Transcatheter Aortic Valve Replacement: Implementation of Shared Decision-Making

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Transcatheter Aortic Valve Replacement: Implementation of Shared Decision-Making

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# TABLE OF CONTENTS

## Section I: Title and Executive Summary

- Title ................................................................................................................. 1
- Executive Summary ..................................................................................... 7

## Section II: Introduction .................................................................................

- Background .................................................................................................... 9
- Problem Description ...................................................................................... 9
- Setting ............................................................................................................. 10
- Aim Statement ............................................................................................... 10
- Available Knowledge .................................................................................... 11
- PICOT Question ............................................................................................. 11
- Search Methodology ...................................................................................... 11
- Integrated Review of the Literature .............................................................. 11
- Summary/Synthesis of the Evidence ............................................................. 15
- Rationale ......................................................................................................... 16
- Theoretical Framework Guiding the Change in Practice ............................ 17

## Section III: Methods .....................................................................................

- Context .......................................................................................................... 18
- Stakeholders .................................................................................................. 19
- Interventions .................................................................................................. 19
- Gap Analysis .................................................................................................. 21
- Gantt Chart ..................................................................................................... 22
- Work Breakdown Structure .......................................................................... 22
<table>
<thead>
<tr>
<th>Appendix</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appendix G. Budget</td>
<td>56</td>
</tr>
<tr>
<td>Appendix H. Communication Plan</td>
<td>58</td>
</tr>
<tr>
<td>Appendix I. KCCQ-12 Questionnaire</td>
<td>59</td>
</tr>
<tr>
<td>Appendix J. Shared Decision-Making Tools</td>
<td>60</td>
</tr>
<tr>
<td>Appendix K. Analysis</td>
<td>62</td>
</tr>
<tr>
<td>Appendix L. Statement of Determination</td>
<td>65</td>
</tr>
<tr>
<td>Appendix M. Organization Letter of Support</td>
<td>71</td>
</tr>
</tbody>
</table>
Section I: Executive Summary

Background: The setting for this study is the structural heart program of a large healthcare organization in the Greater Sacramento area in California. Aortic stenosis (AS) is the most common cardiovascular valvular disease in the elderly. The treatment of AS is complex and over the last decade, the transcatheter aortic valve replacement (TAVR) procedure has changed the management of this high-risk group and has become the standard of care.

Problem: The structural heart team performs an average of 170 TAVR procedures annually. The program is relatively new, and although it is performing above the national averages for specific program outcome measures, the evidence-based best practice of Shared Decision-Making (SDM) has not been formally adopted by this team, and therefore not utilized in the pre-TAVR work-up.

Interventions: The goal of implementing the use of an SDM tool is to improve Quality of Life (QOL) outcomes by facilitating meaningful patient participation in decisions related to treatment options available to them using an individualized risk score based on their comorbidities, as well as to consider personal health and lifestyle goals.

Outcome Measures: The outcome measure for this change in practice project aims to achieve a QOL score of 45 points or greater out of 100 at 30 days post-TAVR procedure using the Kansas City Cardiomyopathy Questionnaire-12 (KCCQ-12). The primary process measure is the utilization rate of the SDM tool for 95% by the structural heart team with patients referred for non-emergent TAVR.

Results: A total of 63 patients underwent the TAVR procedure performed by this structural heart team between March 1 and May 31, 2021. 90.66% of these patients had an increase in their QOL score at or above 45 at 30-days post-TAVR procedure. The SDM tool was utilized with 100% of patients referred to this program for the TAVR procedure within the study period.
**Conclusion:** The implementation of the SDM tool greatly benefitted the team, patients, and caregivers to ensure everyone was clear on what the patient goals were and how they influenced treatment decisions and patient’s QOL.

*Keywords:* shared decision-making, quality-of-life, TAVR, aortic stenosis
Section II: Introduction

Background

Aortic stenosis (AS) is the most common valvular cardiovascular disease in the older patient population, and it results in decreased quality of life (QOL) for patients (American Heart Association [AHA], 2020). The conventional treatment for AS is a surgical procedure to replace the aortic valve. This surgical procedure improves the patient’s QOL and, ultimately, survival. Unfortunately, not all patients with AS are eligible for the conventional surgical aortic valve replacement (SAVR) procedure due to other comorbidities that increase their risk of complications from surgery (American Heart Association [AHA], 2020).

Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure to replace the stenotic aortic valve. The TAVR procedure has transformed the treatment of patients with severe AS who are too high risk for conventional surgery. Currently, TAVR is the standard of care for intermediate, high-risk, and inoperable AS patients. However, one in four patients considered high risk for surgery die within one year following TAVR, challenging the heart team to provide much needed meaningful guidance to patients (Lauck et al., 2016).

Problem Description

The Expert Consensus Decision Pathway from the American College of Cardiology recommends a shared decision-making (SDM) approach for patients with AS who are considering the TAVR procedure (Otto et al., 2017). Patient management relies on SDM based on a comprehensive understanding of the risk-benefit ratio of different treatment modalities and integration of patient preferences and values (Otto et al., 2017). SDM involves educating patients and their families about treatment options available to them. Guidelines also recommend that patient goals and expectations be determined early in the process as related to life expectancy,
improvement in symptoms or survival, and end-of-life context (Otto et al., 2017). Medicare requires documentation of SDM utilizing an evidence-based tool for reimbursement eligibility for certain heart procedures, but it has not been a requirement for TAVR and is not widely used in practice. Research has shown that SDM tools increase patient knowledge about their disease and risk factors of different treatment options available, resulting in patients experiencing less internal conflict when deciding on how to proceed with treatment (Barry & Edgman-Levitan, 2012).

Setting

The setting for this change of practice project is the structural heart program of a large healthcare organization in the Greater Sacramento, California area. At baseline, this structural heart team was not utilizing SDM as a tool to guide the selection process for TAVR patients. This healthcare organization consistently seeks to decrease risk, improve patient satisfaction, and involve patients and families in directional decisions of the organization, making the absence of SDM within direct patient care notable and not aligned with the values of the organization. The aim of this quality improvement project is to explore the integration of an SDM tool into patient selection for patients with AS who are referred for the TAVR procedure within this specific structural heart program.

Aim Statement

Develop, implement, and evaluate a shared decision-making tool process to improve the quality of life for 95% of aortic stenosis patients referred to the structural heart program of a large healthcare organization in the Greater Sacramento, California area for the transcatheter aortic valve replacement procedure by October 1, 2021.
Available Knowledge

PICOT Question

In patients with AS (P), how does an SDM strategy (I), compare to no strategy (C), as part of the TAVR selection process affect QOL post-TAVR, as evidenced by achieving a score of 45 or greater out of 100 possible points on the Kansas City Cardiomyopathy Questionnaire, which consists of 12 questions (KCCQ-12), the answers to which are scored (O) at 30-days post-TAVR (T).

Search Methodology

An electronic search was conducted between February 5 and December 31, 2020, in the Cochrane Database of Systemic Reviews, Cumulative Index to Nursing and Allied Health Literature Complete, and Pub Med databases. Limitations included research studies in the English language, including adults only, with publication dates no earlier than 2010. Search terms included: ethical issues + TAVR, patient selection + TAVR, heart team + TAVR, and shared decision-making + TAVR, which yielded 23 articles. Eight articles were chosen based on relevance to the PICOT question and the population groups included in the studies. The Johns Hopkins Nursing Evidence-Based Practice appraisal tools (Dang & Dearholt, 2018) were used to appraise the evidence for this review (see Appendix A).

Integrated Review of the Literature

The following three studies within the review did not specifically evaluate the use of SDM tools but are important studies to include in this review as they provide valuable evidence regarding the benefits of the TAVR procedure as related to QOL post-procedure. These studies also describe how patients evaluated for the TAVR procedure were able to clearly express their
treatment goal wishes, but also did not feel that they received adequate education from their
treatment team to make an informed decision.

**Health-Related QOL**

In a systematic review and meta-analysis, Straiton et al. (2018) evaluated functional
capacity, as well as health-related quality of life (HRQoL) of TAVR patients for up to 12 months
post-procedure. Results indicated that patients had a significant improvement in both functional
capacity (95% CI 9.69 – 73.28) and in their ability to perform daily tasks post-procedure (95%
CI 3.16 – 7.68). Both outcomes had a positive impact on the HRQoL of patients, as their physical
limitations were reduced, resulting in more independence for the patient.

**Informed Decision-Making and Treatment Goals**

The results of a retrospective qualitative review by Coylewright et al. (2015) determined
that elderly patients with severe AS can define treatment goals, with the most commonly
reported goals being the ability to do a specific activity and spend time with loved ones. Patient
goals were categorized into four groups, varying from the ability to maintain independence to
being able to perform one specific activity. Assessment of achievement of patient goals by the
study team was done via medical record review 30 days following TAVR, as well as patient
assessment by the TAVR coordinator during the follow-up visit. Results showed that 87% of
patients achieved their treatment goals (Coylewright et al., 2015). Although the sample size was
small, it was sufficient for the study design and results were definitive with clear
recommendations for practice.

In a non-experimental, comparative study, Dharmarajan et al. (2017) explored the beliefs
of 407 patients with AS at nine valve centers in the United States. The objective of the study was
to determine if patients received adequate education to enable an autonomous, informed decision
regarding different treatment options and plans of care. Patients were categorized in TAVR (212 patients), SAVR (124 patients), and medical management (71 patients) groups. Statistically significant results showed that medically managed patients were less likely to report they received enough information about the benefits and risks of treatment options ($p = 0.03$), their physicians involved them in treatment decisions ($p < 0.001$), or final decisions were the right decisions ($p < 0.001$). Limitations included a non-randomly selected study population and the sample drawn from nine leading valve centers in the United States, which may make the care provided at these centers not generalizable.

**Benefits of SDM Tools**

Four of the studies evaluated the benefits of SDM tools. In a patient-level meta-analysis of seven randomized control trials, Coylewright et al. (2014) studied the use of SDM aids versus no SDM aids used. The researchers used a random effects model to evaluate the impact of sociodemographic patient information (sex, age, and education) on the outcomes of the discussion of treatment options, decisions made, and patient involvement in SDM. Study results showed that, compared to usual care, patients who used an SDM aid felt their knowledge increased, they had more information available to them regarding risk factors, and they felt less conflicted in making a decision regarding their treatment due to SDM (Coylewright et al., 2014). Only small numbers of people of color were included in the study population, which presents a study limitation. More research is needed to investigate the role of race and the use of SDM aids.

In a study by Coylewright et al. (2020), one of the most surprising findings was that clinicians did not perceive a benefit to the use of an SDM tool. In this mixed-methods study, Coylewright et al. investigated clinician and patient attitudes towards the use of decision tools. Despite the lack of perceived benefit of the tool by clinicians, results from patients indicated
significant improvement in knowledge and SDM with the use of a decision tool by clinicians (79.0% for SDM group versus 17.9% for no SDM tool utilization). Unfortunately, a lack of perceived benefit by clinicians could likely limit full adoption and implementation of the decision tool.

Marsch et al. (2019) used a quantitative benefit-risk analysis to evaluate patient preferences when deciding between TAVR and SAVR. Study results showed that 75.1% of patients favored TAVR over SAVR, favoring the less invasive procedure even with the possibility of a significant increase in certain risks, such as a disabling non-fatal stroke and the need for a permanent pacemaker. This finding supports the need for an SDM tool that guides patients and clinicians to choose the best procedure based on clinical indications and patient risk.

In a prospective, randomized, controlled trial, Korteland et al. (2017) evaluated the use of an SDM tool and the effect on preoperative decisional conflict, patient knowledge, anxiety, and depression in patients referred for valve replacement procedure. Results showed that preoperative decisional conflict did not differ between the groups, but patients aided by SDM felt better informed and experienced less anxiety and depression when the tool was used (Korteland et al., 2017).

**Consensus Statement**

An Expert Consensus Systems of Care document by the American Association for Thoracic Surgery, the American College of Cardiology, the Society for Cardiovascular Angiography and Interventions, and the Society of Thoracic Surgeons (STS) provided a quality framework for TAVR centers in the United States (Bavaria et al., 2019). Despite the recommended framework, it is not mandated and therefore not widely adopted by structural heart centers in the United States. The TAVR procedure continues to be an evolving therapy, and its
approval for a specific patient population does not mean that it is the treatment of choice for all patients within that population. Patient- and family-centered care that includes the use of an SDM tool is recommended by several professional organizations in the consensus statement (Bavaria et al., 2019).

**Summary/Synthesis of the Evidence**

This review answered the PICOT question. Evidence indicated that AS patients are able to articulate the goals of treatment and want to be involved in the decision-making process to determine their best options. The goals of improved QOL and independence were important for most patients. Study results showed that TAVR increased functional capacity and ability to perform daily tasks, making these goals achievable. Unfortunately, results also indicated that patients lacked sufficient patient education to participate in SDM (Dharmarajan et al., 2017).

Physicians reported that patient preference was the most common reason patients selected medical management over TAVR or SAVR. This is an interesting finding given that results indicated that patients in the medical management group did not receive adequate information about the benefits and risks of treatment options, were not involved in decision-making, and were not confident that final decisions were right (Dharmarajan et al., 2017).

Several studies explored the use of SDM tools in the patient selection process for TAVR. Results showed that patients had more information available to make an informed decision, gained more knowledge, and felt that the right decision was ultimately made. Evidence showed that SDM is critical to incorporate patient preferences into treatment choices for optimal, individualized management of AS. Unfortunately, study results also indicated that clinicians did not see a benefit in the use of decision tools, which risks tool implementation and adoption (Coylewright et al., 2020). Finally, a consensus document from multiple professional societies
supports and recommends the implementation of SDM for all TAVR programs in the United States. Efforts are ongoing to develop decision tools to facilitate meaningful patient participation in the TAVR selection process.

QOL outcomes for this structural heart program at 30 days post-procedure based on the KCCQ-12 summary are currently better than other hospitals in the United States at the 50th percentile. The national benchmark at the 50th percentile is 70.9%, and this program performs at 75.9%. Although performance is better than the national benchmark at the 50th percentile, this program performs worse than the national 90th percentile (87.7%; STS/ACC TVT Registry, 2020).

Rationale

Rogers’ (2003) diffusion of innovations theory provides a theoretical framework describing how a group of people adopt a new idea or practice, which is comprised of four main elements: innovation, communication channels, time, and social system. Specifically, Rogers defines diffusion as “the process in which an innovation is communicated through certain channels over time among the members of a social system” (p. 5). Rogers mapped out the process of adoption of a new idea, which he described as a decision to employ “full use of an innovation as the best course of action available” (p. 177) and determined that adoption of an idea is dependent on the innovation-decision process and attributes of the innovation itself across the four elements of the theory. Rogers viewed the innovation-decision process as information seeking and processing by individuals, a process which involves five phases (see Appendix B):

1. Knowledge: The group is exposed to the new idea.
2. Persuasion: Interest is expressed, and the individual seeks more information.
3. Decision: Individual decides to adopt or reject the innovation.
4. Implementation: The innovation is used at varying rates.

5. Confirmation: The ultimate adoption or rejection of the innovation.

It is important to examine why some innovations are implemented successfully, while others never gain full acceptance. The degree to which the change is viewed as an improvement and is in alignment with the team’s values and norms makes adoption more likely. Adoption also depends on complexity, with earlier adoption more likely if the innovation is not complex. The opportunity to test the innovation increases the adoption rate, with sharing results of the pilot being a key tactic to increase visibility of results and the benefits of the innovation. Research showed that innovations offering more relative advantage, compatibility, simplicity, trialability, and observability are adopted more successfully than other innovations (Sahin, 2006).

**Theoretical Framework Guiding the Change in Practice**

Rogers’ (2003) diffusion of innovations theory provided the theoretical framework for implementation of an SDM tool within the selection process of AS patients who are candidates for the TAVR procedure. The tool was the innovation that needed to be adopted. Successful adoption depended on diffusion of the innovative process via effective communication channels over time within the social system (the heart team) thus the fitness of the diffusion of innovations theory for this project. The five phases of the innovation-decision process—in combination with the innovation characteristics of successful adoption framework—supported an ideal path for guiding this change in practice.

The heart team was introduced to and taught (knowledge phase) about the SDM tool. How the heart team both received and perceived information about the new tool were critical as how that information was digested and processed had the potential to affect the rates of adoption.
If the relative advantage was compelling (persuasion phase), members of the team would decide (decision phase) to adopt the tool if it is compatible with team members’ values and perceived needs in practice. The purpose of the SDM tool was communicated clearly to show the benefits for the patient, as well as for the heart team.

Successful spread of tool adoption (implementation phase) was influenced by the complexity of the tool, as well as the ability to pilot its use. The easier to use and improve upon via pilot feedback, the better. Ensuring that the results or impact of the tool were easy to measure and observe assisted in ultimate adoption of the tool (confirmation phase) after its use yielded positive results. While there are five major categories of adopters of an innovation—innovators, early adopters, early majority, late majority, and laggards—effective utilization of the theory elements, the innovation-decision process, and innovation characteristics assisted in very successful adoption within the social system of the heart team as primarily early adopters and early majority (Rogers, 2003).

**Section III: Methods**

**Context**

The structural heart team of this healthcare organization uses a contracted, non-affiliated hospital as the physical location to perform structural heart procedures due to lack of cardiovascular services at any of the organization’s Sacramento facilities. Members who belong to this healthcare organization throughout the Central Valley of California are referred to the program.

Structural heart programs are heavily regulated, and potential TAVR patients must be consulted by a cardiothoracic surgeon and an interventional cardiologist. This program is relatively new, and its first TAVR procedure was performed in October of 2016. An average of
170 TAVR procedures are performed annually. The structural heart team consists of cardiac surgeons, interventional cardiologists, cardiac imagers, anesthesiologists, advanced practice nurses, and TAVR coordinators.

**Stakeholders**

From a patient-centric perspective, patients and their families were the most important stakeholders as they would most greatly benefit from implementation of an SDM tool. Other key stakeholders included a cardiac surgeon and interventional cardiologist. The physicians have the most power and interest in the TAVR program as negative patient outcomes directly affect their health grade ratings and scores. The physicians on the structural heart team were supportive of this project and recognized that the heart team had not incorporated a process to include patient preference in the selection process.

The TAVR coordinators were important stakeholders, as they coordinate care for the patient from the beginning of the referral process through post-operative follow-up and played a key role in the implementation of the SDM tool. Information technology support was vital to facilitate the build of the SDM tool into the electronic health record, as well as to provide ongoing support with potential upgrades or changes in the future. This change in practice project had the support of regional and local leadership to expand and lead in the delivery of care within this cardiovascular specialty.

**Interventions**

The project heart team recognized that the STS risk score provided an opportunity to have meaningful, patient-centered conversations to best inform the SDM process. Additional disciplines – such as life-care planning – were consulted based on the completed SDM tool, as warranted. The implementation of an SDM tool was greatly beneficial to ensure that the team
was clear on what the patient’s goals were prior to treatment and how those goals integrated with treatment decisions.

A validated SDM tool by the American College of Cardiology was adopted and utilized by this structural heart team as the intervention in this study. The tool utilization ensured that the patient was actively involved in the process to determine the best options available to them, whether it was conventional surgery, the TAVR procedure, or medical management. At the time of patient referral to the structural heart team, educational materials were sent out via secure message to the patient to review prior to their consultation. The educational materials provided information to the patient related to the different treatment options available to choose from, as well as the risks and benefits of the different treatment options. If the structural heart team was unable to send the information to the patient electronically prior to their appointment, the patient was given the opportunity to comprehensively review the educational materials at the time of consultation. Given varying socioeconomic and educational backgrounds within the patient population, the consultation included a comprehensive oral discussion, validation of understanding of the educational materials, and a question-and-answer opportunity in order to assure the patients understood their choices and the implications of each.

Following consultation, which included review of the SDM tool with the structural heart team, the patient’s decision was documented in the electronic medical record (EMR) utilizing a smart phrase. The smart phrase specifically indicates that the decision was made to move forward with the treatment option of their choice in collaboration with the structural heart team via SDM. At the time of consultation, a baseline QOL score was obtained by utilizing the KCCQ-12 questionnaire. If the patient proceeded with the TAVR procedure as their treatment
option, this QOL score was recalculated 30 days post-procedure. The goal was to have a score of 45 or above and an increase over baseline after their TAVR procedure.

**Gap Analysis**

An Expert Consensus Systems of Care document provides a quality framework for TAVR centers in the United States (Bavaria et al., 2019). This Consensus document recommends patient- and family-centered care, which includes the use of an SDM tool. An individualized approach is recommended using patient-specific risk data, as well as incorporating patient preferences into the treatment decisions. The project heart team used patient-specific risk data in the decision-making process regarding which treatment plan would be most appropriate, but the score had not been used as a guide to have meaningful conversations with patients and their families.

The consensus statement from multiple professional societies aligns with the evidence showing that an SDM tool could facilitate patient participation in their healthcare decisions related to treatment options available and the risk-benefit ratio of each. At the start of this study, the heart team was not utilizing an SDM tool to incorporate patient preferences into the decisions being made (see Appendix C).

This structural heart program performs better than the national Transcatheter Valve Therapy (TVT) registry benchmark (50th percentile) in risk-adjusted mortality, stroke rate, post-operative bleeding, and paravalvular leak, as well as improvement in QOL score for patients undergoing the TAVR procedure. Though outcomes are above the national average at the 50th percentile, they are below the national average at the 90th percentile, and the evidence-based best practice of an SDM tool has not been adopted by this team.
Defining the proposed project and developing an aim statement for the project began in July 2020. Simultaneously, a comprehensive review of the literature was completed specifically related to the PICOT question. Over the next few months, several pre-implementation tasks were completed. The project was implemented in March 2021. Data were collected and analyzed on a monthly basis (see Appendix D for detailed project timeline).

**Work Breakdown Structure**

A work breakdown structure of the project was completed. Subheadings of the project included a review of the evidence, data analysis, project planning, project implementation, and education. See Appendix E for a breakdown of project deliverables. The review of the evidence section includes the identification of best practices and the quality gap, proposed interventions to be implemented, and the evaluation of results.

The development of project measures, including creation of pre- and post-intervention measurements, submission of proposed project plan, and evaluation of project results, are all part of the data analysis section. Project planning tasks included selecting team members and defining their roles and responsibilities. Buy-in from the physicians was key to ensure successful execution of the project. Development of the communication plan, selection of the SDM tool, and end-user training were the final project planning tasks.

Project implementation started with the actual go-live of the project. During this phase, the project lead – who was the DNP student – actively managed the project by scheduling regular project team meetings, providing weekly team updates, and resolving any issues that arose. Educational activities included identification of learning objectives and development of training materials. The next step was the delivery of the necessary training and education to the TAVR
coordinators and validation that the learning objectives were met. Finally, ongoing support of learning for the TAVR coordinators was key for change management.

**SWOT Analysis**

A SWOT (strengths, weaknesses, opportunities, and threats) analysis of the team and the work environment was performed to provide a framework for identifying and analyzing the internal and external factors that could have an impact on the viability of the SDM tool implementation (see Appendix F). This analysis helped to determine if the project was worth pursuing and what would be needed to make the project successful.

**Strengths**

The following primary strengths were identified. The structural heart team is a high performing team, as evidenced by impressive cohesiveness, strong teamwork, a high degree of collaboration, and a results-oriented mindset. There is strong physician leadership presence, and the team has support from senior leadership for the development and expansion of the structural heart program. The relatively new role of the TAVR coordinator allowed for expansion of the role’s responsibilities. Education and training, with a specific focus on SDM and life-care planning for all the TAVR coordinators, not only increased their knowledge base, but also accomplished better accountability and expanded the role and responsibilities of the coordinators. A key stakeholder for this project was the patient, and there was a great opportunity to make the care more patient-centered and, ultimately, improve the quality of care and service provided. Lastly, data relevant to the TAVR procedure were readily available and accessible to the team.
Weaknesses

The analysis identified several weaknesses. The referral process of patients with AS to the structural heart team for evaluation of the TAVR procedure was not standardized. Lack of a standardized referral process makes the tracking of certain baseline and outcome data, as well as evaluation of patient progress, problematic. Patients are referred to this structural heart program from numerous service areas outside the Sacramento area yielding situations where interventional and inpatient after-care are not provided in or near some patients’ local facilities. Life-care planning was an important component of the decision-making process, and lack of resources in this department resulted in inadequate support from the life-care planning team.

Opportunities

The integrated nature of the studied healthcare system enabled access to software developers for the organization’s EMR system and permitted the SDM tool to be embedded within the system. This facilitated utilization by providers and made data retrieval and tracking easier. Further, this integration was beneficial for patients and the heart team alike as both had access to supportive care service lines such as home health and life-care planning. The existence of the SDM tool assisted in funneling the three local cardiovascular service lines’ workflows through a common pathway that provided a consistent experience for members from that point on, regardless of which of the three medical centers generated the referral. This pathway included acute management of their condition, as well as integrated supportive care offerings the health system offers. Finally, the relationship between the organization’s Greater Sacramento structural heart team and the contracted hospital leadership team is strong, with both parties committed to quality, holistic care. The constant and consistent exposure to other healthcare system cardiovascular services also lent to greater acceptance of changes in workflow.
**Threats**

The biggest threat to the TAVR team and work environment during the study period was the COVID-19 pandemic. The pandemic brought constant change, created many uncertainties, and greatly impacted organizational and team priorities. Focus and priorities consistently shifted as the organization adjusted to the rapidly changing environment to ensure it could accommodate a surge in hospitalizations, as well as safely care for outpatients seeking both urgent and routine care. Additionally, the organization dealt with a tremendous amount of financial uncertainty due to the potential loss of health plan membership as a result of rising unemployment and associated loss of employer-sponsored benefits or individuals’ inability to afford health insurance.

**Budget and Financial Analysis**

A proforma financial budget, showing cost of a TAVR procedure, expenses related to SDM implementation, and a cost-benefit analysis, was created using structural heart volume data from 2019 through 2021. The proposed budget for the project included the costs for training the structural heart team on how to utilize the SDM tool. Five physicians, two TAVR coordinators, a supervisor, and department director received the training. The TAVR coordinators received 4 hours of training calculated at their hourly wage. The five physicians, supervisor, and director each received 2 hours of training calculated at their hourly wage. There was no cost for the adopted SDM tool, as it was a pre-existing, validated tool from the American College of Cardiology and available at no cost to structural heart programs in the United States. Indirect costs included the purchase of an iPad for the structural heart team, at a cost of $650, to use for educational purposes in cases where the patient was unable to view educational materials at home. All educational materials, as well as the SDM tool, were loaded on the iPad and were provided to all patients during consultation. The training costs of the structural heart team, as
well as iPad purchase cost, were a one-time cost in the year 2021. Ultimately, the minimal implementation cost was negligible within the service line budget.

Organizational savings result from the cost-benefit associated with the prevention of a TAVR procedure when multiple treatment options exist depending on patient goals. If the TAVR procedure is avoided due to inappropriate patient selection, the cost-benefit would be the estimated cost of a TAVR ($140,000) minus the training costs of staff and cost of the iPad. Conservatively, assuming one case of this nature per year, the cost-benefit would be $134,830 per one case. The cost-benefit ratio is 27.1, almost 27 times the investment (Waxman, 2017; see Appendix G).

While this is significant, changes in QOL and patient satisfaction with procedure selection and outcomes are difficult to monetize, as neither are directly associated with cost avoidance. However, the associated nature of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient satisfaction survey score with hospital reimbursement was also not helpful in this regard, as this structural heart team’s survey scores cannot be extracted from the contracted hospital unit population and benefits the contract hospital rather than the organization.

Legal action and subsequent settlement costs could potentially stem from cases of patients who undergo TAVR and experience complications post-procedure and were not active participants in the treatment selection decision-making process. Patients have the legal right to determine their own choice of treatment after being provided with accurate, complete, and understandable information to make an informed decision (ANA, 2015). Similarly, legal action could result from patients not being offered the TAVR procedure due to not having all treatment options made available to them. SDM may provide additional cost avoidance of legal fees and
settlements associated with these scenarios; though, no cases specifically associated with these possibilities were found in the literature search. While the author of this paper could not find specific legal costs associated with inappropriate procedure selection for patients who were candidates for TAVR or SAVR, the average general surgical malpractice settlements found ranged from $940,000 to $1,400,000 (Normandie Law Firm, 2021). As patient-centered care becomes more mainstream, it is reasonable to anticipate that settlement costs of this magnitude or more would be associated with cases of inappropriate aortic valve replacement procedure selection, given the nature of adverse cardiac outcomes.

**Communication Plan**

A communication plan was developed to communicate relevant project information to different stakeholders throughout the duration of the project (see Appendix H). Communication was crucial to ensure all participants had the information they needed. Effective communication reinforced the transfer of knowledge and supported adoption of new workflows and the use of the SDM tool by the structural heart team. Communication methods included email and online meetings, as well as in-person meetings. In addition to communication with the different project stakeholders, there was also regular communication with the Doctor of Nursing Practice chair for this change in practice project.

**Study of the Interventions**

Measurement was an important part of the project implementation process. Measures informed the team whether the changes they implemented led to improvement and achievement of the target goals (Institute for Healthcare Improvement, 2021). Evaluation of the implementation of SDM occurred through daily oversight of the specific process and outcome
measures. The data were reviewed and analyzed on a weekly to monthly basis, depending on the source and availability of reports.

KCCQ-12 information from baseline, 30-day post-TAVR procedure, and STS risk score documentation, as well as documentation of the SDM tool utilization, was extracted from the EMR. Weekly measurement meetings were held with the data analyst and the local project implementation team to review the data to identify any necessary revisions or adjustments that could be made immediately. The project lead and data analyst tested and validated all data prior to disseminating to the structural heart team.

Furthermore, the contracted hospital provided weekly reports to the team to ensure that all registry elements, which included the documentation of the baseline and 30-day post-TAVR procedure QOL score, were met. The national quality dashboards are available on the regional cardiovascular services intranet website and are also part of public reporting from the national TVT registry. The results were shared with the frontline structural heart team clinicians to keep them informed of progress or gaps, as well as to recognize and celebrate success.

**Outcome Measures**

The outcome measure for the implementation of the SDM tool focused on achieving a QOL score (KCCQ-12) of at least 45 or greater out of 100 possible points, and an improvement from baseline at 30 days post-procedure in all patients undergoing TAVR. Several primary and secondary drivers played a role in ensuring achievement of the outcome measure. The primary process measure was the use of the SDM tool for patients referred for non-emergent TAVR, with a goal of the tool being utilized by the Greater Sacramento structural heart team for 95% of patients referred to the program for TAVR by October 30, 2021, with documentation of its use targeted at 100% within the EMR. Ninety-five percent was selected as the target due to some
cases coming via emergent circumstances, where SDM becomes impractical and cause delays that may compromise care.

The KCCQ-12 is a shorter version of the KCCQ questionnaire and is a standard patient-reported outcome measure used in clinical trials of surgical and transcatheter valve procedures. The developer of both instruments has validated that the 12-item subset shows similar psychometric properties as the full KCCQ. The KCCQ-12 is a valid instrument for assessing disease-specific health outcomes for patients with AS (see Appendix I). The SDM tool utilized was developed by the American College of Cardiology. All SDM tools from the American College of Cardiology undergo a rigorous development process that includes an extensive review of the literature by experts in the field. The information is summarized in patient-understandable language, and stakeholders review the tools to ensure accurate and unbiased content (American College of Cardiology, 2018). These tools were developed and made available to structural heart teams in the United States to aid clinicians and patients with meaningful conversations about care decisions (CardioSmart, 2020; see Appendix J).

Another important process measure was the referral of patients with a STS risk score of 8.0% and above for a life-care planning consultation. A score of 8.0% and above is indicative of a high risk for mortality from a cardiovascular surgical procedure. The current STS score’s development was based on data from the Adult Cardiac Surgery database from July 2011 to June 2014. Validation was done using data from July 2014 to December 2016. Results showed that the STS risk score performed superior to the previous STS risk model (Shahian et al., 2018). Life-care planning is an essential component of the patient evaluation process and vital to ensure achievement of patients’ goals. A qualitative process measure included feedback from clinicians regarding their perception of the tool’s utility and what benefits it added to the care of the patient.
CQI Method and/or Data Collection Tools

Data were collected on all patients referred to the organization’s Greater Sacramento area structural heart team for evaluation of the patient for TAVR. Outcome and process measure data were manually collected from the EMR due to a delay of approximately 6 months in the reports being published by the national structural heart registry.

Analysis

Data were analyzed utilizing the Microsoft Excel software program. Descriptive statistics were used to summarize and describe the quantitative information, such as sex of participants, KCCQ-12 score at baseline, and KCCQ-12 score at 30 days post-TAVR procedure (see Appendix K). A quantitative process was used to analyze SDM tool utilization, as well as the STS risk score calculation and the accompanied documentation. A qualitative process measure included feedback from the structural heart team on the SDM tool utility, impact, and ease of use.

The outcome measure was analyzed after collection of the 30-day post-procedure QOL score to evaluate if the score increased from the baseline score and that it was above 45. Process measures were studied on a weekly basis, enabling the implementation team to understand and address any gaps or issues in the implementation process. Clear communication and understanding of measures were necessary to ensure the frontline teams performed to expected workflows consistently.

Ethical Considerations

The University of San Francisco (USF, 2019) promotes learning in the Jesuit Catholic tradition. The Jesuit tradition values and views “faith and reason as complementary resources in the search for truth and authentic human development” (USF, 2019, p. 9). These values and views support treating patients with truth, spiritual value, and honor of individual beliefs and
further promotes a culture of service that respects and promotes the dignity of every patient. These values are best upheld when patients are included in the decision-making process, as related to treatment risks, benefits, and expected outcomes, when they are referred for major medical procedures, such as TAVR.

Ethical provisions have been established to guide and provide boundaries of nursing duty and loyalty to the patients (ANA, 2015). Provision 4 of the ANA (2015) Code of Ethics is relevant to this project, “The nurse has authority, accountability, and responsibility for nursing practice; makes decisions; and takes action consistent with the obligation to promote health and to provide optimal care” (p. 15). The TAVR coordinators, who are registered nurses, comply with this provision by ensuring that the patient is actively involved in the decision-making process, which ultimately improves the patient’s QOL and health outcomes. General disclosures include assurance that all patient privacy measures were upheld in the collection of project data, the DNP student leading this project has no conflicts of interest, and the project was approved as a quality improvement project by USF faculty that did not need Institutional Review Board approval (see Appendix L for Statement of Determination).

Section IV: Results

Outcome data pre-SDM implementation for referrals between December 2020 and February 2021 revealed that 33 patients underwent the TAVR procedure. Pre-SDM implementation data showed that 84.84% of patients had an increase in the QOL score to 45 or greater at 30-days post-TAVR procedure.

The SDM project implementation launched March 1, 2021. Between March 1 and May 31, 73 patients were referred for the TAVR procedure. KCCQ-12 baseline data were obtained at the time of consultation for all patients and again at 30-day post-TAVR procedure. The outcome
goal was to achieve a QOL score (KCCQ-12) of at least 45 or greater at 30-days post-TAVR procedure. Outcome measure results for March indicated that 81.80% of patients had an increase in their QOL score to 45 or greater at 30-days post-TAVR procedure. In April, 95.45% of patients had an increase in their QOL score to 45 or greater at 30-days post-TAVR procedure, and in May 94.74% of patients achieved the same. Outcome data post-SDM implementation showed that 90.66% of patients had an increase in their QOL score to 45 or greater at 30-days post-TAVR procedure.

The TAVR volume during the project implementation timeframe was almost double compared to the pre-project volume. A total of 63 patients underwent the TAVR procedure between March 1, 2021, and May 31, 2021, versus 33 patients between December 1, 2020, and February 28, 2021 (see Appendix K for display of data). Between December 2020 and February 2021, the healthcare organization studied in this project had a significant increase in the number of hospitalized SARS-CoV-2 (COVID-19) patients and implemented measures to limit elective surgeries in an effort to keep census manageable and reduce COVID-19 infection risk for perioperative patients. After the surge, the organization’s structural heart program received an increased number of referrals of patients for the TAVR procedure. The increase in the TAVR volume in this period was attributed to the impact to healthcare system from the COVID-19 pandemic. Evidence illustrates that the pandemic has had an indirect effect on patients with cardiovascular disease as a result of delays in seeking care due to fear of exposure to the virus; and delays in receiving care due to increased demand and strain on healthcare systems and cancelation of semi-elective procedures (Wadhera et al., 2021).

Process measure results indicated that 100% of patients received the educational materials explaining all treatment options available to them and that the SDM tool was utilized
for 100% of referred patients which exceeded the 95% outcome measure. A total of 63 patients
moved forward with the TAVR procedure, seven patients chose conventional surgery, and three
patients decided on medical management. The majority of patients who underwent the TAVR
procedure were male, at 68.25% of the studied population. The STS risk score was calculated on
all patients referred for the TAVR procedure and was used as a guide to appropriately refer
patients to other specialties, such as life-care planning.

A qualitative process measure included feedback from clinicians regarding their
perception of the tool’s utility and what benefits it added to the care of the patient. Feedback
from clinicians regarding their perception of the tool’s utility and added benefits was collected
weekly during the TAVR board meetings. Based on the feedback, any suggestions for
improvement were incorporated into the workflows moving forward each week. In general, the
tool and workflows were well received, and the clinicians reported that the tool guided
meaningful conversations around treatment options and expectations that were lacking in detail
and consistency prior to the SDM tool launch.

Section V: Discussion

Summary

An SDM tool was successfully implemented by the structural heart team of a large
healthcare organization in the Greater Sacramento area of California. The goal of the SDM tool
implementation was to improve the QOL for patients with AS who were referred to the structural
heart program for evaluation of the TAVR procedure. Study results indicated that the use of SDM
resulted in a greater percentage of patients with an increase in their QOL post-TAVR procedure
versus baseline.
Rogers’ (2003) diffusion of innovations theory provided the theoretical framework for this project and hugely contributed to the project’s success. A sense of urgency was created by explaining to the structural heart team why the utilization of the SDM tool was critical in the selection process of AS patients referred for the TAVR procedure due to the complexity of these patients’ conditions, concerns, and expectations. This project had the support of local, as well as regional, organizational leadership, which also contributed to successful implementation.

Effective communication among all stakeholders was of the utmost importance and significantly contributed to making the changes necessary for both successful implementation and adoption of the tool. Buy-in from the TAVR coordinators was key, given that they provide first-line guidance and coordination of care for the patient from the start of the referral process through post-procedure follow-up. As the TAVR coordinators are nurses, the nursing profession should include shared decision-making philosophy and methodology within the professional curricula, as well as in standards of practice by professional nursing organizations. The value of trust that patients have in nurses was noted by the coordinators sharing how appreciative patients were for the time and opportunity to discuss treatment options with someone other than the surgeon or interventional cardiologist. It is widely known that nurses are the most trusted professionals in the United States, making their role in SDM critical (Saad, 2020). Standard workflows and the use of a smart phrase for documentation of SDM aided in the adoption of the tool by the TAVR coordinators as well as other members of the structural heart team.

An important lesson learned during the study period was that the global SARS-CoV-2 (COVID-19) pandemic caused major disruptions within healthcare, yielding certain resources unavailable to the team due to more urgent needs within the organization. One of those resources was the information technology team, as they were assigned to other projects to help set up video
and telehealth services to provide care to patients who were unable or unwilling to come to the hospital or medical offices to receive care. Fortunately, this did not derail the project, and the team was able to mitigate the challenge by creating smart phrases as a temporary method to document and capture SDM tool utilization in the EMR.

**Interpretation**

SDM is increasingly recognized as an evidence-based best practice and should be a primary process employed to inform and involve patients directly in their care planning. The Institutes of Medicine and the Affordable Care Act explicitly support SDM (American College of Cardiology, 2018). In addition, the Food and Drug Administration has initiated a Patient Preference Initiative that incorporates the patient perspective into regulatory decision-making, and SDM is now part of the approval process for new drugs and services (Matlock et al., 2020). An action brief by the National Quality Forum (2021) urges healthcare organizations to integrate SDM into their practices.

Implementing this change in practice project aligns with the risk and safety philosophy of the organization where the tool was implemented. SDM ensures that patients are included in all treatment decisions and reduces legal liability in the event of a poor outcome or any adverse events. This project addressed several internal and external risk factors. Patient-physician and patient-care-team relationships and trust improve with SDM, as the patient is an active participant in their care and decisions being made affecting their health and life goals. Additionally, SDM had a positive effect on patient adherence to treatment plans to manage their disease. Evidence indicated that when patients are actively involved in decision-making, they are more motivated and adherent to the treatment plan (Lin & Fagerlin, 2014).
Limitations

The biggest challenge experienced with this project was the incorporation of the SDM tool into the EMR. Due to the COVID-19 pandemic, there were and still are many competing priorities for the organization’s EMR maintenance and development team, as well as for the organization overall. The validated SDM tool will eventually be built into the EMR, but is not yet due to resource constraints and urgent competing needs. The structural heart team is currently utilizing a specific smart phrase as documentation to capture the elements of the tool, including patient participation in the decision-making process and that the patient expressed their wishes regarding their treatment plan during the SDM process.

Conclusion

The management of patients with AS is complex. Only a decade ago, medical management and invasive surgery replacing the aortic valve were the sole treatment options. The TAVR procedure has opened an entirely new pathway for the management of AS patients who are not candidates for open heart surgery. Appropriate patient selection is essential to determine if the TAVR procedure is indicated to achieve treatment goals, enhance QOL, and improve overall outcomes. Several professional organizations recommend an SDM model as part of the clinical pathway for AS patients, but that recommendation has not yet been widely incorporated into clinical practice.

The TAVR procedure continues to be an evolving therapy. The approval of the TAVR procedure for a specific patient population does not mean that it should be the treatment of choice for all patients. An individualized approach using patient-specific risk data and incorporation of patient preferences into the treatment decisions is recommended. A consensus statement by multiple professional societies supports the evidence that an SDM tool could
facilitate meaningful participation of patients in healthcare decisions related to the treatment options available to them and the risks and benefits of each.

Implementation of SDM within the TAVR program in this organization addresses a significant existing risk of patients receiving care that may not align with their personal and treatment goals. The process of SDM also addresses the internal risks associated with organizational opportunities around exclusion of the patient in care planning conversations. Additionally, SDM proactively assists in mitigating challenges in continuity of care by permitting advance planning of post-discharge care, and in the process, helps all parties level-set mutual expectations of adherence to the agreed-upon treatment plan and follow-up. SDM involves patients in conversations about their care and generates active participation in their plan via a better understanding of and concurrence with the treatment and follow-up plans. The implementation of SDM reduces the risk of potential legal action and positions the organization favorably to be ahead of the curve when SDM becomes officially mandated by various regulatory bodies.

This project will be sustained by inclusion of outcome and process measure reporting into existing structural heart team meetings. Tool utilization and subsequent documentation are reviewed during weekly TAVR board meetings. On July 1, 2021, the national Transcatheter Valve Therapy registry from the Society of Thoracic Surgeons and the American College of Cardiology began requiring EMR-documented SDM utilization for all patients referred for the TAVR procedure. Quality reports from the TVT registry are received and reviewed on a quarterly basis, and SDM tool utilization and documentation will now be included in this review process.

This project has the potential to be spread to other structural heart programs, as well as other cardiac surgery programs. More research is needed in the realm of cardiac surgery to
identify best practices to achieve functional SDM and to determine its impact on patient outcomes and satisfaction. The SDM smart phrase utilized by this team was adopted by two other structural heart programs and will also be used by the current team moving forward for any structural heart procedures, not solely TAVR.

**Section VI: Funding**

Implementation educational costs for the structural heart team were approved by department leadership and paid out of the existing operational budget for this team’s department. Direct payment for the purchase of the iPad was approved by the department director and paid out of the department’s monthly operational budget. Costs are incurred one-time only during the first year of implementation. Incremental reporting costs are negligible, given that reporting must be completed for the TVT registry, and SDM tool utilization is just a small component of this and is now required. The benefits clearly outweigh the minimal costs associated with the implementation of SDM.
References


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## Section VIII: Appendices

### Appendix A

### Evaluation Table

<table>
<thead>
<tr>
<th>Citation</th>
<th>Purpose of Article or Review</th>
<th>Conceptual Framework</th>
<th>Design/Method</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
<th>Level of Evidence (Critical Appraisal Score) / Worth to Practice / Strengths and Weaknesses / Feasibility / Conclusion(s) / Recommendation(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bavaria et al. 2019</td>
<td>Expert consensus systems of care document.</td>
<td>N/A</td>
<td>Consensus document summarizing recommendations and requirements for transcatheter aortic valve replacement programs</td>
<td></td>
<td></td>
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<td>Great emphasis on SDM and the promotion of patient-family-centered care.</td>
<td>Level V/A</td>
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<td>Ongoing efforts to develop SDM tools for use by heart teams.</td>
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<tr>
<td>Coylewright et al. 2014</td>
<td>The study evaluated the socio-demographic patient characteristic on how knowledge is transferred, presence of decision</td>
<td>N/A</td>
<td>Meta-analysis</td>
<td>7 RCTs at Mayo Clinic 771 patient-clinician encounters</td>
<td>Usual care versus decision aid care. Evaluated for: Knowledge transfer: general and risk, decision</td>
<td>Ottawa Decision Support Framework to measure knowledge transfer Decisional Conflict Scale to evaluate</td>
<td>Higgins statistics Random effects model</td>
<td>Knowledge transfer general: DA: 62% UC: 45% ($p &lt; 0.0001$) Knowledge transfer risk: DA: 50% UC: 20%</td>
<td>Level I/A Limitations: All RCTs from Mayo Clinic. Sample was predominantly (90%) White. DA used was in English and limited ability to use in</td>
</tr>
<tr>
<td>Citation</td>
<td>Purpose of Article or Review</td>
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<tr>
<td>Coylewright et al. 2015</td>
<td>To study the ability of AS patients to determine treatment goals.</td>
<td>N/A</td>
<td>Qualitative retrospective review</td>
<td>Dartmouth-Hitchcock Medical Center 46 patients</td>
<td>Patients with severe AS provided treatment goals in the following categories: maintaining independence, staying alive, reducing/eliminating pain or symptoms, ability to do a specific activity.</td>
<td>STS scoring tool</td>
<td>Medical record review at 30-days post-TAVR Patient assessment by TAVR RN</td>
<td>KCCQ-12 score at baseline = 36 KCCQ-12 score at 30 days = 77 87% of patients achieved treatment goals</td>
<td>Level III/B Limitations: Lack of prospective data, small sample. Although it was a small sample, it was sufficient for the study design. Results are definitive, with clear recommendations based on the findings.</td>
</tr>
<tr>
<td>Citation</td>
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<tr>
<td>Coylewright et al. 2020</td>
<td>To determine if the use of a DA is associated with greater SDM and better patient outcomes.</td>
<td>N/A</td>
<td>Mixed-methods pilot study</td>
<td>35 patients 6 clinicians at 2 TAVR centers in northern New England</td>
<td>Usual care – control group decision aid group.</td>
<td>Pre-visit and post-visit surveys</td>
<td>Means and SD were used for continuous variables</td>
<td>SDM increased with use of DA: 17.9 (UC) vs. 79.0 (DA)</td>
<td>Patient knowledge and satisfaction increased with use of DA</td>
</tr>
<tr>
<td>Citation</td>
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<td>Dharmarajan et al. 2017</td>
<td>Determine if patient received adequate education to make informed decision Why physicians selected medical management for patients.</td>
<td>N/A</td>
<td>Non-experimental comparative review</td>
<td>9 valve centers 454 patients TAVR: 212 SAVR: 124 Medical management: 118 Total of 47 patients excluded</td>
<td>3 different treatment groups: TAVR, SAVR, medical management. Following outcomes were evaluated: medical history and complexity, physician-reported reasons for medical management, patient-reported beliefs regarding sufficient education, and autonomy in decision-making process.</td>
<td>Wilcoxon rank-sum Kruskal-Wallis tests Chi-square test p value = 0.05 significant</td>
<td>Summary statistics for variables using frequencies and percentages Summary statistics for continuous variables using means with SD and medians with inter-quartile ranges</td>
<td>30-day mortality: TAVR (8.7%), medical management (9.8%) vs. SAVR group (3.4%) (p &lt; 0.001) Medical management: Not receiving adequate information about treatment options (p = 0.03), not involved in decision-making (p &lt; 0.001), and did not feel final decisions were the right ones (p &lt; 0.001) Most common physician-reported</td>
<td>Level III/A Limitations: Study population not randomly selected, sample from leading heart valve centers. Conclusions: Patients reported lack of education regarding treatment options, patients felt uncertain about their final decisions. The study showed that SDM needs to be a part of care for this patient population.</td>
</tr>
<tr>
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<tr>
<td>Korteland et al. 2017</td>
<td>The primary outcome of the study was evaluation of preoperative decisional conflict, and secondary outcomes included patient knowledge, involvement in valve selection, anxiety, and depression.</td>
<td>N/A</td>
<td>Randomized controlled trial</td>
<td>155 patients, 78 control, 77 intervention</td>
<td>Usual care (control) versus SDM group.</td>
<td>DCS was used pre-operatively HRQoL assessed pre-operatively and 3 months post-procedure with a health survey</td>
<td>Continuous variables Kolmogorov-Smirnov test Mann-Whitney U test</td>
<td>No difference in preoperative decision conflict between 2 groups Intervention patients felt better informed and experience less anxiety and depression</td>
<td>Reason for medical management listed as patient preference (31%)</td>
</tr>
<tr>
<td>Marsch et al. 2019</td>
<td>Objective of study was to determine which multiple treatment attributes were studied in patient-preference survey</td>
<td>N/A</td>
<td>Non-experimental study</td>
<td>93 patients</td>
<td>Multiple treatment attributes were studied in Patient-preference survey</td>
<td>An online ASW method (pairwise)</td>
<td>Patients put greater value on attributes</td>
<td>Level III/B Limitations: Relatively small</td>
<td></td>
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</tbody>
</table>

**N/A** indicates information not available.
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</tr>
</thead>
<tbody>
<tr>
<td>Straiton et al. 2018</td>
<td>A meta-analysis evaluated functional capacity and HRQoL of TAVR patients for up to 12</td>
<td>N/A</td>
<td>Systematic review and meta-analysis</td>
<td>20 studies with total sample = 2,775 patients</td>
<td>Functional capacity – objectively measured exercise capacity. HRQoL – ability to</td>
<td>KCCQ-12 questionnaire</td>
<td>compare-son (used to determine attribute tradeoffs) Survey data used to estimate patient weights for treatment attributes Quantitative BRA evaluated preferences for TAVR and SAVR</td>
<td>that favored TAVR (lower invasiveness, quicker recovery, reduced risk of mortality) 71% of patients preferred TAVR to SAVR</td>
</tr>
</tbody>
</table>

Outcomes were important when patients considered TAVR versus SAVR: invasiveness, speed of recovery, mortality rates, complications. KCCQ-12 questionnaire used to determine attribute tradeoffs. Quantitative BRA evaluated preferences for TAVR and SAVR. Significant improvement in functional capacity (95% CI 9.69 – 73.28) Clinically meaningful.
<table>
<thead>
<tr>
<th>Citation</th>
<th>Purpose of Article or Review</th>
<th>Conceptual Framework</th>
<th>Design/Method</th>
<th>Sample / Setting</th>
<th>Major Variables Studied (and their Definitions)</th>
<th>Measurement of Major Variables</th>
<th>Data Analysis</th>
<th>Study Findings</th>
</tr>
</thead>
</table>
|          | months post-procedure.      |                      |              | perform daily physical-based tasks.          | meta-analysis performed using Mantel-Haenszel methodology for functional capacity and HRQoL | p value of 0.05 significant | increase in ability to perform daily tasks (95% CI 3.16 – 7.68) | Conclusions: Substantial improvements in functional capacity and HRQoL post-TAVR procedure is associated with greater independence. The review provides evidence that TAVR procedure increased functional capacity and HRQoL for AS patients and provides a benchmark for future TAVR patients.

Definition of abbreviations:
RCT: randomized control trials
TAVR: transcatheter aortic valve replacement
SDM: shared decision-making
DA: decision aid
STS: Society of Thoracic Surgeons
ASW: adapted swing weighting
(Dang & Dearholt, 2018)

AS: aortic stenosis
OPTION: Observing Patient Involvement scale
UC: usual care
KCCQ-12: Kansas City Quality of Life Score
HRQoL: health-related quality of life
BRA: benefit-risk-analysis
Appendix B

Innovation-Decision Process

Source: Rogers (2003)
Appendix C
Gap Analysis

<table>
<thead>
<tr>
<th>Current State</th>
<th>Future State</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Shared Decision-Making tool is not utilized in the TAVR selection process</td>
<td>• Shared Decision-Making tool utilized in all patients referred for non-emergent TAVR procedure</td>
<td>• Develop and implement a Shared Decision-Making tool to improve QOL for patients with AS for the TAVR procedure</td>
</tr>
</tbody>
</table>
# Appendix D

## Gantt Chart: Project Timeline

<table>
<thead>
<tr>
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<tr>
<td>Aim</td>
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<tr>
<td>Review of the Liter</td>
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<td>Identify Team Members</td>
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</tr>
<tr>
<td>Kick-Off Meeting</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>Education of TAVR Coordinators</td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Education of Structural Heart Physicians</td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Weekly Implementation Meetings</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Analysis of Results</td>
<td></td>
<td></td>
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<td></td>
<td></td>
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<td></td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Final Write Up and Dissemination of Project</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</table>
Appendix E

Work Breakdown Structure
## Appendix F

### SWOT Analysis

#### INTERNAL FACTORS

<table>
<thead>
<tr>
<th>STRENGTHS (+)</th>
<th>WEAKNESSES (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Cohesiveness</td>
<td>• Referral process of patients to the structural heart team is not standardized</td>
</tr>
<tr>
<td>• Teamwork and collaboration among the structural heart team</td>
<td>• Inadequate support from life-care planning team</td>
</tr>
<tr>
<td>• Result-oriented team</td>
<td>• Structural heart team covers referrals from numerous service areas</td>
</tr>
<tr>
<td>• Physician support</td>
<td>• Patient-centered care and quality of care</td>
</tr>
<tr>
<td>• Education and training of TAVR coordinators</td>
<td></td>
</tr>
<tr>
<td>• Senior leadership support</td>
<td></td>
</tr>
<tr>
<td>• Data readily available</td>
<td></td>
</tr>
</tbody>
</table>

#### EXTERNAL FACTORS

<table>
<thead>
<tr>
<th>OPPORTUNITIES (+)</th>
<th>THREATS (-)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Access to software developers</td>
<td>• COVID-19 pandemic</td>
</tr>
<tr>
<td>• Integration allows for access to other support services to support structural heart team</td>
<td>• Financial challenges</td>
</tr>
<tr>
<td>• Strong relationship with leadership team of contracted hospital</td>
<td></td>
</tr>
<tr>
<td>• Common referral pathway that provided a consistent experience for members</td>
<td></td>
</tr>
</tbody>
</table>
Appendix G

Budget

<table>
<thead>
<tr>
<th></th>
<th>2019</th>
<th>2020</th>
<th>2021 Forecast*</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Number of TAVR procedures</td>
<td>147</td>
<td>170</td>
<td>220</td>
</tr>
<tr>
<td>2. Cost Per TAVR Based on Case Rate &amp; Other Revenue Codes</td>
<td>$129,024</td>
<td>$134,400</td>
<td>$140,000</td>
</tr>
<tr>
<td>3. Total Shared Decision-Making Costs</td>
<td>N/A</td>
<td>N/A</td>
<td>$5,170</td>
</tr>
</tbody>
</table>

*Extrapolated to year-end projection based on Jan-June 2021 utilization

DEFINITIONS:

1: Number of TAVR procedures performed yearly
- Annual TAVR procedure volume for years 2019, 2020, and 2021 forecast based on volume for the first six months of the year

2: Cost per TAVR Procedure
- Contracted rate paid by this healthcare organization to contracted hospital with 5% increase in TAVR procedure cost at the start of each calendar year
- This rate includes the DRG case rate plus all other applicable revenue codes

3: Total Shared Decision-Making Costs
- Summary of annual training costs for use of shared decision-making tool utilization, plus
- Costs of equipment to support the use of the tool

Cost-Benefit Analysis

<table>
<thead>
<tr>
<th></th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
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</thead>
<tbody>
<tr>
<td>TAVR Procedure Cost</td>
<td>$140,000</td>
<td>$147,000</td>
<td>$154,350</td>
</tr>
<tr>
<td>Training Expenses:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- TAVR Coordinators (2)</td>
<td>$680</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- Physicians (5)</td>
<td>$3,500</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- Supervisor (1)</td>
<td>$130</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>- Director (1)</td>
<td>$210</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>iPad Purchase Cost</td>
<td>$650</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Net Cost-Benefit*</td>
<td>$134,830</td>
<td>$147,000</td>
<td>$154,350</td>
</tr>
<tr>
<td>Cost-Benefit Ratio*</td>
<td>27.1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*Assumes Shared Decision-Making avoids 1 TAVR annually
* 2021 volume: 220 (assumes 10% increase in cases per year)

Net Cost-Benefit:
- Total Benefits – Total Costs = Net Benefit
- Cost of TAVR procedure – Total Training Cost + iPad Cost = Net Benefits
- $140,000 - $5,170 = $134,830
Cost-Benefit Ratio:
- Total Benefits divided by Total Costs = Cost-Benefit Ratio
- 140,000/5170 = 27.1
## Appendix H

### Communication Plan

<table>
<thead>
<tr>
<th>Information Type</th>
<th>Person Responsible</th>
<th>Distribution</th>
<th>Frequency</th>
<th>Transmittal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outline of project</td>
<td>DNP Student</td>
<td>Senior leadership team&lt;br&gt;Structural heart team&lt;br&gt;Physician leadership</td>
<td>Once</td>
<td>Email</td>
</tr>
<tr>
<td>Project kick-off</td>
<td>DNP Student</td>
<td>Structural heart team&lt;br&gt;TAVR coordinators</td>
<td>Once</td>
<td>TEAMS meeting</td>
</tr>
<tr>
<td>Shared decision-making tool training</td>
<td>DNP Student</td>
<td>Structural Heart team&lt;br&gt;TAVR coordinators</td>
<td>Once</td>
<td>Email, TEAMS meeting</td>
</tr>
<tr>
<td>Life-care planning training</td>
<td>DNP Student</td>
<td>TAVR coordinators</td>
<td>Once</td>
<td>Face-to-face</td>
</tr>
<tr>
<td>Issue resolution</td>
<td>DNP Student</td>
<td>Structural heart team&lt;br&gt;TAVR coordinators</td>
<td>Whenever issues come up</td>
<td>Email, TEAMS meetings, or face-to-face</td>
</tr>
<tr>
<td>Project updates</td>
<td>DNP Student</td>
<td>Structural heart team&lt;br&gt;TAVR coordinators</td>
<td>Monthly</td>
<td>Email, TEAMS meetings, or face-to-face</td>
</tr>
<tr>
<td>Updates to DNP chair</td>
<td>DNP Student</td>
<td>DNP chair</td>
<td>Monthly</td>
<td>Zoom sessions</td>
</tr>
<tr>
<td>Project evaluation</td>
<td>DNP Student</td>
<td>Structural heart team&lt;br&gt;TAVR coordinators</td>
<td>Once</td>
<td>Zoom meeting or face-to-face</td>
</tr>
</tbody>
</table>
### Appendix I

**KCCQ-12 Questionnaire**

#### Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

The following questions refer to your heart failure and how it may affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Heart failure affects different people in different ways. Some feel shortness of breath while others feel fatigue. Please indicate how much you are limited by heart failure (shortness of breath or fatigue) in your ability to do the following activities over the past 2 weeks.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Extremely Limited</th>
<th>Quite a bit Limited</th>
<th>Moderately Limited</th>
<th>Slightly Limited</th>
<th>Not all Limited</th>
<th>Limited for other reasons or did not do the activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Showering/bathing</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>b. Walking 1 block on level ground</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>c. Hiking or jogging (as if catch a bus)</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

2. Over the past 2 weeks, how many times did you swell in your feet, ankles or legs when you woke up in the morning?

<table>
<thead>
<tr>
<th>Every morning</th>
<th>3 or more times per week but not every day</th>
<th>1-2 times per week</th>
<th>Less than once a week</th>
<th>Never over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

3. Over the past 2 weeks, on average, how many times has fatigue limited your ability to do what you wanted?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Several times per day</th>
<th>At least once a day</th>
<th>3 or more times per week but not every day</th>
<th>1-2 times per week</th>
<th>Less than once a week</th>
<th>Never over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

4. Over the past 2 weeks, on average, how many times has shortness of breath limited your ability to do what you wanted?

<table>
<thead>
<tr>
<th>All of the time</th>
<th>Several times per day</th>
<th>At least once a day</th>
<th>3 or more times per week but not every day</th>
<th>1-2 times per week</th>
<th>Less than once a week</th>
<th>Never over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

5. Over the past 2 weeks, on average, how many times have you been forced to sleep sitting up in a chair or with at least 3 pillows to prop you up because of shortness of breath?

<table>
<thead>
<tr>
<th>Every night</th>
<th>2 or more times per week but not every day</th>
<th>1-2 times per week</th>
<th>Less than once a week</th>
<th>Never over the past 2 weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

6. Over the past 2 weeks, how much has your heart failure limited your enjoyment of life?

<table>
<thead>
<tr>
<th>It has extremely limited my enjoyment of life</th>
<th>It has limited my enjoyment of life quite a bit</th>
<th>It has moderately limited my enjoyment of life</th>
<th>It has slightly limited my enjoyment of life</th>
<th>It has not limited my enjoyment of life at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

7. If you had to spend the rest of your life with your heart failure the way it is right now, how would you feel about this?

<table>
<thead>
<tr>
<th>Mostly satisfied</th>
<th>Somewhat satisfied</th>
<th>Mostly dissatisfied</th>
<th>Mostly satisfied</th>
<th>Completely satisfied</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

8. How much does your heart failure affect your lifestyle? Please indicate how your heart failure may have limited your participation in the following activities over the past 2 weeks.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Severely Limited</th>
<th>Limited quite a bit</th>
<th>Moderately limited</th>
<th>Slightly limited</th>
<th>Did not limit at all</th>
<th>Does not apply or did not do for other reasons</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Housework, personal care</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>b. Work or doing household chores</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>c. Social activities</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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</tbody>
</table>

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*Please see Page 2*
Appendix J

Shared Decision-Making Tools

MAKING YOUR DECISION

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 severe aortic stenosis. If you’re still not sure what the best choice is for you, ask yourself

What do you hope for with TAVR or Symptom Management?

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

What concerns do you have with TAVR or Symptom Management?

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

What questions do you have for your clinician?

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________

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

_________________________________________________________________________________
_________________________________________________________________________________
_________________________________________________________________________________
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 severe aortic stenosis. If you’re still not sure what the best choice is for you, ask yourself

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?

_________________________________________________________________________________

_________________________________________________________________________________
Appendix K

Analysis

### Treatment Choice

![Bar chart showing the number of patients referred and the choice of treatment (Patients Referred, TAVR, SAVR, Medical Management)]

### Gender

![Bar chart showing the total number of patients by gender (Total, Female, Male)]

<table>
<thead>
<tr>
<th>Sex</th>
<th>Total</th>
<th>Female</th>
<th>Male</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>63</td>
<td>20</td>
<td>43</td>
</tr>
</tbody>
</table>
SDM Tool Utilization

<table>
<thead>
<tr>
<th></th>
<th>March</th>
<th>April</th>
<th>May</th>
</tr>
</thead>
<tbody>
<tr>
<td>TAVR Referrals</td>
<td>23</td>
<td>27</td>
<td>23</td>
</tr>
<tr>
<td>SDM Tool Completed</td>
<td>23</td>
<td>27</td>
<td>23</td>
</tr>
</tbody>
</table>

KCCQ-12 Data

- **Patients with increased KCCQ-12 score**
- **Patients with decreased KCCQ-12 score**
- **Patients with no change in KCCQ-12 score**
Increase in KCCQ-12 Score

<table>
<thead>
<tr>
<th>Percentage of Patients</th>
<th>Pre-SDM</th>
<th>Post-SDM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>84.84</td>
<td>90.66</td>
</tr>
</tbody>
</table>
Appendix L

Statement of Determination

Doctor of Nursing Practice
Statement of Non-Research Determination (SOD) Form

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

General Information

<table>
<thead>
<tr>
<th>Last Name:</th>
<th>Buchner</th>
</tr>
</thead>
<tbody>
<tr>
<td>First Name:</td>
<td>Liesel</td>
</tr>
<tr>
<td>CWID Number:</td>
<td>20451484</td>
</tr>
<tr>
<td>Semester/Year:</td>
<td>Summer 2020</td>
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<tr>
<td>Course Name &amp;</td>
<td>NURS-791P</td>
</tr>
<tr>
<td>Number:</td>
<td>Addressing the needs of the populations with evidence based interventions</td>
</tr>
<tr>
<td>Chairperson Name:</td>
<td>Dr. Francine Serafin-Dickson</td>
</tr>
<tr>
<td>Advisor Name:</td>
<td>Dr. Francine Serafin-Dickson</td>
</tr>
</tbody>
</table>

Project Description

1. Title of Project

   Transcatheter Aortic Valve Replacement: A shared decision-making approach

2. Brief Description of Project

   Clearly state the purpose of the project and the problem statement in 250 words or less.

   Transcatheter aortic valve replacement (TAVR) is a minimally invasive procedure replacing the stenotic aortic valve. The TAVR procedure has transformed the treatment of patients with severe aortic stenosis (AS) who are too high-risk for conventional surgery. Currently, TAVR is the standard of care for intermediate, high-risk, and inoperable AS patients (Lauck et al., 2016). However, one in four patients considered high-risk for surgery die within one year following TAVR; challenging the heart team to provide much needed meaningful guidance to patients.

   The American College of Cardiology (ACC) recommends a shared decision-making (SDM) approach for patients with AS who are considering the TAVR procedure. Patient management relies on SDM based on a comprehensive understanding of the risk-benefit ratio of different treatment modalities and integration of patient preferences and values. Shared decision-making involves educating patients and their families about treatment options available to them. Guidelines also recommend that patient goals and expectations be determined early in the process as related to life expectancy, improvement in symptoms or survival, and end-of-life context (Otto et al., 2017).

   Medicare requires documentation of SDM utilizing an evidence-based tool for reimbursement eligibility for certain heart procedures, but it has not been a requirement for TAVR and thus is not widely used in practice. Research has shown that SDM tools increased patient knowledge about their disease and risk factors of different treatment options available, resulting in patients experiencing less internal conflict when deciding on how to proceed with treatment (Barry & Edgman-Levitan, 2012). The aim of this project is to explore the integration of an SDM tool into patient selection for patients with AS who are TAVR candidates.
3. **AIM Statement: What are you trying to accomplish?**
   - What do you hope to accomplish with this project? Aims should be SMART, specific, clear, well-defined, and at a minimum describe the target population, the desired improvement, and the targeted timeframe.
   - To improve (your process) from (baseline) % to (target) %, by (timeframe), among (your specific population)

   **Complete this statement:**

   By October 1, 2021, develop, implement, and evaluate a shared decision-making tool.

4. **Brief Description of Intervention (150 words).**

   A shared decision-making tool will be adopted and utilized by the structural heart team for all patients referred for the TAVR procedure. A validated tool from the American College of Cardiology will be adopted by this structural heart team.

   The shared decision-making tool will ensure that the patient is actively involved in the process to determine the best options available to them, whether it is conventional surgery, the TAVR procedure or medical management.

4a. **How will this intervention be implemented?**

   - Where will you implement the project?
   - Attach a letter from the agency with approval of your project.
   - Who is the focus of the intervention?
   - How will you inform stakeholders/participants about the project and the intervention?

   The setting is the structural heart program in the Greater Sacramento area. This organization uses a contracted non-affiliated hospital as the physical location to perform these procedures due to lack of cardiovascular services at any of this organization's Sacramento facilities. Members from throughout the Sacramento Valley and Central Valley are referred to this program.

   Patients and families with Aortic Stenosis referred for the TAVR procedure will be the focus of the intervention.

   The intervention will be communicated to the stakeholders/participants by the Chiefs of the program. This intervention has been discussed with the two Chiefs of the program, and the determination was made that this is a must-do for the program to ensure that patients are involved in the decision process to select the best option available to them to manage their disease.

   **Stakeholders include:**
   - Patients and families
   - Physicians
   - TAVR coordinators
   - Information technology
   - Leadership at a regional and local level
5. Outcome measurements: How will you know that a change is an improvement?

- Measurement over time is essential to QI. Measures can be outcome, process, or balancing measures. Baseline or benchmark data are needed to show improvement.
- Align your measure with your problem statement and aim.
- Try to define your measure as a numerator/denominator.
  - What is the reliability and validity of the measure? Provide any tools that you will use as appendices.
  - Describe how you will protect participant confidentiality.

Outcome Measure:

Achieving a quality of life score (KCCQ-12) of at least 45 points or greater at 30 days post-procedure in all patients who had the TAVR procedure. Score ranges from 0-100.

Process Measure:

The shared decision-making tool will be utilized for 95% of patients referred for the TAVR procedure.

100% of patients with an STS risk score of 8 and above will be referred for a lifecare planning consultation. STS risk score ranges from 0-30.

Balancing Measure:

A qualitative balancing measure will include feedback from clinicians regarding their perception of the tool’s utility and what benefits it adds to the care of the patient.
DNP Statement of Determination
Evidence-Based Change of Practice Project Checklist*

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

Project Title:
Transcatheter Aortic Valve Replacement: A shared decision-making approach

<table>
<thead>
<tr>
<th>Mark an “X” under “Yes” or “No” for each of the following statements:</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>The aim of the project is to improve the process or delivery of care with established/accepted standards, or to implement evidence-based change. There is no intention of using the data for research purposes.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The specific aim is to improve performance on a specific service or program and is a part of usual care. All participants will receive standard of care.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project is not designed to follow a research design, e.g., hypothesis testing or group comparison, randomization, control groups, prospective comparison groups, cross-sectional, case control. The project does not follow a protocol that overrides clinical decision-making.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of established and tested quality standards and/or systematic monitoring, assessment or evaluation of the organization to ensure that existing quality standards are being met. The project does not develop paradigms or untested methods or new untested standards.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project involves implementation of care practices and interventions that are consensus-based or evidence-based. The project does not seek to test an intervention that is beyond current science and experience.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project is conducted by staff where the project will take place and involves staff who are working at an agency that has an agreement with USF SONHP.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The project has no funding from federal agencies or research-focused organizations and is not receiving funding for implementation research.</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>The agency or clinical practice unit agrees that this is a project that will be implemented to improve the process or delivery of care, i.e., not a personal research project that is dependent upon the voluntary participation of colleagues, students and/or patients.</td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>

If there is an intent to, or possibility of publishing your work, you and supervising faculty and the agency oversight committee are comfortable with the following statement in your methods section: “This project was undertaken as an Evidence-based change of practice project at X hospital or agency and as such was not formally supervised by the Institutional Review Board.”

Answer Key:
- If the answer to all of these items is “Yes”, the project can be considered an evidence-based activity that does not meet the definition of research. IRB review is not required. Keep a copy of this checklist in your files.
- If the answer to any of these questions is “No”, you must submit for IRB approval.

*Adapted with permission of Elizabeth L. Hohmann, MD, Director and Chair, Partners Human Research Committee, Partners Health System, Boston, MA.

To qualify as an Evidence-based Change in Practice Project, rather than a Research Project, the criteria outlined in federal guidelines will be used: [http://answers.hhs.gov/ohrp/categories/1569](http://answers.hhs.gov/ohrp/categories/1569)
DNP Statement of Determination
Evidence-Based Change of Practice Project Checklist Outcome

The SOD should be completed in NURS 7005 and NURS 791E/P or NURS 749/A/E

Project Title:
Transcatheter Aortic Valve Replacement: A shared decision-making approach

☐ This project meets the guidelines for an Evidence-based Change in Practice Project as outlined in the Project Checklist (attached). **Student may proceed with implementation.**

☐ This project involves research with human subjects and **must be submitted for IRB approval before project activity can commence.**

Comments:
Aim: By October 1, 2021, develop, implement, and evaluate a shared decision-making tool. The only piece missing is the expected quality improvement. I believe you could add that you are expecting an increase in active patient involvement as measured by an increase in quality of life scores. There is a lot of evidence to support the use of that tool.
Mary Donnelly

Student Last Name: Buchner  
Student First Name: Liesel

CWIID Number: 20451484  
Semester/Year: Summer 2020

Student Signature: Liesel Buchner  
Date: 7.9.2020

Chairperson Name: Francine Serafin-Dickson

Chairperson Signature:  
Date: 8-6-20
DNP SOD Review Committee Member Name: Mary K. O'Connell 12 August 2020

DNP SOD Review Committee Member Signature: ___________________________ Date: _______________
Appendix M

Organization Letter of Support

DNP Project Letter of Support

This is a letter of support for Liesel Buchner to implement her DNP Comprehensive Project: Implementation of a Shared Decision-Making tool at Kaiser Permanente.

Name: Mark Eyrich  Date: 08.18.2020
Assistant Medical Group Administrator