TIGULLIO II Congresso Nazionale di 2024ARITMOLOGIA

16-17 Aprile Sestri Levante (GE)

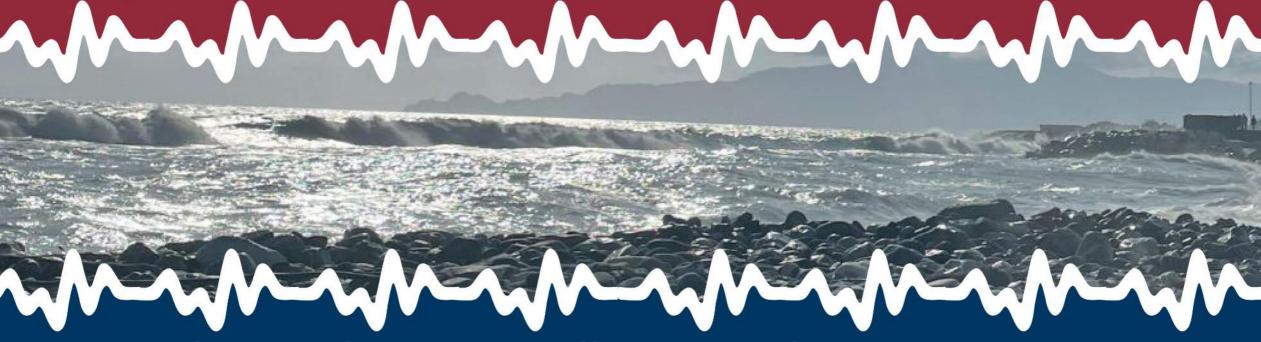
Presidente del Congresso

Guido Parodi, Lavagna

Comitato Scientifico

Paolo Donateo, Lavagna (Responsabile Scientifico) Roberto Maggi, Lavagna Sede Congressuale

Hotel Vis a Vis **** Sestri Levante



Il monitoraggio remoto di pacemaker e defibrillatori

Claudia Amellone S.S. Elettrofisiologia Maria Vittoria- Martini Torino

Dislosures: none





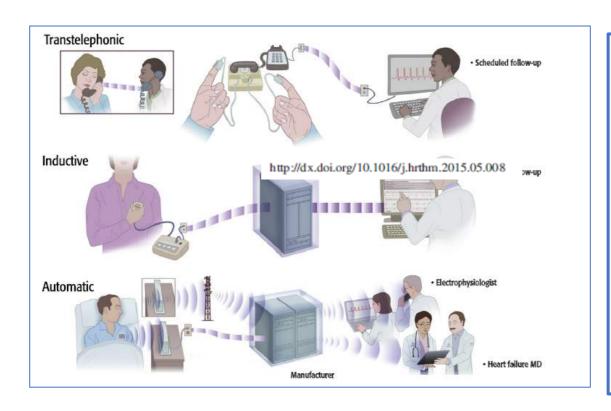








HRS Expert Consensus Statement on remote interrogation and monitoring for cardiovascular implantable electronic devices



Criticità:

 Collaborazione pz, appuntamento con personale, dati tecnici

 Collaborazione pz, nessun dato tra un controllo e il successivo

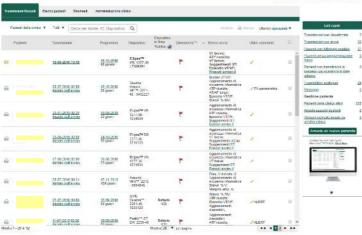
 nessuna azione del pz, dati tecnici e clinici, reazione "real time" ad eventi



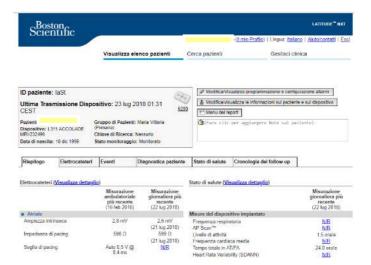
ST. JUDE MEDICAL

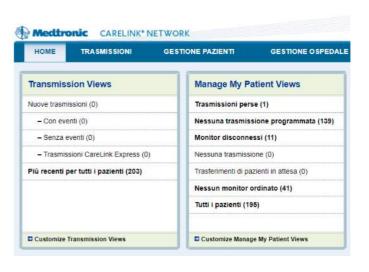
Registrationaria D GAMMARIA Autor Parce of Discount

Merlin.netTM Patient Care Network













2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

2023 HRS/EHRA/APHRS/LAHRS expert consensus statement on practical management of the remote device clinic @

Necessità cliniche del controllo remoto

DRG per controllo remoto: situazione italiana

Sostenibilità economica ed organizzativa

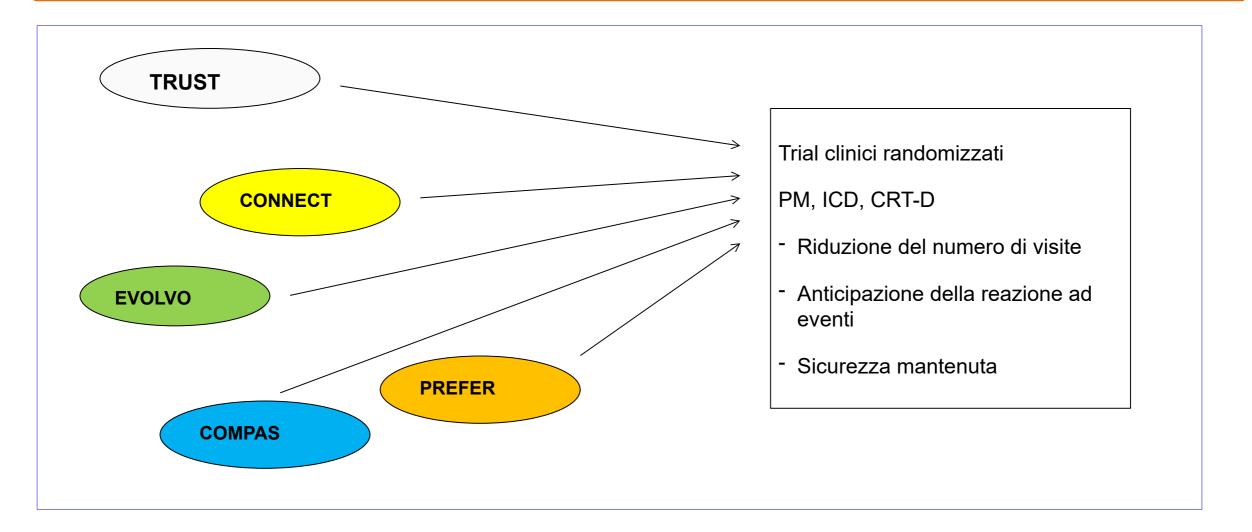
Necessità cliniche

- Controllo dei dati tecnici
- Controllo degli eventi clinici aritmici
- Controllo dello stato di salute e di compenso

Obiettivi:

- 1) garantire la sicurezza del paziente
- 2) migliorare la qualita' di vita (paziente, care giver, staff)
- 3) migliorare la gestione clinica
- 4) Ottimizzare la spesa pubblica
- 5) Riorganizzazione del sistema di controllo dei dispositivi

Obiettivo: SICUREZZA



Obiettivo: migliorare la gestione clinica

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

Telemonitoring Control group p value group (n=333) (n=331)Worsened 63 (18-9%) 90 (27-2%) 0.013* Death 27 (8.2%) 10 (3.0%) 0.004* Overnight admission to hospital for worsening heart failure† 23 (6.9%) 27 (8-2%) Worsened NYHA functional class and global self-assessment 0 (0.0%) 1 (0.3%) Worsened NYHA functional class only 23 (6.9%) 31 (9.4%) Worsened global self-assessment only 7 (2.1%) 4 (1.2%) Improved‡ 111 (33-3%) 105 (31.7%) Unchanged 159 (47-8%) 136 (41.1%)

Data are n (%). Patients are included only once, in the topmost subcategory. *Also statistically significant difference in a post-hoc multivariable logistic regression model after adjustment for use of angiotensin-converting enzyme inhibitors or angiotensin-receptor blockers (the only substantial imbalance between groups at randomisation; data not shown). †Adjudicated by an endpoint committee masked to patients' treatment assignment (appendix). ‡Improved NYHA class or moderately to markedly improved self-assessed condition. NYHA=New York Heart Association.

Table 2: Results for composite clinical score

Brachmann, Thorsten Lewalter, rd, for the IN-TIME study group*

A o peggioramento

	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)

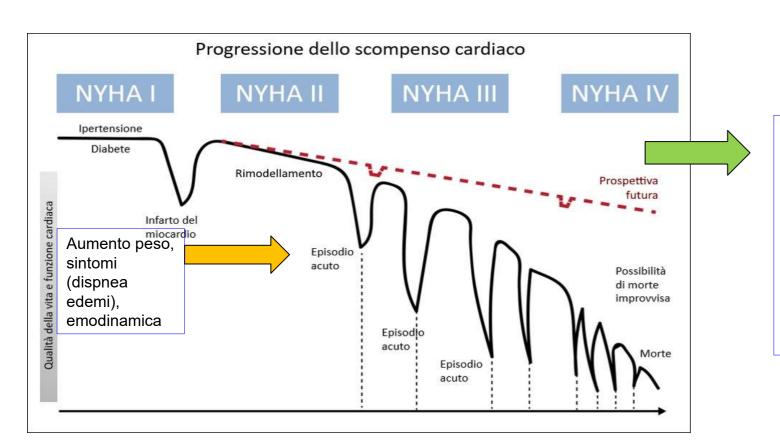
Effetto favorevole di RM con tre meccanismi:

- 1) Diagnosi precoce di aritmie atriali e ventricolari
- 2) Diagnosi precoce di funzionamento subottimale del device (% Biv, shock inappropriati)
- 3) Intervista telefonica alla ricezione dell'alert: verifica dello stato clinico, aderenza alla terapia



Obiettivo: migliorare la gestione clinica





Diagnosi preclinica:

- Fattori scatenanti
- impedenza transtoracica, FP
- valutazione multiparametrica pe anticipare diagnosi e prevenire episodio sintomatico

A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices

Results From the MultiSENSE Study

John P. Boehmer, MD,^a Ramesh Hariharan, MD,^b Fausto G. Devecchi, MD,^c Andrew L. Smith, MD,^d Giulio Molon, MD,^e Alessandro Capucci, MD,^f Qi An, PhD,^g Viktoria Averina, PhD,^g Craig M. Stolen, PhD,^g Pramodsingh H. Thakur, PhD,^g Julie A. Thompson, PhD,^g Ramesh Wariar, PhD,^g Yi Zhang, PhD,^g Jagmeet P. Singh, MD, DPhIL,^h

Physiological Variable	Clinical Relevance
Heart sounds	
First heart sound	Associated with ventricular contraction status
Third heart sound	Associated with early diastolic filling
Thoracic impedance	Associated with fluid accumulation and pulmonary edema
Respiration	
Respiration rate	Rapid shallow breathing patterns associated with shortness of breath
Ratio of respiration rate to tidal volume	
Heart rate	Indicator of cardiac status
Activity	Global patient status and fatigue

Valutazione dell'algoritmo HeartLogic per diagnosi precoce di peggioramento del compenso

ICD biventricolari BS;

development set/ test set

Evento scompenso: terapia IV, oltre 45 giorni dall'avvio della raccolta dati.

HEARTLOGIC, aggiornamento quotidiano

End point: sensibilità per SCC > 40% Allarmi ingiustificati < 2/anno A 100%

Valutazione di singolo parametro inefficace (impedenza transtoracica inefficace)

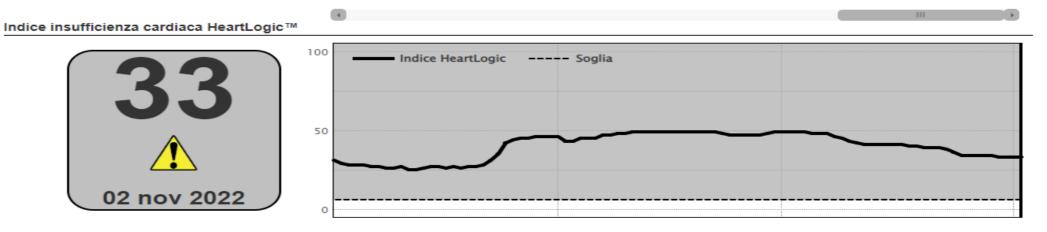
Valutazione multiparametrica quotidiana permette diagnosi preclinica senza alcun coinvolgimento del paziente

Algoritmo implementabile in ICD e PM

The red lines indicate the pre-specified per





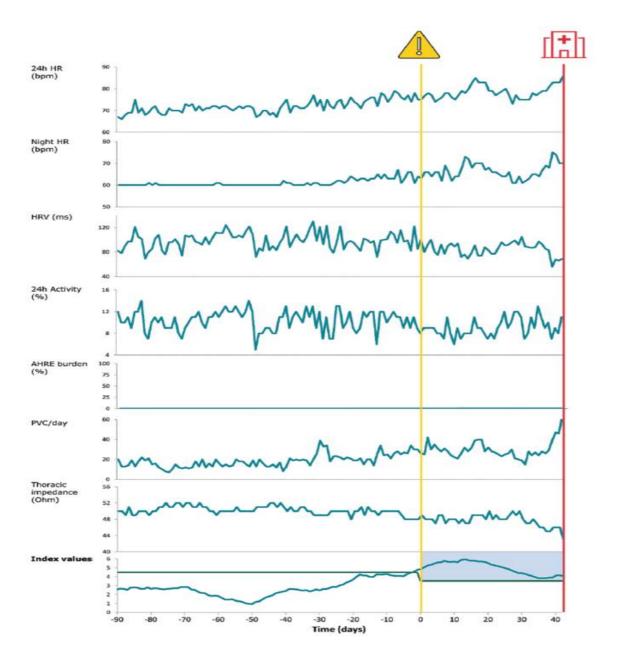


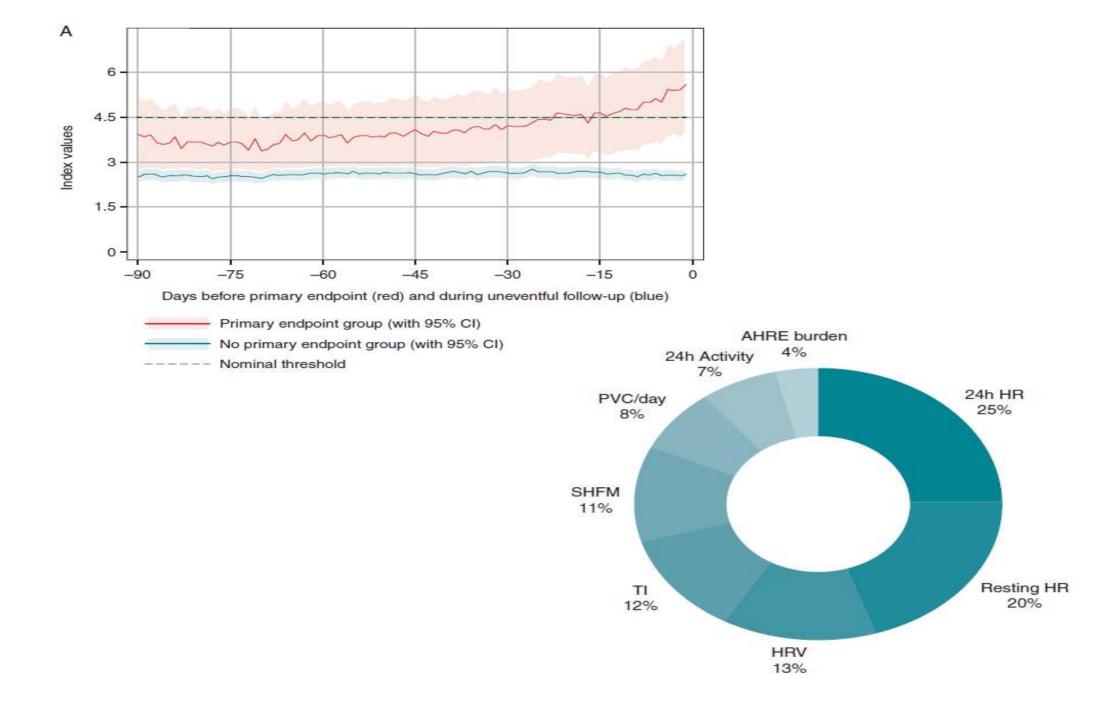
Combining home monitoring temporal trends from implanted defibrillators and baseline patient risk profile to predict heart failure hospitalizations: results from the SELENE HF study

Antonio D'Onofrio^{1*}, Francesco Solimene², Leonardo Calò³, Valeria Calvi⁴, Miguel Viscusi⁵, Donato Melissano⁶, Vitantonio Russo⁷, Antonio Rapacciuolo ⁸, Andrea Campana⁹, Fabrizio Caravati¹⁰, Paolo Bonfanti¹¹, Gabriele Zanotto¹², Edoardo Gronda¹³, Antonello Vado¹⁴, Vittorio Calzolari¹⁵, Giovanni Luca Botto¹¹, Massimo Zecchin¹⁶, Luca Bontempi¹⁷, Daniele Giacopelli ⁸, Alessio Gargaro ¹⁸, and Luigi Padeletti¹⁹

Table I Algorithm compone	ents
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Component	Description
RM variables	Updated every day based on automatic, daily RM data transmission
24 h HR	Mean ventricular rate during 24 h. In the predicting algorithm, the variable is analysed during the last 90 days to detect periods with monotone increases
Night HR	Lowest 10-min average value during resting period (from 1 a.m. to 5 a.m.). In the algorithm, the variable is analysed to detect periods of instability within the last 45 days
HRV	Daily standard deviation of 5-min average atrial—atrial intervals recorded every 5 min. The algorithm searches for periods of monotone decrease of the relative 8-day moving average during the last 90 days
24 h activity	Trend of patient physical activity over the last 25 days assessed by an in-built accelerometer sensor and expressed in percent of 24 h (decreasing activity is indicative)
AHRE burden	Daily burden of atrial fibrillation and high rate atrial episodes over the last 7 days expressed in percent of 24 h
PVC/day	Trend of the number of premature ventricular complexes per hour. The slope of the relative 4-day moving average is analysed during the last 45 days
Thoracic impedance	Corresponding to the changes in thoracic fluid levels. Impedance trend is calculated from daily averages of 24 subthreshold impedance measurements between RV lead and device case. The variable is analysed within the last 90 days to detect periods with monotone decrease in the relative 8-day moving average
SHFM	The Seattle Heart Failure Model ³ score at baseline, before device implantation
Predicting index	Linear combination of the variables after numerical processing

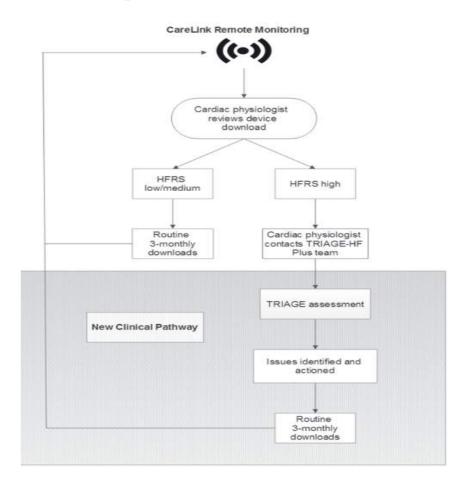


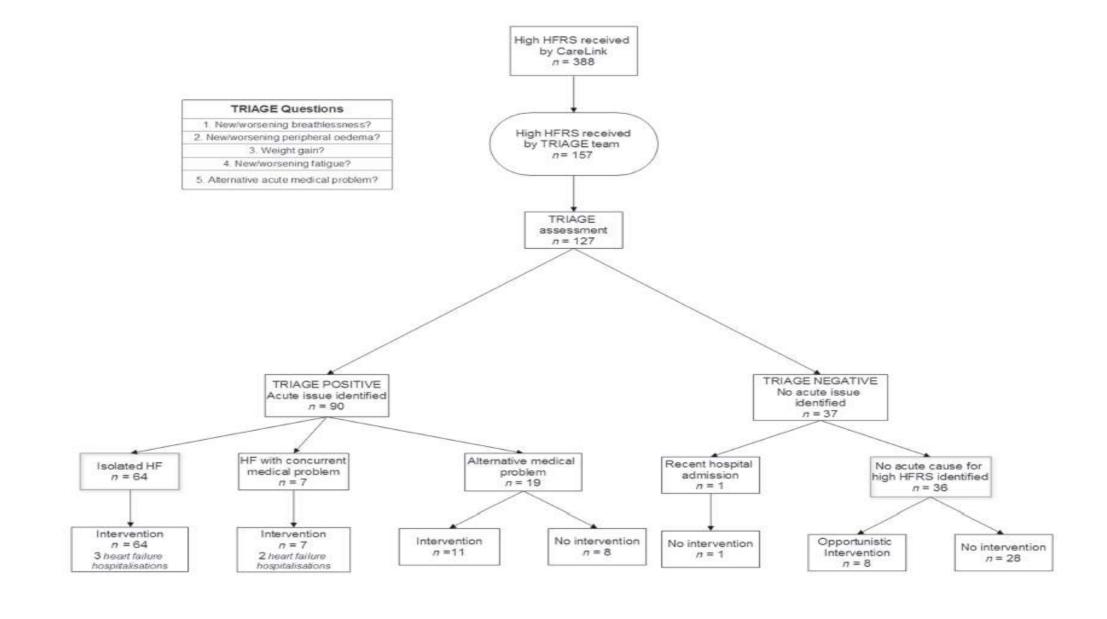


Triage-HF Plus: a novel device-based remote monitoring pathway to identify worsening heart failure

Fozia Zahir Ahmed^{1,2*}, Joanne K. Taylor^{1,2,3}, Caroline Green¹, Lucy Moore¹, Angelic Goode⁴, Paula Black⁴, Lesley Howard⁴, Catherine Fullwood^{5,6}, Amir Zaidi¹, Alison Seed⁴, Colin Cunnington^{1,2} and Manish Motwani^{1,2}

- attivita' pz
- AT/AF burden
- HRV
- aritmie ventricolari
- stimolazione biventricolare %
- impedenza transtoracica/Optivol
- frequenza cardiaca notturna





Telescoperation | - Modes Egreen

Obiettivo: migliorare utilizzo delle risorse della sanita' pubblica

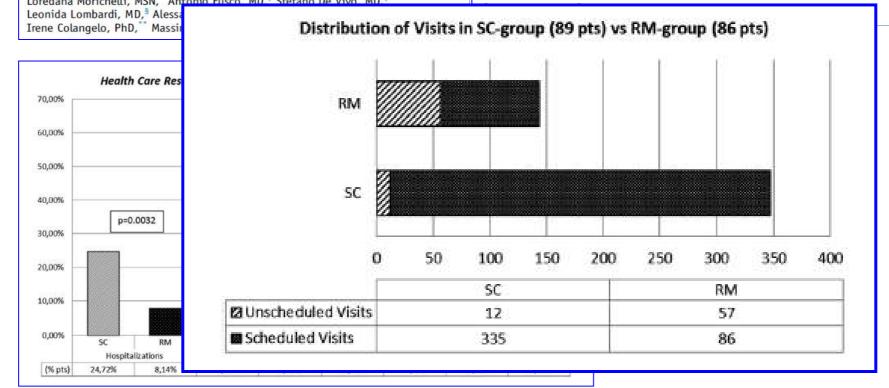
Economic analysis of remote monitoring of cardiac implantable electronic devices: Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study

Renato Pietro Ricci, MD,* Alfredo Vicentini, MD,† Antonio D'Onofrio, MD,‡ Antonio Sagone, MD,§ Giovanni Rovaris, MD, Luigi Padeletti, MD,¶ Loredana Morichelli, MSN,* Antonio Fusco, MD,† Stefano De Vivo, MD,‡

Studio prospettico, multicentrico, non randomizzato di confronto tra RM (102) e SC (107)

Dispositivi SJM Merlin

Costi e benefici per SSN (visita,ospedalizzazione,esami) e paziente (viaggio, lavoro, assistenza)



Obiettivo: migliorare utilizzo delle risorse della sanita' pubblica

Variable	SC	RM	Difference (SC - RM)	P (Wilcoxon rank-sum test
Cardiovascular hospitalization costs (886.67 ± 1979.13 (0, 12436) €)	432.34 ± 2487.86 (0, 20,486)	454.34 (-218.17 to 1126.84)	.0030
Device-related costs (E) 229.07 ± 1186.25 (0, 9384)	$0.00 \pm 0.00 (0, 0)$	229.07 (-20.82 to 478.95)	.0496
Cardiovas cular-relate costs (€)	d 657.61 ± 1470.90 (0, 7523)	432.34 ± 2487.86 (0, 20,486)	225.27 (-388.31 to 838.85)	.0136
Emergency visit costs	15 67 + 66 25 (0 310)	$0.00 \pm 0.00 (0.0)$	15 67 (1 71 to 20 62)	0278

RM riduce spesa sanitaria e spese effettuate dal paziente, vantaggioso per SSN e paziente

visits (€)

Total costs for 3.13 ± 9.40 (0, 46) 15.40 ± 23.54 (0, 116) -12.27 (-17.67 to -6.87) <.0001 unscheduled in-office

follow up vicite (f)

Total health care costs (€) 1044.89 ± 1990.47 (46, 12,542) 482.87 ± 2488.10 (23, 20,534) 562.02 (-111.98 to 1236.01) < .0001

Variable	SC (n= 89)	RM (n = 86)	Difference (SC - RM)	P (Wilcoxon rank-sum test
Total distance traveled (km)	165.54 ± 209.13	45.20 ± 41.87	120.34 (75.43-165.25)	<.0001
Total journey cost (€)	36.81 ± 40.83	10.95 ± 10.75	25.86 (16.97-34.74)	<.0001
Total loss of work or activity for patients (h)	10.43 ± 5.38	2.67 ± 1.97	7.76 (6.55-8.96)	<.0001
Total loss of work or activity for caregivers (h)	11.35 ± 6.30 (69)	$3.36 \pm 2.20 (57)$	7.99 (6.37-9.60)	<.0001
Monetary value of caregiver loss of work or	60.14 ± 33.37 (69)	17.81 ± 11.65 (57)	42.34 (33.78-50.89)	<.0001
Mean annual cost for each patient (€)	169.49 ± 189.50	56.87 ± 80.22	112.62 (69.32-155.92)	<.0001

Impact of Remote Cardiac Monitoring on Greenhouse Gas Emissions

Global Cardiovascular Carbon Footprint Project

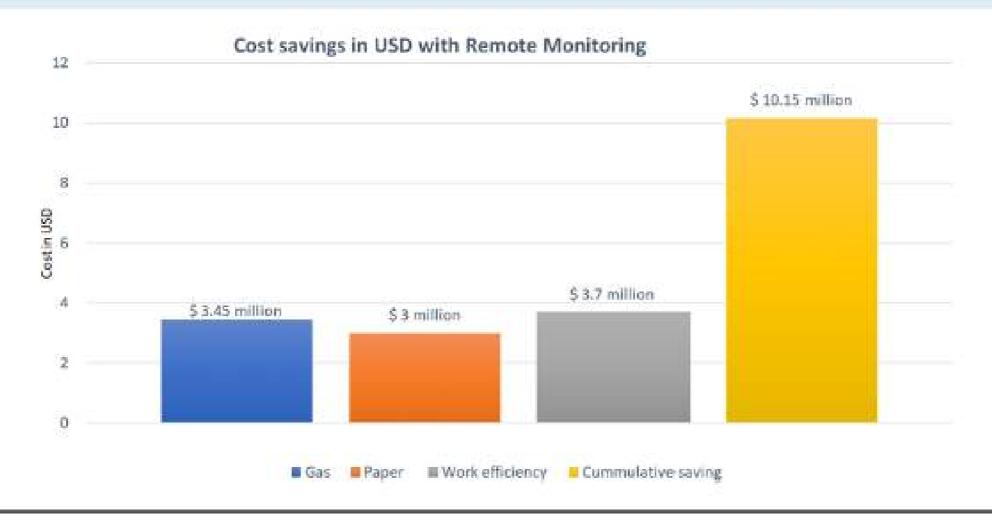
Danish Bawa, MD,^a Adnan Ahmed, MD,^a Douglas Darden, MD,^a Rajesh Kabra, MD,^a Jalaj Garg, MD,^b Shanti Bansal, MD,^c Eric Olsen, MD,^c Donita Atkins, RN,^a Anam Rahim, NP,^d Nicholas Pham, BS,^a Rakesh Gopinathannair, MD,^a Naga Venkata K. Pothineni, MD,^a Peter Park, MD,^a Rangarao Tummala, MD,^a Scott Koerber, MD,^a Andrea Natale, MD,^e Dhanunjaya Lakkireddy, MD^a



Se FIGURE 1 Comparison of Cost and Carbon Accounting Between Conventional Strategy and Remote Monitoring Strategy for Patients V Cardiac Implantable Electronic Devices Pa Zo **Printed pages** cost 3 million Savings of 14.2 million page Vis print out, reduction in 78 metric ton CO2 In s Sta Travel cost Conventional Remote Monitoring Savings of 31.7 million miles in Tro of 3.45 Strategy strategy travel and, reduction in 12,518 million USD metric ton CO2 from gasoline Pro Workforce cost 6.2 reduction of 95 metric ton CO2 million USD

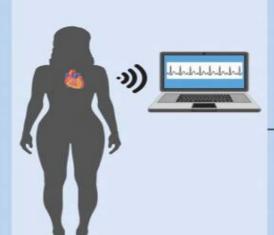
32,811 patients from 67 device clinics

FIGURE 2 Cost Savings With Remote Monitoring of Cardiac Implantable Electronic Device in Gas, Paper, and Work Efficiency



Impact of Remote Monitoring on Greenhouse Gas Emissions





Remote Monitoring Program



31.7 M travel miles



\$3.45 petrodollars



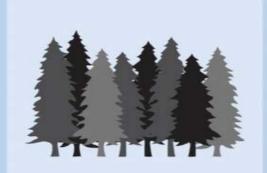
14 M pages of report



\$3.7 M in workforce efficiency



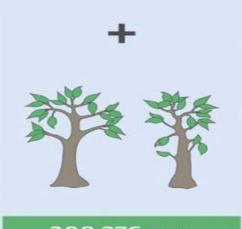
12,597 metric tons of Carbon Footprint reduction



14,907 acres of U.S. forest saved



\$10.15 M saved in healthcare spending



208,276 new trees planted for 10 years

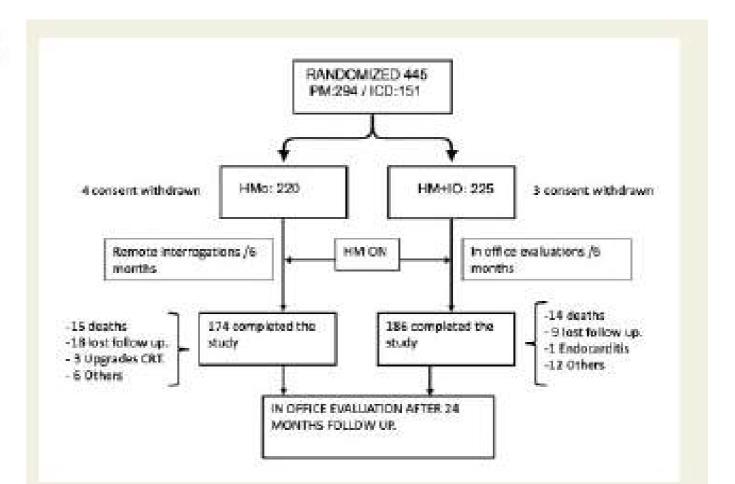
Obiettivo: riorganizzazione dei controlli ambulatoriali

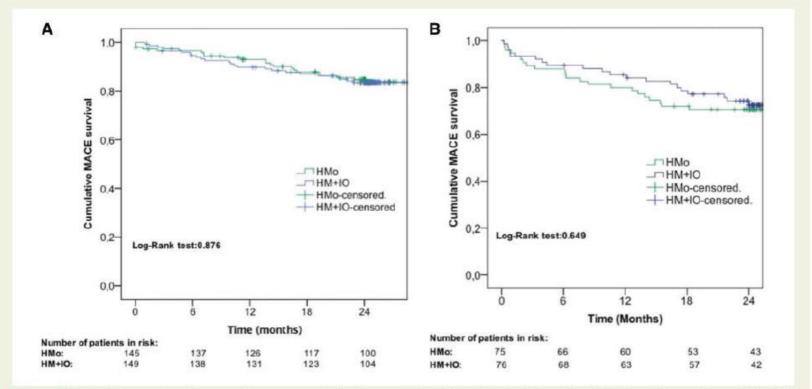


European Heart Journal (2019) 40, 1837-1846

FASTTRACK CLINICAL RESEARCH ESC Munich Hotline

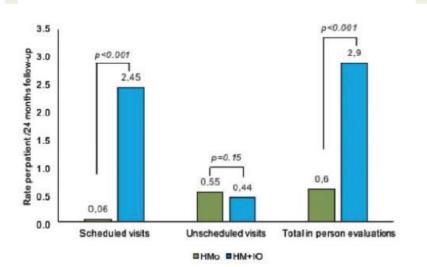
Safety and efficiency of a common and simplified protocol for pacemaker and defibrillator surveillance based on remote monitoring only: a long-term randomized trial (RM-ALONE)

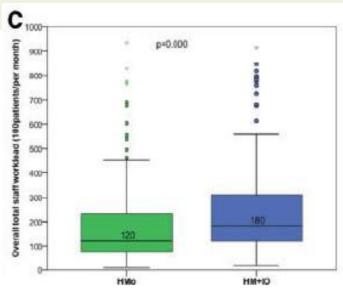




 $\textbf{Figure 3} \ \ \text{Cumulative major adverse cardiac event survival in the pacemaker (A) and implantable cardiac defibrillator (B) population. HM + IO, \\$

home monitoring plus in-office evaluations; HMo, home monitoring only.





2021 ESC Guidelines on cardiac pacing and cardiac resynchronization therapy

Recommendations for pacemaker and cardiac resynchronization therapy-pacemaker follow-up

Recommendations	Classa	Levelb
Remote device management is recommended to reduce the number of in-office follow-ups in patients with pacemakers who have difficulties to attend in-office visits (e.g. due to reduced mobility or other commitments, or according to patient preference). 805,806,809	D	A
Remote monitoring is recommended in the case of a device component that has been recalled or is on advisory, to enable early detection of actionable events in patients, particularly those who are at increased risk (e.g. in the case of pacemaker dependency).	D	С
In-office routine follow-up of single- and dual- chamber pacemakers may be spaced by up to 24 months in patients on remote device management. 805,806	lla	A
Remote device management of pacemakers should be considered in order to provide earlier detection of clinical problems (e.g. arrhythmias) or technical issues (e.g. lead failure or battery depletion).	lla	В

Table 13 Frequency of follow-up for routine pacemaker and cardiac resynchronization therapy, either in person alone or combined with remote device management

	In-office only	In-office + remote
All devices	Within 72 h and	In-office within 72 h and
	2-12 weeks after	2-12 weeks after
	implantation	implantation
CRT-P or	Every 6 months	Remote every 6 months and
HBP		in-office every 12 months ^a
Single/dual-	Every 12 months then every	Remote every 6 months and
chamber	3 - 6 months at signs of bat-	in-office every 18 - 24
	tery depletion	months ^a

Necessita' clinica del controllo remoto

COR	LOE	Recommendations	References
1	A	1. In patients with CIEDs, RM is recommended as part of the standard of care.	1,11,30-38
1	B-R	 In patients with CIEDs on RM, routine surveillance of lead function and battery status is recommended to ensure device integrity. 	30,39,40
1	C-EO	 In patients with CIEDs on RM with a device capable of continuous connectivity, connectivity should be maintained. 	

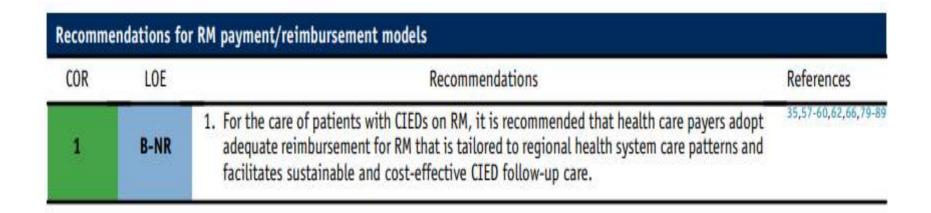
Necessità cliniche del controllo remoto



DRG per controllo remoto: situazione italiana

Sostenibilità economica ed organizzativa

Rimborso: riconoscimento DRG



Costi associati al monitoraggio remoto (software, hardware, rimborso aziende), costi per personale medico, infermieristico, amministrativo Riduzione dei costi per ricoveri ridotti

Current status of reimbursement practices for remote monitoring of cardiac implantable electrical devices across Europe

Giuseppe Boriani © ^{1,2}*, Haran Burri © ³, Emma Svennberg © ⁴, Jacopo Francesco Imberti © ^{1,5}, Josè Luis Merino © ⁶, and Christophe Leclercq © ⁷

Country	Reimbursement tariff for in-clinic device check	Reimbursement tariff for remote CIED management	Reimbursement specific for hardware and services for remote monitoring	Reimbursement tariff for HF disease management
Austria	Yes	No	No	Yes, from 2022
Belgium	Yes	No	No	No.
Bulgaria	No	No	No	No
Czech Republic	Yes	Yes	Yes	No
Denmark	Yes	Yes	No	No
Finland	Yes	Yes	Yes	No
France	Yes	Yes"	Yes ^b	No
Germany	Yes	Yes ^c	Yes for some health insurance	No
Hungary	Yes	Yes	No	No
Italy	Yes	Yes (in 10 of 20 regional health services)	No	No
Norway	Yes	Yes	No	No
Poland	No	No	No	No
Portugal	Yes	Yes	No	Yes
Russia	No	No	No	No
Slovakia	No	No	No	No
Spain	Funded, no tariff	Funded, no tariff	N/A	No
Sweden	Yes	Yes	No	No
Switzerland	Yes	Yes	Yes	Yes
The Netherlands	Yes	Yes	No	Yes ^d
UK	Yes	Not at a national level, it is dependent on Clinical Commissioning Groups and NHS Trusts	Ordered by NHS Trusts	No

DRG: Realta' Regionali



I principi fondamentali su cui si basa il SSN dalla sua istituzione, avvenuta con la legge n.833 del 1978, sono l'universalità, l'uguaglianza e l'equità.

<u>Universalita'</u>:estensione delle prestazioni sanitarie a tutta la popolazione

<u>Uguaglianza</u>:I cittadini devono accedere alle prestazioni del SSN senza nessuna distinzione di condizioni individuali, sociali ed economiche

Equita': A tutti i cittadini deve essere garantita parità di accesso in rapporto a uguali bisogni di salute

RIMBORSO RPM IN ITALIA





- La procedura di controllo da remoto (RPM) dei CIED è codificata nel nomenclatore ambulatoriale
- Non c'è un codice di rimborso Nazionale (LEA)
- Tariffa min: 12,00 € (Friuli Venezia Giulia)
- Tariffa Max: 27,90 € (Emilia-Romagna)
- Alcune Regioni hanno adottato la modalità di rimborso forfettario, altre per ogni servizio erogato



I	89.48.2	CONTROLLO IN REMOTO DI PAZIENTI PORTATORI DI PACEMAKER, DEFIBRILLATORE E LOOP RECORDER, Massimo 4 controlli/anno (2)	25,55	CARDIOLOGIA
		RECORDER. Massimo 4 controlli/anno (2)		

13/6/2016

Trentino: Ampia diffusione, organizzazione e riconoscimento Trento e Rovereto

Alto Adige: Bolzano, non riconoscimento DRG

- REGIONE PIEMONTE BU44 29/10/2020
- Deliberazione della Giunta Regionale 16 ottobre 2020, n. 13-2103.

Codice Catalogo Regionale: 89502

CONTROLLO IN REMOTO DI PAZIENTI PORTATORI DI PACEMAKER **■** DEFIBRILLATORE, LOOP RECORDER E

CCM (ciclo di 4 controlli/Anno) - Codice Prestazione: 89.50.2

Frequenza: Pazienti portatori di PM/ICD non più di una ricetta all'anno; Pazienti portatori di Loop recorder non più di tre ricette all'anno. –

Tariffa: € 23,20



seduta del 5/05/2020 delibera 523

Delibera che equipara controllo ambulatoriale e controllo remoto

1 controllo: 1 DEMA

Rimborso Prestazione Remota Panorama legislativo Italiano



Reg.delib.n. 1010

Prot. n.

VERBALE DI DELIBERAZIONE DELLA GIUNTA PROVINCIALE

OGGETTO:

Integrazione del Nomenclatore delle prestazioni di assistenza specialistica ambulatoriale, di diagnostica per immagini e di laboratorio erogabili nell'ambito del Servizio sanitario Provinciale e altre direttive.

I	89.48.2	CONTROLLO IN REMOTO DI PAZIENTI PORTATORI DI PACEMAKER, DEFIBRILLATORE E LOOP RECORDER. Massimo 4 controlli/anno (2)	25,55	CARDIOLOGIA

Oregon Ground stansars - Antenda Son male Local ARES II 8 Asienda Uspatullara - Article Operation their Sentron private according e. s.c. LAZICores Sp.A. Terrores fective later recore REGIONE PUGLIA x 1179 da 1617/2021 út Registre delle Dell'immelini IDEZIONE DIDETTI DI CIPTADINANZA E COPCIONE SOCIALE Codes CITRA SGO DEL UNIVERSE ETTORE ORGANIZZAZIONE DELLE CURE E PERCORSI CRONICITA REGIONE PREMONTE BU44 29/10/2020 Deliberazione della Gianta Regionale 16 ottobre 2020, n. 13-2103 Estensione del numero di prestazioni ambulatoriali della branca 8 Cardiologia erogabili in regime di escuzione alla compartecipazione della spesa sanitaria e inscrimento nel Nomenclature Tariffario di una nuova prestazione della branca di cardiologia per il controllo e il monitoraggio, anche a distanza, di particolari patologie cardiologiche. DELEBORAZIONE DELLA GIUNTA REGIONALE in 478 del 23 aprile 2009. Insurtamento nel Nomenciatore Tariffario della specialistica ambalanoriale di una morra provinzione della branca A Cardiologia ed extensione del numero di provincioni della siona branca cropabili in regime di nenzione alla compartecipazione della spesa suntaria.

2016 Trento

2019

17 Dic 2020

Piemonte Toscana Lazio



Ministero della Salute

INDICAZIONI NAZIONALI PER L'EROGAZIONE DI PRESTAZIONI IN TELEMEDICINA

27 peoples 2020

ACCORDO STATO REGIONI

SERIE GENERALE

DELLA REPUBBLICA ITALIANA

PARTE PRIMA Roma - Mercoledi, 2 novembre 2022 COUNTY IN COUNTY

ofs submonts numerations

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DECRETO 21 settembre 2022.

Approvazione delle linee guida per i servizi di telemedicina - Requisiti funzionali e livelli di ser-

2022

2021

Emilia R.

Puglia

DECRETO LEGISLATIVO



RAPPORTI ISTISAN 23/21

ISSN: 1123-3117 (cartaceo) • 2384-8936 (online

Documento di consensus nazionale sulla telemedicina per le patologie cardiovascolari: indicazioni per la teleriabilitazione e il telemonitoraggio

Allo stato attuale dell'evoluzione tecnologica, il gruppo di consensus adotta tutte le otto definizioni di prestazioni erogabili in telemedicina presenti nell'Accordo Stato Regioni e PA del 17 dicembre 2020 (10) a cui si rimanda. Esse sono elencate qui di seguito:

- televisita,
- teleconsulto medico,
- telemonitoraggio,
- telecontrollo,
- teleconsulenza medico-sanitaria,
- teleassistenza da parte di professioni sanitarie,
- teleriabilitazione,
- telerefertazione.

Per quanto riguarda il supporto della telemedicina alla cardiologia, è utile riunire le suddette prestazioni in quattro gruppi di riferimento sulla base delle esigenze di cura dei pazienti cardiologici.

1.5.2. Telerefertazione e telecertificazione

La definizione di telerefertazione è presente nel testo dell'Accordo Stato, Regioni e PA del 17 dicembre 2020, a cui si rimanda (10).

Va ricordato che nel medesimo Accordo, è esclusa la telerefertazione per le richieste da parte dell'autorità giudiziaria ed è esclusa anche la possibilità di eseguire una telecertificazione.

Riguardo alla telecertificazione nel suddetto Accordo si trova un espresso reinvio a successivi documenti specifici, dal momento che attualmente la certificazione a distanza è proibita dalle norme italiane.

Per quanto riguarda l'ambito cardiologico, il gruppo di consensus raccomanda che gli esami oggetto di telerefertazione siano:

- elettrocardiogramma a riposo (58),
- elettrocardiogramma dinamico (Holter) (58),
- monitoraggio ambulatoriale della pressione arteriosa (58),
- controllo elettronico di device cardiaci impiantabili (59),
- ecocardiogramma color doppler (60-63).

Necessità cliniche del controllo remoto



DRG per controllo remoto: situazione italiana

Sostenibilità economica ed organizzativa

Sostenibilità economica : gare regionali e nazionale CONSIP

Veneto, Toscana, Emilia, Lombardia, CONSIP

Servizio di controllo remoto quotato a parte

Pacemaker aggiudicabili con queste caratteristiche:

```
Assurity DR (Abbott);
Enitra 6 DR-T (Biotronik);
Proponent MRI DR (Boston Sc.);
Azure S DR (Medtronic);
Borea DR (Microport).

Base d'asta proposta:
2300 euro (pacemaker + elettrocatetere, 2040+130x2) + 250 euro (sistema di monitoraggio)
```

Fino ad ora il Controllo remoto (monitor, servizi tecnici, informatici) aveva costi "compresi" nel prezzo finale del CIED

Quotazione a parte permette di dare maggior rilievo al servizio Controllo remoto ed è coerente con LG

Distinzione beni-servizi necessaria anche per Pay Back

Preoccupazione fittizia per possibile blocco degli acquisti: controllo remoto e' classe IA standard of care, scelta medica

Sostenibilità: ruoli e modelli organizzativi

- 1) Staff
 - personale coinvolto nel controllo remoto
 - modelli organizzativi : intraospedale, Hub-Spoke,
 Third party
 - formazione e certificazioni
- 2) Paziente
- 3) Aziende produttrici





COR	LOE	Recommendations	References
1	B-NR	 For the care of patients with CIEDs on RM, a team-based organizational model with formal policies, procedures, and clear definitions of the roles and responsibilities of qualified staff is recommended to optimize all related RM tasks. 	1,25,28,29,53,90,102-10
1	B-NR	 For the care of patients with CIEDs on RM, it is recommended that there is adequate dedicated time to perform all RM tasks, including scheduled and nonscheduled transmissions, patient follow-up, and administrative tasks. 	25,28,57,104,106,110
1	B-NR	 For the care of patients with CIEDs on RM, it is recommended that the staff-to-patient ratios in RM clinics reflect the increasing unscheduled transmission workload. 	3,28,59,111,112
2a	C-LD	4 For the care of patients with CIEDs on RM, it is reasonable for clinics to have a minimum of 3.0 full time equivalents per 1000 patients on RM, comprising both clinical and administrative staff.	27

Grande rilevanza degli aspetti organizzativi, infrastrutture, staff, workflow, CIED team



Implementation of remote follow-up of cardiac implantable electronic devices in clinical practice: organizational implications and resource consumption

Massimiliano Maines^a, Giancarlo Tomasi^a, Paolo Moggio^a, Francesco Peruzza^a, Domenico Catanzariti^a, Carlo Angheben^a, Marzia Simoncelli^a, Massimo Degiampietro^a, Lucio Piffer^a, Sergio Valsecchi^b and Maurizio Del Greco^a

Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry

Renato Pietro Ricci^{1*}, Loredana Morichelli¹, Antonio D'Onofrio², Leonardo Calò³, Diego Vaccari⁴, Gabriele Zanotto⁵, Antonio Curnis⁶, Gianfranco Buja⁷, Nicola Rovai⁸, and Alessio Gargaro⁸

Intrahospital organizational model of remote monitoring data sharing, for a global management of patients with cardiac implantable electronic devices: a document of the Italian Association of Arrhythmology and Cardiac Pacing

Gabriele Zanotto^a, Donato Melissano^b, Stella Baccillieri^c, Andrea Campana^d, Fabrizio Caravati^e, Massimiliano Maines^f, Francesco Platania^g, Lorenzo Zuccaro^h, Maurizio Landolinaⁱ, Massimo Zoni Berisso^j, Giuseppe Boriani^k and Renato Pietro Ricci^l



Remote Monitoring Staffing Challenges

Challenges in obtaining staff



Lack of dedicated RM personnel





Overwhelming RM data burden ("data deluge")



Challenges facing staff

Lack of dedicated time for RM management ("invisible work")



Poor understanding of RM value/benefits



Lack of adequate reimbursement arrangement



Poor understanding of RM data burden & RM-related work tasks ("invisible work")



Poor understanding of need for RM organizational model (roles/responsibilities)



Lack of resources & need for outsourcing



Lack of dedicated RM personnel



Need for organizational workflow



Need for decision trees for RM transmission review/ standardization of alert criteria



 Alert-based RM transmission review



Programming optimization



Al algorithms



Need for outsourcing



Transmission triage (Access software, ID alerts/ events/routine transmissions)



Initial transmission review



Triage for secondary review



Patient management activities/telephone work



Technology/connectivity troubleshooting



Administrative (documentation/EHR, billing, scheduling)





2015 HRS Guidelines: Personnel Based



- Provides final interpretation & documentation
- Has appropriate certification*
- Supervises mid-level providers



Mid-level Provider (NP/PA)

- Obtains medical history, reviews transmissions, make recommendations for management
- Participates in patient enrollment & education, interpretation of routine transmissions, documentation and billing
- · Provides oversight of allied professionals



- Has IBHRE certification or experience on par with certification
- Reviews data with criteria for involving physician or mid-level & patient contact



- · Performs nonclinical actions:
 - Appointment reminders
 - · Patient connectivity/troubleshooting
- Clinic technology/customer support
- Collects data for review



^{*}American Board of Internal Medicine (ABIM) Clinical Cardiac Electrophysiology certification, American Board of Pediatrics Cardiology certification, or the International Board of Heart Rhythm Examiners (IBHRE) device certification.



2023 HRS Guidelines: Task Based (Implications for Staffing)

Task

Issues Under Evolution

Connectivity/Troubleshooting

- Appointments
- Connectivity
- Patient questions



Patient Education/Enrollment

- What is remote monitoring?
- Why is it needed?
- · Choice of monitor







CIED Data Triage & Review

- Website monitoring
- Initial data processing
- Initial communication with health care team



Data Triage & Review, options:

- Third-party software
 - Single web-based data portal
 - Device and patient management





Final Sign-Off

- Final interpretation
- Final communication with health care team
- Documentation for billing

Alert Management

- Patient calls
- In-office evaluations
- Charting and communication



Physician, APP/ Physiologist

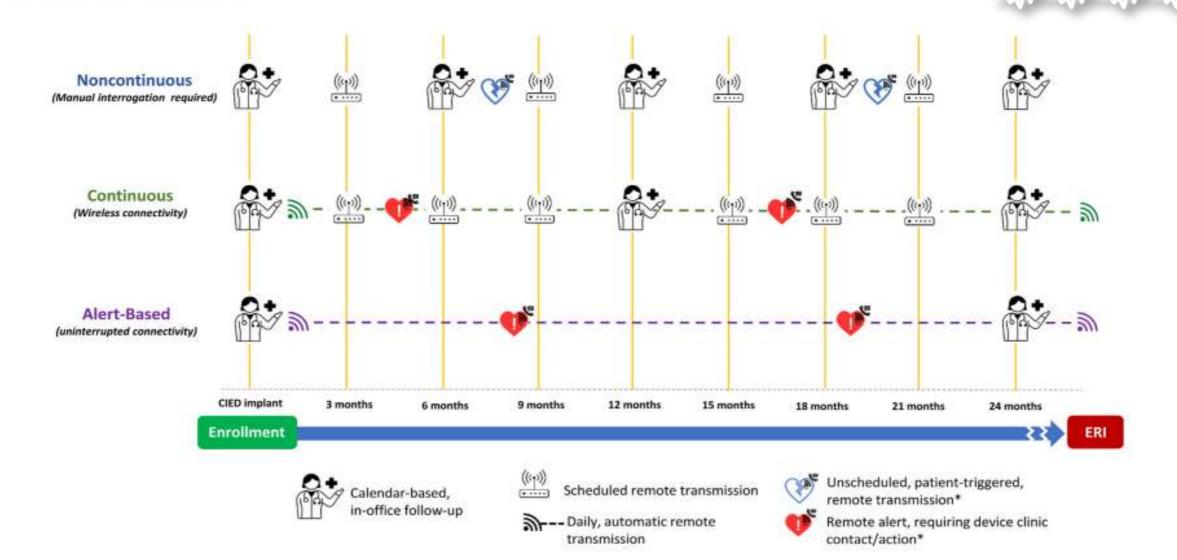
Final sign-off

- Interpretation (middleware vs in-EHR)
- Information interoperability (between EHRs)
- Closing the loop with patients

Alert Management

- In-office CIED management
- Hospital-based remote CIED interrogations
- After-hours alert management





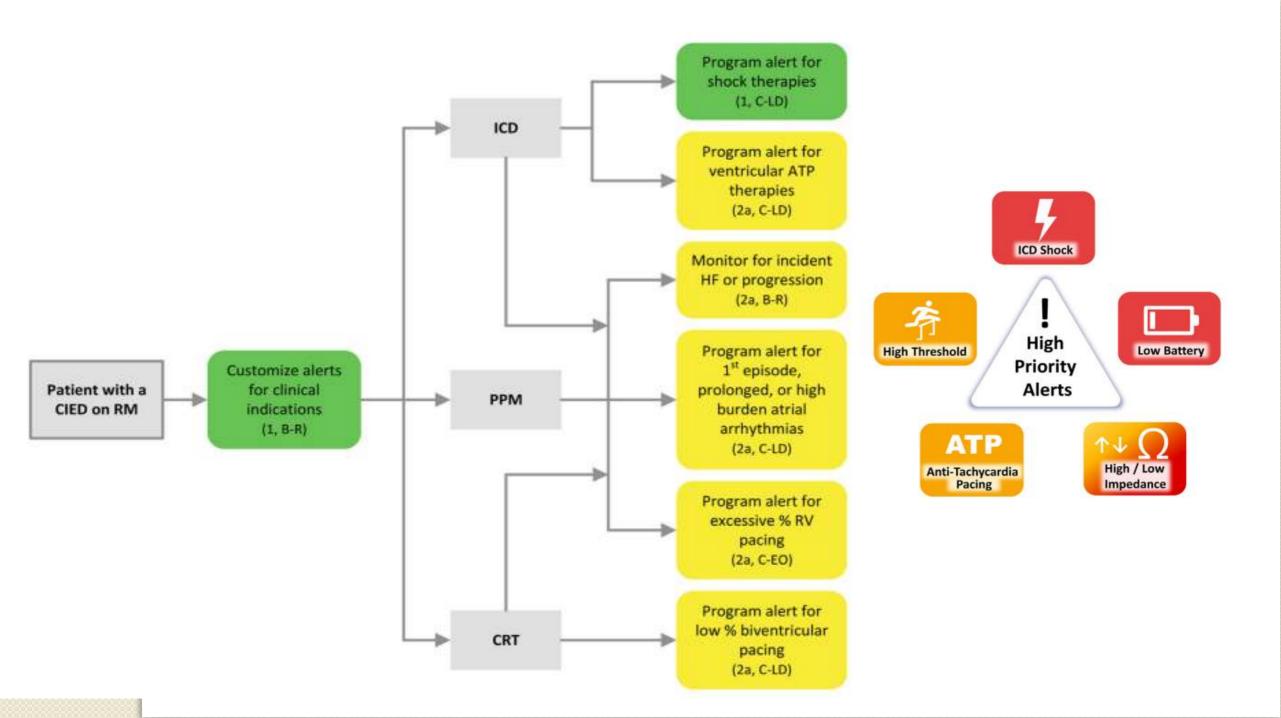


Formazione del personale

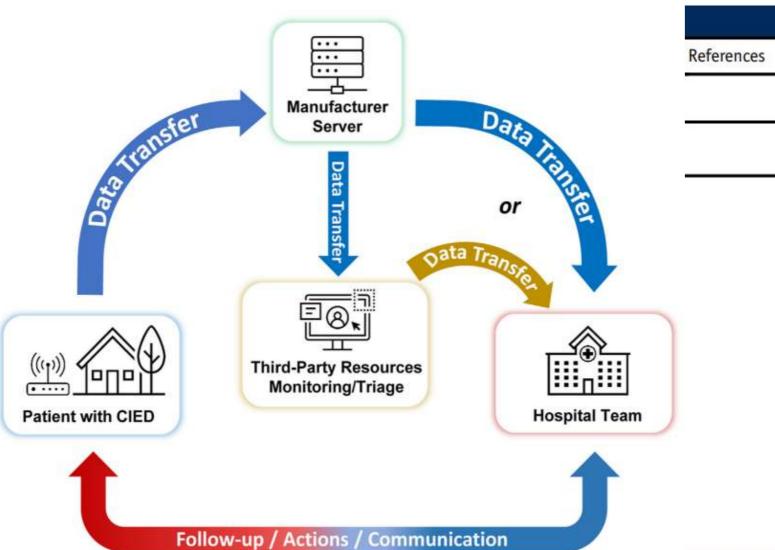
Recommendations for staff credentialing and qualifications for RM				
COR	LOE	Recommendations	References	
1	C-EO	 For the care of patients with CIEDs on RM, it is recommended that clinical providers who independently prescribe, interpret, and document RM possess appropriate education and/or certification. 		
1	C-EO 2. For the care of patients with CIEDs on RM, it is recommended that clinics regularly conduct quality improvement reviews to support current evidence-based standards.			

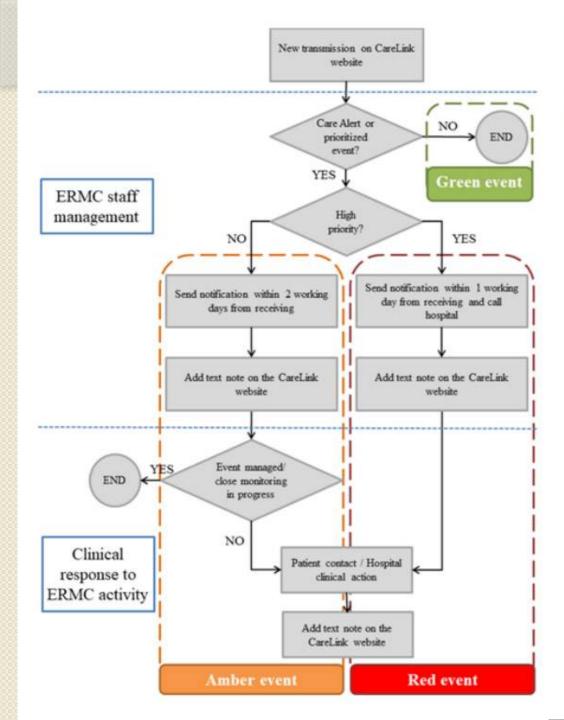
Certificazioni EHRA, IBHRE, AIAC Progetto HANDS ON

COR	LOE	Recommendations	References
1	B-R	 In patients with CIEDs and a component with a safety advisory, it is recommended that continuous connectivity be added to scheduled remote or in-person interrogation to enable early detection of actionable events. 	18,29,31,32,35,39,42,123,12
2a	B-R	 In patients with PMs on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in- person visits every 24 months. 	37,125,126
2a	B-R	 In patients with ICDs on RM with consistent and continuous connectivity, and in the absence of recent alerts or other cardiac comorbidity, it is reasonable to schedule in- person visits every 24 months. 	31,35,57,92,98



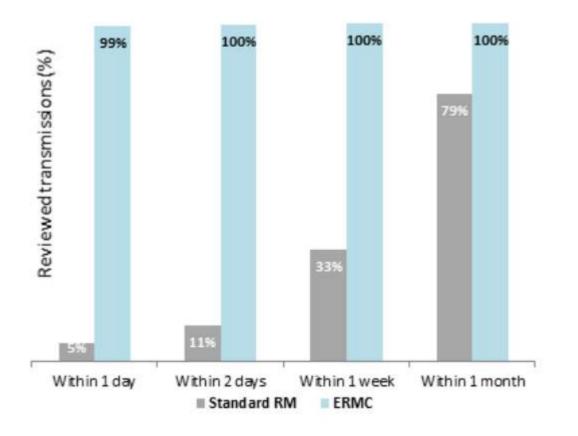
Recommendations for us		
COR	LOE	
2a	C-EO	1
2a	C-EO	2





Outsourcing the Remote Management of Cardiac Implantable Electronic Devices: Medical Care Quality Improvement Project

Gabriele Giannola, MD, PhD; Riccardo Torcivia, MD; Riccardo Airò Farulla, MD; Tommaso Cipolla, MD





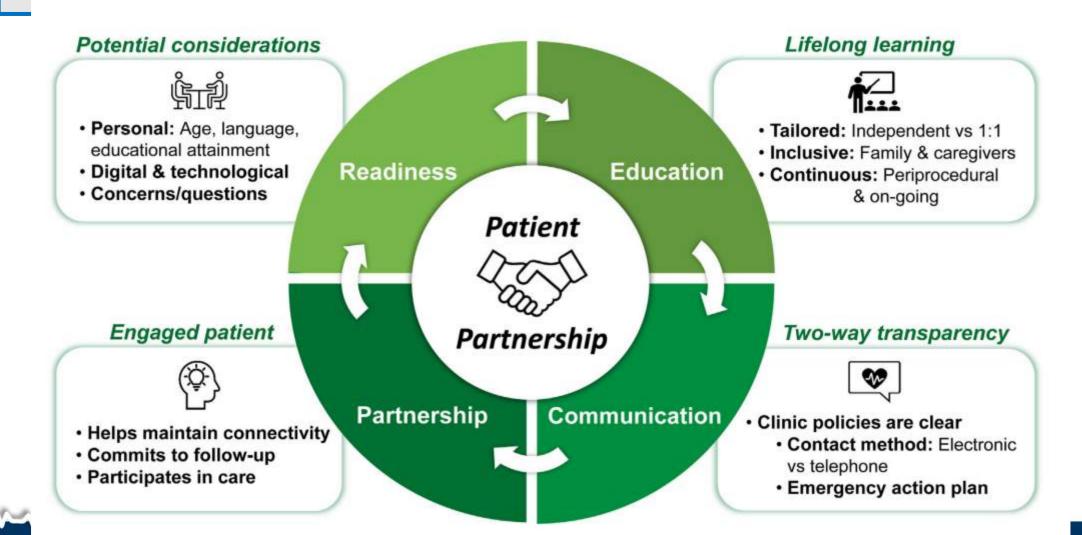
COR	LOE	Recommendations	Reference
1	C-EO	 For patients undergoing CIED implantation, it is recommended that manufacturers provide adequate resources, including personnel as appropriate, to ensure enrollment and connectivity to RM platforms before discharge or within 2 weeks of implantation. 	
1	2. For the care of patients undergoing CIED implantation, it is recommended that manufacturer representatives provide the clinic staff with adequate training to properly program remote alerts specific to the clinical indication to minimize inappropriate alerts and need for consequential reprogramming.		

......

Recommendations for manufacturers' role in the management of patient safety advisories via RM			
COR	LOE	Recommendations	References
 For the care of patients with CIEDs on RM, manufacturers should contact the managing clinics with details of a safety advisory and assist in identifying affected patients both immediately and on a regular basis. 			
1	C-EO 2. For the care of patients with CIEDs with an advisory and on RM, manufacturers should provide guidance to clinics on optimal alert settings to manage the safety advisory.		



Ruolo del paziente





Necessità cliniche del controllo remoto

DRG per controllo remoto: situazione italiana

Sostenibilità economica ed organizzativa





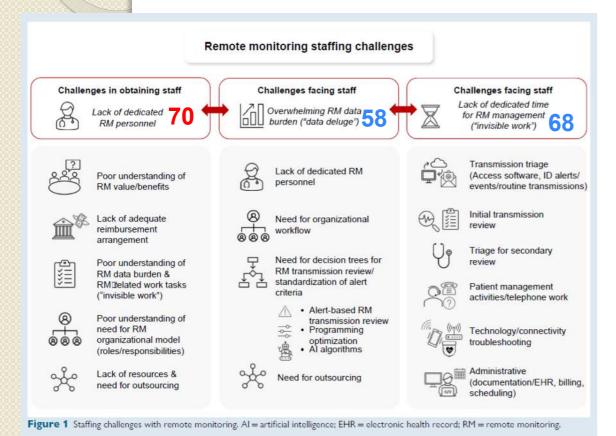
Consensus



Survey

Peso che cias cuno degli aspetti riportati nelle linee guida assume come barriera ancora presente nei centri per l'ottimizzazione della gestione del

monitoraggio remoto



Lack of dedicated RM personnel

Lack of dedicated time for RM management

3

Overwhelming RM data hurden

Lack of resources: 68

Poor understanding of RM data burden & RM related work tasks: 67

Lack of adequate reimbursement: 62

Poor understanding of RM value/benefits: 61

Poor understanding of need for RM organizational model: 56

Patient management activities/telephone work: 72

Organizational issue (administrative/connectivity): 61

Transmission trigae (initial transmission): 52

Triage for secondary review: 47

Lack of dedicated RM personnel: 66

Need for organizational workflow: 52

Need for decision trees for RM transmission review/standardization of alert criteria: 43

Need of outsourcing: 34

^{*} Average score [0 – 100] over 43 responders



Task

Connectivity/Troubleshooting

- · Appointments
- Connectivity
- · Patient questions



Patient Education/Enrollment

- · What is remote monitoring?
- Why is it needed?
- · Choice of monitor



CIED Data Triage & Review

- Website monitoring
- Initial data processing
- Initial communication with health care team



Physician,

APP/

Physiologist

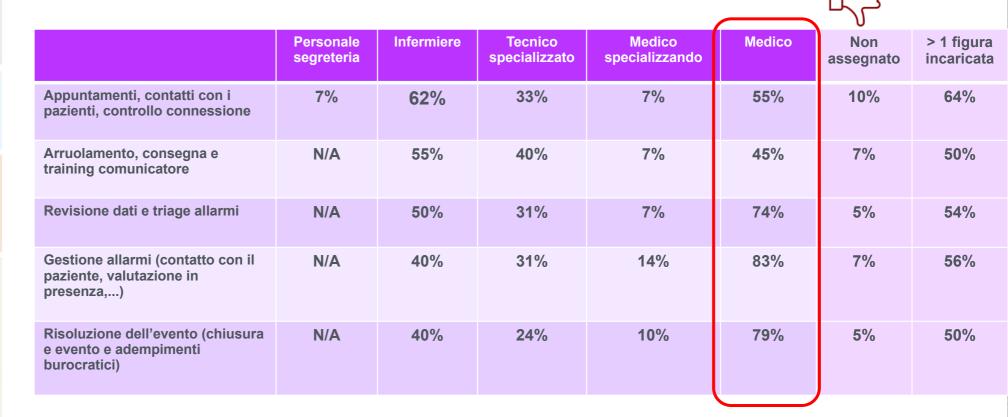
Final Sign Off

- Final interpretation
- Final communication with health care team
- · Documentation for billing

Alert Management

- Patient calls
- · In-office evaluations
- Charting and communication





Each of these tasks is best performed by a different member of the RM team, which includes physicians, advanced practice providers, registered nurses, physiologists, device technicians, and ancillary staff.

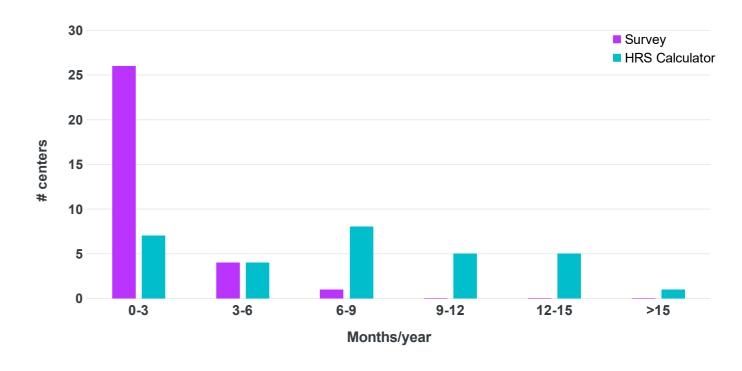
Patients followed in centers (remote and in-clinic)

Device	# pazienti
Pacemaker	700 [163 – 1478]
ICD	300 [100 – 600]
CRT	120 [50 – 300]
Monitor cardiaci impiantabili	100 [17 – 163]

"it is reasonable that clinics maintain a minimum of 3.0 full-time equivalents per 1,000 patients on RM" (From HRS website)

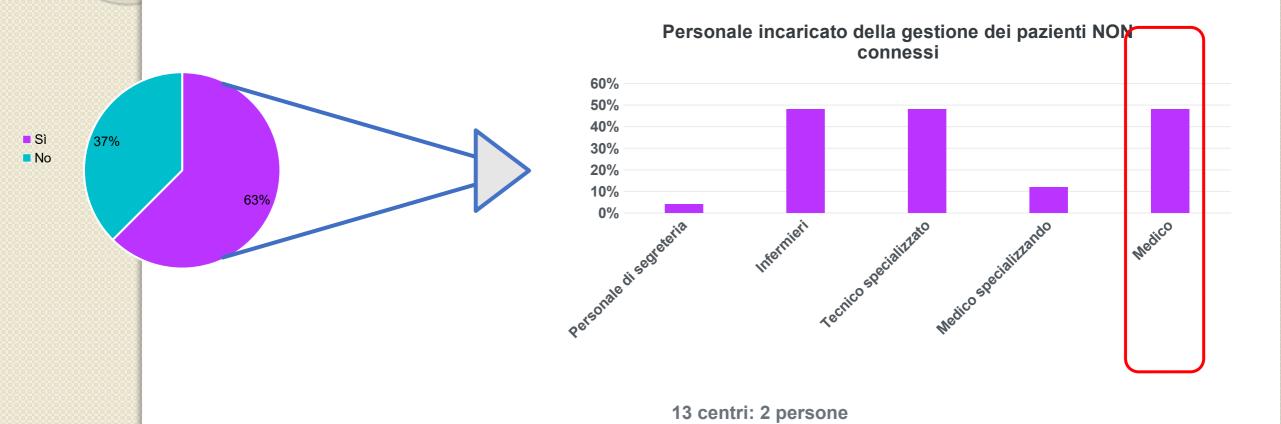
Median full-time equivalent:

- Center availability: 0.525 [0.025 2.6]
- HRS Calculator: 2.839 [0.07 10.1]



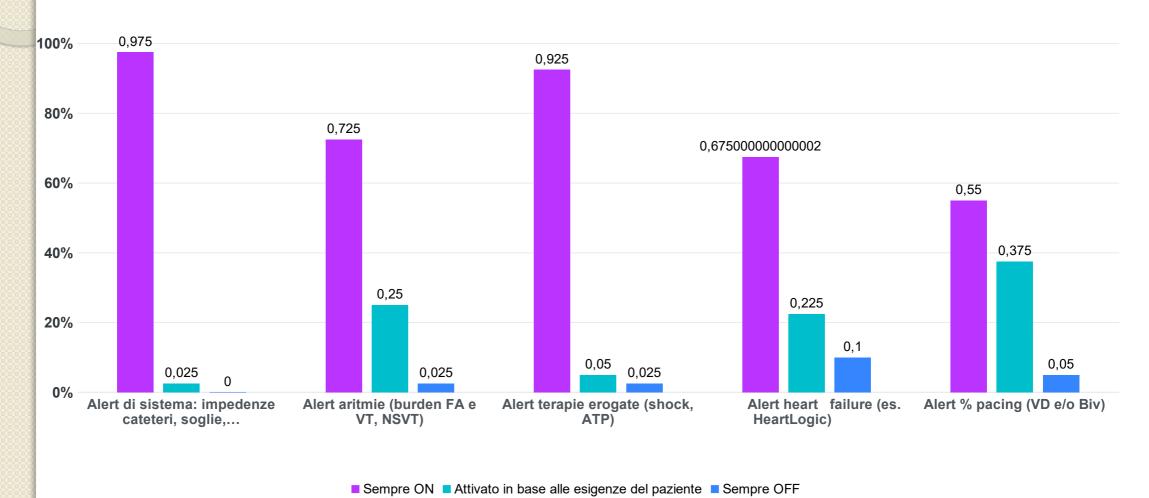
HRS Calculator: CIED Remote Monitoring Clinic Staffing Calculator | Heart Rhythm Society (hrsonline.org)

E' attiva una modalità di gestione dei pazienti che risultano NON connessi?



1 centro: 3 persone

Accensione e programmazione degli alert nei centri.





- -Riduzione spesa sanitaria (ricoveri, peggioramento scompenso, visite superflue)
- Riduzione impatto ambientale
- -Riduzione carico economico-sociale famigliare





Strategie per la sostenibilità organizzativa

Grande attenzione ai modelli organizzativi, ai ruoli differenti ed ai carichi di lavoro

Possibilità di modelli organizzativi tailor made

Necessità di evidenziare il lavoro svolto per ottenere risorse (impegnative, referti)

Importanza della formazione efficace e continua



	Controllo remoto	F.U. tradizionale
Sicurezza		
Dati tecnici real-time		
Eventi aritmici		
Gestione dello scompenso		
Sostenibilita economica		
Organizzazione interna		>4
Riduzione tempi		
Risorse economiche		



PROSPETTIVE FUTURE

