Protocol 16-16 HSRD (Goodney)
Alignment of Treatment Preferences and Repair Type for Veterans with AAA
Funding Agency: HSR&D
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[Version Number 1.9]
May 6, 2020

Abstract

Nearly 5,000 Veterans undergo abdominal aortic aneurysm (AAA) repair each year in VA hospitals. Randomized trials, including the VA-based Open Versus Endovascular Repair (OVER) Trial, have found endovascular AAA repair (EVAR), is associated with lower perioperative morbidity and mortality, less pain, and shorter length of stay than open surgical repair (OSR). However, OSR is more durable, has fewer long-term complications such as late rupture, and Veterans treated with EVAR and OSR have similar survival within two years following surgery. Given these tradeoffs, controversy remains as to which method is best suited for an individual Veteran who needs AAA repair, and preliminary analyses needs have found broad variations across VA hospitals in how Veterans are treated for AAA.

Treatment decisions for AAA need to be aligned with Veterans' preferences. For example, a Veteran for whom a rapid recovery is of primary importance and long-term durability a lesser concern has a treatment preference which aligns most closely with EVAR. Similarly, a Veteran who wishes to avoid repeated follow-up visits and late re-interventions has a treatment preference that aligns most closely with OSR. However, while AAA treatment type varies across VA hospitals, it is unknown if these treatment variations occurs as a result of Veterans' preferences, or independent of Veterans' preferences. Surgeon preferences for repair type have been poorly described, especially for surgeons treating Veterans.

In preliminary work, we have performed observational analyses, surveys, and cognitive interviews. This has demonstrated variation in AAA repair type in VA and refined qualitative methods to better understand Veterans' and surgeons' treatment decisions. In this proposal, in a cohort of Veterans who are candidates for either repair type (OSR or EVAR), we will use a survey explore Veterans' knowledge and preferences for AAA repair,and determine if Veterans who receive a decision aid as well as the survey are more likely to receive their treatment choice.

We describe a cluster-randomized trial comparing two ways to better align Veterans' preferences and treatments for AAA: (1) a validated decision aid describing AAA repair types with a survey measuring Veterans' preference for repair type -- versus (2) the survey alone. Enrolled Veterans will be candidates for either endovascular or open repair, and be followed at VA hospitals by vascular surgery teams who regularly perform both types of repair. In Aim 1, we will determine Veterans' preferences for endovascular or open repair and identify domains associated with each repair type. In Aim 2, we will compare agreement between Veterans' preferences and repair type between the decision aid + survey and survey-alone groups. We will identify factors associated with agreement. Our findings will be reported to the National Surgery Office Vascular Surgery Advisory Board to help ensure Veterans' preferences remain at the center of AAA treatment decisions. We have recruited 22-24 VA Medical Centers and their vascular surgery teams who are anxious to participate in this important trial to help Veterans make the best decisions.

List of Abbreviations

AAA: Abdominal aortic aneurysm

LSI: Local Site Investigator

NIH: National Institute of Health

NHLBI: National Heart, Lung and Blood Institute

PHI: Protected Health Information

TDI: The Dartmouth Institute for Health Policy & Clinical Practice

SVS: Society for Vascular Surgery

VISN: Veterans Integrated Service Network

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1. Introduction

Background

Abdominal aortic aneurysm is the 14th leading cause of death among men over age 60, and a common condition among United States Veterans.[4, 5] Approximately 250,000 Veterans have AAA, and nearly 5,000 patients are treated for AAA annually to prevent rupture.[1, 6-9]

Before the advent of endovascular devices in the late 1990s, open surgical repair of AAA was the only treatment option for patients with AAA. In open surgical repair, a large abdominal incision is necessary, and clamps are applied to the aorta - the largest blood vessel in the body. Surgical reconstruction is performed as shown in Figure 1. The risk of perioperative death is 3-5% for open AAA repair, even in hospitals skilled in this major operation. The chance of major complications such as bleeding, need for further surgery, or heart attack, can approach 20% within the first year.[10-13]

Figure 1: Open AAA Repair

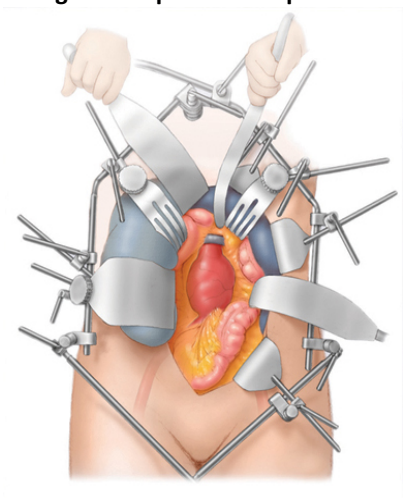
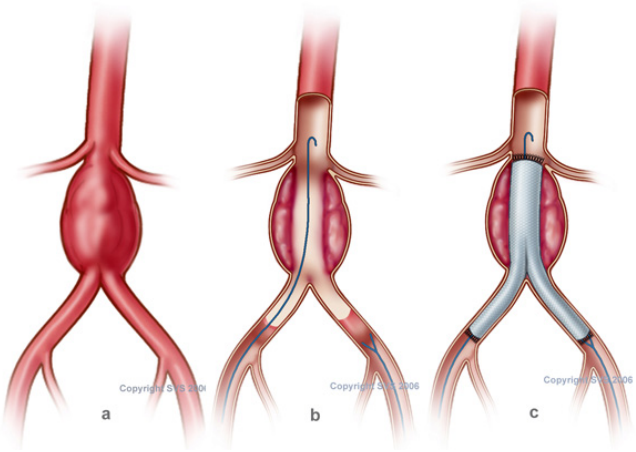


Figure 2: Endovascular AAA Repair



The development of endovascular AAA repair (called EVAR) in the 1990s changed the treatment options available for patients with AAA[14]. Stent-grafts could be placed through small incisions in the groins to exclude the aneurysm from blood flow, without any need for a large abdominal incision or aortic clamping (Figure 2). Short term recovery was now much simpler, and vascular surgeons rapidly adopted this new technique.

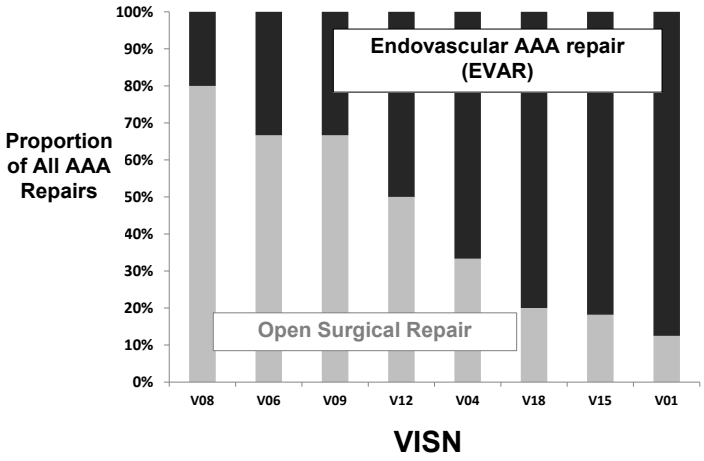
Equipoise between repair types for AAA:
Endovascular repair and open surgery have been compared extensively in a variety of settings, including large randomized trials within VA[1-3, 9]. In these studies, the less-invasive nature of endovascular repair demonstrated several advantages: lower rates of perioperative mortality (less than 2% versus 5%), shorter length of stay (2 versus 7 days), and better patient quality of life earlier after AAA treatment[15]. However, endovascular repair had clear disadvantages as well. For example, Veterans treated with EVAR commonly develop leaks around their graft called endoleaks, which can require secondary procedures, and can result in late aneurysm rupture[16-21].

These tradeoffs have made it difficult to find a clear "winner" between endovascular repair and open surgery. While the randomized trials gave surgeons and Veterans important information about the short and long-term outcomes of each approach, they failed to identify a single AAA repair type that would be best for all Veterans with AAA. Because of these tradeoffs, equipoise remains as to the optimal AAA repair type.

Variation in treatment type for AAA: This equipoise in AAA repair type has led to variation in AAA repair type across VA hospitals (Figure 3). While many have studied changes in AAA repair type in Medicare patients[39-41], variation in repair type in VA hospitals has received less attention. Therefore, to explore this variation, we performed preparatory-to-research analyses[42]. Our work demonstrated four-fold variation in repair type across different VISNs. For example, in 2009, nearly 80% of AAAs were

repaired with open surgery in VISN 8, and 20% underwent endovascular repair (Figure 3). However, in VISN 1, the opposite was true – fewer than 20% of AAAs were repaired using open repair, and more than 80% were repaired with endovascular repair. The results seen at the VISN level were similar in a recent survey of the twenty sites in our study. Preliminary analyses also showed us that measuring AAA repair within the VA itself is necessary. For example, we measured the proportion of AAA treated with open repair in VA in the last five years. We found that the proportion of AAA repaired with open repair declined by 3% in absolute terms, from 36% to 33%[42]. When compared to patients treated at non-VA hospitals, using data from the Society for Vascular Surgery[43], the decline in open repair was 19% in absolute terms (from 40% 21%). These data suggest that treatment preferences for Veterans differ from non-Veteran populations. As such, using data from non-Veterans is unlikely to be a good substitution, and it would be best to learn about our Veterans' preferences directly – from our Veterans themselves.

Figure 3: Variation in Repair Type in VA Hospitals in 2009



Why we need to understand Veterans' preferences: After our preparatory-to-research analyses, two findings were clear: (1) high-quality randomized trials have demonstrated that outcomes such as aneurysm-related mortality and overall mortality are equivalent between endovascular and open repair, and (2) significant variation in AAA repair type exists across VA. One might ask, why does it matter if there is variation in AAA repair type if the two repair types are similar, based on traditional procedure-related outcomes?

The best answer to this question integrates three important concepts: the *disparate nature* of the two repair types, the *risks inherent to each repair type,* and the need to *align treatment for AAA with Veterans' preferences*. Open repair requires a large abdominal incision, a greater physiologic challenge during surgery, and a more prolonged recovery when compared to endovascular repair,but is more durable than endovascular repair. A Veteran who must travel long distances for appointments, for whom reliable follow-up is not possible, or who has chronic worry and anxiety, has treatment preferences likely to align with open repair. Conversely, endovascular repair, while less invasive, requires close follow-up with multiple imaging tests for several years after repair, with the potential for late complications years following the initial treatment. A Veteran who needs to return to work quickly to ensure that his or her job is not endangered by a prolonged recovery has a treatment preference likely to align with endovascular repair. Therefore, aligning Veteran preference and repair type is necessary to achieve the best patient-centered outcomes.

Have Veterans' preferences for AAA repair type been examined before? Significant attention has been dedicated towards determining the comparative effectiveness of endovascular and open repair. However, less attention has been given to understanding Veterans' preferences for repair type. In fact, other than measuring quality of life metrics in the context of VA randomized trials[23], to the best of our knowledge, Veterans' preferences for repair type remain undescribed. Three studies outside of VA – two surveys of National Health Service beneficiaries in England[44, 45] and a report of six focus groups in Canadian patients[46] – have begun to study patient preferences for AAA repair type. However, these findings may, or may not, represent the preferences seen in US Veterans. These preliminary analyses suggest studies within the VA are necessary.

Why would a Veteran receive a AAA repair type that is not aligned with his/her preference? To better understand why a Veteran might receive a repair that was not aligned with his or her preferences, we performed two preliminary cognitive interviews with Veterans who underwent endovascular or open repair in recent years. Findings from these interviews led us to develop a theoretical model built upon

two well-known theories outlined by experts in shared decision making: a lack of informed choice (described by Fowler[9] and Weinstein [47, 48]) and an overestimate or underestimate of risks (described by Barry and Elwyn[5, 6, 8]).

Lack of informed choice: First, the Veteran may not have a preference because he or she was never given the opportunity to clearly understand the options for treatment[47, 48]. If the Veteran has not been fully apprised of the treatment options, he or she is not capable of making a truly "informed" decision.

For example, during our interview, one Veteran at our center described his interaction:

> *The surgeon simply told me, "Your aneurysm needs to be repaired, and it is best for us to fix it using the new way, endovascular." I never knew there was a choice, and they never gave me an option"*

Given the time constraints of current surgical practice, surgeons often use paternalistic care patterns to assign patients with the treatment the surgeon feels is "best" – without reviewing other options with patients. Surgical decisions, especially those made in the context of cardiovascular diseases which require time tradeoffs and competing risks, can be especially difficult for physicians to explain [6, 49, 50]. Therefore, this *lack of informed choice* does little to foster shared decision-making with Veterans about ways to repair AAA[48, 49].

Overestimate or underestimate risks: Even if a physician attempts to engage a patient in sharing knowledge about a health care decision, two tendencies can "derail" the process of shared decision making. First, the description can be biased in a way that reflects the providers' beliefs and assumptions, rather than the patients[51]. Second, patients may not understand the magnitude of the risks, as patients tend to overestimate benefits and underestimate risks [6, 49, 50]. These tendencies can result in providers following the "letter of the law" in shared decision-making, but still ending up with a decision that is unlikely to be aligned with the Veterans' preferences for treatment.

> *My surgeon explained, "Your aneurysm is now large enough that we should repair it. While there are two ways to fix the aneurysm, the better choice for you is an endovascular, because you will recover more quickly." But I ended up having to come back for many visits over the years, because of leaks. I even needed a second procedure Maybe it would have been better to just fix it the old-fashioned way."*

<u>*How considering Veterans' preferences will help to improve outcomes*</u>: Misalignment of treatment preferences can result in poorer satisfaction with surgery[52, 53]. This dissatisfaction can have real effects for Veterans. For example, Veterans treated with open repair may have more complications, more work loss, greater rates of depression, and more social isolation because of the longer recovery time[32, 54-56]. Similarly, for Veterans treated with endovascular repair, the need for continued surveillance with radiation-based CT scans, worries about complications, and the need for family support can have deleterious effects as well[24, 25, 40].

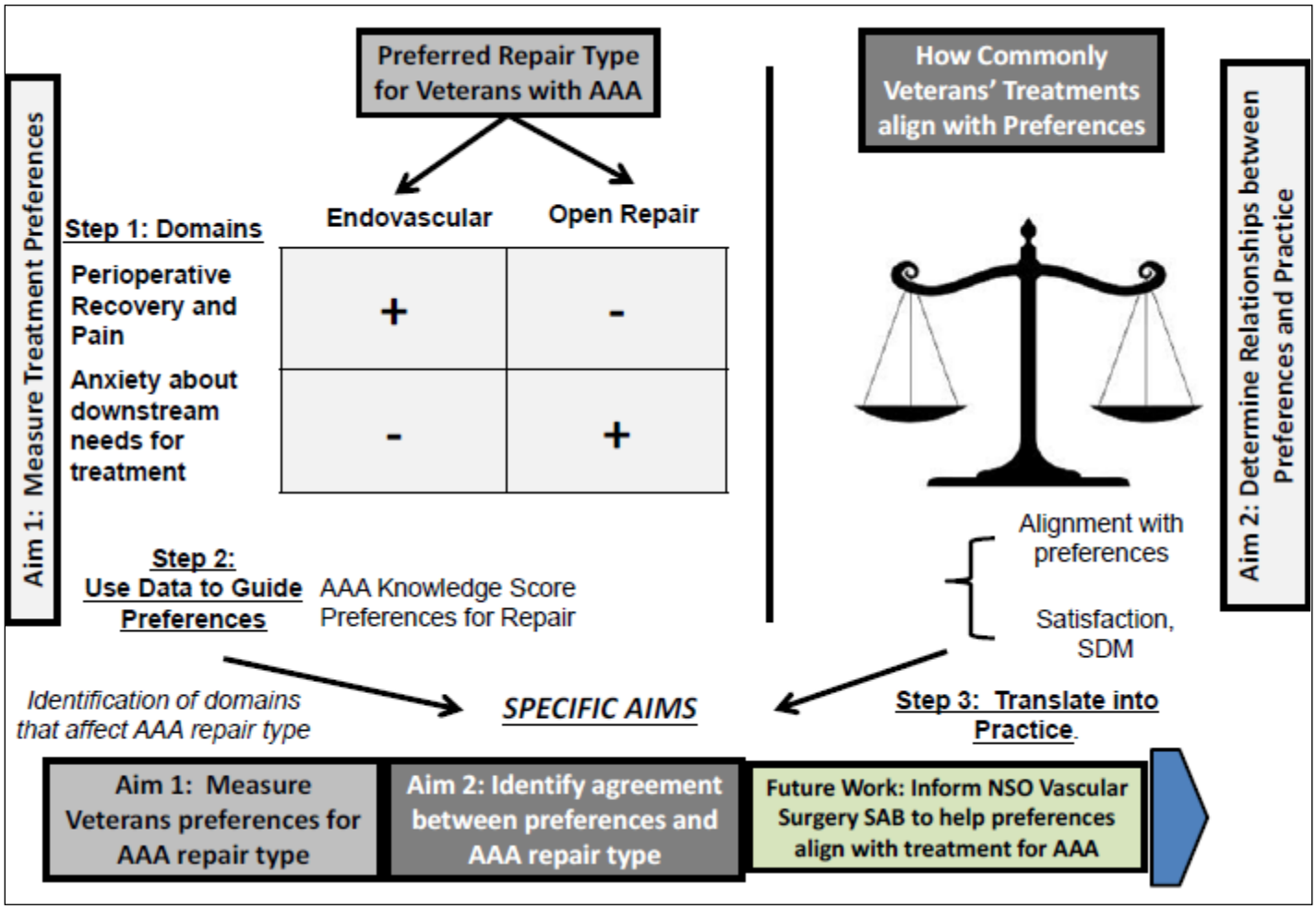
Shared decision-making is an approach where clinicians and patients share the best available evidence when faced with the task of making decisions, and where patients are supported to consider options to achieve informed preferences[57, 58]. The Veterans Health Administration has urged the adoption of shared decision-making for decisions facing elderly Veterans, such as decisions for long-term care[59]. These efforts in VA were developed along with the Informed Medical Decisions Foundation, which is led by Dr. Michael Barry. Dr. Barry is a Co-Investigator in this proposal, and represents an important link to the VA's existing work in shared- decision making[10]. Our proposal will help advance this science by determining how to best use shared decision-making models in the treatment of Veterans with vascular disease in VA. Poor decision satisfaction and limited shared decision-making are likely to result when treatment decisions are made without considering patient preferences[60, 61]. We hypothesize that *overestimating or underestimating* risk may result in poor alignment between Veterans' preferences and the repair type they receive for treatment of their AAA.

What are the barriers and facilitators to implementing a decision aid in a Vascular Surgery VA Clinic?
While a decision aid may guide our patient cohort to make decisions based on personal preferences, its implementation within the clinic environment may have implications as well. Past research has shown the positive effect of using patient support decision interventions; patients gain knowledge, better understanding of probabilities and increased confidence in decisions [4]. However, other studies have shown that clinicians may not always trust or agree with the content of decision tools and are also concerned with the disruption to established clinic workflows[5]. In this project, we plan to identify whether these elements impact the successful implementation of a decision aid in a Vascular Surgery VA Clinic, while also investigating other barriers and facilitators from the perspectives of the clinician, the research coordinator as well as the patient. This qualitative data from these individuals at PROVE-AAA enrolling sites will facilitate the identification of variables that may be vitally important to consider when implementing a decision aid in future practices. Although patient decision support interventions have been shown to increase a patient's knowledge and confidence in a specific procedure[4], we understand that this is an added variable to a surgery clinic visit.

Specific Aims

We describe a cluster-randomized trial comparing two ways to better align Veterans' preferences and treatments for AAA: (1) a validated decision aid describing AAA repair types with a survey measuring Veterans' preference for repair type -- versus (2) the survey alone. Enrolled Veterans will be candidates for either endovascular or open repair, and be followed at VA hospitals by vascular surgery teams who regularly perform both types of repair. The conceptual framework for our study is illustrated in Figure 4.

Figure 4: Conceptual Model - Aims 1 & 2



Aim 1: To identify Veteran and surgeon factors associated with preference for endovascular or open repair. We will use validated survey instruments to determine repair type preference (endovascular or open) for Veterans and surgeons,and identify domains in our survey associated with each repair type.

Hypothesis (H1): We hypothesize Veterans who prioritize concerns about pain or disability will prefer endovascular repair, and Veterans who prioritize concerns about durability will prefer open repair.

Aim 2: To determine the effect of the decision aid on agreement between preference and repair type. AAA growth rate estimates suggest 85% of our cohort will undergo repair within our two – year study period. Among patients in the intervention and control groups who undergo repair, we will compare how commonly Veterans receive the repair type they indicated as their preference. We will study potential explanatory variables from our survey, such as AAA knowledge, between the intervention and control groups. Patient satisfaction and shared decision making will be assessed in both the intervention

and control groups.

Hypothesis (H2): Our intervention will be associated with better agreement between preference and treatment type for Veterans with AAA, as well as higher post-operative satisfaction and greater shared decision-making.

Aim 3: To investigate the facilitators and barriers of implementing a decision aid in a VA surgical clinic. This will be accomplished by interviewing physicians, research coordinators and patients that are participating in the PROVE-AAA study. These individuals will be contacted through face to face or telephone interviews.

Hypothesis (H3): From a physician's perspective, the largest barrier in the implementation of the PROVE-AAA decision aid will be the disruption of normal clinic workflow. Those clinics that have developed an efficient implementation process will see this as less of an obstacle. This will be similar from the research coordinator's perspective, who may also see patient interaction time constraints as a barrier. The patient may understand the decision aid's contents much more when it is being explained to them in the clinic, as opposed to when they are considering it at home. On the other hand, certain facilitators of implementing a decision aid will include efficient clinic coordination, a standardized explanation process of the treatment modalities, and the patient's ability to independently outline the benefits and drawbacks of the treatment modalities.

2. Study Team

Dr. Goodney, the Principal Investigator, is a VA vascular surgeon and Co-Director of the VA Outcomes Group in White River Junction. A current NIH K08 awardee in health services research, he is experienced in conducting multicenter, cluster-randomized clinical trials[61, 62]. He is currently the Principal Investigator of a multicenter cluster-randomized trial of a smoking cessation quality improvement intervention funded by the Society for Vascular Surgery[62]. Dr. Goodney has assembled a team (Table 1) with extensive expertise in survey research (Dr. Sirovich), shared decision- making (Dr. Barry), and analyzing outcomes in VA (Mackenzie). Finally, Dr. Goodney and his team members have worked together before in several projects[63, 64,] many of which have studied physician practice[64-66] , so they are well prepared to collaborate effectively in this study. Their team, including site PIs, have collaborated on several projects which have studied physician practice[71-73] and each has significant time dedicated towards the proposal.

KEY PERSONNEL

Philip P. Goodney, MD, MS Principal Investigator. Dr. Goodney is an Associate Professor of Vascular Surgery and Co-Director of the VA Outcomes Group at the White River Junction VA. He is an affiliated faculty at The Dartmouth Institute for Health Policy & Clinical Practice (TDI) at the Geisel School of Medicine at Dartmouth. He received a Career Development Award in 2010 from the National Heart, Lung and Blood Institute (NHLBI) (K08HL05676) and the 2011 Lifeline Award from the Society for Vascular Surgery (SVS) to study variation in treatment and intensity in vascular care. In 2012, he was appointed Director of Surgical Outcomes Research at Dartmouth-Hitchcock Medical Center, and in 2013 he was named the Co-Director of the VA Outcomes Group at the White River Junction VA. In 2014, he received the Multicenter Trials Planning Grant from the SVS, and in 2015 he received funding from PCORI and FDA for patient-centered research. He has experience in studying the delivery of vascular care, surgical quality improvement efforts, and cluster- randomized trials in patients with vascular disease. In this study, Dr. Goodney will lead the team's efforts in a cluster-randomized trial that will compare the effect of two different strategies (decision aid plus survey versus survey alone) in helping determine the best ways to align Veterans' preferences for repair type in abdominal aortic aneurysm with their treatment. He will have access to PHI for the purpose of assisting other study team members in collecting follow-up data. Dr. Goodney will devote 3.6 calendar months of his time to the project in each of the four years.

Brenda Sirovich, MD, MS Co-Investigator / Survey Research and Veterans' Preferences. Dr. Sirovich is Co- Director of the VA Outcomes Group at the White River Junction VA Medical Center (in partnership

with Dr. Goodney). She is also Associate Professor of Medicine and Community and Family Medicine at Geisel School of Medicine at Dartmouth. With funding from HSR&D and the National Institutes on Aging, she is a nationally recognized researcher studying clinical practice intensity – a measure of practice patterns of physicians, with a focus on their thresholds to make invasive and non-invasive treatment decisions. Her work examining Pap smear screening practices and geographic variation in physician practice has been cited widely in the medical and lay media and has been included in CME training programs. She has led research teams conducting two large successful national physician surveys and has served on the VISN1 Specialty Consult Utilization Council. Given her broad expertise in survey research, she will assist Drs. Goodney, Barry, West, and MacKenzie in the development and execution of the cluster-randomized trial. She will devote 3.6 calendar months of her time in each of the four years of the project.

Michael Barry, MD (IPA) Co-Investigator / Decision Aids and Shared Decision-Making. Dr. Barry is an internationally recognized expert on decision aids and shared decision-making. He has extensive experience in the development, testing, and implementation of decision aids to foster shared decision-making, especially regarding treatments related to surgery. He has collaborated with Dr. Goodney in prior work on the Dartmouth Atlas of Healthcare and will extend these collaborations to this work as well. Specifically, he will work closely with Dr. Goodney to implement the survey and decision aid. He will subsequently analyze and interpret the results of the cluster-randomized trial. He will share his expertise in determining the domains that influence patient preferences. He will also be instrumental in interpreting findings related to the agreement between patient preferences and treatments and will help shape the recommendations that emanate from these findings. He will not have access to PHI. Dr. Barry will dedicate .6 calendar months in year 1, .3 calendar months in years 2 and 3, and 1.2 calendar months in year 4 of the project.

Todd A. MacKenzie, PhD Co-Investigator / Biostatistician (IPA). Dr. MacKenzie, a Senior Biostatistician at Geisel School of Medicine at Dartmouth, has a long history of collaboration with Dr. Goodney, Dr. West, and other VA HSR&D investigators. He has extensive expertise in providing statistical collaboration in clinical trials and multilevel hierarchical modeling. Further, he has previously collaborated with Dr. Goodney and his team on analyses incorporating large observational datasets, including VA datasets, Medicare claims and clinical registry data. Specifically, he has served as a biostatician on Dr. Goodney's NHLBI career development award, and they currently collaborate on a cluster-randomized trial funded by the Society for Vascular Surgery. In this study, in collaboration with Dr. Goodney and Dr. West, Dr. MacKenzie will oversee the implementation of statistical analyses, especially in the multilevel models described in Aim 1, as well as any weighted kappa calculations that are necessary in Aim 2. Dr. MacKenzie will devote 1.2 calendar months of his time in all four years of the project.

Table 1: Key Personnel

Team Member	Role	Skill Set	Task Aims
Philip Goodney, MD, MS	Principal Investigator	Vascular surgery, quantitative analyses, cluster-randomized trials	Overall project execution 1, 2
Brenda Sirovich, MD, MS	Co-Investigator	Assessing physician practice, preference-sensitive care using surveys	Interpret survey results in Aim 1 1
Michael Barry, MD	Co-Investigator	Shared Decision-Making, decision aids	Interpret survey results in Aim 1 and Aim 2 1,2
Todd Mackenzie, PhD	Co-Investigator	Biostatistics, observational dataset analyses, cluster trial design	Observational analyses, cluster trial design, statistical 1,2

OTHER PERSONNEL

Jodi Okrant and Joseph Burgess Central Study Research Coordinators: Our cluster-randomized trial entails the need for extensive coordination, oversight, and technical support for the study participants. To most effectively accomplish this goal, we will use Central Study Research Coordinators. The Central Study Research Coordinators will be responsible for maintaining IRB approval of the Study Protocol, coordinating training meetings for Site Study Coordinators, implementing the randomization scheme, and overseeing enrollment and follow-up goals at each of the study sites. Further, the Central Study Coordinators will work with each of the Site Study Coordinators to receive and catalogue survey data forms and case report forms. Both Central Study Research Coordinators will have access to PHI for the purpose of collecting participant information through CAPRI.

Cory Gaudette Central Study Coordinator: The Central Study Coordinator will work with Dr. Goodney in coordination of study processes filed between the study participants, assist in research coordinator and project analyst supervision, and coordinate the editorial process for manuscripts and reports. She will have access to PHI for the purpose of assisting other study team members in collecting follow-up data. Ms. Gaudette is ideal for this role, having managed several large projects in her role as the Administrative Officer of the VA Outcomes Group, and she coordinated the study sites for this proposal. Ms. Gaudette will devote 6 calendar months of her time in all four years of the project. She will retain her VA appointment at the White River Junction VA Medical Center.

TBA Programmer / Analyst.

Kayla Moore, MPH Research Project Director. Kayla Moore is a seasoned program manager with ten years' experience coordinating federal and privately funded health programs at academic and nongovernmental organizations. She currently works with Dr. Goodney and other surgical investigators at The Dartmouth Institute for Health Policy and Clinical Practice to operationalize surgical health services research projects. For this study, she will be responsible for managing start-up and administrative operations and facilitating IRB approval. Ms. Moore has a VA WOC appointment at the White River Junction VA Medical Center. She will have access to PHI for the purpose of assisting other study team members in collecting follow-up data.

To be Named Analyst Assistant. A part-time assistant will be assigned to work with the analyst on data capture and data entry. This person will have access to PHI for the purpose of data entry.

Greg Tsougranis, BA Student Researcher. Mr. Tsougranis is a medical school student at the Geisel School of Medicine at Dartmouth College. Under the direct supervision of Dr. Goodney, he will be responsible for leading the implementation of specific aim 3. Mr. Tsougranis will have access to PHI for the purposeof conducting face-to-face and/or telephone interviews with study participants.

OTHER PERSONNEL: LOCAL SITE INVESTIGATORS AND SITE STUDY COORDINATORS FOR TWENTY STUDY SITES

Each Local Site Investigator, named in Table 2 below, is a vascular surgeon in active practice at one of the 22-24 local VA hospitals participating in the study. Each Local Site Investigator regularly performs the procedures studied in this trial in routine practice. They will lead enrollment activities at their local site and will provide administrative support to the Site Study Coordinator in all four years of the project. Each Local Site Investigator will dedicate .6 calendar months in years 1 and 2, and .3 calendar months in years 3 and 4 of the study.

To Be Named. The Site Study Coordinator will be responsible for IRB submission, patient enrollment and consent, study intervention, and data submission from each site. Each Site Study Coordinator will identify and follow twelve Veterans from each site and receive specific training and biweekly oversight from the Principal Investigator and the study team. The Site Study Coordinator will dedicate 1.2 calendar months in each year of the study.

Who will have access to protected health information

Local Site Investigators and Site Study Coordinators will have access to protected health information (PHI) for participants only at their sites during recruitment for eligibility screening and during follow-up data collection. They will also have access to patient's records for care received while undergoing treatment for AAA that is not part of this research. Local Site Investigators and Site Study Coordinators will not have access to study data or PHI from any study sites other than their own. All members of the Coordinating Center Team in White River Junction, VT (Dr. Goodney, Ms. Gaudette, Ms. Moore, Ms. Jodi Lee, Mr. Joseph Burgess, and the analyst assistant) will also have access to PHI for the purpose of collecting participant demographic and follow-up information. The Programmer/Analyst will be responsible for assigning unique study IDs to code study data. All VA protocols for maintaining privacy and confidentiality of PHI will be strictly adhered to and the study key will be maintained behind VA firewalls and accessible only to VA credentialed personnel.

CONSULTANTS

Michael Barry, MD, Co-Investigator will be hired as a consultant. As described on page 10 above, his role is to provide expertise regarding the implementation of the survey and decision aid and interpretation of results. As stated on page 10, he will not have access to PHI.

3. Study Sites

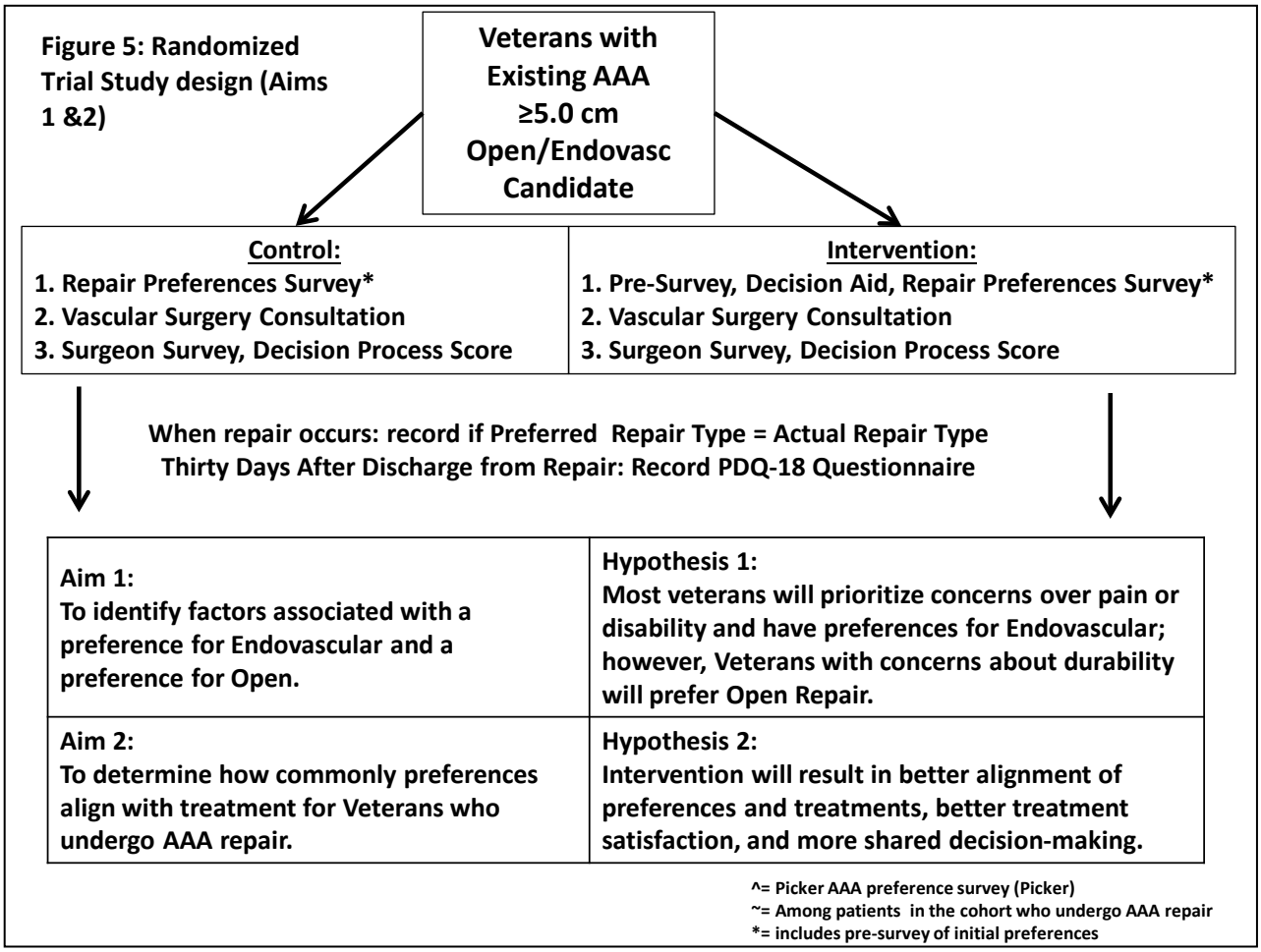
We have recruited a nationally representative sample from twenty VA hospitals across the country (Table

2). Our preparatory-to-research analyses indicate that hospital volumes in AAA repair have been constant (varied by <10% in the last five years), suggesting that our findings will be applicable towards treatment decisions for Veterans with AAA for several years in the future. In a pre-proposal survey, as well as assessment using CDA data, we confirmed that each study site performs at least five aortic repairs and fifteen endovascular repairs (or similar) per year, ensuring adequate ability at these sites to perform either repair type for Veterans. Contact information on each of the sites is listed below.

Table 2 Local Sites

Surgery Site	City/State	Complex/Intermediate	Site Investigator	Contact Information	Annual AAA Volume (Direct) FY 2014	Annual AAA Volume (Endovascular) FY 2014
VA Western New York Healthcare System at Buffalo	Buffalo, NY	Complex	Dr. Hasan Dosluoglu	(716) 862-8937	4	39
Valley Division - Sacramento VA Medical Center	Mather, CA	Complex	Dr. Eugene Lee	(916) 843-7202	0	21
VA Boston Healthcare System, West Roxbury Campus	West Roxbury, MA	Complex	Dr. Joseph Raffetto	(857) 203-6200	27	42
VA Ann Arbor Healthcare System	Ann Arbor, MI	Complex	Dr. Peter Henke	(734) 845-5939	21	33
VA Puget Sound Health Care System, Seattle Division	Seattle, WA	Complex	Dr. Gale Tang	(206) 764-2245	13	18
Durham VA Medical Center	Durham, NC	Complex	Dr. Leila Mureebe	(919) 681-2800	9	27
Michael E. DeBakey VA Medical Center	Houston, TX	Complex	Dr. Panagiotis	(713) 791-1414	2	49
Southern Arizona VA Healthcare System	Tucson, AZ	Complex	Dr. Wei Zhou	(660) 284-9527	2	27
Omaha VA Medical Center	Omaha, NE	Complex	Dr. Jason Johanning	(402) 995-3607	4	14
Atlanta VA Medical Center	Decatur, GA	Complex	Dr. Alabi Olamide	(404) 321-6111	4	30
Malcom Randall VA Medical Center	Gainesville, FL	Complex	Dr. Salvatore Scali	(352) 376-1611	19	37
White River Junction VA Medical Center	White River Junction, VT	Intermediate	Dr. David Stone	(802) 295-9363	0	11
VA Connecticut Healthcare System, West Haven Campus	West Haven, CT	Complex	TBD		2	15
Birmingham VA Medical Center	Birmingham, AL	Complex	Dr. Emily Spangler	(205) 943-2006	3	9
VA Pittsburg Healthcare System	Pittsburg, PA	Complex	Dr. Edith Tzeng	(412-802-3025	7	33
Phoenix VA Health Care System	Phoenix, AZ	Complex	Dr. Vivienne Halpern	(602) 277-5551	7	36
Minneapolis VA Health Care System	Minneapolis, MN	Complex	Dr. Daniel Ihnat	(612) 467-4239	4	94
VA Greater Los Angeles Healthcare System, West Los Angeles Medical Center	Los Angeles, CA	Complex	Dr. Jessica O'Connell	(310) 268-3445	3	14
George E. Wahlen VA Medical Center	Salt Lake City, UT	Complex	Dr. Benjamin Brooke	(801) 582-1565	0	15
James A. Haley Veterans Hospital	Tampa, FL	Intermediate	Dr. James Brooks	(813) 972-2000	11	71
Palo Alto VA Medical Center	Palo Alto, CA	Complex	Dr. Shipra Arya	(650) 493-5000		
Jack C. Montgomery VA Medical Center	Muskogee, OK	Intermediate	Dr. Peter Nelson	(800) 827-1000		
TBA Future Date						
TBA Future Date						

4. Study Design



Study Design: Our cluster-randomized trial has two Specific Aims. First, we will test the effect of an intervention (decision-aid + survey) versus the survey alone on preferences for repair type (Aim 1). We hypothesize that the intervention will be associated with a greater preference for open repair among Veterans who value long-term durability in their repair type.

In Aim 2, we will test the effect of the intervention (decision-aid +survey) versus the survey alone on agreement between Veterans' preference and actual treatment (Aim 2). We hypothesize that the intervention will be associated with greater agreement between Veterans preferences and the repair type they receive.

Our instrument – both the decision aid and survey- was developed and validated by the Picker Institute in England[28]. We modified to use United States English language (Appendix 2). In preparatory-to-research work, we pilot-tested the instrument in two cognitive interviews at White River Junction and administered the instrument to five patients at three sites. We will test the effect of our intervention (versus control) on the following outcomes: (1) Veteran preference for repair type, and the domains associated with preference for each repair type, (2) the agreement between Veterans' preferences and their actual repair type, and (3) the Decision Regret Scale, administered 30 days after repair to assess decision satisfaction.

Qualitative Study Design: Separately from the cluster-randomized trial, we will use qualitative methods to investigate the facilitators and barriers of implementing a decision aid in a VA surgical clinic through

key informant interviews at intervention sites (Aim 3). We hypothesize that from the physician and research coordinators' perspectives, the largest barrier in the implementation of the PROVE AAA decision aid will be the disruption of normal clinic workflow. Those clinics that have developed an efficient implementation process will see this as less of an obstacle. On the other hand, certain facilitators of implementing a decision aid will include efficient clinic coordination, a standardized explanation process of the treatment modalities, and the patient's ability to independently outline the benefits and drawbacks of the treatment modalities.

Definition of "Usual Care": In both the intervention and control groups, Veterans will have "usual care" for the treatment of their AAA. This is defined as a routine outpatient consultation with a VA vascular surgeon for their AAA and AAA repair at the discretion of the surgeon during the study period. Estimates from the MASS trial[80] and RESCAN meta analyses [81, 82] suggest that 85% of enrollees will progress to repair during the study. In this study, usual care will be provided by the study team.

Study Location: Our study will be based in the VA Outcomes Group in White River Junction, Vermont. We will use our secure VA Research Server as the Study Data Core. All study related committees will meet at the offices of the VA Outcomes Group, either in person or using existing secure teleconference facilities. Web-based study team meetings will be held every other week and will use videoconference to minimize expense. Two study meetings will be held at the annual meetings of the Association of VA Surgeons and at the Society for Vascular Surgery during each year of the study. This will serve as a cost-effective way for our group to meet biannually during the study period.

Characteristics and selection of the study population: Our study population will be Veterans, vascular surgeons and coordinators enrolled at 10-12 intervention sites and 10-12 control sites in our cluster-randomized trial. The inclusion criteria for patients will be Veterans with a >=5.0 cm AAA that are candidates for endovascular and open repair. Step C of the Study Procedures describe the recruitment procedures and inclusion criteria in detail.

STUDY PROCEDURES – AIMS 1 & 2

Step A: Recruitment of Surgeons Twenty-two to twenty-four VA hospitals that currently perform both endovascular and open repair are the study sample. (The Study will start with 20 sites and may add up to four additional sites as needed to reach overall patient enrollment targets). Each local site investigator has been interviewed and their credentials vetted by the PI and has accepted to participate in the study. Local site investigators may invite one or two additional surgeons whom they work with at their site to participate in the study. Site Study Coordinators will provide surgeons the Study Invitation and Information Sheet at the start of the study period and document the date. A waiver of documentation of informed consent for surgeons will be requested since the surgeon's participation involves no procedures other than completion of a survey and presents no more than minimal risk.

Step B: Selection of Intervention Centers: In Aim 1, we will conduct the intervention in 120 patients across 10-12 VA hospitals randomly assigned to the intervention arm. We will have a 9:1 stratified randomization scheme, so that we have a similar proportion of Complex and Intermediate Surgical VA hospitals in the intervention and control arms. These are the only two types of VA hospitals that perform AAA repair. Sites will be randomized at IRB approval in a rolling fashion. Site specific Study Coordinators will use the Study Protocol to facilitate IRB approval.[3, 15].

Step C: Recruitment of Patients: *We are requesting a waiver of informed consent for recruitment since potential participants will be identified through the screening process described as follows.*

i. Potential candidate referred to VA vascular surgery clinic. The first contact with potential participants will occur when a referring physician indicates that they should be seen by a vascular surgeon for treatment of their AAA, and the patient is given an appointment for a consultation with a vascular surgeon at a study site.

ii. Identification of 12 Veterans with a >=5.0 cm AAA who are candidates for endovascular and open repair. The Site Study Coordinator will screen all new consultations made to VA vascular surgery clinics for Veterans with AAA that meet size criteria of ≥ 5.0 cm. Baseline audits at three clinics indicate ~15 new AAA referrals per vascular surgeon per month, and 60% of Veterans have an AAA that meets size criteria. Assuming a refusal rate of 50%, we anticipate we will enroll fully three months after enrollment begins, with a screening rate of 8 patients per site per month and an enrollment rate of four patients per site per month. As surgical volume and capacity varies at each site, the exact number of Veterans enrolled per site may vary.

iii. Ensuring Veterans with AAA are candidates for both endovascular and open surgical repair. Radiologic reports for new AAA consultations will be reviewed by the Study Coordinator according to the Site Recruitment Guide (Appendix 1). If a patient has an AAA that meets these size criteria (≥5.0 cm in diameter, the Study Coordinator will contact the Site Principal Investigator. The Site Principal Investigator will review imaging tests and the Veteran's electronic health record to ensure the Veteran is a candidate for endovascular and open repair using anatomic and clinical criteria defined according the Instructions for Use for each individual aortic endoprosthesis. These criteria derive from the Instructions-For-Use protocols determined by the Food and Drug Administration[83]. Site Principal Investigators will have discretion in interpretation for placement of an endovascular prosthesis outside of IFU guidelines. If the Veterans meets criteria for both open and endovascular repair, the Site Principal Investigator will inform the Study Coordinator.

iv. Inviting Veterans who are candidates to participate in the study: Once a candidate has been identified, the Study Coordinator will note the time and location of the Veteran's appointment. Note that many study sites serve a large geographically dispersed population and routinely perform consult visits over the phone. Therefore, the enrollment process will differ depending on whether the Veteran will be seen in person for their consult visit, or via the telephone.

a. For In-Person Consults: When the Veteran arrives for their appointment, they will check in as usual and proceed to the waiting room. The first contact with potential participants will be made by The Study Coordinator or other Study Team member who will take the Veteran to a consult room. Once in the consult room, the Study Coordinator or other Study Team Member will use the Study Introduction Script (Appendix 5), to describe the intervention to the Veteran (decision aid and survey) and invite them to participate. Veterans will be offered some time to review the consent form. If they wish to have more time to discuss it with their family and friends, they may reschedule their appointment and return on a later day. The Veteran will be informed that they will be remunerated $50 at the completion of their first appointment for their time spent completing study documents and surveys.

b. For Phone Consults: In the case where a telephone conversation takes the place of an in-person clinic visit, the study coordinator will mail the Veteran a letter letting them know about the study in advance (see attached). The Coordinator will then call the Veteran prior to their consult with the vascular surgeon to describe the study and invite them to participate. If they wish to have more time to discuss it with their family and friends, or review the survey instruments on paper, the coordinator will offer to reschedule their consult for a later day and mail the Veteran a packet with the study materials. The Veteran will be informed that they will be remunerated $50 at the completion of their first appointment for their time spent completing study documents and surveys.

v. Consent process: Once a Veteran has expressed interest in the study, the Study Coordinator or other Study Team Member will review the consent form or Info Sheet for Veterans with them, answer any questions, and obtain consent. In the cases of telephone enrollment, there will be a waiver of documentation of informed consent. Coordinators will mail the Info Sheet to the Veteran and document the date consent was obtained. After consent has been obtained by the study coordinator, the Veteran will be taken through the survey process. Coordinators will also mail Veterans enrolled via phone a request for HIPAA authorization along with a stamped return address envelope. A cover

letter will instruct the Veteran to return the signed HIPAA authorization form to the study coordinator using the envelope provided, and to retain a copy for their records.

For any Veterans who are unable to read, the study coordinator will read the consent form to them in the presence of a witness. A witness is required to be present during the entire consenting process for illiterate participants and the witness will sign the informed consent to indicate he/she witnessed the participant "making their mark" consenting to be in the study. For any Veterans who identify Spanish as their preferred language, a certified translation of the consent form will be provided and a 24-hour translation service will be contacted to translate the discussion. This translation service will be used as needed for all future discussions with the Veteran.

Step D: Survey administration at intervention and control sites:

Process at the Intervention Sites:

Step 1: The Pre-Survey will be administered with the Veteran by the Study Coordinator. (2 minutes)
Step 1a: The Study Coordinator will review the Decision Aid with the Veteran. (5-10 minutes)
Step 1b: The Study Coordinator will administer the Survey. (10 minutes)
Step 2: The Study Coordinator will escort the patient to the visit with the vascular surgeon.
Step 3: After the Visit, the Study Coordinator will complete the Decision-Process Score with the Veteran. (5 minutes)
Step 4: Thirty days (± 2 weeks) after enrollment, the study coordinator will notify the veteran to complete the PSQ-18, either in-person or over the phone. (See Phone Script_PSQ18) If unable to reach veteran within this timeframe, another member of the study team will try to collect the PSQ-18 outside of the established thirty day +/- 2 week window.
Step 5: Thirty days (± 2 weeks) after AAA repair, the study coordinator will notify the veteran to complete the PSQ-18. (5 minutes), either in-person or over the phone. If unable to reach veteran within this timeframe, another member of the study team will try to collect the PSQ-18 outside of the established thirty day +/- 2 week window.

The decision aid is available in English and Spanish.

The patient will be remunerated at completion of the enrollment visit. Data will be recorded securely by the Site Study Coordinator.

The Veteran will be thanked for their participation by the study team via a formal letter mailed from the Principal Investigator.

Process at the Control Sites:

Step 1: The Study Coordinator will administer the Survey. (10 minutes)
Step 2: The Study Coordinator will escort the patient to the visit with the vascular surgeon.
Step 3: After the Visit, the Site-Specific Research Coordinator will complete the Decision-Process Score with the Veteran. (5 minutes)
Step 4: Thirty days (± 2 weeks) after enrollment, the study coordinator will notify the veteran to complete the PSQ-18, either in-person over the phone. (See Phone Script_PSQ18) If unable to reach veteran within this timeframe, another member of the study team will try to collect the PSQ-18 outside of the established thirty day +/- 2 week window.
Step 5: Thirty days ± 2 weeks after AAA repair, the study coordinator will notify the veteran to complete the PSQ-18, either in-person or over the phone. (5 minutes) If unable to reach veteran within this timeframe, another member of the study team will try to collect the PSQ-18 outside of the established thirty day +/- 2 week window.

The patient will be remunerated at completion of the enrollment visit. Data will be recorded

securely by the Site Study Coordinator.

The Veteran will be thanked for their participation by the study team via a formal letter mailed from the Principal Investigator.

<u>Surgeon survey administration at both the intervention and control sites:</u>

Step 1: The Study Coordinator will administer the Pre-Visit Survey to the surgeon (1 minute, according to pilot testing at four sites in the trial, and two sites outside the trial).

Step 2: The surgeon will have the clinic visit with the Veteran.

Step 3: After the Visit, the Study Coordinator will complete the Post-Visit Survey with the surgeon (1 minute).

Data will be recorded securely by the Study Coordinator.

<u>Recruitment Target:</u> We will recruit a total of 120 Veterans in the intervention arm and a total of 120 Veterans in the control arm. The unit of analysis will be the Veteran. Randomization will occur at the site level, in a stratified 9:1 randomization scheme, based on the VA hospital's Surgical Complexity designation. We will enroll 8-10 Complex and 1-2 Intermediate sites per arm. Randomization will occur at the time of IRB approval. Weekly conference calls with Site Study Coordinators will assess study enrollment rates and help with problem-solving.

<u>Exclusion Criteria</u>: Veterans with AAA who are not a candidate for both endovascular and open surgical repair will be excluded. Veterans who have already undergone AAA repair will be excluded. We will include Veterans who speak English and Spanish, using a translated survey instrument (Appendix 2). Veterans who cannot read will be offered participation by allowing the Site Study Coordinator to administer the survey.

<u>STUDY PROCEDURES – AIM 3</u>

Aim 3 will be conducted after enrollment is complete across all intervention sites in order to avoid potential interference with implementation of the cluster-randomized trial. This will also allow us to identify intervention sites which have readily implemented the use of the decision aid vs intervention sites which have been slower to implement the use of the decision aid during the trial, which will be used to inform sampling for key informant interviews.

<u>Step 1: Selection of Key Informants</u>. We will use a mix of purposive sampling to recruit patients, surgeons and coordinators from intervention sites with the goal of obtaining a wide range of perspectives. Sampling will be conducted iteratively starting with 2-4 intervention sites, and then expand to remaining intervention sites. Efforts will be made to include a mix of perspectives based on study performance, clinic size, gender, and age. All study team members and Veterans from intervention sites will be eligible to participate, although the number of participants invited to participate will depend on how long it takes to reach saturation.

<u>Step 2: Recruitment:</u> Potential key informants will receive a written invitation inviting them to participate in the study. Specifically, study team members (coordinators and surgeons) will be contacted via email. Patients will be contacted via email or invited during the post-surgery survey interviews with study team members. Each invitation will contain an information sheet about the goal of the interview, and contact information for questions or to schedule an interview. Up to three attempts will be made to contact each subject.

<u>Step 2: Informed Consent</u>. The information sheet summarizing the goals of the interview, risks and benefits will be reviewed with each subject prior to the interview and verbal consent will be obtained. As the interviews will not affect patient care and pose minimal risk to subjects, we are requesting a waiver of documentation of informed consent.

Step 3: Interviews. Key informant interviews will be conducted with patients, research coordinators and physicians who are currently study team members at a PROVE-AAA intervention enrolling site. Table 3 shows the list of main topics and probes for each key informant group which will provide structure to the interview process. Interviews will be conducted by the student investigator in a conversational style. Questions will be posed in an open-ended manner and will be adapted in real-time based on the interviewees' responses. Interviews will be either face-to-face or telephone communication using the three Aim 3 Interview Questionnaires, #1 PI Questionnaire, #2 Coordinator Questionnaire, and #3 Participant Questionnaire.

Table 3: Sample Interview Questions

Individual Questioned	Topic investigated	Sample Questions
Physician	Delay of clinic workflow	*How does a decision aid affect your current clinic workflow?*
	Structured process of decision aid implementation	*Is the decision aid implementation process efficient at your site? Can you please describe it?*
	Confidence in decision aid content	*Are you in agreement with the content of the decision aid? If not, which portions of the decision aid do you question?*
	Prioritization of aid in patient visit	*How important is the implementation of a decision aid in comparison to the other aspects of your patient interaction?*
Research Coordinator	Training on patient shared decision making	*Were you trained on how to properly interact with patients who are considering multiple treatment options?*
	Patient interaction time constraints	*Do time constraints limit your interactions with these patients?*
	Appropriate coordination with physician	*Have you coordinated an efficient implementation system with the physician?*
	Standardization of decision aid implementation process	*Is your description of the decision aid consistent from patient to patient?*
Patient	Prolonged clinic visit	*How did the length of the clinic visit (with the decision aid) compare to your normal visits?*
	Overall understanding of decision aid contents	*Did the decision aid make sense even after leaving the clinic? If asked to, could you outline the differences between treatment options?*
	Pre-disposed biases on treatment modality	*If you had an initial preference, did the decision aid make you question it?*
	Comfort and confidence in treatment choice	*Did the decision aid make you more comfortable with your eventual treatment choice?*

Time Frame: Our study timeline is shown in Figure 6. IRB approval and site randomization will occur during the first 0-3 months of Project Year (PY1). Enrollment will begin at PY1 Month 3 and will be

completed by the end of PY1 at all sites (a conservative estimate). After two-year follow-up on all sites in our cohort during PGY2-3, we will examine our final outcomes and complete reports and manuscripts in PY4.

Figure 6: Timeline	Project Year 1				Project Year 2				Project Year 3				Project Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Study Milestones																
IRB approval at Sites 1-24																
Study Coordinator Training																
Enrollment Sites 1-24			25%	50%	75%	100%										
Aim 1 (Intervention, Survey)					25%	50%	75%	100%								
Aim 2 (Follow-up)									25%	50%	75%	100%				
Aim 3 (Interviews at Intervention Sites)																
Training and Analytic Milestones																
IRB submissions																
Dataset repository construction																
Accept initial enrollees																
Patient Screening/Enrollment																
Data Collection / Assessment																
DSMB Auditing																
Fidelity testing by DSMB																
Results testing by DSMB																
Manuscripts, reports, future funding																

Risk to Subjects (Veterans and Surgeon Participants).

Human Subjects Involvement and Characteristics.

Aim 1: Cluster-Randomized Trial of a Decision Aid and Survey (versus Survey alone) for different types of AAA Repair

In our study, we will identify Veterans presenting to Vascular Surgery Clinic with abdominal aortic aneurysms who are candidates for endovascular or open repair.

Sources of Materials.

Aim 1 and Aim 2 Survey Results, Aim 3 Paper Source Documents

The materials for Aim 2 will be the results from our survey administered as described in Aim 1 and Aim 2. The materials for Aim 3 will be the transcribed/dictated ontopaper source documents from the interviews conducted in Aim 3. In accordance with our Data Management Plan, all will be coded to protect PHI, with study entrants being assigned a study identifier throughout the data management process. The study key that allows identification between individual study patients and their protected health information (PHI) will remain behind VA firewalls and will not be routinely used as part of the study analyses. We will create individual random identifiers for each study patient, and all study dates will be removed and replaced with time-to-event variables to limit any potential PHI contained in study datasets.

Potential Risks for Veterans.

Decision Aid, Survey and Interview

Our cluster-randomized trial will compare the effect of a patient educational tool (the decision aid) on survey responses describing patients' preferences for different types of AAA repair. Both types of AAA repair are commonly performed across VA, and both are commonly accepted alternatives for the treatment of AAA.

The intervention consists of provision of standardized information to patients, compared to taking the survey alone. Given that the intervention consists only of a standardized delivery of information that is commonly shared with patients during a routine vascular surgery clinic consultation, there are minimal risks to the

Veterans who will participate in our survey. Similarly, the interviews conducted in Aim 3 consist only of a conversation regarding the Veteran's perceptions of the barriers and facilitators to implementing a decision aid. Given that these interviews will be conducted after the intervention and do not affect patient care, there is minimal risk to participating in the interview. All sites and surgeons will be assigned unique study IDs in our dataset and indexed only through anonymous identifiers. Further, our data will be stored on VA servers, behind VA firewalls.

Potential Risks for Surgeons and Coordinators.

Surgeon Survey and Interview

In both the intervention and control groups, we will examine surgeon preferences for repair type for each Veteran. For the qualitative aim, Surgeons and Coordinators at Intervention Sites may also be invited to participate in an interview. The surgeon and coordinators' names will be assigned to a randomly generated identifier, and a key at each site will be kept to allow the study team members to remain unidentifiable in research datasets.

All surgeons participating in the study will receive the Study Invitation and Information Sheet from the Site Study Coordinator at the time of study initiation. For Aim 3, a separate Interview Invitation and Information Sheet will be provided to the study team members and patients. We anticipate IRB approval for a waiver of documentation of informed consent for study team members to participate in the survey and interviews.

For Veterans, there is a control arm (survey alone) and intervention arm (survey + decision aid). For surgeons, however, all will receive the same surgeon survey. This is simply a validated survey which records the factors they use to make their decisions. Given that the intervention consists only of a standardized delivery of information that is commonly shared with patients during a routine vascular surgery clinic consultation, there are minimal risks to the surgeons who will participate in our survey.

Similarly, given that the interviews will explore perceptions about potential barriers and facilitators to use of the decision aid, and does not include an intervention, there is minimal risk to subjects for participating in the interview. No identifiable data will be made available, placing no risk on study surgeons or coordinators. Surgeons and coordinators will be assigned unique study IDs in our dataset and indexed only through anonymous identifiers. Further, our data will be stored on VA servers, behind VA firewalls.

Adequacy of Protection from Risk.

Recruitment and Informed Consent.

For our survey, we will perform recruitment at each site, as described in our study procedures. Our Site Study Coordinator will obtain consent prior to administering the intervention. Explanation of the anonymous nature of the interviews will be provided to the subjects. Informed consent will be logged electronically and secured at our central server behind the VA firewall.

Protection Against Risk.

The risk of a confidentiality breach is minimized by the fact that these data will be maintained on the White River Junction VAMC's dedicated research server, behind the VA firewall. Only summary statistical analyses are ever exported from the server. Data analysts for this project will use only the anonymous study IDs to distinguish individual subjects in study datasets. The risk of a data breach that will compromise personal information is minimal.

Potential Benefits of Research to Subjects and Others.

There are no direct benefits to Veterans or study team members participating in this research. There is a potential benefit for Veterans enrolled in the intervention arm of this study, which is a clearer pathway for communicating their preferences about their abdominal aortic aneurysm to the surgeon treating their aneurysm. Further, the information to be derived will be of great value for the planning of future

interventions and resource allocation to provide Veterans the best access to the highest quality care for high-risk surgical interventions such as AAA repair.

Importance of Knowledge to be Gained.

This study will yield new information about outcomes for expensive and high-risk conditions/ procedures to support the planning of optimal resource allocation. It will distinguish VA facilities that achieve the best outcomes for further study, and it will identify the components of inpatient services that yield the best outcomes for Veterans with AAA. The knowledge to be gained will help VA planners improve access to care for patients with high-risk surgical conditions, and the benefits will greatly outweigh the limited risks to confidentiality and patient safety.

Data and Safety Monitoring Plan.

As this study involves a survey and interviews only, we do not anticipate any serious adverse events related to the research, and that any adverse events which occur during the study period are likely to be related to underlying, pre-existing medical conditions, and/or the surgery. Therefore, we will not routinely collect any data to assess harms. The Data and Safety Monitoring Committee will be responsible for ensuring that data conduct is commensurate with any potential benefits or harms evident in quarterly analysis of study datasets. **Any unanticipated problems which may arise involving risks to subjects or others, related to research (including data integrity/security issues) will be documented and reported to the IRB within 5 business days after becoming aware of the event, in accordance with VHA Handbook 1058.01 Paragraph 6.** This study will adhere to the **VA Central IRB Table of Reportable Events**. Data accuracy and integrity will meet the standards for VA or Medicare administrative treatment files.

5. Study Committees

We have established a study committee structure as outlined below, consisting of three central committees: A Steering Committee, A Data Safety Monitoring Board, and a Publications Committee. The committees are staffed by Key Personnel and six experienced, VA-funded surgical investigators (Zhou, Nelson, Johanning, Rafetto, Dardik, and Henke). Each Committee will meet quarterly during the study period.

AAA Survey Study Steering Committee,

Philip Goodney,
Brenda Sirovich,
Michael Barry,
Wei Zhou,
Peter Nelson,
Jason Johanning,
Joseph Raffetto,
Alan Dardik
Peter Henke

AAA Survey Study Data Safety Monitoring Board

Todd Mackenzie
Richard Powell (external auditor)

AAA Survey Study Publications Committee:

Philip Goodney
Brenda Sirovich
Michael Barry

6. Coding Guide and Data Management Plan

Procedures for Aims 1 & 2:
Procedures for managing the flow of information from participating sites is detailed below. Any deviation from these procedures that might be relevant to participant protection will be reported to the PI within 24 hours. The PI will have 24 hours to investigate the occurrence and convey the information to the VA Central IRB. All study team members must adhere to the **VA Central IRB Table of Reportable Events** all documented VA security policies and protocols. Removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team.

Step 1:

Each completed survey and consent form will be completed by the Veteran under the supervision of a member of the study team.

Step 2:

The survey document will be sent via secure VA fax to a fax machine located in our coordinating center office within a secure VA building or encrypted email. The building is only accessible by credentialed VA staff.

Step 3:

After confirming secure receipt of the Fax or encrypted email, a PDF copy will be scanned onto our Research Server. The Site Study Coordinator will store the original documents in a locked file until study conclusion. Original documents will be destroyed in accordance with the VA Records Control schedule.

Step 4:

The survey data will be extracted by the Analyst, Analyst Assistant or other member of the Central Study Team and imported into analytic software files (SAS) to allow for analysis by Dr. Mackenzie. In addition, the Coordinating Center Study Team will use real SSN to collect patient demographic information through the VINCI and CDW environment. CAPRI will be used to review charts for other research information needed in regards to the technical aspects of the procedure itself, including description of the nature of the aortic aneurysm and its repair type. All research datasets will be destroyed in accordance with the VA Records Control Schedule.

Long term follow-up Data Collection:

To inform the agreement between preferences and repair type, we will compare the preference identified for each Veteran in Aim 1 and the actual AAA repair type the Veteran receives.

This will be done by the Coordinating Center Team. They will have access to PHI of participants for the purpose of follow-up and for the analytic phase. During the analysis phase, demographics, comorbidities, and variables related to the technical performance of the aortic aneurysm repair (such as aortic aneurysm anatomy and repair type) will be put into datasets for use by the PI and statistician. The data will stay in the VINCI environment and there is no need to ask for or download any data out of VINCI. All data handling will be in full compliance with VA data policy.

During the Study Period, The Coordinating Center Team will audit CAPRI for each enrolled Veteran at all study sites.

If PSQ-18 post-enrollment and post-surgery survey's are not completed within the 30 day +/- 2 week window, The Central Study Research Coordinator will contact the enrolled patients via phone to collect the survey.

If no record of repair exists, the Central Study Research Coordinator or Analyst will contact the enrolled patients via phone to ensure repair has not been performed outside of VA.

Patients who do not undergo repair or who die prior to repair will be excluded from this step in the analysis.

Procedures for Aim 3:

Step1: Transcription. Interviews will be transcribed manually by the student researcher during the interview. Transcripts will be anonymized prior to analyses. The paper source documents will be kept under lock and key and will be destroyed in accordance with the VA Records Control schedule.

7. Data Analysis

(Please note: The following sections are described separately for each Aim).

Aim 1: **To identify Veteran and surgeon factors associated with preference for endovascular or open repair.**

Aim 1. Dependent and Independent Variables: The main dependent variable in Aim 1 is the preference for repair type (endovascular or open) as expressed by Veterans and surgeons in their respective survey instruments. Each survey instrument has a validated coding algorithm which will be used to categorize survey responses into preference for endovascular or open repair (Appendix 2) [44]. Independent variables, such as age, gender, race, ethnicity, and other descriptive variables are recorded as part of the survey instrument by the Site Study Coordinator. Hospital and surgeon characteristics such as annual hospital and surgeon volume of endovascular and open repair for each participating site will be collected via VINCI by the analyst or other member of the Central Study Team. These variables will be measured at the hospital level, as in prior analyses.[65, 97-100]

Aim 1:.Data analytic strategy: tests, strengths, limitations, and alternative approaches: In Aim 1, our main outcome variable will be Veteran and surgeon preference for repair type (endovascular or open repair). The preference will be defined as either preference for endovascular or preference for open repair. Repair type preference will be categorized from several questions in our survey instruments. Several questions allow for differing degrees of choice (e.g., strongly/slightly favor open repair). For these responses, we will use variables that allow this category. We will use a coding algorithm (Appendix 2) which deconstructs survey questions into components that generate binary outcomes (i.e., preference for open or endovascular repair) and allows sensitivity analyses using the gradients. We will compare the proportion choosing each repair type in the intervention and control groups to test the effect of the decision aid on repair type preference. The proportions preferring each repair type will be compared between the two groups accounting for clustering of patients within center and/or surgeon; in particular, we will used the Mantel-Haenszel test (for stratified contingency tables, equivalent to partial likelihood ratio test from fixed effects logistic regression) or a mixed effects logistic regression with fixed effect of group, and random intercept for center effects.

Aim 1 Data Collection Strategy: potential problems and solutions Refer to Section 6 of this Protocol Coding Guide and Data Management Plan.

To identify patient characteristics (such as survey responses) associated with preference for

endovascular or open repair we will use multivariable mixed effects logistic regression. The use of mixed effects is to account for clustering within individual VA centers using a random intercept, e.g. logit Pr[Y_ij=1]=X_ij β+μ_i where Y_ij is the binary preference variable in subject j from cluster i, X_ij is a vector of characteristics, μ_i is a random intercept from a zero mean distribution with standard deviation to be estimated (e.g. normal), and β is a vector of coefficient(s). We will explore the feasibility (e.g. convergence) and sensitivity of findings of patient characteristics of using ether a random intercept for surgeon, or for center, or for surgeon nested within center. We will report both unadjusted and adjusted estimates, after identifying one or more models to adjust for using for instance stepwise regression or LASSO. Stata (e.g.,xtmelogit) and/or R (library lme4 or nlme) software will be used. Dr. MacKenzie has extensive experience in these strategies.

Missing Data: To accommodate missing data where justified (e.g. the variable with missing data is predictive and deserves to be adjusted for, and furthermore the data is believed to be missing at random) we shall use multiple imputation methods, such as implemented in the Stata *mi* routine.

Power Analysis: Comparing the effect of the decision aid on repair type preference. Because the decision aid will inform Veterans more fully about the long-term disadvantages of endovascular repair, we hypothesize that the decision aid will reduce the proportion of Veterans who prefer endovascular repair by 25%, based on similar decision aids studied in surgical settings in breast cancer and back pain[16-18].

Table 3 Sample size and power calculations (assuming a 90% baseline rate of EVAR preference)

Number of clusters*		Number of patients per cluster		Total Number of Patients		Proportion Choosing Endovascular Repair At Control Sites	Decision Aid Effect Size (in relative decline in preference for endovascular repair)	Proportion Choosing Endovasc Repair at Intervention Sites	Power To detect significant difference (ICC 0.01)	Power To detect significant difference (ICC 0.05)	Power To detect significant difference (ICC 0.10)
Intervention	Control	Intervention	Control	Intervention	Control						
10	10	12	12	120	120	0.9	0.25	0.68	0.96	0.86	0.81
10	10	12	12	120	120	0.9	0.20	0.73	0.88	0.75	0.62
10	10	12	12	120	120	0.9	0.15	0.78	0.71	0.50	0.39

*Power calculations use 10 as the minimum number of sites per cluster and 12 at the approximate number of patients per cluster. Increasing the number of sites will make these estimates conservative, thereby increasing power.

We adjusted our sample size calculations for our cluster-randomized trial to account for intra-cluster correlation and allow for variable enrollment size within each cluster. As shown in Table 8, we anticipate that we will have 96% likelihood of detecting a 25% effect size, assuming an ICC of 0.01. Sensitivity analyses around our ICC assumption of 0.01 demonstrate that even if our ICC is ten times higher (ICC=0.10), our sample size would still yield an 81% likelihood of detecting a 25% effect size between intervention/control.

Aim 2: To determine the effect of the decision aid on agreement between preferences and repair type.

Aim 2 Dependent and Independent Variables: After identifying Veterans' preference for endovascular or open repair, we will determine the agreement between their preferences and the repair types they receive. The dependent variable will be the kappa statistic (κ), measuring agreement between the preferred repair type and the repair type the Veteran ultimately receives. Cohen's kappa will be compared between the intervention and control groups. Kappa will be calculated overall and by hospital (using a weighted sum of the kappas for each hospital in that arm. As a secondary outcome, Site Study Coordinators and/or member of the study team will administer two surveys to the Veteran. These two surveys will examine patient satisfaction (PSQ-18) and shared decision making (Decision Process Score, or DPS)[87, 104.] Our group has used these or similar instruments in prior work104, 105. A survey administration training guide for each Site Study Coordinator has been developed. The DPS will be administered at the end of the visit, and the PSQ-18 will be completed at 30-day follow-up clinic visits which are already standard practice after AAA repair for both repair types Completing the surveys in this context will not require any extra visits by Veterans, an important strength given the elderly population of patients involved in our proposal.

Aim 2 Data Collection Strategy: potential problems and solutions: To inform the agreement between preference and repair type, we will compare the preference identified for each Veteran and the actual AAA repair type the Veteran receives at each site. We anticipate that 85% of Veterans will undergo repair within three months after the study visit in which they are enrolled. However, we estimate that 15% of patients will not undergo repair within 3 months of enrollment. Therefore, to ensure we capture the repair type for these patients, the Central Study Research Coordinator or Analyst will audit CAPRI every three months during the study period. At the end of the two years of audits, the Central Study Research Coordinator will contact the enrolled patients via phone to ensure repair has not been performed outside of VA. Patients who do not undergo repair or who die prior to repair will be excluded. Sample size calculations incorporate a dropout rate of 10% for this effect. Re-survey will occur for a delay in repair greater than 3 months, if the pre- survey shows a change in Veteran repair preference from the original enrollment survey.

Aim 2 Data analytic strategy: After we have measured the necessary elements for agreement (preferences for repair type and the actual repair type), we will then calculate Cohen's kappa. We will stratify these analyses for surgeon agreement with the actual repair type (surgeon-preferred repair type matches the actual repair type, surgeon-preferred repair type does not match the actual repair type, and surgeon has no preference in repair type). Of note, Question #8 in the Decision Process Score allows us to measure incidents where discussion with the surgeon changed the Veteran's preference after the survey. We will perform sensitivity analyses including and excluding Veterans who changed preferences. To account for possible agreement of preference and choice with age, gender and race, we will estimate the association of choice with preference in a multivariable binary regression model that includes age, gender and race, and report the odds ratio (via logistic link) and rate ratio (via Poisson link). The fitted value from the logistic regression model will be used to calculate the four proportions used in the calculation of Kappa agreement using the method of average predictions (fitted values). Bootstrapping methods, as described by Efron and Tibshirani[106], will be performed if individual hospital samples are small.

Power analysis in Aim 2: We hypothesized that Veterans who receive the decision aid will be 25% more likely to have a treatment that aligns with their preferences, based on effect sizes seen in similar decision aids[16-18]. This would increase kappa from a baseline of $\kappa=0.7$ in the control group to $\kappa=0.88$ in the treatment group. Using a nomogram by Sim and Wright[107], we assumed a 2-tailed test for a null value of $\kappa=0.7$ in the control group, and $\kappa=0.88$ in the intervention group. We would have 80% power to detect a difference assuming a 50% positive response rate at 101 patients in each arm. Our sample of 120 patients is powered to detect a difference in kappa, accounting for dropout (10%) and patients who do not undergo repair (15%).

Aim 3: To investigate the facilitators and barriers of implementing a decision aid in a VA surgical clinic.

Interview transcripts will be coded iteratively as interviews are conducted to assess potential gaps and adjust the interview guide or sampling technique as needed. Coding will be performed by the student researcher manually. Codes will be developed based on a mix of inductive and deductive methods to identify domains and themes. A final code book will be developed by the student research researcher and checked with the PI for agreement. Once all transcripts have been coded, the results will be summarized in a table depicting domains and thematic statements.

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