Identifying barriers and facilitators to follow-up after endovascular aortic repair (EVAR): Qualitative study design and protocol ☆

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ABSTRACT

Endovascular aortic repair (EVAR) is now first line therapy for most patients with abdominal aortic aneurysms (AAA) as it reduces perioperative morbidity and mortality compared to open surgery. However, up to 40 % of patients do not undergo recommended follow-up, increasing risk of subsequent rupture. Risk factors for loss to follow-up have been studied retrospectively, however, qualitative studies assessing perceived barriers and facilitators to follow-up have not been performed and there are few qualitative protocols within the vascular surgery literature. This article presents a qualitative descriptive study protocol aimed at understanding and improving post-operative follow-up adherence after EVAR developed through an iterative process based on the Theoretical Domains Framework of behavior change. Steps include:

- Selection of target behavior and study design
- Development of study materials, sampling/recruitment strategy, and data collection
- Qualitative data analysis and reporting findings

We demonstrate the feasibility of this study by pilot testing of the semi-structured interview guides on a small group of patients, healthcare providers, and key personnel. This protocol aims to describe key stakeholder experiences within the healthcare system that will ultimately serve as the basis for future multi-institutional research piloting intervention strategies to improve EVAR follow-up.

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Specifications table

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Background

Endovascular aortic repair (EVAR) of abdominal aortic aneurysms (AAA) has been shown in many observational studies to have improved short-term morbidity and mortality compared to open surgical repair [1]. As a result, EVAR is the dominant repair modality for infrarenal AAA in the United States [2,3]. However, randomized controlled trials have not shown a long-term survival benefit of EVAR over open repair [4]. This is thought to be in part due to EVAR having higher graft related complications and reintervention in long-term follow-up compared to open repair. Furthermore, AAA ruptures post-EVAR occur at an estimated rate of 3.4/1000 person-years [5]. For these reasons, long-term follow-up inclusive of aortic imaging within one month of EVAR and annually thereafter is essential [2]. Surveillance imaging allows for early detection of endoleaks that are relatively common after EVAR (seen in up to 30 % of patients) and may lead to aortic degeneration, loss of graft seal, sac re-pressurization, and ultimately rupture [2]. Ideally, routine imaging post-EVAR promotes continued monitoring of these graft-related complications and preemptive elective intervention if needed [6].

Our group and others have previously demonstrated that loss to follow-up (LTF) post-EVAR is associated with up to twice the mortality compared to those who follow-up at any postoperative timepoint [7,8]. Despite this, a significant number of patients do not adhere to postoperative follow-up guidelines, with incomplete follow-up seen in half of all patients and total LTF in up to 40 % of those undergoing EVAR [7,9–11]. Several national database and retrospective studies have identified factors associated with LTF, including male sex, lack of primary care provider, long driving distance to a hospital, discharge to nursing home, and not speaking English [7,10–12]. However, there is a paucity of data in the vascular surgery literature investigating perceived barriers and facilitators to follow-up from multiple stakeholder perspectives. This indicates a need for a scientifically rigorous, systematic evaluation of behavioral patterns in order to effectively develop implementation strategies aimed at improving post-EVAR follow-up [13–15].

The aim of our study is to develop an in-depth understanding of patient-, provider-, and system-level barriers and facilitators to recommended follow-up care after EVAR for both ruptured and elective AAA repair. This study is designed to identify factors associated with complex patient decision making and facilitate methodology that can assist patients and physicians in shared decision making, selecting the operative repair approach that suits the patient's goals and needs. This will be accomplished with semi-structured interviews of key stakeholders, relying on the Theoretical Domains Framework (TDF) of behavioral change to identify key domains of influences on postoperative follow-up behavior as well as potential interventions to mitigate loss of follow-up [16]. The overall goal of this study is to create a foundation for exploration of stakeholder-level factors in other common vascular surgery procedures.

Method details

Theoretical framework

Implementation strategies involve changing both individual and group behavior at multiple stakeholder levels. However, to design an effective intervention, one must understand influences on current behavior, which can help inform behavior change. The Theoretical Domains Framework (TDF) is a theoretical construct of influences that impact behavior change, represented by 14 domains: knowledge, skills, social/professional role and identity, beliefs about capabilities, optimism, beliefs about consequences, reinforcement, intentions, goals, memory, attention and decision processes, environmental context and resources, social influences, emotion, and behavioral regulation [15,16]. This framework has been validated and broadly used in implementation science, specifically in understanding factors that impact a wanted behavior change in the healthcare setting [16–18]. There are seven steps to using the framework: 1) selecting the target behavior (failure to follow-up after EVAR); 2) select the study design (semi-structured interviews); 3) develop study materials (interview guide); 4) Decide the sampling strategy (key stakeholders); 5) Collect the data (conduct interviews); 6) Analyze data (hybrid inductive deductive approach); 7) Report findings (manuscript). The introduction covered step 1. We will continue on to how we performed steps 2–4, and will explain how we will perform steps 5–7 in the future.

Study design selection (TDF step 2)

A qualitative study design was selected in order to gather perspectives about perceived barriers and facilitators to EVAR follow-up that may not be easily attainable through survey instruments. Semi-structured interviews were selected as they optimize both a structured format of questions that allows for consistent data to be collected across participants, but also allows for tailoring of questions for the particular participant and their responses.

Table 1
Projected facilitators and barriers to follow-up after EVAR.

Facilitators	Barriers
Knowledge	
The patient understands that they should follow up	The patient does not know they should follow-up
The patient knows how to follow-up	The patient does not know how to follow-up
KP has knowledge of follow-up schedule	KP does not have knowledge of follow-up schedule
Skills	
The patient has the skill or ability to call and schedule an appointment	The patient does not have the ability to call and schedule an appointment
The patient has the skill to obtain transportation or to navigate telemedicine	The patient is not able to drive or find directions to the appointment
The HCP or KP has the skill to provide telemedicine visits to the patient	The patient, HCP, or KP is unable to navigate telemedicine
Social/Professional Role and Identity	
The patient takes ownership in own health	The patient does not think it is their responsibility to schedule a follow-up
The HCP considers it their responsibility and role to ensure the patient follows up	The HCP does not think it is their responsibility to schedule a follow-up
Beliefs about Capabilities	
The patient believes they are able to get an appointment, or able to navigate telemedicine	The patient does not believe they are able to get an appointment or able to navigate telemedicine
HCP believes patient is capable of follow-up	HCP does not believe patient has capability to follow-up
Optimism	
The patient remains optimistic about their health and believes that following up will improve health	The patient does not think that follow-up will help them or improve their health
The HCP believes that persistence in encouraging follow-up will improve outcomes	The HCP does not think the patient will follow-up regardless of any effort put forward by the HCP
Beliefs about Consequences	
The patient or HCP believes the possible negative consequences of not following up	The patient or HCP does not believe there will be any negative consequences of not following up
The patient or HCP believes there is benefit of follow-up	The patient or HCP does not believe there is any benefit in follow-up
Reinforcement	
The patient has a positive experience and feels valued and cared for by their HCP when they return for initial follow-up	The patient feels like the initial follow-up was a waste of time
	The patient was not able to get in touch with the schedulers to make a new appointment when they tried initially
The patient intends to take ownership of their health	KP is not able to get in touch with the patient to reinforce follow-up importance
Intentions	
The patient intends to take ownership of their health	The patient does not intend to follow-up
The HCP intends to see the patient in follow-up	
Goals	
The goal of preventing late complication is made clear by the HCP to the patient	The patient does not understand the goal of follow-up
The patient's goal is to avoid late complication	The patient's goal does not include preventing late complications or rupture
	The patient's goal is to avoid the healthcare system
Memory, Attention, and Decision Processes	
The patient received a phone call reminding them to follow-up	The patient does not remember to follow-up
The HCP has a follow-up schedule and receives automated prompts to call patients	The HCP or KP does not remember to schedule a patient for follow-up or prompts are not in place
Environmental Context and Resources	
The patient has a safe and secure living situation and feels comfortable attending a follow-up appointment	The patient has other things more pressing on their mind than follow-up (securing shelter, food, etc.)
The patient has reliable transportation	The patient does not have health insurance or ability to drive
The patient's support network is supportive and encouraging of follow-up	The patient's support network is not supportive of follow-up
	The patient does not want to burden their family
Social Influences	
The patient has a personal relationship with a HCP or was a HCP themselves	The patient's family and friends do not trust the physician, healthcare system, or western medicine
The patient had a good overall experience at the hospital during their stay	The patient's family member had a negative experience with HCP
Patient feels like HCP/KP is receptive to their needs	
Emotion	
The patient has positive feelings when they visit the physician	The patient is afraid of what they might learn regarding their health and overall mortality
The patient feels confident that they can have a knolwedgeable conversation with their HCP and will not be forced into any unwanted procedures	The patient is worried they will be forced into having a procedure if they follow-up
The patient feels confidence that their healthcare will not result in financial burden	The patient is worried they cannot pay for adequate healthcare
Behavioral Regulation	
The patient recognizes follow-up may be difficult for them and discusses this ahead of time with their HCP and formulates an action plan	The patient knows they should follow-up but does not have an action plan to schedule the appointment or procrastinates.

Facilitators and Barriers were determined by an expert consensus panel ($n = 4$) using the Theoretical Domains Framework.
KP, key personnel; HCP, healthcare provider.

Table 2

Interview guide for patients with incomplete follow-up.

First, I would like to learn about how you typically approach health care.
1. Are you responsible for managing your health or is someone else? Tell me more about that
2. Does visiting the doctor cause any emotions?
3. Whose advice or influence do you typically trust most when it comes to your health?
I would like to learn a little about your experience with your aneurysm surgery.
4. What was your surgery experience like? Anything that went well or not well?
5. What did you know about the follow up needed with your vascular surgeon?
6. Did you have any concerns about being able to schedule the follow up?
7. Before you had surgery, were you planning on following up?
8. Have you had any follow up visits since your surgery?
8a. If yes: What was your first follow up visit experience like? Anything that went well or not well?
8b. If no: Did you make any efforts to pursue follow up care after your procedure? Tell me more about that. Anything that went well or not well?
9. What do you hope to achieve or avoid related to follow up?
Next, I would like to learn your thoughts about things in your life that make following up easier or harder
10. To what extent is your ability to follow up impacted by your social support?
Next, I'd like to ask you some questions regarding telemedicine
11. Have you had any experiences with telemedicine?
11a. If had a TM visit, what was that experience like?
12. If the follow up visit is offered via telemedicine, do you think you would use this service? Tell me more about that.
I have a couple of final questions to wrap up.
13. Looking back on your experience, is there anything that would have made you more likely to follow up after EVAR? Tell me more about that.
14. Is there anything else that you think is important that you would like to add to our conversation today?

The Interview Guide was pilot tested and adapted for clarity and comprehensiveness.

Interview guide and pilot testing (TDF step 3)

The initial framework for intrinsic and extrinsic factors within each of the 14 domains of the TDF was developed by an expert panel consisting of vascular surgeons, an implementation scientist and a qualitative researcher (Table 1). This framework, along with a review of the literature, was used to create the initial interview guides. Each guide was specific to the stakeholder group being interviewed (e.g. patients with complete follow-up, patients with incomplete follow-up, healthcare providers [HCP], and key personnel [KP]; Table 2, Tables S1–2). The script was pilot tested on two patients (one with complete follow-up and one without), two HCPs, and two KPs to ensure clarity and comprehensiveness of the interview, and was revised appropriately [19,20]. The pilot interviews took 23 min on average. Additionally we plan to update the interview guide iteratively throughout the data collection period to allow for refinement as necessary [21].

Participants and recruitment (TDF step 4)

Participants

We will use purposive sampling, defined as non-random sampling that aims to select stakeholders that will help us understand our particular phenomenon of interest. In our case, this includes patients, Health Care Providers, and Key Personnel, described below.

Patients (Groups 1 and 2): We stratified patients on level of adherence with follow-up recommendations (complete [Group 1] versus incomplete follow-up patterns [Group 2]) [22]. Patients will be further stratified by rupture vs. elective, gender, underrepresented minority, travel distance (over 30 miles), age (over 75), and postoperative complications (Table 3). Living patients who underwent EVAR between October 2019 and October 2021 at a single multihospital healthcare system will be eligible. These patients will be identified through a prospectively maintained registry for all patients undergoing EVAR for elective and emergent repair of AAA. All patients must be at least 18 years of age and English speaking.

Health Care Providers (HCP; Group 3): All HCPs interviewed for the study must be vascular surgeons or vascular surgery advance practice providers (APPs; nurse practitioners or physician assistants) who routinely perform EVAR or care for patients undergoing EVAR in the clinic or inpatient setting at a single multihospital healthcare system. HCPs must voluntarily agree to participate in this research study and will have been employed at the specified healthcare institution for at least a year prior to interview participation.

Table 3

Patient sampling goal.

Follow up Status	Total	Rupture	Female	URM*	Travel Distance†	Age‡	Postoperative Complications
Complete	13	3	6	2	6	3	2
Incomplete	13	3	6	2	6	3	2

Purposive diversity sampling goal for patients stratified upon level of adherence.

  * Underrepresented Minority, including Black, Hispanic/Latino.

  † Over 30 miles.

  ‡ Over 75.

Key personnel (KP; Group 4): KP include administrative assistants to vascular surgeons, schedulers, nurses, and nurse administrators within the division of vascular surgery. Similarly, KPs must voluntarily agree to participate in interviews, be employed for at least a year prior to study participation, and possess an in-depth understanding of outpatient scheduling protocol at the healthcare system.

Of note, providers and system-level key personnel will be stratified based on years in practice or employment and primary patient population.

Sample size

To achieve maximum variation in perspectives, we plan to perform a minimum of 10 interviews per group for the initial data analysis, followed by three additional interviews per group (minimum per group $n = 13$, total of $n = 4$ groups) until we reach thematic saturation (minimum total sample size $n = 52$) [23].

Recruitment

Patients will be identified from a prospectively maintained registry of all patients undergoing elective or emergent EVAR, and will be contacted by phone in order to elicit participation. HCPs and KPs will be contacted by phone and/or email in order to elicit participation. Outreach will be performed by study personnel, including qualitative experts, study recruitment coordinators, and vascular surgery residents. None of the participating outreach personnel had prior relationships with patients, while vascular surgery residents will have a prior relationship with HCPs and some KPs. Patients and KPs will be offered $25 for participation in the form of a gift card. Reasons for non-participation will be tabulated.

Data collection & analysis (TDF steps 5–7)

Data collection

After obtaining informed consent, we will conduct semi-structured interviews by phone using the interview guide. Interviews will be performed by qualitative researchers with significant healthcare interviewing experience, but no prior relationship with participants or expertise in vascular surgery. The interviews are estimated to last 30 min, will be recorded, and subsequently transcribed and de-identified by an experienced member of our institution's Qualitative and Mixed Methods Core. At the end of the interview, participants were instructed to complete a survey using Qualtrics software (Qualtrics, Provo, UT) that queried demographics, general factors that impact patient ability to follow-up, living situation for patients, and professional experience for HCPs/KPs (Table 4; **Table S3**).

Data analysis

Thematic analysis will be conducted by the qualitative team (qualitative experts, vascular surgery residents and attendings) utilizing a hybrid inductive-deductive approach to codebook development, both examining the data through the lens of the TDF, but also being mindful of codes that may emerge outside of the TDF. Transcripts will be read and analyzed for concepts first independently by reviewers, then together in group format to review similarities and differences in concepts and how these may be organized into themes through the technique of constant comparison. The codebook will consist of themes and subthemes within each TDF domain, with corresponding definitions, inclusion and exclusion criteria, and examples. The consistency of the codebook will then be ensured by co-coding of the transcripts by the qualitative team, to an inter-rater kappa statistic of 0.75 or higher. NVivo software (Version 14; Lumivero, Denver, CO) will be used for data management. After coding is complete, the most relevant facilitators and barriers that may serve as a target for intervention will be identified [17]. Differences between groups and stratification factors will be identified as well. Results will be published in a medical journal in accordance with COREQ reporting guidelines [20].

Data management

Data, including code-linking data, will be stored on a password-protected, encrypted folder on an online server managed by the healthcare system. Only research personnel will have access to this data. Data will be deidentified and coded prior to data analysis.

Method validation

The interview guide was pilot tested on two patients (one with complete follow-up and one without), two HCPs, and two KPs to ensure clarity and comprehensiveness of the interview, and was revised appropriately [19,20]. The pilot interviews ranged from 11 to 30 min and took 23 min on average.

Limitations

While our group has significant experience in qualitative research, our study design still has several limitations. Regional differences may limit the overall transferability of our results. However, we hope to mitigate this limitation by collaborating with qualitative clinical researchers in vascular surgery from other institutions. While the most relevant and feasible intervention for patients who get care at the study institution may be different than what is most relevant for patients at other institutions, we think the nature of the semi-structured interview guide will allow for robust participant responses that will account for regional variation in health delivery. Furthermore, development of a comprehensive interview guide will be a tool that can be utilized by any institution.

While EVAR has been a significant advancement in the care of patients with AAAs, it comes at a cost of requiring rigorous follow-up, without which patients risk further aortic degeneration, rupture, and death. Qualitative studies to understand the driving forces

Table 4

Survey questions for patients.

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1. How would you classify your current residence?
a. Assisted living facility
b. At home – alone
c. At home – with others
d. Decline to answer

2. Do you have a primary caretaker (i.e. someone who helps you with your daily activities including bathing, dressing, cooking) *(Yes/No)*
a. If yes, do you live with this person? *(Yes/No)*

3. How much do each of the following impact your ability to follow up? *(1-Does not impact at all, 3-Impacts a little, 5-Impacts a lot)*
a. People in your life or social influences
b. Other responsibilities (i.e. work, family, etc.)
c. Other concerns or priorities (e.g. other medical conditions, food security)
d. Transportation
e. Financial considerations or insurance status
f. Mistrust of medicine or the healthcare system

4. What is your current employment status?
a. Full time
b. Part time
c. Unemployed
d. Self employed
e. Homemaker
f. Student
g. Retired
h. Decline to answer

5. Which income group does your household fall under?
a. Less than $20 K (per year)
b. $21–30K
c. $31–40K
d. $41–50K
e. $51–60K
f. Higher than $60K
g. Decline to answer

6. What is your highest level of education?
a. Less than a high school diploma
b. High school diploma or equivalent
c. Some college or Associate's degree
d. Bachelor's degree
e. Master's degree or higher

7. What is your marital status?
a. Unmarried
b. Married
c. Divorced
d. Separated
e. Widowed
f. Decline to answer

Qualtrics survey to be administered after the completion of interviews.

behind adherence to medical recommendations and follow- up care are underused in many disciplines, including vascular surgery. These forces represent modifiable mechanisms that may underpin the success or failure of any intervention, not limited to EVAR. This research is consistent with the NIH best practice for behavioral intervention development [24], and has implications beyond AAA disease. This project will yield not only generalizable knowledge that will serve as the basis for a multi-institutional pilot study of a theory-based intervention to improve post-operative follow-up after EVAR, but the developed protocols can also be translated for use in understanding medical non-adherence in other procedures and/or specialties. Ultimately, we plan to use what we learn from this project to pilot an intervention at many institutions in various regions throughout the United States.

Additionally, due to the limited number of stakeholders, our analysis may be skewed based on individual biases. This may lead to a future study including more stakeholders validating the results of our semi-structured interviews. Further, it is possible that patients with incomplete follow-up after EVAR may be difficult to recruit for study participation. However, we demonstrate here that contacting and interviewing patients with incomplete follow-up is feasible, and we do not anticipate this to be a significant barrier to project completion; we theorize that incomplete follow-up is not solely reflective of a patient's disinterest in participating in their own health care. Additionally, we anticipate offering phone interviews will eliminate structural barriers to participation.

Ethics statements

The University of Pittsburgh's human research protection office approved the present study (STUDY21060078). Pilot participants consented verbally to interview, be recorded, and answer a brief survey. They could withdraw at any time. Future study participants will be consented verbally as well to be interviewed, recorded, and answer a brief survey. They can withdraw at any time.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Amanda R. Phillips: Conceptualization, Methodology, Writing – original draft, Project administration, Funding acquisition. **Lindsey A. Olivere:** Methodology, Resources, Writing – original draft, Visualization. **Marissa C. Jarosinski:** Methodology, Writing – original draft, Visualization. **Jackie L. Barnes:** Methodology, Investigation, Resources, Writing – review & editing. **Salim Habib:** Methodology, Resources, Writing – review & editing. **Edith Tzeng:** Conceptualization, Methodology, Writing – review & editing, Funding acquisition. **Kimberly J. Rak:** Methodology, Investigation, Resources, Writing – review & editing. **Nathan L. Liang:** Conceptualization, Methodology, Writing – review & editing, Funding acquisition.

Data availability

Data will be made available on request.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.mex.2024.102938.

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