Appendix 1:

1. Control Group Instruments

Survey Administration Guide

Preference Survey

Decision Process Score

Surgeon Survey

PSQ-18

2. Intervention Group Instruments

Survey Administration Guide

Pre-Survey, Decision Aid, Preference Survey

Decision Process Score

Surgeon Survey

PSQ-18

Survey Administration Guide

Control Sites

Survey Administration Guide

Control Group

- Patient deemed eligible for both open repair and EVAR by Site Principal Investigator
- Consent by Study Site Coordinator
- 3. Repair Preferences Survey (naive version), Surgeon Survey (Pre)
- 4. Physician Visit
- 5. Surgeon Survey (Post),
 Decision Process Score at end
 of visit.
- 6. PSQ-18 at 30 days post repair.

Intervention Group

- Patient deemed eligible for both open repair and EVAR by Site Principal Investigator
- 2. Consent by Study Site Coordinator
- 3. Pre-Survey, Decision Aid, Repair Preferences Survey (Decision Aid Version), Surgeon Survey (Pre)
- 4. Physician Visit
- 5. Surgeon Survey (Post), Decision Process Score at end of visit.
- 6. PSQ-18 at 30 days post repair.

Survey of Veteran Preference for Method of Abdominal Aortic Aneurysm Repair

What is the survey about?

This is a survey to explore patient views about abdominal aortic aneurysm (AAA) and the current treatment options as described in the detailed patient decision aid. Information from the survey will improve our understanding of what is important to patients who have this condition and could result in greater patient involvement in future treatment and care.

Why should I complete the survey?

The views of <u>all</u> patients are important. This is your chance to help to shape future care of AAA patients. Taking part in this survey is voluntary.

Who is carrying out the survey?

The survey is being carried out by a research team at the Veterans Administration Hospital in White River Junction, Vermont.

How to complete the survey

Please answer the questions as fully as possible following the instructions given. The questionnaire is short and will take under 15 minutes to complete.

Questions or help?

If you have any questions, please ask the nurse coordinator who administered the survey.

Your answers are confidential.

A Your initial preference

We are interested to know your views of the two main surgical treatment options .

Please mark your answer clearly INSIDE one box for each question

Ex: check **X** one box only

A1 ____

Would you say that you:

- D Had definitely considered the different options for surgical repair
- 2 D Had considered the different options for surgical repair to some extent
- D Had not considered the different options for surgical repair at all

A2 _

Would you say that you:

- D Definitely preferred Open Surgical Repair
- ² D Preferred Open Surgical Repair to some extent
- 3 D Were equally happy with either treatment
- ⁴D Definitely preferred Endovascular Aneurysm Repair (EVAR)
- 5 D Preferred EVAR to some extent
- ⁶ D Did not know / were unsure which treatment option you preferred

- A3 Have you talked to your primary care physician about the surgical treatment options available to you if you need an operation?
 - D Yes, I have talked to my doctor as much as I need to
 - ² D Yes, I have talked to my doctor but I have some unanswered questions
 - 3 D No, I have not talked to my doctor at all
 - 4 D Don't know

A4

Who or what was your **main** source of information about the Open Surgical Repair operation?

- D I did not have any information about the Open Surgical Repair operation
- ₂ D Primary Care Physician
- 3 DA nurse
- ⁴ D A brochure or booklet
- 5 D Internet/website
- 6 D My family/friends
- ⁷ DMedia (e.g. TV, newspapers)
- 8 D Patients' organization(s)
- D Other source (please write in box below)

Please mark your answer clearly INSIDE one box for each question

eg check **X** one box only

A5

Who or what was your <u>main</u> source of information about the endovascular aneurysm repair (EVAR) operation?

- D I did not get any information about the EVAR operation
- ₂ D My primary care physician
- 3 D A nurse
- 4 D Brochure or booklet
- 5 D Internet/website
- 6 D My family/friends
- ⁷ D Media (e.g. TV, newspapers)
- 10D Patients' organization(s)
- ¹¹D Other source (please write in

box below)

A6 ----

Have you ever been given written information about the two different surgical treatments?

- D Yes, I was given written information about both treatment options
- ² D I was only given written information about open surgical repair
- 3 D I was only given written information about endovascular aneurysm repair
- ⁴ D No, I was not given any written information
- 5 D I don't know if I was given any written information

A7 _____

Had your view of the different surgical treatment options been <u>influenced</u> by any of the following people?

Check

X

all that apply

- D My primary care physician
- ₂ DA surgeon
- 3 D A radiologist
- ₄ D A nurse
- 5 D My family or friends
- 6 D Someone else
- D My view was not influenced by anyone
- 8 D Don't know / unsure

B Your current preference

There are two choices for repair:

- the standard treatment is "Open Surgical Repair" and
- the newer treatment is called "EndoVascular Aneurysm Repair" (EVAR).

Patients who are suitable for both treatments may be asked to decide between these two options.

Please mark your answer clearly INSIDE one box for each question

eg check **X** one box only

- B2 If your surgeon asked you today which treatment method you prefer AT THIS MOMENT, would you say that you:
 - D Definitely prefer Open Surgical Repair
 - ² D Prefer Open Surgical Repair to some extent
 - 3D Are equally happy with either treatment at present
 - ⁴D Definitely prefer Endovascular Aneurysm Repair (EVAR)
 - 5 D Prefer EVAR to some extent
 - 6 DDon't know / unsure

Please mark your answer clearly INSIDE one box for each question

one box only eg check **B3** Thinking about your answer to the previous question, what would you say is the MAIN factor influencing your preference? 1 D Invasiveness of surgery ₂ D Size of scar 3 D Type of anesthetic ⁴ D Length of hospital stay 5 D Recovery time at home ₆ D Risk of post-operative complications ₇ D Risk of infection 8 D My medical history or existing condition D Likelihood of survival 10 D I would take the doctor's advice D Don't know / unsure ₁₂ D Other (please write in box below)

- **B4** Thinking about your answer at B2, how informed would you say you are about OPEN SURGICAL REPAIR?
 - D I definitely have all the information I need
 - ₂ D I have most of the information I need, but have some unanswered questions
 - 3 D I have many unanswered questions
 - ⁴ D I do not have any of the information I need
 - 5 D Don't know / unsure
- **B5** Thinking about your answer at B2, how informed would you say you are about ENDOVASCULAR ANEURYSM **REPAIR (EVAR)?**
 - D I definitely have all the information I need
 - ₂ D I have most of the information I need, but have some unanswered questions
 - 3 D I have many unanswered questions
 - ⁴ D I do not have any of the information I need
 - 5 D Don't know / unsure

C The things that are important to you

These questions will help us understand the sort of things that are important to you in considering the treatment option you prefer.

Please mark your answer clearly INSIDE <u>one</u> box for each question

eg check



one box only

- **C1** We found that patients often made a trade off between:
 - a) EVAR being less invasive (with an associated lower risk of death during or immediately after the operation)....

as opposed to....

b) Open Surgical Repair having a lower risk of post operative complications requiring further intervention.

We would like to explore your view of these factors.

Would you say that you....

- invasive surgery (even with a possible increased risk of post operative complications)
- 2 D Prefer less invasive surgery to some extent (even with a possible increased risk of post operative complications)
- 3 D Have no preference
- ⁴D Definitely prefer a lower risk of post operative complications (even with the need for more invasive surgery)
- 5 D Prefer a lower risk of post operative complications to some extent (even with the need for more invasive surgery)
- 6 D Don't know / are unsure
- C2 One difference between Open Surgical Repair and EVAR is the scar size. How important to you is the size of the scar?
 - DExtremely important
 - ² D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 DDon't know / unsure

Please mark your answer clearly INSIDE one box for each question

eg check **X** one box only

- C3 Another difference between Open Surgical Repair and EVAR is the average length of the hospital stay. How important to you is it to have a shorter hospital stay?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 DDon't know / unsure
- C4 Another difference between Open Surgical Repair and EVAR is the need for post operative care in an intensive care unit. How important to you is it to AVOID a stay in intensive care?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - 4 D Not very important
 - 5 D Not important at all
 - ₆ D Don't know / unsure

- C5 Another difference between
 Open Surgical Repair and EVAR
 is the average length of time
 before you recover to resume
 normal day to day activities.
 How important to you is it to
 have a shorter
 recovery time?
 - 1 D Extremely important
 - ² D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 D Don't know / unsure
- C6 There is a known risk of impotency with Open Surgical Repair, but the risk of impotency with EVAR is as yet unknown. How important to you is the risk of impotency?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 D Don't know / unsure

- C7 Another difference is that EVAR can be carried out under local anesthesia but Open Surgical Repair requires general anesthesia. Would you say that you.....
 - D Would definitely prefer general anesthesia
 - ² D Would prefer general anesthesia to some extent
 - 3 D Have no preference
 - ⁴ D Would definitely prefer local anesthesia
 - 5 D Would prefer local anesthesia to some extent
 - 6 D Don't know / unsure
- C8 Please use the space below to tell us anything else which influences your views of the two main treatment options

D Making a decision

These next questions explore whether or not the decision aid helped you in making a decision.

Please mark your answer clearly INSIDE one box for each question eg

- prefer to leave decisions in the hands of the decision about which of the two main surgical treatments for AAA you prefer, would you say that you......
 - D Would definitely prefer to be actively involved in the decision
 - D Would like to be involved to some extent, but would prefer to leave the final decision in the hands of the surgeon
 - D Would prefer to leave the decision wholly in the hands of the surgeon
 - ⁴ D Don't know or are unsure how involved you would like to be in the decision

Ε	Abou	ıt y	/Ol	l
_				

By answering these questions you will help us understand a bit more about the sort of things that influence views of the different treatment options.

F1 What was	your	year	of	birth	າ?
-------------	------	------	----	-------	----

(Please write in) e.g.			1	9	3	4	
	1	9	Y		Υ		

Please mark your answer clearly INSIDE one box for each question

eg: check X one box only

F2 What is the highest level of education you completed

- $_{\scriptscriptstyle 1}$ D did not finish high school
- ₂ D High school
- 3 D College or higher

F3 Which of these **best** describes your current situation?

- □ D Working
- $_{\scriptscriptstyle 2}$ D Unemployed
- 3 D Retired
- ⁴ D Unable to work because of disability or ill health
- 5 D In full time education / training
- 6 D Other (Please tell us about this in box)

71	10

	I
Please mark your answer clearly INSIDE one box for each question	
eg: check X one box only	
F4 Do you have any long-standing illness, disability or condition? DYesGotoF5	F7 Do you have any children aged under 18? 1 D Yes 2 D No
₂ DNoGotoF6	
3 D Don't know / unsure Go to F6	F8 Do you provide care to a spouse, relative or friend to help them take care of
F5 If you answered yes to the previous question, does this condition(s) cause you difficulty	themselves? (eg help with personal needs or household chores)
with any of the everyday activities that people your age can usually do?	D Yes
₁ D Yes	₂ D No
₂ D No	F9 If you were to need care at home following an operation, is
3 D Don't know / unsure	there someone who could provide this care:
F6 Overall, how would you rate your health during the past 4	D Spouse/partner
weeks?	₂ D Relative
D Excellent	₃ D Friend
₂ D Very good	4 D Someone else
3 D Good	5 D No one
4 D Fair	
₅ D Poor	

 $_{\scriptscriptstyle 6}$ D Very poor

F10 To which of these ethnic groups would you say you belong? (Tick ONE only)

- D White/Caucasian
- ₂ DAfrican American
- 3 DAsian American
- ⁴ D American Indian
- ₅D Prefer not to answer
- ₆D Other

(Please write in box)

•		,

ANY OTHER COMMENTS

If you have any other comments you would like to make, please use the space below.

Thank you

for taking part in this survey.

SHARED DECISION MAKING ASSESSMENT DECISION PROCESS SCORE (Adapted for AAA Study)

PROCESS OF DECISION MAKING: OPEN OR EVAR Michael Barry, MD, Floyd J. Fowler, PhD

Adapted by Barry et al from instruments validated in "Decision-making process reported by Medicare patients who had coronary artery stenting or surgery for prostate cancer." Fowler et al, J. Gen Intern Med 2012. 27 (8): 911-6. The Site Study Coordinator, at the end of the enrollment visit, asks the Veteran the questions below.

As you probably know, there are two different ways to do surgery to repair an aneurysm: an open surgical repair and an endovascular aneurysm repair, also called an EVAR.

- 1. Did a doctor talk with you about having an open surgical repair of your aneurysm? (YES/NO)
 - a. (IF YES) Did a doctor talk about an open surgical repair as an approach you should seriously consider? (YES/NO)
- 2. How much did a doctor talk with you about the reasons you might want have an open surgical repair—a lot, some, a little or not at all?
- 3. How much did a doctor talk with you about the reasons you might not want an open surgical repair—a lot, some, a little or not at all?
- 4. Did a doctor talk with you about having an Endovascular Aneurysm Repair (EVAR)?
 - a. (IF YES) Did a doctor talk about an EVAR procedure as an approach you should seriously consider? (YES/NO)
- 5. How much did a doctor talk with you about the reasons you might want have an EVAR-- a lot, some, a little or not at all?
- 6. How much did a doctor talk with you about the reasons you might not want an EVAR-- a lot, some, a little or not at all?
- 7. Has a doctor asked you if you would prefer to have an open repair or an EVAR? (YES/NO)
- 8. What type of repair did you want after reading the survey? (open surgical repair/EVAR) What type of repair did you want after talking with your doctor? (open surgical repair/EVAR)

SURGEON SURVEY INSTRUMENT								
PRE-VISIT RECOMMENDATION	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly			
When I meet with this Veteran about his or her AAA, I will recommend:								
How important were each of the following factors in the type of repair you recommended for this Veteran?	Not at all important	Somewhat important	Moderately important	Very important				
Anatomic considerations, such as neck length or access								
Type of anesthesia required								
Fewer procedural complications, including mortality								
Quicker recovery, faster return to work and activity								
Lower 5-year risk of requiring a reintervention								
Less intensive follow-up surveillance requirement								
Planned procedure	Open Repair	Endovascular Repair						
If I were to repair this Veteran's AAA tomorrow, I would perform the following type of repair:								

SURGEON SURVEY INSTRUMENT							
POST-VISIT RECOMMENDATION	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly		
When I met with this Veteran about his or her AAA, I recommended:							
Veteran's preference	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly		
This Veteran stated a preference for:							
Check here if you are uncertain of the Veteran's preference							
How important were each of the following factors in the type of repair you recommended for this Veteran?	Not at All important	Somewhat important	Moderately important	Very important			
This Veteran's preference							
Please rate the following factors only if y	our responses	differ from the	Pre-Visit Surve	у			
Anatomic considerations, such as neck length or access							
Type of anesthesia required							
Fewer procedural complications, including mortality							
Quicker recovery, faster return to work and activity							
Lower 5-year risk of requiring a reintervention							
Less intensive follow-up surveillance requirement							
Planned procedure	Open Repair	Endovascular Repair	Not a candidate for repair				
If I were to repair this Veteran's AAA tomorrow, I would perform the following type of repair:							

SHORT-FORM PATIENT SATISFACTION QUESTIONNAIRE (PSQ-18)

These next questions are about how you feel about the medical care you receive.

On the following pages are some things people say about medical care. Please read each one carefully, keeping in mind the medical care you are receiving now. (If you have not received care recently, think about what you would <u>expect</u> if you needed care today.) We are interested in your feelings, good and bad, about the medical care you have received.

How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

		Strongly <u>Agree</u>	Agree	Uncertain	Disagree	Strongly Disagree
1.	Doctors are good about explaining the reason for medical tests	1	2	3	4	5
2.	I think my doctor's office has everything needed to provide complete medical care	1	2	3	4	5
3.	The medical care I have been receiving is just about perfect	1	2	3	4	5
4.	Sometimes doctors make me wonder if their diagnosis is correct	1	2	3	4	5
5.	I feel confident that I can get the medical care I need without being set back financially	1	2	3	4	5
6.	When I go for medical care, they are careful to check everything when treating and examining me	1	2	3	4	5
7.	I have to pay for more of my medical care than I can afford	1	2	3	4	5
8.	I have easy access to the medical specialists I need	1	2	3	4	5

How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

		Strongly <u>Agree</u>	Agree	<u>Uncertain</u>	Disagree	Strongly <u>Disagree</u>
9.	Where I get medical care, people have to wait too long for emergency treatment	1	2	3	4	5
10.	Doctors act too businesslike and impersonal toward me	1	2	3	4	5
11.	My doctors treat me in a very friendly and courteous manner	1	2	3	4	5
12.	Those who provide my medical care sometimes hurry too much when they treat me	1	2	3	4	5
13.	Doctors sometimes ignore what I tell them	1	2	3	4	5
14.	I have some doubts about the ability of the doctors who treat me	1	2	3	4	5
15.	Doctors usually spend plenty of time with me	1	2	3	4	5
16.	I find it hard to get an appointment for medical care right away	1	2	3	4	5
17.	I am dissatisfied with some things about the medical care I receive	1	2	3	4	5
18.	I am able to get medical care whenever I need it	1	2	3	4	5

Survey Administration Guide

Intervention Sites

Survey Administration Guide

Control Group

- Patient deemed eligible for both open repair and EVAR by Site Principal Investigator
- Consent by Study Site Coordinator
- 3. Repair Preferences Survey (naive version), Surgeon Survey (Pre)
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 Decision Process Score at end
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- 6. PSQ-18 at 30 days post repair.

Intervention Group

- Patient deemed eligible for both open repair and EVAR by Site Principal Investigator
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- 4. Physician Visit
- 5. Surgeon Survey (Post), Decision Process Score at end of visit.
- 6. PSQ-18 at 30 days post repair.

Pre-Survey

Your current preference

There are two choices for repair:

- the standard treatment is "Open Surgical Repair" and
- the newer treatment is called "EndoVascular Aneurysm Repair" (EVAR).

Patients who are suitable for both treatments may be asked to decide between these two options.

Please mark your answer clearly INSIDE one box for each question eg check one box only

If your surgeon asked you today which treatment method you prefer AT THIS MOMENT, would you say that you:

- D Definitely prefer Open Surgical Repair
- ² D Prefer Open Surgical Repair to some extent
- 3D Are equally happy with either treatment at present
- ⁴D Definitely prefer Endovascular Aneurysm Repair (EVAR)
- 5 D Prefer EVAR to some extent
- 6 DDon't know / unsure



A Veteran's Guide to Abdominal Aortic Aneurysm

This information pack contains medical words and terms that you may not know. A list of these words and their meanings is shown at the end of the booklet.

These words are in **bold** and <u>underlined</u> in the text.

Introduction

This information booklet is written for patients like you, who have an **abdominal aortic aneurysm**.

We want to help you understand what it means to have an <u>abdominal aortic aneurysm</u>. We will discuss who needs treatment for their aneurysm. We will also discuss the types of treatment available and the risks and benefits of each one. We hope this booklet will help you be actively involved in planning your future care.

Remember, this is a general information booklet and your care and treatment will be shaped to meet your specific needs.

If you still have any questions after reading this booklet, you should contact either your primary care doctor or your vascular surgeon.

This booklet was developed and tested by the Vascular Surgery Research Group (VSRG) of Imperial College London and was modified for Veterans by the Veterans Affairs Outcomes Group in White River Junction, Vermont.

What is an abdominal aortic aneurysm?

An aneurysm is a weak point in an <u>artery</u> (blood vessel). This weakness can cause the artery to stretch out like a balloon. This ballooning is called an aneurysm. Aneurysms happen most often in the <u>aorta</u>.

The aorta is the main blood vessel in your body. It carries blood from the heart down through the chest and branches out to all of the body's major organs. A normal aorta is about ¾-1 inch in diameter.

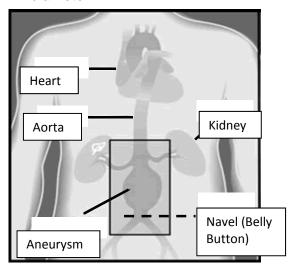


Figure 1: Diagram showing where the aorta is in the body, and an example of an abdominal aortic aneurysm.

Most people won't know they have an aortic aneurysm. Aneurysms usually don't have any symptoms. Some patients—about 1 in 4—will have pain or tenderness in their stomach, chest or back. They may also have reduced blood flow to their legs. When an **abdominal aortic aneurysm** gets bigger, the **artery** wall can leak or even burst. This risk increases when the diameter is o ver 2 ½ inches. This leak or burst is called a "**rupture**" and leads to dangerous bleeding inside the body.

A rupture is very dangerous. It causes severe pain in the stomach or back area, a rapid heartbeat, a pulsing sensation in the stomach and skin feeling "cold and sweaty," Only 2 in 10 people survive an aortic aneurysm <u>rupture</u> and just half of all patients manage to get to a hospital at all.

Luckily, many cases of ruptured aneurysm can be prevented by early diagnosis, careful monitoring and—when needed—planned treatment.

What causes an abdominal aortic aneurysm?

Aortic aneurysm can occur when the wall of the **aorta** is damaged or weakened. This damage can be caused by:

- Smoking
- High blood pressure
- Fatty deposits in the artery (<u>Atherosclerosis</u>)
- Inherited aortic wall weakness / family history
- Age

Rarely, Infection and injury can cause the **artery** to expand and form an aneurysm.

Who gets an abdominal aortic aneurysm?

About every 1 in 20 men over the age of 65 will get an aneurysm. Men are four to five times more likely than women to get one. Aneurysms can run in families.

How is abdominal aortic aneurysm diagnosed?

Aneurysms are often found when you have an x-ray, CT-scan, or ultrasound for another reason.

Will I need treatment?

Not necessarily. Your surgeon may recommend repair if your aneurysm grows too big or too quickly.

Many smaller aneurysms never need treatment. Instead, they are measured with regular ultrasound or CT scans. They will need to be measured every 3-6 months or every year, depending on the size. When the aneurysm is over 2 inches (5centimeters) in diameter, you will meet with a Vascular Surgeon.

During this meeting, you will probably discuss "elective" (planned) aneurysm repair. He or she will take into account your specific needs and your medical history when planning your repair.

Living with an aneurysm

You probably can't make your aneurysm go away. However, you can do things to keep it from getting bigger quickly. For example, if you smoke, quit. Quitting smoking can slow the growth of the aneurysm. You should also keep healthy with exercise, a low-fat diet checking your blood pressure regularly. Your doctor may also recommend a "statin" medication (to lower cholesterol levels) and a mini-aspirin (to thin the blood).

In general, you can keep up your usual activities or hobbies e.g. gardening, DIY, swimming or other sports, unless your doctor tells you to stop These activities don't have any effect on the chances of your aneurysm rupturing.

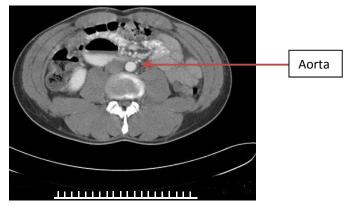
Before surgery is considered, most patients will have a CT scan of the aneurysm. Your surgeon will use this to determine whether your aneurysm should be repaired with one technique, or whether you could have either.

Figure 2: Two photographs showing CT scans of a normal abdominal aorta and an abdominal aortic aneurysm

1. Normal abdominal aorta

This aorta is normal.

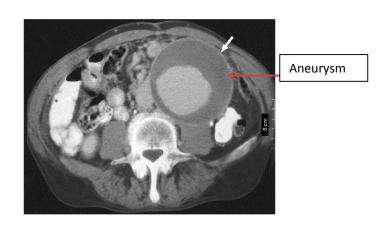
It measures just under an inch.



2. Abdominal aorta aneurysm

This is an aneurysm.

It measures 3 inches.



What are the treatment options?

Option 1: Open surgical repair

Open surgical repair of an abdominal aortic aneurysm is a major operation done by **Vascular Surgeons**.

The surgeon first makes a large cut lengthways to open the abdomen to expose the **aorta**. Next, the surgeon opens the aneurysm and takes out any blood clot or debris. The surgeon then sews the **graft** to the aorta—replacing the aneurysm. The graft lies inside what used to be the aneurysm. The surgeon sews the aneurysm over graft to protect it. (see Figure 3 below). The surgery usually takes 2-3 hours.

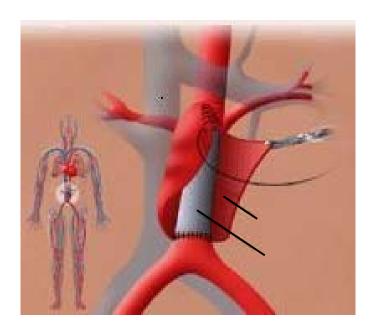


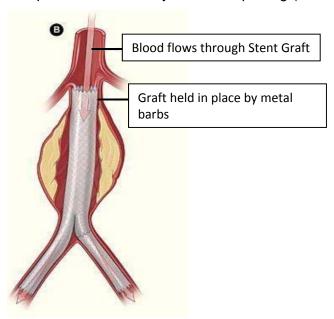
Figure 3: Diagram showing the Open Surgical method for aortic aneurysm repair

Hospital stay, recovery time and follow-up: Most patients will spend the first day or two after an open repair in an Intensive Care Unit (ICU). Their hospital stay will be 4-8 days. Full recovery can take up to 2-3 months. Long term complications after a successful repair are rare. The grafts last 20- 30 years, so patients will not need to see their surgeon regularly after they've recovered from the operation.

Option 2: Endovascular stent-graft repair (EVAR) of an abdominal aortic aneurysm

EVAR is a less invasive alternative to open aneurysm repair done by Vascular Surgeons.

The surgeon first makes small cuts over each artery in the groin. The surgeon uses these cuts to thread catheters into the aneurysm. Using an x-ray, the surgeon places the stent-graft at the top and bottom of the aneurysm. The surgeon then expands the stent graft and seals off the aneurysm. The graft strengthens the weakened **aorta** wall and prevents the aneurysm from rupturing (see Figure 4, page 15).



There may be a need for additional <u>endovascular</u> or surgical procedures before, during or after the main procedure in order to complete the EVAR deployment successfully. These may include <u>stents</u> in the <u>iliac</u> arteries, "blocking off" of selected arteries or bypass grafting. <u>Endovascular repair</u> usually takes 2 to 3 hours to complete.

Hospital stay, recovery time and follow-up: Most patients will stay in the hospital for 2-4 days after their EVAR. Patients can return to normal activity within 4 to 6 weeks. We do not know the long term results of endovascular repair, so patients need to have yearly CT scans and follow-up visits to monitor the old aneurysm and the endovascular stent-graft.

Comparison table of the options for aortic aneurysm repair

The following table highlights the differences between the two main methods for abdominal aortic aneurysm repair.

	Open Surgical	Endovascular
	Aneurysm Repair	Aneurysm Repair
Scar	Single, large cut	Two small cuts,
	lengthways to abdomen	one in each groin
Anesthesia	General	General or Local
Intensive Care Unit (ICU) stay	1-2 days	Unlikely / None
Total Hospital Stay	6-8 days	2-3 days
Complete Recovery	2-3 months	4-6 weeks
Risk of death (one month)	4-8 in 100	Approx. 2 in 100
Risk of Complications within 4 years of repair*	6 in 100	41 in 100
Risk of Re-intervention within 4 years of repair*	6 in 100	21 in 100
Risk of impotence	Approx. 1 in 10	20 in 100
Long term follow-up with CAT scan needed	No	No

5. Which is the best treatment option?

There is **no** "**best treatment**" when considering the two techniques currently available for aneurysm repair. National and international clinical studies have shown that each method has its own associated benefits and disadvantages. Patients must fully understand what each method involves and the long term uncertainties and implications associated with undergoing EVAR.

6. What happens next?

The next steps will be specific to you and your aneurysm. Together, you and your surgeon will discuss the options available to you and reach a decision as to the best treatment for your aneurysm.

7. Key references

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9. Glossary of terms and abbreviations

Abdominal aortic aneurysm Balloon-like stretching of the part of the aorta in the

stomach area

Angiography/ Angiogram A special X-ray which uses contrast (dye) injected

into the bloodstream to see blood flow in the vessels. The picture obtained is called an

angiogram.

Aorta This is the largest artery in the human body and

carries oxygenated blood from the heart to the rest

of the body

Artery Blood vessel that carries oxygen-rich blood

Atherosclerosis Hardening, "furring up" and narrowing of the

arteries which restricts normal blood flow

Catheter A tube that can be inserted into a blood vessel to

allow access by a surgical instrument e.g. a graft

sheath

Contrast (dye) The contrast that contains iodine which is used in

CT and angiography to see blood vessels and

watch blood flow in the body

Computed Tomography Scan

(CT Scan)

A special X-ray machine that provides very

detailed images of internal organs

Diameter (maximum)The width of the aneurysm from one side to the

other, at its largest point

Endoleak A blood leak into the original abdominal aortic

aneurysm after a stent-graft has been put in place

Endovascular Within the blood vessel

Endovascular aneurysm

repair (EVAR) A method of aneurysm repair where an

endovascular stent-graft is positioned within an aneurysm via the blood vessels and restores

normal blood flow

Endovascular stent-graft A "man-made" fabric graft covering a supportive

metal stent that has metal fixings at the top and bottom that can be used to attach the stent-graft to

the vessel wall

Femoral artery Blood vessel that carries blood to the thigh in

each leg

Heparin A medicine that helps to prevent blood clotting

Iliac arteryBlood vessel that connects the lower part of the

aorta to the femoral artery in each leg

Impotence Inability to develop or maintain an erection of the

penis

Interventional Radiologist A doctor who uses image guidance methods, such

as X-ray, to gain access to vessels and organs. Interventional radiologists can treat certain conditions through the skin that might otherwise

require surgery.

Lumen The inner open space or cavity of a tube-like

structure

Open surgical repair A method of aneurysm repair involving a large cut

to the abdomen, and replacement of the aneurysmal aorta with an artificial graft which

restores normal blood flow

Rupture Bursting of the artery wall leading to serious

internal bleeding

Sheath A long plastic tube that contains the endovascular

graft and is used to position the graft in place within

the aneurysm

Statins A group of drugs that lower cholesterol levels in the

body

Stents Metal parts of the endovascular graft that provide

support and hold it in place

Ultrasound Method of obtaining pictures of the inside of the

body using sound waves

Vascular Relating to the vessels that carry blood

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Survey of Veteran Preference for Method of Abdominal Aortic Aneurysm Repair

What is the survey about?

This is a survey to explore patient views about abdominal aortic aneurysm (AAA) and the current treatment options as described in the detailed patient decision aid. Information from the survey will improve our understanding of what is important to patients who have this condition and could result in greater patient involvement in future treatment and care.

Why should I complete the survey?

The views of <u>all</u> patients are important. This is your chance to help to shape future care of AAA patients. Taking part in this survey is voluntary.

Who is carrying out the survey?

The survey is being carried out by a research team at the Veterans Administration Hospital in White River Junction, Vermont.

How to complete the survey

Please answer the questions as fully as possible following the instructions given. The questionnaire is short and will take about 15 minutes to complete.

Questions or help?

If you have any questions, please ask the nurse coordinator who administered the survey.

Your answers are confidential.

A Your initial preference

We are interested to know your views of the two main surgical treatment options BEFORE reading the decision aid.

Please mark your answer clearly INSIDE one box for each question

Ex: check X one box only

- A1 BEFORE you looked at the decision aid, would you say that you:
 - D Had definitely considered the different options for surgical repair
 - D Had considered the different options for surgical repair to some extent
 - 3 D Had not considered the different options for surgical repair at all
- **A2** BEFORE you looked at the decision aid, would you say that you:
 - D Definitely preferred Open Surgical Repair
 - 2 D Preferred Open Surgical Repair to some extent
 - 3 D Were equally happy with either treatment
 - ⁴D Definitely preferred Endovascular Aneurysm Repair (EVAR)
 - 5 D Preferred EVAR to some extent
 - ⁶ D Did not know / were unsure which treatment option you preferred

- A3 Have you talked to your primary care physician about the surgical treatment options available to you if you need an operation?
 - D Yes, I have talked to my doctor as much as I need to
 - ² D Yes, I have talked to my doctor but I have some unanswered questions
 - 3 D No, I have not talked to my doctor at all
 - 4 D Don't know
- A4 BEFORE you looked at the information pack, who or what was your main source of information about the Open Surgical Repair operation?
 - D I did not have any information about the Open Surgical Repair operation
 - ₂ D Primary Care Physician
 - 3 D A nurse
 - ⁴ D A brochure or booklet
 - 5 D Internet/website
 - 6 D My family/friends
 - ⁷ DMedia (e.g. TV, newspapers)
 - 8 D Patients' organization(s)
 - D Other source (please write in box below)

Please	mark	your	answer	clearly
INSIDE	one	box fo	r each	question

eg check **X** one box only

- A5 <u>BEFORE</u> you looked at the decision aid, who or what was your <u>main</u> source of information about the endovascular aneurysm repair (EVAR) operation?
 - about the EVAR operation
 - ₂ D My primary care physician
 - 3 D A nurse
 - 4 D Brochure or booklet
 - 5 D Internet/website
 - 6 D My family/friends

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- ⁷ D Media (e.g. TV, newspapers)
- 10D Patients' organization(s)
- ¹¹D Other source (please write in

DOX	DCIOV	,	

- A6 Apart from the decision aid we sent you with this questionnaire, have you ever been given written information about the two different surgical treatments?
 - D Yes, I was given written information about both treatment options
 - ² D I was only given written information about open surgical repair
 - D I was only given written information about endovascular aneurysm repair
 - ⁴ D No, I was not given any written information
 - 5 D I don't know if I was given any written information

A7 <u>BEFORE</u> you looked at the decision aid, had your view of the different surgical treatment options been <u>influenced</u> by any of the following people?

Check X all that apply

- D My primary care physician
- ₂ DA surgeon
- 3 D A radiologist
- ₄ D A nurse
- 5 D My family or friends
- 6 D Someone else
- D My view was not influenced by anyone
- 8 D Don't know / unsure

B Your current preference

You will see from the decision aid that there are two main methods of abdominal aortic

aneurysm repair currently available:

- the standard treatment is "Open Surgical Repair" and
- the newer treatment is called "EndoVascular Aneurysm Repair" (EVAR).

Patients who are suitable for both treatments may be asked to decide between these two options.

Please mark your answer clearly INSIDE one box for each question

eg check **X** one box only

- B2 If your surgeon asked you today which treatment method you prefer AT THIS MOMENT, would you say that you:
 - D Definitely prefer Open Surgical Repair
 - ² D Prefer Open Surgical Repair to some extent
 - 3D Are equally happy with either treatment at present
 - ⁴D Definitely prefer Endovascular Aneurysm Repair (EVAR)
 - 5 D Prefer EVAR to some extent
 - 6 DDon't know / unsure

Please mark your answer clearly INSIDE one box for each question

one box only eg check **B3** Thinking about your answer to the previous question, what would you say is the MAIN factor influencing your preference? 1 D Invasiveness of surgery ₂ D Size of scar 3 D Type of anesthetic ⁴ D Length of hospital stay 5 D Recovery time at home ₆ D Risk of post-operative complications ₇ D Risk of infection 8 D My medical history or existing condition D Likelihood of survival 10 D I would take the doctor's advice D Don't know / unsure ₁₂ D Other (please write in box below)

- **B4** Thinking about your answer at B2, how informed would you say you are about OPEN SURGICAL REPAIR?
 - D I definitely have all the information I need
 - ₂ D I have most of the information I need, but have some unanswered questions
 - 3 D I have many unanswered questions
 - ⁴ D I do not have any of the information I need
 - 5 D Don't know / unsure
- **B5** Thinking about your answer at B2, how informed would you say you are about ENDOVASCULAR ANEURYSM **REPAIR (EVAR)?**
 - D I definitely have all the information I need
 - ₂ D I have most of the information I need, but have some unanswered questions
 - 3 D I have many unanswered questions
 - ⁴ D I do not have any of the information I need
 - 5 D Don't know / unsure

C The things that are important to you

These questions will help us understand the sort of things that are important to you in considering the treatment option you prefer.

Please mark your answer clearly INSIDE one box for each question

eg check



one box only

- **C1** We found that patients often made a trade off between:
 - a) EVAR being less invasive (with an associated lower risk of death during or immediately after the operation)....

as opposed to....

b) Open Surgical Repair having a lower risk of post operative complications requiring further intervention.

We would like to explore your view of these factors.

Would you say that you....

- invasive surgery (even with a possible increased risk of post operative complications)
- 2 D Prefer less invasive surgery to some extent (even with a possible increased risk of post operative complications)
- 3 D Have no preference
- ⁴D Definitely prefer a lower risk of post operative complications (even with the need for more invasive surgery)
- 5 D Prefer a lower risk of post operative complications to some extent (even with the need for more invasive surgery)
- 6 D Don't know / are unsure
- C2 One difference between Open Surgical Repair and EVAR is the scar size. How important to you is the size of the scar?
 - DExtremely important
 - ² DSomewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 DDon't know / unsure

Please mark your answer clearly INSIDE one box for each question

eg check **X** one box only

- C3 Another difference between Open Surgical Repair and EVAR is the average length of the hospital stay. How important to you is it to have a shorter hospital stay?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 DDon't know / unsure
- C4 Another difference between Open Surgical Repair and EVAR is the need for post operative care in an intensive care unit. How important to you is it to AVOID a stay in intensive care?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - 4 D Not very important
 - 5 D Not important at all
 - ₆ D Don't know / unsure

- C5 Another difference between
 Open Surgical Repair and EVAR
 is the average length of time
 before you recover to resume
 normal day to day activities.
 How important to you is it to
 have a shorter
 recovery time?
 - 1 D Extremely important
 - ² D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 D Don't know / unsure
- C6 There is a known risk of impotency with Open Surgical Repair, but the risk of impotency with EVAR is as yet unknown. How important to you is the risk of impotency?
 - **DExtremely important**
 - ₂ D Somewhat important
 - 3 D Neither important nor unimportant
 - ⁴ D Not very important
 - 5 D Not important at all
 - 6 D Don't know / unsure

- C7 Another difference is that EVAR can be carried out under local anesthesia but Open Surgical Repair requires general anesthesia. Would you say that you.....
 - D Would definitely prefer general anesthesia
 - ² D Would prefer general anesthesia to some extent
 - 3 D Have no preference
 - ⁴ D Would definitely prefer local anesthesia
 - 5 D Would prefer local anesthesia to some extent
 - 6 D Don't know / unsure
- C8 Please use the space below to tell us anything else which influences your views of the two main treatment options

D Making a decision

These next questions explore whether or not the decision aid helped you in making a decision.

Please mark your answer clearly INSIDE one box for each question eg

- D7 Some people like to be fully involved in decisions about their health, others prefer to leave decisions in the hands of the doctor. In terms of the decision about which of the two main surgical treatments for AAA you prefer, would you say that you......
 - D Would definitely prefer to be actively involved in the decision
 - ² D Would like to be involved to some extent, but would prefer to leave the final decision in the hands of the surgeon
 - D Would prefer to leave the decision wholly in the hands of the surgeon
 - ⁴ D Don't know or are unsure how involved you would like to be in the decision

E About you

By answering these questions you will help us understand a bit more about the sort of things that influence views of the different treatment options.

F1 What was your year of birth?

(Please write in) e.g.

1	9	3	4

1	9	Υ	Y
---	---	---	---

Please mark your answer clearly INSIDE <u>one</u> box for each question

eg: check X one box only F2 What is the highest level of education you completed

- D did not finish high school
- ₂ D High school
- 3 D College or higher
- **F3** Which of these **best** describes your current situation?
 - □ D Working
 - ₂ D Unemployed
 - 3 D Retired
 - D Unable to work because of disability or ill health
 - 5 D In full time education / training
 - 6 D Other (Please tell us about this in box)

Please mark your answer clearly INSIDE one box for each question					
eg: check X one box only					
F4 Do you have any long-standing illness, disability or condition?	F7 Do you have any children aged under 16?				
DYes GotoF5	¹ D Yes				
_	₂ D No				
₂ DNoGotoF6					
₃ D Don't know / unsure Go to F6	F8 Do you provide care to a spouse, relative or friend to help them take care of				
F5 If you answered yes to the previous question, does this condition(s) cause you difficulty	themselves? (eg help with personal needs or household chores)				
with any of the everyday activities that people your age	₁ D Yes				
can usually do?	₂ D No				
1 D Yes					
₂ D No	F9 If you were to need care at home following an operation, is				
3 D Don't know / unsure	there someone who could provide this care:				
F6 Overall, how would you rate your health during the past 4	D Spouse/partner				
weeks?	₂ D Relative				
1 D Excellent	₃ D Friend				
₂ D Very good	4 D Someone else				
3 D Good	5 D No one				
4 D Fair					
5 D Poor					

 $_{\scriptscriptstyle 6}$ D Very poor

F10 To which of these ethnic groups would you say you belong? (Tick ONE only)

- D White/Caucasian
- ₂ DAfrican American
- 3 DAsian American
- ⁴ D American Indian
- ₅D Prefer not to answer
- ₆D Other

(Please write in box)

•		,

ANY OTHER COMMENTS

If you have any other comments you would like to make, please use the space below.

Thank you

for taking part in this survey.

SHARED DECISION MAKING ASSESSMENT DECISION PROCESS SCORE (Adapted for AAA Study)

PROCESS OF DECISION MAKING: OPEN OR EVAR Michael Barry, MD, Floyd J. Fowler, PhD

Adapted by Barry et al from instruments validated in "Decision-making process reported by Medicare patients who had coronary artery stenting or surgery for prostate cancer." Fowler et al, J. Gen Intern Med 2012. 27 (8): 911-6. The Site Study Coordinator, at the end of the enrollment visit, asks the Veteran the questions below.

As you probably know, there are two different ways to do surgery to repair an aneurysm: an open surgical repair and an endovascular aneurysm repair, also called an EVAR.

- 1. Did a doctor talk with you about having an open surgical repair of your aneurysm? (YES/NO)
 - a. (IF YES) Did a doctor talk about an open surgical repair as an approach you should seriously consider? (YES/NO)
- 2. How much did a doctor talk with you about the reasons you might want have an open surgical repair—a lot, some, a little or not at all?
- 3. How much did a doctor talk with you about the reasons you might not want an open surgical repair—a lot, some, a little or not at all?
- 4. Did a doctor talk with you about having an Endovascular Aneurysm Repair (EVAR)?
 - a. (IF YES) Did a doctor talk about an EVAR procedure as an approach you should seriously consider? (YES/NO)
- 5. How much did a doctor talk with you about the reasons you might want have an EVAR-- a lot, some, a little or not at all?
- 6. How much did a doctor talk with you about the reasons you might not want an EVAR-- a lot, some, a little or not at all?
- 7. Has a doctor asked you if you would prefer to have an open repair or an EVAR? (YES/NO)
- 8. What type of repair did you want after reading the survey? (open surgical repair/EVAR) What type of repair did you want after talking with your doctor? (open surgical repair/EVAR)

SURG	SURGEON SURVEY INSTRUMENT								
PRE-VISIT RECOMMENDATION	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly				
When I meet with this Veteran about his or her AAA, I will recommend:									
How important were each of the following factors in the type of repair you recommended for this Veteran?	Not at all important	Somewhat important	Moderately important	Very important					
Anatomic considerations, such as neck length or access									
Type of anesthesia required									
Fewer procedural complications, including mortality									
Quicker recovery, faster return to work and activity									
Lower 5-year risk of requiring a reintervention									
Less intensive follow-up surveillance requirement									
Planned procedure	Open Repair	Endovascular Repair							
If I were to repair this Veteran's AAA tomorrow, I would perform the following type of repair:									

SURGEON SURVEY INSTRUMENT						
POST-VISIT RECOMMENDATION	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly	
When I met with this Veteran about his or her AAA, I recommended:						
Veteran's preference	Open Repair, Strongly	Open Repair, Somewhat	No preference	Endovascular Repair, Somewhat	Endovascular Repair, Strongly	
This Veteran stated a preference for:						
Check here if you are uncertain of the Veteran's preference						
How important were each of the following factors in the type of repair you recommended for this Veteran?	Not at All important	Somewhat important	Moderately important	Very important		
This Veteran's preference						
Please rate the following factors only if y	our responses	differ from the	Pre-Visit Surve	у		
Anatomic considerations, such as neck length or access						
Type of anesthesia required						
Fewer procedural complications, including mortality						
Quicker recovery, faster return to work and activity						
Lower 5-year risk of requiring a reintervention						
Less intensive follow-up surveillance requirement						
Planned procedure	Open Repair	Endovascular Repair	Not a candidate for repair			
If I were to repair this Veteran's AAA tomorrow, I would perform the following type of repair:						

SHORT-FORM PATIENT SATISFACTION QUESTIONNAIRE (PSQ-18)

These next questions are about how you feel about the medical care you receive.

On the following pages are some things people say about medical care. Please read each one carefully, keeping in mind the medical care you are receiving now. (If you have not received care recently, think about what you would <u>expect</u> if you needed care today.) We are interested in your feelings, good and bad, about the medical care you have received.

How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

		Strongly <u>Agree</u>	Agree	Uncertain	Disagree	Strongly Disagree
1.	Doctors are good about explaining the reason for medical tests	1	2	3	4	5
2.	I think my doctor's office has everything needed to provide complete medical care	1	2	3	4	5
3.	The medical care I have been receiving is just about perfect	1	2	3	4	5
4.	Sometimes doctors make me wonder if their diagnosis is correct	1	2	3	4	5
5.	I feel confident that I can get the medical care I need without being set back financially	1	2	3	4	5
6.	When I go for medical care, they are careful to check everything when treating and examining me	1	2	3	4	5
7.	I have to pay for more of my medical care than I can afford	1	2	3	4	5
8.	I have easy access to the medical specialists I need	1	2	3	4	5

How strongly do you AGREE or DISAGREE with each of the following statements?

(Circle One Number on Each Line)

		Strongly <u>Agree</u>	Agree	<u>Uncertain</u>	Disagree	Strongly <u>Disagree</u>
9.	Where I get medical care, people have to wait too long for emergency treatment	1	2	3	4	5
10.	Doctors act too businesslike and impersonal toward me	1	2	3	4	5
11.	My doctors treat me in a very friendly and courteous manner	1	2	3	4	5
12.	Those who provide my medical care sometimes hurry too much when they treat me	1	2	3	4	5
13.	Doctors sometimes ignore what I tell them	1	2	3	4	5
14.	I have some doubts about the ability of the doctors who treat me	1	2	3	4	5
15.	Doctors usually spend plenty of time with me	1	2	3	4	5
16.	I find it hard to get an appointment for medical care right away	1	2	3	4	5
17.	I am dissatisfied with some things about the medical care I receive	1	2	3	4	5
18.	I am able to get medical care whenever I need it	1	2	3	4	5