2011

Catheter Reduction Toolkit

Developed by the Forum of ESRD Networks' Medical Advisory Council (MAC)

The Forum MAC has developed a series of QAPI toolkits to assist dialysis facilities in meeting the requirements of the Conditions of Coverage.

Forum Medical Advisory Council (MAC)
The Forum of ESRD Networks

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THE NATIONAL FORUM OF ESRD NETWORKS

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Note: Some tools contained in this toolkit were originally created by the Fistula First project and ESRD Networks. The catheter worksheet and instructions (p. 28 - 32) were developed by the Network of New England, Inc.

This Toolkit is a guide, created by experienced professionals using the available evidence, produced by the Medical Advisory Council (MAC) of the Forum of ESRD Networks. The details of the sections may change as technology and regulations change, and the MAC anticipates revisions and additions to the Toolkit over time. The Toolkit is meant as a resource and should not be referenced as a regulatory statement. As with other MAC Toolkits (Medical Director, QAPI, Medication Reconciliation, Vaccination and Assurance of Diabetes Care Coordination) this document is meant to help guide medical directors in meeting their obligations.

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CATHETER REDUCTION
QUALITY ASSESSMENT and PERFORMANCE IMPROVEMENT (QAPI)

INTRODUCTION

The goal of this toolkit is to suggest quality improvement approaches that a facility can use to ensure care coordination for patients.

Coordination of care for serious, chronic diseases is a challenge for patients and providers. In the absence of coordination, tests may be duplicated, important problems may be overlooked, medications with significant adverse interactions may be prescribed, and patient safety is threatened. We hope that this toolkit will assist the facility in improving patient care and safety by using quality improvement processes.

Chronic Venous Catheter (CVC) use, in particular, is associated with increased infectious complications and mortality. While there are some situations in which a catheter may be the appropriate access (e.g., the need for emergency dialysis and the inability to establish an internal access), the use of a catheter should be avoided when an AVF is feasible. K-DOQI Guidelines specify that less than 10% of chronic maintenance hemodialysis patients should be maintained on catheters (continuously for 90 days or longer) as their permanent chronic dialysis access. While the K-DOQI prescribed AVF rates have not been reached, nationally, the use of AVFs has been increasing, while AVG usage has declined. Catheter usage, on the other hand, remains high. According to the 2007 Clinical Performance Measures (CPM) Project, *CVCs in use in prevalent hemodialysis patients ≥ 90 days with no other access* was 17.7% in the US. There has been growing recognition of the impact of AVFs that fail to mature requiring interventions leading to decreased cumulative survival along with the impact of increased costs due to the number of interventions required to maintain patency.

HOW TO USE THIS TOOLKIT

The enclosed Toolkit will assist the facility to design a QAPI (Quality Assessment and Performance Improvement) project (also known as CQI, or Continuous Quality Improvement) with the goal of improving care for ESRD patients. QAPI is a major focus of responsibility for the dialysis unit and the unit's Medical Director as outlined in the Conditions for Coverage of October 2008. According to the new ESRD Conditions for Coverage (494.110) "The dialysis facility must develop, implement, maintain and evaluate an effective, data driven, quality assessment and performance improvement program with participation by the professional members of the interdisciplinary team (IDT). The dialysis facility must maintain and demonstrate evidence of its quality improvement and performance improvement program for review by CMS".

It is recognized that there are many different practice patterns, resources and non-facility factors that contribute to the complexity of any process of care in the dialysis facility. This Toolkit can help the facility understand and improve its own particular processes. It is not meant to provide formulas for a facility to adopt; each facility will need to determine its own goals, challenges and solutions.

We start with a generic description of QAPI, then provide narrowly focused examples along with background information, flowsheets, references, etc.; facilities should feel free to redefine and expand the scope of their projects as they identify additional opportunities for improvement. We also included reference materials that outline the duties of the major facility personnel. Note that the Medical Director is charged with the leadership role in quality improvement, and that all personnel have important roles and responsibilities.

Any materials can be downloaded, revised, printed and distributed without restriction to meet the needs of the facility.

QUALITY IMPROVEMENT

There is no one right way to do quality improvement; the important thing is to identify and describe the problem(s), analyze the causes, determine what resources are available, brainstorm and prioritize solutions, implement a plan, then determine whether improvement occurred, quantitate it, and analyze the findings. There are numerous templates that can be utilized. So called "rapid cycle change" seeks to simplify and accelerate the process, and asks three questions: What are we trying to accomplish, what changes will bring about an improvement, and how will we know a change is an improvement? It forgoes complex flow charts and step by step instructions in favor of small scale changes that can be tested, revised and staged.

We have outlined the basic processes of a QAPI project below in narrative form. The facility should use its internal, interdisciplinary resources to "fill in the blanks" to design its own project. Importantly, the facility should feel free to start with a small piece of the identified problem, work through the QAPI process, then use the information and experience gained to tackle the next project.

Problem: Define the problem that needs to be addressed. It could be an outcome or a process.

Goal: State what you would like to see instead. Important: You can do this in stages. You do not have to address all aspects of the problem or even all patients in the first project.

GET STARTED

First, decide what data you need from patient charts, facility logs, etc.

Next, decide which persons at your facility should be included in the team effort. The team should be interdisciplinary, tailored to the problem.

To get started, consider what the root causes and barriers prevent your facility from performing optimally. These may be personnel factors, patient factors, equipment or physical plant issues, lack of processes or faulty processes, language barriers, financial or reimbursement problems, etc.

Decide on an "AIM" Statement; what are you trying to accomplish? Establish goals. For example, you may aim for 90% success in reaching an identified clinical goal, or may want to see a particular clinical process performed the same way 100% of the time.

How will you measure improvement? This may require chart audits, review of logs, observation of practices in the facility, questionnaires or other means of assessing improvement.

Measurement: decide on a numerator and an appropriate denominator.

Brainstorm potential solutions based on barriers / root cause prioritized by your QI team. You can prioritize the root causes as well as the solutions. Prioritization will help you determine which root causes are most critical and significant. Potential solutions can be prioritized by how "doable" they are, as well as by their anticipated impact. Not all root causes or solutions need to be addressed in every QAPI project.

PLAN: Plan a specific intervention(s). Keep it simple and focused; do not over-reach. Your initial project may be quite limited; you may learn more than you think. You can use what you learn to determine what the next project should be.

Designate personnel and resources for each intervention.

Consider whether to target a specific subgroup for initial intervention.

Determine a timeline; when and how will you collect your follow-up information?

DO: Implement your intervention. Each intervention should have a timeframe and designated personnel.

Collect your follow-up data at the agreed-upon timeline.

Tabulate and/or graph your data, using numerators and denominators where appropriate. Calculate percent changes. **Document.**

STUDY: Examine your results and re-evaluate with your team. Is the process working? If not, why not? What is working well? If necessary, re-evaluate the root causes/barriers as well as your interventions.

Document your progress and findings and revisions in goals and interventions as appropriate.

ACT: If you have not met your goals, begin again with your new plan. If you met your goals, consider whether to expand to another aspect of the problem.

DO NOT HESITATE TO INVOLVE YOUR ESRD NETWORK AND MEDICAL REVIEW BOARD QI RESOURCES. The outline above is intentionally simplified. Your Network Quality Improvement Director will have expertise as well as additional resources and references for you. The Forum of ESRD Networks will soon have a toolkit available that will explain in greater detail the theory and techniques of QAPI (Quality Assessment and Performance Improvement). But you don't need to wait for this to get started on your own projects!

PDSA CYCLE

4-*ACT

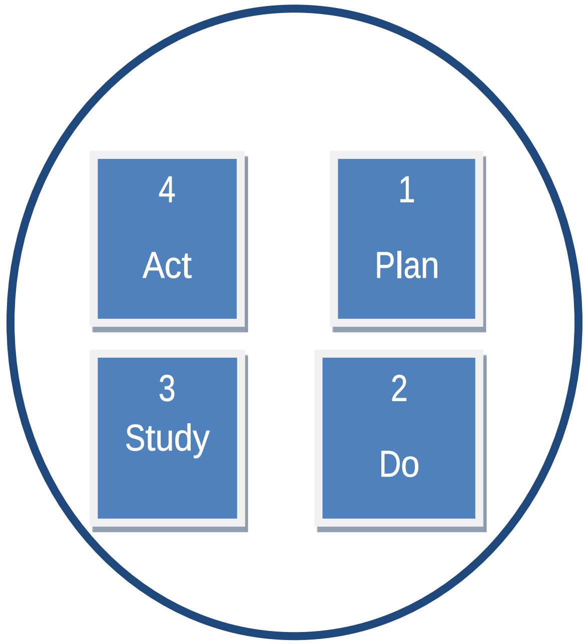
-Adopt the change *or*

-Abandon it *or*

-Run through the cycle again, possibly under different environmental conditions

3- Study the results

What did we learn?



1-Plan a change or a test aimed at improvement

2-Carry it out

(Preferably on a small scale)

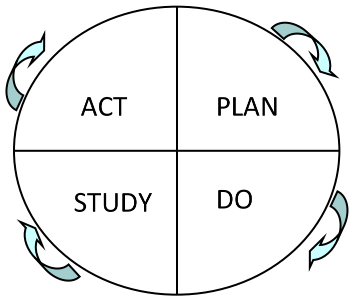
Begin a new PDSA Cycle!

QI PROJECT PHASES	ACTIVITIES	KEEP IN MIND
Plan	Make a plan for the change, collect baseline data, plan to carry out the cycle (who, what, where, when)	Brainstorming, motivating
Do	Carry out the plan, document problems and unexpected observations, continue to monitor data	Flowchart, run chart
Study	Complete the analysis of the data, compare data to predictions, summarize what was learned	Fishbone diagram, Pareto chart, control chart, histogram
Act	What changes are to be made? Develop ongoing evaluation/monitoring, next cycle?	Flowchart, brainstorming

PDSA WORKSHEET

(Adapted from the Institute for Healthcare Improvement © 2004)

CYCLE #: **DATE:**



Task:	
Project:	
Contact:	
BACKGROUND:	
PLAN: **What is the objective of this improvement cycle?**	
Predictions (what do we want to have happen):	
Plan for change or test: who, what, when, where	
Plan for collection of data: who, what, when, where, how will we collect it?	
DO: **Was the cycle carried out as planned? What did we observe that was not a part of our plan?**	
STUDY: **How did or didn't the results of this cycle agree with the predictions that we made earlier?**	
List what new knowledge we gained by this cycle:	
ACT: **List actions we will take as a result of this cycle:**	
Plan for the next cycle:	

ASSESSING CURRENT FACILITY PRACTICE AND OPPORTUNITIES FOR IMPROVEMENT

ASSESSING CURRENT FACILITY PRACTICE AND OPPORTUNITIES FOR IMPROVEMENT

The following forms are provided to assist in evaluating your current facility outcomes and to help guide the QAPI process and identify areas for intervention. Please select the tools you feel are most appropriate.

1. QUALITY ASSESSMENT PERFORMANCE IMPROVEMENT (QAPI) INSTRUCTION SET

1. **Problem/Process to improve**: Catheter usage
2. **Measures to be addressed:** % patients in facility with a CVC
3. **Baseline**:___% -CVC usage
4. **Reassess baseline:** on a monthly basis
5. **Root Cause(s):** State the underlying root cause(s) for the difference between the desired level of performance and the facility's actual performance
6. **Reassess root cause(s): on a monthly basis**
7. **Interventions:** For each root cause, describe the specific actions your facility will take to achieve improvement in the measure. Actions may include modifying specific protocols, processes and procedures as needed to obtain a change
8. **Goal:** Describe in measurable terms, the goal to be achieved for the associated measure
9. **Time Frame:** Provide the time frame for the implementation of all improvement action(s) listed
10. **Monitoring & Evaluation:** Describe the evaluation process that your facility will use to ensure that measure performance improvement is achieved and monitor process monthly

2. QAPI - QUALITY IMPROVEMENT PROJECT – WORKSHEET

1. **What seems to be the problem? What do I want to improve? What am I trying to accomplish?**

2. **Write the problem statement.**

3. **Do I have a baseline data? Yes ☐ No ☐ if not, what data can be collect, by whom, when and how?**

4. **What performance improvement tools can I use?**

5. **What are my performance goals?**

6. **What are my performances measures?**

7. **How will I know that a change is an improvement?**

8. **How will I evaluate and monitor progress and how often?**

9. **Who should be on the team for this QI project?**

10. **What will be my next steps?**

3. QUALITY ASSESSMENT PROCESS IMPROVEMENT – QAPI EXAMPLE

The blue wording is provided as an example only. Please use this sheet and fill in your own facilty's information as appropriate.

Opportunity (Problem/Aim) Statement

A. An opportunity exists to improve – Catheter reduction.
(*Name the process)*

B. beginning with July 2011 and ending with December 2011.
(Timeline starts) ***(Timeline ends)***

C. This effort should improve the morbidity and mortality rate
(Outcomes)

D. for the Beach Dialysis Center
(Facility name)

E. The process is important to work on now because: the facility catheter rate has increased 30% over the last month. The number of hospitalizations related to catheter usage has doubled. The DFR reports received from the Network also state that this facility has maintained a high SMR (>1.5) for the last 3 years.

4. QAPI – KEEPING TRACK OF ACCOUNTABILITY

FACILITY NAME:

DATE:

QI PROJECT NAME:

PROJECT NAME	**PROJECT LEADER**	REPORT TO	WHEN	**BASELINE**	IMPROVEMENT	STATUS
Project A	**Empower staff**	***Emphasize accountability***	**Date**	***Focus on inter-ventions***	**Increase motivation**	**Complete, follow up etc**
CVC reduction	Vascular Access (VA) Manager	Meet VA Manager once a week	Date of meetings	Referrals Reschedule appointment for permanent access Etc.	Facility reduced CVC usage by 1% this month	Review VA report monthly

Note: This tool may be used in conjunction with an action plan and/or quality improvement plan.

CATHETER REDUCTION PROGRAM

The **KEY COMPONENTS** of a catheter reduction program include a standard process to provide:

1. Systematic identification of catheter patients
2. Education of catheter patients about advantages, options and process of obtaining an alternative access
3. Evaluation of catheter patients for alternative access and/or PD therapy
    a. Vessel mapping
    b. Surgical evaluation
4. Obtaining alternative access placement
5. Evaluation of maturing accesses
6. Prompt referral for imaging and/or correction of identified problems for non-maturing access
    a. Image AVF if not maturing after 4 weeks
    b. Image AVG if not usable after 4 weeks
7. Prompt removal of catheter when alternative access is usable

Each of these steps needs to be coordinated into a standard structure to help insure that the process moves expeditiously (see attached flow charts). This is crucial because **the longer a catheter remains in a patient, the longer they are exposed to an increased risk of infection, hospitalization and/or death.** Ideally a CVC insertion can be averted if permanent VA placement is provided in a timely manner prior to imminent need for dialysis (see next page, nephrologist barriers). This process is multidisciplinary by definition. It is important to include nursing, social workers, interventionalists and surgeons in the planning, execution and evaluation of the catheter reduction program.

Successful programs have utilized a number of **"BEST PRACTICES"** to help expedite catheter prevention, conversion and removal.

- Early referral by the nephrologist for permanent vascular access placement prior to the need for dialysis.
- Routine CKD education: Standard CKD and vascular access education with coordinated referral from the physician's office for all patients based on a physician determined GFR threshold (<25 ML/min).
    - Metric: % of patients qualified patients who received education
- Automatic education and referral for vascular mapping and surgical evaluation upon admission of catheter patient to the dialysis facility except for patients with documented medical exclusion
    - Metric: % of new patients presenting with catheter access
    - Metric: % of new patients presenting with catheter access who receive an alternative access
    - Metric: Time until placement of alternative access
    - Metric: Time until catheter removal
- Imaging and correction of identified problems if AVF not developing by 4 weeks or AVG not usable > 4 weeks after placement

- Inclusion of surgeons and interventional nephrologists/radiologists in data review and CQI team

SAMPLE BARRIERS AND INTERVENTIONS

Patient Barriers	Interventions	Who is responsible
Patient barriers		
Patient does not want alternative access	Identify and address reason o Fear of needles o Financial constraints o Cosmetic o Waiting for transplant o Fear of surgery Educate patient and family Discuss potential risks of catheters	Nephrologist, RN, Dialysis tech
Nephrologist Barriers		
Nephrologist not evaluating and/or referring patient	Discuss patient at care management meeting Adopt catheter reduction program with entire medical department Review patient individually with nephrologist	Care team, RN, Dialysis tech Medical director, administrator Medical director
Nephrologist not taking responsibility for patients access management	Discuss patient at care management meeting Review patient individually with nephrologist	Care team, RN, Dialysis tech Medical director, administrator
Facility Barriers		
Lack of systematic catheter reduction program	Develop and institute CQI program	Medical director, CQI team
Lack of standard processes and forms	Develop and institute CQI program	Medical director, CQI team
External Barriers		
Hospital discharging patients with catheters and no access plan	Work with hospital to include them in the VA CQI program	Medical director
Non-cooperative surgeons	Include surgeons in CQI process Consider referral to regional center	Medical director, nephrologist Nephrologist

The integration of these activities is illustrated in the process flow charts/algorithms contained in the next section of the toolkit. A series of data and data collection tools is also provided in the section following the flow charts. It is often helpful to begin by answering the questions on the “Definition of Terms on this Data Collection Tool" (on page 29 of this document). This tool may help provide more insight into the areas that you wish to initially address.

CATHETER REDUCTION PROGRAM: Flow chart - Summary

The intent of the following flow charts is to provide an overview of the recommended steps to address catheter reduction in the facility:

- The first flow chart (Catheter Reduction Program) is a general overview addressing both active patients with catheters only and catheters with AVF or AVG.
- The second flow chart (Catheter Reduction Program: Patient with catheter only) indicates a breakdown of the steps related to patients with catheters only.
- The third flow chart (Catheter Reduction Program: Patient with Catheter and AVF or AVG) indicates a breakdown of the steps related to patients with catheters and AVF or AVG.
- Note for all flowcharts: There currently is insufficient published data to permit a full understanding of the proper role of the HeRo™ catheter.

Flow chart 2: Patients with catheter only

1. From the total number of patients in the facility with catheters only, identify all patients that are possible candidates for an alternative access, (i.e. AVF, AVG, PD catheter or HeRo™). These patients should have no documented reason for medical exclusion.
2. Physician initiates evaluation within < 4 weeks. If no documentation of physician evaluation, refer to QI and/or medical director for appropriate follow-up.
3. Patient evaluated for alternative access (i.e. AVF, AVG, PD catheter or HeRo™).
4. If patient is a candidate for alternative access, ensure access placement is scheduled and completed.
5. If patient is not a candidate for alternative access, (medical exclusion for alternative access placement identified) please document the medical exclusion and the reason for exclusion in the medical record. Appropriate documentation by the physician and/or surgeon is required to be included in the medical record.
6. If the patient refuses alternative access placement, ask the patient why they don't wish to have a permanent vascular access placed. If appropriate, provide patient an access educational program including further discussion with their physician.
7. If the patient continues to refuse alternative access, please document this in the medical record.
8. If the patient accepts an alternative access placement, the physician needs to ensure actions, regarding the access placement, are scheduled, evaluated and followed up.

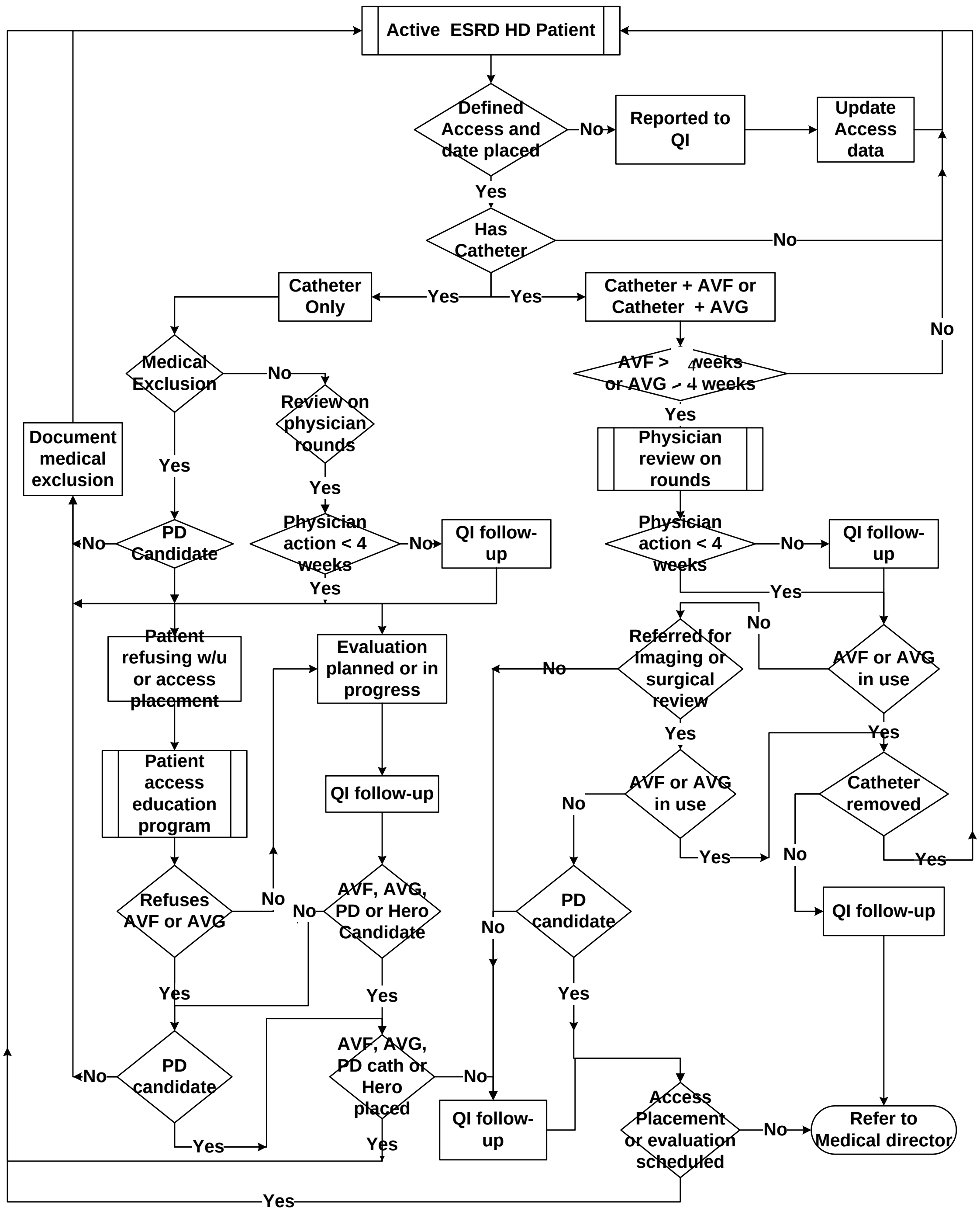
9. If the physician does not take timely action regarding the assessment for an alternative access placement, the medical director should be notified.

Flow chart 3: Patients with catheter and AVF or patients with catheters and AVG

1. From the total number of patients, identify all patients with, catheters in place who also have a maturing AVF or AVG.
2. Please have the physician review the status of all AVF created greater than 4 weeks, or, AVG created greater than 4 weeks previously,
3. If the AVG or AVF is in use, place an order for catheter removal.
4. For those AVF or AVG that are not in use, refer the patients for imaging, surgical review and repair.
5. Once access intervention completed, follow patient until AVF or AVG is in use and catheter is removed.
6. If AVF or AVG is not salvageable, assess for an alternative access such as and AVF, AVG, HeRo™ or placement of PD catheter.
7. For patients deemed eligible for alternative access, physician needs to ensure actions are taken regarding scheduled placement, evaluation and follow up.
8. If any medical exclusion for alternative access placement is identified, appropriate documentation by the physician and/or surgeon is required in the medical record.
9. If the patient refuses alternative access placement, provide patient an access educational program including further discussion with their physician.
10. If the patient continues to refuse alternative access, please document the reasons for continued refusals in the medical record (*see sample Refusal Form, page 46*).
11. The physician also needs to identify the patients refusing alternative access placement, and ensure their enrollment in an access educational program. Reasons for continued refusals should be documented in the medical record.

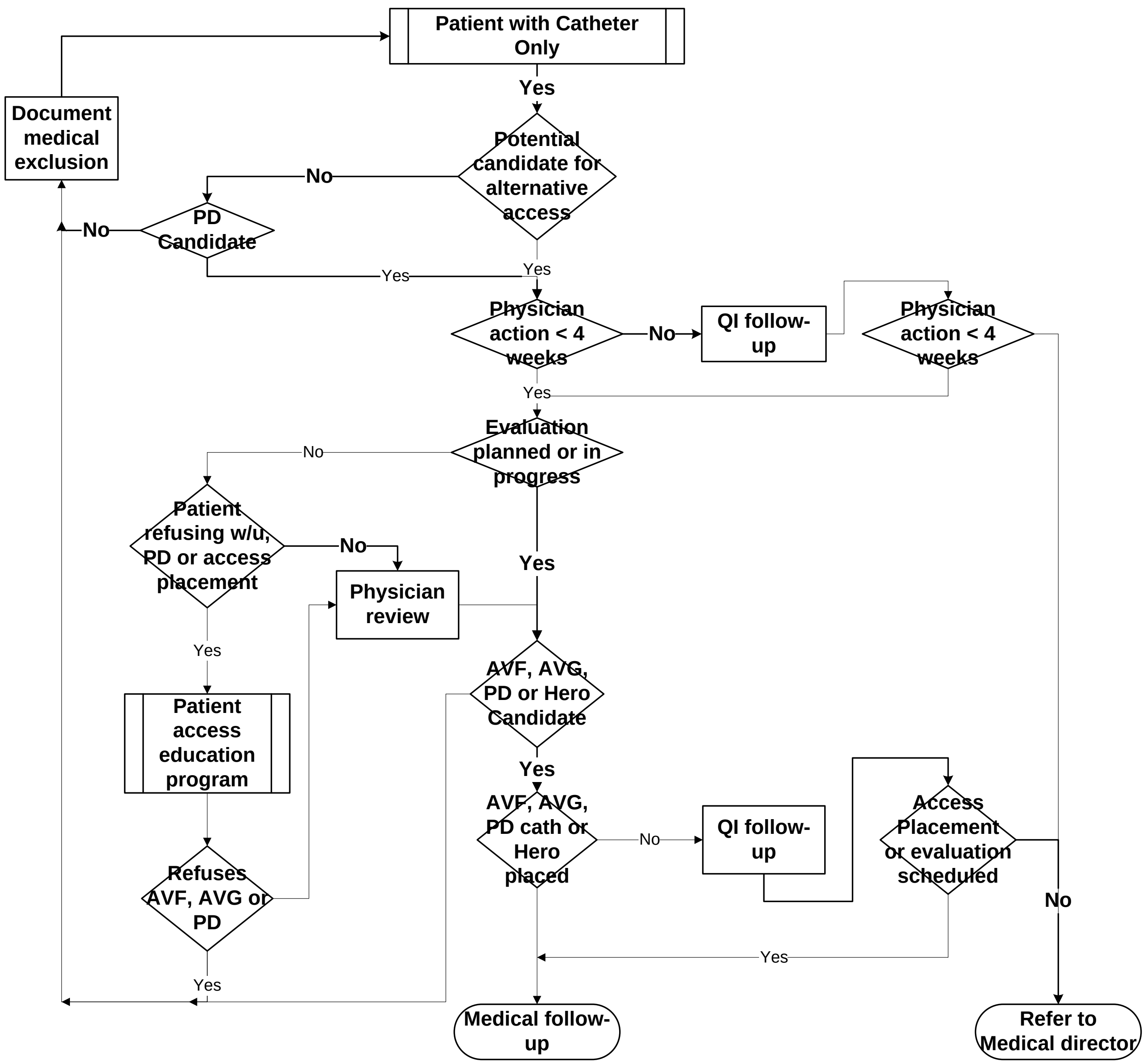
Catheter Reduction Program

August 2011



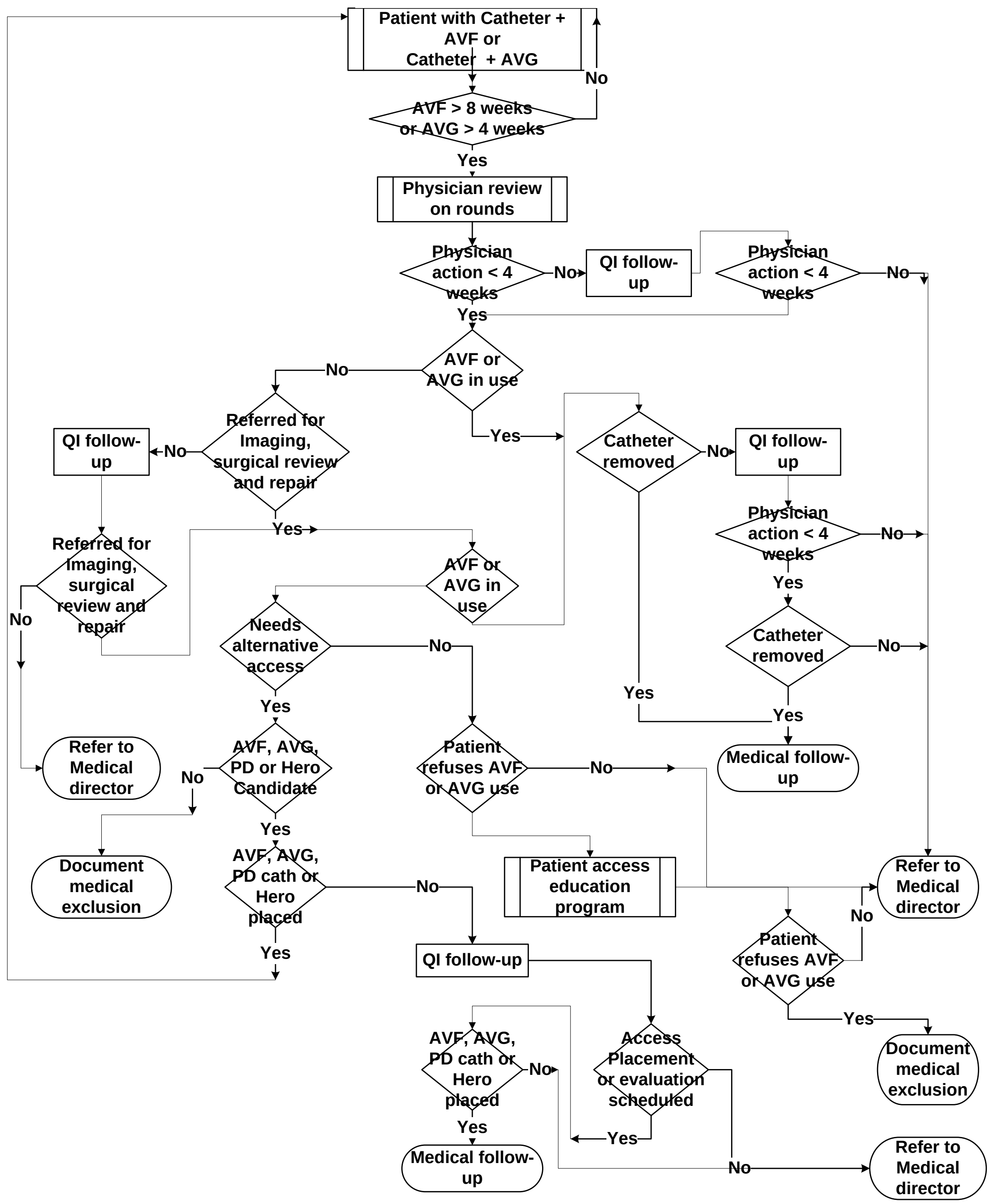
Catheter Reduction Program: Patient with catheter Only

August 2011



Catheter Reduction Program: Patient with Catheter and AVF or AVG

August 2011



DATA and DATA COLLECTION TOOLS

DATA AND DATA COLLECTION TOOLS: GENERAL INFORMATION

The following section provides sample data collection tools. In is not intended or necessary that you use all the tools provided. Most programs will select one or two of the data collection tools and adapt it for use in their QIPI program. This will typically include one tool that addresses individual patients' clinical interventions and a second tool that provides aggregate, facility wide outcome data. The following is a listing of the sample tools provided in this section. Some are very simple and some are more complex. Please select and adapt the tools that are most appropriate for your facility QIPI goals, intervention targets and approach.

Patient specific outcome tools

1. Catheter reduction worksheet
2. Interactive tool CVC reduction

Facility aggregate outcomes

1. Monthly Catheter tracking tool
2. On Goal Report Catheter Reduction Tool

CATHETER REDUCTION WORKSHEET

COMPLETE THIS ON ALL CATHETER PATIENTS

Answer the remaining questions for all of your hemodialysis patients who were dialyzing by catheter access monthly

	A Enter total # Hemodialysis patients here (Include all access types): ______	B Was patient assessed with a VA management tool?		Did patient have a vascular access plan?		C How long has catheter been used?		D If Catheter >= 90 days, WHY? (check the ONE that best describes this patient's situation)												E If D4 = yes, what was the outcome? (check the ONE that best describes this patient's situation)					
		B-1	B-2			C-1	C-2	D-1	D-2	D-2a	D-3	D-4	D-5	D-6	D-7	D-7a	D-8	D-9	D-8	E-1A	E-1B	E-2	E-3	E-4	E-6
	Patient ID - Please complete each line for all patients listed that you report with a catheter & add any that are not listed	Yes	No	Yes	No	< 90 days	>= 90 days	Permanent access placed & maturing	Complication of permanent access (i.e., clotted graft)	Patient scheduled for living transplant	All other sites exhausted	Patient was referred to a Surgeon	Patient refused permanent access placement	Perm. access not feasible due to medical condition	Patient has access plan, but it was not followed	Patient has NO access plan	Patient Educated about PD and refused	Patient referred for HERO and refused	Other (check here and explain on reverse side)	Access surgery scheduled	PD Catheter Scheduled	Patient did not keep surgical app't.	Patient refused permanent access placement	Surgeon determined patient not suitable candidate for permanent access @ this time	Patient's appointment scheduled for future. Enter date below.
1																									
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1

Directions for Completing the Data Collection Tool
Definition of Terms on this Data Collection Tool

Facility-specific evaluation of existing VA program

1 **Does this facility have a vascular access management program?**

Does your facility have a **formalized program** specifically addressing vascular access issues? This would assume that there is a protocol regarding how assessments would take place, who perform them, patient education, etc. Considering this definition, if your facility has a VA management program, please answer yes.

2 **If yes, is it written?**

Is the vascular access management program you have at your facility in a written format and formally adopted by your Governing Body? If so, please answer yes.

3 **Do you use an access team or an access coordinator?**

Does your facility have one designated person, or a team of persons, who educates the patients regarding their options for vascular access (VA), refer to surgeons for placement of permanent VA, coordinate appointments and follow-up regarding care of the new VA? If so, please answer yes.

4 **Do you routinely evaluate all vascular accesses on admission?**

When a patient enters your clinic for the first time, do you have a process by which the vascular access is assessed using a tool or algorithm? If you have a process for systematically assessing all patients' vascular accesses, please answer yes.

5 **5. Do you routinely have an access plan for all patients?**

Does each patient have a written vascular access plan that describes the current vascular access type(s), date of creation, surgeon's name (if applicable), a listing of complications or special circumstances, and sequential listing of all vascular accesses that the patient has had? If your facility has this practice, please answer yes.

If you have a written program, please submit a copy.

If your facility has a written vascular access management program, please submit a copy of it to the network office with this completed form.

Section A

Enter Total # Hemodialysis patients here:

Please enter the total number of hemodialysis patients dialyzing at your facility as of the date listed on the top margin. Please do not count any peritoneal patients who are dialyzing on hemo as a backup. Please do not count any "transient" patients (< 14 treatments with you). Please enter data for "seasonal" patients (with you more than 13 treatments, but not more than 6 months). We are trying to capture the total number of your regular hemo population at this point in time.

Patient ID

Please complete each line for all patients listed that you reported with a catheter on the 2nd Quarter Clinical Indicator Project. Add any patients with catheters that are not listed

Is this catheter a new sub-cutaneous type device?

Is the catheter used on this patient considered a new "subcutaneous device" such as a LifeSite (by Vasca) or a Dialock System (by BioLink), or potentially a similar device by another company? If so, please answer yes.

Section B

Was this patient assessed with a vascular access (VA) management tool?

B1 For this catheter patient, was a vascular access management tool (e.g., algorithm, etc.) used in the assessment? If yes, place checkmark in the block.

B2 If no vascular access management tool (e.g., algorithm, etc.) was used in the assessment of this patient's access, place a checkmark in the block marked "No".

Did Patient have a vascular access plan?

Does a written vascular access plan for this patient exist? If so, please answer yes. If you have no patient-specific written vascular access plan, please answer no.

Section C

How long has [this] catheter been used?

C1 **< 90 days**

If the patient has been dialyzing continuously by catheter for 89 days or less, please place a check mark in this block.

C2 **>= 90 days**

If the patient has been dialyzing continuously by catheter for 90 days or more, please place a check mark in this block.

Section D

If Catheter >= 90 days, WHY?

D1 **Permanent access placed & maturing**

The permanent access refers to an AV-fistula or AV-graft placed in the patient's body, but not yet ready to cannulate for use during hemodialysis.

D2 **Complication of permanent access (i.e., clotted graft)**

Refers to a temporary complication or interruption in the use of the primary access due to clotting, infection, or revision of the AV-fistula or AV-graft. The patient has a functioning AV-fistula or AV-graft previously placed; catheter use is expected to be short (< 90 days). Please do not count peritoneal patients temporarily on hemodialysis back-up.

D2a **Patient is scheduled for a living donor transplant**

Check this box only if a living donor transplant is planned for this patient and will take place soon such that surgery for a more permanent access type was not appropriate.

D3 **All other sites exhausted**

Refers to a patient who has a documented assessment of access placement by a surgeon, and is then determined ineligible for any further vascular access types but a catheter, based on the patient's medical condition.

D4 **Patient was referred to a Surgeon.**

The Nephrologist has written an order and the patient has been referred to a Surgeon for assessment (e.g., venography, etc.) and placement of a permanent internal vascular access (i.e., AV-fistula or AV-graft).

D5 **Patient refused placement of permanent access**

The patient refuses to consent to the procedure for placement of an AV-fistula or AV-graft.

D5a **Permanent access not feasible at this time due to severe vasculitis**

The patient has severe vasculitis that prevents surgery for access within the next 30 days.

D5b **Permanent access not feasible at this time due to dermatologic conditions**

Dermatologic conditions involving extremities precludes graft/fistula placement within next 30 days (I.e., scleroderma, calciphylaxis, etc.)

D5c **Cardiac Stress**

This patient is unable to tolerate increased cardiac output by a graft/fistula due to cardiac condition (I.e., severe coronary artery failure).

D5d **Severe peripheral vascular disease**

This patient has severe peripheral vascular disease, which precludes graft/fistula placement.

D6 **Permanent access not feasible at this time**

This patient is not a surgical candidate (medically) at this time and is projected to have no improvement in condition for at least the next 30 days. This should be documented in medical record.

D7 **Patient has an access plan, but it was not followed**

The nephrology team at the dialysis unit did generate a plan of action to address elimination of a catheter access and placement of a permanent vascular access (AV-fistula or AV-graft), but the plan was not followed.

D7a **Patient had NO access plan**

Please mark this column if there was NO access plan in place for this patient.

D8 **Other (CHECK HERE & EXPLAIN REASONS ON REVERSE SIDE).**

This block is reserved for patients who do not meet any of the other categories. Some reasons for falling into this category may include (but not limited to) insurance failure to approve surgical referral, age of the patient < 12 years, awaiting peritoneal dialysis training, awaiting transplant with next 30 days. *Any patient listed in this category must have a detailed explanation provided on the reverse side of the data collection sheet.*

Section E

If D4 = yes [i.e., patient has been referred to a Surgeon], what was the outcome?

E1 **Access surgery scheduled**

The patient was evaluated by a vascular surgeon, a planned date of surgery to create a permanent vascular access (AV-fistula or AV-graft) has been identified and coordinated.

E2 **Patient did not keep surgical appointment**

The patient did not appear for evaluation by the surgeon (i.e., the patient was a "no show" for the surgeon).

E3 **Patient refused placement of permanent access**

The patient has been educated about the benefits of a permanent vascular access *by the surgeon*, but refuses to consent to the procedure for placement of an AV-fistula or AV-graft.

E4 Surgeon determined patient not suitable candidate for permanent access at this time

Over the course of the evaluation, the Surgeon determined the patient not suitable for permanent vascular access at this time. There should be a written document from the surgeon's office to this effect. The delay may be due to an acute episode (i.e., current infection) or an acute episode of a chronic problem (i.e., management of chronic congestive heart failure is undergoing revision), or some other specified problem. The patient may be eligible for a permanent vascular access at a later time.

E5 Patient appointment scheduled in the future

As of December 1, 2001, had an appointment been made for the patient that had not come to pass at the time of data collection? If yes, enter appointment date.

INTERACTIVE TOOL CVC REDUCTION

Facility: ABC Dialysis Center

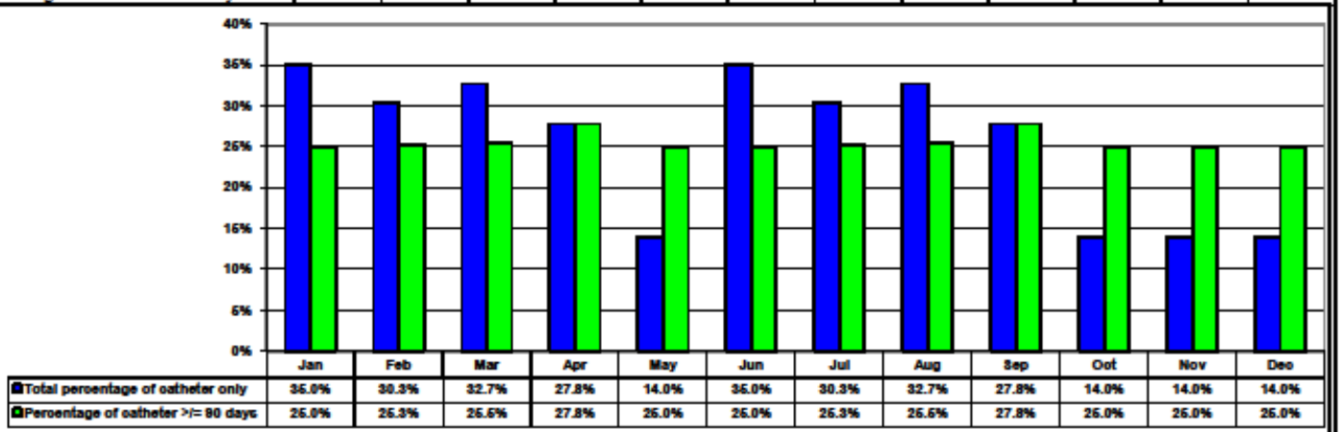
Highlighted are calculated cells-Do not enter data into highlighted cells

#	Patient Name (admitted with CVC Only)	Admit Date	Date Permanent Access within 90 days	Date Permanent Access Placed	Variance (+ or - 90 days)	Comments
1	John Doe	7/10/2008	10/8/2008	9/8/2008	-30	
2			Blank		0	
3			Blank		0	
4			Blank		0	
5			Blank		0	
6			Blank		0	
7			Blank		0	
8			Blank		0	
9			Blank		0	
10			Blank		0	
11			Blank		0	
12			Blank		0	
13			Blank		0	
14			Blank		0	
15			Blank		0	
16			Blank		0	
17			Blank		0	
18			Blank		0	
19			Blank		0	
20			Blank		0	
21			Blank		0	
22			Blank		0	
23			Blank		0	
24			Blank		0	
25			Blank		0	
26			Blank		0	
27			Blank		0	
28			Blank		0	
29			Blank		0	
30			Blank		0	

FMQAI: The Florida ESRD Network

Monthly Catheter Tracking Tool

Facility:							Year:						
	Data should reflect the facility's ending census on the last day of the month												
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
1	How many chronic non-transient, in-center hemodialysis patients did you have on the last day of the month?	100	99	98	90	100	100	99	98	90	100	100	100
2	Of the patients in question #1 above, how many were using a catheter only for vascular access?	35	30	32	25	14	35	30	32	25	14	14	14
3	Of the patients in question #2 above, how many have been using a catheter for **90 or more days**?	25	25	25	25	25	25	25	25	25	25	25	25
4	Of the patients in question #2 above, how many have been referred for mapping and permanent access?	10	12	8	4	7	9	2	3	4	5	6	7
5	Of the patients in question #4 above, how many have been scheduled for **AVF / AVG placement**?	2	2	2	2	2	2	2	2	2	2	2	2
		Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec
	Total percentage of catheter only	35.0%	30.3%	32.7%	27.8%	14.0%	35.0%	30.3%	32.7%	27.8%	14.0%	14.0%	14.0%
	Percentage of catheter >/= 90 days	25.0%	25.3%	25.5%	27.8%	25.0%	25.0%	25.3%	25.5%	27.8%	25.0%	25.0%	25.0%



ON GOAL REPORT CATHETER REDUCTION TOOL

CATHETER RE DUC TION PROJECT

Is Your Facility On Goal For Catheter Reduction?

Facility: ABC Dialysis **Provider # 102345**

Month / Year: Jan 2008

Is Your Facility On Goal For Catheters < 90 Days

Enter Numbers in Yellow Highlighted Areas Only

Number of Patients in Your Facility	50
Number of Patients With Catheters > 90 Days	25
Percentage of Patients with Catheter > 90 Days	50%
To Reach KDOQI Goal of **10%**, You Need to Decrease This Many Catheters	20
Total number of Catheters removed this month	5

Suggestions To Do List:

Evaluate Root Causes Regarding Catheter Use	
Evaluate All Catheter Patients For an AVF	
Refer Eligible Patients to Nephrologist or "Champion Surgeon"	
Review Permanent vascular access referral process with your Medical Director	
Review your vascular access tracking tool for access maturation	

For electronic copy of Catheter Reduction Tool contact ____________________________

This tool was developed for tracking catheter reduction on a monthly basis. Data is entered onto a worksheet for each month. As data is entered for each month, the graph will automatically populate to display trended results.

1 Enter Facility Name and Provider for each month.

2 The month and year are already populated for each tab.

3 Enter the facility data into the yellow highlighted areas.

4 The percentage of patients with catheter > 90 days will automatically populate.

5 The number of catheters to reduce to reach 10% will automatically populate.

6 Enter the total number of catheters that were removed during the month.

7 The graph will automatically populate the monthly results. (the graph displays 2008 dates-a revised tool will become available for use in 2009).

8 The "Suggestions To Do List" section provides some examples. Text can be deleted and facility specific "To Do Lists" can be entered into this section.

REFERRAL LETTERS

REFERRAL LETTER TO A SURGEON

Date

Dear Dr_____________.

I am referring (patient name) to you today for permanent hemodialysis vascular access creation. As per K-DOQI guidelines, I would prefer, if at all possible, that the patient have a native AV Fistula. This is the ideal vascular access for long-term hemodialysis.

Please evaluate the patient for an arteriovenous fistula and for pre-operative vein mapping. If you need any assistance in getting a referral for the procedure or for the mapping, please let us know.

If for some reason after evaluating and examining this patient you feel that an AVF cannot be created, please contact me by phone at (number) to discuss the situation before any access surgery has been scheduled.

Similarly, I do not wish the patient to have a central venous catheter without having a discussion with you about it first as there are many contraindications and complications associated with this type of access.

If the patient is a good candidate for an AVF, please contact (name) at my office at (phone) with the surgery details (date, time, etc.).

Should you have any additional questions, please do not hesitate to contact me.

Sincerely,

Nephrologist Name

This educational item was produced through the AV Fistula First Breakthrough Initiative Coalition, sponsored by the Centers for Medicare and Medicaid Services (CMS), Department of Health and Human Services (DHHS), CMS contract no: HHSM-500-2006-018C. The content of this publication does not necessarily reflect the views or policies of the DHHS, nor does mention of trade names, commercial products, or organizations imply endorsement by the U.S. Government. The author(s) assume full responsibility for the accuracy and completeness of the ideas presented, and welcome any comments and experiences with this product.

Forum of ESRD Networks, 2009

REFERRAL LETTER – ALTERNATIVE ACCESS

Date:

Name: -- (Surgeon or Interventional Nephrologist)

Address: --

RE: **Referral for evaluation of an alternative access**

Dear Dr. -----------------:

I am referring the following patient for evaluation for placement of an alternative (permanent) vascular access (i.e.: AVF, AVG, HeRo™).

Patient name: ---

Dialysis facility -- (*facility name*)

My preference is for the patient to receive an__________________ (i.e.: AVF, AVG, HeRo).

A fistulagram (*or state other study*) was performed on (*date*) at (*place*) and is available for your review.

Enclosed you will find additional clinical information to help you evaluate and treat this patient (i.e.: progress note, medication list, labs etc).

As you know, dialysis catheters markedly increase the risk of patient morbidity and mortality. Please contact me you have any questions regarding this referral or if you do not feel the patient is a candidate for AVF placement. I can be reached at (   ) ----------------- (*physician phone number*).

Sincerely,

Physician name and address

REFERRAL LETTER – NON-MATURING FISTULAE

Date:

Name: --- (Surgeon or Interventional Nephrologist)

Address: ---

RE: **Referral for evaluation of non-maturing fistulae**

Dear Dr. ----------------:

I am referring the following patient for evaluation with possible revision of a non-maturing fistulae which was placed on _______________.

Patient name: ---

Dialysis facility -- (*facility name*).

A fistulagram (*or state other study*) was performed on (*date*) at (*place*) and is available for your review.

Enclosed you will find some information regarding this patient (i.e.: progress note, medication list, labs etc).

As you know, dialysis catheters markedly increase the risk of patient morbidity and mortality. Please contact me you have any questions regarding this referral or if you do not feel the patient is a candidate for AVF salvage. I can be reached at (   ) ---------------- (*physician phone number*).

Sincerely,

Physician name and address

REFERRAL LETTER – PD CATHETER

Date:

Name: -- (Surgeon or Interventional Nephrologist)

Address: --

RE: **Referral for evaluation of a peritoneal dialysis (PD) catheter**

Dear Dr. -----------------:

I am referring the following patient for evaluation and placement of a peritoneal dialysis catheter.

Patient name: --

Dialysis facility --- (*facility name*).

Enclosed you will find some information regarding this patient (i.e.: progress note, medication list, labs etc).

As you know, dialysis catheters markedly increase the risk of patient morbidity and mortality. Please contact me you have any questions regarding this referral or if you do not feel the patient is a candidate for PD catheter placement, I can be reached at (   ) ------------------ (*physician phone number*).

Sincerely,

Physician name and address

HEMODIALYSIS ACCESS REFERRAL: EXISTING ACCESS

Date: ___/___/___ Referred to ☐ Interventional radiologist/nephrologist ☐ Surgeon

Dr.________________________ Phone #: ____________ Fax #: ____________

HEMODIALYSIS UNIT CONTACTS

Referring Nephrologist: ________________ Phone #: ____________ Fax #: ____________

Referring Dialysis Unit : ____________ Contact Person: ____________ Phone #: ____________ Fax #: ____________

PATIENT DEMOGRAPHICS

Patient's Name ________________ SS# ____________ DOB ___/___/___

Address ________________ City ____________ State _____ Zip _____

Patient's Phone ____________ Emergency Contact ____________ Phone ____________

Insurance ________________ Phone ____________

REASON FOR REFERRAL AND PROCEDURE REQUESTED

Reason ________________________________

Procedure/Evaluation Requested ________________________________

Desired Access ________________________________

Date of Scheduled Procedure (if known) ___/___/___ Location: ________________

CURRENT ACCESS

Type: ☐ Fistula ☐ Graft ☐ Catheter ☐ Port Side: ☐ Left ☐ Right Extremity: ☐ Arm ☐ Leg

Location: ☐ Upper ☐ Lower ☐ IJ ☐ Other

Access Insertion Date: ___/___/___ Surgeon ________________ Hospital ________________

Most Recent Access Blood Flow Rates/Pressures: (Check all that apply)

☐ Most recent Blood Flow Rate _____ cc/min.
☐ Most recent Static Venous Pressure (SVP) _____
☐ Most recent Dynamic Venous Pressure _____
☐ Most recent Arterial Pressure _____

Recent Surgical/Radiologic Interventions to Access:

1. ________________ Date___/___/___ Physician ________________
2. ________________ Date___/___/___ Physician ________________

Recent Access Problems/Complication - Check all that apply:

☐ Difficult cannulation ☐ Hematoma/Infiltration ☐ Change in bruit or thrill ☐ Pseudoaneurysm
☐ Pain in extremity ☐ Infected Access ☐ ↓ URR or Kt/V ☐ Prolonged bleeding during/after dialysis
☐ Severe swelling/extremity ☐ High venous pressure ☐ Possible Steal Syndrome ☐ Problems with arterial flow
☐ Other (Specify) ________________

SYNOPSIS OF MEDICAL HISTORY

	Yes	No
SEAFOOD OR DYE ALLERGIES * - If yes, fistulagram may be contraindicated → contact Nephrologist	☐	☐
Diabetes	☐	☐
Peripheral Vascular Disease	☐	☐
History of Clotted Access	☐	☐
Anticoagulation Medicines - If yes ✓ specific medicine(s) below	☐	☐
☐ Coumadin ☐ Ticlid ☐ ASA ☐ Plavix ☐ Other-list :	☐	☐
Recent PT/PTT – if yes, results:	☐	☐
Recent CBC	☐	☐
Recent Chest x-ray	☐	☐
Recent EKG	☐	☐
Other pertinent medical history:		

DIALYSIS TREATMENT INFORMATION

Patient's Dialysis Schedule: ☐ M-W-F ☐ T-Th-S on am / midday / pm shift Date of Last Dialysis___/___/___

Weight today:____________ Estimated Dry Weight: ____________ Last time patient ate or drank: ________________

Stat K+ drawn @ ___:___am/pm on ___/___/___ → __________meq/dl.

Transportation Service ________________ Phone________________

Comments:

VASCULAR ACCESS DIAGRAM – FAX to Dialysis Facility and/or Nephrologist

Patient Name:______________________________ Procedure Date:______________

Diagram Completed by: ☐ Surgeon ☐ Interventional Radiologist ☐ Interventional Nephrologist

Name (Surgeon or Interventionalist):______________________ Phone: (____)______________

FAX to: ☐ Nephrologist Name:______________________ FAX #: (____)______________

☐ Facility Name:______________________ FAX #: (____)______________

Procedure(s): (Check all that apply)	Access Type	Configuration	Location
SURGERY ☐ New Access ☐ Thrombectomy ☐ Revision ☐ Other- specify: ______________ **INTERVENTIONAL (Endovascular)** ☐ Thrombolysis / Thrombectomy ☐ PTA ☐ Stent ☐ Catheter insertion or revision ☐ Diagnostic Fistulogram only ☐ Other- specify: ______________	☐ A/V Graft ☐ A/V Fistula ☐ Port device ☐ Central venous Catheter If new catheter, priming volume: ______ ml ☐ Cuffed ☐ Non-cuffed **Graft Material** ***(if applicable)*** ☐ PTFE ☐ Other – specify: ______________ ______________	**Graft *(if applicable)*** ☐ Loop ☐ Straight ☐ Curved **Fistula Construction** ***(if applicable)*** ☐ Radio-cephalic ☐ Brachio-cephalic ☐ Transposed Type: ______________ ______________ ______________ ☐ Other – specify: ______________	☐ Right ☐ Left ☐ Forearm ☐ Upper arm ☐ Leg/Thigh ☐ Other—specify: ______________ ☐ Subclavian ☐ Internal Jugular ☐ Femoral ☐ Other – specify: ______________

NOTE: Please show Configuration of access, Vessels Involved, and Direction of Access Flow

NOTES:

Were diagnostic evaluations performed prior to procedure? If yes, describe: ....

....

Brief description of procedure (if preferred access not placed, explain reason): ....

....

Procedure findings (if relevant): ....

....

Was procedure successful? Yes No (circle one)

Recommendations/Comments: ....

....

Additional care information/instructions: ....

....

Special cannulation instructions: ....

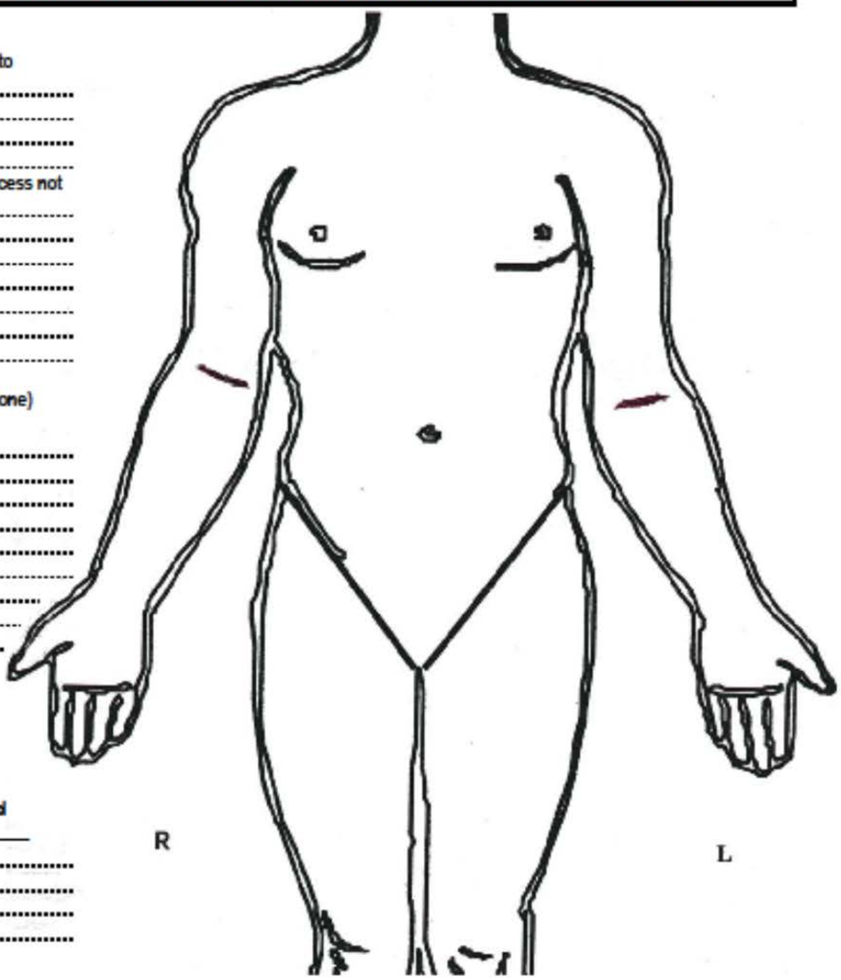
....

Patient follow-up:

1. Patient to schedule appointment with Surgeon/Nephrologist (circle one) in ___ days/weeks (circle one).
2. Patient appointment has been scheduled ________(date) with Dr. ______________

Other Notes: ....

....



HEMODIALYSIS ACCESS REFERRAL: NEW ACCESS

Date: ____________

Referred to (Surgeon): ________________ Phone #: ______________ Fax #: ____________

Referred by (Nephrologist): ______________ Phone #: ______________ Fax #: ____________

PATIENT DEMOGRAPHICS

Patient's Name ______________________ SS# ________________ DOB ___/___/___

Address ______________________ City ____________ State _____ Zip _____

Patient's Phone ____________ Emergency Contact ________________ Phone ____________

Insurance ______________________ Phone ____________

TO BE COMPLETED BY NEPHROLOGIST (attach med list / labs if applicable)

Our patient is being referred to you for access placement. The desired access for this patient is:

- ☐ fistula
- ☐ graft
- ☐ central cath
- ☐ other: ____________

STOP In the event you are not planning to place the desired access, please call the referring physician *prior* to placing *any* other access

Site preference:

☐ Right ☐ Left

- ☐ upper arm
- ☐ lower arm
- ☐ thigh
- ☐ chest
- ☐ other: ____________

IF AV fistula:

- ☐ radial-cephalic
- ☐ brachial-cephalic
- ☐ transposed: Vein type: ____________
- ☐ other: ____________

If Catheter:

- ☐ IJ vein
- ☐ SC vein
- ☐ Femoral vein
- ☐ other: ____________

Diagnostic evals pre-referral: ☐ No ☐ Yes: date/result: ______________________ (attach)

The anticipated dialysis start date is: ☐ ____________

Most recent GFR or serum creatinine: ____________ mg/dl Date: ____________

Most recent creatinine clearance: ____________ ml/min Date: ____________

Taking Coumadin or other Anti-Coagulant? ☐ Yes ☐ No

Allergy Alert:

If patient has any dye or seafood allergies, fistulagram may be contraindicated. Contact Nephrologist for orders re: patient's plan of care.

Allergies: ☐ Yes ☐ No List all Allergies: ______________________

Comments / Additional Information:

SURGEON:

- PLEASE FILL OUT THE "VASCULAR ACCESS DIAGRAM" AND FAX TO NEPHROLOGIST and/or DIALYSIS FACILITY

NEPHROLOGIST:

- PLEASE FAX THIS FORM, ALONG WITH THE COMPLETED "VASCULAR ACCESS DIAGRAM" TO THE DIALYSIS FACILITY.

VASCULAR ACCESS DIAGRAM – FAX to Dialysis Facility and/or Nephrologist

Patient Name:______________________________________ Procedure Date:____________

Diagram Completed by: ☐ Surgeon ☐ Interventional Radiologist ☐ Interventional Nephrologist

Name (Surgeon or Interventionalist):_______________________ Phone: (____)__________________

FAX to: ☐ Nephrologist Name:_______________________ FAX #: (____)__________________

☐ Facility Name:_______________________ FAX #: (____)__________________

Procedure(s): (Check All That Apply)	Access Type	Configuration	Location
SURGERY ☐ New Access ☐ Thrombectomy ☐ Revision ☐ Other- specify: ____________ **INTERVENTIONAL (Endovascular)** ☐ Thrombolysis / Thrombectomy ☐ PTA ☐ Stent ☐ Catheter insertion or revision ☐ Diagnostic Fistulogram only ☐ Other- specify: ____________	☐ A/V Graft ☐ A/V Fistula ☐ Port device ☐ Central venous Catheter If new catheter, priming volume: ________ml ☐ Cuffed ☐ Non-cuffed **Graft Material** ***(if applicable)*** ☐ PTFE ☐ Other – specify: ____________	Graft (if applicable) ☐ Loop ☐ Straight ☐ Curved **Fistula Construction** ***(if applicable)*** ☐ Radio-cephalic ☐ Brachio-cephalic ☐ Transposed Type: ____________ ____________ ____________ ☐ Other – specify:	☐ Right ☐ Left ☐ Forearm ☐ Upper arm ☐ Leg/Thigh ☐ Other—specify: ____________ ☐ Subclavian ☐ Internal Jugular ☐ Femoral ☐ Other – specify: ____________

NOTE: Please show Configuration of access, Vessels Involved, and Direction of Access Flow

NOTES:

Were diagnostic evaluations performed prior to procedure? If yes, describe: ....
....
....

Brief description of procedure (if preferred access not placed, explain reason): ....
....
....

Procedure findings (if relevant): ....
....

Was procedure successful? Yes No (circle one)

Recommendations/Comments: ....
....

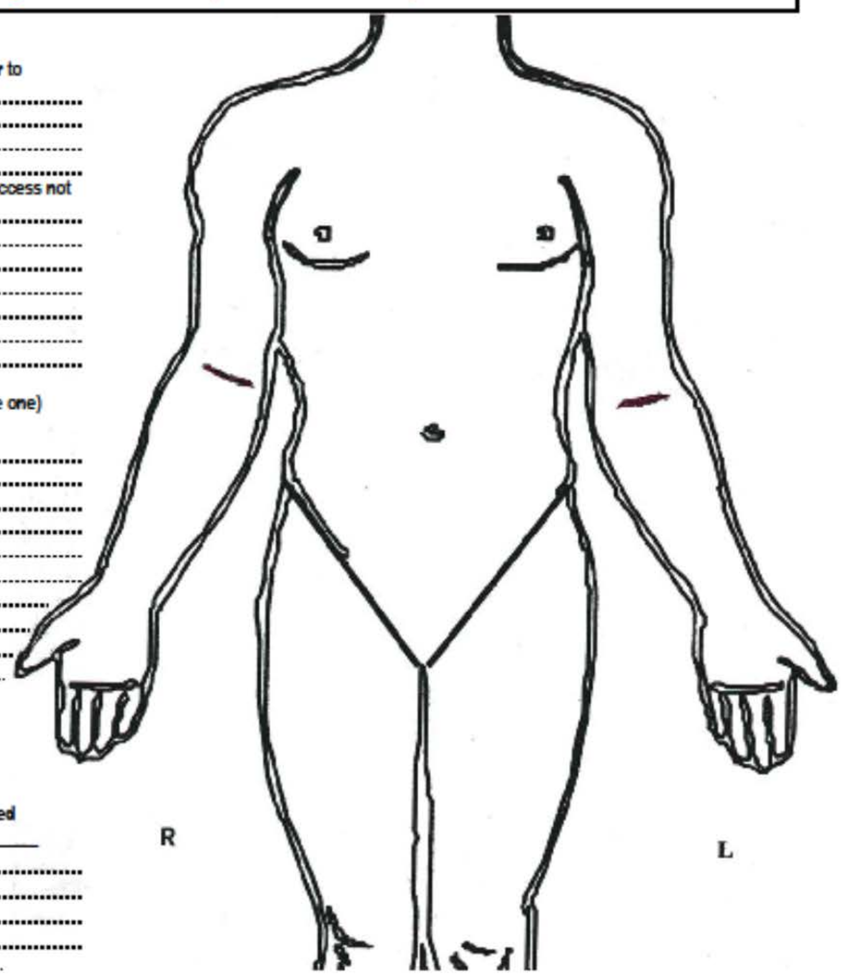
Additional care information/instructions: ....
....

Special cannulation instructions: ....
....
....

Patient follow-up:

1. Patient to schedule appointment with Surgeon/Nephrologist (circle one) in ___ days/weeks (circle one).
2. Patient appointment has been scheduled ________(date) with Dr. ______________

OTHER NOTES: ....
....
....
....



REFUSAL FORM

I, ________________________________, the undersigned, do hereby attest to the following:

1. ____I have been educated about the benefits of a permanent vascular access (fistula, graft) by the staff at _______________________________on at least (3) separate occasions.

2. ____I have been educated about the benefits of a permanent access by my nephrologist (Kidney doctor) on at least (3) occasions.

3. **____I am aware that catheter access poses a greater risk of longer hospital stays, infection, and possibly death.**

4. ____I have been provided with documentation of the above stated facts.

5. ____Nevertheless, I am rejecting the possibility of fistula or graft placement.

6. **____It is my desire to retain my current catheter as my access of choice, despite the inherent risks.**

7. ____The main reason for my refusal is ______________________.

Patient Signature/Date:

____

Caregiver Signature/Date:

____

Staff Witness/Date:

____

RESOURCES AND REFERENCES

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI) FOR ESRD MEDICAL DIRECTORS

Medical Directors set the course for their dialysis center. Patients and staff members rely on the Medical Director to lead effectively. The Conditions for Coverage released on 4/15/08 by the Centers for Medicare & Medicaid Services (CMS) has updated the responsibilities of ESRD facility Medical Directors. As Pay for Performance (P4P) becomes a reality, it is increasingly important for facilities to achieve and sustain clinical performance targets in order to receive reimbursement. Medical Directors are encouraged to read carefully and become very familiar with the new Conditions.

The Medical Director has operational responsibility for the QAPI program and ensures that program data is used to develop actions to improve quality of care and must ensure that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The dialysis facility must maintain and demonstrate evidence of its QAPI program for review by the Centers for Medicare & Medicaid Services (CMS).

This portion of the toolkit contains references that may help with the details of setting up a QAPI project; it is not intended to be complete or authoritative.

The table below contains a breakdown of some Medical Director QAPI and responsibilities.

Patient Clinical Outcomes	**Reuse & Water Treatment**	**Patient Safety & Satisfaction**	**Staff Training**	**Involuntary Discharge of Patients**	**Oversight of Attending Physicians**	**Biohazard & Infection Control**	**Facility Policies & Procedures**
Adequacy of dialysis Nutritional status Mineral metabolism Anemia management Vascular access	Reuse program Deviations from AAMI standards (corrective action plan) Water treatment equipment Pt did not reach target weight	Medical injuries Medical errors Patient satisfaction Grievances	Ensure that staff receive appropriate education and training to competently perform job	Written and signed order from both Med. Dir. and attending physician prior to discharge (Note: The new *discharge/transfer process is very lengthy, specific, and progressive.)	Inform medical staff of facility P&P including QAPI Written and signed order from both Med. Dir. and attending physician prior to pt discharge Assure the attending physicians adhere to P&P	Adverse events Infection control issues	Participate in developing P&P Assure the attending physicians & other staff adhere to P&P

The QAPI team includes all interdisciplinary members and physicians.

Work together to:

- Track
- Trend
- Analyze data
- Formulate strategies
- Intervene
- Set goals
- Set timelines
- Document your efforts

This resource was created while under contract with Center for Medicare and Medicaid Services, Baltimore, Maryland. Contract #HHSM-500-2006-NW012C. The contents presented do not necessarily reflect CMS policy.

QUALITY ASSESSMENT AND PERFORMANCE IMPROVEMENT (QAPI)
TEAM MEMBER RESPONSIBILITIES & ROLES

The ESRD Conditions for Coverage that were released by the Centers for Medicare & Medicaid Services (CMS) on April 15, 2008, require that dialysis facilities establish a written Quality Assessment and Performance Improvement (QAPI) Program. The program is led by the Medical Director of the facility and designed to assist the facility in achieving clinical performance excellence. Below is a listing of possible QAPI team members and examples of their various responsibilities and roles. Facilities are encouraged to utilize this resource as they develop the written facility QAPI program.

Team Member	Responsibilities related to QAPI	Role in QAPI
Patients	Patients are responsible to adhere to the physician ordered plan of care and dialysis treatment prescription to the best of his/her ability. Patients are encouraged to ask questions of the dialysis care team when clarification is necessary. Patients are encouraged to work cooperatively with the team to ensure that he/she receives the highest quality of renal care.	
Medical Director ____________________ Name	The Medical Director (MD) has operational responsibility for the Quality Assessment and Performance Improvement (QAPI) program and ensures that program data is used to develop actions to improve quality of care. The Medical Director ensures that the facility's QAPI program is effectively developed, implemented, maintained, and periodically evaluated. The Medical Director ensures that the facility achieves clinical outcomes that include but are not limited to: adequacy of dialysis, nutritional status, anemia management, vascular access, medical injuries, and medical errors identification, hemodialysis reuse program, patient satisfaction and grievance. The Medical Director is in charge of oversight of attending physicians. The Medical Director controls the involuntary patient discharge/transfer process. The Medical Director The Medical Director ensures that the facility participates in ESRD Network activities and pursues Network goals.	Meet monthly with the QAPI team Review aggregate patient data and formulate an overall facility plan for improvement, including a timeline Adjust individual patient care plans (with attending physicians if applicable) to facilitate the meeting of clinical care goals for that patient. Make recommendations to the team on how to improve the quality of care delivered to the patients Control the involuntary patient discharge/transfer process for the facility Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and act upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Nephrologist ____________________ Name ____________________ Name ____________________ Name ____________________ Name	The Nephrologist is responsible to assist the Medical Director in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. He/she agrees to adhere to and enforce facility policies and procedures. The nephrologist agrees not to dismiss or transfer a patient involuntarily without first discussing it with the Medical Director. The nephrologist will utilize clinical data to develop action plans to improve quality of care. The nephrologist will adjust individual patient care plans to facilitate achievement of clinical goals. The nephrologist agrees to promote participation in ESRD Network activities and the pursuit of Network goals.	Meet monthly with the QAPI team Review patient data and formulate patient specific plans for improvement, including a timeline Adjust individual patient care plans to facilitate the meeting of clinical care goals for that patient. Make recommendations to the team on how to improve the quality of care delivered to the patients Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Advanced Practice Nurse ____________________ Name ____________________ Name	The Advanced Practice Nurse (APN) is to practice under the authority of the Medical Director and Nephrologist. He/she is responsible to assist the Medical Director and Nephrologist in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. To adhere to and enforce the facility policies and procedures. The APN agrees not to dismiss or transfer a patient involuntarily without first discussing it with the Medical Director. The APN utilizes data to develop actions to improve the patients' quality of care. The APN adjusts individual patient care plans to facilitate achievement of clinical goals. The APN promotes participation in ESRD Network activities and the pursuit of Network goals.	Meet monthly with the QAPI team Assist the team with tracking, trending, and analysis of the clinical data. Make recommendations to the team on how to improve the quality of care delivered to the patients Review patient data and formulate patient specific plans for improvement, including a timeline Adjust individual patient care plans to facilitate the meeting of clinical care goals for that patient. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Unit Administrator _____________________ Name	To assist the Medical Director (MD) in the coordination of the Quality Assessment and Performance Improvement (QAPI) program. The MD monitors facility management and patient care staff actions to assure that patient safety is a top priority and that the desired clinical outcomes are being achieved. The MD supports facility participation in ESRD Network activities and pursuit of Network goals.	Meet monthly with the QAPI team Educate the patient care staff regarding QAPI requirements Assist the team with tracking, trending, and analysis of the clinical data. Suggest changes in policies and procedures that would facilitate achievement of clinical performance goals, promote patient safety, and/or improve patient satisfaction. Track and trend medical injuries, medical errors, hemodialysis reuse program, patient satisfaction, and grievances Work with the physicians and patient care staff to identify patient safety or grievance issues Monitor and track patient satisfaction, grievances, patient safety, and other issues Ensure that physicians' orders are carried out. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Registered Nurse ______________________ Name	The registered nurse is responsible for assisting the Unit Administrator in helping the patient care staff to adhere to and deliver the patients prescribed plan of care and the dialysis prescription.	Meet monthly with the QAPI team Educate the patient care staff regarding QAPI requirements Maintain written minutes and notes from the QAPI meetings and distribute them as directed by the Unit Administrator Under the direction of the Unit Administrator, assigns staff members to coordinate the following performance measures: Adequacy of dialysis, nutritional status, and anemia management Work with the Unit Administrator and patient care staff to identify patient safety or grievance issues Ensure that physicians' orders are carried out. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Vascular Access Coordinator ____________________ Name	The vascular access coordinator is responsible for monitoring adherence to the patients prescribed plan of vascular access care and dialysis prescription and coordinating education and care related to the selection, creation, and maintenance of the vascular access.	Meet monthly with the QAPI team Educate the patient care staff regarding QAPI requirements Track and trend catheter usage, arteriovenous fistula, and arteriovenous grafts. Track and trend vascular access infections Work with the Unit Administrator and patient care staff to identify vascular access issues and/or the need for interventions Coordinate vascular access care (surgical referrals, etc.) Ensure that physicians' orders are carried out. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Registered Dietitian ______________________ Name	The registered dietitian is responsible for counseling patients on management of protein, sodium, potassium, phosphorus, and fluid controlled diets, translating the chemistry of these limits into meals for patients; monitoring vitamin and mineral supplementation including iron levels and their effect on erythropoietin; managing glycemic control of diabetic patients by manipulation of diet; and assessing nutritional status by using clinical and biochemical measures.	Meet monthly with the QAPI team Work with the care team to identify patient dietary issues and/or the need for interventions Make recommendations for interventions Implement interventions as directed by the team Perform follow up to assess improvements Ensure that physicians' orders are carried out. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Social Worker _____________________ Name	The Social Worker is responsible to assist patients to achieve and sustain an effective level of vocational, emotional and social wellbeing. The social worker evaluates and addresses challenging or disruptive behavior as well.	Meet monthly with the QAPI team Work with the care team to identify patient issues and/or the need for interventions Make recommendations for interventions Implement interventions as directed by the team Perform follow up to assess improvements Ensure that physicians' orders are carried out. Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

Additional Team Members ____________________ Name ____________________ Name ____________________ Name	The team members assist the QAPI team to improve the quality of care provided to the patients. Team members perform specific duties as assigned by the Unit Administrator and/or Medical Director.	Meet monthly with the QAPI team Work with the care team to identify patient issues and/or the need for interventions Make recommendations for interventions Implement interventions as directed by the team Perform follow up to assess improvements Ensure that physicians' orders are carried out. Support other team members as directed by the Unit Administrator and/or Medical Director Ensure that the facility participates in ESRD Network activities and pursues Network goals. Receive and acts upon recommendations from the ESRD Network. Cooperate with the ESRD Network in fulfilling the terms of the Networks current statement of work

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Hemodialysis Vascular Access Modifies the Association between Dialysis Modality and Survival

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ABSTRACT

Several comparisons of peritoneal dialysis (PD) and hemodialysis (HD) in incident patients with ESRD demonstrate superior survival in PD-treated patients within the first 1 to 2 years. These survival differences may be due to higher HD-related mortality as a result of high rates of incident central venous catheter (CVC) use or due to an initial survival advantage conferred by PD. We compared the survival of incident PD patients with those who initiated HD with a CVC (HD-CVC) or with a functional arteriovenous fistula or arteriovenous graft (HD-AVF/AVG). We used multivariable piece-wise exponential nonproportional and proportional hazards models to evaluate early (1 year) mortality as well as overall mortality during the period of observation using an intention-to-treat approach. We identified 40,526 incident adult dialysis patients from the Canadian Organ Replacement Register (2001 to 2008). Compared with the 7412 PD patients, 1-year mortality was similar for the 6663 HD-AVF/AVG patients but was 80% higher for the 24,437 HD-CVC patients (adjusted HR, 1.8; 95% confidence intervals [CI], 1.6 to 1.9). During the entire period of follow-up, HD-AVF/AVG patients had a lower risk for death, and HD-CVC patients had a higher risk for death compared with patients on PD. In conclusion, the use of CVCs in incident HD patients largely accounts for the early survival benefit seen with PD.

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CLINICAL EPIDEMIOLOGY

The survival benefits of peritoneal dialysis (PD) *versus* hemodialysis (HD) in the treatment of patients with end-stage renal disease continue to be debated. In HD, vascular access type is significantly associated with patient survival. The use of a central venous catheter (CVC) is associated with a substantially greater risk of sepsis, hospitalization, and mortality when compared with the use of an arteriovenous fistula (AVF) or an arteriovenous graft (AVG).[1–5] This association may directly relate to CVC-associated infectious and noninfectious complications. However, the association may also be confounded by case-mix differences between patients initiating HD with either a CVC (HD-CVC) or an AVF/AVG (HD-AVF/AVG). These differences may include: the acuity of dialysis initiation, the absence of timely access to predialysis care, the presence of comorbid conditions, and surgical vascular access eligibility, all of which may be independently associated with patient survival.

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Case-mix differences between patients treated with PD and HD have limited the interpretation of studies that have examined the effect of dialysis modality on patient survival. Although several observational studies have used robust statistical techniques to account for confounding, none have accounted for the role of HD vascular access at the time of dialysis initiation.[6–16] We speculate that compared with patients initiating HD with a CVC, patients initiating HD with an AVF or an AVG are more likely to share characteristics similar to those of incident PD patients. These features include ambulatory initiation of dialysis, timely access to predialysis care, and willingness to make decisions regarding dialysis modality and vascular access choice. In this regard, patients starting HD with an AVF or AVG may serve as more appropriate comparators for PD patients. In this report, our objective was to use data from the Canadian Organ Replacement Register (CORR) to compare survival between PD and HD patients with the latter stratified by HD vascular access type at dialysis initiation. We also sought to test our hypothesis that the early relative survival benefits attributed to PD are attenuated when compared with HD that is initiated with a functioning AVF or AVG.

RESULTS

Baseline Characteristics

40,526 incident chronic dialysis patients were registered in CORR between 2001 and 2008. Over 95% (n = 38,512) of patients had documentation of both dialysis modality and incident HD vascular access. Among these patients, PD was the initial dialysis modality for 19% (n = 7412). Among HD patients, 21.4% (n = 6 663) initiated dialysis with an AVF or AVG, whereas the remainder initiated HD with a CVC.

Table 1 lists the baseline characteristics of the study population. Over the course of the study period, there was a trend toward increased CVC use ($P < 0.0001$) and decreased PD utilization ($P = 0.02$). Compared with PD patients, HD-CVC patients were more likely to be older; to be Caucasian; to have a higher frequency of diabetes mellitus, coronary artery disease, and peripheral vascular disease; and to have a history of malignancy. Compared with PD patients, HD-CVC patients were also more likely to be referred late to a nephrologist (49.7% *versus* 15.2%) and initiate dialysis with lower hemoglobin, serum albumin, and estimated GFR (eGFR).

Compared with PD patients, HD-AVF/AVG patients were more likely to be older and Caucasian and have more extensive comorbidity. HD-AVF/AVG and PD patients initiated dialysis with similar levels of serum hemoglobin, serum albumin, and eGFR, but HD-AVF/AVG patients were less likely to be referred late to a nephrologist (3.6% *versus* 15.2%).

Patient Survival by Dialysis Modality and Hemodialysis Vascular Access

15,327 patients died over the course of follow-up. Among the 11,369 who had available information regarding cause of death, cardiovascular causes remained the most common cause of death (40.6% PD, 32.3% HD-CVC, and 34.4% HD-AVF/AVG), whereas the second most common cause was death caused by infection (11.5% PD, 11.7% HD-CVC, and 11.5% HD-AVF/AVG). Table 2 summarizes the results from the primary analysis. HD patients had higher adjusted 1-year mortality compared with PD patients (adjusted hazard ratio [AHR], 1.5; 95% CI, 1.4 to 1.7). When HD patients were stratified by incident vascular access type, HD-CVC patients had a higher unadjusted 1-year mortality (HR, 2.7; 95% CI, 2.4 to 2.9) and higher adjusted 1-year mortality (AHR, 1.8; 95% CI, 1.6 to 1.9) compared with PD patients. In contrast, 1-year mortality risk was similar in HD-AVF/AVG patients compared with PD patients (HR, 1.1; 95% CI, 1.0 to 1.3; and AHR, 0.9; 95% CI, 0.8 to 1.1). During the initial 5 years of follow-up, cumulative mortality remained higher among HD-CVC patients (AHR, 1.2; 95% CI, 1.1 to 1.2) and lower among HD-AVF/AVG patients, relative to PD patients (AHR, 0.80; 95% CI, 0.8 to 0.9) (Figure 1). After the first year, HD-CVC patients had a time-dependent mortality risk similar to that of PD patients. Over the entire course of follow-up, unadjusted cumulative mortality was 31% (PD), 44.1% (HD-CVC), and 33.9% (HD-AVF/AVG). During this time, mortality was greater in HD-CVC patients (AHR, 1.2; 95% CI, 1.1 to 1.2), and risk of death was lower in HD-AVF/AVG patients (AHR, 0.8; 95% CI, 0.8 to 0.9) relative to PD patients. Irrespective of vascular access type, patients who started HD were less likely to receive a kidney transplant over the course of follow-up compared with those initiating PD (HD-CVC [AHR, 0.8; 95% CI, 0.8 to 0.9] and HD-AVF/AVG [AHR, 0.9; 95% CI, 0.8 to 0.9]).

Sensitivity Analyses

Table 3 summarizes the results of the sensitivity analyses. Referral timing, eGFR, and albumin were missing in 7, 9, and 15% of patients, respectively. Imputation of values for these missing results did not appreciably change the direction and magnitude of our results. Mortality within 90 days of dialysis initiation was highest among HD-CVC patients (15.6% for HD-CVC, 6.1% for HD-AVF/AVG, and 7.4% for PD; $P < 0.001$). After exclusion of patients who died within 90 days of starting dialysis, the increased 1-year mortality risk persisted among HD-CVC-treated patients relative to PD patients. Similar results were seen in the models that excluded patients who were referred late and after censoring patients 60 days or more after a change in dialysis modality. Using the inverse probability of treatment and censoring weighting analysis led to similar results compared with the primary model. The models used to derive the propensity score demonstrated reasonable prediction efficiency with an area under the receiver operating characteristic of 0.8 for HD-CVC *versus* PD and 0.7 for HD-AVF/AFG *versus* PD.

Prespecified Interactions

Figure 2 demonstrates the results of the prespecified subgroup analyses. A higher overall mortality risk was seen in HD-CVC-treated patients relative to PD patients in those less than 65 years of age compared with those over the age of 65. Moreover,

Table 1. Baseline patient characteristics at dialysis initiation in Canada, 2001 to 2008

	PD (*n* = 7,412)	HD-AVF/AVG (*n* = 6,663)	HD-CVC (*n* = 24,437)	*P*
Era of dialysis initiation (%)				<0.0001
2001 to 2004	19.7	18.1	62.3	
2005 to 2008	18.9	16.6	64.6	
Age (%)				
18 to 44 years	15.4	9.5	11.0	
45 to 54 years	16.7	12.5	11.1	
55 to 64 years	22.6	20.2	19.4	
65 to 74 years	25.2	29.1	26.9	
75+ years	20.0	28.6	31.5	
Race (%)				<0.0001
Caucasian	70.4	76.5	75.8	
Asian	8.6	5.8	5.0	
black	3.4	2.8	3.4	
other	12.6	10.0	11.2	
unknown	5.0	4.9	4.6	
Female gender (%)	42.7	34.4	41.7	
Primary renal diagnosis (%)				<0.0001
glomerulonephritis	16.7	12.3	10.1	
diabetes	36.2	38.4	35.4	
renal vascular disease	17.2	20.2	20.1	
polycystic kidney disease	6.9	7.7	2.2	
other	11.8	11.2	18.5	
unknown	11.2	10.2	13.7	
Comorbidities (%)				
diabetes mellitus	42.6	47.3	46.5	<0.0001
coronary artery disease[a]	24.8	32.0	36.1	<0.0001
peripheral vascular disease	13.5	17.8	20.8	<0.0001
malignancy	7.4	10.6	12.6	<0.0001
lung disease	6.6	12.3	14.1	<0.0001
pulmonary edema	12.9	18.6	28.6	<0.0001
hypertension	85.4	86.6	80.1	<0.0001
current smoker	12.1	12.0	13.8	<0.0001
BMI (median, IQR) (kg/m^2)	26.0 (22.9, 29.6)	27.1 (23.6, 31.6)	25.9 (22.6, 30.3)	<0.0001
Late referral (%)	15.2	3.6	49.7	<0.0001
Time from referral to dialysis initiation (median, IQR) (days)	637 (212, 1490)	851 (399, 1620)	188 (11, 784)	<0.0001
Hemoglobin (g/L)	111 (101, 120)	108 (98, 119)	98 (87, 110)	<0.0001
eGFR (ml/min per 1.73 m^2)	9.1 (7.1, 11.9)	8.9 (7.0, 11.4)	8.6 (6.3, 11.8)	<0.0001
Serum albumin (g/L)	36 (32, 40)	35 (32, 39)	31 (26, 36)	<0.0001

IQR, interquartile range; eGFR, eGFR as determined by the modification of diet in renal disease formula.[33]
[a]Coronary artery disease was determined from the presence of a history of at least one of the following: coronary artery bypass grafting, previous myocardial infarction, or previous angina.

the era of dialysis initiation (2005 to 2008 *versus* 2001 to 2004) modified survival comparisons only between HD-CVC- and PD-treated patients but not between HD-AVF/AVG- and PD-treated patients. In this regard, even lower survival in HD-CVC-treated patients was seen relative to PD patients in the more contemporary era compared with the prior era. Diabetes as a cause of ESRD modified the relationship between HD-CVC and HD-AVF/AVG and PD (Table 4). The mortality risk of diabetic HD-CVC patients relative to diabetic PD patients (AHR, 1.0; 95% CI, 0.9 to 1.1) was attenuated compared with the relationship in nondiabetics (AHR, 1.3; 95% CI, 1.2 to 1.4). Similarly, compared with HD-AVF/AVG patients without diabetes (AHR, 0.9; 95% CI, 0.8 to 1.0), diabetic HD-AVF/AVG patients had a significantly lower risk of death compared with diabetic PD patients (AHR, 0.8; 95% CI, 0.7 to 0.8). No significant interactions were seen between eGFR, Body mass index (BMI), and dialysis modality.

DISCUSSION

In this registry-based, observational cohort study, we identified the important influence of HD vascular access type on survival comparisons between incident HD and PD patients.

Table 2. Results of the piecewise proportional hazards model for the relationship between dialysis modality and death

	Adjusted[b] Time dependent[a] HR [95% CI]		Univariate Time dependent[a] HR [95% CI]	Adjusted[b] Time dependent[a] HR [95% CI]	Adjusted[b] Time average[c] HR [95% CI]
Overall[d]					
PD	1.0	PD	1.0	1.0	1.0
HD	1.0 [1.0, 1.1]	HD-CVC	1.7 [1.6, 1.7]	1.2 [1.1, 1.2]	1.2 [1.1 1.2]
		HD-AVF/AVG	1.1 [1.0, 1.1]	0.8 [0.8, 0.9]	0.8 [0.8,0.9]
Year 1					
PD	1.0	PD	1.0	1.0	1.0
HD	1.5 [1.4,1.7]	HD-CVC	2.7 [2.4, 2.9]	1.8 [1.6, 1.9]	1.6 [1.5, 1.8]
		HD-AVF/AVG	1.1 [1.0, 1.3]	0.9 [0.8, 1.1]	0.9 [0.8,1.1]
Year 2					
PD	1.0	PD	1.0	1.0	1.0
HD	1.0 [0.9, 1.1]	HD-CVC	1.5 [1.4, 1.6]	1.1 [1.0, 1.2]	1.4 [1.3, 1.5]
		HD-AVF/AVG	0.9 [0.8, 1.0]	0.8 [0.7, 0.9]	0.8 [0.8,0.9]
Year 3					
PD	1.0	PD	1.0	1.0	1.0
HD	0.8 [0.7, 0.9]	HD-CVC	1.2 [1.1, 1.4]	0.9 [0.8, 1.0]	1.2 [1.2, 1.3]
		HD-AVF/AVG	0.9 [0.8, 1.0]	0.7 [0.6, 0.8]	0.8 [0.7, 0.9]
Year 4					
PD	1.0	PD	1.0	1.0	1.0
HD	0.8 [0.7,1.0]	HD-CVC	1.3 [1.1, 1.5]	0.9 [0.8, 1.0]	1.2 [1.1, 1.2]
		HD-AVF/AVG	1.1 [0.9, 1.3]	0.8 [0.7, 1.0]	0.8 [0.7,0.9]
Year 5					
PD	1.0	PD	1.0	1.0	1.0
HD	0.8 [0.7, 0.9]	HD-CVC	1.2 [1.1, 1.5]	0.9 [0.7, 1.0]	1.2 [1.1,1.2]
		HD-AVF/AVG	1.1 [0.9, 1.3]	0.8 [0.7, 1.0]	0.8 [0.8,0.9]

[a]Time-dependent hazard ratios within each year were used to assess annual mortality risk.
[b]Intention to treat, adjusted for age, race, gender, era of dialysis initiation, end-stage renal disease comorbidity index, primary renal diagnosis, serum albumin, estimated glomerular filtration rate, province of treatment, and late referral.
[c]Time-averaged hazard ratios from a proportional hazards model were used to assess the cumulative treatment effect from day 0 through the end of years 1 to 5, respectively.
[d]Overall model and time average models constructed using 29,647 subjects using proportional hazards model, remainder of time-dependent models using nonproportional hazards model.

Patients starting HD using a CVC had a higher risk of death in the first year compared with those who started PD, whereas there was no difference in survival between HD-AVF/AVG and PD patients. These relationships persisted over a 5-year follow-up with a small survival benefit in the HD-AVF/AVG group.

Our findings should prompt a reconsideration of conclusions drawn from previous studies comparing HD and PD. Large registry-based studies,[7,9,14,16,17] including a previous analysis of this Canadian registry,[7] have demonstrated a survival advantage with PD over HD during the first 1 to 2 years of therapy with similar or inferior survival thereafter. Greater relative preservation of residual kidney function with the use of PD in the initial period after dialysis initiation has been cited as a possible mechanism for this finding.[18] However, we found that vascular access type significantly modified this early survival benefit because it was only observed in PD patients when compared with the subgroup of patients who initiated HD with a CVC. This suggests that vascular access-related morbidity/mortality and case-mix differences that coincide with HD vascular access type are more likely to explain the higher early mortality attributed to HD.

Higher 1-year mortality in incident HD patients compared with PD patients has recently been reported by the Australian and New Zealand Dialysis and Transplant (ANZDATA) registry[14] and by the United States Renal Data System (USRDS).[16] These studies did not adjust for vascular access type. However, in the USRDS study, 1-year survival was similar between HD- and PD-treated patients, once deaths within the first 90 days of dialysis initiation were excluded. Although the USRDS analysis did not directly account for vascular access type, HD patients who were successfully matched to PD patients had characteristics that were likely associated with incident AVF/AVG use as compared with their unmatched counterparts. In the United States, initiatives such as *Fistula First* may have resulted in the stabilization of prevalent and incident CVC use.[19] In contrast, Canada has one of the highest rates of CVC use among developed countries,[20] and this may be contributing to early HD-related mortality as CVC use continues to increase.

In addition to the direct effects of CVC use on morbidity and mortality, initiation of HD with a CVC is a proxy for both measured and unmeasured comorbid patient characteristics that are associated with reduced survival among dialysis patients. HD-CVC patients were older, had a greater comorbidity

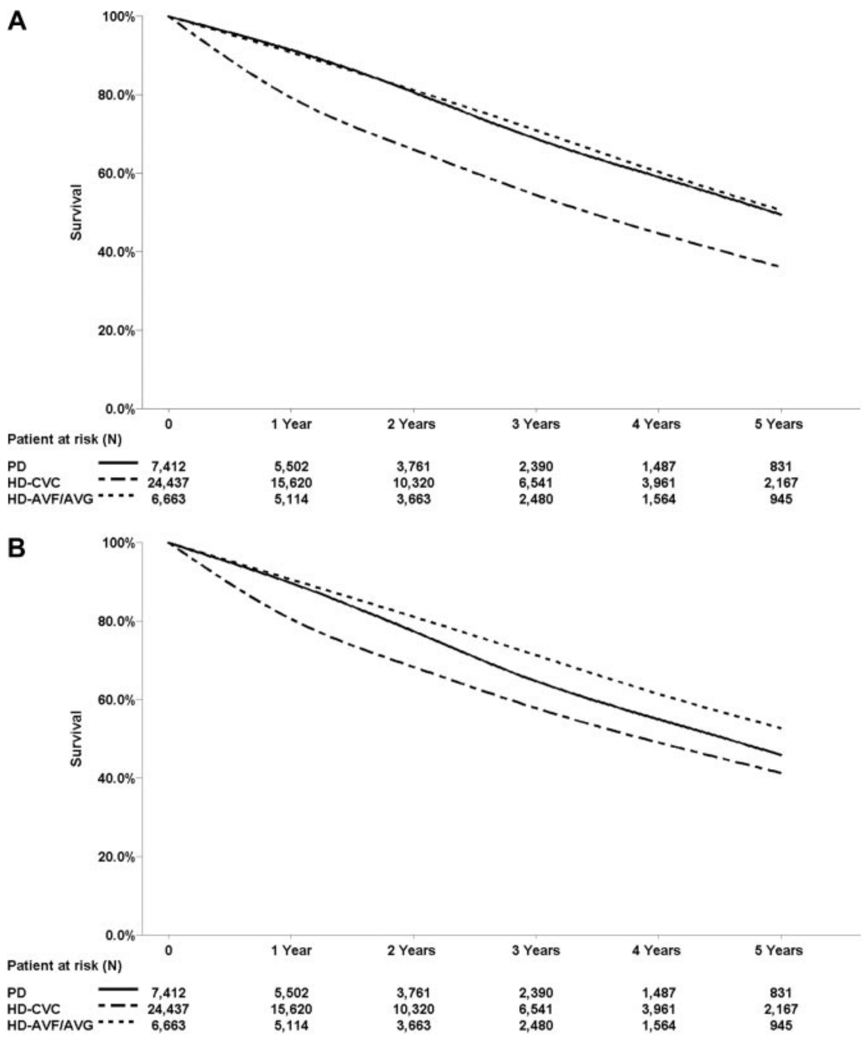

Figure 1. Survival curves for HD-CVC (short-dashed line), HD-AVF/AVG (long-dashed line), and PD (solid line) demonstrate higher 1-year mortality in HD-CVC patients. (A) Unadjusted. (B) Adjusted on the basis of a stratified Cox proportional Hazards model stratified by HD-CVC, PD, and HD-AVF/AVG and adjusted for age, race, gender, era of dialysis initiation, end-stage renal disease comorbidity index, primary renal diagnosis, serum albumin, eGFR, province of treatment, and late referral.

profile, and had less exposure to predialysis care as compared with PD and HD-AVF/AVG patients. Not surprisingly, patients initiating HD with a CVC were more likely to die within 90 days of dialysis initiation. Despite extensive and robust adjustment for case-mix differences, large unmeasured differences likely persist with respect to the severity of comorbidities between CVC- and AVF/AVG-treated HD patients. This would imply that AVF or AVG use at dialysis initiation would be associated with healthier HD patients. Comparing incident PD patients to HD patients who initiated dialysis with an AVF/AVG offered a unique opportunity to assess the effect of dialysis modality in a more homogeneous cohort of incident dialysis patients. Both groups shared similar laboratory profiles including similar serum albumin levels and fewer comorbidities relative to HD-CVC patients. With this analysis, we were unable to demonstrate any early survival differences between PD patients and HD-AVF/AVG patients within the first year of dialysis. Perhaps most importantly, the ability to commence dialysis with PD or HD using an AVF or AVG suggests that exposure to some form of predialysis care is associated with improved early survival, which was likely lacking in many patients who started HD with a CVC. Predialysis care is an important determinant of survival and hospitalization, particularly in the early ESRD period.[21,22]

After the first year of dialysis, we found that HD-AVF/AVG patients had consistently improved survival compared with PD patients. This finding persisted even after accounting for the effect of a change in modality in a sensitivity analysis that censored patients at the time of a change in dialysis modality. Possible reasons may relate to unmeasured case-mix differences between HD-AVF/AVG and PD patients, which persisted despite extensive multivariable adjustment. It is possible that the very ability to create an AVF or AVG is associated with favorable vascular health and that the inability to create an AVF or AVG may have been a factor in the selection of PD for some patients.[23] However, in our cohort, HD-AVF/AVG patients had improved survival despite being older and having a higher burden of documented comorbidities as compared with PD patients. Moreover, our findings remained robust to several sensitivity analyses. It is also possible that survival differences between HD-AVF/AVG patients and PD patients may be due to the effects of informative censoring. Both in this study and in others, higher rates of kidney transplantation have been observed among PD patients relative to HD patients.[24,25] Although patients were censored at the time of kidney transplantation, selective removal of a population of transplant-eligible, healthy patients from the PD cohort may have led to reduced survival among the remaining PD patients, many of whom may have been ineligible for transplantation. We partially accounted for this bias by performing an inverse probability of treatment and censoring weight analysis that exhibited little deviation in either the direction or magnitude of the results from our primary analysis.

Many studies have demonstrated that dialysis modality-related survival is modified in particular subgroups of patients.[8,10,14–17,26–28] In keeping with previous studies, we found that PD was generally associated with more favorable outcomes in patients ≤65 years old, those without diabetes, and those without additional comorbidities[7,14–17,26]. Temporal

Table 3. Results of the sensitivity analysis, piecewise proportional hazards model for the relationship between dialysis modality and death

	Censored at 60 Days after Modality Switch[a]	Modality at 90 Days after Dialysis Initiation[a]	Multiple Imputation of Missing Data[a,b]	IPTCW[a,c]	Exclusion of Late-referral Patients[a,d]
Overall					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	1.2 (1.1, 1.2)	1.1 (1.0, 1.1)	1.2 (1.1, 1.2)	1.1 (1.0, 1.1)	1.1 (1.1, 1.2)
HD-AVF/AVG	0.8 (0.8, 0.9)	0.8 (0.7, 0.9)	0.8 (0.8, 0.9)	0.7 (0.6, 0.8)	0.8 (0.8, 0.9)
Year 1					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	1.8 (1.6, 2.0)	1.4 (1.3, 1.6)	1.8 (1.6, 1.9)	1.3 (1.1, 1.5)	1.6 (1.5, 1.8)
HD-AVF/AVG	1.0 (0.9, 1.2)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.7 (0.6, 0.9)	1.0 (0.9, 1.1)
Year 2					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	1.1 (1.0, 1.3)	1.1 (1.0, 1.2)	1.0 (0.9, 1.1)	1.1 (1.0, 1.3)	1.0 (0.9, 1.2)
HD-AVF/AVG	0.9 (0.8, 1.0)	0.8 (0.7, 0.9)	0.7 (0.7, 0.8)	0.8 (0.6, 1.1)	0.8 (0.7, 0.9)
Year 3					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.9 (0.7, 1.0)	0.9 (0.8, 1.0)
HD-AVF/AVG	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	0.7 (0.6, 0.8)	0.5 (0.4, 0.7)	0.7 (0.6, 0.8)
Year 4					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	0.9 (0.7, 1.0)	0.9 (0.8, 1.0)	0.9 (0.8, 1.0)	0.9 (0.7, 1.1)	0.9 (0.8, 1.1)
HD-AVF/AVG	0.8 (0.6, 1.0)	0.8 (0.7, 0.9)	0.9 (0.7, 1.0)	0.8 (0.5, 1.2)	0.8 (0.7, 0.9)
Year 5					
PD	1.0	1.0	1.0	1.0	1.0
HD-CVC	0.7 (0.6, 0.9)	0.8 (0.7, 1.0)	0.9 (0.7, 1.0)	1.0 (0.8, 1.3)	0.9 (0.8, 1.1)
HD-AVF/AVG	0.7 (0.6, 1.0)	0.8 (0.6, 1.0)	0.9 (0.7, 1.0)	0.9 (0.6, 1.4)	0.8 (0.6, 0.9)

IPTCW, inverse probability of treatment and censoring weighting.
[a]Adjusted for age, race, gender, era of dialysis initiation, end-stage renal disease comorbidity index, primary renal diagnosis, serum albumin, estimated glomerular filtration rate, province of treatment, and late referral.
[b]Assuming monotone missing pattern, the predictive mean matching method was used to impute missing values.
[c]Pairwise PD-HD(CVC) and PD-HD(AVF/AVG) propensity scores were used.
[d]Exclusion of 11,076 HD-CVC, 1126 PD, and 240 HD-AVF/AVG patients who had 3 months or less of predialysis care by a nephrologist.

trends toward improving survival in PD patients relative to HD patients have been observed in several studies.[25,29] Potential reasons have included both technologic advances in PD connectology, PD solutions, and favorable changes in PD-related practices.[29] In comparing two eras (2005 to 2008 *versus* 2001 to 2004), we found that the relative risk of death among HD-CVC-treated patients compared with PD patients was higher in the more recent era. In contrast, era did not modify survival differences in comparisons between PD and HD-AVF/AVG comparisons. We speculate that survival differences over time between HD and PD patients in Canada reflect a more contemporary HD patient population characterized by both a higher burden of comorbidities and higher rates of incident CVC use.

The study has several limitations. The major threat to validity is selection bias introduced by nonrandom allocation of patients to both dialysis modality and incident HD vascular access. Residual confounding may remain on the basis of unmeasured differences between patients that may influence both incident vascular access and dialysis modality choice while at the same time being associated with survival. Large administrative datasets such as the one that we used are subject to limitations arising from data validity and the availability of data elements that may be germane to the research question being posed. Comorbidities captured within CORR have been recently validated[30] and are therefore likely to offer reliable information.[31] Several data elements were incomplete. We partially accounted for this by performing multiple data imputation, which demonstrated little change in either the direction or the effect size of our primary results. Changes in vascular access type were not recorded. We were therefore unable to perform as-treated analyses that accounted for: (*1*) vascular access immediately after PD technique failure; (*2*) conversion to a functional AVF or AVG among incident HD-CVC patients; and (*3*) vascular access failure among HD-AVF/AVG patients. It is possible that the conversion to an AVF or AVG in a subset of patients who initiated HD with a CVC may explain the absence of a mortality difference between the HD-CVC and PD patients after the second year of follow-up.

Notwithstanding these limitations, we have demonstrated that incident HD vascular access type at the time of dialysis initiation is an important modifier of the relationship between dialysis modality and survival among incident Canadian dialysis patients. These findings need to be confirmed among other patient populations where regional practice patterns related to HD vascular access and dialysis modality selection may vary. The adverse effects of starting

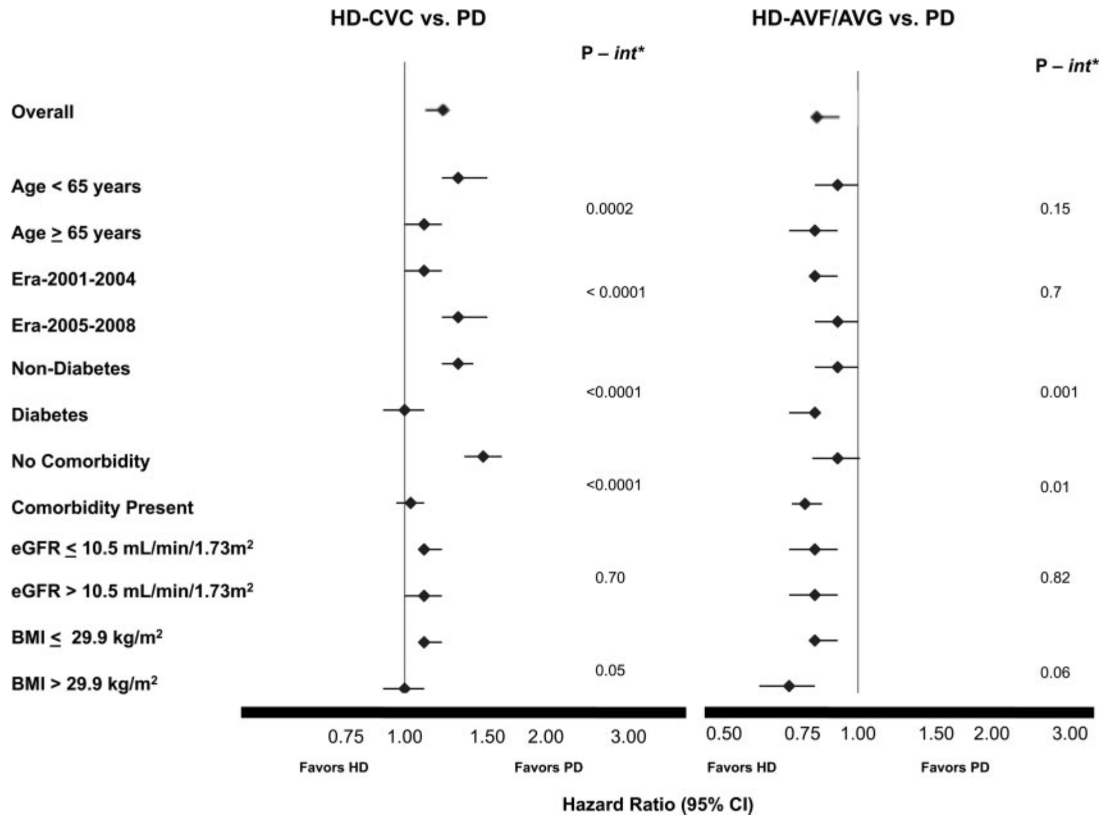

Figure 2. Hemodialysis vascular access affects the association between modality and survival in selected subgroups. **P* value for interaction (int). The models were adjusted for age, race, gender, era of dialysis initiation, ESRD comorbidity index, primary renal diagnosis, serum albumin, estimated GFR, province of treatment and late referral.

HD with a CVC may have largely driven the relative survival benefits that have been previously attributed to PD. Initiation of HD with an optimal vascular access may be associated with reduced overall mortality as compared with initiating dialysis with PD, but this observation requires confirmation via further prospective studies. In a subset of patients who would otherwise start HD with a CVC because of late referral or ineligibility for a surgical vascular access or who defer a dialysis modality choice or surgical vascular access creation, PD offers the opportunity to avoid HD initiation with a CVC. In this regard, the adverse effects of starting HD with a CVC may be largely driving the relative survival benefits associated with PD.

Table 4. Results stratified by diabetes and era of dialysis initiation

Patient Subgroup	HD-CVC *versus* PD		HD-AVF/AVG *versus* PD	
	HR (95% CI)	*P*	HR (95% CI)	*P*
Diabetes	1.0 (0.9, 1.1)	0.6	0.8 (0.7, 0.8)	<0.0001
Nondiabetes	1.3 (1.2, 1.4)	<0.0001	0.9 (0.8, 1.0)	0.04
Era 2001 to 2004	1.1 (1.0, 1.2)	0.02	0.8 (0.8, 0.9)	<0.0001
Era 2005 to 2008	1.3 (1.2, 1.5)	<0.0001	0.9 (0.8, 1.0)	0.02

The values are adjusted for age, race, gender, era of dialysis initiation, end-stage renal disease comorbidity index, primary renal diagnosis, serum albumin, estimated glomerular filtration rate, province of treatment, and late referral.

CONCISE METHODS

Study Design

This is an observational study of consecutive adult patients (age, 18 years or older at the start of chronic dialysis) who registered in the CORR and initiated their first form of dialysis between January 1, 2001 and December 31, 2008.

Data Source, Definitions, and Collection

Patients were identified from the CORR, a national registry that, during the period studied, captured the incidence, prevalence, treatment changes, and outcomes of over 99% of chronic dialysis and solid organ transplant patients in Canada.[31] The data were collected by completion of a registration form by the dialysis provider on each patient at dialysis initiation and yearly thereafter. A change of status form is completed to document patient death, transplantation, or a switch in dialysis modality. CORR data has recently been validated.[30] We restricted our analysis to patients with documented incident dialysis modality (PD *versus* HD) and incident vascular access type reported as an AVF, AVG, or CVC (any type). Only patients undergoing 3 to 5 hours of conventional HD three times weekly were included in the primary analysis. Because of the limited number of patients who initiated HD with an AVG ($n = 660$), we combined AVF or AVG into one category. All of the subtypes of PD (continuous ambulatory PD and automated PD) were included. Three cohorts of incident patients were established: PD, HD-CVC, and HD-AVF/AVG.

Baseline comorbidities were documented by the individual facilities using the CORR registration forms. Information on the presence or absence of coronary artery disease (angina, myocardial infarction, and coronary artery bypass surgery), peripheral vascular disease, hypertension, diabetes mellitus, and cerebrovascular disease were categorized as "yes," "no," and "unknown." The unknowns were combined into the "no" group. Diabetes was classified as a single variable including diabetes as a comorbidity or a cause of end-stage renal disease. Current smokers were documented as those having smoked in the last 3 months. Late referral was defined as never having been seen by a nephrologist before dialysis initiation or first seeing a nephrologist within 3 months before starting dialysis. BMI was calculated using the height and weight collected at the start of dialysis. Baseline laboratory parameters included hemoglobin, serum albumin, and serum creatinine measured as the value closest to but preceding the initial dialysis treatment. eGFR was calculated using the four-variable Modification of Diet in Renal Disease equation.[32]

Outcome

The primary outcome was mortality at 1 year from the time of first dialysis. Secondary outcomes included overall mortality during the study period and annual mortality risk within the first 5 years after dialysis initiation. Annual mortality risk was assessed using time-dependent hazard ratios within each year. Time-averaged hazard ratios from a proportional hazards model were used to assess the cumulative treatment effect from day 0 through the end of years 1 to 5, respectively. Patients were censored at kidney transplantation, loss to follow-up, or at the end of the observation period (December 31, 2008).

Statistical Analyses

Categorical variables were compared using the chi-squared test. The Kruskal-Wallis test was used to analyze differences among continuous variables. In the primary analysis, study subjects were analyzed in an intention-to-treat manner, using complete-case analysis. Prespecified interactions with the exposure of interest included age (<65 *versus* ≥ 65 years), the presence or absence of diabetes, the presence or absence of any comorbidities, BMI (≤ 29 kg/m^2 *versus* >29 kg/m^2), eGFR above and below the median value (≤ 10.5 ml/min per 1.73 m^2 *versus* >10.5 ml/min per 1.73 m^2), and era of dialysis initiation (2001 to 2004 *versus* 2005 to 2008).

Proportional and nonproportional piecewise exponential survival models were used to compare mortality between PD, HD-CVC, and HD-AVF/AVG patients within sequential 12-month intervals during the first 60 months. Average or time-independent hazard ratios of death for PD compared with HD-CVC and HD-AVF/AVG patients were estimated using a proportional hazards model, whereas time-dependent relative risks were estimated using a nonproportional hazards model. Hazard ratios and corresponding 95% CI were adjusted for case-mix differences in the cohorts including: age, gender, race, cause of ESRD, weighting of comorbidities (diabetes mellitus, coronary artery disease, peripheral vascular disease, malignancy, lung disease, and pulmonary edema) on the basis of a validated ESRD comorbidity index,[33] body mass index, eGFR, serum albumin, late referral, province of treatment, and era of dialysis initiation.

Several additional analyses were performed to test the robustness of our findings. First, to account for the effect of missing data on our results, an analysis was performed assigning values for missing data via multiple data imputation using the predictive mean matching method. This strategy has been used successfully in previous studies to avoid exclusion of patients with missing values.[34] An additional analysis excluded deaths that occurred after patients were established on a new dialysis modality by censoring patients at 60 days after a change in dialysis modality. To limit the potential for selection bias, an analysis was performed excluding patients who died within 90 days of dialysis initiation. In order to minimize confounding caused by the strong association between late referral and CVC use, a separate analysis was also performed excluding those patients who were referred late.

In addition to traditional multivariable adjustment, outcomes were also compared using a marginal structural model with inverse probability of treatment and censoring weighting. This technique[25,35] allowed us to adjust for measured covariates in a single summary propensity score and simultaneously adjust for the effect of informative censoring caused by potential differences in the rates of kidney transplantation between PD patients compared with HD-AVF/AVG and HD-CVC patients. In the first step, propensity scores (PS) were determined as an estimate of each study subject's probability of initial PD treatment. Because our exposure of interest was not binary (*i.e.* three levels: HD-CVC *versus* HD-AVF/AVG *versus* PD]), we used two separate multivariable logistic regression models (PD *versus* HD-CVC and PD *versus* HD-AVF/AVG) using all available covariates to calculate our PS. The areas under receiver operating characteristic curves were evaluated to test the discriminatory capacity of each model. In the second step, we determined stabilized censoring weights by estimating the probability of remaining transplant free for each individual in successive 1-year time intervals. Each observation was then weighted both by the inverse probability of treatment with PD (1/PS) for each individual and by the stabilized censoring weights. All of the analyses were performed using SAS version 9.1.3 (Cary, NC).

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DISCLOSURES

J.P. has received speaking honoraria from Amgen Canada and Baxter Healthcare Canada and holds an unrestricted educational fellowship from Baxter Healthcare Canada. P.M. has received speaking honoraria from Biovail, Boehringer Ingelheim, Bristol Myers Squibb, GlaxoSmithKline, Merk, Novartis, and Sanofi-Aventis and has served on advisory boards for Amgen Canada, Baxter Healthcare Canada, Biovail, Boehringer Ingelheim, Bristol Myers Squibb, Fresenius, Merk Novartis, Ortho-Biotech, Sanofi-Aventis, and Schering. R.W. has served on advisory boards for Amgen, Gilead, and Fresenius Kabi and receives an unrestricted educational fellowship from Amgen. J.B. has served on advisory boards for Amgen, Takeda, and Hospira and has received speaking honoraria from Baxter Healthcare Canada, Amgen Canada, and Genzyme Canada. E.V. has served as a consultant for Baxter Healthcare. V.J. has served on advisory boards for Amgen Canada and has received speaking honoraria from Baxter Healthcare Canada. L.M. has served on advisory boards for Amgen Canada and Merck Frosst.

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Early Fistula Failure: Back to Basics

Related Article, p. 782

Maintenance of a well-functioning vascular access for hemodialysis is a major challenge in caring for patients with end-stage renal disease (ESRD). Vascular access dysfunction is one of the most important sources of morbidity and contributes substantially to the cost of ESRD care.[1] Vascular access practices have evolved over the past 3 decades, and these changes have been accompanied by an increased understanding of the processes underlying vascular access failure, particularly failure of synthetic arteriovenous (AV) grafts. We now recognize that stenosis, the cause of most episodes of graft thrombosis, is the result of aggressive neointimal hyperplasia. In this issue of *AJKD*, Roy-Chaudhury and colleagues use careful histologic and morphometric analysis to demonstrate that the same lesion may underlie maturation failure of native AV fistulas.[2]

During the 1980s and 1990s, use of the AV graft became widespread, in large part because of the ability to place grafts in the vast majority of patients regardless of vessel characteristics. An additional advantage of grafts is that, in contrast to native fistulas, they do not require a prolonged period of maturation and thus can usually be used within 1 to 2 weeks after placement. However, as use of grafts increased it became apparent that their advantages are countered by a high rate of thrombosis requiring frequent interventions to restore patency, and an average overall lifespan of only 2 to 3 years.[3] Recognition that stenosis at or near the graft-vein anastomosis is present in most thrombosed grafts led to the incorporation of percutaneous angioplasty into approaches for restoring graft patency, and, shortly thereafter, to prophylactic angioplasty of stenoses that are identified prior to thrombosis.[4-7] Unfortunately, beneficial effects of angioplasty are short-lived, and stenosis usually recurs within several months or sooner.[4,8,9]

Neointimal hyperplasia in stenotic AV grafts has been characterized histologically in previous work by Roy-Chaudhury's group and others.[10-12] The lesion contains smooth muscle cells, myofibroblasts, fibroblasts, and extracellular matrix. Macrophages can be present along the luminal surface of the graft, and microvessel formation is apparent in the intima and adventitia. Multiple factors are thought to contribute to neointimal hyperplasia of AV grafts; these include hemodynamic factors involving alterations in wall shear stress and venous hypertension, differences in compliance between the graft and the downstream vein, inflammation induced by the graft itself, activation of platelets by frequent needle cannulation, and the general vasculopathic state associated with kidney failure. Although there are no pharmacologic or biologic interventions that are clearly effective in preventing graft thrombosis, current investigational approaches are focused on systemic or local administration of antiproliferative agents directed at neointimal hyperplasia.[13-17]

The morbidity and cost associated with complications of synthetic grafts have led to recommendations in clinical practice guidelines for preferential creation of native fistulas, and have triggered major initiatives, such as the Fistula First Program of the Centers for Medicare and Medicaid Services, promoting the use of native fistulas.[18,19] Although the development of neointimal hyperplasia and stenosis is not unique to grafts, thrombosis rates and the need for interventions, as well as the risk of infection, are lower for fistulas than for grafts. Despite widespread agreement that the native fistula is the best type of vascular access, and a substantial increase during the past few years in the proportion of patients for whom fistula creation is attempted, fewer than half of the patients undergoing hemodialysis in the United States receive dialysis with a fistula.[20] Maturation failure, the subject of Dr Roy-Chaudhury's investigation, is probably the most important reason for the low prevalence of native fistulas.

In order to be used for dialysis, a newly created fistula must mature; that is, the artery and vein must undergo dilation and remodeling to

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accommodate the markedly increased blood flow that results from creating the AV anastomosis. Mechanisms underlying fistula maturation failure are not well understood.[21] Anatomic factors such as the diameters of the feeding artery and draining vein are thought to be important, and it is now considered standard practice to perform preoperative vascular evaluation either with ultrasound or angiography to identify vessels that appear anatomically suitable for fistula creation. However, there is clearly more to maturation than sufficient vessel diameter. For both the artery and vein a minimal diameter appears to be necessary for successful creation of a fistula, but above this threshold, no clear relationship exists between vessel size and fistula outcome.[22] Nonanatomic factors that are likely to contribute to maturation failure include the underlying vascular pathology and impaired endothelial function associated with chronic kidney disease, vein trauma from surgical manipulation, and the hemodynamic stresses (ie, altered shear stress and venous hypertension) that result from creating an AV anastomosis.[21] Importantly, several of these functional factors are potentially modifiable.

Roy-Chaudhury and colleagues examined tissue specimens obtained at the time of surgical revision from venous segments of 4 fistulas that had failed to mature. Three of the fistulas were patent and 1 had thrombosed. Neointimal hyperplasia together with less prominent medial hypertrophy was present in all 4 fistulas. The degree of stenosis was 80% or greater in all of the fistulas, and morphometric measurements revealed an eccentric geometry of the hyperplastic lesion. By immunohistochemistry, the predominant cell type contained both α-smooth muscle actin and vimentin but not desmin, marking it as a myofibroblast; contractile smooth muscle cells were also present but to a lesser degree.

This study is important because it provides the first demonstration of neointimal hyperplasia in fistulas with maturation failure. The histologic findings reported by Roy-Chaudhury et al complement recent observations by others that stenosis is a frequent angiographic finding in nonmaturing fistulas.[23,24] However, unlike many of the fistulas in angiography series, the fistulas examined in the present study had never been cannulated for dialysis. Thus, we can conclude that processes involved in the development of

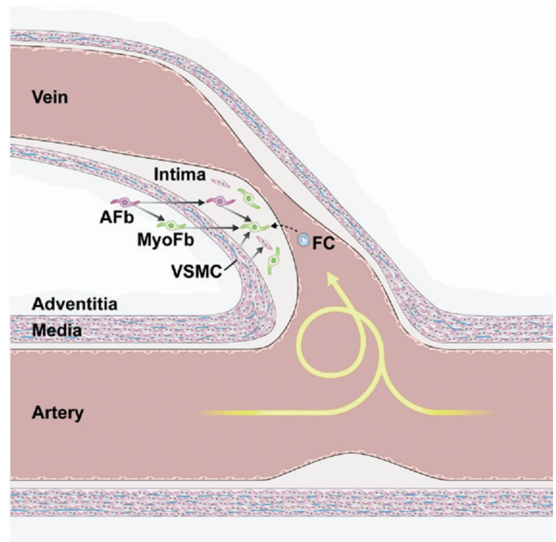

Figure 1. Eccentric venous neointimal hyperplasia at the juxta-anastomotic site of an arteriovenous (AV) fistula may occur at regions of low or oscillating wall shear stress and lead to failed fistula maturation. These regions of altered wall shear stress typically occur at the "heel" of the AV anastomosis as well as at the arterial wall opposite the opening of the fistula. The thickened neointima is composed of a variety of cells, including myofibroblasts (MyoFb), vascular smooth muscle cells (VSMC), endothelial cells involved in neovascularization, and inflammatory cells (the latter two are not shown), as well as extracellular matrix. Denuded areas of endothelium may also be seen. Myofibroblasts, a principal component of the neointima, are specialized synthetic and contractile cells involved in wound healing. Ultrastructurally, these cells contain α-smooth muscle actin coupled to extracellular fibronectin by a fibronexus junction that helps to provide support for injured tissue while the tissue is remodeled and new matrix formed. Myofibroblasts may originate from several sources including differentiation and migration of adventitial fibroblasts (AFb), dedifferentiation and migration of VSMC within the media, transdifferentiation from endothelial cells or possibly infiltration from circulating bone marrow-derived fibrocytes (FC). Regulating myofibroblast formation, proliferation, and migration may be key for controlling the eccentric neointimal hyperplasia that leads to fistula failure.

neointimal hyperplasia are independent of needle insertion into the vein, compression of the vein to promote coagulation after needle removal, or hemodynamic alterations induced by the dialysis machine blood pump. The observation that the lesions are eccentric is consistent with a role of hemodynamic stresses in the development of neointimal hyperplasia since those stresses should be distributed in a nonuniform manner along the circumference of the vein. The cellular phenotyping suggests that the composition of neointimal hyperplasia is similar whether it occurs in venous segments of nonmaturing fistulas or in venous segments downstream of synthetic grafts. Moreover, the abundant presence of myofibroblasts within the neointima is consistent with (but does not prove) a role for the adventitia as a source of cells for neointimal proliferation (Fig 1). This suggests that new therapies using periadventitial delivery systems may hold promise in preventing fistula maturation failure.

The study has limitations that should be noted. The small sample size prevents conclusions about the frequency with which neointimal hyperplasia is present in fistulas with maturation failure. Additionally, one cannot exclude the possibility that stenoses were present in the veins before fistula creation. Although the degree of stenosis in each fistula appeared substantial by histologic examination, the hemodynamic significance of the lesion was not evaluated before the samples were obtained. Moreover, the investigators did not provide information about distance between the AV anastomosis and stenosis, or the orientation of the eccentric lesions with respect to the feeding artery. Such information might have enabled some evaluation of existing hypotheses about rheologic and hemodynamic influences on development of neointimal hyperplasia. Finally, the identification of myofibroblasts as the predominant cell type could have been further confirmed by ultrastructural studies looking for typical features such as the specialized focal adhesion complexes known as the fibronexus.[25,26]

As is the case with most new observations, the findings of Roy-Chaudhury et al raise many questions. Most importantly, what are the triggers for such a marked hyperplastic response early after fistula creation? How important is preexisting vascular disease present in many individuals with chronic kidney disease? How important is the surgical trauma associated with mobilizing the vein or creating the anastomosis? How important are the relative orientations of the artery and vein making up the fistula? What is the source of the cells that populate the neointima and what would happen to the fistula if their migration, proliferation, or both were inhibited? These are not easy questions to answer, and it is likely that multiple factors interact to set the stage for neointimal hyperplasia. Roy-Chaudhury's group clearly recognizes the need for investigating the basic biology and physiology of fistula maturation and maturation failure. Such efforts are crucial for identifying interventions to improve vascular access outcomes.

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Decreased Cumulative Access Survival in Arteriovenous Fistulas Requiring Interventions to Promote Maturation

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Summary

Background and objectives New arteriovenous fistulas (AVF) are frequently unsuitable for hemodialysis because of AVF nonmaturation. Aggressive endovascular or surgical interventions are often undertaken to salvage nonmaturing AVFs. The effect of early interventions to promote AVF maturation on subsequent long-term AVF outcomes is unknown.

Design, setting, participants, & measurements We evaluated 173 hemodialysis patients from two academic centers who received a new AVF. Of these, 96 (56%) required no further intervention, 54 (31%) required one intervention, and 23 (13%) required two or more interventions to achieve suitability for dialysis. We calculated AVF survival and frequency of postmaturation interventions in each group.

Results Cumulative AVF survival (access cannulation to permanent failure) in patients with two or more *versus* one *versus* zero interventions before maturation was 68% *versus* 78% *versus* 92% at 1 year, 57% *versus* 71% *versus* 85% at 2 years, and 42% *versus* 57% *versus* 75% at 3 years. Using Cox regression analysis with interventions before maturation, age, sex, race, diabetes, peripheral vascular disease, access site, and obesity in the model, intervention before maturation (two or more) was the only factor associated with cumulative AVF survival. The number of interventions required to maintain patency after maturation was 3.51 ± 2.20 *versus* 1.37 ± 0.31 *versus* 0.76 ± 0.10 per year in patients with two or more *versus* one *versus* zero interventions before maturation.

Conclusions Compared with AVF that mature without interventions, AVF that require interventions have decreased cumulative survival and require more interventions to maintain their patency for hemodialysis.

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Introduction

Vascular access is truly the "lifeline" for the hemodialysis patient (1–4). Approximately one billion dollars are spent annually in the United States treating complications from vascular access dysfunction (4–7). The National Kidney Foundation Kidney Disease Quality Initiative guidelines for vascular access (8) and the Fistula First Breakthrough Initiative (9–11) have promoted the arteriovenous fistula (AVF) as the preferred vascular access of choice because of better long-term survival and fewer complications compared with arteriovenous grafts and tunneled catheters, if the AVF matures for dialysis (12,13). AVFs that fail to mature, because of either early thrombosis or failure to obtain suitability for dialysis use (4,14,15), are the major obstacle to increasing the proportion of dialysis patients with AVFs in the United States. Consequently, we have seen a major effort to aggressively treat and salvage nonfunctioning AVFs to improve AVF maturation outcomes (16–22). Although these interventions are beneficial in promoting AVF maturation and eventual suitability for dialysis, the biologic changes resulting from the interventions may have a deleterious effect on long-term AVF outcomes (23).

To evaluate this question, we compared the long-term outcomes of AVFs requiring interventions to achieve maturation with those obtained in a control group of AVFs not requiring such interventions. The primary clinical outcomes studied were (*1*) cumulative access survival (time from access cannulation to failure) and (*2*) the frequency of interventions to maintain access patency after first cannulation. As a secondary analysis, we compared AVF outcomes for endovascular *versus* surgical interventions in nonmaturing AVFs.

Materials and Methods

Study Population

Prospective access databases from the University of Cincinnati (UC) and University of Alabama at Birmingham (UAB) were queried to identify prevalent hemodialysis patients requiring a new AVF placement from 2005 to 2007. All of the patients were under the care of university nephrologists at their respective medical centers. At UC all of the vascular accesses are placed by one dedicated vascular access surgeon, and subsequent vascular access revisions or interventions are performed by the same vascular access surgeon or by interventional nephrologists at a dedicated outpatient vascular access center. At UAB, initial vascular access and subsequent vascular access placements are performed by a team of four transplant surgeons and interventional radiologists or nephrologists. The AVF prevalence at UC and UAB was approximately 35 and 40%, respectively, during 2007, in a largely inner-city population (comparable with the overall renal network prevalence for these regions at the time) (9).

Vascular Access Management

At UC, either preoperative ultrasound mapping or angiography is performed to assist the surgeon for vascular access surgery. When preoperative ultrasound mapping was performed, a minimum threshold of 2.5 mm for the vein and 2.0 mm for the artery was used to determine creation of an AVF (8). The patients are evaluated by the surgeon at 2- and 6-week clinic visits after creation of an AVF. If there was an abnormality detected on physical exam by the surgeon, the patient either had salvage procedures performed by the surgeon or was referred to interventional nephrology. These procedures could include endovascular (angioplasty) or surgical revisions to the AVF. AVFs are typically allowed to mature for 3 to 6 months before initial cannulation, and permission for initial AVF cannulation is given by the vascular access surgeon.

At UAB all of the patients receive preoperative ultrasound mapping before new vascular access evaluation with creation of an AVF requiring a minimum vein diameter of 2.5 mm and artery diameter of 2.0 mm (12,24,25). The patients were evaluated for 1 to 2 weeks after AVF placement by the surgeons and assessed clinically for maturation by dialysis nurses and nephrologists. If AVFs were felt to be unsuitable for cannulation or not maturating adequately, a postoperative ultrasound was ordered (25). The ultrasound was used to screen for remediable causes of AVF immaturity and was followed by specific surgical or endovascular salvage procedures (25). AVFs were typically cannulated at 8 to 12 weeks. Radiocephalic, brachicephalic, and basilic vein transpositions AVFs were the three types of fistulas created in our study population.

Data Collection and Analyses

Information related to access history, surgeries, procedures, and outcomes were collected from the access databases from both centers. The databases included information about vascular access placements and subsequent surgical or endovascular procedures.

From the respective access databases, we identified a comprehensive list of AVFs placed in prevalent hemodialysis patients over a 3-year period. We identified 221 patients (128 patients at UC and 93 patients at UAB) who had new AVFs placed and were on hemodialysis during this study period. After excluding primary failures from both centers, a total of 173 AVFs remained for analysis (108 from UC and 65 from UAB). The primary failure rate was 21% in the initial study population. Cumulative access survival was calculated from the time of access cannulation to permanent failure. Access cannulation was deemed successful when the patient's tunneled catheter was removed. All of the patients were dialyzing with tunneled catheters before AVF surgery. The clinical outcome of each AVF was determined from the databases.

Demographic and clinical information was collected using electronic medical records on each patient including sex, race, presence or absence of diabetes, peripheral vascular disease (PVD), BMI ≥30, and age ≥65. Institutional review board approval from both centers was obtained before initiation of this study.

Statistical Analyses

The data were reported as percentages (means ± SE) as appropriate. The clinical characteristics were analyzed using contingency table analysis, ANOVA, and t tests. A P value <0.05 was considered statistically significant. Cumulative access survival was plotted using Kaplan-Meier survival techniques with patients censored for death, kidney transplant, or end of follow-up, and the log-rank test was used to compare the survival between patient groups. A P value <0.05 was considered to be statistically significant. Univariable and multivariable Cox proportional hazard models were performed, and hazard ratios (HR) and their associated 95% confidence intervals (CIs) were computed. For the analysis comparing cumulative survival between angioplasty and surgical interventions, those patients who had both surgical and angioplasty (six in total) procedures to promote AVF maturation were placed in the angioplasty group for the survival analysis. All of the statistical analyses were performed using the JMP® 8.0 (Cary, NC) statistical software package.

Results

Patient Population

The study population was comprised of 173 patients. 74% of the patients were men, 75% were black, 50% had diabetes, and 20% had PVD. 68% of patients had upper arm AVFs placed. Only 28% of patients were ≥65 years of age, and 34% had BMI ≥30. Table 1 summarizes the demographic and clinical characteristics of the patient population by number of interventions before maturation. Diabetes, PVD, BMI ≥30, and female sex were associated with more interventions before AVF maturation (Table 1). Age ≥65, race, or access site did not differ by number of interventions before maturation (Table 1). The proportion of interventions was similar for groups with zero, one, and two or more interventions in both first and subsequent AVFs (Table 1). The median duration of dialysis treatment (dialysis vintage) was 251 days in the group with one intervention and 167 days in the group with two or more interventions.

Cumulative Access Survival

Cumulative survival, defined from the time of access cannulation to permanent failure, was shorter in patients

Table 1. Baseline demographics by number of interventions to promote AVF maturation

	Zero Interventions	One Intervention	Two or More Interventions	*P*
Patients (*n* = 173)	96 (55.5%)	54 (31.2%)	23 (13.3%)	
Sex				0.0107
female	17 (17.7%)	16 (29.6%)	11 (47.8%)	
male	79 (82.3%)	38 (70.4%)	12 (52.2%)	
Race				0.2664
black	71 (74.0%)	38 (70.4%)	20 (87.0%)	
white	25 (26.0%)	16 (29.6%)	3 (13.0%)	
Diabetes				0.0422
yes	41 (42.7%)	30 (55.6%)	16 (69.6%)	
no	55 (57.3%)	24 (44.4%)	7 (30.4%)	
PVD				0.0415
yes	18 (18.8%)	7 (13.0%)	9 (39.1%)	
no	78 (81.2%)	47 (87.0%)	14 (60.9%)	
Access site				0.7710
upper arm	66 (68.8%)	38 (70.4%)	14 (60.9%)	
forearm	30 (31.3%)	16 (29.6%)	9 (39.1%)	
Age ≥65				0.4021
yes	24 (25%)	16 (28.3%)	9 (39.1%)	
no	72 (75%)	38 (71.7%)	14 (60.9%)	
BMI ≥30				0.0491
yes	28 (29.2%)	17 (31.5%)	13 (56.5%)	
no	68 (70.2%)	37 (68.5%)	10 (43.5%)	
First *versus* subsequent fistula				0.1727
first	61 (63.5%)	38 (70.4%)	19 (82.6%)	
subsequent	35 (36.5%)	16 (29.6%)	4 (17.4%)	

who had two or more interventions before AVF maturation compared with those with zero interventions (HR, 2.07; 95% CI, 1.21 to 2.94; *P* = 0.0001) (Figure 1). When comparing cumulative survival among patients with one intervention to those with zero interventions before maturation, there was a trend toward worse cumulative survival in patients receiving one intervention before maturation (HR, 1.91; 05% CI, 0.944 to 3.81; *P* = 0.07) (Figure 1). Cumulative survival in patients with two or more *versus* one *versus* zero interventions before maturation was 68% *versus* 78% *versus* 92% at 1 year, 57% *versus* 71% *versus* 85% at 2 years, and 42% *versus* 57% *versus* 75% at 3 years (Figure 1). The median duration of

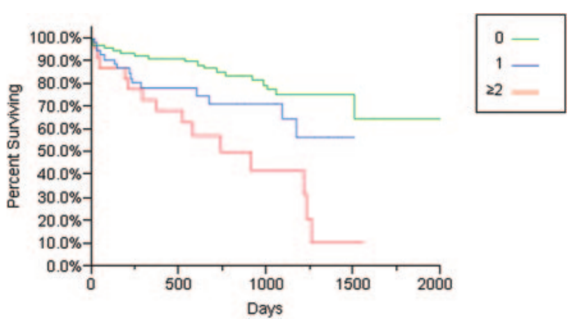

Figure 1. | Cumulative access survival (time from fistula cannulation until failure) by number of interventions before manipulation (zero, one, or two or more). By log-rank test, *P* = 0.0001 for all three groups, *P* = 0.0620 for zero *versus* one intervention, and *P* < 0.0001 for zero *versus* two or more interventions.

follow-up was 672 days. There was no difference in cumulative survival by center.

After performing a Cox regression analysis adjusting for interventions before maturation, sex, race, diabetes, peripheral vascular disease, access site, age ≥65, and BMI ≥30, interventions before maturation (two or more) was the only factor associated with cumulative access failure (HR, 1.67; 95% CI, 1.01 to 2.70; *P* = 0.02; *P* = 0.004 for the overall model).

Number of Interventions to Maintain Access Patency after Dialysis Use

Patients who had two or more interventions before maturation required a significantly higher mean number of interventions/years after cannulation to maintain patency, as compared with those requiring one intervention (3.51 *versus* 1.37; *P* = 0.04) and no interventions before maturation (3.51 *versus* 0.755; *P* = 0.004) (Table 2). There was no difference in the number of interventions after AVF use when comparing those AVFs that had zero or one intervention before maturation (0.755 *versus* 1.37; *P* = 0.37) (Table 2).

Surgical versus Endovascular Intervention to Promote AVF Maturation

Among the 77 patients who received interventions to promote AVF maturation, 55 received endovascular interventions, 16 received surgical revisions, and six patients received both surgical and endovascular interventions. The six patients who required both surgical and endovascular interventions were placed in the endovas-

Table 2. Number of interventions after cannulation by number of interventions to promote AVF maturation

	Zero Interventions	One Intervention	Two or More Interventions	*P*
Number of patients	96	54	23	
Mean number of interventions per year after AVF cannulation (± SE of mean)	0.755 ± 0.0971	1.37 ± 0.308	3.51 ± 2.20[a]	0.0152

When comparing: zero *versus* one intervention, $P = 0.37$; 0 *versus* two or more interventions, $P = 0.004$; one *versus* two or more interventions, $P = 0.04$.
[a]Indicates which group differs from others.

cular group for the purposes of the analysis. There was no difference in cumulative survival when comparing patients who had endovascular *versus* surgery to promote AVF maturation ($P = 0.8298$) (Figure 2).

Discussion

In an effort to improve vascular access outcomes, both the Fistula First Initiative (9–11) and National Kidney Foundation Kidney Disease Quality Initiative guidelines (8) have promoted increased AVF use in hemodialysis patients. In one respect, these initiatives have been hugely successful, resulting in a progressive increase in AVF use over the past few years, which currently exceeds 50% in the United States hemodialysis population (26). Unfortunately, there has been a concurrent increase in AVFs that fail to mature for dialysis (14,24,27–29), which was as high as 60% in a recent large, multi-center, randomized clinical trial (14). Although there is not a standard definition for AVF nonmaturation, the recently published Dialysis Access Consortium study considered nonmaturation as AVFs not cannulated by two needles with optimal dialysis blood flow within 4 to 5 months after AVF creation (14). The most common etiology for AVF nonmaturation is a lack of vein dilation or aggressive neointimal hyperplasia (4). Nonmaturing AVFs frequently have identifiable anatomic abnormalities (most commonly peri-anastomotic stenosis), which can be recognized by physical examination (evaluation of pulse, thrill, and augmentation) (30), postoperative ultrasound

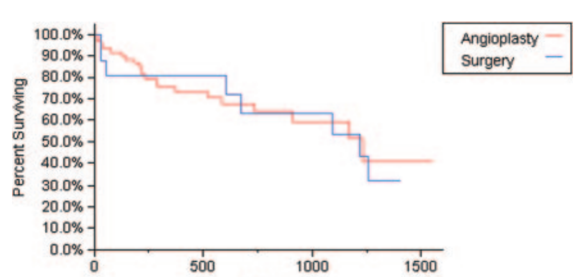

Figure 2. | Cumulative access survival (time from fistule cannulation until access failure) comparing angioplasties *versus* surgery before AVF use. $P = 0.8298$ by log-rank test. Patients who received both angioplasty and surgery to promote AVF maturation were placed into the angioplasty group for analysis.

(31,32), or angiogram (19,20,33,34). Targeted percutaneous or surgical interventions to repair these abnormalities are often successful in salvaging nonmaturing AVFs to make them suitable for dialysis (19–21,35–37).

The few published studies evaluating long term outcomes in AVFs requiring interventions to promote maturation reported cumulative survival rates of 68 to 82% at 1 year (19,20,35,36) and 62% at 2 years (35), similar to the rates observed in our investigation. Unfortunately, previous studies did not provide a comparison with a concurrent control group of AVFs not requiring such interventions. The current study evaluated the association between the number of interventions required to promote maturation (zero, one, or two or more) and cumulative fistula survival and observed significantly inferior long-term AVF survival in patients requiring two or more interventions to achieve AVF maturation, as compared with those requiring zero or one interventions. Moreover, AVFs requiring two or more interventions to promote maturation also required more interventions to maintain long-term patency after dialysis use.

Why might interventions to promote fistula maturation be associated with shortened AVF survival and a greater need for future AVF interventions? One possible explanation is that these interventions, particularly endovascular procedures, induce endothelial injury that leads to aggressive neointimal hyperplasia, rapid restenosis, and access failure. In support of this hypothesis, Chang *et al.* (23) observed that restenotic lesions in AVF after angioplasty had greater cellular proliferation activity within the intima and media, as compared with AVFs with primary stenosis. Likewise, in cardiovascular models of vascular injury after coronary interventions, a sequence of inflammation, granulation, extracellular matrix remodeling, smooth muscle cell proliferation, and migration occurs, leading to neointimal thickening and restenosis, as well as the inability of the vessels to undergo dilation after injury (38–41). An alternative hypothesis is that AVFs that require interventions to achieve maturation are simply created from "poor quality vessels," which in turn leads to shortened cumulative AVF survival.

The type of vascular intervention may affect long-term fistula survival. Some have speculated that the injury resulting from angioplasty is greater than that obtained with surgical revision. Previous retrospective studies comparing surgical revision and angioplasty of previously functional forearm AVFs that had developed stenosis provided conflicting results, with one study showing improved postintervention AVF patency in the surgery group *versus* the angioplasty group (42) and another demonstrating no difference in postintervention patency between the two types of intervention (43). Unlike this study, the interventions in these prior studies were used to treat stenosis in functional forearm AVF, rather than to salvage immature AVFs before dialysis use. However, our small sample size precluded definitive conclusions about the relative effect of surgical *versus* endovascular intervention to promote AVF maturation. We continue to believe, however, that a randomized study examining this issue is desperately needed.

At present, there are no effective pharmacologic treatments to promote AVF maturation, largely due to our limited understanding of the pathophysiology of AVF maturation (1–3,17,44,45). In this regard, a large randomized, double-blinded clinical trial found that clopidogrel significantly reduced early AVF thrombosis but failed to decrease AVF nonmaturation (14). Until effective pharmacologic interventions are established, the mainstay approach to salvaging nonmaturing AVF remains the performance of endovascular or surgical interventions. Whereas such interventions are clearly beneficial in converting immature AVFs to ones that are suitable for dialysis, the use of such interventions is associated with shortened cumulative AVF survival and the need for frequent interventions to maintain their patency.

Finally, we would like to emphasize that we are not arguing against the use of endovascular or surgical intervention for enhancing AVF maturation. In particular, we are completely cognizant of the fact that a lack of intervention would likely have resulted in primary AVF failure in the patients in the intervention group (46). However, we do want to bring to the attention of the dialysis access community the fact that multiple interventions may have at least some negative effect in the long term, both on survival and on the number of interventions required to maintain patency. The latter is likely to significantly influence overall cost (which could become an important determinant of practice patterns in the context of a possible future bundling of dialysis access within overall dialysis care).

This study has some limitations. First, it was a retrospective study. However, both participating centers used similar prospective access databases with all procedures performed at a single hospital or outpatient interventional nephrology center. Thus, we have a high degree of confidence that the access events captured were accurate and comprehensive. Second, due to the retrospective study design, we cannot determine whether the shortened cumulative AVF survival was a consequence of the interventions performed to achieve maturation or whether the need for two or more interventions to achieve AVF maturation was simply a marker for “poor vessels.” Third, we included in our analysis only those AVFs that successfully matured for dialysis. However, our intention was to specifically evaluate access survival after successful cannulation for dialysis, because the major advantages of AVFs over arteriovenous grafts are their longer cumulative survival and lower frequency of interventions, once primary failures are excluded (12,47). Finally, our study evaluated only prevalent dialysis patients; therefore, our results may not be applicable to an incident population. A major strength of our study is that it is multi-center, from two academic centers with large dialysis patient populations. Thus, our results are likely to be broadly applicable to other dialysis centers.

Conclusions

Our results suggest that repeated interventions to promote AVF maturation are associated with shorter long-term AVF survival and an increase in interventions to maintain access patency after successful dialysis use. Furthermore, our results (*1*) emphasize the importance for further research evaluating the mechanisms of injury associated with interventions to promote maturation and (*2*) underscore the need for development of novel pharmacologic therapies to enhance cumulative AVF survival in patients whose AVFs require interventions to achieve maturation and decrease the number of interventions to maintain access patency. Thus, we hope that in the future it may be possible to combine novel anti-stenotic therapies and devices with surgical or endovascular interventions to enhance AVF maturation. Unfortunately, we do not have access to such interventions at present, hence the need to quantify the effect of repeated endovascular and surgical interventions on AVF survival.

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Disclosures

Dr. Lee is a consultant for Proteon Therapeutics. Dr. Roy-Chaudhury is on the advisory board/consultant for Pervasis Therapeutics, Inc., Proteon Therapeutics, WL Gore, Bioconnect Systems, Philometron, and NanoVasc and receives research support from BioConnect Systems and WL Gore. Dr. Allon is a consultant for CorMedix. These funding sources had no involvement in the design or execution of this study.

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