January 2013

Remote Monitoring Of Implantable Cardioverter-Defibrillators From 2006 To 2010: Patterns Of Utilization And The Impact Of New Current Procedural Terminology Codes

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Remote Monitoring of Implantable Cardioverter-Defibrillators from 2006 to 2010: Patterns of Utilization and the Impact of New Current Procedural Terminology Codes

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A Thesis Presented to
The Faculty of The Yale School of Public Health
Yale University

In Candidacy for the Degree of
Master of Public Health

2013

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Abstract

Background: The PREDICt-RM study found that Remote Patient Monitoring (RPM) was used by less than half of eligible patients with implantable cardioverter-defibrillators (ICDs) between 2006 and 2010 despite guideline recommendations. We investigated whether the addition of new Current Procedural Terminology (CPT) codes for RPM in January 2009 had impact on utilization of RPM technology and whether the impact varied by race or geographic region.

Methods: We used multivariable logistic regression to determine whether subjects in the PREDICt-RM study cohort receiving an ICD post-coding change were more likely to enroll in an RPM program or activate RPM (transmit RPM data) within 180 days of implant, versus those implanted pre-coding change. Rate differences between the post and pre-coding change periods were calculated overall and for racial and regional subgroups.

Results: Subjects implanted after the 2009 coding change were less likely to enroll (OR 0.76) and more likely to activate (OR 1.27). Enrollment rates in the Post period were significantly lower than the Pre period in most regions and among all races. Activation rates were higher in most regions, but only among white subjects.

Conclusion: The 2009 CPT coding change was not associated with an appreciable rise in RPM utilization, and minorities continue to underutilize the technology to a greater extent than white patients. There is a need for the professional community to standardize the implementation of RPM technology in routine practice, and further studies should examine patient and provider motivations for utilizing RPM.

Acknowledgements

Foremost, the author would like to thank her advisors, Dr. Judith Lichtman and Dr. Jeptha Curtis for their generous mentorship and guidance throughout the thesis process. The author is also indebted to following staff members of the Center for Outcomes Research & Evaluation (CORE): Ms. Valerie L. Solli and Ms. Kelly M. Coles for their administrative support, Ms. Bonnie Garmisa for her coordination and organization, Ms. Jinghong Gao for her patient technical assistance, and Dr. Haikun Bao for his statistical expertise.

Table of Contents

Background

Implantable cardioverter-defibrillator (ICD) therapy is indicated for patients at risk of sudden cardiac death due to ventricular arrhythmias[1]. These devices are implanted in patients to monitor cardiac rhythm and deliver antiarrhythmic therapies if potentially lethal arrhythmias are detected. Current practice guidelines recommend routine patient follow-up visits every 3 to 6 months after ICD implant in order to both evaluate system function and lead integrity, download telemetry, and make programming changes if necessary[2]. The longer a patient has had an ICD, the greater the risk for device malfunction, poor signal-to-noise ratios, under-detection of significant clinical events, and inappropriate shock delivery[3].

As indications for ICD therapy have expanded over the last decade, there has been a concomitant increase in the number of implants and the rate of in-person follow up[1,4] Traditionally, follow-up evaluations occur during regularly scheduled office visits, imposing significant burden on patients, physicians and health care facilities[5]. Remote patient monitoring (RPM) has emerged as an alternative mode of follow-up that may supplant office visits. RPM systems allow patients to transmit ICD data to their health care providers through a communicator device installed in the home[6]. Compared to traditional monitoring, this model has been found to enhance the discovery of clinically significant events, reduce hospitalizations, and expedite clinical decision-making[7-10] without adding substantial burden to clinicians' workload[11]. Furthermore, studies suggest that RPM may reduce the risk of mortality and reduces health care costs compared with in-office follow up visits[12-14].

Successful use of RPM consists of two steps. Providers must first enroll patients into an RPM program, and patients must then activate RPM by making an initial data transmission from

home. These actions must both occur to begin RPM, and potential barriers to utilization exist at both stages.

On January 1st, 2009, new current procedural technology (CPT) codes for remote monitoring of ICDs went into effect. CPT codes are developed by the American Medical Association (AMA) and provide a systematic way of describing medical services for documentation and billing purposes. The addition of RPM codes for ICDs in January 2009 was a signal of RPM's acceptance as part of professional practice, as new CPT codes typically emerge as a result of the professional community demonstrating support and need for their inclusion[15]. However, the lack of a uniform process for billing remote device interrogation before the January 2009 coding change[5] coding change could conceivably have been a barrier to uptake of RPM. Conversely, standardization of billing for RPM may have facilitated its uptake.

The recent Patient RElated Determinants of ICD Remote Monitoring (PREDICt-RM) study found that less than half of patients implanted with Boston Scientific Corporation (BSC) ICDs between 2006 and 2010 utilized RPM technology[16] Investigators also identified lower rates of utilization in coastal regions of the U.S. and among racial minorities. In the present investigation, we build on the findings of the PREDICt-RM study by examining whether the January 2009 CPT coding change had a measurable impact on enrollment and activation rates in the PREDICt-RM cohort. Secondarily, we explore race and region-based variation in the differences in enrollment and activation rates between the period before the coding change and the period after. Given increasing indications for ICD therapy and the increasing acceptance of RPM among practitioners, we expect enrollment and activation rates to increase following the advent of new CPT codes.

Methods

Data sources and cohort derivation

Derivation of the study database and study cohort are described in detail in the methods section of the parent PREDICt-RM study[16].Briefly, a de-identified, limited data set from the BSC ALTITUDE database was indirectly linked to a limited data set from the National Cardiovascular Data Registry (NCDR®) ICD Registry™ based on Hospital Medicare provider number (MPN), patient age, patient gender, and date of implantation. The ALTITUDE database, which encompasses patients implanted with RPM-capable ICDs manufactured by BSC, includes data on ICD implantation date, device model number, patient age, gender, and zip code, dates of enrollment into BSC's LATITUDE RPM program and dates of device data transmission.

Patients who could not be linked between the ALTITUDE and ICD Registry data sets were excluded. The linked cohort was then subjected to the following exclusion criteria: patients who had received a cardiac transplant or surgical epicardial lead, patients implanted at hospitals not reporting all of their ICDs, patients with unknown vital status, patients who died during the implanting hospital stay, and patients with invalid enrollment and activation dates. The final cohort consists of 39,158 subjects who underwent ICD implantation between January 2006 and March 2010.

The study cohort was divided into two subcohorts according to the date of ICD implantation. The "Pre" subcohort consisted of subjects who underwent ICD implantation between January 2006 and December 2008, prior to the January 1st, 2009 CPT coding change, The "Post" subcohort consisted of subjects who received ICDs between January 2009 and March 2010, after the coding change.

Outcomes

As defined in the PREDICt-RM study, the primary outcomes of interest were enrollment and activation of RPM. Subjects were classified as "enrolled" if enrollment in the LATITUDE RPM program occurred within 180 days of device implantation. Subjects who were not enrolled by 180 days post-implant were considered "not enrolled." Similarly, out of those enrolled, subjects were classified as "active" if they first transmitted data from home within 180 days of implant. Subjects not activated by 180 days post-implant were considered "inactive." The 180-day timeframe captures the majority of enrollments and activations, which typically occur within weeks after ICD implantation. Enrollments and activations taking place after the 180-day period are likely related to interim changes in health status, and therefore may not reflect the context of routine RPM use.

As enrollment is a pre-condition for activation, activated subjects are a subset of enrolled subjects. Subjects who enrolled in RPM but never transmitted data were considered enrolled but inactive. All subjects in the study database were categorized based on enrollment and activation status.

Statistical Analysis

Demographic, clinical, physician, hospital and regional characteristics were compared between the Pre and Post subcohorts using Chi-square tests for categorical variables and student's t-tests for continuous variables, using a significance level of α=0.05. For categorical variables with a missing rate less than or equal to 5%, missing values were assumed to represent the most common category. A "missing" category was added for categorical variables with a missing rate greater than 5%. For continuous variables, the median value for the overall cohort was used to impute missing values. Rates of enrollment and activation were calculated as follows.

Enrollment rate was defined as the percentage of subjects who enrolled in RPM within 180 days of implant, out of those who received ICDs. Activation rate was defined as the percentage of subjects who activated RPM within 180 days of implant, out of enrolled subjects.

Absolute differences between Pre and Post enrollment and activation rates were calculated overall and for racial and regional subgroups. Rate differences were tested for significance using Chi-square tests for equality of proportions (α=0.05). Breslow-Day tests for heterogeneity were conducted to determine whether the association of time period with enrollment and activation varied based on race or region (α=0.05). Breslow-Day tests were Tarone-adjusted to account for low frequencies in minority racial groups and less populated geographic regions.

Multivariable logistic regression analyses were performed to determine whether the time period (Pre or Post coding change) was an independent predictor of enrollment and of activation. Covariates were selected from the models for RPM enrollment and activation developed in the PREDICt-RM Phase I study. To develop these models, Phase I investigators performed multivariable logistic regression with stepwise selection (p-value for variable entry = 0.1, p-value for variable retention = 0.05), followed by a bootstrapping procedure with 1000 iterations. The final enrollment and activation models included variables that were selected in over 70% of the iterations. In the present investigation, we included the same covariates identified in these prior analyses, and included an indicator for Pre or Post status to each baseline model and assessed for significance. The baseline enrollment model included 21 variables, and the baseline activation model included 17 variables. Likelihood ratios were compared between the baseline models and the new models to determine whether addition of the Pre Post indicator improved model fit. C-statistics were also compared to assess whether the indicator improved model discrimination.

SAS version 9.3 (SAS Institute, Cary, NC) was used for all analyses. Tables and figures were created in SAS 9.3 and Microsoft Excel version 12.3.4 (Microsoft Corporation, Redmond, WA).

Results

Subject Characteristics and Overall Trends

The quarterly volume of RPM-capable Boston Scientific ICD implants increased over the study period, suggesting rising acceptance of RPM-capable technology into routine practice (Figure 1). Although the Post-CPT coding change period was 9 months shorter than the Pre period (15 months vs. 24 months), implant volumes were nearly equal in the two periods. Of the 39,158 subjects in the overall cohort, 19,669 received ICD implants in the Pre period, and 19,489 in the Post period (Table 1). Post subjects were significantly younger than Pre subjects (65.6 years vs. 67.9 years, $p<0.0001$) and more likely to be non-white ($p<0.0001$). Both groups were predominantly male, and gender distributions were not significantly different ($p=0.5689$). Post subjects were slightly more likely to have undergone implantation in the New England, Central and Mountain regions ($p=0.0026$).

Enrollment rates appear generally higher in the Pre period than the Post period (Figure 2a). Activation rates remained above 60% over the entire period and did not appear significantly different in the Post period than the Pre period (Figure 2b).

Enrollment and Activation Rates

Table 2 contains enrollment and activation rates stratified by race and region, as well as the absolute rate differences between the Pre and Post periods. Overall, enrollment in the post period was 7.5% lower than in the Pre period (95% CI -8.5%, -7.5%; $p<0.0001$) while activation was 3.4% higher (95% CI 2.5%, 4.5%; $p<0.0001$). Post enrollment rates were significantly lower

than Pre enrollment rates in all U.S. regions except for New England, and Other, where there was no significant difference between enrollment rates in the two periods, The drop in enrollment was most pronounced in the Atlantic and Pacific regions (-10.2% and -10.7%, respectively) Post activation rates were significantly higher in the Atlantic, Central, Pacific and Other regions, but did not significantly change in New England or the Mountain region. The Other region saw the greatest rise in enrollment in the Post period (7.0%, 95% CI 1.42%, 12.6%). Among all racial subgroups, enrollment rates were significantly lower in the Post period. Only the white subgroup had a significantly higher Post activation rate. In non-white racial subgroups, Post activation rates were not significantly different than Pre rates.

Within regions, enrollment rate differences in racial subgroups were similar to the difference observed in the region overall: enrollment rates decreased across all racial groups in the Atlantic and Pacific, and for all except Other races in the Central region. The significantly higher overall Post activation rates observed in the Atlantic, Central, Pacific and Other regions were mirrored in the white subgroup only. Minority racial subgroups within those regions did not experience any changes in activation rates. In general, enrollment rates did not rise in any racial or regional subgroups, and only white patients experienced a modest rise in activation rates (4.0%, 95% CI 2.9%, 5.2%). Race-based variation in Pre vs. Post differences in activation rates demonstrate that minority patients continue to underutilize RPM to a greater extent than white patients following the coding change.

The Breslow-Day test revealed heterogeneity in the effect of time period on enrollment by race ($p=0.0055$) and by region ($p<0.0001$). Hispanic and Other subjects had greater decreases in enrollment (-11.6%, -12.7%, respectively) than white and black subjects (-6.0%, -9.5%, respectively). Enrollment decreased more in the Atlantic, Mountain and Pacific regions (-10.2%,

-9.1%, -10.7%, respectively) than in the Central and Other regions (-5.8%, -1.8%, respectively). and there was also heterogeneity by race within the Pacific region (p=0.0006): black, Hispanic, and Other subjects experienced sharper drops in enrollment rates than white subjects (- 21.0%, -20.6%, and -19.6%, respectively, vs. -5.5%). The effect of time period on activation was heterogeneous by race overall and in the Central region (p=0.0425, p=0.0017, respectively)

Risk-Adjusted Analyses

Post subjects were significantly less likely to enroll in RPM than Pre subjects in risk-adjusted analyses (OR 0.76, 95% CI 0.73, 0.80; Figure 3). The likelihood ratio test indicated that the addition of the time period variable to the enrollment model significantly improved fit (p<0.0001). Model discrimination also improved slightly (c=0.671 vs. c=0.668 for the baseline model).

Post subjects were significantly more likely to activate RPM than Pre subjects (OR 1.27, 95% CI 1.19, 1.36; Figure 4). The likelihood ratio test indicated that model fit was significantly better with the addition of the time period variable (p<0.0001). There was a modest increase in discriminatory power (c=0.622 vs. c=0.618 for the baseline model).

Discussion

Our findings demonstrate that even though there was an overall increase in the number if RPM-capable ICD implants over the 2006-2010 period, there was a decrease in RPM enrollment rates after the 2009 CPT coding change. Despite the decrease in enrollment, the proportion of subjects that activated RPM out of those who enrolled increased. However, the increase in activation was not experienced by minority subgroups, and enrollment decreases in those groups were more pronounced than for the white subgroup. The observed drop in RPM enrollment rates

following the January 2009 coding change is unexpected, particularly against a backdrop of the professional community's increasing support for the use of RPM[17,18]. Although the overall increase in activation represents a favorable trend, it is not enough to offset the impact of decreased enrollment. The observed racial disparities in RPM utilization also merit further study. It is possible that physician bias plays a role in underutilization among minorities, whereby minority patients are less likely to be encouraged to enroll in RPM programs.

The Phase I parent study concluded that enrollment was primarily dependent on provider and institutional factors, while activation relied more on patient-related factors. In the latest investigation, the discrepancy between increased likelihood of enrollment and decreased likelihood of activation after the coding change further highlights the fact that enrollment and activation are two separate processes with distinct determinants. These findings raise questions about the patient and physician factors contributing to the utilization of RPM technology. Providers and patients may jointly determine that RPM is less appropriate than in-office follow up for a variety of reasons. Providers may prefer in-office follow-up for certain patients out of concern for lack of compliance with data transmission procedures. Providers that have successfully cared for ICD patients in person for years may be hesitant to adopt RPM. Similarly, patients may feel more comfortable seeing their providers in person. These factors may influence the decision not to enroll in RPM, but they do not fully explain why some patients enroll but never activate.

Although RPM has evolved and matured over the past decade, it is still a relatively new technology, and guidelines for its usage are not yet prescriptive[19]. Despite the advent of a unified billing scheme for RPM, the parameters for the application of RPM in routine practice have yet to be standardized. Ideally, each provider and institution should have protocols in place for

managing their remotely monitored ICD patients that address such details as the division of administrative and clinical responsibilities among members of the remote monitoring care team, procedures for responding to detected clinical events, and handling of confidential remote monitoring data. It remains unclear what the best practices are in each of these domains. In addition, the nature of providers' and institutions' legal liability surrounding an RPM-detected event is poorly defined. For instance, it is unclear whether failure to immediately respond to an event alert constitutes negligence[19]. The professional community will need to clarify the logistical, ethical, and legal framework of RPM in anticipation of its more widespread adoption. In the meantime, the absence of an established framework for implementing RPM in a clinical context may pose a significant barrier to its uptake by providers and institutions.

Limitations

The present study did not take into account in-person office visits, so it is unclear whether those who did not enroll in or activate RPM elected to use the traditional mode of follow-up, or whether they neglected to follow up altogether. Secondly, the PREDICt-RM database included only RPM-capable ICDs from Boston Scientific Corporation. Non-RPM capable devices, and devices from other manufacturers were not taken into account. Furthermore, all the devices in the database were landline-dependent, which may have posed a barrier to patients of lower socioeconomic status who are less likely to have landline access[6,16]. Wireless RPM systems that can transmit data over cellular networks are becoming increasingly available, reducing the reliance on landlines. Thus, the findings of this study may not be generalizable to the utilization of other types of RPM systems. Further, the racial and regional subgroups in which Post rates were not significantly different than Pre rates (Table 2) had the fewest subjects, implying insufficient statistical power to detect a difference rather than a true lack thereof.

This analysis was also unable to capture physician and patient rationales for not utilizing RPM. Future qualitative studies examining patients' and providers' decision-making processes surrounding enrollment in and activation of RPM are warranted, as are prospective studies of whether patients in the PREDICt-RM cohort who utilized RPM experience better clinical outcomes.

Conclusion

The 2009 CPT coding change that incorporated uniform codes for remote patient monitoring of ICDs is not associated with an appreciable rise in RPM utilization. Unexpectedly, RPM enrollment rates were significantly lower after the coding change, whereas activation rates were higher, although the increase was limited to white patients. Enrollment rates decreased most sharply in the Atlantic, Mountain and Pacific regions and among racial and ethnic minorities. A qualitative investigation of patients' and providers' respective motivations for utilizing RPM technology would help elucidate the modifiable provider-related, institution-related, and patient-related factors that could be targeted to facilitate further RPM uptake.

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Table 1. Characteristics of Pre and Post Subcohorts

Table 1. Characteristics of Pre and Post Subcohorts

Variable (%)*	Pre Jan 2006-Dec 2008 (N=19,669)	Post Jan 2009-Mar 2010 (N=19,489)	P-value **
Patient Characteristics			
Age Mean (SD)	67.9 (12.2)	65.6 (13.4)	<0.0001
Age			<0.0001
≤ 50	9.0	13.3	
50-60	16.5	18.8	
60-70	27.0	27.6	
70-80	32.9	27.9	
>80	14.6	12.4	
Female Gender	28.6	28.3	0.5689
Race			<0.0001
White non-Hispanic	78.4	75.5	
Black non-Hispanic	12.7	14.3	
Hispanic	5.4	5.6	
Other	3.5	4.6	
Syncope	16.6	18.6	<0.0001
Family History Sudden Death	4.2	4.9	0.0012
CHF Duration			<0.0001
No	12.0	22.4	
< 9 months	27.1	27.1	
> 9 months	61.0	50.5	
Prior CHF Hospitalization			<0.0001
Not Hospitalized	49.6	59.2	
< 6 months	30.3	25.0	
> 6 months ago	20.1	15.9	
NYHA Class			<0.0001
I/II	28.0	46.8	
III	66.8	49.5	
VI	5.3	3.7	
Cardiac Arrest	6.8	11.2	<0.0001
Atrial Fibrillation/Flutter	32.5	30.1	<0.0001
Ventricular Tachycardia	27.7	33.4	<0.0001
Sinus Node Dysfunction	27.1	22.7	<0.0001
Non-Ischemic Dilated Cardiomyopathy			<0.0001
No	62.2	63.7	
< 9 months	12.6	13.9	
> 9 months	25.2	22.4	
Ischemic HD/Previous MI	55.6	56.1	0.3310
Previous CABG/PCI	36.8	34.5	<0.0001
Previous Valvular Surgery	8.4	7.3	<0.0001
Pacemaker Insertion	12.8	8.5	<0.0001
Cerebrovascular Disease	14.3	14.2	0.6916
Chronic Lung Disease	24.1	23.3	0.0907
Diabetes	39.5	37.2	<0.0001
Hypertension	76.7	77.6	0.0501
Renal Failure-Dialysis	3.9	3.9	0.9374
EF % ≤ 35	93.2	86.2	<0.0001
QRS Duration ≤ 120	31.7	53.7	<0.0001
Intraventricular Conduction			<0.0001
Normal	25.7	45.4	
LBBB	43.1	26.3	
RBBB	7.9	7.4	
Paced	8.6	6.2	
Other	14.7	14.7	
Creatinine Level			<0.0001
≤ 1.5	78.6	81.8	
1.5-2.5	16.9	13.4	
>2.5	4.5	4.8	
BUN Level			<0.0001
≤ 20	46.6	52.6	
20-40	41.8	38.0	
>40	11.6	9.3	
Sodium Level			0.8787
≤ 135	16.8	16.7	
135-145	82.2	82.3	
>145	1.1	1.0	
Systolic BP			0.0010
≤ 100	8.1	7.5	
100-130	47.7	46.7	
>130	44.2	45.9	

Table 1. Continued

Variable (%)*	Pre Jan 2006-Dec 2008 (N=19,669)	Post Jan 2009-Mar 2010 (N=19,489)	P-value **
Median Household Income ≤ 50K	73.7	74.3	0.1277
% Age ≥25 with ≥4 Yrs College	21.8 (13.3)	21.7 (13.4)	0.4934
% Occupied Housing Unit with Telephone	97.4 (2.1)	97.4 (2.1)	0.6119
Population Density per Square Mile ≤ 3000	88.4	88.8	0.1550
Distance from patient to Facility			
≤ 25	69.6	69.8	0.6237
25-50	14.8	14.6	
50-100	8.8	9.0	
>100	6.8	6.6	
ICD Procedure			
Insurance Payors			<0.0001
Medicare	66.0	59.1	
Medicaid	4.9	6.7	
Governmental Insurance	0.9	1.1	
Commercial/HMO	25.6	29.2	
Non-US/None	2.6	4.0	
Admission Reason			<0.0001
Admitted for this Procedure	63.2	60.4	
Cardiac reason	16.0	12.4	
Non-Cardiac reason	18.1	24.1	
Unknown	2.7	3.1	
ICD Indication			<0.0001
Primary Prevention	86.9	81.9	
ICD Type			<0.0001
Single Chamber	8.4	21.4	
Dual Chamber	20.1	39.2	
Biventricular	71.5	39.4	
Adverse Events	3.5	2.7	<0.0001
Physician Characteristics			
EP operator ICD training			<0.0001
EP Board-certified/eligible	69.0	73.9	
Surgery board	0.8	1.3	
Other	9.3	12.1	
Missing	20.9	12.7	
Boston Scientific device Rate (%)			<0.0001
≤ 11	28.4	25.8	
11-18	25.9	25.3	
18-28	24.8	24.3	
>28	20.9	24.6	
Hospital Characteristics			
Owner			0.0682
Public	7.1	7.7	
Not-for-profit	78.5	78.1	
Private	14.4	14.2	
Core Based Statistical Area			0.8501
Urban	99.9	99.9	
Rural	0.1	0.1	
Beds set up and staffed			0.0002
≤ 200	11.2	12.3	
200-400	41.1	41.6	
> 400	47.4	46.1	
Teaching status			0.6505
Council of Teaching Hospitals	30.1	30.1	
Teaching	25.5	25.1	
Other	44.4	44.8	
Cardiac facility			<0.0001
CABG	86.3	84.9	
CATH	2.3	3.8	
Other	11.5	11.3	
Region			0.0026
Other	3.3	3.3	
New England	3.7	3.8	
Atlantic	36.9	36.1	
Central	40.3	41.5	
Mountain	4.8	5.2	
Pacific	11.1	10.1	

Percentages may not sum to 100% due to rounding

* Table values are mean ± SD (continuous variables) and column % (categorical variables)

**p-values are for student t-test (continuous variables) or $\chi 2$ test (categorical variables)

Table 2. Enrollment and Activation Rates by Race and Region

Race	Outcome	Region							
		Overall (N=39158)	**New England** (N=1451)	**Atlantic** (N=14291)	**Central** (N=16002)	**Mountain** (N=1958)	**Pacific** (N=4165)	**Other** (N=1291)	**P-value** ***
Overall (N=39158)	**Enrollment (%)**								<0.0001
	Pre	65.3	57.1	58.8	72.3	62.5	64.8	67.7	
	Post	57.8	59.9	48.5	66.5	53.4	54.1	65.9	
	p*	<0.0001	0.2812	<0.0001	<0.0001	<0.0001	<0.0001	0.5026	
	Post-Pre Difference (95% CI)	-7.5 (-8.5, -6.5)	2.8 (-2.3, 7.9)	-10.2 (-11.9, -8.6)	-5.8 (-7.2, -4.4)	-9.1 (-13.5, -4.8)	-10.7 (-13.7, -7.7)	-1.8 (-6.9, 3.4)	
	Activation (%)								0.1088
	Pre	74.2	74.1	73.0	76.4	78.7	67.5	73.9	
	Post	77.7	74.0	76.6	79.8	76.0	71.7	80.9	
	p*	<0.0001	0.9697	0.0004	<0.0001	0.2763	0.0218	0.0143	
	Post-Pre Difference (95% CI)	3.4 (2.4, 4.5)	-0.1 (-6.0, 5.8)	3.5 (1.6, 5.5)	3.4 (1.8, 4.9)	-2.7 (-7.6, 2.2)	4.3 (0.7, 7.9)	7.0 (1.42, 12.6)	
White (N=30142)	**Enrollment (%)**								<0.0001
	Pre	68.4	58.2	61.5	75.1	66.1	66.8	74.2	
	Post	62.4	62.7	51.8	71.0	56.0	61.3	69.8	
	p*	<0.0001	0.0999	<0.0001	<0.0001	<0.0001	0.0018	0.1313	
	Post-Pre Difference (95% CI)	-6.0 (-7.1, -4.9)	4.6 (-0.1, 10.0)	-9.7 (-11.6, -7.8)	-4.1 (-5.6, -2.5)	-10.0 (-14.7, -5.3)	-5.5 (-9.0, -2.1)	-4.4 (-10.1, 1.3)	
	Activation (%)								0.0727
	Pre	75.8	74.7	75.5	76.9	79.0	70.0	77.0	
	Post	79.8	75.1	79.1	81.5	76.6	75.1	84.0	
	p*	<0.0001	0.8976	0.0012	<0.0001	0.3479	0.0130	0.0202	
	Post-Pre Difference (95% CI)	4.0 (2.9, 5.2)	0.4 (-5.8, 6.6)	3.6 (1.4, 5.7)	4.6 (3.0, 6.2)	-2.5 (-7.6, 2.7)	5.1 (1.1, 9.1)	7.1 (1.1, 13.0)	
Black (N=5289)	**Enrollment (%)**								0.3899
	Pre	56.5	51.8	53.5	58.5	50.0	67.2	71.3	
	Post	47.0	36.2	43.7	49.9	52.4	46.2	65.8	
	p*	<0.0001	0.1123	<0.0001	0.0002	0.8653	0.0005	0.3960	
	Post-Pre Difference (95% CI)	-9.5 (-12.2, -6.8)	-15.6 (-34.6, 3.4)	-9.8 (-13.6, -6.1)	-8.6 (-13.1, -4.1)	2.4 (-25.1, 29.9)	-21.0 (-32.6, -9.5)	-5.4 (-17.9, 7.0)	
	Activation (%)								0.0676
	Pre	68.1	69.0	64.8	73.3	75.0	70.9	58.2	
	Post	69.4	47.1	69.6	70.7	45.5	68.2	68.4	
	p*	0.4467	0.1417	0.0594	0.3662	0.2238**	0.7147	0.2040	
	Post-Pre Difference (95% CI)	1.4 (-2.1, 4.8)	-21.9 (-51.0, 7.2)	4.9 (-0.2, 9.9)	-2.6 (-8.1, 3.0)	-29.6 (-65.8, 6.7)	-2.8 (-17.5, 12.0)	10.2 (-5.5, 25.8)	
Hispanic (N=2155)	**Enrollment (%)**								0.3928
	Pre	47.6	48.3	43.6	55.4	34.9	60.1	21.9	
	Post	36.0	42.5	28.9	43.3	33.3	39.5	12.0	
	p*	<0.0001	0.634	<0.0001	0.0028	0.8269	<0.0001	0.3768**	
	Post-Pre Difference (95% CI)	-11.6 (-15.8, -7.5)	-5.8 (-29.6, 18.0)	-14.6 (-21.2, -8.1)	-12.1 (-20.0, -4.2)	-1.6 (-15.5, 12.4)	-20.6 (-30.2, -10.9)	-9.9 (-26.2, 6.4)	
	Activation (%)								0.9087
	Pre	62.9	71.4	60.8	69.3	86.7	50.0	64.3	
	Post	65.6	76.5	65.5	71.2	77.4	49.4	66.7	
	p*	0.4129	1.0000**	0.4194	0.7121	0.3476	0.9351	1.0000**	
	Post-Pre Difference (95% CI)	2.6 (-3.7, 9.0)	5.0 (-26.1, 36.1)	4.7 (-6.6, 16.0)	2.0 (-8.4, 12.3)	-9.3 (-28.3, 9.9)	-0.6 (-14.7, 13.6)	2.4 (-56.6, 61.3)	
Other (N=1572)	**Enrollment (%)**								0.3861
	Pre	55.8	52.4	53.8	61.5	62.5	53.4	45.0	
	Post	43.1	61.1	39.9	52.5	45.7	33.8	40.9	
	p*	<0.0001	0.5836	0.0038	0.0581	0.1182	<0.0001	0.789	
	Post-Pre Difference (95% CI)	-12.7 (-17.7, -7.8)	8.7 (-22.3, 39.8)	-13.9 (-23.2, -4.5)	-9.1 (-18.3, 0.2)	-16.9 (-37.6, 3.9)	-19.6 (-28.2, 11.0)	-4.1 (-34.1, 25.9)	
	Activation (%)								0.2914
	Pre	68.9	72.7	72.9	76.9	64.0	58.1	88.9	
	Post	66.4	72.7	65.3	65.8	76.2	64.4	77.8	
	p*	0.4528	1.0000**	0.2403	0.0545	0.3708	0.3454	1.0000**	
	Post-Pre Difference (95% CI)	2.5 (-9.2, 4.1)	0.0 (-37.2, 37.2)	-7.6 (-20.4, 5.1)	-11.1 (-22.1, 0.1)	12.2 (-14.0, 38.4)	6.4 (-6.8, 19.5)	-11.1 (-45.2, 22.9)	
	P-value* Enrollment**	0.0055	0.2039	0.3731	0.1938	0.5036	0.0006	0.9118	
	P-value* Activation**	0.0425	0.5243	0.3391	0.0017	0.3008	0.6092	0.7926	

*p values for Chi-square test for equality of proportions
**p values for Fisher's Exact test due to expected cell frequencies <5
***p values for Breslow-Day Test, with Tarone Adjustment

Figure 1. Total Number of RPM-Capable Boston Scientific ICD Implants, by Calendar Quarter

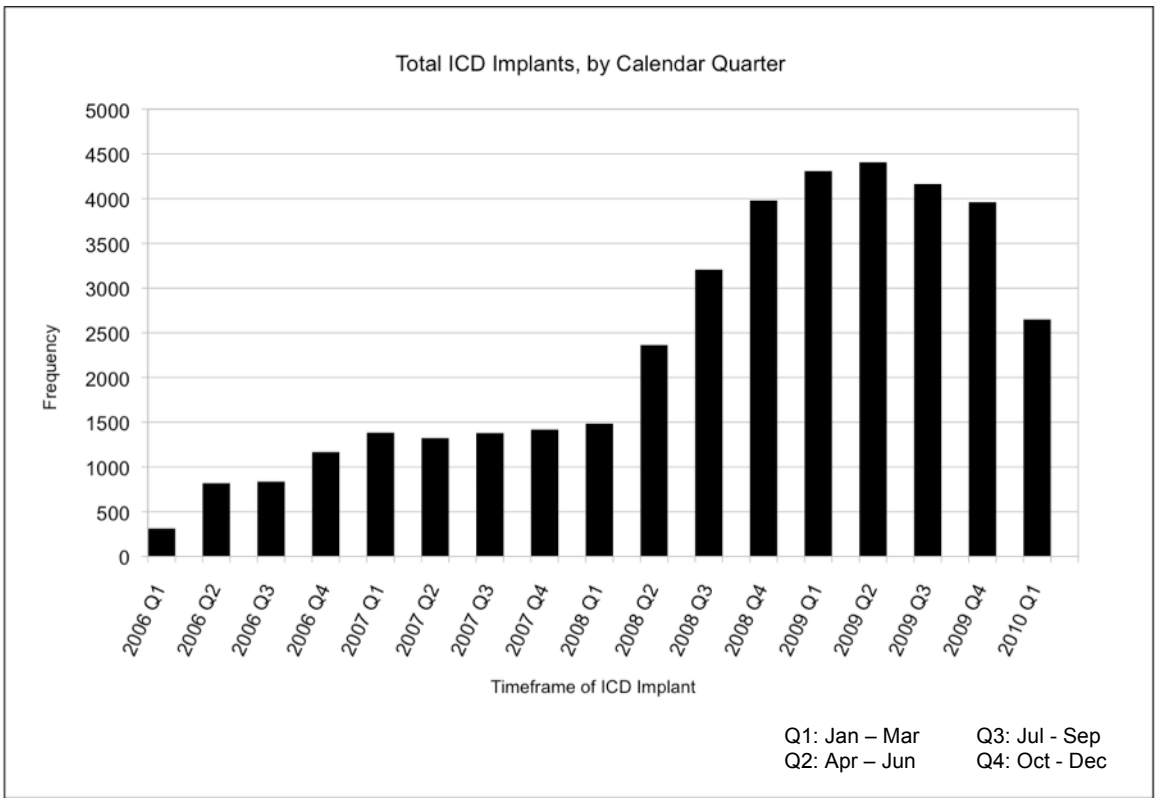

Figure 2a. Overall RPM Enrollment Rates, by Calendar Quarter

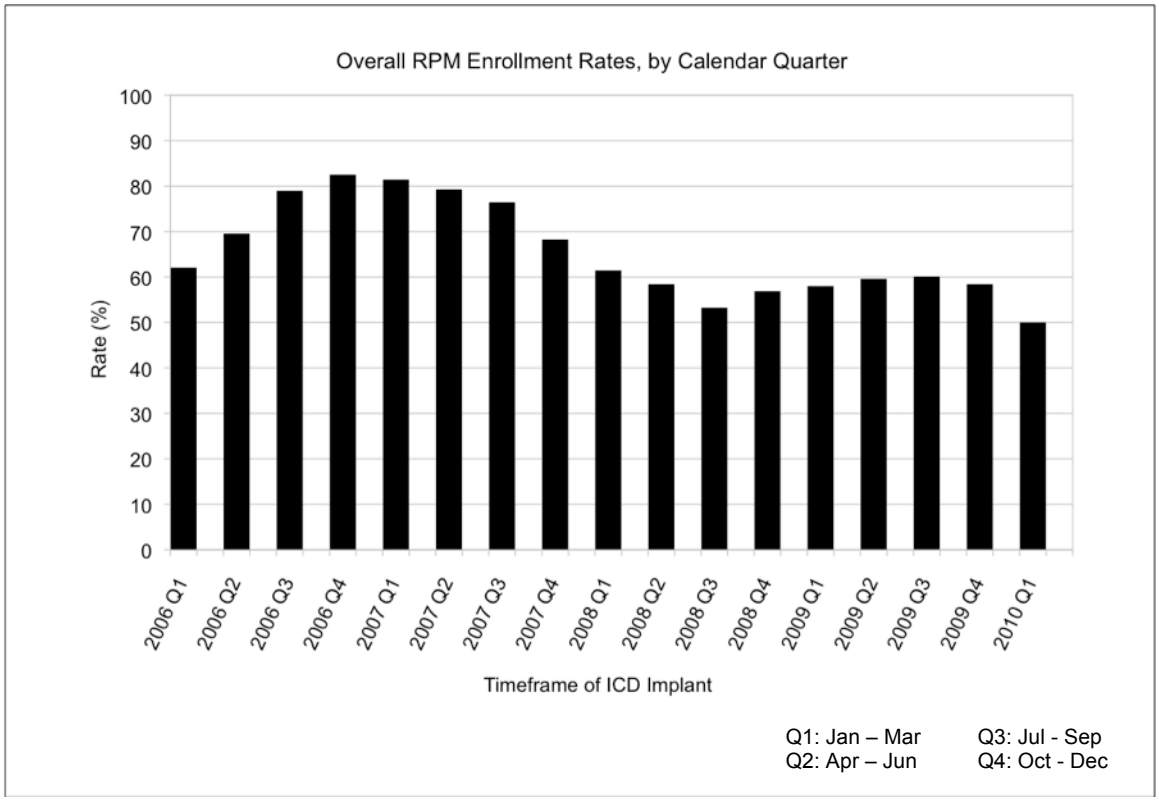

Figure 2b. Overall RPM Activation Rates, by Calendar Quarter

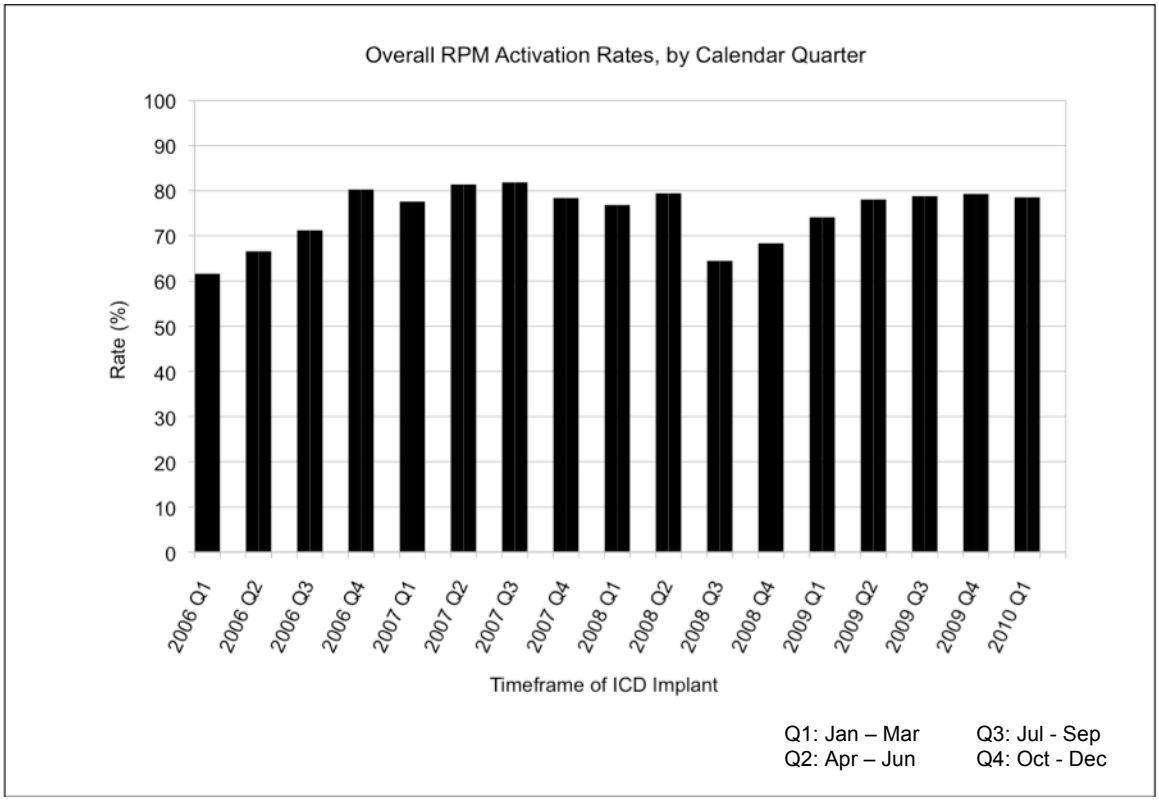

Figure 3. Logistic Model: Enrollment

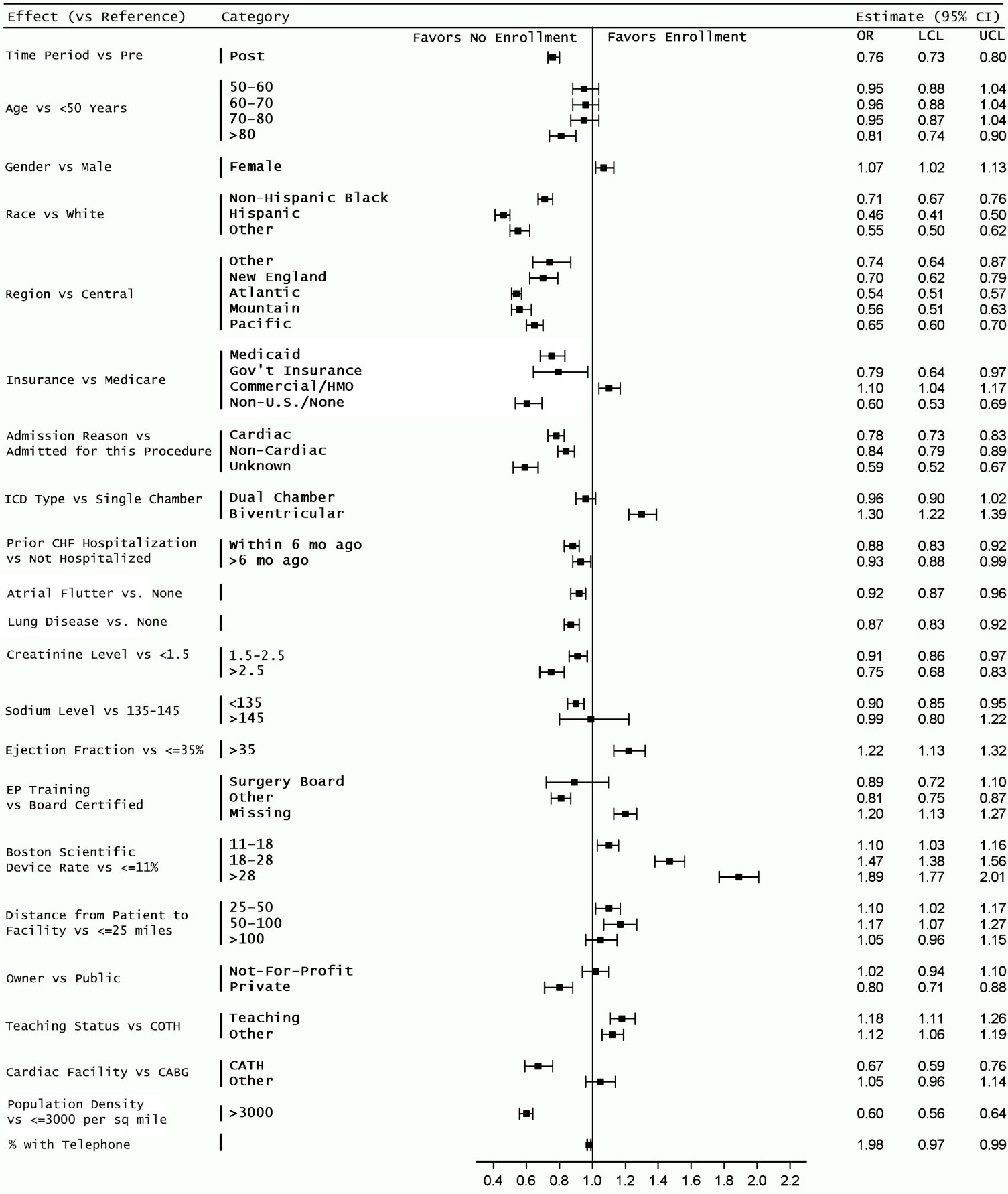

Figure 4. Logistic Model: Activation