alerts
- "testing" sessions



AUTOMATIC FOLLOW-UP



Clinical staff may schedule automatic transmissions

Transmission to a Central Information Service



(each center has acess limited to is patient's using a password code in a w*eb page)*

- sensing and impedances
- % of pacing
- arrhythmic events (EGMs)



- system integrity
- events (arrhythmias, >"thoracic fluid")
- other ("team decision")

alerts can be selected and reconfigured for individual patients

		Ν	/IyCareLi	nk TM - <i>We</i>	bsite		
Quick Look II	Current EGM	Episodes	Cardiac Compass	More Reports 🔻	Comments and Notes	History	
Device: Protecta™ XT	CRT-D D354TRG		Serial Num	ber: PSF610582S	Date of	f Interrogation: 02-Deo-2013 0	0:18:06
Arrhythmia		V. Sensin	g	Rate Drop Re	esponse		
C List		Clist		C List			
I EasyEGM™ S	ummary						
Current EGM	02-Dec-2013	12:18 AM					
		Atip to Aring					
		Can to RVcoil	400m				
		Sense Pace					

Arrhythmia Episodes with EGM since: 01-Nov-2013

Non-sustained VT Episodes: 3	With EGM: 3						
			Time	Duration		Full EG	M
Туре	ID#	Date	hh:mm	hh:mm:ss	Avg bpm A/V	View	Print
VT-NS	#103	24-Nov-2013	14:00	:01	101/176	-	
Interval (ms)		Atip to Arin Rytip to RV					

Remote Yellow Alert Reconfiguration

Yellow Alerts can be remotely re-configured according to each patient's clinical indications through the secure website without bringing the patient into the hospital

• Arrhythmias

- Shock therapy delivered to convert arrhythmia
- Accelerated arrhythmia episode (ventricular)
- Atrial Arrhythmia Burden
- Patient-triggered event stored

>0, 0.5, 1, 3, 6, 12, 18, 24 hours

• Weight change

 At least .91 kg average over two days or at least 2.27 kg in a week

• Battery

- Voltage was too low for projected remaining capacity
- Explant indicator reached
- Cardiac Resynchronization Therapy Pacing
- Right Ventricular Pacing
- Therapy history corruption detected

Ventricular pacing leads

- Low right ventricular intrinsic amplitude
- Low left ventricular intrinsic amplitude
- Low left ventricular pacing lead impedance
- High left ventricular pacing lead impedance

Atrial pacing leads

- Low atrial intrinsic amplitude
- Low atrial pacing lead impedance
- High atrial pacing lead impedance



<50, 60, 70, 80, 85, 90, 95 % >10, 20, 30, 40, 50 %

Red Alert Notification

Red Alerts (Clinical Event Notification) will always appear on the secure website; your local representative can call you as well





- Remote monitoring disabled due to limited battery capacity
- High or low shock lead impedance
- High or low shock lead impedance detected when attempting to deliver a shock
- High or low right ventricular pacing lead impedance
- High voltage detected on shock lead during charge
- Tachy mode set to value other than Monitor + Therapy
- PG has detected a possible device malfunction
- Device parameter error

remote monitoring is not a substitute for calling the **emergency** system!

AND IF SOMETHING FAILS?!

Hospitals are experts in health domain, not in information systems and knowledge representation Even the best monitoring systems in the world are not foolproof!

LATITUDE[®] Experience



Defined as the number of patients who received an alert during 73,215 Patient Monitoring Years in 2008, where Patient Monitoring Years is defined as the total number of days each patient was active in LATITUDE[®] in 2008 converted into years.

Yellow alerts are individually selected. Not all alerts were enabled for all patients.

Patients may have triggered more than one alert simultaneously and some patients may have triggered more than one type of alert.

Reports

	ME INANSHISS	IONS	MAI	ALGE MY	PATIENTS	MANAGE MY C	LINIC		Clinic: Test (clinic	
tive	Transmissions Rep	orts List	Advanced	Search	Transmission Sch	hedule					
an	smissions: Active	Transmir	ssions (5)							
lect	a Viewc				Keyword Se	arch: (patient name or 6); device model	or serial nu	mber)		
5've	Transmissions		•		Advanced Se	and Se	larch				
	Dismiss Transmission	Print / De	port. Report		* Update St	atus •				25 p	er page 💌 🖣
All	Patient Name	Receiv	ved 🔻	C Alerts	Event Summary	y	Status	Battery	Device	Φ	Next Send
	Stevens, Kimberly	28-Ji 11:4	<u>in-2012</u>		No Events		New		Revo™ 6-Aug-2011		Not Scheduled
1	Johnson, Rea PEH456709321 (Report Available)	21.Ji 09:4	m.2012	•	Symptom + Del Pause Episode	lected Episode,	New		Reveal LINQ [™] 1-Mar-2012	•	15-Jul-2012 Summary Report
1	Gomez, Maria PID12340765 (Papot Avaliable)	28.Ji 00:11	n.2012		Tachy Episodes	, AT/AF Episodes	New		Reveal LING ¹⁶⁶ 1-Mar-2012	Φ	01-Jul-2012 Summery Report
1	Lee, John PEDESE789326 (Report Available)	28-Ji 90:19	<u>m-2012</u>	•	Tachy Episodos	, AF Episode	New		Reveal LINQ™ 15-Jun-2012	0	15-Jul-2012 Summary Report
1	Amstrong, Jason	25.Ji 18:00	<u>m-2012</u>	•	Electrical Reset Pacing <90%, 1	t, Patient Akert, V. IV. Sensing Episode	Viewed		Consulta TM CRT-D 15-Apr-2009	θ	15-Jul-2012 Missed
1	Coleman, Edward P30456765897	25_Ji 10:00	m-2012		No Eventa		Hew		Revo ¹⁴⁴ 10-Jan-2012	Φ	Not Scheduled
										25 p	er page 🔹 🖣



Comparison of different remote monitoring systems



Why Remote Monitoring?

	Accessibility	Quality	Efficiency	Costs	Financial incentive
Patients	Increased, especially if remote	Better care received Quality of life Reduced mortality and morbidity ^a	Less travel Less time spent	No extra cost	Less costs (travel, meals, accompanying person, etc.)
Medical personnel	Increased access to patient data	Better care given Increased satisfaction	Quicker follow-up Fewer missed visits Increased flexibility Less administrative work	No extra cost	Possibility to increase total number of follow-ups
Hospital	Networking of patient data	Reputation Increased satisfaction of personnel	More efficient use of hospital resources	Transmitter purchase ^b Data analysis Patient education	Shorter hospital stay (for same DRG)
Device manufacturer	Data centralization	Product quality control	Increased (avoids participation in in-office follow-up)	Transmitter Telecom Database servicing Helpline Scientific studies	Marketing value
Insurance company	Data on healthcare use	Better patient care	Management of healthcare system	Transmitter ^b	Cost control Fewer cost-intensive clinical events ^a
State	Increased access of patient care	Better public service	Management of healthcare system	Transmitter ^b	Cost control Fewer cost-intensive clinical events ^a

...the consensus document of the *Heart Rhythm Society* and *European Heart Rhythm Association* suggests annual hospital visits for ICD/CRT-D patients in a regular remote monitoring follow-up.

...an individualized approach

Lautuue				
Summary Events	s Settings	Health		Configure Patient
Alerts and Status Leads	Battery Rhythm ID			
-				
My Alerts: 2 Red	d, 1 Yellow			
High shock in lead. Contact	mpedance detected on 23 0 t LATITUDE Customer Supp	ct 2008 11:48. Schedule in-office ort.	follow-up to evaluate shock	
V-Tachy mod tachy therapy	e set to value other than Mo	nitor + Therapy on Oct 2008 21:37	. Device will not provide	
Y High left vent	tricular pacing lead impedan	ce detected on 23 Oct 2008 11:48	. Schedule in-office follow-up	0
• to evaluate L	v pacing lead.			
Patient/Equipmen	t Information	Health Summary		
Patient Status	Monitored	Measure	Most Recent Measurem	ent
Physician (Device)	Green, Charles	Mean Heart Rate	min ⁻¹ 1	5 Jan 2009
Implant Date	8 July 2008			
		Most Recent Presentin	g EGM: 16 Jan 2009	
U Leads		(Click for details)		
High shock lead impe	edance	P Evente		
C Pattern		CVents		and the second second
Battery	volanti 7 vanra from 40		Since Last Follow-up	Percent
Jan 2009	explant. 7 years from 16		909 Oct 2008	Paced
One Very Demoister	\frown	VF Therapy	0	A 90%
One rear Remaining		VT Therapy	0	BV 95%
Explant	BOL	VT 1 Therapy	0	
Patient-Initiated Interro	ogations On	vi-1 Inerapy	0	L 99%
		ATR > 48 hr	0	



...an individualized approach

Home Monitoring ™		
Monitoring	Patient 21 / 49 (filter	ed) 🖸 🧲
Patients for review All patients	U Status on 29-Oct-2009 00:26 Lexos VR-T / SN: 7982	4524
New patient	Status Implant settings Holter History Patient profile Options	e/print (PDF
Administration	Timeline Archive	
Patient groups		
Transmitters	Patient profile comment	
Ontion templates	No comments entered.	
Option templates	Finding options comment	
Site tools	Telm: 96 987 95 94early detection of a lead fracture »» replacement before sympto	ms
Home	Timeline	
👔 What's new		
User profile		
Contact		
👔 Imprint		~t 2009
(2) Help	30-jui-2003 10-Aug 24-Aug 07-Sep 21-Sep 03-Oct 29-0	
Sign out	Display <u>10</u> <u>20</u> 50 II _ 1 - 19 of 1	9 🖻 📄
	22-Sep-2009 02:03:06 Inding "VT1 detected" close 1.	Status
	21-Sep-2009 09:23:41 Finding "VT1 detected" acknowk dged by Dr. Nogueira Silva (nogueira).	Status
	21-Sep-2009 08:32:19 Finding "VT1 detected" Initially detected.	Status
	17-Sep-2009 02:03:59 Finding "VT1 detected" closed.	Status
	16-Sep-2009 15:33:08 Finding "VT1 detected" acknowledged by Dr. Nogueira Silva (nogueira).	Status
	01-Sep-2009 01:37:34 Finding "VT1 detected" Initially detected	Status
	17-Jul-2009 02:03:32 Finding "VT1 detected" closed.	Status
	16-Jul-2009 15:04:22 Finding "VT1 detected" acknowledged by Dr. Nogueira Silva (nogueira).	Status
	04-Jul-2009 15:21:18 Finding "VT1 detected" Initially detect d.	Status
	01-Jul-2009 02:41:07 Finding "VT1 detected" closed.	Status
	30-Jun-2009 18:23:59 Finding "VT1 detected" acknowle (ged by Dr. Nogueira Silva (nogueira).	Status
	16-Jun-2009 02:03:33 Finding "VT1 detected" Initially detected.	Status
	12-Jun-2009 01:54:21 Findule "VT1 detected" closed.	Status



DEVICE BASED MONITORING FEATURES IN HEART FAILURE

% BIV pacing in CRT devices (... but also % RV pacing in ICD patients)

Arrhythmias (VT, VF, NSVT, AF, AT)

Heart Rate, Heart Rate Variability

Physical Activity, Respiratory Rate

IntraThoracic Impedance

Hemodynamics – intracardiac pressure, pulmonary pressure, heart sound amplitude

Body Weight, Blood Pressure

pressure or fluid index (derived from intrathoracic impedance) or autonomics can predict HF events and change outcomes

Bourage R, et al. JACC 2008 Catanzariti D, et al. PACE 2009

In ALTITUDE, pts followed remotely showed <u>higher survival rates</u> than those followed in-clinic. Also, survival outcomes were better than those observed previously in clinical trials, suggesting that <u>closer management with remote monitoring</u> <u>allows to intervene more effectively</u> with impact on survival.

Comprehensive patient Heart Failure Report through integration of device diagnostics

	LA	TITUDE® Patient Manageme	nt	Report Created 0	3 Mar 2009	
Scientific	H R R R R R R R R R R R R R R R R R R R	eart Failure Managem art ID 105225564 a of thm 05 Mar 1958 codes 160-0 Profile the Mode Newtor + Therapy	ent Report	Latest Sand 23 Feb 2039 Last Office Inferrogation 17 Dec 2008 Implant Date 19 Mar 2036		
My Alerts		of at least 0.27 ke is a weak				
A 23 Feb 2009 - 0	Cardiac Re	synchronization Therapy pacir	a of < 90% (52%).	erage over a tile o	i note day pr	
Trends			••••••			
Weight		0 ** 2008	Jan 2009	Fet	2009	
	75				1.0	
				100	and a	
	·· • • •		Merrow and		1.1.1.1	
	04.8					
Blood Pressure		Dec 2008	Jan 2008	Fel	2009	
Systolic	14					
Diastolio	124	And a second sec	And the second s	source and	and the second	
	revers and			1000 Total 100		
	74	and have made in the	and the second of the	and mark of	and the	
	14	An A data of the A		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		
Heart Rate	1.00	Deo 2008	Jan 2008	Fel	2009	
Max	104					
Mean	*** TH	***************************************				
		**********	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
	-					
Activity Level		0 eo 2008	Jan 2008	Fel	2009	
% of day active	4					
8	. ;					
	:					
HEV/ Ecotoriat		0.00 2008	Jan 2009	E a l	2008	
nev Poorprint	74		00112000	1		
			and an	1	a change.	
	5 a					
	-					
	1		1 MART	020		
SDANN	344	0 66 2008	Jan 2009	Fel	2009	
	148					
	FIS 128					
		L				
Autonomic Balance		Deo 2008	Jan 2008	Fel	2009	
Monitor						
	,					
	1					
		Copyright 2005, 2008, 20	07, 2008 by			
		Boston Scientific Con	noteroop			
		CF FR ATTENDED AT POST	198811192			

"Pts should weigh themselves on a regular basis to monitor weight change, preferably as part of a regular daily routine"

ESC Guidelines, 2008

Who should deal with the information?

DATA RECORDED



Increases in body weight are associated with hospitalization for HF and begin at least 1 week before admission

- compared with control pts, HF cases experienced gradual weight gain beginning 30 days before hospitalization
- within the week before hospitalization, the risk of HF hospitalization increases in a monotonic fashion with increasing amounts of weight gain
- any weight gain of ≥1 kg is associated with increased risk of HF hospitalization



Activity level as predictor of CRT outcome: "Early physical activity", measured by the accelerometer on implanted CRT-D and ICD devices, is a strong predictor of outcome in patients with CHF.

Conraads et al. (submitted)

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

Whellan DJ, et al. JACC 2010

HF Device Diagnostic Parameter	Description	Algorithm
AF duration	The AF duration trend records the total time spent in AF on a daily basis; the detection algorithm for AF has been proven to be highly accurate (11).	AF ≥6 h on at least 1 day in patients without persistent AF (7 consecutive days with ≥23 h AF)
Ventricular rate during AF	This trend computes the daily average ventricular rate occurring during AF on that day (12).	AF = 24 h and the average ventricular rate during AF ≥90 beats/min on at least 1 day
Fluid index (OptiVol)	The fluid index corresponds to changes in thoracic fluid levels. The fluid index trend is the cumulative difference between the daily average and patient-specific reference intrathoracic impedances. The intrathoracic impedance is calculated from the voltage measured from an asynchronous current applied between the right ventricular lead and the device case (8,9).	High fluid index on at least 1 day; thresholds included ≥60, ≥80, and ≥100
Patient activity	This trend measures the total time active per day using a capacitive accelerometer. A minute is considered active if the counts exceed a threshold equal to walking approximately 70 steps/min (7).	Average patient activity <1 h over 1 week (nonoverlapping weekly windows)
Night heart rate	This trend measures the average ventricular rate from 12 AM (midnight) to 4 AM (7).	Average night heart rate >85 beats/min for 7 consecutive days (nonoverlapping weekly windows)
HRV	The median atrial heart rate is determined every 5 min, and a variability value is computed each day. HRV is not computed if >80% of the time is atrial pacing or AT/AF (7).	HRV <60 ms everyday for 1 week (minimum 5 measured days) (nonoverlapping weekly windows)
% of pacing CRT	This trend records the percentage of ventricular pacing on each day (13).	Ventricular pacing <90% for 5 of 7 days (nonoverlapping weekly windows)
ICD shock for potentially lethal VT/VF	This trend records whether a patient has received an automatic ICD shock for an episode detected as VT/VF and includes both appropriate and inappropriate shocks (14).	≥1 shocks during the evaluation period

Powerful Cardiac Monitoring

IMPLANTABLE EVENT RECORDER

Small. Nearly 90% Smaller.

Simple. Minimally Invasive

Connected. Continuous, Wireless Monitoring

Precise. Superior Data Quality





CareWireless Transmissions

- Daily audit at scheduled time
- Device wirelessly sends
 - Lifetime Episode Counters and Histograms
 - 10 sec Current ECG
 - 30 sec of ECG for 1 episode, if any new episodes have been detected
 - 10 sec Longest AF of the day
- A report is auto-generated if:
 - Your CareAlert criteria are met, triggering an Event Report
 - You have scheduled a Summary Report





Date of Birth: 01-Jan-1952	10. 543-22-4242	Physician Dr. Robert		Syncopal episodes every 4-	-6 owert
Phone (555)-555-5555 (555)-555-0000	Reason for Monitoring Syncope	Date of Implant 06-Dec-2011	UK	NSR, PVCs, Brady episoder	s.
😵 Heart i	Rate Summary: Pa	tient Symptom Mar	ked Near	Pause Episode	
Rade (0pm) +800 -000			**************************************	Event Timing, 25 • Detected: 18:01 Pause recorded Duration: 3 seco	2-Jan-201
فيتند تهده فتر	مراجع المنظمة المراجع		-	Median V Rate Recording Term Patient Sympton 18.03	98 bpm Inated In Mark:
ECG Summary: A		in in the second se Second second		Madais V Pate Becording Tem Patient Sympton 18:03	98 bpm Inated n Mark:
ECG Summary: A				Media V Rate Recording Sum Patient Sympton 18:03	98 bpm inated n Mark:
ECG Summary R				Modia V Rate Recording Sum Patient Simpler 1803	Se born inated in Mark:



All Patients	Add a Patient	Pending Patient	Transfers	I ransfer Ir	<u>Advan</u>	ced Search Iran:	smission So	hedule	Equipment	<u>Orders</u>	
Patient Det	ails: Johnso	on, Rea				Total	Sends: Nex	t Schedul	.ast Send: ed Report: 3	5- <u>May-2013</u> Tran 3-Jun-2013 Disc	sfer Out
Reveal LIN	Q™ Date of I	mplant: 7-Mar-201	2								
Overview	Profile	Equipment	History	Sch	edule	CareAlert N	otification				
Change the alert groupings just for this patient by making selections below. This does not impact the patient's device settings, only how specific alerts for this patient are categorized on the Transmissions list. Display more Use Clinic's ③ Alert Groups for this patient. Save											
					Cli	nic Settings			Customize	d Patient Setting	5
Clinical Manag	gement Alerts			Red Alerts	Yellow Alerts	Website-Only Alerts	No Alerts	Red Alerts	Yellow Alerts	Website-Only Alerts	No Alerts
Symptom (Pat	ient Activated) Episode		•				0	\odot	۲	0
Symptom (Pat	ient Activated) + Detected Epis	ode	•				۲	0	0	0
Tachy Episode						0		\bigcirc	\bigcirc	۲	\bigcirc
Pause Episode						0		\bigcirc	\bigcirc	۲	\bigcirc
Brady Episode						0		\bigcirc	\bigcirc	۲	\bigcirc
AF Episode							0	\bigcirc		0	۲
AT Episode							0	\bigcirc	\bigcirc	0	۲
AT/AF Daily B Time: 12 hrs/d Enable notif Phone: 555	ay → cation on patie	hold			•			0	0	۲	0





Review on Remote Monitoring Technology Applied to Implantable Electronic Cardiovascular Devices

P.Costa, et al. TELEMEDICINE and e-HEALTH 2010

20 studies

Remote monitoring is presently a safe technology, widely accepted by patients and physicians, for its convenience, reassurance, and diagnostic potential. **ADVANTAGE**

Before remote monitoring can be routinely used, technical, procedure, and ethical/legal issues should be addressed. **DISADVANTAGE**

Benefits of Remote Monitoring Systems

- \checkmark reducing the number of hospital visits
- ✓ patient and health team satisfaction
- ✓ efficacy and safety
- $\checkmark\uparrow$ survival & \downarrow hospitalization due to HF

EASY TO USE



The clinical relevance of remote monitoring

- Better patient compliance when compared to conventional follow-up TRUST
- Decreases the number of patients lost to follow-up TRUST
- Detection of events with clinical impact on ICD programming/intervention 79% more rapidly than in conventional follow-up - CONNECT
- Detection of events with impact on PM programming/intervention more rapidly than in conventional follow-up³ - *PREFER*
- 18% reduction of emergency care visits and non-scheduled out-patient visits in heart failure patients - EVOLVO
- Time consuming for the remote evaluation is 60% less⁵



¹The TRUST Study. Varma N. Am Heart J. 2007;154:1029-1034.
²The CONNECT Trial. Crossley GH, et al. J Am Coll Cardiol. 2011;57:1181-1189.
³Wilkoff BL. PREFER trial. Heart Rhythm Society 2008 Scientific Sessions. May 15, 2008.
⁴Evolvo Study: Circulation. 2012;125:2965-2967
⁵Raatikainen MJ et al. Europace, 2008: (10): 1145-51

FOLLOW-UP OF CARDIAC IMPLANTABLE DEVICES

- \checkmark human resources with specific training (doctors, nurses, AP)
- ✓ multidisciplinarity (EP & HF team)
- ✓ scheduled every 3-6 months + alerts (ALL EQUIPMENTS!)
- $\checkmark\,$ detection and resolution of problems
- ✓ identification and interpretation of detected arrhythmias (EGMs)
- ✓ CRT patients »»» higher complexity!
- \checkmark population with important co-morbidities

COMPLEX (AND AMBICIOUS) TASK



Questions regarding medico legal implications related to the use of remote monitoring have been raised.

REMOTE MONITORING IS NOT AN EMERGENCY CARE TOOL!!

Practical issues in Remote Monitoring

implementation methodology management and organization "remote monitoring for all"?... maintaining (high) performance levels develop algorithms for alert notifications legal aspects / responsibility data protection reimbursement

HUMAN (AND LOGISTIC) RESOURCES

Informed Consent

- ▶ it is not an emergency service!!!
- benefits and limitations!!
- > authorization of transmission, recording, analysis, use of data for clinical and scientific purposes
- respect for privacy and confidentiality

The "VIRTUAL" HEART FAILURE CLINIC

((•))

General Practicioner

Specialized NURSE

active communication between the treating physicians provide comprehensive information about the findings

((•))

data obtained by RM should be reviewed within reasonable time and frequency during office hours and immediate action should be undertaken when problems are identified

<u>SANTA MARTA HOSPITAL – remote monitoring (ICD/CRT-D)</u>

Efficacy and Safety of Remote Monitoring in ICD Patients

- 30% reduction in the number of scheduled visits (1 year follow-up)
- VT/VF, SVT/AF, arrhythmic storm, inappropriate shocks, electrode dysfunction in 35 patients

And if the patient has symptoms? What is the recommended approach?

With the physician's permission, communication can be initiated by the patient, who simply has to push a button on the communicator to begin the ad-hoc interrogation process in addition to scheduled interrogations

Examples of clinical impact of remote monitoring

Early identification of ...

Atrial Fibrillation

Ventricular Tachycardia

Heart Failure Progression

Loss of CRT Therapy

Clinical Action taken ... • Anticoagulation

- Cardioversion
- Ablation
- Device reprogramming
- Ablation
- Office visit
- Medication
- Electronic Repositioning

Practical issues in Remote Monitoring

- \rightarrow uniformity and consensus in the team's response to the transmission of alerts.
- → expand the debate (multidisciplinarity), justifying the studies focused on relevant aspects of clinical practice.
 - reorganization of the functions in the arrhythmology/HF team:
 - analysis data transmitted (*daily basis/ weekly "shifts"* $AP \rightarrow EP/HF$ physician)
 - decision-making in the management of the "alerts"
 - contact with patients and type of information available
 - request unscheduled visits
 - possibility for remote monitoring intensification
 - guidance for reprogramming or for revision of the equipment

Remote monitoring of cardiac implantable devices: present and future

feasibility

efficacy

rnsts

✓ Is a major issue in the follow-up of implantable cardiac devices. growing population

- \checkmark Is a safe technology, widely accepted by the patients and health team.
- It allows physicians to respond more proactively, both for monitoring device status and treatment, and to identify potential harmful situations more efficiently.
- ✓ It may contribute to cost (and time) savings in healthcare.
- It still needs to be determined which pts will benefit most and in which cohort this modality proves to be more cost-effective.
- Further studies are needed to adress technical issues, organization of hospital resources and ethical/legal questions.