Doctor of Nursing Practice Final Report: Implantable Cardioverter-Defibrillator Implantation Guideline Adherence in a Single Community Hospital

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Abstract

Background and Purpose: Sudden cardiac death secondary to dysrhythmia is a potentially preventable cause of death with proper utilization of an implantable cardioverter-defibrillator (ICD). Published guidelines offer eligibility criteria for device implantation yet compliance varies widely across the nation (Shah et al., 2009; Levine et al., 2015; Al-Khatib et al., 2011). Adherence to the guidelines has the potential to affect billing and reimbursement as well as patient outcomes. While national rates of compliance are available in the literature ranging from 0-80% (Shah et al., 2009), no known study of ICD guideline compliance has been conducted at Providence St. Vincent Medical Center (PSVMC) in Portland, Oregon. The hypothesis of this project is that PSVMC will fall in the upper quartile of the national average as described by Shah et al. (2009).

Methods: A retrospective chart review was conducted for the period of January 1, 2017 through June 30, 2017. An initial patient list was compiled showing all patients with an ejection fraction of $\leq 40\%$ as this is a minimum threshold for consideration of an ICD. The guidelines for primary prevention of sudden cardiac death detailed in ***Table 2.2*** of the *2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy* (AUC) were applied to these patients to determine if the applicable guidelines were followed. Consideration was given to comorbidities potentially affecting device placement per ***Table 3.1*** of the AUC. Additionally, the electrophysiology operative schedule for the same time period was searched and all patients receiving an ICD within this window were reviewed for appropriateness and guideline compliance.

Conclusions: Overall compliance with the AUC for PSVMC was found to be 73.88%. This places PSVMC in the upper quartile of the national average for guideline compliance consistent

with the original hypothesis of this project. While 17% of patients had no mention of ICD consideration, this does not necessarily mean that the clinicians were not considering this therapy. Unfortunately, without adequate documentation there is no way to confirm this.

Implications for Practice: Continued adherence to the AUC is essential for promotion of evidence based medicine, positive patient outcomes, and safety. While PSVMC is in the upper echelon of the national average, there is still room for improvement. Improvements in clinician documentation, dissemination of the AUC, and follow-up will allow for greater future compliance. Further study is required to determine if such measures will be effective.

Keywords: Implantable cardioverter-defibrillator, ICD, guideline, primary prevention, appropriate use criteria

Introduction

In the United States, sudden cardiac death (SCD) accounts for greater than 300,000 (Zhang et al., 2015), or more than half, of all deaths related to coronary artery disease (CAD) annually (Garg, 2015). In fact, the number of sudden cardiac deaths each year is greater than the combined totals of breast cancer, lung cancer, AIDS, and stroke (Gialama et al., 2014). Implantable cardioverter-defibrillator (ICD) placement for primary prevention of SCD has the potential to greatly reduce fatalities secondary to dysrhythmia (Goldenberg et al., 2006; Moss et al., 2002). Prior to placement, a series of steps outlined by the *2013 Appropriate Use Criteria for Implantable Cardioverter-Defibrillators and Cardiac Resynchronization Therapy* (henceforth to be referred to as the AUC) should be adhered to in order to promote the best possible outcome for patients. The AUC outlines the time from myocardial infarction (MI), coronary artery bypass graft (CABG) or percutaneous coronary intervention (PCI), and initiation of guideline directed medical therapy (GDMT) to device placement with the knowledge that a patient's ejection fraction (EF) can often recover to a point no longer necessitating device placement. Despite publication of these guidelines, there is great variation across the nation with regard to adherence (Shah et al., 2009).

The factor most likely to contribute to SCD secondary to ventricular dysrhythmia is a diminished left ventricular ejection fraction (LVEF) < 35% secondary to ischemia (Deyell et al., 2010). Placement of an ICD has provided a 30-54% reduction in SCD in this population (Goldenberg et al., 2006). Despite this, there is still a demographic of patients who meet guidance parameters to have an ICD placed but fail to have the procedure performed. One study, assessing patients from the Oregon Sudden Unexpected Death Study (Oregon SUDS) at the time of cardiac arrest (the halting of effective myocardial contractility resulting in unresponsiveness

without effective respiration or circulation) for the presence of appropriate pre-arrest ICD placement, found that, of the one-fifth of the population eligible for ICD placement prior to arrest, only 13% of patients had actually received an ICD (Narayanan et al., 2013). Nationally, adherence to the AUC has been found to be widely variable with appropriate device placement ranging from 0-80% depending on the region (Shah et al., 2009).

Literature Review

A literature search was conducted using PubMed, Google Scholar, and UpToDate with no restriction on date. Key MESH terms included combinations of "implantable cardioverter defibrillator", "ischemic cardiomyopathy", "ventricular arrhythmia", "guidelines", "appropriate use criteria", "ventricular tachycardia", "arrhythmia", "primary prevention", and "sudden cardiac death". For articles from PubMed and Google Scholar, abstracts were reviewed and articles found to be pertinent were read in entirety. UpToDate articles were scanned by title and introduction and those articles found to be pertinent were read in entirety.

Background and Factors Related to Device Placement

In the United States, SCD accounts for more than half of all deaths related to CAD annually (Garg, 2015). The factor most likely to result in SCD secondary to ventricular dysrhythmia is a LVEF < 35% secondary to ischemia (Deyell et al., 2010). Placement of an ICD has provided a 30-54% reduction in SCD in this population (Goldenberg et al., 2006). Despite this, there is still a population of patients who meet guidance parameters to have an ICD placed but, fail to have the procedure performed.

Frequently, a theme noted throughout the literature is that ICD placement is more commonly carried out in men than women (Shah et al., 2009; Hoang et al., 2014; Zhang et al., 2015). Additionally, younger, non-smokers, non-alcoholic patients were found to be more likely

to receive appropriate device therapy (Zhang et al., 2015). Depending on the individual article reviewed, there is also the potential addition of a racial determinant to appropriate ICD placement. In some studies, whites received devices more commonly than blacks (Shah, et al., 2009) while others show a statistically negligible difference in implantation between the races (Hoang et al., 2014; Zhang et al., 2015; Narayanan et al., 2013). Institutional factors found to correlate with improved AUC compliance included hospitals that had a greater number of beds, an academic affiliation, a dedicated cardiology team, and a proportionally greater number of CABG's or PCI's performed annually when compared to other facilities (Shah et al., 2009).

Guideline Directed Medical Therapy (GDMT)

The AUC mandates that a patient receive at least three months of GDMT prior to carrying out placement of an ICD (Russo et al., 2013). The intent of this time window is to allow the EF to recover following myocardial stunning in the setting of an ischemic event (Deyell et al., 2010). The PREDICTS (Prediction of ICD Treatment Study) found that, following MI, 57% of patients had an EF that recovered to > 35% within this time frame (mean follow-up 81.3 +/- 32.9 days), potentially eliminating the need for ICD placement (Brooks et al., 2016). Interestingly, the PREDICTS trial noted that those patients most likely to recover a normal, or near normal, EF (>50%) were those who experienced an episode of VF or cardiac arrest (Brooks et al., 2016).

GDMT for the patient with heart failure with reduced ejection fraction (HFrEF) includes: treatment with an angiotensin converting enzyme inhibitor (ACE-i) or angiotensin receptor blocker (ARB); a beta blocker; diuretics as needed for management of fluid retention; blood pressure which is appropriately managed with agents such as hydralazine; rate management of tachyarrhythmias; and medical management of comorbidities such as diabetes (Russo et al.,

2013). Further demonstrating the importance of GDMT, optimization of patients with a beta blocker and/ACE-i or ARB prior to discharge has been linked to a significantly decreased one year mortality rate in patients with HFrEF hospitalized for acute heart failure (Yamaguchi et al., 2018).

When considering those patients with HFrEF of ischemic origin, the addition of aspirin and a statin are also mandated (Russo et al., 2013). Unfortunately, many patients do not receive appropriate GDMT prior to placement of an ICD. Fonarow & Ziaeian (2016) pointed out that only slightly more than 60% of patients received a beta blocker and an ACE-I or ARB prior to ICD placement and only 28.3% received enough medication to cover at least 80% of the mandated three months of GDMT. Similarly, Hess et al., (2015) noted an inverse relationship between age and approriate prescription of full GDMT wherein the more advanced a patients age the less likely the patient was to receive full treatment. This finding was supported by Yamaguchi et el., (2018) who also noted that the survival benefit of GDMT persisted regardless of age. This creates a scenario wherein the patient undergoes a costly procedure that requires lifelong follow-up when the potential exists that their EF could have increased to a point that would negate the need for device placement.

Guideline Deviation

ICD placement for primary prevention, the subject of this project, is defined as prevention of dysrhythmia in those patients who are at risk for, but have not yet experienced, an episode of sustained ventricular tachycardia (VT), ventricular fibrillation (VF), or cardiac arrest (Russo et al., 2013). It has been noted that there is wide variation in adherence to the guidelines across the United States (Hoang et al., 2014). One report by Shah et al. (2009), identified the national rate of appropriate actual or planned ICD use at only 20%, with a range of 0-80%, while

a similar finding by Hoang et al. (2014) identified a rate of 38% in a single community study comprised of two hospitals from different health systems. Variability in compliance was associated with the region assessed within the United States with some areas showing excellent adherence while others were found to be less compliant (Shah et al., 2009).

In fact, the literature review did not reveal a single absolute perspective on why such variability in guideline adherence exists. Possible explanations for nonadherence to the AUC include the presence of comorbidities, advanced patient age, gender, health insurance status (Zhang et al., 2015), and physician or patient refusal (Hoang et al., 2014). A lack of a cardiology team or an inadequate number of cardiologists or electrophysiologists to perform device implantation has also been offered as an explanation in smaller rural community facilities but, as pointed out by Shah et al. (2009), this does not excuse the provider from making an appropriate referral for device placement. Other rationales presented include inadequate dissemination of the guidelines and provider perceptions that there will be an inadequate benefit to justify the cost of placement (Hoang et al., 2014).

Of course, patient interest cannot be overlooked as a potential reason for not implanting an ICD in an otherwise appropriate candidate. A study by Yuhas et al. (2012) sought to find the reasons why appropriate candidates may refuse device placement. Three items were found to be important in the decision process, these were: a lack of patient understanding of the seriousness of their disease and likelihood for SCD; the perception that ICD placement was presented as an option rather than a prescription by the provider; and the patient fully understands the implications of refusal but does not want any invasive life prolonging measures (Yuhas et al., 2012). Additional patient concerns addressed by Yuhas et al. regarded device malfunction or

recall, risks of surgical complication, and inaccurate beliefs regarding longterm impact on quality of life (2012).

Apart from the above mentioned reasons, the Centers for Medicare & Medicaid Services (CMS) guidance on ICD placement adds an additional layer of complication to many cases. In order to have device placement paid for as primary prevention, a patient who has an EF ≤ 35% more than 40 days after an MI must have an inducible dysrhythmia during electrophysiology study more than four weeks after the ischemic event or a properly charted prior MI with an LVEF less than 30% and a QRS interval > 120 ms (Centers for Medicare & Medicaid, 2016). This potentially offers a conflict with the AUC put forth by Russo et al. (2013) in one important way, the CMS guidelines (2016) mandate that an inducible rhythm must be present whereas the AUC consider the presence of an EF ≤ 35% more than 40 days after an MI to be sufficient grounds to warrant ICD placement. Furthermore, CMS guidance requires that an ICD candidate not have New York Heart Association (NYHA) class IV heart failure, symptomatic hypotension, or cardiogenic shock while in a stable baseline rhythm (2016). Such stipulations can make it difficult to know which guidelines to follow. Ultimately, the clinician must use their best judgement to act within AUC criteria, CMS guidance, and in the best interest of the patient.

In contrast, there are those patients who have had an ICD placed outside the guideline recommendations. Al-Khatib et al. (2011) found that more than 22% of patients with an ICD received it outside the parameters of the published guidelines. This demographic would include those not meeting the criteria in ***Fig. 1*** who:

- have had an ICD placed < 40 days following MI;
- are < 3 months status post PCI/CABG;
- have an EF >35%;

- have an EF of 36-40% without asymptomatic nonsustained VT (NSVT);
- have an EF of 36-40% without an electrophysiology study (EPS) with inducible VT/VF;
- have an EF of 36%-40% and have undergone an EPS without inducible VT/VF;
- have not received three months of appropriate GDMT.

Levine et al. (2015) found that, between those patients who had an appropriately placed ICD and those whose providers elected to implant one outside the guidelines, there was no difference in time from implantation to first appropriate device therapy. Appropriate therapy is considered either defibrillation or utilization of anti-tachycardia pacing (ATP) to return the heart to a physiologically acceptable rate.

Indeed, what was noted as significantly different was the more than 10% increase in mortality rate of those patients who underwent non-guideline directed ICD implantation (Levine et al., 2015). Reasons for these occurrences could include multiple factors. Perhaps the provider ordering the ICD felt the patient needed the device immediately due to clinical instability in the setting of serious illness despite the guideline advice. In such a case, one may be able to attribute an increased mortality rate compared with otherwise healthy individuals to the higher acuity of the patient. If this were the case, it could allay some concern that the mortality rate was higher. In contrast, perhaps the provider disregarded or did not know the appropriate indications for ICD placement and thus omitted key steps such as the adherence to the GDMT or waiting the mandated 40 days following MI before device placement. To support this rationale, the literature is clear that there is no long-term survival benefit associated with early (< 40 days post MI) ICD implantation (Brooks et al., 2016).

Comorbidities

The AUC provided by Russo et al., (2013) incorporates a list of patient comorbidities that leave some ambiguity as to whether or not device placement is appropriate. Aside from meeting the AUC for device placement, the consideration of the patient's overall health status and likelihood to benefit from an ICD must also be taken into account. A combined analysis of the results of MADIT-I (Multicenter Automatic Defibrillator Implantation Trial), MADIT-II, DEFINITE (Defibrillators in Non-Ischemic Cardiomyopathy Treatment Evaluation), and SCD-HeFT (Sudden Cardiac Death in Heart Failure Trial) conducted by Steinberg et al. (2014) found an increased number of comorbidities was inversely related to the amount of benefit a patient may be expected to derive from ICD therapy. This finding is supported by Fernandez-Cisnal et al., (2015) who noted an increase in inappropriate device therapy in patients with a history of atrial fibrillation and advanced age. Similarly, Parkash, Stevenson, Epstein, & Maisel, (2006) noted that among patients with ≥ 2 major comorbidities (age > 80, history of atrial fibrillation, NYHA class III-IV HF, or serum creatinine > 1.8) at the time of ICD placement there was a 21% mortality rate at one year post device placement.

Paradoxically, obesity, despite being well known to contribute to atrial and ventricular arrhythmia, as well as many other comorbidities, has actually been shown to be protective where ICD placement is concerned (Attanasio et al., 2016). Obese patients suffered fewer procedural complications, such as bleeding and pneumothorax, during device placement than those with a body mass index < 30 kg/m^2 (Attanasio et al., 2016). A review similar to that conducted by Steinberg et al. (2014) found that, perhaps unsurprisingly, older patients have a greater number of comorbidities when compared with younger patients (Hess et al., 2015).

Regardless of the number of comorbidities, however, appropriate ICD placement has been found to be beneficial to the patient, regardless of age, with the caveat that an increase in age is associated with a lesser degree of benefit from the device (Hess et al., 2015). Possible contributors to this finding may be the common increase in concomitant illness with increased age, comorbidities, other fatal disease processes, and a smaller cohort of older adults available for study inclusion with advancing age (Hess et al., 2015). The AUC identifies age as a relative contraindication for ICD placement based on NYHA class. However, as pointed out by Hess et al. (2015), age should not, in itself, be a determining factor in whether or not a patient receives a device. Consideration of the patient's physiologic age must be considered in addition to the chronologic age. Randomized study data on patients requiring ICD therapy who are greater than 75 years of age is minimal thus requiring careful assessment of each patient and determination of the merits of device placement on an individualized basis (Hess et al., 2015).

To illustrate, AUC guidance states that a patient with less than one-year of remaining life expectancy is considered to be rarely appropriate for ICD placement. In spite of this, a patient on the heart transplant list is considered to always be appropriate for implantation according to the AUC ***Table 3.1*** (Russo et al., 2013). This criteria is less than ideal as there is always the potential that a cancer patient expected to die in six months may live an additional two years while a patient on the transplant list may die in a week. For such reasons, patients must be carefully assessed on a case by case basis rather than solely allowing published guidance to dictate therapy.

Of course, there are other potentially mitigating factors where the patient is concerned. In one such circumstance, when the patient is noncompliant with medical therapy, ICD placement is listed as rarely appropriate under the comorbidity table (Russo et al., 2013). Where

this becomes unclear, and has the potential to place some burden back on the provider, is in determining the reason why the patient is noncompliant. Zhang et al. (2015) identified that patients with private insurance were more likely to receive appropriate device therapy than those without. With this in mind, whether or not the patient who is noncompliant with medical therapy can afford their medications, much less access and afford followup care through a specialist referral to electrophysiology (EP), must be taken into consideration and appropriately addressed. At this point there is the potential for an ethical dilemma. The patient who is noncompliant with medical therapy due to inability to afford medication may be less likely to afford device implantation and maintenance as well as follow up care. While the inability to afford care should not be considered in the determination of whether or not to provide a potentially life saving intervention, such scenarios must be considered to ensure adequate delivery of care to the patient.

Financial Considerations

ICD device therapy runs into the tens of thousands of dollars and requires continuous maintenance and followup for as long as the patient has the device (Gialama et al., 2014). The cost benefit of ICD therapy has potential to be of concern to the patient as well as the health system overall. However, the cost benefit of device placement for prevention of SCD and future hospitalization related to dysrhythmia mediated arrest is supported by Gialama, Prezerakos, & Maniadakis' (2014) observation that the high initial cost of device therapy is likely attenuated over time through prevention of further hospitalization and increased medication requirements. This view is shared by Boriani et al. (2014) in an article exploring the cost benefit of ICD placement for primary prevention. Narayanan et al. (2013) expounded on the importance of health insurance in the case of ICD placement additionally noting that socioeconomic factors

play a substantial role in determining whether a patient undergoes appropriate device placement. Zhang et al. (2015) noted that, while they were unable to determine if a patient had been refused an ICD on insurance status alone, patients with private insurance were more likely to receive appropriate ICD placement ($p = 0.03$).

In cases where a Medicare patient falls outside the Medicare guidelines for some reason but still requires an ICD, the only options remaining for placement are for the hospital to provide the service without charge or to inform the patient that the procedure will need to be paid out of pocket (Fogel et al., 2014). Here, the financial consideration is extremely pertinent to the provider and the hospital. Billing for placement of an ICD, in a Medicare patient, outside of the national coverage determination opens both the provider and hospital to the potential for allegations of fraud (Fogel et al., 2014; Kaiser et al., 2015). Overall, there seems to be a general consensus that ICD placement in appropriate patients is as cost-effective, if not more so, than other generally accepted treatment regimens such as medication (Gialama et al., 2014).

Frameworks/models/theories to explain problem

No frameworks, models, or theories were implemented in the execution of this project. The intended purpose of this project was strictly fact finding to establish the rates of AUC compliance at PSVMC which did not require the use of any additional theoretical models or frameworks. Primarily, this was due to the fact that the presence of a problem was not able to be established or refuted without implementation of this project.

Project Aim

The AUC is based on the professional recommendation of a panel of experts. The category of the recommendation is based on the number of experts agreeing with the stated provision creating three levels of appropriateness for implantation labeled: Appropriate (benefits

outweigh risks); May be appropriate; Rarely appropriate (Russo et al., 2013). As identified by Kaiser et al. (2015), ICD's are often placed in situations that do not fall within the established parameters set forth in the guidelines.

Compliance with the published guidelines has the potential to impact billing and reimbursement, patient outcomes as demonstrated in the literature, as well as implementation of best practice for evidence based medicine. Patients potentially requiring device placement are widely varied with multiple possible combinations of comorbidities and primary cardiac ailments. This project focused on the following criteria based on ***Table 2.2*** of the AUC (attached to the end of this document) for patients who:

- Do not already have an ICD in situ;
- Have ischemic cardiomyopathy;
- Are more than forty days status post MI;
- Have a LVEF less than or equal to 40%;
- Have not undergone PCI or CABG in the last three months;
- Have heart failure in NYHA class I-III OR do not have documented class IV NYHA heart failure;
- Have been on at least three months of GDMT;
- Are receiving an ICD for primary prevention of a fatal arrhythmia.

The primary outcome of the project was to determine if, at Providence St. Vincent Medical Center (PSVMC), the guidelines are being adhered to with regard to ICD placement in an effort to identify how many patients warrant ICD placement but did not receive it. Incidence and prevalence of appropriate versus inappropriate intervention was determined following

completion of data collection. Appropriateness was determined by the adherence to the above listed criteria or documentation of a reason for deviation from the guidelines.

Approach to Conduct of the Project

Setting

PSVMC is a well-known cardiac center falling under the greater organization of Providence St. Joseph Health & Services. Located in Portland, Oregon the hospital has 523 beds with a staff of more than 3,000 people (Providence Health & Services, 2018). With dedicated cardiology and electrophysiology teams, a significant number of cardiac surgeries and PCI's performed annually, as well as the number of beds, PSVMC meets many of the criteria outlined by Shah et al. (2009) as contributing to an expected higher level of AUC compliance.

As there was no proposed intervention associated with this project, organizational readiness to change did not factor into the overall conduct of the project. Likewise, barriers, facilitators, and challenges to change were not considered. Members of the electrophysiology team were integral to the data collection process through support and clinical judgment. Similarly, members of hospital administrative staff facilitated conduct of the project through their assistance in accessing hospital records.

Participants/Population

At the outset of this project, two separate lists were analyzed. One list of all patients who have, or had, a LVEF $\leq 40\%$ which was collected through the use of myHiway, an internal source of information reporting and data collection at Providence. This list was obtained with the assistance of the clinical performance support manager for PSVMC. Data was limited to those patients falling within the specified timeline who had a LVEF report generated through any

means including: transthoracic echocardiogram (TTE), transesophageal echocardiogram (TEE), computed tomography (CT), invasive angiography, or nuclear medicine.

This list initially had 901 candidates which was screened to remove those patients appearing on the list more than once as patients often had more than one LVEF assessed within the six-month study window. Following removal of the 243 duplicate patients, 658 remained for chart review. Retrospective chart review was conducted with the guidance of the algorithm in ***Fig. 1*** to identify those patients meeting all inclusion criteria who:

- Did not already have an ICD in situ;
- have ischemic cardiomyopathy;
- are ≥ forty days status post MI;
- have not had PCI or CABG in the last three months;
- have class I-III NYHA heart failure OR do not have documented class IV NYHA heart failure;
- have an ejection fraction (EF) ≤ to 40%;
- have been on ≥ three months guideline directed medical therapy (GDMT);
- are receiving an ICD for primary prevention of a fatal arrhythmia.

These criteria eliminated all but 74 patients who were eligible for an ICD but did not yet have one in place.

The second list was comprised of those patients known to have received an ICD between January 1, 2017 and June 30, 2017. This list was obtained by searching the EPIC operative schedule for electrophysiology within the prescribed date range. Initially 61 patients were found to have received a defibrillator. Those patients appearing on the previous EF list were eliminated as duplicates. The criteria in ***Fig 1.*** was again applied to ensure that the patients met all criteria

for device placement. Following elimination of those who did not meet criteria for this study for primary prevention and ischemic cardiomyopathy 14 patients remained. In all, 88 charts were selected to be included in the final cohort.

A six-month window was chosen in order to allow for enough charts to be reviewed to provide a representative and current cohort. The early half of 2017 was selected in comparison to the latter half as this project was planned to begin in September of 2017 and a complete collection of data was felt to be preferable to an ongoing influx of information over the remaining months of the year. As this was a retrospective chart review, no recruitment was required.

Protection of health information and patient confidentiality was maintained at all times. Home access to EPIC was granted by PSVMC for the purpose of conducting this review. The list of patient ejection fractions was maintained on the Providence server which was only accessible by individualized username and password encryption. Likewise, the laptop used to access EPIC and the Providence server was password encrypted and kept in a locked state in a secure location whenever not in use.

All steps outlined in the project proposal with respect to maintenance of confidentiality were adhered to. Institutional Review Board (IRB) approval was granted by PSVMC. The Oregon Health & Science University (OHSU) IRB deferred full review to PSVMC IRB. Both certificates of determination are attached to the end of this document (***Fig. 4*** and ***Fig. 5***).

Outcome Evaluation

Implementation Procedure

Following obtaining access to both the hospital wide EF list and the EP ICD placement list, a Microsoft Excel spreadsheet was created with one book for each list. This spreadsheet had

assigned row numbers to maintain confidentiality while maintaining a way to reference those patients in each respective list on the secure servers. Patients were located by searching the medical record number (MRN) from the master list in the patient station tab.

- Results review tab: The most recent LVEF within the time window was used as an initial determination for inclusion. EF and method of determination (TTE, TEE, etc.) was noted in the Excel sheet. While in this tab, if an EP procedure was incidentally noticed the corresponding report would be reviewed to see if, and when, the patient had an ICD placed.
- Snapshot tab: Problem list was reviewed for: ischemic cardiomyopathy (ICM) diagnosis; CABG; PCI; MI; cardiac arrest; and ICD in situ or any derivatives thereof. If these were present, a corresponding date was sought and recorded in the Excel sheet. If all of these were not found in the Snapshot, the EPIC search bar was used to search: ischemic cardiomyopathy; cardiomyopathy; CABG; PCI; MI; implantable cardioverter-defibrillator; defibrillator; ICD; cardiac resynchronization therapy defibrillator; CRT-D; cardiac arrest.
- EPIC search bar: In addition to the above-mentioned search terms the following were also sought through the search bar feature: New York Heart Association; NYHA.
- Medication tab: Medication history was reviewed to find the earliest date of prescription for ACE-i/ARB, beta blocker, aspirin, statin, and, if applicable, calcium channel blocker, diabetic management, and hypertension management. Prescription dates were reviewed to ensure consistent and current use. If a patient's medications had been stopped due to lack of tolerance or comorbidity precluding continued use, every effort was made to find

the note documenting the medication cessation and appropriately document this in the Excel sheet.

- Chart review tab: Notes were searched for the most recent history and physical (H&P), cardiology, or EP office visit. These were reviewed to search for any incidental findings that may have been missed in previous searches which would affect candidacy for ICD therapy.
- For those patients with an EF of 36-40% additional searches were conducted for the terms: inducible; non-sustained ventricular tachycardia; NSVT; electrophysiology study; EPS; ventricular tachycardia; VT; ventricular fibrillation; VF.

All information collected was recorded in the Excel sheet and individually reviewed to determine the patient's eligibility for an ICD. In an effort to ensure accuracy and provide appropriate care, those patients found warranting an ICD who did not have one or were not scheduled to receive one were referred to the EP team through the use of the In-Basket feature in EPIC. The same process was followed for those patients on the EP list with the modification that an ICD was known to already be in place. Once the final list was compiled those patients meeting inclusion criteria were separated into one of three categories: those appropriately receiving or scheduled to receive a device; those appropriately not receiving or scheduled to receive a device; those inappropriately not receiving or scheduled to receive a device (***Fig.2 and Fig. 3***).

Final numbers for each category were compiled for reporting in this document. Additionally, percentages were calculated for each category. Where possible, patients were further categorized by the reason for device placement or absence of device placement and again

reported by both number and percent. As an unavoidable consequence of using percentages, some rounding error is inherent in the final reporting of figures.

Measures and Outcomes

The chart review was conducted electronically via EPIC utilizing the inclusion/exclusion criteria previously discussed. EF was considered accurate as charted for inclusion or exclusion of the respective cohorts. Results were input into the Microsoft Excel spreadsheet with no patient identifiers. The columns of the spreadsheet include a stepwise approach working through the algorithm in ***Fig. 1*** to arrive at a final end point of the three previously mentioned cohorts. Where it was possible, every attempt was made to ascertain the reasons why an individual appropriate for ICD therapy did not receive a device. It was expected that the comorbidities outlined in ***Table 3.1*** of the AUC would be responsible for appropriate refusal of ICD placement in some cases. In such events, the chart was reviewed to determine if a discussion between provider and patient was documented explaining the reason an ICD was not feasible. Similarly, apart from patient conversations regarding refusal of device therapy, the chart was searched for provider documentation recording appropriate refusal of device therapy. This data is detailed in ***Fig. 2*** and ***Fig. 3*** below.

To help ensure the accuracy of information, those patients at the end of the time allotment for the chart review who warrant, but have not yet received, an ICD were reviewed carefully. If a prescription has been made in the chart for ICD placement with intent to schedule the procedure, this was documented as appropriate therapy so as not to skew the data due to scheduling conflicts. If, however, the same case occurs and there was no prescription for ICD placement and no documentation of scheduling and ICD implantation, this was counted as a patient who warrants placement but did not receive appropriate therapy.

The only ethical considerations in this retrospective chart review were the appropriate safeguarding of patient information and accurate reporting of the results of data collection. As previously mentioned, all patient information was de-identified prior to the presentation of the final project so as to protect patient anonymity. To the same end, any and all electronic data was only accessed on machines with individualized password encryption to further prevent the risk of compromising patient records.

With regard to the accuracy of reporting, every attempt was made to ensure accurate and unbiased data collection and presentation of the resultant data. Very little bias should be applicable to a project such as this as the information is either charted or it is not thus requiring minimal interpretation. With that said, as the doctoral candidate was the sole data collector, some inadvertent bias cannot be excluded. Were any questions to arise with regard to the appropriate categorization of an individual value or trait, the EP team was consulted. As this project was conducted at a facility where EPIC access was already available to the doctoral candidate, and there was no other faculty or staff enlisted to assist with data collection, the only cost was the time spent on data collection. For this reason, there was no known out of pocket expense to the hospital, EP team, or doctoral candidate.

Implementation of Project

Evolution of Project Over Time

Following IRB approval few modifications were required. One area requiring adjustment centered on a failure to anticipate the number of patients who would have ICD's in place prior to the study window. As these were placed prior to the initiation of the study the decision was made by both the DNP candidate and the DNP chair to eliminate these individuals from the study. This became difficult in one particular scenario where patients had previously undergone

device implantation but had to have the device removed and reimplanted due to infection or device malfunction. In such a case, if reimplantation occurred within the study window the patient was included in the final cohort if meeting all criteria detailed in ***Fig. 1***.

A second modification to the original algorithm was required concerning documentation of the NYHA heart failure classification. The majority of patient charts reviewed did not include a NYHA heart failure score. By the original algorithm, the decision could have been made to eliminate all of these patients as they did not have a current classification. Instead, the decision was made to ensure there was not a diagnosis of NYHA class IV heart failure which would, in most cases, have eliminated the patient as an eligible candidate for device placement.

A third challenge was the use of multiple imaging modalities for determination of LVEF. While cardiac MRI is often considered the gold standard for LVEF evaluation, TTE is more commonly used for its ease of use, lack of radiation, and availability (Pickett, Cheezum, Kassop, Villines, & Hulten, 2015). Often patients who had a LVEF assessed by TEE had this done in the setting of an electrophysiology procedure to ensure there existed no thrombus in the left atrial appendage. In this setting, the ejection fraction would logically be decreased as the atrial contribution to ventricular filling and overall cardiac output was diminished (Michaud & Stevenson, 2015). A similar problem was noted in patients undergoing nuclear imaging where substantial differences existed between LVEF measured by TEE, TTE, and single photon emission computed tomography (SPECT). Consistently, the SPECT estimated the LVEF at substantially lower values than those noted on TEE and TTE. In the course of chart review one progress note was found which had been authored by an attending nonelectrophysiology cardiologist and specifically addressed this noting that, at PSVMC, the SPECT LVEF results were consistently low. While the literature is unclear on this, a paper by Shojaeifard et al.,

(2015) identified the potential for significant variation, including underestimation, of LVEF with SPECT based on the individual software package in use.

Unintended Consequences

As there is no institutional change being proposed or promoted by this project there have been no unintended consequences to report.

Details of Missing Data or Information

The greatest difficulty in obtaining missing data came from searching for documentation from charts that were outside the Providence system. Care Everywhere was utilized to obtain outside records when possible. Veteran's Administration patient's records were especially difficult, or impossible, to locate as were some records from institutions such as the Oregon Clinic. In cases such as these, chart notes were searched and reviewed and determinations regarding eligibility for device placement were deferred to the clinicians who documented lab results, medication adherence, and study results from outside institutions.

One issue relating to missing data or information centered on charting. Often it was noted that provider notes did not adequately or fully describe patient history. While some variation is expected based on service and specialty in note format and focus, many notes did not include basic information. As an example, NYHA was not documented for the majority of the patients reviewed. Many of those patients having a reduced EF may have been under consideration for placement of an ICD but without documentation of this thought in the charts there is no way to be certain whether the proper consideration was, in fact, being given to this therapy. Absence of documentation of consideration for an ICD was noted in the majority of those patients in the category of "inappropriately not having a device planned or in place". This issue has also been seen in the literature as noted by Zhang et al., (2015).

Key Findings

Results were calculated both without the EP list of known device placements and with. The reason for this decision is that inclusion of the EP list patients has the potential to skew results as many of the patients from the EP list had been scheduled to receive the device prior to the start of the study window. ***Fig. 2*** and ***Fig. 3*** below detail the findings of this project. In summary, PSVMC was 68.916% compliant with the AUC where appropriately placing or appropriately withholding an ICD is concerned. The EP team was 100% compliant with the AUC where device placement for primary prevention was concerned. When including the patients from the EP list into the percentage for overall hospital compliance it was found that PSVMC is 73.88% compliant with the AUC. In contrast, this also means that 31.08% and 26.15% of the time, respectively, PSVMC was not compliant with the published guidelines providing room for future study and improvement.

Outcomes

Comparison of Findings to Literature and Expected Results

The initial hypothesis was that St. Vincent would fall within the upper quartile of the national average (60-80%) for overall compliance with the criteria in ***Fig. 1*** and ***Table 2.2*** as a whole. An upper limit of 80% was chosen based on the report by Shah et al. (2009) identifying the national rate of appropriate actual or planned ICD use at only 20% with a range of 0-80%. This was supported by the findings of Hoang et al. (2014) placing compliance at 38% for two hospitals from different systems in the same community. With that, the overall findings of this project supported the initial hypothesis. As the hospital fell within the national average the literature was validated.

As described above, PSVMC's AUC compliance for primary prevention of SCD in patients with ICM was within the upper quartile of the national compliance average validating the initial hypothesis. The electrophysiology team exceeded the expectations of the initial hypothesis by obtaining 100% compliance with the AUC. Without consideration given to the EP team's compliance figures, the hospital as a whole was 68.916% compliant (***Fig. 2***). In the cohort detailed in ***Fig. 2*** the most commonly noted subcategory was that there was no mention found giving consideration for an ICD (*n*=15, 20.2%). Additional subcategories worth mentioning included those patients: whose LVEF recovered to the point that they no longer met criteria for device placement and appropriately did not receive a device (*n*=11, 14.87%); appropriately receiving or scheduled to receive a device (*n*=12, 16.216%); and those with a documented expected remaining lifespan of less than one year (*n*=8, 10.8%).

Explanation of Differences Between Expected and Observed Results

While the hospital as a whole met the expectations of the initial hypothesis, EP exceeded those expectations significantly. The reasons for this could be many but likely center on the ultra-specialization of the field. EP focuses explicitly on heart rhythm including pacing and ICD therapy. With this level of focus it would be logical to expect a higher level of compliance than with other services with a wider focus of practice. This is supported by the findings of Al-Khatib et al., (2011) noting that EP had a substantially higher rate of guideline compliance when compared with other providers in different subspecialties. Further explanation offered included better familiarity with the published guidelines and the data surrounding utilization of the ICD in primary prevention settings (Al-Khatib et al., 2011).

Impact of Project on System

The intent of this project was not to propose or implement any form of institutional change but rather to fact find regarding PSVMC's compliance with the AUC. This information has been relayed to the EP team at the hospital for further use and interpretation as may be deemed necessary. There is the potential to increase billings for procedures based on additional device placements should those patients missed be contacted and scheduled for ICD placement, which has already happened in several cases, thus providing a financial benefit to the hospital and a health benefit to the patient.

While this project has no direct impact on PSVMC or the system at large, the implications of these findings have the potential to be far reaching. Al-Khatib et al., (2011) conducted a study on non-evidence based placement of ICD's based on the national cardiovascular data registry (NCDR). The NCDR was established in 2005 when Medicare expanded coverage of ICD placement to include primary prevention with the stipulation that all Medicare patients receiving a device must be entered into the registry (Al-Khatib et al., 2011). What was noted in this study was that: the government was the primary insurance payer in 66% of patients included in their study; length of stay was three-fold longer in non-evidence based ICD placements than in their evidence based counterparts; nonelectrophysiologists were significantly more likely to deviate from the guidelines than electrophysiologists; and risk of post-procedural complication and mortality was higher in non-evidence based ICD placement (Al-Khatib et al., 2011). Taking these factors into consideration provides perspective on the importance of continued quality improvement and adherence to the AUC. As described by Fonarow and Ziaeian (2016), appropriate delivery of care through guideline adherence provides

the best outcomes of care to the patient while minimizing costly and unnecessary procedures and interventions.

Practice Related Implications, Recommendations, Limitations

The implications of this project for PSVMC have the potential to be substantial. While the EP team itself was 100% compliant with the AUC, the hospital as a whole was not. This reveals a shortfall in knowledge, application of knowledge, or proper referral/follow-up throughout the hospital. An appropriate referral by other departments (e.g. emergency medicine or hospital medicine) to EP may allow for an increased number of appropriately placed devices in the future with the hopeful outcome of a reduced patient mortality rate.

Recommendations for change are not the focus of this project. Those areas potentially warranting future attention (i.e. improvement in and consistency of charting, appropriate referral, and dissemination of knowledge and the AUC) have previously been addressed above. While improvement is always possible and should be encouraged, PSVMC is in the upper quartile of the national average for AUC compliance indicating that process improvement should be sought but is not a point requiring critical intervention at present.

A potential area for improvement suggested by Hoang et al., (2014) that may be useful at PSVMC is the utilization of electronic medical record prompts encouraging the clinician to consider ICD placement in those patients with a LVEF $\leq 35\%$. This could be further augmented by provider education to the patient and the incorporation of a dedicated nurse coordinator capable of conducting chart review and patient education to help identify those patients best suited for, and willing to undergo, treatment with an ICD. Such education, combined with the additional time provided by a nurse coordinator role, would help ensure patients with a low

LVEF had an adequate understanding of the importance of the utilization of GDMT and the potential for reduced mortality offered by ICD placement.

Several limitations on this study exist. As a retrospective chart review, all information had to be gleaned from hospital documentation. This did not allow for real time assessment of situations or discussions with the providers or patients making decisions in that moment to determine what was being considered. As a chart review certain events, such as discussions with patients, may have taken place which, if not documented, have the potential to unfavorably skew the outcome of this study.

An additional limitation is the inclusion of patients from outside the Providence hospital system who had a LVEF assessed at PSVMC within the study window. With the difficulties encountered in acquiring hospital records from outside institutions it is possible that some patients received devices at another hospital, again potentially skewing results. This was further complicated by relying solely on Care Everywhere to locate patient records from outside institutions. The decision was made not to contact these hospitals directly so as not to inadvertently create any potential compromise of patient confidentiality or violation of IRB approval as such contact was not included in the initial project proposal.

Reliance on keywords deemed to be the most likely to appear in the charting also has the potential to be a limitation. In using the EPIC search bar, it is possible that uncommon acronyms, abbreviations, or misspelled text would have been overlooked which has the potential to skew results. In such a case, a discussion regarding device placement in which the patient refused but none of the keywords searched appeared in the documentation, an inappropriate designation could have been given to that patient for the purposes of this study. To minimize the risk of missing important information, every effort was made to alleviate this by reviewing the

most recent H&P, cardiology, or EP note in addition to any other notes incidentally found which could guide the outcome of this study.

The search for patients to be included in this project was limited to the list of all patients known to have an LVEF ≤ 40% and those patients known to have an ICD placed based on the EP operating schedule. The report of LVEF's was supplied by hospital staff but could be subject to error by those inputting data or failing to include all patients in the MyHiway dataset. The possible outcome of this scenario is that patients may have been missed who either did or did not receive appropriate device therapy resulting in skewed results.

This study focused explicitly on patients with ICM warranting ICD placement for primary prevention of SCD. This was done to the exclusion of patients with nonischemic etiologies of cardiomyopathy and those receiving or warranting device placement for secondary prevention. The initial assumption of this project was that primary prevention of SCD in ICM patients would form the greater majority of those patients found. A more complete review of all patients warranting, or having undergone, device placement may affect overall compliance averages at PSVMC though, such review was beyond the scope of this project.

Finally, as the sole reviewer of the complete dataset it is possible that unintentional bias may have been present in reviewing charts. Without the benefit of a peer check system for every chart reviewed the unintentional application of individual judgement cannot be eliminated. Every attempt was made to nullify this possibility by adhering to the protocol as outlined in ***Fig. 1*** and consulting the EP team directly in cases of uncertainty.

Conclusions

Overall compliance at PSVMC is acceptable. Continued delivery of care at this level is sustainable as demonstrated by the consistency of ICD placement over time in this chart review.

The potential exists to expand influence within the hospital through continued teaching and throughout the hospital system through repetition of this project at other hospitals known to place ICD's for primary prevention in order to expand the assessment to a system wide approach.

This approach to quality improvement could be further expanded in the future to include those patients eliminated by this study including those receiving ICD's for secondary prevention and nonischemic etiologies of heart failure. Such an expansion would allow for a more comprehensive view of overall hospital compliance as, of the 719 charts reviewed only 88 were included in the final cohort. Such an inclusion was beyond the scope and means of the current project but could potentially be an interesting and useful area of future study.

Usefulness

This project has been demonstrated as useful through the identification of several patients who met criteria for placement of an ICD for primary prevention yet did not have one in situ or scheduled to be placed. As discussed above, SCD is a leading cause of death in the United States (Garg, 2015; Zhang et al., 2015) and ICD placement has a demonstrated benefit in mortality reduction (Goldenberg et al., 2006). The utility of the ICD cannot be overstated in a patient appropriate to receive device therapy. This project has allowed identification of not only patients who merit, yet have not received, devices, but also a gap in care allowing for better delivery of evidence based care to additional patients.

Sustainability

While the hospital as a whole could reasonably continue on without change or adaptation in methods given the relatively high compliance rate, this would still allow for patients to be missed, potentially contributing to unnecessary mortality. The EP team will be able to sustain their current operational tempo while increasing the number of patients reached and treated as

they have recently added an additional physician and nurse practitioner, with further intentions to continue to grow their group. Aside from speculation, as no change in policy or procedure was proposed, it is not possible to assess sustainability of any such action.

Potential to Increase Influence

Increasing influence was not the intended outcome of this project. Despite this, there is potential to improve compliance through continued teaching and training of staff. Participation in open forum events such as grand rounds, heart failure dinners, journal clubs, or scheduled seminars provided by the EP team would allow for broader dissemination of the latest guidelines and therapies to hospital services which may have less exposure to the more intricate details of cardiology and heart failure intervention. Similarly, hospital and system based interventions such as an electronic reminder in EPIC to prompt consideration of an ICD in patients with a low LVEF has proven effective at increasing appropriate referral in other healthcare systems (Gupta, Gholami, Turakhia, Friday, & Heidenreich, 2012).

Summary and Next Steps

Sudden cardiac death is known to be a major contributor to American mortality (Garg, 2015; Zhang et al., 2015). Appropriate, guideline directed intervention has been shown to greatly reduce the rate of SCD (Moss et al., 2002; Goldenberg et al., 2006). The guidelines are in place to allow for the best outcomes for the patient including the greatest chance of recovery of cardiac function lost in the setting of myocardial stunning secondary to an ischemic event (Deyell et al., 2010). This includes waiting the prescribed period of time following an ischemic event or reperfusion intervention, appropriate use of GDMT, and the absence of comorbidities or diagnoses that would make ICD utilization impractical, unsafe, or ineffective.

There is great variability in national compliance with the AUC (Shah et al., 2009; Hoang et al., 2014). PSVMC supported the initial hypothesis that the hospital would be within the upper quartile of the national compliance average with a final hospital wide compliance rate of 68.916%, EP group compliance of 100%, and total combined compliance of 73.88%. Those patients noted to merit an ICD, yet not have one in situ or scheduled for placement, were referred back to the EP group during the course of this study for further follow up.

The purpose of this project was to identify the rate of AUC compliance at PSVMC. This has been successfully achieved. No further intervention was planned or proposed. The information gleaned from this study has been supplied to the EP group at PSVMC to act on as deemed necessary in the interest of patient safety, implementation of evidence based medicine, and compliance with the published guidelines. To determine the effectiveness of any possible action or intervention, further study would be required.

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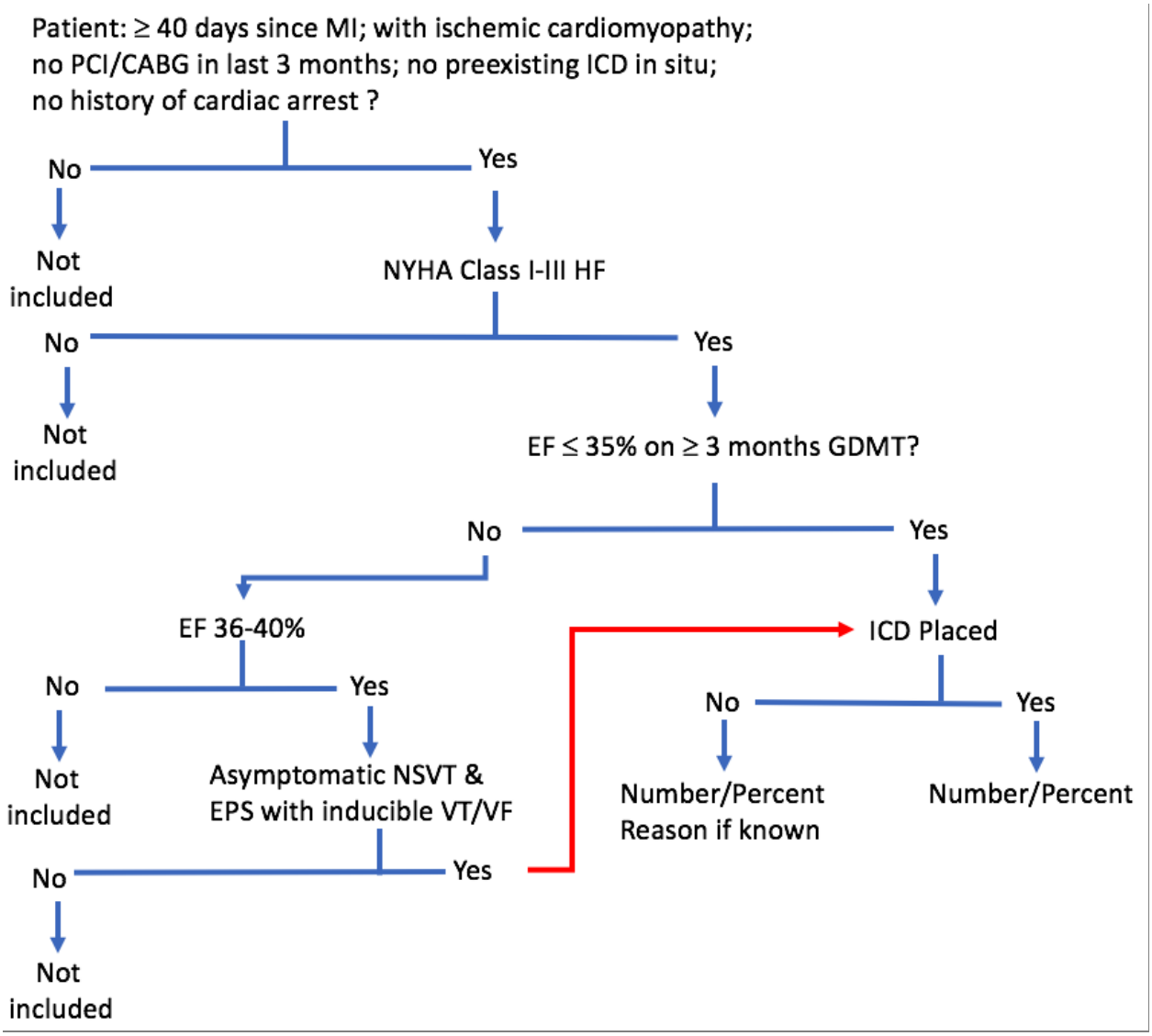

Fig. 1 Inclusion criteria for ICD placement

ALL EJECTION FRACTION LIST – *n*=74					
	Appropriate			**Inappropriate**	
Pt has gotten or is getting ICD	***n / %***	**Pt does not have or is not getting ICD**	***n / %***	**Pt does not have or is not getting ICD**	***n / %***
New device	8/10.8	Patient refusal	6/8.1	No mention of ICD	15/20.27
Replaced s/p explant for infection	1/1.35	< 1 year life expectancy	8/10.8	Lost to f/u	4/5.4
Documented need for device, Patient left country for placement	1/1.35	Preexisting device removed w/ no replacement	3/4.05	Outside hospital patient brought in by EMS, no further records found	1/1.35
Patient referred for device but has not gotten it yet	2/2.7	Comorbidities	5/6.75	Incomplete f/u, no repeat EF study	2/2.7
		Patient noncompliance	1/1.35	Charted need for device w/out placement	1/1.35
		Recovery of EF	11/14.87		
		Documented, risk > benefit	1/1.35		
		Documented, waiting to optimize GDMT	3/4.05		
		Reason not documented, Patient has advanced comorbidity	1/1.35		
Total *n*=12, 16.216%		Total *n*=39, 52.7%		Total *n*=23, 31.08%	

Fig. 2 Breakdown of all patients included based on the hospital list of all EF studies performed

ALL EJECTION FRACTION LIST WITH EP PATIENT LIST – *n*=88					
	Appropriate			**Inappropriate**	
Pt has gotten or is getting ICD	***n / %***	**Pt does not have or is not getting ICD**	***n / %***	**Pt does not have or is not getting ICD**	***n / %***
New device	8/9.09	Patient refusal	6/6.82	No mention of ICD	15/17.05
Replaced s/p explant for infection	1/1.14	< 1 year life expectancy	8/9.09	Lost to f/u	4/4.55
Documented need for device, patient left country for placement	1/1.14	Preexisting device removed w/ no replacement	3/3.41	Outside hospital patient brought in by EMS, no further records found	1/1.14
Patient referred for device but has not gotten it yet	2/2.27	Comorbidities	5/5.68	Incomplete f/u, no repeat EF study	2/2.27
EP patients receiving ICD for primary prevention	14/15.91	Patient noncompliance	1/1.14	Charted need for device without placement	1/1.14
		Recovery of EF	11/12.5		
		Documented, risk > benefit	1/1.14		
		Documented, waiting to optimize GDMT	3/3.41		
		Reason not documented, patient has advanced comorbidity	1/1.14		
Total *n*=26, 29.55%		Total *n*=39, 44.33%		Total *n*=23, 26.15%	

Fig. 3 Breakdown of all patients included based on hospital list of all EF studies performed with addition of those patients known to have received an ICD based on the EP OR schedule

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Section 3: Comorbidities

It should be noted that the scenarios in this section refer to ICDs implanted for primary prevention.

Table 3.1. Special Conditions/Comorbidities in Patients for Primary Prevention (Meeting Indications of ICD Implant Related to HF Diagnosis With LVEF ≤30% on Guideline-Directed Medical Therapy >3 Months) (Fig. 14)

	Indication	Appropriate Use Score (1–9)			
	Life Expectancy				
134.	• Life expectancy <1 year from cardiac or noncardiac conditions				R (1)
135.	• Noncardiac disease with life expectancy 1 to 2 years				M (4)
	Elderly				
		NYHA Class			
		I	II	III	IV
136.	• 80 to 89 years old	M (4)	M (5)	M (5)	
137.	• ≥90 years old	R (3)	M (4)	M (4)	
	Cognitive Impairment				
138.	• Not able to understand or provide informed consent • Health care proxy consents to ICD				M (4)
139.	• Not able to understand or provide informed consent • No health care proxy can be identified				R (3)
	Advanced Psychiatric Impairment				
140.	• Significant psychiatric illnesses that may be aggravated by device implantation or that may preclude regular follow-up				R (1)
	Renal Disease				
		NYHA Class			
		I	II	III	IV
141.	• Severe symptomatic peripheral vascular disease (e.g., peripheral interventions or clinical claudication)	M (6)	A (7)	A (7)	
142.	• Chronic kidney disease on dialysis • Not a candidate for renal transplant	M (5)	M (6)	M (6)	
143.	• Chronic kidney disease with CrCl <30 ml, not yet on dialysis but candidate for dialysis	M (6)	M (6)	M (6)	
	Other Comorbidities				
144.	• IV drug abuse (ongoing)				R (2)
145.	• Unresolved infection associated with risk for hematogenous seeding				R (2)
146.	• Noncompliance with medical therapy and follow-up				R (3)
	Class IV Heart Failure				
147.	• On waiting list for heart transplant				A (8)
148.	• Not candidate for cardiac transplantation, CRT, or VAD • Refractory symptoms on oral therapy				R (2)
149.	• Patient with a VAD				M (6)
150.	• Not a candidate for transplant or VAD • Does not meet CRT criteria • Planned outpatient continuous intravenous inotropic therapy for palliation				R (2)

NOTE: grey shaded boxes indicate "not rated."
A = Appropriate; CrCl = creatinine clearance; CRT = cardiac resynchronization therapy; HF = heart failure; ICD = implantable cardioverter-defibrillator; IV = intravenous; LVEF = left ventricular ejection fraction; M = May Be Appropriate; NYHA = New York Heart Association; R = Rarely Appropriate; RV = right ventricular; VAD = ventricular assist device; VT = ventricular tachycardia.

Retrieved from: Russo et al., (2013), p. 1337

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March 26, 2013:1318–68

Table 2.2. Post-Myocardial Infarction (>40 Days) With Ischemic Cardiomyopathy (Fig. 10)

	Indication	Appropriate Use Score (1–9)			
	No Recent PCI or CABG (≤3 Months)				
		NYHA Class			
		I	II	III	IV
96.	• LVEF ≤30%	A (8)	A (9)	A (9)	
97.	• LVEF 31% to 35%	A (7)	A (9)	A (9)	
98.	• LVEF 36% to 40% • Asymptomatic NSVT • No EPS				M (5)
99.	• LVEF 36% to 40% • Asymptomatic NSVT • EPS without inducible VT/VF				M (5)
100.	• LVEF 36% to 40% • Asymptomatic NSVT • EPS with inducible sustained VT/VF				A (8)

Retrieved from: Russo et al., (2013), p. 1335

APPROVAL OF SUBMISSION

November 15, 2017

Benjamin Hartwig

benjamin.hartwig@providence.org

Dear Benjamin Hartwig:

On 11/13/2017, the IRB reviewed the following protocol:

Type of Review:	Initial Study
Title of Study:	Implantable Cardioverter-Defibrillator Implantation Guideline Adherence in a Single Community Hospital
Investigator:	Benjamin Hartwig
IRB ID:	STUDY2017000637
Sponsor:	None
IND, IDE, or HDE:	None
Documents Reviewed:	• Protocol, dated 11/09/17
IRB of Record:	Providence Health and Services (Oregon)

The IRB approved the study from 11/13/2017 to 11/12/2018 inclusive. Before 11/12/2018 or within 30 days of study closure, whichever is earlier, you are to submit a continuing review with required explanations. You can submit a continuing review by navigating to the active study and clicking Create Modification / CR.

If continuing review approval is not granted on or before 11/12/2018, approval of this study expires after that date.

In conducting this study, you are required to follow the requirements listed in the Investigator Manual (HRP-103), which can be found by navigating to the IRB Library within the IRB system.

Sincerely,

Stephanie Penuel

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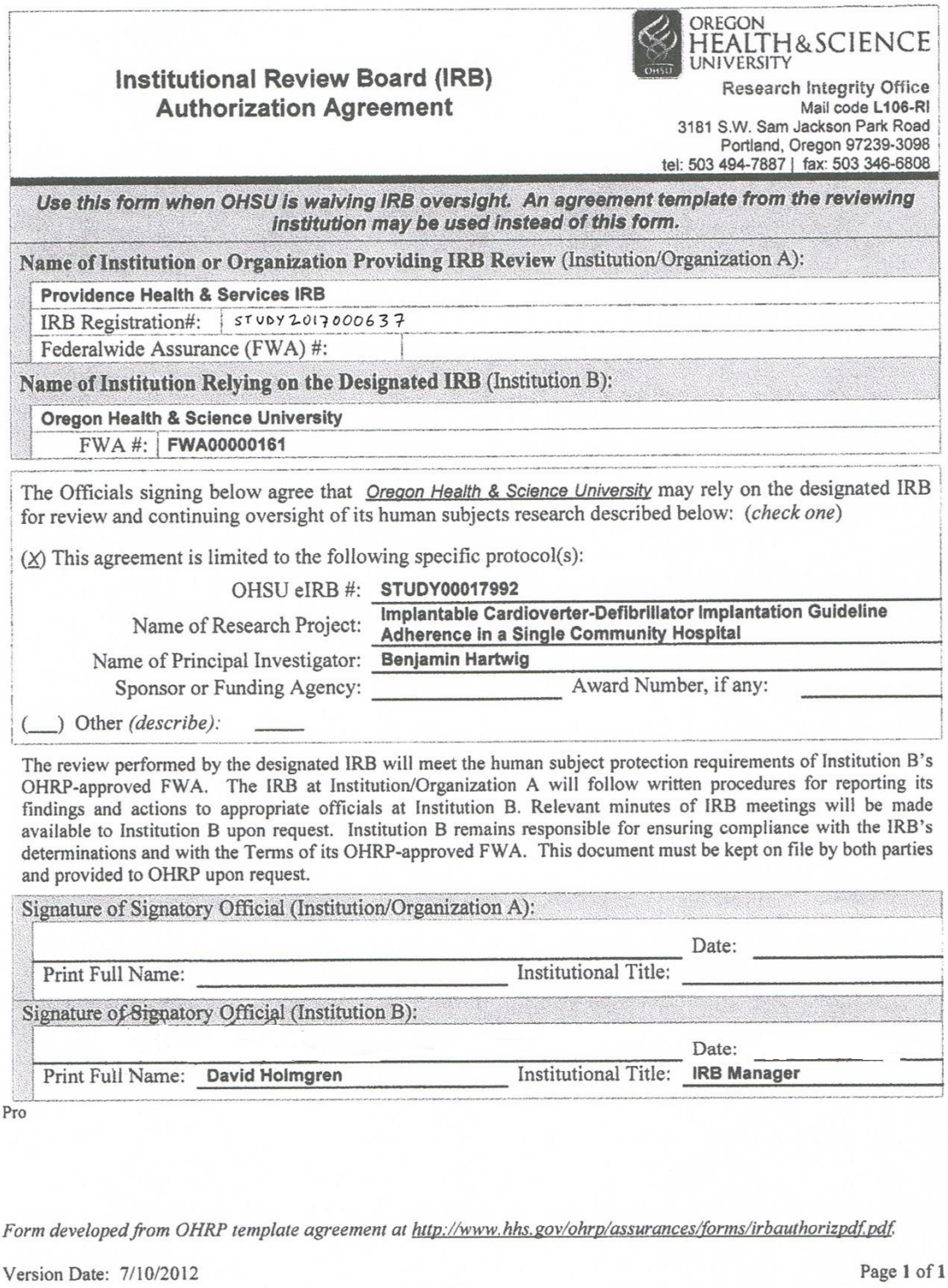
Fig 4. Providence St. Vincent IRB determination



Institutional Review Board (IRB)
Authorization Agreement

OREGON HEALTH & SCIENCE UNIVERSITY
Research Integrity Office
Mail code L106-RI
3181 S.W. Sam Jackson Park Road
Portland, Oregon 97239-3098
tel: 503 494-7887 | fax: 503 346-6808

Use this form when OHSU is waiving IRB oversight. An agreement template from the reviewing institution may be used instead of this form.

Name of Institution or Organization Providing IRB Review (Institution/Organization A):

Providence Health & Services IRB
IRB Registration#: STUDY2017000637
Federalwide Assurance (FWA) #:

Name of Institution Relying on the Designated IRB (Institution B):

Oregon Health & Science University
FWA #: **FWA00000161**

The Officials signing below agree that *Oregon Health & Science University* may rely on the designated IRB for review and continuing oversight of its human subjects research described below: (*check one*)

(X) This agreement is limited to the following specific protocol(s):

OHSU eIRB #: **STUDY00017992**
Name of Research Project: **Implantable Cardioverter-Defibrillator Implantation Guideline Adherence in a Single Community Hospital**
Name of Principal Investigator: **Benjamin Hartwig**
Sponsor or Funding Agency: _____ Award Number, if any: _____

(___) Other *(describe)*: _____

The review performed by the designated IRB will meet the human subject protection requirements of Institution B's OHRP-approved FWA. The IRB at Institution/Organization A will follow written procedures for reporting its findings and actions to appropriate officials at Institution B. Relevant minutes of IRB meetings will be made available to Institution B upon request. Institution B remains responsible for ensuring compliance with the IRB's determinations and with the Terms of its OHRP-approved FWA. This document must be kept on file by both parties and provided to OHRP upon request.

Signature of Signatory Official (Institution/Organization A):

Date: _____
Print Full Name: _____ Institutional Title: _____

Signature of Signatory Official (Institution B):

Date: _____
Print Full Name: **David Holmgren** Institutional Title: **IRB Manager**

Pro

Form developed from OHRP template agreement at http://www.hhs.gov/ohrp/assurances/forms/irbauthorizpdf.pdf.

Version Date: 7/10/2012

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Fig. 5 OHSU determination to defer to PSVMC IRB