Implementing Routine Referral for Outpatient Prehabilitation in Adults with End-Stage Heart Failure Under Evaluation for Heart Transplant or Ventricular Assist Device

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Abstract

Objective: In adult heart failure (HF) patients under evaluation for heart transplant or ventricular assist devices (VAD), preoperative participation in cardiac rehabilitation (prehabilitation), has the potential to improve functional capacity and reverse frailty (Gimeno-Santos et al., 2020).

Aim: The aim of this quality improvement project was to develop a process for routine referral to prehabilitation in adult HF patients who are under evaluation for heart transplant or VAD.

Methods: Adults ages 18 and older with HF under evaluation for heart transplant or VAD were eligible for participation in this project. A new process for referral to prehabilitation services was implemented to be performed by the Transplant Coordinators. Education regarding the benefit of prehabilitation was added to the pre-heart transplant class and Transplant Coordinators were educated on the new material. Referrals to prehabilitation was tracked to evaluate the intervention, and attendance rates at prehabilitation were tracked to assess patient adherence.

Results: Six adult HF patients were evaluated as possible transplant or VAD candidates, 83% were referred to prehabilitation, 100% received provider authorization, 17% received insurance authorization, 17% were denied insurance authorization, 33% were pending insurance authorization, and 0% attended prehabilitation.

Conclusion: Prehabilitation is a useful intervention aimed at addressing physical deconditioning and frailty in patients with HF awaiting a heart transplant or VAD (O'Connor et al., 2009). In the Heart Failure and Transplant program with no prior process for referring patients to prehabilitation, 83% of patients were referred indicating successful implementation of routine referral to prehabilitation.

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Introduction

Problem Description

Heart failure (HF) is a complex syndrome resulting from structural and functional cardiac abnormalities (Goldman, Schafer, & Cecil, 2020). The HF patient population presents with decreased skeletal muscle mass, capillary density, oxidative capacity, and strength manifesting as dyspnea, fatigue, and exercise intolerance (Laddu et al., 2021). These symptoms result in a reluctance to preform physical activity leading to functional decline and risk for frailty. Frailty is "a syndrome of reduced physiologic reserve resulting in a reduced capacity for an individual to tolerate minor or major stressors" (Macdonald, 2021, pp. 2352-2353). According to Denfeld and colleagues, nearly 45% of patients with HF are also frail (2017). In patients with end-state HF for whom conventional treatment has failed, surgical implantation of a ventricular assist device (VAD) or heart transplant are considered the definitive treatments (Gimeno-Santos et al., 2020). Frailty and HF create a vicious cycle of physical inactivity and functional decline placing heart transplant and VAD candidates at risk for poor surgical outcomes. Participation in preoperative cardiac rehabilitation, also called "prehabilitation" is a useful intervention to address frailty and physical deconditioning which has been proven to improve functional capacity and has the potential to reverse frailty (Gimeno-Santo et al., 2020; O'Connor et al., 2009).

After meeting with key stakeholders, including the Heart Failure Section Head, Program Manager, and the Transplant Coordinators, patient frailty and physical deconditioning were identified as two significant preoperative concerns needing to be addressed. A cause-and-effect diagram (Appendix A) outlined the interplay of different variables leading to patient physical

deconditioning and implementation of a process to refer patients to prehabilitation, which does not currently exist, was identified as a strategy to address physical deconditioning and frailty.

Available Knowledge

Prehabilitation is a preoperative intervention that has been proposed as an approach to prevent or reverse frailty. It is recognized as "the process of enhancing an individual's functional capacity before scheduled surgery and aimed at improving the patient's tolerance to upcoming physiologic stress" (Kow, 2019, p. 388). The aims of prehabilitation are multimodal and include preparing the patient for surgery, prevention of complications, and improvement in functioning after surgery (Sanches et al., 2021). While there is no clear consensus on how prehabilitation should be structured, many studies have applied the same exercise structure as cardiac rehabilitation (CR) which involves three 60-minute session a week for 12 weeks with a combination of aerobic training and resistance training (O'Connor et al., 2009; Rengo et al., 2018).

Randomized controlled trials evaluating the role of prehabilitation have demonstrated improvement in measurements of functional capacity and peak oxygen consumption (Acanfora et al., 2016; Gimeno-Santos et al., 2020; O'Connor 2009; Steinmetz et al., 2020). These findings support the 2022 Guidelines for the Management of Heart Failure recommendation "for patients with HF who are able to participate, exercise training (or regular physical activity) is recommended to improve functional status, exercise performance, and quality of life" (Heidenreich et al., 2022, p. e926). While prehabilitation has been shown to improve measures of functional capacity, other studied metrics, such as left ventricular function, all-cause mortality, and rate of hospitalization, have not been as conclusive (Acanfora et al., 2016; Long et al., 2019). A Cochrane review evaluating 44 trials comprised of 5783 participants primarily with HF with

reduced ejection fraction, found CR did not have any significant impact on all-cause mortality in the short team (<1 year), but it may improve all-cause mortality in the long term (>1 year), and CR probably decreases the rate of hospitalization in the short term (Long et al., 2019).

The effects of exercise are transient, and to ensure sustained effects, exercise must be consistent. Interruption of physical activity in adult transplant patients due to the COVID-19 pandemic resulted in rapid loss of improvements in functional capacity and frailty (Aili et al., 2021). Exercise programs should include strategies to increase adherence, such as supervision during the exercise sessions, individualized evaluation of patient barriers and facilitators, enjoyment of the activity, and patient education to optimize the impact of physical activity programs (Collado-Mateo et al., 2021). Educational sessions increase awareness of the health benefits of exercise and allow opportunities for collaboration on ways to turn perceived obstacles into drivers for participation, both of which may increase patient adherence (Gay, Chabaud, Guilley & Coudeyre, 2016; Collado-Mateo et al., 2021). Prehabilitation is a reliable intervention shown to improve functional capacity in patients with HF, and when combined with patient education, increases the likelihood of long-term adherence.

Rationale

This quality improvement initiative will apply the principles of the Advancing Research and Clinical Practice through close Collaboration (ARCC) Model as a framework to develop, test, and implement change. First designed as a mentorship framework to assist advanced practice nurses in implementing quality improvement, the ARCC model has developed to function as a guide to advance system-wide implementation and sustainability of QI projects (Melnyk, et al., 2010). The steps of the ARCC model include (1) assessment of organizational culture and readiness for QI projects; (2) identification of potential strengths and barriers to

implementation of QI; (3) development and utilization of change agents; and (4) implementation of QI (Melnyk, Fineout-Overholt, Giggleman, & Cruz, 2010).

To assess organizational culture and readiness for change, a meeting was arranged with the key stakeholders. One potential barrier to the implementation of change is the lack of change agents due to inexperience with QI projects, but this is balanced by a potential strength in administrative support and staff excitement to participate in change, which may further aid in the development of change agents to promote continuity of this project.

Specific Aims

The aim of this quality improvement project was routine referral to prehabilitation in adult HF patients who are under evaluation for heart transplant or VAD implantation. To achieve this aim, a process for routine referral to prehabilitation was developed for Transplant Coordinators, and an education module was created to increase awareness of the importance of physical activity.

Methods

Context

The Heart Failure and Transplant department functions within a 576-bed multi-organ certified transplant center located in a populous metropolitan area. The Heart Failure and Transplant team consists of five physicians, two advanced practice providers, two pharmacists, four Transplant Coordinators, four VAD coordinators, and one social worker. The team averages 75 patient referrals for evaluation, performs 12-15 heart transplants and 10-15 VAD surgeries annually, and there are approximately 10 patients waitlisted for transplant.

The transplant center serves patients living within approximately 98,466 square miles of the hospital, with an estimated 33% of the patients referred for heart transplant or VAD living in

a rural area necessitating a commute of 6 hours or more for services. The time required to access healthcare services poses a barrier to attending prehabilitation 3 times a week. Further complicating access, the American Association for Cardiovascular and Pulmonary Rehabilitation only recognizes 29 cardiac rehabilitation centers within the transplant center's service area, and all of them are located within 45 minutes of an interstate or major state highway. Additionally, the patient's degree of physical deconditioning may preclude them from participation in prehabilitation as it may be unsafe for the patient. In this scenario, exercise physiologists may deny a patient's enrollment into prehabilitation and instead refer the patient to physical therapy.

Intervention

The QI project occurred from November 16th, 2022 through February 28th, 2023. The full project timeline is available in Appendix C. The primary interventions of this quality improvement project were twofold: the development of a process to refer patients to prehabilitation and the creation of an education module aimed at patients to highlight the importance of exercise. A meeting was arranged with the Heart Failure and Transplant Program Manager and the Transplant Coordinators to introduce the new process for referral to prehabilitation, as well as educate the Transplant Coordinators on the importance of prehabilitation. It was important for the Transplant Coordinators to understand the benefits of prehabilitation as they were responsible for educating patients on prehabilitation. Also occurring at this time, two slides (Appendix B) addressing the physiological and psychologic benefits of exercise, safe participation in exercise, and reasonable goal setting were developed in conjunction with the Transplant Coordinators and Heart Failure and Transplant HF Program Manager, and added to the preexisting Pre-Heart Transplant Class slides. The Pre Heart-Transplant Class introduces new patients to the transplant and VAD evaluation process, explains

how waitlisting occurs, provides an overview of post-transplant medications, and highlights the responsibilities of the patients.

The initial education session to introduce patients to the transplant and VAD evaluation process was identified for inclusion in the education module discussing physical activity as the Pre Heart-Transplant Class slide must be presented to each new patient. At the conclusion of the education session with the patient, Transplant Coordinators entered the order to refer patients to prehabilitation. These orders were then sent to the patient's provider for authorization.

Study of the Intervention

A single-center retrospective chart review for quality improvement was performed on every patient evaluated for heart transplant or VAD during the project implementation period. Specific criteria reviewed included patient age, city and county of residence, primary language, cause of HF diagnosis, New York Heart Association functional class and American Heart Association HF stage (Appendix D & E), current level of activity, referral to prehabilitation, provider authorization of referral, and patient attendance at prehabilitation. In patients with HF due to valvular disease who have an EF < 50%, participation in physical activity is not recommended; therefore these patients were excluded from data analysis.

Measures

To evaluate successful process implementation and the consistency of Transplant Coordinators referrals, the percentage of patients who attended the educational session and were referred to prehabilitation was calculated. The percentage of patients who were referred prehabilitation and received insurance authorization was calculated to investigate for systems-based barriers to prehabilitation. Mean attendance at prehabilitation was calculated to assess patient adherence. At the conclusion of the project period, a focus group was scheduled with the

Transplant Coordinators to understand barriers and process issues with implementation of this QI project. Questions asked during the focus group are available in Appendix G.

Data Analysis

Statistical analysis was completed through the use of SPSS software. Patient characteristics were stratified (e.g. age, gender, heart failure diagnosis, etc). To interpret the data from the focus group, thematic analysis was performed. Data collected for this project was securely stored on an encrypted server.

Ethical Considerations

This quality improvement project was reviewed by the Institutional Review Board at Oregon Health and Science University and was deemed not to be research. All staff working within the Heart Failure and Transplant department were informed of this project by email and in-person meetings, and participation was entirely voluntary. Non-participation or non-attendance at prehabilitation did not impact the patient's evaluation for heart transplant or VAD.

Results

Over the course of this initiative, six patients were referred for evaluation for heart transplant or VAD with the Heart Failure and Transplant department. Patient demographics are available in Apendix F. Retrospective review of patient charts revealed 83% patients were referred to prehabilitation. All 5 patients referred to prehabilitation received provider authorization. At the time of chart review, one patient had received insurance authorization, 2 patients were pending authorization, 1 patient had been denied due to recent participation in cardiac rehabilitation, and 1 patient died during their evaluation, and we were unable to ascertain the outcome of their insurance determination. The 1 patient who received insurance authorization was admitted to the hospital requiring mechanical circulatory support prior to scheduling their

intake appointment. None of the patients attended prehabilitation. None of the patients attended prehabilitation, therefore attendance was not tracked, and the utility of the prehabilitation-focused patient education was not evaluated.

All patients under evaluation for transplant or VAD with the Heart Failure and Transplant program undergo cardiopulmonary exercise testing (CPET) which measures peak oxygen consumption (peak VO2). Four patients had CPET results available at the time of chart review. The average peak VO2 was 15.875 ml/kg/min (SD ± 5.36 ml/kg/min) reflecting moderate cardiovascular impairment, and the patient who was not referred to prehabilitation had a VO2 of 12.9 ml/kg/min, reflecting cardiovascular impairment to exercise and an elevated risk for adverse events. Peak VO2 is considered the best measurement of cardiovascular fitness and has been used to assess HF prognosis as well as select patients for heart transplant (Adachi, 2017; Paolillo et al., 2019). While peak VO2 of 14 ml/kg/min or 12ml/kg/min in patients taking beta blockers has been used to guide selection of patients for advanced HF therapies, as the management of patients with HF evolves, new research suggest peak VO2 must be considered in combination with patient demographics, HF etiology, patient commitment to follow up, and functional status (Paolillo et al., 2019).

The two pre-Transplant Coordinators attended the focus group meeting. During the project, one of two post-transplant coordinators was on a leave of absence. Due to staffing reassignments one pre-transplant coordinator was responsible for patient intake, education, referral, and care coordination of all pre-transplant and VAD patients. A reoccurring theme of the focus group was the belief that HF patients are “delicate” and “too sick” for prehabilitation. The pre-transplant coordinator shared “In the provider’s mind, and also in the patient’s mind, they reach a point where they are too sick, and they are doing daily symptom management and

they are not engaged in doing much more than that." This notion is supported by the cause-and-effect diagram detailed in Appendix A.

Discussion

Summary

Within the Heart Failure and Transplant program, the routine referral to prehabilitation was successfully implemented with 83% of patients referred during the project timeline when compared with 0% of patient referrals prior to the QI intervention. While a particular strength of this project was the open communication between Transplant Coordinators and the Heart Failure and Transplant providers, the open communication may have caused dynamic changes to the process of referral to prehabilitation.

Interpretation

After implementation of the process for referring patients to prehabilitation, the percentage of patients referred to prehabilitation was 83% which reflects a better than average referral rate. While there are a lack of studies measuring referral rate to prehabilitation, studies evaluating referral and attendance rates at cardiac rehabilitation, which has a preestabilished value, show less than 20% of patients eligible for cardiac rehabilitation are referred, and of those referred only 34% enroll (Chindhy et al., 2020). Based on this, the rate of referral to prehabilitation is likely much smaller due to prehabilitation's burgeoning utility. The beneficial effects of cardiac rehabilitation in patients with HF such as decreasing the resting heart rate, increasing chronotropic reserve, even in patients taking a beta-blocker, and reduction of sympathetic activity, have led to the AHA/ACC giving cardiac rehabilitation a class IA recommendation in the setting of chronic HF with reduced ejection fraction <35% (Chun & Kang, 2020; Heidenreich et al., 2022). By recognizing the value of cardiac rehabilitation,

standardizing referral to prehabilitation will preoperatively address the surgical risk for poor outcomes which is common in patients with frailty and physical deconditioning.

Unfortunately, there was a lack of standardization in the referral process. Standardizing referrals to prehabilitation prevents referral biases due to sex, race, comorbid conditions, and perception of patient's illness (Chindhy et al., 2020). The intention for this project was for the referral to prehabilitation to be ordered with the other transplant evaluations and screenings (e.g., pulmonary testing, dental evaluation, social work evaluation, nutritional evaluation, etc.). However, the Transplant Coordinators first discussed patient candidacy for prehabilitation with the Heart Failure and Transplant providers, then based on the provider's determination of patient candidacy for prehabilitation the Transplant Coordinators would enter the referral. Interestingly, the patient who was not referred to prehabilitation due to biases regarding the patient's physical fitness, may have had the greatest benefit from referral. During the intake appointment for prehabilitation, trained exercise physiologists perform an extensive assessment to determine whether a patient will be able to participate in exercise safely and effectively. If the results of the assessment indicate the patient may be at risk for an adverse event, it is within the exercise physiologist's capacity to recommend the patient instead work with physical therapy.

Limitations

Provider skepticism and the belief that HF patients are "delicate" or "too sick" for exercise served as a barrier to referral to prehabilitation. Most studies have found no evidence to support that exercise causes and increased risk of harm in patients with chronic stable HF; additionally, the risk for acute event can be greatly reduced if exercise occurs in conjunction with electrocardiogram monitoring (Chun & Kang, 2020). As the utility of prehabilitation expands,

future QI projects should focus on educating providers with research and additional evidence emphasizing the benefits and risks of prehabilitation.

Insurance authorization of prehabilitation may be a limiting factor for some patients. At the conclusion of the project, one patient had received insurance authorization, one had been denied, and two were still pending authorizations. The Centers for Medicare and Medicaid cover two, one-hour center-based rehabilitation sessions per day, up to thirty-six sessions, annually, and with the case of the patient denied authorization, the patient had attended rehabilitation within the previous six months (Chindhy et al., 2020). Alternative options for prehabilitation should be investigated to provide patients options. Home-based cardiac rehabilitation has been shown to potentially expand patient access and participation (Chindhy et al., 2020). A randomized controlled trial showed that smartphone based cardiac rehabilitation had higher uptake (80% vs 62), adherence (94% vs 68%) and completion (80% vs 47%) (Chindhy et al., 2020). Additionally, a Cochrane review comparing home-based cardiac rehabilitation to center-based cardiac rehabilitation noted no significant difference in mortality, cardiac events, or exercise capacity (Chindhy et al., 2020). Owing to the lengthy process from insurance authorization to enrollment in prehabilitation, none of the patients attended prehabilitation.

Conclusion

Prehabilitation is a useful intervention aimed at addressing physical deconditioning and frailty in patients with HF awaiting a heart transplant or VAD. While this project was achievable within the current organizational framework, future efforts to standardize the referral process will ensure long-lasting sustainability. Further QI projects should also focus on addressing provider skepticism of prehabilitation through education, whether it be didactics or exposure to cardiac rehabilitation centers.

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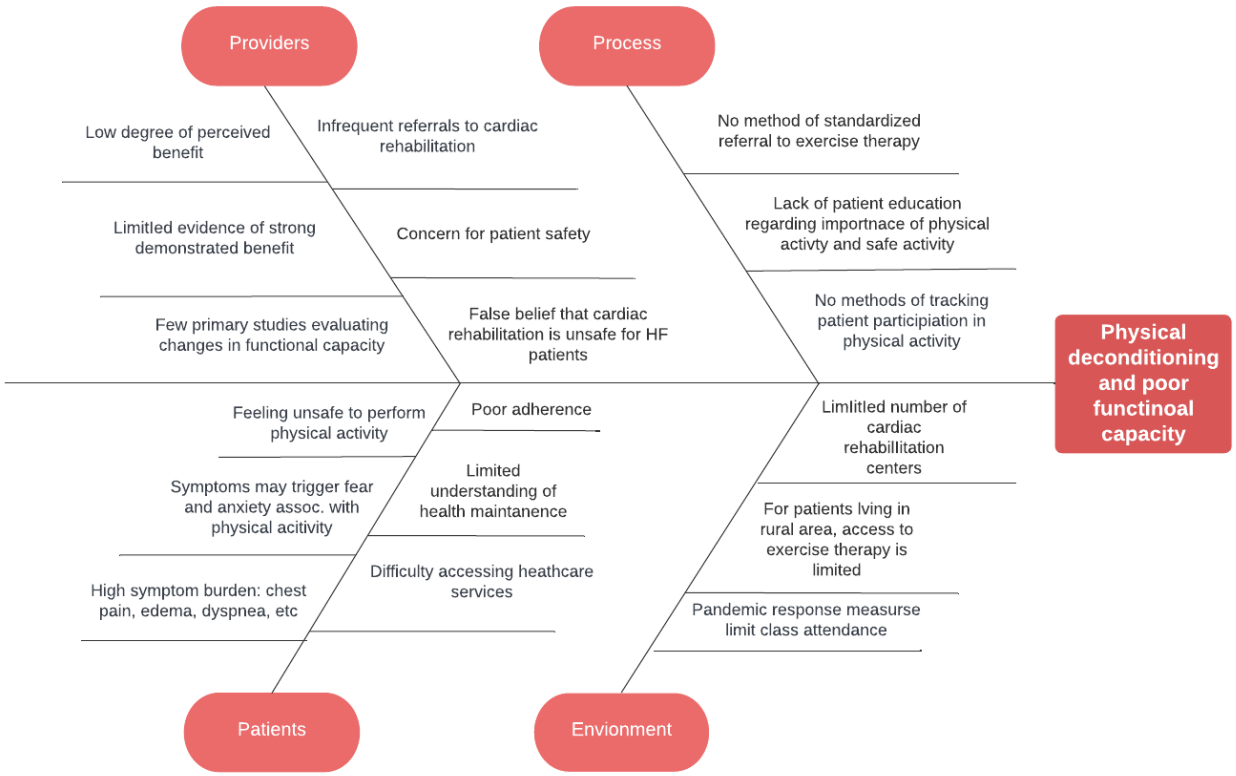
Appendix A: Cause and Effect Diagram



(Chindhy et al., 2020; Chun & Kang, 2020; Sanches et al., 2021)

Appendix B: Education Materials

Cardiac Rehabilitation

- Physical Benefits
  - Regulates dilation and constriction of blood vessels
  - Strengthens respiratory muscles
  - Improves transport of oxygen and nutrients to large muscle groups
- Psychosocial Benefits
  - Social interaction with other heart patients
  - Builds confidence
  - Reduces social isolation

1

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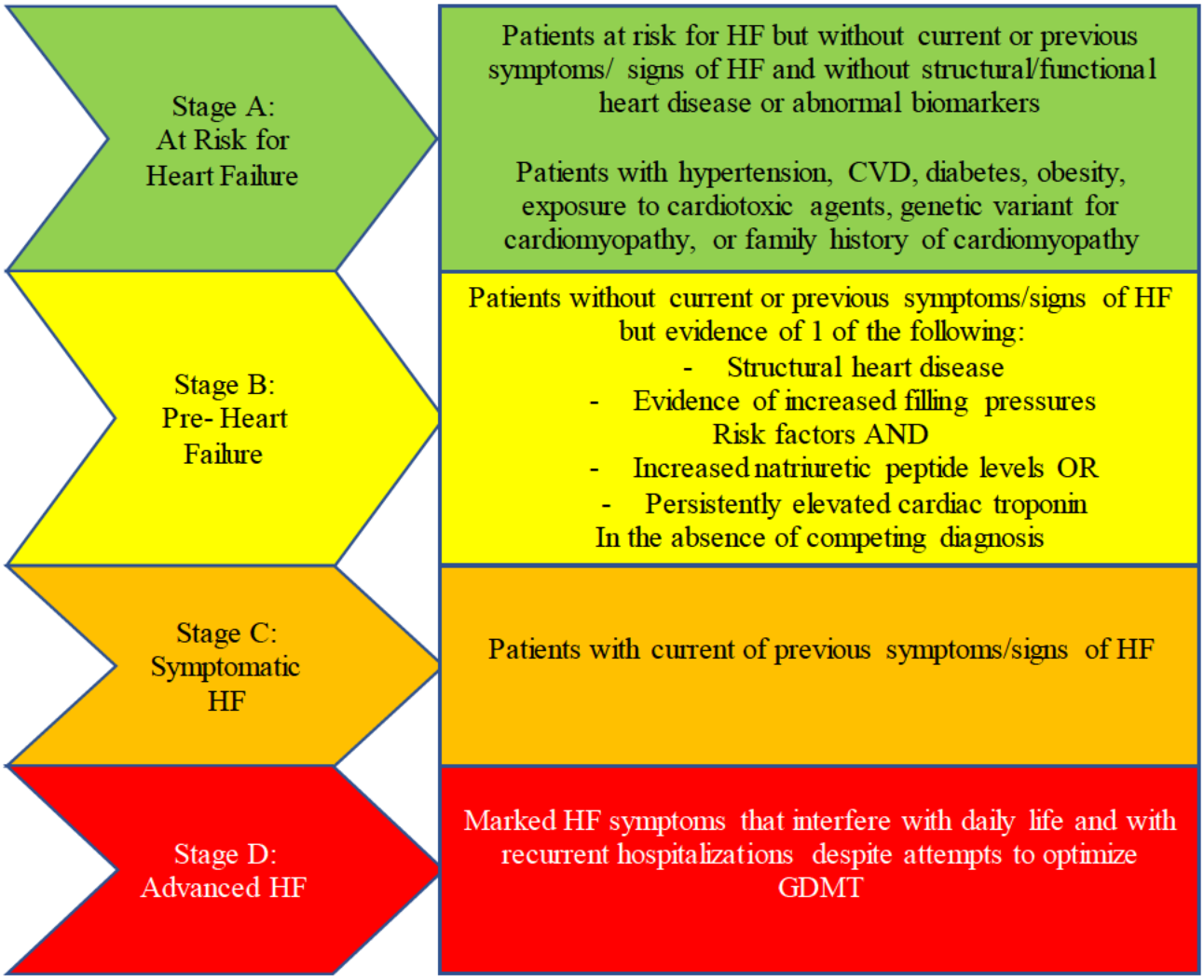
Cardiac Rehabilitation

- Safety
  - Heart rate and rhythm are mor for the entire class.
  - Level of effort is individualized patient-driven.
- Goal- Setting
  - Reasonable pre-transplant goa
    - Stand and fold laundry
    - Walk the aisles of the gro store
    - Cook dinner
  - It is not expected to be able to preform rigorous activity

Appendix C: Project Timeline

	Sept 2022	Oct 2022	Nov 2022	Dec 2022	Jan 2023	Feb 2023	Mar 2023	April 2023
Finalize project design and approach	X							
Complete IRB determination or approval		X						
Project Implementation			X	X	X	X		
Final data analysis				X	X	X	X	
Write sections 13-17 of final paper							X	
Prepare for project dissemination (703B)								X

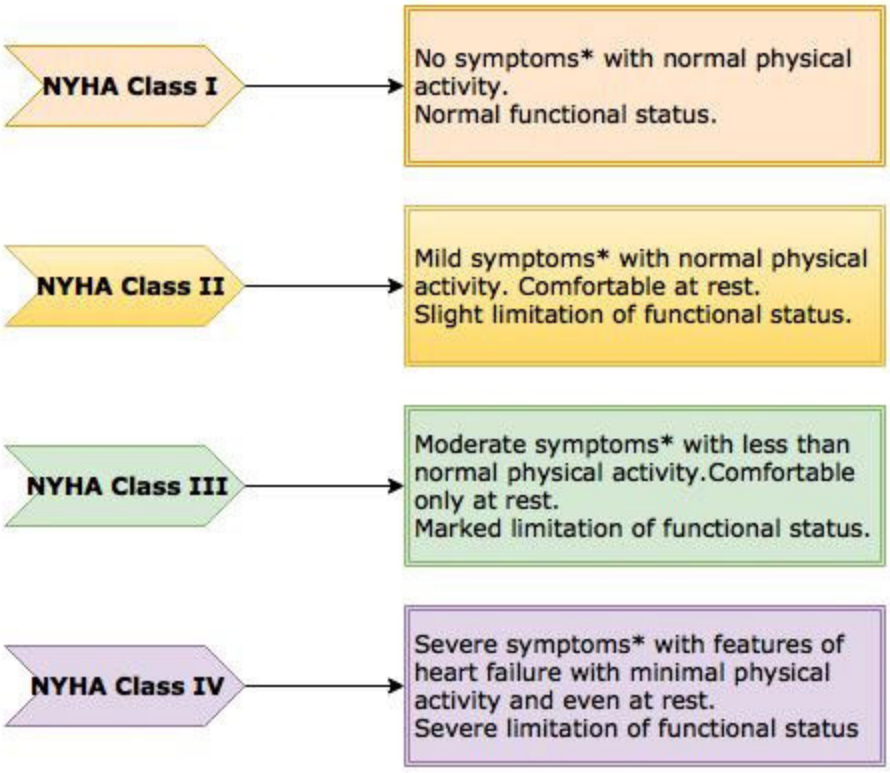
Appendix D: American Heart Association Stages of Heart Failure



(Heidenreich et al., 2022)

Appendix E:

New York Heart Association (NYHA) Classification of severity of Heart Failure



Symptoms - Fatigue, palpitations, chest pain, dyspnea, syncope

(Pahal & Sharma, 2022)

Appendix F: Patient Demographics

	N	%
New Transplant or VAD Referrals	6	
Mean Age [Range]	59	[41-68]
Sex		
Women	4	67%
Men	2	33%
Heart Failure Diagnosis		
Non-Ischemic Cardiomyopathy	2	33%
Ischemic Cardiomyopathy	2	33%
Arrhythmogenic Right Ventricular Cardiomyopathy / Dysplasia	2	33%
New York Heart Association Functional Class		
II – III	1	17%
III	4	67%
Not Available	1	17%
American Heart Association Heart Failure Stage		
C	1	17%
C – D	2	34%
D	1	17%
Not Available	2	34%
Referred to Prehabilitation	5	83%
Provider Approval for Prehabilitation	5	100%
Insurance Authorization		
Authorized	1	17%
Pending	2	33%
Denied	1	17%
Attendance at Prehabilitation	0	0%

Appendix G: Focus Group Questions and Feedback

Questions:

1. **What worked well in this project?**
   a. No change in workload

2. **What areas of this project need improvement?**
   a. I can put the referral in, but the provider still has to approve it

3. **Were there any barriers to referring patients to prehabilitation?**
   a. "Some of the providers didn't think it (prehabilitation) was appropriate for their patients"
      i. Providers believed their patients were too sick and it would not have been appropriate.
      ii. The providers could benefit from some "fine tuning" in that area.
      iii. Its (prehabilitation) not new, but it is new for them (as a process for them department)
   1. Maybe standardizing it could help a little
   b. Some of the patients would not have been participatory
   c. Belief that heart failure patients are a delicate population
   d. In the providers mind and also in the patients mind they reach a point where they are "too sick" and they are doing daily symptom management and they are not engaged in doing much more than that

4. **Did the patients understand the value of prehabilitation?**
   a. I don't know. They've been told their whole life that they need to exercise and improve their diet and unfortunately the power point is overwhelming in and of itself so it maybe didn't get as much attention as a specific slide as it could of.

5. **How do you assess patient understanding?**
   a. No one asked questions about it. I think it's one of those things where we discussed it and I spoke with them about referring them.

6. **Is this project sustainable?**
   a. I think so. I would like to see a little more come of it.

Appendix H: IRB Determination

IRB MEMO

Research Integrity Office
3181 SW Sam Jackson Park Road - L106RI
Portland, OR 97239-3098
(503)494-7887 irb@ohsu.edu

NOT HUMAN RESEARCH

October 11, 2022

Dear Investigator:

On 10/11/2022, the IRB reviewed the following submission:

Title of Study:	Exercise Therapy in Heart Transplant and Ventricular Assistive Device Candidates: A Quality Improvement Initiative
Investigator:	Benjamin Schultze
IRB ID:	STUDY00024910
Funding:	None

The IRB determined that the proposed activity is not research involving human subjects. IRB review and approval is not required.

Certain changes to the research plan may affect this determination. Contact the IRB Office if your project changes and you have questions regarding the need for IRB oversight.

If this project involves the collection, use, or disclosure of Protected Health Information (PHI), you must comply with all applicable requirements under HIPAA. See the HIPAA and Research website and the Information Privacy and Security website for more information.

Sincerely,

The OHSU IRB Office

Appendix I: Letter of Support

Letter of Support from Clinical Agency

Date: *10/13/2022*

Dear Jennifer Ericson,

This letter confirms that I, Heather Miller-Webb allow Jennifer Ericson (OHSU Doctor of Nursing Practice Student) access to complete his/her DNP Final Project at our clinical site. The project will take place from approximately 10/14/2022 to 04/01/2023

This letter summarizes the core elements of the project proposal, already reviewed by the DNP Project Preceptor and clinical liaison (if applicable):

- **Project Site(s)**: OHSU Heart Failure and Transplant - Center for Health & Healing Building 1 3303 S. Bond Ave. Portland, OR 97239
- **Project Plan:**
  - The Heart Failure and Transplant program at OHSU do not currently have a process in place for the routine referral of heart transplant and ventricular assistive device candidates to preoperative cardiac rehabilitation. Preoperative functional capacity is one of the strongest indicators of postoperative recovery.
  - This project aims to improve the understanding of the importance of physical activity in patients and Heart Failure and Transplant staff and patients as measured by pre- and postsurvey. The second aim of this project is to evaluate the effectiveness of the education module on patient's functional capacity as measured by cardiac rehabilitation attendance, 6 Minute Walk Test (6MWT) and Quality of Life questionnaire. While access to patient EHR will be needed to obtain attendance records, 6MWT, and QoL scores, this data will be deidentified and stored on a password protected and encrypted device.
  - This intervention is expected to lead to improvement through the utilization of the Advancing Research and Clinical Practice through close Collaboration (ARCC) Model which encourages the development of EBP mentors to foster curiosity and long-term sustainability. The clinical site agrees to support the quality improvement project by providing access to employees for education sessions, space to conduct activities, distribute questionnaires to persons who may quality for inclusion, and retrieve patient data from EHR.

During the project implementation and evaluation, Jennifer Ericson will provide regular updates and communicate any necessary changes to the DNP Project Preceptor.

Our organization looks forward to working with this student to complete their DNP project. If we have any concerns related to this project, we will contact Jennifer Ericson and Dr Rose Milano (student's DNP Project Chairperson).

Regards,