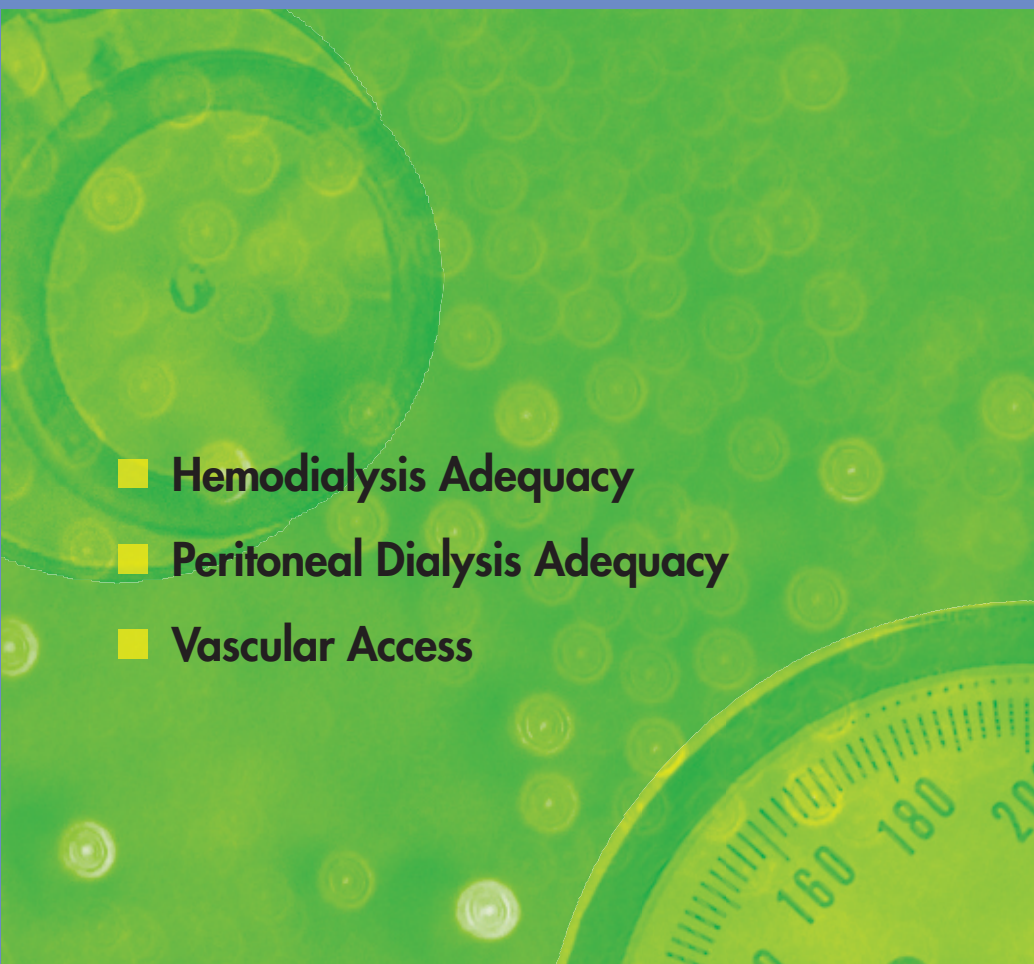




2006 Updates Clinical Practice Guidelines and Recommendations



- 
- Hemodialysis Adequacy
 - Peritoneal Dialysis Adequacy
 - Vascular Access

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In citing this document, the following format should be used: National Kidney Foundation. *KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for 2006 Updates: Hemodialysis Adequacy, Peritoneal Dialysis Adequacy and Vascular Access*. Am J Kidney Dis 48:S1-S322, 2006 (suppl 1).

Support for the development of the KDOQI Clinical Practice Guidelines and Clinical Practice Recommendations for Hemodialysis Adequacy 2006, Peritoneal Dialysis Adequacy 2006 and Vascular Access 2006 was provided by: **Amgen, Inc., Baxter Healthcare Corporation, Fresenius USA, Inc., Genentech, Inc., and Watson Pharmaceuticals, Inc.**

The National Kidney Foundation gratefully acknowledges the support of Amgen, Inc. as the founding and principal sponsor of KDOQI.

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VASCULAR ACCESS

Vascular Access 2006

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Vascular Access

Acronyms and Abbreviations

aOR	Adjusted odds ratio
AMI	Acute myocardial infarction
AUC	Area under the curve
AV	Arteriovenous
AVF	Arteriovenous fistula
AVG	Arteriovenous graft
BFR	Blood flow rate
BP	Blood pressure
BTM	Body Thermal Monitor
CDC	Centers for Disease Control and Prevention
CHF	Congestive heart failure
CI	Confidence interval
CKD	Chronic kidney disease
CLS	Catheter lock solution
CMS	Centers for Medicare & Medicaid Services
CPG	Clinical Practice Guideline
CPM	Clinical performance measure
CPR	Clinical Practice Recommendation
CQI	Continuous quality improvement
CRB	Catheter-related bacteremia
CrCl	Creatinine clearance
CVC	Central venous catheter
CVD	Cardiovascular disease
DD	In line dialysance
DDU	Duplex Doppler ultrasound
DOPPS	Dialysis Outcomes and Practice Patterns Study
DOQI	Dialysis Outcomes Quality Initiative
DRIL	Distal revascularization—interval ligation
DSA	Digital subtraction angiography
DU	Doppler ultrasound
DVP	Dynamic venous pressures
FDA	Food and Drug Administration
FFBI	Fistula First Breakthrough Initiative
GFR	Glomerular filtration rate
GPT	Glucose pump infusion technique
Hct	Hematocrit
HD	Hemodialysis

HDM	Hemodynamic monitoring
HTN	Hypertension
IAP	Intra-access pressure
IgG	Immunoglobulin G
INR	International normalized ratio
IV	Intravenous
IVC	Inferior vena cava
IVUS	Intravascular ultrasound
KDOQI	Kidney Disease Outcomes Quality Initiative
KLS	Kidney Learning System
KRT	Kidney replacement therapy
LVH	Left ventricular hypertrophy
MAP	Mean arterial (blood) pressure
MRA	Magnetic resonance angiography
N	Number of subjects
NCC	Noncuffed catheter
nd	No data reported
NKF	National Kidney Foundation
NS	Not significant
NVAII	National Vascular Access Improvement Initiative
OABF	Optodilution by ultrafiltration
ORX	Optodilutional recirculation measurement technique
ΔP	Pressure gradient
PAVA	Proximal arteriovenous anastomosis
PD	Peritoneal dialysis
PE	Pulmonary embolism
PFSS	Percutaneous fibrin sheath stripping
P_{IA}	Intra-access pressure
PICC	Peripherally inserted central catheter
PSV	Peak systolic velocity
PTA	Percutaneous angioplasty
PTFE	Polytetrafluoroethylene
PU	Polyurethane
PVD	Peripheral vascular disease
Q_A	Access blood flow
QA/CQI	Quality assurance/continuous quality improvement
Q_B	Blood pump flow delivered to the dialyzer
Q_{BP}	Blood pump flow
Q_f	Ultrafiltration rate
QIP	Quality improvement project
QOL	Quality of life
RCT	Randomized controlled trial
ROC	Receiver operating characteristic

RR	Relative risk
rTPA	Recombinant tissue plasminogen activator
SGA	Subjective global assessment
SVC	Superior vena cava
SVR	Systolic velocity ratio
TCC	Tunneled cuffed catheter
TD	Thermal dilution
tPA	Tissue plasminogen activator
TQA	Transcutaneous optodilution flow method
UDT	Ultrasound dilution technique
UK	Urokinase
UOP	Urine output
UreaD	Urea dialysance
UrCl	Urea clearance
URR	Urea reduction ratio
US	Ultrasonography
USRDS	United States Renal Data System
VAT	Vascular access team
VDP	Venous drip chamber pressure
VFDU	Variable flow Doppler ultrasound

Glossary

Anastomosis: An opening created by surgical, traumatic, or pathological means between 2 normally separate spaces or organs.

Aneurysm: An abnormal blood-filled dilation of a blood vessel wall (most commonly in arteries) resulting from disease of the vessel wall.

Pseudoaneurysm: A vascular abnormality that resembles an aneurysm, but the out-pouching is not limited by a true vessel wall, rather by external fibrous tissue.

Angioplasty: The repair of a blood vessel abnormality.

Percutaneous transluminal angioplasty: The repair of a lesion using an endoluminal approach, usually with a balloon that can be inflated to pressures up to 30 atmospheres.

Antibiotic lock: Instillation of an antibiotic solution into the lumen of a dialysis catheter for the entire interdialytic period; antibiotics tested include vancomycin, aminoglycosides, and minocycline.

Antimicrobial lock: Instillation of an antimicrobial solution into the lumen of a dialysis catheter for the entire interdialytic period; antimicrobial solutions include high-concentration citrate, high-concentration EDTA, and taurolidine.

Antimicrobial: Any agent capable of destroying or inhibiting the growth of microorganisms.

Antiseptic: Any agent capable of preventing infection by inhibiting the growth of microorganisms.

Cannulation: The insertion of cannulae (by definition, a needle with a lumen) or angiocaths into a vascular vessel.

Buttonhole technique or constant-site technique: The repeated cannulation into the exact same puncture site so that a scar tissue tunnel track develops. The scar tissue tunnel track allows the needle to pass through to the outflow vessel of the fistula following the same path with each cannulation time. Only used in fistulae. Should not be used for accessing grafts.

Catheter: A device providing access to the central veins or right atrium, permitting high-volume flow rates.

Exit site: The location on the skin that the catheter exits through the skin surface.

Insertion site: Location at which the catheter enters the vein, for example, the right internal jugular vein is the preferred insertion site.

Long-term catheter: Also known as tunneled cuffed catheter (TCC); a device intended for use for longer than 1 week that typically is tunneled and has a cuff to promote fibrous ingrowth to prevent catheter migration and accidental withdrawal.

Port catheter system: Subcutaneous device for hemodialysis access that is cannulated with needles; the device contains a ball-valve system that is connected to 1 or more central venous catheters (CVCs).

Short-term catheter: A device intended for short-term use (<1 week) that typically is not tunneled. Intended for use in hospitalized patients; not for outpatient maintenance dialysis.

Diagnostic testing: Specialized testing that is prompted by some abnormality or other medical indication and that is undertaken to diagnose the cause of the vascular access dysfunction.

Dialysance: The number of milliliters of blood completely cleared of any substance by an artificial kidney or by peritoneal dialysis in a unit of time, usually a minute, with a specified concentration gradient.

Distal revascularization—interval ligation (DRIL): A surgical procedure to reduce ischemia to the hand caused by steal syndrome.

Elastic recoil: The recurrence of stenosis following angioplasty.

Fistula (plural, fistulae): Autogenous autologous arteriovenous fistula, also referred to as native.

Brescia-Cimino (radiocephalic) fistula: An autologous fistula constructed between the radial artery and the cephalic vein at the wrist.

Gracz fistula: An autologous fistula constructed between the brachial artery and a branch of the medial antecubital vein, the perforating vein, below the elbow.

Snuff-box fistula: An autologous fistula constructed between a branch of the radial artery and an adjacent vein in the anatomic snuff box of the hand.

Fistula maturation: The process by which a fistula becomes suitable for cannulation.

Rule of 6s: A fistula in general must be a minimum of 6 mm in diameter with discernable margins when a tourniquet is in place, less than 6 mm deep, have a blood flow greater than 600 mL/min, and should be evaluated for nonmaturation if, after 6 weeks from surgical creation, it does not meet these criteria.

Flow: The amount of blood flowing through a system.

Q_A : Access blood flow.

Q_f : Ultrafiltration rate.

Q_B : Blood pump flow delivered to the dialyzer.

Flow measurement methods:

Crit line: Using changes in hematocrit (Hct) induced by ultrafiltration.

GPT: Glucose pump (infusion) technique.

HDM: Hemodialysis monitor using magnetic detection of differential conductivity.

Ionic dialysance: A method that uses a change in dialysis fluid sodium concentration to calculate flow.

ORX: Optodilutional recirculation measurement technique.

TD: Thermal dilution method.

TQA: Direct transcutaneous optodilutional flow method.

UDT: Ultrasound dilution technique.

VFDU: Variable flow Doppler ultrasound.

Graft: A conduit of synthetic or biological material connecting artery to vein.

Synthetic: Made of plastic polymers, such as polytetrafluoroethylene (PTFE), polyurethane (PU).

Biological: Made of biological materials, such as bovine carotid artery, cryopreserved human femoral veins, etc.

Tapered: Grafts for which internal diameter varies from the arterial to the venous end.

Untapered: Grafts with a uniform diameter, usually 6 mm.

Kt/V: A dimensionless quantity that assesses the amount of dialysis delivered.

Monitoring: The evaluation of the vascular access by means of physical examination to detect physical signs that suggest the presence of dysfunction.

Magnetic resonance angiography (MRA): A technique to visualize the arterial and venous systems using gadolinium as the imaging agent.

Neointimal hyperplasia: The myoendothelial proliferation of cells and matrix that produces stenosis, primarily in grafts.

Online: The conductance of a test during a hemodialysis procedure.

Physical examination (of the access): Inspection, palpation, and auscultation of the access.

Pressure: Force applied uniformly over a surface, measured as force per unit of area; stress or force acting in any direction against resistance.

Mean arterial pressure (MAP): Usually recorded in the arm opposite the vascular access.

P_{IA}: Pressure in the access when there is no external blood flow for dialysis, also referred to as the “static pressure.”

Venous drip chamber pressure (VDP): Also referred as dynamic venous pressure (DVP). Measured in the venous tubing and equal to the pressure required to infuse blood back into the vascular access at the blood pump flow set.

Recirculation: The return of dialyzed blood to the systemic circulation without full equilibration.

Cardiopulmonary recirculation: Resulting from the return of dialyzed blood without full equilibration with all systemic venous return.

Access recirculation: Resulting from the admixture of dialyzed blood with arterial access blood without equilibration with the systemic arterial circulation. Occurs under conditions in which blood pump flow is greater than access flow.

Receiver operating characteristic (ROC) curve: A technique to evaluate the sensitivity and specificity of a diagnostic test to detect/predict the presence of a disease state.

Steal syndrome: Signs and symptoms (pain, coldness, cyanosis, necrosis) produced by an access as a result of the diversion of arterial blood flow into the fistula.

Acronecrosis: Gangrene occurring in the distal part of the extremities, usually fingertips and toes.

Stenosis: A constriction or narrowing of a duct or passage; a stricture.

Cephalic arch stenosis: A common site for stenosis of the cephalic vein at an anatomic site where there is a narrowing of the cephalic vein as it arches over the shoulder in the region of the deltopectoral groove before the vein junction with the axillary vein.

Surveillance: The periodic evaluation of the vascular access by means of tests, which may involve special instrumentation and for which an abnormal test result suggests the presence of dysfunction.

Tissue plasminogen activator (tPA): A natural lytic used to dissolve fibrin or nonorganized thrombus.

Transposition: The movement of a vein from its normal position either by elevation to bring the vein closer to the skin or laterally to permit easier cannulation.

Ultrasound: The use of ultrasonic waves for diagnostic or therapeutic purposes, specifically to image an internal body structure.

Doppler ultrasound (DU): Ultrasound that uses the Doppler effect to measure movement or flow in the body and especially blood flow; also referred to as Doppler ultrasonography.

Duplex Doppler ultrasound (DDU): Combines Doppler and B-mode (grayscale) imaging to provide diagnostic ultrasound used for quantitative color velocity imaging, also referred to as Doppler sonography.

Systolic velocity ratio (SVR): The ratio of velocity in an abnormal vessel relative to a normal vessel.

Urokinase: A natural lytic used to dissolve fibrin or nonorganized thrombus.

Vascular access team (VAT): Patient and group of professionals involved in management of vascular access (includes caregivers who construct, cannulate, monitor, detect problems in, and repair vascular accesses). Caregivers include nephrologist, nephrology nurse, patient care technician, nurse practitioner, physician assistant, interventionalist, surgeons, and vascular access coordinator.

Foreword

The publication of the second update of the Clinical Practice Guidelines (CPGs) and Clinical Practice Recommendations (CPRs) for Vascular Access represents the second update of these guidelines since the first guideline on this topic was published in 1997. The first set of guidelines established the importance of placing fistulae in long-term hemodialysis patients. Several of these guidelines have been selected as clinical performance measures by regulatory agencies to drive the process of quality improvement in long-term dialysis patients, and an initiative in the United States called “Fistula First” recently was started in an effort to increase the percentage of patients who have an arteriovenous fistula placed for long-term hemodialysis therapy.

Several major changes have occurred since the publication of the first set of guidelines. First, a number of clinical trials have been performed to determine the efficacy of different methods of identifying an access that is beginning to fail. Thus, this update of the guideline includes a substantial revision of accepted methods for access dysfunction detection. Second, cannulation techniques have been updated to include the importance of training staff in cannulation techniques and the appropriate uses of the buttonhole technique for arteriovenous fistulae. Finally, urokinase was removed from the market and other thrombolytic agents have been developed to assist with reestablishing patency in dialysis catheters. The use of these newer agents is addressed in this update.

This document has been divided into 3 major areas. The first section consists of guideline statements that are evidence based. The second section is a new section that consists of opinion-based statements that we are calling “clinical practice recommendations,” or CPRs. These CPRs are opinion based and are based on the expert consensus of the Work Group members. It is the intention of the Work Group that the guideline statements in Section I can be considered for clinical performance measures because of the evidence that supports them. Conversely, because the CPRs are opinion based, and not evidence based, they should not be considered to have sufficient evidence to support the development of clinical performance measures. The third section consists of research recommendations for these guidelines and CPRs. We have decided to combine all the research recommendations for the guidelines into 1 major section and also have ranked these recommendations into 3 categories: critical importance, high importance, and moderate importance. Our intended effect of this change in how the research recommendations are presented is to provide a guidepost for funding agencies and investigators to target research efforts in areas that will provide important information to benefit patient outcomes.

This final version of the Clinical Practice Guidelines and Recommendations for Vascular Access has undergone extensive revision in response to comments during the public review. While considerable effort has gone into their preparation during the past 2 years and every attention has been paid to their detail and scientific rigor, no set of guidelines and clinical practice recommendations, no matter how well developed, achieves its

purpose unless it is implemented and translated into clinical practice. Implementation is an integral component of the Kidney Disease Outcomes Quality Initiative (KDOQI) process and accounts for the success of its past guidelines. The Kidney Learning System (KLS) component of the National Kidney Foundation is developing implementation tools that will be essential to the success of these guidelines.

In a voluntary and multidisciplinary undertaking of this magnitude, many individuals make contributions to the final product now in your hands. It is impossible to acknowledge them individually here, but to each and every one of them, we extend our sincerest appreciation. This limitation notwithstanding, a special debt of gratitude is due to the members of the Work Group and their co-chairs, Anatole Besarab of Henry Ford Hospital and Jack Work of Emory University. It is their commitment and dedication to the KDOQI process that has made this document possible.

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INTRODUCTION

More than 300,000 individuals in the United States rely on a vascular access to receive hemodialysis (HD) treatment.¹ Vascular access continues to be a leading cause for hospitalization and morbidity in patients with chronic kidney disease (CKD) stage 5.² Appropriate care of HD patients with CKD stage 5 requires constant attention to the maintenance of vascular access patency and function. An ideal access delivers a flow rate to the dialyzer adequate for the dialysis prescription, has a long use-life, and has a low rate of complications (eg, infection, stenosis, thrombosis, aneurysm, and limb ischemia). Of available accesses, the surgically created fistula comes closest to fulfilling these criteria. Studies over several decades consistently demonstrate that native fistula accesses have the best 4- to 5-year patency rates and require the fewest interventions compared with other access types.³⁻⁵ However, in the United States between 1985 and 1995, the growth of the CKD Stage 5 HD program was accompanied by decreased use of native fistulae and increased use of grafts and cuffed central catheters for permanent HD access.^{5,6} In 1995, the United States Renal Data System (USRDS) reported, for the 1990 incident cohort of patients, that insertion of polytetrafluoroethylene (PTFE) grafts occurred almost twice as often as construction of native accesses.⁶ Significant geographic variation in the ratio of native fistula construction to graft placement also was noted.

The substitution of grafts for fistulae increased patient care costs, in part because of the increased number of procedures needed to maintain patency of grafts compared with native fistulae.⁷ A review of Medicare billing showed that the first-year total yearly costs for patients initiating HD therapy using a fistula were lowest (\$68,002) compared with grafts (\$75,611) and catheters (\$86,927).⁸ Although the second-year total yearly costs were lower for all groups, catheters still resulted in the highest costs at \$57,178 compared with \$54,555 for grafts and \$46,689 for fistulae. Similarly, in a single-center Canadian study, the cost of vascular access-related care was lower by more than 5-fold for patients who began the study period with a functioning fistula compared with those treated with a long-term catheter or graft.⁹

Before the first dissemination of the Dialysis Outcomes Quality Initiative (DOQI) recommendations on vascular access in 1997, many studies showed that practice patterns were contributing to patient morbidity and mortality, as well as costs. The failure of access was noted to be a major cause of morbidity for patients on HD therapy, with a number of reports indicating that a high percentage of hospitalizations for patients with CKD stage 5 were caused by vascular access complications.^{6,7,10-12} The USRDS reported that HD access failure was the most frequent cause of hospitalization for patients with CKD stage 5,⁶ and, in some centers, it accounted for the largest number of hospital days.¹³ Reports also indicated a decreasing interval between placement of a vascular access and a surgical procedure needed to restore patency,^{7,12} with significant costs to restore patency.^{6,13} Since then, a study using data from the USRDS Morbidity and Mortality Study Wave 1 showed that patients receiving catheters and grafts have greater mortality risk than patients dialyzed with fistulae.¹⁴ In patients with and without diabetes mellitus, cause-specific analyses found higher infection-related deaths for cuffed central catheters.

In patients without diabetes, relative risks (RRs) were 1.83 ($P < 0.04$) with catheters and 1.27 ($P < 0.33$) with arteriovenous (AV) grafts (AVGs). In patients with diabetes, the RR was even higher than in those without diabetes: RR of 2.30 ($P < 0.06$) for catheters and RR of 2.47 ($P < 0.02$) for grafts compared with fistulae. Cardiac cause of death was highest in patients with central venous catheters (CVCs). A number of subsequent epidemiological studies, both in the United States^{15,16} and abroad,¹⁷ reaffirmed that greater use of fistulae was associated with reduced mortality and morbidity.

It was shown that an aggressive policy for monitoring hemodynamics within an AVG or AV fistula (AVF) to detect access dysfunction may reduce the rate of thrombosis (see Clinical Practice Guideline [CPG] 4). Thus, much access-related morbidity and associated costs might be avoided. The number of interventions required to maintain access patency may be decreased further by the use of fistulae rather than AVGs. Studies showed that the number of access events is 3- to 7-fold greater in prosthetic bridge grafts than in fistulae,^{3,18} thereby contributing to the increased cost of grafts. Whether utilization of such interventions to reduce thrombosis rates ultimately prolongs the useable life of the access are unknown and should not be the sole outcome measure. Thrombosis is associated with additional risks to the patient that are not present with simple percutaneous angioplasty (PTA).¹⁹

The National Kidney Foundation (NKF) issued the Kidney Disease Outcomes Quality Initiative (KDOQI) CPGs for Vascular Access in an effort to improve patient survival and quality of life (QOL), reduce morbidity, and increase efficiency of care. Vascular access patency and adequate HD are essential to the optimal management of HD patients with CKD stage 5. The first is a necessary prerequisite for the second. To improve QOL and overall outcomes for HD patients, 2 primary goals were originally put forth in the vascular access guidelines²⁰:

- Increase the placement of native fistulae
- Detect access dysfunction before access thrombosis.

We believe these goals still apply, with the emphasis on placement of the functioning fistula. The Centers for Medicare & Medicaid Services (CMS) has actively collected data on 3 Clinical Performance Measures (CPMs) derived from the original and revised KDOQI Guidelines for Vascular Access. The failure to “adequately” increase the number of fistulae among either incident or prevalent HD patients during the past 6 years² or to reduce the use of catheters led to a CMS mandate that the ESRD networks develop Quality Improvement Projects (QIPs) on Vascular Access. These have been distilled into 3 key points: avoid central catheterization, thus avoiding loss of central patency; maintain existing access by detecting impending failure, followed by prompt intervention; and maximize creation of fistulae as the best long-term access. Out of these concepts has grown the National Vascular Access Improvement Initiative (NVAII), emphasizing a fistula-first approach. Recently, the target for fistula creation was set as 65% by 2009 (www.cms.hhs.gov/ESRDQualityImproveInit/04_FistulaFirstBreakthrough.asp). The Work Group acknowledges the importance of increasing the number of fistulae in use, *but* believes that the emphasis should be shifted from the fistula construction rate to the

rate of usable fistula accesses. This shift in emphasis is important to minimize wasted time and effort and reduce the primary failure rate and salvage procedures.

A number of barriers need to be overcome to achieve the goals set for vascular fistula construction; chief among these is the late referral of patients for permanent access placement, reflected in patient hospitalizations. In some regions, up to 73% of patients are hospitalized for initiation of HD therapy, almost invariably for dialysis catheter access placement.²¹ Unexpectedly, the modest increases in fistula use rates have been accompanied by increases in the use of catheters.² Early referral of patients with CKD stage 5 to a nephrologist is absolutely essential to allow for access planning and thus increase the probability of fistula construction and maturation, thereby decreasing the need for catheter placement.

To achieve these objectives, the current Work Group has developed and revised the vascular access practice guidelines and strategies for implementation and has made a concerted effort to differentiate guidelines from recommendations. At the core of these guidelines is the goal of early identification of patients with progressive kidney disease and the identification and protection of potential fistula construction sites—particularly sites using the cephalic vein—by members of the health care team and patients.

After access has been constructed, dialysis centers need to use a multifaceted continuous quality improvement (CQI) program to detect vascular accesses at risk, track access complication rates, and implement procedures that maximize access longevity. Vascular access databases that are available to all members of the vascular access team (VAT) are crucial. The Work Group has developed explicit guidelines regarding which tests to use to evaluate a given access type and when and how to intervene to reduce thrombosis and underdialysis. The Work Group believes that the guidelines are reasonable, appropriate, and achievable. Attainment of these goals will require the concerted efforts of not only practicing nephrologists, but also nephrology nurses, access surgeons, vascular interventionalists, patients, and other members of the health care team.

In this update of the Vascular Access Guidelines, the Work Group did not perform a comprehensive review of all the guidelines. Seven topics underwent systematic review, and these are identified. The other guidelines were unified and consolidated. More recent references, including reviews, were included when appropriate.

I. CLINICAL PRACTICE GUIDELINES FOR VASCULAR ACCESS

GUIDELINE 1. PATIENT PREPARATION FOR PERMANENT HEMODIALYSIS ACCESS

Appropriate planning allows for the initiation of dialysis therapy at the appropriate time with a permanent access in place at the start of dialysis therapy.

- 1.1 Patients with a glomerular filtration rate (GFR) less than 30 mL/min/1.73 m² (CKD stage 4) should be educated on all modalities of kidney replacement therapy (KRT) options, including transplantation, so that timely referral can be made for the appropriate modality and placement of a permanent dialysis access, if necessary. (A)
- 1.2 In patients with CKD stage 4 or 5, forearm and upper-arm veins suitable for placement of vascular access should not be used for venipuncture or for the placement of intravenous (IV) catheters, subclavian catheters, or peripherally inserted central catheter lines (PICCs). (B)
- 1.3 Patients should have a functional permanent access at the initiation of dialysis therapy.
 - 1.3.1 A fistula should be placed at least 6 months before the anticipated start of HD treatments. This timing allows for access evaluation and additional time for revision to ensure a working fistula is available at initiation of dialysis therapy. (B)
 - 1.3.2 A graft should, in most cases, be placed at least 3 to 6 weeks before the anticipated start of HD therapy. Some newer graft materials may be cannulated immediately after placement. (B)
 - 1.3.3 A peritoneal dialysis (PD) catheter ideally should be placed at least 2 weeks before the anticipated start of dialysis treatments. A backup HD access does not need to be placed in most patients. A PD catheter may be used as a bridge for a fistula in “appropriate” patients. (B)
- 1.4 Evaluations that should be performed before placement of a permanent HD access include (Table 1):
 - 1.4.1 History and physical examination, (B)
 - 1.4.2 Duplex ultrasound of the upper-extremity arteries and veins, (B)
 - 1.4.3 Central vein evaluation in the appropriate patient known to have a previous catheter or pacemaker. (A)

BACKGROUND

Since implementation of the NKF KDOQI Vascular Access Guidelines in 1997, which encouraged increased placement of fistulae, CMS has embraced this recommendation with the implementation of the Fistula First Breakthrough Initiative (FFBI). This initiative endorses the goals recommended by the NKF KDOQI: fistula rates of 50% or

greater for incident—and at least 40% for prevalent—patients undergoing HD. The FFBI promotes the placement of fistulae in all suitable HD patients. Working through the ESRD Networks, the FFBI promotes the placement of fistulae using 11 “Change Concepts” that encourage the development of specific strategies; these 11 Change Concepts have been identified to help the kidney community improve the rate of fistula placement. Five of these strategies emphasize the same goals as CPG 1 and Clinical Practice Recommendation (CPR) 1: education of patients regarding fistulae, protection of vessels, vessel mapping, and sufficient lead-time for fistula maturation (NVAII; www.fistulafirst.org). The breakthrough initiative has reset the goal for fistula creation to 65% by 2009.

RATIONALE

Characteristics of a patient’s arterial, venous, and cardiopulmonary systems will influence which access type and location are most desirable for each patient.^{22–27} The patient’s life expectancy and planned duration of CKD stage 5 therapy also can influence the type and location of the access. All patients should be evaluated as in Table 1.

Venipuncture complications may render veins potentially available for vascular access unsuitable for construction of a primary fistula. Patients and health care professionals should be educated about the need to preserve veins to avoid loss of potential access sites in the arms and maximize chances for successful fistula placement and maturation. Subclavian vein catheterization is associated with central venous stenosis.^{28–30} Significant subclavian vein stenosis generally will preclude the use of the entire ipsilateral arm for vascular access. Thus, subclavian vein catheterization should be avoided for temporary access in patients with kidney disease.³¹ The incidence of central vein stenosis and occlusion after upper-extremity placement of peripherally inserted long-term catheters (PICCs) and venous ports was 7% in 1 retrospective study of 150 patients.³² PICCs also are associated with a high incidence of upper-extremity thrombosis. The incidence of upper-extremity venous thrombosis varies between 11% and 85%, which leads to loss of potential upper-extremity fistulae.^{33–35} Because of the substantial risk for loss of useable upper-extremity veins and central venous stenosis with PICCs, the Work Group recommends strongly that PICCs not be used in patients with CKD.

Ideally, patients should have a functional permanent access at the time of dialysis therapy initiation. Function implies that the access not only delivers adequate blood flow for dialysis, but may be cannulated easily. In general, such an access has a flow of approximately 600 mL/min, is less than 0.6 cm below the surface of the skin, and has a minimal diameter of 0.6 cm (Rule of 6s) Both the size and anatomic qualities of venous and arterial components of primary fistulae can influence fistula maturation time. An aggressive policy of primary fistula creation may result in failures in patients with marginal anatomy. However, timely attempts to create a primary fistula before the anticipated need for dialysis therapy will allow adequate time for the fistula to mature and will allow sufficient time to perform another vascular access procedure if the first attempt fails, thus avoiding the need for temporary access. Early referral of a patient with CKD to a nephrologist is needed to facilitate CKD therapy with medications and diets that preserve kidney func-

Table 1. Patient Evaluation Prior to Access Placement

Consideration	Relevance
Patient History	
History of previous CVC	Previous placement of a CVC is associated with central venous stenosis.
Dominant arm	To minimize negative impact on quality of life, use of the nondominant arm is preferred.
History of pacemaker use	There is a correlation between pacemaker use and central venous stenosis.
History of severe CHF	Accesses may alter hemodynamics and cardiac output.
History of arterial or venous peripheral catheter	Previous placement of an arterial or venous peripheral catheter may have damaged target vasculature.
History of diabetes mellitus	Diabetes mellitus is associated with damage to vasculature necessary for internal accesses.
History of anticoagulant therapy or any coagulation disorder	Abnormal coagulation may cause clotting or problems with hemostasis of accesses.
Presence of comorbid conditions, such as malignancy or coronary artery disease, that limit patient's life expectancy	Morbidity associated with placement and maintenance of certain accesses may not justify their use in some patients.
History of vascular access	Previously failed vascular accesses will limit available sites for accesses; the cause of a previous failure may influence planned access if the cause is still present.
History of heart valve disease or prosthesis	Rate of infection associated with specific access types should be considered.
History of previous arm, neck, or chest surgery/trauma	Vascular damage associated with previous surgery or trauma may limit viable access sites.
Anticipated kidney transplant from living donor	Catheter access may be sufficient.
Physical Examination	
Physical Examination of Arterial System	
Character of peripheral pulses, supplemented by hand-held Doppler evaluation when indicated	An adequate arterial system is needed for access; the quality of the arterial system will influence the choice of access site.
Results of Allen test	Abnormal arterial flow pattern to the hand may contraindicate the creation of a radial-cephalic fistula.
Bilateral upper extremity blood pressures	Pressures determine suitability of arterial access in upper extremities.
Physical Examination of Venous System	
Evaluation for edema	Edema indicates venous outflow problems that may limit usefulness of the associated potential access site or extremity for access placement.
Assessment of arm size comparability	Differential arm size may indicate inadequate veins or venous obstruction which should influence choice of access site.
Examination for collateral veins	Collateral veins are indicative of venous obstruction.
Touriquet venous palpation with vein mapping	Palpation and mapping allow selection of ideal veins for access.
Examination for evidence of previous central or peripheral venous catheterization	Use of CVCs is associated with central venous stenosis; previous placement of venous catheters may have damaged target vasculature necessary for access.
Examination for evidence of arm, chest, or neck surgery/trauma	Vascular damage associated with previous surgery or trauma may limit access sites.
Cardiovascular Evaluation	
Examination for evidence of heart failure	Accesses may alter cardiac output.

tion. In addition, counseling patients about CKD stage 5 treatment options is essential to plan for ideal access (ie, PD and HD access) (see CPG 2) (Table 1).

The Work Group's consensus is that maturation of an AVG access site—defined as reduction of surgically induced swelling and the graft's adherence to its tunnel tissue—usually requires about 3 weeks. Thus, ideally, AVGs should be placed 3 to 6 weeks before use.

Long-term catheters are the method of choice for temporary access of longer than 1 week duration. Catheters are suitable for immediate use. To maximize their use-life, they should not be inserted until needed. However, the Work Group recommends that a catheter be used for dialysis access for as brief a period as necessary (see CPG 2).

A vein must be mature, both physically and functionally, before use for vascular access. The time required for fistula maturation varies among patients. The Work Group does not advise use of the fistula within the first month after construction because

premature cannulation of a fistula may result in a greater incidence of infiltration, with associated compression of the vessel by hematoma and permanent loss of the fistula. In general, allowing the fistula to mature for 6 to 8 weeks before investigating the reason for failure to mature is appropriate (see CPG 2). For a fistula to be considered successful, it must be usable. In general, a working fistula must have all the following characteristics: blood flow adequate to support dialysis, which usually equates to a blood flow greater than 600 mL/min; a diameter greater than 0.6 cm, with location accessible for cannulation and discernible margins to allow for repetitive cannulation; and a depth of approximately 0.6 cm (ideally, between 0.5 to 1.0 cm from the skin surface). This combination of characteristics can be remembered easily as the Rule of 6s.

Although there are no definitive data in the literature, any intervention that increases blood flow to the extremity may improve the chances of successful fistula development. Therefore, regular hand-arm exercises, with or without a lightly applied tourniquet, are recommended until the fistula matures. Failure of a fistula to mature occasionally is caused by venous side branches that drain critical flow from the primary vessel. Ligating these side branches may result in successful maturation (see CPG 6).

Studies relating to preoperative venous imaging/mapping for AVF construction underwent systematic review. Duplex ultrasound is the preferred method for preoperative vascular mapping. Vascular mapping in preparation for the creation of a vascular access refers to the evaluation of vessels, both arterial and venous, of patients with CKD who have selected HD therapy, and it should be performed in all patients before placement of an access. Preoperative vascular mapping was shown to substantially increase the total proportion of patients dialyzing with fistulae.³⁶⁻³⁹ Several studies support the 2.0- to 2.5-mm vein diameter threshold for successful creation of a fistula.^{39,40} Radiocephalic fistulae constructed in veins less than 2.0 mm in diameter had only a 16% primary patency at 3 months compared with 76% for those with veins greater than 2.0 mm.⁴⁰ In a pivotal study,³⁹ a threshold of 2.5-mm vein diameter, assessed by using duplex ultrasound, was used; this resulted in an increase in fistula creation to 63% compared with a retrospective 14% rate in the absence of vascular mapping.²² A similar study using the same duplex ultrasound criteria showed a fistula increase from 34% in historical controls to 64%. Importantly, in this study, duplex ultrasound altered the surgical plan based entirely on the surgeon's clinical evaluation, resulting in increased placement of fistulae.⁴¹

There is no generally accepted "standard" for what constitutes vascular mapping. The arterial evaluation should include pulse examination, differential blood pressure measurement, assessment of the palmar arch for patency, arterial diameter assessed by using duplex ultrasound, and the presence of arterial calcification. A preoperative arterial diameter less than 1.6 mm has been associated with a high failure rate in radiocephalic fistulae.^{42,43} Other studies suggested that a minimum diameter of 2.0 mm is required for successful fistula creation.³⁹ Venous evaluation should include a luminal diameter of 2.5 mm or greater, continuity with the proximal central veins, and absence of obstruction.³⁹ The central veins may be assessed indirectly by using duplex ultrasound.⁴⁴ Compared with invasive venography, duplex ultrasound had a specificity of 97% and sensitivity of 81% for detecting central vein occlusion.⁴⁵ Alternatively, venography or magnetic

resonance angiography (MRA) may be used to evaluate central veins.⁴⁶ (See CPR 1.4 for suitable imaging studies for central veins).

LIMITATIONS

There has been no study comparing vascular access surgery based only on the clinical evaluation to preoperative vascular mapping outcomes. Such a study would be the equivalent of requiring a randomized prospective study comparing the efficacy of pulmonary clinical evaluation (tactile fremitus and auscultation, ie, physical examination only) with a chest radiograph (imaging) in identifying lung pathological states. Such a study is unlikely, based on current data showing that vascular mapping increases fistula creation. Although the level of evidence of a prospective randomized trial is not available, the Work Group consensus based on many studies supports vascular mapping as a guideline.

GUIDELINE 2. SELECTION AND PLACEMENT OF HEMODIALYSIS ACCESS

A structured approach to the type and location of long-term HD accesses should help optimize access survival and minimize complications.

The access should be placed distally and in the upper extremities whenever possible. Options for fistula placement should be considered first, followed by prosthetic grafts if fistula placement is not possible. Catheters should be avoided for HD and used only when other options listed are not available.

2.1 The order of preference for placement of fistulae in patients with kidney failure who choose HD as their initial mode of KRT should be (in descending order of preference):

2.1.1 Preferred: Fistulae. (B)

2.1.1.1 A wrist (radiocephalic) primary fistula. (A)

2.1.1.2 An elbow (brachiocephalic) primary fistula. (A)

2.1.1.3 A transposed brachial basilic vein fistula: (B)

2.1.2 Acceptable: AVG of synthetic or biological material, such as: (B)

2.1.2.1 A forearm loop graft, preferable to a straight configuration.

2.1.2.2 Upper-arm graft.

2.1.2.3 Chest wall or “necklace” prosthetic graft or lower-extremity fistula or graft; all upper-arm sites should be exhausted.

2.1.3 Avoid if possible: Long-term catheters. (B)

2.1.3.1 Short-term catheters should be used for acute dialysis and for a limited duration in hospitalized patients. Noncuffed femoral catheters should be used in bed-bound patients only. (B)

2.1.3.2 Long-term catheters or dialysis port catheter systems should be used in conjunction with a plan for permanent access. Catheters capable of rapid flow rates are preferred. Catheter choice should be based on local experience, goals for use, and cost. (B)

2.1.3.3 Long-term catheters should not be placed on the same side as a maturing AV access, if possible. (B)
Special attention should be paid to consideration of avoiding femoral catheter access in HD patients who are current or future kidney transplant candidates. MRA imaging of both arteries and veins is the diagnostic procedure of choice for evaluating central vessels for possible chest wall construction.

2.1.4 Patients should be considered for construction of a primary fistula after failure of every dialysis AV access. (B)

- 2.1.5 While this order of access preference is similar for pediatric patients, special considerations exist that should guide the choice of access for children receiving HD. Please refer to CPR 8 for specific recommendations.**
- 2.1.6 In the patient receiving PD who is manifesting signs of modality failure, the decision to create a backup fistula should be individualized by periodically reassessing need. In individuals at high risk for failure (see the PD Adequacy Guidelines), evaluation and construction should follow the procedures in CPG 1 for patients with CKD stage 4.**
- 2.2 Fistulae:**
- 2.2.1 Enhanced maturation of fistulae can be accomplished by selective obliteration of major venous side branches in the absence of a downstream stenosis. (B)**
- 2.3 Dialysis AVGs:**
- 2.3.1 The choice of synthetic or biological material should be based on the surgeon's experience and preference. The choice of synthetic or biological conduits should consider local experience, technical details, and cost. (B)**
- 2.3.2 There is no convincing evidence to support tapered versus uniform tubes, externally supported versus unsupported grafts, thick-versus thin-walled configurations, or elastic versus nonelastic material. (A)**
- 2.3.3 While the majority of past experience with prosthetic grafts has been with the use of PTFE, other prosthetics (eg, polyurethane [PU]) and biological conduits (bovine) have been used recently with similar outcomes. (B)**
- 2.3.4 Patients with swelling that does not respond to arm elevation or that persists beyond 2 weeks after dialysis AV access placement should receive an imaging study or other noncontrast study to evaluate central venous outflow (see CPG 1). (B)**
- 2.4 Catheters and port catheter systems:**
- 2.4.1 The preferred insertion site for tunneled cuffed venous dialysis catheters or port catheter systems is the right internal jugular vein. Other options include the right external jugular vein, left internal and external jugular veins, subclavian veins, femoral veins, and translumbar and transhepatic access to the IVC. Subclavian access should be used only when no other upper-extremity or chest-wall options are available. (A)**
- 2.4.2 Ultrasound should be used in the placement of catheters. (B)**
- 2.4.3 The position of the tip of any central catheter should be verified radiologically. (B)**

RATIONALE

Order of Placement (CPG 2.1)

There are no randomized controlled trials (RCTs) comparing the recommended anatomic order of distal-to-proximal access construction. However, good surgical practice makes it obvious that when planning permanent access placement, one should always consider the most distal site possible to permit the maximum number of future possibilities for access.²³ In general, a peripheral-to-central sequence of fistulae construction should be envisioned in the ideal case, beginning with the “snuff box” fistula at the base of the thumb, followed by the standard Brescia-Cimino wrist fistula, followed by a forearm cephalic fistula at dorsal branch and finally a midforearm cephalic fistula. If a forearm fistula is not feasible, an antecubital fistula,⁴⁷ cephalic fistula at elbow, and, finally, a transposed basilic fistula should be considered. In cases in which a fistula is not constructed initially, a graft can be used as a “planned bridge” to a fistula. Failing forearm grafts can be converted to upper-arm fistulae, and lower-level fistulae can be converted to higher-level fistulae. If a graft is constructed, preference is given to the following sequence: forearm loop; upper-arm, straight or curved; upper-arm loop. All upper-extremity options should be considered before using the thigh. At times, “exotic” grafts can be constructed on the anterior chest wall or to the internal jugular vein. Even in these situations, a systematic radiological evaluation of the venous systems should be conducted before placement.

Maintaining long-term functioning access can be difficult and frustrating for physicians and patients; starting distally and moving proximally provides for the possibility of preserving as many potential sites as possible for future access creation. It is a tragedy for patients and caretakers alike to exhaust anatomic sites prematurely by initially bypassing more distal sites. The decision to use a more proximal site initially should be documented by preoperative imaging studies or the likelihood for the development of arterial “steal.”^{23,48} (See CPGs 1, 5, and 6.) However, if upper-extremity options have been exhausted, the anatomic locations left for permanent access are the thigh (where grafts^{49,50} and, less commonly, fistulae⁵¹ can be constructed) and upper chest, where a variety of graft accesses can be constructed.⁵² The possibilities in the chest usually are defined by preoperative evaluation of the central venous system and, at times, angiography⁵³ or MRA is required.⁵⁴ Because vascular access infection is intrinsically more likely in the thigh, access construction in this site usually is deferred to one of last resort. Graft patency in the thigh is minimally better than in the upper arm,⁵⁵ and the greater risk for infection mandates against its initial use. In extreme cases, the forgotten Thomas shunt can be constructed.⁵⁶

The preference of fistulae over all other forms of access arises from their functional advantages because of a lower rate of complications.

- Fistulae have the lowest rate of thrombosis⁵⁷ and require the fewest interventions,^{57,58} providing longer survival of the access.^{3,4,57,58} The number of access events is 3- to 7-fold greater in prosthetic bridge grafts than in native fistulae.^{4,57,58}
- As a result, costs of implantation and access maintenance are the lowest.^{4,6,8}
- Fistulae have lower rates of infection than grafts, which, in turn, are less prone to infection than percutaneous catheters and subcutaneous port catheter systems.⁵⁹

Vascular access infections in HD patients are common, can be severe, and contribute to infection as the second leading cause of death in patients with CKD stage 5.⁶⁰

- Fistulae are associated with increased survival and lower hospitalization.
 - Patients receiving catheters (RR = 2.3) and grafts (RR = 1.47) have a greater mortality risk than patients dialyzed with fistulae.¹⁴
 - Epidemiological evidence also indicates that greater use of fistulae reduces mortality and morbidity.¹⁴⁻¹⁷

Wrist (radiocephalic)⁶¹ and elbow (brachiocephalic)⁶² primary fistulae are the preferred types of access because of the following characteristics:

- Superior patency to other accesses after they are established and matured.^{3,4,23,24,57,58,63-69}
- Lower complication rates compared with other access options,^{3,23,24,63-69} including lower incidence of conduit stenosis, infection, and vascular steal phenomenon.
- In most cases, flow increases early (first week), with little additional increase as the fistula matures (see CPG 5).⁷⁰⁻⁷² Failure of fistula flow to increase is a sign of access dysfunction (see CPG 4).

The Work Group concluded that the 3 advantages of wrist and elbow primary fistulae, as listed, outweigh the following 4 potential disadvantages:

- The vein may fail to enlarge and/or increase blood flow to satisfactory levels (ie, fail to mature).^{23,24,73}
- Comparatively long maturation times (1 to 4 months) must elapse after creation of these fistulae before they can be used. Thus, the access must be created several months in advance of the anticipated need for dialysis or an alternative temporary method of vascular access must be used while the fistula matures (see CPG 1).
- In some individuals, the vein may be more difficult to cannulate than an AVG. However, this can be addressed by mobilizing the vein superficially.⁷⁴
- The enlarged vein may be visible in the forearm and be perceived as cosmetically unattractive by some individuals.

The wrist fistula is the first choice of access type because of the following advantages:

- It is relatively simple to create.^{61,75}
- It preserves more proximal vessels for future access placement.^{23,24,73}
- It has few complications. Specifically, the incidence of vascular steal is low, and in mature fistulae, thrombosis and infection rates are low.^{3,4,24,57,58,65,66}

The only major disadvantage of the wrist (radiocephalic) fistula is a lower blood flow rate (BFR) compared with other fistula types. If adequate flow to support the HD prescription is not achieved with a radiocephalic fistula within 4 months after appropriate evaluation for correctable or modifiable factors (see CPG 4), another type of access should be established (see CPG 1). The major drawback of a radiocephalic fistula is the relatively high primary failure rate (15%) and only moderate secondary patency rate at 1 year (62%).⁷⁶

The elbow (brachiocephalic) primary fistula is the second choice for initial placement of an access. Its advantages include the following:^{62,63,68,77-79}

- It has a higher blood flow compared with the wrist fistula.
- The cephalic vein in the upper arm usually is comparatively easier to cannulate and is easily covered, providing a potential cosmetic benefit.

The disadvantages of the elbow (brachiocephalic) primary fistula include the following:^{26,66,77-80}

- It is slightly more difficult to create surgically than a radiocephalic fistula.
- It may result in more arm swelling than a radiocephalic fistula.
- It is associated with an increased incidence of steal compared with a radiocephalic fistula.
- It is associated with a greater incidence of cephalic arch stenosis than a forearm radiocephalic fistula.

If a wrist radiocephalic or elbow brachiocephalic fistula cannot be created, the patient should be considered for a transposed basilic vein fistula. In some cases, a forearm graft can be a viable alternative to mature the venous system for an elbow fistula as a secondary access. Transposed brachiobasilic fistulae have several disadvantages compared with other fistulae:^{62,66,79,81-83}

- The transposition procedure may create significant arm swelling and patient pain.
- They have a greater incidence of steal and arm swelling than other fistula types.
- They are more technically challenging, especially in obese individuals.

The NVAII, now recognized as the FFBI, is a CMS-mandated 3-year CKD Stage 5 Network improvement project emphasizing a fistula-first approach.⁸⁴⁻⁸⁸ The Work Group agrees with the “mission statement” to “increase the likelihood that every eligible patient will receive the most optimal form of vascular access for him/her, in the majority of cases an arterial venous fistula.” For FFBI to optimally succeed, all its recommendations must be followed (NVAII, www.fistulafirst.org; last accessed 2/20/2006). However, the Work Group recognizes that in some cases, the “fistula first at all costs” approach may not be the most cost-effective or optimal for each individual. A functional fistula is the goal, not the insertion of a fistula with a poor chance at maturing. A graft can be used as a “planned bridge” to a fistula, and failing forearm grafts can be converted to upper-arm fistulae. Similarly, fistulae at a lower level can be converted to more proximal fistulae.

AVGs have the following advantages:

- A large surface area and vessel available for cannulation initially.^{64,89-91}
- They are technically easy to cannulate.⁶⁴
- The lag-time from insertion to maturation is short. For PTFE-derived grafts, it is recommended that not less than 14 days should elapse before cannulation to allow healing and incorporation of the graft into local tissues,^{25,64,92} although ideally, 3 to 6 weeks are recommended.

- Multiple insertion sites are available.^{26,64,67,90-94}
- A variety of shapes and configurations is available to facilitate placement.^{64,67,89-92,94}
- It is easy for the surgeon to handle, implant, and construct the vascular anastomosis.^{25,26,64,91,92,94-104}
- The graft is comparatively easy to repair either surgically^{65,94,101,105-107} or endovascularly.¹⁰⁸⁻¹¹²

The sum of the available data, until recently, supported PTFE grafts over other biological and other synthetic materials, based on lower risk for disintegration with infection, longer patency, better availability, and improved surgical handling. Biological grafts (bovine heterografts) have greater reported rates of complications compared with synthetic grafts.^{91-93,100}

For nearly 2 decades, PTFE has been the material of choice for bridge grafts. However, during the past decade, modifications¹¹³ and the use of other materials, such as PU,^{114,115} cryopreserved femoral vein,^{116,117} bovine mesenteric vein, and hybrids¹¹⁸ with self-sealing composite material, have been developed and used.¹¹⁹ None of these has shown any “survival” patency over plain PTFE, except for the composite/PU graft. The latter has an advantage because of its self-sealing property to be cannulated within hours, *if needed*, for dialysis. As a result, it can be placed without having to use a catheter for initiation of dialysis therapy, in some cases. Direct comparisons between PTFE and human umbilical cord vein grafts and other synthetic polymers have not been made.

The lure to construct AVGs using larger more proximal vessels should be resisted. Although these have higher flow and better initial function and/or patency, they limit potential sites for future placement.^{23,25,73} A synthetic dialysis AVG is expected to last 3 to 5 years.⁷³ Grafts using smaller more peripheral vessels can experience more frequent thromboses that require treatment. However, these grafts have the advantage of preserving more proximal sites for new access creation should this become necessary in the future.^{4,23-25} The 2 preferred graft site types are the antecubital loop graft and upper-arm curved graft. Femoral placement of access has been associated with proximal venous stenosis, which may be problematic later in patients receiving kidney transplantation.

Potential sites for arterial inflow include radial artery at the wrist, brachial artery in the antecubital fossa, brachial artery in the lower portion of the arm, brachial artery just below the axilla, axillary artery, and femoral artery. Potential sites for venous outflow include median antecubital vein, proximal and distal cephalic vein, basilic vein at the level of the elbow, basilic vein at the level of the upper arm, axillary vein, jugular vein, and femoral vein.

Fistulae (CPG 2.2)

A 70% AV “working” fistula access rate can be achieved, even in patients who have diabetes⁸⁵⁻⁸⁸ and women.⁸⁴ Results from the Dialysis Outcomes and Practice Patterns Study (DOPPS) indicate that the fistula can be cannulated as early as 1 month after construction.¹²⁰ Thus, an access that shows evidence of maturation failure on physical examina-

tion or by using duplex ultrasound⁷² should undergo investigation. A study found that combining venous diameter (>0.4 cm) and flow volume (>500 mL/min) increased the predictive power of adequate fistula maturation to 95% (19 of 20) versus neither criterion met (33%; 5 of 15).⁷² Women were less likely to have an adequate outcome vein diameter of 0.4 cm or greater: 40% (12 of 30) compared with 69% in men (27 of 39). However, of note, the accuracy of experienced dialysis nurses in predicting eventual fistula maturity was excellent at 80% (24 of 30).

Many accesses with multiple outflow veins can be salvaged by ligation of side branches.^{121,122} As more older patients have fistula constructions, the possibility of the access failing to mature is likely to increase.¹²³ Failure to mature should be evaluated by 6 weeks after construction by physical examination and, if needed, ultrasound.^{72,124} Prompt correction should be undertaken.^{125,126}

Exercises to Mature the Fistula (B-)

Isometric exercise has been shown to increase the diameter of forearm veins,¹²⁷ and exercise should be prescribed if there is sufficient lead time before surgery.

Dialysis AVGs (CPG 2.3)

Graft patency is independent of manufacturer,¹²⁸⁻¹³⁰ unaffected by an external wrap around the graft,¹³¹ and is not affected by wall thickness.^{131,132} The provision of a cuff or hood at the venous outflow to enlarge the outflow and reduce shear stress has produced only a marginal increase in graft patency.¹³³⁻¹³⁶ To control inflow or shear stresses, a variety of tapers have been examined at both arterial and venous anastomoses. There seems to be little effect from using a 6- to 8-mm graft compared with the standard straight 6 mm.¹³⁷ A straight 8 mm also can be used and gives the highest flows.¹³⁸ Arterial tapers are used to restrict inflow and reduce the risk for steal syndrome. Their effectiveness is questionable, and they may negatively affect patency and survival.¹³⁹

As previously discussed in CPG 2.1, a variety of modifications to the graft or other materials is available to the surgeon.¹¹³⁻¹¹⁹ Several studies are available to guide the interested reader.¹⁴⁰⁻¹⁴² Predictors for successful placement of AVGs have been analyzed.¹⁴³

The neointimal hyperplasia that produces stenosis has been considered to be, in part, a reaction to injury. No improvement in patency was noted in an RCT that compared staples with standard sutures at the vascular anastomoses.¹⁴⁴ Use of nitinol surgical clips produces less intimal damage than conventional sutures,¹⁴⁵ but RCTs showing a resulting change in outcome are lacking.

It should be remembered that a short segment of graft material can be used to develop a predominant fistula at the elbow.¹⁴⁶

Catheters and Port Catheter Systems (CPG 2.4)

Basic Principles

1. Long-term catheter systems—tunneled cuffed catheters (TCCs) and tunneled port catheter systems—should have their tips within the right atrium confirmed by fluoroscopy for optimal flow.

2. Short-term catheter tips should be in the superior vena cava (SVC) and confirmed by using chest radiograph or fluoroscopically at the time of placement before initiating dialysis therapy.
3. Uncuffed HD catheters should only be used in hospitalized patients and for less than 1 week. Uncuffed femoral catheters should only be used in bed-bound patients.
4. There should be a plan to: i) discontinue, or ii) convert any short-term catheter to a long-term catheter within 1 week.
5. Long-term catheters and port catheter systems, if possible, should not be placed on the same side as a maturing AV access.
6. Femoral catheters should be a suitable length to deliver high-volume flow and be positioned to minimize recirculation. One that does not reach the IVC frequently cannot deliver 300 mL/min. Longer catheters (24 to 31 cm) are more likely to reach the desired position, although there is more resistance from the catheter length.
7. There currently is no proven advantage of 1 long-term catheter design over another, although this area is undergoing a great deal of study. Catheters capable of a rapid BFR (>350 mL/min at prepump pressures not more negative than 250 mm Hg) are preferred. Catheter choice should be based on local experience, goals for use, and cost.
8. **Pediatric exception:** Some pediatric data exist suggesting that the twin-catheter system may provide better performance than the standard dual-lumen catheter configuration. Please refer to the Pediatric Guidelines.
9. Dialysis port catheter systems may be used in lieu of long-term catheters for a bridge access or as a permanent access for patients.

Catheter devices can be defined according to design, intent, and duration of use. For the entirety of the discussion, catheters will be referred to as acute short-term noncuffed catheters (NCCs) or long-term TCCs intended as access for dialysis over weeks to months. The term right arterial catheter should be avoided. They are either NCCs and placed predominantly for acute use (3 to 5 dialyses within 1 week) or TCCs and placed when the need for dialysis therapy is believed to be longer than 1 week. Long-term catheters usually are tunneled. The catheters themselves usually are dual lumen and can be coaxial (now unusual) or “double D” (most common) and are either stepped (ie, the arterial and venous tips are staggered by 1 to 2 cm) or split so that the tips are not next to each other. Newer designs incorporate a spiral separator allowing either lumen to be used as the arterial port catheter system.

Port catheter systems are a distinct kind of catheter-based device system in which the catheter tubing is connected to a subcutaneously placed device. In the only port device currently in use for HD, access to the catheter lumen occurs percutaneously by using a buttonhole technique. These port catheter systems have a pinch valve mechanism that requires special cannulation needles to open the valves accessing the circulation.

Tunneled Cuffed Venous Catheters

Tunneled cuffed venous catheters have been shown to have the following advantages, relative to other access types:

1. They are universally applicable.
2. They can be inserted into multiple sites relatively easily.
3. No maturation time is needed, ie, they can be used immediately.
4. Skin puncture not required for repeated vascular access for HD.
5. They do not have short-term hemodynamic consequences, eg, changes in cardiac output or myocardial load.
6. They have lower initial costs and replacement costs.
7. They possess the ability to provide access during a period of months, permitting fistula maturation in patients who require immediate HD.^{73,147-155}
8. They facilitate correcting thrombotic complications.^{147,156-158}

Tunneled cuffed venous catheters possess the following disadvantages relative to other access types:

1. High morbidity caused by:
 - Thrombosis^{148,156-158} and
 - Infection.^{30,148,159}
2. Risk for permanent central venous stenosis or occlusion.^{30,148,160,161}
3. Discomfort and cosmetic disadvantage of an external appliance.
4. Shorter expected use-life than other access types.^{64,69,156,162}
5. Overall lower BFRs, requiring longer dialysis times.¹⁶³

Tunneled cuffed venous catheters should be placed in an area where ultrasound guidance and fluoroscopy are available. The preferred site is the right internal jugular vein because this site offers a more direct route to the right atrium than the left-sided great veins. Catheter insertion and maintenance in the right internal jugular vein are associated with a lower risk for complications compared with other potential catheter insertion sites.¹⁶⁴⁻¹⁶⁶ Catheter placement in the left internal jugular vein potentially puts the left arm's vasculature in jeopardy for a permanent access on the ipsilateral side. Catheter placement in the left internal jugular vein may be associated with poorer BFRs and greater rates of stenosis and thrombosis.^{150,166} Femoral and translumbar vein placement are associated with the greatest infection rates compared with other sites.¹⁶⁷ Catheters should not be placed in the subclavian vessels on either side because of the risk for stenosis,^{30,168} which can permanently exclude the possibility of upper-extremity permanent fistula or graft. Catheters should not be placed on the same side as a slowly maturing permanent access. Catheter-induced central vein stenosis is related to the site of insertion,^{169,170} number and duration of catheter uses, and occurrence of infection.^{170,171}

Ultrasound insertion has been shown to limit insertion complications.¹⁷²⁻¹⁷⁴ Evidence is sufficient to recommend that ultrasound guidance be used for all insertions because it minimizes inadvertent arterial cannulation.^{175,176} Fluoroscopy allows ideal catheter tip placement^{177,178} to maximize blood flow.¹⁷⁹ At the time of placement, the

tip(s) of the catheter should be in the midatrium, with the arterial lumen facing the mediastinum.

Use of catheters presents a conundrum because of the need for immediate vascular access versus the risk for complications from prolonged catheter use.¹⁸⁰ Blood flow for dialysis obtained from catheters typically is less than that obtained from fistulae or grafts.² Catheter length becomes crucial when TCCs are placed in the femoral area or through the translumbar or transhepatic routes.¹⁸¹ Correlations between arterial prepump or venous return pressures and dialyzer blood flows are not linear.^{182,183} It is possible to develop an optimal relationship between catheter length and diameter to achieve standardized (average, low, and high) blood flows regardless of the lengths of the catheters by incorporating the pressure-flow relationships, as well as Poiseuille's equation.¹⁸³

Use of catheters as first choice for long-term vascular access is discouraged because of infection, susceptibility to thrombosis, and inconsistent delivery of blood flow. In patients with documented inadequate vascular access anatomy, use of catheters is feasible with both double-lumen¹⁸⁴⁻¹⁸⁸ and twin-catheter systems.¹⁸⁹⁻¹⁹¹ However, exceptions may occur in children.

In the United States, the demand for greater blood flows to reduce treatment times has resulted in catheters with larger lumens being placed. A variety of catheters can consistently deliver a flow greater than 350 mL/min to the dialyzer at prepump pressure of -200 to -250 mm Hg. The decision to use a step or a split design should be decided by local preferences. In general, all catheters will develop recirculation at some point,^{182,192} particularly if the arterial and venous blood tubing are reversed for any reason.¹⁹³ This is minimized by using a split-tip catheter,^{194,195} but other designs are likely to produce the same effect.

The decision to use the femoral vein for long-term access (catheter or graft) as reported by some^{196,197} should be undertaken with great care. Any patient who has the option of undergoing a kidney transplantation should not have a femoral catheter placed to avoid stenosis of the iliac vein, to which the transplanted kidney's vein is anastomosed. The Work Group recommends the concept of shared governance in this type of decision,¹⁹⁸ with both dialysis staff and transplant team planning long-term access for such patients. There are no data on the effect of catheter length from the femoral vein site. Although length increases resistance, it also reaches anatomic sites with greater IVC flow. If dialysis blood flow is less than 300 mL/min from a properly placed femoral catheter, guidewire exchange to a longer catheter should be considered.

Noncuffed Double-Lumen Catheters

These catheters are suitable for percutaneous bedside insertion and provide acceptable BFRs (300 mL/min) for temporary HD.^{64,147,161,199,200} These catheters are suitable for immediate use, but have a finite use-life and therefore should not be inserted until they are needed.^{64,147,161} The rate of infection for internal jugular catheters suggests they should be used for no more than 1 week.^{60,64,147,161,201,202} Infection and dislodgment rates for femoral catheters require that they be left in place for no more than 5 days and only in bed-bound patients with good exit-site care. To minimize recirculation, femoral catheters

should be at least 19 cm long to reach the IVC.²⁰³ The Work Group believes that TCCs are preferred for longer durations of HD therapy over NCCs because they are associated with lower infection rates and greater BFRs.^{60,64,147,149,151-153,155,161,184,201-204} Short-term catheters may be used for up to 1 week. Beyond 1 week, the infection rate increases exponentially. Actuarial analysis of 272 catheters (37 TCCs versus 235 NCCs) showed a difference in infection rates by 2 weeks.²⁰⁵ Infection rates per 1,000 days at risk for NCCs were more than 5 times as great as with internal jugular TCCs and almost 7 times greater with femoral NCCs.²⁰⁵

Ultrasound-directed cannulation of NCCs minimizes insertion complications, as it does with TCCs, and should be used when available.^{206,207} Because most NCCs are placed at the bedside, the need for a postinsertion chest radiograph after internal jugular or subclavian insertion is mandatory to confirm the position of the catheter tip in the SVC and exclude such complications as pneumothorax and hemothorax.^{28,64,147,151,208-212} Although there are no studies reporting on the safety of patients with NCCs going home while awaiting placement at a dialysis center, the Work Group believes that the risk for infection, inadvertent removal, hemorrhage, air embolism, and patient comfort mandates that patient safety come first. Therefore, a patient with an NCC should not be discharged. A short-term catheter can be converted to a TCC if there is no evidence of active infection.²¹³

Port Catheter Systems

In an effort to surmount many of the infection problems associated with long-term catheters, totally implantable access systems have been designed.^{214,215} Clinical data support the use of subcutaneous HD access systems as a bridge device²¹⁶⁻²¹⁸ in patient populations at greater risk for fistula maturation failure or needing longer periods to mature fistulae (>1 operation or multiple attempts need to be made). Studies also documented the utility of subcutaneous HD access systems in catheter-dependent patients who have exhausted other access options²¹⁹ and in children.²²⁰ The most significant limitation of these devices has been infection, particularly of the implantation pocket. Although these can be treated successfully,²²¹ prevention is key. Recommended procedures for accessing and maintaining these devices are mandatory to achieve optimal device performance.

Complications of catheter access are detailed more fully in CPG 7, and accessing the patient's circulation is discussed in CPG 3.

LIMITATIONS

The recommendations made in this section are based on the best currently available information and basic principles of surgery. No RCTs will ever be performed comparing the 3 access types available, nor should they be in view of the known risks of catheters. However, developments in the future of synthetic materials or the prevention of neointimal hyperplasia may permit such trials.

SUMMARY

Management of the patient who requires HD access for KRT demands continuous attention from the VAT. With the increase in incidence of HD-dependent patients with CKD

within our population, the multidisciplinary KDOQI CPGs and CPRs presented provide a pathway and strategy for HD access insertion and/or creation. The most appropriate initial access depends on immediate need for HD, history and physical examination findings, and suitability of available veins in the extremity. Percutaneous catheter-based access affords the luxury of immediate access and absence of requirement for cannulation; however, these devices are plagued by their propensity for infection, thrombosis, inadequate blood flow, and—most importantly—damage to large central veins, leading to stenosis and jeopardizing long-term permanent access. The fistula access, while at times less successful in the immediate short term, is always the preferred long-term access type because of its greater longevity, fewer interventions for maintenance, and lower infection rates. The surgeon should focus on sites distally on the extremity, reserving proximal sites for potential future access insertions should the initial access site fail. In the absence of a suitable vein for a fistula, prosthetic access can be considered. When all sites in the upper extremities have been exhausted, the lower extremity or chest should be considered for access creation. Long-term catheters and port catheter systems should be reserved for last except in those with severe comorbidities, such as congestive heart failure (CHF) and severe peripheral vascular disease (PVD), the very elderly, those with inadequate vascular anatomy, or those with limited life expectancy.

GUIDELINE 3. CANNULATION OF FISTULAE AND GRAFTS AND ACCESSION OF HEMODIALYSIS CATHETERS AND PORT CATHETER SYSTEMS

The use of aseptic technique and appropriate cannulation methods, the timing of fistula and graft cannulation, and early evaluation of immature fistulae are all factors that may prevent morbidity and may prolong the survival of permanent dialysis accesses.

3.1 Aseptic techniques:

3.1.1 For all vascular accesses, aseptic technique should be used for all cannulation and catheter accession procedures. (See Table 2.) (A)

3.2 Maturation and cannulation of fistulae:

3.2.1 A primary fistula should be mature, ready for cannulation with minimal risk for infiltration, and able to deliver the prescribed blood flow throughout the dialysis procedure. (See Table 3.) (B)

3.2.2 Fistulae are more likely to be useable when they meet the Rule of 6s characteristics: flow greater than 600 mL/min, diameter at least 0.6 cm, no more than 0.6 cm deep, and discernible margins. (B)

3.2.3 Fistula hand-arm exercise should be performed. (B)

3.2.4 If a fistula fails to mature by 6 weeks, a fistulogram or other imaging study should be obtained to determine the cause of the problem. (B)

3.3 Cannulation of AVGs:

Grafts generally should not be cannulated for at least 2 weeks after placement and not until swelling has subsided so that palpation of the course of the graft can be performed. The composite PU graft should not be cannulated for at least 24 hours after placement and not until swelling has subsided so that palpation of the course of the graft can be performed. Rotation of cannulation sites is needed to avoid pseudoaneurysm formation. (See Table 4.) (B)

3.4 Dialysis catheters and port catheter systems:

Infection-control measures that should be used for all HD catheters and port catheter systems include the following:

3.4.1 The catheter exit site or port cannulation site should be examined for proper position of the catheter/port catheter system and absence of infection by experienced personnel at each HD session before opening and accessing the catheter/port catheter system. (B)

3.4.2 Changing the catheter exit-site dressing at each HD treatment, using either a transparent dressing or gauze and tape. (A)

3.4.3 Using aseptic technique to prevent contamination of the catheter or port catheter system, including the use of a surgical mask for staff and patient and clean gloves for all catheter or port catheter system connect, disconnect, and dressing procedures. (A)

Table 2. Skin Preparation Technique for Subcutaneous AV Accesses

- Locate, inspect and palpate the needle cannulation sites prior to skin preparation. Repeat prep if the skin is touched by the patient or staff once the skin prep has been applied, but the cannulation not completed.
- Wash access site using an antibacterial soap or scrub and water.
- Cleanse the skin by applying 2% chlorhexidine gluconate/70% isopropyl alcohol or 70% alcohol and/or 10% povidone iodine as per manufacturer's instructions for use.

Notes:

- 2% chlorhexidine gluconate/70% isopropyl alcohol antiseptic has a rapid (30 s) and persistent (up to 48 hr) antimicrobial activity on the skin. Apply solution using back and forth friction scrub for 30 seconds. Allow area to dry. Do not blot the solution.
- Alcohol has a short bacteriostatic action time and should be applied in a rubbing motion for 1 minute immediately prior to needle cannulation.
- Povidone iodine needs to be applied for 2-3 minutes for its full bacteriostatic action to take effect and must be allowed to dry prior to needle cannulation.
- Clean gloves should be worn by the dialysis staff for cannulation. Gloves should be changed if contaminated at any time during the cannulation procedure.
- New, clean gloves should be worn by the dialysis staff for each patient with proper infection control measures followed between each patient.

RATIONALE

There is considerable evidence that the use of maximal sterile precautions, as opposed to clean aseptic technique, for cannulation of AV accesses and catheter accession is both impractical and unnecessary.²²²⁻²²⁵ However, the importance of strict dialysis precautions²²⁶ and aseptic technique²²² cannot be overemphasized in the prevention and minimization of all access infection.²²⁷ Despite the general acceptance of the importance of standard precautions for hand washing and glove changes, these simple acts to minimize transmission of disease frequently are skipped. An audit in a selection of Spanish HD units examined opportunities to wear gloves and wash hands per the standard preventive guidelines (high-risk activities of connection, disconnection, and contact between patients during dialysis). Gloves were worn by only 19% and hands were washed after

Table 3. Technique for Mature AVF Cannulation

Technique	Rationale
After skin preparation, apply a tourniquet to increase the venous pressure, and pull skin taut in opposite direction of needle insertion. Avoid excessive pressure to the cannulation site to prevent flattening of the vessel. Stabilize but do not obliterate the vessel.	Compresses peripheral nerve endings between epidermis and dermis. Increases surface tension thereby facilitating smoother incision of skin with less surface area contacting cutting edge of needle. Enables better stabilization of graft or vessel to be cannulated.
For easily palpated vessel, use approximately 25° angle with the bevel up. Arterial needle placement can be in antegrade (up or in the direction of the blood flow) or retrograde (down or against the direction of blood flow). The venous needle should always be in the same direction as the blood flow.	Less steep angles increase risk of dragging cutting edge of needle along surface of vessel. Steeper angles increase risk of perforating underside (backwall) of vessel. Needle direction of the venous needle in the same direction as the blood flow will prevent excessive pressure at the needle site. The arterial needle in either direction will not increase the risk of recirculation as long as the access blood flow is greater to the blood pump setting.
Once the vessel has been penetrated:	Any manipulation may traumatize the intima of the vessel. The use of a backeye needle will eliminate the need to rotate the needle due to poor flows.
<ul style="list-style-type: none"> • Advance the needle slowly with cutting edge facing top of vessel and do not rotate axis. 	Pressing the needle shaft flat against the skin moves the needle tip from the desired position within the vessel lumen
<ul style="list-style-type: none"> • Tape the needle at the same angle or one similar to the angle of insertion 	Avoid trauma to any intima by dragging cutting edge along it. Avoid pressing cutting edge into intima when applying pressure for HD.
<ul style="list-style-type: none"> • Remove needle at same or angle similar to angle of insertion, and NEVER APPLY PRESSURE BEFORE NEEDLE IS COMPLETELY OUT. 	

Table 4. Technique for AVG Cannulation

Technique	Rationale
After skin preparation, pull skin taut in opposite direction of needle insertion. Avoid excessive pressure to the cannulation site to stabilize and prevent flattening of the graft material.	Compresses peripheral nerve endings between epidermis and dermis. Facilitates smoother incision of skin with less surface area contacting cutting edge of needle. Enables better stabilization of graft or vessel to be cannulated.
Use approximately 45° angle of insertion.	Less steep angles increase risk of dragging cutting edge of needle along surface of vessel. Steeper angles increase risk of perforating underside of vessel.
Once the vessel has been penetrated, there are basically 2 methods employed in current practice:	
a) Advance the needle slowly with cutting edge facing top of vessel and do not rotate axis.	a) Any manipulation may traumatize the intima of the vessel. This is the preferred method for routine AVG cannulation technique.
b) For a deep, hard to palpate AVG immediately rotate the axis of the needle 180° and advance slowly with bevel cutting edge facing bottom of the vessel.	b) Rotating the axis avoids traumatizing the top of intima and prevents the tip of the needle from entering the backside of the graft material. This should only be utilized when the graft backwall location is difficult to determine and the risk of continuing the needle advancement into the backwall is high.
Tap the needle at the same angle or one similar to the angle of insertion.	Pressing the needle shaft flat against the skin moves the needle tip from the desired position within the vessel lumen.
Remove needle at same or angle similar to angle of insertion, and NEVER APPLY PRESSURE BEFORE NEEDLE IS COMPLETELY OUT.	Avoid trauma to any intima by dragging cutting edge along it. Avoid pressing cutting edge into intima when applying pressure for HD.

patient contact on only 32% of all occasions.²²⁸ Mandatory hand washing before patient contact occurred only 3% of the time. A decade later, wearing of gloves improved to 92%, but the practice of hand washing before or after these patient-oriented procedures remained low at 36% after and 14% before such activities.²²⁹ Greater adherence was found in acute than in long-term HD units. A greater patient-nurse ratio independently influenced hand-washing rates. With the increasing microbial resistance to mainstream antibiotics,²³⁰ infection prevention must be considered the first rule of vascular access maintenance.²³¹ Data from prospective studies in both Canada and the United States clearly show that great variability exists between centers in infection rates, indicating the need to have not only a national registry, but also a local (ie, in-center) infection surveillance program.²³²⁻²³⁴ Increased awareness at the individual center level is key to stemming access infection and its extreme consequences, such as endocarditis and metastatic infections (eg, spinal abscesses), conditions that are disabling at best, sometimes fatal, and prohibitively costly to treat.^{235,236}

In the effort to prevent infection, it is not only staff that must be vigilant to potential breaks in technique and the need for the appropriate use of masks. Patients also must be taught that lapses in their use of masks and poor personal hygiene are known to increase their risk for infection. Patients with type 2 diabetes are at increased risk for nasal staphylococcal carriage and catheter-related bacteremia (CRB) as a result.^{237,238}

Maturation and Cannulation of Fistulae (CPG 3.2)

If the fistula is created with both adequate inflow artery and outflow vein, the increased flow in the vein should be immediately apparent postoperatively, evidenced by larger appearance and the presence of a continuous audible and palpable thrill along the vein, as well as actual flow measurements.¹²⁶ Experienced staff should examine the fistula and the outflow vein each time the patient comes to dialysis to monitor the maturation progress. Aspects of the physical examination are summarized in Table 5. The ability of

Table 5. Access Physical Examination

Exam Steps	Fistula (Normal)	AVG (Normal)	Stenosis or Poor Maturation (Abnormal)	Infection or Steal Syndrome (Abnormal)
Look	Well developed main venous outflow, no irregular/dilated areas or aneurysm formations, areas of straight vein that can be used for cannulation. Vessel partially collapses when arm is elevated above head.	Uniform sized graft in a loop or straight configuration. No irregular areas or aneurysm formations with organized site rotation used for cannulation sites.	Fistula with poor maturation—multiple venous outflow veins (accessory veins), poorly defined cannulation areas. Fistula: Stenosis can occur in artery or any of the venous outflow veins. Look for a narrowing of the outflow vein or aneurysm formations. Fistula or Graft: Dilated neck veins or small surface collateral veins in the arm or neck above the vascular access.	Infection: Redness, swelling, broken skin, drainage, induration. Steal Syndrome: Hand of the access limb may appear discolored due to poor arterial blood flow to the hand. Check nail beds, fingers and hand for skin color changes.
Listen with a stethoscope	Low pitch continuous diastolic and systolic	Low pitch continuous diastolic and systolic	High pitch discontinuous systolic only	Steal Syndrome: Fistula may have a very strong bruit
Feel with your finger tips	Thrill at the arterial anastomosis and throughout the entire outflow vein that is easy to compress	Thrill strongest at the arterial anastomosis, but should be felt over entire graft and easy to compress	Fistula: Pulse at the site of a stenotic lesion Pulse has a water-hammer feel Graft: Thrill and/or pulse strong at the site of a stenotic lesion pulse has a water-hammer feel. A graft with a low intra-access blood flow feels mushy. Local area of the graft that feels mushy or irregular in shape can be a site of aneurysm formation.	Infection: Warm to touch, swelling Steal Syndrome: Feel bilateral limbs (hands and fingers) and compare for the access limb to be the same as the nonaccess limb. Compare temperature, grip strength and range of motion, and any complaints of pain. If the access limb has any major differences than the nonaccess limb, consider steal syndrome.

“trained, experienced dialysis nurses” to accurately predict eventual fistula maturity is excellent.⁷² This is even more reason to have a protocol for regular clinical examination in place in dialysis centers to teach the skills of physical examination (see CPG 4 and CPG 5) to all staff members and assess the developing fistula and not focus on the access in current use only. The optimal time to do this examination is before fluid removal because hypotension can confound the findings. Patients who are not yet on dialysis therapy should be taught how to perform self-examination and be given appropriate contact information for questions and concerns. Poor prognostic signs, such as significant decrease in the thrill, should be referred immediately back to the surgeon or the interventionalist for prompt evaluation and intervention. At a minimum, all newly created fistulae must be physically examined by using a thorough systematic approach by a knowledgeable professional 4 to 6 weeks postoperatively to ensure appropriate maturation for cannulation.²³⁹ The steps for cannulation are summarized in Table 3.

Protocol for Initial Cannulation of AVFs

If the physical assessment has shown that the fistula is adequately matured, ideally, the next step is to perform a trial cannulation. In general, the earliest that this situation occurs is when the vein diameter is greater than 0.4 cm, has a flow greater than 500 mL/min,⁵⁹ and at least 1 month has elapsed since fistula creation⁶⁰ (Table 3). If possible, the trial cannulation of the fistula should be done on a nondialysis day. This serves to eliminate any potential complications associated with the administration of heparin.

If a trial cannulation is not possible, it is best to perform the initial cannulation of the new access at the patient's midweek HD treatment. Performing the initial cannulation midweek helps avoid such complications as fluid overload and elevated chemistry test results associated with the weekends.

To ensure that the needle is placed properly, needle placement should be confirmed with a normal saline flush before connecting the needles to the blood pump and starting the pump. Blood return alone is not enough to show good needle placement. One option to easily check for proper needle placement is the use of "wet" needles. The needle is purged of air and the saline in the attached syringe is used to flush the needle. If an infiltration has occurred, the normal saline is less harmful to the surrounding AVF tissue. The wet needle also prevents the risk for a blood spray or spill if dry needles are used for cannulation and the caps are opened to "bleed out" the needle from the air. The opening of the needle is a risk for blood exposure to the dialysis team member, patient, and nearby patients. For these reasons, use of a wet needle is a safer technique for the AVF, patient, and dialysis team members, especially for the initial AVF cannulation. This option should be considered as part of the dialysis unit's cannulation policy and procedures. The recommended procedure is described next.

1. Attach a 10-mL syringe filled with 8 mL of normal saline solution to the AVF needle, but do not prime the needle until immediately before the cannulation.
2. Grasp the fistula needle by the butterfly wings and prime the needle with normal saline until all the air is purged. Clamp the needle closed. Remove the protective cap and immediately proceed with the cannulation technique.
3. When the needle has advanced into the vessel, blood flashback will be visible (the needle may need to be unclamped to see the blood flashback) and, if visible, aspirate back 1 to 5 mL with the 10-mL syringe. Flush the needle with the normal saline solution and clamp. The syringe must aspirate and flush with ease. Monitor for signs or symptoms of infiltration. Patients usually experience immediate sharp pain upon infiltration of saline or blood into the tissues.

Needle selection for the initial cannulation is critical. One method used to select the appropriate needle size is a visual and tactile examination. This examination allows the cannulator to determine which needle gauge would be most appropriate, based on the size of the vessels in the fistula. Alternately, place 17 G and 16 G needles with the protective cap in place (prevents a needle stick) over the cannulation site. Compare the vein size with the needle size with and without the tourniquet applied. If the needle is larger than the vein with the tourniquet, it is too large and may infiltrate with cannulation. Use the needle size that is equal to or smaller than the vein (without the tourniquet) for the cannulation.

The smallest needle available, usually a 17 G, typically is used for initial cannulation attempts. It is important to keep in mind that blood flow delivered by a 17 G needle is limited. Prepump arterial monitoring is recommended to ensure that blood pump speed does not exceed that which the needle can provide. Prepump arterial pressure should not exceed -250 mm Hg. Based on performance of the fistula using a 17 G needle, the decision to increase the needle size for subsequent cannulation can be made.

A needle with a back eye should always be used for the arterial needle to maximize the flow from the access and reduce the need for flipping the needle.

1. Apply a tourniquet to the access arm.
2. After disinfecting the access site per unit protocol, carefully cannulate the fistula, using a 25° insertion angle.
3. When blood flash is observed, flatten the angle of the needle, parallel to the skin, and advance slowly. When the needle is in the vessel, remove the tourniquet and tape the needle securely per unit protocol.
4. Assess for adequate blood flow by alternately aspirating and flushing the needle with a syringe.
5. Assess carefully for signs of infiltration, ie, pain, swelling, or discoloration.
6. Repeat steps 1 to 5 for the second needle.

Cannulation Tips

1. A fistula that only works with a tourniquet in place is still underdeveloped, usually because of inflow stenosis, and needs more time or reevaluation by the VAT before use.
2. The combined use of the new fistula and bridge vascular access (ie, TCC as a return for blood) may be necessary until the fistula is well developed.
3. Cannulation performed at a nonturnover time may provide more time for the cannulation procedure.

Infiltrations, Problems, and Tips

1. Infiltrations with the cannulation can occur before dialysis, during dialysis with the blood pump running, or after dialysis with the needle removal.
2. Monitor closely for signs and symptoms of infiltration. A quick response to a needle infiltration can help minimize damage to the access.
3. If the infiltration occurs after the administration of heparin, care must be taken to properly clot the needle tract and not the fistula. In some cases, the decision to leave the needle in place and cannulate another site may be appropriate. The immediate application of ice can help decrease the pain and size of the infiltration and may decrease bleeding time.
4. Use caution when taping needles. Avoid lifting up on the needle after it is in the vein. An improper needle flip or taping procedure can cause an infiltration.
5. If the fistula is infiltrated, it is best to rest the fistula for at least 1 treatment. If this is not possible, the next cannulation should be above the site of the infiltration. If the patient still has a catheter in place, restart use of the fistula with 1 needle and advance to 2 needles, larger needle size, and greater BFRs as the access allows.
6. Proper needle removal prevents postdialysis infiltrations. Apply the gauze dressing over the needle site, but do not apply pressure. Carefully remove the needle at approximately the same angle as it was inserted. This prevents dragging the needle across the patient's skin. Using too steep of an angle during needle removal may cause the needle's cutting edge to puncture the vein wall.
7. Do not apply pressure to the puncture site until the needle has been completely removed.

Fistula Hand-Arm Exercise (CPG 3.2.3)

Strengthening the forearm by using isometric exercises to increase handgrip strength (eg, squeezing a rubber ball with or without a lightly applied tourniquet) may increase blood flow, thereby enhancing vein maturation,²⁴⁰ and has been shown to significantly increase forearm vessel size,^{127,241} thereby potentially increasing flow through a fistula created using these vessels. The resulting muscle mass increase also may enhance vein prominence. Exercise also may decrease superficial fat. Correction of anemia also could increase cardiac output and decrease peripheral resistance, potentially resulting in increased flow through the fistula.

Access Flow for Dialysis in Fistulae (CPG 3.3)

After appropriate physical examination, a fistulogram is the gold standard for evaluating poor maturation of the fistula if the patient is already on dialysis therapy. Use of a non-nephrotoxic contrast material, carbon dioxide, or ultrasound should be used for patients not yet on dialysis therapy. Although a fistula can maintain patency at lower blood flows than grafts, thrombosis still occurs and, if not treated promptly, can lead to permanent loss of the access. Thrombosis rates can be reduced by prospective correction of problems.²⁴² Delivery of dialysis is flow dependent: access flow less than 350 mL/min is likely to produce recirculation and inadequate delivery of dialysis. (See the HD Adequacy Guidelines.) Some centers have used diluted contrast (25%), and there are now published data that suggest this diluted contrast does not adversely impact residual kidney function.⁶³⁹ The images are of acceptable quality. The appropriate intervention for poor maturation is based on the cause of the dysfunction and may involve PTA of stenotic lesions, ligation or occlusion of vein branches (if the problem is simply > 1 major outflow vein),^{122,243} and/or surgical intervention, including revision of the anastomosis.^{75,125,126}

Cannulation of AVGs (CPG 3.4)

Manufacturers' guidelines are based on the time needed for tissue-to-graft incorporation, thereby preventing the possibility of a hematoma dissecting along the perigraft space. However, most patients experience significant tissue swelling as a result of the tunneling, and palpation of the graft is difficult for the cannulator and painful for the patient.

Placement of a graft that allows for early cannulation may be advantageous in the patient who needs to begin dialysis therapy, has no other access, and does not have veins suitable for a fistula. Such an access would preclude the necessity to place a catheter while a conventional graft matures. This type of graft confers no additional benefit beyond early cannulation.^{114,119,128}

Biografts are more likely to become aneurysmal than PTFE grafts,¹¹⁶ and cannulation techniques should be a hybrid of the techniques for a graft regarding depth of the access and the texture of an autogenous vein. Rotation of cannulation sites should be observed in these grafts; however, constant cannulation (buttonhole) has not been studied.²⁴⁴

Dialysis Catheters and Port Catheter Systems (CPG 3.5)

A dislodged (cuff exposed) or potentially infected catheter or exit site requires further assessment and possibly an intervention before being deemed safe to access for dialysis.

Table 6. Considerations for Accessing Catheters and Cleansing Catheter Exit Sites

Prepare procedure site using dialysis precautions
Conduct procedures using aseptic technique (correct hand-washing, masks for patient and staff, "no-touch" technique, and disposable clean gloves).
Chlorhexidine 2% with 70% alcohol is the preferred solution for cleansing of long-term catheter sites.* For patients with sensitivities to chlorhexidine 2% with 70% alcohol, chlorhexidine aqueous* may be used instead. For patients with sensitivities to chlorhexidine aqueous, povidone solution* may be used.
Skin cleansing should include the following steps: <ul style="list-style-type: none">▪ Apply solution/swab in a circular motion working from catheter exit site outwards.▪ Cover an area 10 cm in diameter.▪ Repeat this step twice. Do not rinse off or blot excess solution from skin.▪ Allow solution to dry completely before applying dressing.
To cleanse the connection between any CVC hub and cap use 2 swabs: <ul style="list-style-type: none">▪ Grasp connection with 1 swab.▪ Use second swab to clean from catheter connection up catheter for 10 cm.▪ Cleanse hub connection site and cap vigorously with the first swab. Discard swab.▪ Do not drop a connection site once it is cleaned.
To cleanse the section of the catheter that lies adjacent to the skin, gently swab the top and undersides of the catheter starting at the exit site and working outwards.
a. Check catheter manufacturer's warnings about effect of disinfectants on catheter material b. Use according to manufacturer's directions.

The Centers for Disease Control and Prevention (CDC) has no preference between transparent dressing and gauze, except in the case in which the exit site is oozing, which requires gauze.²²² Standard practice is to clean the exit site and redress at each dialysis treatment (see Table 6).

Airborne contaminants from both patients and staff are prevented best by the use of surgical masks when the catheter lumens or exit site are exposed. Wearing clean gloves and avoiding touching exposed surfaces further decreases the risk for infection. Aseptic technique includes minimizing the time that the catheter lumens or exit site are exposed.^{222,226} Manufacturers' directions should be adhered to for the types of disinfectants recommended for safe cleaning of the skin and device. If not contraindicated, the CDC recommends use of 2% chlorhexidine,²²² shown to be superior to povidone-iodine.^{245,246} Careful attention to hub care can decrease the CRB rate almost 4-fold to a rate approaching 1 episode/1,000 days.²⁴⁷

LIMITATIONS

Many of the guidelines are based on good standards of clinical practice. Those relating to the use of "aseptic" technique follow the recommendations of the CDC. It is unlikely that randomized trials will ever be done in this area.

AUXILIARY MATERIALS

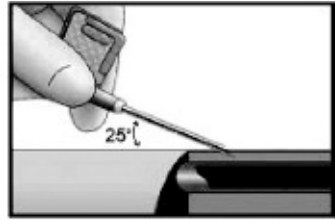
Establishing Constant-sites in Native Fistulae by Using Standard Sharp Fistula Needles

1. Perform a complete physical assessment of the fistula and document the findings.
2. Select the cannulation sites carefully. Consider straight areas, needle orientation, and ability of the patient to self-cannulate. Sites should be selected in an area without aneurysms and with a minimum of 2 inches between the tips of the needles.

Figure 1. Starting a buttonhole. Reproduced with permission from Medsystems Inc.



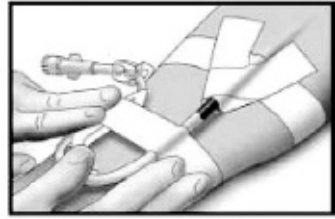
A



B



C



D

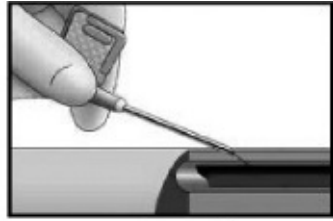
3. Remove any scabs over the cannulation sites.
 4. Disinfect the cannulation sites per facility protocol.
 5. Using a sharp fistula needle, grasp the needle wings and remove the tip protector. Align the needle cannula, with the bevel facing up, over the cannulation site and pull the skin taut (Fig 1A).
- Cannulate the site at a 25° angle; self-cannulators may require a steeper angle (Fig 1B). It is important to cannulate the developing constant-site access in exactly the same place, using the same insertion angle and depth of penetration each time.* This requires that a single cannulator perform all cannulations until the sites are well established.
 - A flashback of blood indicates the needle is in the access. Lower the angle of insertion. Continue to advance the needle into the fistula until it is appropriately positioned within the vessel (Fig 1C).
 - Securely tape the fistula needle (Fig 1D) and proceed with dialysis treatment per facility protocol.

*Note: It takes approximately 6–10 cannulations using a sharp needle to create a scar tissue tunnel track. Arterial and venous sites may not develop at the same rate. Once a scar tissue tunnel track is well formed, the antistick dull bevel needles should be used. If standard sharp needles are used beyond the creation of the buttonhole sites, the scar tissue tunnel can be cut. More pressure and more needle manipulation will be required to advance the antistick needle down the tunnel track. This can lead to bleeding or oozing from the needle site during use on HD. The sharp needle can also puncture the vessel at a new site or cause an infiltration. The quick transition to the antistick needle will preserve the integrity of the buttonhole site and prevent complications.

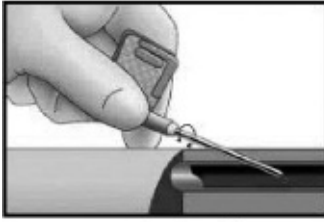
Figure 2. Cannulating a buttonhole. Reproduced with permission from Medisystems Inc.



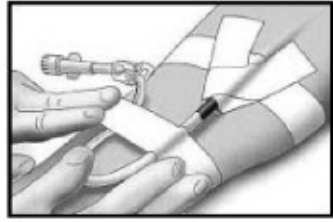
A



B



C



D

Cannulating Mature Constant Sites in Native Fistulae Using an Antistick Dull Bevel

1. Perform a complete physical assessment of the fistula and document the findings.
 2. Remove any scabs over the cannulation sites.
 3. Disinfect the cannulation sites per facility protocol.
 4. Using an antistick dull bevel, grasp the needle wings and remove the tip protector. Align the needle cannula, with the bevel facing up, over the cannulation site and pull the skin taut (Fig 2A).*
- Carefully insert the needle into the established cannulation site (Fig 2B). Advance the needle along the scar tissue tunnel track. If mild to moderate resistance is met while attempting to insert the needle, rotate the needle as you advance it, using gentle pressure (Fig 2C).
 - A flashback of blood indicates when the needle is in the access. Lower the angle of insertion. Continue to advance the needle into the fistula until it is appropriately positioned within the vessel.
 - Securely tape the needle set (Fig 2D) and proceed with the dialysis treatment per facility protocol.

*Note: Ensure that the same needle insertion angle and depth of penetration are used consistently for each cannulation of a constant site.

GUIDELINE 4. DETECTION OF ACCESS DYSFUNCTION: MONITORING, SURVEILLANCE, AND DIAGNOSTIC TESTING

Prospective surveillance of fistulae and grafts for hemodynamically significant stenosis, when combined with correction of the anatomic stenosis, may improve patency rates and may decrease the incidence of thrombosis.

The Work Group recommends an organized monitoring/surveillance approach with regular assessment of clinical parameters of the AV access and HD adequacy. Data from the clinical assessment and HD adequacy measurements should be collected and maintained for each patient's access and made available to all staff. The data should be tabulated and tracked within each HD center as part of a Quality Assurance (QA)/CQI program.

4.1 Physical examination (monitoring):

Physical examination should be used to detect dysfunction in fistulae and grafts at least monthly by a qualified individual. (B)

4.2 Surveillance of grafts:

Techniques, not mutually exclusive, that may be used in surveillance for stenosis in grafts include:

4.2.1 Preferred:

4.2.1.1 Intra-access flow by using 1 of several methods that are outlined in Table 7 using sequential measurements with trend analysis. (A)

4.2.1.2 Directly measured or derived static venous dialysis pressure by 1 of several methods. (A) (Protocol provided in Table 8 for using transducers on HD machines to measure directly; criteria in Table 9 for derived methods.)

4.2.1.3 Duplex ultrasound. (A)

4.2.2 Acceptable:

4.2.2.1 Physical findings of persistent swelling of the arm, presence of collateral veins, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in a graft. (B)

4.2.3 Unacceptable:

4.2.3.1 Unstandardized dynamic venous pressures (DVPs) should not be used. (A)

4.3 Surveillance in fistulae:

Techniques, not mutually exclusive, that may be used in surveillance for stenosis in AVFs include:

4.3.1 Preferred:

4.3.1.1 Direct flow measurements. (A)

- 4.3.1.2 **Physical findings of persistent swelling of the arm, presence of collateral veins, prolonged bleeding after needle withdrawal, or altered characteristics of pulse or thrill in the outflow vein. (B)**
- 4.3.1.3 **Duplex ultrasound. (A)**
- 4.3.2 **Acceptable:**
 - 4.3.2.1 **Recirculation using a non-urea-based dilutional method. (B)**
 - 4.3.2.2 **Static pressures (B), direct or derived. (B)**
- 4.4 **When to refer for evaluation (diagnosis) and treatment:**
 - 4.4.1 **One should not respond to a single isolated abnormal value. With all techniques, prospective trend analysis of the test parameter has greater power to detect dysfunction than isolated values alone. (A)**
 - 4.4.2 **Persistent abnormalities in any of the monitoring or surveillance parameters should prompt referral for access imaging. (A)**
 - 4.4.3 **An access flow rate less than 600 mL/min in grafts and less than 400 to 500 mL/min in fistulae. (A)**
 - 4.4.4 **A venous segment static pressure (mean pressures) ratio greater than 0.5 in grafts or fistulae. (A)**
 - 4.4.5 **An arterial segment static pressure ratio greater than 0.75 in grafts. (A)**

Table 7. Flow Methods in Dialysis Access

Duplex Doppler Ultrasound (Quantitative color velocity imaging): [DDU]
Magnetic Resonance Angiography: [MRA]
Variable Flow Doppler Ultrasound (Specs USA):[VFDU]
Ultrasound dilution (Transonics):[UDT]
Crit-Line III (optodilution by ultrafiltration;HemaMetrics): [OABF]
CritLine III direct transcutaneous (HemaMetrics): [TQA]
Glucose pump infusion technique [GPT]
Urea dilution [UreaD]
Differential Conductivity (GAMBRO): [HDM]
In Line Dialysance (Fresenius):[DD]

RATIONALE

Definitions

The following terms will apply to HD vascular access

Monitoring—the examination and evaluation of the vascular access by means of physical examination to detect physical signs that suggest the presence of dysfunction.

Surveillance—the periodic evaluation of the vascular access by using tests that may involve special instrumentation and for which an abnormal test result suggests the presence of dysfunction.

Diagnostic testing—specialized testing that is prompted by some abnormality or other medical indication and that is undertaken to diagnose the cause of the vascular access dysfunction.

Purpose of Access Surveillance

Vascular access function and patency are essential for optimal management of HD patients. Low BFRs and loss of patency limit HD delivery, extend treatment times, and, in too many cases, result in underdialysis that leads to increased morbidity and mortality.²⁴⁸ Between 1991 and 2001, the incidence of vascular access events in patients undergoing HD increased by 22%.²⁴⁹ In long-term AV accesses, especially grafts, thrombosis is the leading cause of loss of vascular access patency. Thrombosis increases health care spending^{7,250} and adversely affects QOL,^{162,250–253} and vascular access–related complications account for 15% to 20% of hospitalizations among patients with CKD stage 5 undergoing HD.^{7,12,252} Prevention of access dysfunction by maintaining adequate flow and preventing thrombosis translates into a policy of “Dialysis Dose Protection.” (See the KDOQI HD Adequacy Guidelines.) It is not feasible for any one individual to manage all aspects of access care. Multidisciplinary teams should be formed at each HD center,^{254–256} with a VAT coordinator, if possible. Whatever the team’s size and composition, its most important function is to work proactively to ensure the patient is receiving an adequate dialysis dose by maintaining access function and patency.

The basic tenet for vascular access monitoring and surveillance is that stenoses develop over variable intervals in the great majority of vascular accesses and, if detected and corrected, underdialysis can be minimized or avoided (dialysis dose protection) and the rate of thrombosis can be reduced. Whether prospective monitoring and surveillance can prolong access survival currently is unproven. However, it fosters the ability to salvage vascular access sites through planning, coordination of effort, and elective corrective intervention, rather than urgent procedures or replacement.²⁵⁷ A number of monitoring and surveillance methods are available: sequential access flow, sequential dynamic or static pressures, recirculation measurements, and physical examination.

Failure to detect access dysfunction has consequences on morbidity and mortality.^{248,249} In a recent study of 721 randomly selected patients from all 22 long-term HD units in northeast Ohio, barriers found to significantly ($P < 0.001$) and independently relate to inadequate dialysis dose delivery were patient noncompliance, low dialysis prescription, catheter use, and access thrombosis.²⁵³ Every 0.1 decrease in Kt/V was independently and significantly ($P < 0.05$) associated with 11% more hospitalizations, 12% more hospital days, and a \$940 increase in Medicare inpatient expenditures. Vascular access–related complications accounted for 24% of all hospital admissions.²⁵⁸ The reader is referred to the KDOQI HD Adequacy Guidelines for additional information on the importance of achieving the prescribed dialysis dose with regard to mortality.

Table 8. Static Intra-Access Pressure (IAP) Surveillance

- a) Establish a baseline when the access has matured and shortly after the access is first used. Trend analysis is more useful than any single measurement.
- b) Assure that the zero setting on the pressure transducers of the dialysis delivery system being used has been calibrated to be accurate within ± 5 mm Hg.
- c) Measure the mean arterial blood pressure (MAP) in the arm contralateral to the access.
- d) Enter the appropriate output or display screen where venous and arterial pressures can be visualized (this varies for each dialysis delivery system). If a gauge is used to display pressures, the pressure can be read from the gauge.
- e) Stop the blood pump and cross clamp the venous line just proximal to the venous drip chamber with a hemostat (this avoids having to stop ultrafiltration for the brief period needed for the measurement). On the arterial line, no hemostat is needed since the occlusive roller pump serves as a clamp.
- f) Wait 30 seconds until the venous pressure is stable, then record the arterial and venous intra-access pressure (IAP) values. The arterial segment pressure can only be obtained if a pre-pump drip chamber is available and the dialysis system is capable of measuring absolute pressures greater than 40 mm Hg.
- g) Unclamp the venous return line and restore the blood pump to its previous value.
- h) Determine the height correction, Δh between the access and the drip chamber(s) either by direct measurement (A) or using a formula (B) based on the difference in height between the top of the drip chamber and the top of the arm rest of the dialysis chair (Δ). Both measurements need to be in cm. Height corrections are not needed if the measurements in step 6 are done with access level with the drip chamber
 - Measure the height from the venous or arterial needle to the top of the blood in the venous drip chamber. The offset in Hg = height (cm) x 0.76
 - Use the formula, offset in mm Hg = $3.6 + 0.35 \times \Delta$.
- i) The same correction values can be used for both if the 2 drip chambers are at the same height. If the drip chambers are not at equal heights, the arterial and venous height offsets must be determined individually. In a given patient with a given access the height offsets need to be measured only once and then used until the access location is altered by construction of a new access.
- j) Calculate the normalized arterial and venous segment static IAP ratio(s), P_{IA}/MAP
 Arterial ratio = (arterial IAP + arterial height correction)/MAP
 Venous ratio = (venous IAP + venous height correction)/MAP

Table 9. Criteria for Intervention

Degree of Stenosis	Access Pressure Ratio				
	Graft		Fistula		
	Arterial Segment	Venous Segment	Arterial Segment	Venous Segment	
<50% of diameter	0.35-0.74	0.15-0.49	0.13-0.43	0.06-0.34	
>50% of diameter	>0.75	or and	>0.5	or and	>0.35
Venous outlet	>0.65		<0.5		<0.35
Intra-access			>0.43		<0.35
Arterial inflow	<0.3		Clinical findings	<0.13 + clinical findings	Clinical findings

Asymptomatic, but hemodynamically significant, stenoses usually are detected through a systematic monitoring and surveillance program. Detection of such stenoses is important to prevent progression to a functionally significant stenosis, currently defined as a decrease of greater than 50% of normal vessel diameter, accompanied by hemodynamic or clinical abnormality, such as abnormal recirculation values, elevated

venous pressures, decreased blood flow, swollen extremity, unexplained reduction in Kt/V , or elevated negative arterial prepump pressures, that prevent increasing to acceptable blood flow.²⁵⁹ This definition evolves from an analysis of hemodynamics and clinical correlation.

Normal Hemodynamics

Access flow and pressure are related in a permanent AV access through the relationship:

$$Q_A = \Delta P / R$$

The driving force for access flow, Q_A , is the pressure gradient, ΔP , between the artery and central veins. This driving force tends to be the same for both fistulae and grafts. Within the constraints imposed by the arterial anastomotic site, the ultimate access flow in mature accesses tends to be similar in fistulae and grafts.^{260,261} What differs is the rate of maturation. Grafts reach their maximum flow rate in a matter of days to weeks, as opposed to fistulae, which may require weeks to months to mature.^{71,138,262-264} This difference in achieving maximum flow may explain the difference in the incidence of immediate steal between the 2 access types, with the fistulae permitting more time for adaptation to occur.

Figure 3. Pressure profiles in grafts (top) and fistulae (bottom). Symbols: P, pressure; ΔP , change in pressure; R, resistance; Q_{AC} , access flow; A, arterial; V, venous. Figure adapted from Sullivan K, Besarab A: Strategies for maintaining dialysis access patency. Chapter 11. In Cope C (ed): Current Techniques in Interventional Radiology (ed 2). Philadelphia, PA, Current Medicine, 1995, pp 125–131.

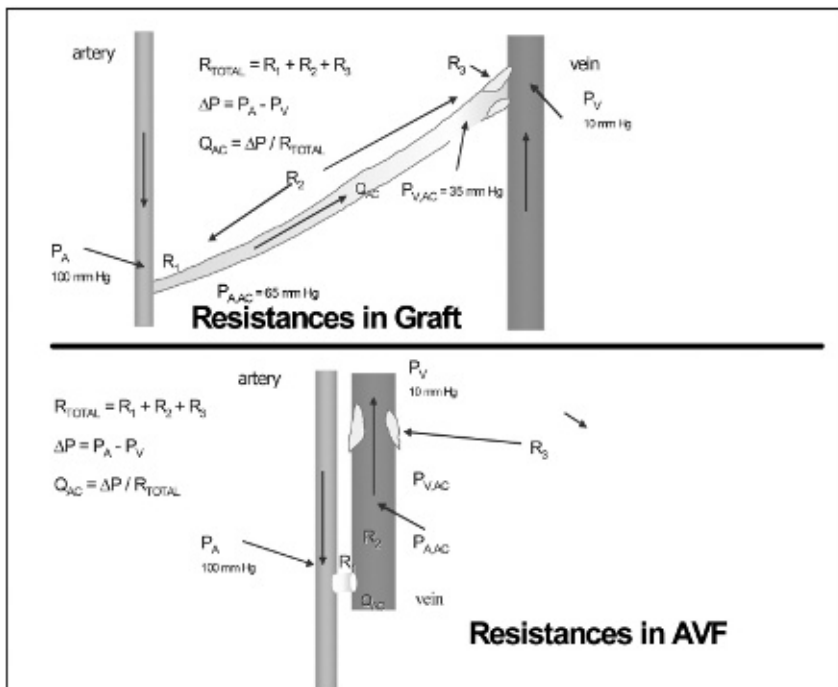
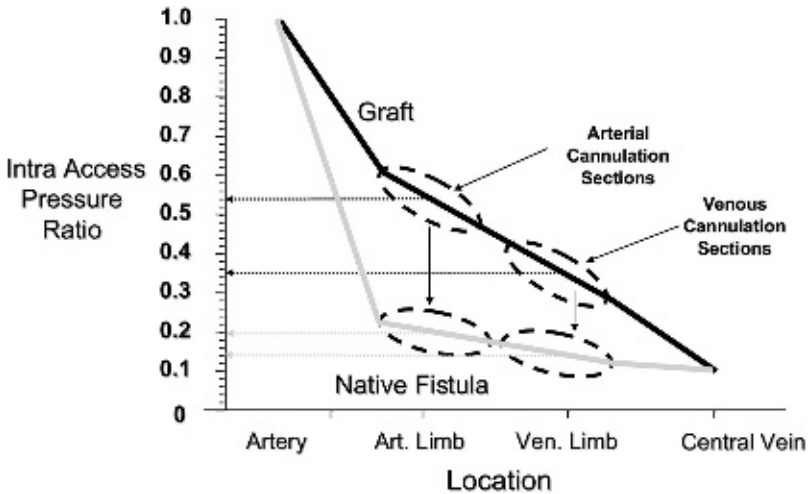


Figure 4. IAPs within normal grafts and fistulae. Reprinted with permission: Besarab A, Frinak S, Aslam M: Pressure measurements in the surveillance of vascular accesses. In Gray R (ed): A Multidisciplinary Approach for Hemodialysis Access. Philadelphia, PA, Lippincott Williams & Wilkins, 2002, Chapter 21, pp 137–150.



The pressure profile differs in the 2 access types. As shown in Fig 3, the pressure decrease profile in a graft progressively decreases along the length of the graft. At both anastomoses, there are pressure gradients, even in the absence of stenosis (illustrated as the luminal incursions). Within the body of the graft, there is a 20- to 30-mm ΔP that is the effective driving force.²⁶⁵⁻²⁶⁷

Conversely, in a fistula, the preponderance of the arterial pressure is dissipated within the first few centimeters of the access; pressures in the “arterial segment” are only approximately 20% of those in the feeding artery.²⁶⁵⁻²⁶⁷ Fig 4 shows the difference in profiles.

The IAP ratio refers to the actual pressure at the site of measurement divided by the mean arterial blood pressure (MAP). The effective ΔP in the fistula generally is only 8 to 10 mm Hg, frequently 25%, and seldom more than half those noted in grafts. Despite these differences in pressure profiles, access flow in grafts and fistulae are approximately equal at 6 months²⁶⁷ because the overall ΔP is the same. However, fistulae—unlike grafts—have an intact endothelial lining that allows them to actively dilate and remodel over extended periods. As a result, progressive flow increases are limited only by cardiac factors. Fistulae also differ from grafts in having side branches that reduce resistance to flow (parallel circuits). However, multiple accessory veins can limit the development of the major superficial vein needed for cannulation (see CPGs 1 and 2). Ligation of accessories or spontaneous occlusion of side branches within a fistula results in an access that hemodynamically mimics the profile of a graft.

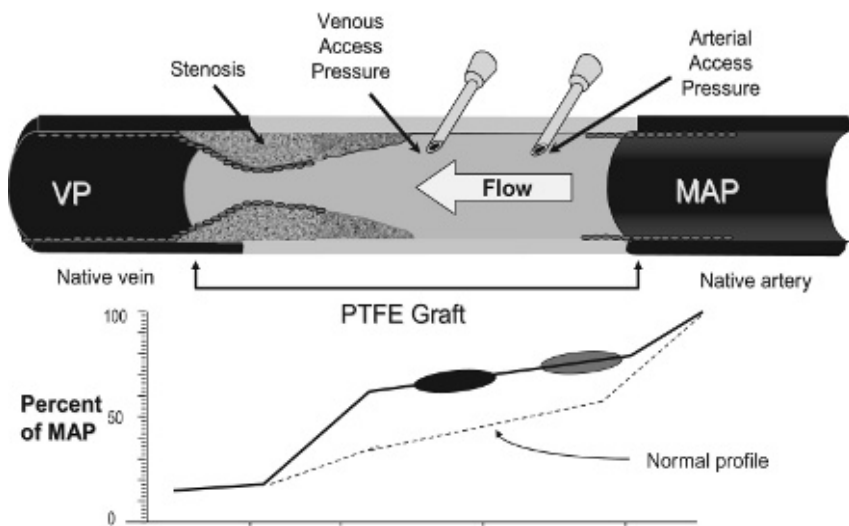
It is immediately apparent that 2 anatomic factors determine access function: (1) quality and (2) physical dimensions of the artery and vein. The major determinant of

Q_A in a given patient will be determined by the capacity of the artery to dilate and its general "health." In general, arteries at more distal sites have less capacity to deliver flow than more proximal sites, ie, radial < brachial < axillary < femoral. Arteries that are calcified or affected by atherosclerosis will result in lower flow accesses whether supplying a fistula or a graft. If the artery is healthy, flow capacity will be determined by the characteristics of the vein used in access construction. Too small a vein will limit the flow in both a fistula and graft. Unfortunately, arterial disease is not uncommon; access inflow stenosis occurs in one third of the patients referred to interventional facilities with clinical evidence of venous stenosis or thrombosis.²⁶⁸ This is much greater than has been traditionally reported.^{10,24,105,108,269} Thus, it is very important to assess the access by using physical examination early after its construction. Because flow and pressure measurements are not performed routinely until the access is cannulated, initial assessment of the access depends on the physical examination, which can detect many problems in a fistula.

Effect of Stenosis on Hemodynamics: Access Flow, IAP, Access Recirculation, and Physical Examination

In grafts, the majority of stenoses develop in the venous outflow, frequently right at or within several centimeters of the venous anastomosis.^{10,24,105,108} Lesions within the graft also occur, and most accesses have more than 1 lesion at any 1 time.^{10,266,267,269} The pathophysiological state of graft failure arises from neointimal hyperplasia. In a fistula, there may be ischemic effects, as well as injury resulting from recurrent cannulation and subsequent fibrosis. Stenoses in a fistula tend to occur at the surgical swing sites (including the arterial anastomosis) or the puncture zone of the vein. The outcome is the same in both fistulae and grafts: a reduction in access flow rate. However, the effect on

Figure 5. Effect of venous outlet stenosis on pressure profile. Reproduced with permission from Medisystems Inc.



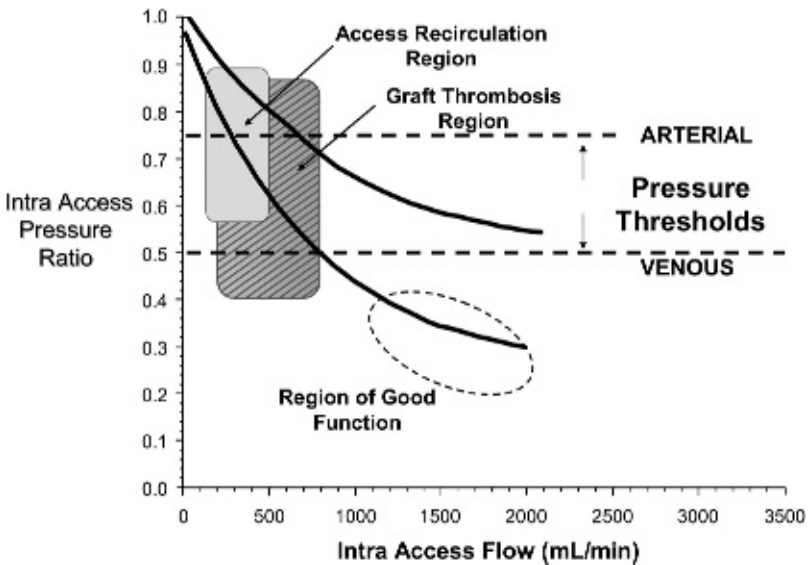
IAP differs according to access type and site of stenosis. As illustrated in Fig 5, an outlet stenosis in a graft will increase the pressure at all locations upstream from the stenosis. Conversely, an inflow lesion will decrease all pressures downstream of the stenosis. An intragraft stenosis between the needles will decrease flow while increasing pressure upstream and decreasing pressure downstream of the lesion.

In a fistula, pressure profiles depend on the location of the lesion and the presence or absence of collateral or accessory veins. Arterial inflow lesions that develop after acceptable maturation are detected more easily by using Q_A , the inability to deliver blood flow to the dialyzer, reductions in adequacy, and recirculation measurements^{270,271} than by IAP measurements. Intra-access pressure (P_{IA}) with inflow lesions tends to remain unchanged or decrease as Q_A decreases over time.²⁷² An outflow lesion will produce a pressure profile similar to that seen in grafts; the magnitude of the pressure elevation is dictated by the number of venous tributaries. Not uncommonly, in upper-arm fistulae, there is spontaneous or deliberate occlusion of side branches (as with transposition); an outflow lesion then produces a pressure profile very similar to that of grafts.

For a given graft access, the access flow pressure profile resulting from venous outflow stenosis is illustrated in Fig 6.

An initially well-functioning graft with an access flow approaching 2 L/min (usually in the upper arm) will manifest decreasing flow as both the arterial and venous pressure slowly increase with the development of outflow tract stenosis. Hemodynamic simulations indicate that flow decreases by less than 20% until the stenosis process produces a 40% to 50% decrease in luminal diameter. Thereafter, flow decreases rapidly as

Figure 6. Effect of graft venous outlet stenosis. Reprinted with permission: Besarab A: Blood Purif 2006;24:77–89 (DOI: 10.1159/000089442). S. Karger AG, Basel.



the degree of stenosis increases to 80%.²⁷³ Because the intimal hyperplasia process progresses with time, its detection requires sequential measurements of flow or pressure or both to detect a threshold at which action should be taken. Note that the graft thrombosis region by flow shown in the hatched area is reached long before a graft would show recirculation and therefore affect the delivered dose of dialysis. Access recirculation in grafts is a late manifestation of stenosis and a poor predictor of imminent thrombosis; it occurs in less than 20% of cases.²⁷¹ For this reason, the Work Group no longer recommends recirculation measurements in grafts. Conversely, because fistulae typically can maintain patency at much lower flows than grafts, recirculation occurs much more frequently; 1 study reported that about one third of fistulae had a significant recirculation fraction by using an ultrasound dilution technique.²⁷¹ When recirculation was measured by using the Fresenius Body Thermal Monitor (BTM), the device was able to detect fistulae requiring revision with a sensitivity of 81.8% and specificity of 98.6%, although the BTM method does not differentiate between access and cardiopulmonary recirculation.²⁷⁴

The main issue for most HD clinics is which surveillance test best meets their needs. The following discussion summarizes the methods available and the reason for the ordering of the test by the Work Group in CPGs 4.2 and 4.3.

Physical Examination (Look, Touch, Listen)

Physical examination can be used as a monitoring tool to exclude low flows associated with impending graft failures.^{275,276} There are 3 components to the access examination: inspection (look), palpation (touch), and auscultation (listen).²⁷⁶ The Work Group is convinced that the basic skills have been largely abandoned in favor of technology and need to be taught to all individuals who perform HD procedures.²⁷⁷ Simple inspection can reveal the presence of aneurysms. A fistula that does not at least partially collapse with arm elevation is likely to have an outflow stenosis. This logic applies to the case in which a tourniquet does not appear necessary for optimal cannulation. Strictures can be palpated and the intensity and character of the bruits can suggest the location of stenosis. Downstream stenosis also produces an overall dilation of the vein, giving it “aneurysmal” proportions.

In grafts, one can determine the direction of flow in a loop configuration and avoid inadvertent recirculation by erroneous needle insertion. In a patent graft in which blood flow is less than the blood pump flow setting, the presence of recirculation can be detected easily by occluding the graft between the needles and looking at the arterial and venous pressures. A strong pulse too often is misinterpreted as being evidence of good flow, rather than the opposite. A pulse suggests lower flows.²⁷⁸ In a newly thrombosed graft, the arterial pulse often is transmitted into the proximal end of the graft, leading to erroneous cannulation, which could be avoided easily by simply using a stethoscope to confirm absence of flow. A bruit over an access system and its draining veins that is only systolic is always abnormal; it should be continuous. An intensification of bruit suggests a stricture or stenosis.²⁷⁸ Palpable thrill at the arterial, middle, and venous segments of the graft predicts flows greater than 450 mL/min.²⁷⁸ A palpable thrill in the axilla correlates with a flow of at least 500 mL/min.²⁷⁹ The character of pulse and thrill correlates

with postintervention outcome for stenosis.²⁸⁰ The interested reader is referred to additional literature for further enjoyment and enlightenment.²⁷¹

Of note, a preliminary study has shown that sounds acquired by using electronic stethoscopes that were then digitized and analyzed on a personal computer could be used to characterize stenoses.²⁸¹ Stenotic vessel changes were found to be associated with changes in acoustic amplitude and/or spectral energy distribution. Acoustic parameters correlated well ($r = 0.98$; $P < 0.0001$) with change in degree of stenosis, suggesting that stenosis severity may be predicted from these parameters. Furthermore, acoustic parameters appeared to be sensitive to modest diameter changes of 20%. These results suggest that, in the future, readily available computerized analysis of vascular sounds may be useful in vessel patency surveillance.

Access Flow

Access flow can be measured by using a number of techniques, as summarized in Table 7. Doppler ultrasound (DU)²⁸²⁻²⁸⁷ and MRA^{46,54,288-290} are direct techniques for assessing flow in vascular accesses. Duplex Doppler ultrasound (DDU) requires an accurate measurement of the cross-sectional diameter of the access. The method is operator dependent and subject to error caused by variation in cross-sectional area and the angle of insonation.^{291,292} Because turbulence in the access can limit the accuracy of the measurements, flow measurements can be made in the feeding artery (usually the brachial) or distal part of the access.²⁷² The difference between the flow in the artery and the access usually is less than 10%. Despite these operator-related and equipment-related limitations, *sequential* measurements have been used extensively to detect and refer patients for interventions or predict the risk for thrombosis. In addition to flow measurements, both DDU and MRA provide anatomic assessment and direct evidence for the presence, location, and severity of access stenosis. However, the current cost of these methods, as well as the inability to make measurements during HD, limits their use. Research and development are needed to simplify procedures and reduce costs.

Indirect methods use an indicator dilution technique; the major techniques include ultrasound dilution (UDT),^{272,293} a timed ultrafiltration method²⁹⁴; transcutaneous access flow rate (TQA), a method that can be performed during or independently of HD^{295,296}; glucose infusion^{297,298}; differential conductivity^{299,300}; and, finally, ionic dialysance.^{301,302} All the methods described, except for TQA, variable flow DU, and glucose infusion, require measurements with the blood tubing initially in the normal position and then reversed to induce access recirculation.

With UDT, access flow is measured from the induced recirculation when the needles are reversed. The software calculates the area under the curves (AUC) as a measure of recirculation.

$$Q_A = Q_{BP} (1/R - 1)$$

where Q_{BP} is blood pump flow and R is degree of recirculation induced. The UDT method is the only one that independently measures actual flow in the tubings, rather than accepting the readings on the HD system for the roller pump.

Pitfalls in measurement have been identified and recently reviewed.³⁰³ Accurate calibration of the blood pump is essential with most methods, but frequently is not performed regularly. The indicator injection also must not affect flow in the access itself. The technique must separate access recirculation from cardiopulmonary recirculation that is unavailable with high-efficiency dialysis. Finally, access flow is a function of the ratio of systemic to access resistance, and measurements should be conducted within the first 90 minutes of dialysis to minimize effects of hypotension. Table 10 summarizes the recommendations for access flow surveillance. All methods require some modification/interruption of the dialysis treatment, except perhaps ionic dialysance.

With ionic dialysance, alteration of the proportioning ratio of dialysate to water alters the dialysis sodium concentration, as well as blood sodium level. The resulting change in blood sodium level, as well as the change in dialysate conductivity, serves as the indicator for calculating Q_A .

$$Q_A = [(D \cdot Dr)/(D - Dr)] \cdot [1/\text{blood water fraction}]$$

where D is the dialysance in the normal blood tubing position and Dr is the value with the tubing reversed. As with UDT, ultrafiltration should be minimized and recirculation must be absent in the normal blood tubing configuration. At flow rates less than 1,000 mL/min, the method consistently underestimates access flow compared with UDT.^{301,302}

With the timed ultrafiltration method, a difference in hematocrit (Hct) is the indicator

$$Q_A = Q_f H_0 (\Delta H_r - \Delta H_n)$$

where Q_f is ultrafiltration rate, H_0 is initial Hct, and ΔH is change in Hct induced by ultrafiltration with the tubing in reversed (r) and normal (n) positions. The method correlates well with UDT.

The TQA method has not been extensively used.

The variable-flow DU method³⁰⁴⁻³⁰⁶ measures velocity between the 2 dialysis needles at varying dialyzer blood flows. Using a conservation of volume approach, a computer

Table 10. Access Flow Protocol Surveillance

Access flow measured by ultrasound dilution, conductance dilution, thermal dilution, Doppler or other technique should be performed monthly. The assessment of flow should be performed during the first 1.5 hr of the treatment to eliminate error caused by decreases in cardiac output or blood pressure related to ultrafiltration/hypotension. The mean value of 2 separate determinations (within 10% of each other) performed at a single treatment should be considered the access flow.

Graft

If access flow is <600 mL/min in a graft, the patient should be referred for fistulogram. If access flow 1,000 mL/min that has decreased by more than 25% over 4 mo, the patient should be referred for fistulogram.

algorithm solves for access flow without the need to measure the cross-sectional diameter of the access.³⁰⁶ The method's accuracy is best at flows less than 1,000 mL/min.

The easy availability of urea as a marker has led some to use it as an indicator substance to calculate recirculation and therefore derive flow. Such measurements underestimate flow compared with conductivity.³⁰⁷ Although Q_A can be estimated by using the urea method, the sensitivity and specificity of a low value is a poor predictor of access outcome and may lead to cost-ineffective investigations.³⁰⁷

Variation in access flow during dialysis³⁰⁸ can result from changes with cardiac output,³⁰⁹⁻³¹¹ MAP,^{309,310} and changes in blood volume.³¹¹ Access flow can increase by up to 11% or decrease by up to 30% from initial values by the end of dialysis, potentially impairing the ability of Q_A to predict impending vascular access failure.³¹² Access resistance remains stable during treatments and could be a more useful measure of vascular access performance as part of an access surveillance program. For all these reasons, it is recommended that measurements be made early in the HD treatment.

Access Pressure

Measurements of pressure from the HD circuit were not originally designed to assess access (dys)function, either directly or indirectly. Rather, they were used to calculate the mean transmembrane pressure so that the appropriate ultrafiltration rate could be achieved. Volumetric control systems made these measurements unnecessary. Pressure measurements were retained to provide safety. During HD, blood is drawn out of the vascular access through the arterial needle by the blood pump on the HD machine.

Prepump pressures are now used to determine whether the prescribed dialyzer blood flow can be delivered without generating excessive negative pressures. At high negative pressures, the collapse of the pump segment reduces the true flow and true flow may differ from "displayed" flow by up to 15%.^{313,314} The degree of collapse is affected, in turn, by differences among manufacturer tubing sets.³¹⁵ These considerations are important in evaluating the relationship of flow to access pressure. Excessively negative pressures can result in hemolysis.³¹⁶ Differences in blood tubing performance are of obvious importance to manufacturers, leading to improvements. The newer generations available may show little differences with the improved blood flow delivered during dialysis, benefiting all patients.

When blood passes through the dialyzer, the blood traverses the venous drip chamber and returns to the patient's vascular access through the venous needle. The pressure required to infuse blood back into the access is recorded as the venous drip chamber pressure (VDP) or DVP. The original purpose of VDP was to detect infiltration or malpositioning of the needle because partial occlusion of the needle orifice or infiltration would quickly increase and sound an alarm. There still is no "alarm" for detecting accidental withdrawal of the needle outside the body; exsanguinations have occurred.

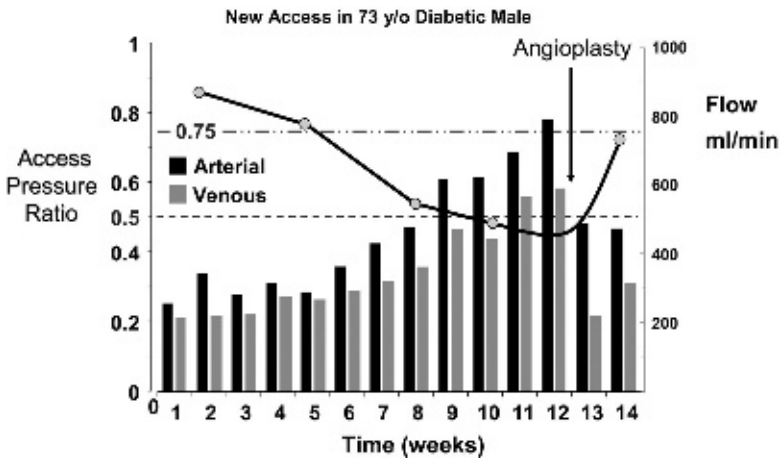
One of the components of the VDP is the actual IAP (P_{IA}). As shown in Fig 4, the IAP (P_{IA}) in a graft is usually less than 50% of MAP. Most of this pressure decrease occurs at the arterial anastomosis, unless there is intragraft stenosis. When outflow stenosis develops

(eg, because of neointimal hyperplasia at or downstream from the graft-vein anastomosis), P_{IA} increases and flow decreases. When P_{IA} increases to greater than 50% of MAP (P_{IA}/MAP greater than 0.50), graft flow commonly has decreased into the thrombosis-prone range of 600 to 800 mL/min (Fig 6), and the presence of stenosis is likely. If a stenosis develops in the body of a graft between the areas used for arterial and venous limb cannulation, P_{IA} at the venous needle remains normal or can even decrease despite increasing stenosis.^{270,271} Stenosis at the arterial anastomosis of both grafts and fistulae causes P_{IA} to decrease. Conversely, a high basal P_{IA} can be observed with a healthy artery in the absence of stenosis when the flow delivered is in excess of the venous system's initial capacity. Because of these pressure confounders, there is little correlation between a single measurement of flow and P_{IA}/MAP .³¹⁷ Serial measurements of pressure in each patient are more valuable than isolated measurements of either P_{IA} or P_{IA}/MAP ratio. This is illustrated in Fig 7. Note that the arterial pressure ratio is approximately 0.2 units higher than the venous ratio and the baseline initial value for both ratios is lower than usual because of the use of a 4- to 6-cm taper at the arterial anastomosis that limits inflow to prevent steal.

In fistulae, blood entering the venous system returns through multiple collateral veins. As a consequence, P_{IA}/MAP in a fistula is, on average, less than in a graft and may not increase with outlet stenosis. The test, therefore, theoretically is less valuable as a surveillance tool for stenosis in fistulae. However, most elbow-level fistulae do not have or lose collaterals and often behave hemodynamically like grafts. In both fistula types, elevation of P_{IA}/MAP indicates the development of a stenosis in the venous outflow from the access and is associated with an increased probability of access failure or need for revision to provide adequate blood flow for HD.^{10,265,266,317}

Like access flow, measurement of P_{IA} has evolved.

Figure 7. Relationship of IAP ratio to access flow. Reprinted with permission: Besarab A: Blood Purif 2006;24:77-89 (DOI: 10.1159/000089442). S. Karger AG, Basel.



Direct measurement of static pressure. Pressures in the access can be measured directly at the site of cannulation in the “arterial” and “venous” segments of the graft or fistula by using a pressure-measuring device. Although one can use a sophisticated electronic method (separate transducers placed in line with the dialysis tubing)²⁶⁵⁻²⁶⁷ as originally reported, a much simpler technique uses a device consisting of a hydrophobic Luer-Lok connector that connects a standard dialysis needle to an aneroid manometer.³¹⁸

IAPs also can be measured by using the pressure transducers of the dialysis machine. Under conditions of no blood flow and no ultrafiltration, the only difference between the pressure measured by an independent transducer and the machine transducer is that resulting from the height differential between the location of the machine transducers and the access. The two pressures can be equated by either moving the access to the level of the venous drip chamber or moving the drip chamber to the level of the access. Alternatively, the height difference, Δh , can be measured and the additional pressure ($0.76 \cdot \Delta h$) can be added to the machine transducer reading.³¹⁹

Table 8 provides the sequence of steps for measuring static pressure. It is important that the pressure transducers be calibrated accurately.

Interpretation. Venous outlet stenosis can be detected with venous P_{IA} alone. Trend analysis is more useful than any single measurement. The greater the degree of stenosis at the outlet, the greater the venous pressure ratio. Strictures between the area of arterial and needle cannulation cannot be detected by measuring venous (P_{IA}) pressure alone.²⁷¹ Detection of these lesions requires simultaneous measurement of pressures from both the arterial and venous needles. Central stenoses that have collateral circulation may have “normal” pressures, but these usually present with significant ipsilateral edema. Accesses can be classified into the categories listed in Table 9. Using the equivalent P_{IA} ratios from the arterial or venous needles, the criteria must be met on each of 2 consecutive weeks to have a high likelihood of a 50% diameter lesion.

Patients who develop a progressive and reproducible increase in venous or arterial segment greater than 0.25 units more than their previous baseline, irrespective of access type, also are likely to have a hemodynamically significant lesion. Intra-access strictures usually are characterized by the development of a difference between the arterial and venous pressure ratios greater than 0.5 in grafts or greater than 0.3 in native fistulae. Because fistulae can remain patent at much lower flows than grafts, sequential measurement of conductance (ie, a blood pump/absolute value of prepump pressure), particularly at maximum prepump pressure permitted by the system, can detect fistula dysfunction and stenosis.^{320,321}

Although measuring static pressure as described in Table 8 is straightforward, it is tedious, time consuming, and not “user friendly.” Staff frequently bypass crucial steps, leading to poor-quality data being collected and recorded. This has led to a reevaluation of statistical methods to use the information within the dynamic pressure.

VDP or DVP and extraction of equivalent P_{IA} . DVP (also referred to as VDP under conditions of blood flow) is measured routinely during HD in the presence of extracorporeal blood flow. These pressures can be read off the dialysis machine or stored

electronically with the blood pump running. One of the components of DVP is the actual IAP (P_{IA}) because the pressure needed to return blood into the access is the sum of that needed to overcome the needle resistance and IAP. DVP/VDP has been used to detect venous outlet problems,³²² but measurements are meaningful only if obtained at the beginning of dialysis and usually with low BFRs (50 to 225 mL/min) because at high BFRs, much of the resistance to flow is from the needle, and not the vascular access.

Measurement of DVP is less sensitive and specific than direct measurements of access flow rates or static pressure measurements. The reason for “poorer” performance results from many factors, including the lack of consistency about which flow should be the standard, varying in studies from 50 to 425 mL/min³²²⁻³²⁵; differences in needle design (wall thickness, actual length); and effects of viscosity affected chiefly by Hct. In addition, use of DVP as a method also requires that studies be performed to standardize the critical value as a function of needle gauge, length, and inner diameter (wall thickness). Consistency requires that a uniform flow value to test at be determined.

Indirect methods for determining P_{IA} . Most HD systems can store the blood pump values associated with DVP. A computerized algorithm has been developed that uses an empirical formula to calculate an equivalent P_{IA} from the DVP made during treatment. During a given treatment, many measurements at different flows can be made along with the simultaneous MAP, and an average equivalent P_{IA} /MAP can be calculated. The average values can be trended with each treatment and examined for an upward trend. When the ratio exceeds 0.55, the access has a greater risk for clotting.³²⁶ This technique has been commercialized, providing monthly reports and trend analysis. Its ability to predict thrombosis is equal to that of direct measurement of P_{IA} . In the evolution of the IAP ratio to detect stenosis, the discriminator value has progressively increased from 0.4 using the ratio of systolic pressures, 0.45 using the ratio of mean pressures measured directly, 0.5 using transducers on the machine, and finally 0.55 when deriving P_{IA} from the dynamic pressure.

Recirculation: Method, Limits, Evaluation, and Follow-Up

Recirculation is the return of dialyzed blood to the dialyzer without equilibration with the systemic arterial circulation. The technique is not recommended as a surveillance tests in grafts. However, up to one third of dysfunctional fistulae will show an increase in recirculation that may be manifested as a decrease in urea reduction ratio (URR) or Kt/V , but this occurs late.

Access recirculation in a properly cannulated access is a sign of low access blood flow¹⁹² and a marker for the presence of vascular access stenosis, particularly in fistulae. Such stenoses can be corrected, preventing underdialysis and decreasing the risk for access thrombosis.³²⁷ Access recirculation can be measured accurately by using UDT³²⁸ or conductivity.²⁹⁹ A K^+ -dilution method is more reliable than the 2-needle urea-based method and compared with UDT, has 100% sensitivity, 95% specificity, 91% positive predictive value, and 100% negative predictive value.³²⁹ In analogy to access flow measurement, glucose infusion also has been used to measure recirculation.³³⁰

The amount of recirculation occurring with reversed needles usually is substantial (>20%), as confirmed when the tubings are deliberately reversed for access flow

measurements. However, even with ideal sample timing and proper cannulation, laboratory variability in urea-based measurement methods will produce variability in calculated recirculation.³³¹ Therefore, individual recirculation values less than 10% by using urea-based methods may be clinically unimportant. The Work Group believes that they do not prompt further evaluation. Values greater than 10% by using urea-based recirculation measurement methods require investigation.

New loop grafts are at particular risk for reversed needle placement because of a lack of familiarity with the access anatomy. When possible, an access diagram that depicts the arterial and venous limbs should be obtained from the surgeon who constructed the access to aid in proper cannulation. If not available, the anatomy can be deduced by temporarily occluding the graft at its midportion. The portion retaining a pulse is the arterial limb.

Comparison of Surveillance Methods

Accuracy and Reproducibility

Only 1 study has directly compared many of the available flow techniques with regard to reproducibility.³³² Reproducibility is assessed by using duplicate measurement at unchanged conditions, whereas accuracy is determined under controlled change in a relevant measurement condition (2 different blood flows for ultrasound, changed sensor position in TQA). An accurate method produces the same result. In most studies using some form of dilution or concentration of an indicator, UDT is taken as the reference method for comparison because it most accurately separates cardiopulmonary from access recirculation and independently measures blood flow to the dialyzer. Ultrasonic flow is approximately 10% to 15% less than indicated by the blood roller pump, the magnitude correlating inversely with negative arterial blood tubing pressure.³³³ It shows very high reproducibility, for measurement at the same extra corporeal blood flow, Q_B (correlation coefficient of duplicate measurement, $r = 0.97$; $n = 58$) and measurement at 2 different Q_B ($r = 0.97$; $n = 24$), justifying its current status of a reference method in Q_A evaluation.³³⁴ The coefficient of variation usually is less than 8%.³²⁷ Slightly lower reproducibility is found with thermal dilution (TD) or Fresenius BTM at the same Q_B ($r = 0.92$; $n = 40$) and 2 different Q_B ($r = 0.851$; $n = 168$); this inaccuracy can be overcome by increasing the number of measurements with averaging. Use of the simple Krivitski formula, $Q_A = Q_{BP} (1/R - 1)$ in TD (which measures total recirculation, ie, sum of access recirculation and cardiopulmonary recirculation) brings about underestimation of Q_A , which progressively increases from Q_A of about 600 mL/min upward. High correlation of TD versus UDT ($r = 0.95$; $n = 54$) makes TD a viable clinical alternative in Q_A evaluation. Consistently different Q_A values obtained at 2 different Q_B s should prompt closer investigation of anatomic conditions of the access. Good correlation ($r = 0.87$; $n = 27$) also is found between Q_A measured by using DDU and UDT.^{332,335}

The direct TQA method showed very high reproducibility ($r = 0.97$; $n = 85$); however, only for unchanged sensor position. Correlation of Q_A measured at 2 different sensor positions was much worse ($r = 0.73$; $n = 22$). Correspondence of TQA with UDT was satisfactory ($r = 0.81$; $n = 36$). Skilled and experienced operators are a must with this method. Similar results were found by others who reported, for triplicate measurements,

coefficients of variation of 7.5% for differential conductivity by hemodynamic monitoring (HDM), 9.1% for UDT, and 17.4% for optodilution by ultrafiltration (OABF).³⁵⁶ Repeatability data (variation among temporally separated measurements) showed values of 10.6% for HDM, 13.0% for UDT, and 25.2% for OABF. Fewer comparisons have been made with the other methods. Glucose pump test (GPT) flow measurements correlate well with UDT measurements and have acceptable replicability.²⁹⁸

Ionic dialysance or conductivity dialysance, as it frequently is referred to, is being used increasingly by clinicians to measure access flow in both the United States and Europe, particularly with Fresenius dialysis delivery systems, in which the methodology is built into the machines as on-line clearance. Major refinements have been made to increase the replicability and accuracy of this method at lower BFRs, but preliminary reports comparing the measurements with UDT have not yet been formally published.

Detection of Stenosis or Predicting Thrombosis

As important as accuracy of a method is, the goal of any surveillance method is to detect access stenosis in a timely way so that appropriate correction can be undertaken before thrombosis. A hemodynamically significant stenosis is the substrate for thrombosis by reducing flow, increasing turbulence, and increasing platelet activation and residence time against the vessel wall.

Table 11 summarizes the available studies in which the presence and degree of stenosis was confirmed by using angiography. As reflected by data in the table, DDU is most accurate because it can directly visualize the degree of stenosis. When DDU is used to measure flow, rather than identify anatomic stenosis, sensitivity and specificity decrease. A quick survey of the table clearly shows that none of the tests consistently achieves a sensitivity of 90% and specificity greater than 80%.

Because of the accuracy of DDU in detecting the presence of a 50% (by diameter) stenosis,³³⁷ it has been used in some studies as the reference method, rather than angiography, to avoid invasive procedures. As shown in Table 12, Table 12 UDT has good accuracy, whereas physical examination has high specificity, but poor sensitivity.

Table 13 shows that DDU and UDT are equivalent in predicting thrombosis.

Data are still limited for some of the newer surveillance tests. Table 14 summarizes the observations. There is excellent correlation between flow measurements by means of GPT and UDT ($r > 0.9$).²⁹⁸ GPT also has been validated recently as a surveillance technique in grafts. Using DDU to assess for the presence of stenosis, GPT picked up severe stenosis in 14 of 112 grafts (100% sensitivity) and performed better than UDT (86% sensitivity).²⁹⁷ Specificity was less than 60% for both tests. Diagnostic efficiency (percentage of grafts with agreement between test result and factual situation) was 90% and 80% ($P = 0.056$) for GPT and UDT, respectively. MRA also can provide anatomic³³⁸ and Q_A measurements, but it is prohibitively expensive. Intravascular ultrasounds (IVUSs) can be used to evaluate abnormalities in fistulae²⁹⁷ and may find abnormalities not seen with angiography. However, it is too expensive for routine use, but may be a valuable adjunct in evaluating the efficacy or completeness of the intervention on the access.

Table 11. Diagnostic Accuracy of Tests Used for Access Surveillance in the HD Population: Angiogram for Stenosis vs. Other Test

Author, Year	N	Type of Access		Applicability	Test 1*	Threshold Value for Stenosis	Results			Quality		
		AVF	AVG				Sens	Spec	AUC		CI	
Bosman 1997 ³⁴⁰	42 (70 grafts)	0%	100%	↑↑	UDT	ND	-	-	0.72 ^b	(0.66, 0.78)	●	
Tessitore 2003 ³³⁹	127	100%	0%	↑↑	UDT	750 mL/min	84%	91%	0.91	(0.88, 0.94)	●	
Schwartz 2003 ³³⁷	66	100%	0%	↑↑	UDT	465 mL/min	66%	89%	0.79	(0.66, 0.91)	○	
Schwartz 2003 ³³⁷	66	100%	0%	↑↑	DDU	390 mL/min	76%	76%	0.80	(0.65, 0.94)	○	
Gadgil ³⁴¹	56	54%	66%	↑↑	DDU	°	100%	100%			○	
Robbin 1998 ³⁴¹	41	100%	0%	↑↑	DDU	‡	92%	50% ^c			○	
Bosman 1997 ³⁴⁰	42 (70 grafts)	0%	100%	↑↑	Venous pressure	ND			0.63 ^d	(0.78, 0.88)	●	
Laiassy 1999 ³³⁸	19	100%	0%	↑↑	MRA	f	92%	85%			○	
Plankton 2003 ³³⁸	15	53%	47%	↑	MRA	f	Observer 1:			0.74		○
							100%	0%	74%			
							Observer 2:			0.81		

AUC=area under curve; AVF=arterio-venous fistula; AVG=arterio-venous graft; CI=confidence interval; DDU=duplex Doppler ultrasound; MRA=magnetic resonance angiography; ND=no data; PSV=peak systolic velocity; Sens=sensitivity; Spec=specificity; UDT=ultrasound dilution technique.

a. This test is compared to the "reference standard", angiogram

b. Based on number of grafts

c. Access stenosis defined by > 50% narrowing or reduction of luminal diameter of vessel

d. Access stenosis defined by PSV ratio > 2.0 or > 50% stenosis

e. Derived specificity calculated based on data provided

f. Access stenosis defined by 50% vessel stenosis or 40% stenosis with turbulent flow

Table 12. Comparison of Diagnostic Tests for Access Surveillance and Monitoring in the HD Population: Duplex Doppler Ultrasound As Reference

Author, Year	N	Type of Access — AVF	AVG	Applicability	Test 1 ^a	Threshold Value for Stenosis	Results	Quality
May 1997 ²⁶⁵	170 (220 accesses)	22%	78%	↑↑↑	UDT ^b	ND	r = 0.79 P = 0.0001	●
Malki 2002 ¹²⁴	193 (258 exams)	72%	28%	↑↑	Physical exam	ND	Sensitivity = 36% Specificity = 93%	○

AVF=arterio-venous fistula; AVG=arterio-venous graft; ND=no data; r=correlation coefficient; UDT=ultrasound dilution technique.

a. This test is compared to the "reference standard", duplex US.

b. Access stenosis defined by doubling of systolic velocity in vessel narrowed more than 50%.

Table 13. Comparison of Diagnostic Tests to Predict Thrombosis in Chronic Hemodialysis Patients

Author, Year	Study Design	N	Type of Access — AVF	AVG	Follow-up (maximum)	Applicability	Test 1	Test 2	Prediction Difference	Quality
Lok 2003 ³⁰³	Prospective with historical control	401	63%	37%	ND	↑↑	DOU ^a	UDT ^a	NS ^b	○
May 1997 ²⁸⁵	Prospective, uncontrolled	170 (220 accesses)	0%	100%	ND	↑↑	DDU	UDT	+ ^c	○

AVF=arterio-venous fistula; AVG=arterio-venous graft; DOU=doplex Doppler ultrasound; ND=no data; NS=not significant; PTA=percutaneous transluminal balloon angioplasty; UDT=ultrasound dilution technique.

+ Statistically significant beneficial effect of treatment compared to control (or intervention 1 vs. intervention 2).

a. Coupled with angiogram and PTA, or surgery for those with access stenosis defined by doubling of systolic velocity in vessel narrowed more than 50%, or UDT flow < 650 mL/min for AVG or < 500 mL/min for AVF or 15% decrease from previous measurement.

b. NS both AVG and AVF.

c. UDT, but not DDU, predicts thrombosis in multivariate analysis.

Table 14. Comparison of Newer Tests to Established Tests for Stenosis Detection

Author, Year	N	Type of Access AVF	Type of Access AVG	Applica- bility	Test 1 ^a	Test 2	Results	P-Value or 95% CI	Quality
Alrab-Zadeh 2002 ³⁴	22	100%	0%	↑↑	Angiogram ^b	IVUS	Author's conclusion: IVUS feasible		●
Smits 2002 ⁴⁶	18	39%	61%	↑	Angiogram ^a	MRA	Mean difference in maximum stenosis between tests	Observer 1: 3.2% (-26.7%, 33.1%)	●
							Mean interobserver difference	Observer 2: 4.1% (-23.8%, 32.1%)	
								Mean MRA: 3.2% (-28.8%, 35.2%) DSA: 3.6% (-9.4%, 16.7%)	
Planien 2003 ³⁶	15	53%	47%	↑	Angiogram ^b	MRA	Interobserver agreement on access stenosis	DSA: k = 0.69 MRA: k = 0.81	●
Ram 2003 ²⁴	33	24%	76%	↓	UDT	GPT	r = 0.901	<0.001	●

AVF=arterio-venous fistula; AVG=arterio-venous graft; DSA=digital subtraction angiography; GPT=glucose pump infusion technique; IVUS=intravascular ultrasound; k= kappa statistic for interobserver agreement; MP4=magnetic resonance angiography; PSV=peak systolic velocity; r=correlation coefficient; UDT=ultrasound dilution techniques; CI=confidence intervals

a. This test represents "gold standard" unless otherwise specified

b. Access stenosis defined by > 50% narrowing or reduction of luminal diameter of vessel

An important issue in fistulae is the assessment of such abnormalities as aneurysms and extreme tortuosity in “well-functioning” fistulae. DU is a very valuable technique, particularly in fistulae; in addition to measuring flow and identifying stenosis directly, it can detect other abnormalities in presumably well-functioning accesses.³⁴⁵ Pseudoaneurysms do not decrease access flow; Q_A is significantly greater than the mean (1,204 mL/min) in fistulae with aneurysms, calcifications, and tortuous vessels and, of course, less in those with stenosis. No correlation is noted between Q_A or the presence of stenosis with fistula age. Some degree of stenosis was detected in 64% of fistulae, with 57% of stenoses located in the anastomotic region; 22%, in the vein junction; 19%, at 1 or both ends of the aneurysm; and 2%, in the remaining region of the efferent vein.³⁴⁵ Chronic venous occlusion with collateral veins was detected in 6% of fistulae.³⁴⁵ Aneurysms were observed in 54% of fistulae with a mean diameter of 12.4 mm, with 96% of them located at puncture sites. Ten patients had a small thrombus in an aneurysm and at puncture sites. Thus, although a high level of abnormalities is present in well-functioning mature fistulae, the abnormalities are not sufficient to affect the functioning of the HD fistula and, in most cases, need only observation. More advanced lesions require therapy (see CPG 5).

DDU is a particularly useful modality to determine reasons for maturation failure of fistulae 4 to 12 weeks after construction,³⁴⁶ even if preoperative vein mapping had shown adequate vein size (≥ 3 mm) and outflow. Using the criteria of peak systolic velocity ratio (SVR) of 2:1 or greater to detect a 50% or greater stenosis involving arterial inflow, and venous outflow and an SVR of 3:1 or greater to detect a 50% or greater anastomotic stenosis, DDU of 54 native fistulae (23 brachiocephalic, 14 radiocephalic, and 17 basilic vein transpositions) found that 20% were occluded and 26% were normal. The remainder showed a variety of lesions: 16 fistulae (42%), venous outflow; 13 fistulae (34%), anastomotic; and 2 fistulae (5%), inflow stenoses. In 7 fistulae (18%), branch steal with reduced flow was found. Sensitivity, specificity, and accuracy of DDU in detecting stenoses of 50% or greater were 93%, 94%, and 97% compared with fistulography, respectively. Because many of these fistulae cannot be studied by using other surveillance techniques, routine DDU surveillance of primary fistulae should be considered to identify and refer for correction of flow-limiting stenoses that may compromise the long-term patency and use of the fistula.

Inflow stenosis is more common than previously believed (ie, $<5\%$ of cases). An inflow stenosis is defined as stenosis within the arterial system, artery-graft anastomosis (graft cases), artery-vein anastomosis (fistula cases), or juxta-anastomotic region (the first 2 cm downstream from the arterial anastomosis) with a 50% or greater reduction in luminal diameter judged by comparison with either the adjacent vessel or graft. Such stenosis was found in nearly a third of 223 cases referred to an interventional facility serving several centers.²⁶⁸ All referred accesses had a coexisting stenosis on the venous side. The frequency of inflow stenosis was less in grafts (29% of cases) than fistulae (40 of 101; 40%). Of these, 22 (54%) had a coexisting lesion on the venous side. Access inflow stenosis thus is much greater than traditionally reported in cases referred to interventional facilities with clinical evidence of venous stenosis or thrombosis.

Attempts to combine the various surveillance techniques have been performed. One study found no difference in the ability to detect stenoses in grafts from using Q_A by UDT compared with static venous pressure ratios.³⁴⁰ However, DVPs were of little use. Use of a P_{IA} compared with Q_A also was examined in 125 grafts followed up for 80.5 patient-years.³⁴⁷ Standardized monitoring of either P_{IA} , Q_A , or the combination of both, followed by subsequent corrective intervention, decreased the thrombosis rate in grafts compared with a historical control rate.³⁴⁸ Rates in 2 separate parts of the study for thrombosis not preceded by a positive test result were 0.24 and 0.32 episodes/patient-year at risk compared with a historical rate greater than 0.7, respectively. The surveillance strategies were equally effective in decreasing thrombosis rates, and access survival curves were not significantly different between subgroups.³⁴⁷ Again, DVP alone was not useful because either Q_A or P_{IA} turned positive before the dynamic pressure limit (>150 mm Hg at 200 mL/min) was reached. Unlike these 2 studies showing limited to no utility of DVP alone, another study was able to find some utility for DVP measurements for grafts.³⁴⁹ Stenosis greater than 50% by diameter on fistulography or a thrombotic event was defined as a “vascular access impairment episode,” whereas stenosis less than 50% or the absence of a thrombotic event was defined as “no vascular access impairment episode.” By combined dynamic pressure readings and flow surveillance (DVP > 120 mm Hg; $Q_A < 500$ mL/min in fistulae and < 650 mL/min in grafts or a decrease in $Q_A > 25\%$ compared with the highest previously measured value were considered positive), improved sensitivity over flow alone for fistulae, but not grafts, was observed.²⁶⁸ Sensitivity and specificity of the combined surveillance protocol for fistulae were 73.3% and 91%; in grafts, they were 68.8% and 87.5%, respectively. The rate of thrombotic events was less in patients with fistulae who underwent early repair, but in grafts, the addition of DVP did not decrease the thrombosis rate any further than surveillance based on Q_A alone. Finally, when UDT, DDU flow, DVP, and pre-pump pressure were examined as predictors of thrombosis in 172 grafts, DVP used alone was not predictive.²⁸⁵

In summary, available data suggest that the utility of DVP at flows of 150 to 225 mL/min to predict stenosis or thrombosis is limited or absent in grafts. Studies are needed to determine whether the method retains any utility in fistulae. Conversely, flow measurements, DDU assessment for stenosis, and static pressure measurements (direct or indirect by using computers) can detect hemodynamically significant stenosis in grafts and fistulae. Although the location of stenosis in fistulae (inflow) favors Q_A over P_{IA} , no direct comparisons have been made by using DDU anatomic imaging or contrast angiography to determine the accuracy of the techniques in this access type. If the prescribed Kt/V is not delivered in a patient who is using a fistula, measurement of access flow should be performed by using a recommended method (Table 7).

The Work Group believes there is insufficient evidence to suggest 1 surveillance technique from those listed in the guidelines as “preferred or acceptable” because the choice at a particular site is affected by many variables; chief among these are access type, technology, effect of operator, and cost (usually labor). Although DDU studies are predictive of access stenosis and the likelihood for failure,³⁵⁰ frequency of measurement is limited

by expense. In addition, interobserver variability in measurement of DDU flow in some instances can reduce the reliability of DDU flow measurement.³⁵¹ Variation in the internal software used for calculating DDU flow measurements by different manufacturers also is a factor preventing standardization. Magnetic resonance flow is accurate, but expensive. Both DDU flow and magnetic resonance are difficult to perform during HD sessions.

Conversely, flow measurements performed by using UDT and other techniques can be done on-line during HD, thereby providing rapid feedback. The same applies for P_{IA} . Both access flow and IAP techniques have been validated in prospective observational studies.^{10,322,347,349,352,353} Measuring static venous pressures is the least expensive method of surveillance for stenosis.^{322,354} Because of efficiency or cost, these methods are listed as preferred. In-line access flow measurements (DDU) are available and have been improved in terms of accuracy and replicability. However, there are no data yet on efficacy in detecting stenosis or effect on thrombosis rate.

The Work Group believes that recirculation is a relatively late predictor of access dysfunction and, if used, has a minor role in fistulae only. Non-urea-based recirculation measurements are very accurate, but require specialized devices.

Unexplained decreases in delivered dialysis dose, measured by using Kt/V or URR, frequently are associated with venous outflow stenoses.³⁵⁵ However, many other factors influence Kt/V and URR, making them less sensitive and less specific for detecting access dysfunction. Inadequate delivery of dialysis dose is more likely to occur with a fistula than a graft.

In primary fistulae, inadequate flow through the access is the main functional defect predictive of thrombosis and access failure (defined as thrombosis or failure to provide adequate dialysis dose). Indirect measures of flow, such as dynamic and static venous dialysis pressure, may be less predictive of thrombosis and access failure in fistulae compared with grafts. However, measurement of recirculation becomes a more useful screening tool in fistulae compared with grafts because flow in fistulae, unlike grafts, can decrease to a level less than the prescribed blood pump flow (ie, <300 to 500 mL/min) while still maintaining access patency.^{192,270,271} DDU may be useful in fistulae.³⁴⁶ Comparative studies using HDM (Q_A , P_{IA}) and DDU need to be performed before firm recommendations can be made by the Work Group.

Regular assessment of physical findings (monitoring) may supplement and enhance an organized surveillance program to detect access dysfunction. Specific findings predictive of venous stenoses include edema of the access extremity, prolonged postvenipuncture bleeding (in the absence of excessive anticoagulation), failure of the vein to collapse with arm elevation, and changes in physical characteristics of the pulse or thrill in the graft.^{108,354} Physical examination is a useful screening tool to exclude low flow (<450 mL/min) in grafts with impending failure.^{275,277,278} In the context of proper needle position, an elevated negative arterial prepump pressure that prevents increasing the BFR to the prescribed level also is predictive of arterial inflow stenoses.

When a test indicates the likely presence of a stenosis, angiography should be used to definitively establish the presence and degree of stenosis. Currently, the Work Group is in agreement with the Society for Interventional Radiology, which recommends

angioplasty if the stenosis is greater than 50% by diameter. Angioplasty by its very nature is a “disruptive” force on the vessel and can injure endothelium and underlying smooth muscle; each angioplasty can produce benefit or harm. However, there have been no large-scale trials to determine whether correction of only “hemodynamically” significant lesions (those associated with “low” access flows or “high” pressures or a change in access flow or pressure) is superior to correction of all stenosis greater than 50%. At the time of intervention, hemodynamic evaluation of each stenosis generally is not carried out.

Until such studies are conducted, the Work Group believes that the value of routine use of any technique for detecting anatomic stenosis alone—without concomitant measurement of access flow, venous pressure, recirculation, or other physiological parameters—has not been established. Stenotic lesions should not be repaired merely because they are present. If such correction is performed, then intraprocedural studies of Q_A or P_{IA} before and after PTA should be conducted to show a functional improvement with a “successful” PTA.

The Patient as His or Her Own Surveyor and Protector

The Work Group strongly advocates that all patients should be taught the “basics” of *how to take care of their vascular access*, including steps in personal hygiene, cleanliness, avoidance of scab picking, and so on, as discussed in Table 15. In addition, patients should be taught where and how to detect a “pulse,” where and how to feel for a thrill, how to recognize infection, and—most importantly—when to notify a member of the dialysis staff of physician when the pulse or thrill is absent. Delay in recognizing loss of patency may influence the likelihood of restoring patency.

Table 15. Patient Education Basics

All patients should be taught how to:

- a. Compress a bleeding access;
- b. Wash skin over access with soap and water daily and before HD;
- c. Recognize signs and symptoms of infection;
- d. Select proper methods for exercising fistula arm with some resistance to venous flow;
- e. Palpate for thrill/pulse daily and after any episodes of hypotension, dizziness, or lightheadedness;
- f. Listen for bruit with ear opposite access if they cannot palpate for any reason.

All patients should know to:

- a. Avoid carrying heavy items draped over the access arm or wearing occlusive clothing;
 - b. Avoid sleeping on the access arm;
 - c. Insist that staff rotate cannulation sites each treatment;
 - d. Ensure that staff are using proper techniques in preparing skin prior to cannulation and wearing masks for all access connections;
 - e. Report any signs and symptoms of infection or absence of bruit/thrill to dialysis personnel immediately.
-

The patient must be taught the reason for avoiding “1-site-itis.” Topical anesthetics should be used judiciously if they help the patient comply with the policy of rotation of needle sites. To avoid aneurysm formation, the patient should insist on site rotation unless a buttonhole method is being used in a native fistula. With the large staff turnover ratios prevalent in HD units in the United States, the patient must be diligent that staff uses the proper aseptic techniques whenever the access is palpated, inspected, or cannulated.

Surveillance and Thrombosis

Nonrandomized Trials

In dialysis AVGs, thrombotic events result primarily, but not solely, from progressive venous outflow stenosis.^{10,24,105,300,354,356–358} Thrombotic events that cannot be resolved (ie, patency restored) are the leading cause of access loss. These stenoses are caused by intimal and fibromuscular hyperplasia in the venous outflow tract, typically at the graft venous anastomosis,^{359–362} but can occur in the body of the graft, as well. The details of pathophysiology are beyond the limits of this discourse except to state that, to date, promising therapies in animal models have not yielded success in humans. Possible future therapeutic approaches have been summarized.³⁶³

As stenoses increase in severity, they produce a resistance to flow, increasing P_{IA} with an accompanying decrease in blood flow.^{266,318} Cross-sectional studies using DDU or UDT showed a progressive increase in risk for access thrombosis during a follow-up interval of 1 to 6 months. The absolute value of the “critical or threshold” Q_A depends on the method used. Average access flow rates obtained by DDU are less (600 to 900 mL/min)^{252,335,364} than those measured by using magnetic inductance (mean, 1,100 mL/min) or UDT (mean range, 900 to 1,200 mL/min).³³⁶ Studies also showed that when access flow is measured repeatedly, trends of decreasing flow add predictive power for the detection of access stenosis or thrombosis.^{284–286,300,311,318,349,364–371} Grafts with access blood flows less than 600 to 800 mL/min have a greater rate of access thrombosis than grafts with flow rates greater than 800 mL/min.^{268,284,286,300,311,318,372} In addition to this absolute value, a decrease of 25% in access flow from a previous “stable” baseline greater than 1,000 mL/min has been suggested as a criterion for further diagnostic evaluation of grafts to detect the presence of at least one 50% (by diameter) stenosis within the access.^{285,364,369–371} In general, the interval that is present to correct the lesion in grafts before the access thromboses varies inversely with the access flow, being less than 8 weeks at a flow less than 450 mL/min³⁷¹ and 3 months at flow rates of 600 to 800 mL/min.²⁸⁵

Although many centers refer patients directly for angiographic study without intermediate studies when a critical value is obtained, there may be a role for DDU anatomic scanning.²⁸² Because fistulae maintain patency at lower flows than grafts, criteria for intervention in fistulae are not as well established. Values of 400 to 650 mL/min have been proposed. Higher values increase sensitivity, but lose specificity. Some fistulae can maintain patency for years at flows less than 400 mL/min, but with high-efficiency/high-flux dialysis, the treatment time requires extension. Conversely, intervention with PTA almost invariably triggers a process of repeated need for PTA because the frequency of at least 1

abnormality in an access is so high. Optimal care of a particular patient requires individualization, and not rigid application of protocols.

Because the development and severity of stenosis evolve to varying degrees among patients over time, the likelihood of detecting a hemodynamically significant stenosis increases if the surveillance test is repeated frequently. Therefore, surveillance should be performed at intervals of 1 month or less—depending on the complexity and cost—to detect access dysfunction early and permit sufficient lead time for intervention. The Work Group concluded that trend analysis could be as important as any individual value for any monitoring technique. Because access pressure measurements do not require complex technology, their frequency should be greater than that for access flow measurements. For direct measurement of access pressure, a frequency of twice a month appears sufficient. With methods more likely to produce variation under real-world clinical practice conditions (such as those from the HD system transducers), measurements once every 1 to 2 weeks are needed to detect a trend. The Work Group believes that measurement of static pressures every 2 weeks is the minimum frequency that is compatible with current HD staffing patterns. Derived static pressures need analysis from all available treatments for the month. Dynamic pressures should not be performed in grafts.

Measurement of access flow also was shown to be a valuable tool in determining the success of a therapeutic intervention. Failure to increase access flow by at least 20% after an intervention reflects failure of the intervention to correct the underlying problem.^{282,369} In 1 study, values before PTA and ΔQ_A correlated with the subsequent decrease in Q_A ($P < 0.005$).²⁸² It was observed that Q_A increased after PTA (from 371 mL/min to 670 mL/min in a total of 65 grafts and 33 fistulae), but in a substantial percentage of cases, not to levels greater than 600 mL/min. Q_A values before PTA and the increase in Q_A values correlated with long-term outcomes, whereas angiographic results did not. Unfortunately, in many of the studies, the literature has admixed results for flow and outcome for both fistula and graft, making it impossible to sort out effects in grafts as opposed to fistulae. The Work Group believes there may be important differences in the response of fistulae (compared with grafts) to PTA, and surgical approaches also may influence outcomes. Research is needed in this area.

A large number of studies that used historical control data showed that prospective surveillance/monitoring to detect stenosis reduces the rate of thrombosis, although at the expense of increased procedures.^{10,322,343,373,374} A seminal study showed that a prospective program of dynamic pressure surveillance could detect stenotic lesions, reduce thrombosis rates, and reduce access replacement rates.³²² In that study, fistulae and grafts were not differentiated with respect to efficiency of the test. Unfortunately, criteria developed with needles designed for low-efficiency dialysis (16 G; pressure > 150 mm Hg at a flow of 200 mL/min) were not adapted for larger bore needles (15 G and 14 G), and other investigators did not independently standardize their pressure criteria for the flow actually used (150 to 225 mL/min). Accordingly, results of this study generally were not duplicated.³⁴⁰ Until such standardization is performed, DVP alone is not recommended. Additional studies using static pressure,¹⁰ physical examination alone,^{352,353}

DVP combined with access recirculation plus physical finding,³⁷³ DDU,^{284,374} and Q_A ^{341,366,369,375} all showed a 41% to 67% reduction in thrombosis rate in grafts. A review suggested that the effect may be smaller in fistulae.³⁷⁴

Receiver operating characteristic (ROC) curve analyses have been performed to assess the overall performance of access flow and pressure in predicting thrombosis. Although in some studies, a good AUC of 0.84 to 0.9 was achieved for access flow, overall AUC for 10 studies was only 0.7.³⁷⁶ Addition of a change in flow increased AUC slightly to 0.82, but not to the value of 0.9 that an excellent test would produce (90% sensitive and 80% specific).³⁷⁷ The sum of Q_A and ΔQ_A did not perform any better than P_{IA}/MAP .

Unfortunately, the high baseline rate of thrombosis in grafts precludes a sensitive test that can unequivocally predict the likelihood of thrombosis or not over a specified time. During a 3-month observation period, grafts can clot in the absence of any stenosis and do so at flows equal to those that remain patent, 1,209 versus 1,121 mL/min.²⁷⁰ In these cases, P_{IA} remains unchanged. Grafts that required intervention or that thrombosed because of an anatomic lesion had much lower access flows, 656 mL/min and 609 mL/min, respectively. At flows greater than the threshold, the incidence of thrombosis may be as high as 20% per 6-month period.³⁷⁵ Even with flows in the highest quartile, greater than 1,395 mL/min, another study found a thrombosis rate of 9% during a period of 3 months (annualized risk, 36%).²⁸⁵ Until more studies are performed that examine the frequency of thrombosis in the absence of stenosis and the frequency of patency in the presence of arterial or venous stenosis, the debate will go on.³⁷⁸⁻³⁸¹

At the present time, the development of a surveillance abnormality should be correlated with other findings on physical examination and adequacy of HD. Any abnormality (Q_A , P_{IA}) must be confirmed before further referral for either DDU (stenosis characterization) or angiography.

Randomized Trials of Preemptive PTA in Response to Surveillance

To date, only a small number of studies have been performed prospectively to assess the impact of surveillance on outcome. These are summarized in Table 16. Table 16

The concept that prophylactic or preemptive PTA would decrease graft thrombosis initially was refuted.³⁸² In a study of 64 patients identified to have a 50% stenosis by using DDU and confirmed by using angiography, preemptive PTA produced no change in 6-month or 12-month patency. Because of confounding issues, a subanalysis was performed on 21 "virgin" grafts that had not previously clotted or required intervention.³⁸³ Preemptive PTA from the time of diagnosis of stenosis reduced the thrombosis rate from 0.44 to 0.10 episodes/patient-year at risk. Both rates were much less than the rate of 0.91 in patients without virgin grafts. However, sample size was small ($n = 19$). It should be noted that in this study, only anatomic assessment was obtained; no hemodynamic assessment was performed.

The small number of patients in this and all other prospective studies has limited assessment of efficacy. One prospective study using P_{IA} was performed.³⁸⁴ Although the study itself was well designed, it was flawed by the surveillance technique. A preliminary

Table 16. Access Surveillance Studies with PTA Intervention

Author, Year	Study Design	Surveillance Test	N	Type of Access	Follow-up (maximum)	Applicability	Difference in Access Survival	Quality
Maist 2003 ³⁸⁶	RCT	UDT	112	100% AVG	450 d	††	NS	○
Riam 2003 ³⁸⁷	RCT	UDT and DDU	101	100% AVG	900 d	††	NS*	○
Damber 2004 ³⁸⁴	RCT	Static venous pressure ^a	64	100% AVG	Median 8.1 mo for Surveillance test and 16.5 mo for control (3.3 yr)	††	NS ^c	○
Lumsden 1997 ³⁸⁸	RCT	DDU	64	100% AVG ^d	Mean 15.2 mo (24 mo)	††	NS	○
Marrin ^e 1999 ³⁸³	RCT	DDU	21	100% AVG	3.5 yr	†	NS	○
Tessitore 2003 ³⁸⁶	Prospective with concurrent control	UDT vs. Clinical exam	60	100% AVF ^f	Median 17.5 mo for UDT 13 mo for no PTA (40 mo)	††	+	○

AVF=arterio-venous fistula; AVG=arterio-venous graft; DDU=duplex Doppler ultrasound; NS=not significant; PTA=percutaneous transluminal balloon angioplasty; RCT=randomized controlled trial; UDT=ultrasound dilution technique.

Access Survival defined as time to abandonment or time to intervention.

+ Statistically significant beneficial effect of surveillance compared to "standard clinical evaluation"

a. UDT was ineffective; DDU for stenosis detection reduced thrombosis but increased PTA rates; no effect on graft survival

b. Static pressure ratio defined as systolic pressure in graft/mean arterial pressure; action level >0.4

c. Time to intervention was shorter in surveillance group. Proportion of patients with a thrombotic event was greater in the Observation group (72%) than in the Intervention group (44%) (P=0.04), but overall thrombosis rates were similar in the 2 groups.

d. Inclusion criteria: functional stenotic AVG

e. Subgroup of Lumsden 1997 with "virgin" AVGs

f. Inclusion criteria: functional stenotic AVF

study was performed in which monthly static venous pressure measurements were made during 2 consecutive HD sessions in all patients with a functioning upper-extremity graft in 2 HD units during a 16-month period. The method for deriving P_{IA} ratio differed significantly from that originally described¹⁰ in that the ratio of systolic P_{IA} pressure to MAP was calculated instead of the ratio of systolic P_{IA} pressure/systolic blood pressure.³⁸⁵ The net effect of this error is that the ratio would have been falsely elevated and the threshold value of 0.4 would not apply. In addition, measurements were performed less frequently than recommended. Not surprisingly, ROC analysis yielded curves with areas less than 0.64.³⁸³ Subsequently, 64 patients with “elevated static venous pressure” measured in an upper-extremity graft were randomized to intervention (underwent angiography and repair of identified stenoses) or observation (underwent stenosis repair only in the event of access thrombosis or clinical evidence of access dysfunction), with the primary end point being access abandonment. Information on the fraction in the interventional group who had a stenosis is not provided. There was no difference in access abandonment (14 patients in each group) during the 3.5-year study period or in time to access abandonment. However, the proportion of patients with a thrombotic event was greater in the observation group (72%) than the intervention group (44%; $P = 0.04$), but overall thrombosis rates were similar in the groups (ie, there was a difference in mean number of thrombosis per graft in the intervention group in grafts that did thrombose). Not detailed was the number of PTAs that had to be performed in both groups during the entire study period.

Two randomized studies examined the role of access surveillance by using Q_A . In the first, it was found that stenotic lesions are detected more commonly by using Q_A ($Q_A < 650$ mL/min or 20% decrease in Q_A) than “routine surveillance” (physical examination plus $DVP > 150$ mm Hg) in a total of 112 patients, but elective PTA for lesions greater than 50% did not alter thrombosis rate.³⁸⁶ Rates of graft loss, times to graft loss, and overall thrombosis rates did not differ between the 2 groups. However, interventions increased by 30% in the intervention group. In the second study, 101 patients were randomized to 3 groups: control, low surveillance Q_A (Transonics) monthly, or stenosis detection by using DDU quarterly.³⁸⁷ Referral for angiogram was based on clinical characteristics in all, less than 600 mL/min in Q_A , and greater than 50% diameter in the DDU stenosis groups. Q_A was measured in all 3 groups, but only used for referral in the flow surveillance group. Baseline thrombosis rates were 0.7 and 0.9/patient-year in the control and Q_A groups, respectively. Results showed that Q_A increased PTA rate marginally (from 0.22 to 0.33/patient-year) and had no effect on thrombosis rate. Stenosis surveillance increased PTA to 0.65/patient-year and reduced thrombosis rates to 0.5/patient-year, but did not affect 2-year survival rate. Q_A less than 600 mL/min was found in 4 of 18, 4 of 31, and 3 of 11 in the control, Q_A , and stenosis groups in grafts that clotted (overall, 11 of 60). However, 26 of 35 in the stenosis group underwent PTA for “stenosis.” In both studies, 20% to 25% of accesses clotted without a surveillance abnormality, ie, in a totally unexpected manner.

However, the overriding conclusion of the studies that surveillance using Q_A and PTA in response to a threshold value of Q_A did not alter graft survival has to be tempered

by the small sample size of the studies, the comparator used, and the efficacy of the intervention. Graft survival studies require a sample size of approximately 700 patients to detect an increase in graft survival of 1 year or a 33% difference in survival by 3 years (H. Feldman, personal communication). None of the studies had 20% of this number. It also is important to assess the skill level of the staff. If the staff can reach a positive predictive value of 80% (when stenosis is present and needs intervention) through use of physical examination and clinical characteristics (monitoring), use of a surveillance method that has a sensitivity of only 80% will produce no benefit over good monitoring. Determining which lesions should undergo correction has already been addressed. Elastic recoil needs to be assessed.

In contrast to grafts, the role of Q_A surveillance appears to be more established in fistulae. In 1 study, the positive predictive value, negative predictive value, sensitivity, and specificity of ultrafiltration method for vascular access stenosis (OABF CritLine III) were 84.2%, 93.5%, 84.2%, and 93.5%, respectively. Vascular access thrombosis rates in 50 Q_A surveillance patients were less (2 of 50 patients; 4%) than in 94 patients not followed up with flow measurements (16 of 94 patients; 17%; $P = 0.024$).²⁴²

In a second study, a 5-year RCT of blood flow surveillance and preemptive repair of subclinical stenoses (1 or both of angioplasty and open surgery) with standard monitoring and intervention based upon clinical criteria alone was carried out in Italy.³⁸⁸ Surveillance with blood pump flow (Q_B) monitoring during HD sessions and quarterly Q_A or recirculation measurements identified 79 fistulae with angiographically proven significant (>50% diameter) stenosis that were then randomized to either a control group (intervention done in response to a decrease in delivered dialysis dose or thrombosis; $n = 36$) or preemptive treatment group ($n = 43$). Kaplan-Meier analysis showed that preemptive treatment decreased the failure rate ($P = 0.003$) and the Cox hazards model identified treatment ($P = 0.009$) and greater baseline Q_A ($P = 0.001$) as the only variables associated with favorable outcome. Access survival was significantly greater in preemptively treated than control fistulae ($P = 0.050$), with greater postintervention Q_A as the only variable associated with improved access longevity ($P = 0.044$). This study provides evidence that active blood flow surveillance and preemptive repair of subclinical stenosis reduce the thrombosis rate and prolong the functional life of mature forearm fistulae and that Q_A greater than 350 mL/min before intervention portends a superior outcome with preemptive action in fistulae.

Finally, in a third study, a prospective controlled open trial to evaluate whether prophylactic PTA of stenosis not associated with access dysfunction improves survival in native virgin radiocephalic forearm fistulae, 62 stenotic functioning fistulae (ie, able to provide adequate dose of dialysis) were enrolled: 30 were allocated to control, and 32, to PTA.³⁸⁹ Kaplan-Meier analysis showed that PTA improved fistula functional failure-free survival rates ($P = 0.012$) with a 4-fold increase in median survival and a 2.87-fold decrease in risk for failure. A Cox proportional hazards model identified PTA as the only variable associated with outcome ($P = 0.012$). It was found that PTA increased Q_A by 323 mL/min ($P < 0.001$), suggesting that improved fistula survival is the result of increased access flow. PTA also was associated with a significant decrease in access-related

morbidity, halving the risk for hospitalization, central venous catheterization, and thrombectomy ($P < 0.05$). Because prophylactic PTA of stenosis in functioning forearm fistulae improves access survival and decreases access-related morbidity, it supports the use of a surveillance program for the early detection of these stenoses.

LIMITATIONS

At present, a vascular surveillance program to identify patients who may benefit from angiography and PTA appears to offer the most likelihood of benefit and may reduce thrombosis rates. However, we need additional studies to examine the characteristics of stenoses that produce incomplete responses to PTA so that patients are adequately treated at the time of their interventions.

GUIDELINE 5. TREATMENT OF FISTULA COMPLICATIONS

Appropriate interventions for access dysfunction may result in an increased duration of survival of the AVF.

5.1 Problems developing in the early period after AVF construction (first 6 months) should be promptly addressed.

5.1.1 Persistent swelling of the hand or arm should be expeditiously evaluated and the underlying pathology should be corrected. (B)

5.1.2 A program should be in place to detect early access dysfunction, particularly delays in maturation. The patient should be evaluated no later than 6 weeks after access placement. (B)

5.2 Intervention:

Intervention on a fistula should be performed for the presence of:

5.2.1 Inadequate flow to support the prescribed dialysis blood flow. (B)

5.2.2 Hemodynamically significant venous stenosis. (B)

5.2.3 Aneurysm formation in a primary fistula. Postaneurysmal stenosis that drives aneurysm also should be corrected. The aneurysmal segment should not be cannulated. (B)

5.2.4 Ischemia in the access arm (B).

5.3 Indications for preemptive PTA:

A fistula with a greater than 50% stenosis in either the venous outflow or arterial inflow, in conjunction with clinical or physiological abnormalities, should be treated with PTA or surgical revision. (B)

5.3.1 Abnormalities include reduction in flow, increase in static pressures, access recirculation preempting adequate delivery of dialysis, or abnormal physical findings. (B)

5.4 Stenosis, as well as the clinical parameters used to detect it, should return to within acceptable limits following intervention. (B)

5.5 Thrombectomy of a fistula should be attempted as early as possible after thrombosis is detected, but can be successful even after several days. (B)

5.6 Access evaluation for ischemia:

5.6.1 Patients with an AVF should be assessed on a regular basis for possible ischemia. (B)

5.6.2 Patients with new findings of ischemia should be referred to a vascular access surgeon emergently. (B)

5.7 Infection:

Infections of primary AVFs are rare and should be treated as subacute bacterial endocarditis with 6 weeks of antibiotic therapy. Fistula surgical excision should be performed in cases of septic emboli. (B)

RATIONALE

Initial Problems (CPG 5.1)

Minor swelling normally is found postoperatively after placement of an AVF regardless of location and type of anastomosis. This “physiological” swelling disappears within the first week. Swelling of the hand or area of the fistula should be treated with hand elevation and patient reassurance. Because prevention is always preferable to therapy, a major aspect of preventing postoperative swelling is to rest the arm. Persistent swelling requires further attention to exclude major outflow obstruction. Hematoma, infection, and venous hypertension also should be excluded by clinical examination^{277,391,392}; noninvasive ultrasound examination helps confirm extravasations and hematomas or purulent infiltrations, as well as strictures/stenoses of the venous outflow tract.^{45,124,393} Although angiography (fistulography) can show a venous stenosis causing venous hypertension, DDU is the preferred diagnostic method because it avoids any diagnostic cannulation of the newly created AVF and thereby avoids iatrogenic damage of the thin wall of the freshly arterialized vein. If a stenosis is found, it should be treated with a balloon angioplasty.

Persistent hand edema usually follows a side-to-side anastomosis for creating the fistula and invariably results from downstream stenosis forcing the flow through venous collaterals. This process can produce classic chronic venostasis with skin ulceration. The lesion should be treated early by ligation of the tributaries. If delayed healing of the wound is noted in patients, the surgical technique should be examined closely. The surgical technique to close the skin preferably should use degradable suture material in an exclusively subcutaneous position supported by externally applied sterile adhesive strips to minimize the thickness of the scar.

Risk for bleeding and hematoma formation is greatest in the early stages of use of a fistula and greater in brachio basilic fistulae than other types of fistulae at the wrist or elbow.⁷⁷ Manifestations of an infiltration or hematoma aside from the obvious discoloration and swelling include the presence of high-frequency bruit on auscultation and a difference in intravascular pressure on palpation.^{277,391,392} Because hematoma may lead to access loss,⁷⁷ hematomas should be treated surgically if they are compromising the lumen of the arterialized vein (producing stenosis).³⁸⁸ In the absence of luminal compromise by physical examination or DDU, the access should be rested until the margins of the fistula are again well demarcated.

Proficiency in cannulating fistulae is suboptimal in the United States despite considerable efforts to remedy the situation.^{120,394-396} One can improve needle design to minimize trauma³⁹⁷ and develop methods to increase the efficiency of buttonhole development,³⁹⁸ but it is for naught if the fistula cannot be cannulated consistently without infiltrations. Because an inability to “be sure of the location” of the 2 lateral borders of the fistula contributes to miscannulation (particularly in those who are obese or have deep fistulae) and is manifested by so-called clot aspiration and because DDU is very precise in depicting the borders of vessels (see CPG 1),^{344,399,400} patients should be referred for access mapping and photography. A useful procedure is for the ultrasonographer to draw a map on the surface of the skin with a washable marker directly over the center of the lumen (or the 2 lateral

borders), make a digital photo map of the fistula based on ultrasound, and send the photograph of the usable portion of the fistula access to the dialysis center. Alternatively, the access can be marked with indelible ink that permits the establishment of a series of subsequent successful puncture sites to demarcate the center of the vessels if the rotating-site system of cannulation is used (see CPG 3). These techniques both educate the staff and develop expertise and confidence. In addition, they should foster greater expertise in assessing fistulae during the first postoperative weeks for delayed maturation. Prospective studies are needed to demonstrate this opinion-based strategy.

The majority of fistula creations can be performed on an outpatient basis. A crucial element is the postoperative examination and surveillance follow-up that is scheduled by either the surgeon or a vascular access coordinator representing the interdisciplinary VAT. The primary purpose is to detect problems of maturation (see CPG 2). Although a variety of factors can produce maturation failure,^{86,123,125} a greater than 70% successful fistula access rate can be achieved, even among patients who have diabetes^{86,87,401,402} and women.⁸⁴ In a multiple logistic regression analysis of 148 grafts (60% forearm, 40% elbow), predictive factors of early failure were distal location (adjusted odds ratio [aOR], 8.21; 95% confidence interval [CI], 2.63 to 25.63; $P < 0.001$), female sex (aOR, 4.04; 95% CI, 1.44 to 11.30; $P = 0.008$), level of surgical expertise (aOR, 3.97; 95% CI, 1.39 to 11.32; $P = 0.010$), and diabetes mellitus (aOR, 3.19; 95% CI, 1.17 to 8.71; $P = 0.024$).⁴⁰³ Much of the prevention of delayed fistula maturation must occur preoperatively (see CPG 1) through appropriate selection of arterial and venous vessels, as well as procedures most suitable for the individual patient. Although it is the vein that must dilate and accept higher flows, the artery must be healthy too. The resistive index of the artery used to construct the fistula is a strong predictor of early primary HD fistula failure.⁴⁰⁴ However, despite selection of the best available artery and vein, maturation failure can still occur. By combining venous diameter (>0.4 cm) and flow volume (>500 mL/min) during DDU evaluation within the first 4 months after access construction, one can predict the likelihood of maturing a fistula,⁷² ie, one that can be cannulated and provides sufficient blood flow for dialysis, with 95% certainty (19 of 20 fistulae). Women were less likely to have an adequate fistula diameter of 0.4 cm or greater: 40% (12 of 30) compared with 69% for men (27 of 39). However, of note, the accuracy of experienced dialysis nurses in predicting eventual fistula maturity was excellent at 80% (24 of 30).⁷² This is more reason to have a protocol for regular clinical examination in place in dialysis centers to teach the skills of physical examination (see CPG 4) to all staff members and assess the developing fistula and not focus on only the access in current use. A new fistula should be monitored regularly during the postoperative 4 to 6 weeks for swelling, hematoma, infiltration, wound healing, and failure to mature.

Intervention (CPG 5.2)

Inadequate Flow

A primary fistula should be revised when it is unable to sustain adequate HD blood flow, manifested by the inability to achieve the prescribed Kt/V within a reasonable HD duration. Low access blood flow has a major effect on the delivery of dialysis: inadequate blood flow may result in inadequate dialysis, thereby increasing patient mortality and

morbidity.^{405,406} Impaired flow in fistulae is caused by impaired arterial inflow related to the site of cannulation. Location of the anatomic reason varies between arterial and venous lesions, as well as lesions within the anastomotic area.

Arterioatherosclerotic narrowing of the feeding artery with reduced flow and stenosis of the artery are found in an increasing portion of the elderly, patients with hypertension, and patients with diabetes. Therefore, careful preoperative evaluation should document data on anatomic and functional status of the arterial vasculature, including flow in the brachial artery (see CPG 1).

As stated, peripheral location of first fistula, female sex, diabetes mellitus, and, finally, surgical expertise are the main predictive factors of early fistula failure.⁷² Because it is known that arterial calcification in patients with diabetes is more pronounced in the wrist than elbow region,⁴⁰⁷ selection of a more proximally located site for creation of the AV anastomosis, eg, the proximal radial or beginning brachial artery in the proximal forearm, may be the better alternative. Inadequate flow in the area of the AV anastomosis is produced primarily by surgical factors. Two studies^{403,408} emphatically stressed that the early failure rate of fistula may be 3-fold greater when constructed by “occasionally” working access surgeons compared with experienced surgeons.

However, an initially adequate artery may become inadequate in time. Four of 40 patients had brachial artery lesions contributing to access dysfunction.⁴⁰⁹ In a larger series, 41 of 101 fistulae had arterial inflow lesions at the time of therapeutic intervention for dysfunction.²⁶⁸

In case of reduced flow caused by arterial inflow, 2 therapeutic options exist: stenosis of the feeding artery may require interventional angioplasty or surgical revision, or inadequate quality of the feeding artery (caused, eg, by calcification) may require a more proximally located new AV anastomosis. Although chronic arterial lesions in upper limbs bearing vascular access devices for HD most often manifest themselves as insufficient flow for HD treatment, the process may be severe enough to produce thrombosis and ischemia. For correcting stenoses, PTA is a safe and effective technique with a low rate of reintervention.²⁶⁸

Juxta-anastomotic venous stenosis is a commonly observed lesion. It occurs from the change in hemodynamic flow character from the artery into the vein and from devascularization of the venous wall during exposure, even after excellent surgery. Placement of the “arterial needle” downstream of this stenosis obviously supports the phenomenon of impaired flow. At times, it may be impossible to traverse the AV anastomosis by using the retrograde approach, and antegrade puncture of the brachial artery will be needed.⁴¹⁰ Although interventional procedures are successful with this type of lesion,⁴¹¹ construction of a new AV anastomosis (revision) at a more proximal location is the preferred procedure.¹¹² However, the therapeutic strategy depends on the type of lesion and variability of local expertise.

Hemodynamically Significant Venous Stenosis

The commonly used parameter to characterize the hemodynamic relevance of a stenosis is a reduction in vessel diameter exceeding 50% based on angiographic and/or ultra-

sonographic findings. In contrast to an exact diagnosis in a synthetic AVG with a known standard diameter, it may be difficult to describe reliably the percentage of narrowing in a native vein, particularly because this vein may present a prestenotic and/or poststenotic aneurysmic enlargement. The hemodynamic relevance of a 50% stenosis in a native AVF therefore should be supported by clinical symptoms, abnormal physical findings, and flow measurements (see CPG 4). The diagnosis of “hemodynamically relevant venous stenosis” based on a combination of clinical and technical findings should initiate a corrective procedure, either percutaneous or surgical intervention.

In AVFs, significant stenoses may not elevate dynamic or static pressures, although such lesions can result in decreased access flow and elevated recirculation (see CPG 4) that are associated with increased risk for thrombosis.³⁶⁹ Treatment of hemodynamically significant venous stenosis prolongs the use-life of the AVF.^{322,356,358,369,412} A study of 32 patients and 30 controls showed a beneficial effect on AVF survival of prophylactic angioplasty of stenoses.³⁹⁰ Subsequent Kaplan-Meier analysis of a larger cohort of patients over 5 years showed that preemptive treatment decreased the failure rate ($P = 0.003$), and the Cox hazards model identified treatment ($P = 0.009$) and greater baseline access flow ($P = 0.001$) as the only variables associated with favorable outcome.³⁸⁹ A significant increase in access blood flow rate was observed, as well as a significant decrease in access-related morbidity by approximately halving the risk for hospitalization, central venous catheterization, and thrombectomy. This group showed, in a population of 120 patients with AVFs, that UDT measurements were reproducible and highly accurate in detecting stenosis and predicting thrombosis in forearm AVFs. Neither Q_A /MAP nor ΔQ_A improved the diagnostic performance of Q_A alone, although its combination with ΔQ_A increased the test’s sensitivity for stenosis.³⁵⁹ These data support the value of monitoring and surveillance in AVFs (see CPG 4). In AVFs, 75% of stenoses producing low flow are at or near the AV anastomosis and 25% are in the outflow track.

Aneurysm Formation in a Primary Fistula

Progressive enlargement of an aneurysm eventually can compromise the skin above the fistula, leading to possible rupture. This can result in hemorrhage, exsanguination, and death. In the Work Group’s opinion, large aneurysms can prevent access to the adjacent fistula for needle placement, thereby limiting potential cannulation areas.

Aneurysm formation in a primary fistula can be observed in the following situations:

1. Within the first postanastomotic venous segment in the presence of a hemodynamically relevant stenosis in the juxta-anastomotic position. The therapy of choice is a new AV anastomosis using a “healthy” venous segment located a few centimeters more proximally, but as close to the former anastomosis as possible, to preserve the maximum area for cannulation. Here, surgery may provide better results than angioplasty. Secondary patency rates may be very similar, although repeated angioplasty is far more expensive, with increased morbidity, risk for catheter placement, and inadequate HD sessions.
2. Within cannulation areas. This type of aneurysm is caused mainly by the so-called “I-site-itis” cannulation⁴¹³ and should lead to abandonment of the area for cannulation

(see CPG 3) and strict enforcement of the “rope-ladder” cannulation method if a buttonhole does not seem practical. The latter is by far the best available method for prevention. For hemodynamic reasons, aneurysms of this type are combined at times with a preaneurysm stenosis, but more commonly with a postaneurysm stenosis.

Therapeutic options for managing the aneurysms include the following:

1. Cannulation should *not* be continued along any type of venous aneurysm, particularly in patients for whom the skin layer within the aneurysm is thin and prone to infection—a sign of impending perforation.
2. In cases of progression of aneurysm and stenosis, a series of surgical procedures are available, including: i) partial resection of the wall of the aneurysm and insertion of the resected material as patch along the stenosis, forming a patch from a segment of a venous branch; ii) mobilizing an adjacent venous branch for local repair by a “swing-by-technique”; and iii) other options. In all cases in which surgery can provide a (nearly) perfect inner diameter while preserving cannulation sites, angioplasty should be the second choice. Currently, stent insertion should be avoided along cannulation sites in fistulae.
3. Aneurysms along the venous outflow tract where cannulations are not performed routinely are found for anatomic reasons (eg, in junctions of veins, areas of venous valves with a rigid basic ring, and cases of old venous lesions caused by former venotomy, catheter insertion, and so on) as nucleus for a stenosis followed by a prestenotic aneurysm. Sometimes these lesions are caused by “1-site-itis,” in which the same area is cannulated repeatedly without any attempt at buttonhole development. It is particularly prone to develop when intra-AVF pressures are high, as in arm AVFs with cephalic arch stenosis, or in high-flow AVFs. The therapy of choice for these stenoses is angioplasty; when elastic recoil occurs, PTA should be combined with stent insertion in these more central outflow veins. Recurrent stenoses should undergo surgery.

Indications for Preemptive PTA (CPG 5.3)

Preemptive PTA may be indicated in certain cases of abnormal physical findings (see Fig 8). These findings are more important than other criteria. See also the rationale for CPG 5.2. However, certain facets should be kept in mind. This may be particularly important in “underserved” areas where the dialysis staff has no choice other than to rely on abnormal physical findings.

Tools for physical examination have been described in CPG 4. However, Table 17 provides a quick summary.

To detect the early beginning of an abnormality requires continuous meticulous education and daily practice. When a high level of expertise is achieved, a definitive diagnosis can be achieved in approximately 60% to 80% of cases through the presence of abnormal physical findings that lead to an intervention. These findings should be documented and preserved in the chart and—if possible—electronically to continue the observation of the very earliest abnormality. In the remaining 20% to 40% of patients

Figure 8. Treatment of stenosis. (Courtesy of Dr. Thomas Vesely)

KDOQI Guideline 4
Treatment of Stenoses

Stenoses should be treated if:

Clinical or physiologic abnormality + Anatomic abnormality
 • decreased access blood flow (<600ml/min, decrease in flow)
 • elevated venous pressure
 • decreased dialysis dose (Kt/V)
 • abnormal physical exam

• > 50% stenoses

without a definitive diagnosis after physical examination, further diagnostic steps should be undertaken using (preferably first) ultrasound followed by, if necessary, angiographic techniques, including the option of angioplasty during the same session; however, this is dependent on local availability and expertise.

Previous Thrombosis in the Access

It was shown repeatedly that thrombosis of AVFs is caused by anastomotic disorders, predominantly stenosis. Episodes of hypotension during HD may be contributory in some cases. No data exist to determine whether hypotension alone, even if for a few hours, can produce thrombosis in the absence of an underlying stenosis limiting flow into the access. Irrespective of type of treatment given for the previous episode(s) of access thrombosis, these patients should be considered at risk because anastomotic residuals or recurrent development of stenosis at the same site are common. Therefore, special attention should be taken to prevent recurrence of clinical signs. This strategy requires repeated continuous physical examination—a quick chairside procedure in the hands of experienced personnel preceding any cannulation procedure.

Persistent Abnormal Surveillance Test (see CPG 4.2)

Because surveillance test results at times are observer dependent, an abnormal isolated finding in any case should be supported by abnormal physical symptoms. Persistence of abnormal physical findings and surveillance test results (elevated pressures, low flows,

Table 17. Summary of Physical Examination

Inspection	Examine for erythema, swelling, gangrene, change of size of aneurysms over time. Feel for intravascular pressure along the veins; examine for segmental differences in quality. Feel for elevated/low skin temperature; check the quality of pulsation along arteries and veins. Check for pain caused by finger pressure.
Palpation	
Auscultation	Check for the presence of typical low-frequency bruit with systolic and diastolic components. Examine for abnormal high-frequency bruit produced by turbulence due to a stenosis.

abnormal recirculation) require that further diagnostic steps be initiated to establish an exact diagnosis and lead to timely treatment (see CPG 4).

Stenosis (CPG 5.4)

In the absence of method errors, repeated failure to deliver the prescribed dialysis dose by using an AVF should result in immediate evaluation of the vascular access when other reasons can be excluded, eg, technical errors, timing errors, and so on. (See the Guidelines for HD Adequacy and also the rationales for CPG 5.1 and CPG 5.2.)

The degree of stenosis is graded by the percentage of narrowing of the access, the reference being the diameter of the immediately upstream or downstream “normal vessel.” The reference diameter can be difficult to determine when the AVF is irregular or aneurysmal or at the confluence of 2 vessels. Grading of severity also can be done on the basis of the drop-off in systolic or mean pressure across the stenosis.^{414,415} The degree of residual effacement tolerated varies among interventionalists. Some demand no residual at all unless it is the first PTA ever done. Swelling, local or generalized in the arm, caused by central venous stenosis may take additional time to resolve.

Dilation often is painful locally and local anesthesia may be needed at times. Venous stenosis in the outflow may be “rock hard” and require high-pressure balloons (bursting pressures of 25 to 30 atmospheres), as well as more prolonged inflation periods. Resistant stenoses are less common, usually less than 1% in forearm and 5% of upper-arm fistulae.¹¹² There is no convincing proof that such lesions respond better to cutting balloons⁴¹⁶ because studies have been small and not prospective. The Work Group recommends that high-pressure balloons be used first because cutting devices have not been studied adequately.

Thrombectomy (CPG 5.5)

In most patients, thrombosis is the final complication after a period of AVF dysfunction. Treatment of thrombosis should start as early as possible. The risk of delay is progressive growth of the thrombus that makes interventional/surgical procedures more difficult and risky with regard to long-term success. The vascular access should be reopened as soon as possible to resume regular dialysis treatment and avoid resorting to a short-term catheter. In addition, delay produces a longer period of contact between the surface of the thrombus and the vessel wall, thereby increasing the risk that extraction of thrombus may further damage the endoluminal layer. This could favor future thrombotic events. Early intervention increases the likelihood that the same AVF can be used to provide future dialyses.

Although thrombectomy procedures are more challenging in fistulae than grafts, results are more rewarding.⁴¹⁷ Better long-term patency has been achieved in the largest series to date as long as the underlying stenoses are sufficiently dilated: 1-year primary patency rates of 50% and secondary patency rates of 80% have been reported.⁴¹⁸ Results reported in the upper arm are not as good. The unmasking of stenoses in close to 100% of cases warrants stenosis-detection programs similar to those for grafts.⁴¹⁹

After thrombosis is established, resolution depends on local expertise. Interventional thrombectomy and PTA of the underlying stenosis have gained wide acceptance. Nevertheless, there are no results from a larger series of surgical treatment of AVF thromboses

available. This leads to the astonishing fact that there are no comparable data available in this important field of access care.

Thrombosed fistulae can be declotted by using purely mechanical methods (dilation and aspiration),⁴¹⁹ a thrombolytic,⁴²⁰ or a combination of both.⁴²¹ Success rates are greater than 90% for the techniques. If a central vein stenosis is found, interventionalists frequently resort to the use of stents. Long-term results after dilation in the largest series are better in forearm native fistulae compared with grafts. Initial success rates for de-clotting are better in grafts compared with forearm fistulae, but early rethrombosis is frequent in grafts; thus, primary patency rates can be better for native fistulae after the first month's follow-up.⁴¹⁹ Although AVF function may be reestablished successfully as long as a week after thrombosis occurs, most should be treated as soon as possible.⁴²²

A variety of devices are available for mechanical thromboaspiration. With all, there are the issues of residual clots and cost-effectiveness of the devices over the simple procedure of catheter-directed aspiration. A meta-analysis should be performed.

Surgical thrombectomy is performed by using a Fogarty thrombectomy catheter, supported by retrograde digital expression of the thrombotic material and followed by correction of the stenosis by using a couple of techniques according to the individually varying condition. However, there are only scattered reports with initial success rates of only 65%⁴²³ compared with 90% or better for endovascular techniques. In a small study of 29 patients, a primary patency rate of 50% at 4 months was reported.⁴²⁴ Surgery seems to be the preferred technique to treat thrombosis in forearm AVFs with juxta-anastomotic stenoses, mainly by placement of a new anastomosis.⁴²⁴ With more proximally/centrally located thromboses, preference should be given to interventional endoluminal techniques. Early recurrence of stenosis/thrombosis can be decreased by insertion of a stent. On occasion, when both the artery and vein are thrombosed, conversion from a side-to-side to end-to-side anastomosis can be attempted, with the goal of using the newly created fistula immediately. This procedure was successful in 57% of 72 patients, particularly those with thrombosis of the AVF to the first side branch only, with the remaining fistula maintaining patency through collateral flow.⁴²⁵

Access Evaluation for Ischemia (CPG 5.6.1)

This evaluation should be a part of regular monitoring conducted routinely in all dialysis facilities. Particularly elder and hypertensive patients with a history of peripheral arterial occlusive disease and/or vascular surgery, as well as patients with diabetes, are prone to develop access-induced steal phenomenon and steal syndrome. In any case, clinical examination is mandatory, followed by ultrasound or radiological evaluation, as necessary. The patient must be referred to a vascular surgeon to decide on additional procedures. Delay can lead to catastrophic gangrene and hand amputation. The importance of this type of monitoring will increase in the future because of demographic changes in the dialysis population.

An AVF normally produces an alteration in blood flow patterns, a "physiological" steal phenomenon,⁴²⁶ that is seen in forearm AVFs and in a greater incidence in elbow/upper-arm AVFs.⁴²⁷ Physiological steal occurs in 73% of AVFs and 91% of AVGs.⁴²⁸ With the

aging of the HD population and the increase in arterial changes caused by diabetes and hypertensive remodeling, the incidence of symptomatic peripheral ischemia to the hand/arm (pain, necrosis of ≥ 1 fingertips) is increasing, but fortunately is still uncommon ($\leq 1\%$ to 4%).⁴⁸ Milder symptoms of coldness and some pain during dialysis may occur in up to 10% of cases and fortunately improve over weeks to months.⁴²⁹ It also is more common with prosthetic bridge grafts; less than 2% versus 4%.^{48,430} A decrease in distal perfusion pressures is found regularly and is more pronounced in patients with advanced arteriomedial sclerosis. In this type of patient, occurrence of a steal syndrome seems less dependent on access flow volume than on degree of the peripheral arterial obstructive disease.

Recently, staging according to lower-limb ischemia was proposed⁴⁸:

1. Stage I, pale/blue and/or cold hand without pain;
2. Stage II, pain during exercise and/or HD;
3. Stage III, pain at rest;
4. Stage IV, ulcers/necrosis/gangrene.

It is important to differentiate the findings of hand ischemia from those of carpal tunnel compression syndrome, tissue acidosis, and edema from venous hypertension. Non-invasive evaluation should be performed, including digital blood pressure measurement, DDU, and—if available—transcutaneous oxygen measurement.⁴⁸

Corrective results may be good at an early point in the process, but in any of these patients, one should be aware that the process of arterial damage could be progressive. Particularly in older patients with diabetes with an elbow/upper-arm AVF, monomelic ischemic neuropathy can be observed; an acute neuropathy with global muscle pain, weakness, and a warm hand with palpable pulses starting within the first hours after creation of the AVF.⁴³¹ Diagnosis of monomelic ischemic neuropathy is a clinical diagnosis, and immediate closure of the AVF is mandatory.

Emergent Referral to a Vascular Access Surgeon (CPG 5.6.2)

Although most ischemic manifestations occur early after surgery, in about a quarter of all patients, they can develop months to years after arterial constrictions. Fingertip necroses are an alarming symptom with an initially slow progression in most patients over weeks and a rapid final deterioration leading to necrosis and gangrene, indicating that one should aim for early intervention. If ischemic manifestations threaten the viability of the limb, the outflow of the fistula should be ligated.

Therapeutic options depend on the cause of steal syndrome. Arterial stenoses proximal to the anastomosis obstructing the arterial inflow may be dilated by angioplasty,⁴¹¹ but not in the case of advanced general arterial calcification. High-flow–induced steal syndrome requires a decrease in AVF flow volume. Banding procedures of the postanastomotic vein segment using different techniques as practiced in the past were not as successful as expected.⁴³² It is more beneficial to decrease the diameter of the anastomosis or create a new AV anastomosis distally. The success of the procedure after surgery should be evaluated by using access flow measurements.

In cases in which a physiological steal phenomenon becomes clinically symptomatic, ligation of the peripheral limb of the radial artery may be successful. Clinically symptomatic steal syndromes with normal or low BFRs represent the majority of cases with access-related peripheral ischemia. Since the new technique of the distal revascularization—interval ligation (DRIL) operation was published in 1988,⁴²⁹ several groups have confirmed the good results.^{48,433} In patients with a venous anastomosis to the brachial artery, with the DRIL procedure, the anastomosis is bridged by a venous bypass, after which the artery is ligated closely peripherally to the anastomosis. BFR into the AVF does not change substantially. Most patients do significantly better, presumably because of an increase in peripheral arterial perfusion.

In patients with low BFRs and signs of peripheral ischemia, the proximal AV anastomosis technique provides satisfactory results.⁴³⁴ The idea is to ligate the preexisting anastomosis to the brachial artery in the region of the elbow or distal upper arm and place a new arterial anastomosis in the proximal upper arm, somewhere near the beginning of the subclavian artery. Blood volume is brought down to the vein through an interposed vein graft or small-diameter PTFE graft. Thus, a sufficient BFR into the vein is provided and peripheral perfusion pressure is reestablished; cannulation for HD can be continued immediately.

Infection (CPG 5.7)

Although infections of fistulae are rare, any episode of infection potentially is lethal in face of the impaired immunologic status of long-term dialysis patients.

Very rare access infections at the AV anastomosis require immediate surgery with resection of the infected tissue. Should an arterial segment be resected, an interposition graft using a vein can be attempted or a more proximal new AV anastomosis may be created with exclusive use of degradable suture material.

More often, infections in AVFs occur at cannulation sites. Cannulation at that site must cease, and the arm should be rested.

In all cases of AVF infection, antibiotic therapy is a must, initiated with broad-spectrum vancomycin plus an aminoglycoside. Based on results of culture and sensitivities, conversion to the appropriate antibiotic is indicated. Infections of primary AVFs should be treated for a total of 6 weeks, analogous to subacute bacterial endocarditis.⁴³⁵ A serious complication of any access-related bacteremia is represented by metastatic complications, as described.¹⁵⁹

LIMITATIONS

Considerably fewer data have been published regarding management of complications in fistulae compared with grafts. Some aspects are “accepted” as the standard of care because they are described in standard surgical textbooks and surgeons/interventionalists accept them.

GUIDELINE 6. TREATMENT OF ARTERIOVENOUS GRAFT COMPLICATIONS

Appropriate management and treatment of AVG complications may improve the function and longevity of the vascular access.

6.1 Extremity edema:

Patients with extremity edema that persists beyond 2 weeks after graft placement should undergo an imaging study (including dilute iodinated contrast) to evaluate patency of the central veins. The preferred treatment for central vein stenosis is PTA. Stent placement should be considered in the following situations:

6.1.1 Acute elastic recoil of the vein (>50% stenosis) after angioplasty. (B)

6.1.2 The stenosis recurs within a 3-month period. (B)

6.2 Indicators of risk for graft rupture:

Any of the following changes in the integrity of the overlying skin should be evaluated urgently:

6.2.1 Poor eschar formation. (B)

6.2.2 Evidence of spontaneous bleeding. (B)

6.2.3 Rapid expansion in the size of a pseudoaneurysm. (B)

6.2.4 Severe degenerative changes in the graft material. (B)

6.3 Indications for revision/repair:

6.3.1 AVGs with severe degenerative changes or pseudoaneurysm formation should be repaired in the following situations:

6.3.1.1 The number of cannulation sites are limited by the presence of a large (or multiple) pseudoaneurysm(s). (B)

6.3.1.2 The pseudoaneurysm threatens the viability of the overlying skin. (B)

6.3.1.3 The pseudoaneurysm is symptomatic (pain, throbbing). (B)

6.3.1.4 There is evidence of infection. (B)

6.3.2 Cannulation of the access through a pseudoaneurysm must be avoided if at all possible and particularly so if the pseudoaneurysm is increasing in size. (B)

6.4 Treatment of stenosis without thrombosis:

Stenoses that are associated with AVGs should be treated with angioplasty or surgical revision if the lesion causes a greater than 50% decrease in the luminal diameter and is associated with the following clinical/physiological abnormalities:

6.4.1 Abnormal physical findings. (B)

6.4.2 Decreasing intragraft blood flow (<600 mL/min). (B)

6.4.3 Elevated static pressure within the graft. (B)

6.5 Outcomes after treatment of stenosis without thrombosis:

After angioplasty or surgical revision of a stenosis, each institution should monitor the primary patency of the AVG. Reasonable goals are as follow:

6.5.1 Angioplasty:

6.5.1.1 The treated lesion should have less than 30% residual stenosis and the clinical/physiological parameters used to detect the stenosis should return to acceptable limits after the intervention. (B)

6.5.1.2 A primary patency of 50% at 6 months. (B)

6.5.2 Surgical revision:

6.5.2.1 The clinical/physiological parameters used to detect the stenosis should return to acceptable limits after the intervention. (B)

6.5.2.2 A primary patency of 50% at 1 year. (B)

6.6 If angioplasty of the same lesion is required more than 2 times within a 3-month period, the patient should be considered for surgical revision if the patient is a good surgical candidate.

6.6.1 If angioplasty fails, stents may be useful in the following situations:

6.6.1.1 Surgically inaccessible lesion. (B)

6.6.1.2 Contraindication to surgery. (B)

6.6.1.3 Angioplasty-induced vascular rupture. (B)

6.7 Treatment of thrombosis and associated stenosis:

Each institution should determine which procedure, percutaneous thrombectomy with angioplasty or surgical thrombectomy with AVG revision, is preferable based upon expediency and physician expertise at that center.

6.7.1 Treatment of AVG thrombosis should be performed urgently to minimize the need for a temporary HD catheter. (B)

6.7.2 Treatment of AVG thrombosis can be performed by using either percutaneous or surgical techniques. Local or regional anesthesia should be used for the majority of patients. (B)

6.7.3 The thrombectomy procedure can be performed in either an outpatient or inpatient environment. (B)

6.7.4 Ideally, the AVG and native veins should be evaluated by using intraprocedural imaging. (B)

6.7.5 Stenoses should be corrected by using angioplasty or surgical revision. (B)

6.7.6 Methods for monitoring or surveillance of AVG abnormalities that are used to screen for venous stenosis should return to normal after intervention. (B)

6.8 Outcomes after treatment of AVG thrombosis:

After percutaneous or surgical thrombectomy, each institution should monitor the outcome of treatment on the basis of AVG patency. Reasonable goals are as follows:

6.8.1 A clinical success rate of 85%; clinical success is defined as the ability to use the AVG for at least 1 HD treatment. (B)

6.8.2 After percutaneous thrombectomy, primary patency should be 40% at 3 months. (B)

6.8.3 After surgical thrombectomy, primary patency should be 50% at 6 months and 40% at 1 year. (B)

6.9 Treatment of AVG infection:

Superficial infection of an AVG should be treated as follows:

6.9.1 Initial antibiotic treatment should cover both gram-negative and gram-positive microorganisms. (B)

6.9.1.1 Subsequent antibiotic therapy should be based upon culture results.

6.9.1.2 Incision and drainage may be beneficial.

6.9.2 Extensive infection of an AVG should be treated with appropriate antibiotic therapy and resection of the infected graft material. (B)

BACKGROUND

In this update of the KDOQI Guidelines, the Work Group did not perform a comprehensive literature and data review of recent studies of AVG complications. The primary change from previous versions of the KDOQI Vascular Access Guidelines is consolidation of related material on AVGs into a single unified guideline. However, the fundamental tenets are unchanged from previous editions. Newer references, including reviews, are included when appropriate.

RATIONALE

Extremity Edema and Stenosis (CPG 6.1)

The AVG, although decreasing in frequency of use, remains a major type of vascular access for HD in the United States.² The natural history of an AVG is the progressive development of neointimal hyperplastic stenoses in the outflow track. Although these stenotic lesions most commonly occur at the venous anastomosis, they also can occur at the arterial anastomosis and within the native veins that provide outflow from the AVG. This resulting increase in venous pressure leads to edema proximally and, in extreme circumstances, evidence of venous collateral flow. The presence of a hemodynamically significant stenosis can decrease the ability of the access to deliver adequate flow and increase the risk for AVG thrombosis. Early detection and treatment of hemodynamically significant stenoses is considered a primary tenet of a vascular access management program.

Extremity edema persisting beyond 2 weeks (immediate postoperative period) after placement of an AVG may indicate inadequate venous drainage or central venous obstruction.^{30,436} In many cases, the stenosis results from the prior placement of a subclavian catheter; risk for stenosis is increased by previous catheter infection.¹⁷⁰ PTA of the stenotic or obstructed venous segment can lead to resolution of the edema. However, acute elastic recoil may occur after angioplasty of large central veins.⁴³⁷ Studies have shown that the use of stents may improve long-term patency of the central vein in certain circumstances.^{438–442} Surgical treatment of central venous stenosis is associated with substantial morbidity and should be reserved for extraordinary circumstances.⁴⁴³

Graft Degeneration and Pseudoaneurysm Formation (CPG 6.2, CPG 6.3)

Repeated cannulation of an AVG may cause degeneration of the graft material that can progress to involve the subcutaneous tissues overlying the vascular access.^{444,445} These degenerative changes may eventually compromise the circulation to the skin. Degeneration of the AVG and necrosis of the overlying subcutaneous tissue may lead to a progression of clinical problems, including difficulty achieving hemostasis upon needle withdrawal, spontaneous bleeding from cannulation sites, severe hemorrhage, and—ultimately—acute graft rupture. The degeneration of AVGs combined with a venous outflow stenosis fosters formation of a pseudoaneurysm. Progressive enlargement of a pseudoaneurysm produces thinning of the overlying skin, thereby accelerating skin necrosis that increases the risk for acute graft rupture. A large pseudoaneurysm can limit the availability of needle cannulation sites. Dialysis needles must not be inserted into a pseudoaneurysm. A severely degenerated graft or enlarging pseudoaneurysm should be repaired to decrease the risk for acute rupture and restore additional surface area for cannulation.

A pseudoaneurysm is treated most effectively by resection and segment interposition.^{106,446} Pseudoaneurysms that are not resected may expand and rupture, resulting in significant blood loss. Pseudoaneurysms that exceed twice the diameter of the graft or those that are increasing in size should be surgically corrected because of their increased risk for rupture. At times, an endovascular covered stent option may exist.⁴⁴⁷ Pseudoaneurysm expansion that threatens the viability of the skin places the patient at risk for graft infection. In these cases, surgical correction is indicated.

Treatment of Stenoses (CPG 6.4–6.8)

Venous stenosis is the most common lesion in AVGs, although in many cases, more than 1 lesion is present within the graft or at the anastomoses. Although previous studies suggested that arterial inflow lesions were uncommon (<5% of all lesions),^{108,266} more recent experience suggests the arterial or arterial anastomotic lesion affecting blood flow into the AVG may be up to 20% to 25% of all lesions identified by angiography.

A hemodynamically significant outflow stenosis decreases intragraft blood flow and increases intragraft pressure.¹⁰ The lower blood flow, in turn, may reduce the efficiency of HD treatment^{327,355} and increase the risk for vascular access thrombosis.^{285,287,322,340,347,364,376,448,449} Conversely, inflow lesions and intragraft lesions may be

associated with low pressure in the body of the graft and venous outflow. A hemodynamically significant stenosis is defined as a 50% or greater reduction in normal vessel diameter accompanied by a hemodynamic, functional, or clinical abnormality (see CPG 4).^{449,450} By means of angiography, about 90% of thrombosed grafts are associated with stenosis, predominantly in the outflow, at the venous anastomosis, and more centrally.^{109,110,451,452}

PTA or surgical repair of a hemodynamically significant stenosis associated with a non-thrombosed AVG can maintain functionality and delay thrombosis of the vascular access.^{269,453,454} Many nonrandomized trials have shown that preemptive treatment of stenoses reduces the rate of thrombosis^{10,322,374,455} and perhaps prolongs the useful life span of the AVG.^{10,322,374} A number of observational, but not randomized, studies show that a greater fraction of grafts remain free of interventions or thrombosis if the AVG is patent at the time of intervention.^{111,112,269,354,456} The fraction of AVGs free of further intervention or thrombosis ranged from 71% to 85% among 4 studies if PTA was performed preemptively compared with only 33% to 63% if PTA was performed after thrombectomy of the graft.^{10,322,374,455}

Although these results would suggest that elective correction of stenoses before thrombosis might increase the long-term survival of the AVG, recent studies suggested that prophylactic treatment of stenoses, although reducing thrombosis events, does not extend the useful life span of AVG rates.^{384,386} Thus, the major reason for surveillance is the prevention of thrombosis (see CPG 4).

No convincing evidence exists showing that repair of an asymptomatic anatomic stenosis (>50% diameter reduction) improves function or delays thrombosis of the vascular access. Therefore, prophylactic treatment of a stenosis that fulfills the anatomic criteria (>50% diameter reduction), but is not associated with a hemodynamic, functional, or clinical abnormality, is not warranted and should not be performed.^{10,322,354}

Arterial stenosis associated with diminished access inflow and frequently suspected by the presence of excessively negative dialysis circuit prepump pressures (arterial tubing to pump) should be evaluated and corrected when found.

After PTA, anatomic success is defined as residual stenosis less than 30%.^{20,457} Published series have consistently reported a 6-month primary (unassisted) patency rate of 40% to 50% after PTA of stenoses associated with nonthrombosed AVGs.^{108,111,112,269,354,456} The expected primary patency rate after surgical repair of stenoses associated with nonthrombosed grafts is less well established.⁴⁵⁸ Previous Vascular Access Work Groups have determined that a 1-year primary patency rate of 50% after surgical revision should be the goal.

Individual patients may have a rapid recurrence of stenoses that requires repeated PTA.^{108,453} In these patients, repeated angioplasty may not be cost-effective, and surgical revision may be beneficial. Previous Vascular Access Work Groups have defined rapid recurrence of a stenosis as the need for more than 2 angioplasty procedures within a 3-month interval.

Previous studies reported that the use of endovascular stents as the primary treatment for venous stenosis provides long-term results that are similar to those obtained with an-

gioplasty alone.^{382,459–461} Stents should be reserved for patients with contraindications to surgical revision and for treatment of angioplasty-induced venous rupture.^{462–464}

Several studies have directly compared percutaneous thrombectomy with surgical thrombectomy with revision for treatment of AVG thrombosis.^{465–470} A review of comparative and noncomparative studies reveals conflicting results and does not yield a definitive preference.^{24,106,356,467–479} In the opinion of the Work Group, percutaneous thrombectomy or surgical thrombectomy with revision are both effective techniques for the treatment of AVG thrombosis and associated stenosis. The thrombectomy procedure should be performed expeditiously to avoid the need for a short-term catheter. Hospitalization and general anesthesia increase the cost and risk of the thrombectomy procedure and should be avoided when possible.

An underlying stenosis frequently (>85%) is the cause of AVG thrombosis.^{108,480,481} Intraprocedural imaging should be used to evaluate the outflow veins for improved detection of significant stenoses.^{382,470} Identification and treatment of all significant stenoses are essential to optimize long-term patency of the thrombectomy procedure. PTA of stenoses associated with AVG thrombosis correlates with poorer outcomes compared with nonthrombosed AVGs.²⁶⁹ After percutaneous thrombectomy, the majority of reported 3-month primary (unassisted) patency rates range from 30% to 40%.^{471,473,476,478,480,481} The Work Group believes that percutaneous thrombectomy should achieve a 3-month primary patency rate of 40%. After surgical thrombectomy, the achievable goals are a 6-month primary patency rate of 50% and a 1-year primary patency rate of 40%. Surgical procedures are held to a higher standard because the AVG usually is extended farther up the extremity when a surgical revision of a stenosis is performed, using up “venous capital.”

Infection (CPG 6.9)

While cardiac causes account for almost half the deaths in adult patients with CKD stage 5, the second leading cause of death is infection, much of it related to the type of vascular access in use.⁶⁰ AVGs have a greater rate of infection than autologous fistulae, and, unfortunately, antibiotics alone frequently are inadequate and surgical procedures are needed.⁴⁸² Management of an AVG infection is a balance between achieving resolution of the infection while preserving the vascular access.^{59,483} Superficial infections should be treated initially with broad-spectrum antibiotic therapy. Subsequent antibiotic therapy should be based upon the identification of the causative bacterial organism.^{201,484} A more extensive AVG infection can lead to bacteremia, sepsis, and death. Surgical exploration and removal of infected graft material, combined with antibiotic therapy, often is necessary for complete resolution.⁴⁸⁴

Subclinical infection can develop in AVGs, typically resulting from retained graft material. Diagnosis may require performance of indium-labeled white blood cell or gallium scans. Such infection frequently is manifested as resistance to epoetin therapy, along with evidence of a systemic inflammatory response; frequently, it occurs in abandoned and non-functioning grafts. Epoetin responsiveness is restored only after removal of the graft.

LIMITATIONS AND COMPARISON TO OTHER GUIDELINES

These updated CPGs are essentially unchanged in content from those of previous editions of the KDOQI Vascular Access Guidelines. More evidence now is available for the guidelines than in previous editions. However, there is still a paucity of RCTs to better define the effect of interventions on clinically important outcomes. These guidelines also are comparable to those recommended by the Society of Interventional Radiology,⁴⁵⁷ American College of Radiology,⁴⁸⁵ and a joint committee of several surgical societies.⁴⁵⁸

GUIDELINE 7. PREVENTION AND TREATMENT OF CATHETER AND PORT COMPLICATIONS

Catheters and ports are essential tools for providing urgent and, in some cases, long-term vascular access. Prevention and early treatment of complications should greatly reduce associated morbidity and mortality.

- 7.1 Catheters and ports should be evaluated when they become dysfunctional. Dysfunction is defined as failure to attain and maintain an extracorporeal blood flow of 300 mL/min or greater at a prepump arterial pressure more negative than -250 mm Hg. (B)
- 7.2 The exception is pediatric or smaller adult catheters that are not designed to have flows in excess of 300 mL/min. (B)
- 7.3 Methods that should be used to treat a dysfunctional or nonfunctional catheter or port include:
 - 7.3.1 Repositioning of a malpositioned catheter. (B)
 - 7.3.2 Thrombolytics, using either an intraluminal lytic, intradialytic lock protocol, or an intracatheter thrombolytic infusion or interdialytic lock. (B)
 - 7.3.3 Catheter exchange with sheath disruption, when appropriate. (B)
- 7.4 Treatment of an infected HD catheter or port should be based on the type and extent of infection.
 - 7.4.1 All catheter-related infections, except for catheter exit-site infections, should be addressed by initiating parenteral treatment with an antibiotic(s) appropriate for the organism(s) suspected. (A)
 - 7.4.2 Definitive antibiotic therapy should be based on the organism(s) isolated. (A)
 - 7.4.3 Catheters should be exchanged as soon as possible and within 72 hours of initiating antibiotic therapy in most instances, and such exchange does not require a negative blood culture result before the exchange. (B) Follow-up cultures are needed 1 week after cessation of antibiotic therapy (standard practice).
 - 7.4.4 Port pocket infections should be treated with systemic antibiotics and irrigation, in conjunction with the manufacturers' recommendations. (B)

RATIONALE

Evaluation of Dysfunction (CPG 7.1)

Catheter dysfunction can be attributed to many causes, and progression of dysfunction to nonfunction varies accordingly.¹⁸² The most common complications are thrombosis and infection.^{486,487} Even with care, fewer than half the catheters placed as “long-term access” are in use a year after their placement,⁴⁸⁸ and about a third are removed because they fail to deliver adequate blood flow. The definition of adequate blood flow varies inversely with the “efficiency” of HD. High-efficiency dialysis as practiced in the United States requires

dialyzer-delivered BFRs greater than 300 mL/min to achieve the target single-pool Kt/V of 1.2 (see the KDOQI HD Adequacy Guidelines). Conversely, in Europe, BFRs less than 300 mL/min frequently are used because dialysis treatment durations are longer.²⁰³ Adequacy of dialysis is influenced additionally by the site of placement and degree of recirculation.^{489,490} Recirculation in femoral catheters is significantly greater than that in internal jugular catheters (13.1% versus 0.4%; $P < 0.001$).¹⁹³ In addition, femoral catheters shorter than 20 cm have significantly greater recirculation (26.3%) than those longer than 20 cm (8.3%; $P = 0.007$). This length dependency may result from the ultimate tip position of longer catheters in the IVC as opposed to the common iliac vein with shorter catheters. The greater blood flow available to the catheter at the IVC site reduces recirculation. When dialysis dose delivery is a priority, placing the short-term catheter in the internal jugular vein is an advantage. Recirculation may increase when the “lines are reversed” (inversion of inlet and outlet lumens), even in “well functioning” nonsplit catheters (from 2% to 3% to >10%).⁴⁹¹ Although reversal of tubings may increase urea clearance by increasing blood flow temporarily,¹⁸⁴ it usually is at a BFR less than 300 mL/min and should never be used except temporarily until the problem is definitively corrected.

A dysfunctional catheter usually is easier to salvage than a nonfunctional catheter, thereby preventing complications of a new placement.²⁴⁹ Early treatment also reduces the likelihood and minimizes the extent of inadequacy of dialysis caused by catheter dysfunction. Delivery of adequate dialysis dose is dependent upon blood flow and treatment duration. For any given dialyzer, low BFRs during HD extend treatment times and all too often still result in underdialysis (caused by unrecognized recirculation). A BFR less than 300 mL/min was noted in 15% of treatments with catheters.²⁴⁹ Catheter dysfunction leads to 17% to 33% of untimely catheter removals,^{487,488} and thrombosis of the catheter occurs in access loss in 30% to 40% of patients.

It is to be noted that the criterion for determining access dysfunction, ie, blood flow greater than 300 mL/min, is qualified by the prepump arterial pressure¹⁸² factored for the length and lumen diameter of the catheter.^{183,490} Prepump arterial pressure monitoring is essential to ensure valid blood flows, and adequacy is determined largely by the amount of blood pumped to and through the dialyzer.^{189,191,200} Consequences of catheter dysfunction are many, including increases in morbidity and mortality,^{20,248,258} increase in economic expenditures,²⁵⁰ and a “real” concern to patients, 60% of whom report fear of thrombosis second only to pain in decreasing their QOL.²⁵²

In CVCs, the most likely cause for low BFRs is thrombotic occlusion. In the likely event that low BFR or occlusion will occur at some time during the useful life of a catheter, prospective monitoring is essential to detect dysfunction. Regular assessment of dialysis performance is strongly recommended to ensure dialysis adequacy.¹⁸⁹ Catheter performance parameters to consider are shown in Table 18 and include maximal consistently achievable BFR, resistance to blood flow indicated by arterial and venous pressures during HD, and blood recirculation rate.^{492,493} Of these, the one favored by the Work Group is the ratio of dialyzer BFR achieved, factored by the prepump arterial limb pressure in absolute units.

Table 18. Signs of CVC Dysfunction: Assessment Phase

Blood pump flow rates <300 mL/min
Arterial pressure ↑ (< -250 mm Hg)
Venous pressure ↑ (>250 mm Hg)
Conductance ↓ (<1.2) : the ratio of blood pump flow to the absolute value of prepump pressure
URR progressively <65% (or Kt/V <1.2)
Unable to aspirate blood freely (late manifestation)
Frequent pressure alarms—not responsive to patient repositioning or catheter flushing
Trend analysis of changes in access flow is the best predictor of access patency and risk for thrombosis.

Early detection of access dysfunction is most likely if all members of the VAT are involved.¹⁹⁸ The use of CQI in catheter access necessitates collaboration among team members, with specific tasks assigned to certain individuals, who then provide input and/or feedback.

The minimally accepted dialyzer BFR of 300 mL/min is easily achieved by using newer catheters that are capable of achieving rates of 400 mL/min or greater when properly placed.⁴⁹⁴ Therefore, 300 mL/min is a conservative value in current adult practice and waiting until blood flow decreases to 300 mL/min may be too late to avoid loss of the catheter and unnecessary loss of the access site.

Prevention of catheter and access thrombosis by using antiplatelet agents and anticoagulation has not been successful (see Table 19).

Use of an antiplatelet agent is not recommended because it was not effective in grafts and was associated with more bleeding.⁴⁹⁷ A similar conclusion was reached in a prospective nonrandomized comparison of warfarin to aspirin.⁴⁹⁸ Use of a low fixed dose (1 mg) of warfarin also was found to be ineffective.⁴⁹⁵ Further studies in this area with a higher target international normalized ratio (INR) are warranted.

The first step in assessing dysfunction is shown in Fig 9, which begins with a determination of the age of the catheter.

In catheters recently placed, inadequate blood flow usually is the result of mechanical obstruction, improper tip location affected by patient position, or a problem of catheter integrity, as shown in Table 20.⁴⁹²

The need to use a Trendelenberg position to achieve adequate blood flow from a catheter placed in great veins leading to the right atrium always implies that the catheter is improperly placed. If the problem is not obvious and not easily correctable, the patient should be referred to an interventional center for study to diagnose the cause. Although mechanical problems can develop acutely in catheters previously giving good performance, access dysfunction occurring after 2 weeks more likely is the result of progressive occlusion of the catheter tip by fibrin or thrombus. The location of obstruction may reside in the following areas:

1. *Intraluminal thrombus*—within lumen of catheter, partial or complete occlusion.
2. *Catheter tip*—in catheters with side holes at tip of arterial limb, thrombus may occlude or act like “ball valve.”

Table 19. Prophylaxis of TCC-Related Thrombosis

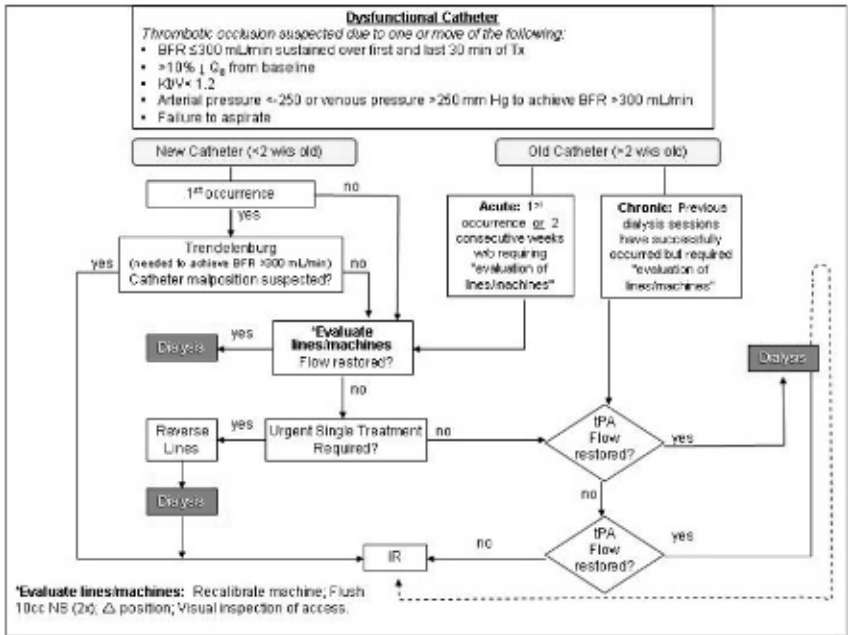
Author, Year	Study Design	N	Follow-up (maximum)	Applicability	Intervention 1	Intervention 2	Outcome	Results	P-Value	Quality
Mokrzycki 2001 ^{48a}	RCT	105	12 mo	↑↑↑	Low dose Warfarin	Placebo	TCC failure	RR 0.8	NS	●
Schenik 2000 ^{49b}	RCT ^a	12	8 mo	↑↑	Interdialytic rTPA lock	Heparin lock (1000 U/s/mL)	Blood flow increase ^b Thrombosis	ND 0% (rTPA) vs. 20% (heparin)	0.0001 ND	○

ND=no data; NS=not significant; RR=relative risk; RCT=randomized controlled trial; rTPA=recombinant tissue plasminogen activator; TCC=tunneled cuffed catheter

a. Cross-over study

b. Flow is statistically significant without an estimator of effect size between the 2 treatment groups

Figure 9. Assessing dysfunction of catheters. Symbols: IR, imaging for correct position. Abbreviation: tPA, tissue plasminogen activator; IR, intervention. (Courtesy of Drs Asif and Anatole Besarab).



3. *Fibrin sheath* (fibrin sleeve)—fibrin adheres to external surface of catheter, thrombus trapped between sheath and catheter tip.
4. *Fibrin tail* (fibrin flap)—fibrin adheres to CVC end, “ball valve” effect.

Methods That Should be Used to Treat a Dysfunctional or Nonfunctional Catheter or Port (CPG 7.3)

A catheter that has migrated out of the mid-right atrium should be repositioned. Catheters of inadequate length should be exchanged over a guide wire to the appropriate position or replaced.⁴⁹⁹

Table 20. Causes of Early Catheter Dysfunction

Mechanical
Kinks (angulation in tunnel)
Misplaced sutures
Catheter migration
Drug precipitation (some antibiotic locks or IV IgG)
Patient position
Catheter integrity
Holes
Cracks

All catheters are “locked” with some anticoagulant. The purpose of the lock is to prevent thrombosis. Loss of anticoagulant by diffusive transport would be expected. However, it has been known for several years that some fraction of the anticoagulant will leak into the systemic circulation^{500,501} by nondiffusive processes and increase the partial thromboplastin time, thus possibly contributing to minor or even major bleeding. In vitro simulations suggest an early leak within 30 seconds, followed by a slower loss of locking solution during the next 30 minutes.⁵⁰² The specific gravity of the locking solution likely also influences the rate of leak.⁵⁰³ Locking solution lost is replaced by blood. It therefore is not surprising that thrombosis is so common in catheters because blood is likely to be in the lumen of the catheter for prolonged times interdialytically. The loss of anticoagulant permits the entry of clotting factors into the catheter lumen. The presence of these processes is manifested by a change in flow long before there is occlusion.

After assessment precludes mechanical dysfunction (see Fig 9), such as a kink or dislodgement, thrombotic occlusion—partial (poor flow on aspiration) or total (unable to aspirate or push)—is the most common cause of catheter dysfunction and/or occlusion.^{151,504-506} Pharmacological intervention for catheter-occlusive dysfunction involves treatment with thrombolytics that convert plasminogen to plasmin. Thrombolytics are noninvasive, confer no additional trauma to the patient, have a high level of safety and efficacy, and are cost-effective.⁵⁰⁷ A thrombolytic can be administered in the dialysis setting. Because of such advantages and the less practical alternative treatment options, thrombolytic therapy directed at salvaging the catheter should be considered before access replacement because it is the least invasive and least costly of all catheter salvage techniques.

A variety of thrombolytics have been used (Table 21), although at the present time, only tissue plasminogen activator (tPA) is approved by the Food and Drug Administration (FDA). Urokinase (UK) is still available (but is no longer manufactured), as is reteplase, but neither of these lytics currently is available in convenient dosages and must be aliquoted and frozen for use. Teneplase, another lytic, has not been used for access thrombosis. Formulations of some lytics have been tried in studies and are used “off label” at various institutions.

Thrombolytics have proved highly effective in opening partially and fully occluded lumens.^{496,508-525} (See also: Abbott Laboratories, prescribing information for abbokinase [urokinase] Chicago, IL, 2003; Boehringer Mannheim GmbH, prescribing information for Reteplase® [reteplase], 2000; Genentech, prescribing information for Cathflo® Activase® [alteplase], 2001.^{525A-C}) The most common use of lytics occurs late in the “dysfunction process,” when prescribed blood flows are not attained and there is difficulty even in initiating a dialysis treatment. Currently, the package insert only describes the use of the agent for catheters in a timed dwell, based on clinical trials in nondialysis catheters.^{526,527} The recent Cathflo Activase Pediatric Study has led the FDA to approve tPA as a thrombolytic in all age groups for the same indications as in the package insert.

In situations in which the obstructive process has progressed to a more severe state, dialysis is urgent, and the catheter is extremely dysfunctional (ie, unable to provide a BFR

Table 21. Available Thrombolytics

Streptokinase ^{502,503}	<ul style="list-style-type: none">• Highly antigenic• Low fibrin affinity
Urokinase ¹⁵¹	<ul style="list-style-type: none">• Available for PE treatment• No longer manufactured (11/2004)
Reteplase ⁵⁰⁴	<ul style="list-style-type: none">• Used in treatment of AMI• Must be aliquoted and frozen
Alteplase, tPA ⁵⁰⁵	<ul style="list-style-type: none">• High Fibrin specificity• FDA approved• Available in single dose vials• No antigenicity

of 200 mL/min), tPA reconstituted appropriately and instilled at a lumen fill volume permits resumption of dialysis in 50% to 90% of instances (see Table 22), although a second dwell may be required. Per the package insert, this lytic should be allowed to dwell for 1 hour or longer. Table 23 summarizes the major studies with tPA in totally occluded catheters.

In general, efficacy increases with longer dwell times with tPA as the lytic. Fewer studies are available with the other agents, but results are similar.^{514,517} A recent study showed that a lower dose of 1 mg/lumen of tPA also is effective, restoring catheter patency in 72% with 1 dose, increasing to 83% with a second dose,⁵¹³ values only slightly lower than with the “standard” dose of 2 mg/lumen.

The Work Group believes that the use of lytics late in the thrombosis process without adequate prior diagnostic evaluation is in itself “dysfunctional” and *recommends* that the procedures described in Fig 9 be used to evaluate a catheter access on a recurrent basis. Tracking the relationship of prepump pressure, VDP, and flow (see Fig 9) can alert the clinician to the development of catheter dysfunction before late manifestations set in. The emphasis for managing catheter dysfunction should shift to intervention at an earlier stage of dysfunction.

Although endoluminal brushes have been used to clear thrombi from dialysis catheters,⁵²⁸ there are no convincing data about efficacy and they are expensive. The Work Group does not currently advocate their routine use. Such brushes were originally developed to obtain biofilm specimens from catheters.

The management of fibrin sheaths is discussed further in CPR 7. Currently, the Work Group recommends change of catheter with disruption of the sheath by using a balloon. Fibrin sheath stripping rarely is used because of cost and increased patient morbidity.

Table 22. Effect of Lytics in Occluded Hemodialysis Catheters

Author, Year	Dwells (n)	Catheters (n)	Patients (n)	Change in BFR (mL/min)	Success Rate Outcome	Dwell Time	Applicability	Quality
Zacharias, 2003 ⁴⁵	164	66	30	132 to 256	88%	30 min to 2 h	↑↑	●
Deelhaigh, 2000 ⁴⁶	56	28	22	75 to 248	88% ^a	2-56 h	↑	●
Crowther, 2000 ⁴⁸	42	23	23	>250	88% ^b	272 h	↑	○
Paulsen, 1993 ⁵¹	18	18	8	37 to 260 ^a	83% ^a	30 min to 4 d	↑	○
O'Mara, 2001 ⁵⁰	62	25	111 to 243	58% ^a		30 min	↑	○

BFR=blood flow rate

a. Data for all catheters.

b. Successful completion of dialysis.

^aFlow measured was that recorded at the blood pump

Table 23. Treatments of TCC Fibrin Sheath Occlusion

Author, Year	Study Design	N	Follow-up (maximum)	Applicability	Intervention 1	Intervention 2	Outcome	Results	Quality
Gray 2000 ⁵³	RCT	57	100 d	↑↑	UK IV infusion for 4 h	Percutaneous fibrin sheath stripping	Primary patency rates Angiogram patency	Urokinase PFSS 97% 87% NS 76% 87% ND	●
							Median secondary patency	32 d	42 d ND
							TCC patency ^a		
							Exchange	PFSS	
Merpoint 2000 ⁵²	RCT	30	120 d	↑↑	Exchange over wire	Percutaneous fibrin sheath stripping	Mean catheter life % patency at 1 mo % patency at 4 mo	52 d 25 d 93% 31% 23% 0	● +

IV=intravenous; ND=no data; NS=not significant; PFSS=percutaneous fibrin sheath stripping; RCT=randomized controlled trial; TCC=lumened cuffed catheter; UK=urokinase

↑ Statistically significant beneficial effect of treatment compared to control (or intervention 1 vs. intervention 2)

a. Flow > 200 mL/min

Treatment of an Infected HD Catheter or Port (CPG 7.4)

Definitions

Exit-site infection. Inflammation confined to the area surrounding the catheter exit site, not extending superiorly beyond the cuff if the catheter is tunneled, with exudate culture confirmed to be positive.

Tunnel infection. The catheter tunnel superior to the cuff is inflamed, painful, and may have drainage through the exit site that is culture positive.

Catheter-related bacteremia. Blood cultures are positive for the presence of bacteria with or without the accompanying symptom of fever.

The Work Group recommends the following CDC definitions for catheter-related infections.

Definite bloodstream infection: the same organism from a semiquantitative culture of the catheter tip (>15 colony-forming units per catheter segment) and from a peripheral or catheter blood sample in a symptomatic patient with no other apparent source of infection.

Probable bloodstream infection: defervescence of symptoms after antibiotic therapy with or without removal of catheter, in the setting in which blood cultures confirm infection, but catheter tip does not (or catheter tip does, but blood cultures do not) in a symptomatic patient with no other apparent source of infection.

Possible bloodstream infection: defervescence of symptoms after antibiotic treatment or after removal of catheter in the absence of laboratory confirmation of bloodstream infection in a symptomatic patient with no other apparent source of infection.

Although thrombotic occlusions leading to flow delivery problems are more common than infection, catheter-related infection has emerged as the primary barrier to long-term catheter use. The greater infection rate in catheters compared with grafts and fistulae is its major limitation. Infection is the leading cause of catheter removal and morbidity in dialysis patients.^{148,156,201,532,533} The most recent USRDS data indicate that the rate of septicemia in HD patients continues to increase, and hospital admissions for vascular access infection doubled in the last decade.²³⁵ The use of long-term HD catheters instead of short-term catheters has not yet translated into a significant reduction in the incidence of CRB and resultant infective endocarditis in our population.^{234,534-539}

Accurate and early diagnosis is essential. A meta-analysis of 8 different methods comparing those that do and do not require catheter removal showed that paired quantitative blood cultures from the peripheral blood and the catheter are the most accurate,⁵⁴⁰ but are not routinely performed. However, routine culture methods have negative predictive power (>99%), whereas the positive predictive value increases with the pretest probability for infection. Dialysis programs should monitor vascular access and especially catheter-related infections with attention to incidence, bacteriology, and outcomes.

Significant risk factors ($P < 0.05$) for bacteremic episodes include the presence of diabetes, peripheral atherosclerosis, a previous history of bacteremia, nasal carriage of *Staphy-*

lococcus aureus, longer catheter use duration, more frequent UK catheter infusion, and local infection.^{532,537} One report identified elderly women as being more at risk.⁵⁴¹

Infection monitoring should be in place to identify outbreaks that can result from manufacturing defects.⁵⁴² A doubling of the rate is cause for concern.⁵⁴² One study provides a means to standardize the reporting of vascular access infection rates.⁵⁴³ Analyzing nearly 40,000 dialysis sessions, infection rates were greatest among short-term catheters (recommended for in-hospital use only) and least among permanent native AVFs or synthetic grafts. Another analysis in Canada of 184 bloodstream infections in 133,158 dialysis procedures confirmed these findings.²³² AVFs were associated with the lowest risk for bloodstream infection (0.2/1,000 dialysis procedures; RR increased 2.5-fold with AVGs, 15.5-fold with TCC access, and 22.5-fold with uncuffed CVC access; all $P < 0.001$). Significant variation in infection rates was observed among centers, even when controlling for types of access used, suggesting that access-specific infection rates within and among centers could be used to develop quality improvement. Experience with femoral TCCs has been mixed. Some reports indicated no increase in infection rate,^{544,545} but that has not been the experience of members of the Work Group. Even if there is no decrease in infection-free survival,⁵⁴⁵ use of femoral catheters is associated with ipsilateral vein thrombosis in about 26% of patients that necessitates use of anticoagulants with uncertain effects on the upstream iliac vein (see CPG 2).

All indwelling vascular catheters are colonized by microorganisms within 24 hours after insertion.⁵⁴⁶ The formation of “biofilm” on the external and internal surface of vascular catheters is thought to have an important role in the colonization process. The biofilm is produced by a combination of host factors (eg, fibrinogen, fibrin, fibronectin, and extracellular polysaccharides) and microbial products (eg, glycocalyx or “slime”) and has a critical role in bacterial antimicrobial resistance and recalcitrant infections.⁵⁴⁷ Prevention of infection is the key first step, and the reader should consult the recommendations of the CDC.²²² Although documented by a variety of methods, the relationship of thrombin sheath to infection has not been evaluated clinically. Proteins in the fibrin sheath provide adhesions for organism binding, particularly by *S aureus*. Whether more aggressive prevention of fibrin sheaths could reduce the infection rate is unknown. Sporadic reports suggested that concomitant use of a lytic with antibiotics could salvage more catheters.

In general, uncuffed catheters have a greater rate of infection, 3.8 to 6.6 episodes/1,000 days, compared with TCCs, with 1.6 to 5.5 episodes/1,000 days.^{534,542,544,548} This wide range obviously reflects differences in practice.⁵⁴⁴ Rates as low as 1/1,000 days at risk have been achieved with detailed catheter protocols.²⁴⁷ Programs with greater rates of infection in long-term catheters should institute CQI analysis techniques. Catheter infection usually requires replacement of the catheter in half the episodes despite antibiotic therapy.⁵³² Systemic antibiotics used to treat bacteremia do not penetrate into the biofilm and therefore do not eradicate it,⁵⁴⁹ leading to potential treatment failures and eventual sacrifice of the catheter. Among uncuffed short-term catheters, femoral catheters have the highest infection rate, averaging 7.6 episodes/1,000 days, with more than 10% being infected by 1 week.¹⁹⁹

Catheter exit-site infections alone usually can be salvaged with topical and oral antibiotics without the need for catheter replacement.^{148,149,151,550} CRB is the major reason for catheter loss¹⁵⁶ and has been associated with substantial morbidity, including metastatic infection.¹⁵⁹ It is a life-threatening condition requiring initial hospitalization and parenteral antibiotic therapy if the patient is clinically septic. The observation in a large trial of patients with CRB that systemic antibiotics alone were able to salvage less than 25% of catheters⁵³³ led to the commonly used “salvage of site rather than salvage of catheter” approach.^{551,552} Attempts to salvage the catheter in situ were associated with recurrence of infections soon after the antibiotics were discontinued.⁵³³ Conversely, studies using catheter guide wire exchange in stable patients without tunnel involvement under the cover of antibiotics alone salvaged 80% to 88% of sites without apparent ill effects.^{158,551,552} There is no advantage in delaying replacement of the catheter by several days.⁵⁵³ A decision-tree hypothetical analysis showed that TCC exchange over a guide wire reduced net charges by approximately \$5,200 and \$750 (US dollars in year 2000) compared with TCC salvage and immediate TCC removal, respectively.⁵⁵⁴ Expected 3-month patient survival for TCC guide wire exchange and immediate TCC removal were similar (93%), whereas survival for TCC salvage was worse.⁵⁵⁴ A negative culture result is not required before catheter exchange.⁵⁵¹

An alternative to this management of dialysis CRB (systemic antibiotics with catheter exchange, as well as removal of the infected catheter) is catheter salvage by combining systemic antibiotics in conjunction with antibiotic locks.⁵⁵⁵⁻⁵⁵⁹ The former is burdensome at times and expensive and creates short-term problems for dialysis access if the infectious disease consultant demands that a 24- to 48-hour catheter-free period is needed before the catheter can be placed. As stated previously, bacterial biofilms form routinely in the catheter lumen and act as the nidus for bacteremic episodes. Instillation of a concentrated antibiotic-anticoagulant solution into the catheter lumen (antibiotic lock) at concentrations orders of magnitude higher than those achievable in the blood may permit successful eradication of the infection while salvaging the patient’s catheter. A number of studies now confirm the validity of this approach,⁵⁵⁶⁻⁵⁵⁹ with salvage of the catheter and without recurrence of infection in about 65% to 70% of cases, comparing favorably with the catheter-exchange approach. With the latter method, catheter replacement is necessary in patients with persistent fever or positive surveillance blood culture results. A direct head-to-head RCT of the 2 methods is needed (see Research Recommendations).

Bacteremia with tunnel-tract involvement should prompt catheter removal. Unstable patients require removal of the catheter for rapid response to therapy. The Work Group believes that a minimum of 3 weeks of systemic antibiotic therapy is needed to treat CRB and that new permanent access should not be placed until culture results have been negative for at least 48 hours after cessation of antibiotic therapy.

Prevention of CRB can be difficult despite the use of rigorous infection-control techniques. As shown in Table 24, silver impregnation of the catheter was ineffective,⁵⁶⁰ whereas a gentamycin/citrate solution⁵⁶¹ and a taurolidine solution used as interdialytic

Table 24. Prophylaxis for Dual-Lumen TCC-Related Infections

Author, Year	Study Design	N	Follow-up (maximum)	Applicability	Intervention 1	Intervention 2	Infection rate ^a		Quality	
							Treatment	Control		
Trerocola 1998 ⁵⁹	RCT	100	730 d	↑↑	Silver coated catheter	Non-silver coated catheter	1.1	1.4	NS	●
Dogra 2002 ⁵⁸	RCT	83 (112 catheters)	288 d	↑↑	Gentamicin + citrate CLS (40 mg/mL and 3.13% citrate)	Heparin CLS (5000 U/mL)	0.3	4.2	+	●
Alton 2003 ⁵⁰	Prospective with concurrent control	50	90 d	↑↑	1.35% tauridine and 4% sodium citrate CLS	Heparin CLS (5000 U/mL)	0.6	5.3	+	○

CLS=catheter lock solution; NS=not significant; RCT=randomized controlled trial; TCC=unneled cuffed catheter.

+ Statistically significant beneficial effect of treatment compared to control (or intervention 1 vs. intervention 2)

a. Per 1000 catheter days

antibiotic locks were effective.^{562,563} Minocycline/rifampin coating has not been tested in dialysis catheters.

The subject of antibiotic locking has been discussed extensively.⁵⁶⁴ Other pharmacological measures that may be useful for prophylaxis against CRB include application of an antimicrobial ointment (mupirocin or polysporin) to the catheter exit site.^{565,566} Subcutaneous port catheter devices do not reduce the frequency of CRB unless an antimicrobial solution is used with the device.⁵⁶⁷ A preliminary study showed that a topically applied “Medihoney” was as effective as mupirocin in reducing catheter infection.⁵⁶⁸ The former has a lower likelihood for selecting out resistant organisms. It unfortunately is forgotten that good practice and attention to “hub care” can significantly reduce CRB by 4-fold.²⁴⁷

However, with all preventive strategies other than good catheter care (see CPG 3), there are few long-term data on the development of antimicrobial resistance, and future studies are required. Until such data are available, it is unlikely that the use of such locks and ointments will receive official approval from the FDA.

LIMITATIONS

Considerable uncertainty exists about the most effective regimen for preventing catheter dysfunction by using lytics because there are no sufficiently powered studies to compare the efficacy and economics of different protocols. The same applies to prevention of CRB.

GUIDELINE 8. CLINICAL OUTCOME GOALS

8.1 Goals of access placement:

8.1.1 Each center should establish a database and CQI process to track the types of accesses created and complication rates for these accesses.

8.1.2 The goals for permanent HD access placement should include:

8.1.2.1 Prevalent functional AVF placement rate of greater than 65% of patients. (B)

8.1.2.2 Cuffed catheter for permanent dialysis access (eg, not as a bridge) in less than 10% of patients. Long-term catheter access is defined as the use of a dialysis catheter for more than 3 months in the absence of a maturing permanent access—graft or fistula. (B)

8.2 The *primary* access failure rates of HD accesses in the following locations and configurations should not be more than the following:

8.2.1 Forearm straight grafts: 15%. (B)

8.2.2 Forearm loop grafts: 10%. (B)

8.2.3 Upper-arm grafts: 5%. (B)

8.2.4 Tunneled catheters with blood flow less than 300 mL/min: 5%. (B)

8.3 Access complications and performance:

8.3.1 Fistula complications/performance should be as follows:

8.3.1.1 Fistula thrombosis: fewer than 0.25 episodes/patient-year at risk. (B)

8.3.1.2 Fistula infection: less than 1% during the use-life of the access. (B)

8.3.1.3 Fistula patency greater than 3.0 years (by life-table analysis). (B)

8.3.2 Graft complications/performance should be as follows:

8.3.2.1 Graft thrombosis: fewer than 0.5 thrombotic episodes/patient-year at risk. (B)

8.3.2.2 Graft infection: less than 10% during the use-life of the access. (B)

8.3.2.3 Graft patency greater than 2 years (by life-table analysis). (B)

8.3.2.4 Graft patency after PTA: longer than 4 months. (B)

8.3.3 Catheter complications/performance should be as follows:

8.3.3.1 Tunneled catheter-related infection less than 10% at 3 months and less than 50% at 1 year. (B)

8.3.3.2 The cumulative incidence of the following insertion complications should not exceed 1% of all catheter placements: (B)

- Pneumothorax requiring a chest tube
- Symptomatic air embolism

- Hemothorax
- Hemomediastinum
- Hematoma requiring evacuation.

8.3.4 Cumulative patency rate of TCCs: Not specified. (B)

8.4 Efficacy of corrective intervention:

The rate of certain milestones after correction of thrombosis or stenosis should be as follows:

8.4.1 AVF patency after PTA: greater than 50% unassisted patency at 6 months (and <30% residual stenosis postprocedure or lack of resolution of physical findings postprocedure);

AVF patency following surgery: greater than 50% unassisted patency at 1 year. (B)

8.4.2 AVG patency after PTA: please refer to CPG 6.5.1;

AVG patency after surgery: please refer to CPG 6.5.2;

AVG after either PTA or surgery: greater than 90% with postprocedure restoration of blood flow and greater than 85% postprocedure ability to complete 1 dialysis treatment. Please refer to 6.8. (B)

8.4.3 Surgical correction is set to a higher standard because of the use of venous capital. (B)

BACKGROUND

HD access failure is a major cause of morbidity and mortality for patients on HD therapy.^{7,8,14-17} Expenditures for reconstituting patency are substantial and increasing.^{2,8,9,12}

Throughout this document, methods and recommendations have been proposed to improve vascular access results. These include:

1. Establishment of QA programs that track access complication rates and outcomes:
 - a. Formation of VATs
2. Improvement of the skill set of staff:
 - a. Physical examination of the accesses
 - b. Cannulation techniques among staff
 - c. Aseptic techniques
3. Increasing the percentage of patients with native or primary AVFs by implementing the FFBI. Key portions of the program include the following:
 - a. Early identification and referral of patients with progressive kidney disease to nephrologists, allowing access construction well in advance of the need for HD
 - b. Protection of veins
 - c. Adequate artery and vein evaluation by using DDU and/or angiography
 - d. Reevaluation for a native AVF after every access failure
4. Periodic monitoring of accesses to detect hemodynamically significant stenoses before thrombosis:
 - a. Expedient referral of patients for appropriate angioplasty or surgical revision after the detection and characterization of stenoses

- b. Documentation of functional improvement in access function after corrective intervention
5. Improved catheter care.

The following Clinical Outcome goals are target suggestions for measuring improvement in performance.

RATIONALE

Goals of Access Placement (CPG 8.1)

Data should be updated periodically and methods should be identified to increase the rate of AVF placement. Flow charts should be developed and root-cause analysis should be carried out to identify barriers to fistula placement, causes for excessive thrombosis rates, and reasons for excessive catheter-related infection.

These goals are greater than those previously recommended in the KDOQI Vascular Access Guidelines.^{20,348} They represent the goals expected by CMS, which has set the target for fistula prevalence of 65% by 2009. Although there has been slow improvement in fistula rates since implementation of the FFBI, rates have increased only slowly (NVAII, www.fistulafirst.org; last accessed 2/20/2006). The Work Group believes that with the reimbursement of DDU procedures and early referral of patients by nephrologists for access evaluation and constructions, rates will improve. In some cases, this will require the use of brachial artery level constructions. An increase in percentage of native AVFs is accomplished best by early determination of the patient's preferred dialysis modality while dialysis therapy initiation is still months away (see CPG 1) because primary AVFs ideally need an extended period of 1 to 6 months to mature. However, those entering the CKD stage 5 program with inadequate or no prior medical care for CKD will continue to blunt the impact of such efforts.

These goals are achievable.^{37,38,88,569} A primary AVF using the cephalic vein confers the best permanent access with the fewest complications (see CPG 2). Native accesses have the best 4- to 5-year patency rates and require fewer interventions compared with other access types. In many patients, a previous native or synthetic access produces dilation of arm veins, permitting construction of a new primary AV access at a site not previously available.

Catheter usage presents a conundrum. On one hand, catheters provide access that is immediately available; on the other hand, complications are high.^{180,359} Blood flow frequently is inadequate, thrombolytics frequently are required, and the infection rate is an order of magnitude higher than with grafts or fistulae. Cuffed catheters are associated with lower BFRs compared with grafts and fistulae. As a result, long-term catheter use without appropriate adjustments in treatment duration can compromise dialysis adequacy. Compromise of dialysis adequacy is associated with increased morbidity and mortality. Systemic and local infections occur more frequently with cuffed catheters and account for some of the excess mortality associated with this access type. Finally, long-term catheter access is associated with a risk for central venous stenosis development, which can preclude the establishment of a permanent vascular access for HD (see CPG 2). The

initial success, ease of use, and painless access to the patient's blood offered with a dialysis catheter may foster reluctance in some patients to accept more permanent access options with a fistula or graft despite the greater risk for infection and inadequate dialysis associated with long-term permanent catheter use. Patients should be educated on these issues and strongly encouraged to allow creation of a fistula for permanent access whenever possible.

When a catheter must be used either initially or to bridge the patient to the next permanent access, "time-urgency" for initiating/continuing HD therapy with a permanent access does not justify substitution of a graft for a fistula because cuffed catheters are an effective means of bridging the longer time necessary for primary AVF maturation.^{148,178,184,200} Although catheters can be used for long-term dialysis,^{187,189} they should be reserved for patients with comorbid conditions limiting life expectancy, those with systolic hypotension in whom attempts to create/maintain a permanent access have met with failure, and those in whom all available sites for fistula or graft (including chest-wall loop grafts) have been exhausted or are not feasible.

The Primary Access Failure Rates (CPG 8.2)

Primary failure is defined as the inability to use the graft at 30 days or obtain sufficient blood flow from the catheter within the first week after insertion. By proposing these goals for 30-day primary failure rates for various graft configurations, the Work Group does not wish to imply that upper-arm grafts should be elected over forearm grafts solely on the basis of these recommended primary failure rates. The Work Group encourages the creation and maintenance of access sites as distally as possible to preserve more proximal veins for future access options. For example, a forearm straight or a brachial loop graft may be used to develop a vein for fistula construction. The Work Group realizes that in some instances, a dialyzer BFR of 300 mL/min might be excessive and produce disequilibrium during the first or second treatment of a very uremic patient. However, by the third treatment, this should not be an issue, and a limit of 1 week is set to determine that the catheter can deliver adequate blood flow.

Primary access failure is considered failure of patency within the first 30 days after placement. Primary failure of dialysis AVGs is caused by technical problems or selection of inappropriate vessels (artery or vein). Neointimal hyperplasia is unlikely to be so virulent as to cause access graft failure within 30 days of construction. It is the Work Group's opinion that the primary failure rate reflects a center effect that is influenced by surgical access construction, patient demographics, adequacy of workup (see CPG 1 and CPG 5), comorbidities, and graft loss caused by premature cannulation and hematoma formation. Primary failure rates of dialysis AVGs at the same anatomic sites vary depending on whether the grafts are the primary, secondary, or tertiary access. The rates provided are derived from the published literature for first graft accesses constructed in a general HD population.^{24-26,65,67,92,423,570} Failure of a graft before use reflects surgical construction problems. Prosthetic bridge graft survival is decreased in patients with diabetes, even at 30 days, and may be affected adversely by increasing age in patients without diabetes.⁵⁷¹ Patient demographics, characteristics, and comorbidities may differ across centers and

explain some of the center effect. Each center should monitor its performance, recognizing the influence of some demographic factors, but tracking its own problems in access construction and use (see CPG 8.1.1). Marked deviations from the recommended patency rate should invoke a multidisciplinary evaluation of possible factors and their modification.

A modern properly placed catheter (see CPG 2.4 and CPG 7.1) can deliver more than 300 mL/min at a prepump pressure of -250 mm Hg in adults. A catheter that cannot deliver a flow of 300 mL/min is not being run at a sufficient negative pressure, is improperly positioned, or is dysfunctional for some other reason. Because blood flow with time is a major determinant of adequacy of dialysis, the cause must be determined quickly and corrected. The Work Group believes that catheter blood flow is an indicator of quality in a program. Data for performance should be collected and analyzed to improve quality and protect the patient from underdialysis.

Access Complications and Performance (CPG 8.3)

The Work Group believes that it cannot provide a reasonable estimate of expected cumulative patency of dialysis catheters. The use of cuffed catheters as permanent vascular access is discouraged, except in particular patient groups (see CPG 3).

The current national average rate of thrombosis of dialysis AVGs can only be approximated because there is no mandatory reporting. It is likely to be greater than the overall rate (all permanent accesses) of approximately 0.8 episodes/patient-year at risk^{10,29} because these rates include the much lower rate of thrombosis of fistulae. In grafts, rates varying from 0.5 to almost 2 episodes/graft-year at risk have been reported in the absence of surveillance or monitoring programs.^{10,29,374,572} The rate of graft thrombosis is determined largely by the presence of unrecognized hemodynamically significant stenosis.^{10,266,572} Six published studies showing the value of surveillance reported baseline thrombosis rates varying from 0.5 to 0.8 episodes/graft-year at risk, which then decreased by 43% to 67% to rates of 0.2 to 0.4 episodes/graft-year.^{10,322,343,352,373,374} Implementation of surveillance techniques should reduce stenosis and make a rate of 0.5 achievable, even in programs with greater than average rates of thrombosis. Therefore, dialysis grafts should be monitored/undergo surveillance to permit early detection of hemodynamically significant stenosis with the goal of reducing the thrombosis rate to a maximum of 0.5 thrombosis/y for AVGs.

PTA is performed to dilate a stenotic lesion within a vascular access or its draining vein. Adequacy of the procedure is measured best by the duration of effect: ie, duration of subsequent patency until either another PTA is required for recurrence of stenosis or thrombosis occurs. A number of observational studies showed that a greater fraction of grafts remained free of interventions or thrombosis if the AVG was patent at the time of intervention (see CPG 6). The fraction of AVGs free of further intervention or thrombosis ranged from 71% to 85% among 4 studies if PTA was performed preemptively compared with only 33% to 63% if PTA was performed after thrombectomy of the graft.^{373,374} After PTA of stenoses associated with nonthrombosed AVGs, published series consistently reported a 6-month primary (unassisted) patency rate of 40% to 50% (see CPG 6).

The duration of effect after thrombectomy and correction of stenosis is considerably shorter. The 4-month criteria are meant to foster 2 processes: (1) preemptive PTA, and (2) assessment of the adequacy of the intervention (PTA or surgery) because inadequate correction typically is manifested by thrombosis or recurrence of the lesion within weeks.

The rate of fistula thrombosis is much less than that of grafts. Fistulae have the lowest rate of thrombosis,⁵⁷ require the fewest interventions,^{57,58} and provide longer survival of the access.^{3,57,58} For native fistulae, access events are only 14% to 33% of those observed in grafts.^{3,57,58} Therefore, a fistula thrombosis rate that is half that of grafts should result in at least a 1-year longer access survival in well-functioning dialysis programs.

Infectious complications of accesses are a leading cause of morbidity and mortality in dialysis patients. The current national combined infection rates for permanent accesses for local and bacteremic infections are calculated to be 1% to 4% for primary AVFs and 11% to 20% for AVGs during their expected periods of use.^{4,16,232,543,573-577} Significant variance among dialysis centers is noted.^{232,543,575,577} Rates of 1% and 10% are the lower end of the published ranges and will demand more attention to aseptic technique (see CPG 3) by some centers.

The catheter infection rate is highly variable^{532,578,579} and clearly depends on the duration of use.^{156,211,533} At 2 weeks of catheterization, the incidence of infection of non-cuffed central catheters generally is less than 8%.⁵⁸⁰ One study reported a bacteremia rate of less than 5% in cuffed catheters used less than 3 months and a 50% removal rate for cuffed catheter infection at 12 months of use.¹⁵⁶ Other factors include being an incident patient, changing from 1 vascular access to another, and poor patient hygiene.²³⁸ The National Nosocomial Infections Surveillance data show that national surveillance of health care-associated infections combined with an intervention prevention program can reduce infection rates, reduce morbidity and mortality, and improve patient safety.⁵⁸¹ Establishment of such health care-associated infection surveillance and prevention systems in countries throughout the world should be a priority.

The Work Group's recommendations are significantly less than the experiences of some centers. The Work Group believes infection rates can be decreased significantly through meticulous attention to detail and, in the case of catheters, following the recommendations in CPG 3 and CPG 7. Catheter infection rates can be decreased to less than 1.5 episodes/1,000 days by paying scrupulous attention to the hub,²⁴⁷ a rate that is significantly less (<5%) than the 10% rate proposed. Infection rates also can be decreased by paying attention to skin preparation at the time of placement,⁵⁸² appropriate use of topical antibiotics,^{578,583} and use of nonocclusive dressings.⁵⁸⁴ Programs with high infection rates should consider the importance of nurse and patient training⁵⁸⁵ (see CPG 3.5).

Complications related to the insertion of TCCs depend on operator skill. Cuffed catheters can be inserted with reference to anatomic landmarks, with or without ultrasound guidance,^{151,579,586-588} but always with the use of fluoroscopy to verify proper positioning of the catheter tip (see CPG 2.4). Cuffed catheters can be placed by nephrologists, surgeons, or radiologists. Cumulative complication rates less than 5% are obtained routinely without ultrasound guidance.^{151,579} A recommended complication rate less

than 2% is less than values reported in the literature. However, published results are based on procedures obtained without benefit of ultrasound guidance. The RR for complication decreased 5-fold with the use of ultrasound.⁵⁸⁷ In the Work Group's opinion, rates of 1% should be obtainable in almost all centers and should be the goal.

Double-lumen cuffed catheters are used as both temporary access while a permanent access is maturing and as permanent access in patients who have exhausted other options. This variation in intended use creates significant variation in catheter survival rates. A study reported a median cumulative catheter survival rate of 18.5 months; 65% of silicone dual-lumen catheters survived 1 year.^{151,587} Conversely, another group reported a 1-year cumulative patency of 30%.⁵⁷⁹ Another study using 2 single-lumen Silastic catheters (with the majority serving to bridge a period until permanent access was established) reported an average catheter survival of 57 days.¹⁵² Others reported a 50% catheter survival rate at 12.7 months¹⁵⁶ and median survival period of 289 days.¹⁸⁶ Finally, 1 study reported an 80% survival rate at 1 year,⁵⁸⁹ no doubt in part the result of an all-cause infection rate less than 2 episodes/1,000 days.

Numerous studies reported 1-year patency rates of grafts between 63% and 90%.^{24,25,67,590} One report described an overall average patency rate of 70%.⁴ Many investigators reported patency rates at 2 and 3 years, as well.^{4,24,25,67,73} Outflow obstruction, followed by thrombosis, accounts for the majority of AVG failures. The Work Group believes that prospective surveillance and monitoring (see CPG 4) may improve this reported experience despite the aging of the population and increasing percentage of patients with diabetes or peripheral vascular disease. Thus, cumulative patency targets for grafts of 70% at 1 year, 50% at 2 years, and 50% at 3 years should be achievable. Because fistulae have a lower thrombosis rate, their cumulative survival should be greater. Despite the current problems with maturation and early failure, the Work Group believes that rates comparable to those in Europe can be achieved.^{3,87,591,592}

With respect to grafts, there now has been sufficient time to assess the effect of the efforts made since the previous guidelines, at which the time the Work Group recommended that the primary failure rate of AVFs not be used as an indicator of quality. This was done for fear that during the learning curve of fistulae construction, patients with more complex vascular anatomy (ie, patients at greater risk for failure) might be discouraged. The Work Group recommended that primary failure of native AVFs be examined in dialysis centers as part of their QA/CQI vascular access programs. Since then, many studies documented the superior patency (with lower thrombotic rates) of fistulae compared with grafts.^{3,37,57,570,593-598} The median patency of 3 years is based on current data and may improve if we can improve cannulation skills.

II. CLINICAL PRACTICE RECOMMENDATIONS FOR VASCULAR ACCESS

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 1: PATIENT PREPARATION FOR PERMANENT HEMODIALYSIS ACCESS

Factors that may be helpful in preparing the patient for placement of a permanent HD access include the following:

- 1.1 The veins of the dorsum of the hand should be the preferred site for IV cannulation.**
- 1.2 Sites for venipuncture should be rotated if arm veins need to be used.**
- 1.3 Patients with CKD stage 5 should be educated on the risks and benefits associated with catheters and strongly encouraged to allow the evaluation for and creation of a fistula for long-term access when appropriate. Such discussions with the patient should be initiated months before the anticipated start of dialysis therapy.**
- 1.4 Alternative imaging studies for central veins include DDU and magnetic resonance imaging/MRA.**

RATIONALE

Venipuncture complications of veins potentially available for vascular access may render such vein sites unsuitable for construction of a primary fistula. Patients and health care professionals should be educated about the need to preserve veins to avoid loss of potential access sites in the arms and maximize chances for successful fistula placement and maturation. Subclavian vein catheterization is associated with central venous stenosis.²⁸⁻³⁰ Significant subclavian vein stenosis generally will preclude the use of the entire ipsilateral arm for vascular access. Thus, subclavian vein catheterization should be avoided for temporary access in patients with kidney disease.³¹ The incidence of central vein stenosis and occlusion after upper-extremity placement of PICCs and venous ports was 7% in 1 retrospective series of 150 patients.³² PICCs also are associated with a high incidence of upper-extremity thrombosis. The incidence of upper-extremity venous thrombosis varies between 11% and 85%, which leads to loss of potential upper-extremity fistulae.³³⁻³⁵ Because of the substantial risk for loss of useable upper-extremity veins and central venous stenosis with PICCs, the Work Group recommends strongly that PICCs not be used in patients with CKD.

Ideally, patients should have a functioning permanent access at the time of dialysis therapy initiation. Function implies that the access not only deliver adequate blood flow for dialysis, but also may be cannulated easily and repetitively. Timely attempts to create a primary fistula before the anticipated need for dialysis therapy will allow adequate time for the fistula to mature and sufficient time to perform another vascular access procedure if the first attempt fails, thus avoiding the need for temporary access. Early referral of a patient with CKD to a nephrologist is needed to facilitate CKD therapy with medications

and diets that preserve kidney function. In addition, counseling patients on CKD treatment options is essential to plan for ideal access (ie, PD and HD access).

Duplex ultrasound is the preferred method for preoperative vascular mapping. Vascular mapping in preparation for the creation of a vascular access refers to the evaluation of vessels, both arterial and venous, of patients with CKD who selected HD in preparation for the creation of a vascular access. Vascular mapping should be performed in all patients before placement of an access. Preoperative vascular mapping was shown to substantially increase the total proportion of patients dialyzing with fistulae.³⁶⁻³⁹ Several studies support the 2.0- to 2.5-mm vein diameter threshold for successful creation of a fistula.^{36,39} Radiocephalic fistulae constructed in veins with a less than 2.0-mm diameter had only 16% primary patency at 3 months compared with 76% for those with veins greater than 2.0 mm.³⁶ In a pivotal study,³⁹ a threshold of 2.5-mm vein diameter assessed by using duplex ultrasound was used; this resulted in an increase in fistula creation of 63% compared with a retrospective 14% rate in the absence of vascular mapping.²² A similar study using the same duplex ultrasound criteria showed a fistula increase from 34% in historical controls to 64%. Importantly, in this study, duplex ultrasound altered the surgical plan based entirely on the surgeon's clinical evaluation, resulting in increased placement of fistulae.⁷²

Although angiography remains the standard for evaluating the central veins, the central veins may be assessed indirectly by using duplex ultrasound.⁴⁴ Compared with invasive venography, duplex ultrasound had a specificity of 97% and sensitivity of 81% for detecting central vein occlusion.⁴⁵ Alternatively, MRA may be used to evaluate central veins.⁴⁶

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 2: SELECTION AND PLACEMENT OF HEMODIALYSIS ACCESS

Recommendations for fistulae:

2.1 When a new native fistula is infiltrated (ie, presence of hematoma with associated induration and edema), it should be rested until the swelling is resolved.

RATIONALE

There are no studies evaluating the need to rest a fistula after an infiltration. Common sense dictates that cannulation should be avoided in the involved area until landmarks can be seen clearly. The most common reason for infiltration is poor cannulation. Successful cannulation and use of the fistula can be engendered by providing a digital photo map of the fistula based on ultrasound. This educates the staff and develops expertise. Dialysis units should develop a new AVF cannulation protocol to prevent trauma to the newly cannulated AVF, such as progressive evolution of needle gauge used for cannulation (see CPG 3). The needle gauge and BFR should be increased slowly to prevent infiltrations and should be detailed clearly in the fistula “break-in” cannulation protocol. The role of improving the cannulation needles requires further investigation.³⁹⁷

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 3: CANNULATION OF FISTULAE AND GRAFTS AND ACCESSION OF DIALYSIS CATHETERS AND PORTS

3.1 Cannulation skill:

Staff should be appropriately trained and observed for technical mastery before cannulating any AV access. Only those with said technical mastery should be allowed to cannulate a new fistula. A protocol for minimizing vessel damage should be used for cannulation failure. Recannulation should be attempted only when the cannulation site is healed and the vessel is assessed to be normal and appropriate for cannulation. Heparin management should be reviewed on a case-by-case basis to minimize postdialysis bleeding.

3.2 Self-cannulation:

Patients who are capable and whose access is suitably positioned should be encouraged to self-cannulate. The preferred cannulation technique is the buttonhole.

3.3 Buttonhole:

Patients with fistula access should be considered for buttonhole (constant-site) cannulation. (See protocol in CPG 3.)

3.4 Elevation of arm for swelling:

The AVG access arm should be elevated as much as possible until swelling subsides, which may take as long as 3 to 6 weeks. Increase in symptoms requires urgent evaluation.

RATIONALE

Data from DOPPS⁵⁹⁹ show that a functional fistula should have an outflow vein that can be successfully cannulated 1 month postoperatively. The previous KDOQI Vascular Access Guidelines recommendation of 3 to 4 months after access creation was opinion based as a result of anecdotes of early cannulation failure with resulting tissue infiltrations and vessel damage. Consideration should be given to marking, with the aid of ultrasound, veins that are difficult to see and feel, with accompanying measurements of the vein margins to prevent aspiration of clots when the needle is placed too close to the vein wall.

Many centers have higher doses of heparin for catheter-dependent patients than for patients with subcutaneous access. New fistulae are more likely to bleed for a variety of reasons: infiltrations, patient and staff inexperience with hemostasis, and lack of clarity regarding when to reduce the heparin dose if a patient is using both a fistula and 1 lumen of the catheter.

There is growing evidence that buttonhole (constant-site) cannulation may be less likely to infiltrate, may be pain free for the patient, may help preserve the integrity of the outflow vein,²⁴⁴ and may be easier for patients to self-cannulate.

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 4: DETECTION OF ACCESS DYSFUNCTION: MONITORING, SURVEILLANCE, AND DIAGNOSTIC TESTING

4.1 Monitoring the access:

- 4.1.1 Access patency should be ensured before each treatment before any attempts to cannulate the access.
- 4.1.2 All caregivers, including fellows in training, should learn and master the methods for examining a vascular access.
- 4.1.3 Access characteristics, such as pulsatility and presence of thrill, as well as flow and pressure, should be recorded and tracked in a medical record and be available to all caregivers of the VAT.

4.2 Frequency of measurement is dependent on the method used:

- 4.2.1 It is not clear that access flow measurements performed at a monthly frequency provide sufficient data stability to make decisions. Until additional studies are performed to determine the optimal frequency, more frequent measurements are recommended.
- 4.2.2 Static pressure measurements require less technology and should be made more frequently than flow measurements. Direct measurements of static pressure ratios should be made every 2 weeks. Less-direct measurements should be made weekly. Dynamic pressures, if used (see CPG 4.2.3), should be measured with each dialysis treatment, but derivation of a static pressure should be attempted, rather than using the raw numbers.
- 4.2.3 Measurement of recirculation is not recommended as a surveillance technique in grafts.

4.3 Frequency of measurement for access complications:

- 4.3.1 Thrombosis in fistulae develops more slowly than in grafts. Flow measurements performed at a monthly frequency appear to be adequate. Until additional studies are performed to determine the optimal frequency, less frequent measurements are not recommended.
- 4.3.2 Because static pressure measurements are inherently less accurate in detecting access stenosis in fistulae, the frequency should not be less than in grafts. Direct measurements of static pressure ratios should be made every 2 weeks. Less-direct measurements should be made weekly. Dynamic pressures should be measured with each dialysis. Increased recirculation can indicate reduced effective blood pump flow, resulting in inadequate dialysis.

4.4 Diagnostic testing:

- 4.4.1 Characteristics of access (see CPR 4.1), as well as blood pump flow and pressure performance, should be recorded and tracked in medical records.

- 4.4.2 Data should be analyzed at least monthly to evaluate access dysfunction.**
- 4.4.3 After intervention, the surveillance parameter should be restored to normal.**
- 4.4.4 Data should be analyzed to improve success rates and ensure that interventions are appropriately assessed. For example, PTA and surgical revision rates, recurrence rates, and number of procedures per patient year should be systematically analyzed in a CQI process.**
- 4.4.5 A multidisciplinary team should be involved.**
- 4.4.6 Preemptive correction of hemodynamically significant stenoses should remain the standard of care.**

RATIONALE

There is considerable debate concerning whether PTA interventions improve long-term outcomes. Until sufficiently powered clinical studies are performed, the rationale for monitoring and surveillance are provided in CPG 4. It is the belief of the Work Group that physical examination and clinical evaluation are forgotten skills that, if restored, could be as valuable as any surveillance method.

The utility of any method develops on sequential assessment and evaluation. This requires collection and storage of observations and/or data. Because stenoses evolve over time, observations and data should change over time. Because observers may change, data must be available to all caretakers.

Quality and outcome improvement cannot be determined without analyses of data.

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 5: TREATMENT OF FISTULA COMPLICATIONS

5.1 If a new fistula access has vein margins that are difficult to discern on physical examination and cannulation frequently is associated with aspiration of clot, the patient should be referred for access marking by means of DDU to define the center of the vessel and depth of the fistula. A diagram of these findings should be sent to the dialysis unit.

5.1.1 The patient should be taught to examine his or her access daily, while at home, for thrombosis.

RATIONALE

Many patients present with an occluded access. In a fistula, successful declotting decreases with the duration of thrombosis (see CPG 5.4.2). Thrombus may propagate into side branches or become organized, increasing resistance to extraction. Most thromboses occur at home, and when questioned, many patients cannot recall when they last felt for the access thrill or pulse. The Work Group believes that this area is ripe for research on the efficacy of simple teaching on the early detection of thrombosis and the degree of early, as well as late, patency achieved by intervention.

CLINICAL PRACTICE RECOMMENDATIONS FOR GUIDELINE 7: PREVENTION AND TREATMENT OF CATHETER AND PORT COMPLICATIONS

7.1 Treatment of catheter dysfunction:

Catheter dysfunction should be treated when a dialyzer blood flow of 300 mL/min is not being attained in a catheter previously able to deliver greater than 350 mL/min at a prepump pressure of –250 torr.

7.1.1 A dysfunctional catheter (blood flow < 300 mL/min) for 2 consecutive treatments should be treated in the HD unit by using an intraluminal interdialytic thrombolytic lock protocol between 2 dialysis treatments (ie, 35 to 69 hours).

7.2 Radiological evaluation:

Any dysfunction that cannot be managed in the dialysis unit should be sent for radiographic study to diagnose dysfunction and document the condition of the vessel.

7.2.1 Catheter imaging with contrast infusion can identify other correctable problems (eg, residual lumen thrombus, external fibrin catheter sheath, malpositioned catheter tip). Appropriate interventions may follow, such as:

7.2.1.1 Repositioning of the catheter.

7.2.1.2 Angioplasty of a vessel.

7.2.1.3 Replacement of a malpositioned catheter over guide wire.

7.2.1.4 Higher-dose lytic infusion for occlusive thrombus (eg, right atrial) or fibrin sheath.

7.3 Choice of thrombolytic and use of other modalities:

7.3.1 A special brush is used to remove thrombus from the lumens of a conventional catheter by using a protocol specific to this procedure.

7.4 Treatment of infection:

7.4.1 Catheter exit-site infections, in the absence of a tunnel infection, should be treated with topical and/or oral antibiotics, ensuring proper local exit-site care. In general, it should not be necessary to remove the catheter.

7.4.2 If a patient with bacteremia is afebrile within 48 hours and is clinically stable, catheter salvage might be considered by using an interdialytic antibiotic lock solution and 3 weeks of parenteral antibiotics in appropriate situations. A follow-up blood culture 1 week after completion of the course of antibiotics should be performed. (see Table 24)

7.4.3 Antibiotic lock with antibiotic to which the organism is sensitive is indicated when follow-up cultures indicate reinfection with the same organism in a patient with limited catheter sites.

7.4.4 Short-term catheters should be removed when infected. There is no conclusive evidence to support a rationale for scheduled replacement except for those in the femoral area.

RATIONALE

Treatment of Catheter Dysfunction (CPR 7.1)

Locking with tPA maintains the conductance of a catheter better than locking with heparin.⁴⁹⁶ Alternatively, intracatheter lytic infusion (eg, UK, 20,000 U/lumen/h for 6 hours,⁶⁰⁰ or alteplase, 2.5 mg/lumen over 1 to 2 hours) during the dialysis can restore blood flow.^{601,602}

Several studies evaluated the effect of tPA infusion in restoring patency to dysfunctional catheters. In general, infusion of 1 to 4 mg/lumen over 1 to 4 hours permits restoration of flow (>200 mL/min) sufficient to permit completion of a dialysis treatment,⁶⁰¹⁻⁶⁰³ permitting control of serum potassium levels and fluid removal. Infusion may succeed when a simple timed dwell fails. The difference in efficacy may result from the amount of lytic that gets to the fibrin/thrombus in a limited time. With the dwell technique, only the lytic at the catheter tip is biochemically active; the amount that has not leaked immediately must slowly diffuse to the fibrin or thrombus at the tip or exterior to the catheter. Conversely, push or infusion techniques more rapidly deliver the lytic in the lumen to the area of need. However, there have been no head-to-head comparisons. There should be little fear to use tPA as a long lock dwell or as infusions of doses less than 10 mg. The half-life of tPA is on the order of minutes, and it is only active when bound to fibrin. At the doses and infusion rates used, there is virtually no risk for systemic thrombolytic effect.

Very few head-to-head comparisons have been made among the available lytics.^{525,604,605} Two studies showed an advantage of tPA over UK, but neither was randomized. In 1 of the studies, “the push” protocol was used as opposed to the “passive dwell.”⁵²⁵ The choice of agent to be used is governed by many factors, including availability, convenience, cost, and comparative efficacy.

Unfortunately, when the fibrin deposition/thrombus formation process is allowed to advance to a severe degree, the occlusive process recurs and repeated doses of lytic must be administered^{496,516,517,523} at a median intertreatment interval of only 5 to 7 additional dialysis sessions.⁵¹⁶ This is believed to result from the presence of a fibrin sheath that, at times, is so extensive as to occlude the SVC.⁶⁰⁶

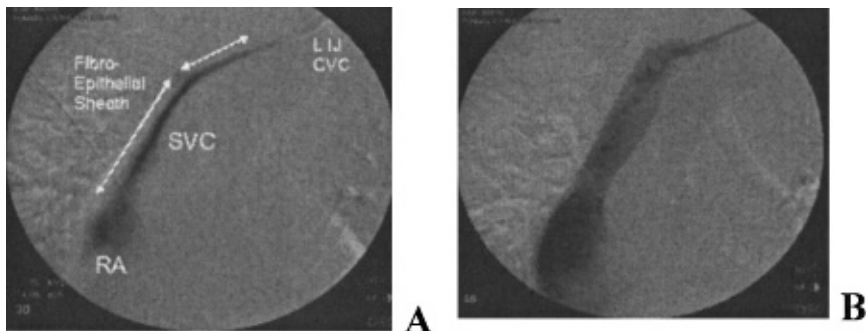
Endoluminal brushing, although not used widely in the United States, can remove clots effectively and also provides material for culture to rule out or confirm infection.⁵²⁸

Radiological Evaluation (CPR 7.2)

A fibrin sheath can only be diagnosed by performing a contrast study and requires partial pull back of the catheter. A representative example is shown in Fig 10.

A fibrin sheath can be treated in 1 of several ways: fibrin sheath stripping, guide wire catheter exchange, and lytic infusion.^{156,157,579,607-609} Studies have shown the success of tPA infusion,^{607,608} as well as stripping of the catheter.^{156,609} No difference in outcome

Figure 10. Fibrin sheath (A) prior to therapy; (B) after treatment with PTA. Abbreviations: LIJ, Left internal jugular; RA, Right atrium; SVC, Superior Vena Cava. (Courtesy of Dr A. Asim).



was found between percutaneous stripping and UK infusion.⁵³⁰ See Table 24 in CPG 7.6 for additional information.

There have been no comparisons of sheath disruption with an angioplasty balloon compared with the other 2 techniques. It is intermediate in complexity. Until such studies are done, the Work Group's preferred intervention for a fibrin sheath is removal of the catheter over a guide wire, disruption of the sheath with a balloon, and placement of a new catheter (catheter exchange).⁵³¹

Catheter Maintenance (CPR 7.3)

Increasing focus should be placed on prevention or control of growth of the fibrin sheath through periodic high-dose lytic infusion⁶⁰⁰ triggered by a progressive decrease in achievable BFR. Also, some centers are using weekly instillation of tPA or UK to maintain flow characteristics of long-term catheters.^{496,531} There is sufficient evidence of effectiveness for the Work Group to recommend these approaches for long-term catheter management with the proviso that this is an area for future research to optimize the best regimens that are cost-effective.

CLINICAL PRACTICE RECOMMENDATION 8: VASCULAR ACCESS IN PEDIATRIC PATIENTS

8.1 Choice of access type:

- 8.1.1 Permanent access in the form of a fistula or graft is the preferred form of vascular access for most pediatric patients on maintenance HD therapy.
- 8.1.2 Circumstances in which a CVC may be acceptable for pediatric long-term access include lack of local surgical expertise to place permanent vascular access in small children, patient size too small to support a permanent vascular access, bridging HD for PD training or PD catheter removal for peritonitis, and expectation of expeditious kidney transplantation.
- 8.1.3 If surgical expertise to place permanent access does not exist in the patient's pediatric setting, efforts should be made to consult vascular access expertise among local adult-oriented surgeons to either supervise or place permanent vascular access in children.
- 8.1.4 Programs should evaluate their patients' expected waiting times on their local deceased-donor kidney transplant waiting lists. Serious consideration should be given to placing permanent vascular access in children greater than 20 kg in size who are expected to wait more than 1 year for a kidney transplant.

8.2 Stenosis surveillance:

An AVG stenosis surveillance protocol should be established to detect venous anastomosis stenosis and direct patients for surgical revision or PTA.

8.3 Catheter sizes, anatomic sites, and configurations:

- 8.3.1 Catheter sizes should be matched to patient sizes with the goal of minimizing intraluminal trauma and obstruction to blood flow while allowing sufficient blood flow for adequate HD.
- 8.3.2 External cuffed access should be placed in the internal jugular with the distal tip placed in the right atrium.
- 8.3.3 The BFR of an external access should be minimally 3 to 5 mL/kg/min and should be adequate to deliver the prescribed HD dose.

INTRODUCTION

Applicability of Previous KDOQI Vascular Access Guidelines to Pediatric Patients

Provision of validated evidence-based pediatric vascular guidelines is hampered by a number of pediatric CKD stage 5-related epidemiological issues. Most of the recommendations outlined in the first edition of the KDOQI Vascular Access Guidelines are pertinent to pediatric patients, although few published data exist to support more than opinion-based recommendations. Some pediatric HD vascular access descriptive and

comparative clinical research has been conducted since the first edition of the KDOQI Vascular Access Guidelines, which provide data to formulate a first set of both evidence- and opinion-based recommendations for children receiving maintenance HD. Rather than restating the previous CPGs in their entirety with annotation of the few areas in which the emphasis may be different for pediatric patients, we have opted to present separate pediatric Vascular Access Guidelines based on the available pediatric literature. For specific vascular access areas not addressed in these pediatric guidelines, the practitioner should refer to the relevant adult KDOQI Guidelines.

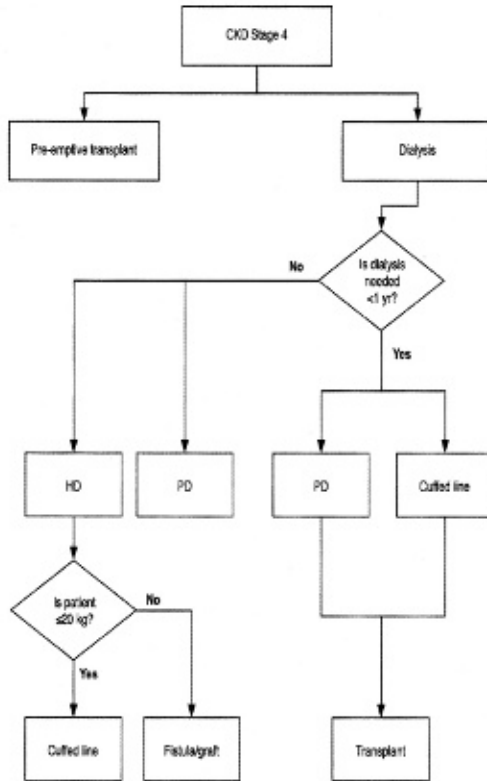
RATIONALE

Choice of Access Type (CPR 8.1)

Kidney transplantation remains the preferred and predominant therapy for pediatric patients with CKD stage 5; therefore, many pediatric patients receive maintenance HD through an indwelling catheter in light of short deceased-donor waiting list times or a readily available living-related donor (see Fig 11).⁶¹⁰ Because fewer than 800 pediatric patients receive maintenance HD therapy in the United States, surgical expertise for placing fistulae or grafts in small patients may be limited by the infrequent need and sporadic caseload. Smaller patients, especially those less than 10 kg, present technical challenges in terms of both surgical and nursing skill; therefore, the majority of smaller patients receive PD for their maintenance dialysis modality.

Recent data show that AVFs and AVGs typically function longer^{75,611-613} than catheters⁶¹⁴⁻⁶¹⁶ in pediatric patients receiving maintenance HD therapy. Functional survival rates of AVFs and AVGs are similar to adult patient standards and those recommended by KDOQI Vascular Access Guidelines, with centers recently reporting 4-year functional survival rates of 40% to 60%. Despite this, the most recent CMS CPM and North American Pediatric Renal Transplant Cooperative Study data⁶¹⁷ show that 62% to 78% of pediatric maintenance HD patients have catheters as their vascular access. While reports of successful permanent vascular access in children less than 10 kg in size exist,^{611,612,618} maturation can take up to 4 to 6 months, making routine permanent access placement impractical in many pediatric situations. Since the late 1970s, both AVFs and AVGs have been placed in children requiring maintenance HD.⁶¹⁹ The major complications of pediatric fistulae include a primary nonfunction rate of 20% to 33%, usually because of lack of maturation or clotting. Pediatric fistulae can develop stenosis anywhere along the fistula, most of which is amenable to either surgical correction or PTA.⁶²⁰ Given the relatively long life expectancy for pediatric patients with CKD stage 5 (79% at 10 years and 66% at 20 years),⁶²¹ all efforts should be made to use distal sites for initial fistula creation, ie, the radiocephalic fistula configuration. For patients less than 10 kg in size with a creatinine clearance between 20 and 25 mL/min/1.73 m² in whom imminent dialysis is not required, microsurgical techniques should be used for fistula creation.^{611,612} Fistulae in smaller children may require 4 to 6 months for adequate maturation.

Figure 11. Pediatric progress from CKD stages 1 to 5 and KRT/access algorithm.



Stenosis Surveillance (CPR 8.2)

AVGs offer the advantage of more flexible surgical configurations, which include the use of thigh vessels. Recent data show that AVGs can function well in pediatric patients receiving maintenance HD, with functional survival rates similar to adult patient standards and KDOQI Vascular Access Guidelines.⁶¹³ As with AVFs, the more distal anatomic sites should be used for first access to preserve more proximal sites for access in later life. AVG venous outflow stenosis predisposes pediatric patients to AVG thrombosis. Recent pediatric data show that UDTs are very sensitive to predict venous stenosis.³⁶⁵ A proactive ultrasound dilution venous stenosis assessment protocol directing patients to angioplasty with a corrected access flow less than 650 mL/min can lead to a significant decrease in AVG thrombosis rates.^{622,623} One pediatric study found that static venous pressure

monitoring did not help in the diagnosis of venous stenosis.⁶²⁴ No data exist about the long-term effect of decreased thrombosis rates on AVG survival in children.

Catheter Sizes, Anatomic Sites, and Configurations (CPR 8.3)

The choice of catheter size and configuration depends on the size of the patient. Studies to date suggested that children as small as 4 to 5 kg can tolerate dual-lumen 8 Fr catheters, and as the child becomes larger in size, a larger volume access can be placed.⁶²⁵ Table 25 serves as a guideline for matching catheter size to patient size. Choices often are limited based on availability, but considerations should include flow characteristic, recirculation risk, and ease of placement. Data suggest that for the appropriately sized patient, twin single-lumen catheters (the Tesio System) may provide better performance than standard dual-lumen catheters.⁶¹⁶ Longer and more narrow catheters result in greater resistance to flow.⁶²⁶

Catheter placement considerations in pediatrics are similar to those in adults, with a preference for internal jugular veins over subclavian veins. Right atrial placement may prevent inlet or outlet hole occlusion by blood vessels and thus allow for the high flow rates needed to provide adequate dialysis. Data have suggested that subclavian stenosis occurs in excess of 80% of patients in pediatrics who have subclavian catheters (Denis Geary, personal communication). Femoral access can be used when upper-anatomy venous access is no longer available.⁶²⁷

Flow rates for vascular access should be sufficient to result in a Kt/V greater than 1.2. Kt/V is influenced further by the recirculation rate. Because flow rates in pediatrics vary by the size of catheter, which varies by the size of the patient, a recommended flow rate of 3 to 5 mL/kg/min is acceptable in most patients.⁶²⁸

Table 25. Semipermanent HD Catheter and Patient Size Guideline

Patient Size (kg)	Catheter Options
<10 kg	Made on a case by case basis
10-20 kg	8 French dual lumen
20-25 kg	7 French twin catheter
20-40 kg	10 French dual lumen
	10 French Split catheter
	10 French twin catheter
>40 kg	10 French twin catheter
	11.5 or 12.5 French dual lumen

III. RESEARCH RECOMMENDATIONS

PREAMBLE

RCTs are the optimal study design to answer intervention questions. A recent review concluded that between 1966 and 2002, the number of RCTs published in nephrology from 1966 to 2002 (2,779) is fewer than in all other specialties of internal medicine.⁶²⁹ In addition, the overall quality of RCT reporting in nephrology is low and has not improved for 30 years. Issues identified included unclear allocation concealment (89%), lack of reported blinding of outcome assessors (92%), and failure to perform “intention-to-treat analysis” (50%). The challenges of improving the quality and quantity of trials in nephrology are substantial. We need to use standard guidelines and checklists for trial reporting, give greater attention to trial methods, and cease to focus on results of small underpowered studies. We must involve experts in trial design and reporting, expect multicenter collaboration, and do larger, but simpler, trials. Many of the research recommendations made in this section require multicenter trials to enroll sufficient patients to obtain clear-cut answers. Many will not receive external support from government or other grant agencies. However, they can be performed by collaboration between those in academic centers and those in clinical practice. We should emulate cardiology, for which there has been a 6-fold growth in clinical research trials, particularly in the number of patients (usually in the thousands) enrolled into the studies.

RANKING OF RECOMMENDATIONS

Research recommendations have been grouped into 3 categories: critical research, important research, and research of interest. These rankings were made by the Work Group based on current evidence and the need for research to provide additional evidence for the current CPGs and CPRs. No attempt was made to rank research recommendations within each of the 3 research categories.

Although the Vascular Access Work Group was restricted by the NKF to a thorough literature review in only 4 areas, the Work Group has developed research questions for all CPGs. These questions should not be viewed as comprehensive, but as a stimulus to the nephrology community to begin to ask, hopefully, better questions regarding vascular access with a goal of better outcomes for our patients.

CRITICAL RESEARCH RECOMMENDATIONS

Guideline 1. Patient Preparation for Permanent HD Access

Studies are required to determine the optimal vascular mapping criteria based on outcome goals of working fistulae.

Studies are needed to determine the optimal stratification of patients for fistula placement. Is there an age component to sizing of the artery and vein for fistula creation? Specifically, should the minimal vein diameter for such higher risk groups as female, diabetic, and elderly patients be larger to have acceptable working fistula outcomes?

Randomized studies should be performed comparing 1-stage with 2-stage brachial basilic vein transposition fistula outcomes.

Studies are needed to determine the optimal surgical techniques for fistula creation with outcomes to identify factors that minimize the development of surgical swing segment stenosis in fistulae.

Guideline 2. Selection and Placement of HD Access

Patients should be considered for construction of a primary fistula after failure of every HD access. There is a paucity of information about the success of this strategy. If a forearm loop AVG is placed as initial access, does this lead to successful construction of elbow-level fistulae? How often? Do we need an RCT? In what patients would a graft before fistula be cost- and resource effective? None? Some? Would a PU “immediate use” type of graft be preferable to a catheter if one had to do immediate (ie, within days) dialysis?

How often is primary conversion of dysfunctional grafts to fistulae successful? Is it affected by the previous history of thrombosis or angioplasty (if applicable)? What are the guidelines for number of angioplasties/thrombectomies performed before compromising the ability to convert to a fistula? What is the optimal timing for conversion?

The preference for fistulae is based on lower morbidity associated with their creation and maintenance compared with other access types. Is this still true for the US CKD stage 5 population? Has this remained true as the population has grown older and the health care system in the United States has been stretched? Late referrals, lower skill sets in the staff delivering dialysis and cannulating accesses, increased comorbidity in the United States compared with Europe, Japan, or Canada—do these factors influence the selection of initial access and the progression and choices among different access types?

Guideline 3. Cannulation of Fistulae and Grafts and Accession of HD Catheters and Port Catheter Systems

Can intensive structured cannulation training lead to better access outcomes?

Can increased remuneration for expert cannulators lead to better access outcomes?

Can self-cannulation lead to better outcomes?

Guideline 4. Detection of Access Dysfunction: Monitoring, Surveillance, and Diagnostic Testing

Studies are needed to compare outcomes of physical examination with “high-tech” methods in determining the best timing for intervention.

The role of DDU as an intermediate diagnostic test should be examined to determine the “timing” for access intervention with PTA or surgery.

There may be important differences in the susceptibility of grafts and fistulae to thrombosis as a function of absolute access flow or change in access flow over time. The “best” therapy for the access also may differ according to type. Future studies should carefully separate the surveillance data, type of intervention (PTA or surgical), response

to therapy, and both short-term and long-term outcomes according to access type, either graft or fistula. Because more proximal accesses have greater flow rates, data also should be categorized to access location, primarily the feeding artery (radial or ulnar versus low brachial, high brachial, and axillary for the upper arm and femoral for the thigh).

Studies are needed to establish objective criteria for endovascular intervention.

Guideline 5. Treatment of Fistula Complications

The efficacy of physical examination in detecting abnormalities in accesses difficult to cannulate should be studied.

Comparative trials are required to assess interventional versus surgical modalities to correct maturation failure with measurement of access flow longitudinally before and after correction.

Studies should examine the effect of intervention on: recurrent stenosis, elastic recoil, and juxta-anastomotic stenoses.

Guideline 6. Treatment of AVG Complications

Assessing adequacy of the intervention. Is PTA an effective intervention for treatment of vascular access-related stenosis? We cannot answer this question. A fundamental problem is our inability to reliably predict the outcomes of our percutaneous and surgical interventions. The true determinants of HD graft patency and longevity remain unknown. It certainly is a complex and multifactorial process. The primary determinants of graft failure likely are regulated by both physiological and genetic factors and therefore are variable within the patient population. To add to the confusion, neointimal hyperplastic stenoses develop simultaneously and sequentially in multiple locations. Our success in treating 1 stenosis is negated by the rapid development of another lesion. And there is another important variable: delayed elastic recoil can cause rapid recurrence of the stenosis after an apparently successful angioplasty procedure. This phenomenon can occur minutes to hours after balloon dilation, and our anecdotal experience suggests that elastic recoil of a stenosis may happen after 10% to 15% of our angioplasty procedures. Our current challenge is to identify the determinants for successful angioplasty and optimize our techniques to improve our clinical outcomes. In addition, we need to develop pharmacological means to reduce/prevent the recurrence of neointimal hyperplasia after successful angioplasty.

Criteria for success. An end point is used to define the successful completion of a procedure. The definition of a successful procedure can be viewed from several different perspectives. For example, the end point for clinical success is alleviation of the patient's symptoms. Hemodynamic success is restoration of normal blood flow throughout the treated vascular segment. And for treatment of stenoses, the end point for anatomic success is less than 30% residual diameter reduction. These clinical, hemodynamic, and anatomic end points serve as the determinants of a successful endovascular intervention. Our clinical experience has shown that these commonly used end points are *unreliable* for predicting the long-term patency of an HD graft or fistula. Although we use end points

to define immediate success, there is no postprocedural end point that correlates with long-term patency. Our inability to predict the long-term outcome of our endovascular procedures continues to frustrate both the physician and patient.

After an endovascular intervention, the standard definition of anatomic success is a residual stenosis with less than 30% diameter reduction. Although there are well-recognized physiological concepts that support the use of 50% stenosis as the definition of a hemodynamically significant lesion, there is no such scientific basis for the use of less than 30% residual stenosis to define a successful treatment. A consensus committee reached the value of 30% with representatives from interventional radiology and vascular surgery. This well-accepted standard end point (<30% residual stenosis) has no hemodynamic or physiological meaning. In addition, the residual stenosis does not allow for proper remodeling of the vein and may contribute to recurrence of stenosis. Therefore, it is not surprising that use of this parameter as a determinant of success is not predictive of the long-term patency of an HD graft or fistula. This poor correlation between degree of residual stenosis and subsequent patency was substantiated in a study that reported analysis of 96 interventions performed in native AVFs.⁶³⁰ After angioplasty, 17 lesions had greater than 30% residual stenosis and, by definition, had failed treatment. However, there was no difference in the long-term patency of this group compared with patients who had lesions with less than 30% residual stenosis on final fistulography.

Obviously, criteria used for success need to be examined by well-designed outcome studies.

Multiple lesions and criteria for intervention. According to the KDOQI guidelines, lesions with less than 50% stenosis should not be treated. However, it is not uncommon for a graft or fistula to have multiple areas of endoluminal irregularity that, when measured individually, represent less than 50% stenosis and therefore should not be treated. However, a hemodynamic abnormality may still exist. The basic principles of hemodynamics state that the effects of multiple stenoses are additive, similar to an electrical circuit with a series of multiple resistors. Therefore, our current concepts that emphasize the evaluation of individual stenoses using anatomic criteria are flawed.

New methods⁵⁴ that provide a more global assessment of the entire vascular access circuit suggest that subtle lesions can have substantial hemodynamic effects. The assessment of intragraft blood flow during angioplasty procedures may provide additional information regarding the hemodynamic importance of lesions that are greater than 30% but less than 50% stenosis.

We need to identify physiological/objective criteria for successful intervention.

IMPORTANT RESEARCH RECOMMENDATIONS

Guideline 1. Patient Preparation for Permanent HD Access

Studies are needed to determine the optimum timing of access placement.

Studies should be performed to examine the effect of exercises to mature vessels (arterial and venous) before and after fistulae are constructed.

The use of diluted contrast to characterize the venous system peripherally and centrally in patients with CKD and the effect on residual kidney function should be studied.

Additional studies are needed to compare the accuracy of MRA and DDU in evaluating central veins.

How can we align incentives for the creation of fistulae for all stakeholders: patients, nephrologists, surgeons, and dialysis providers?

Guideline 2. Selection and Placement of HD Access

What is the relative benefit of arm exercises performed before or after fistula construction and maturation or both?

We need RCTs to determine the effect of exercise either before or after access construction, alone or combined, on access maturation, time to cannulation, primary and secondary patency, ease of cannulation, number of procedures needed during the life span of the access, and cost analysis. Is pressure inside the fistula important in the maturation process? Is it flow or intraconduit pressure or both that allow an access to tolerate cannulation without infiltration? Should a nonocclusive tourniquet be used during exercise? Do we use/measure mere clinical end points for these studies or does fistula flow need to be measured as well, or does it not matter what the flow is? Brachial artery flow can be measured as a surrogate for access flow.

If intrafistula flow is important, what flow is needed to mature a fistula?

Guideline 3. Cannulation of Fistulae and Grafts and Accession of HD Catheters and Port Catheter Systems

Additional studies are needed of disinfectants, the role of antibiotic locks, and which patients may benefit most from CVC salvage. Risk-benefit outcomes, as well as long-term antibiotic susceptibility studies, should be done to detect resistance.

Studies are needed to examine the effectiveness of data on rotation of sites, buttonhole, flow/pressure curves, and so on.

Does the bevel-up cannulation method decrease access complications?

What needle tip-to-tip measurements minimize recirculation or prevent erroneous access flow measurements?

Can buttonhole (constant-site) cannulation be used in biografts?

Should an infiltrating needle be removed after the patient undergoes systemic anticoagulation with heparin?

How should the timing of flushing and locking of heparin in a catheter occur in a patient who is using 1 needle in the fistula and 1 side of the catheter for return?

Do transparent dressings, where the exit site is clearly visualized, need to be changed at each dialysis treatment?

Guideline 4. Detection of Access Dysfunction: Monitoring, Surveillance, and Diagnostic Testing

Further evaluation of the acoustic stethoscope is needed in detecting hemodynamically significant stenoses.

The relationship of access flow to pressure varies among individuals, affected chiefly by the health and capacity of the artery to deliver flow into the access. Within a population, there may be no obvious relationship between access flow and P_{IA} if measurements are made cross-sectionally because the important determinant in an individual is baseline flow (which may vary from 500 to 3,000 mL/min), the presence of 1 or more stenoses, their location, and the rate of evolution of the stenosis or stenoses. Additional studies are needed to determine the natural course of stenoses in grafts and fistulae. Stable stenoses may need no intervention if they are not associated with increased risk for thrombosis. Conversely, there may be significant risk for thrombosis, even with access flows exceeding 1,000 mL/min. Noninterventional trials should be conducted with the clock starting from the time of construction.

Large-scale trials are required to determine whether correction only of “hemodynamically” significant lesions (those associated with “low” access flows or “high” pressures or a change in access flow or pressure) is superior to correction of all stenosis greater than 50%.

Guideline 5. Treatment of Fistula Complications

Studies are required to compare strategies for treating aneurysms in fistula: surgery with new anastomosis versus surgical creation of new anastomosis. Cost and outcome analyses should be performed.

Studies are needed to examine the efficacy of endoluminal interventional versus surgical procedures for the management of aneurysms in fistulae.

Comparative trials should be performed to study the efficacy of surgery compared with interventional endoluminal procedures in correcting stenoses/thrombosis, with the same methods used for outcomes.

The role of thrombolytics in reestablishing or maintaining patency after fistula thrombosis should be examined. Low doses of thrombolytics have been used to keep costs controlled—does it make a difference in outcomes?

Data from RCTs are needed on the duration of thrombosis and success in reestablishing/maintaining patency. Is surgery more effective early or later?

Guideline 6. Treatment of AVG Complications

Assessing effectiveness of interventions. It is well accepted that a stenosis causing greater than 50% diameter reduction is considered to be a hemodynamically significant lesion. This value is based on both experimental modeling of flow stenosis⁶³¹ and correlation of thrombosis rates and degree of stenosis.¹⁰ This value is based upon the physiology of a “critical arterial stenosis.”^{450,451} A 50% reduction in luminal diameter corresponds to a 75% reduction in cross-sectional area, the critical point at which blood flow begins to dramatically decrease.

Measuring technical success. What determines technical success for endovascular interventions? Should technical success be based upon anatomic criteria, the measurement of which is both subjective and fraught with error and usually not assessed in 2 orthogonal views? Or should it be based upon normalization of a hemodynamic

parameter that is less subjective and more reflective of vascular access performance? Possibilities include the use of flow measurements, static pressure, or ultrasound imaging during the PTA procedure or angiography after the procedure. Continued clinical investigation hopefully will provide scientific support for the use of hemodynamic end points, not anatomic end points.

Endovascular stents would seem to be an ideal method to treat angioplasty failures. Stents can oppose elastic recoil and optimize endoluminal dimensions, thereby improving intragraft blood flow and prolonging graft patency. However, the majority of clinical studies showed that the routine use of stents does not provide an additional benefit compared with angioplasty alone.^{460,461} The neointimal hyperplastic tissue continues to grow unabated through the meshwork of the metallic stent. For these reasons, use of endovascular stents to treat HD-related stenoses continues to be a controversial subject. A recent study reported that use of nitinol stents provided superior results compared with stainless steel stents.⁶³² Continued improvements in stent design, the use of stent grafts, or the use of drug-eluting stents may provide better long-term results. Covered stents have been used to salvage AVGs, but efficacy has not been compared with other strategies.

Balloon sizing and selection. Balloons are now available in various sizes, have cutting edges, and are capable of delivering drugs. The proper selection and use of these balloons requires additional studies.

Mechanical thrombectomy devices. Comparative studies are needed on efficacy and cost. A reanalysis of existing data with differing devices should be performed.

Thrombolytics and anticoagulation. Although heparin typically is used during an endoluminal thrombectomy procedure, the proper role of thrombolytics is unknown. The spectrum has shifted from pharmacolytic to mechanical thrombectomy. Whether some lytics and their efficacy are superior to others in terms of outcomes is unknown. Several small series also suggested that dialysis within hours of thrombectomy influences patency.

Comparison of intervention methods. Do percutaneous and surgical techniques provide similar results or are we using percutaneous techniques simply because of the unavailability of surgical manpower for performing large numbers of vascular access-related procedures in an expedient manner? From another perspective, are we sacrificing long-term patency of the AVG to avoid insertion of an HD catheter?

Several reasonable studies reported that surgical techniques for AVG repair can provide substantially better outcomes compared with percutaneous techniques.^{467,468,472} By establishing substantially higher primary patency goals after surgical repair, the KDOQI guidelines have acknowledged the superiority of surgical techniques. However, because of a variety of factors, including the unavailability of surgeons, the growth of interventional nephrology, the trend toward outpatient vascular access services, and the profitability of percutaneous procedures, the superiority of surgical techniques seems to have been forgotten.

Do surgical techniques for AVG repair provide more durable results with better long-term patency compared with percutaneous techniques? Is this a political issue, a manpower issue, or a financial issue?

Prevention of stenosis. This is a particularly important area. Both basic studies and pharmaceutical interventions are needed.

Guideline 7. Prevention and Treatment of Catheter and Port Complications

The ideal catheter diameter is not established. Are there concomitantly increased complications associated with larger diameter catheters?

Studies are needed to evaluate the risk versus benefit of higher dose warfarin therapy (INR > 1.6) on catheter patency.

A comparison of lytic treatments is needed to examine:

- “Dwell” versus push versus infusion for catheters unable to deliver BFR of 300 mL/min
- Comparison of lytic agents for efficacy, cost, and long-term performance
- A number of studies on “anticoagulant locks” should be done in which primary outcome parameters of maintained access flow, resource use, and cost of care are evaluated. These include:
 1. Comparison of heparin at different concentrations (1,000 U and 5,000 U/mL) for all 3 dialysis sessions per week versus substitution of one of the heparin locks by tPA lock
 2. Use of high dose tPA (2.5–5 mg/lumen) where the catheter blood flow delivered at –250 mm Hg falls to <300 mL/min or decreases by 100 mL/min from its best flow ever

A definitive study should be performed to determine the natural history of catheter/port-related complications in the central veins, by using central venograms, that begins with de novo catheter placement, every 6-month follow-up, and with each the lowest rate in the last four decades catheter complication (CRB, fibrin sheath, and all other types of catheter dysfunction).

Studies are needed to determine the association between infection and fibrin sheaths in catheters.

The optimal duration of antibiotic therapy for catheter-related infections should be examined.

Prospective studies are needed to examine antibiotic locks as an adjunct to save catheter versus “site salvage.” Outcomes as primary and economics as secondary factors should be considered.

RESEARCH RECOMMENDATIONS OF INTEREST

Guideline 1. Patient Preparation for Permanent HD Access

Does patient education on the various risks/benefits of catheters versus fistulae/grfts alter success in placement? Is it an ethical study?

What demographic variables influence the likelihood of permanent access construction among a cohort of patients seen in a CKD clinic?

Guideline 2. Selection and Placement of HD Access

Studies are needed to determine the optimum duration of rest of a young (in use for <3 months) fistula after it has been infiltrated (ie, presence of hematoma with associated induration and edema). What parameters should be examined and how should such a study be designed?

The effects of catheter tip location on catheter or port catheter system performance should be studied—in the SVC/right atrium, common iliac, low IVC, and high IVC/right atrium. For the same French and luminal diameter, pressure flow curves should be performed keeping catheter design constant (ie, without mixing stepped and split catheters).

Studies are required to examine the effect of jets from catheter tips on central veins.

Guideline 3. Cannulation of Fistulae and Grafts and Accession of HD Catheters and Port Catheter Systems

What effect does correction of anemia have on access flow in fistulae? Prospective observational studies are needed.

Guideline 4. Detection of Access Dysfunction: Monitoring, Surveillance, and Diagnostic Testing

Research is needed on portable ultrasound devices for assessing flow easily and repetitively without operator effects.

Studies are needed to determine whether a properly performed DVP test retains any utility in detecting stenoses in fistulae.

Comparisons of surveillance techniques (access flow, DVP, P_{IA}) are required in fistulae using DDU anatomic imaging or contrast angiography to determine sensitivity and specificity. Low-end techniques (physical examination + derived $P_{IA} \pm$ flow achieved/prepump pressure) should be compared with high-end methods (Q_A by UDT or GPT alone \pm flow by in-line dialysance, DDU).

Guideline 5. Treatment of Fistula Complications

Comparative trials are needed to examine interventional versus surgical modalities to correct maturation failure, with measurement of access flow longitudinally before and after correction.

Guideline 6. Treatment of AVG Complications

Treatment of infection. There are few informative data on the treatment of infected grafts. Decisions on using antibiotics, removal or not of the AVG, and duration of antibiotic use usually are made based on experimental considerations and recommendations from infectious disease consultants and CDC publications. Most of these recommendations are extrapolations and are not based on specific studies of dialysis patients with AVGs.

Arterial lesions and steal. In an increasingly older population with a greater incidence of diabetes, arterial lesions are not uncommon in patients undergoing vascular access constructions.⁴⁰⁹ Steal occurs with high-flow fistulae. Prediction of its occurrence^{80,633} and means to prevent its development⁶³⁴ require prospective outcome studies. Once developed, several methods can be used to correct the problem,^{411,431,433,635,636} but without consensus about the best procedure.^{48,637} When distal digital ischemic changes or gangrene appear ipsilateral to a functioning graft, we need more studies to determine whether the problem is purely “ischemic” or perhaps embolic.^{431,638}

Prediction of successful AVG function. A multitude of factors probably influence the longevity of AVG function,¹⁴³ including the individual’s genetic predisposition for neointimal hyperplasia, surgical techniques, cannulation, and so on. These factors have not been systemically studied.

Guideline 7. Prevention and Treatment of Catheter and Port Complications

Studies should examine the value of sequential measurement of dialyzer flow rates and delivered and prepump arterial pressures during sequential dialysis treatments in detecting problems while they are still amenable to pharmacological or mechanical intervention. With modern catheters, what is the value of the conductance (BFR/arterial prepump pressure) in predicting catheter dysfunction?

Research is needed to define the optimum value of flow rate: 300 versus 350 mL/min if the initial flow is greater than 400 mL/min. Outcome parameters should include effects on adequacy, manpower utilization, and cost of intervention.

Studies should culture the tips of all catheters removed for both CRB and fibrin sheath disruption to determine the frequency of occult “silent” infection.

Additional studies are required to define the agents and concentrations of antibiotic locks that can be used, including studies of systemic levels during prolonged periods.

Long-term studies are needed on antibiotic and antimicrobial resistance to antibiotic locks and ointments used to prevent infection.

WORK GROUP BIOGRAPHIES

Anatole Besarab, MD (Co-Chair), received his medical degree from the University of Pennsylvania, USA, and then carried out his internship and residency in medicine at Pennsylvania Hospital. Dr Besarab then spent 3 years as renal Fellow at Harvard Medical School (under Dr Frank Epstein) in Boston, MA, before moving to Thomas Jefferson University in Philadelphia, PA, for 19 years, followed by his first stint at Henry Ford Hospital, Detroit, MI. For 2 years he was Section Chief at West Virginia University. He currently is on the faculty of the Division of Nephrology and Hypertension at Henry Ford Hospital, and has his academic appointment at Wayne State University. In the past decade, Dr Besarab's work has focused on optimizing the management of anemia and detecting vascular access dysfunction before thrombosis. His current research interests include evaluation of diagnostic tests to detect angioaccess dysfunction and developing algorithms that maximize hematopoietic response to epoetin. He is author of more than 100 papers, 30 chapters, and several monographs and has spoken extensively at national meetings and academic centers. He has served on various committees for the Forum of ESRD Networks of End-Stage Renal Disease Networks, the American Society of Nephrology, ASAIO (American Society for Artificial Internal Organs), and the National Institutes of Health. He has served on the editorial board of several journals, reviews extensively for many journals, and is a reviewer for UpToDate. He is the current Chairman of the National Kidney Foundation Work Group on Vascular Access. Dr Besarab has received research funds, grants or contracts from Abbott Laboratories, Advanced Magnetics, Affymaz, American Regent Inc. Amgen, Inc., Baxter, Genentech, Hoffman-La Roche, Rockwell International, Transonic Systems Inc., VascAlert, and Watson Pharmaceuticals.

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ACRONYMS AND ABBREVIATIONS

AVF	Arteriovenous fistula
AVG	Arteriovenous graft
BP	Blood pressure
CHF	Congestive heart failure
CPR	Clinical Practice Recommendations
CrCl	Creatinine clearance
CVD	Cardiovascular disease
DOQI	Dialysis Outcomes Quality Initiative
GFR	Glomerular filtration rate
HD	Hemodialysis
HTN	Hypertension
KDOQI	Kidney Disease Outcomes Quality Initiative
Kt/V	Measure of dialysis adequacy calculated from K (dialyzer clearance), t (time) and V (volume of body water in a given patient)
LVH	Left ventricular hypertrophy
NKF	National Kidney Foundation
PD	Peritoneal dialysis
RCT	Randomized controlled trial
ROC	Receiver operating characteristics
SGA	Subjective global assessment
TPA	Tissue plasminogen activator
UOP	Urine output
UrCl	Urea clearance
US	Ultrasonography

APPENDIX 1. METHODS FOR EVALUATING EVIDENCE

AIM

The overall aim of the project was to update the 2000 Kidney Disease Outcomes Quality Initiative (KDOQI) Clinical Practice Guidelines on Hemodialysis and Peritoneal Dialysis Adequacy, and Vascular Access. The Work Group sought to update the guidelines using an evidence-based approach. After topics and relevant clinical questions were identified for the updates, the available scientific literature on those topics was systematically searched and summarized.

OVERVIEW OF PROCESS

Update of the guidelines required many concurrent steps to:

- Form the Work Groups and Evidence Review Team that were to be responsible for different aspects of the process;
- Confer to discuss process, methods, and results;
- Develop and refine topics;
- Define exact populations of interest;
- Create draft guideline statements and rationales;
- Create data extraction forms;
- Create and standardize quality assessment and applicability metrics;
- Develop and perform literature search strategies;
- Screen abstracts and retrieve full articles;
- Review articles;
- Extract data and perform critical appraisal of the literature;
- Tabulate data from articles into summary tables;
- Write guideline statements and rationales based on literature and Work Group consensus.

Separate Work Groups were created for each subject area: hemodialysis adequacy, peritoneal dialysis adequacy, and vascular access. The 3 groups worked in parallel to create the guidelines. The Work Group Chairs conferred regarding overlapping topics across guidelines. The Evidence Review Team, comprised of experts in systematic review and guideline development, guided the Work Groups in all methods and aspects of guideline development.

Creation of Groups

The KDOQI Advisory Board selected the Work Group Chairs and the Director of the Evidence Review Team then assembled groups to be responsible for the development of the updates. These Work Groups and the Evidence Review Team collaborated closely throughout the project.

The Work Groups consisted of domain experts, including individuals with expertise in nephrology, surgery, radiology, pediatrics, nursing and nutrition. For each guideline

update, the first task of the Work Group members was to define the overall topics and goals of the updates. They then further developed and refined each topic, literature search strategies, and data extraction forms (described below). The Work Group members were the principal reviewers of the literature, and from their reviews and detailed data extractions, they summarized the available evidence and took the primary roles of writing the guidelines and rationale statements. Completed data extractions were posted on a National Kidney Foundation (NKF) website for direct access by Work Group members.

The Evidence Review Team consisted of nephrologists (1 senior nephrologist and 2 nephrology fellows), methodologists, and research assistants from Tufts-New England Medical Center with expertise in systematic review of the medical literature. They instructed the Work Group members in all steps of systematic review and critical literature appraisal. The Evidence Review Team also coordinated the methodological and analytical process of the report, defined and standardized the methodology of performing literature searches, of data extraction, and of summarizing the evidence in summary tables. They organized abstract and article screening, created forms to extract relevant data from articles, organized Work Group member data extraction, and tabulated results. Throughout the project the Evidence Review Team led discussions on systematic review, literature searches, data extraction, assessment of quality and applicability of articles, evidence synthesis, and grading of the quality of the body of evidence and the strength of guideline recommendations.

Refinement of Update Topics and Development of Materials

The Work Group reviewed the 1995 Dialysis Outcomes Quality Initiative (DOQI) Clinical Practice Guidelines and the 2000 KDOQI updates and decided which of the guideline recommendations required updates and which should remain unchanged. These assessments were based primarily on expert opinion regarding the currency of the previous guidelines and the likelihood of availability of new evidence. Preliminary literature searches were made to inform this process. To allow for timely review, it was determined that each set of guidelines would be able to have systematic reviews on only a limited number of topics. After literature review, the experts decided which recommendations would be supported by evidence or by opinion. As described below, recommendations based on adequate evidence were categorized as Guidelines (CPGs), while opinion-based statements were categorized as Clinical Practice Recommendations (CPRs).

The Work Groups and Evidence Review Team developed: a) draft guideline statements; b) draft rationale statements that summarized the expected pertinent evidence; and c) data extraction forms containing the data elements to be retrieved from the primary articles. The topic refinement process began prior to literature retrieval and continued through the process of reviewing individual articles.

Literature Search

Based on the draft guideline statements, the Work Group members agreed on topics that would be systematically reviewed and formulated questions defining predictors, interventions, comparators, and outcomes of interest. Search strategies were developed based

on these questions and topics, in addition to the study designs and years of publications of interest to the Work Group. Articles of interest were identified through MEDLINE searches of English language literature of human studies in May through July 2004. Broad search terms were used to avoid missing potentially pertinent articles. The searches were supplemented by articles identified by Work Group members through June 2005.

Only full journal articles of original data were included. The searches were limited to studies published since January 1997 since earlier publications were reviewed in the previous DOQI guidelines. Editorials, letters, abstracts, and unpublished reports were not included. Selected review articles, however, were included for background material. No systematic process was followed to obtain review articles.

Abstracts and titles from the MEDLINE search results were prescreened by members of the Evidence Review Team for general relevance. A second round of screening was performed on the abstracts by Work Group members for relevance using predefined eligibility criteria, described below. Articles were retrieved by the Evidence Review Team and then rescreened by Work Group members and/or the Evidence Review Team. Eligible studies were extracted using standardized extraction forms. Domain experts made the final decisions regarding the eligibility of all articles.

Generation of Data Extraction Forms

Data extraction forms were designed to capture information on various aspects of the primary articles. Forms for all topics included study setting and demographics, eligibility criteria, causes of kidney disease, numbers of subjects, study design, study funding source, dialysis characteristics, comorbid conditions, descriptions of relevant risk factors or interventions, description of outcomes, statistical methods, results, study quality (based on criteria appropriate for each study design (see below), study applicability (see below), and sections for comments and assessment of biases. Training of the Work Group members to extract data from primary articles occurred by emails and teleconferences. Work Group members were assigned the task of data extraction of articles.

Generation of Evidence Tables

The Evidence Review Team condensed the information from the data extraction forms into evidence tables, which summarized individual studies. These tables were created for the Work Group members to assist them with review of the evidence and are not included in the guidelines. All Work Group members (within each Update) received copies of all extracted articles and all evidence tables. During the development of the evidence tables, the Evidence Review Team checked the data extraction for accuracy and rescreened the accepted articles to verify that each of them met the initial screening criteria determined by the Work Group. If the criteria were not met, the article was rejected, in consultation with the Work Group.

Format for Summary Tables

Summary Tables describe the studies according to the following dimensions: study size and follow-up duration, applicability or generalizability, results, and methodological quality. Within each table, the studies are first grouped by outcome type.

Data entered into Summary Tables were derived from the data extraction forms, evidence tables, and/or the articles by the Evidence Review Team. All Summary Tables were reviewed by the Work Group members.

Within each outcome, studies are ordered first by methodological quality (best to worst), then by applicability (most to least), and then by study size (largest to smallest). When relevant, outcome thresholds (eg, of access flow measurement) are included. Results are presented by using the appropriate metric or summary symbols, as defined in the table footnotes.

Systematic Review Topics, Study Eligibility Criteria, and Studies Evaluated

The topics for each Update were selected by the respective Work Group members for systematic review (Table 1, Table 2, Table 3). The eligibility criteria were defined by the Work Group members of each Update in conjunction with the Evidence Review Team.

Literature Yield for Hemodialysis Adequacy (Table 4)

A total of 2,526 citations were screened, of which 319 were review articles and 14 were added by Work Group members. There were 223 articles (191 studies in adults and 32 in children) that were potentially relevant. These articles were retrieved for full review. Of these, 87 adult articles were accepted for full data extraction by the Work Group members. Eight articles in children were formally data extracted by a pediatric nephrologist on the Work Group. Articles in adults were randomly assigned to individual Work Group members for data extraction. Of these, 23 studies answered questions pertinent to topics chosen for systematic listing in Summary Tables.

Literature Yield for Peritoneal Dialysis Adequacy (Table 4)

A total of 2,307 citations were screened and 7 were added by Work Group members. There were 293 articles (263 studies in adults and 30 in children) that were potentially relevant. These articles were retrieved for full review. Of these, 101 adult articles were accepted for full data extraction by the Work Group members. Nine articles in children were formally data extracted by a pediatric nephrologist on the Work Group. Articles in adults were randomly assigned to individual Work Group members for data extraction. Of these, 27 studies answered questions pertinent to topics chosen for systematic listing in Summary Tables.

Literature Yield for Vascular Access (Table 4)

A total of 2,892 citations were screened, of which 388 were review articles. There were 112 articles (89 studies in adults, 13 in children, 10 review articles) that were potentially relevant. These articles were retrieved for full review. Of these, 58 articles were accepted for full data extraction by the Work Group members. Because of small sample sizes, articles in children were not formally data extracted but reviewed in detail by the 2 pediatric nephrologists on the Work Group and used to write the narrative summary in the pediatric section. Articles in adults were randomly assigned to individual Work Group members for data extraction. Five additional articles were added by Work Group experts and the Evidence Review Team. Finally, 24 studies answered questions pertinent to topics chosen for systematic listing in Summary Tables.

Search terms for all updates are shown in Appendix 2.

Table 1. Topics and Eligibility Criteria for Systematic Review: Hemodialysis Adequacy, Update 2006

Topic 1 (guideline 6)	What is the role of residual kidney function compared to dialysis dose for clinical outcomes, including hospitalization and mortality?
Population	Patients on HD
Predictor/Intervention	Direct comparisons of dialysis dose versus residual kidney function Direct comparisons of including or excluding residual kidney function in calculating dialysis dose
Outcomes	Clinical outcomes (death, hospitalization, CVD/CHF events, other events)
Screening Criteria	Minimum duration: 6 months Any study design (prospective or retrospective)
Topic 2 (guideline 4)	What should be the recommended minimum dose for adequate dialysis using urea kinetics? Should separate goals be set for specific subgroups of patients such as race, gender, age or residual kidney function?
Population	Patients on HD
Predictor/Intervention	Kt/V
Outcomes	Clinical outcomes (death, hospitalization, CVD/CHF events, other events)
Screening Criteria	Minimum duration: 6 months Any study design (prospective or retrospective)
Topic 3 (guideline 5)	Does the use of a particular type of dialyzer reuse (or lack of reuse) have either an adverse or beneficial effect on either intermediate outcomes or mortality? Are these benefits seen only in specific subgroups of patients, such as race, gender, age, or residual kidney function?
Population	Patients on HD
Predictor/Intervention	Dialyzer reuse or lack of reuse, and method of "cleaning" for reuse
Outcomes	Clinical outcomes (death, hospitalization, CVD/CHF events, other events) Adverse events (allergy, toxicity, etc.) Intermediate outcomes (clearance and filtration measures)
Screening Criteria	Clinical Outcomes Minimum follow-up 6 months; Direct comparisons only; Prospective or retrospective Adverse events No minimum follow-up; Any study design Intermediate outcomes No minimum follow-up; Direct comparisons only; Prospective or retrospective

Grading of Individual Studies

Study Size and Duration

The study (sample) size is used as a measure of the weight of the evidence. In general, large studies provide more precise estimates of prevalence and associations. In addition, large studies are more likely to be generalizable; however, large size alone, does not guarantee applicability. A study that enrolled a large number of selected patients may be less generalizable than several smaller studies that included a broad spectrum of patient populations. Similarly, longer duration studies may be of better quality and more applicable, depending on other factors.

Applicability

Applicability (also known as generalizability or external validity) addresses the issue of whether the study population is sufficiently broad so that the results can be generalized

Table 2. Topics and Eligibility Criteria for Systematic Review: Peritoneal Dialysis Adequacy, Update 2006

Topic 1 (guideline 2)	What is the association between achieved (or target) clearance values and clinical outcomes?
Population	Patients on PD
Predictor/Intervention	Clearance measured as achieved total Kt/V (including residual kidney function), CrCl, or prescription (dialysis dose)
Outcomes	Clinical outcomes = death, hospitalization, technique survival, nutrition (albumin, SGA, possibly others), growth (pediatrics), cognitive (pediatrics), allowed other pediatric outcomes
Screening Criteria	Study design: Longitudinal cohorts and RCTs Minimum Duration: Death, Hospitalization/Technique survival 1 year; Others 1 month
Topic 2 (guideline 2)	What is the association between achieved (or target) level of fluid/Na removal parameters and clinical outcomes?
Population	Patients on PD
Predictor/Intervention	Net fluid/volume removal (+/-residual kidney function) Net sodium removal (including dietary Na restriction) Ultrafiltration volume; Volume status; Blood pressure
Outcomes	Clinical outcomes: death, hospitalization, technique survival, nutrition (albumin, SGA, possibly others), growth (pediatrics), cognitive (pediatrics), allowed other pediatric outcomes, BP/HTN, LVH
Screening Criteria	Study design: Longitudinal cohort studies (RCTs if available) No minimum study duration (except >= 1 year for mortality) Search 1989-2004
Topic 3 (guideline 3)	What treatments are effective to preserve residual kidney function and maximize urine output? Among studies that answer this question, is there evidence that the treatments affect clinical outcomes?
Population	Patients on PD
Predictor/Intervention	Pharmacological interventions
Outcomes	Kidney: Residual kidney function for solute clearance (GFR from U-Cr and CrCl), salt and water excretion (UOP) Clinical: death, hospitalization, technique survival, growth (pediatrics), cognitive (pediatrics), allowed other pediatric outcomes
Screening Criteria	Study design: Direct comparisons only (either RCT, uncontrolled parallel comparison, observational single cohort cross-over (from solution A to solution B: no minimum wash-out period)) Minimum study duration: shorter for residual kidney function and longer for clinical outcomes (determine exact thresholds upon reviewing available studies) Search: 2000-2004

to the population of interest at large. The study population is typically defined primarily by the inclusion and exclusion criteria. The target population was defined to include patients with kidney failure, specifically those on dialysis. A designation for applicability was assigned to each article, according to a three-level scale. In making this assessment, sociodemographic characteristics were considered, as well as comorbid conditions and prior treatments. Applicability is graded in reference to the population of interest as defined in the clinical question. For example for the question of treatment of catheter-related infections the reference population is that of HD patients with infected cuffed tunneled HD catheters.



Sample is representative of the target population, or results are definitely applicable to the target population irrespective of study sample.

Table 3. Topics and Eligibility Criteria for Systematic Review: Vascular Access, Update 2006

Topic 1 (guideline 1)	Effectiveness of preoperative venous imaging/mapping for planning AVF construction
Population	Patients on HD or for future HD, undergoing imaging study in preparation for AVF construction
Predictor/Intervention	Duplex US
Outcomes	Maturation and function of new AVF, as defined in study (If several outcomes were reported, the following were extracted: successful use for first dialysis and delivery of adequate dialysis dose for at least 1 month) Change in approach to access placement
Screening Criteria	Longitudinal studies, prospective or retrospective, including before/after comparisons, any duration Exclude studies of feasibility or diagnostic accuracy (sensitivity/specificity) Exclude studies with venograms as predictor
Topic 2.1 (guideline 7)	Treatment of catheter-related infection and the use of antibiotic locks
Population	HD patient with cuffed, tunneled HD catheter and catheter-related infection, as defined by the Centers for Disease Control and Prevention, including bacteremia
Predictor/Intervention	Catheter removal versus no catheter removal with or without use of antibiotic locks Different methods of removal; Different durations of line holiday prior to reinstitution
Outcomes	Infection clearing rates; Reinfection rates
Screening Criteria	Prospective controlled trials of any duration
Topic 2.2 (guideline 7)	Prophylaxis of catheter-related infection and the use of antibiotic locks
Population	HD patient with cuffed, tunneled HD catheter without current catheter-related infection
Predictor/Intervention	Prophylaxis with "antibiotic lock" (mixture of antibiotic and coagulant placed intra-catheter)
Outcomes	Infection free time; Catheter survival; Infection rate/1000 patient days
Screening Criteria	Prospective controlled trials Minimum 1000 days at risk (total)
Topic 3.1 (guideline 7)	Treatment of malfunctioning cuffed tunneled HD catheter with thrombolytics
Population	HD patient with cuffed, tunneled HD catheter, which is malfunctioning.
Predictor/Intervention	Treatment with: TPA; Reteplase (Retavase); Urokinase; Other investigational agents in phase 3 studies; Any methods of fibrin sheath stripping (including continuous infusion, catheter exchange, angioplasty)
Outcomes	Re-establishment of patency/function, ability to restart HD treatment, access survival
Screening Criteria	Prospective controlled trials of any duration Only cuffed/tunneled catheters, not uncuffed For fibrin sheath stripping studies, only those with radiographic evidence of fibrin sheath Exclude studies using streptokinase
Topic 3.2 (guideline 7)	Prophylaxis of cuffed tunneled HD catheter malfunctioning with thrombolytics
Population	HD patient with functional cuffed, tunneled HD catheter
Predictor/Intervention	Prophylaxis with: TPA; Reteplase (Retavase); Urokinase; Other investigational agents in phase 3 studies; Any methods of fibrin sheath stripping (including continuous infusion, catheter exchange, angioplasty)
Outcomes	Maintenance of patency/function, blood flow achieved, access survival
Screening Criteria	Prospective controlled trials Minimum 1000 days at risk Only cuffed/tunneled catheters, not uncuffed Exclude studies using streptokinase
Topic 4 (guideline 4)	Performance of different techniques for access surveillance and efficacy of periodic access monitoring for prolonging access life and maintaining access function
4.1	How do different tests compare to each other?
Population	HD patient with functional AVFs or AVGs
Predictor/Intervention	Diagnostic test studies comparing performance of one technique of measuring access function with another reference test
Outcomes	Sensitivity, specificity ROC curves
Screening Criteria	Cross-sectional diagnostic test studies
4.2	How do different methods of access surveillance compare for predicting access clotting?
4.3	How should one act on abnormal test results to prevent access clotting?
Population	HD patient with functional AVFs or AVGs
Predictor/Intervention	Periodic access surveillance by physical exam or other methods which measure access flow Static pressures; Dynamic pressures; Pericatheterization; New/other parameters
Outcomes	Maintenance of function; Maintenance of patency, or access survival Exclude studies only reporting blood flow

Table 4. Literature Search and Review by Topic

Guideline Topic	Citations Screened	Articles Retrieved	Articles Added by Experts	Articles Data-Extracted*	Articles Included in Summary Tables*
Hemodialysis	2,512	223	14	87	23
1			0	31	0
2			0	5	2
3			0	19	11
4			0	27	10
5			0	7	1
Peritoneal Dialysis	2,300	293	7	101	27
1			0	28	17
2			0	21	4
3			0	12	4
4			0	26	1
5.1			0	17	5
5.2			0	8	0
Vascular Access	2,892	112	5	58	24
1			0	10	0
2.1			0	2	0
2.2			0	4	3
3.1			0	6	2
3.2			0	3	3
4.1			0	10	9
4.2			2	17	4
4.3			3	7	4

*Columns do not add up because some studies were data-extracted for more than 1 topic and used in more than 1 Summary Table.



Sample is representative of a relevant sub-group of the target population. For example, sample is only representative of people with virgin arteriovenous fistulas, or only a specific relevant subgroup, such as elderly individuals or incident dialysis patients.



Sample is representative of a narrow subgroup of patients only, and not well generalizable to other subgroups. For example, the study includes only a small number of patients or patients with a rare disease or virgin fistulas with no access dysfunction. Studies of such narrow subgroups may be extremely valuable for demonstrating exceptions to the rule.

Results

The type of results available in each study is determined by the study design, the purpose of the study, and the question(s) being asked. The Work Group decided on the eligibility criteria and outcomes of interest (see Tables 1-3).

Diagnostic Test Studies

For studies of diagnostic tests, sensitivity and specificity data or area under the curve were included when reported. When necessary, sensitivity and specificity data were calculated from the reported data. Diagnostic tests were evaluated according to a hierarchy

of diagnostic tests.* Each test was assessed according to diagnostic technical capacity, accuracy, diagnostic and therapeutic impact, and patient outcome. This ultimately affected the overall strength of a recommendation regarding a diagnostic test.

Methodological Quality

Methodological quality (or internal validity) refers to the design, conduct, and reporting of the clinical study. Because studies with a variety of types of design were evaluated, a 3-level classification of study quality was devised:

- Least bias; results are valid. A study that mostly adheres to the commonly held concepts of high quality, including the following: a formal study; clear description of the population and setting; clear description of an appropriate reference standard; proper measurement techniques; appropriate statistical and analytical methods; no reporting errors; and no obvious bias. Not retrospective studies or case series.
- ◐ Susceptible to some bias, but not sufficient to invalidate the results. A study that does not meet all the criteria in the category above. It has some deficiencies but none likely to cause major bias.
- Significant bias that may invalidate the results. A study with serious errors in design or reporting. These studies may have large amounts of missing information or discrepancies in reporting.

Summarizing Reviews and Selected Original Articles

Work Group members had wide latitude in summarizing reviews and selected original articles for topics that were determined not to require a systemic review of the literature.

Guideline Format

The format for each guideline chapter is outlined in Table 5. Each guideline contains 1 or more specific “guideline statements” that represent recommendations to the target audience. Each guideline contains background information, which is generally sufficient to interpret the guideline. The rationale for each guideline describes the evidence upon which each guideline recommendation is based. The guideline concludes with a discussion of limitations of the evidence review and a brief discussion of clinical applications, and implementation issues regarding the topic. Research recommendations for each guideline update are summarized in a separate section at the end of each guideline update.

Rating the Strength of Recommendations

After literature review, the experts decided which recommendations were supported by evidence and which were supported by consensus of Work Group opinion. Evidence-based guideline recommendations were graded as strong (A) or moderate (B). Recommendations based on weak evidence (C) and/or consensus of expert opinion were labeled as Clinical Practice Recommendations (CPRs). An “A” rating indicates “it is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is

*Fineberg HV, Bauman R, Sosman M: Computerized cranial tomography. Effect on diagnostic and therapeutic plans. JAMA 238:224-227, 1977

Table 5. Format for Guidelines

Introductory Statement
Guideline or CPR Statement 1
Guideline or CPR Statement 2
BACKGROUND
RATIONALE
Definitions (if appropriate)
<i>Rationale statement 1</i>
Supporting text and tables
<i>Rationale statement 2</i>
Supporting text and tables
LIMITATIONS
IMPLEMENTATION ISSUES

Research Recommendations are presented in a separate chapter.

strong evidence that the practice improves health outcomes, and benefits substantially outweigh harm.” The “B” rating indicates “it is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.” A “CPR” rating indicates “it is recommended that clinicians consider following the guideline for eligible patients. This recommendation is predominantly based on consensus of opinions of the Work Group and reviewers that the practice might improve health outcomes.” (See Table 6).

The strength of each guideline recommendation is based on the quality of the supporting evidence as well as additional considerations. Additional considerations, such as cost, feasibility, and incremental benefit were implicitly considered. The quality of evidence was not explicitly graded. It was implicitly assessed according to the criteria outlined in Table 7, and considered: i) the methodological quality of the studies; ii) whether

Table 6. Rating the Strength of Guideline Recommendations

Grade	Recommendation
A	It is strongly recommended that clinicians routinely follow the guideline for eligible patients. There is strong evidence that the practice improves health outcomes.
B	It is recommended that clinicians routinely follow the guideline for eligible patients. There is moderately strong evidence that the practice improves health outcomes.
CPR	It is recommended that clinicians consider following the guideline for eligible patients. This recommendation is based on either weak evidence or on the opinions of the Work Group and reviewers that the practice might improve health outcomes.

Health outcomes are health-related events, conditions, or symptoms that can be perceived by individuals to have an important effect on their lives. Improving health outcomes implies that benefits outweigh any adverse effects.

Table 7. Rating the Quality of Evidence

Outcome	Population	Methodological Quality		
		Well designed and analyzed (little, if any, potential bias)	Some problems in design and/or analysis (some potential bias)	Poorly designed and/or analyzed (large potential bias)
Health outcome(s)	Target population	Strong ^a	Moderately strong ^b	Weak ^c
Health outcome(s)	Other than the target population	Moderately strong ^b	Moderately strong ^d	Weak ^c
Surrogate measure for health outcome(s)	Target population	Moderately strong ^b	Weak ^e	Weak ^c
Surrogate measure for health outcome(s)	Other than the target population	Weak ^c	Weak ^e	Weak ^d

Strong: Evidence includes results from well-designed, well-conducted study/studies in the target population that directly assess effects on health outcomes.
Moderately strong: Evidence is sufficient to determine effects on health outcomes in the target population, but the strength of the evidence is limited by the number, quality, or consistency of the individual studies. OR: evidence is from a population other than the target population, but from well-designed, well-conducted studies; OR: evidence is from studies with some problems in design and/or analysis; OR: evidence is from well-designed, well-conducted studies on surrogate endpoints for efficacy and/or safety in the target population.
Weak: Evidence is insufficient to assess the effects on net health outcomes because it is from studies with some problems in design and/or analysis on surrogate endpoints for efficacy and/or safety in the target population; OR: the evidence is only for surrogate measures in a population other than the target population. OR: the evidence is from studies that are poorly designed and/or analyzed.

or not the studies were carried out in the target population, ie, patients on dialysis, or in other populations; and iii) whether the studies examined health outcomes directly, or examined surrogate measures for those outcomes, eg, blood flow instead of access survival.

Limitations of Approach

While the literature searches were intended to be comprehensive, they were not exhaustive. MEDLINE was the only database searched, and searches were limited to English language publications. Hand searches of journals were not performed, and review articles and textbook chapters were not systematically searched. However, important studies known to the domain experts that were missed by the literature search were included in the review.

Because of resource limitations and other practical considerations, there were several deviations from the original protocol for several of the update topics. These primarily resulted in nephrologists in the Evidence Review Team, rather than Work Group members, performing the primary article screening and the data extraction for articles included in several Summary Tables. However, all articles that met criteria for all topics, all completed data extraction forms, and all Summary Tables were distributed to relevant Work Group members for critical review and incorporation into guidelines.

APPENDIX 2. MEDLINE SEARCH STRATEGIES

HEMODIALYSIS ADEQUACY, UPDATE 2006

Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process

Search from 1/1/97 through 6/22/04

#	Search History	Results
1	esp Renal Dialysis/	19447
2	HD.mp.	10309
3	hemodialysis.mp.	2737
4	or/1-3	22640
5	equilibrate\$.mp.	1478
6	pool.mp.	15057
7	ionic dialysance.mp.	28
8	urea reduct\$.mp.	176
9	flux.mp.	11892
10	urea kinetic\$.mp.	230
11	dialysis adequacy.mp.	299
12	recirculation.mp.	1314
13	clearance.mp.	27570
14	kt.af.	2305
15	"dialysis dose".af.	299
16	"dialyzer membrane".af.	77
17	"dialyzer reuse".af.	42
18	conductance.af.	13812
19	pump.af.	16174
20	"residual renal function".af.	427
21	cellulose.af.	7347
22	synthetic.af.	45739
23	or/5-22	138437
24	4 and 23	3474
25	limit 24 to (human and English language and yr=1997-2004) (Limit not valid in: Ovid MEDLINE[R] In-Process & Other Non-Indexed Citations; records were retained)	2747
26	limit 25 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nith or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index) (Limit not valid in: Ovid MEDLINE[R] In-Process & Other Non-Indexed Citations; records were retained)	235
27	25 not 26	2512
28	limit 27 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multicase or review of reported cases or review, tutorial)	319
29	27 not 28	2193

Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process
 Search from 1/1/97 through 10/27/04 (search from 6/22/04 with “Artificial Kidney”
 added)

#	Search History	Results
1	exp Renal Dialysis/	20552
2	HD.mp.	10819
3	hemodialysis.mp.	2835
4	"Kidney, Artificial/	215
5	or/1-4	23751
6	equilibrate\$.mp.	1536
7	perit.mp.	15700
8	ionic dialysance.mp.	29
9	urea reduct\$.mp.	184
10	flux.mp.	12000
11	urea kinetic\$.mp.	235
12	dialysis adequacy.mp.	314
13	recirculation.mp.	1363
14	clearance.mp.	28747
15	kt.af.	2011
16	"dialysis dose".af.	321
17	"dialyzer membrane".af.	81
18	"dialyzer reuse".af.	44
19	conductance.af.	14164
20	pump.af.	16882
21	"residual renal function".af.	442
22	cellulose.af.	7628
23	synthetic.af.	47875
24	or/6-23	443780
25	5 and 24	3642
26	(200407\$ or 200408\$ or 200409\$ or 200410\$ or 20040621\$ or 20040626\$ or 20040625\$ or 20040628\$ or 20040627\$ or 20040628\$ or 20040629\$ or 2004063\$).ed.	209970
27	25 not 26	3487
28	limit 27 to (human and English language and yr=1997-2004) [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	2795
29	limit 28 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	237
30	28 not 29	2518
31	limit 30 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multi case or review of reported cases or review, tutorial)	324
32	30 not 31	2194

PERITONEAL DIALYSIS ADEQUACY, UPDATE 2006

Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process. Search from 1/1/97 through 5/28/04

#	Search History	Results
1	exp PD* and PD.mp	13610
2	exp ultrafiltration* and ultrafiltration.mp.	6801
3	or#1-2	20002
4	clearance.mp.	75604
5	exp urae* or urea.mp.	88704
6	fluid removal.mp	373
7	sodium removal.mp.	129
8	exp dialysis solutions* or dialysis solution.mp.	3200
9	iodocontrast.mp.	195
10	peritoneal membrane.mp. (mp,pt, dt, ab, rw, sh)	664
11	or#4-10	164459
12	limit 11 to yr=1989-2004	93187
13	residual renal function.mp.	618
14	peritoneal equilibration test.mp.	283
15	or#13-14	868
16	limit 15 to yr=2000-2004	334
17	3 and 12	2938
18	3 and 16	222
19	17 or 18	2999
20	limit 19 to (human and English language) [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	2498
21	limit 20 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index) [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	223
22	20 not 21	2275
23	limit 21 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multicase or review of reported cases or review, tutorial)	25

VASCULAR ACCESS, UPDATE 2006

Search #1. Ovid MEDLINE, Ovid MEDLINE Daily Update, Ovid MEDLINE In-Process. Search from 1/1/97 through 5/5/04

#	Search History	Results
1	exp Renal Dialysis*	19138
2	HD.mp.	10126
3	exp Kidney Diseases* or exp Kidney Failure, Chronic*	88052
4	exp Catheters, Indwelling*	3871
5	exp Catheterization, Central Venous*	3330
6	exp Vascular Fistula*	2369
7	exp Arteriovenous Fistula*	1637
8	vascular access.mp	1388
9	fistula.mp.	10910
10	catheter's bw.	34890
11	or#1-3	77948
12	or#4-10	48219
13	11 and 12	3513
14	limit 13 to human [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	3175
15	limit 14 to English language	2914
16	limit 15 to yr=1997-2004	2620
17	limit 16 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index) [Limit not valid in: Ovid MEDLINE(R) In-Process & Other Non-Indexed Citations; records were retained]	694
18	16 not 17	1926
19	limit 18 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multicase or review of reported cases or review, tutorial)	338
20	18 not 19	1588

VASCULAR ACCESS, UPDATE 2006 PEDIATRIC SEARCH^a

Ovid MEDLINE <1996 to July Week 3 2004>

Search from 1/1/97 through 7/28/04

N	Search History	Results
1	exp Renal Dialysis/	19635
2	HD.mp.	9798
3	exp Kidney Diseases/ or exp Kidney Failure, Chronic/	70092
4	exp Catheters, Indwelling/	3963
5	exp Catheterization, Central Venous/	3437
6	exp Vascular Fistula/	2443
7	exp Arteriovenous Fistula/	1678
8	vascular access.mp.	1352
9	fistula.mp.	10892
10	catheter\$.hw.	34022
11	or#1-3	79524
12	or#4-10	47279
13	11 and 12	3549
14	limit 13 to human	3408
15	limit 14 to English language	2938
16	limit 15 to yr=1997-2004	2646
17	limit 16 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	717
18	16 ncl 17	1929
19	limit 18 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multicase or review of reported cases or review, Lularia)	351
20	18 ncl 19	1578
21	limit 20 to ("infant (1 to 23 months)" or "preschool child (2 to 5 years)" or "child (5 to 12 years)" or "adolescent (13 to 18 years)")	292
22	20 not 21	1285
23	limit 22 to ("all adult (19 plus years)" or "newborn infant (birth to 1 month)")	918
24	20 not 23	660
25	20 not (21 or 23)	368

a. This search is a subset of search #1

VASCULAR ACCESS, UPDATE 2006 SEARCH #2

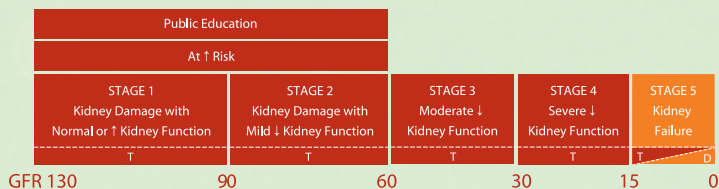
Ovid MEDLINE <1966 to August Week 2 2004>

Search from 1/1/97 through 8/19/2004 (original search date 5/5/04 with terms “shunt” and “graft” added)

#	Search History	Results
1	exp Renal Dialysis/	61137
2	HD.mp.	26861
3	exp Kidney Diseases/ or exp Kidney Failure, Chronic/	265127
4	exp Catheters, indwelling/	10418
5	exp Catheterization, Central Venous/	6308
6	exp Vascular Fistula/	9039
7	exp Arteriovenous Fistula/	8071
8	vascular access.mp.	2650
9	fistula.mp.	34765
10	catheter\$.tw.	94388
11	or1-3	203156
12	or4-10	137098
13	11 and 12	8846
14	limit 13 to human	8464
15	limit 14 to English language	6689
16	limit 15 to yr=1997-2004	2741
17	limit 16 to (addresses or bibliography or biography or case reports or congresses or consensus development conference or consensus development conference, nih or dictionary or directory or editorial or festschrift or government publications or interview or lectures or legal cases or legislation or letter or news or newspaper article or patient education handout or periodical index)	736
18	15 not 17	2005
19	limit 18 to (guideline or meta analysis or practice guideline or review or review, academic or review literature or review, multicase or review of reported cases or review, tutorial)	372
20	18 not 19	1633
21	follow-up studies/	207082
22	(follow-up or followup).tw.	307677
23	exp Case-Control Studies/	261329
24	(case adj20 control).tw.	36852
25	exp Longitudinal Studies/	488492
26	longitudinal.tw.	56837
27	exp Cohort Studies/	501708
28	cohort.tw.	51894
29	(random\$ or rct).tw.	291685
30	exp Randomized Controlled Trials/	33666
31	exp random allocation/	51582
32	exp Double-Blind Method/	79233
33	exp Single-Blind Method/	8332
34	randomized controlled trial.pt.	192490
35	clinical trial.pt.	389032
36	(blind\$ adj trial\$).tw.	80094
37	((single\$ or double\$ or triple\$ or trip\$) adj (blind\$ or mask\$)).tw.	75835
38	exp placebos/	23205
39	placebo\$.tw.	85529
40	exp Research Design/	183137
41	exp Evaluation Studies/	495146
42	exp Prospective Studies/	175689
43	exp Comparative Study/	1142862
44	or21-43	2574058
45	20 and 44	1016
46	20 not 45	587
47	exp arteriovenous shunt, surgical/	5614
48	(Arteriovenous adj\$ graft\$).tw.	646

Kidney Learning System (KLS)[™]

A Curriculum for CKD Risk Reduction and Care



Light-shaded boxes indicate the scope of content targeted in this resource.

GFR = Glomerular Filtration Rate; T = Kidney Transplant; D = Dialysis

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Support for these KDOQI Clinical Practice Guidelines and Recommendations was provided by an educational grant from:

Amgen, Inc., Baxter Healthcare Corporation, Fresenius USA, Inc., Genentech, Inc. and Watson Pharmaceuticals, Inc.

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ISBN 1-931472-22-X

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