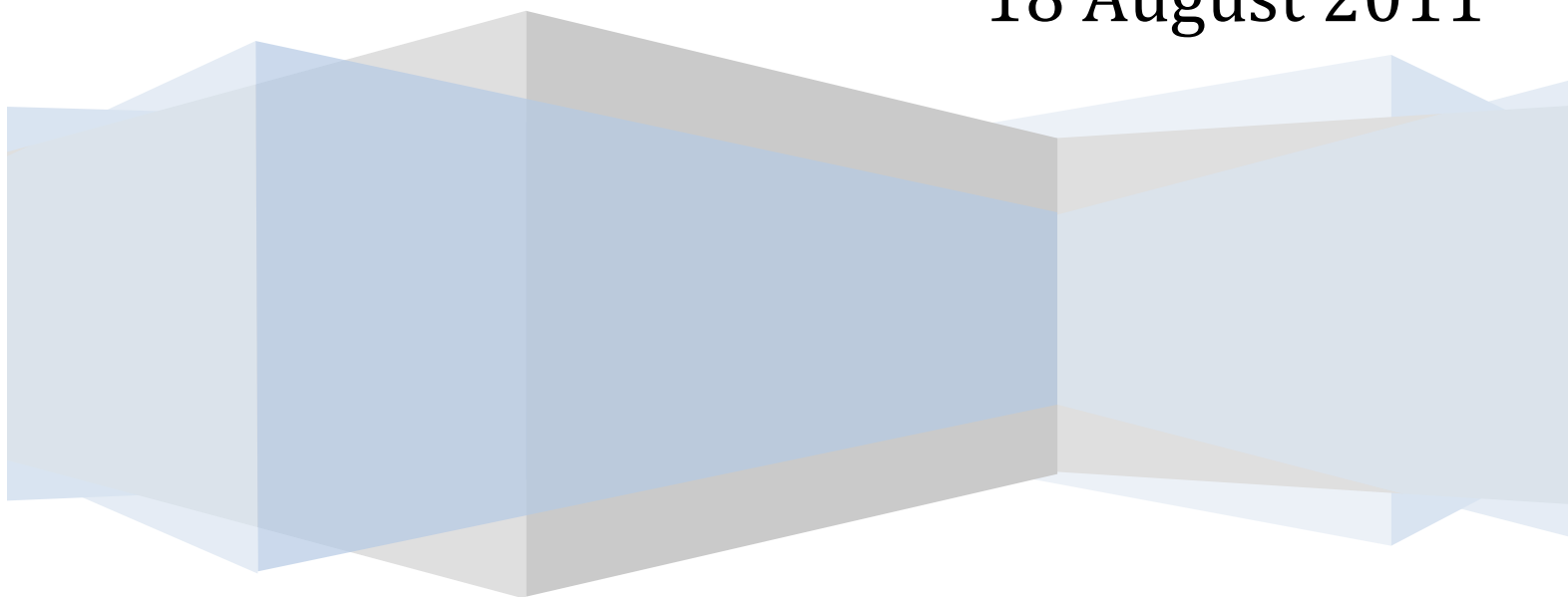


Report of the CSN Vascular Access Working Group (VAWG): Appendices

18 August 2011



Appendix 1:

Mini – Review of CSN 2006 Vascular Access Guidelines

The purpose of the mini-review was to address, 5 years later, the current relevance of the evidence supporting the 2006 guideline recommendations. We have approached this by dividing this into 4 categories;

1. Summary of the Guidelines
2. Quality of Evidence of the Guidelines
3. Acceptance of the Guidelines
4. Future Direction

1. Summary of the Guidelines

The vascular access guidelines were published in 2006, and were developed on the premise that use of an AVF for vascular access is superior to CVCs use, as they are associated with lower morbidity and mortality. The guidelines can be categorized into 3 areas:

- (i) Vascular Access Planning & Placement
- (ii) Vascular Access Monitoring & Surveillance
- (iii) Management of Vascular Access Complications

In keeping with the mandate of the CSN VAWG to encourage more functional AVF use and reduce inappropriate CVC use, our focus will be on (i) and (ii) above.

(i) Vascular Access Planning & Placement

The published guidelines outline the importance of preparation and planning during the care of chronic kidney disease (CKD) patients in anticipation of their eventual need for renal replacement therapy. The recommendations can be summarized as follows:

- [[Establishment of a dedicated, multidisciplinary vascular access team. It is expected that a multidisciplinary approach should ultimately lead to improved success in timely successful AVF creation
- [[Placement and adequate maturation of an AVF before commencing hemodialysis requires
- [[Timely patient education and counseling
- [[Clinical examination of both arms
- [[Non-invasive evaluation of vessels
- [[Surgical evaluation
- [[AVF creation several months before its expected use

Preservation of arms suitable for AVF/AVG once the eGFR is < 30 ml/min. This is based on the assumption that these patients may go on to require renal replacement therapy. Thus, upper extremity and neck vessels should be intact for eventual creation of an AVF.

The preferred form of vascular access is the AVF, followed by an AVG, and least of all the CVC. The preferred sites for placing the AVF should be the distal extremity, preserving more proximal sites if the distal AVF does not mature or later fail. The preferred sites (in order of preference) are the wrist (radiocephalic) and the elbow (brachiocephalic). If it is not possible to establish either of these types of fistula, access may be established using either a transposed brachial-basilic vein fistula or an AV graft of synthetic material (e.g., polytetrafluoroethylene [PTFE]). The AVF should be created when a patient has progressive renal decline and an eGFR 15-20 ml/min. Early referral and fistula creation will likely result in higher number of incident patients commencing hemodialysis with a functioning fistula.

(ii) Vascular Access Monitoring & Surveillance

These guidelines focus on the importance of maintaining a successfully created AVF. The recommendations are built on the premise that vascular access monitoring and surveillance will detect early problems of hemodynamic significance in the AVF/AVG that may subsequently lead to access failure. If these problems are detected in a timely manner, then intervention (i.e. angioplasty and/or thrombectomy) can prevent loss of the access. The surveillance recommendations can be summarized as follows:

- ⌈ Access blood flows should be measured bimonthly in an AVF or monthly in an AVG
- ⌈ Alternatively, venous pressures can be used to monitor the function of an AVG
- ⌈ Angiography should be performed if access flow decreases > 20%
- ⌈ Angiography should be performed if access flow decreases < 500 ml/min in an AVF and < 650 ml/min in an AVG

The CSN VAWG is aware that there is new evidence in the area of vascular access monitoring and surveillance, and recommends that the next formal CSN VA access guideline update thoroughly consider this data, particularly as it may affect the overall “well being” of the access, as well as have resource implications

2. **Quality of Evidence of the Guidelines**

The evidence supporting each recommendation is graded into four levels A-D. The level of grading is based upon the scheme developed by the Canadian Hypertension Education Program and can be found in the “Introduction” section of the Vascular Access Guidelines document. The published vascular access guidelines are based on either Grade C or Grade D evidence. These levels of evidence can be summarized as follows:

Grade C:

- 1) RCT with statistical significant result in a positive study or negative study with adequate power or SR with homogeneous results AND neither a clinically important nor validated surrogate outcome.
- 2) Observational study with statistical significant result in a positive study or negative study with adequate power AND
- 3) Clinically important outcome AND study population representative of the population recommendation is for
- 4) Outcome is a validates surrogate OR results need to be extrapolated from study population to real population

Grade D:

- 1) Neither Adequate RCT nor adequate subgroup analysis nor systematic review (SR) of RCT/Subgroups with similar treatment arm nor observational study.
- 2) RCT with inadequate statistical power or SR with non-homogeneous groups AND neither a clinical important difference nor a validated surrogate outcome.
- 3) Observational study with inadequate power to rule out clinical important difference in a negative study.

3. Accepting the 2006 Guidelines

We conclude that the current CSN guidelines are relevant to this working group and do not require modification. Placement of an AVF before initiation of hemodialysis is considered the standard of care. However, the evidence supporting this recommendation is based only on observational data, as there have been no randomized control trials to date comparing outcomes of AVF vs CVCs. The primary benefit found in numerous observational studies is that AVF use is associated with a lower risk of death than catheter use. However, these studies have not restricted the study populations to patients who were eligible for both fistulae and catheters. Second, they usually focus on the benefits of AVF use (i.e. “functioning” AVFs) rather than AVF attempts. Since the primary failure rate of AVF can approach 50%, there may be an overestimation of the benefits when we recommend AVF to patients. Other studies demonstrate that AVF use is associated with lower rates of hospitalization, procedures, and overall lower health care costs but they suffer from the same methodological limitations as the mortality studies. There have been limited data comparing the outcomes of AVF vs AVG and most suffer from the same methodological issues as for comparisons between AVF vs CVC. The prospective and randomized trials data comparing AVF and AVG deserves re-examination.

Essential concepts that need to be taken into consideration for future research or quality assurance work are:

- ⌈ Timing of VA creation is a complex decision making process
- ⌈ Poor prognostic tools are available to guide decision making in the timing of access creation
- ⌈ There are limited randomized control trials comparing outcomes among patients with different access types so the true benefit of AVF is not known

- ⌈ Few studies evaluating effectiveness of different approaches toward timing of access creation exist
- ⌈ It is not clear that early AVF creation “for all” is best; subgroups of patients may not be eligible for fistula or benefit from them if they are attempted.
- ⌈ There is uncertainty about how many interventions will be necessary to make a functional AVF and whether increasing fistula attempts reduce subsequent procedure rates.
- ⌈ It is uncertain whether the overall balance of intervention attempts to facilitate a functional fistula in relation to its use is beneficial.

4. Future Directions

Although we accept the current CSN guidelines, we strongly encourage CSN and the international community to facilitate further research to measure the benefits of AVF attempts. CSN should also facilitate the collection of quality assurance data to ensure patient who undergo AVF attempts are having the expected outcomes. The CSN should make recommendations to ensure there are safeguards in place to protect the patients against access-related complications, if CSN is to make such aggressive push towards AVF creation.

Appendix 2

Vascular Access Metrics

Much of the following appendix is based upon this publication:

Lee T, Mokrzycki M, Moist L, Maya I, Vazquez M, Lok C:
Standardized definitions for hemodialysis vascular access.
Semin Dial in press

Patient Level Data:

a) *Proposed minimal data set to be added to the CORR incident and longitudinal data collection:*

1.0 Incident Access: At the **first** chronic hemodialysis session:

- (i) What access (es) was **in place?** (Circle one or more):
fistula, graft, catheter, other Indicate other: _
- (ii) What access was **used?** (Circle one or more):
fistula, graft, catheter, other Indicate other: _

2.0 Prevalent Access (on date of CORR cross sectional annual survey)

- (i) What access (es) was **in place?** (Circle one or more):
fistula, graft, catheter, other Indicate other: _
- (ii) What access was **used?** (Circle one or more):
fistula, graft, catheter, other Indicate other: _
- (iii) If a catheter was being used, was a CVC in use for > 90 days? Y / N

b) *Additional Vascular Access Indicators (to be collected at individual sites and not part of the CORR data collection)*

☐ Arteriovenous Fistula and Graft Patency Definitions

☐ Time-dependent patency definitions:

(i) Primary Unassisted Patency:

Primary unassisted patency is defined as the time from access creation or placement until any first intervention (endovascular or surgical) to maintain or restore blood flow, first occurrence to access thrombosis, or reaching a censored event (death, transfer to another hemodialysis unit, transfer to peritoneal dialysis, transplantation, and end of study period). It can be additionally calculated at 30 and 90 days, and at 6, 12, 18, and 24 months.

(ii) Cumulative Survival (or Secondary Patency):

Cumulative survival is defined as the time from access creation or placement until access abandonment or achievement of a censored event (death, transfer to another hemodialysis unit, transfer to peritoneal dialysis, transplantation, and end of study period), and includes all surgical and endovascular interventions.

(iii) Time of Successful AVF/AVG Use:

Time when AVF/AVG can provide independent dialysis as indicated by the removal of the previously supporting CVC.

3.0 Vascular Access Maturation Definitions

a) Immediate Access Failure:

This is defined as an access that has either no appearance of or a loss of bruit or thrill within 72 hours of creation as determined by a health care provider skilled at assessing AVF or AVG (e.g. surgeon, nephrologist, hemodialysis nurse, vascular access coordinator). In addition, an access that is lost due to iatrogenic reasons, for

example, emergency ligation of a fistula or graft due to steal syndrome will also be included, even though an initial or apparent bruit or thrill may be present.

Regarding b) and c) below, these 2 metrics are relevant to patients receiving hemodialysis. It should be noted that suitability can and should also be assessed in predialysis patients who have not yet initiated hemodialysis. The literature provides no validated approaches to this group. Vascular access in such patients might be judged “not suitable for dialysis by an experienced observer”. This is a preliminary and opinion based statement, and requires refinement by the standing CSN VA committee and by the international nephrology community.

b) Early Dialysis Suitability Failure:

This is defined as an access that, despite radiological or surgical intervention, cannot be used successfully for dialysis by 3 months following its creation.

c) Late Dialysis Suitability Failure:

This is defined as an access that, despite radiological or surgical intervention, cannot be used successfully for dialysis by 6 months following its creation.

d) Cannulation Failure:

Cannulation failure is defined as the inability to place and secure 2 adequately sized dialysis needles to provide prescribed dialysis.

4.0 Hemodialysis Catheters

Definition of Catheter Infections:

a) Catheter Related Bacteremia:

Definite:

a. The same organism grown from at least 1 percutaneous blood culture and from a culture of the catheter tip; or

b. A blood culture drawn from a catheter that has a ≥ 3 -fold greater colony count of microbiologic isolates than those drawn from a peripheral vein.

Probable:

Positive blood cultures obtained from a catheter in a symptomatic patient, when a peripheral sample cannot be obtained, and there is no clinical evidence for an alternative source of infection.

Discussion: The definitions above are similar to those published by the Intravenous Guideline Subcommittee of the Infectious Disease Society of America (2001) and the Public Health Agency of Canada (1997). Definitions related to catheter infection should be unified and kept as simple as possible.

b) Catheter Exit Site Infection:

Definite:

The presence of a purulent discharge, or erythema, induration, and/or tenderness at the catheter exit site with a positive culture of serous discharge.

Probable:

The presence of erythema, induration, or tenderness at the catheter exit site without a positive culture of serous discharge and no other sources of findings, such as irritation from gauze or cleansing agent.

c) Catheter Tunnel Infection:

Definite:

The presence of a purulent discharge from the tunnel, or erythema, induration, and/or tenderness over the catheter tunnel, with a positive culture of the discharge.

Probable:

The presence of a purulent discharge from the tunnel, or erythema, induration, and/or tenderness over the catheter tunnel, without a positive culture result of the serous discharge, and no other sources of findings.

d) Cumulative Thrombolytic Rate of Instillations:

Cumulative thrombolytic rate of instillations is defined as the number of thrombolytic instillations/1000 catheter days.

5.0 The CSN VAWG Recommendation:

The CSN VAWG recommends that the following facility level data collection be added to the CORR data submissions, starting in 2012.

1. In the year
- a) How many fistula were created in your center
- b) How many grafts were created
- c) How many CVC are inserted
- d) How many surgeons perform vascular access surgery in your center

2. What is the average wait time from
- a) surgery referral to surgery consult visit ...days
- b) surgery consult visit to surgerydays

3. Do you have a vascular access coordinator? Y/N

Appendix 3

Canadian Vascular Access Guidelines/Tools (March 7, 2011)

Title	Type of Resource	Creation/ Revision Date	SARP VA Resources	Eastern Canada
Assessment of Newly Created AVFs & AVGs	(BC) Full Guideline	August 2007	Post op wound care guidelines.	AV fistula and grafts for hemodialysis (Oct 2007)
	(BC) Summary Guideline	August 2007		
	(BC) Assessment Poster			
Best Practices in VA Clinics	(BC) Report	September 2007		
Buttonhole Cannulation of AVFs	(BC) Full Guideline	December 2009	Buttonhole cannulation. March 2010	Buttonhole cannulation (Nov 2010)
	(BC) Summary Guideline	December 2009		
Cannulation of AVFs & AVGs	(BC) Full Guideline	May 2007	Needling AVF/AVG March 2010.	Cannulation of a new fistula (May 2009)
	(BC) Summary Guideline	May 2007		
	(BC) Matching Cannulators & Accesses	May 2008		
	(BC) Care of your Fistula & Graft Poster			
	(BC) Ways to Prevent Aneurysms in Fistulas Poster			

Title	Type of Resource	Creation/ Revision Date	SARP VA Resources	Eastern Canada
	(BC) Buttonhole Cannulation of AVFs	Dec 2009		
Cannulation Teaching Tools	(BC) Novice Cannulator	May 2008		<p>-Initiation du traitement de l'hémodialyse avec une fistule ou une greffe (03/2007)</p> <p>-Protocol for first use of a new AVG/AVG (12/2010)</p> <p>-Discontinuation of hemodialysis for patients with a fistula or graft (12/2010)</p> <p>-Restitution du traitement d'hémodialyse avec une fistule ou une greffe (03/2007)</p> <p>-Initiation du traitement d'hémodialyse par le catheter</p> <p>-Reparation d'un clamp au catheter d'hémodialyse (12/2006)</p>
	(BC) Skilled Cannulator	May 2008		Decision tree cannulation
	(BC) Advanced Cannulator	May 2008		

Title	Type of Resource	Creation/ Revision Date	SARP VA Resources	Eastern Canada
Insertion & Removal of Tunneled HD Catheters	(BC) Full Guideline	May 2007		Insertion du catheter temporaire a l' unite de soins (07/2006) -Removal of Non tunneled HD catheter (12/2010) -Removal of tunneled HD catheter (12/2010) -Insertion/Change of non-tunneled hemodialysis catheter (12/2010) Central venous catheter repair (06/2008)
	(BC) Summary Guideline	May 2007		
Provincial VA Recommendations	(BC) Full Guideline	2006 <small>Prov VA Guideline</small>		Evaluation de soins infirmiers – acces arterioveineux en Hemodialyse
Referrals and Transfers	(BC) Guide to referrals and transfers	October 2008	CKD referrals policy	
Selection of Permanent HD VA	(BC) Full Guideline	May 2007		
	(BC) Summary Guideline	May 2007		
	(BC) Form	May 2007		
Use of Alteplase in an Occluded Catheter	(BC) Full Guideline	July 2006	Cathflo/Alteplase in HD CVC. Updated sep 2010	

Title	Type of Resource	Creation/ Revision Date	SARP VA Resources	Eastern Canada
VA Radiology	(BC) Full Guideline	2006 <small>VA Radiology Guideline</small>		
VA Related Infections	(BC) Full Guideline	March 2008	SARP CVC Antibiotic protocol. Appendix 1: Algorithm for suspected CRB. Updated March 2010	
	(BC) Summary Guideline	March 2008	App 2: ABX protocol for CRB. Updated June 2009	
	(BC) Pre-printed Orders	March 2008	App3: Pharmacy related procedures for GEntamycin protocol. March 2007	
	(BC) Pharmacy Formula Card	March 2008	App4: Vancomycin, gent, and ancef dosing. March 2007.	
			AVF management of Infection. Feb 2007	

Title	Type of Resource	Creation/ Revision Date	SARP VA Resources	Eastern Canada
	(BC) Ways to Prevent Infection Poster			
VA Surgical Procedure	(BC) Full Guideline	2010	Summary of Vascular Access policy. (protocols for access surgery 2006 and reviewed 2010)	
Vein Preservation	Full Guideline	In progress	SARP Cards for the lab developed to assist with preferred phlebotomy sites. March 2009	
Diascan Access Flow Monitoring			Description of how to perform flow monitoring using ionic dialysance. May 2007	
Transonic Access Flow Monitoring			Description of how to perform access flow monitoring using Ultrasound dilution. Aug 2007.	-Assessing access recirculation and flow using Transonic HD03 hemodialysis monitor -Effectuer un transonic (03/2008)

Data Management/CQI Processes

Title	Description	Frequency of report	SARP	Eastern Canada
Fistula Incidence report	(BC) Fistula incidence of all CKD patients in BC starting chronic dialysis	q 6 months	SARP AVF incidence Q 4 months	
Fistula Prevalence report	(BC) Fistula prevalence report	q 6 months	SARP AVF prevalence Q4 months	Prevalence of functional AVF in HD patients
Infection rate reports	(BC) Fistula infection, and Catheter infections (bacteremia, exit site)	q 6 months	Not yet reported	
Why catheter report	(BC) Report looking at reasons that patients started chronic HD with a catheter (including time from referral <input type="checkbox"/> assesement <input type="checkbox"/> surgery, GFR at referral, etc.), previously mapped?, previous attempts, etc..	q 6 months	Not reported.	
Wait time report				AV Fistula/Graft surgery – wait time from clinic appt to access surgery

Patient Teaching Materials

Title	Type of Resource	Creation/ Revision Date	SARP	Eastern Canada
Fistula, Graft or Catheter?	(BC) Pamphlet		Pamphlet	
Your Fistula	(BC) Pamphlet		Pamphlet	Pamphlet (01/2010)
Your Graft	(BC) Pamphlet		Pamphlet	Pamphlet (12/2009)
Your Catheter	(BC) Pamphlet		Pamphlet	
Fistula Exercises	(BC) Pamphlet		Pamphlet	Pamphlet (03/2009)
Bleeding Fistula or Graft: Emergency Measures	(BC) Pamphlet		Pamphlet	
Is it Time to Take Charge of My Own Needles?	(BC) Pamphlet	Jan 2010		
Self-Needling Your Fistula Using the BH Method	(BC) Pamphlet	Jan 2010		
Your Buttonhole Track	(BC) Pamphlet	Jan 2010		
You are on Vacation & Have a BH Track	(BC) Pamphlet	Jan 2010		
Care of Your Fistula or Graft	(BC) Poster			
VA Assessment	(BC) Poster			

Appendix 4

Wait Times and Resource Availability Targets for Vascular Access

Introduction

Creation and maintenance of vascular access for Hemodialysis requires collaboration between Nephrology, Interventional Radiology and Surgery. Monitoring outcomes is crucial so that a program can continue to evolve or modify its approaches to VA. Quality indicators should be developed and reported on an ongoing basis.

Depending on the renal program and the amount of coordination or collaboration between Nephrology, Surgery and Interventional Radiology, some or all of the following 11 indicators could be used to build quality indicators.

Indicators for AVF/AVG Surgical Creation Wait Times

1. Time from initial referral for vascular access to surgical consult:
Target 80% of patients referred for vascular access should be seen within 4 weeks.
2. Wait time from surgical consult visit to OR:
Target 80% of patients should have their surgery within 4 weeks following the clinic appointment.
3. Follow-up up after AVF creation:
Target 100% should be evaluated within 4 weeks of creation by a knowledgeable vascular access nurse/coordinator, nephrologist or surgeon. If the fistula does not appear to be maturing, the patient should be re-evaluated by the surgeon within 4-6 weeks from the time of creation and the appropriate intervention planned and implemented within 2-4 weeks.

Indicators for Surgical Intervention of AVF/AVG Wait Times

1. Surgical intervention for bleeding or infection.
Target: 90% should be seen within 24 hours.
2. Surgical assessment and intervention for clotted AV fistula.
Target: 90% should be seen within 24 hours by Surgery and/or Interventional Radiology.
3. Surgical assessment and intervention for clotted graft thrombosis.
Target: 90% should be seen within 72 hours by Surgery and/or Interventional Radiology.

Indicators for Interventional Radiology Wait Times

Angiograms/angioplasties/ thrombolysis and surgical intervention should be categorized:

Very Urgent: Target: 100% of procedures should be done within 24 hours.

- ☐ Declot of AVF
- ☐ Removal of a catheter due to a clinically suspected catheter related bacteremia or sepsis with associated symptoms or hemodynamic instability (catheter may be removed by Nephrology)
- ☐ Infected graft
- ☐ Pending aneurysmal rupture
- ☐ Placement of tunneled CVC if needed for HD within 24 hours

Urgent: Target: 100% of procedures should be done within 48-72 hours.

- ☐ Declot of AV-graft
- ☐ Placement of tunneled CVC if needed for HD within then declot of AVF over the next 72 hours

Semi-urgent: Target: 100% of procedures in less than 1 week.

Wait times for fistulogram indicated by consistent abnormal clinical signs/symptoms determined by routine monitoring (+/- surveillance). Ancillary surveillance measures that may be helpful include:

- a) Access flow less than 500 ml/min in an AV fistula, after a falling trend.
- b) Access flow less than 650 ml/min in an AV graft, after a falling trend.
- c) Access flow which is consistently declining greater than 20% from previous measurements.

Non-urgent: Target: 100% of procedures in less than 3 weeks.

- [[Ligation of collaterals, angioplasty of stenosis and other facilitative procedures for a failing fistula

Indicators Regarding Transition of Vascular Access (Exploratory)

Time from surgical creation of AVF or AVG to time of catheter removal:

1. Proportion of catheters removed within 90 days of dialysis initiation.
Corresponding question: Was the catheter removed within 90 days of dialysis start? (yes/no)
2. Proportion of catheters removed within 183 days of AVF or graft creation.
Corresponding question: Was the catheter removed within 183 days of AVF or graft creation? (yes/no)