Appendix 3 Evidence tables

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Section 2 General Concepts					
2.2 Remote Monitoring Considerations					
Crossley GH, et al. Clinical benefits of remote versus transtelephonic monitoring of implanted pacemakers **Year Published:** 2009 **PMID:** 19926006	**Aim:** To test the hypothesis that an Internet-based remote pacemaker interrogation system would be useful to identify clinically actionable information sooner than the current standard practice of TTM and in-office follow-up. **Endpoints:** Mean time to first diagnosis of clinically actionable events (CAE) comparing RM arm vs control arm. **Study Type:** Randomized, prospective, multicenter **Size:** 897 pts	**Inclusion:** Recipients of VVI/DDD PMs with Medtronic CareLink RM System. **Exclusion:**	FU of 375±140 days. Mean time to first diagnosis of CAE was 5.7 months in RM arm vs. 7.7 months in the control arm. .p: 0.0001.		**Limitations:** The study was not powered to detect a decrease in the clinical end points of stroke and congestive heart failure. The study involved only the Medtronic CareLink system. **Conclusions:** Mean time to first diagnosis of CAE was shorter in the RM arm.
Varma N, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial **Year Published:** 2010 **PMID:** 20625110 **Study Name:** TRUST follow-up	**Aim:** to test the hypothesis that remote home monitoring with automatic daily surveillance is safe and effective for implantable cardioverter-defibrillator follow-up for 1 year and	**Inclusion:** Recipients of VVI/DDD ICDs according to Guidelines, **Exclusion:** pacemaker dependent patients	a) In-hospital device evaluation was 2.1 per pt/year in the RM arm vs 3.8 per pt/year in the control arm. P<0.001 b) Overall adverse event rate was 10.4% in both groups at 12 months. P <0.005 for non inferiority c) RM advanced by >30 days the detection of arrhythmia onset.		**Limitations:** Follow-up limited to 12 months. CRT devices not included **Conclusions:** RM was safe in supplanting 'routine' in-office visits allowing an early event detection in ICD recipients.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	enables rapid physician evaluation of significant events. **Endpoints:** a) Total in-hospital device evaluations. b) Overall adverse event rate. c) Time from arrhythmia onset to physician evaluation. **Study Type:** Randomized, prospective, multicenter **Size** 1339 patients				
Varma N, et al. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial - testing execution of the recommendations **Year Published:** 2014 **PMID:** 24595864 **Study Name:** TRUST follow-up	**Aim:** To test recommended ICD follow-up methods by 'in-person evaluations'(IPE) vs. 'remote Home Monitoring' (HM) **Endpoints:** the comparative efficacy of in-person vs. remote management specifically regarding achievement of the core guideline objective of maintaining structured follow-up. The trial	**Inclusion:** **Exclusion:** see reference 19 (TRUST Trial)	Conventional management suffered greater patient attrition during the trial (20.1 vs. 14.2% HM, P = 0.007). Three month follow-up occurred in 84% in both groups. There was 100% adherence (5 of 5 checks) in 47.3% Conventional vs. 59.7% HM (P < 0.001). Between 3 and 15 months, HM exhibited superior (2.2×) adherence to scheduled follow-up [146 of 2421 (6.0%) in HM vs. 145 of 1098 (13.2%) in Conventional, P , 0.001] and punctuality. In HM (daily transmission success rate median 91%), transmission loss caused only 22 of 2275 (0.97%) failed HM evaluations between 3 and 15 months; Overall IPE failure rate in Conventional [193 of 1841 (10.5%)		**Limitations:** **Conclusions:** Automatic remote monitoring better preserves patient retention and adherence to scheduled follow-up compared with IPE.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	hypothesis was that remote management would more effectively achieve the key aims of patient retention, and adherence to and punctuality of regular periodic assessments **Study Type:** see reference 19 (TRUST trial) **Size** see reference 19 (TRUST Trial)		exceeded that in HM [97 of 1484 (6.5%), P , 0.001] by 62%		
Hindricks G, et al. Quarterly vs. yearly clinical follow-up of remotely monitored recipients of prophylactic implantable cardioverter-defibrillators: results of the REFORM trial **Year Published:** 2014 **PMID:** 23868932 **Study Name:** REFORM	**Aim:** To investigate the possibility of longer in-office follow-up intervals in primary prevention ICD patients under remote monitoring with automatic daily data transmissions from the implant memory. **Endpoints:** **.**Scheduled and unscheduled ICD visits .Difference in Quality of life scores at baseline and after 27 months.	**Inclusion:** ICD implanted according to MADIT II criteria. **Exclusion:** . myocardial infarction within 30 days before enrolment, . NYHA class IV . secondary prevention indication for ICD therapy .living in an area lacking the GSM mobile phone coverage . indication for pacing or CRT	FU: 24 months .FU visits reduced by 58% (3.8 Q- arm to 1.6 Y-arm per-pt/year. P <0.001 .Unscheduled FU per pt-year was 0.27 in Q-arm vs 0.64 in Y-arm. P =0.03 .All cause mortality was not different between groups. P=n.s. .Y-group did not exceed one additional visit per pt-year p <0.001		**Limitations:** No blind Economic aspects not evaluated **Conclusions:** RM safely reduces the ICD FU burden during 27 months after implantation. There is a favorable impact of RM on quality of life. No impact on mortality and hospitalization rate

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	.Total and CV mortality. .Rate and length of all cause and CV hospitalizations **Study Type .** Randomized, parallel-design .Quarterly clinic visits (Q-arm) vs. yearly clinic visits (Y-arm) **Size** 155 patients				
Boriani G, et al. The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring **Year Published:** 2013 **PMID:** 23965236 **Study Name:** MORE-CARE	**Aim:** The main objective of Phase 1 is to evaluate if RM strategy is able to reduce time from device-detected events to clinical decisions **Endpoints:** The primary endpoint of Phase 1 was the delay between an alert event and clinical decisions related to the event **Study Type:** Multicenter randomized controlled trial **Size** 154 patients	**Inclusion:** patients in sinus rhythm with de novo implantation of CRT-D for systolic heart failure with NYHA class III/IV (and a LVEF <35%) **Exclusion:**	1) The median delay from device-detected events to clinical decisions was considerably shorter in the Remote group compared to the Control group: 2 (25th-75th percentile, 1-4) days vs 29 (25th-75th percentile, 3-51) days respectively, *P*=.004. 2) In-hospital visits were reduced in the Remote group (2.0 visits/patient/year vs 3.2 visits/patient/year in the Control group, 37.5% relative reduction, *P*<.001). 3) Automatic alerts were successfully transmitted in 93% of events occurring outside the hospital in the Remote group. 4) The annual rate of all-cause hospitalizations per patient did not differ between the two groups (*P*=.65).		**Limitations:** Phase 1 of MORE-CARE was not powered for evaluating the impact of RM on cardiovascular and device-related hospitalizations and mortality, which were studied in Phase 2 **Conclusions:** RM in CRT-D patients with advanced heart failure allows physicians to promptly react to clinically relevant automatic alerts and significantly reduces the burden of in-hospital visits.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Crossley GH, et al. The CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) trial: the value of wireless remote monitoring with automatic clinician alerts **Year Published:** 2011 **PMID:** 21255955 **Study Name:** CONNECT	**Aim:** to determine the impact of wireless remote monitoring with automatic clinician alerts on the time from clinical events to clinical decisions and on health care utilization. **Endpoints:** a) Time from a clinical event to a clinical decision. b) Health care use for cardiovascular (CV) reasons. **Study Type:** Randomized. prospective, multicenter **Size:** 1997 pts	**Inclusion:** Recipients of ICDs and CRT-D according to Guidelines. **Exclusion:** 1) permanent AF, 2) chronic warfarin therapy; 3) having had aprevious ICD, CRT device, or pacemaker; 4) < 18 years of age; and 5) life expectancy <15 months	a) 22 days (in-office arm) vs. 4.6 days (RM arm). P<0.001 b) Health care use for CV reasons: 4 days (in-office arm) vs. 3.3 days (RM arm). P 0.007 LOS per hospitalization was 3.2 in RM arm vs 4.3 days in-office arm. P 0.007		**Limitations:** events were not adjudicated to verify relatedness to specific disease states. Only adverse events that resulted in a HCU were collected **Conclusions:** .RM reduced the time to a clinical decision. .RM reduced mean length of stay (LOS)
Guédon-Moreau L, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial **Year Published:** 2013 **PMID:** 23242192 **Study Name:** ECOST report	**Aim:** to evaluate the safety and economic impact of ICD follow-up schedule with Home Monitoring **Endpoints:** . Incidence of MAE (all cause and CV death).	**Inclusion:** Recipients of ICDs according to Guidelines. **Exclusion:** NYHA class IV	FU: 24.2 months .MAE: 40.3% vs 43.3% in the RM and control arm respectively. HR 0,90 (non inferiority) .Appropriate and inappropriate shocks delivered were 71% lower in the RM arm. P 0.02 .76% reduction of capacitor charges. P<0.005		**Limitations:** Investigators not blinded to the patient assignment; CRT not included **Conclusions:** .RM was as safe as standard FU. .RM reduces appropriate and inappropriate shocks. .Battery longevity increased in RM arm

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	. Procedure-related complications and device-related adverse events. **Study Type:** Randomly, prospective multicenter **Size:** 433 patients				
Mabo P, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial) **Year Published:** 2012 **PMID:** 22127418 **Study Name:** COMPAS	**Aim:** to evaluate the benefits of remote monitoring after first implantation or replacement of dual chamber pacemakers and, specifically, to determine whether remote monitoring could replace the standard long-term follow-up of patients with regard to the adverse events related or unrelated to the implanted devices **Endpoints:** .MAE: Hospitalization for PM´s related complications and CV events, death. .Incidence of each MAE.	**Inclusion:** DDD PM indications according to guidelines **Exclusion:** Pacemaker dependent patients	FU: 18 months. .MAE:17.3% in RM arm vs.19.1% in control arm. OR 0.90 .Hospitalization due to PM complications: 0.4% in RM arm vs. 2.8% in control arm. OR 0.14 .Mean number of unscheduled FU per pt-year: 56% lower in RM arm. P <0.001		**Limitations:** The study involved only the Biotronik Home Monitoring system. **Conclusions:** .RM was safe and reduced in-office visits. .RM allowed earlier detection of clinical and device-related adverse events.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	.RM reduction of in-office visits. **Study Type:** Randomized. prospective, multicenter **Size:** 538 patients				
Landolina M, et al. Remote monitoring reduces healthcare use and improves quality of care in heart failure patients with implantable defibrillators: the evolution of management strategies of heart failure patients with implantable defibrillators (EVOLVO) study **Year Published:** 2012 **PMID:** 22626743 **Study Name:** EVOLVO	**Aim:** to test the hypothesis that remote management can reduce emergency healthcare utilization in heart failure patients implanted with wireless-transmission-enabled ICD/CRT-D endowed with specific diagnostic features for HF, as compared with standard management **Endpoints:** . Rate of emergency department or urgent in-office visits for heart failure (HF), arrhythmias or ICD-related events . Economic impact of RM in ICD pts with HF. **Study Type**	**Inclusion:** .LVEF ≤35%. .Medtronic ICD or CRT-D with thoracic impedance measurement capabilities (OptiVol). **Exclusion:**	FU:16 months Total events: 0.59 in RM vs. 0.93 events per pt/year in control arm. P<0.005 Number of urgent visits pt/year for heart failure, arrhythmias, or ICD-related: 4.4 in RM vs 5.7 in control. P<0.001 Time from ICD alert to review: 1.4 days in RM vs 24.8 days in control p<0.001 . Costs €1962 vs €2130 p=0.8 . Costs for pts: €291 versus €381 Cost-utility: pts in RM had a cost saving of €888 per-pt and gained 0.065 QALYs more over 16 m. P<0.01		**Limitations:** The results were obtained with ICD/CRT-D equipped with advanced diagnostic and alerting capabilities and cannot be fully extended to different technologies. The study was not powered to demonstrate reduction in hospitalization **Conclusions:** RM reduced emergency department or urgent in-office visits and health care use. RM increased efficiency of healthcare . No significant annual cost savings for the health care system. . Significant reduction of the annual cost for the pts and gained QALYs in the RM arm

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Randomized. prospective, multicenter **Size** 200 patients				
Varma N, et al. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial **Year Published:** 2010 **PMID:** 20716717 **Study Name:** TRUST follow-up	**Aim:** To prospectively evaluate and compare in-person evaluations and automatic remote home monitoring in checking the performance of ICD generators and leads **Endpoints:** **Study Type:** Randomized. prospective, multicenter **Size** 1339 patients	**Inclusion:** **Exclusion:** As in TRUST Trial	Sixty-two device-related events (53 in HM versus 9 in conventional) were observed in 46 patients (40 [4.4%] in HM versus 6 [1.39%] in conventional, P=0.004). Forty-seven percent were asymptomatic. HM detected generator and lead problems earlier (HM versus conventional: median, 1 versus 5 days; P=0.05).		**Limitations:** small number of failure in short-term follow-up **Conclusions:** Automatic HM enhanced discovery, permitted prompt detection, and facilitated management decisions.
Varma N, et al. Same-day discovery of implantable cardioverter defibrillator dysfunction in the TRUST remote monitoring trial: influence of contrasting messaging systems **Year Published:** 2013 **PMID:** 23258817 **Study Name:** TRUST	**Aim:** To assess whether automatic remote home monitoring (HM) permits same-day evaluation of ICD system dysfunction **Endpoints:** Detection time from event onset to physician evaluation **Study Type:** Randomized. prospective, multicenter	**Inclusion:** **Exclusion:** As in TRUST Trial	Forty-three system-related alerts occurred; 42% were asymptomatic, 42% were actionable, and 22 of 43 (51%) were viewed within 24 h. 11/18 (61%) redundant notifications (ERI, pacing or shock impedance anormalities) were detected in < 24 hours		**Limitations:** A relatively small number of system-related events occurred in this short-term post-implant study **Conclusions:** Same-day discovery of ICD dysfunction, even if asymptomatic, was achievable. For those events not evaluated within 24 h, repetitive messaging promoted earlier discovery

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Size 908 patients from TRUST				
2.3 Remote Monitoring Payment/Reimbursement Models					
Boriani G, et al. Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial **Year Published:** 2016 **PMID:** 27568392 **Study Name:** MORE-CARE	**Aim:** To evaluate the clinical efficacy and safety of RM in CRT-D **Endpoints:** primary endpoint (deaths, cardiovascular or device-related hospitalizations). Economic endpoints: Healthcare resource and costs at 2 years **Study Type:** prospective, multicentre, randomized controlled trial **Size:** n=918	**Inclusion:** *de novo* implant of a Medtronic CRT-D with wireless transmission capabilities within the last 8 weeks before enrolment **Exclusion:** NA	1) Assuming a device clinic managing 100 patients, cost saving from RM was €2899 at 2 years driven by a 41% reduction in scheduled outpatient visits, despite a small increase in unscheduled visits, but no increase in ED admissions. 2) Cost-savings from patient perspective (Estimated 2-year expenses for patient travel were €373 in the Remote arm and €518 in the Standard arm (i.e., cost saving of €145).	Reduction in scheduled outpatient visits was important from an economic perspective since most of device follow-ups are routine checks with no actionable events or device programming.	**Perspective:** Italian health system and patient **Limitations:** Costing based on tariffs rather than prospectively collecting cost/billing data. Application of Italian tariffs to entire trial population enrolled from multiple centers (patterns of health resource use may vary between countries). **Conclusions:** RM is cost savings from the perspective of the health system and the patient.
Heidbuchel H, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring **Year Published:** 2015 **PMID:** 25179766 **Study Name:** EuroEco	**Aim:** To evaluate the cost for providers when relying on Home Monitoring (HM)-based FU compared with classical FU with only in-office visits. **Endpoints:** 1) total FU-related cost for providers; 2) rate of in-office FU visits with relevant	**Inclusion:** de novo or replacement VVI or DDD Biotronik ICD, age ≥ 18y **Exclusion:** NA	1) The total FU cost for providers was not different for HM ON vs. OFF [mean (95% CI): €204 (169–238) vs. €213 (182–243)]. From a payer perspective, FU-related costs were similar while the total cost per patient (including other physician visits, examinations, and hospitalizations) was numerically (but not significantly) lower. There was no difference in the net financial impact on providers [profit of €408 (327–489) vs. €400 (345–455); range for difference (€−104 to 88), NS]	There are country-dependent variations in provider costs and income. Although provider costs for follow-up are similar for HM ON or OFF patients in all countries, the net income impact of either follow-up strategy is dependent on the existing reimbursement provision for RM-activities.	**Perspective:** Health provider and health system payer (Belgium, Netherlands, Germany, UK, Spain) **Limitations:** Cost data were derived from country-based national databases and tariffs, rather than prospective microcosting data (increased imprecision). Only a few centres per country participated in the trial; patterns of health resource

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	findings; 3) quality of life **Study Type:** randomized, non-blinded, parallel-design trial **Size:** n=312, 1:1 randomization				use may not reflect average practice in each country. **Conclusions:** FU-related costs for providers are not different for remote FU vs. purely in-office FU, despite reorganized care. However, there was differential impact on provider budget among countries which suggests a need for proper reimbursement to ensure effective RM implementation.
Health Quality Ontario Remote Monitoring of Implantable Cardioverter-Defibrillators, Cardiac Resynchronization Therapy and Permanent Pacemakers: A Health Technology Assessment **Year Published:** 2018 **PMID:** 30443279	**Aim**: To conduct a health technology assessment of remote monitoring of ICDs, CRTs, and permanent pacemakers plus clinic visits compared with clinic visits alone. **Endpoints:** Clinical benefits and harms, value for money, and patient preferences. **Study Type:** Health technology assessment including cost-utility analysis (Markov model) **Size:** NA	**Inclusion:** Hypothetical ICD/CRT cohort with average age of 65 years, 70% men and NYHA Class II symptoms; hypothetical pacemaker cohort with average age 70 years old and 65% men **Exclusion:** NA	1) Among ICD and CRT-D recipients, RM plus clinic visits provided greater health gains for an incremental cost compared to clinic visits alone. The point estimate for the ICER was $23,374 per QALY gained. Using a $50,000 per QALY gained willingness-to-pay threshold, RM was cost-effective in 71% of simulations. 2) Among pacemaker recipients, RM plus clinic visits provided greater health benefits at lower costs compared to clinic visits alone (cost-savings). Assuming a willingness-to-pay threshold of $50,000 per QALY gained, 53% of simulations were dominant (lower cost, more effective), 20% were cost-effective (increased costs, more effective, but below threshold).	Factors that had the most impact on the economic model were the probabilities of emergency visits and hospitalizations, since these events were the main drivers of cost.	**Perspective**: Ontario Ministry of Health and Long-Term Care (Canadian provincial health system payer) **Limitations:** May not be generalizable to other health system settings. RM follow up was alternating between remote monitoring plus clinic visits every 6 months for ICD and CRT-D recipients and every year for pacemaker recipients. Analysis did not include downstream costs of battery replacement (i.e., complications), patient costs (i.e., out-of-pocket travel expenses), or societal costs. **Conclusions:** Remote monitoring is a cost-effective option for patients implanted with cardiac electronic devices.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Ricci RP, et al. Economic analysis of remote monitoring of cardiac implantable electronic devices: Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study **Year Published:** 2017 **PMID:** 27614025 **Study Name:** TARIFF	**Aim:** To assess cost and benefits of RM versus standard care (SC) **Endpoints:** health resource use, costs, patient expenses **Study Type:** Prospective observational, non-randomized study **Size:** n=209 (102 RM, 107 SC)	**Inclusion:** *de novo* implants of St. Jude ICD or CRT for standard indications **Exclusion:** NA	1) Overall mean annual cost per patient in the SC group (€1044.89 ± €1990.47) was significantly higher than in the RM group (€482.87 ± €2488.10) ($P < .0001$), with a cost reduction of 54% being achieved in the RM group. 2) The annual cost incurred by patients was significantly higher in the SC group than in the RM group (SC: €169.49 ± €189.50 vs RM: €56.87 ± €80.22; $P < .0001$)	The primary driver of cost reduction was the cost of cardiovascular hospitalizations (SC: €886.67 ± €1979.13 vs RM: €432.34 ± €2488.10; $P = .0030$).	**Perspective:** Healthcare system and patients (Italian) **Limitations:** Non-randomize cohort, potential selection bias re: RM participation. **Conclusions:** RM of patients with CIEDs is cost saving from the perspectives of the healthcare system, patients, and caregivers.
Sequeira S, et al. Cost-effectiveness of remote monitoring of implantable cardioverter-defibrillators in France: a meta-analysis and an integrated economic model derived from randomized controlled trials **Year Published:** 2020 **PMID:** 32424395	**Aim:** (i) To perform a systematic review identifying all RCTs comparing RM vs. standard care (SC), (ii) to conduct a meta-analysis evaluating clinical outcomes and cost, and (iii) cost-effectiveness study comparing RM to SC **Endpoints:** Costs, QALY, Incremental cost effectiveness ratio (ICER) **Study Type:** Cost-utility analysis (Markov model) **Size:** NA	**Inclusion:** Hypothetical cohort of patients discharged from hospital following ICD ± CRT-D implantation. **Exclusion:** NA	1) RM provided a cost-saving of €4142.32 and a QALY gain of 0.29 compared to SC per patient over 5 years. 2) RM was the preferred strategy over SC in 70% of cases	Findings of cost-effectiveness analysis consistent with author's systematic review of studies reporting costs and health resource use between RM and SC. Annual costs per patient for direct healthcare costs (seven studies, difference in means −276.1, 95% standard error [SE]: 66.0, $I^2 = 76.3\%$).	**Perspective:** French healthcare system **Limitations**: Marked difference in cost-savings estimated in base case deterministic sensitivity analysis and probabilistic sensitivity analysis. Limited data on quality of life / utilities. **Conclusions:** RM is cost-effective and a dominant solution over in-clinic management.
Burri H, et al. Cost-consequence analysis of daily continuous remote monitoring of implantable cardiac defibrillator	**Aim**: To compare the long-term cost and consequences of using daily Home Monitoring® (HM)	**Inclusion:** Hypothetical cohort of patients who have undergone an ICD or CRT-D implantation and are	1) Over a 10-year time horizon, HM is predicted to be cost neutral in either treatment arm (-£34), with all costs for the initial investment into HM and	The model is conservative, without assuming a reduction of cardiovascular events by HM such as	**Perspective:** UK National Health Service perspective **Limitations:** Lack of probabilistic sensitivity analysis to account for

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
and resynchronization devices in the UK **Year Published:** 2013 **PMID:** 23599169	instead of conventional periodical in clinic follow up. **Endpoints:** Costs, and clinical / device events (incl. scheduled and unscheduled FU visits, battery replacements, lead malfunctions, atrial fibrillation/flutter (AF), inappropriate shocks, stroke, hospital admission for heart failure, sustained ventricular arrhythmias, appropriate shocks, and death. **Study Type:** Cost-consequence analysis (Markov model) **Size:** NA	managed in an outpatient setting **Exclusion**: NA	fees for ongoing remote monitoring included. 2) There were fewer inappropriate shocks (−51%), and prolonged battery life in the RM arm due to the reduced the need for replacing devices for battery depletion (−7%). 3) The number of follow up visits was predicted to be halved by HM.	decompensated heart failure or mortality, or considering cost savings such as for transportation.	uncertainty in model inputs. Cost difference dependent on time horizon (cost-savings at 15 years). Authors unclear regarding choice of 10-year time horizon for base case analyses. **Conclusions:** HM is cost neutral over 10 years. This is mainly accomplished by reducing the number of battery charges and inappropriate shocks, resulting in fewer device replacements, and by reducing the number of in-clinic FU visits.
Guedon-Moreau L, et al. Costs of remote monitoring vs. ambulatory follow-ups of implanted cardioverter defibrillators in the randomized ECOST study **Year Published:** 2014 **PMID:** 24614572 **Study Name:** ECOST	**Aim**: To evaluate the economic impact of long-term RM of ICDs from the ECOST trial. **Endpoints:** Costs per patient **Study Type**: Prospective economic substudy alongside	**Inclusion:** Patients undergoing implantation of a single- or dual-chamber ICD compatible with a Biotronik Home Monitoring® system. **Exclusion:** NA	1) Over a follow-up of 27 months, the mean non-hospital costs per patient-year were €1695 ± 1131 in the active, vs. €1952 ± 1023 in the control group (P = 0.04), a €257 difference mainly due to device management. 2) Hospitalization costs per patient-year were €2829 ± 6382 and €3549 ± 9714 in the active and control groups, respectively (P = 0.46)	The patient preferred ICD follow-up strategy was based on 194 (44.8%) questionnaires completed at the end of the study. A preference in favour of RM was expressed by 73.7% of patients assigned to the active group vs. 65.3% assigned	**Perspective:** French health insurance system **Limitations:** Of 433 enrolled in ECOST trial, only 310 (71.6%) provided consent to use hospital billing information for economic evaluation substudy. **Conclusions**: From the French health insurance perspective,

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	randomized control trial (ECOST). **Size:** n=310 (1:1 randomization to RM (active group) vs. ambulatory follow-ups (control group))		3) Adding the ICD to the non-hospital costs (total costs), the savings were €494 (P = 0.005) or, when the monitoring system was included, €315 (P = 0.05) per patient-year.	to the control group (*P* = 0.21).	the remote management of ICD patients is cost saving.
Bautista-Mesa RJ, et al. Long-term cost-utility analysis of remote monitoring of older patients with pacemakers: the PONIENTE study **Year Published:** 2020 **PMID:** 33198629 **Study Name:** PONIENTE	**Aim**: To perform a cost-utility analysis comparing remote monitoring (RM) versus conventional monitoring (CM) in hospital of older patients with pacemakers, 5 years after implant. **Endpoints**: **Study Type**: Cost-utility analysis of a retrospective cohort of patients with pacemakers **Size:** n=83	**Inclusion:** older patients (81 years old on average) recruited in the Poniente Hospital (Almeria–Spain) implanted with commercially available pacemakers equipped with the Medtronic CareLink® Network **Exclusion**: NA	1) Total costs per patient were 23% lower for the RM group than the control group, corresponding to a saving of €82.10 per patient (RM: €274.52 ± 128.45; CM: €356.62 ± 144.12; *p* = 0.033). 2) The reduction of in-hospital visits derived from RM exhibited insignificant impact on the costs from the PHS perspective (€215.48 RM vs. €253.64 CM; *p* = 0.144).	No difference in distance between home and hospital between RM and control groups. However, there was a significant reduction of travel cost for patients in RM group (€17.11 ± 14.81) in compared to CM group (€42.42 ± 46.49) (*p* = 0.006). From the perspective of the patient/caregiver, RM provided a cost saving of 42.66% (RM: €59.05 ± 43.24; CM: €102.98 ± 58.77; *p* = 0.002).	**Perspective:** Spanish public health system, patient perspective **Limitations:** Economic study based on small, non-randomized retrospective study. RM assignment based on patient preference introducing selection bias. **Conclusions:** RM of older patients with pacemakers is cost-savings driven by decreased patient borne costs, rather than reduced inhospital / clinic costs.
Buchta P, et al. The impact of remote monitoring of implanted cardioverter-defibrillator (ICD) and cardiac resynchronisation therapy device (CRT-D) patients on healthcare costs in the Silesian population: three-year follow-up **Year Published:** 2017 **PMID:** 28150288	**Aim:** To assess the impact on costs for the healthcare system of RM in patients with ICD or CRT-D. **Endpoints:** Direct costs per patient **Study Type:** Retrospective cohort study	**Inclusion:** Patients with first implantation or generator exchange of a single- or dual-chamber ICD or CRT-D for primary or secondary prophylaxis of sudden cardiac death **Exclusion:** NA	1) After matching, there were 287 patients in each group. Mean age was 62 years, mean LVEF was 25% and a CRT-D was implanted in 49% ofpatients. 2) Over 3-years of follow up, there was a cost reduction of 34% in the RM group compared to non-RM group. Cost reduction was greater among those with CRT-Ds (43% reduction) versus ICDs along (31% cost reduction)	The costs of outpatient visits were slightly higher in the RM group (p = NS). In the follow-up period, there was no reduction in the number of medical contact events (p = NS)	**Perspective:** Polish national health insurance payer **Limitations**: Study unable to quantify number of transmissions (which underestimates costs associated with RM group in the setting of device clinic time to review data). Underestimation of physician costs as private consulting fees not captured.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	(matched RM and non-RM cohorts) **Size:** 842 patients				**Conclusions:** RM of ICDs or CRT-Ds reduces costs from the perspective of the Polish healthcare payer.
Calo L, et al. Economic impact of remote monitoring on ordinary follow-up of implantable cardioverter defibrillators as compared with conventional in-hospital visits. A single-center prospective and randomized study **Year Published:** 2013 **PMID:** 23515883	**Aim:** To compare the direct costs of 1-year ICD follow-up based on RM compared with conventional quarterly in-hospital follow-ups. **Endpoints:** Direct costs **Study Type:** single-center prospective and randomized study **Size:** n=233	**Inclusion:** Patients with standard indications for ICD with or without CRT. No restriction in selecting implant devices or RM systems. **Exclusion:** NA	1) The costs associated with RM and standard follow-up were USD 103 ± 27 and 154 ± 21 per patient/year, respectively (p = 0.01). 2) The hospital costs associated with RM strategy were lower than for standard follow-up strategy, with cost savings of almost USD 50.14 per patient/year 3) In terms of societal costs, RM resulted in reduction of costs for the patients, who enjoyed mean cost savings of about USD 191 per year.	The number of scheduled in-hospital visits was significantly lower in the RM group than in the control group. The time spent by hospital staff was significantly reduced in the RM group (with a gain of 56 min per patient/year); the difference between the two groups was mainly due to a shorter time spent by physicians on follow-up activities.	**Perspective:** Italy National Health Service **Limitations:** Single center, small cohort, use of DRG gross costing rather than microcosting methods with hospital bills **Conclusions:** The time spent by the hospital staff was significantly reduced in the RM group. If the costs for the RM system service are not charged to patients or the provider, patients could save about USD 190 per patient/year while the hospital could save USD 51 per patient/year.
Capucci A, et al. Economic impact of remote monitoring after implantable defibrillators implantation in heart failure patients: an analysis from the EFFECT study **Year Published:** 2017 **PMID:** 28407139 **Study Name:** EFFECT analysis	**Aim:** To conduct an economic evaluation of the results from the EFFECT trial, which was a multicentre observational study that evaluated the clinical effectiveness of RM compared with in-office visits standard management (SM)	**Inclusion**: Patients who had undergone ICD/CRT-D implantation in 25 Italian centres **Exclusion:** NA	1) In the non-adjusted analysis, the annual cost for each patient was €817 in the SM group and €604 in the RM group (*P* = 0.014). 2) In the propensity score analysis, in which 292 RM patients were matched with 292 SM patients, confirmed the results of the non-adjusted analysis (€872 in the SM group vs. €757 in the RM group; *P* < 0.0001). There was a cost reduction of €115.	The rate of hospitalizations was 0.27/year in the SM group and 0.16/year in the RM group (risk reduction =0.59; *P* = 0.0004).	**Perspective:** Italy National Health Service **Limitations:** Lack of study randomization. Did not include sensitivity analyses to account for uncertainty in cost sources or clinical effectiveness of RM. **Conclusions:** There is a reduction in direct healthcare costs of RM (€115) for HF patients with ICDs, particularly CRT-D, compared to standard monitoring.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Endpoints: Direct costs at 12 months **Study Type:** Multicentre observational study. Economic substudy used propensity score matching to take into account the lack of randomization in the study design. **Size:** n=858				
Chew DS, et al. Clinical and Economic Outcomes Associated with Remote Monitoring for Cardiac Implantable Electronic Devices: A Population-Based Analysis **Year Published:** 2022 **PMID:** 35093464	**Aim:** To assess the clinical and economic outcomes associated with remote monitoring from the perspective of the Canadian public healthcare system **Endpoints:** Costs, QALYs **Study Type:** Population-based cohort study to identify clinical effectiveness and cost inputs for cost-utility analysis (Markov model). **Size:** n=2,799	**Inclusion:** adults with *de novo* ICD or CRT-D implantation **Exclusion:** NA	1) Cost savings were observed over 5 years with an estimated savings of $12,195 per person (95% CI -$21,818 to -$4,790). 2) The model estimated a cost-savings associated with RM strategy in 99% of simulations.	The input with the greatest variation effect on the results was the annual mean cost difference between RM and in-clinic groups for inpatient hospitalizations. The differences in hospitalization rates and inpatient costs were the primary driver of cost savings in the model.	**Perspective:** Canadian public healthcare payer **Limitations:** Non-randomization (RM and non RM-groups) may subject findings to residual confounding from unmeasured factors. Microcosting data were not available as inputs, which may underestimate the patient-level heterogeneity in costs **Conclusions:** RM technology was associated with improved patient outcomes and cost savings. These data support greater implementation of RM technology to improve health system efficiency.
Hummel JP, et al. Outcomes and costs of remote patient monitoring among patients with implanted cardiac	**Aim:** To assess the long-term economic benefits from the PREDICT RM database, which	**Inclusion:** Patients (ages 65 to 89) who received a Boston Scientific device from 2006 to 2010 **Exclusion:** NA	1) Compared with no RPM, RPM was associated with an incremental gain of 0.64 QALYs and an increase in costs of $6914, resulting in an	Patients with RM had fewer subsequent rehospitalizations (by 0.08 per patient-year) and lower hospitalization	**Perspective:** US Medicare payer **Limitations:** Model inputs drawn from non-randomized observational data. Data

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
defibrillators: An economic model based on the PREDICT RM database **Year Published:** 2019 **PMID:** 30938894	compared outcomes with and without remote monitoring. **Endpoints:** rehospitalization, mortality, and the cost-effectiveness **Study Type:** Cost-utility analysis using Discretely Integrated Condition Event (DICE) simulation. **Size:** n=15,254		incremental cost-effectiveness ratio (ICER) of $10,752/QALY.	costs (by $554 per patient year) offset by higher outpatient and physician claims.	drawn from Medicare population (age>65), which limits extrapolation to younger patient populations. **Conclusions:** RPM was associated with improved survival, reduced hospitalization rates, and decreased healthcare costs PPY when compared with conventional care. Even when RPM does not have a direct effect on mortality, RPM is the preferred strategy, dominating no RPM.
Ladapo JA, et al. Health Care Utilization and Expenditures Associated With Remote Monitoring in Patients With Implantable Cardiac Devices **Year Published:** 2016 **PMID:** 26996767	**Aim:** To compare health care utilization and expenditures associated with remote monitoring and in-office monitoring in patients with CIEDs **Endpoints:** health resource utilization, expeditures **Study Type:** Population-based cohort study using the Truven Health MarketScan Commercial Claims and Medicare Supplemental Databases	**Inclusion:** patients newly implanted with an ICD, CRT-D, or pacemaker **Exclusion:** NA	1) Remote monitoring was associated with lower health care expenditures in office visits among patients with PPMs (mean difference -$-70; p=0.025) and CRT-Ds (mean difference -$-180; p=0.006) 2) RM was assocaited with lower total inpatient and outpatient expenditures in patients with ICDs (mean difference -$4269; p <0.0001)	Patients with CIEDs who were followed with RM over a 24-month period tended to experience similar or less frequent utilization of emergency and hospital care, compared with those followed in the office alone, with reductions in utilization most pronounced among remotely monitored patients with ICDs.	**Perspective**: US commercial insurance payer **Limitations:** Non-randomized data. Authors used propensity score matching, but there still is the possibility of residual confounding from unmeasured factors. Patient population includes individuals enrolled in the Truven Marketscan database; patients who are uninsured or enrolled in other health plans are not captured in these administrative claims data **Conclusions:** RM of patients with CIEDs may be associated with reductions in health care utilization and expenditures compared with exclusive in-office care

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Size: ICD (n=2,254), CRT-D (n=854), PM (n=2590)				
Mairesse GH, et al. Implementation and reimbursement of remote monitoring for cardiac implantable electronic devices in Europe: a survey from the health economics committee of the European Heart Rhythm Association **Year Published:** 2015 **PMID:** 25713012	**Aim:** To assess the implementation and funding of RM of CIEDs in Europe **Endpoints:** frequency of surveillance of RM and the effect of RM on in-office visits **Study Type:** Survey **Size:** 43 centres in 15 European countries	**Inclusion:** 152 centres participating in the EHRA Electrophysiology research network **Exclusion:** NA	1) RM was available in 22% of PM patients, 74% of ICD patients, and 69% of CRT patients. 2) Physicians report that RM has clinically significant applications and that its implementation has led to reductions in in-office visits. This, however, has been achieved at the expense of an increased workload without appropriate reimbursement.	Lack of reimbursement was the most frequently reported barrier to the implementation of RM, affecting over 80% of centres for all devices.	**Limitations:** Survey limited to a minority of European centres across the EHRA network. Low response rate. **Conclusions**: Physicians perceive that RM of CIEDs as a clinically useful technology, which leads to reductions in in-office consultations. However, RM is perceived as increasing workload. Reimbursement for RM is generally lacking and this is perceived as a major barrier to implementation.
Piccini JP, et al. Impact of remote monitoring on clinical events and associated health care utilization: A nationwide assessment **Year Published:** 2016 **PMID:** 27544748	**Aim:** To determine whether RM was associated with reduced hospitalization and costs in clinical practice **Endpoints:** all-cause hospitalization, health care expenditures **Study Type:** Population based cohort study using the Truven Health Analytics MarketScan database	**Inclusion**: Patients implanted with PM, ICD, CRT from any manufacturer between March 31, 2009, and April 1, 2012. **Exclusion:** Patients without follow-up and those without a clinic visit or RM follow-up within 120 days of implant	1) cohort characteristics: mean age 72 ± 13 years; 63% men; mean follow-up of 19 ± 12 months; 59% pacemaker, 30% ICD and 11% CRT 2) Only 37% used RM 3) RM was associated with a 30% reduction in hospitalization costs ($8720 mean cost per patient-year vs $12,423 mean cost per patient-year) 4) For every 100,000 patient-years of follow-up, RM was associated with 9810 fewer hospitalizations, 119,000 fewer days in hospital, and $370,270,000 lower hospital payments.	Patients with RM had lower adjusted risk of all-cause hospitalization (adjusted hazard ratio 0.82; 95% confidence interval 0.80–0.84; *P* < .001) and shorter mean length of hospitalization (5.3 days vs 8.1 days; *P* < .001) during follow up.	**Limitations:** Retrospective analysis, and unable to exclude residual or unmeasured confounding. Study focuses on hospitalization expenditures only. **Conclusions:** RM is associated with reductions in all-cause hospitalization and associated health care costs.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Size: n=92,566				
Chew, et al. Alert-driven vs scheduled remote monitoring of implantable cardiac defibrillators: A cost–consequence analysis from the TRUST trial **Year Published:** 2022 **PMID:** 36503177	**Aim:** To conduct a cost-consequence analysis to compare 3 postimplant implantable cardioverter-defibrillator (ICD) follow-up strategies: (1) in-person evaluation (IPE) only; (2) RPM-conventional (hybrid of IPE and RPM); and (3) RPM-alert (alert-based ICD follow-up) **Endpoints:** Incremental Cost **Study Type:** Cost-utility analysis using aggregate and patient-level data from the TRUST trial **Size:** NA	**Inclusion:** Hypothetical cohort of patients with single- or dual-chamber ICDs capable of home monitoring and implanted for class I/II indications. **Exclusion:** NA	1) Mean cumulative follow-up costs per patient were $12,688 in the IPE group, $12,001 in the RPM–conventional group, and $11,011 in the RPM–alert group. 2) Compared to the IPE group, both the RPM–conventional and RPM–alert groups were associated with lower incremental costs of –$687 (95% confidence interval [CI] –$2138 to +$638) and –$1,677 (95% CI –$3134 to –$304), respectively. 3) RPM–alert strategy was most cost-effective, with an estimated cost-savings in 99% of simulations.	In a post-hoc threshold analysis, reimbursement could be increased up to $162 per remote assessment, in which the RPM–conventional strategy would be cost-neutral and the RPM–alert strategy would remain cost-savings compared to the IPE strategy.	**Perspective:** US Medicare payer **Limitations:** Clinical effectiveness inputs were primarily based on a single randomized controlled trial that enrolled patients >10 years ago using a remote monitoring platform from a single manufacturer. RPM–alert strategy was not directly assessed in the TRUST trial but was modeled based on the outcomes during the exclusive remote monitoring period **Conclusions:** Alert-based RPM with minimized scheduled evaluation (in-person or remote assessment) is an efficient model of care. This approach is cost-savings compared to both conventional RPM and clinic-only follow-up strategies.
Section 3 Administrative and nonclinical staff					
3.1 Patient Enrollment Techniques					
Mittal S, et al. Improved survival in patients enrolled promptly into remote monitoring following cardiac implantable electronic device implantation **Year Published:** 2016 **PMID:** 26860839	**Aim:** To compare patient outcome according to timing of RM initiation **Endpoints:** all-cause mortality **Study Type:** retrospective, nationwide,	**Inclusion:** new CIED implants (Abbott) **Exclusion:** ILR; non-automatic RM devices; follow-up <90 days; enrolled in another trial; RM initiated >1y after implant	**Intervention:** Prompt RM initiation (<91 days) **Comparator:** Delayed RM initiation (91-365 days) **Results:** Overall FU 2.61 years. 18% improved survival in prompt RM group. HR 1.18 (95% CI 1.13 -1.22; p<0.001).		**Limitations:** Very limited demographics available (only age, sex, race, and some socio-economic class). **Conclusions:** Prompt initiation of RM my improve patient survival.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	observational cohort study **Size:** n=106 027		Consistent in all CIED subgroups, largest in CRT-D (HR 1.20 (1.13-1.28, p<0.001).		
Varma N, et al. Role of Automatic Wireless Remote Monitoring Immediately Following ICD Implant: The Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) Trial **Year Published:** 2016 **PMID:** 26661687 **Study Name:** TRUST follow-up	**Aim:** To study the role of automated RM immediately after ICD implant **Endpoints:** need for in-person evaluation (IPE) in the first 3 m **Study Type:** multicenter, prospective RCT **Size:** n=1339 Home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	In first 3 m: 85% HM vs 88% controls had no IPE (p=0.31). In case of IPE, actionability was non-significant higher in HM (36.2% vs 24.2%, p=0.12). Time to actionable event detection was shorter with HM (p=0.025). HM did not result in an increase in non-actionable IPEs (p=0.72).	Enhanced arrhythmia detection in HM (mostly silent arrhythmic episodes). More device reprogramming / lead revision in first 3 months in HM group (30% vs 15%, p=0.018). 64% of HM-driven IPEs were actionable.	**Limitations:** Low incidence of device-related events in first 3 months. Endpoints such as actionability are surrogate endpoints. **Conclusions:** Automatic remote monitoring should be activated soon after implant.
Section 4 Staffing of remote monitoring clinics					
4.1 Recommended Staffing Requirements for Remote Monitoring					
Afzal MR, et al. Resource Use and Economic Implications of Remote Monitoring With Subcutaneous Cardiac Rhythm Monitors **Year Published:** 2021 **PMID:** 33516715	**Aim:** Reports resource use and economic implications of rhythm monitoring with subcutaneous cardiac rhythm monitoring. **Endpoints:** Resource assessment included time commitment of personnel of device clinic and	**Inclusion:** All transmissions received from subcutaneous cardiac rhythm monitors followed in a single center. **Exclusion:** None	1,457 transmissions were received during study period- 462 alerts/995 full downloads. Average device clinic personnel time for adjudication for 1 transmission was average of 15 ± 6 minutes which totaled 364 hours over a 4 week period divided among 2.3 full time staff. The average time spent for the electrophysiologist was 1.5 ± 1 minutes which totaled 37 hours. The total cost for personnel translates into a salary cost of $12,000 US dollars and an estimated cost of $9600 US dollars. Of the 1427 transmissions, 512 (35%) resulted in		**Limitations:** Single center study and may not be translatable to other centers. The resource utilization heavily dependent on the expertise of device personnel and electrophysiologist. The findings might be variable in low volume centers who may use cardiologists to staff remote monitoring. **Conclusions:** Ambulatory rhythm monitoring for subcutaneous cardiac rhythm monitoring requires significant

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	electrophysiologist time for data adjudication, incidence and characteristics of false positives. The impact of custom programing on false positives and resources was analyzed. **Study Type:** Analysis of consecutive transmission during a 4 week period in a single center adult device clinic. **Size:** Review of 1457 transmissions from 1,811 subcutaneous cardiac rhythm monitors implanted between 1/2017-9/2019.		no additional reimbursement as they were multiple transmissions from a single patient. Overall combined incidence of false positives was 50%. The incidence of false positives was higher in the alert (60%) compared to full download (49%) (p=0.04). Custom programming was utilized in 205 consecutive patients.		resources for timely adjudication. Custom programming for arrhythmia detection can mitigate the high incidence of false positives and minimize resource use for data adjudication.
Ricci RP, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry **Year Published:** 2013 **PMID:** 23362021	**Aim:** 1. Implementation of Home Guide model for remote monitoring for CIEDs which includes expert nurses and responsible physician with an agreed list of	**Inclusion:** Adult patients with Biotronik Home Monitoring within the 75 Italian sites and enrolled between 3/2008-9/2011. **Exclusion:** None	Mean follow up of 20.4 ± 12.6 months, 3364 home monitoring sessions were performed during which 15,984 patient reports were reviewed. Each session had a median duration of 5.5 (2.0-11.1) minutes to review 3 (1-6) patient reports if conducted by a nurse and 4.6 (1.8-10.5 minutes) to review 2 (1-4) patient reports if conducted by a physician.		**Limitations** Unable to confirm generalization to all Home monitoring practices as work flow is not universal. **Conclusions** Implementation of the HomeGuide model showed patient clinic workload and resource consumption was remarkable low.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	respective tasks and responsibilities. 2. Collect and document all major cardiovascular events that are normally observed and managed to assess the rate of events and to measure the healthcare resources needed. **Endpoints:** NA **Study Type:** Investigator-initiated prospective multicenter observational study. **Size:** 1650 patients-3364 home monitoring sessions, enrolled in 75 Italian centers		Overall, the HomeGuide model workflow, home monitoring required a median 55.5 (22-107.0) minutes x health personnel per month every 100 patients.		
Husser D, et al. Remote monitoring and clinical outcomes: details on information flow and workflow in the IN-TIME study **Year Published:** 2019 **PMID:** 30016396 **Study Name:** IN-TIME	**Aim:** Analyzes the information flow and work flow details from the IN-TIME study. **Endpoints:** Differences of message content, information speed and completeness and workflow which may contribute to	**Inclusion:** Patients enrolled in the IN-TIME randomized controlled trial. **Exclusion:** NA	After 12 months, all-cause mortality was improved with the remote monitoring arm. On average, 113 patients (between 73-140) were followed by the central monitoring unit for the study period of 104 weeks. The central monitoring unit sent 938 alerts or 1.29 alerts per day. Most alerts were sent Mondays which included the backlog from the weekend since per protocol, the		**Limitations:** The data from this study is derived from working days (mon-Fri) and did not include all days in real time**.** The data from the medical event to clinical action could not be recreated exactly. **Conclusions:** Only limited data on information flow and workflow have been published prior to this study. A

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	heterogenous results. **Study Type:** IN-TIME was a randomized controlled trial. These results are published elsewhere. This is a follow up study with the above specific aims. **Size:** 644 patients with ICD were randomized to daily remote monitoring (n= 333) vs control n=331).		central monitoring unit did not work most weekends. Patients were contacted a median delay of 1 day (IQR 0-6 days).		comparison to those data to IN-TIME, suggests that the ability to see a patient earlier after clinical events may be inferior to the IN-TIME set up.
Dario C, et al. Large Controlled Observational Study on Remote Monitoring of Pacemakers and Implantable Cardiac Defibrillators: A Clinical, Economic, and Organizational Evaluation **Year Published:** 2016 **PMID:** 26764170	**Aim:** Analyze the impact of remote monitoring for pacemaker and ICD in a "real world" connect compared with in person follow up. **Endpoints:** The following outcomes were considered: specialist visits, hospital admission for any causse, emergency room visits, timeliness of detection of acute episodes recorded by the device,	**Inclusion:** patients with a pacemaker/ICD who had given consent; > 18 years of age, not pregnant, absence of comorbidities, life expectancy > 12 months. **Exclusion:** those who did not fall into inclusion criteria	1871 patients were enrolled in the I-group (remote monitoring) and 230 in U group (control-in clinic visits) from 10/2011-11/2012. There were no important differences between the 2 groups. There was no significant difference in mortality between the I-group and U-group. Organizational Evaluation: None of the facilities had integrated remote monitoring data with cardiology EMR. As a result, staff used different portals to access data and had to manually enter results. About 48% (7.3/15.2 minutes per patient per year of time was spent by nurses entering data into the EMR and to communicate with the patient. The mean time spent by physicians and		**Limitations:** The assignment to each group was not randomized. The U group was significantly smaller than the I group. The use of 5 different vendors might have introduced a systematic bias in the assessment of remote monitoring performance. **Conclusions:** This study continues to support the evidence that remote monitoring increases effectiveness and efficiency in detecting and managing device alerts through limited use of personnel and resources. The reduction in time spent by physicians delivering care to pacemaker

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	workload and direct costs. **Study Type:** Multi center (6 cardiology departments in Italy), multi vendor, controlled observational, prospective study. **Size:** 2101 patients enrolled- 1871 in the I-group (enrolled in remote monitoring) and 230 enrolled in the U group (control group)		nurses for each group was reported. The I group (which includes the time of telemedicine service only and as the time spent to carry out remote monitoring plus in clinic follow up). The I group with clinic performed follow up was longer for physician-pacemaker patients, physician ICD patients and nurse ICD patients. The nurse pacemaker patients time was minimally lower in the control group. An economic analysis showed statistically significant gains (p=<0.001) for the pacemaker I-group.		and ICD patients in the I group compared to the U group was apparent.
Seiler A, et al. Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation **Year Published:** 2021 **PMID:** 34156344	**Aim -** To characterize the workflow and quantify clinic staff time requirements for managing patients with CIEDs. **Endpoints -** Mean cumulative staff times required to review remote device transmissions and perform in-person clinic visits (including all necessary clinical and administrative tasks). Annual staff time to manage a patient with a CIED	**Inclusion -** Workflow measurements included all CIED types (permanent pacemaker, ICD, CRT, ICM) all device manufacturers found within the clinic (Abbott, Biotronik, Boston Scientific, Medtronic, and Microport), and all activities related to managing patients with CIEDs categorized into 3 groups: in-person clinic visits, remote transmission review, and other patient management activities (eg, patient triage and scheduling, identifying patients lost to follow-up, and telephone	276 in-person clinic visits and 2173 remote monitoring activities were analyzed Mean staff time required per RM transmission: 9.4 to 13.5 minutes for therapeutic devices (pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy) and 11.3 to 12.9 minutes for insertable cardiac monitors (ICMs). Mean staff time per in-person visit was 37.8 to 51.0 min and 39.9 to 45.8 min for therapeutic devices and ICMs, respectively. The estimated annual time to manage a patient with a CIED (including all RM and in-person f/u)	A total of 54 distinct workflow steps were observed and timed	**Limitations -** Generalizability of these observations to other centers with different device populations and staffing resources is unknown. **Conclusions -** CIED patient management workflow was found to be substantial & complex, requiring significant staff time. Findings were consistent despite different geographical regions studied.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	was modeled using CIED transmission volumes, clinical guidelines, and published literature. **Study Type** - Time and motion workflow evaluation **Size** – 11 international clinics	communication with patients). **Exclusion -** Owing to insufficient data collection on remote transmission review workflow activities at the German site, these observations were excluded from the analysis.	was 1.6 to 2.4 hours for therapeutic devices and 7.7 to 9.3 hours for ICMs. The staff time required for other patient management tasks such as calling patients, troubleshooting device connectivity issues, identifying loss to follow-up, and triaging patients or transmissions was approximately 17.3 minutes per patient annually, translating to 1659.2 hours of staff time per year (31.9 hours per week).		
Maines M, et al. Implementation of remote follow-up of cardiac implantable electronic devices in clinical practice: organizational implications and resource consumption **Year Published:** 2020 **PMID:** 32628426	**Aim – To** evaluate the impact of adopting remote follow-up on the organization of a clinic and to measure healthcare resource utilization. **Endpoints –** 1) workload generated by a new organizational model as represented by number of transmissions received and managed over 1 year & number of in-hospital examinations performed, 2) total healthcare resource consumption, via mean time spent by	**Inclusion** All CIED patients actively on RM at this single center **Exclusion** Patients not on RM	"Primary Nursing" organizational model: Each patient is assigned to an experienced nurse and a doctor in charge, with established responsibilities: Nurse's duties included contact with the patient, educational interventions, uploading data to the website, systematic screening of data and identification of critical issues, review of transmissions and alarms, clinical discussion of critical cases with the physician, and filling out a report. Physicians validated the report entered into the patient's electronic medical record in the Trentino Region's database. Of 2024 active CIED patients, 1887 patients were on RM. 13,859 device transmissions were received Only 21% of transmissions were submitted to the physician for further		**Limitations –** Single-center, observational, non-randomized study in Italy only; may not be generalizable to other centers with different proportions of device types in active follow-up, different patient profiles, or different countries that may require additional documentation/administrative duties. **Conclusions –** Primary nursing model with specified protocols was able to be implemented and efficiently managed by nursing staff with minimal physician support in this single center Italian study.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	the nurse and physician in analyzing a single transmission, activating the service and performing in-hospital examinations over a 3 month period, 3) patient satisfaction questionnaire **Study Type -** Observational **Size** – 1887 remotely monitored CIED patients		clinical evaluation, and 3% of transmissions necessitated an unplanned in-hospital visit for further assessment. Nurses' total workload was 3596 h per year, = 1.95 FTE (1038 patients/nurse). Physicians workload was 526 h per year, (0.29FTE).		
Ryan P, et al. Enhancing efficiency in a cardiac investigations department by increasing remote patient monitoring **Year Published:** 2019 **PMID:** 31867661	**Aim -** To re-design processes and enable the expansion of RM To improve time management, work flow and optimize use of resources within RM services in a single center **Endpoints –** RM enrollment and unscheduled visits **Study Type -** Quality improvement via the LSS DMAIC (Lean Six Sigma Design, Measure, Analyse, Improve	**Inclusion** - CIED RM service within the single center 600 bed teaching hospital **Exclusion** n/a	Analysis of clinic data prior to LSS for a single month reveled 64% of patients were physically attending the clinic (of which 51% were unscheduled visits), with 24% of patients on RM. LSS implementation including recruitment of additional staff, improved use of physical space with dedicated cubicle for RM, additional computers for RM enrollment & RM, protecting staff time and space to ensure new eligible patients are registered for RM and that RM follow-ups occur as appropriate, and improvements in patient education, led to remote monitoring activity increasing by 194% (target 45%) with	Issues uncovered: • Lack of guidelines for recruitment and management of patients on RM • No dedicated cardiac physiologist rostered to RM • No dedicated office space for RM • Absence of RM education for patients • Lack of multidisciplinary awareness of issues	**Limitations –** single center study **Conclusions** - streamlined workflow reduced the number of unscheduled attendances to clinic and increased the use of RM among the eligible patient population allowing for safer, more timely responses to cardiac events and enhanced patient education & care quality.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	and Control) approach **Size** – Single center 600-bed teaching hospital in the Mater Misericordiae University Hospital, Dublin, Ireland		a70% decrease in unscheduled attendances (target 25%)	surrounding RM recruitment	
Andersen TO, et al. Unpacking telemonitoring work: Workload and telephone calls to patients in implanted cardiac device care **Year Published:** 2019 **PMID: 31445281**	**Aim –** To study the time and clinical workload involved in telephone contact to & from CIED patients on RM **Endpoints -**Time consumption and activity in the Remote section of the CIED Clinic Rigshospital, University of Copenhagen, Denmark **Study Type –** Single center combined quantitative and qualitative observational study **Size -** 260 encounters (beginning and end-time of a patient-to-clinician telephone call or a complete review of a transmission with/	**Inclusion –** Observation, audio recording and annotation of all remote follow-ups and telephone calls in the Remote section of the CIED clinic between 8 a.m. to noon, noon to 3 p.m., or the whole workday, over a 38-day period. **Exclusion –** Any work activities outside of the Remote section of the CIED clinic (ie Outpatient section, Acute section)	Average times to handle: Transmissions *without* events: 3.08 ± 0.30 min Transmissions *with* events but *without* telephone calls: 5.27 ± 1.38 min Transmissions *with* events *and* telephone call: 20.07 ± 8.10 min. Missed transmissions that did not require a telephone was 4.57 ± 1.47 min Missed transmissions slowed workflow efficiency leading to calls that consumed ~ hour / day In calls from patients to clinician most frequent topics were the home monitoring box (63%), transmission data (40%), symptoms (21%), and appointments (21%) In calls from clinicians to patients most common topics were transmission data (84%), symptoms (53%), appointments (32%) and medication (26%)	5 types of clinical work were performed: inclusion, coordination, diagnostic, education, and comfort. Inclusion work and diagnostic work were dominant.	**Limitations –** Single center study; type of transmission (i.e., scheduled, patient-initiated, device-initiated), or type of event e.g., AT/AF, VT/VF, lead or device problems, and antitachycardia therapies) were not analysed **Conclusions -** Telephone contact carries a high workload and should be recognized as integral to the clinical work in CIED remote monitoring.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	without a telephone call) were observed and analyzed		Calls from clinician to patient after an event generally took a longer time indicating higher complexity.		
Liljeroos M, et al. Patients' and Nurses' Experiences and Perceptions of Remote Monitoring of Implantable Cardiac Defibrillators in Heart Failure: Cross-Sectional, Descriptive, Mixed Methods Study **Year Published:** 2020 **PMID:** 32985997	**Aim - T**o describe, explore, and compare the experiences and perceptions, concerning remote patient monitoring (RPM) of ICD, of patients with heart failure (HF) and nurses performing ICD follow-up. **Endpoints –** A purpose-designed, 8-item questionnaire to assess experiences of RPM **Study Type -** Cross-sectional, descriptive, mixed methods design **Size –** 175 patients and 30 ICD nurses	**Inclusion** All adult ICD recipients having a verified HF diagnosis according to the European Society of Cardiology guidelines (N=177) were invited to participate in the study during their yearly follow-up visit at the in-hospital device clinic, from January to December 2018. The ICD nurses were identified by contacting the National Swedish Pacemaker and ICD Registry, which provided names and email addresses for all ICD nurses (N=50) working at an ICD clinic in Sweden at the time. **Exclusion** Age less than 18 years old and not being able to understand Swedish.	The majority of patients (154/175, 88.0%) and nurses (23/30, 77%) experienced RPM as very good; however, the nurses noted more downsides than did the patients. Nurses found it difficult to handle different systems with different platforms, especially for smaller clinics with few patients. Another difficulty was to set the correct number of alarms for the individual patient. This caused a high number of transmissions and a risk to miss important information.		**Limitations –** small study; only 60% of invited ICD nurses responded to the questionnaire **Conclusions –** Benefits to patients obvious; providers report challenges with additional work and workflow
Ricci RP, et al. Manpower and outpatient clinic workload for remote monitoring of patients with cardiac implantable electronic devices: data from the HomeGuide Registry **Year Published:** 2014 **PMID:** 24964380`	**Aim -** To assess the manpower and resource consumption of the Home Guide workflow model for remote monitoring of cardiac Biotronik	**Inclusion -** All patients undergoing a first implant with, or an upgrading to a PM or an ICD, with or without the cardiac resynchronization therapy (CRT) option, could be enrolled in the study if	A total of 1,650 patients were enrolled in 75 sites: 25% pacemakers (PM), 22% dual-, 27% single chamber implantable defibrillators (ICD), 2% PM with cardiac resynchronization therapy (CRT), and 24%		**Limitations –** Data limited to Biotronik CIEDs; no requirement to communicate data in Italy to other providers; data did not include ILRs capable of daily remote data transmission.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	implantable electronic devices in daily clinical practice. **Endpoints - T**o estimate the effectiveness of CIED remote monitoring in clinical event detection and management and to analyze the associated outpatient clinic workload as well as its impact on resource consumption. **Study Type –** investigator-initiated, observational study **Size –** 1650 patients were enrolled in 75 sites	the implanted device was provided with the HM feature, and patients gave their written consent to be remotely monitored by HM and to participate in the study. **Exclusion -** Patients were excluded if they were indicated to a device replacement or they normally resided in areas with insufficient GSM coverage.	ICD-CRT. During a median follow-up of 18 (10–31) months, 3,364 HM sessions were performed (74% by the RN, 26% by the responsible physician [RP]) to complete 18,478 remote follow-ups. Median duration of remote follow-ups was 1.2 (0.6–2.0) minutes, corresponding to a manpower of 43.3 (4.2–94.8) minutes/month every 100 patients for nurses and 10.2 (0.1–31.1) for physicians. The RN submitted 15% of remote transmissions to the RP, who decided unscheduled follow-ups in 12% of the cases. The median manpower for phone calls was 1.9 (0.8–16.5) minutes/month every 100 contacted patients. There were 2.84 in-hospital visits/patient, 0.46 of which triggered by HM findings. A cumulative per-patient HM follow-up time of 15.4 minutes (20% of total follow-up time) allowed remote detection of 73% of actionable events.		**Conclusions -** HM implemented in the HomeGuide workflow model required <1 hour/month every 100 patients to detect the majority of actionable events with limited administrative workload.
Guédon-Moreau L, et al. Validation of an Organizational Management Model of Remote Implantable Cardioverter-Defibrillator Monitoring Alerts **Year Published:** 2015 **PMID:** 26105725	**Aim -** To validate an institutional model of RM organization for ICD recipients. **Endpoints -** The main study end points were the professional interventions prompted by, and	**Inclusion** We enrolled consecutive patients who, between February 2004 and August 2011, had undergone implantation of an ICD for primary or secondary prevention of sudden cardiac death according to current professional practice guidelines.	During the first period, 1134 alerts occurred in 427 patients (286 patient-year), of which 376 (33%) were submitted to cardiologists' reviews, compared with, 1522 alerts in 562 patients (458 patient-year), of which 273 (18%) were submitted to cardiologists' reviews during the second period (P<0.001). An intervention was prompted by 73 of 376 (19.4%) alerts in the first versus		**Limitations –** single center; ICD patients only **Conclusions -** An optimized RM organization based on automated alerts and decisional trees enabled a focus on clinically relevant events and a decrease in the consumption of resources

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	times allocated to, RM alerts. **Study Type –** Observational study **Size -** 562 ICD recipients	**Exclusion -** None	77 of 273 (28.2%) in the second period (*P*=0.009). The mean time to manage an alert was 4 minutes 31 s in the first versus 2 minutes 10 s in the second period (*P*<0.001). The annual numbers of alert-related hospitalizations were 10.8 versus 8.1 per 100-patient-year (*P*=0.230), and annual numbers of alert-related visits were 9.8 and 6.1 per 100-patient-year (*P*=0.081), respectively.		without compromising the quality of ICD recipients' care.
Ricci RP, et al. Diagnostic power and healthcare resource consumption of a dedicated workflow algorithm designed to manage thoracic impedance alerts in heart failure patients by remote monitoring **Year Published:** 2018 **PMID:** 29283915	**Aim -** To evaluate the diagnostic accuracy and workload of a remote monitoring (RM) workflow algorithm which leverages intrathoracic impedance and other device diagnostics. **Endpoints –** To evaluate the diagnostic accuracy and healthcare resource consumption of a clinical and organizational workflow designed to improve care of heart failure patients by	**Inclusion -** 126 consecutive patients undergoing ICD/CRT-defibrillator implantation who received a device capable of monitoring thoracic impedance from 2009 to 2012. **Exclusion -** None	Out of 2176 remote transmissions, 893 (41%) in 111 patients (88.1%) showed clinically relevant events triggered by 574 alerts [2.2 (95% confidence intervalU2.0–2.4) per patient per year]. Among 309 alerts with intrathoracic impedance crossing, heart failure deterioration was confirmed in 116 (37.5%). Clinical actions followed 76/116 (65.5%) true heart failure alerts and 17/193 (8.8%) false-positive alerts (P<0.001). In particular, drug therapy change followed 72/116 (62.1%) true heart failure alerts and 15/193 (7.8%) false-positive alerts (P<0.001). Healthcare utilization occurred in 65.5% true heart failure alerts and in 24.9% false-positive alerts (P<0.001).		**Limitations –** single center; small number of patients; single type of system (Medtronic Carelink). **Conclusions -** A dedicated workflow algorithm resulted in more focused clinical surveillance which led to prompt detection and treatment of acute heart failure events.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	thoracic impedance RM. **Study Type –** single center, observational study **Size –** 126 patients with an ICD or CRT-D device				
Heidbuchel H, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring **Year Published:** 2015 **PMID:** 25179766 **Study Name:** EuroEco	**Aim –** To compare the total follow-up related cost for providers, comparing Home Monitoring facilitated follow-up to regular in-office follow-up during the first 2 years after ICD implantation. **Endpoints -** The total follow-up related cost for providers, the net financial impact on providers (taking national reimbursement into account), and costs from a healthcare payer perspective. **Study Type – A r**andomized, non-blinded, parallel-	**Inclusion –** Patients receiving a new or replacement Biotronik VVI- or DDD-ICD enabled with HM technology capable of electrogram transmission. **Exclusion –** Age < 18 years.	Resource use with HM ON was clearly different: less follow-up visits (3.79+1.67 vs. 5.53+2.32; P , 0.001) despite a small increase of unscheduled visits (0.95+1.50 vs. 0.62+1.25; P , 0.005), more non-office-based contacts (1.95+3.29 vs. 1.01+2.64; P , 0.001), more Internet sessions (11.02+15.28 vs. 0.06+0.31; P , 0.001) and more in-clinic discussions (1.84+4.20 vs. 1.28+2.92; P , 0.03), but with numerically fewer hospitalizations (0.67+1.18 vs. 0.85+1.43, P ¼ 0.23) and shorter length-of-stay (6.31+15.5 vs. 8.26+18.6; P ¼ 0.27), although not significant. For the whole study population, the total follow-up cost for providers was not different for HM ON vs. OFF [mean (95% CI): E204 (169 –238) vs. E213 (182 –243); range for difference (E236 to 54), NS]. From a payer perspective, follow-up related costs were similar while the total cost per patient (including other		**Limitations –** ICD patients only; devices from a single manufacturer **Conclusions -** For all the patients as a whole, follow-up related costs for providers were not different for remote vs. purely in-office follow-up, despite reorganized care.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	design trial of 17 centers from six European countries. **Size –** 312 patients with an ICD		physician visits, examinations, and hospitalizations) was numerically (but not significantly) lower. There was no difference in the net financial impact on providers [profit of E408 (327 –489) vs.E400 (345–455); range for difference (E2104 to 88), NS], but there was heterogeneity among countries, with less profit for providers in the absence of specific remote follow-up reimbursement (Belgium, Spain, and the Netherlands) and maintained or increased profit in cases where such reimbursement exists (Germany and UK). Quality of life (SF-36) was not different.		
Papavasileiou LP, et al. Work burden with remote monitoring of implantable cardioverter defibrillator: is it time for reimbursement policies? **Year Published:** 2013 **PMID:** 22644407	**Aim** To evaluate the workload associated with RM systems Endpoints Study Type Observational, single centre **Size** 154 consecutive RM pts	**Inclusion** Consecutive pts Exclusion: pt unable to tx	1744 tx. Median 11.3 per pt Scheduled every 3 mths, Fidelis mthly 402 phone calls, 28% missed tx , 70.6% due to events 9.7hrs work for every 100 patients a month	RM allows early detection but increased number of f/up visits. Many missed tx, extra workload for trouble shooting	**Limitations: Small size, no control group** **Conclusions Work burden is high for managing. Reimbursement policies should be considered**
Ricci RP, et al. Economic analysis of remote monitoring of cardiac implantable electronic devices: Results of the Health Economics Evaluation Registry for Remote Follow-up (TARIFF) study **Year Published:** 2017 **PMID:** 27614025	**Aim:** To assess cost and benefits of RM compared to standard care **Study Type:** Observational, Prospective, non ramdomised multicentre	**Inclusion: Consecutive SJM patients** **Exclusion**	Cost per pt sig higher in std care. P<0.001, due to cost of hospitalizations. Pt costs higher in std care p<0.001	Time spent reviewing scheduled 4.46+/-3.35min, alert 5.89+/-8.58min. Mean annual tx time calculated at 47.92 hrs/100 pts	**Limitations:** Non randomised, alert settings investigators discretion. DId not include time related to enrolment, calls, unsuccess attempts, or contacting physician **Conclusions** RM cost saving to both health system and pt

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Study Name: TARIFF	**Size: 209 pts, 102 RM, 107 SC**				compared to std care. Lace of reimburse critical issue
O'Shea CJ, et al. Remote Monitoring Alert Burden: An Analysis of Transmission in >26,000 Patients **Year Published:** 2021 **PMID:** 33602404	**Aim:** Assess tx burden **Study Type:** Observational, retrospective, multicentre **Size:** 26713pt, 25centres. 46.7%PM, 34.5%ICD 18.8% ILR	**Inclusion:** Consecutive pts enrolled Pacemate Exclusion	40% of tx are alerts. 54.8% pts at least 1 alert. PM 31%, ICD 18.9%, ILR 50.1% alerts. 4.8% red alerts. 52.7% red alerts PM 29.3%. VT/VF alerts 17.3% PM, 29.2% , ATP and shock 2.9%. Lack of uniformity of alert programming. High workload	Most freq red alerts AF, Sig burden in managing tx. Lack of uniformity of alert acuity programming	**Limitations:** **Conclusions:** 54% pts at least 1 alert. ICD underrepresented, ILR overrepresented High acuity alerts mostly ICDs. Need management strategy to reduce time addressing non actionable
Maines M, et al. Scheduled versus alert transmissions for remote follow-up of cardiac implantable electronic devices: Clinical relevance and resource consumption **Year Published:** 2021 **PMID:** 33930512	**Aim:** Evaluation of action taken to document effectiveness and efficiency **Study Type:** Observational, retrospective, single centre **Size** 2309 pts 55% PM, 18% ICD	**Inclusion:** **Exclusion:**	33% alerts from 45% of patients. 9% scheduled required clinical discussion. 24% clinical discussion p <0.001. 7% clinically meaningful (unknown). 4.7 tx ICD and 6 PM		**Limitations:** **Conclusions:** 2/3 data are scheduled. Scheduled less ability to detect clinically relevant events. Careful programming of alerts for non meaningful tx and alert only f/up could reduce workload.
Cronin EM, et al. Remote monitoring of cardiovascular devices: a time and activity analysis **Year Published:** 2012 **PMID:** 22864266	**Aim :**To determine impact of RM on device clinic workload **Endpoints:** 2 week analysis **Study Type:** Observational, prospective, single centre **Size:** 434 pts with 500 tx	**Inclusion:** All RM transmissions over a 2 week period Exclusion	Mean time per tx 11.5 +/- 7.7 min per tx. 21 +/- 7.4min for actionable 27.6% unscheduled with 40.6% having clinically impt Overall, 27% clinically impt with 8.2% required physician review 49.2% of scheduled missed due to patient compliance	Mean time for RM f/up less than in clinic	**Limitations:** 4x manufacturers systems with manual and automatic tx **Conclusions:** Analysis of RM tx has significant findings for clinic workflow. Faster than in clinic. Non actionable rapidly processed. Poor patient compliance impacts efficiency

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	346ICD, 84PM, 70ILR				
Ricci RP, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry **Year Published:** 2013 **PMID:** 23362021	**Aim:** To estimate the effectiveness of device RM in clinical event detection and management. **Endpoints:** 1) major cardiovascular events; 2) response time **Study Type:** prospective, multicentre observational study **Size:** n=1650	**Inclusion:** class I/II indications for PM, ICD or CRT. **Exclusion:** NA	1) During a 20 ± 13 months FU, 2471 independently adjudicated events were collected in 838 patients (51%): 2033 (82%) were detected during RM sessions; 438 (18%) during in-person visits. 95% of asymptomatic and 73% of actionable events were detected during RM sessions 2) Median reaction time was 3 days [interquartile range (IQR), 1–14 days].	RM was associated with remarkably low manpower and resource consumption.	**Limitations:** observational study design **Conclusions:** RM was highly effective in detecting and managing clinical events in CIED patients in daily practice with remarkably low manpower and resource consumption.
Varma N, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial **Year Published:** 2010 **PMID:** 20625110 **Study Name:** TRUST follow-up	**Aim:** To study the safety and efficacy of automated remote monitoring **Endpoints:** 1) Number of in-hospital device evaluations; 2) adverse event rate (death, stroke, surgical intervention); 3) Detection time of clinically significant problems **Study Type:** multicenter, prospective RCT **Size:** n=1339	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	1) HM resulted in 45% reduction in-hospital device evaluations without affecting morbidity. In HM, 86% of FU was remote only. 2) No difference in adverse event rate with 10.4% for HM and 10.4% for conventional monitoring, non-inferiority p-value = 0.005 3) Median time to evaluation for arrhythmic events <2 days in HM vs 36 days in conventional (p<0.001).	No differenece in mortality (3.4% HM vs 4.5% controls, p=0.226)	**Limitations:** 12m FU does not address long-term device and lead problems. PM-dependent patients excluded given lack of automated threshold testing at that era. No CRT included. **Conclusions:** Automated home monitoring is safe and allows rapid detection of actionable events.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Automated home monitoring (HM) = 908 Conventional = 431				
Varma N, et al. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial - testing execution of the recommendations **Year Published:** 2014 **PMID:** 24595864 **Study Name:** TRUST follow-up	**Aim:** To study efficacy and implementation of scheduled ICD FU and to identify sources of failure. **Endpoints:** Patient adherence and attritiion. **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	HM was associated with less patient attrition (14.2% vs. 20.1%, p=0.007). Proportion of patients with 100% adherence to scheduled checks was 60% in HM vs 47% in conventional monitoring (p<0.001).	Transmission loss was 0.97% in HM but failure to show-up for in-person evaluation in conventional monitoring was 10.5%, p<0.001.	**Limitations:** Unexpected high patient attrition rates. **Conclusions:** Automatic remote monitoring preserves patient retention and adherence when compared with conventional in-person FU.
Boriani G, et al. The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring **Year Published:** 2013 **PMID:** 23965236 **Study Name:** MORE-CARE	**Aim:** To evaluate if RM strategy is able to reduce time from device-detected events to clinical decisions **Endpoints:** 1) delay between an alert event and clinical decisions related to the event; 2) quality of life **Study Type:** international, multicenter RCT	**Inclusion:** de novo Medtronic CRT-D implant, sinus rhythm **Exclusion:** <18 years	1) Median delay from device-detected events to clinical decisions was considerably shorter in the RM group compared to the Control group: 2 (1-4) days vs 29 (3-51) days, respectively, P=0.004. In-hospital visits were reduced in the RM group (2.0 visits/patient/year vs 3.2 visits/patient/year in the Control group, 37.5% relative reduction, P<.001). 2) There was no difference in quality of life (p=0.45)	The annual rate of all-cause hospitalizations per patient did not differ between the two groups (p=0.65).	**Limitations:** phase 1 report, not powered for major cardiovascular events. **Conclusions:** RM is associated with a significant reduction in delay from event onset to clinical decisions. There was no significant difference in quality of life and clinical status.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Size: n=154; 1:1 randomization				
Varma N, et al. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial **Year Published:** 2010 **PMID:** 20716717 **Study Name:** TRUST follow-up	**Aim:** To study the impact of automated RM on lead and generator performance **Endpoints:** 1) Detection of device-related events 2) Detection time of clinically significant problems **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	1) Total of 62 device related events in 46 patients (4.4% HM vs 1.4% in conventional, p=0.004). Of these, 47% were asymptomatic or silent events. A total of 20 device events required surgical intervention (15 in HM vs 5 conventional). 2) HM detected events earlier (median 1 d vs 5 d, p=0.05).	4 cross-overs from conventional to HM for advisories (Fidelis lead). Successful check 92.7% in HM vs 89.2% in conventional (p<0.001). 81% of HM events were by automatic event triggers.	**Limitations:** Pacing threshold not tracked by HM. Most device / lead related events will occur later in FU. **Conclusions:** ICD lead and generator malfunction was infrequent and often asymptomatic. Automated HM enhanced discovery, permitted prompt detection, and facilitated management decisions.
Ricci RP, et al. Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation **Year Published:** 2009 **PMID:** 19011260	**Aim:** To evaluate the impact of Home Monitoring (HM) technology on detection and treatment of atrial fibrillation **Endpoints:** detection of AF **Study Type:** prospective, single-center, observational cohort study	**Inclusion:** patients with PM, ICD, or CRT-D **Exclusion:** NA	During 488 ± 203 days follow-up 42 patients (26%) had alerts for AF; 22 patients of these had no history of AF before implant. Actions: no further action (n=9); unscheduled FU (n=33). In four cases the arrhythmia was not confirmed (false positive). The median time to the first intervention for AF was 50 days (148 days before the scheduled follow-up).		**Limitations** **Conclusions:** HM technology allowed early detection of AF in paced patients and early reaction to optimize medical treatment.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Size: n=160				
Sanna T, et al. Cryptogenic stroke and underlying atrial fibrillation **Year Published:** 2014 **PMID:** 24963567 **Study Name:** CRYSTAL AF	**Aim:** To assess whether long-term monitoring with an insertable cardiac monitor (ICM) is more effective than conventional follow-up for detecting AF in patients with cryptogenic stroke. **Endpoints:** 1) time to first detection of atrial fibrillation within 6 months; 2) time to first detection of atrial fibrillation within 12 months **Study Type:** multicenter RCT **Size:** n=441, 1:1 randomization	**Inclusion:** ≥ 40 y; TIA or stroke in past 90 days; negative ambulatory ECG monitoring. **Exclusion:** history of AF or atrial flutter; indication or contraindication for oral anticoagulation; indication for pacemaker or ICD.	1) By 6 months, atrial fibrillation had been detected in 8.9% of patients in the ICM group vs 1.4% of patients in the control group (HR 6.4; 95% CI 1.9 to 21.7; P<0.001). 2) By 12 months, atrial fibrillation had been detected in 12.4% of patients in the ICM group vs 2.0% of patients in the control group (HR 7.3; 95% CI, 2.6 to 20.8; P<0.001).		**Limitations:** lack of causal relation between AF and stroke; unknown significance of brief AF episodes detected by ICM; limited ICM memory **Conclusions:** ICM was superior to conventional follow-up for detecting atrial fibrillation after cryptogenic stroke.
Varma N, et al. Detection of atrial fibrillation by implanted devices with wireless data transmission capability **Year Published:** 2005 **PMID:** 15683480	**Aim:** To test the ability of home monitoring (HM) to define temporal AF patterns. **Endpoints:** 1) Reliable detection of AF; 2) reliability of HM transmissions	**Inclusion:** class I or II pacemaker indications **Exclusion:** NA	1) AF developed in 29 patients (10.5%), representing a total of 645 AF day, defined as >20%/24h, over 12 ± 2 months of monitoring. 2) 89% of 22,356 transmissions were successful, of which >90% were received in <5 minutes. Data integrity was 100% preserved.		**Limitations:** retrospective study design, limited sample size, Biotronik only **Conclusions:** HM enabled rapid detection of AF and anticoagulation decisions.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: retrospective, single-center, observational cohort study **Size:** n=276				
Mabo P, et al. A randomized trial of long-term remote monitoring of pacemaker recipients (the COMPAS trial) **Year Published:** 2012 **PMID:** 22127418 **Study Name:** COMPAS	**Aim:** To assesses the efficacy and safety of RM only in patients with pacemakers. **Endpoints:** 1) major adverse events (death, device-related hospitalization, CV hosp); 2) number of in-office FU; 3) Quality of life (SF-36); 4) delay in management **Study Type:** Prospective, multicenter RCT **Size:** n=538, 1:1 randomization	**Inclusion:** Biotronik DDD PM implanted for at least 1 m. **Exclusion:** spontaneous ventricular rate <30 bpm.	1) Major adverse event rate was 17.3% RM only vs 19.1% control (p=0.63). 2) mean n interim FU/y 0.5 RM only vs 1.2 in controls (p<0.001) = 36% reduction. 51% of RFU did not need any interim FU. 3) No significant difference in quality of life. 4) Median delay 17 d in RFU vs 139 d in control.		**Limitations:** only pacemakers, small proportion of generator changes **Conclusions:** Over 18m FU, RM only was safe, enabled early detection, and decreased n of ambulatory FU sessions.
Watanabe E, et al. Remote Management of Pacemaker Patients With Biennial In-Clinic Evaluation: Continuous Home Monitoring in the Japanese At-Home Study: A Randomized Clinical Trial **Year Published:** 2020 **PMID:** 32342703	**Aim:** To study safety and efficacy of continuous home monitoring (HM) **Endpoints:** 1) Composite: death, stroke, CV events requiring surgery; 2) n of in-office FU; 3) costs comparison; 4) battery longevity.	**Inclusion:** >20y; VVI/DDD Biotronik PM indication; PM <45 days or scheduled for PM; geographically stable, likely to return for in-office evaluations **Exclusion:** Life expectancy <27 m; likely to undergo heart transplant; in other study	1) Composite endpoint: 10.9% HM vs 11.8% controls, p=0.0012 non-inferiority. 2) Median in-office FU: 0.5 HM vs 2.0 controls (p<0.001). 70% reduction in-ioffice FU; actionable in-office FU: 9% HM vs 11.7% controls (p=0.42). 3) Total cost reduced 11% in HM, but FU reimbursement slightly higher in HM due to combi of remote + in-office.	1.4% of HM events required in-office FU (lead function, medical, other). Daily HM performance was 90.1%, 1.3% did not transmit any data.	**Limitations:** pacemaker only **Conclusions:** Replacing periodic in-office follow-ups with remote FU for 2 years in PM results in equal occurrence of MACE and reduced resource consumption.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: Prospective, multicenter, RCT **Size:** n=1274, 1:1 randomization		4) No difference in remaining battery capacity (85% HM vs 86% controls, p=0.21).		
García-Fernández FJ, et al. 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) **Year Published:** 2019 **PMID: 30793735** **Study Name:** RM-ALONE	**Aim:** To study safety and efficacy of continuous RM only **Endpoints:** 1) MACE over 24 m FU (all-cause mortality, stroke, cardiac/device related hospitalization, device-related surgical intervention); 2) decrease in in-office FU and workload. **Study Type:** Prospective, multicenter, RCT **Size:** n=445; 1:1 randomization	**Inclusion:** >18y; CIED with HM; cell coverage; controlled medical/physical status. **Exclusion:** generator changes; CRT	1) MACE: 20% RM only vs 19.5% controls (p=0.006 for non-inferiority, HR p=0.838). Time to first MACE not different. Confirmed in both PM and ICD subgroup. 2) RM only 79% reduction in-office visits. No difference in unscheduled visits (p=0.160). No difference in reasons for unscheduled visits. Reduction in total clinician time (5.9 min RM only vs 10.2 min controls, p<0.0001) and nurse time (6.3 RM only vs 11.1 min controls, p<0.0001). .	Early study termination: 20% RM only vs 17% controls (p=0.337). Overall attrition: 12.7% RM only vs 10.2% controls (p=0.461).	**Limitations:** No CRT included; study did not capture late complications; Biotronik platform only. **Conclusions:** Significant reduction in scheduled visits, no difference in unscheduled visits. This without affecting MACE endpoints. Equal results in both PM and ICD patients.
Heidbuchel H, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring **Year Published:** 2015 **PMID:** 25179766 **Study Name:** EuroEco	**Aim:** To evaluate the cost for providers when relying on Home Monitoring (HM)-based FU compared with classical FU with only in-office visits. **Endpoints:** 1) total FU-related cost for providers; 2) rate of	**Inclusion:** de novo or replacement VVI or DDD Biotronik ICD, age ≥ 18y **Exclusion:** NA	1) The total FU cost for providers was not different for HM ON vs. OFF [mean (95% CI): €204 (169–238) vs. €213 (182–243); range for difference (€−36 to 54), p=NS]. From a payer perspective, FU-related costs were similar while the total cost per patient (including other physician visits, examinations, and hospitalizations) was numerically (but not significantly) lower. There was no difference in the net financial impact	HM ON was associated with less FU visits despite a small increase of unscheduled visits, more non-office-based contacts, more Internet sessions and more in-clinic discussions.	**Limitations:** no CRT-D patients, large heterogeneity in reimbursement models per country. **Conclusions:** FU-related costs for providers are not different for remote FU vs. purely in-office FU, despite reorganized care.

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Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	in-office FU visits with relevant findings; 3) quality of life **Study Type:** randomized, non-blinded, parallel-design trial **Size:** n=312, 1:1 randomization		on providers [profit of €408 (327–489) vs. €400 (345–455); range for difference (€−104 to 88), NS] 2) In the HM ON group, 32.0% of in-office FU visits resulted in a clinically relevant finding/action compared with 26.8% in the HM OFF group (P < 0.05). 3) There was no significant difference in quality of life.		
Varma N, et al. Alert-Based ICD Follow-Up: A Model of Digitally Driven Remote Patient Monitoring **Year Published:** 2021 **PMID:** 33640345	**Aim:** To study the impact of fully remote alert-based follow-up **Endpoints:** 1) reduction in nonactionable in-person evaluation (IPE); 2) event discovery rates and IPEs **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	Nonactionable IPEs were reduced 81% by HM (0.7 per patient year) compared with conventional monitoring (3.6 per patient year; p < 0.001); but event discoveries remained similar (2.9 per patient year). In HM, the alert rate was median 1 per patient (interquartile range: 0 to 3) with >50% actionability, indicating low volume but high clinical value. Unscheduled IPE was the basis for discovery of 100% of intercurrent problems in HM and also 75% in conventional care, indicating limited value of appointment-based follow-up for problem discovery.	No diff in safety event rate (4.0% HM vs 4.9% in controls). Actionable events 16.2% with HM vs 11.8% for controls (p<0.001). HM reduced in-clinic load with 78%. Shorter time to detection for silent events.	**Limitations:** Reevaluated data from >10 years ago **Conclusions:** Automated RM promotes quantitative reduction with qualitative improvement in IPEs with respect to capturing clinically salient events. Automated RM reduced unnecessary work.
Varma N, et al. Role of Automatic Wireless Remote Monitoring Immediately Following ICD Implant: The Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) Trial **Year Published:** 2016 **PMID:** 26661687 **Study Name:** TRUST follow-up	**Aim:** To study the role of automated RM immediately after ICD implant **Endpoints:** need for in-person evaluation (IPE) in the first 3 m	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	In first 3 m: 85% HM vs 88% controls had no IPE (p=0.31). In case of IPE, actionability was non-significant higher in HM (36.2% vs 24.2%, p=0.12). Time to actionable event detection was shorter with HM (p=0.025). HM did not result in an increase in non-actionable IPEs (p=0.72).	Enhanced arrhythmia detection in HM (mostly silent arrhythmic episodes). More device reprogramming / lead revision in first 3 months in HM group (30% vs 15%, p=0.018). 64% of HM-	**Limitations:** Low incidence of device-related events in first 3 months. Endpoints such as actionability are surrogate endpoints. **Conclusions:** Automatic remote monitoring should be activated soon after implant.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431			driven IPEs were actionable.	
Section 6 Alert-based remote monitoring					
Chew DS, et al. Arrhythmic Burden and the Risk of Cardiovascular Outcomes in Patients With Paroxysmal Atrial Fibrillation and Cardiac Implanted Electronic Devices **Year Published:** 2022 **PMID:** 35089799	**Aim:** To assess the dose-response relationship between device-detected AF burden and subsequent cardiovascular outcomes. **Endpoints:** 1) all-cause mortality; 2) all-cause hospitalization; 3) cardiovascular hospitalization; 4) ischemic stroke **Study Type:** nationwide, observational cohort **Size:** n=39 710	**Inclusion:** patients aged ≥ 65 with paroxysmal atrial fibrillation and CIED implant between 2010-2016. **Exclusion:** persistent AF	1) all-cause mortality at 1-year increased with baseline AF burden: 8.5% with AF burden 0%, 8.9% with AF burden 0% to 5%, and 10.9% with AF burden 5% to 98% (P<0.001) 2) all-cause hospitalization at 1-year increased with AF burden: 38.6% with AF burden 0%, 40.7% with AF burden 0% to 5%, and 44.0% with AF burden 5% to 98% (P<0.001) 3) Cardiovascular hospitalization at 1-year increased with AF burden: 28.8% with AF burden 0%, 31.1% with AF burden 0% to 5%, and 33.5% with AF burden 5% to 98% (P<0.001) 4) Ischemic stroke at 1-year was not significant different between AF burden categories: 1.2% with AF burden 0%, 1.0% with AF burden 0% to 5%, and 1.4% with AF burden 5% to 98% (P=0.112), but was in Cox regression analysis when analyzed per 10% increase in AF burden.		**Limitations:** Predominantly Abbott only; large proportion of 0% AF burden; possible lack of correlation between atrial high rate episode and AF burden; no adjustment for rhythm control strategies. **Conclusions:** In paroxysmal AF, there is a clinically relevant dose-response relationship between AF burden and risks of cardiovascular hospitalization, ischemic stroke, and mortality.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Ricci RP, et al. Effectiveness of remote monitoring of CIEDs in detection and treatment of clinical and device-related cardiovascular events in daily practice: the HomeGuide Registry **Year Published:** 2013 **PMID:** 23362021	**Aim:** To estimate the effectiveness of device RM in clinical event detection and management. **Endpoints:** 1) major cardiovascular events; 2) response time **Study Type:** prospective, multicentre observational study **Size:** n=1650	**Inclusion:** class I/II indications for PM, ICD or CRT. **Exclusion:** NA	1) During a 20 ± 13 months FU, 2471 independently adjudicated events were collected in 838 patients (51%): 2033 (82%) were detected during RM sessions; 438 (18%) during in-person visits. 95% of asymptomatic and 73% of actionable events were detected during RM sessions 2) Median reaction time was 3 days [interquartile range (IQR), 1–14 days].	RM was associated with remarkably low manpower and resource consumption.	**Limitations:** observational study design **Conclusions:** RM was highly effective in detecting and managing clinical events in CIED patients in daily practice with remarkably low manpower and resource consumption.
Varma N, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial **Year Published:** 2010 **PMID:** 20625110 **Study Name:** TRUST follow-up	**Aim:** To study the safety and efficacy of automated remote monitoring **Endpoints:** 1) Number of in-hospital device evaluations; 2) adverse event rate (death, stroke, surgical intervention); 3) Detection time of clinically significant problems **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	1) HM resulted in 45% reduction in-hospital device evaluations without affecting morbidity. In HM, 86% of FU was remote only. 2) No difference in adverse event rate with 10.4% for HM and 10.4% for conventional monitoring, non-inferiority p-value = 0.005 3) Median time to evaluation for arrhythmic events <2 days in HM vs 36 days in conventional (p<0.001).	No differenece in mortality (3.4% HM vs 4.5% controls, p=0.226)	**Limitations:** 12m FU does not address long-term device and lead problems. PM-dependent patients excluded given lack of automated threshold testing at that era. No CRT included. **Conclusions:** Automated home monitoring is safe and allows rapid detection of actionable events.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Varma N, et al. Superiority of automatic remote monitoring compared with in-person evaluation for scheduled ICD follow-up in the TRUST trial - testing execution of the recommendations **Year Published:** 2014 **PMID:** 24595864 **Study Name:** TRUST follow-up	**Aim:** To study efficacy and implementation of scheduled ICD FU and to identify sources of failure. **Endpoints:** Patient adherence and attritiion. **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	HM was associated with less patient attrition (14.2% vs. 20.1%, p=0.007). Proportion of patients with 100% adherence to scheduled checks was 60% in HM vs 47% in conventional monitoring (p<0.001).	Transmission loss was 0.97% in HM but failure to show-up for in-person evaluation in conventional monitoring was 10.5%, p<0.001.	**Limitations:** Unexpected high patient attrition rates. **Conclusions:** Automatic remote monitoring preserves patient retention and adherence when compared with conventional in-person FU.
Boriani G, et al. The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring **Year Published:** 2013 **PMID:** 23965236 **Study Name:** MORE-CARE	**Aim:** To evaluate if RM strategy is able to reduce time from device-detected events to clinical decisions **Endpoints:** 1) delay between an alert event and clinical decisions related to the event; 2) quality of life **Study Type:** international, multicenter RCT **Size:** n=154; 1:1 randomization	**Inclusion:** de novo Medtronic CRT-D implant, sinus rhythm **Exclusion:** <18 years	1) Median delay from device-detected events to clinical decisions was considerably shorter in the RM group compared to the Control group: 2 (1-4) days vs 29 (3-51) days, respectively, P=0.004. In-hospital visits were reduced in the RM group (2.0 visits/patient/year vs 3.2 visits/patient/year in the Control group, 37.5% relative reduction, P<.001). 2) There was no difference in quality of life (p=0.45)	The annual rate of all-cause hospitalizations per patient did not differ between the two groups (p=0.65).	**Limitations:** phase 1 report, not powered for major cardiovascular events. **Conclusions:** RM is associated with a significant reduction in delay from event onset to clinical decisions. There was no significant difference in quality of life and clinical status.

Appendix 3 Evidence tables *(continued)*

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Varma N, et al. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial **Year Published:** 2010 **PMID:** 20716717 **Study Name:** TRUST follow-up	**Aim:** To study the impact of automated RM on lead and generator performance **Endpoints:** 1) Detection of device-related events 2) Detection time of clinically significant problems **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	1) Total of 62 device related events in 46 patients (4.4% HM vs 1.4% in conventional, p=0.004). Of these, 47% were asymptomatic or silent events. A total of 20 device events required surgical intervention (15 in HM vs 5 conventional). 2) HM detected events earlier (median 1 d vs 5 d, p=0.05).	4 cross-overs from conventional to HM for advisories (Fidelis lead). Successful check 92.7% in HM vs 89.2% in conventional (p<0.001). 81% of HM events were by automatic event triggers.	**Limitations:** Pacing threshold not tracked by HM. Most device / lead related events will occur later in FU. **Conclusions:** ICD lead and generator malfunction was infrequent and often asymptomatic. Automated HM enhanced discovery, permitted prompt detection, and facilitated management decisions.
Ricci RP, et al. Remote control of implanted devices through Home Monitoring technology improves detection and clinical management of atrial fibrillation **Year Published:** 2009 **PMID:** 19011260	**Aim:** To evaluate the impact of Home Monitoring (HM) technology on detection and treatment of atrial fibrillation **Endpoints:** detection of AF **Study Type:** prospective, single-center, observational cohort study **Size:** n=160	**Inclusion:** patients with PM, ICD, or CRT-D **Exclusion:** NA	During 488 ± 203 days follow-up 42 patients (26%) had alerts for AF; 22 patients of these had no history of AF before implant. Actions: no further action (n=9); unscheduled FU (n=33). In four cases the arrhythmia was not confirmed (false positive). The median time to the first intervention for AF was 50 days (148 days before the scheduled follow-up).		**Limitations** **Conclusions:** HM technology allowed early detection of AF in paced patients and early reaction to optimize medical treatment.

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Varma N, et al. Detection of atrial fibrillation by implanted devices with wireless data transmission capability **Year Published:** 2005 **PMID:** 15683480	**Aim:** To test the ability of home monitoring (HM) to define temporal AF patterns. **Endpoints:** 1) Reliable detection of AF; 2) reliability of HM transmissions **Study Type:** retrospective, single-center, observational cohort study	**Inclusion:** class I or II pacemaker indications **Exclusion:** NA	1) AF developed in 29 patients (10.5%), representing a total of 645 AF day, defined as >20%/24h, over 12 ± 2 months of monitoring. 2) 89% of 22,356 transmissions were successful, of which >90% were received in <5 minutes. Data integrity was 100% preserved.		**Limitations:** retrospective study design, limited sample size, Biotronik only **Conclusions:** HM enabled rapid detection of AF and anticoagulation decisions.

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Watanabe E, et al. Remote Management of Pacemaker Patients With Biennial In-Clinic Evaluation: Continuous Home Monitoring in the Japanese At-Home Study: A Randomized Clinical Trial **Year Published:** 2020 **PMID:** 32342703	**Aim:** To study safety and efficacy of continuous home monitoring (HM) **Endpoints:** 1) Composite: death, stroke, CV events requiring surgery; 2) n of in-office FU; 3) costs comparison; 4) battery longevity.	**Inclusion:** >20y; VVI/DDD Biotronik PM indication; PM <45 days or scheduled for PM; geographically stable, likely to return for in-office evaluations **Exclusion:** Life expectancy <27 m; likely to undergo heart transplant; in other study	1) Composite endpoint: 10.9% HM vs 11.8% controls, p=0.0012 non-inferiority. 2) Median in-office FU: 0.5 HM vs 2.0 controls (p<0.001). 70% reduction in-office FU; actionable in-office FU: 9% HM vs 11.7% controls (p=0.42). 3) Total cost reduced 11% in HM, but FU reimbursement slightly higher in HM due to combi of remote + in-office.	1.4% of HM events required in-office FU (lead function, medical, other). Daily HM performance was 90.1%, 1.3% did not transmit any data.	**Limitations:** pacemaker only **Conclusions:** Replacing periodic in-office follow-ups with remote FU for 2 years in PM results in equal occurrence of MACE and reduced resource consumption.

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Heidbuchel H, et al. EuroEco (European Health Economic Trial on Home Monitoring in ICD Patients): a provider perspective in five European countries on costs and net financial impact of follow-up with or without remote monitoring **Year Published:** 2015 **PMID:** 25179766 **Study Name:** EuroEco	**Aim:** To evaluate the cost for providers when relying on Home Monitoring (HM)-based FU compared with classical FU with only in-office visits. **Endpoints:** 1) total FU-related cost for providers; 2) rate of	**Inclusion:** de novo or replacement VVI or DDD Biotronik ICD, age ≥ 18y **Exclusion:** NA	1) The total FU cost for providers was not different for HM ON vs. OFF [mean (95% CI): €204 (169–238) vs. €213 (182–243); range for difference (€−36 to 54), p=NS]. From a payer perspective, FU-related costs were similar while the total cost per patient (including other physician visits, examinations, and hospitalizations) was numerically (but not significantly) lower. There was no difference in the net financial impact	HM ON was associated with less FU visits despite a small increase of unscheduled visits, more non-office-based contacts, more Internet sessions and more in-clinic discussions.	**Limitations:** no CRT-D patients, large heterogeneity in reimbursement models per country. **Conclusions:** FU-related costs for providers are not different for remote FU vs. purely in-office FU, despite reorganized care.

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Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	in-office FU visits with relevant findings; 3) quality of life **Study Type:** randomized, non-blinded, parallel-design trial **Size:** n=312, 1:1 randomization		on providers [profit of €408 (327–489) vs. €400 (345–455); range for difference (€−104 to 88), NS] 2) In the HM ON group, 32.0% of in-office FU visits resulted in a clinically relevant finding/action compared with 26.8% in the HM OFF group (P < 0.05). 3) There was no significant difference in quality of life.		
Varma N, et al. Alert-Based ICD Follow-Up: A Model of Digitally Driven Remote Patient Monitoring **Year Published:** 2021 **PMID:** 33640345	**Aim:** To study the impact of fully remote alert-based follow-up **Endpoints:** 1) reduction in nonactionable in-person evaluation (IPE); 2) event discovery rates and IPEs **Study Type:** multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	Nonactionable IPEs were reduced 81% by HM (0.7 per patient year) compared with conventional monitoring (3.6 per patient year; p < 0.001); but event discoveries remained similar (2.9 per patient year). In HM, the alert rate was median 1 per patient (interquartile range: 0 to 3) with >50% actionability, indicating low volume but high clinical value. Unscheduled IPE was the basis for discovery of 100% of intercurrent problems in HM and also 75% in conventional care, indicating limited value of appointment-based follow-up for problem discovery.	No diff in safety event rate (4.0% HM vs 4.9% in controls). Actionable events 16.2% with HM vs 11.8% for controls (p<0.001). HM reduced in-clinic load with 78%. Shorter time to detection for silent events.	**Limitations:** Reevaluated data from >10 years ago **Conclusions:** Automated RM promotes quantitative reduction with qualitative improvement in IPEs with respect to capturing clinically salient events. Automated RM reduced unnecessary work.
Varma N, et al. Role of Automatic Wireless Remote Monitoring Immediately Following ICD Implant: The Lumos-T Reduces Routine Office Device Follow-Up Study (TRUST) Trial **Year Published:** 2016 **PMID:** 26661687 **Study Name:** TRUST follow-up	**Aim:** To study the role of automated RM immediately after ICD implant **Endpoints:** need for in-person evaluation (IPE) in the first 3 m	**Inclusion:** VVI/DDD ICD with home monitoring **Exclusion:** pacing-dependent patients	In first 3 m: 85% HM vs 88% controls had no IPE (p=0.31). In case of IPE, actionability was non-significant higher in HM (36.2% vs 24.2%, p=0.12). Time to actionable event detection was shorter with HM (p=0.025). HM did not result in an increase in non-actionable IPEs (p=0.72).	Enhanced arrhythmia detection in HM (mostly silent arrhythmic episodes). More device reprogramming / lead revision in first 3 months in HM group (30% vs 15%, p=0.018). 64% of HM-	**Limitations:** Low incidence of device-related events in first 3 months. Endpoints such as actionability are surrogate endpoints. **Conclusions:** Automatic remote monitoring should be activated soon after implant.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: multicenter, prospective RCT **Size:** n=1339 Automated home monitoring (HM) = 908 Conventional = 431			driven IPEs were actionable.	
Section 7 Programming considerations for optimal remote monitoring					
7.2 Programming for Clinical Indications with Different Types of CIEDs					
Hindricks G, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial **Year Published:** 2014 **PMID:** 25131977 **Study Name:** IN-TIME	**Aim:** To evaluate the incremental benefit of automatic multiparameter telemonitoring for patients with heart failure treated with an ICD or a CRT-D. **Endpoints:** Primary outcome was worsening of a composite clinical score at 12 months; Secondary outcome measures were all-cause mortality and hospital admission because of worsening HF. **Study Type:** Randomized controlled trial. **Size:** 716 patients	**Inclusion:** ≥ 18yo, chronic HF lasting for at least 3 months, NYHA functional class II-III, LVEF of no more than 35%, indication for dual-chamber ICD or CRT-D. **Exclusion:** Uncontrolled hypertension, permanent atrial fibrillation, rare adverse disorders (restrictive or infiltrative or hypertrophic cardiomyopathy, constrictive pericarditis, acute myocarditis, tricuspid valve replacement, severe mitral regurgitation, or symptomatic aortic stenosis).	At 1 year, 63 (18·9%) of 333 patients in the telemonitoring group versus 90 (27·2%) of 331 in the control group (p=0·013) had worsened composite score (odds ratio 0·63, 95% CI 0·43-0·90). Ten versus 27 patients died during follow-up.	The telemonitoring group and the control group did not differ significantly for the number of hospital admissions for worsening HF (44 vs 47, p=0·38) or the number of patients affected (27 vs 34, p=0·35). In a post-hoc exploratory analysis, no significant interaction between subgroups and treatment effect was detected, except for history of atrial fibrillation: patients with a history of atrial fibrillation were more likely to benefit from telemonitoring than were patients without such a history.	**Limitations:** Inability to mask patients and investigators to the treatment allocation; medium-term length of follow-up and the fact that the authors neither enforced standardized treatment after telemonitoring observations nor thoroughly recorded clinical actions. **Conclusions:** Automatic, daily, implant-based, multiparameter telemonitoring can significantly improve clinical outcomes for patients with HF.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Guédon-Moreau L, et al. Validation of an Organizational Management Model of Remote Implantable Cardioverter-Defibrillator Monitoring Alerts **Year Published:** 2015 **PMID:** 26105725	**Aim:** To evaluate and optimize the use of resources and the remote management of ICD recipients as part of the standard clinical practice. **Endpoints:** Number of transmissions, time spent in the management of transmissions by caregivers, reactions to alerts, and clinical outcomes. **Study Type:** Prospective, single-center study. **Size:** 562 patients.	**Inclusion:** Consecutive patients, ICD for primary or secondary prevention **Exclusion:**	During the first period, 1134 alerts occurred in 427 patients (286 patient-year), of which 376 (33%) were submitted to cardiologists' reviews, compared with, 1522 alerts in 562 patients (458 patient-year), of which 273 (18%) were submitted to cardiologists' reviews during the second period (P<0.001). An intervention was prompted by 73 of 376 (19.4%) alerts in the first versus 77 of 273 (28.2%) in the second period (P=0.009). The mean time to manage an alert was 4 minutes 31 s in the first versus 2 minutes 10 s in the second period (P<0.001). The annual numbers of alert-related hospitalizations were 10.8 versus 8.1 per 100-patient-year (P=0.230), and annual numbers of alert-related visits were 9.8 and 6.1 per 100-patient-year (P=0.081), respectively.		**Limitations:** Not randomized **Conclusions:** An optimized RM organization based on automated alerts and decisional trees enabled a focus on clinically relevant events and a decrease in the consumption of resources without compromising the quality of ICD recipients' care.
Maines M, et al. Scheduled versus alert transmissions for remote follow-up of cardiac implantable electronic devices: Clinical relevance and resource consumption **Year Published:** 2021 **PMID:** 33930512	**Aim:** To measure the relative contribution of scheduled and alert transmissions to the detection of relevant conditions, and the workload generated by their management. **Endpoints:** Number of transmissions received; transmissions that necessitated in-hospital access for	**Inclusion:** All patients remotely monitored according to the established protocol. **Exclusion:** Not applicable.	Of 8545 transmissions received from 1697 pacemakers and ICDs, 5766 (67%) were scheduled and 2779 (33%) were alert transmissions received from 764 patients (45%); 499 (9%) scheduled transmissions required clinical discussion with the physician, but only 2 of these necessitated in-hospital visits for further assessment. Of the alert transmissions, 664 (24%) required clinical discussion, and 75 (3%) necessitated in-hospital visits. The proportion of alerts judged clinically meaningful was 7%.		**Limitations:** Observational study of clinical practice, not-randomized. **Conclusions:** Scheduled transmissions generate 67% of remote data reviews for pacemakers and ICDs, but their ability to detect clinically relevant events is very low.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	further assessment; transmissions that required clinical discussion with the physician; transmissions whether the alert was clinically meaningful. **Study Type:** Observational. **Size:** 2309 patients.				
Varma N, et al. Alert-Based ICD Follow-Up: A Model of Digitally Driven Remote Patient Monitoring **Year Published:** 2021 **PMID:** 33640345	**Aim:** To test whether continuous automatic remote patient monitoring (RPM) linked to centralized analytics reduces nonactionable in-person patient evaluation (IPE) but maintains detection of at-risk patients and provides actionable notifications. **Endpoints:** The primary efficacy endpoint was measured by reduction in number of nonactionable IPEs by RPM. Secondary objectives assessed were problem discovery rates	**Inclusion:** Patients receiving ICD for Class I/IIa indications. **Exclusion:** Not applicable.	Nonactionable IPEs were reduced 81% by RPM (0.7 per patient year) compared with conventional care (3.6 per patient year; $p < 0.001$) but event discoveries remained similar (2.9 per patient year). In RPM, alert rate was median 1 per patient (interquartile range: 0 to 3) with >50% actionability, indicating low volume but high clinical value. Unscheduled IPE was the basis for discovery of 100% of intercurrent problems in RPM and also 75% in conventional care, indicating limited value of appointment-based follow-up for problem discovery. The number of IPEs needed to discover an actionable event was 8.2 in Conventional, 4.9 in RPM, and 2.1 when alert driven ($p < 0.001$).		**Limitations:** The data were collected more than a decade ago, and technological advances since may have further changed the impact of remote monitoring. **Conclusions:** Alert-based evaluation during continuous remote monitoring with minimized appointment-based (in-person or remote) evaluation leads to fewer IPEs but with enriched actionability and better achieves follow-up goals. Reducing the large volume of low-yield scheduled interrogations that are currently undertaken has significant cost advantages for patients and payers and major implications for value-based health care initiatives.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	(including those clinically asymptomatic) and IPEs directed to at-risk patients (i.e., those reporting prespecified adverse events). **Study Type:** Randomized clinical trial. **Size:** 1450 patients				
Ploux S, et al. Towards eradication of inappropriate therapies for ICD lead failure by combining comprehensive remote monitoring and lead noise alerts **Year Published:** 2018 **PMID:** 29858871	**Aim:** To assess the effectiveness of remote monitoring associated or not with a lead noise alert for early detection of ICD lead failure. **Endpoints:** ICD lead failure and subsequent device interventions in patients with and without a lead noise alert in their remote monitoring system. **Study Type:** Prospective single-center cohort. **Size:** The initial cohort consisted of 578 patients and rose to 1958 patients (median 1224).	**Inclusion:** Remotely monitored ICD patients from October 2013 to April 2017. **Exclusion:** Not applicable.	During a follow-up of 4457 patient years, 64 lead failures were diagnosed. Sixty-one (95%) of the diagnoses were made before any clinical complication occurred. Inappropriate shocks were delivered in only one patient of each group (3%), with an annual rate of 0.04%. All high voltage conductor failures were identified remotely by a dedicated impedance alert in 10 patients. Pace-sense component failures were correctly identified by a dedicated alert in 77% (17/22) of the with-lead noise alert group versus 25% (8/32) of the without-lead noise alert group (p=0.002). The absence of a lead noise alert was associated with a 16-fold increase in the likelihood of initiating either a shock or ATP (OR: 16.0, 95% CI 1.8-143.3; p=0.01).		**Limitations:** No structural lead analysis was performed; absence of control group; calculation and comparison of delay from first event to diagnosis were not possible between manufacturers because the different systems do not send similar information. **Conclusions:** Remote ICD monitoring with systematic analysis of all the remotely transmitted EGMs alleviates the clinical adverse events associated with ICD lead failure. Diagnoses of lead failure are facilitated by dedicated noise alerts which reduce inappropriate detection of ventricular arrhythmias.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Boriani G, et al. The MOnitoring Resynchronization dEvices and CARdiac patiEnts (MORE-CARE) randomized controlled trial: phase 1 results on dynamics of early intervention with remote monitoring **Year Published:** 2013 **PMID:** 23965236 **Study Name:** MORE-CARE	**Aim:** To evaluate if RM strategy can reduce time from device-detected events to clinical decisions. **Endpoints:** Delay between an alert event and clinical decisions related to the event in the first 154 enrolled patients followed for 1 year. **Study Type:** Multicenter randomized controlled trial **Size:** 154 patients	**Inclusion:** Patients in sinus rhythm with de novo implantation of CRT-D for systolic HF with NYHA class III/IV, LVEF <35%. **Exclusion:** Not applicable.	The median delay from device-detected events to clinical decisions was considerably shorter in the Remote group compared to the Control group: 2 (25(th)-75(th) percentile, 1-4) days vs 29 (25(th)-75(th) percentile, 3-51) days respectively, P=.004. In-hospital visits were reduced in the Remote group (2.0 visits/patient/year vs 3.2 visits/patient/year in the Control group, 37.5% relative reduction, P<.001). Automatic alerts were successfully transmitted in 93% of events occurring outside the hospital in the Remote group. The annual rate of all-cause hospitalizations per patient did not differ between the two groups (P=.65).		**Limitations:** Not powered for evaluating the impact of RM on cardiovascular and device-related hospitalizations and mortality. There were only a few cases of system integrity alerts because of the limited 1-year follow-up. **Conclusions:** RM in CRT-D patients with advanced HF allows physicians to promptly react to clinically relevant automatic alerts and significantly reduces the burden of in-hospital visits.
Guédon-Moreau L, et al. A randomized study of remote follow-up of implantable cardioverter defibrillators: safety and efficacy report of the ECOST trial **Year Published:** 2013 **PMID:** 23242192 **Study Name:** ECOST report	**Aim:** To compare the safety of remote monitoring vs. ambulatory follow-ups of ICD. **Endpoints:** The primary study endpoint was the proportion of patients who experienced ≥1 major adverse events (MAE), including death from any cause, cardiovascular, and procedure- or device-related MAE.	**Inclusion:** First implant or replacement of an ICD. **Exclusion:** Patients in NYHA functional class IV at the time of ICD implantation.	Over a follow-up of 24.2 months, 38.5% of patients in the active and 41.5% in the control group experienced ≥1 MAE (P < 0.05 for non-inferiority). The overall number of shocks delivered was significantly lower in the active (n = 193) than in the control (n = 657) group (P < 0.05) and the proportion of patients who received inappropriate shocks was 52% lower in the active (n = 11) than in the control (n = 22) group (P < 0.05). At the end of the follow-up, the battery longevity was longer in the active group because of a lower number of capacitor charges (499 vs. 2081).		**Limitations:** The investigators who made decisions regarding hospitalizations, which was a criterion to classify MAE, were aware of the assignments; CRT-D recipients were not evaluated. **Conclusions:** Long-term HM of ICD is at least as safe as standard ambulatory follow-ups with respect to a broad spectrum of MAE. It also lowered significantly the number of appropriate and inappropriate shocks delivered and spared the device battery.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: Multicenter randomized controlled trial **Size:** 473 patients.				
Varma N, et al. Automatic remote monitoring of implantable cardioverter-defibrillator lead and generator performance: the Lumos-T Safely RedUceS RouTine Office Device Follow-Up (TRUST) trial **Year Published:** 2010 **PMID:** 20716717 **Study Name:** TRUST follow-up	**Aim:** To compare the safety and utility of automatic remote monitoring in recipients of ICDs with standard in-clinic follow-up. **Endpoints:** Safety (stroke, death, and need for a cardiovascular procedure), efficacy (reduction in health care utilization), and early detection of events. **Study Type:** Prospective, randomized, multicenter clinical trial. **Size:** 1339 patients.	**Inclusion:** Recipients of single and dual-chamber ICDs with HM implanted for class I/II indications; at least 1 in-office follow-up. **Exclusion:** Pacemaker-dependent patients.	HM and conventional patients were similar (age, 63.3±12.8 versus 64.0±12.1 years; 72.0% versus 73.1% male; New York Heart Association II class, 55.9% versus 60.4%; left ventricular ejection fraction, 29.0±10.7% versus 28.5±9.8%; coronary artery disease, 64.8% versus 71.7%; primary prevention, 72.2% versus 73.8%; DDD devices, 57.8% versus 56.6%). Four patients crossed over from conventional to HM because of advisories. Scheduled checks were more successfully accomplished in HM (92.7% versus 89.2% in conventional, P<0.001). Sixty-two device-related events (53 in HM versus 9 in conventional) were observed in 46 patients (40 [4.4%] in HM versus 6 [1.39%] in conventional, P=0.004). Forty-seven percent were asymptomatic. HM detected generator and lead problems earlier (HM versus conventional: median, 1 versus 5 days; P=0.05). A total of 20 device problems (eg, lead fracture, elective replacement indicators) requiring surgical revision (0.012 per patient-year) were found, 15 in HM and 5 in the conventional groups. Other events were managed nonsurgically (eg, reprogramming, initiation of antiarrhythmics).		**Limitations:** Short follow-up; pacemaker-dependent patients were excluded; prolonged mean time to physician evaluation (exceeded 4 days). **Conclusions:** ICD lead and generator malfunction was infrequent and often asymptomatic. Only a minority of detected events required surgical intervention. Automatic HM enhanced discovery, permitted prompt detection, and facilitated management decisions. Longitudinal parameter trending, with component function evaluated daily by remote monitoring, may enable long-term performance assessment.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Ahmed FZ, et al. Remote monitoring data from cardiac implantable electronic devices predicts all-cause mortality **Year Published:** 2022 **PMID:** 34601572	**Aim:** To determine if remotely monitored physiological data from cardiac implantable electronic devices (CIEDs) can be used to identify patients at high risk of mortality. **Endpoints:** Mortality. **Study Type:** Prospective, single-site observational. **Size:** 439 patients.	**Inclusion:** ≥18 years with Medtronic CIEDs capable of measuring OptiVol™ 2.0 fluid-index under follow-up. **Exclusion:** Not applicable.	285 patients (65%) had a high-risk episode and 60 patients (14%) died (50 in high-risk group; 10 in never high-risk group). Significantly more cardiovascular deaths were observed in the high-risk group, with mortality rates across groups of high vs. never-high 10.3% vs. < 4.0%; P = 0.03. Experiencing any high-risk episode was associated with a substantially increased risk of death [odds ratio (OR): 3.07, 95% confidence interval (CI): 1.57–6.58, P = 0.002]. Furthermore, each high-risk episode ≥14 consecutive days was associated with increased odds of death (OR: 1.26, 95% CI: 1.06–1.48; P = 0.006).		**Limitations:** The parameters which feed into the HFRS may differ, not only according to device type but also between patients; periods without transmitted data were observed in 36 patients; whether a cardiovascular condition contributed to death was not examined. **Conclusions:** Remote monitoring data from CIEDs can be used to identify patients at higher risk of all-cause mortality as well as HF events. Distinct from other prognostic scores, this approach is automated and continuously updated.
Ricci RP, et al. Effect of daily remote monitoring on pacemaker longevity: a retrospective analysis **Year Published:** 2015 **PMID:** 25444853	**Aim:** To retrospectively compare longevity of a specific dual-chamber pacemaker model in patients with HM on and patients with HM off. **Endpoints:** Primary end point was device replacement due to battery depletion. Secondary end points were the total number of inhospital visits and	**Inclusion:** All patients who had received a Biotronik Cylos DR-T dual-chamber pacemaker as a first implant or a replacement. **Exclusion:** Patients included in other interventional clinical studies.	The frequency of inhospital visits with significant device reprogramming was higher in the HM-on group than in the HM-off group (33.3% vs 25.0%, respectively; P = .03). Lower ventricular pulse amplitude (2.3 ± 0.4 V vs 2.7 ± 0.5 V; P < .0001) and pacing percentage (49% ± 38% vs 64% ± 38%; P = .02), both calculated as time-weighted averages, were observed with HM on as compared with HM off. Patient attrition was significantly lower in the HM-on group (9.7%; 95% CI 3.0%-28.7%) than in the HM-off group (45.6%; 95% CI 30.3%-64.3%) (P < .0001).		**Limitations:** Retrospective; small sample; restricted to 1 pacemaker model (old technology) **Conclusions:** In normal practice, energy demand of HM, if present, was overshadowed by programming optimization likely favored by continuous monitoring. Pacemakers controlled remotely with HM showed an 11-month longer longevity. Patient retention was superior.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	the proportion of active follow-ups. **Study Type:** Retrospective, observational. **Size:** 201 patients.				
Varma N, et al. Automatic remote monitoring utilizing daily transmissions: transmission reliability and implantable cardioverter defibrillator battery longevity in the TRUST trial **Year Published:** 2018 **PMID:** 29016878	**Aim:** To assess both transmission reliability of daily transmissions and their impact on battery longevity during extended follow-up. **Endpoints:** Mean battery percentage at 15 months. **Study Type:** Prospective randomized trial. **Size:** 1450 patients.	**Inclusion:** Recipients of single and dual chamber ICDs with HM implanted for Class I/II indications. **Exclusion:** Pacemaker dependent.	Transmission success per patient was 91% (median follow-up of 434 days). Overall, daily HM transmissions were received in 315 795 of a potential 363 450 days (87%). Only 55/3759 (1.46%) of unsuccessful scheduled evaluations in HM were attributed to transmission loss. Shock frequency and pacing percentage were similar in HM vs. CM. Fifteen-month battery longevity was 12% greater in HM (93.2 ± 8.8% vs. 83.5 ± 6.0% CM, P < 0.001). In extended follow-up of HM patients, estimated battery longevity was 50.9 ± 9.1% (median 52%) at 36 months.		**Limitations:** Study groups are imbalanced; evaluated only one automatic wireless remote monitoring technology. **Conclusions:** Automatic remote HM demonstrated robust transmission reliability. Daily transmission load may be sustained without reducing battery longevity. Home Monitoring conserves battery longevity and tracks long term device performance.
Wilkoff BL, et al. A Device Histogram-Based Simple Predictor of Mortality Risk in ICD and CRT-D Patients: The Heart Rate Score **Year Published:** 2017 **PMID:** 28156008	**Aim:** To determine the impact of Heart Rate Score on survival. **Endpoints:** Percent of beats in the histogram in the tallest 10 beats/min range bin. **Study Type:** Prospective, observational. **Size:** 125.822 ICDs and CRT-Ds followed.	**Inclusion:** DDD ICD or CRT-D patients implanted in 2006-2011, on remote monitoring. **Exclusion:** Persistent atrial fibrillation.	Of 57,893 ICDs and 67,929 CRT-Ds followed for 2.4 ± 1.5 years, each 10% increase in Heart Rate Score was associated with decreased survival (CRT-D hazard ratio [HR] 1.07 95%, confidence interval 1.06-1.07, P < 0.0001; ICD HR 1.05, 95% confidence interval 1.04-1.06, P < 0.0001). Multivariate analysis showed survival decreased with increasing age, atrial fibrillation, presence of a shock in first-year follow-up, and increasing programmed lower pacing rate in ICD and CRT-D patients. Increased percent right ventricular pacing predicted mortality in ICD patients,		**Limitations:** **Conclusions:** Heart Rate Score predicts survival in ICD and CRT-D patients independent of the available variables, and even when SDANN is unavailable.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
			while male gender and lower percent left ventricular pacing predicted mortality in CRT patients. Heart Rate Score predicted survival independent of those variables. Heart Rate Score correlates with heart rate variability (standard deviation of average R-R intervals [SDANN]) when both are obtainable, but SDANN was only present in 6% of patients with Heart Rate Score >70%.		
Wintrich J, et al. Remote Monitoring With Appropriate Reaction to Alerts Was Associated With Improved Outcomes in Chronic Heart Failure: Results From the OptiLink HF Study **Year Published:** 2021 **PMID:** 33301362 **Study Name:** OptiLink HF Study results	**Aim:** To analyze the effects of appropriate contacting and reaction to fluid index threshold crossing (FTC) on clinical outcomes. **Endpoints:** Composite of CV death or first HF hospitalization. The first hospitalization due to HF, first hospitalization due to CV causes, CV death, all-cause death as well as the total number of CV and HF hospitalizations per 100 patient-years were defined as secondary endpoints.	**Inclusion:** Newly implanted or replacement single-, dual-chamber ICD or CRT-D Medtronic device. NYHA class II or III and LVEF ≤35%. **Exclusion:** Renal failure; COPD; subjects with transplanted hearts or listing for transplantation; planned valve replacement or interventional valve therapy; recent MI, stroke, cardiac surgery, percutaneous coronary intervention; complex and uncorrected congenital heart disease; life expectancy < 18 months; not eligible to receive a CareLink monitor.	In the RM group, at least one FTC alert was transmitted in 356 patients (70.5%; n=505). Of note, only 55.5% (n=758) of all transmitted FTCs (n=1365) were followed by an appropriate contact. While 113 patients (31.7%; n=356) have been contacted appropriately after every FTC, in 243 patients (68.3%; n=356) at least one FTC was not responded by an appropriate contact. Compared to UC, RM with appropriate contacts to FTC alerts independently reduced the risk of the primary endpoint (Hazard ratio, 0.61; 95% confidence interval 0.39–0.95; p=0.027).		**Limitations:** The definition of appropriate contacts after FTC alert transmission was not pre-specified; the classification of contacts after FTC was based on retrospective reviews; compliance with therapy was not assessed. **Conclusions:** RM appropriate reactions to FTC alerts are associated with significantly improved clinical outcomes in patients with advanced HF and ICD.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: Post-hoc exploratory analysis. **Size:** 1002 patients.				
Chiu CSL, et al. Effect of remote monitoring on clinical outcomes in European heart failure patients with an implantable cardioverter-defibrillator: secondary results of the REMOTE-CIED randomized trial **Year Published:** 2022 **PMID:** 34410384	**Aim:** To elucidate the effect of partly substituting In-Clinic visits by RPM on clinical outcomes in ICD patients. **Endpoints:** Composite of all-cause mortality and cardiac hospitalization, mortality and cardiac hospitalization as independent endpoints and ICD therapy. **Study Type:** Prospective, multicentre, randomized trial. **Size:** 595 patients.	**Inclusion:** Patients who received ICD/CRT-D, NYHA Class II-III; LVEF ≤ 35%. **Exclusion:** < 18 or > 85yo; waiting list for a heart transplantation; history of psychiatric illness other than affective/anxiety disorders; cognitive impairments; insufficient knowledge of the language in the country where patients were recruited.	The incidence of mortality and hospitalization did not differ significantly as independent, nor as composite endpoint between the RPM and In-Clinic group (all Ps < 0.05). The results were similar regarding ICD therapy, except for appropriate ICD therapy (odds ratio 0.50; 95% confidence interval 0.26–0.98; P = 0.04). Exploratory subgroup analyses indicated that the effect of RPM differs between patients with specific characteristics, i.e. ≥ 60 years and permanent atrial fibrillation (all Ps < 0.05)		**Limitations:** High number of dropouts and crossovers; study sample consisted of relatively young patients with mild heart failure; RPM system from a single manufacturer; low incidence of inappropriate ICD therapy. **Conclusions:** RPM is non-inferior to conventional In-Clinic visits regarding clinical outcomes. Routine In-Clinic follow-up may partly be substituted by RPM without jeopardizing safety and efficiency, and thus reducing unnecessary In-Clinic visits.
Abraham WT, et al. Wireless pulmonary artery haemodynamic monitoring in chronic heart failure: a randomised controlled trial **Year Published:** 2011 **PMID:** 21315441	**Aim:** To evaluate if implantable haemodynamic monitoring systems reduces rates of hospitalisation in patients with HF. **Endpoints:** Primary efficacy endpoint was the rate of HF-related	**Inclusion:** NYHA III for at least 3 months, irrespective of LVEF or cause, hospitalisation for HF within the past 12 months, had to be given drug and device treatments for HF at optimum or best-tolerated stable doses. **Exclusion:** Recurrent pulmonary embolism or	In 6 months, 84 heart-failure-related hospitalisations were reported in the treatment group (n=270) compared with 120 in the control group (n=280; rate 0·32 vs 0·44, hazard ratio [HR] 0·72, 95% CI 0·60–0·85, p=0·0002). During the entire follow-up (mean 15 months [SD 7]), the treatment group had a 37% reduction in heart-failure-related hospitalisation compared with the control group (158 vs 254,		**Limitations:** Challenges inherent in maintaining patient masking and in minimisation of the effect of investigator–patient and device–patient interactions on outcome; not powered to detect a mortality benefit. **Conclusions:** The results show a significant and large

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	hospitalisations at 6 months. Safety endpoints were freedom from device-related or system-related complications and freedom from pressure-sensor failures. **Study Type:** Prospective, multicentre, single-blind, clinical trial. **Size:** 550 patients.	deep venous thrombosis, CRT implantation within the preceding 3 months, and stage IV or V chronic kidney disease.	HR 0·63, 95% CI 0·52–0·77; p < 0.0001. Eight patients had DSRC and overall freedom from DSRC was 98·6% (97·3–99·4) compared with a prespecified performance criterion of 80% (p < 0.0001); and overall freedom from pressure-sensor failures was 100% (99·3–100·0).		reduction in hospitalisation for patients with NYHA class III who were managed with a wireless implantable haemodynamic monitoring system. The addition of information about pulmonary artery pressure to clinical signs and symptoms allows for improved HF management.
Kurek A, et al. Impact of Remote Monitoring on Long-Term Prognosis in Heart Failure Patients in a Real-World Cohort: Results From All-Comers COMMIT-HF Trial **Year Published:** 2017 **PMID:** 28176442 **Study Name:** COMMIT-HF	**Aim:** To analyze the impact of RM on mortality and hospitalization rate using an all-comers prospective observational registry from a high-volume cardiovascular center. **Endpoints:** Long-term all-cause mortality. **Study Type:** Single-center, prospective observational registry. **Size:** 574 patients.	**Inclusion:** Consecutive patients with a first implantation of an ICD/CRT-D hospitalized with systolic HF (LV-EF ≤ 35%). **Exclusion:** Patients with acute coronary syndrome during the index hospitalization.	Lower 1-year mortality was detected in the RM group (2.1% vs. 11.5%, P < 0.0001). This was also maintained during a 3-year follow-up (4.9% vs. 22.3%, P < 0.0001). Multivariate analysis showed that RM was associated with an improved prognosis (hazard ratio 0.187, 95% confidence interval 0.075-0.467, P = 0.0003).		**Limitations:** Non-randomized study; the accurate reasons of death in this group of patients were not possible to be determined with full credibility; the unequal distribution of patients prohibits detailed comparison of system-specific advantages. **Conclusions:** RM of HF patients with ICDs/CRT-Ds significantly reduced long-term mortality in a real-world clinical condition.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Hindricks G, et al. Daily remote monitoring of implantable cardioverter-defibrillators: insights from the pooled patient-level data from three randomized controlled trials (IN-TIME, ECOST, TRUST) **Year Published:** 2017 **PMID:** 29688304 **Study Name:** IN-TIME, ECOST, TRUST	**Aim:** To verify, with appropriate time-to-event statistics, if remote monitoring improves survival. **Endpoints:** All-cause death; CV death; all-cause death or any hospitalization; all-cause death or CV hospitalization; all-cause death or hospitalization for worsening heart failure (WHF); CV death or CV hospitalization; WHF death or WHF hospitalization. **Study Type:** Meta-analysis. **Size:** 2436 patients.	**Inclusion:** Randomized controlled trials using specific remote monitoring system (Biotronik Home Monitoring, Biotronik SE & Co. KG, Berlin, Germany). **Exclusion:** Not applicable.	The absolute risk of death at 1 year was reduced by 1.9% in the HM group (95% CI: 0.1–3.8%; P = 0.037), equivalent to a risk ratio of 0.62. Also, the combined endpoint of all-cause mortality or hospitalization for worsening heart failure (WHF) was significantly reduced (by 5.6%; P = 0.007; risk ratio 0.64). The composite endpoint of all-cause mortality or cardiovascular (CV) hospitalization tended to be reduced by a similar degree (4.1%; P = 0.13; risk ratio 0.85) but without statistical significance.		**Limitations:** Except for all-cause mortality and CV mortality, all other endpoints were composite events that were not studied in this form in the original trials; study procedures differed slightly, which might have translated into certain differences in clinical effects. **Conclusions:** In a pooled analysis of the three trials, HM reduced all-cause mortality and the composite endpoint of all-cause mortality or WHF hospitalization. The similar magnitudes of absolute risk reductions for WHF and CV endpoints suggest that the benefit of HM is driven by the prevention of heart failure exacerbation.
Parthiban N, et al. Remote Monitoring of Implantable Cardioverter-Defibrillators: A Systematic Review and Meta-Analysis of Clinical Outcomes **Year Published:** 2015 **PMID:** 25983009	**Aim:** To conduct a systematic literature review and meta-analysis of RCTs comparing RM with IO follow-up. **Endpoints:** All-cause mortality, hospitalizations, unscheduled visits, shock delivery, and atrial fibrillation detections.	**Inclusion:** RCTs which results were published in peer-reviewed journal articles or as published abstracts with extractable data. **Exclusion:** Studies that provided outcome data only from nonrandomized cohorts or case series, evaluated ICDs but not RM, or evaluated RM in contexts other than ICD patients.	RM demonstrated clinical outcomes comparable with office follow-up in terms of all-cause mortality (odds ratio [OR]: 0.83; p ¼ 0.285), cardiovascular mortality (OR: 0.66; p ¼ 0.103), and hospitalization (OR: 0.83; p ¼ 0.196). However, a reduction in all-cause mortality was noted in the 3 trials using home monitoring (OR: 0.65; p ¼ 0.021) with daily verification of transmission. Although the odds of receiving any ICD shock were similar in RM and IO patients (OR: 1.05; p ¼ 0.86), the odds of inappropriate shock were		**Limitations:** Analyses are performed on reported data in the published literature rather than on primary study data. **Conclusions:** Meta-analysis of RCTs demonstrates that RM and IO follow-up showed comparable overall outcomes related to patient safety and survival, with a potential survival benefit in RCTs using daily transmission verification. RM benefits include more rapid clinical event detection

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: Systematic Review and Meta-Analysis **Size:** 6.469 patients.		reduced in RM patients (OR: 0.55; p ¼ 0.002).		and a reduction in inappropriate shocks.
Geller JC, et al. Implant-based multi-parameter telemonitoring of patients with heart failure and a defibrillator with vs. without cardiac resynchronization therapy option: a subanalysis of the IN-TIME trial **Year Published:** 2019 **PMID:** 30874886 **Study Name:** IN-TIME subanalysis	**Aim:** To explore the differences between ICD and CRT-D patients in the endpoint rate and in the benefit of telemonitoring. **Endpoints**: The primary outcome was a worsened composite clinical score at 12 months in the intention-to-treat population. Secondary outcome measures were all-cause mortality and overnight admission to hospital associated with worsening heart failure. **Study Type:** Prospective, multicenter, randomized, controlled, trial. **Size:** 664 patients.	**Inclusion**: Chronic HF (≥ 3 months) and NYHA functional class II-III, a LVEF ≤ 35%, optimized drug therapy, and a recently implanted dual-chamber ICD or CRT-D capable of automatic daily multiparameter telemonitoring (Home Monitoring; Biotronik SE & Co. KG, Berlin, Germany). **Exclusion:** Permanent atrial fibrillation.	The prevalence of worsened score at study end was higher in CRT-D than ICD patients (26.4% vs. 18.2%; P = 0.014), as was mortality (7.4% vs. 4.1%; P = 0.069). With telemonitoring, odds ratios (OR) for worsened score and hazard ratios (HR) for mortality were similar in the ICD [OR = 0.55 (P = 0.058), HR = 0.39 (P = 0.17)] and CRT-D [OR = 0.68 (P = 0.10), HR = 0.35 (P = 0.018)] subgroups (insignificant interaction, P = 0.58-0.91).		**Limitations** **Conclusions:** Daily multiparameter telemonitoring has a potential to reduce clinical endpoints in patients with chronic systolic heart failure both in ICD and CRT-D subgroups. The absolute benefit seems to be higher in higher-risk populations with worse prognosis.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Husser D, et al. Remote monitoring and clinical outcomes: details on information flow and workflow in the IN-TIME study **Year Published:** 2019 **PMID:** 30016396 **Study Name:** IN-TIME	**Aim:** To evaluate the transmission performance of HM, describing the CMU performance, and estimating delays from alerts to FU visits. (from the IN-TIME study) **Endpoints:** Time from post-implant hospital discharge to first HM transmission; number of days with HM message divided by the total days between randomization and study termination and length of transmission gaps; a linear fit of the share of patients with a HM message as a function of time after randomization, an estimation based on the distribution of the time to the next successful transmission for all days between randomization and study termination; delay from an event until the	**Inclusion:** Chronic HF, NYHA Class II/III, LVEF ≤ 35%, and an indication for dual-chamber ICD or CRT-D treatment. **Exclusion:** Permanent atrial fibrillation.	Messages were received on 83.1% of out-of-hospital days. Daily transmissions were interrupted 2.3 times per patient-year for more than 3 days. During 1 year, absolute transmission success declined by 3.3%. Information on medical events was available after 1 day (3 days) in 83.1% (94.3%) of the cases. On all working days, a central monitoring unit informed investigators of protocol defined events. Investigators contacted patients with a median delay of 1 day and arranged follow-ups, the majority of which took place within 1 week of the event being available.		**Limitations** **Conclusions:** The difference between studies may be caused by differences in content of transmitted data, speed and completeness of transmission, and workflow to contact the patient when needed.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	information is received, working time compliance of the central monitoring unit, delay from alert to patient contact and follow-up. **Study Type:** Observational retrospective. **Size:** 702 patients.				
Boehmer JP, et al. A Multisensor Algorithm Predicts Heart Failure Events in Patients With Implanted Devices: Results From the MultiSENSE Study **Year Published:** 2017 **PMID:** 28254128 **Study Name:** MultiSENSE	**Aim:** To develop and validate a device-based diagnostic algorithm to predict HF events. **Endpoints:** Heart failure events, NYHA functional class, LVEF, unexplained alert rate. **Study Type:** Multicenter, nonrandomized study. **Size:** 974 patients.	**Inclusion:** Age ≥ 18yo, currently implanted with a CRT-D system, NYHA Class II, III or IV within the last six months **Exclusion:** Pacemaker dependent, unable to rest comfortably in a semi-recumbent position for up to 20 minutes, implanted with active Medtronic Fidelis lead models, : 6930, 6931, 6948 or 6949, currently implanted with unipolar RA, RV, or LV leads, LV sensitivity programmed to less than 0.7 mV AGC, Subjects that have a history of appropriate tachycardia therapy for rates <165 bpm within 1 week of enrollment, device battery status indicates approximate time to explant < 2 years, likely to	Coprimary endpoints were evaluated using 320 patient-years of follow-up data and 50 HFEs in the test cohort (72% men; mean age 66.8 ± 10.3 years; New York Heart Association functional class at enrollment: 69% in class II, 25% in class III; mean left ventricular ejection fraction 30.0 ± 11.4%). Both endpoints were significantly exceeded, with sensitivity of 70% (95% confidence interval [CI]: 55.4% to 82.1%) and an unexplained alert rate of 1.47 per patient-year (95% CI: 1.32 to 1.65). The median lead time before HFE was 34.0 days (interquartile range: 19.0 to 66.3 days).		**Limitations:** Studied only in patients with CRT-D, just 1-year follow-up, some events were excluded because of inadequate data due to noncompliance with the study follow-up schedule, multisensor algorithm has not been studied as a specific therapeutic approach. **Conclusions:** The HeartLogic multisensor index and alert algorithm provides a sensitive and timely predictor of impending HF decompensation.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
		undergo lead or PG revision during the course of the study as determined by the investigator, receiving regularly scheduled IV (IV) inotropic therapy as part of their drug regimen, subjects that have received a heart or lung transplant, receiving mechanical circulatory support, subjects who have been referred or admitted for Hospice care, life expectancy of less than 12 months per physician discretion, enrolled in any concurrent study, without Boston Scientific written approval, subjects whose devices have previously been converted to the SRD and withdrawn from this study, subjects who have received a sub-pectoral COGNIS implant prior to February 1st 2011 that has been listed, women who are known to be pregnant or plan to become pregnant within the course of the study, LV offset is programmed to a value greater than zero			

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Burri H, et al. Risk stratification of cardiovascular and heart failure hospitalizations using integrated device diagnostics in patients with a cardiac resynchronization therapy defibrillator **Year Published:** 2018 **PMID:** 28679168	**Aim:** To validate the heart failure risk status for stratifying patient risk, evaluate its association with heart failure (HF) symptoms, and investigate its utility for triage of automatic alerts. **Endpoints:** Activation of automatic alerts; heart failure events. **Study Type:** Post hoc analysis of a randomized clinical trial. **Size:** 722 patients.	**Inclusion:** Sinus rhythm with de novo implantation of CRT-D for systolic HF with NYHA class III/IV and LVEF <35%. **Exclusion:** Permanent AT/AF; previously implanted with a CRT/CRT-D device; medical conditions that would limit study participation; <18yo.	A high heart failure risk status was associated with a significantly increased risk of admission over the next 30 days with a relative risk for cardiovascular hospitalization (CVH) of 4.5 (95% CI: 3.1–6.6, P < 0.001), of HF hospitalization of 6.3 (95% CI: 3.9–10.2, P < 0.001) and of non-HF related CVH of 3.5 (95% CI: 2.0–6.9, P < 0.001). The negative predictive value of low or medium HFRS for these admissions was >_98%. A high HFRS was associated with an increased risk of HF symptoms. Of all the automatic remote monitoring alerts generated during the study, only 10% had a high HFRS.		**Limitations:** Results may not apply to all manufacturers. **Conclusions:** The HF risk status is able to risk-stratify CRT-D patients, which is potentially useful for managing automatic remote monitoring alerts, by focusing attention on the minority of high-risk patients.
D'Onofrio A, et al. Combining home monitoring temporal trends from implanted defibrillators and baseline patient risk profile to predict heart failure hospitalizations: results from the SELENE HF study **Year Published:** 2022 **PMID:** 34392336 **Study Name:** SELENE	**Aim:** To validate an algorithm for prediction of HF hospitalizations using remote monitoring data transmitted by implant. **Endpoints:** Primary endpoint was the first post-implant hospitalization for worsening HF; secondary endpoint was a composite of hospitalization, outpatient intravenous	**Inclusion:** Patients with an ICD capable of atrial sensing or a CRT-D, LVEF ≤ 35%, NYHA class II or III before the implantation. **Exclusion:** Permanent atrial fibrillation, acute HF, previous stroke, planned cardiac surgery, short-life expectancy (< 6 months) or insufficient mobile phone service coverage at home.	After a median follow-up of 22.5 months since enrolment, patients were randomly allocated to the algorithm derivation group (n = 457; 31 endpoints) or algorithm validation group (n = 461; 29 endpoints). In the derivation group, the index showed a C-statistics of 0.89 [95% confidence interval (CI): 0.83–0.95] with 2.73 odds ratio (CI 1.98–3.78) for first HF hospitalization per unitary increase of index value (P < 0.001). In the validation group, sensitivity of predicting primary endpoint was 65.5% (CI 45.7–82.1%), median alerting time 42 days (interquartile range 21–89), and false (or unexplained) alert rate 0.69 (CI 0.64–		**Limitations:** Authors analysed only the subset of adjudicated and usable events leading to IVI, hospitalization, or death. Therefore, we cannot exclude that some algorithm alerts classified as 'false' were actually related to decompensating conditions which did not ultimately lead to a study endpoint. **Conclusions:** With the developed algorithm, two-thirds of first post-implant HF hospitalizations could be predicted timely with only 0.7 false alerts per patient-year.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	intervention, or death related to worsening HF. **Study Type:** Observational, multicentre, prospective. **Size:** 918 patients.		0.74) [or 0.63 (CI 0.58–0.68)] per patient-year. Without the baseline risk-stratifier, the sensitivity remained 65.5% and the false/unexplained alert rates increased by 10% to 0.76/0.71 per patient-year.		
Böhm M, et al. Fluid status telemedicine alerts for heart failure: a randomized controlled trial **Year Published:** 2016 **PMID:** 26984864	**Aim:** To evaluate whether early automated fluid status alert notification via telemedicine improves outcome in HF patients. **Endpoints:** The primary endpoint was a composite of all-cause death and cardiovascular hospitalization. **Study Type:** Prospective, multi-center, randomized, and unblinded study. **Size:** 1002 patients.	**Inclusion:** Patients recently implanted with an ICD with or without CRT therapy were eligible if one of three conditions was met: prior HF hospitalization, recent diuretic treatment, or recent brain natriuretic peptide increase. **Exclusion:** Patients with chronic renal failure requiring dialysis, severe chronic obstructive pulmonary disease, or with planned heart transplantation.	The primary endpoint occurred in 227 patients (45.0%) in the intervention arm and 239 patients (48.1%) in the control arm [hazard ratio, HR, 0.87; 95% confidence interval (CI), 0.72–1.04; P = 0.13]. There were 59 (11.7%) deaths in the intervention arm and 63 (12.7%) in the control arm (HR, 0.89; 95% CI, 0.62–1.28; P = 0.52). Twenty-four per cent of alerts were not transmitted and 30% were followed by a medical intervention.		**Limitations:** Optional extended follow-up beyond 18 months; potential heterogenous treatment of the intervention patients. **Conclusions:** Among ICD patients with advanced HF, fluid status telemedicine alerts did not significantly improve outcomes.
Morgan JM, et al. Remote management of heart failure using implantable electronic devices **Year Published:** 2017 **PMID:** 28575235 **Study Name**	**Aim:** To assess the clinical and cost-effectiveness of remote monitoring (RM) of HF in patients with cardiac implanted electronic devices (CIEDs).	**Inclusion:** NYHA Class II–IV, with ICD, CRT-D, CRT-P) implanted at least 6 months previously, stable and optimal medical therapy for heart failure for 6 weeks prior to enrolment, the ability to independently comprehend and complete quality of life	The incidence of the primary endpoint did not differ significantly between active RM and UC groups, which occurred in 42.4 and 40.8% of patients, respectively [hazard ratio 1.01; 95% confidence interval (CI) 0.87–1.18; P = 0.87]. There were no significant differences between the two groups with respect to any of the		**Limitations** **Conclusions:** Among patients with heart failure and a CIED, RM using weekly downloads and a formalized follow up approach does not improve outcomes.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Endpoints: The primary study endpoint in the time-to-event analysis was the 1st event of the composite of death from any cause or an unplanned hospitalization for cardiovascular reasons. The secondary endpoints were death from any cause; cardiovascular death; non-cardiovascular death; cardiovascular-related death or unplanned cardiovascular hospitalization; death from any cause or unplanned hospitalization for non-cardiovascular reason; unplanned cardiovascular hospitalization; unplanned hospitalization for non-cardiovascular reasons. **Study Type:** Randomized, event-	questionnaires and to give informed consent. **Exclusion:** Any device change or lead replacement procedure within 30 days, acute myocardial infarction or any cardiac surgical procedure within 3 months, were unable to use the technology due to mental or physical limitations, age <18years, were pregnant, were on a planned heart transplantation list, had a life expectancy of less than a year due to non-cardiovascular disease, had current CIED complications, or were unable to understand written and spoken English.	secondary endpoints or the time to the primary endpoint components.		

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	driven, multicentre, open label, and parallel group clinical trial. **Size:** 1650 patients.				
Boriani G, et al. Effects of remote monitoring on clinical outcomes and use of healthcare resources in heart failure patients with biventricular defibrillators: results of the MORE-CARE multicentre randomized controlled trial **Year Published:** 2017 **PMID:** 27568392 **Study Name:** MORE-CARE results	**Aim:** To evaluate the clinical efficacy and safety of remote monitoring in patients with heart failure implanted with a biventricular defibrillator (CRT-D) with advanced diagnostics. **Endpoints:** The primary endpoint was a composite of death and cardiovascular (CV) and device-related hospitalization. The secondary endpoints were: the utilization of healthcare resources for CV reasons, combining any duration of CV hospitalizations and CV emergency department (ED) admissions together with both scheduled and unscheduled outpatient visits; the number of	**Inclusion:** All patients who received de novo implant of a Medtronic CRT-D with wireless transmission capabilities within the last 8 weeks before enrolment. **Exclusion:** Patients/devices unable to use CareLink™ System.	No significant difference was found in the primary endpoint between the Remote and Standard arms [hazard ratio 1.02, 95% confidence interval (CI) 0.80–1.30, P = 0.89] or in the individual components of the primary endpoint (P > 0.05). For the composite endpoint of healthcare resource utilization (i.e. 2-year rates of CV hospitalizations, CV emergency department admissions, and CV in-office follow-ups), a significant 38% reduction was found in the Remote vs. Standard arm (incidence rate ratio 0.62, 95% CI 0.58–0.66, P < 0.001) mainly driven by a reduction of in-office visits.		**Limitations** **Conclusions:** In heart failure patients implanted with a CRT-D, remote monitoring did not reduce mortality or risk of CV or device-related hospitalization. Use of healthcare resources was significantly reduced as a result of a marked reduction of in-office visits without compromising patient safety.

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	hospitalizations, ED admissions, and outpatient visits separately; the costs related to utilization of healthcare resources for CV and device reasons both from the healthcare and from the patient perspective; and the safety of RM in CRT-D patient management **Study Type:** Prospective, multicentre, randomized controlled trial. **Size:** 865 patients.				
Varma N, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial **Year Published:** 2010 **PMID:** 20625110 **Study Name:** TRUST follow-up	**Aim:** To determine whether HM could safely reduce in-hospital device evaluation yet enable earlier problem discovery. **Endpoints:** Number of total in-hospital device evaluations in HM compared with conventional care; adverse event rate, comprising incidence of death, strokes, and events	**Inclusion:** Recipients of single- and dual-chamber ICDs with HM implanted for class I/II indications. **Exclusion:** Pacemaker dependent.	HM reduced total in-hospital device evaluations by 45% without affecting morbidity. In the HM group, 85.8% of all 6-, 9-, and 12-month follow-ups were performed remotely only, indicating that HM provided sufficient assessment in the majority. Median time to evaluation was <2 days in the HM group compared with 36 days in the conventional group (P<0.001) for all arrhythmic events.		**Limitations:** The 12-month postimplantation evaluation period does not address the majority of device and lead problems; pacemaker-dependent patients were excluded; patients with resynchronization devices were not assessed. **Conclusions:** HM is safe and allows more rapid detection of actionable events compared with conventional monitoring in patients with implantable electronic cardiac devices.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	requiring surgical interventions. **Study Type:** Prospective, randomized, multicenter clinical trial. **Size:** 1450 patients.				
Varma N, et al. Detection of atrial fibrillation by implanted devices with wireless data transmission capability **Year Published:** 2005 **PMID:** 15683480	**Aim:** To test the ability of HM to define temporal AF patterns. **Endpoints:** Mode switch burden >20% per 24 hours (in patients without AV block, mode switch events associated with a reduction in AV synchrony index of < 80%, with an accompanying increase in ventricular heart rate); days with mean ventricular rates > 80 beats/min and > 100 beats/min to assess rate control; management decisions resulting from transmissions. **Study Type:** Multicenter retrospective observational study. **Size:** 107 patients.	**Inclusion:** Patients with pacemakers implanted for Class I/II indications. **Exclusion:** Not described.	AF developed in 29 patients (10.5%), representing a total of 645 AF days (mean = 22.2 ± 29.6 AF, median = 9 days), over 12 ± 2 months of monitoring. AF was infrequent (50% of 24 hours. Ventricular rates during 645 AF days in 29 patients averaged 95.1 ± 9.9 beats/min (median = 94 beats/min). Ventricular rates were >80 beats/min in 25 ± 30 AF days (median = 11 days). HM enabled rapid anticoagulation decisions.	89% of 22,356 transmissions were successful, of which >90% were received in < 5 minutes. Data integrity was 100% preserved.	**Limitations:** The characteristics of AF in paced patients may not be similar to those of other groups of patients; equating mode switch with AF is prone to false positive errors; the 20%/24 hour mode switch threshold for an "AF day" is likely to have considerably limited the number of far-field R wave sensing events. **Conclusions:** In recipients of implantable devices, automatic wireless telemetry with HM was efficient and reliable. Its application may overcome some current challenges in AF management by early notification and precise measurement of both AF burden and ventricular rate during AF.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Martin DT, et al. Randomized trial of atrial arrhythmia monitoring to guide anticoagulation in patients with implanted defibrillator and cardiac resynchronization devices **Year Published:** 2015 **PMID:** 25908774	**Aim** **Endpoints:** First occurrence of stroke, systemic embolism, or major bleeding. Secondary analyses included AT burden in relation to events. **Study Type:** Multicentre, single-blinded, randomized trial. **Size:** 2718 patients.	**Inclusion:** Patients with ICD or CRT-D devices, CHADS2 risk score ≥ 1 and ability to tolerate anticoagulation. **Exclusion:** Patients with permanent AF or contraindications to anticoagulation.	A total of 945 patients (34.8%) developed AT, 264 meeting study anticoagulation criteria. Adjudicated atrial electrograms confirmed AF in 91%; median time to initiate anticoagulation was 3 vs. 54 days in the intervention and control groups, respectively (P < 0.001). Primary events (2.4 vs. 2.3 per 100 patient-years) did not differ between groups (HR 1.06; 95% CI 0.75 – 1.51; P = 0.732). Major bleeding occurred at 1.6 vs. 1.2 per 100 patient-years (HR 1.39; 95% CI 0.89 – 2.17; P = 0.145). In patients with AT, thromboembolism rates were 1.0 vs. 1.6 per 100 patient-years (relative risk 235.3%; 95% CI 270.8 to 35.3%; P = 0.251). Although AT burden was associated with thromboembolism, there was no temporal relationship between AT and stroke.	The trial was stopped after 2 years median follow-up based on futility of finding a difference in primary endpoints between groups.	**Limitations:** Poor compliance with the anticoagulation plan in the intervention group; greater use of antiplatelet therapy, combined with the protocol-specified starting of anticoagulation in the intervention group might have increased bleeding asymmetrically. **Conclusions:** The strategy of early initiation and interruption of anticoagulation based on remotely detected AT did not prevent thromboembolism and bleeding.
Marcantoni L, et al. Impact of remote monitoring on the management of arrhythmias in patients with implantable cardioverter-defibrillator **Year Published:** 2015 **PMID:** 25032715	**Aim:** To evaluate the impact of remote monitoring on the management of cardiovascular events associated with supraventricular and ventricular arrhythmias during long-term follow-up. **Endpoints:** Occurrence of supraventricular and ventricular	**Inclusion:** Consecutive patients undergoing ICD implantation or replacement from January 2006 to December 2010 **Exclusion:** Not applicable.	During a median follow-up of 842 days (interquartile range 476-1288 days), 32 (15.5%) patients experienced supraventricular arrhythmia-related events and 51 (24.6%) patients experienced ventricular arrhythmia-related events. Remote monitoring had a significant role in the reduction of supraventricular arrhythmia-related events, but it had no effect on ventricular arrhythmia-related events. In multivariable analysis, remote monitoring remained as an independent protective factor, reducing the risk of supraventricular		**Limitations:** Limited sample size; mortality was not an endpoint; the devices used were not identical. **Conclusions:** Remote monitoring systems improved outcomes in patients with supraventricular arrhythmias by reducing the risk of cardiovascular events, but no benefits were observed in patients with ventricular arrhythmias.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	arrhythmia-related cardiovascular events (ICD shocks and/or hospitalizations). **Study Type** **Size:** 207 patients		arrhythmia-related events of 67% [hazard ratio, 0.33; 95% confidence interval (CI), 0.13-0.82; P = 0.017].		
7.3 Special Programming Considerations for Implantable Loop Recorders (ILRs)					
Afzal MR, et al. Resource Use and Economic Implications of Remote Monitoring With Subcutaneous Cardiac Rhythm Monitors **Year Published:** 2021 **PMID:** 33516715	**Aim:** investigate the resource use and economic implications of ICM **Endpoints:** time commitment of device clinic, and incidence and characteristics of false positive were assessed **Study Type:** single center and observational study for 4 weeks **Size:** total of 1,457 transmissions (alert=462, full downloads=995)	**Inclusion:** During Jun 2017-Sep 2019, Reveal LINQ, Confirm Rx, BioMonitor II and III were nominal setting, and after April 2019, custom programming was set. **Exclusion**	A total of 1,457 transmissions (alert=462; full download=995) were received during study period. Average device clinic personnel time for adjudication of 1 transmission was 15±6 min. This totaled to 364 h spent (2.3 full-time staff) over the 4-week period, which translated into a salary cost of $12,000 U.S. dollars. Average time spent by an electrophysiologist for 1 transmission was 1.5±1 min and totaled to 37 h for 4 weeks, which translated into an estimated cost of $9.600 USD. Of 1,457 transmissions, 512 (35%) represented multiple transmissions from the same patients. Incidence of false positive (FP) episodes was 50% (alert 60%, full downloaded 49%). When the custom programming was compared with nominal programming, FP episode significant decreased (16% vs. 55%; p=0.01), which translated to a 34% reduction in resource use for data adjudication.	No adverse events	**Limitations:** single center study **Conclusions:** ICM data adjudication requires significant resource. Custom programming may overcome the data deluge.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
O'Shea CJ, et al. Remote Monitoring Alert Burden: An Analysis of Transmission in >26,000 Patients **Year Published:** 2021 **PMID:** 33602404	**Aim:** to determine the remote monitoring (RM) alert burden in CIEDs. **Endpoints:** Alerts were analyzed according to type, acuity (red and yellow alert) and CIED category **Study Type:** multicenter, retrospective cohort **Size:** 12,473 pacemaker patients, 9,208 ICD patients, and 5,032 ICM patients	**Inclusion:** 82,797 of the 205,804 RM transmission were alerts and a total of 14,638 (54.8%) patients transmitted at least 1 alert between November 2018 and November 2019. **Exclusion:** none	Pacemakers were responsible for 25,700 (31.0%) alerts, ICD for 15,643 (18.9%) alerts, and ILRs for41,454 (50.1%) alerts, with 3,935 (4.8%) red alerts and 78,862 (95.2%) yellow alerts. ICDs transmitted 2,073 (52.7%) red alerts; 5,024 (32.1%) ICD alerts were for ventricular tachyarrhythmias and anti-tachycardia pacing/shock delivery.	No adverse events	**Limitations:** no standardization of alert programming between clinics. **Conclusions:** In an RM cohort of 26,713 patients with CIEDs, 54.8% of patients transmitted at 1 alert during a 12-month period, totaling over 82,000 alerts. ILRs were overpresented, and ICDs were underpresented, in these alerts. The enormity of the number of transmissions and the growing ILR alert burden highlight the need for new management pathways for RM.
Afzal MR, et al. Incidence of false-positive transmissions during remote rhythm monitoring with implantable loop recorders **Year Published:** 2020 **PMID:** 31323348	**Aim:** to investigate the incidence and causes of false-positive (FP) diagnosis during remote monitoring with ILR **Endpoints** **Study Type:** retrospective, single-center study **Size:** A total of 695 remote transmissions in 559 patients with ILRs	**Inclusion:** During a 4-week study period, remote transmission in patients with ILR implanted for AF, cryptogenic stroke and syncope. **Exclusion**	A total of 695 remote transmissions (scheduled downloads 414; alert 281) from 559 ILR patients were adjudicated. Patients had ILR for AF (321), cryptogenic stroke (168) and syncope (70) with nominal programming for rhythm diagnosis. Incidence of FP transmission during the study period was 46%, 86%, and 71% in patients with AF, CS, and syncope, respectively. Incidence of FP transmission was higher in patients with CS and syncope than in patients with AF (p<.001). For scheduled transmissions, primary causes of FP were signal dropout and undersensing; for alert transmissions, primary reasons for FP were	No adverse events	**Limitations:** single center study. programmed with manufacture recommended nominal setting in ILRs **Conclusions:** Incidence of FP during remote monitoring with nominal settings on the ILR was substantial, ranging from 46% to 86% depending on the indication for implantation.

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
			premature atrial and ventricular ectopy.		
Sanders P, et al. Performance of a new atrial fibrillation detection algorithm in a miniaturized insertable cardiac monitor: Results from the Reveal LINQ Usability Study **Year Published:** 2016 **PMID:** 26961298	**Aim:** investigate the improvement AF detection algorithm in the Reveal LINQ ICM. **Endpoints:** **Study Type:** non-randomized, prospective, multicenter trial **Size:** 151 patients with Reveal LINQ	**Inclusion:** study designed 2 phase. First 30 patients were enrolled any indications for ICM, the second enrolling 121 patients had a documented AF history. **Exclusion:**	151 patients included AF ablation or AF management in 81.5% (n=123), syncope in 12.6% (n=19), and other indications in 5.9% (n=9). Of the 138 patients with an analyzable Holter recording, a total of 112 true AF episodes were identified in 38 patients (27.5%). The overall accuracy to detect durations of AF or non-AF episodes was 99.4%, and the AF burden measured by the ICM was highly correlated with the Holter.	No adverse events	**Limitations: c**omparing between ICM and Holter recording was only 24 hours in this study. **Conclusions: T**he new AF detection algorithm in the Reveal LINQ ICM accurately detects the presence or absence of AF. Additionally, it showed high sensitivity in detecting AF duration in patients with a history of intermittent and symptomatic AF.
Section 8 Managing alerts					
8.1 Defining High-Priority Alerts					
Varma N, et al. Efficacy and safety of automatic remote monitoring for implantable cardioverter-defibrillator follow-up: the Lumos-T Safely Reduces Routine Office Device Follow-up (TRUST) trial **Year Published:** 2010 **PMID:** 20625110 **Study Name:** TRUST follow-up	**Aim:** comparing the efficacy and safety of automatic daily remote monitoring (HM) in ICD recipients with standard in-clinic follow-up **Endpoints:** Primary end points: 1) number of total in-hospital device evaluations in HM compared with conventional care, 2) adverse event	**Inclusion:** Class I/II indication for ICD implant and an ability to use the HM system throughout 15 months of the study **Exclusion:** Pacemaker-dependent patients	<u>Reduction of in-hospital device evaluations</u> HM reduced total in-hospital device evaluations by 45% without affecting morbidity. <u>Adverse Events</u> No difference in safety between groups (10.4% HM vs. 10.4% conventional group over 12 months; (noninferiority P=0.005, 1 sided; P=0.010, 2 sided) <u>Detection times of clinically significant problems</u>	<u>Percentage of sufficient assessment</u> In the HM group, 85.8% of all 6-, 9-, and 12-month follow-ups were performed remotely only, indicating that HM provided sufficient assessment in the majority. <u>Overall survival</u> 96.4% vs. 94.2% (HM vs. conventional group; (P=0.174).	**Limitations:** -Short evaluation duration (12-month post-implantation) - exclusion of pacemaker-dependent patients - not assessing the patients with CRT-devices **Conclusions:** HM is safe and allows more rapid detection of actionable events compared with conventional monitoring in patients with implantable electronic cardiac devices

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	rate (death, strokes, and events requiring surgical interventions) between the 2 groups. Secondary end point: detection times of clinically significant problems (time from first occurrence of arrhythmia to physician evaluation). **Study Type:** prospective, randomized, multicenter clinical trial **Size:** HM (n=908), Conventional (n=431) **Follow-up:** 3, 6, 9, 12, and 15 months after implantation		Median time to evaluation was <2 days in the HM group compared with 36 days in the conventional group (P<0.001) for all arrhythmic events.		
Varma N, et al. Same-day discovery of implantable cardioverter defibrillator dysfunction in the TRUST remote monitoring trial: influence of contrasting messaging systems **Year Published:** 2013 **PMID:** 23258817 **Study Name:** TRUST	**Aim:** to assess the possibility of same-day evaluation of ICD system dysfunction through automatic remote home monitoring (HM) **Endpoints:** not specified (detection time from event	**Inclusion** Class I/II indication for ICD implant and an ability to use the HM system throughout 15 months of the study **Exclusion:** Pacemaker-dependent patients	<u>Detection time from event onset to physician evaluation</u> 61% were detected in <24 h. 44% events were detected on the same day. 56% were detected between 1 and 39 days (mean 10.0 ± 13.0 days). Ten of 14 events were detected by HM and 4 at the time of office visits. <u>Detection time of redundant</u>	<u>ICD system problems automatically triggered notifications:</u> repeatedly ('redundant') for impedance deviations and elective replacement indication (ERI), but only a single transmission for '30 J ineffective'.	**Limitations** - small number of system-related events occurred - short follow up duration, however, most device-related problems are anticipated to manifest several years post-implant. **Conclusions:** Same-day discovery of ICD dysfunction, even if

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	onset to physician, detection time of redundant, system-related alerts) **Study Type:** sub analysis of the TRUST trial **Size:** 908 HM patients		Mean detection time of redundant events was 1.1 ± 1.8 vs. single transmission 5.6 ± 10.9 days (P = 0.05). <u>System-related alerts</u> 42% were asymptomatic, 42% were actionable, and 51% were viewed within 24 h. <u>Redundant notifications</u> 1 ERI 9 shock impedance 2 ventricular and 6 atrial pacing impedance		asymptomatic, was achievable. For those events not evaluated within 24 h, repetitive messaging promoted earlier discovery. Reorganization of clinical follow-up methods may maintain early reaction ability.
Hindricks G, et al. Implant-based multiparameter telemonitoring of patients with heart failure (IN-TIME): a randomised controlled trial **Year Published:** 2014 **PMID:** 25131977 **Study Name:** IN-TIME	**Aim:** to assess the impact of Home Monitoring on the early detection of worsening congestive heart failure and the clinical status of heart failure patients **Endpoints:** Packer Score (including mortality, heart failure hospitalisation, NYHA classification and a patient self assessment)	**Inclusion:** -Indication according to ESC guidelines for ICD / CRT-D -Chronic HF (≥3 months) -NYHA Class II or III for 1 month prior to screening LVEF ≤35% within 3 months prior to screening -Indication for therapy with diuretics -Stable optimal drug therapy -Transmission performance of Home Monitoring ≥80% or corrective action initiated if performance <80% **Exclusion:** Restrictive, infiltrative or hypertrophic	At 1 year, 18·9% in the telemonitoring group versus 27·2% of 331 in the control group (p=0·013) had worsened composite score (odds ratio 0·63, 95% CI 0·43–0·90).	Ten versus 27 patients died during follow-up.	**Limitations:** - inability to mask patients and investigators to the treatment allocation. -The potential bias inherent in a non-blinded intervention study - medium-term length of follow-up **Conclusions:** Automatic, daily, implant-based, multiparameter telemonitoring can significantly improve clinical outcomes for patients with heart failure. Such telemonitoring is feasible and should be used in clinical practice

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	Study Type: multicenter randomised controlled trial **Size:** 333 HM, 331 control	cardiomyopathy, constrictive pericarditis, acute myocarditis; NYHA class I or IV; Uncontrolled hypertension; Permanent atrial fibrillation; Tricuspid valve replacement, severe mitral regurgitation, symptomatic aortic stenosis; Participation in another telemonitoring concept or another study; Known drug or alcohol abuse, expected non-compliance or life expectancy <1 year; Pregnancy; Age <18 years; planned cardiac surgery within next 3 months; Acute coronary syndrome, cardiac surgery or stroke within last 6 weeks			
Guédon-Moreau L, et al. Validation of an Organizational Management Model of Remote Implantable Cardioverter-Defibrillator Monitoring Alerts **Year Published:** 2015 **PMID:** 26105725	**Aim:** Validation of an organizational management model of remote ICD monitoring alert with comparing 2 remote monitoring (RM) periods consisting of iterative, qualitative, and quantitative (1) device diagnostic evaluations by nurses and	**Inclusion:** consecutive patients who had undergone ICD-implantation according to practice guidelines **Exclusion:** N/A	<u>Number of transmissions</u> During the first period: - 1134 alerts in 427 patients -> 33% were submitted to cardiologists' reviews, During the second period> - 1522 alerts in 562 patients -> 18% were submitted to cardiologists' reviews during (P<0.001). <u>Reactions to alerts</u> An intervention was prompted by 73 of 376 (19.4%) alerts in the first	<u>The annual numbers of alert-related hospitalizations</u> 10.8 versus 8.1 per 100-patient-year (P=0.230), <u>The annual numbers of alert-related visits</u> 9.8 and 6.1 per 100-patient-year (P=0.081),	**Limitations** - single-center study, not randomized - using a historical control group **Conclusions** An optimized RM organization based on automated alerts and decisional trees enabled a focus on clinically relevant events and a decrease in the consumption of resources

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	cardiologists; and (2) selected decisional trees. **Endpoints:** (1) number of transmissions, (2) time spent in the management of transmissions by caregivers, (3) reactions to alerts, and (4) clinical outcomes **Study Type:** observational study **Size:** 562 ICD recipients		versus 77 of 273 (28.2%) in the second period (P=0.009). <u>Time spent in the management of transmissions by caregivers</u> 4 minutes 31 s in the first versus 2 minutes 10 s in the second period (P<0.001).		without compromising the quality of ICD recipients' care.
Otsuki S, et al. Efficacy of antitachycardia pacing alert by remote monitoring of implantable cardioverter-defibrillators for out-of-hospital electrical storm **Year Published:** 2021 **PMID:** 34346080	**Aim:** To assess the efficacy of antitachycardia pacing (ATP) alert by remote monitoring (RM) of ICDs for out-of-hospital electrical storm (ES) **Endpoints:** 1) Number of appropriate ICD shock in cases where VT could be temporarily terminated within	**Inclusion:** Patients who had an RM introduced and had experienced the onset of an out-of hospital ES episode. **Exclusion:** Patients who refused examination/hospitalization requested by their attending physicians for ES confirmed with RM.	<u>VT Termination</u> In 35 of 54 episodes of ES, ventricular tachycardia (VT) could be terminated within 24 h of ES onset just by ATP (ATP-alert-on: 14, ATP-alert-off: 21). <u>Episodes that led to shock delivery</u> Episodes that led to shock delivery 24 h or longer after the ES onset were significantly less common in the ATP-alert-on group (ATP-alert-on: 1/14, ATP-alert-off: 9/21, p = 0.03). <u>Number of shock deliveries</u> Although there were no significant differences in the number of shock deliveries between episodes in the two groups, the number of ATP	Multivariate logistic regression analyses showed that the only ATP-alert significantly reduced ATP deliveries (HR = 0.14, 95%CI = 0.04-0.57, p = .003).	**Limitations** - Retrospective single-center study with a small sample size - Potential data bias with regard to device selection and programming (differences in programming) - The time required for reacting to alert messages was left up to the judgment of attending the physicians **Conclusions** Remote monitoring with an ATP-alert function during electrical storm may reduce appropriate ICD therapy

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	24 h of ES onset by ATP. 2) clinical effectiveness of alert message for ATP in all ES episodes, such as reduction in appropriate ICD therapies between the two groups ((ATP-alert-on; ATP-alert-off) **Study Type:** Observational **Size:** 42 patients with ICD/CRT-D with 54 episodes		deliveries were significantly fewer in the ATP-alert-on group (12[7-26] vs. 29[16-53] in ATP-alert-off group, p = 0.03).		through prompting early review.
Section 9 Remote monitoring reporting					
9.3 Techniques for Incorporating Reports into Electronic Health Records					
Seiler A, et al. Clinic Time Required for Remote and In-Person Management of Patients With Cardiac Devices: Time and Motion Workflow Evaluation **Year Published:** 2021 **PMID:** 34156344	**Aim:** To characterize the workflow processes and clinic staff time required for remote and in-person device follow-up of patients with CIEDs. **Endpoints:** Activities related to managing patients, categorized into 3 groups: in-person clinic visits, remote transmission review, and other	**Inclusion:** Not applicable. **Exclusion:** Not applicable.	Mean staff time required per remote transmission ranged from 9.4 to 13.5 minutes for therapeutic devices (pacemaker, implantable cardioverter-defibrillator, and cardiac resynchronization therapy) and from 11.3 to 12.9 minutes for diagnostic devices such as insertable cardiac monitors (ICMs). Mean staff time per in-person visit ranged from 37.8 to 51.0 and from 39.9 to 45.8 minutes for therapeutic devices and ICMs, respectively. Including all remote and in-person follow-ups, the estimated annual time to manage a patient with a CIED ranged from 1.6 to 2.4 hours		**Limitations:** Study measurements were reliant on the workflow taking place during the data collection week and were not systematically controlled for patient or center characteristics; the time and motion methodology was designed as a clinic-perspective workflow characterization and did not follow patients longitudinally; it was unable to measure patient clinical metrics, such as device connectivity success

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	patient management activities not attributable to a specific patient device check (eg, patient triage and scheduling, identifying patients lost to follow-up, and telephone communication with patients). **Study Type:** Observational. **Size:** 276 in-person clinic visits and 2173 remote monitoring.		for therapeutic devices and from 7.7 to 9.3 hours for ICMs.		and patient adherence to follow-ups; extrapolations were made using externally published data and HRS guidelines for patient follow-up, and these assumptions may not be generalizable to all clinics. **Conclusions:** The associated workflows require significant clinical and administrative staff time across in-person clinic visits, remote transmission review, and other patient management tasks.
Section 10 Patient education for remote monitoring					
10.1 Patient education for participation and compliance					
Strachan PH, et al. Readability and content of patient education material related to implantable cardioverter defibrillators **Year Published:** 2012 **PMID:** 21926915	**Aim:** To assess the readability and content of ICD-related print education materials **Endpoints:** Readability (‘‘simple measurement of gobbledygook’’ and Fry methods) and content measurements (plain-language criteria, thematic content analysis,	**Inclusion:** Educational materials reported as used by interviewees who had accepted or declined an ICD for primary prevention as part of a larger study exploring patients’ decision making **Exclusion:** None	Text-reading levels in the majority of materials exceeded recommendations. Twelve major content themes were recognized. Content focuses more on the positive than negative aspects of ICD, which could influence decision making.		**Limitations:** Acquisition of materials for review was based on patient reporting. No observations were made regarding the provision or comprehension of the materials. No assessment of individual patient reading levels. **Conclusions:** Print-based patient education materials exceed recommendations. The current focus on positive rather than negative aspects of ICDs is a possible source of

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
	and rhetoric analysis) **Study Type:** Patient education material assessment **Size:** n=21				bias for patient decision making.
Timmermans I, et al. The patient perspective on remote monitoring of patients with an implantable cardioverter defibrillator: Narrative review and future directions **Year Published:** 2017 **PMID:** 28612995	**Aim: T**o ascertain patient experiences and preferences for follow-up **Endpoints:** Questionnaire responses **Study Type:** Substudy of the REMOTE-CIED study, which was randomized and unblinded, 32 sites **Size:** n=300	**Inclusion:** Symptomatic heart failure (LVEF 35, NYHA II or III); first-time Boston-Scientific ICD or CRT-D **Exclusion:** Age < 18, > 85; heart transplant waiting list; psychiatric history other than affective or anxiety disorders; inability to complete the questionnaire due to cognitive impairment or language problems	Median patient satisfaction 9 out of 10 (IQR 8-10), though 53% of patients had issues, such as challenges with data transmission. Of the 221 patients who reported preferences on follow-up, 43% preferred remote monitoring and 19% preferred in-clinic follow-up.	Patients with a preference for RPM were more likely to be higher educated (P = 0.04), employed (P = 0.04), and equipped with a new LATITUDE model (P = 0.04), but less likely to suffer from chronic obstructive pulmonary disease (P = 0.009).	**Limitations:** Unblinded, only Boston Scientific **Conclusions:** Though most patients preferred remote monitoring, there were certain patients that preferred in-person visits. Differences between those who preferred remote versus in-person monitoring included education, newer equipment, and comorbidities.
Laurent G, et al. Role of patient education in the perception and acceptance of home monitoring after recent implantation of cardioverter defibrillators: the EDUCAT study **Year Published:** 2014 **PMID:** 25218008 **Study Name:** EDUCAT	**Aim: T**o ascertain education impact on perception and acceptance of home monitoring **Endpoints:** Questionnaire response **Study Type:** 2 Questionnaires, 6 months apart, 46 sites, Industry-sponsored **Size:** n=571	**Inclusion:** Implantation of a LUMAX VR-T ICD, a DR-T ICD or a HF-T ICD (Biotronik) **Exclusion:** NYHA IV at the time of ICD implantation	Improved comprehension associated with younger patients ($p<0.001$); high-quality training (7 of 11 parameters with $p \leq 0.04$); and better anxiety/acceptance levels ($p<0.001$/$p<0.001$).	Mean data transmission rate was unrelated to the comprehension scores.	**Limitations:** Non-randomized, unblinded, evaluated only Biotronik devices and only ICDs, selection bias **Conclusions:** Clear understanding was associated with higher acceptance of health monitoring and lower anxiety related to its use.
Section 11 Manufacturer responsibilities with remote monitoring					
11.1 Manufacturers' role to optimize individual patient care					

Appendix 3 Evidence tables *(continued)*

Author; Title; Year published; PMID; Study Name	Aim of study; Endpoints; Study type; Study size (N)	Patient population with inclusion and exclusion criteria	Results	Other relevant findings or adverse events	Limitations; Other comments; Conclusions
Fraiche AM, et al. Patient and Provider Perspectives on Remote Monitoring of Pacemakers and Implantable Cardioverter-Defibrillators **Year Published:** 2021 **PMID:** 33757780	**Aim:** Understand pt and clinician perceptions regarding RM of CIEDs **Endpoints:** Interview **Study Type:** Qualitative interview **Size:** 15 patients, 13 providers	**Inclusion:** CIED clinic pts with RM **Exclusion:** Cognitive dysfunction	Similar themes across interviewees, limited knowledge and understanding of RM. Clinicians wanted to involve pts in decision making but actual is challenging given, personnel needs, diverse technology and pt and physician preferences, and large volume of data. Knowledge gaps in how to communicate alerts		**Limitations:** Single centre, some pts volunteered so potential selection bias. Small sample **Conclusions:** RM provides opportunities for improved patient care but is underutilized and confusing. Conflicting perceptions and knowledge gaps despite high trust