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Transcatheter Aortic Valve Replacement (TAVR): A Needs Assessment for Norton Healthcare

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The document mentioned above has been reviewed and accepted by the student's advisor, on behalf of the advisory committee, and by the Assistant Dean for MSN and DNP Studies, on behalf of the program; we verify that this is the final, approved version of the student's DNP Project including all changes required by the advisory committee. The undersigned agree to abide by the statements above.

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Running head: TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Final DNP Project Report

Transcatheter Aortic Valve Replacement (TAVR): A Needs Assessment for Norton Healthcare

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School of Nursing

Fall 2016

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TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

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Abstract

Purpose: The purpose of this study was to conduct an initial needs assessment on the TAVR program at Norton Healthcare (NHC). Baseline data were collected on patient quality of life as evidenced by Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, frailty scores, Katz index, Lawton scale, Society of Thoracic Surgeons (STS) mortality score, and comorbidities. A secondary purpose was to identify trends in patient outcomes such as increased morbidity, mortality, readmission rates, complications, discharge disposition, and increased length of stay.

Setting and Population: The population for this study was all patients at Norton Audubon Hospital (NAH) who underwent TAVR between October 1, 2014 and December 31, 2015. A total of 51 patients were included in the chart review.

Procedures: This needs assessment utilized a retrospective electronic medical record review. The records were assigned a study number that was used on all electronic data collection forms. Data were collected using an investigator developed data collection instrument. The data were then directly entered into Data Analysis Statistical Package for the Social Sciences (SPSS) software for analysis.

Results and Conclusions: A review of the patients' health history and co-morbid burden was conducted. Forty-three patients (84.3%) had hypertension, 33 (64.7%) had coronary artery disease or a myocardial infarction, 37 (72.5%) had hyperlipidemia, nine (17.6%) had a permanent pacemaker and/or AICD, 14 (27.5%) had previous coronary artery bypass grafting (CABG), 24 (47.1%) had an arrhythmia such as atrial fibrillation, 11 (21.6%) had a previous stroke, 26 (51%) had some form of pulmonary disease, 16 (31.4%) had some form of renal disease, 12 (23.5%) had history of cancer, and 13 (25.5%) were diabetic. Pre-procedure quality of life metrics were examined using KCCQ scores, Katz index, Lawton scale, STS score, and

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frailty score were included. The mean pre-procedure KCCQ score (n=50) was 29.16 (SD=11.919), Katz index (n=35) was 5.26 (SD= 1.094), Lawton scale (n=35) was 4.71 (SD= 2.573), STS score (n=51) was 12.28535 (SD= 5.638508), and frailty score (n=19) was 5.11 (SD= 1.100). Post-procedure metrics included 30-day KCCQ score, length of stay, discharge disposition, and 30-day readmission. The mean 30-day KCCQ score (n= 27) was 47.96 (SD=10.886). The median length of stay was five days. Thirty-three (64.7%) were discharged home, 13 (25.5%) went to a sub-acute rehabilitation facility, one (2%) went to the Veterans Affairs Medical Center (VAMC), three (5.9%) died, and one (2%) went to a long-term acute care (LTAC) facility. Seven patients (13.7%) were readmitted to a Norton facility within thirty days of being discharged from the hospital.

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Background

As patients age, calcium can build up on the leaflets of their aortic valve. The valve will become stiff, making it unable to open and close properly leading to a condition called aortic stenosis (AS). With the disease sequelae of AS, symptoms of angina, fatigue, shortness of breath, and syncope will occur. According to the website for the Edwards Lifesciences New Heart Valve, more than one in eight patients over the age of 75 will have moderate to severe aortic stenosis. In fact, once patients begin exhibiting symptoms of severe AS, they only have a 50 percent chance of living two more years without a valve replacement. (Edwards Lifesciences New Heart Valve website, 2015). Transcatheter aortic valve replacement (TAVR) was developed in 2002 as an alternative to surgical aortic valve replacement (SAVR) for patients that had been deemed non-surgical candidates or high risk for surgical intervention. Thirty percent of patients with severe AS will not be candidates for SAVR due to advanced age, poor left ventricular dysfunction, or multiple comorbidities (Leon et al., 2010). Patients are quantified as high operative risk utilizing the STS mortality score. The STS score takes many factors into account including age, renal function, left ventricular dysfunction, underlying coronary disease, comorbid lung disease as well as re-operative heart surgery status and other comorbid conditions. However, it does not quantify a patient's frailty and functional status. A percentage of the patient's overall mortality for an open SAVR is given with the STS mortality score. With the indications for the PARTNER trial and original FDA indications, a patient with an overall STS mortality score greater than 8% is considered high operative risk. The STS scale has been utilized in the TAVR trials all around the country and found to be more reliable than other mortality scales. It is measured from 0-100%.

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There have been several studies showing the benefit of TAVR in the high operative risk aortic stenosis patient. The Placement of Aortic Transcatheter Valves (PARTNER) trial was a multicenter, randomized clinical trial sponsored by Edwards Lifesciences. The PARTNER trial compared patients who underwent TAVR to those who received standard therapy. Between May 11, 2007, and March 16, 2009, a total of 358 patients with severe aortic stenosis who were not suitable candidates for surgery were enrolled at 21 sites (17 in the United States) and were randomly assigned to TAVR using the Edwards Lifesciences heart valve (179 patients) or standard therapy (179 patients). Standard therapy consists of medication and may include balloon aortic valvuloplasty. The study showed that patients who underwent TAVR had lower endpoint mortality rate, fewer repeat hospitalizations, and improved cardiac symptoms than the standard therapy group (Leon et al., 2010).

The PARTNER II trial was a follow up to the PARTNER trial and included patients who were of intermediate STS risk score (Leon et al., 2016). It also showed results comparable to SAVR. In the PARTNER II trial the indications were expanded to the intermediate risk patients with AS. Another study, conducted using the Medtronic Core Valve, a self-expanding valve, showed similar outcomes. Patients who were high risk or not candidates for SAVR, showed improved health status after undergoing TAVR (Arnold et al., 2015).

A follow up report utilizing the PARTNER study was released in 2015 with the five-year trial results. It showed TAVR outcomes to be superior to standard therapy with a decrease in the stroke risk. The researchers found that without treatment 94% of patients in the standard therapy group died within five years. In the treatment group of randomized TAVR patients there was 21.8% absolute reduction in mortality at five years (Kapadia et al., 2015).

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The functional scales utilized to evaluate patients for TAVR have been extensively reviewed in the literature for their validity and reliability. The Katz Index of Independence in Activities of Daily Living ranges (Shelkey, 2012) 0 to 6 (lower scores indicating poorer functionality) and measures activities of daily living (ADLs). These are routine activities that people perform everyday without needing assistance. The six basic ADLs include eating, bathing, dressing, toileting, transferring (walking) and continence. Instrumental activities of daily living (IADLs), are measured using the Lawton Instrumental Activities of Daily Living Scale (Graf, 2008), which is scored 8 to 0 (again lower scores indicates lower functionality). These activities are not necessary for fundamental functioning, but they are required to function independently in a community. The IADLs include housework, preparing meals, taking medications as prescribed and managing money. The Clinical Frailty Score (Dalhousie University, 2015) is a scale in which the provider determines the patients overall fitness and ability to perform ADLs and IADLs. It is measured 1 to 9 (lower scores indicate higher functionality). It is a subjective scale but allows the provider to utilize clinical judgment in functionality. The Katz and Lawton scales are both determined by the patient.

The area served by NHC has a very high volume of heart disease given the geographical region. NHC services Jefferson County Kentucky, the neighboring counties of Oldham, Shelby, Spencer, and Bullitt, as well as southern Indiana. This area lies along the Ohio River and includes both urban and rural communities. In a report entitled, “Heart Disease Hospitalization Rates by State, Medicare Beneficiaries Ages 65 and Older, 2000–2006” Kentucky is at 92.8 per 1,000 admissions and the US is 75.2 per 1,000 admissions. Only Louisiana and West Virginia were calculated at a higher number of admissions than Kentucky (Casper et al., 2009). This helps illustrate the importance of a successful TAVR program at NHC.

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Purpose

The purpose of this project was to conduct a needs assessment for the TAVR program at NHC. A needs assessment is a systematic approach that progresses through a defined series of phases. It focuses on the outcomes to be attained, rather than the process. The results of a needs assessment will aid in further setting priorities and determines criteria for solutions in the area of interest to make sound decisions. A needs assessment sets criteria for determining how best to allocate available money, people, and other resources.

Baseline data were collected on patient quality of life as evidenced by Kansas City Cardiomyopathy Questionnaire (KCCQ) scores, Katz Index of Independence in Activities of Daily Living, Lawton Instrumental Activities of Daily Living Scale (see appendices A, B, and C), frailty score, and other quality metrics including 30-day hospital readmission rate, STS overall mortality score, length of stay, discharge disposition, and common complications including stroke, acute renal failure, convert to sternotomy, the need for permanent pacemaker, and vascular complications. Also collected were pre-procedure comorbid conditions. These comorbidities were chosen for their strong connection to heart disease and/or poor functional status. The second aim of this project was to identify trends in patient outcomes such as increased morbidity and mortality, readmission rates, discharge disposition, and increased length of stay that decreased quality of life.

Methods

Approval was obtained from the Norton Healthcare Office of Research Administration (NHORA) and the University of Kentucky Institutional Review Boards for expedited review for research involving human subjects prior to data collection. This project was a needs assessment

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using a retrospective electronic medical record (EMR) review of all patients between the ages of 60 and 100 who underwent TAVR at NHC from October 1, 2014 to December 31, 2015. Data were collected from the EMR of these patients who were also the first 51 patients to undergo TAVR at NHC. All patients who underwent TAVR at NAH after December 31, 2015 were excluded. Note that all TAVR procedures at NHC are performed at Norton Audubon Hospital (NAH). A data collection instrument was developed and is included in Appendix D. The data were then analyzed for trends and compared to national outcomes. Based on the data collected, recommendations have been made for the TAVR program at NHC as well as future research. Research questions addressed were:

- What are the current gaps in care of the TAVR program at Norton Healthcare?
- What is the comparison of Norton Healthcare to other facilities in the nation in regards to TAVR patient outcomes?
- Where can Norton Healthcare take steps to improve patient outcomes in the TAVR population?

Procedures

This study design was a retrospective descriptive electronic medical record review of all patients who underwent TAVR at Norton Healthcare between October 1, 2014 and December 31, 2015. The records were assigned a study number that was used on all electronic data collection instruments. Data were collected on the data collection instrument depicted in Appendix D, which was kept secure on Norton's H drive, along with the master list during the data collection process. The H drive is both password and firewall protected. The data was then entered into statistical analysis software. Data Analysis Statistical Package for the Social Sciences (SPSS) software was used in the analysis of data.

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No identifiable data were reported in this study. Upon completion of the study, the primary investigator (PI) will have deleted the password-protected documents that contain patient personal medical record numbers using data overwriting software to ensure that the data will not be reconstituted. The PI maintained study data with study numbers so as to perform further analysis and validate the accuracy of data. Data collected will be maintained for six years after study completion. At that time, electronic data files will be deleted according to Norton Healthcare's policy for deleting electronic files.

Results

Sample Characteristics

Included in the study were 19 (37.3%) males and 32 (62.7%) females with an average age of 81.02 (SD 7.22) years. Fifty (87.7%) were Caucasian and one (1.8%) was African American (see Table 1). All patients had a classification of NYHA stage III or IV heart failure prior to their procedure and were in need of an aortic valve replacement.

As mentioned previously, at the time of the chart review, FDA indications for TAVR only included those deemed inoperative or high operative risk. TAVR was not approved for intermediate risk patients until after the time frame of this study. All patients reviewed in this needs assessment were deemed non-operable or high-risk and their STS mortality risk scores were greater than 8%.

Study Results

A review of the patients' health history was conducted, which examined 11 different preselected comorbidities (see Figure 1). Forty-three (84.3%) had hypertension, 33 (64.7%) had

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coronary artery disease or a myocardial infarction, 37 (72.5%) had hyperlipidemia, nine (17.6%) had a permanent pacemaker and/or AICD, 14 (27.5%) had had a CABG previously, 24 (47.1%) had an arrhythmia such as atrial fibrillation, 11 (21.6%) had had a previous stroke, 26 (51%) had some form of pulmonary disease, 16 (31.4%) had some form of renal disease, 12 (23.5%) had had cancer, and 13 (25.5%) were diabetic.

Next, pre-procedure quality of life metrics were examined (see Table 2) which included KCCQ scores, Katz index, Lawton scale, STS scores, and frailty score. Unfortunately not all participants had their scores recorded in the electronic medical record. Some were well documented, such as pre-procedure KCCQ score (N=50) and STS score (n=51), but others had less than half recorded, such as the frailty score (n=19).

The mean pre-procedure KCCQ score (n=50) was 29.16 (SD=11.919), Katz index (n=35) was 5.26 (SD= 1.094), Lawton scale (n=35) was 4.71 (SD= 2.573), STS score (n=51) was 12.28535 (SD= 5.638508), and frailty score (n=19) was 5.11 (SD= 1.100).

Post-procedure metrics included 30-day KCCQ score, length of stay, discharge disposition (see Figure 2), and 30-day readmission. The mean 30-day KCCQ score (n= 27) was 47.96 (SD=10.886). The median length of stay was five days. Thirty-three (64.7%) were discharged home, 13 (25.5%) went to a sub-acute rehabilitation facility, one (2%) went to the Veterans Affairs Medical Center (VAMC), three (5.9%) died, and one (2%) went to a long-term acute care (LTAC) facility. Seven patients (13.7%) were readmitted to a Norton facility within 30 days.

Discussion

In October 2014, Norton Healthcare (NHC) performed its first TAVR procedure at Norton Audubon Hospital. Since then NHC has performed over 100 procedures and the program

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is anticipated to perform higher volumes with the new FDA indications for intermediate risk patients.

As shown in the results of this study, the program has struggled with getting patients to comply with post-operative follow-up and routine follow-up care, attending follow-up appointments, and required follow-up testing and surveys. Many of the quality of life metrics were under reported showing a lack of reporting and follow-up either on the part of the healthcare provider or the patient. Thirty patients (52.6%) did not have a 30-day KCCQ recorded, 38 (66.7%) did not have a frailty score, and 22 (38.6%) did not have a Katz index or Lawton scale reported. Metrics that are consistently documented are more reliable than those that are not. Generalizations to the entire TAVR population can be deduced using the data of more consistently collected data. Metrics with less consistent documentation are more likely to be biased and lead to incorrect assumptions.

The only directly comparable metric was the pre-procedure KCCQ score and the 30-day KCCQ score. A higher KCCQ score implies less severe heart failure symptoms and a better quality of life. It measures how often activities are limited by their heart failure, leg swelling, fatigue, shortness of breath, and how often heart failure has limited the enjoyment of their life. The mean pre-procedure KCCQ score was 29.16 (SD=11.919) and the mean 30-day KCCQ score was 47.96 (SD=10.886). Although this shows an improvement in the quality of life for patients after undergoing the TAVR procedure, the low number of 30-day KCCQ scores (n=27) makes generalization and reliability of this finding poor. Had more scores been reported, this finding would have been stronger.

National statistics were similar to what was found in this study. A report from the STS/ACC TVT registry showed 50.5% of patients with TAVR procedures from 2012 to 2014

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were male, with a mean age of 82 years. Less than 5% of all TAVR patients nationally were African American. Common comorbidities listed in the national database were prior revascularization (either percutaneous coronary intervention or coronary artery bypass graft), prior stroke, diabetes, peripheral arterial disease, moderate or severe chronic lung disease and prior myocardial infarction. Approximately 83% of patients were in New York Heart Association functional class III/IV. Approximately 82% had evidence of frailty, the mean KCCQ score (reported in 76% of patients) was 41, indicating poor health status, including reduced function and quality of life. Finally, a history of or current atrial fibrillation was identified in approximately 41% of patients. This is representative of all TAVR patients across the United States.

When compared to average STS scores of TAVR patients from PARTNER I, PARTNER II, and Medtronic trials, the patients who underwent TAVR at NHC had significantly higher scores. This may be related to the population in the region serviced by NHC having overall poorer health. Patient selection could have also been of influence here with the higher STS scores.

Implication for Practice

There are many factors that can reduce quality of life. One particular study identified that these factors include but are not limited to physical limitation, debilitating symptoms, difficulties coping with treatment, lack of knowledge, distress emotions, multiple comorbidities, and other personal struggles (Riegel & Carlson, 2002). This study recommended a stepped approach to patient education and counseling, an approach that may be beneficial in the TAVR population at NHC. Utilizing this practice model at NHC could potentially aid patients in adhering to their

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treatment plan with regard to following up with their providers. There have been several research studies on ways to improve patient adherence to treatment regimens, but none have been conclusive. One article suggested that multiple approaches be utilized, such as educating patients, providing written action plans, shortening the time interval between office visits, simplifying treatment regimens, and providing patients with reminder strategies (Aslam, 2015).

A standardized plan for providers to utilize for data collection and data entry is also needed in order to make research more accurate. Placing the frailty instrument into the EMR is one way we can improve adherence to collection on behalf of the providers. With accurate data, providers will be able to clearly see what is working well and where improvements in the program can be made. Many facilities have created an APRN or RN role for a nurse who is responsible for ensuring all pre- and post- procedure testing and appointments are completed and that all data are properly collected and entered into the EMR. For NHC to create this role, leadership will need to approve it and then they will need to hire and educate an individual for the position.

Implications for Future Inquiry

The data from this study shows the importance of program monitoring to ensure continued positive patient outcomes. Future studies should include follow-up of this needs assessment with patients who have undergone TAVR at NAH since January 1, 2016. The volume of patients who undergo TAVR at NAH has increased so there will be the need for a larger number of records which will need to be reviewed and evaluated. As the numbers increase, this will make data more reliable and generalizable to the TAVR population. Also, the electronic medical records of patients who have undergone TAVR at NHC more recently will be more

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complete as the protocol for entering and collecting data has improved. A TAVR nurse was hired to aid with patient education, appointment scheduling, and data entry. A study of more recent patients can be compared to this study to show the evolution of the TAVR program at NHC and any changes to the program, such as the TAVR nurse position, can be evaluated based on patient outcomes.

Limitations

The small sample size (n=51) was a significant limitation in this study. The small sample has made the data less reliable. Also, the newness of the TAVR program is a limitation. The experience of the providers and the process for choosing participants has evolved since the beginning of the program; therefore more recent patients have had more success. Finally, the omission of data on the part of the provider and the lack of follow-up on the part of the patient at one month, three months, and one year have limited the accuracy and of the study findings. Data omission likely occurred because of lack of protocols for data collection. Multiple providers were collecting data and no one person had ownership of data entry, which contributed as well to possible omissions of data. Following the completion of this study, a TAVR nurse position was established and it is one of his/her responsibilities to ensure that all required testing be completed and data be entered in a timely and uniform fashion.

Conclusion

Due to the newness of the TAVR program at NHC, continued and frequent analysis of the program and patient outcomes, and comparison to national benchmarks are necessary to maintain a safe and effective program. One area for improvement is improved adherence to the

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documentation protocol by providers. Without collecting the data and accurate reporting, any areas for improvement may not be identified. For the TAVR program to maintain positive outcomes for patients and minimize complications, it is important that the ability to monitor outcomes be achieved. Another area of improvement is completion of pre-procedure patient education so that patients are fully aware of the post-procedure requirements. This will make the patients more likely to keep their follow-up appointments at one month, three months, and one year. Implementing follow-up appointments that are made prior to discharge and setting up reminder calls and text messages prior to each appointment has proven beneficial in other programs. Having a standard process as well as a designated person responsible for collecting and reporting data on the part of the providers will make omitted data from the EMR less likely. NHC has taken steps to implement a process used by other centers and recommended in the PARTNER study by hiring a TAVR nurse coordinator. This nurse coordinator is responsible for all data collection and documentation as well as contacting patients for appointments. This is a new position and was not in place at the time of the study, therefore, this limitation may have already been resolved.

As the TAVR program at NHC continues to grow and evolve, and use of technology improves, the ability to help this particular patient population will also improve. Norton Healthcare's continued dedication to its patients and healthcare providers is evident in its continued work to attain the highest standard of care for the people in this community and bring cutting edge treatments and therapies to this area.

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3991(01)00165-3

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TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Table 1.

Demographic Characteristics of Study Sample (N = 51)

Age, Mean (SD)	81.02 (7.22)
Sex, n(%)	
Male	19 (37.3)
Female	32 (62.7)
Race, n(%)	
Caucasian	50 (87.7)
Other	1 (1.8)

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Table 2.
Quality of Life Metrics

	<i>Mean (SD)</i>
Pre-procedure KCCQ score (n=50)	29.16 (11.919)
Katz Index (n=35)	5.26 (1.094)
Lawton Score (n=35)	4.71 (2.573)
STS score (n=51)	12.28535 (5.638508)
Frailty score (n=19)	5.11 (1.100)
30-day KCCQ score (n=27)	47.96 (10.886)

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

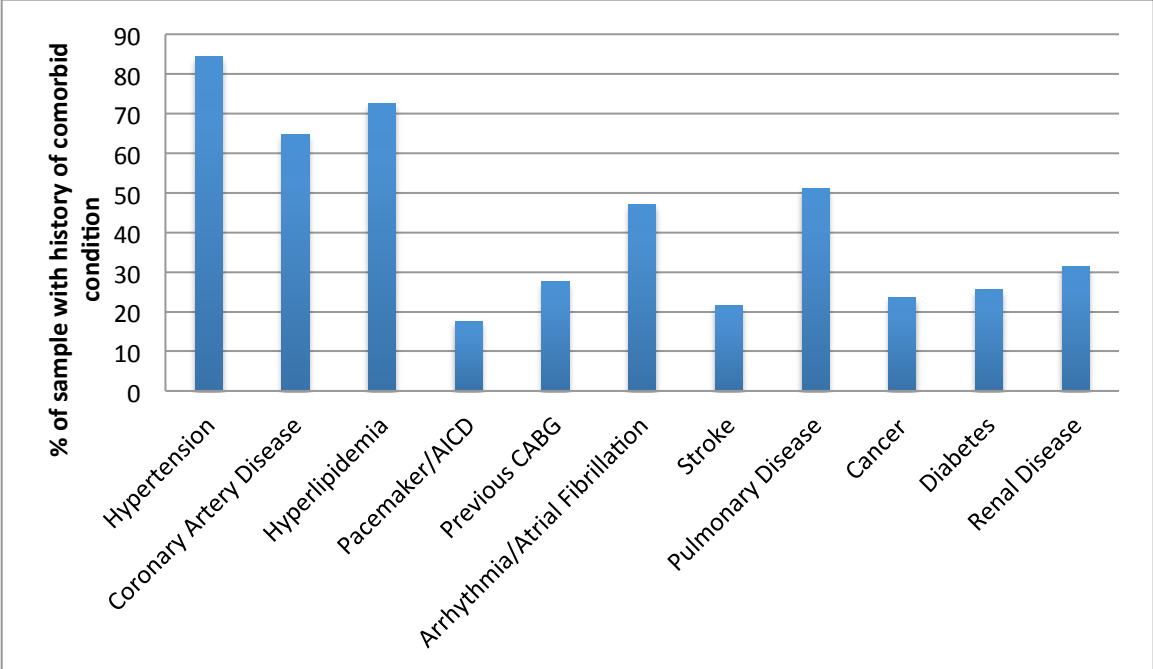


Figure 1. Comorbidities (N= 51)

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

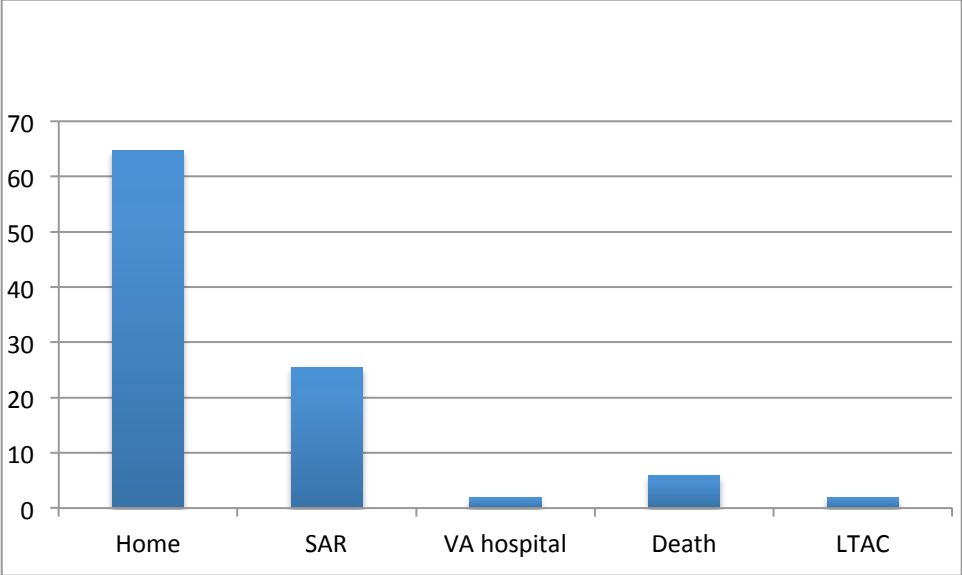


Figure 2. Discharge Disposition

Appendix A

The Lawton Instrumental Activities of Daily Living Scale

THE LAWTON INSTRUMENTAL ACTIVITIES OF DAILY LIVING SCALE

Ability to Use Telephone

- 1. Operates telephone on own initiative; looks up and dials numbers1
- 2. Dials a few well-known numbers1
- 3. Answers telephone, but does not dial1
- 4. Does not use telephone at all0

Shopping

- 1. Takes care of all shopping needs independently1
- 2. Shops independently for small purchases0
- 3. Needs to be accompanied on any shopping trip0
- 4. Completely unable to shop0

Food Preparation

- 1. Plans, prepares, and serves adequate meals independently1
- 2. Prepares adequate meals if supplied with ingredients0
- 3. Heats and serves prepared meals or prepares meals but does not maintain adequate diet0
- 4. Needs to have meals prepared and served0

Housekeeping

- 1. Maintains house alone with occasion assistance (heavy work)1
- 2. Performs light daily tasks such as dishwashing, bed making1
- 3. Performs light daily tasks, but cannot maintain acceptable level of cleanliness1
- 4. Needs help with all home maintenance tasks1
- 5. Does not participate in any housekeeping tasks0

Laundry

- 1. Does personal laundry completely1
- 2. Launders small items, rinses socks, stockings, etc1
- 3. All laundry must be done by others0

Mode of Transportation

- 1. Travels independently on public transportation or drives own car1
- 2. Arranges own travel via taxi, but does not otherwise use public transportation1
- 3. Travels on public transportation when assisted or accompanied by another1
- 4. Travel limited to taxi or automobile with assistance of another0
- 5. Does not travel at all0

Responsibility for Own Medications

- 1. Is responsible for taking medication in correct dosages at correct time1
- 2. Takes responsibility if medication is prepared in advance in separate dosages0
- 3. Is not capable of dispensing own medication0

Ability to Handle Finances

- 1. Manages financial matters independently (budgets, writes checks, pays rent and bills, goes to bank); collects and keeps track of income1
- 2. Manages day-to-day purchases, but needs help with banking, major purchases, etc1
- 3. Incapable of handling money0

Scoring: For each category, circle the item description that most closely resembles the client's highest functional level (either 0 or 1).

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Appendix B

Katz Index of Independence in Activities of Daily Living

KATZ INDEX OF INDEPENDENCE IN ACTIVITIES OF DAILY LIVING*

Activities <i>POINTS (1 OR 0)</i>	Independence <i>(1 POINT)</i> <i>NO supervision, direction, or personal assistance</i>	Dependence <i>(0 POINT)</i> <i>WITH supervision, direction, personal assistance, or total care</i>
BATHING Points: ____	(1 point) Bathes self completely or needs help in bathing only a single part of the body such as the back, genital area, or disabled extremity.	(0 points) Needs help with bathing more than one part of the body, getting in or out of bathtub or shower. Requires total bathing.
DRESSING Points: ____	(1 point) Gets clothes from closets and drawers and puts on clothes and outer garments complete with fasteners. May have help tying shoes.	(0 points) Needs help with dressing self or needs to be completely dressed.
TOILETING Points: ____	(1 point) Goes to toilet, gets on and off, arranges clothes, and cleans genital area without help.	(0 points) Needs help transferring to the toilet, cleaning self, or uses bedpan or commode.
TRANSFERRING Points: ____	(1 point) Moves in and out of bed or chair unassisted. Mechanical transferring aides are acceptable.	(0 points) Needs help in moving from bed to chair or requires a complete transfer.
CONTINENCE Points: ____	(1 point) Exercises complete self-control over urination and defecation.	(0 points) Is partially or totally incontinent of bowel or bladder.
FEEDING Points: ____	(1 point) Gets food from plate into mouth without help. Preparation of food may be done by another person.	(0 points) Needs partial or total help with feeding or requires parenteral feeding.
TOTAL POINTS: ____ <i>6 = High (client independent)</i> <i>0 = Low (client very dependent)</i>		

* Slightly adapted with permission from Gerontological Society of America. Katz, S., Down, T.D., Cash, H.R., et al. (1970). Progress in the development of the index of ADL. The Gerontologist, 10, 20-30.

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Appendix C

Kansas City Cardiomyopathy Questionnaire (KCCQ-12)

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.

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
a. Showering/bathing	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
b. Walking 1 block on level ground	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c. Hurrying or jogging (as if to catch a bus)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
	1	2	3	4	5	6

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

Every morning	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5

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

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7

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

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5	6	7

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**?

Every night	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 2 weeks
<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
1	2	3	4	5

Rev. 2012-04-11

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Appendix D

Data Collection Tool

	Patient 1	Patient 2	Patient 3	Patient 4
Age				
Sex				
Ethnicity				
Comorbidities: ARF, HTN, prior CABG, stroke, DM, etc.				
Pre-procedure KCCQ score				
30 day KCCQ score				
Frailty score				
Length of stay				
Discharge Disposition				
Complications: Stroke, ARF, PPM, vascular complications, convert to sternotomy, death				
Katz Index				
Lawton scale				
STS mortality score				
30-day readmission				

Appendix E

Letter of Approval: NHORA



Office of Research Administration (NHORA)

224 E. Broadway Louisville, KY 40202 (502) 629-3501 Phone (502) 629-3480 Fax
nhora@nortonhealthcare.org www.nortonhealthcare.org

May 25, 2016

Anna Chumbley, RB, DNPs 1 Audubon Plaza Louisville, KY 40217

NHORA# 16-N0091/ IRB# 16-0352-P2H / Transcatheter Aortic Valve Replacement (TAVR): A Needs Assessment for Norton Healthcare Dear Ms. Chumbley:

The Norton Healthcare Office of Research Administration (NHORA) is pleased to notify you that your application to conduct the above-mentioned research study in the following Norton Healthcare (NHC) facility has been approved.

• **Norton Audubon Hospital** Please note: NHORA approval reflects permission to conduct the study within a Norton Healthcare facility from a regulatory and contractual perspective, and is

independent of approval by the sponsor for initiation of the study. The sponsor or site may have additional requirements to address before the study can begin. The following items must be submitted to the NHORA if your study continues to be conducted in a NHC facility and are applicable to your study:

- **Annual Progress Report/Continuation Review form**
- **Annual Approval letters and current Informed Consent Forms approved by the IRB, if applicable**
- **Amendments and Amendment Approval letters**
- **Revised HIPAA documents such as revised Partial Waivers/Complete Waivers of authorization for each change in personnel**
- **Changes in the Conflict of Interest status**
- **Status change of study, i.e. closed to enrollment, study termination etc.** To comply with HIPAA regulations:
- **A copy of the Partial Waiver of Authorization must be filed with the medical record of every patient screened for the study, if applicable.**

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

- **For retrospective chart reviews, a copy of the Complete Waiver of Authorization must be filed with the medical record of every patient whose chart is reviewed for the study.** For studies utilizing an Informed Consent Form, **a signed copy of the Informed Consent Form and Research Authorization must be filed with the medical record of each subject enrolled in your study in a NHC facility. If applicable, the Research Patient ID form must be submitted to NHORA Billing daily with reportable activity. Please email the form to NHORABilling@nortonhealthcare.org. Please contact Regina Schaefer at 502-629-3580 for specific instructions regarding the notification of your subject enrollment at NHC. If the study will include the use of sponsor provided and/or personal equipment of any type (for example: tablets, ECG machines, ePROs, personal laptops etc.), that equipment must be checked, tracked and/or inspected by Norton Healthcare’s Clinical Engineering department prior to its use or placement in a patient care setting. Request an initial incoming inspection of the equipment as follows:**
 - Norton employed researchers – contact Clinical Engineering on NSITE at <http://nsite/departments/clinicalengineering/SitePages/Home.aspx>
 - Non-Norton employed researchers – contact Clinical Engineering by calling 502-629-3590 In the event your study will utilize personal and/or sponsor provided equipment, please ensure that you comply with the procedure outlined above. We look forward to the successful completion of your study. If you have any further questions or need assistance, please contact the NHORA at (502) 629-3501. Please let us know how we are doing. Follow the link <https://www.surveymonkey.com/s/NHORAatisfaction> to complete the NHORA Satisfaction Survey in less than two minutes. Your feedback helps NHORA improve the services we provide and meet the needs of the research community. Sincerely, Rhonda Hoffman System Director
Research Norton Hospital □Kosair Children’s Hospital □□Norton Audubon Hospital Norton Suburban Hospital □□Norton Immediate Care Centers □Norton Brownsboro Hospital

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

Appendix F

Letter of Approval: University of Kentucky IRB



Expedited Initial Review

Office of Research Integrity
IRB, IACUC, RDRC
315 Kinkead Hall
Lexington, KY 40506-0057

859 257-9428
fax 859 257-8995

www.research.uky.edu/ori/

Approval Ends May 15, 2017

TO:

FROM:

IRB Number 16-0352-P2H

Anna Chumbley, RB, DNPs College Nursing c/o Tricia MacCallum 202 CON Bldg. 0232

PI phone #: (502)759-0587

Chairperson/Vice Chairperson Medical Institutional Review Board (IRB)

Approval of Protocol Number 16-0352-P2H May 19, 2016

SUBJECT: DATE: On May 16, 2016, the Medical Institutional Review Board approved your protocol entitled:

Norton Transcatheter Aortic Valve Replacement (TAVR): A Needs Assessment for Norton Healthcare

Approval is effective from May 16, 2016 until May 15, 2017 and extends to any consent/assent form, cover letter, and/or phone script. If applicable, attached is the IRB approved consent/assent document(s) to be used when enrolling subjects. **[Note, subjects can only be enrolled using consent/assent forms which have a valid "IRB Approval" stamp unless special waiver has been obtained from the IRB.]** Prior to the end of this period, you will be sent a Continuation Review Report Form which must be completed and returned to the Office of Research Integrity so that the protocol can be reviewed and approved for the next period.

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

In implementing the research activities, you are responsible for complying with IRB decisions, conditions and requirements. The research procedures should be implemented as approved in the IRB protocol. It is the principal investigators responsibility to ensure any changes planned for the research are submitted for review and approval by the IRB prior to implementation. Protocol changes made without prior IRB approval to eliminate apparent hazards to the subject(s) should be reported in writing immediately to the IRB. Furthermore, discontinuing a study or completion of a study is considered a change in the protocol's status and therefore the IRB should be promptly notified in writing.

For information describing investigator responsibilities after obtaining IRB approval, download and read the document "PI Guidance to Responsibilities, Qualifications, Records and Documentation of Human Subjects Research" from the Office of Research Integrity's IRB Survival Handbook web page [<http://www.research.uky.edu/ori/IRB-Survival-Handbook.html#PIresponsibilities>]. Additional information regarding IRB review, federal regulations, and institutional policies may be found through ORI's web site [<http://www.research.uky.edu/ori>]. If you have questions, need additional information, or would like a paper copy of the above mentioned document, contact the Office of Research Integrity at (859) 257-9428.

Robyn Cheung, PhD, RN, MSN, ARNP

Chairperson/Vice Chairperson

An Equal Opportunity University

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)



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WAIVER OF AUTHORIZATION APPROVAL LETTER

In Compliance with section 164.512(i)(2)(iv)(C) of the HIPAA privacy rules, a representative from Medical IRB#2 has reviewed the use of Protected Health Information (PHI) by expedited review.

The expedited review was conducted in accordance with 45CFR 46.110 (b)(2), the minor changes provision.

The IRB protocol# 16-0352 meets the criteria for the waiver of authorization according to 164.512(i)(2)(ii), which are as follows:

The use or disclosure of protected health information involves no more than a minimal risk to the privacy of the individual based on:

-An adequate plan to protect the identifiers from improper use/disclosure

-An adequate plan to destroy the identifiers at the earliest opportunity consistent with the research justification unless health, research or legal justifications to retain the identifiers.

-An adequate written assurance that the PHI will not be reused or disclosed to any other person unless required by law, authorized oversight or as permitted by the following subpart:

-the research could not practicably be conducted without the waiver or alteration;

and

-the research could not practicably be conducted without access to and use of the PHI.

Robyn Cheung

IRB Chairman or Designee

Digitally signed by Robyn Cheung
DN: cn=Robyn Cheung, o=University of KY HealthCare, ou=Nursing
Practice & Support, email=robyn.cheung@uky.edu, c=US
Date: 2016.05.16 16:31:53 -0400

May 16, 2016

Date

TRANSCATHETER AORTIC VALVE REPLACEMENT (TAVR)

160352P2H Norton Transcatheter Aortic Valve Replacement (TAVR): A Needs Assessment for Norton Healthcare

Verified "Consent Authorized" N PI Chumbley Anna

akch2261@uky.edu

KP Burckardt Elizabeth Elizabeth.Burckardt@uky.edu

CITI through UofL

KP Melander Sheila sheila.melander@uky.edu

Trained: Date:

DunnChad: Citi: Other Test

Authorized

Y 11/11/15 N

Y 09/05/14 N

Y 01/08/16 N

Y N Unassigned

RB, DNPs

Y N N NHC TAVR Coordinator

RN, MSN

Y N N Academic Advisor
