

**Implementation of the Seattle Heart Failure Model
In a Specialty Cardiology Clinic**

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DNP 670 Scholarly Project

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Abstract

Background: Due to the increasing complexity of caring for heart failure patients and identifying those patients that are in need of palliative care referrals or advanced therapies, an order set was created to guide the decision-making process of those individuals.

Methods: A mixed method design using qualitative pre- and post-surveys were used to measure the providers perception of using the model within their practice.

Findings: The limited participation of providers in the project implementation site rendered the results of this project inconclusive. Reflections on two case-based patient encounters is provided to demonstrate the use of the Seattle Heart Failure Model with patients who have been diagnosed with heart failure.

Conclusions: Integration of the Seattle Heart Failure Model order set within in the electronic health record of the entire cardiology practice was a strong first step for encouraging implementation of the tool throughout the system for all providers who see patients diagnosed with heart failure. Further projects that are disseminated system-wide to educate providers about this evidence-based tool are needed.

Keywords: *disease management, outpatients, heart failure, prognosis, Seattle Heart Failure Model, heart assist devices, patient readmission, advance care planning*

Implementation of the Seattle Heart Failure Model In a Specialty Cardiology Clinic

According to the American College of Cardiology (ACC), an estimated 6.2 million Americans had a diagnosis of heart failure (HF) from 2013-2016, with the diagnosis of 550,000 new cases annually and a mortality rate that ranges from 5% - 75% (Benjamin et al., 2019; Levy et al., 2006). Savarese & Lund (2017) discuss HF as a global pandemic that is affecting approximately 26 million people worldwide. The incidence of HF in the United States (U.S.) is characterized by 10 per 1,000 individuals over age 65 having the diagnosis (Savarese & Lund, 2017). The most recent statistics for hospital discharges reveal HF as a primary diagnosis in one million patients and as a secondary diagnosis for an additional two million patients each year (Heidenreich et al., 2013; Hollenberg et al., 2019). Hospital readmission is common among patients diagnosed with HF, thought to be approximately 27%, and it is the most frequent cause of hospitalization among all diagnoses (Bui & Fonorow, 2012). The overall cost of the disease burden of HF is 1% - 2% of the annual healthcare budget in the U.S. (Hollenberg et al., 2019). These statistics are reflective of the difficulty of management of HF and indicate a growing need for a proactive pathway of caring for patients with HF (Bui & Fonorow, 2012).

The complexity of this disease, to include the role of neurohormones affecting blood pressure and fluid/sodium retention, creates a significant challenge in the management of patients diagnosed with HF (Brashers, 2019). While there are a number of guidelines in place to direct treatment of individuals diagnosed with HF, many challenges remain to adequately manage patients with HF (Pellicori et al., 2020).

The diagnosis of HF typically affects individuals ages 65 years and older (Savarese & Lund, 2017; Uchmanowicz et al., 2019). Understanding the trajectory of HF allows for recognition of the impact a prognostic model may have in treating this population of patients. Kheirbek et al., (2013) describes how HF is characterized by “periods of stability interrupted by episodes of acute exacerbation” (p. 478), typically with some recovery of functional ability after each episode.

The treatment of HF has evolved over many years, with a current focus on early identification and treatment of HF, along with improved care coordination, management of co-morbidities and improved patient self-management. These strategies not only help prevent hospitalization for patients with HF but improve quality of life, functional ability and decreases the financial burden of managing HF (Bui & Fonorow, 2012; Kurmani & Squire, 2017; Pellicori et al., 2020).

The trajectory of HF is different than most terminal diagnoses and requires a different approach to advance care planning versus advanced treatment options, making prognostic tools an essential part of comprehensive care of patients with HF. Treatment options for patients with advanced HF include options such as transplants and mechanical circulatory and heart rhythm support that are accompanied by serious decisions about care at the end of life. Healthcare providers who care for this population must have prognostic tools to assist patients in making healthcare decisions that are in alignment with the patient's overall goals and preferences for their ongoing care (McIlvennan & Allen, 2016).

The Seattle Heart Failure Model (SHFM) is a validated prognostic tool used to predict survival of individuals diagnosed with heart failure. The usefulness of the SHFM in the outpatient setting can help guide healthcare providers regarding treatment options for their patients diagnosed with HF. This model is differentiated from other prognostic models due to the ability to revise patient survival estimates by adding or deleting devices or medications. For example, a patient with HF being treated with digoxin alone and who has a 20% risk of mortality will live approximately four years. Use of the SHFM would recommend the addition of an ACE inhibitor, extending this patient's predicted lifespan to approximately five years. Further addition of a beta blocker will extend the predicted lifespan to six-and-a-half years (Degginger, 2006).

Heart failure has no cure and typically worsens over time but with treatment, HF can be optimally managed. Primary care providers and specialty outpatient care providers can use the SHFM to comprehensively address all aspects of care for patients with HF and establish goals of care.

Review of Literature

A systematic review of literature was performed to identify the utility of the SHFM in various aspects of the heart failure population in relation to prognosis and treatment. The model originates back to 2006 when it was initially studied and found to be useful in this population.

Seattle Heart Failure Model

The SHFM model was developed by Dr. Wayne Levy and his colleagues at the University of Washington using multiple variables that more readily individualizes treatment options for patients with HF. The first version of the model was published in 2006. The SHFM uses variable risks for predicting survival of patients with HF, to include age, gender, ischemic etiology, the New York Heart Association (NYHA) Functional Classification, ejection fraction, systolic blood pressure, potassium-sparing diuretic use, statin use, allopurinol use, hemoglobin, % lymphocyte count, uric acid, sodium, cholesterol, and diuretic dose/kg as significant predictors of survival. Healthcare providers who use the SHFM can provide an estimate of one-, two- and/or three-year survival for patients diagnosed with HF (Levy et al., 2006).

When the SHFM was initially developed and validated, patients diagnosed with HF had a five-year survival rate. The SHFM prognostic value was validated in six large clinical trials, with a total of 9942 patients with HF and 17,307 person-years of follow-up (Levy et al., 2006). One of the earliest trials looked at patients ($n=4077$) diagnosed with HF and found the predictive value of the SHFM at one, two and three years survival to be accurate (May et al., 2007).

An update to the original SHFM was completed in 2013, based on newer guidelines for treatment of HF. Additions to the model include the allowance to add intravenous diuretics, intra-aortic balloon pumps (IABP), ventilators, ultrafiltration, and inotrope usage. Other changes include changing the parameters required to be eligible for advanced therapies and the option of adding a statin was removed (Bilchick et al., 2017; Levy, 2013).

In 2017, the model was applied in hospitalized patients. In addition to the variables previously used by the SHFM, additional variables such as incorporation of newer left ventricular assistive devices (LVADs) and newer guidelines for implantable cardioverter defibrillators (ICD), cardiac resynchronization therapy (CRT), and the cardiac resynchronization defibrillator (CRT-D) (Li et al., 2019). Cardiac resynchronization therapy is a treatment solution for individuals who are diagnosed with systolic heart failure (Normand et al., 2018, Rao & Faddis, 2017). The most recent guidelines for receiving a CRT device include those “patients who remain in NYHA classes II and III, despite

optimal medical therapy with a wide QRS complex and reduced left ventricular ejection function (LVEF) of less than 30-35% (Normand et al., 2018).

There are several organizations that contribute evidence-based literature regarding the benefits of using CRT or upgrading a conventional pacemaker or implantable defibrillator to CRT. This can create confusion for providers on whether this treatment will be beneficial for patients with HF (Normand et al., 2018; Rao & Faddis, 2017). The SHFM is able to predict the mortality and survival rate if a prospective patient receives CRT therapy, providing guidance to the patient and provider regarding the risks and benefits of CRT.

The SHFM risk calculator predicts mortality based on current treatment and it can also show changes of the mortality and survival rates based on the addition or deletion of treatment options. The inclusion of medications and implantable devices helped the SHFM show superiority over other models previously used, such as the ADHERE or Toronto models (Levy, 2013). Utilizing the SHFM within an electronic health record in an ambulatory, outpatient setting can help direct treatment of patients with HF and promote adherence with prescribed treatments.

There is extensive evidence to demonstrate the usefulness of the SHFM in patients who have HF with dilated cardiomyopathy, mitral stenosis, implantable defibrillator devices, and those seeking heart transplantation (Bilchick et al., 2017; Dziewiecka et al., 2020; Heyl et al., 2020; Nguyen et al., 2018). The SHFM was shown to be one of the most validated models for patients seeking advanced therapies, such as heart transplantation, in relation to the mortality rate while on the transplant list (Nguyen et al., 2018). The ability of this model to have predictive power for survival of patients with mitral stenosis and dilated cardiomyopathy is attributed to the model's linearity and large number of parameters (Dziewiecka et al., 2020; Heyl et al., 2020).

There are several guidelines for treatment of patients with HF outlined by the ACC, the American Heart Association (AHA), and the Heart Failure Society of America (HFSA). These guidelines outline the appropriate pharmacotherapy for heart failure and its comorbidities, diagnostics, and important measures that should be assessed in the outpatient setting. Recommendations from the ACC regarding caring for patients with HF include documentation on "symptom and activity, left ventricular ejection fraction (LVEF) assessment, angiotensin converting enzyme inhibitors (ACEI)

and angiotensin-receptor blockers (ARB) therapy for patients with left ventricular systolic dysfunction (LVSD), beta blocker therapy, and patient self-care education” (American College of Cardiology Foundation, 2021).

The complexity of managing HF in the outpatient setting provides challenges for many providers and research continues to validate the use of the SHFM to predict mortality in an ever-widening range of patients who experience HF. Clemens et al., (2012) studied the use of the SHFM for patients diagnosed with HF and undergoing CRT. They found the model accurately predicted survival for this population, findings that further validated the predictive value of the SHFM.

Patients with adult congenital heart disease (ACHD) are often diagnosed with HF and have a high risk of significant disease and death from HF. Several studies have looked at patients with ACHD and the use of the SHFM to determine the usefulness of the SHFM as a prognostic tool, particularly to differentiate high risk versus low risk patients with ACHD (Stefanescu et al., 2014).

Clinical data collected during the Heart Failure: A Controlled Trial Investigating Outcomes of Exercise Training (HF-ACTION) trial compared patients’ SHFM scores, number of hospitalizations, number of inpatient days and medical costs. Their findings confirmed high scores on the SHFM more accurately predicted an elevated risk of death for patients with HF and that patients with heart failure and higher SHFM scores incurred more hospitalizations, inpatient days and higher medical costs than patients with lower SHFM. Further findings in HF-ACTION trial associated higher SHFM scores in older white men, with increased hospitalizations (Yanhong et al., 2014).

Most recently, Li et al., (2019) looked at the increased risk of mortality after hospitalizations and whether the SHFM model could accurately predict risk of mortality post-hospitalization for patients with HF. This group studied patients who were diagnosed with acute HF ($n=2242$) upon discharge to analyze all-cause mortality. The SHFM was able to accurately predict mortality in patients age 65 years or under but advancing age showed diminishing accuracy in the 18-months post-discharge. These findings are particularly helpful when discussing end of life issues with patients and families (Li et al., 2019).

Rationale and Framework

The Diffusion of Innovation Theory was created by E.M. Rogers in 1962 and popularized by Clayton Christensen in the late 1990s. The theory is used to explain how an idea, or innovation, gains momentum and diffuses in a group or population, resulting in adoption of a new idea or behavior. Adoption, in this sense, refers to a person acknowledging the value of the new idea or innovation, then doing something in a different way than it was done previously. This change is a diffusion of the new way of doing something (LaMorte, 2019).

The theory acknowledges several levels of personal characteristics that can predict how individuals adopt an innovative idea or purpose, with the first being the innovators who want to be the first to develop and adopt a new idea. Second is the early adopters, who are typically the opinion leaders who embrace change. Third is the early majority who are not usually leaders but will listen and weigh new ideas. Fourth are the late majority who are skeptical of change and have to see how the innovation or idea works and is accepted by the majority. Finally, there are the laggards who are bound by old ideas, are very conservative and very resistant to change (LaMorte, 2019).

This theory also suggests that people adopt innovation in stages by becoming aware of the new idea or innovation, deciding to adopt the innovation, and continued use of the innovation (Harting et al., 2019). Innovation and diffusion of current tools for managing the health of patients who have HF is acknowledging the need to use evidence-based practice for these patients. The SHFM is one such tool that has not been previously used in this cardiology practice. The introduction of use of the SHFM in this practice during the implementation of this project should stimulate peer discussion among providers in the practice and the results of implementation of the SHFM will provide awareness, applicability and usefulness of the tool in treating patients with HF.

Purpose

The purpose of this quality improvement project is implementation and sustained use of the Seattle Heart Failure Model prognostic calculator tool for healthcare providers in a suburban cardiology practice as a means of providing optimal treatment for patients diagnosed with heart failure.

Methods

This was a three-month QI project that implemented the SHFM in a local cardiology clinic. A mixed-methods design was utilized. Qualitative pre- and post-surveys were administered to measure the providers perception of using the model within their practice.

Participants

A convenience sample of eight providers were included in the project. Inclusion criteria for the survey participants included all providers caring for patients with the diagnosis of heart failure. The providers included degrees of medical doctor (MD), Doctor of Osteopathy (DO), physician's assistants (PA) and nurse practitioners (NP). Exclusion criteria for the survey participants included any locum tenens healthcare providers who are working with a limited contract and not regular employees of the cardiology clinic.

Measures

A chart review was conducted at the conclusion of the three-month implementation period to examine commonalities of the patients for which the SHFM was applied. A retrospective chart review could not be conducted as there were no data to compare.

Procedures

This QI project was approved by the Institutional Review Board (IRB) at Lenoir-Rhyne University, Hickory, North Carolina & by the IRB of Catawba Valley Health System (CVHS). The PI for this project met with the data manager from the Information Technology (IT) department of CVHS to discuss and explain all details to be included into the order set titled "Seattle Heart Failure." After the data manager had input the order set into the CVHS electronic health record platform (eClinicalworks), another meeting was held to approve the order set which allowed the providers to initiate the treatment algorithms included in the SHFM prognostic tool. Approval was obtained for the addition of a link to the SHFM to be included within this heart failure order set, allowing providers to open this model in another webpage and enter in the appropriate information. After entering in the required information, the provider can use this tool when caring for patients diagnosed with HF to direct further treatment needs based on the calculated mortality and survival rates.

A pre-recorded ZOOM presentation was completed and emailed to all recruited participants within the cardiology practice with specific education and instructions on how to utilize the order set and SHFM. A booklet which contained detailed explanation of how to utilize the order set appropriately was created and distributed to all recruited participants.

A pre-education survey (see Appendix A) was administered using Survey Monkey™ and sent via email to establish the participant's baseline knowledge of the SHFM. The providers were given a deadline of one week to respond to the survey. The SHFM is available online to healthcare providers after accepting a SHFM End User License Agreement which gives providers permission to use this tool. Each provider had to accept this agreement prior to being allowed access to the model. This agreement recurs each time the link is accessed. A post-implementation survey was provided at the end of the three-month timeframe, to establish updated knowledge base and compliance related to SHFM. The providers had an additional week after the completion of the project to respond.

Results

Analysis

Due to the limited participation in this project no statistical analyses could be performed to show if there was a correlation or impact the SHFM may have had on the treatment plan. Descriptive statistics were applied to data from the nine patients who were evaluated using the SHFM to measure commonalities on this patient population. An analysis of two patients that were used in the project is provided. An analysis of the pre-education and post-implementation surveys identified the participants' increased knowledge of the model and feedback on the SHFM order set embedded in the EHR.

Descriptive Statistics

Descriptive statistics were used to report patient age, gender, NYHA class, and ejection fraction where the SHFM was applied. The average age of the patients in the post-intervention group was 67.11 years and average EF was 23.67%. Six of the patients were male, while three patients were female. The most common NYHA class is III.

Case Study Analyses

In the nine patient's for which the SHFM was utilized during the duration of this project, there were two patients the provider was unsure whether a treatment change would impact the patient's overall prognosis related to HF. After using the model, there was evidence that initiating certain treatments did improve survival rates and decrease mortality rates for these two patients. The following two case studies demonstrate the use of the SHFM during this project.

Patient A

Patient A is an 82-year-old female with a diagnosis of HF with reduced EF (20%), with a history of ischemic heart disease and has EKG findings consistent with a wide QRS and left bundle branch block. The NYHA class for this patient was Grade IIIB. This patient was currently on the following guideline-directed therapy: ACE-I and beta blocker, and has no implantable devices. She has never been on an aldosterone blocker due to her baseline potassium of 4.9 (normal value 3.5-5.5). After utilizing the SHFM and adding an aldosterone blocker to this patient's medication regimen, her five-year survival rate increased from 45% to 58% and her five-year mortality rate decreased from 55% to 42%. In this same patient, the model was utilized to see if this patient could benefit from bi-ventricular pacing via an implantable cardioverter-defibrillator (ICD). By adding only a bi-ventricular ICD (Bi-V ICD) this patient's five-year survival rate increased from 45% to 60%, while her five-year mortality rate decreased from 55% to 40%. By adding the aldosterone blocker and a Bi-V ICD her five-year survival rate increased to 70%, while her mortality rate decreased to 30%. This tool allowed the provider to see the benefit of adding this medication and/or device and helped guide care decisions for the healthcare provider, the patient and the family.

Patient B

Patient B is a 78-year-old male with a diagnosis of ischemic heart failure with a reduced EF (30%). He is on the following guideline directed therapy: ACE-I, beta-blocker, and aldosterone blocker. He has an implanted pacemaker with EKG findings consistent with a wide QRS and left bundle branch block. His pacing report shows his right ventricle pacing 90% of the time. A high burden of pacing within the right ventricle can cause left ventricular dysfunction and lead to worsening heart function (Cho et al., 2019). The SHFM was utilized in the decision-making process for this patient to determine if a bi-ventricular (BiV) pacing or Bi-V ICD would be more beneficial.

With the Bi-V pacing alone the five-year survival rate increased from 44% to 55%, while the five-year mortality rate decreased from 56% to 45%. By upgrading the pacemaker to a Bi-V ICD, it showed a larger increase in five-year survival rate to 59% and a five-year mortality rate of 41%. This model was beneficial in guiding treatment recommendations for this patient and decisions regarding placement of an internal pacing device.

Content Analysis

Of the recruited participants surveyed using an anonymous questionnaire there was a 37.5% (three of eight providers) response obtained in the pre-education survey and 25 % (two of eight providers) response obtained in the post-implementation survey. The nature of questions asked using a Likert scale plus the limited response obtained made thematic analysis of this data unfeasible. Of the providers that participated in the pre-education survey, most were unaware of the SHFM and how it could be useful in directing treatment of heart failure patients.

Discussion

The SHFM embedded in the EHR within the heart failure order set was not successful in demonstrating a quality improvement change within the cardiology practice due to the small volume of data obtained during the project time-frame. The SHFM is still available for use within the entire CVHS, allowing more providers outside the cardiology setting to utilize the model. While the addition of this evidence-based tool is an innovative addition to the entire CVHS, further demonstration of the effectiveness of the model is needed for widespread adoption in this particular healthcare system. The limited participation in the project does not clearly show this model helped guide clinical decision-making in the care of heart failure patients for this practice.

Limitations

There were several limitations noted during this project. Only two of the eight of providers in this practice participated in the project, one of which had only included the inpatient setting population, which rendered this data unusable for this particular project. There was no way to track when the order set was used during inpatient rounds, making it difficult to report provider adherence. Education and presentation of the SHFM in an in-person venue was not possible due to the

restrictions surrounding the COVID-19 pandemic and was likely a contributing factor to the smaller number of participating providers.

The small number of patients seen and evaluated using the SHFM is not a true reflection of the usefulness of the SHFM in guiding the care and decision-making for patients diagnosed with HF in this practice.

The SHFM is a validated prognostic tool last updated in 2013. Since this time there have been updates to the guideline therapy for HF patients and new medications have been approved by the Food and Drug Administration (FDA) (Yancy et al., 2017). Further studies to update SHFM treatment recommendations aligned with guideline updates is needed.

Reflection

Conducting a QI project throughout the COVID-19 pandemic proved to have many challenges. The first two project ideas created could not be implemented due to the staffing strains and unavailable resources impacted by COVID-19. Implementing a project that is aimed to promote a system change within an organization is a difficult task and by completing this project it allowed opportunities for this prognostic model to be added to the system EHR based on evidence found in the literature but was unable to be proven effective for this cardiology practice due to constraints imposed by COVID-19.

In future QI initiatives, implementation of the “Seattle Heart Failure” order set can be included in all practices within the CVHS. One key observation noted during this project was that most of the patient population were on the medications recommended by the latest clinical practice guidelines for heart failure. The SHFM was used primarily to see if advanced therapies, such as implantable cardiac defibrillators or bi-ventricular pacing, would benefit the patient population. The use of the order set in primary care settings to ensure patients are on the appropriate medication may be more useful, especially in those patients who have not been referred to a specialty practice.

Another observation noted during implementation of this project was how infrequently a laboratory test for serum uric acid was ordered. In future projects education and implementation about the role uric acid contributes to heart disease where elevated uric acid levels are associated with

increased mortality in heart failure, can better educate providers on obtaining this value (Huang et al., 2019).

Conclusions

The increasing prevalence of heart failure cases in the U.S., as well as internationally, shows the importance of providers utilizing a prognostic tool to help guide clinical decision-making among this population (Benjamin et al., 2019; Savarese & Lund, 2017). Healthcare providers should consider how the accuracy of information within the model can provide an evidence-based reflection of the patient's plan of care and long-term prognosis, which can impact changes in the treatment plan and overall quality of care.

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Appendix A

Pre/Post Questionnaire for DNP Quality Improvement Project Implementation of the Seattle Heart Failure Model in a Specialty Cardiology Clinic: Aimed at Assessing Usability and Benefits of Prognostic Model in Heart Failure Patients

Thank you for participating in this survey questionnaire. All responses will remain anonymous. Your responses are a part of a quality improvement project aimed at if a prognostic tool for heart failure, in an outpatient setting will aid providers in deciding the best treatment for these patients. These questions are to evaluate initial responses on the topic prior to implementation.

Pre-education Survey of Providers

Please respond to the questions below:

Knowledge/Confidence

- 1. The Seattle Heart Failure Model is a validated tool for the care of patients with heart failure.**

1- Not Aware at All	2- Slightly Aware	3- Moderately Aware	4-Very Aware	5- Extremely Aware
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- 2. There is high quality evidence for use of the Seattle Heart Failure Model for the treatment of patients with heart failure.**

1- Not Aware at All	2- Slightly Aware	3- Moderately Aware	4-Very Aware	5. Extremely Aware
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- 3. The Seattle Heart Failure Model provides testing and treatment guidelines provide recommendations for management of patients with heart failure.**

1- Not Aware at All	2- Slightly Aware	3- Moderately Aware	4-Very Aware	5.Extremely Aware
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- 4. I routinely use the Seattle Heart Failure Model to guide the care and treatment of my patients with heart failure.**

1- Not at All	2- Rarely	3- Occasionally	4 – Often	5-Always
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Post-Implementation Survey of Providers

- 1. The Seattle Heart Failure Model is a practical tool to use in the outpatient setting to guide evidence-based treatment.**

1- Strongly Disagree	2 Disagree	3 Neutral	4- Agree	5 Strongly Agree
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- 2. There is high quality evidence for use of the Seattle Heart Failure Model for the treatment of patients with heart failure.**

1- Not Aware at All	2- Slightly Aware	3- Moderately Aware	4-Very Aware	4- Extremely Aware
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- 3. The Seattle Heart Failure Model provides testing and treatment guidelines provide recommendations for management of patients with heart failure.**

1- Not Aware at All	2- Slightly Aware	3- Moderately Aware	4-Very Aware	5.Extremely Aware
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- 4. The Seattle Heart Failure Model is easy to use in the outpatient setting.**

1- Strongly Disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly Agree
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- 5. I will routinely use the “Seattle Heart Failure” order set in my practice.**

1- Strongly Disagree	2- Disagree	3- Neutral	4- Agree	5- Strongly Agree
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Provide additional feedback: