

# Remote Patient Monitoring: What Have We Learned and Where Are We Going?

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#### Abstract

**Purpose of Review** Remote monitoring (RM) of cardiac implantable electronic devices (CIEDs) is an important part of patient follow-up. The increasing number of patients with CIEDs and the recent pandemic pose several challenges for already limited device clinic resources. This review focuses on recent evolutions in RM and identifies future needs to improve RM. **Recent Findings** RM has been associated with multiple clinical benefits, including improved survival, early detection of actionable events, reduction in inappropriate shocks, longer battery lives, and more efficient healthcare utilization. The survival benefit was driven by studies using alert-based continuous RM with daily transmissions and fast reaction times. Patients report a high satisfaction rate without significant differences in quality of life between RM and in-office follow-up. The increasing workload, due to the increasing number of CIEDs implanted with daily remote transmissions, results in several challenges for the future of RM. RM requires appropriate reimbursement for RM device clinics to optimize patient/staff ratios, including sufficient non-clinical and administrative support. Universal alert programming and data processing may minimize inter-manufacturer differences, improve the signal-to-noise ratio, and allow the development of standard operating protocols and workflows. In the future, programming by remote control and true remote programming may further improve remote CIED management, patient quality of life, and device clinic workflows.

**Summary** RM should be considered standard of care in management of patients with CIEDs. The clinical benefits of RM can be maximized by an alert-based continuous RM model. Adapted healthcare policies are required to keep RM manageable for the future.

**Keywords** Remote monitoring  $\cdot$  Remote programming  $\cdot$  Remote control programming  $\cdot$  Cardiac implantable electronic devices  $\cdot$  Pacemaker  $\cdot$  Implantable cardioverter-defibrillator

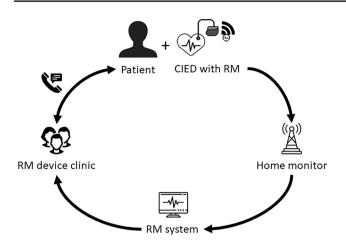
## Introduction

Remote monitoring (RM) is an important part of follow-up in patients with cardiac implantable electronic devices (CIEDs) [1]. The increasing number of CIEDs implanted, as well as unexpected challenges such as the COVID-19 pandemic, have

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resulted in high demands on in-person services and a shift towards virtual outpatient clinics [2, 3]. RM requires cooperation of various indispensable components (Fig. 1). First and foremost, the patient has a central position in RM and the patient's cooperation and adherence to RM are crucial to obtain the associated clinical benefits. Second, the remote device clinic which covers the multidisciplinary team involved with RM including clinical, non-clinical, and administrative staff. Third, the home monitor and the remote monitoring platform [1]. The home monitor is the remote telemetry device which is either positioned strategically in the proximity of the patient (individual-based RM) or the monitor is enrolled to a specific site and can be used to collect data for many individual patients (site-based RM) [4]. These data can be accessed by the remote device clinic staff using the RM platform. A limited overview of RM systems is provided in Table 1. Lastly, RM refers to automated transmissions of pre-specified alerts and should be differentiated from remote follow-up, which refers to scheduled



**Fig. 1** Remote monitoring components. In RM the patient with a CIED is central. By wireless connection data from the CIED is transmitted to the home monitor and subsequently from the home monitor to the RM system. The device clinic team reviews all remote transmissions and communicates with the patient. The patient can also contact the device clinic team autonomously. Abbreviations: CIED: cardiac implantable electronic device; RM: remote monitoring

transmissions imitating routine in-person clinic visits [1, 5]. Importantly, some manufacturers have devices that provide or can be programmed to provide daily remote transmissions (Table 1). Daily updates, to confirm patient connectivity and absence of alerts, allow near continuous RM and may facilitate an alert-based RM follow-up, a fully remote patient management strategy [6••, 7•]. In this review, we will discuss recent evolutions in RM, practical considerations in RM, and identify barriers to facilitate optimal RM.

## **Benefits of Remote Monitoring**

RM has been associated with several clinical and economic benefits for both physicians, patients, and healthcare systems.

#### Mortality

Several randomized clinical trials (RCT) have studied the impact of RM on survival. In 2014, the IN-TIME trial randomized 664 patients with heart failure and an implantable cardioverter-defibrillator (ICD) or cardiac resynchronization defibrillator (CRT-D) 1:1 between automated continuous RM and standard of care without RM [8]. The 1-year all-cause mortality was significantly lower in the RM group when compared to the standard of care group (3.4% vs. 8.7%, p = 0.004) [8]. A meta-analysis by Parthiban et al. included data from 9 RCTs, corresponding to a total of 6469 patients [9••]. While the overall analysis did not find a significant survival benefit for RM (OR 0.83, 95% CI 0.58–1.17, p = 0.285), they identified a potential survival benefit when using continuous RM (Biotronik Home Monitoring, Biotronik, Germany) [9..]. This finding was confirmed in the pooled analysis of the 3 RCTs using continuous RM (IN-TIME, ECOST, and TRUST) [7•, 8, 10, 11]. At 1-year follow-up, continuous RM was associated with a 1.9% reduction in all-cause mortality (95% CI 0.1–3.8%, p = 0.037 [7•]. Until now, studies with non-continuous RM have failed to show a survival benefit.

The survival benefit of RM in CIEDs was further confirmed in large, real-world registries [12, 13, 14•]. The ALTITUDE survival analysis reported survival data from 194 006 patients with heart failure and showed a significant survival benefit of RM in both ICD and CRT-D patients [12]. Later, Varma et al. reported on the association between survival and time in continuous RM in 269 471 patients [14•]. Besides a significant survival benefit in patients with continuous RM, they also found that patients with  $\geq$  75% continuous remote transmission had a significant lower allcause mortality compared to those with < 75% continuous remote transmissions [14•]. This finding was present not only in patients with ICDs and CRT-Ds but also in patients with pacemakers [14•].

Table 1 Overview of remote monitoring system per manufacturer

Manufacturer	Abbott	Biotronik	Boston Scientific	Medtronic	MicroPort
Remote monitoring system	Merlin.net <sup>TM</sup>	Home Monitoring <sup>TM</sup>	Latitude™	CareLink <sup>TM</sup>	SmartView™
Home monitor	Merlin@Home <sup>™</sup>	CardioMessenger	Latitude™ NXT Com- municator	MyCareLink <sup>™</sup>	SmartView <sup>TM</sup>
Frequency of transmis- sions	<ul><li>Scheduled or daily</li><li>Programmed alerts</li></ul>	<ul> <li>Daily</li> <li>Programmed alerts</li> </ul>	<ul> <li>Scheduled or daily</li> <li>Programmed alerts</li> </ul>	<ul><li>Scheduled</li><li>Programmed alerts</li></ul>	<ul><li>Scheduled or daily</li><li>Programmed alerts</li></ul>
Programmability of fre- quency of transmissions	Yes	No	Yes	Yes	Yes
Real-time intracardiac electrogram at remote follow-up	30 s	30 s	10 s	10 s	7 s

#### **Quality of Life and Patient Satisfaction**

Three RCTs reported on quality of life comparing RM and standard of care group with routine in-office visits [15–17]. None of these studies reported any significant difference in physical, mental, and overall quality of life using the SF-12 or SF-36 questionnaire [15, 16]. More data are available on patient satisfaction and preferences with regards to RM. While all studies reported excellent patient satisfaction rates for RM, in 2 RCTs there was no significant difference in patient satisfaction when comparing RM versus in-clinic only follow-up [18–24]. Several surveys reported a patient preference for RM over in-office visits [22-24]. Timmermans et al. found that only 19% of their patients preferred in-office follow-up [22]. Reasons to prefer inoffice follow-up were human contact with physicians, trust, short travel distance to the hospital, and prior negative experiences with RM [22].

#### **Early Detection of Actionable Events**

Actionable events can be defined as any clinical or devicerelated event detected by RM of which short-term management may improve a patient's outcome. As such, this does not only concern patients with ICDs, but also patients with pacemakers or implantable loop recorders (ILR). Observational data have shown that only 6% of scheduled inoffice follow-up visits resulted in device reprogramming or changes in patient management [25]. Additionally, the time from event detection to medical intervention was significantly shorter in patients with RM, and could even be reduced to 1 day using continuous RM [15, 26].

There are three main advantages to RM with regards to detection of events. In the first place, RM allows early detection of device and lead malfunctioning, such as lead failure or battery depletion, which is particularly useful for CIEDs on advisories or recall [1, 27, 28]. The continuous surveillance resulted in a significant reduction in inappropriate shocks and symptomatic pacing inhibition in patients with lead failure [29]. The benefit of RM may even be highest immediately following implant where data from the TRUST trial showed earlier detection of actionable events requiring device reprogramming or lead revision without increasing the incidence of non-actionable events [30].

Second, RM allows early notification and adjudication of ICD therapies. Differentiation between appropriate and inappropriate ICD interventions is particularly useful to guide the treatment intervention required. While some actionable events might require simple pharmacological optimization or device reprogramming, other might require further diagnostic exams, electrical cardioversion, or surgical intervention [31]. Due to early detection of actionable events, RM has been found to reduce the number of inappropriate ICD

shocks and even prolong battery longevity with approximately 12% [32–34].

Finally, RM facilitates early arrhythmia detection and for ILRs this is even the main indication for implanting the device [35]. Early detection of atrial fibrillation, or so-called subclinical atrial fibrillation, and quantification of arrhythmia burden by CIEDs is routinely used in clinical practice and in RCTs on atrial fibrillation [35, 36]. While subclinical atrial fibrillation in CIED patients has been associated with an increased risk of stroke and a metaanalysis suggested a benefit in stroke prevention with RM, results from RCTs on the use of anticoagulation in RM mediated detection of atrial fibrillation (e.g. ARTESIA trial [ClinicalTrials.gov Identifier: NCT01938248]) are still awaited [37–39].

#### **Healthcare Utilization**

RM shifts healthcare utilization from face-to-face inoffice visits to remote patient contact by using phone visits and automated messages (Table 2). The At-Home study reported a 70% reduction in in-office visits with a significant decrease is staff workload [40]. In the RM-ALONE study the reduction in in-office visits was even 83% [41]. In the TRUST study, a fully remote alertbased RM was associated with a reduction of 81% in nonactionable events, while actionable events remained unchanged  $[6 \bullet \bullet]$ . This all occurred without an increase in major cardiac events  $[6 \bullet \bullet, 40, 41]$ . Furthermore, a recent cost-consequence sub-analysis of TRUST showed that an alert-based RM strategy was associated with a significant lower cost compared to in-person evaluations only and a remote follow-up strategy [42••]. The Euro-Eco trial reported a more efficient healthcare utilization with a reduction in follow-up visits despite an increase in unscheduled visits and fewer hospitalization with a shorter length of stay [43].

In a Health Technology Assessment, blended RM models combining RM with scheduled in-office follow-up were less costly and more effective in patients with pacemakers. Among patients with ICDs, the cost of the blended RM model was higher but also increased the quality-adjusted life years [44]. An economic analysis in the TARIFF study showed that RM was cost-effective for the patients, caregivers, and the health care systems [45]. Therefore, RM has the potential to be cost-effective depending on the local reimbursement policies.

#### **Heart Failure Monitoring**

There has been continuous interest in using RM as a tool in heart failure monitoring, more specifically to use

		COMPAS 2012 [15]	RM-ALONE 2019 [41]	At-Home 2020 [40]	TRUST 2021 [6••]
Design	Population	DDD PM	VVI/DDD PM or ICD	VVI/DDD PM	VVI/DDD ICD
	Included subjects	N=538	N=445, 66.1% PM	N=1274	N=1339
	Randomization	1:1	1:1	1:1	2:1
	Intervention	Daily RM	Daily RM + remote FU q6m	Daily RM + in-office at 24 m	Daily RM + remote FU q3m
	Control	As per physician's discre- tion	Hybrid remote FU+in- office q6m	Hybrid remote FU+in- office q6m	In-office q3m
	Primary endpoint	Death, cardiovascular/ device event requiring hospitalization	Death, stroke, cardio- vascular/device event requiring surgery or hospitalization	Death, stroke, cardiovas- cular event requiring surgery	Reduction in non-actiona- ble in-person evaluations
Endpoints*	Primary endpoint	17.3% vs. 19.1% ( <i>p</i> =0.63)	20.0% vs. 19.5% ( <i>p</i> =0.006 for non- inferiority)	10.9% vs. 11.8% ( <i>p</i> =0.001 for non- inferiority)	81% reduction ( <i>p</i> < 0.001)
	All in-office visits	36.2% reduction	79.2% reduction	69.5% reduction	37.5% reduction (includes study initiation and end visit)
	Follow-up/year	1.0/year vs. 1.6/year ( <i>p</i> < 0.001)	0.3/year vs. 1.5/year (p<0.001)	0.5/year vs. 2.0/year (p < 0.0001)	2.5/year vs. 4.0/year (p<0.001)
	Actionable events	62% vs. 29% (p <0.001, includes all changes in management)	NA	<ul> <li>1.6% vs. 1.4% of total (p=0.81)</li> <li>9.0% vs. 11.7% of unscheduled in-office visits (p=0.42)</li> </ul>	16.2% vs. 11.8% ( <i>p</i> < 0.001)
	Economic analysis	NA	NA	11% reduction in total cost/year	13% reduction in total cost at 2 years

 Table 2
 Healthcare utilization in major RM trials

<sup>\*</sup>Data are presented as intervention vs. control group or % reduction in the intervention group when compared to the control group Abbreviations: *FU*, follow-up; *ICD*, implantable cardioverter-defibrillator; *NA*, not applicable; *PM*, pacemaker; *RM*, remote monitoring

measures of thoracic impedance as marker of congestion, as well as other cardiac markers to predict heart failure decompensation, hospitalization, and cardiovascular mortality [1]. Several recent studies showed comparable outcomes between RM-enabled heart failure management and conventional in-office follow-up, for example the REMOTE-CIED and the MORE-CARE trials [46, 47]. These studies focused predominantly on markers estimating lung fluid accumulation. The success of other studies could be explained by two main reasons [48, 49]. First, in the OptiLink HF trial, an appropriate response to alerts, defined as telephone contact within 2 days and follow-up contacts, was associated with a reduction in cardiovascular death and heart failure hospitalization [49]. Second, the MultiSENSE study performed multi-parameter heart failure assessment, including thoracic impedance, heart rate, and biventricular pacing percentage [48]. Furthermore, hemodynamic monitoring parameters with automated analysis of heart sounds and pulmonary artery pressures have been successfully used as well to manage heart failure and avoid hospitalizations [48, 50]. Taken together, the combination of novel markers with a rapid follow-up of these findings was needed to see the benefits.

# **Practical Remote Monitoring Considerations**

#### **Patient Education and Enrollment**

Patient education is essential for CIED patients and should include the concept of remote monitoring. Patient education about RM should start before CIED implant and include essential knowledge on ensuring RM connectivity and RM compliance.

In an ideal scenario, RM enrollment is performed prior to hospital discharge, but this requires a continuous stock of RM receivers in the hospital while some providers prefer the RM receiver to be delivered at home. Due to technical circumstances, absence of primary caregivers in the hospital, and difficulty coping with the decision to implant a CIED, enrollment post-implant—either a virtual enrollment or enrollment at the first in-office visit—might be preferred. For ILRs, it is recommended to initiate RM prior to hospital discharge given the continuous availability of diagnostic data which may affect patient management [1]. As 1 out of 4 patients fail to initiate RM at home, a "handshake transmission" to verify a first successful remote transmission can be used [51]. The timing of patient enrollment is highly variable in studies and no direct comparison for any outcome has been performed. Mittal et al. studied the effect of time from implant to RM initiation on all-cause mortality in a national retrospective cohort of 106 027 patients with a CIED in the USA [52]. Of these, 62.3% had a first successful RM transmission within 91 days of implant, and this was associated with a 18% higher survival when compared to > 91 days from implant to first RM transmission [52]. This survival advantage with early RM transmission was present across all CIED types, but was greatest for patients implanted with CRT-D devices [52].

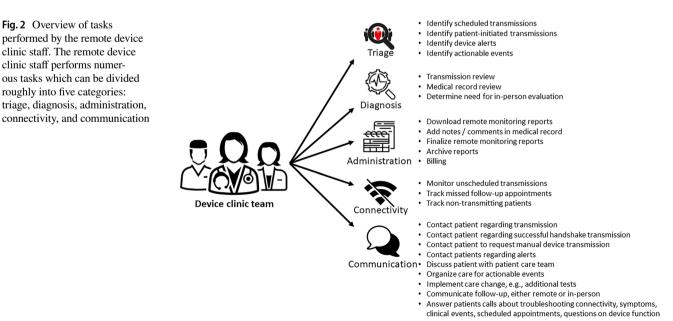
#### **Remote Device Clinic Staff**

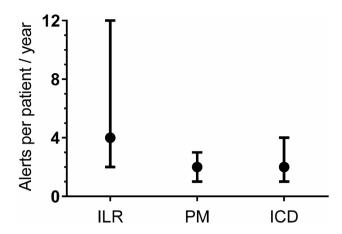
The remote device clinic consists of a multidisciplinary team, including physicians, allied professionals, and administrative staff [1]. The increasing workload due to increasing number of patients with CIEDs and continuous RM, requires an efficient team-based organization with well-defined tasks and procedures [53]. The device clinic staff has several other essential tasks to complete on a continuous basis besides RM. These include patient education, assisting in CIED implant procedures, and inoffice CIED visits. Reviewing RM transmissions is only a small part of managing a CIED patient on RM. Throughout the EuroEco trial, the required dedicated time to manage a RM patient did not differ significantly from a patient with in-office clinic visits [43]. The remote device clinic workflow includes transmission review and diagnosis, patient communication and clinical action, and electronic charting and billing (Fig. 2) [54]. These include numerous "invisible tasks," such as phone calls, troubleshooting connectivity issues, alert triage, and scheduling in-office visits to address actionable events.

The workload burden also differs between CIED types, ranging between an estimated annual workload for a pacemaker of 0.8 h, up to 8.4 h for a patient with an ILR [54, 55]. Contemporary data show that while ILRs accounted 18.8% of CIEDs followed in the remote device clinic, they delivered > 50% of the alerts [56•]. As such, the increasing use of ILRs results in a disproportionate increase in workload (Fig. 3). Dedicated workflows and decision-trees for each CIED type may be required.

#### **Remote Monitoring Connectivity and Adherence**

Consistent connectivity and patient adherence to remote monitoring are critical elements for the success of RM. The clinical benefit of RM is directly related to early detection of actionable events and a timely response by the remote device clinic. Therefore, patient connectivity should be monitored, and connectivity issues should be addressed as quickly as possible. Troubleshooting connectivity issues is a time-consuming process and was identified as one of the invisible tasks of the remote device clinic [54]. Furthermore, a prior problem with connectivity was identified as a reason for patient preference of in-office visits and was associated with low patient adherence [22]. Adequately trained staff and a dedicated workflow to address connectivity issues, including when to contact device manufacturers, are crucial to maximize RM connectivity and patient adherence.





**Fig.3** Alerts per patient per year by CIED type. The graph illustrates the median number of alerts for patients with an ILR, PM, or ICD. ILRs are associated with a higher alert burden when compared to PMs and ICDs. Data are presented as the median and interquartile range. Based on data presented by O'Shea et al. [56•]. Abbreviations: ICD: implantable cardioverter-defibrillator; ILR: implantable loop recorder; PM: pacemaker

#### **Defining Actionable Events and Alerts**

The programming of RM alerts and actionable events should be tailored to the patient and the CIED type [57]. Unfortunately, there is a large variability between manufacturers on the type and number of programmable alerts which makes it challenging to develop standardized workflows. In general, alerts concerning ICD therapies, lead integrity, and battery capacity should be identified as high-priority or critical alerts (Table 3) as immediate action is indicated and has been shown to beneficial for the patient [8, 10, 26, 58, 59]. Other alerts should be tailored to the patient and CIED indication (Table 3). For example, in patients with CRT, loss of biventricular pacing warrants an alert while in patients without pacing indication, the ventricular pacing percentage should be monitored to reduce the risk for pacing-induced cardiomyopathy. To avoid repeating non-actionable events, alert programming should be adjusted once sufficient clinical data has been received. For example, new-onset atrial fibrillation warrants a first alert, but once the patient is anticoagulated and the atrial fibrillation is adequately managed, the alert should be adjusted to avoid repetitive non-actionable events.

#### **Challenges in Remote Monitoring**

#### **Geographic and Socioeconomic Disparities**

Data on geographic and socioeconomic disparities of RM availability and adherence are scarce. In 2013, Lau et al. presented an update on the use of RM in the Asia–Pacific

region describing large geographic disparities with limited use in South-East Asia and India, while RM was used in more than half of CIED patients in Japan [60]. Even when RM is set-up, RM availability does not equal adherence. Data from the USA showed significant geographic disparities in RM adherence, with up to 20% of patients not using their RM even when it is available [61]. Joint efforts by health care organization and manufacturers should focus on identifying barriers to remote monitoring availability and adherence, including socio-economic and geographical disparities.

#### Signal-to-Noise Ratio

It has been estimated that > 10 million scheduled remote transmissions would be generated annually if all patients in the USA with a CIED would use RM [62]. In the midst of this humongous workload of normal scheduled transmission, false alerts, and non-actionable events, there are a limited number of critical alerts and actionable events [63]. In a retrospective study, 16 560 RM transmission from 1849 patients with pacemakers, ICDs, or CRT-Ds were analyzed [63]. Of these transmissions, only 4.1% were critical events. The critical event rate that was lower in patients with a pacemaker (0.9%) compared to patients with an ICD (5.0%) and CRT-D (5.9%) [63]. These data illustrate that process optimization will be crucial in order to streamline the increasing workload of the remote device clinic and to keep it manageable. This requires appropriate staffing, dedicated workflows, and optimized alert programming.

#### Universal Data Formatting and Processing

Currently, RM alert options are highly variable between CIED manufacturers. This variability ranges from type and number of alerts independent of preferred clinician settings, to manufacturer-specific automated alert settings which results in the same event being reported as an event by one manufacturer but not by the other. Furthermore, the timing of transmissions differs significantly between manufacturers as some transmit whenever a patient is in range, while others only transmit at a preset time. This lack of harmonization makes it currently impossible to create standard operating procedure templates and RM device clinic workflows. The Heart Rhythm Society Interoperability Workgroup collaborates with the CIED vendors, electronic medical record vendors, and RM vendors aiming to develop standardized nomenclature and interoperability to evolve to a universal Implantable Device Cardiac Observation (IDCO) profile [64].

Device integrity

Type

Critical

LRs	
ICD	ILR
End of service/low battery voltage	
Device reset or safety mode	
RV lead impedance out of range	
Shock lead impedance out of range	

Table 3 Critical vs. non-critical RM alerts in pacemakers, ICDs, and ILRs

Pacemakers

End of service/low battery voltage

in pacemaker-dependent patients Device reset or safety mode in

		pacemaker-dependent patients	Device reset of safety mode	
		RV lead impedance out of range in pacemaker-dependent patients	RV lead impedance out of range	
		Noise episode in pacemaker- dependent patients	Shock lead impedance out of range	
			Long charge time	
			VF detection/noise episode	
	Clinical		ICD shock delivered	Pause/asystole > 6 s
				Tachyarrhythmia > 30 beats > 231 bpm
Non-critical	Device integrity	Elective replacement indicated	Elective replacement indicated	Battery depletion
		RA/LV lead impedance out of range	RA/LV lead impedance out of range	
		Pacing threshold out of range	Pacing threshold out of range	
		MRI mode	MRI mode	
		Device reset or safety mode in pace- maker non-dependent patients		
		RV lead impedance out of range in pacemaker non-dependent patients		
		Noise episode in pacemaker non- dependent patients		
	Clinical	RV pacing % > programmed value	RV pacing % > programmed value	Pause/asystole > 3 s
		Biventricular pacing % < pro- grammed value	Biventricular pacing % < pro- grammed value	Bradycardia < 30 bpm
		Detection of new-onset atrial fibril- lation	Detection of new-onset atrial fibril- lation	Tachyarrhythmia > 16 beats > 180 bpm*
		Atrial burden > programmed value	Atrial burden > programmed value	Detection of new-onset atrial fibrillation*
		Ventricular high-rate episodes	ATP delivered	
			Ventricular high-rate episodes	

<sup>\*</sup>Depending on the indication for ILR

Abbreviations: ATP, anti-tachycardia pacing; bpm, beats per minute; ILR, implantable loop recorder; MRI, magnetic resonance imaging; LV, left ventricle; PM, pacemaker; RA, right atrium; RV, right ventricle; VF, ventricular fibrillations

#### Reimbursement

Reimbursement of RM varies widely by country and may even vary within country by health jurisdiction [55, 65]. Reimbursement models also vary between capitation payments, fee-for-service, and global budgets. In a survey by the European Heart Rhythm Association, the single most reported barrier to implement RM in all patients with CIEDs was lack of reimbursement [66]. While all physicians considered RM a useful technology, it was mostly perceived as an increased workload for the entire team [66]. Several economic assessments have confirmed that RM is cost-effective, as in there are increased clinical benefits for additional costs that fall within country-specific, societally accepted thresholds for healthcare value [44, 67, 68]. Given the continuously increasing workload in RM device clinic, implementation of appropriate reimbursement models adapted to local healthcare systems and taking into account added indirect workloads and appropriate staffing ratios, should be a priority.

# **The Future of Remote Monitoring**

#### **Towards Alert-Based Remote Monitoring**

It has been recommended to interrogate CIEDs every 3 months, either in-person or remotely [1]. In most centers the standard practice for CIED follow-up is a blended strategy with annual or bi-annual in-office visits

in combination with RM (Fig. 4). The RM component can either be scheduled remote transmissions where RM is used to mimic a clinic visit, or continuous RM. Scheduled in-office visit leave interim events unattended until the next scheduled visit, therefore delaying treatment of potential actionable events. For scheduled remote transmissions, this will depend on RM programming. Thanks to advances in telecommunication technologies, contemporary RM systems are evolving to continuous RM where device and disease-related alerts are generated as and when they occur [5]. The available data steer the future of RM in the direction of continuous RM, which will minimize the time from detection of actionable events to clinical action [7•, 8, 10, 11]. Continuous RM may facilitate the implementation of alert-based RM, which is a combination of continuous RM with clinic visits prompted only by detection of actionable events, hence extending remote patient management beyond calendarbased follow-up (Fig. 4). Alert-based RM was necessitated during the recent COVID-19 pandemic and may replace structured calendar-based follow-up, whether it is in-office or remote  $[3, 6^{\bullet\bullet}]$ . RCTs have shown that it is safe to extend the time interval between in-office visits up to 24 months for both pacemakers and ICDs in selected patients [6.., 10, 15, 30, 40, 41, 43, 69–71]. Conditions to be met for patients to be eligible for alert-based RM are consistent connectivity with near-perfect patient adherence and absence of cardiac comorbidities that may require more frequent follow-up.

# Remote Programming and Remote Control Programming

#### **Remote Programming**

Experiences during the COVID-19 pandemic have reinforced the interest in remote programming. The optimal remote programming arrangement would be to deliver this care to the patient where they are, even if that is in their home. Current RM setups consist of unidirectional data transmissions between the CIED and the RM system. While technologically feasible, bidirectional communication with the ability to remotely reprogram the CIED is restricted due to cybersecurity and liability

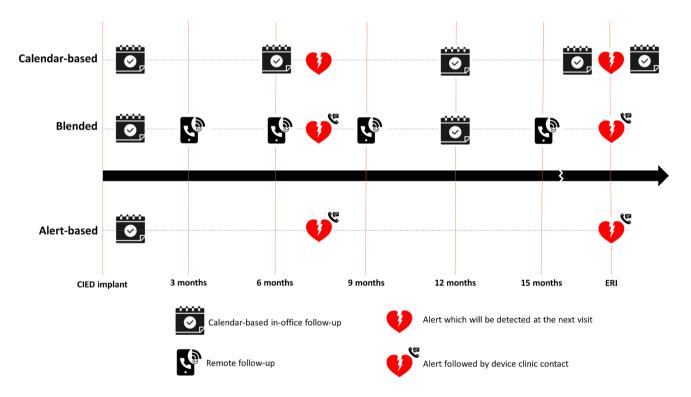
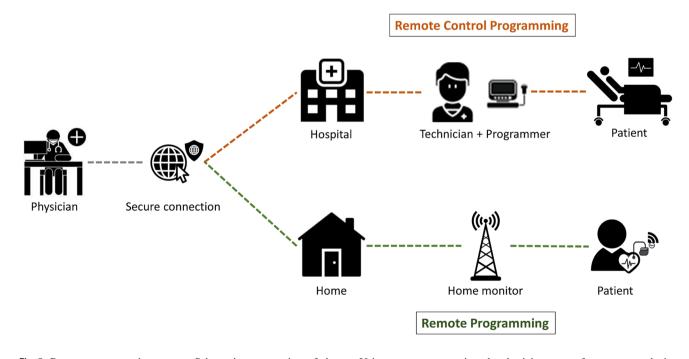


Fig. 4 Schematic presentation of scheduled and alert-based remote monitoring. Schematic presentation of three different types of CIED follow-up. Calendar-based follow-up consists of recommended biannual scheduled follow-up without RM. Therefore, alerts will either be diagnosed at the next in-person visit or upon clinical presentation due to symptoms associated with the alert. When the device approaches ERI, calendar-based follow-up is intensified to avoid end-of-service device behavior. The blended follow-up combines at least annual calendar-based visits with scheduled remote interrogations. If alerts are activated these will be transmitted to the device clinic and trigger an actionable event managed by the device clinic team. Alert-based RM consists of continuous RM with clinic visits prompted only by detection of actionable events and may extend the time interval between in-office visits up to 24 months. Abbreviations: CIED: cardiac implantable electronic device; ERI: elective replacement indicated concerns [72]. For example, in 2016, the Muddy Waters report outlined possible cybersecurity vulnerabilities that required firmware upgrades in St. Jude Medical (now Abbott) pacemakers [73]. While there have not been any reports of harm, several issues limiting the implementation of remote programming and potential mitigation strategies were identified [72]. First, the perceived and actual cybersecurity risk may be mitigated by using a closed loop communication system which requires physical action by both the patient and the physician prior to remote programming. Second, remote programming may result in a lack of clinical input by the bedside device clinic staff. Third, immediate feedback on the consequences of the altered programming will be lacking. The latter two issues may be mitigated by increased clinical surveillance.

True remote programming using bidirectional communication in the setting of a patient's home remains challenging (Fig. 5). In a first step, the functionality of remote programming could be limited to minor alterations in CIED programming, such as rate response settings, in a subgroup of patients without major comorbidities who have shown near perfect RM connectivity and compliance. However, in the end, the patient's personal preferences and trust in remote programming should be considered prior to implementing remote programming as part of standard care.

#### **Remote Control Programming**

Recent reports have confirmed the feasibility of an intermediate form of remote programming by acquiring remote control of CIED programmers (Fig. 5) [74•, 75-77]. This remote control programming setup requires the patient to go a hospital or clinic near their home (but not in their home), where the connection between the CIED and the programmer is initiated by a technician. Subsequently, a remotely located physician can acquire remote control of the programmer and perform a routine interrogation and reprogram the device. Kloosterman et al. and Siddamsetti et al. used the Medtronic (Minneapolis, US) remote control application which is compatible with their 2090 Medtronic programmer to perform remote device checks before and after respectively 50 and 209 magnetic resonance imaging scans [76, 77]. Ploux et al. used a custom multivendor solution which allowed them to perform remote interrogations in 110 patients (Abbott, Illinois, US; Biotronik, Berlin, Germany; and MicroPort, Shanghai, China), of which 55% were pacemaker dependent [74•]. Remote control programming was performed in about half of interrogations without any failure and a time lag < 1 s [74•]. These setups overcomes the key issues described above, but still requires the patient's presence at the hospital or clinic. Therefore, remote control programming is predominantly associated with benefits for the remote device clinic staff and patients at remote locations.



**Fig. 5** Remote programming setups. Schematic presentation of the difference between remote control programming and true remote programming. In remote control programming, the patient has to present to a healthcare facility where a connection between the CIED and the programmer is initiated by a member of the device clinic team.

Using a secure connection, the physician can perform a remote device interrogation and reprogramming using the local programmer. In true remote programming, the physician would reprogram the CIED using the patient home monitor allowing the patient to stay at home

# Conclusions

RM has proven its clinical value over time. RM should be considered standard of care. The clinical benefits of RM, such as early detection of actionable events and more efficient use of healthcare resources, can be maximized by using continuous RM and evolving towards an alert-based RM model. Given the progressively increasing workload there is an urgent need of adapted healthcare strategies to maintain the cost-effectiveness of RM and that allow device clinics to prepare themselves for the future. These strategies should aim for optimized RM device clinic staffing with sufficient support by administrative and non-clinical staff, appropriate reimbursement models, and universal data processing that allow development of standard operating protocols and workflows.

# Declarations

**Conflict of Interest** SRR: consultant to Lundbeck LLC, Theravance Biopharma, and Amneal Pharma related to neurogenic orthostatic hypotension; consultant to Servier Affaires Médicales, Regeneron, argenx BV, and Antag Pharma related to postural orthostatic tachycardia syndrome. Honoraria from Spire Learning and Medscape for developing CME materials on neurogenic orthostatic hypotension. DMSB Chair for a Phase 2 study of an irritable bowel syndrome medication for Arena Pharmaceuticals with compensation. Past-President of the American Autonomic Society without financial compensation. Bert Vandenberk declares no competing interests.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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- •• Of major importance
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