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Alert-driven versus scheduled remote monitoring of implantable cardiac defibrillators: A Cost-Consequence Analysis from the TRUST Trial

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Abstract

Background: Alert-driven RPM or fully virtual care without routine evaluations may reduce clinic workload and promote more efficient resource allocation, principally by diminishing nonactionable patient encounters. The study objective was to conduct a cost-consequence analysis to compare three post-implant ICD follow-up strategies: (a) IPE only, (b) RPM-conventional (hybrid of IPE and RPM), and (c) RPM-alert (alert-based ICD follow up).

Methods: We constructed a decision-analytic Markov model to estimate the costs and benefits of these three strategies over a two-year time horizon from the perspective of the US Medicare payer. Aggregate and patient-level data from the TRUST (Lumos-T Safely RedUceS RouTine Office Device Follow-up) randomized clinical trial informed clinical effectiveness model inputs. TRUST randomized 1,339 patients 2:1 to conventional RPM or IPE alone, and found that RPM was safe and reduced the number of non-actionable encounters. Cost data was obtained from the published literature. The primary outcome was incremental cost.

Results: The 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. 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]-\$2,138 to +\$638) and −\$1,677 (95% CI

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−\$3,134 to −\$304), respectively. Therefore, the RPM-alert strategy was most cost-effective with an estimated cost-savings in 99% of simulations.

Conclusions: Alert-driven RPM was economically attractive and, if patient outcomes and safety are comparable to conventional RPM, may be the preferred strategy of ICD follow up.

Keywords

Remote monitoring; implantable cardioverter defibrillators; remote follow up; telemedicine; patient monitoring; economics; cost consequence analysis; economic evaluation

INTRODUCTION

Implantable cardioverter defibrillator (ICD) follow up is structured around 3 monthly evaluations.^{1, 2} This paradigm of follow up reflects technology from over 2 decades ago where ICDs required frequent threshold and battery tests as well as capacitor reformation. Advances in ICD technology have rendered this rationale obsolete yet the practice of frequent routine scheduled patient assessments persists.²

The TRUST (Lumos-T Safely RedUceS RouTine Office Device Follow-up) and other subsequent clinical trials demonstrated that remote follow up dramatically reduced the need for in person evaluation.^{3, 4} This laid the foundation for current guideline recommendations.¹ Adoption of these recommendations requires a shift of clinician workload from visible clinic interactions to largely "invisible" patient evaluations involving management of data transmissions requiring clinic coordination and interpretation.⁵ Few routinely scheduled evaluations require clinical action; for example, only 6.6% of all 3 month scheduled in-person or remote transmissions in TRUST were clinically actionable. Routine evaluations represent a burden to physicians, patients and healthcare systems.⁴ Recent data suggests that the indirect workload may be even more substantial as an unintended consequence of alert management, continuous remote monitoring, patienttriggered transmissions, and time-intensive implantable loop recorder interpretations on top of non-actionable routinely scheduled evaluations.⁵

In the current environment, reimbursement appears insufficient for clinic workforce needs, forcing delegation of remote management to third parties.⁶ Increasing volume and complexity of patients receiving cardiac implantable electronic devices (CIEDs) will aggravate this condition.⁶ However, device clinic workload may be alleviated if activity is directed more to "actionable" work by reducing the number of routinely scheduled, but clinically low yield routine evaluations. Alert-based remote monitoring, without routine evaluations, has been proposed as a more efficient follow up strategy and was enacted in some clinical practices during the pandemic.⁷ However, the economic implications of alert-based remote monitoring are currently undefined. These requisite data are pivotal to inform policy-level health care funding decisions, and reimbursement models that directly impact the uptake of remote monitoring and device clinic structuring.

The purpose of this study is to assess the economic implications of three different strategies of ICD follow up: (1) in clinic visits only; (2) conventional remote monitoring follow-up

consisting of a hybrid of in person and remote follow up; and (3) alert-driven remote monitoring, where in person visits are scheduled only if necessary. We report the findings of this cost-consequence analysis, where incremental costs and incremental benefits (i.e., quality-adjusted life years) are reported separately, rather than a cost-effectiveness analysis which provides an aggregated incremental cost effectiveness ratio.

METHODS

The study protocol and report were prepared in accordance with the Consolidated Health Economic Evaluation Reporting Standards (CHEERS) Statement.⁸

Trial Design and Patient Population

The TRUST trial design and methods have been reported previously in detail.^{3, 4, 9} TRUST enrolled participants with single- or dual-chamber ICDs capable of home monitoring and implanted for class I/II indications. Participants from 102 centers across the US were enrolled within 45 days of successful ICD implantation and randomized in a 2:1 ratio to scheduled remote home monitoring and clinic visits (augmented by automated alert transmissions for critical events), or scheduled in-clinic visits alone. Trial enrollment occurred between November 2005 and February 2008 with follow up for 15 months. Approval of the appropriate institutional review board or ethics committee was obtained at all sites, and all patients provided written informed consent [\(ClinicalTrials.gov](http://ClinicalTrials.gov) Identifier [NCT00336284\)](https://clinicaltrials.gov/ct2/show/NCT00336284).

Model Design and Structure

We constructed a decision-analytic Markov model to project the costs of three follow up strategies after ICD implantation: (a) in-person evaluations ("IPE") alone, consisting of scheduled in person visits every 3 months; (b) conventional remote patient monitoring ("RPM-conventional"), consisting of scheduled in-person visits at 3 and 12 months supplemented by remote evaluations every 3 months between clinic visits as well as unscheduled visits driven by device alerts; and (c) alert-driven only care ("RPMalert"). In the RPM-alert strategy, there would be no scheduled in-person or remote evaluations following an initial post-operative assessment, unless a device alert prompted an unscheduled clinic visit.

A two-state Markov model was constructed in TreeAge Pro 2022 (Williamstown, MA) consisting of two health states: alive and dead. Each monthly cycle, the cohort of patients in the alive health state could be admitted to hospital (i.e., a transient health event associated with costs and decrement to patient quality of life), experience an unscheduled clinic or emergency department visit, undergoing lead or device system revision, die or remain event free (Figure 1). From the perspective of the US Medicare payer, a 2-year time horizon was chosen to reflect the follow up duration of the TRUST trial.^{3, 4} The primary outcome was the incremental cost per patient. The secondary outcome was incremental quality-adjusted life expectancy. We hypothesized that RPM-alert and/or RPM-conventional strategies would be associated with cost-savings, in which case a negative incremental cost-effectiveness ratio (ICER) would not be meaningful to interpret. Thus, the pre-planned economic plan was

to perform a cost-consequence analysis, where costs and clinical outcomes were reported separately without the ICER summary endpoint.

Medical Resource Use

Clinical effectiveness inputs (Table 1) were informed directly by the TRUST randomized trial, which compared a strategy of IPE to RPM-conventional (i.e., hybrid of IPE supplemented by remote evaluations). TRUST prospectively collected medical resource use data and reported the annualized rates of emergency department visits and hospitalization, total clinic visits, and device malfunction requiring lead extraction and system revision. Since TRUST reported the aggregate rates of ED and hospitalization visits, we assumed that 82% of reported visits were due to inpatient hospitalization based on medical resource use patterns from the Agency for Healthcare Research and Quality's Healthcare Cost and Utilization Project Nationwide Emergency Department Sample and National Inpatient Sample that described a national cohort of patients with heart failure.¹⁰ For the RPMalert strategy, we were required to make several model assumptions since TRUST only empirically compared the IPE and RPM-conventional strategies. Specifically, we assumed that scheduled RPM-alert strategy had similar medical resource use and clinical outcomes as the RPM-conventional strategy with regard to unscheduled emergency department visits, hospitalizations and clinic visits. Additionally, the model assumed that there was no difference in mortality between the IPE, RPM-conventional and RPM-alert strategies. This conservative assumption is consistent with the TRUST findings and prior studies reporting heterogenous impact of remote monitoring on mortality.¹¹

Survival Parametrization and Model Validation

Using individual patient data from the TRUST trial, survival was modelled using a parametric model fit to a Weibull distribution, which was selected among other plausible distributions (i.e., Weibull, Log-Normal, Gompertz, Exponential) according to the smallest Akaike Information Criterion or Bayesian Information Criterion goodness-of-fit statistic.¹² Parameterization of survival was performed using Stata 16 (College Station, TX).

To assess model agreement with empirical TRUST survival results, we compared the model estimates of undiscounted life expectancy to the restricted mean survival times derived directly from the TRUST trial data. The modelled and empiric survival estimates were compared over the trial follow up.

Costing Sources

Costs of outpatient encounters (such as in clinic visits or remote evaluation) were assigned using the 2021 Medicare Physician Fee Schedule based on Current Procedural Terminology codes.13 The cost of an emergency department visit was obtained from a published analysis of several national datasets including the Medical Expenditure Panel Survey, National Hospital Ambulatory Medical Care Survey, and the Healthcare Cost and Utilization Project's Nationwide Inpatient Sample.¹⁴ For hospitalization costs, we obtained the average cost per patient of a heart failure hospitalization with a median length of stay of 5 days from an analysis of the national 5% sample of Medicare beneficiaries.15 Medication costs were

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not included as medication use was expected to be similar between the RM and in-clinic groups.

Device clinic nursing costs were based on the average hourly wage for a Registered Nurse reported in the 2021 Occupational Employment and Wage Statistics published by the U.S Bureau of Labor Statistics.¹⁶ The hourly wage was applied to the average visit times reported in a time and motion workflow evaluation study of in-person clinic visits and remote monitoring evaluations across 11 centers in the United States and Europe.¹⁷ In this study, the mean visit time for US centers, including direct and indirect patient care, was 12.7 minutes per remote transmission review and 51.0 minutes per in-clinic visit. Consistent with this time and motion study, our analysis assumed a two-level review process where interrogations and/or transmissions were preliminarily reviewed by device clinic nurses to determine further escalation for intervention by a physician or other clinician. Costs were valued in 2021 USD, and adjusted using the US Medical Care Consumer Price Index, where appropriate.¹⁸

Sensitivity Analyses

The base case analysis assumed that the remote monitoring equipment was bundled into the procurement cost of the implantable cardioverter defibrillation. Depending on the hospital, these equipment or infrastructure costs may be absorbed by industry or included in the marked-up procedure cost, or considered part of capital costs for existing hospital infrastructure to manage. For better understanding into the value proposition of remote monitoring, we conducted a sensitivity analysis assuming an additional cost of \$2,500 for the remote monitoring equipment, which were costs assumed to be absorbed by industry or included in the device prices, or associated costs associated with hospital infrastructure.

Concordant with economic evaluation best practices,19 we conducted an exploratory analysis to project costs and outcomes over a (remaining) lifetime horizon to better reflect the potential long-term consequences of the RPM strategies. During the lifetime extrapolation, we assumed that the RPM-alert strategy would require an in-person clinic visit every 2 years. Furthermore, we included a cost of \$31,503 (2021 USD) for each ICD generator replacement²⁰ every 6 years assuming (a) an average of 6 years of battery longevity consistent with the current ICD technology during the TRUST study, and (b) that there was no substantial difference in battery longevity between the IPE and RPM strategies.²¹ Medical resource use observed in the TRUST trial by follow up strategy (IPE versus RPM) was assumed to be the same during the extrapolation period.

Variability and Uncertainty

All model outputs were probabilistic. Distributional assumptions of the input parameters were as follows: log-normal distributions for all hazard ratios, β-distributions to all probabilities and utilities, and γ -distributions to all costs. A Monte Carlo simulation with 10,000 iterations was used to describe the impact of uncertainty in individual model parameters on a distribution of expected costs. Deterministic one-way sensitivity analyses were also performed that varied one input parameter at a time using the lower and upper 95% interval bounds and recorded the change in the incremental cost.

Variables, for which confidence intervals were not provided, were modelled with wide distributions $(\pm 50\%)$ to enhance external validity and to evaluate the robustness of the findings. A 3% discount rate was applied to all future costs and benefits.¹⁹

RESULTS

Model Validation

The model estimates of survival were comparable to the empirically observed survival in TRUST. Specifically, modelled life expectancies compared with restricted mean survival times were 0.496 life year (LY) versus 0.496 LY (0.493 to 0.498) at 6 months, 0.983 LY versus 0.981 LY (0.974 to 0.989) at 12 months, and 1.22 LYs versus 1.22 LYs (1.21 to 1.23) at 15 months.

Cost-Consequence Analysis

At 2 years, the mean cumulative 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. 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)-\$2,138 to +\$638) and −\$1,677 (95% CI −\$3,134 to −\$304), respectively (Table 2). Of the three groups, the RPM-alert strategy was considered the preferred, optimal strategy with an estimated cost-savings in 99% of simulations.

There was no difference in discounted life expectancy between the IPE, RPM-conventional and RPM-alert arms. Quality-adjusted life expectancy between groups was also similar with an estimated 1.59 QALYs (95% CI 1.06 to 1.85) over the 2-year time horizon.

Sensitivity Analyses

For the one-way sensitivity analyses, we made the conservative assumption that emergency department visits and hospitalizations were not significantly different between the IPE and RM strategies. Under these conditions, when comparing the IPE and RPM-alert strategies, the inputs with the greatest variation effect on the model included the cost and frequency of scheduled in-person clinics (Figure 2A). However, cost-savings was estimated in all one-way sensitivity analyses across the plausible range for each model input. Similarly, across one-way sensitivity analyses, RPM-Alert was cost saving compared to the RPMconventional strategy (Figure 2B). Notably, the cost of remote monitoring assessments did not appear to be an influential factor when varied between \$32 to \$96 per alert-driven assessment.

To assess the maximum reimbursement for a remote monitoring evaluation where the RPM strategies would still be considered cost-savings, we conducted a post-hoc threshold analysis. Reimbursement could be increased up to \$162 per remote assessment, where the RPM-conventional strategy would be cost-neutral and the RPM-alert strategy would remain cost-savings compared to the IPE strategy.

While the remote monitoring equipment is often bundled into the initial cost of device, we conducted a sensitivity analysis assuming that \$2,500 of additional costs for the monitoring

equipment. In this scenario, the RPM-alert and RPM-conventional strategies were associated with $+$ \$827 and $+$ \$991 increased costs, respectively, compared to the IPE strategy. Thus, remote monitoring would not be considered economically attractive due to the cumulative increased costs assuming an equipment price of \$2,500 over a limited 2-year time horizon.

Lifetime Horizon

The base case time horizon was limited to 2 years based on the empiric follow up of TRUST trial and to limit the uncertainty in medical resource use beyond this time period. An exploratory analysis over a lifetime horizon was conducted to assess the potential long-term consequences of the RPM strategies. Over a lifetime horizon, the cumulative costs were \$114,274 for IPE, \$109,449 for RM-conventional, and \$105,274 for RM-alert. Compared to the IPE strategy, the total incremental cost-savings were −\$4,826 (95% CI −\$12,043 to +\$2,056) with RPM-conventional and −\$9,000 (95% CI −\$16,249 to −\$2,104) with RPM-alert.

There were 7.9329 discounted QALYs estimated in the IPE strategy. The RPM-alert and RPM-conventional strategies were associated with +0.0002 additional QALYs compared to IPE due to a non-significant lower rate of ED visits and hospitalizations. The RPM-alert strategy was the preferred strategy in 99% of simulations compared to both the RPMconventional and IPE strategies due to the observed cost-savings (Figure 3).

In a sensitivity analysis that included the additional fees for remote monitoring equipment, both the RPM-conventional and RPM-alert strategies were cost-savings (i.e., −\$4,185 and −\$6,401, respectively) compared to the IPE alone strategy.

DISCUSSION

The main finding of our analysis indicates that alert-based remote monitoring of patients with ICDs is economically attractive through provision of cost-savings to the US Medicare payor compared to either strategies of in-person evaluations alone or conventional remote monitoring consisting of scheduled remote evaluations and in-person evaluations. Due to these cost-savings, the RPM-alert strategy is considered a high value healthcare intervention as per the American College of Cardiology / American Heart Association Cost and Value Framework.²²

Over 2-year time horizon of the primary analysis, the estimates of cost-savings remained consistent in the sensitivity analyses where the model inputs were varied over their reported ranges. The model inputs with the most influence on the estimated incremental costs were the cost and frequency of scheduled in-person clinics. Cost-savings would still be achieved even if reimbursement for a remote monitoring assessment was increased by over two-fold, which acknowledges the Medicare reimbursement variability by state.

This economic analysis has important implications in the United States given that over 100,000 de novo ICDs are implanted in the United States annually but implementation of remote monitoring remains limited.²³ Even without considering the larger prevalent population with existing ICDs, a strategy of alert-based remote monitoring would save over

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80 million dollars annually compared to a strategy to in-person evaluations alone, or 50 million dollars compared to conventional remote monitoring. These findings are particularly relevant for health policymakers when considering value-based health care initiatives.

Our results are consistent with prior cost-consequence and cost-minimization studies conducted in the United States, 24 Canada, 25 and Europe, 26 where conventional remote monitoring (with scheduled in clinic visits) met country-specific thresholds for good value in health care. For example, remote monitoring was associated with \$3,703 (2012 US dollars) in cost savings compared to in-clinic visits alone in a US nationwide cohort study of patients with pacemakers, ICDs, and cardiac resynchronization therapy using the IBM MarketScan database. These cost-savings were driven primarily through a 30% reduction in hospitalization costs associated with a remote monitoring strategy. When compared to the current economic analysis, our model provides a more conservative estimate of economic benefit when comparing remote monitoring to in-person evaluations alone. Consistent with clinical findings of the TRUST randomized clinical trial, our economic model assumed that there are no significant cost-offsets during follow up from reduced hospitalization visits, or fewer emergency department visits. However, hospital length of stay was not available in the TRUST study, which may provide additional cost benefits in favor of remote monitoring. For example, the CONNECT (Clinical Evaluation of Remote Notification to Reduce Time to Clinical Decision) randomized study, enrolling 1,997 patients with ICDs, found that remote monitoring was associated with a significant decreased length of stay per CV hospitalization.27 Postulated mechanisms of shorter hospital length of stay include shortened response time from device alerts to clinical decision and earlier intervention for clinical deterioration enabled with remote monitoring. Additionally, TRUST did not include patients at the highest risk of HF and re-hospitalization such as those with CRT-D or pacemaker dependence. There may be a greater value proposition among those at higher HF risk due to the benefits of continuous remote monitoring and earlier intervention when acting upon alert transmissions.²⁸

Prior economic models have not specifically assessed the cost-effectiveness of alert-based only models of care, as there is limited data available regarding clinical outcomes associated with fully virtual remote monitoring. The current study is enabled by patientlevel randomized control trial data from the TRUST trial, which reported medical resource use and outcomes over a 1-year period of exclusive alert-based follow up in a post-hoc analysis.⁴ The finding that alert-based monitoring yields the greatest cost-savings has implications for value-based health care initiatives. That is, the current study supports the economic benefits of moving toward a solely alert-based remote monitoring model instead of conventional remote monitoring requiring a hybrid of scheduled in person clinic visits and routine transmissions; less than 7% of these routine evaluations are non-actionable.4, ²⁹ Importantly, the economic model was limited to a 2-year time horizon to approximate the follow up of the TRUST trial. Whether an alert-based remote monitoring approach is safe and effective beyond 2 years without some form of in person assessment remains to be assessed. This form of fully virtual CIED care will be assessed in the upcoming Remote Patient Management of Cardiac Implantable Electronic Devices Tachy Study (RPM CIED Tachy) [\(clinicaltrials.gov](http://clinicaltrials.gov) [NCT03405740\)](https://clinicaltrials.gov/ct2/show/NCT03405740). The advantages of alert-based care are likely to be amplified with time, since likelihood of device/lead related issues increase, battery longevity

improves (and ERI can be notified by alerts promptly without intensified frequency of interrogations), unnecessary shock therapies and related hospitalizations are reduced, improved technology behind device alerts, and opportunities for disease modification (AF and HF) increase.^{3, 21, 28} We also did not include the reduction in patient costs (time, transportation). Therefore, our estimates are considered conservative.

Limitations

The results of the study need to be interpreted in the context of several limitations. First, the clinical effectiveness inputs were primarily based on a single randomized control trial that enrolled patients from over 10 years ago using a remote monitoring platform from a single manufacturer. However, the remote monitoring capabilities of the platform used in the TRUST study have remained largely unchanged, maintaining consistent daily connectivity, which underpins the practice of alert based follow up. The alert notification portfolio included all critical device- and arrhythmia-related parameters. Our results are considered conservative as current and future innovation could enhance remote monitoring value and efficiency, including artificial intelligence-based surveillance, longer battery longevity, and the potential for remote reprogramming. Extrapolation of the study findings to remote monitoring platforms developed by others manufacturers may be limited depending on the features included within each platform.30 Prior studies suggest that daily verification of transmissions is a key feature associated with reduction in clinical endpoints such as HF hospitalization.28, 31

Second, TRUST compared a strategy of IPE versus RPM-conventional. The RPM-alert strategy was not directly assessed in the TRUST trial, but modelled based on the outcomes of during the exclusive remote monitoring period (i.e., 3 months to 15 months of follow up) without scheduled in person clinic visits (elimination of scheduled evaluations did not compromise ability for problem discovery or patient safety). However, we were able to model an RPM-alert strategy as this analysis benefit from the use of patient-level data to simulate the outcomes associated with a solely alert-driven model of care. Effectiveness of an alert-driven model is contingent upon patient adherence and home monitoring connectivity; however, data from the TRUST trial suggests improved adherence among the RPM-conventional group compared to the IPE group.^{3, 4} Nonetheless, application of an actionable care model is contingent upon demonstration of the safety of alert-driven management without scheduled interrogation (in person or remote) in a longer-term study.³²

Third, costing inputs for the study were obtained from external costing studies, rather than prospective bill collection alongside the clinical trial. However, the costing inputs were obtained from studies derived from Medicare or Medicaid reimbursements to ensure consistency with the study perspective of the US Medicare payer. Additionally, the value proposition of alert-based remote monitoring did not appear substantially affected by the costing inputs. Finally, we did not include indirect patient costs, such as out-of-pocket payments, clinic travel and caregiver costs, or lost productivity associated with device related care. The economic benefits of alert-based remote monitoring would likely be greater if adopting a broader societal perspective.

CONCLUSIONS

Alert-based remote patient monitoring with minimized scheduled evaluation (in person or remote assessment) is an efficient and transformative model of care. This approach is cost-savings compared to both conventional RPM and clinic only follow up strategies, with implications for value-based health care initiatives.

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Conflicts of Interest:

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Figure 1.

Conceptual Model of Follow Up for Patients with Implantable Cardioverter Defibrillators: IPE (In-person evaluations only), RPM- Conventional (hybrid in-person evaluations and remote evaluation), RPM-Alert (Alert-based care).

Nb. Idealized follow-up for IPE and RPM-Conventional strategies based on 2008 and 2015 Heart Rhythm Society Expert Consensus Documents. IPE versus RM-conventional directly assessed in the TRUST RCT. RM-Alert group modelled based on TRUST data. Abbreviations. ERI – end replacement indicator; RM – Remote monitoring; VT – ventricular tachycardia.

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Figure 2.

Tornado diagram summarizing one-way sensitivity analyses on incremental costs: **A**. RPM-Alert – IPE Strategies; **B**. RPM-Alert versus RPM-Conventional Strategies. Grey and black bars denote the effects of the upper and lower bounds of each variable input, respectively. That is, the upper bound may have differential effects on the incremental costs depending on the variable input. Abbreviations: ED – emergency department; IPE – in person evaluation; RPM – remote patient monitoring; USD – United States Dollar.

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Figure 3.

Incremental cost-effectiveness plane comparing the In-Person Evaluation (IPE) Only Strategy to Remote Patient Monitoring (RPM) Alert Strategy. Costs and benefits accrued over a lifetime horizon.

Table 1.

Base case clinical and costing inputs

* Cost of remote monitoring equipment added for sensitivity analysis.

Abbreviations: ED – emergency department; HF – heart failure; ICD – implantable cardioverter defibrillator; IPE – in-person evaluation; RPM – remote patient management.

Table 2.

Base case results (2-year time horizon).

