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Impacts of a care process model and inpatient electrophysiology service on cardiovascular implantable electronic device infections: a preliminary evaluation

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Abstract
Purpose Cardiovascular implantable electronic device infection (CIEDI) rates are rising. To improve outcomes, our institution developed an online care process model (CPM) and a specialized inpatient heart rhythm service (HRS).
Methods This retrospective review compared hospital length of stay (LOS), mortality, and times to subspecialty consultation and procedures before and after CPM and HRS availability.
Results CPM use was associated with shortened time to surgical consultation (median 2 days post-CPM vs. 3 days pre-CPM, $p = 0.0152$), pocket closure (median 4 vs. 5 days, $p < 0.0001$), and days to new CIED implant (median 7 vs. 8 days, $p = 0.0126$). Post-HRS patients were more likely to have a surgical consultation (OR 7.01, 95% CI 1.56–31.5, $p = 0.011$) and shortened time to pocket closure (coefficient − 2.21 days, 95% CI − 3.33 to − 1.09, $p < 0.001$), compared to pre-HRS.
Conclusions The CPM and HRS were associated with favorable outcomes, but further integration of CPM features into hospital workflow is needed.

Keywords ICD · CRT · Infection · Cardiac device

1 Introduction

The increased rate of cardiovascular implantable electronic device (CIED) implantation in elderly patients with comorbidities has been associated with increased rates of CIED infection (CIEDI) [1], which were out of proportion to the rates of new device implantation [2]. In 2003, the American Heart Association (AHA) issued a scientific statement on management of cardiovascular device infections [1].

With the availability of the 2003 AHA document, there was an assumption that outcomes of CIEDI should improve. However, in a retrospective chart review of 189 cases of CIEDI admitted to Mayo Clinic Rochester from 1991 to 2010, we did not find these expected changes before and after the availability of guidelines [3].

Our goal has been to improve the quality of CIEDI management. Mayo Clinic originally published a "care process model" (CPM) on management of CIEDI on February 1, 2012. This CPM was available in Ask Mayo Expert (AME), which is accessible on the Mayo Clinic intranet but not within the electronic medical record. Because online usage of AME is recorded, we sought to determine if CPM usage had an impact on CIEDI management and outcomes. A similar

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methodology was recently used at our medical center in a study that examined the use of a "Lower Extremity Cellulitis" CPM and was successful in improving the selection of antibiotic regimens [4]. Electronic decision support tools have been applied to the management of other conditions, such as sepsis. The goals of these electronic tools are to improve patient outcomes and compliance with patient management guidelines. However, these goals may not necessarily be achieved due, in part, to low utilization [5].

In 2014, Mayo Clinic created a primary inpatient electrophysiology service (abbreviated "HRS" for *Heart Rhythm Service*), which preferentially admitted CIEDI cases with the expectation of providing expedited subspecialist care. HRS is staffed by a cardiologist specializing in electrophysiology, a nurse practitioner or physician assistant, and a clinical assistant who schedules various appointments and follow-ups. Prior to 2014, CIEDI cases were admitted to either general cardiology, medical, or surgical services, depending on bed availability.

Outcomes of CIEDI cases were evaluated to determine if either CPM use or direct admission to HRS had an impact on patient outcomes.

2 Materials and methods

2.1 Patients

This is a retrospective review of patients identified from the electronic medical record and an existing institutional database, which has accumulated a list of CIEDI cases since 1990. The electronic medical record was searched using the Advanced Cohort Explorer (ACE), which is our institution's data retrieval software. Search terms included *cardiac*, *cardiovascular*, *device*, *infection*, *pacemaker*, *implant*, *defibrillator*, and the following International Classification of Diseases (ICD) codes: 996.61 (ICD-9, infection and inflammatory reaction due to cardiac device, implant, and graft) or T82.7XXA (ICD-10, infection and inflammatory reaction due to other cardiac and vascular devices, implants and grafts, initial encounter).

Eligibility criteria included adults with Minnesota Research Authorization who were at least 18 years of age and were hospitalized at Mayo Clinic Rochester for CIEDI. The types of infections included superficial infections (e.g., pocket infections or device erosions) as well as systemic infections (e.g., bloodstream infection or endocarditis). Exclusion criteria included lack of research authorization and diagnosis of endocarditis that was not associated with CIED. This study did not involve direct contact with human subjects. A Health Insurance Portability and Accountability Act (HIPAA) and informed consent waivers were obtained from our Institutional Review Board (IRB).

Demographic factors included age, gender, and ethnicity. The Charlson Comorbidity Index was used to quantify the severity of comorbid medical conditions [6]. Variables included hospital and intensive care unit (ICU) LOS; mortality; duration of antibiotics and temporary pacemaker use; and times to consultation of specialty services, CIED extraction, pocket closure, and new CIED implantation.

2.2 Care process model

The CPM was introduced on February 1, 2012, and a screenshot of the clinical management algorithm is shown in Fig. 1a, b. A flowchart guides the clinician through the various stages of diagnosis and management of CIEDI. Each box contains a link to more detailed information on recommended tests and treatments. The algorithm first asks clinicians to distinguish between superficial and deep pocket site infections, which may be complicated by bloodstream infection. The algorithm then guides clinicians through a comprehensive management plan for patients with systemic infections, which includes a transesophageal echocardiogram and complete CIED extraction. Lastly, the algorithm provides a clinical decision aid for new device implantation and final antibiotic durations (Fig. 1b).

The pre-CPM period ranged from July 16, 2008 to December 31, 2011. The post-CPM period ranged from January 1, 2012 to December 13, 2013. Provider usage of the CPM was monitored and associated with the corresponding patient based on clinical documentation. These specific pre- and post-CPM date ranges (July 16, 2008 to December 31, 2011; January 1, 2012 to December 13, 2013) were chosen based on the availability of CPM usage data. CIEDI patients were allocated into two groups: (1) those hospitalized prior to CPM availability in 2012 ("pre-CPM") and (2) those hospitalized after 2012. Also, the post-CPM period specifically ended in 2013 to avoid confounding effects of the HRS, which was formed in 2014 (described next).

2.3 Heart rhythm service

The HRS was initiated on January 2, 2014. Pre- and post-HRS periods were defined to include an approximately 2-year time frame (December 31, 2011 to January 1, 2014 and January 2, 2014 to February 2, 2016, respectively). CIEDI cases were divided into those admitted before HRS formation in 2014 ("pre-HRS"), after 2014 to other services ("post-non-HRS"), and HRS admissions ("HRS").

2.4 Statistical analysis

Statistical analysis was performed with SAS 9.4. Descriptive statistics for categorical variables were reported as frequencies and percentages while continuous variables were reported as

(a)

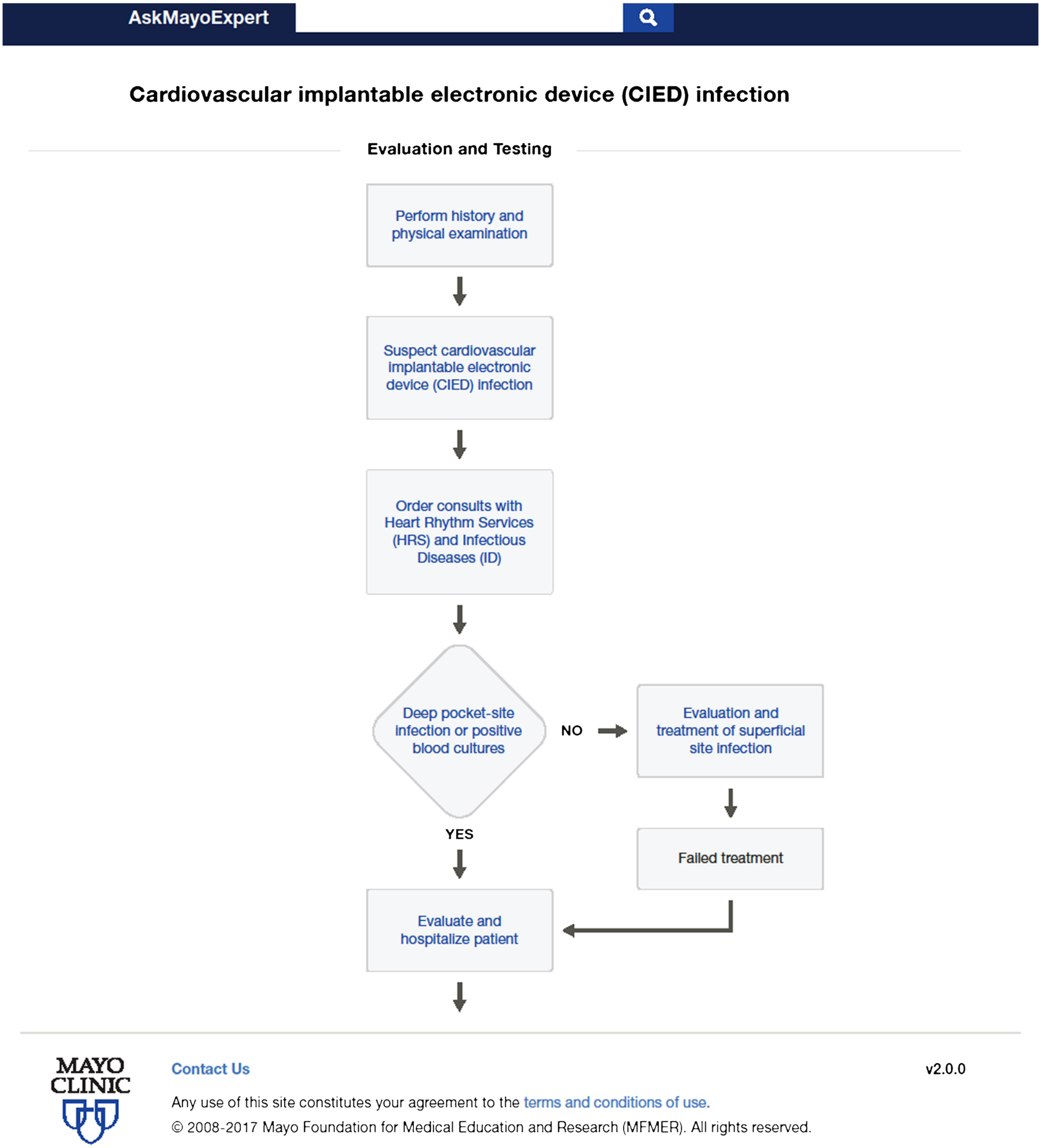


Fig. 1 The Ask Mayo Expert (AME) care process model (CPM) guides clinicians through the initial management of cardiovascular implantable electronic device infections (CIEDI) (**a**). After assisting clinicians in differentiating superficial and systemic infections, the algorithm recommends transesophageal echocardiogram and complete CIED extraction for those with systemic infections. The flowchart then proceeds to assist clinicians in planning new device placement and final antibiotic durations (**b**)

mean (standard deviation) and median (range). Categorical variables were compared between pre- and post-periods using the Chi-square test or Fisher's exact test, and continuous variables were compared using the two-sample *t* test, Wilcoxon

(b)

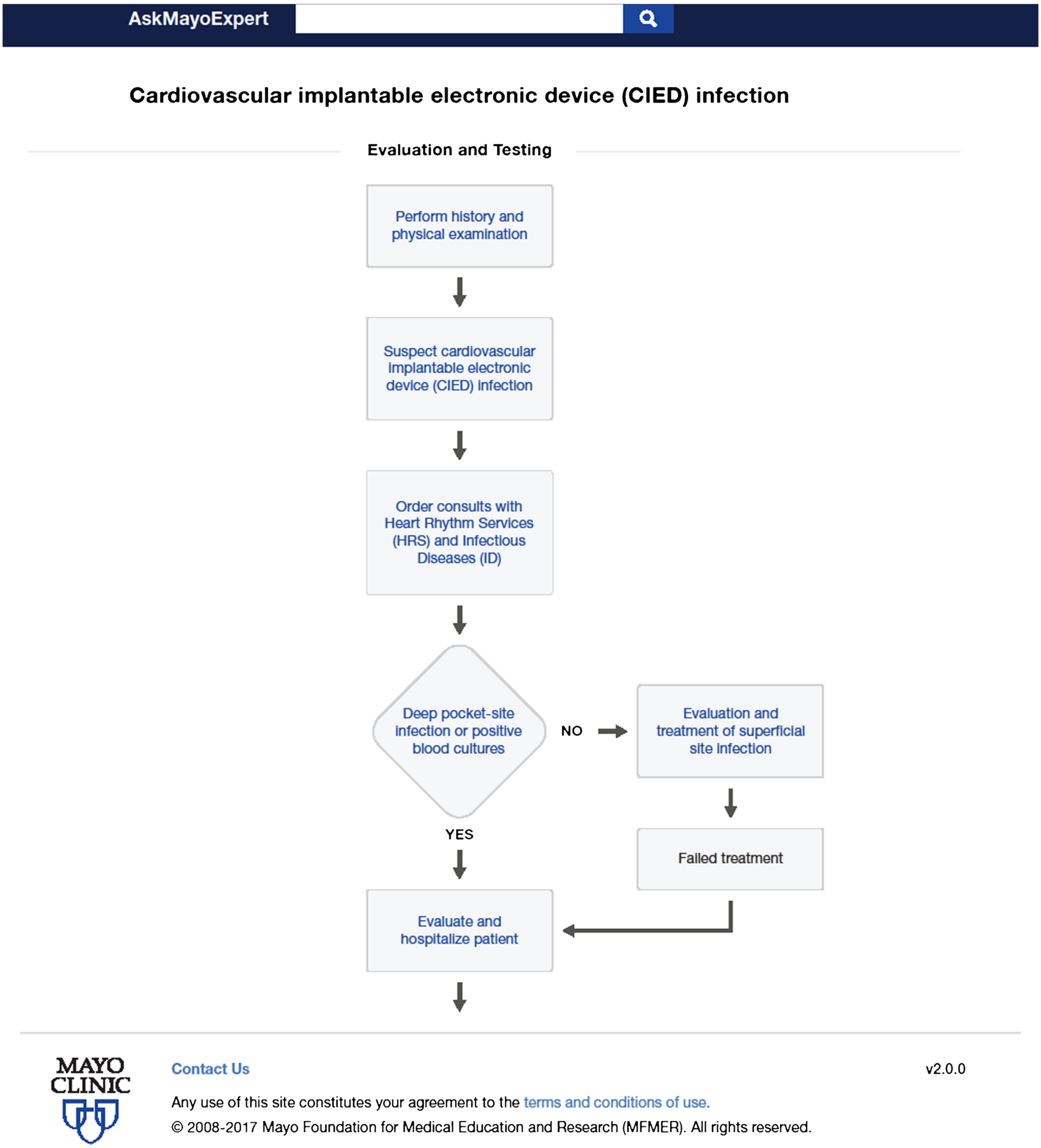


Fig. 1 (continued)

rank-sum test, or Kruskal-Wallis test where appropriate. All statistical tests were two-sided, and alpha was set at 0.05 for statistical significance. Logistic regression was performed to adjust for different infection types. Kaplan-Meier analysis and Cox proportional hazards model were used to determine differences in survival among groups.

3 Results

3.1 CPM usage and patient outcomes

There were 212 pre-CPM and 98 post-CPM cases (Table 1). Cohorts were similar in age, gender, ethnicity, and CIED type.

Table 1 Baseline characteristics and outcomes of cardiovascular implantable electronic device infection (CIEDI) cases seen before (July 16, 2008, to February 1, 2012) and after (February 2, 2012 to January 1, 2014) care process model (CPM) availability

	Pre-CPM (*n* = 212)	Post-CPM (*n* = 98)	Total (*n* = 310)	*P* value
Age, years (median, Q1-Q3)	71 (60–80)	69 (56–78)	70 (58–80)	0.4969
% male	72.6%	72.4%	72.6%	0.9718
% Caucasian	89.6%	93.9%	91.0%	0.2243
Infection type	50.5% pocket 49.5% systemic	51.0% pocket 49.0% systemic	50.6% pocket 49.4% systemic	0.9284
Charlson Comorbidity Index	3 (1.25–5)	3 (1–4)	3 (1–5)	0.1497
Hospital LOS (days)	12 (8–20)	12 (8–20)	12 (8–20)	0.3803
Intensive care unit LOS	0 (0–3)	0 (0–2)	0 (0–3)	0.2917
Surgical consult	61.8%	71.4%	64.8%	0.0985
Days to surgical consult	3 (1–5)	2 (1–4)	2 (1–5)	0.0152
Days to CIED extraction	2 (1–5)	3 (1–5)	2 (1–5)	0.4431
Days to pocket closure	5 (4–7)	4 (2–5)	5 (3–6)	<0.0001
Days to new CIED implant	8 (7–11.5)	7 (4–10)	8 (6–11)	0.0126
Days from new CIED implant to discharge	1 (1–5)	2 (2–5)	2 (1–5)	0.0224
Antibiotic duration	17 (14–34.5)	22 (14–42)	18.5 (14–42)	0.2467

CPM care process model, *Q1-Q3* interquartile range from 25% (Q1) to 75% (Q3), *LOS* length of stay, *CIED* cardiovascular implantable electronic device infection

The post-CPM cohort had a statistically significant decrease in days to surgical consult (median 2 days post-CPM vs. 3 days pre-CPM, $p = 0.0152$); days to pocket closure after device extraction (median 4 days post-CPM vs. 5 days pre-CPM, $p < 0.0001$); and days to new CIED implant (median 7 days post-CPM vs. 8 days pre-CPM, $p = 0.0126$). However, the post-CPM cohort had a statistically significant increase in days from new CIED implantation to discharge date (median 2 days post-CPM versus 1 day pre-CPM, $p = 0.0224$). In univariate linear regression models, the main factor affecting days to pocket closure was the pre- vs. post-CPM period. The number of CPM hits for a given patient did not impact days to pocket closure significantly.

Overall survival following diagnosis of CIEDI is demonstrated using Kaplan-Meier survival analysis (Fig. 2). Estimated Kaplan-Meier survival rates at 1 year were 76.0% for pre-CPM and 76.2% for post-CPM. There were no statistically significant differences in survival between the two groups ($p = 0.7461$). In a multivariate analysis using Cox proportional hazards model, the following were predictors of worse overall survival: age [HR 1.02 (1.01–1.04), $p < 0.001$], Charlson comorbidity index [HR 1.20 (1.11–1.30), $p < 0.001$], systemic infection [HR 2.03 (1.41–2.92), $p < 0.001$], and lack of device extraction [HR 1.83 (1.25–2.69), $p = 0.0019$].

3.2 HRS comparisons

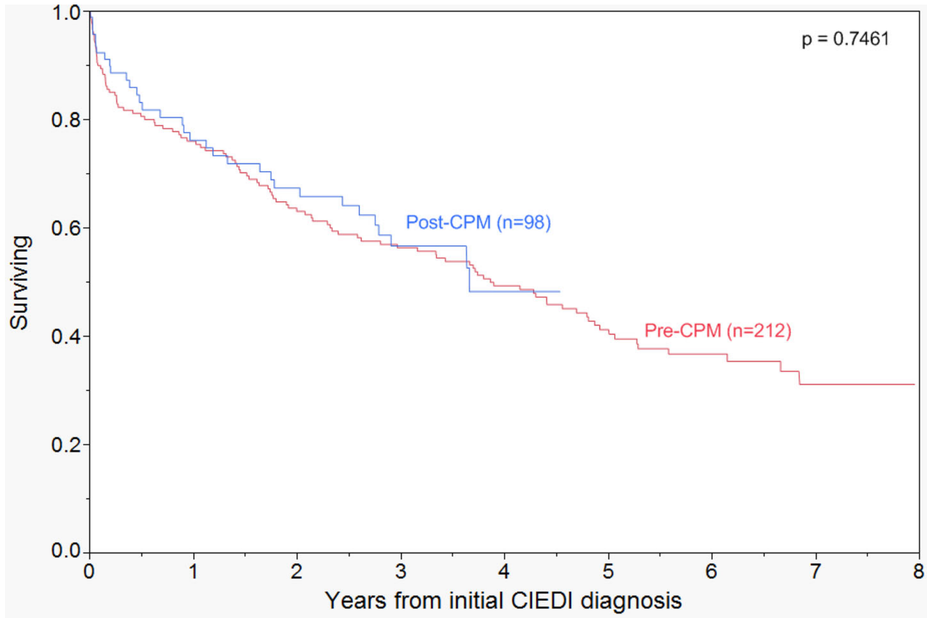
There were a total of 210 CIEDI cases: pre-HRS $n = 102$, HRS $n = 48$, and post-non-HRS $n = 60$. Groups were similar in age, gender, ethnicity, and CIED type. However, there was a significantly higher percent of pulse generator pocket infections (83.3%) admitted to HRS as compared to post-non-HRS (21.7%, $p < 0.0001$) (Table 2).

Given significant baseline differences in infection type (and therefore, treatments), multivariate adjustments were performed. Post-non-HRS patients (78.3% systemic infections, such as endocarditis) were treated with a median of 42.0 days of antibiotics, compared to post-HRS patients (83.3% pocket infections) who were treated for shorter durations (15.0 days).

After adjusting for infection types, HRS patients were more likely to have had a surgical consult (OR 7.01, 95% CI 1.56–31.5, $p = 0.011$) and shortened time to pocket closure (coefficient − 2.21 days, 95% CI − 3.33 to −1.09, $p < 0.001$) compared to pre-HRS.

Overall survival following diagnosis of CIEDI is demonstrated using Kaplan-Meier survival analysis (Fig. 3). Estimated Kaplan-Meier survival rates at 1 year are 76.0% for pre-HRS, 59.8% for post-non-HRS, and 74.0% for post-HRS. There was no statistically significant difference in survival among the groups ($p = 0.0620$). In multivariate analysis using Cox proportional hazards model, there were two independent predictors of worse overall survival: systemic infection [HR 2.42 (95% CI 1.40–4.16), $p = 0.0015$] and age [HR 1.04 (95% CI 1.02–1.06), $p < 0.001$].

Fig. 2 Overall survival following diagnosis of cardiovascular implantable electronic device infection (CIEDI) is demonstrated using Kaplan-Meier survival analysis for cohorts before and after availability of the care process model (pre-CPM versus post-CPM). Estimated Kaplan-Meier survival rates at 1 year are 76.0% for pre-CPM and 76.2% for post-CPM (p = 0.7461). Figure created using JMP software from SAS



Number at risk	Start	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Pre-CPM(n=212)	212	167	105	91	76	50	29	12
Post-CPM (n=98)	98	54	43	28	6	-	-	-

4 Discussion

4.1 Impact of the CPM

Automated clinical decision support (CDS) systems have been previously studied in the management of other scenarios, such as ventilator weaning, identification of acute respiratory distress syndrome, and sepsis, and barriers to CDS implementation have been defined. For example, in a 2015 randomized controlled trial that included an electronic tool for sepsis management, providers opened the electronic tool in less than 60% of available cases [5]. In our study, CPM usage was even

Table 2 Baseline characteristics and outcomes of cardiovascular implantable electronic device infection (CIEDI) cases that were admitted before heart rhythm service (HRS) formation in 2014 (“pre-HRS”), after 2014 to other services (“post-non-HRS”), and HRS admissions (“HRS”)

	Pre-HRS (n = 102)	Post-non-HRS (n = 60)	Post-HRS (n = 48)	Total (n = 210)	P value
Age, years (median, Q1-Q3)	69.0 (56.9–78.0)	65.2 (57.0–77.5)	72.2 (58.5–80.5)	68.0 (57.0–78.5)	0.4595
% male	71.6%	78.3%	64.6%	71.9%	0.2855
% Caucasian	94.1%	91.7%	89.6%	92.4%	0.6022
Infection type	50.0% pocket, 50.0% systemic	21.7% pocket, 78.3% systemic	83.3% pocket, 16.7% systemic	49.5% pocket, 50.5% systemic	< 0.0001
Charlson Comorbidity Index	3 (1.75–4)	3 (2–4)	2 (1–4)	3 (1–4)	0.2010
Hospital LOS (days)	12.0 (8.0–20.0)	16.5 (9.5–27.5)	9.0 (7.0–12.0)	12.0 (8.0–20.0)	0.0001
Intensive care unit LOS	0.0 (0.0–2.0)	2.0 (0.0–7.5)	0.0 (0.0–0.0)	0.0 (0.0–3.0)	< 0.0001
Surgical consult	71.6%	70.0%	95.8%	76.7%	0016
Days to CIED extraction	3.0 (1.0–5.0)	5.0 (3.0–8.0)	2.0 (1.0–4.0)	3.0 (1.0–6.0)	< 0.0001
Days to pocket closure	4.0 (2.0–6.0)	2.0 (2.0–3.0)	2.0 (2.0–2.0)	2.0 (2.0–4.0)	< 0.0001
Days to new CIED implant	7.0 (4.0–10.0)	7.0 (6.0–14.0)	5.0 (4.0–9.0)	7.0 (4.5–10.0)	0.0986
Days from new CIED implant to discharge	2.0 (2.0–5.0)	5.0 (2.0–10.0)	1.0 (1.0–3.0)	2.0 (1.0–5.5)	< 0.0001
Antibiotic duration	22.0 (14.0–42.0)	42.0 (19.0–44.0)	15.0 (14.0–21.0)	22.0 (14.0–42.0)	0.0003

HRS heart rhythm service, *Q1-Q3* interquartile range from 25% (Q1) to 75% (Q3), *LOS* length of stay, *CIED* cardiovascular implantable electronic device infection

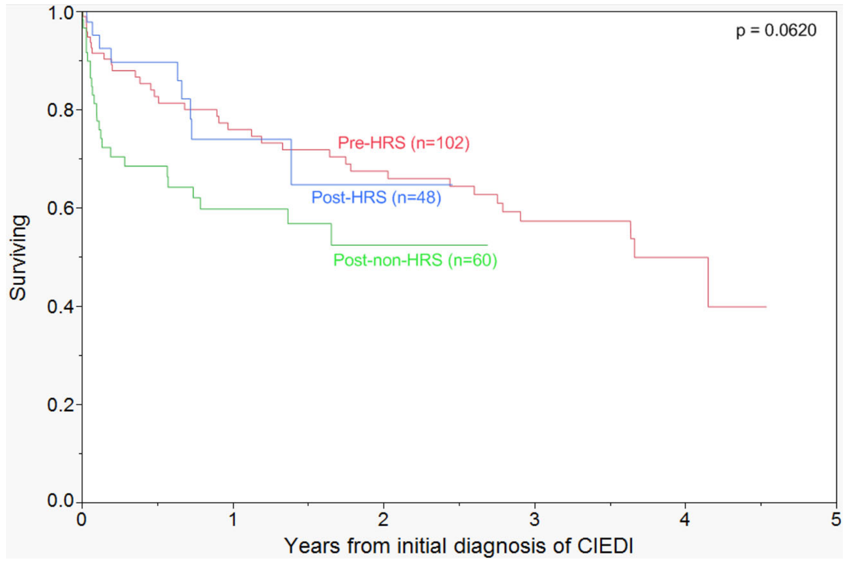


Fig. 3 Overall survival following diagnosis of cardiovascular implantable electronic device infection (CIEDI) is demonstrated using Kaplan-Meier survival analysis for cohorts admitted before Heart Rhythm Service (HRS) formation in 2014 ("pre-HRS"), after 2014 to other services ("post-non-HRS"), and HRS admissions ("HRS"). Estimated Kaplan-Meier survival rates at 1 year are 76.0% for pre-HRS, 59.8% for post-non-HRS, and 74.0% for post-HRS ($p = 0.0620$). Figure created using JMP software from SAS

Number at risk	Start	Year 1	Year 2	Year3	Year 4
Pre-HRS (n=102)	102	56	45	30	8
Post-HRS (n=48)	48	13	4	-	-
Post-non-HRS (n=60)	60	22	9	-	-

lower; of 391 patients included in the analysis, CPM use occurred in 93 (23.8%) patients.

A 2005 systematic review attempted to identify features of CDS that are critical to success: (1) automatic provision of decision support as part of clinician workflow, (2) provision of decision support at the point of care, (3) provision of recommendation rather than assessment, and (4) computer-based generation of decision support [7]. Our CPM did not provide automatic decision support as part of clinician workflow, as it was not available via the electronic medical record. First, it is unknown how many providers were aware of the CPM's existence. Secondly, when a provider encountered a patient for whom the CPM would be applicable, there was no automated alert to remind the provider to use the CPM. To access the CPM, the clinician must open a separate browser window, search for a CPM keyword such as *CIED*, and then manually click through the algorithm. These reasons may contribute to the CPM's overall low usage.

A future improvement would involve creating an automated alert that the CPM may be applicable to a certain patient. Such an alert may be produced by automatically scanning admission diagnoses. However, even if providers were alerted to use the CPM, the abundance of alerts in our era of electronic medical records may lead to "alert fatigue." Providers often bypass alerts unless they are electronically forced to use the tool or document a reason for not using it [5].

Even after consultation of the CPM, another potential barrier would be providers' noncompliance with the CPM's recommendations. A 2015 study analyzed dental providers' attitudes toward implementation of CDS tools. Provider characteristics that were correlated with a positive attitude toward the CDS included satisfaction with the electronic medical record, job satisfaction, acceptance of change, degree of control perceived over work, and a perception of having adequate tools to get work done [8]. A future study may involve surveying providers within our institution regarding their attitudes and usage of the CPM.

Another limitation of our study was that CPM data could not always be correlated with patient care due to the lack of documentation in some instances. There has been discussion locally regarding the inclusion of features of the CPM in inpatient "order entry" to hopefully enhance its utilization.

4.2 Impact of the primary inpatient electrophysiology service

Patients under the care of an HRS specialist had more favorable outcomes in terms of surgical consultation rates and shortened time to pocket closure. The impact of physician specialization on patient outcomes has been studied in other clinical scenarios. A 2016 study assessed the impact of physician specialization on patient outcomes following endovascular aneurysm repair, which can be performed by interventional radiologists, cardiologists, general surgeons, cardiothoracic surgeons, and vascular surgeons. The study noted that vascular surgeons had an advantage over other specialties in terms of both complication and mortality rates, hospital LOS, and costs. This advantage may be due to differences in subspecialty training and operative experience, as the vascular surgeons in this study performed a high annual volume of endovascular aneurysm repairs [9].

In a similar manner, electrophysiologists may be the most appropriate primary inpatient providers for patients with CIEDI. Our study found that HRS patients had a higher odds of surgical consultation and, consequently, shorter time to pocket closure. Perhaps, this favorable outcome was a result of electrophysiologists' early recognition of the need for timely surgical consultation.

4.3 Limitations

A significant limitation lies in the triaging of CIEDI cases to inpatient services. In addition to HRS, patients can be admitted to general medical or surgical services, and such triaging decisions are often made based on bed availabilities, which can be highly variable from day to day. Results showed that patients with overt signs of CIEDI, such as pacemaker pocket purulence, were more often triaged to HRS. However, patients who initially present with vague symptoms (such as fever and malaise) may be triaged to general medical services and subsequently discovered to have CIEDI-related endocarditis. As discussed in the Sect. 2, the post-CPM analysis period ended in 2013 to avoid confounding effects of the HRS, which was initiated in 2014. From 2014 to 2016, both the CPM and HRS were in effect, so it is possible that any significant trends seen in the HRS time period may have been due to the concomitant presence of the CPM.

5 Conclusion

The CPM and HRS were associated with favorable outcomes. Nevertheless, there were no definitive changes seen in other measured outcomes, such as overall survival. Since age and systemic infection were predictors of worse overall survival, it is certainly plausible that the older cohort with associated comorbid conditions was at risk for worse outcomes, in general, and may have impacted clinical outcomes. We believe that aspects of the CPM should be included in our electronic orders with continued monitoring of outcomes to further substantiate its utility in improving patient outcomes.

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Compliance with ethical standards

Conflict of interest Muhammad R. Sohail, MD, has a research grant from Medtronic and has also received consulting fees (all less than $10,000) from Medtronic, Spectranetics, and Boston Scientific. Larry M. Baddour, MD, has received royalty payments from *UpToDate* and has received payments for Editor-in-Chief duties from Massachusetts Medical Society (*NEJM Journal Watch Infectious Diseases)*.

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Ethical approval Formal consent was not required for this retrospective study. This study did not involve any patient contact.

Informed consent No patient contact was required for this retrospective chart review. A waiver of informed consent was approved by the Mayo Clinic Institutional Review Board.

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