Breaking Down Care Process and Patient-level Barriers to Arteriovenous Access Creation Prior to Hemodialysis Initiation

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Acronyms

AV: Arteriovenous HIPAA: Health Insurance Portability and Accountability Act

CKD: Chronic Kidney Disease IRB: Institutional Review Board

eGFR: Estimated Glomerular Filtration Rate

REDCap: Research Electronic Data Capture (database)

UNC: University of North Carolina at Chapel Hill

GHS: Geisinger Health System

BACKGROUND

Vascular access is one of the most challenging and expensive aspects of hemodialysis care. Use of an AV access (fistula or graft) is associated with improved quality of life, lower sepsis risk, and lower hospitalization and mortality rates as compared to use of a central venous catheter. (1-5) However, <20% of individuals in the US start maintenance hemodialysis with a viable AV access. (6) To date, no effective intervention for improving AV access creation rates prior to dialysis initiation has been identified. Furthermore, we lack essential data on key barriers to pre-dialysis AV access creation. Despite substantial evidence that hemodialysis initiation with an AV access is superior to initiation with a central venous catheter, rates of AV access creation prior to dialysis remain low. Evidence-based, pre-dialysis initiation interventions to improve these rates and associated clinical outcomes are lacking. Interventions that simultaneously focus on care process barriers such as health system navigation and patient barriers such as attitude, fear and knowledge may improve the rates of hemodialysis initiation with an AV access.

We will implement a Vascular Access Navigation and Education Quality Improvement Program in the Geisinger Danville, PA chronic kidney disease clinic among individuals with advanced CKD who are nearing dialysis. The Program addresses both care process and patient-level barriers to AV access creation prior to hemodialysis initiation. The program includes: 1) vascular access care navigation, 2) vascular access education, 3) needs and barriers assessment, 4) peer mentoring, and 5) an electronic health record dashboard to track patient progress through the vascular access placement process.

STUDY OBJECTIVE

The overall objective of the Quality Improvement Program is to assess the feasibility, acceptability, and capacity to improve AV access care process confidence and knowledge and potential to yield improvements in pre-emptive AV access creation. This protocol pertains to the research portion of the Quality Improvement Program. The objective of the research portion is to evaluate the Quality Improvement Program's effect on patient's vascular access knowledge and confidence and providers' confidence helping patients navigate vascular access-related care processes.

SPECIFIC AIM AND HYPOTHESES

Specific Aim 1: Evaluate the Vascular Access Navigation and Education Quality Improvement Program's effect on patient vascular access knowledge by comparing pre- and post-program scores on a vascular access questionnaire. We hypothesize that patient vascular access knowledge will improve pre- to post-program.

Specific Aim 2: Evaluate the Vascular Access Navigation and Education Quality Improvement Program's effect on patient vascular access confidence (self-efficacy) by comparing pre- and post-program scores on the Self-Efficacy for Managing Chronic Disease questionnaire (adapted to be specific to vascular access). We hypothesize that patient vascular access confidence will improve pre- to post-program.

Specific Aim 3: Evaluate the Vascular Access Navigation and Education Quality Improvement Program's effect on providers' confidence helping patients navigate vascular access-related care processes by comparing pre- and post-program scores on a provider vascular access confidence questionnaire. We hypothesize that provider confidence helping patients navigate vascular access-related care processes will improve pre- to post-program.

SUBJECT SELECTION

Inclusion Criteria

Patients

- 1) Receive care at the GHS Danville Nephrology Clinic
- 2) Age \geq 18 years
- 3) eGFR ≤25 mL/min/1.73m² and 2-year kidney failure risk >10% (depending on sample size and data distribution) based on the Kidney Failure Risk Equation, or nephrologist recommendation for vascular access
- 4) Participation in the Vascular Access Navigation and Education Quality Improvement Program

Providers

1) In a professional role involved in hemodialysis vascular access care or process at Geisinger Danville Nephrology Clinic or associated Vascular Surgery, Transplant Surgery, and Radiology Clinics

Exclusion Criteria

Patients

- 1) Too far into the AV access creation process to benefit from the pilot intervention (e.g. completed vascular access surgery appointment or has a surgery appointment scheduled within the next 4 weeks)
- 2) Inability to consent, or
- 3) Inability to complete interviews in English

Providers

1) None

Source and Recruitment

Source:

<u>Patients:</u> Up to 40 advanced chronic kidney disease patients meeting selection criteria will be recruited from the Geisinger Health Systems Danville Nephrology Clinic.

<u>Providers and personnel</u>: 30-40 providers and staff involved in AV access creation (nephrologists, vascular surgeons, interventionalists, vascular access navigator, and clinic nurses, managers and schedulers) will be recruited from the Danville Nephrology Clinic and associated Vascular Surgery, Transplant surgery, and Radiology Clinics.

Recruitment:

<u>Patients</u>: Geisinger nurses serving as the Vascular Access Navigators in the Danville Nephrology Clinic will enroll eligible patients into the Vascular Access Navigation and Education Quality Improvement Program using a program-developed GHS chronic kidney disease patient registry. Of those patients who are enrolled into the Quality Improvement Program, the Vascular Access Navigators will query interest in participating in the Aim 4 research study and request patient permission to be contacted by research staff for recruitment.

Geisinger research staff will contact potentially eligible patient participants by telephone, in-person at a previously scheduled, routine clinical appointment using a prepared script, or through a mailed prenotification letter.

<u>Provider Participants:</u> Eligible providers will be identified by the medical director of the GHS Danville Nephrology Clinic and other GHS nephrologists and vascular surgeons and invited to participate by trained GHS research staff. Recruitment will be performed over the telephone, in person, or by email by trained GHS research staff and will not interrupt work duties or patient care.

Research staff will obtain verbal consent via telephone for research study surveys when preferred by the provider or patient. For in-person program survey participants, additional study information can be found in the written informed consent forms.

SUBJECT ENROLLMENT

Informed Consent Process

Trained study staff at Geisinger will obtain verbal consent over the telephone or written consent in-person prior to enrolling participants in the study. For both in-person and telephone consent, the consent process will be reviewed and all will be allowed to ask questions, request time to consider, and refuse at any time prior to or post consent. For verbal consent over the telephone, the date and name/initials of the research staff member obtaining consent will be documented in the study database.

Geisinger trained research staff obtaining consent will take as much time as needed to explain the study to the participants and answer any questions. Geisinger trained research staff will be available workday/weekend hours to answer any questions. Any voice mail messages or emails will be returned in a timely manner. Participants will be told they are not required to take part in the study and are offered an opportunity to refuse at any time. Participants are also advised they can stop their participation in the study at any time. They are also told their participation will not affect their care or employment.

STUDY PROCEDURES

Research Design

Consented patient and provider participants will complete questionnaires before and after program implementation. We will use a pre- and post-assessment design to evaluate the primary and secondary outcomes. We will collect patient and provider data via questionnaires.

Sample Size

We will recruit up to 40 patients and 30-40 providers and staff.

Study procedures

GHS trained research staff will administer questionnaires to patient and provider/clinic personnel participants. We will obtain verbal or written informed consent prior to enrolling participants in the study. Following screening, recruitment and consent procedures, trained GHS research staff will administer pre-implementation questionnaire questions to participating patients in person (at a previously scheduled, routine clinical appointment or at a time and location of their choosing) or over the telephone (**Appendix A**). Questionnaire administration will not disrupt routine clinical care. Similarly, following screening, recruitment and consent procedures, trained GHS research staff will administer the pre-implementation questionnaire questions to participating providers and clinic personnel at a time that does not interfere with their professional duties in person or over the telephone (**Appendix B**).

The patient and provider/clinic personnel questionnaire questions will take approximately 10 minutes to complete. For both telephone and in person administration of the questionnaires, interviewers will read the questions exactly as written and the response choices for each question. Participants may refuse to answer any question(s). The number of incomplete questionnaires will be monitored.

Patient and provider/personnel participants will also be asked to complete a demographic card (**Appendices C & D**). Patient demographic information collected will include: sex, age, race, ethnicity, education level, and income level. Provider/personnel demographic information collected will include: sex, age, race, ethnicity, professional role, time worked in role at Geisinger and total, and time worked with chronic kidney disease patients, dialysis patients, and with patients going through the vascular access creation process.

At the conclusion of the quality improvement program, trained GHS research staff will administer the post-implementation questionnaire questions to participating patients in person (at a previously scheduled, routine clinical appointment or at a time and location of their choosing) or over the telephone and to participating providers/clinic personnel at a time that does not interfere with their professional duties in person or over the telephone. Questionnaire administration will not disrupt routine clinical care.

Remuneration

There will be no cost to study participants. Patient participants will receive \$25 total remuneration for pre- and post-implementation questionnaires. Participants electing to terminate the questionnaire early will receive the full amount. A \$10 gift card will be given to patient participants for pre-implementation questionnaires, and a \$15 gift card will be given to patient participants for post-implementation questionnaires. A compensation letter will accompany the remuneration.

DATA ANALYSIS AND POWER

Data Collection Variables

See research pre-/post-intervention questionnaires for data collected from patient and providers (**Appendices A & B**).

Data Collection

Table 1 provides an overview of the data to be collected. The outcomes are patient and provider vascular access-related confidence (self- efficacy) and patient vascular access knowledge. Patient confidence will be evaluated using a questionnaire with 11 total items (3 research team-developed questions and 8 Perceived Kidney Disease Self-Management Scale questions (a validated scale).(7) Patient knowledge will be evaluated using an 8-item research team-developed questionnaire. Provider confidence will be evaluated by an 11-item research team-developed questionnaire.

Table 1. Data Collection Variables.

Outcomes	Pre-	Post-
	Implementation	Implementation
Patient confidence navigating the vascular access creation process (self-efficacy)	X	X
Patient vascular access knowledge	X	X
Provider confidence helping patients navigate the vascular access creation	X	X
process (self-efficacy)		
Demographics		
Patient age, sex, ethnicity, race, education level, income level	X	
Provider age, sex, ethnicity, race, professional role, time worked in role at GHS	X	
and total, and time worked with CKD patients, dialysis patients, and patients		
going through the vascular access creation process		

Data Analysis

Pre- and post-implementation confidence and knowledge measures scores will be calculated according to measure scoring instructions (kidney disease self-management: mean of 8 items, (7) patient vascular access process confidence: mean of 3 items, patient vascular access knowledge: mean of 8 items, provider confidence: mean of 11 items). We will use a paired sample student's t-test to compare pre and post-test score means. Analyses will be performed in SAS v9.4 and R v3.3.2 or later.

RISKS AND DISCOMFORTS

The research poses no more than minimal risk to the participants. Participants will be told that if they want their participation dropped from the study, the researchers will do so at any time, and that if they change their mind about participating in the study, they can stop at any time. Participants will be told they will not have any change in the medical care they receive (patients) or their employers (providers/staff) and that their information will not be released to their physicians, employers, health care organization, or any other party without their permission.

In-person appointments for questionnaire completion will be optional. In cases where a participant chooses to participate in an in- person questionnaire, written informed consent will be obtained at the time of the encounter. In cases where a participant prefers to participate in an over-the-telephone questionnaire, verbal consent will be obtained.

The main risk is loss of privacy or confidentiality. There is minimal risk of loss of confidentiality associated with participating in any study. Every effort will be made to protect patient and staff confidentiality. Participants will be told we will do all we can to keep their information private. But this cannot be guaranteed and that their personal information may be disclosed if required by law. Participant concerns about confidentiality will be addressed by the following safeguards. The nature of the project and its associated risks and benefits will be explained fully to all participants at the time of recruitment and again at the time of the questionnaire administration. No individual will be subjected to any pressure to participate or to answer any questions they may not wish to answer. Participants may stop the questionnaire at any time without sustaining adverse consequences.

There is minimal risk of emotional distress. The risk is minimal, however, as the issues covered in the questionnaires are issues often discussed during the course of routine clinical care. There is minimal risk of distress when discussing the AV access placement process. However, licensed social workers and physicians employed by the GHS Danville Nephrology Clinic will be available to participating patients if fears or concerns are uncovered.

POTENTIAL BENEFITS

<u>Individual</u>: There are minimal anticipated direct benefits to the subjects participating in this study. However, participation will provide patients and providers an opportunity to discuss their experience with the vascular

access creation process in a supportive environment. The topics discussed may increase patient interest and engagement in their own care, and provider interest and engagement in the vascular access creation process. Participants will be told that they are helping researchers and Geisinger Health System develop ways to improve the care of patients with kidney disease.

<u>Society</u>: The study will provide critical knowledge on the effectiveness of integrated health system quality improvement initiatives to improve the care and clinical outcomes of patients with kidney disease. If we find the quality improvement initiative is effective, it will provide a model for other health systems to implement. In particular, we will identify ways to implement effective health system tools to inform patient centered kidney transitions care, and we will identify ways to implement care management and behavioral programs that will improve patients' transitions to kidney failure.

MONITORING AND QUALITY ASSURANCE

Eligible participants' information will be kept private and data secure. We will only utilize PHI that is absolutely necessary for our identification of potential participants' eligibility for the study. Our study staff are trained in research ethics and HIPAA privacy compliance. Study participants' information will not be released to their physicians, employers, health care organization, or any other party without the participants' permission. PHI will not be used or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study.

All hardcopy study data will be stored in locked file cabinets within research offices and not the clinical sites, as well as on secure servers where only study staff have access. No personal identifiers, such as participant names, are being collected. All paper and electronic documents will be identified with a unique study ID. All paper documents containing study IDs will be shredded after they are scanned, and saved on the secure server. All responses will be kept confidential and stripped of participant identifiers other than unique study IDs.

Telephone contacts to locate the study subject will not suggest the content of the study. All telephone contacts will be made in private offices or within the private Geisinger research facilities. Only unique patients IDs are on hardcopy files. Patients' data stored on secure servers will not be kept with their identifiable information and only with a unique patient ID. In addition, in-person contact will be made in private offices or within private Geisinger research facilities.

GHS research staff will obtain contact information for eligible patients from the GHS EHR (using a HIPAA waiver) to recruit patients for participation in the pre- and post- implementation questionnaires. Questionnaires will be administered by trained GHS research staff. Data collected by GHS research staff will be entered directly into a Geisinger REDCap database. REDCap is a secure, web-based, password protected, application developed at Vanderbilt University to support data capture for research studies. Duke University and Geisinger are active REDCap consortium members.

ADVERSE EVENTS

Ascertainment of Adverse Events and Serious Adverse Events Adverse events

Adverse events will not be collected in this trial since "any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the intervention" will be occurring in the course of routine care, not research.

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APPENDICES

Appendix A. Patient Pre-Implementation & Post-Implementation Questionnaires

[Interviewer reads each question and answer options to the participant, and records their response on this document. Interviewer can repeat questions and answer options as needed, and answer participants' general questions, but should not provide additional information that would alter the participant's response.]

1.1 Perceived Kidney Disease Self-Management Scale + Self-efficacy Scale for Vascular Access Process We would like to know how much you agree or disagree with the following statements about your kidney

dis	sease. For each	statement, please cho	oose a number between	l (strongly	y disagree) and 5 (st	rongly agree).
1.	It is difficult a. Choice	ees: 1	ve solutions to problems	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
2.	I find efforts	to change things I dor	n't like about my kidne	y disease a	re ineffective.	
	a. Choic	es: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
3.	I handle mys	elf well with respect to	o my kidney disease.			
	a. Choic	ees: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
4.	I am able to r	nanage things related	to my kidney disease a	s well as m	nost other people.	
	a. Choic	es: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
5.	I succeed in t	he projects I undertak	te to manage my kidney	disease.		
	a. Choic	ces: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
6.	Typically, my	y plans for managing	my kidney disease don	't work out	well.	
	a. Choic	es: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
7.	No matter ho	w hard I try, managin	g my kidney disease do	oesn't turn	out the way I would	l like.
	a. Choic	es: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
8.	I'm generally	able to accomplish m	ny goals with respect to	managing	my kidney disease.	
	a. Choic	es: 1	2	3	4	5
		Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree

Foi					-			_		_	_	lialysis vascular access. fident", and 10 is "totally
1.	How confide	ent de	o you	feel cor	npleting	g the ste	eps invo	lved in	getting	a dialys	sis vas	cular access?
	Not at al Confider	1 nt 1	2	3	 4	5	6	7	8	9	10	Totally Confident
2.	How confide	ent de	o you	feel tha	t you kı	now wh	o to go	to for q	uestions	s about	vascul	ar access?
	Not at al Confider	1 nt 1	2	3	 4	5	6	7	8	9	 10	Totally Confident
3.	How confide	ent de	o you	feel tha	t you uı	nderstan	nd the ir	nportan	ce of ge	etting a	vascul	ar access?
	Not at al Confider	1 nt 1	2	3	 4	5	6	7	8	9	 10	Totally Confident
1.	machine] a. It h b. It n c. It n d. Do	a vas elps nakes nakes n't ki	scular you fi s a wa s a wa now	gure ou y for yo y for yo	do? [co t what y our doctour bloo	ou can or to kn d to get	eat and ow how to the l	drink v v well y nemodia	vhen yo our kidı ılysis m	u start h neys are achine	nemod doing	
2.	[Interviewe	er asi ption ey no tula aft heter	ks par es. Int ame c	ticipani erviewe	t to nam r record	e the 3 Is partic	kinds oj cipant's	f vascul respon	ar acce. ses belo	sses. Ini ow by ci	terviev rcling	ula, graft, catheter] wer <u>does not</u> read off the each of the vascular ·".]
3.	. What kind a. Fis		ascula	r access	can ge	t infecte	ed most	easily?	[correc	et answe	er= ca	theter]

b. Graftc. Catheterd. Don't know

- 4. What kind of vascular access usually lasts the longest? [correct answer= fistula]
 - a. Fistula
 - b. Graft
 - c. Catheter
 - d. Don't know
- 5. Who picks the kind of vascular access and where it will go on the body? [correct answer= kidney doctor, patient, and surgeon together]
 - a. Kidney doctor only
 - b. Patient only
 - c. Surgeon only
 - d. Kidney doctor, patient, and surgeon together
 - e. Don't know
- 6. Vein mapping helps you figure out the best place on your body for your access. [correct answer= true]
 - a. True
 - b. False
 - c. Don't Know
- 7. Vein mapping happens after vascular access surgery. [correct answer= false]
 - a. True
 - b. False
 - c. Don't Know
- 8. A fistula is ready to be used for dialysis (in other words, ready to be stuck with a needle for dialysis) within one week after it is made. [correct answer= false]
 - a. True
 - b. False
 - c. Don't Know

Appendix B. Provider/Personnel Pre-Implementation & Post-Implementation Questionnaire

[Interviewer reads each question and answer options to the participant, and records their response on this document. Interviewer can repeat questions and answer options as needed, and answer participants' general questions, but should not provide additional information that would alter the participant's response.]

1.1. Vascular Access Confidence Questionnaire

We would like to know how confident you feel about the dialysis vascular access creation process. For each question, please give an answer between 1 and 10, where 1 is "not at all confident", and 10 is "very confident".

1.	process? a. Choices: 1	234	5678	patients through the vascular access creation 910 Very
2.	. How confident are y process?	you in knowing	how far your patients	s have progressed in the vascular access creation
	a. Choices: 1	234	5678	910
	Not	at all	Somewhat	Very
3.	a. Choices: 1	234	5678	e vascular access creation steps? 910 Very
4.	a. Choices: 1	234	ity to explain vascula5678 Somewhat	r access to your patients? 910 Very
5.	a. Choices: 1	234	5678	cular access creation process to your patients? 910 Very
6.	a. Choices: 1	234	5678	nts overcome barriers to vascular access creation? .910 Very
7.	the vascular access of a. Choices: 1	creation process	s? 5678	with your patients about their emotions surrounding 910 Very

8. How confident are you in communicating appropriate and timely information to other providers about your patients who are going through the vascular access creation process?

a.	Choices: 12	34.	5	6	7	8	9	10
	Not at all		Some	what	t		Ver	y

9.	How confident are you that you are receiving appropriate and timely information from other providers about
	your patients who are going through the vascular access creation process?

a. Choices: 1....2....3....4....5....6....7....8....9....10

Not at all Somewhat Very

10. How confident are you that you are giving your patients the educational materials and information they need to get through the vascular access creation process?

a. Choices: 1....2....3....4....5....6....7....8....9....10

Not at all Somewhat Very

11. How confident are you that your health care system is set up to support your patients' successful navigation of the vascular access creation process?

a. Choices: 1....2....3....4....5....6....7....8....9....10

Not at all Somewhat Very

Appendix C. Patient Demographic Card

Study ID
What is your sex?
□ Male
☐ Female
How old are you? years
What is your racial background?
☐ African American
☐ American Indian/Alaskan
☐ Asian American
☐ Hawaiian/Pacific Islander
□ White
☐ Other (please describe):
What is your ethnicity?
☐ Hispanic
□ Non-Hispanic
□ 1von-rnspame
What is the highest grade you completed?
□ 8 th grade or less
☐ Some high school but did not graduate
☐ High school graduate or GED
☐ Some college or 2 year degree
☐ 4 year college degree or more
What is your household income per year?
☐ Less than \$25,000
□ \$25,000 to \$49,999
□ \$50,000 to \$74,999
□ \$75,000 to \$99,999
☐ More than \$100,000

Appendix D. Provider/Personnel Demographic Card

Study	y ID
What	t is your sex? □ Male □ Female
How	old are you? years
What	t is your racial background? African American American Indian/Alaskan Asian American Hawaiian/Pacific Islander White Other (please describe):
What	t is your ethnicity? ☐ Hispanic ☐ Non-Hispanic
What	t is your job title?
How	long have you worked in your current role within Geisinger? years
How	long have you worked in your current role, including time worked outside Geisinger? years
How	long have you been working with CKD patients? years Dialysis patients? years With patients going through the vascular access creation process? years