Doctor of Nursing Practice   School of Nursing

4-14-2020

Implementation of Peer Support and Shared Decision-Making Aids for the Transcatheter Aortic Valve Replacement Population

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Implementation of Peer Support and Shared Decision-Making Aids for the Transcatheter Aortic

Valve Replacement Population

A Scholarly Project Presented to the Faculty of the School of Nursing

Boise State University

In partial fulfillment of the requirements

For the Degree of Doctor of Nursing Practice

By

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Date: April 14, 2020

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Abstract

Background: Patients at a community hospital verbalized fear, stress and anxiety about transcatheter aortic valve replacement (TAVR). Patients with aortic stenosis eligible for TAVR may experience low self-efficacy and anxiety while considering valve replacement which may lead to poor quality of life, interfere with understanding information from medical providers, and other health complications.

Methods: All patients eligible for TAVR between June and August of 2019 were invited to participate in a pilot project using peer support and use of shared decision-making (SDM) aids. Former TAVR patients were trained to be Mended Hearts TAVR peer volunteers. Participants were connected by telephone with a peer by the valve coordinator and SDM aids from the American College of Cardiology were initiated and reviewed during appointments. Patients' anxiety and self-efficacy were measured before and after peer support using the General Anxiety Disorder-7 and the Cardiac Self-Efficacy scales. Patients evaluated the helpfulness of the SDM aids using the Preparation for Decision-Making scale and open-ended questions were used to gather additional information beyond questionnaire scale questions.

Results: Eleven TAVR patients evaluated anxiety and CSE and twelve patients evaluated the SDM aids. Post-GAD-7 scores showed four patients had a decrease in anxiety, five had no change, and two had an increased anxiety score. Post CSE scores showed increases in confidence for 58% of patients in one or more areas of self-efficacy and all patients rated the SDM aids as 'somewhat to a great deal helpful'. All patients responded positively during interviews, stating that even if they felt confident before the interventions, they felt even greater confidence afterwards.

Conclusion: The interventions empowered patients to discuss their health and procedural concerns and personal values with their medical team. Patients feel more confident with their decisions regarding TAVR after receiving peer support and the shared decision-making aids.

Key Words: Peer Support, Shared Decision-Making, Transcatheter Aortic Valve Replacement (TAVR), Aortic Stenosis

Goals and Vision of the Program

Patients with aortic stenosis, eligible for transcatheter aortic valve replacement (TAVR), may experience low cardiac self-efficacy and anxiety while waiting for treatment decisions. A referral for TAVR and completing the workup process does not equate approval for TAVR. Determining eligibility is a multidisciplinary team approach with a complex shared decision-making process engaging patient values, consideration of health history, quality and length of life outcomes before final recommendations are made. During the shared decision-making (SDM) process, patients must cope with the knowledge of a poor life expectancy without valve replacement, knowledge of potential procedural risks, and the possibility of being declined TAVR.[1] The uncertainty during the workup process may lead to low self-efficacy and anxiety, which in turn may result in insomnia, a decrease in quality of life, an increased need for anesthesia, increase in pain medications and interference with understanding and following instructions from medical providers.[2]

Patients at a community hospital verbalized their fear, stress and anxiety about needing and making decisions about valve replacement during TAVR work up appointments. A pilot project was designed and implemented to evaluate peer support and use of SDM aids with the TAVR population to address these issues (Appendix A). The aims of the project were to:

- Decrease anxiety and increase self-efficacy in patients pursuing TAVR through peer support.

- Integrate shared decision-making aids into the TAVR shared decision-making process and evaluate the patient perception of the usefulness of the SDM aids.

Local Challenges in Implementation

While limited evidence regarding the use of supportive interventions is available with the TAVR population, evidence does exist for supportive interventions in the open-heart surgery population (Appendix B). Open-heart patients have benefited from peer support[3] and it was speculated that similar support might be helpful with the TAVR population. The local Mended Hearts chapter, a national cardiac peer support group, provides face-to-face support at the project site for open-heart patients; however similar support was not previously available for TAVR patients. Peers for patients pursuing TAVR needed to be identified, recruited, trained, and a pathway for support identified.

The use of SDM aids in the general population has been found to decrease patient anxiety, lead to faster recoveries, increase compliance with treatment recommendations, provide information on the health condition, treatment options, and provide patients a platform for sharing personal values.[4,5] The Center for Medicare and Medicaid (CMS) requires SDM in the aortic stenosis population pursing TAVR[6], yet there is little information in the literature (Appendix B) from TAVR patients regarding the usefulness of SDM aids in assisting with the decision-making process. SDM aids needed to be identified and integrated into the current TAVR process.

Design of the Initiative

All patients eligible for TAVR between June and August of 2019 were invited to participate in the pilot project. A logic model provided the framework for organizing the planning, implementation, and evaluation of the project[7] (Appendix C). To evaluate the effectiveness of the interventions, patients rated their anxiety level using the General Anxiety Disorder-7 (GAD)[8] scale (Appendix D) and their perceived cardiac self-efficacy using the Cardiac Self-Efficacy (CSE)[9]

scale (Appendix E) before and after peer support. The Preparation for Decision Making Scale (Appendix F) was used to evaluate the helpfulness of the SDM aids and was completed by patients after use of the aids.[10] Open-ended interview questions were used to collect information beyond the select answers available on questionnaire scales (Appendix G). Interview questions allowed patients to express, in their own words, their experience with the interventions. To mitigate potential conflicts of interest, and to ensure the project protected participants, the project was submitted to the medical center's Institutional Review Board and designated as exempt (Appendix H).

Peer Support

The valve coordinator recruited past TAVR patients to be peers. Peers were required to participate in training by the local Mended Hearts chapter and to become members. Training included information on listening skills, patient privacy, how to share one's personal experience, and instructions not to provide medical advice. Once it was determined that a new patient was a TAVR candidate, the coordinator connected the patient with a peer. Support was provided by telephone before the procedure, rather than face-to-face as to not burden new TAVR patients with additional appointments during the workup process. TAVR peers were asked to record the number of attempts to reach a patient and the number of minutes providing support so that insight could be gained regarding the time required to provide support.

Shared Decision-Making Aids

Patients with aortic stenosis have three treatment options to consider: surgery, TAVR, or medical therapy. The shared decision-making aids *Treatment Options for Severe Aortic Stenosis for Patients Deciding Between TAVR and Surgery* (Appendix I) and *Treatment Options for Severe Aortic Stenosis, TAVR vs. Symptom Management* (Appendix J) were used. The aids are

produced and endorsed by the American College of Cardiology and present information with side by side comparisons of the risks and benefits of each therapy option.[11] For the pilot project, both aids were presented to all patients and reviewed with patients during their consultation appointment.

Implementation of the Initiative

Peer Support

The coordinator randomly selected six past TAVR patients, whose procedure was completed within the last one to two years, and invited them to participate as peers in the project (Appendix K). Four patients agreed to attend in-person training from Mended Hearts. One patient was not able to participate due to health complications, one attended the training but declined to participate and the remaining two patients completed training and became Mended Hearts TAVR volunteers. The Mended Hearts training session provided at the medical center took approximately 60 minutes. TAVR volunteer peers were provided with a list of topics to discuss with new patients, such as managing aortic stenosis symptoms while awaiting TAVR, personal experience with the workup process, including hospital stay, procedure details, and the recovery process.

Twelve patients were considered for TAVR during the project timeframe and all agreed to participate. There were an equal number of men and women participants. The majority were married (75%) and their ages ranged from 63 to 89 years old. Participants were provided with information regarding the project, signed a consent, and were offered both interventions (Appendix L). The coordinator obtained verbal permission to connect the patient with a peer and then provided the TAVR peer with the new patient's phone number to initiate contact and support.

Shared Decision-Making Aids

The SDM aids were introduced at the first contact with the new patient before consultation with the interventional cardiologist or cardiac surgeon. The coordinator conducted a frailty assessment at these appointments for all patients and it felt natural to introduce the aids at this time. Patients were provided with a brief education about aortic stenosis treatment options with the information provided in the SDM aids prior to consulting with the physicians. The coordinator answered questions about the treatment options and/or indicated that the questions would be further discussed during the consult with the physicians. As the aids were used to enhance the education already being provided during the frailty assessment, it added minimal additional time to the assessment.

Success of the Initiative

Peer Support

TAVR peers were able to connect with new patients on the first attempt 45% of the time, 36% on the second attempt, 18% on the third attempt. One person was unable to be reached. Peers provided support by phone for an average of 14 minutes per participant. TAVR peers shared that patients asked questions about pain, the hospital stay, what the procedure was like, and the recovery process. One peer felt skeptical at first about whether or not new patients would want to talk to him, but felt the pre-introduction given by the coordinator helped open the door for conversation. The TAVR peers expressed a personal sense of gratification in being able to give back to their community and help others feel more confident about a procedure.

After receiving peer support, new patients provided feedback. Post-GAD-7 scores showed that four patients had a decrease in anxiety, five had no change, and two had an increased score (Figure A). Of the two patients with an increase in anxiety, outside factors may

have influenced the score as one received news of a health complication that delayed the TAVR

procedure and the other had recent news of a personal family complication. Post CSE scores

showed small increases in confidence for 58% of the patients in one or more areas of self-

efficacy (Figure A).

While questionnaires showed minimal or no decrease in anxiety and a minimal increase

in self-efficacy, interviews provided further insight into the impact of the interventions. All

patients responded positively when asked, "Tell me about your experience with peer support."

Patients relayed they felt more confident about moving forward with a procedure, felt less

anxious about the procedure, and felt they had increased knowledge regarding the procedure and

recovery process (Figure B). All patients recommended that future patients have the opportunity

to speak with a peer who has been through the TAVR process.

Another positive outcome of this project is that the TAVR peer volunteers have both

independently decided to pursue advanced Mended Hearts training. This training will allow them

to offer support in the hospital setting. The TAVR volunteers are becoming active members of

the local Mended Hearts chapter and will assist in recruiting and training future TAVR peers.

Shared Decision-Making Aids

Patients were asked to reflect on their visits with the surgeon and cardiac interventionalist

and evaluate the SDM aids. Patients in the pilot project found the aids were 'somewhat' to 'a

great deal helpful' in assisting them to be more prepared for appointments, promoting

discussions with their doctor, and increasing their confidence in the decision-making process

(Figure C). Interview responses also indicated that the aids helped patients discuss their options

with their doctor. For example, one patient stated, "I would have been lost without the shared

decision aid," and it helped me "open up more" about concerns regarding treatment options

(Figure B). As low surgical risk eligibility for TAVR was approved by CMS shortly after implementation of the project, it has led to an easy transition of sharing the SDM aid with all aortic stenosis patients at the pilot site.

Translation to Other Settings

Peer support and the use of SDM aids are cost-effective and resource-friendly interventions that could be implemented at other valve centers (Appendix M, N, O). While the pilot project relied on the coordinator to connect peers and educate patients on the SDM aids, the time commitment was minimal. In addition to the coordinator, other ancillary staff could assist in connecting peers and SDM aids could be integrated into the care process by other members of the healthcare team such as the cardiac surgeon, interventional cardiologist, or general cardiologist. While not all valve centers may have an existing Mended Hearts chapters, peer support can be accessed through support outreach programs provided by one of the valve companies. Patients could be provided with the contact information for these resources at their appointments. The SDM aids for aortic stenosis are easily accessible for use and printing from the American College of Cardiology CardioSmart website (https://www.cardiosmart.org/SDM/Decision-Aids).

Summary of the Experience, Future Direction and Challenges

Coping with aortic stenosis and needing valve replacement is an uncertain and vulnerable time for patients. Peer support and use of the SDM aids empowered patients to be active participants in the decision-making process. As all aortic stenosis patients now have the option to be TAVR candidates, and more transcatheter based procedures, with similar stressors, will be available for other heart valves in the future, SDM and peer support becomes even more important as more treatment options are available. All patients needing transcatheter based care

will need similar support as the TAVR population. While further studies should be done to

define the benefits of peer support in the TAVR population and validate the SDM aids, the

benefits were sufficient to continue the interventions at our facility. Future direction for our

program will include continued peer support into the post procedure recovery period and

building peer support and use of SDM aids into pathways for all patients who are candidates for

any new transcatheter based therapies as they become available.

ARTICLE INFORMATION

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Supplemental Materials

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Figure A, B, C

A	General Anxiety Disorder Scale (GADS) – Pre and Post Measures (n=11) Cardiac Self-Efficacy Scale (CSES) Pre and Post Ratings (n=11)				
Gender	GAD-7 Pre/Post	Decrease/Increase/No Change GAD-7	CSES Pre/Post	Decrease/Increase/No Change CSE	
Female	9/6	Decrease	28/27	Decrease	
Male	6/2	Decrease	35/26	Decrease	
Male	3/2	Decrease	51/42	Decrease	
Female	3/2	Decrease	48/51	Increase	
Female	19/21	Increase	40/47	Increase	
Male	3/5	Increase	56/58	Increase	
Male	3/3	No Change	46/51	Increase	
Male	1/1	No change	47/53	Increase	
Female	0/0	No change	59/59	No change	
Male	0/0	No Change	8/26	Increase	
Female	0/0	No Change	55/59	Increase	
Male	1/		27/		

B	Commonalities of Patient Responses to Interview Questions

Tell me about your experience with TAVR peer support (n=11)
- Felt more confident about moving forward with procedure: "Good to have a past patient to talk to, even if you are not concerned about it yourself" & "Reassuring to talk to someone who had recently been through it, you don't have to be anxious and it helps keep your blood pressure down"
- Connected with peer over having multiple health problem: "If she can do it, I can do it"
- Felt less anxious about the procedure: "It's ok to be nervous about things"
- Increased knowledge regarding procedure and recovery process: "They've done it and you haven't"

How did the use of a decision aid enable you to engage with your physician during the TAVR work up the process? (n=12)
- Felt more informed that a decision needed to be made and clarified options: "I was able to open up more about concerns about options when talking with the doctor" & "It helped quite a bit"
- Better understanding of what the physician was explaining regarding treatment options: "I would have been lost without the SDM aid" & "Gained more organization with the question to ask physician"

C	The Preparation for Decision Making Scale (% ratings) n=12 patients					
Did this Educational Material:		5	4	3	2	1
1.	Help you think about how involved you want to be in this decision	33.3%	58.3%	16.7%	---	---
2.	Help you recognize that decision needs to be made	25.0%	58.3%	16.7%	---	---
3.	Help you think about which pros and cons are most important	33.3%	41.7%	16.7%	---	---
4.	Help you know that the decision depends on what matters most to you	25.0%	58.3%	16.7%	---	---
5.	Prepare you for a follow up visit with your doctor	25.0%	58.3%	16.7%	---	---
6.	Prepare you to talk to your doctor about what matters most to you	16.7%	58.3%	25.0%	---	---
7.	Help you think about the pros and cons of each option	16.7%	50.0%	33.3%	---	---
8.	Prepare you to make a better decision	16.7%	41.7%	41.7%	---	---
9.	Help you organize your own thoughts about the decision	16.7%	41.7%	41.7%	---	---
10.	Help you to identify questions you want to ask your doctor	18.2%	45.5%	18.2%	18.2%	---
1=not at all; 2=A little; 3=Somewhat; 4=Quite a bit; 5=A great deal.						

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Appendix A
Timeline

Project: Reducing Fear and Anxiety in the Aortic Stenosis TAVR Population: A Peer Support & Care Transitions Pilot Project								
	Month/Year							
Project Timeline	Mo/Yr Sept – Dec 2017	Mo/Yr Jan-Feb 2018	Mo/Yr May-July 2018	Mo/Yr Sept to Dec 2018	Mo/Yr Jan to April 2019	Mo/Yr May to July 2019	Mo/Yr Sept to Dec 2019	Mo/Yr Jan to May 2020
Planning								
Literature Review to identify the problem, mission, vision, problem statement	�							
Problem Statement	▓							
Literature review to identify intervention to the problem		▓						
Timeline Development			▓					
Financial cost analysis				▓				
Selection of Measurement Tools				▓				
Develop Analysis Plan				▓				
Project Proposal: Oral & Written				▓				
IRB					▓			
Recruitment of Past TAVR Patients to be Peer Support Partners					▓			
Past TAVR Patients Complete Mended Hearts Training					▓			
Develop & meet with Mended Hearts & TAVR Mended Hearts Stakeholder Team					▓			

Project Proposal: Oral & Written					███				
Implementation/Data Collection									
Refer new patient for TAVR Peer Support						███			
Use SDM during TAVR nurse or IC appointment						███			
Request patient to complete Pre/Post Questionnaires (Cardiac Self Efficacy & GAD -7)						███			
Request patient complete Preparation for Decision Making Scale						███			
TAVR Mended Heart Peer Complete Peer Support Data Collection Activity Log Form						███			
PI interviews new patients after they receive the interventions						███			
Data Analysis									
Interpret information from data collection								███	███
Questionnaires								███	███
Interview Questions								███	███
Activity Logs								███	███
Dissemination									
Oral & written dissemination of project outcomes									███
Local Mended Hearts Chapter Community Meeting								███	
Clinical Inquiry council									███
Boise State University School of Nursing									███
Final Report									███

Appendix B
Literature Review Summary Table: John Hopkins EPB Tool

John Hopkins Nursing Evidence –Based Practice
Appendix G: Individual Evidence Summary Tool

EBP Question: In patients with aortic stenosis pursuing TAVR, is peer support and use of a DA an effective intervention to decrease feeling of anxiety and increase self-efficacy clinical work up pathway or in the recovery period?
Date: February 25, 2018 & July 2018

Article #	Author & Date	Evidence Type	Sample Setting & Size	Study findings that help answer the EBP question: Peer Support	Limitations	Evidence Level & Quality
1	Colella & King (2004)	V	**Location study:** Authors from Alberta Canada **Sample Size**: Review of the literature focused on cardiac surgery, transitions, social support, peer support	Peer support for CABG is reasonable intervention for supporting patients through the process of cardiac surgery. 5 categories identified: Social support, relationship between social support & health, peer support, Peer support & cardiac recovery, the peer supporter. Peer support was found to improve readiness for surgery, increase motivation for participating in cardiac rehabilitation, improved long-term compliance to adherence to medical recommendations, and is identified by patients as an important emotional support tool. Support was provided by face-to-face encounters and telephone. Discussed need for training to develop volunteer competency for communication skills, problem-solving techniques needed to provide support.	Review is dated – 2004. Articles reviewed, for the previous 15 year period	B

| 2 | Colella & King-Shier (2018) | I | **Location study:** Toronto, Canada **Sample Size:** 185 61 peer support 124 usual care **Setting:** community | Peer support provided by telephone three to four-day post op and weekly for six weeks post-surgery by a peer. Compared to control group no effect on depression scores. Intervention group (peer support) showed lower uses of health service and ER utilization. The authors conclude this leads to decreased health cost and may have assisted patients in early problem identification and problem solving. Volunteers were recruited by poster at cardiac rehab program & hospital, and by letter to past CABG patients. Volunteer trained by researcher on communication skills, recovery norms, and when to refer patient to nurse practitioner for medical help. | Self-reported measure relies on patient's ability to identify and share health information. Patients may under or over rate their symptoms leading to scoring challenges. | B |
| 3 | Esmaeili, Jannati, Ghafari, Charati & Jelodar (2015) | I | **Location of Study:** Mazandaran Heart Center, Iran **Sample size:** 3 groups of 50 people All groups received usual education, in the Peer education group, peer education was added & in the orientation group they received the OP program, first time CABG patients | Mean anxiety score was not significant between groups one day prior to surgery, but one hour prior to surgery the peer support group and orientation group were lower than the control group, but no statistical significance between peer education and orientation group. "peer education group members communicate better with their peers (patients) and encourage them to conduct themselves in suitable healthy behaviors, since they can share their weak and strong points as well as experiences at neglible or no cost" Supporting peers enable patient to be more mentally prepared for surgery. Orientation program assist patients by educating them on the hospital and surgical experience and may walk them through the hospital setting where they will receive care In the non-intervention group anxiety significantly increased one hour prior to surgery. | Does not say who provided the orientation program. Medical staff. While overall sample size 150, there are only 50 people in each of the two intervention groups. | B |

			Setting: Hospital & community	Support proved face-to-face pre and post-surgery. Peer volunteer selected by researcher.		
4	Hildingh & Fridlund (2004)	III	**Study Location:** Sweden **Sample Size**: 220 patients, after 3 years 160 patients were still participating **Setting:** Hospital/Clinic	Study followed patients over three years in an existing support group. Group support was provided post cardiac event. Peer support included exercise group, stress management groups, discussion groups, cardiopulmonary resuscitation group, smoking cessation, and group lectures. People who participated in heart & lung school were more likely to continue exercising, smoke and had a denser support network of non-family members.	While study results note increased social support by participating in peer group, does not identify effects of increased peer support on anxiety, fear or depression related to cardiac disease	B
5	Junehag, Asplundb, Svedlund, (2014)	III	**Location of Study**: Sweden **Sample size:** 20, Men & Women Patients who lived in a rural area, 1rst time MI, **Setting:** Community	Three themes: having a different life, having to manage the situation and having access to support, with 11 subthemes. During their recovery, the participants experienced psychosocial consequences, consisting of anxiety and the fear of being afflicted again. Most mentees appreciated their mentor and some of those without mentors wished they had received organized support. Participants were often more dissatisfied than satisfied with the follow-up provided during recovery. Mentorship was offered for one-year post cardiac event. Peer volunteers recruited from postings in heart and lung advertisements. Volunteers were not provided any training to provide support.	Distance and available time to meet between PI and patients providing mentorship made it difficult for some mentees to receive as much support as they would have liked. If the mentee does not feel	B

					adequate in their role this could skew results of the perception of the one being mentored	
6	Lockhart, Foreman, Mase, & Heisler (2015)	III	**Location of Study**: Florida, US **Sample Size:** 28 patients, male & female with a mean age of 72 **Setting:** Community	Themes identified: peer support, friendship, information exchange, acceptance and control, comparing self to others, depression, effectiveness of program materials. Poor group attendance, low functional health status For some, peer support provided hope for living with heart failure & felt it provided extra emotional support. For some, they felt too ill to participate and did not feel the type of support to navigate ill health was offered, these people were less engaged in the peer support Patients found value in talking to peers who were living with the same health condition, even if they had great family support. The peer was offered provided a greater level of emotional support of "understanding what it is like". Lessened feeling of being alone. "Many participants who developed friendships with their peers' partners reported taking better care of themselves and being able to better manage their HF". Patients found peers were able to clarify information they had received from doctors promoting better self-management of health. Engaging with peers increased confidence comfort and reassurance, feeling of	While study does not specifically address d anxiety, it provides good information about what patient gain by participating in peer to peer support programs	A

				being inspired. Support was provided by NP led group, and/or peer to peer telephone. Those in the study attended two or more group session and/or participated in 17min or more telephone support.		
7	Malickaa, Kozłowskaa, Woźniewskia, Rymaszewskab and Szczepańska-Gieracha (2016)	III	**Location of Study:** Poland **Sample Size:** 48 women mean age of 66 23 women had cardiac surgery 25 women had breast cancer treatment with mastectomy **Setting:** Community	Study used existing peer support group. Oncology group had high acceptance of disease than cardiac both groups showed social support was associated differently to parameters of emotional state. Women treated for breast cancer were in better mental shape than those with cardiac disease. Support from women with cancer in the mastectomy group was more effective than usual social support the women had. In Wroclaw there is an established social support group for "Women After Mastectomy Club". While women's heart disease receives much less attention. 1. Both groups experienced high levels of anxiety 2. Support from women with a similar experience is more effective than usual support circle and influence how women cope and accept their disease.	Study done in Poland. May have different cultural values that could influence perception of illness, quality of life and anxiety when compared to the US population Small study sample. No information on how often patient attended group.	B
8	Mase, Halasyamani, Hwajung Choi, and Heisler (2014)	III	**Study Location:** Michigan **Sample Size:** 52 Mean age 66 **Setting:** patients recruited from specialty in-patient units & from HF clinic	Peer support provided by NP led group or peer to peer telephone call over 6-month period used existing peer volunteers. Older white women who reported higher baseline health status, functioning, social support, confidence in their ability to manage, and less difficulty with the physical and emotional aspects of living with heart failure were the most likely to engage in program activities. Minority status and reporting	Sample size only represented 38% of those who declined to participate in original research study, PI were not	B

			who had been hospitalized once in the past 12 months for HF	a need for social support were both correlated with higher enrollment but lower engagement in the intervention. (p1) Low participation rate for participation 31% Of those who completed the pre-enrollment questions, those who refused were older, white, less educated, not employed, and reported greater satisfaction with their social support, better HF self- management and better general health status. (p5)	able to contact with those who consented to participate, but did not participate, study was conducted in only one health system	
9	Parent & Fortin (2000)	III	**Study location:** Quebec Canada **Sample size:** 56 males **Setting:** Hospital	Experimental group showed decrease in anxiety & improve levels of self-efficacy, walking & climbing stairs, improved self-efficacy. Experimental group showed decrease in anxiety during hospitalization & improved levels of self-efficacy, and increased walking & climbing stairs, at 5 days and 4 weeks after surgery. Peer support provided listening, affirmation, feedback regarding concerns, and social comparison. Provided pre-support 24 hour prior to cardiac surgery & 5 days & 4 weeks post-surgery. Peer volunteer were recruited & trained by researchers. Training included empathetic listening, reflecting on feelings, cardiac disease and treatment.	Only male participants Patients admitted 48 hours prior to surgery, this is not common practice in the US. In addition, pt received a visit POD#5, visit stays post-surgery can be as little as 3 days in the US	B
10	Winder, Hiltunen, , Sethares, & Butzlaff (2004)	III	**Study Location:** United States **Sample size:** 45 Patients older than 65 &	Themes identified: establishing peer support role- helping connect and communicate, acknowledging abilities -increasing confidence, overcoming difficulties- navigating the health problem. Discovering the benefits of APN for the	Narrative data taken sole from APN perspective which may	B

			unpartners (single or widowed). First time CABG **Setting:** Community	peer providing support to the patient undergoing & recovering from CABG. Themes identified: establishing peer support role- helping connect and communicate, acknowledging abilities - increasing confidence, overcoming difficulties- navigating the health problem Identifies professionals provide physical support, while peers provide more friendship and emotional support. Peer volunteers were selected & trained by NP after having attended cardiac rehab. Peer contact was primarily by phone for approximated 10 minutes a session for 12 weeks.	have bias as they are invested in the program. No details on how volunteer were trained by NP.	
11	Wright & Smith (2002)	III	**Study location:** Hamilton, Ontario, Canada **Sample size:** 16 women **Setting:** Community	Used existing group for study. Group setting, monthly 2-hour sessions, provided a venue for the women to express their feelings of anxiety, loneliness and fear. Women also used a telephone network for support. Women felt having an expert facilitator assisted the group promote caring and ease for expressing struggles regarding recovering from a cardiac event.	Only women in the study	B
Article #	**Author & Date**	**Evidence Type**	**Sample Setting & Size**	**Study findings that help answer the EBP question:** Decision Aid	**Limitations**	**Evidence Level & Quality**
12	Baily, Pfeifer, Shillington, Harshaw, Funnell, VanWingen (2016)	I	**Study Location:** US **Sample Size:** 225 patients **Setting:** primary care & endocrinology	Use of a decision aid for shared decision making that provided information about medication; hypoglycemia control improved knowledge by 35% and improved self- efficacy of disease management and decreased decisional conflict. A summary sheet and an online tool was used to provide information about antihyperglycemic medication and treatment options. DA was	No blinding of clinicians on patient participants, which could under estimate the tool.	A

				developed based on EBP for DM. The online tool allowed to note-taking, recording of questions, and comments to be shared between the doctor and patient.		
13	Barton, Koening, Evans-Young, Trupin, Anderson, Ragouzeo, …& Yelin, (2014) II	III	**Study Location:** California, US **Sample Size:** not defined **Setting:** Clinic	Study describes the process of developing a decision aid to increase knowledge and shared decision making for patients with rheumatoid arthritis. Patients and clinicians where a part of the team that developed the aid. Both gave feedback on the content, visual appeal and use of the DA as it was being developed. Information was obtained through interviews of clinicians & patients. The DA went through three drafts during field-testing. The aid focused on medication issues and patient goals. Cards led to providers increasing discussion and consideration of patient preferences in their care.	Does not measure increase in knowledge or SDM	C
14	Coylewrite, Palmer, O'Neil, Robb, &Fried (2016)	III	**Study Location:** United States **Sample Size:** 46 patients who have had TAVR **Setting:** Dartmouth-Hitchcock Medical Center	To promote SDM, the study retrospectively analyzed goal statement from patients pursuing TAVR. The study showed that it was feasible and easy to ask a goal setting question in regards to the treatment plan during a clinic visit. This information can be obtained by a nurse and shared the multidisciplinary team meeting. This information assists in keeping the patient at the center of care	Does not evaluate intermediate risk patients, is retrospective and only asks patients to define their goals after treatment, does not include a decision aid	C
15	Den Ouden, Vos, & Rutten (2017)	I	**Study Location:** Netherlands **Sample Size:** 17 clinics	Use of a SDM tool for patients with diabetes (DM), that provided information on the connection between treatment intensity for DM and CV events. The OPTIMAL paper decision	SDM tool did not mention age, how long pt had been DM	A

			participated in the intervention & 18 clinics in the control group. 153 patients participated in the study. **Setting:** Clinic	tool was used. Patients who identified goals for BP & A1C targets, through SDM had higher success rates than patients in the usual care group, but not statistically significant difference. However, the SDM tool did generate conversation between the patient and provider about patient centered goals for care.	or other comorbidities	
16	Holloway. (2006)	**III**	**Study Location:** United Kingdom **Sample Size:** 22 patients interviewed **Setting:** clinic	Development of a care pathway framework for people with Parkinson's. The tool-contained information regarding local information, a problems/Need form, a clinic summary and service record sheet. Aid allowed for tracking of appointments, writing down questions to be discussed at appointments, and provided information on the disease and medication. Patients used the problems need form to stimulate discussion with their doctor and care team. The tool was in the form of a paper based information packet. Patients found the tool improved knowledge of disease, helped them be more prepared for appointments, and allowed them to ask more directed questions at their appointments.	Not tested in regards to management of the chronic illness .	C
17	Kelly-Blake, Clark, Dontje, Olomu, Henry, Rovner, Rothert, & Holmes-Rovner. (2013)	**III**	**Study Location:** Michigan, US **Sample Size:** 10 **Setting:** Clinic	Report on the results of an improvement of a DA used by patients with CAD. A cognitive interview process was used to improve the DA. DA format was a booklet. Timing of when to introduce the DA & the content of the DA was changed based on patient interview feedback. Interviews identified hard to understand medical term and found tear out "talking points" useful. The DA provided patients with education	Small sample size which does not allow for capturing greater population needs when using the DA.	B

				regarding CAD, PCI, & medical therapy. It allowed patient to engage in meaningful discussion with their physician. Revision included checklist for recording decisions, scheduling appointments, and test results that can go with patient, clinician and EHR.		
18	Lauck, Baumbush, Achtem, Forman, Carroll, Cheung, Ye, Wood, & Webb. (2016)	**III**	**Study Location:** Vancouver, BC **Sample Size:** 15 **Setting:** Hospital clinic	Qualitative study that found TAVR patients consider system burden, experience of peers, expectations of quality of life, healthcare system and information support, logistical barriers of travel to a treatment center, and obligation and responsibilities key elements of what they consider when making decisions.	Study only done at one center. Does not use a SDM tool, but identifies components of what TAVR patients consider when making decisions	C
19	Olomu, Hart-Davidson, Lou, Kelly-Blake & Holmes-Rovner. (2016)	**II**	**Study Location:** Michigan, US **Sample Size:** 95 patients **Setting:** Primary Care Clinic	In patients with DM, use of SDM & DA as a part of routine care increased medication compliance; pat satisfaction with communication and confidence in decision of care. Patients attended on group visit to learn, SDM, communication, and review DA tool with a health coach. Clinic staff used Office-Gap checklist tools during clinic visit with patient to prompt SDM conversation. Physician & patient signed the tool after discussion. DA tools included 35min video on CHD, a pamphlet, & Living with DM booklet. Tools were used to set goals with patients and for agreements on lifestyle changes.	Not RCT which limit generalizability. No evaluation of implementation cost of project.	B

c The Johns Hopkins Hospital/Johns Hopkins University.

Appendix C

Logic Model

Resources/Inputs	Activities	Outputs		Outcomes: Short Term	Outcomes: Intermediate	Outcomes: Long term
Program development **Human** -Valve Coordinator -Mended Hearts Members Chapter ▉ -Past TAVR patients **Space** Clinic or hospital conference room **Time** -Team Meeting -Valve coordinator provides supervision support -Mended Heart volunteer provides supervision **Financial** -Cost of Mended Hearts Memberships	a) Build stakeholder peer support team for Chapter ▉ ○ Valve Coordinator ○ 2 Current Mended Hearts Members ○ 2 Past TAVR patient (b) Peer support team meets to define structure of TAVR Peer Support Pilot Program ○ Peer goals & objectives ○ TAVR volunteer eligibility ○ Timing of referral process for peer support ○ Mended Hearts contact person for TAVR volunteers ○ Financial commitment (Membership fees) ○ TAVR Peer volunteer roles & responsibility ○ Method of contact	(a) Identified number of Mended Hearts members & 2 of past TAVR patients on stakeholder TAVR peer support team (b) Identified number of meetings to define structure of TAVR peer support (b) TAVR peer support program training ○ Time of referral defined ○ Identified number of Mended Hearts members are contact members for TAVR volunteers ○ 1st year of membership fee is waved	Valve Coordinator Mended Hearts Chapter ▉ Past TAVR patients	1. At the medical center in the Pacific Northwest, a structured peer support program is developed for TAVR patients who are in the work up process by May of 2019. (CO)	7. Peer support program patients is implemented at the other medical center that are a part of the medical center in the Pacific Northwest Network. (CO)	

-Cost of printing new Mended Hearts brochure **Materials** -Mended Hearts brochure	o Time commitment for volunteers o Contact peer communication and documentations o Supervision of volunteers (c) Recruitment of TAVR peer volunteers o TAVR coordinator identifies past patients to invite to be peer volunteers (d) Training of TAVR peer volunteers	o Volunteer role defined o Method of contact defined: Telephone o Amount of time defined for providing TAVR peer support o Identify number of contact attempts defined to reach new patient o Supervision: (2) Mended Heart member & Valve Coordinator (c) Identified number of past TAVR patients invited and agree to be volunteers (d) Identified number of patients complete Mended Heart TAVR peer support training				

Human
-Past TAVR patient
-TAVR coordinator
-Interventional Cardiologist (IC) Cardiologist
-Cardiothoracic Surgeon (CTS)
-DV director
 	
Material
-SDM tool
 	
Space
 	
-Meeting space for team discussions
 	
Financial
-$ For printing materials
	(a) Locate Shared Decision Aid Tool
	
	(b) Request approval to use Shared Decision Aid Tool
	  o IC Cardiologist
	  o Surgeon
	
	(c) Request financial approval for printing of Decision Aid Tool from CV director
	
	(d) Identify when Decision Aid Tool will be provided to new TAVR patient
	
	(e) Use the Decision Aid Tool during TAVR nurse visits
	
	(f) Document use of Decision Aid Tool use in EHR
	
	(g) Share information gained from tool use is shared at bi-monthly Structural Heart Multidisciplinary clinical conference
		(a) Locate Shared Decision Aid Tool
		  o SDM questions
		  o Aortic Stenosis
		  o SAVR vs TAVR
		  o TAVR vs Medical Therapy
		  o Risk Benefits
		  o Patient goals & values
		
		(b) Decision Aid Tool is approved by CTS Surgeon, IC Cardiologist, & Valve Coordinator
		
		(c) Financial approval received to printing Decision Aid Tool
		
		(d) Patient receives Decision Aid Tool at first contact with valve coordinator
		
		(e) Use of Decision Aid Tool documented in EHR
			New TAVR patients
			Past TAVR Patients
			Multidisciplinary team staff:
			
			-CTS Surgeon
			-IC Cardiologist
			-Valve Coordinator
				2. At the medical center in the Pacific Northwest, a Decision Aid Tool is used 95% of the time with patients on the TAVR pathway work up from June of 2019 to Aug of 2019 and 80% of patients indicated the Decision Aid Tool enhanced the shared decision-making process (PO).	8. Decision Aid Tool used with TAVR patients is a piloted in another Medical Center in the Pacific Northwest. (CO).	11.The medical center network in the Pacific Northwest system adopts the use of a Decision Aid Tool for shared decision making for aortic stenosis as evidence by a written procedure accessible through the intranet at the organization policy and procedures portal. (CO)

		(f/g) Patient information (goals/values) obtained from tool shared Bi-Monthly at Structural Heart Multidisciplinary clinical conference				
Peer Volunteer Supporters **Human** **-**Past TAVR Patients -Mended Hearts Chapter 382 -Valve Coordinator (DNP Student) -Patient in work up process **Space** **-**Clinic exam room **Material** -Peer documentation form -Telephone **Time** - For volunteer & new TAVR patient to connect via phone	(a) Develop peer data collection form (b) Train volunteer how to fill out form for data collection (c) Valve coordinator connects patient in TAVR work up process with peer (d) TAVR peer volunteer completes peer data collection form o Peer attempts to connect with new patient by phone o Peer connects with new patient by phone	(a) Peer data collection form developed (b) Identified number of TAVR peer volunteers trained to complete peer data collection form (c) Valve coordinator referred new TAVR patients for peer support between May & Aug 2019 (d) (x) number of peer data collection forms completed o (x) of attempts made by TAVR support volunteer to contact new TAVR patient o (x) # of peer to peer contacts where made	New TAVR patients Past TAVR patient volunteer Valve Coordinator	3. At the medical center in the Pacific Northwest, of the 4 past TAVR patients selected for training, 50% are trained and provide 1:1 peer support to patients in the TAVR work up process from June through August of 2019. (CO)	9. Peer support is part of routine care for of TAVR patients in the work up process for TAVR at the medical center in the Pacific Northwest. (PO)	12. Those participating in peer support have increased satisfaction with care and support throughout the TAVR work up and recovery process. (CO)

		with (x) # of patients in the TAVR work up process				
New TAVR Patients Receiving Support **Human** -Past TAVR Patients -Mended Hearts Chapter 382 -Valve Coordinator (DNP Student) -Patient in work up process **Space** -Clinic exam room **Material** -Telephone -Questionnaire **Time** - For volunteer & new TAVR patient to connect via phone	(a) Valve Coordinator identify and refer new patients to refer for peer support (b) Valve Coordinator request patients to answer pre/post peer support General Anxiety Disorder -7 (GAD-7) (c) Patients participate in peer support	(a) Identified number of patients identified for peer support (b) Identified number of TAVR patients completed GAD-7 tool (c) Identified number of patients referred for peer support (d) Identified number of patients on the TAVR pathway that receive peer support	New TAVR patients Past TAVR patient volunteer Valve Coordinator	4. At the medical center in the Pacific Northwest, 50% of patients who received peer support show a decrease in anxiety as evidenced by pre and post General Anxiety Disorder -7 (GAD-7) scale by Sept 2019. (CO)		

Human -Past TAVR Patients -Mended Hearts Chapter ▆ -Valve Coordinator (DNP Student) -Patient in work up process **Space** -Clinic exam room **Material** -Telephone -Questionnaire **Time** - For volunteer & new TAVR patient to connect via phone	(a) Identify new patients to refer for peer support (b) Valve Coordinator request patients to answer Cardiac Self-Efficacy questionnaire pre/post peer support (c) Valve Coordinator refers new TAVR patients for peer support (d) Patients participate in peer support	(a) Identified number of patients identified for peer support (b) Identified number of TAVR patients completed APAIS tool (c) Identified number of patients referred for peer support (d) Identified number of patients on the TAVR pathway that receive peer support	New TAVR patients Past TAVR patient volunteer Valve Coordinator	5. At the medical center in the Pacific Northwest, 50% of patients who received peer support show an increase in cardiac self-efficacy as evidenced by the Cardiac Self Efficacy questionnaire by Sept 2019. (CO)		

| Care Coordination Model Human -Valve coordinator -Clinical Inquiry Council Time -To develop & write document | (a) Develop process for TAVR care coordination integrating peer support into process of care for TAVR patients
o Recruitment of volunteers
o Training of volunteers
o Referral of new patients
o Supervision of program
o Follow up with volunteers
o Follow up with new TAVR patient
o Documentation of intervention
o Facilitate information sharing between patient and multidisciplinary team (b) Develop process for TAVR care coordination integrating a Decision Aid Tool into process of care for TAVR patients
o Appointments to use Decision Aid Tool
o Identify patient goals & values | (a/b) Integrate Decision Aid Tool and peer support into the Enhanced TAVR Care Coordination Model into practice (c)Enhanced TAVR Care Coordination Model presented to Clinical Inquiry Council (d) Enhanced TAVR Care Coordination Model presented Local Mended Hearts Chapter | Multidisciplinary team Valve Coordinator Magnet steering committee Leadership Team for Cardiovascular Services Local Mended Hearts Chapter | 6. The Enhanced TAVR Care Coordinator Model is submitted to Magnet Steering Council and the medical center in the Pacific Northwest's Cardiovascular System Leadership Team by May 2020. (CO) | (c.) Enhanced TAVR Care Coordination model is used to guide TAVR care at the other medical center that are a part of the medical center in the Pacific Northwest Network. (PO) | 13. Peer support and use of a Decision Aid Tool is adopted as part of TAVR coordination nationally by TAVR centers in the United States leading to improved support for patients on the TAVR work up pathway. (CO) |

	- Document use of Decision Aid Tool - Document patient preferences shared at Multidisciplinary meeting (d) Present Enhanced TAVR Care Clinical Inquiry Council (e) Present Enhanced TAVR Care Coordination to Local Mended Hearts Chapter

Appendix D
GAD- 7

Generalized Anxiety Disorder 7-item (GAD-7) scale

Over the last 2 weeks, how often have you been bothered by the following problems?	Not at all sure	Several days	Over half the days	Nearly every day
1. Feeling nervous, anxious, or on edge	0	1	2	3
2. Not being able to stop or control worrying	0	1	2	3
3. Worrying too much about different things	0	1	2	3
4. Trouble relaxing	0	1	2	3
5. Being so restless that it's hard to sit still	0	1	2	3
6. Becoming easily annoyed or irritable	0	1	2	3
7. Feeling afraid as if something awful might happen	0	1	2	3
Add the score for each column	+	+	+	
Total Score *(add your column scores)* =				

If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?

Not difficult at all _____
Somewhat difficult _____
Very difficult _____
Extremely difficult _____

Source: Spitzer RL, Kroenke K, Williams JBW, Lowe B. A brief measure for assessing generalized anxiety disorder. *Arch Inern Med.* 2006;166:1092-1097.

Appendix E

The Cardiac Self-Efficacy (CSE) Questionnaire

The CSE uses a 13-item Likert-scale to measure patient's cardiac confidence. The items are rated 0 through 4 (0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident) or may select "not applicable".

How confident are you that you know or can:

1. Control your chest pain by changing your activity level
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

2. Control your breathlessness by changing your activity levels
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

3. Control your chest pain by taking your medications
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

4. Control your breathlessness by taking your medications
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

5. When you should call or visit your doctor about your heart disease
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

6. How to make your doctor understand your concerns about your heart
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

7. How to take your cardiac medications
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

8. How much physical activity is good for you
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

9. Maintain your usual social activities
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

10. Maintain your usual activities at home with your family
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

11. Maintain your usual activities at work
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

12. Maintain your sexual relationship with your spouse
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

13. Get regular aerobic exercise (work up a sweat and increase your heart rate)
0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident

Sullivan, M. D., Lacroix, A. Z., Russo, J., & Katon, W. J. (1998). Self-efficacy and self-reported functional status in coronary heart disease: A six-month prospective study. *Psychosomatic Medicine*, *60*(4), 473–478. https://doi.org/10.1097/00006842-199807000-00014

Appendix F

Preparation for Decision Making Scale

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Preparation for Decision Making Scale

Please indicate your opinion about the <u>effect of the educational material</u> by circling the appropriate number to show the extent to which you agree with each statement.

Did this educational material . . .	Not at all	A little	Some-what	Quite a bit	A great deal
1. Help you recognize that a decision needs to be made?	1	2	3	4	5
2. Prepare you to make a better decision?	1	2	3	4	5
3. Help you think about the pros and cons of each option?	1	2	3	4	5
4. Help you think about which pros and cons are most important?	1	2	3	4	5
5. Help you know that the decision depends on what matters most to you?	1	2	3	4	5
6. Help you organize your own thoughts about the decision?	1	2	3	4	5
7. Help you think about how involved you want to be in this decision?	1	2	3	4	5
8. Help you identify questions you want to ask your doctor?	1	2	3	4	5
9. Prepare you to talk to your doctor about what matters most to you?	1	2	3	4	5
10. Prepare you for a follow-up visit with your doctor?	1	2	3	4	5

Preparation for Decision Making Scale © ID Graham, AM O'Connor 1996, revised 2005 University of Ottawa

Appendix G

Interview Questions

- How did the use of a decision aid enable you to engage with your physician during the TAVR work up process?
- Tell me about your experience with TAVR peer support.

Appendix H

IRB Approval Letter

System Institutional Review Board

DATE: March 5, 2019

TO: Kimberlee Einfeld, MN RN

FROM: ██████████ System Institutional Review Board

PROJECT TITLE: [1384874-1] Reducing Anxiety and Increasing Self-Efficacy in the TAVR Population:

REFERENCE #:	[1384874-1]
SUBMISSION TYPE: ACTION:	New Project DETERMINATION OF EXEMPT STATUS
DECISION DATE:	March 5, 2019
REVIEW CATEGORY:	Exemption category 3: Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collected

Thank you for your submission of New Project materials for this project. The ██████████████ Institutional Review Board (IRB) has determined this project is EXEMPT FROM IRB REVIEW according to federal regulations.

This determination of exemption shall be effective indefinitely. Modifications may not be made to exempt research because of the possibility that proposed changes may change the research in a way that it no longer meets the criteria for exemption. A new application for exempt determination must be submitted and reviewed prior to modifying the research activity, unless the investigator believes that the change must be made to prevent harm to participants. All such changes must be reported to the ██████████ System IRB.

We will retain a copy of this correspondence within our records.
If you have any questions, please contact the IRB with your project title and reference number. The IRB is covered under Human Subjects Assurance number FWA 00003906.

Appendix I

Treatment Options for Severe Aortic Stenosis for Patients Deciding Between TAVR and Surgery

A DECISION AID FOR
TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS FOR PATIENTS DECIDING BETWEEN TAVR AND SURGERY

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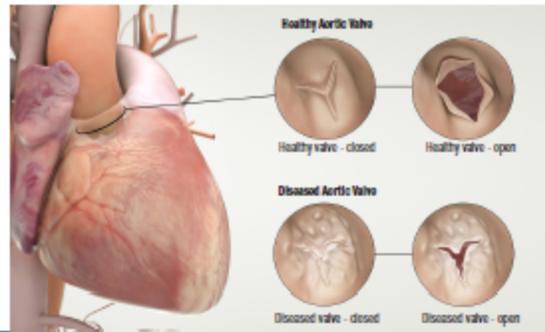For Clinicians: For Patients with INTERMEDIATE OR HIGH SURGICAL RISK

This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. You, your family, and your clinicians can begin to discuss which treatment option is best for you.

ALONG THE WAY, WE WANT YOU TO THINK ABOUT:

▶ What your goals are for treating your AS

▶ What concerns you have about your treatment options

▶ What additional questions you have for your clinician

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery   **1**   CardioSmart
INTERMEDIATE OR HIGH SURGICAL RISK   American College of Cardiology

UNDERSTANDING AS

Aortic Stenosis (AS) is tightening of the aortic valve in the heart. This can get worse over time. AS makes it harder for the heart to do its job.

Healthy Aortic Valve

Healthy valve - closed   Healthy valve - open

Diseased Aortic Valve

Diseased valve - closed   Diseased valve - open

SYMPTOMS OF SEVERE AS INCLUDE:

- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. **Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.**

What options do I have to fix my valve?
THIS IS THE BIG QUESTION!

FIXING YOUR VALVE: Most people decide between two different procedures: **TAVR and SAVR.** The rest of this brochure will help you understand these options.

Most people with severe AS symptoms choose to have their valve fixed. Other people may not be sure if their symptoms are caused by AS. These people should talk with their clinician about their options.

Sometimes people do not fix their valve right away, often because:

1. They aren't sure their symptoms are from AS. Other common problems share a lot of symptoms with AS, including:

- Being out of shape
- Cancer
- Depression
- Arthritis

- Kidney disease
- Lung disease
- Other heart disease
- Alzheimer's

2. They have more urgent health care needs, such as:
- Serious infections
- Cancer

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery
INTERMEDIATE OR HIGH SURGICAL RISK

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▶ TREATMENT OPTIONS

TAVR	SAVR
Transcatheter Aortic Valve Replacement transcatheter procedure	**Surgical Aortic Valve Replacement** open-heart surgery

WHAT:
TAVR is a procedure where a new valve is placed in the heart through a small tube (called a "catheter") typically in the leg.

WHAT:
SAVR is open-heart surgery where a new valve is placed in the heart directly, replacing the old valve.

HOW:
This procedure involves a small incision where a catheter is inserted to access the heart to replace the valve.
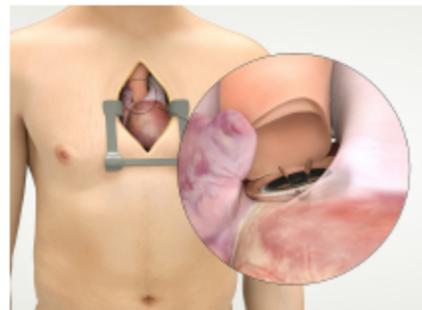
HOW:
This surgery usually involves an incision along the breastbone to access the heart to replace the valve.

WHO:
This method is an option for both patients who are and those that are not candidates for open-heart surgery.

WHO:
Those without other severe health problems are good candidates for open-heart surgery.

HOSPITAL STAY:
On average, 2-3 days

HOSPITAL STAY:
On average, 1 week

RECOVERY TIME:
On average, 1-2 weeks

RECOVERY TIME:
On average, 6-8 weeks

VALVE TYPE:
A bioprosthetic valve is used

VALVE TYPE:
A bioprosthetic valve or mechanical valve is used

Every patient is different, and we cannot see into the future to know how long your new valve will last. At this time, we know more about how long surgically replaced valves last than we do about TAVR valves. While valve replacements are durable, eventually your new valve may need to be replaced. The timing of this is different for every patient. Talk to your clinician about any concerns you have about how long your valve might last, and what your options might be if it ever needs to be replaced.

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery
INTERMEDIATE OR HIGH SURGICAL RISK

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THE RISKS & BENEFITS OF YOUR OPTIONS
TAVR vs. SAVR: Which is the best decision for me?*
*Leon et al. (2016). New England Journal of Medicine; Reardon et al. (2017). New England Journal of Medicine

TAVR	SAVR
⊕ BENEFITS:	**⊕ BENEFITS:**

⊕ BENEFITS:
- Helps you live longer
- Helps you feel better
- Less invasive procedure
- Shorter recovery time

Nearly **9 in 10** patients are still living within two years and just over **1 in 10** patients will die.

86% live
14% die

⊖ RISKS:

Nearly **1 in 10** patients suffer from a **stroke within 2 years**

8%

Nearly **1 in 10** patients suffer from **serious injury to blood vessels**

9%

2 in 10 need a **pacemaker** within 2 years

20%

⊕ BENEFITS:
- Helps you live longer
- Helps you feel better
- Over 50 years of experience with procedure

Just over **9 in 10** patients are still living within two years and just over **1 in 10** patients will die.

85% live
15% die

⊖ RISKS:

Nearly **1 in 10** patients suffer from a **stroke within 2 years**

8%

Less than **1 in 10** patients suffer from **serious injury to blood vessels**

6%

1 in 10 need a **pacemaker** within 2 years

10%

Both TAVR and SAVR have **POTENTIAL PROCEDURAL RISKS** including:

- Death	- Bleeding	- Stroke
- Heart attack	- Infection	- Blood clots

These risks are different for different patients. Talk to your doctor about your individual risks.

IN SUMMARY:

- TAVR and SAVR are each effective options for helping your aortic valve
- TAVR is a less invasive procedure

- The risk for needing a pacemaker implanted is higher after TAVR

- More is known about how long mechanical valves last (used in SAVR)

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery
INTERMEDIATE OR HIGH SURGICAL RISK

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TREATMENT SCENARIO 1

- **JANE IS AN 80-YEAR-OLD WOMAN WITH SEVERE AS.**
- She also has moderate lung disease and diabetes.
- She has shortness of breath when she walks across a room.
- Her clinician thinks it might be related to her aortic valve. Jane talked to her clinician to better understand the risks and benefits involved with her options.
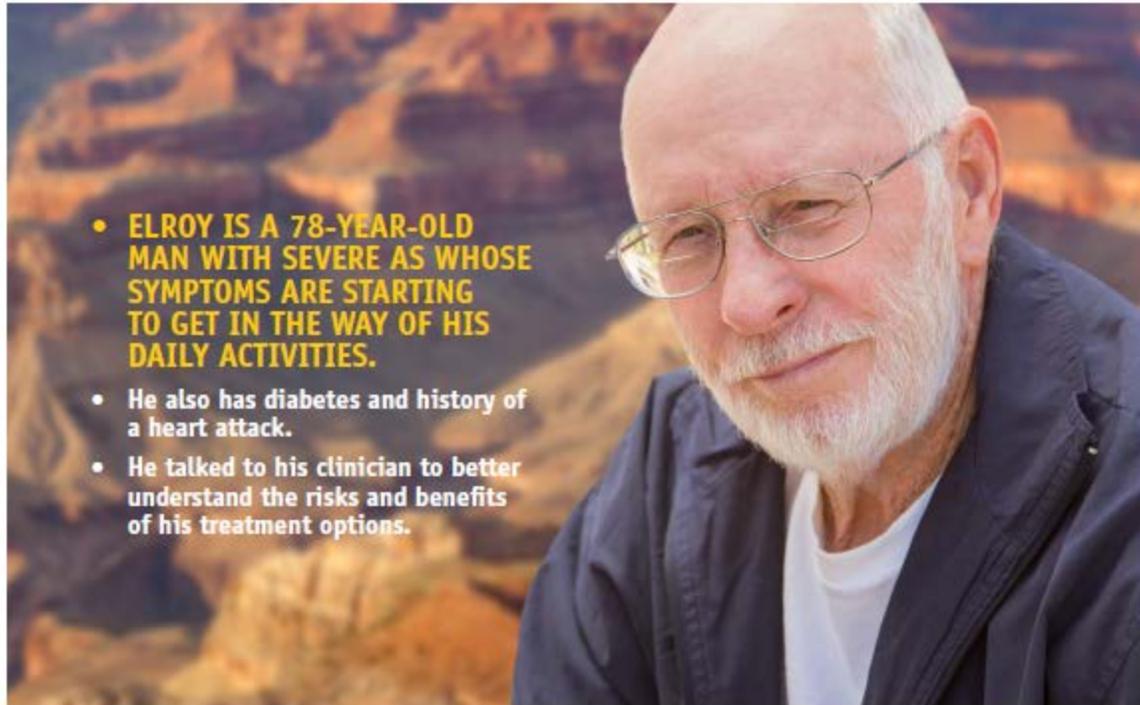
Option 1: Choose TAVR

- TAVR is less invasive.
- The recovery time is shorter.
- Jane can expect similar results.

After talking to her clinician, Jane decided the **TAVR procedure** was the best option for her. She is concerned her other illnesses will make recovering from open-heart surgery more difficult.

Option 2: Choose SAVR

- TAVR is a newer procedure, while SAVR has been around for a long time.
- Jane knows people who have had open-heart surgery.

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery
INTERMEDIATE OR HIGH SURGICAL RISK

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TREATMENT SCENARIO 2

- **ELROY IS A 78-YEAR-OLD MAN WITH SEVERE AS WHOSE SYMPTOMS ARE STARTING TO GET IN THE WAY OF HIS DAILY ACTIVITIES.**
- He also has diabetes and history of a heart attack.
- He talked to his clinician to better understand the risks and benefits of his treatment options.

Option 1: Choose TAVR

- TAVR is less invasive.
- The recovery time is shorter.
- Elroy can expect similar results.

Option 2: Choose SAVR

- TAVR is a newer procedure, while SAVR has been around for a long time.
- Elroy knows people who have had open-heart surgery.

✔ Elroy decided the **SAVR procedure** was the best choice for him. He wanted a valve that is known to last and he wasn't concerned about the longer recovery time.

Treatment Options for Severe Aortic Stenosis
for patients deciding between **TAVR and Surgery**
INTERMEDIATE OR HIGH SURGICAL RISK

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MAKING YOUR DECISION

TAVR and SAVR are each effective options for helping your aortic valve; the choice is ultimately a very personal one based on your overall health, values and individual preference.

There is a lot to think about when trying to decide which path is right for you. Take some time to consider what you have learned about treatments for AS. If you're still not sure what the best choice is for you, ask yourself these questions.

What do you hope for with TAVR or SAVR?

_____

_____

_____

_____

What concerns do you have with TAVR or SAVR?

_____

_____

_____

_____

What questions do you have for your clinician?

_____

_____

_____

_____

What questions do you have for your family and loved ones?

_____

_____

_____

Treatment Options for Severe Aortic Stenosis
for patients deciding between TAVR and Surgery
INTERMEDIATE OR HIGH SURGICAL RISK   **7**   CardioSmart
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Appendix J
Treatment Options for Severe Aortic Stenosis TAVR vs. Symptom Management

A DECISION AID FOR
TREATMENT OPTIONS FOR SEVERE AORTIC STENOSIS (TAVR vs Symptom Management)

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For Patients With Prohibitive Surgical Risk/Inoperable
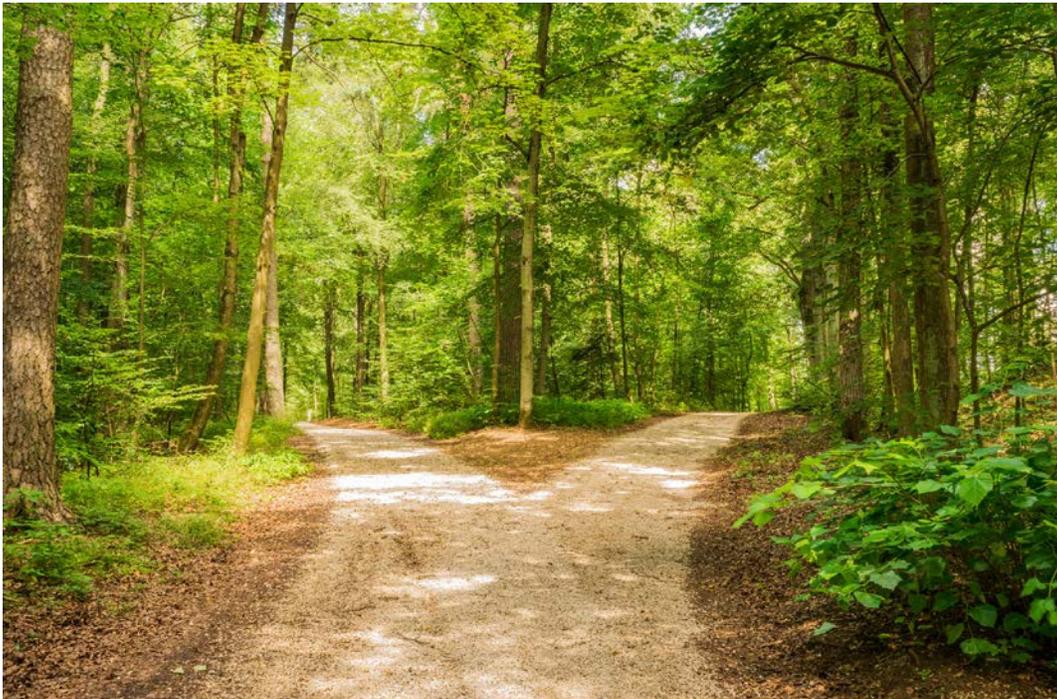
This booklet will help you understand what aortic stenosis (AS) is and what treatment options are available. This booklet is specifically for individuals who cannot have open-heart surgery. You, your family, and your clinicians can begin to discuss which treatment option is best for you.

ALONG THE WAY, WE WANT YOU TO THINK ABOUT:

▶ What your goals are for treating your AS

▶ What concerns you have about your treatment options

▶ What additional questions you have for your clinician

A decision aid for Treatment Options for Severe Aortic
Stenosis (TAVR vs Symptom Management)
FOR PATIENTS WITH **PROHIBITIVE SURGICAL RISK/INOPERABLE**   **1**   CardioSmart
                                                                                    American College of Cardiology

▶ UNDERSTANDING AS

Aortic Stenosis (AS) is tightening of the aortic valve in the heart. This can get worse over time. AS makes it harder for the heart to do its job

Healthy Aortic Valve

Healthy valve - closed   Healthy valve - open

Diseased Aortic Valve

Diseased valve - closed   Diseased valve - open

SYMPTOMS OF SEVERE AS INCLUDE:

- feeling dizzy like you might pass out
- feeling tired
- trouble breathing
- chest pain
- swelling of the legs

You may be experiencing some of these symptoms. They may make it harder to do the things you want to do. If left untreated, these symptoms usually get worse over time and can lead to death. **Prior to the decision, you may need to have additional testing to help your clinician understand what your options are.**

? Will Treatment Help?
THIS IS THE BIG QUESTION!

If symptoms are from severe AS, fixing your aortic valve may help you feel better and live longer.

OR

If symptoms are from OTHER health problems, fixing your aortic valve may NOT help you feel better OR help you live longer.

It is important to understand whether treatment for severe AS will help you feel better and/or live longer.

ician about your symptoms and what could be causing them.

A decision aid for Treatment Options for Severe Aortic
Stenosis (TAVR vs Symptom Management)
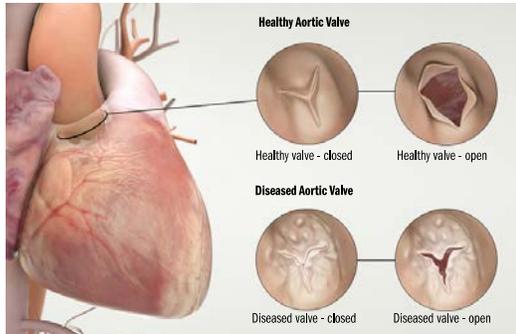FOR PATIENTS WITH **PROHIBITIVE SURGICAL RISK/INOPERABLE**

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▶▶ TREATMENT OPTIONS

TAVR
Transcatheter Aortic Valve Replacement
Transcatheter Procedure

SYMPTOM MANAGEMENT
Taking Medication Only

WHAT:
TAVR is a procedure where a new valve is placed in the heart through a small tube (called a "catheter") typically in the leg.

HOW:
This procedure involves a small incision where a catheter is inserted to access the heart to replace the valve.

WHO:
This method is an option for both patients who are and those who are not candidates for open-heart surgery.

HOSPITAL STAY:
On average, 2-3 days

RECOVERY TIME:
On average, 1-2 weeks

WHAT:
Partnering with your clinician to try and control symptoms with medications, without fixing the valve.

HOW:
This option involves using medications that will not prolong life but may limit the symptoms of severe AS.
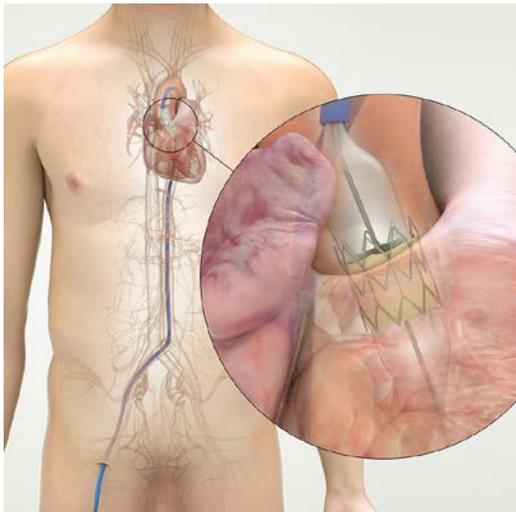
WHO:
This method is an option for patients who do not wish to have surgery or have too many other health problems that are not related to severe AS.

HOSPITAL STAY:
No procedure that involves a hospital stay.

RECOVERY TIME:
No procedure to recover from

MORE INFORMATION ON YOUR TREATMENT OPTIONS FOR AS — BENEFITS

TAVR	Symptom Management

⊖⊕ BENEFITS:
- Helps you live longer
- Helps you feel better

⊖⊕ BENEFITS:
- Focus on symptom management and comfort
- No surgery or procedures and no recovery time

It can be scary to think about life and death. However, many people in your position also feel it is important to have information about how likely it is for TAVR to help patients live longer.

♡ = Unaffected

♥ = Lived longer with TAVR

*Makkar et al. (2012).
New England Journal of Medicine

The choice between **TAVR** and **Symptom Management** is ultimately a very personal one that is based on your overall health, values and individual preferences.

MORE INFORMATION ON YOUR TREATMENT OPTIONS FOR AS — RISKS

TAVR	Symptom Management

RISKS:
- Death (from procedure)
- Bleeding
- Stroke
- Heart attack
- Infection
- Blood clots
- Increased chance of needing a pacemaker implanted
- Vascular injury (puncture)

RISKS:
- Death (from AS)
- Ongoing symptoms that may get worse
- Medications do not fix your valve

> Medications will focus on relieving symptoms themselves. People who choose Symptom Management are often interested in **palliative care** (See below).

What is palliative care?

Palliative care is medical care for people with serious illness. It helps provide relief from symptoms, pain and stress. It also provides emotional and spiritual support. The goal of palliative care is to improve quality of life for patients and caregivers.

What is hospice?

Hospice is care given by health professionals for patients near the end of their lives. This care includes medical, emotional, and spiritual support, and helps to provide comfort and quality of life for patients. Hospice care usually occurs within a patient's home. It can also occur in other settings such as a hospice facility or nursing home.

Whether you decide **TAVR** or **Symptom Management** is the right choice for you, there are services available to help with symptoms and suffering of advanced illness.

A decision aid for Treatment Options for Severe Aortic Stenosis (TAVR vs Symptom Management) FOR PATIENTS WITH **PROHIBITIVE SURGICAL RISK/INOPERABLE**

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▶ TREATMENT SCENARIO 1

- **JANE IS AN 80-YEAR-OLD WOMAN WITH SEVERE AORTIC STENOSIS.**
- **She also has moderate lung disease and diabetes.**
- **She has shortness of breath when she walks across a room.**
- **Her clinician thinks it might be related to her aortic valve. Jane talked to her clinician to better understand the risks and benefits involved with her options.**

Option 1: TAVR	Option 2: Symptom Management
The majority of Jane's symptoms are from severe AS. Replacing her valve would likely improve her symptoms and may also extend her life.	Replacing her valve won't fix all of Jane's symptoms. Jane is concerned about some of the risks that can happen with the TAVR procedure. Jane is worried her other illnesses like diabetes may continue to get worse.

After talking to her clinician, Jane decided the **TAVR procedure** was the best option for her. She hoped replacing her valve would improve her symptoms caused by AS and help her feel better.

▶ TREATMENT SCENARIO 2

Heard TAVR but
was not sure if it would help
his symptoms.

Option 1: TAVR	Option 2: Symptom Management
TAVR might help some of George's symptoms.	Replacing his valve might NOT help George's symptoms. George will still have symptoms of heart failure and difficulties from his stroke. George is more concerned with symptom management than aggressive treatment at this time.

After talking to his clinician George decided **Symptom Management** was the best choice for him. He and his family are not sure TAVR will help him with his symptoms and he does not want any more procedures.

A decision aid for Treatment Options for Severe Aortic
Stenosis (TAVR vs Symptom Management)
FOR PATIENTS WITH **PROHIBITIVE SURGICAL RISK/INOPERABLE**

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Appendix K

Telephone Requirement Script

Past TAVR Patient to invite them to become Mended Hearts Members and Participate in the SP Pilot Project

Hello Mr./Ms Name of Patient

This is Kim, your TAVR coordinator. I am a student at Boise State University in the Doctor of Nursing Practice. As part of my program, I am working to assist our local Mended Hearts chapter to develop support for patients who are going to have or are trying to decide if they should have the TAVR procedure.

I am calling to ask if you would be interested in sharing your experience with having a TAVR with someone else that in the workup process for TAVR and becoming a member of the local Mended Hearts Chapter. This is an opportunity for you to share your experience with TAVR, give back to our community, and improve our TAVR program.

If the patient states yes:

If you are willing to be a peer support partner for TAVR you will:
- Become a Mended Hearts Member
  - Cost of the first year Member Hearts membership as a TAVR patient will be waived as we are trying to build TAVR patient members
- Complete Mended Hearts training in person or online to learn how to provide peer support
  - You are invited to attend an in-person training session. This session will take approximately 60 minutes.
  - If you do not have a computer, you can come to the Cardiac Office, and I will help you gain access to a computer and complete the training.
  - While Mended Hearts volunteers do one to one visit in the hospital, this requires additional volunteer training with the hospital. At this time, only training through Mended Hearts is needed to be able to contact people by phone.
- Be available to call a new TAVR patient
  - You may be asked to contact 2 to 4 new patients a month by phone
  - This phone call will take about 15 to 20 minutes
  - During your phone call, it is recommended you share
    - Your experience with the TAVR work up process
    - Your experience with managing your aortic stenosis symptoms while waiting for TAVR
    - Your experience with the TAVR procedure
    - Your experience with the hospital stay
    - Your experience with the TAVR recovery process
- As TAVR peer support is new for our Mended Hearts chapters, I will have you:
  - Track the number of times it takes you to contact the new TAVR patient

- o Track the number of minutes you spent sharing your experience with the new TAVR patients

You may decline to become a Mended Hearts member and participate in this program. If you would like to become a Mended Hearts member and participate in this program or learn more about this opportunity, you can come to a meeting with myself and a current Mended Hearts member on (Date to be determined). We will meet in the cardiac surgery office.

If you would like to think about it and get back to me, you can call me at █████████

Thank you for your time.

Appendix L

Patient Consent to Participate in Project

CONSENT TO PARTICIPATE IN PILOT PROJECT

Reducing Anxiety and Increasing Self-Efficacy in the TAVR Population: Implementation of an Enhanced TAVR Care Coordination Model Pilot Project

Kimberlee Einfeld, Master in Nursing, from the Cardiothoracic Surgery clinic at ▮▮▮▮▮▮▮ is conducting a pilot project.

You were selected as a possible participant in this study because your doctor has recommended you as a possible candidate for TAVR. Your participation in this project is voluntary.

Why is this study being done?

The purpose of this project is to help patients feel less anxious and have more confidence about managing their aortic stenosis symptoms while in the work up process for TAVR, about the TAVR procedure, and in making decisions about treatment options.

What will happen if I take part in this pilot study?

If you volunteer to participate in this study, the researcher will ask you to do the following:
- Be given written information about TAVR and symptom management. This is called a Shared Decision-Making Tool.
  - The TAVR Coordinator and/or Interventional Cardiologist will take approximately 10 minutes to review this information with you at your clinic visit
- You will be asked to complete a survey rating Shared Decision-Making Tool. This survey allows you to share your opinion on how useful or not useful you felt this tool was.
- Connect with a Mended Hearts volunteer who has had TAVR. This is called peer support. This will be done by phone and take about 10 to15 minutes. You will be asked if you would like the volunteer to call you or if you would like to be the one to call the volunteer.
  - The volunteer will share with you:
    - What it was like to manage their aortic stenosis symptoms while waiting to here if they would be able to have TAVR.
    - What the work up process for TAVR was like.
    - What the TAVR procedure was like.
    - What it was like to go home after TAVR.
- You will be asked to fill out two surveys before you connect with the Mended Hearts volunteer and again after you talk to the volunteer
  - The surveys will ask you to rate
    - Survey two will ask you to rate your confidence level taking care of your heart health

                         ▪ Survey three will ask you to rate
- An interview approximately 10 to 15 minutes by phone or in person at the clinic with the TAVR coordinator. This allows you the chance to share more about your experience with TAVR peer support and use of the Shared Decision-Making Tool.

How long will I be in the project study?

Participation will last as long as it takes to make a treatment decision for TAVR or symptom management and/or a TAVR procedure is scheduled.

Are there any potential risks or discomforts that I can expect from this study?

I will make every effort to protect your confidentiality. If you are uncomfortable answering any of the interview questions or questions on a questionnaire, you may decline to answer.

In the unlikely event that some of the survey or interview questions make you uncomfortable or upset, you are always free to decline to answer or to stop your participation at any time.

Are there any potential benefits if I participate?

You may benefit from the study by
- A better understanding of your health condition.
- Improved communication with your health care team.
- Decreased anxiety about the procedure and medical treatment decisions
- Increased confidence regarding caring for your heart condition.
- Talk to someone who has been through the process.

The results of the project may help improve the TAVR program and improve the experience for future patients who will need a new aortic valve by the TAVR procedure.

Will information about me and my participation be kept confidential?

Any information that is obtained in connection with this study and that can identify you will remain confidential. It will be disclosed only with your permission or as required by law. Confidentiality will be maintained by means of not including your name will not be used in any written reports or publications, which result project. Also, the organization will not be named in any written reports or publications.

Any surveys you answer will not include your name. Your answers for surveys or interview questions will be stored in a secure computer and only be accessible by the project coordinator and by the project sponsor, ███████████████████████████████

What are my rights if I take part in this study?

- You can choose whether you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and remain in the study.

Who can I contact if I have questions about this study?

- **The project team:**
  If you have any questions, comments or concerns about the project, you can talk to the one of the project coordinators. Please contact:

  Kimberlee Einfeld MN, PCCN-K, RN ██████████████████
  ████████████████████

- **PeaceHealth System Institutional Review Board:**
  If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, please call the IRB at ████████████████████████████████

You will be given a copy of this information to keep for your records.

SIGNATURE OF STUDY PARTICIPANT

Name of Participant

Signature of Participant   Date

SIGNATURE OF PERSON OBTAINING CONSENT

Kimberlee Einfeld, MN, RN, PCCN-K   ██████████████
Name of Person Obtaining Consent   Contact Number

Signature of Person Obtaining Consent   Date

Appendix M

Expense Report

Project: Implementation of Peer Support and Shared Decision-Making Aids for the Transcatheter Aortic Valve Replacement Population

Source of Expense	Expense Description	Dollar Value	Type of Cost (fixed or variable)	Description of Cost	Estimated Volume	Expense per Unit
Program Development		Cost ($)				
Salaries	Project development salary					
Project Manager (PM)	$45/hour x 15 hours a month x 7 months x 1 Project Manager	$4, 500	Fixed	Salary	1@ 100 hours	$45/hour
Valve Coordinator (VC)	$45/hour x 15 hours a month x 7 months x 1 Valve Coordinator	$4,500	Fixed	Salary	1@ 100 hours	$45/hour
Interventional Cardiology* (IC)	$101/hour x 7 hours x 1 hour for 7 months x 1 IC	$707	Fixed	Salary	1 @ 7 hours	$101/hour
Mended Heart Volunteer** (4 volunteers)	$11.50/hour x 7 hours x 1 hour for 7 months x 4 volunteers. Project development stakeholder team meeting	$322	Fixed	Volunteer Hours	4 @ 7 hours	$11.50/hour
Materials (In-Kind)						
Decision Aid Publishing	$0.24 x 30 Decision Aids	$7.20	Variable	Publishing cost	30 Decision Aids	$0.24/unit
Assessment Tools	$0.05 x 4 pages x 75 pages	$3.75	Variable	Printing cost	15 data collection forms	$0.05/page

	Printing cost of data collection form, Cardiac Self-Efficacy Questionnaire, General Anxiety Disorder-7 questionnaire, Preparation for Decision Making Scale				30 Cardiac Self-Efficacy Questionnaires 30 General Anxiety Disoer-1 Questionnaires 15 Preparation for Decision Making Scale	
Space	Use of clinic space to meet with stakeholder team for one hour a month for 6 months	$20	Fixed	Room Space Rental	6 @ 1 hour	$20/hour
Mended Hearts Membership	$34 x 12 months x 1 person. Cost of annual membership for Mended Hearts & Training to become Mended Heart TAVR peer volunteer included in membership fee	$70	Fixed	Annual Fee	2 TAVR peers	$35/person
Program Implementation	**Expense Description**	**Dollar Value**	**Type of Cost (fixed or variable)**	**Description of Cost**	**Estimated Volume**	**Expense per Unit**
Salary						
Project Manager	$45 x 24 hours over 3months x 1 project manager. Data entry of questionnaires. One to one interview data collection x 15 patients	$1,080	Fixed	Salary	1 @ 24 hours	$45/hour
Valve Coordinator	$45 x 100 hours over 3 months x Valve Coordinator. Data collection, connect TAVR patient to peer, present	$4,500	Fixed	Salary	1@ 100 hours	$45/hour

	patient with decision aid and initiate shared decision-making process					
Multidisciplinary Team -Valve Coordinator -Interventional Cardiologist (IC) -Cardiac Surgeon -Cardiologist	$45 x 2 hours x a month $101.00 x 2 hours x a month x 3 months $121 x 2 hours a month x 3 months $101 x 2 hours a month x 3 months	$270 $606 $726 $606	Fixed Fixed Fixed Fixed	Salary Salary Salary Salary	1 @ 6 hours 1 @ 6 hours 1 @ 6 hours 1 @ 6 hours	$45/hour $101.00/hour $121/hour $101.00/hour
Mended Hearts TAVR Volunteer	$5.75 x 30minutes per TAVR peer x 15 new TAVR Patient. Time providing peer to peer support	$86.25	Variable	In Kind	1@ 30 minutes	$5.75/30 minutes
Evaluation/Assessment	**Expense Description**	**Dollar Value**	**Type of Cost (fixed or variable)**	**Description of Cost**	**Estimated Volume**	**Expense per Unit**
Analysis of pre and post Cardiac Self-Efficacy & General Anxiety & Preparation for Decision Making Scale & questionnaires & Interview questions	$45 x 75 hours x 1 Project Manager $45 x 25 hours x 1 Valve Coordinator. Personal time for preparation, follow - up and survey data entry/analyses and dissemination of finding	$3,375 $1,125	Fixed Fixed	Salary Salary	1 @ 75 hours 1 @ 25 hours	$45/hour $45/hour

*Physician (Interventional Cardiologist, Cardiologist), Surgeon, and Marketing salary rates based on information from the Bureau of Labor Statistic for Washington State.

** Volunteer salary rate based on Washington State minimum wage

Appendix N

Scholarly Project 3-Year Budget Plan

Expenses	Year 1	Year 2	Year 3	Rationale
Operating Expense				
Personnel	**Salary**	**Salary**	**Salary**	
Valve Coordinator	$10,125	$6,674.40	$8, 020.32	--105 hours during the first year only for development of the program. Year 1 = 4 TAVR patient procedures a month = 4 patients a month = 12 hours a month for year 1 (48 patients a year) --1 patient = 2 hours of Valve Coordinator time for use of decision aid, pre/post assessment of anxiety & cardiac self-efficacy --Year 2 and 3 expect TAVR program growth of additional 1 patient a month receiving TAVR procedure due to growth in number of aging population Year 2 = 5 patients a month = 60 patients, a year Year 3 = 6 patients a month = 72 patients, a year --Hour bi-monthly multidisciplinary meeting (24 hours a year). --3% increase in annual salary year 2 and 3 per organization annual rate
Project Manager	$9,180	$0	$0	--204 hours during the first year only for development of the program,

				implementation and evaluation for the project manager (DNP student). —Continued evaluation during year 2 and year 3 will be done during the multidisciplinary bi-monthly team meetings.
Interventional Cardiology	$3,131	$2,496.72	$2,569.20	Interventional Cardiologist provided an additional 7 hours during the first year only for support of program development from, in addition to hour bi-monthly multidisciplinary meeting --hour bi-monthly multidisciplinary meeting. --3% increase in annual salary year 2 and year 3 per Organization rate annual rate
Cardiothoracic Surgeon Cardiology	$2,904 $2,424	$2,991.12 $2,495.72	$3,080.64 $2,569.20	--hour bi-monthly multidisciplinary meeting. --3% increase in annual salary year 2 and year 3 per Organization rate annual rate
Mended Hearts Volunteers	$633	$720	$972	--1 hour of volunteer time per patient. Washington state minimum wage increase for year 2 and year 3 based on Washington State Department of Labor & Industries. --An additional 7 hours a volunteer for the first year only for program development team meetings.

Membership & Training	Annual Fee	Annual Fee	Annual Fee	
Mended Hearts Membership & Training	$70	$0	$0	Non-profit organization, no membership/training fee increase. Mended Hearts Member providers one to one TAVR peer support to new TAVR patients Year 1 = $35/ 1-person x 2 TAVR organization sponsored first year peer support membership fees
Materials				
Decision Aid	$ 5.75	$ 14.40	$17.28	--4-page Decision Aid. $0.06 a page x 4 pages x patients for year 1. Year 1 = $ 0.24 1 Decision Aid for 24 patients (program begins in June of 2019) Year 2 = $ 0.24/ 1 Decision Aid x 60 patients Year 3 = $ 0.24/1 Decision Aid x 72 patients --Year 2 and year 3 at a 2.7% inflation rate (US Inflation Calculator, n.d.).
Assessment Tools	$ 7.50	$ 0	$0	--3-page anxiety, cardiac self-efficacy assessment & data collection tool. $0.10 a pages x 4 pages x 15 patients for year 1. Assessment tools only used in year 1 for 3 months.
Conference Room Rental				

| Space for meeting/conference room | $140 | $0 | $0 | --Meeting space to meet with Mended Hearts Volunteers for program development. Year 1 only for 7 hours. --Value of $20 an hour --Year 2 and year 3 TAVR peer volunteers will be a part of the routine monthly Mended Hearts meeting at Organizations education center. |
| **Total Operating Expenses** | $28,620.25 | $15,392.36 | $17,228.64 | |

US Inflation Calculator. (n.d.) Current US inflation rates: 2008-2018. Retrieved from: https://www.usinflationcalculator.com/inflation/current-inflation-rates/

Appendix O

Statement of Operations

Statement of Operations	
2019	
Revenue	
Mended Hearts Training & Membership	$140
Program Materials	$13.25
• Decision Aid, Assessment Tool	
Meeting Space (In-Kind)	$140
Project Manager (In-Kind)	$9,180
Peer Support Volunteer Personnel (In-Kind)	$656
Salary	$18,584
Valve Coordinator, Interventional Cardiology, Cardiothoracic Surgeon, Cardiology, (In-Kind)	
Total	$28,713.25
Expenses	
Mended Hearts Training & Membership	$140
Program Materials	$13.25
• Decision Aid, Assessment Tool	
Meeting Space (In-Kind)	$140
Project Manager (In-Kind)	$9,180
Peer Support Personnel	$656
Salary	$18,584
• Valve Coordinator, Interventional Cardiology, Cardiothoracic Surgeon, Cardiology, (In-Kind)	
Total	$28,713.25
Operating Income	**$0.00**

*Physician (Interventional Cardiologist, Cardiologist), Surgeon, and Marketing salary rates based on information from the Bureau of Labor Statistic

** Volunteer wage value based on Washington State mini

Appendix P

Theoretical Model

Bandura's self-efficacy theory was selected as a theoretical framework as it brings together identifying and describing the phenomena of coping and stress and provides a format for evaluating why the phenomena occur (Lazarus & Folkman, 1987). Self-efficacy is a social-cognitive theory that was developed in 1977 by Albert Bandura. Self-efficacy is a person's belief about how they can overcome stressful event, cope with a life challenge or perceived threat (Bandura, 1994). High perceived self-efficacy is the thinking that one can overcome a challenge and leads to more positive thoughts about good outcomes from a procedure, while low self-efficacy, thoughts about not being able to cope with a disease process or feeling overwhelmed by needing a heart procedure can lead to poor health outcomes. Low self-efficacy is associated with stress, anxiety, and feelings of helplessness, which can lead to poor health outcomes (Zulkosky, 2009). Improving self-efficacy can assist people in overcoming negative feelings, build confidence and lead to positive health outcomes.

Increasing a person's self-efficacy leads to being able to overcome the fear and anxiety associated with managing a complex health condition, navigating the health system, increase confidence to be an active participant in treatment decision and having a medical procedure. It promotes quality of life and improved health outcomes. This theory provides a framework for supporting the peer support and use of a decision aid intervention in the pilot project.

Theoretical Model: Bandura's Self-Efficacy
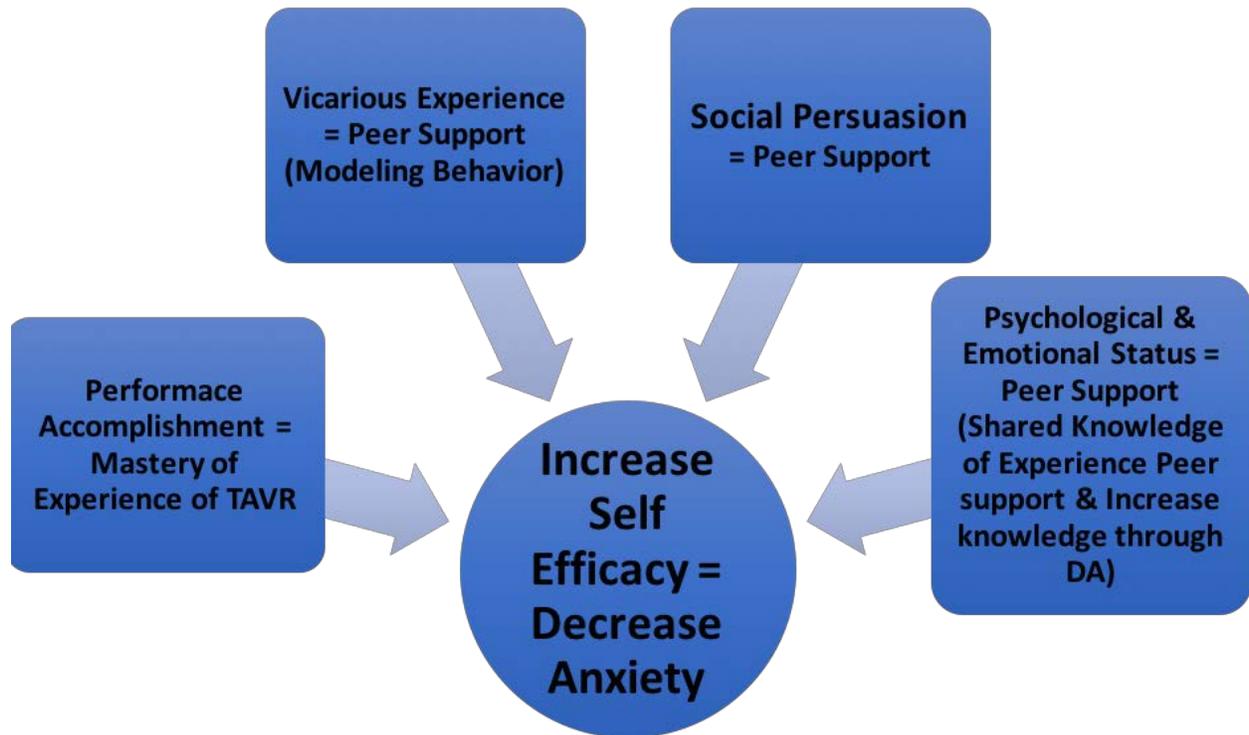
Appendix E
Memorandum of Understanding

Memorandum of Understanding

Memorandum of Understanding

Between

Kimberlee Einfeld, Doctor of Nursing Practice (DNP) student

Boise State University

and

[REDACTED]

This Memorandum of Understanding (MOU) outlines the terms and understanding between the Kimberlee Einfeld a DNP student at Boise State University, and [REDACTED] Center, to pilot a project to enhance the Transcatheter Aortic Valve Replacement (TAVR) Care Coordination to include peer support and use of a decision aid for the aortic stenosis population in the TAVR work up process.

Background

Aortic stenosis is a progressive disease affecting 1.5 million people in the US, of which a portion are experiencing symptoms of shortness of breath, lightheadedness and dizziness, chest pain, edema, and decreasing quality of life (Moore, Chen, Mallow & Rizzo, 2016). Once the valve becomes severely stenotic and symptoms develop, there is a death rate of 50% within two years if left untreated and the only viable treatment option is replacement (Leon et al., 2010). Valve replacement by open-heart surgery (SAVR) or by minimally invasive transcatheter approaches (TAVR) are the only therapies that can relieve symptoms, improve quality of life and decrease mortality (Nishimura et al., 2014; Smith et al., 2011, Svensson, et al., 2013). Patients in Bellingham, Washington pursuing transcatheter aortic valve replacement (TAVR), experience anxiety and are at risk for low self-efficacy related to the ongoing need to manage aortic stenosis symptoms, navigate multiple provider appointments, multiple tests, and make and understand multiple complex medical decisions while waiting for recommendations from the treatment team. During this time they must cope with the knowledge of a poor life expectancy without valve replacement, knowledge of potential procedural risk and the possibility of being declined TAVR and being recommended for medical therapy (Lauck et al., 2016 & Olsson, et al., 2016). This uncertainty during the work up process can lead to anxiety and low self-efficacy, which is

associated with poor health outcomes, such as decreased quality of life (Parent & Fontin, 2000 & Winder, Hiltunen, Suthares & Butzlaff, 2004).

The TAVR population is growing due to advances in medicine and changes in eligibility criteria allowing more people to be treated by TAVR. Implementing evidence-based interventions aimed at decreasing anxiety and increasing self-efficacy in the TAVR population has the potential to improve health outcomes, quality of life and patient satisfaction; therefore, these interventions should be sought, implemented and evaluated. This scholarly project will propose peer support and use of a shared decision-making tool as interventions to decrease anxiety and increase self-efficacy in the TAVR population.

Purpose

The purpose of the project is to decrease anxiety and increase self-efficacy, through peer support and use of a decision aid that enhances shared decision-making. The student will engage the local Mended Hearts chapter and past TAVR patients to develop and implement peer support in the TAVR population. The student will engage the Structural Heart Multidisciplinary team to identify and implement a shared decision making tool to be used during pre-TAVR physician and/or nurse consultations with patients in the work up process. The interventions will be evaluated for their effectiveness and to gain insight from patients into how to improve the TAVR program.

Intended Project Outcomes

The purpose of this pilot project for the TAVR population is to:

- Decrease anxiety for patients while waiting for TAVR.
- Increase self-efficacy for managing aortic stenosis symptoms while in the work up process.
- Provide shared experience through peer support to those pursing TAVR during the work up process
- Assist the local Mended Hearts chapter expand services to TAVR population.
- Implement a decision aid for shared decision making to increase patient knowledge regarding treatment decisions and care pathway for TAVR

Duration

The Scholarly Project will begin within the organization during December of 2018 and the project will be completed in May of 2020. During this timeframe the student will engage stakeholders of the TAVR program for planning and development of TAVR peer support and development/identification of a decision aid, implementation of the interventions, evaluation of the interventions, and discrimination of the evaluation findings.

Reporting

The DNP Scholarly Project will include a final report, an abstract, an oral presentation of the report and potential publication. The DNP student will submit a Final Project Report for publication in ScholarWorks. ScholarWorks is a collection of services designed to capture and showcase all scholarly output by the Boise State University community, including doctoral dissertations and doctoral project reports. The Enhanced TAVR Care Coordinator Model will be

submitted to Magnet Steering Council and ▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓ am by May 2020.

No personal identifiers will be included, and all data will be reported in aggregate form. The project will be submitted t ▓▓▓▓▓ or IRB approval. The author welcomes any comments or suggestions from ▓▓▓▓▓▓▓▓▓▓▓▓▓ but reserves the right to publish findings and analysis according to professional standards and principles of academic freedom. For any work of a scholarly nature, the author agrees to follow the organization(s) preferences in how it is to be named (or not) in the work. For the final report, abstract, publication and presentation purposes, the ▓▓▓▓▓▓▓▓▓▓▓▓ will be referenced in the DNP Scholarly Project as a primary care hospital located in the Pacific Northwest.

Student Contact Information
Kimberlee Einfeld
Phone: ▓▓▓▓▓▓▓▓▓▓▓▓▓▓
Email: ▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓▓

Kimberlee Einfeld _____ Date: *N/34/19*
(DNP Student signature)
Kimberlee Einfeld, Boise State University DNP student

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(Organizational Contact signature)
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Appendix Q

Outcome Evaluation Table

Outcome	Data Collection Instrument / Data	Analysis Goal	Analytic Technique
1. At the medical center in the Pacific Northwest a structured peer support program is developed for TAVR patients who are in the work up process by May of 2019. (PO)	**Instrument:** A Yes/No checklist and activity log will be used to track specific program elements as being completed and implemented. The checklist will quantify the task completed by a yes/no question. The activity log counts the number of meetings, hours, and stakeholders involved to create the program. **Data:** Yes/No questions for checklist developed with the stakeholder team • The TAVR peer support program was implemented by May of 2019? Activity Log • Number of meetings with stakeholder team • Number of hours from Valve Coordinator to provide supervision of the program elements • Number of past TAVR patients who become certified volunteers	1. Checklist will quantify the tasks completed. 2. Checklist and activity logs will provide insight into program activities and provide information on whether or not the outcome was met. This information is important to note for replication of the program at another organization. 3. Provides insight into resources and time needed to make a TAVR peer support program successful.	Information of program task completed as noted by yes/no on checklist. No further analysis
2. At the medical center in the Pacific Northwest, a Decision Aid Tool is used 95% of the time with patients on the TAVR pathway work up from June of 2019 to Aug of 2019 and 80% of patients indicated the Decision Aid	**Instrument:** Activity log will provide a count of how often the Decision Aid Tool was used during the shared decision-making process in patients in the TAVR pathway. For the pilot project, the tool will be used during consultation with the interventional cardiologist and/or with patient visits with the Valve Coordinator.	1. Activity log will capture • If and when the tool was used • If patient information from the tool was shared at the multidisciplinary structural heart team meetings.	One on One interviews conducted by the project manager with TAVR program participants. Feedback will be aggregated and categorized by frequency of

| Tool enhanced the shared decision-making process (PO). | Preparation for Decision Making Scale Questionnaire. Uses ten questions to evaluate the if the patients found the aid helpful in assisting with SDM and scores them 1 to 5 on a Likert scale. The scale asks series of questions related to, did this educational material . . . and scores them one equals not at all through while 5 equals a great deal.

Interview question will be used to determine the common patient reported factors of using the Decision Aid Tool. The project manager will the conduct interviews. The answers will be reviewed for commonalties and key elements that provide insight into what patients liked or did not like about the decision aid or shared decision-making process.

Data:
Activity Log
• Number of times valve coordinator provides patient with Decision Aid Tool at first contact
• Number of times Decision Aid Tool is used at consult with patient and Interventional Cardiologist
• Number of times use of Decision Aid tool documented in EHR
• Number of time Decision Aid tool information regarding patient information (goals/values) shared at bi-monthly Structural Heart Multidisciplinary clinical conference & documented in meeting notes

Preparation for Decision Making Scale to evaluate the effect of the SDM aid
• Help you recognize that a decision needs to be made?
• Prepare you to make a better decision?
• Help you think about the pros and cons of each options? | 2. Activity log provides insight into resources and time needed to incorporate a decision-making tool for shared decision making into the TAVR work up process.

3. Use of open-ended interview questions patients will indicate if the use of a Decision Aid Tool enhanced the shared decision-making process.

4. The use the decision-making scale will quantify the usefulness of the SDM tool and allow patients to provide feedback for how useful they found the tool.

5. Interview questions provides insight into the patient experience with the decision-making process for TAVR.

6. Data collection of the interview questions provide an opportunity for patients to give feedback on the shared | responses. The information will be presented in a summary table for visualization of the feedback responses. |

	• Help you think about which pros and cons are the most important? • Help you know that the decision depends on what matters most to you? • Help you organize your own thoughts about the decision? • Help you think about how involved you want to be in this decision? • Help you identify questions you want to ask your doctor? • Prepare you to talk to your doctor about what matters most to you? • Prepare you for a follow-up visit with your doctor? Interview Questions • How did the use of a decision aid enable you to engage with your physician during the TAVR work up process?	decision-making process and decision aid. 7. The patient feedback will be used to confirm the benefits of using a decision aid and/or make improvements to the aid and shared decision-making process.	
3. At, the medical center in the Pacific Northwest of the 4 past TAVR patients selected for training, 50% are trained and provide 1:1 peer support to patients in the TAVR work up process from June through August of 2019. (CO)	**Instrument:** Activity logs will capture program actions completed by the Mended Hearts TAVR peers and the time they spend providing support. An interview question will be used with both Mended Hearts TAVR peer partners and new TAVR patients to gain insight into their experience with peer support. **Data:** Activity Log • Number of past TAVR patients that complete Mended Hearts training to become certified peer support partners • Number of patients referred for TAVR peer support between May & Aug 2019	1. Activity log will capture the time and resource needs to provide peer support. 2. Log quantifies the number of past and new TAVR patients participating in the program. 3. The data provides insight into resources and time needed to incorporate peer support	One on One interview conducted by the project manager with TAVR program participants. Feedback will be aggregated and categorized by frequency of responses. The information will be presented in a summary table for visualization of the feedback responses.

	• Number of peer data collection forms completed by Mended Hearts TAVR peer • Data Collection Form for Mended Hearts TAVR peer • Number of attempts to reach new TAVR patient by phone • Number of minutes TAVR peer spent with new TAVR patient providing support and sharing TAVR experience Open Ended Interview Question • Tell me about your experience with TAVR peer support.	into the TAVR work up process. 4. Interview question will provide data regarding the experience of Mended Hearts and new TAVR patients with peer support. 5. Open-ended questions provide an opportunity for patients to share their experience in their own words. This information will be examined for common feedback elements that will be used to support, customize, and improve the intervention.	
4. At the medical center in the Pacific Northwest, 50% of patients who received peer support show a decrease in anxiety as evidenced by the General Anxiety Disorder -7 (GAD-7) scale by Sept 2019. (CO)	**Instrument:** A pre-then-post design is used to compare anxiety before and after receiving peer support for patents in the TAVR work up process. The pre-then-post evaluation of anxiety is evaluated by the six questions, using the validated, **Data** The validated General Anxiety Disorder-7 (GAD-7) scale will be used. Patients are requested to rate • Feeling nervous, anxious, or edge? • Not being able to stop or control worrying?	1. To quantify patient's perception of anxiety in regards to the TAVR work up process 2. Evaluate the impact of peer support in decreasing anxiety. 3. Provides information to the stakeholders of the program regarding	Descriptive statistics. The GAD-7 was selected for its ease of use due to its short format, low cost, ability to collect the data in a timely manner and simplicity in scoring.

		effectives of Peer Support.	
	- Worrying to much about different things? - Trouble relaxing? - Being so restless that it is hard to sit still? - Becoming easily annoyed or irritable? - Feeling afraid as if something awful might happen to you? If you checked off any problems, how difficult have these made it for you to do your work, take care of things at home, or get along with other people?		
5. At the medical center in the Pacific Northwest, 50% of patients who received peer support show an increase in cardiac self-efficacy as evidenced by the Cardiac Self Efficacy questionnaire by Sept 2019. (CO)	**Instrument:** The validated Cardiac Self-Efficacy Questionnaire measures self-efficacy in patients with cardiac disease. The questionnaire provides information on a patient's confidence with knowing or acting on 16 items. The scale queries patient's perception on control of symptoms and ability to maintain function. **Data:** The Cardiac Self-Efficacy (CSE) Questionnaire. The CSE uses a 13-item Likert-scale to measure patient's cardiac confidence. The items are rated 0 through 4 (0= not at all, 1=somewhat confident, 2=moderately confident, 3 very confident, 4=completely confident) or may select "not applicable". **How confident are you that you know or can:** - Control your chest pain by changing your activity level - Control your breathlessness by changing your activity levels - Control your chest pain by taking your medications - Control your breathlessness by taking your medications - When you should call or visit your doctor about your heart disease	1. Quantify patient's perception on anxiety and Cardiac Self-Efficacy in regards to the TAVR work up process. 2. Evaluate the impact of peer support in increasing cardiac self-efficacy 3. Provides information to the stakeholders regarding effectives of Peer Support.	Descriptive statistics The Cardiac Self-Efficacy questionnaire was selected for its targeting of questions related to self-efficacy of cardiac disease, low cost, ability to collect the data in a timely manner and simplicity in scoring.

	• How to make your doctor understand your concerns about your heart • How to take your cardiac medications • How much physical activity is good for you • Maintain your usual social activities • Maintain your usual activities at home with your family • Maintain your usual activities at work • Maintain your sexual relationship with your spouse • Get regular aerobic exercise (work up a sweat and increase your heart rate)		
6. The Enhanced TAVR Care Coordinator Model is submitted to Magnet Steering Council and the medical center in the Pacific Northwest's Cardiovascular System Leadership Team by May 2020. (CO)	**Instrument:** Yes/No checklist will be used to quantify the action as complete or incomplete. **Data:** Yes/No Question • Was a document written detailing integration of a Decision Aid Tool and TAVR peer support into the Enhanced TAVR Care Coordination Model? • Was the Enhanced TAVR Care Coordination Model presented to Clinical Inquiry Council committee by May of 2020? • Was the enhanced TAVR Care Coordination Model presented to local Mended Hearts Chapter?	1. Checklist provides a mechanism for sharing of information regarding whether or not the program outcome was met.	Information of program task planned completed answer by yes/no require no further analysis

Appendix R

Policy Implications

Policy sets practice and organizational standards that we must all adhere to and provides guidance for what and how something should be done (Mason et al., 2016). Cardiac surgeons or cardiac interventionalists may have a bias toward treatment options, and peer support and use of SDM aid can assist in neutralizing this bias. This DNP project has demonstrated that the use of peer support and the use of a shared decision-making (SDM) aids can be effective interventions to decrease anxiety and increase self-efficacy in the TAVR population while also enhancing the shared decision-making process which decreases bias of the presentation of treatment options.

The Center for Medicare and Medicaid Services (CMS) identifies SDM as an essential component of patient care and recommends it be a part of routine care for every patient (CMS, 2018). The CMS requirement for SDM in the TAVR population, works to improve quality, and ensure organizations are held to national standards of care. In the initial recommendations for the 2019 TAVR guidelines, it was proposed that the use of decision aids without commercial bias be used in the SDM process and be documented as part of the TAVR decision-making process between patients and their providers (Bavaria et al., 2018). The use of the SDM aids was not included in the 2019 CMS guidelines; however, the use of a SDM process was maintained as a core essential in the 2019 national coverage decision guidelines (CMS, 2019). The TAVR population is growing due to advances in medicine and changes in eligibility criteria allowing more people to be treated by TAVR. Next steps for policy should include further research with the TAVR population to validate the SDM aids and/or to improve upon the aids and to include their use in the CMS guidelines for all patients needing aortic valve replacement.

Appendix S

Dissemination

Preliminary project results were presented at the local Mended Hearts chapter meeting with approximately 50 community members present in August of 2019 and final results were presented at Boise State University in March of 2020. Due to changes in leadership at the pilot project site, the project was not presented to the Magnet Steering committee or Cardiovascular System Leadership team (Outcome 6). Instead, the project was presented in February 2020 at the project center's Clinical Inquiry Council as this council tracks and provides a pathway for dissemination of all research and projects done at the medical center. A poster presentation was accepted for presentation at the April 2020 Western Institute of Nursing Research Information Exchange and at annual nursing conference at the project site in May of 2020. A manuscript is in progress and will be submitted in the spring/summer of 2020 to a selected journal.