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Standardized Definitions for Hemodialysis Vascular Access

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Abstract

Vascular access dysfunction is one of the leading causes of morbidity and mortality among end-stage renal disease patients [1,2]. Vascular access dysfunction exists in all 3 types of available accesses: arteriovenous fistulas, arteriovenous grafts, and tunneled catheters. In order to improve clinical research and outcomes in hemodialysis access dysfunction, the development of a multidisciplinary network of collaborative investigators with various areas of expertise, and common standards for terminology and classification in all vascular access types is required. The North American Vascular Access Consortium (NAVAC) is a newly formed multidisciplinary and multicenter network of experts in the area of hemodialysis vascular access, who include nephrologists and interventional nephrologists from the United States and Canada with: (1) a primary clinical and research focus in hemodialysis vascular access dysfunction, (2) national and internationally recognized experts in vascular access, and (3) a history of productivity measured by peer-reviewed publications and funding among members of this consortium. The consortium's mission is to improve the quality and efficiency in vascular access research, and impact the research in the area of hemodialysis vascular access by conducting observational studies and randomized controlled trials. The purpose of the consortium's initial manuscript is to provide working and standard vascular access definitions relating to (1) epidemiology, (2) vascular access function, (3) vascular access patency, and (4) complications in vascular accesses relating to each of the vascular access types.

Complications in maturation and patency in surgically created arteriovenous vascular accesses, arteriovenous fistulas (AVF) and grafts (AVG), and infections and thrombosis in

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tunneled and temporary catheters (CVC) remain significant barriers in improving vascular access care in hemodialysis patients. In recent years, randomized controlled trials and observational studies have been used to answer intervention and outcome questions in vascular access research. The challenges required to improve the quality of research in vascular access studies are substantial including the need to standardize definitions. Standard definitions should be used uniformly by surgeons, interventionists, and nephrologists, and will be essential for improving the quality and the design of successful future observational and interventional studies. Previous reporting standards regarding access function, patency, and complications have been published from only radiology and surgical societies [3–5]. The purpose of this review is to provide comprehensive working and standard vascular access definitions for clinical care and research in hemodialysis vascular access.

EPIDEMIOLOGY

Epidemiologic studies of hemodialysis vascular access commonly compare incidence and prevalence access assessments and rates of vascular access-related hospitalization. We suggest the following definitions when referring to these parameters:

1. Incidence

the proportion of patients who initiated an event or entered a study at a specified time point (e.g. the proportion of patients who initiated chronic hemodialysis therapy using an AVF, AVG or CVC in a given year). For example, we calculate the proportion of incident AVF use in dialysis unit X in 2011 as the number of patients using an AVF at the start of dialysis divided by all patients who started chronic HD from January 1, 2011 to December 31, 2011.

2. Prevalence

most commonly indicates “point prevalence” when referring to existing cases, particularly in vascular access studies. However, “period prevalence” has also been reported in the literature, thus both terms are defined.

a. ***Point prevalence***: percentage of patients using a specific vascular access at a certain point in time. For example, the point prevalent use of AVF on January 1, 2011 would be the number of patients using an AVF on January 1, 2011 divided by all patients using a vascular access on January 1, 2011 (multiplied by 100 for percentage).

b. ***Period prevalence***: percentage of patients using a specific vascular access over a certain period of time. For example, the period prevalent use of AVF in January, 2011 would be the number of patients using an AVF between January 1 and January 31, 2011, inclusive, divided by all patients using a vascular access during that same time period (multiplied by 100 for percentage).

Discussion: A key point is that when referring to “incident” and “prevalent”, it must clearly be stated what event(s) incident and prevalent are describing to limit erroneous assumptions. For example, when referring to incident AVF use, a patient must be dialyzing with an AVF at hemodialysis start. A non-functioning fistula in place at the initiation of

dialysis should not be considered in the incident AVF calculation; in this instance, the incident access would be a catheter.

3. Hospitalization days/1000 access days

- **a.** Numerator is the total number of days of hospitalization for the study population
- **b.** Denominator is calculated by adding the days from access creation or start date of study period to permanent access failure (unsalvageable), end of study period, or access censored for patient death, transfer of dialysis unit or modality change (peritoneal dialysis or transplantation). The calculated rate of total number of hospitalizations/total number of access days is divided by 1000.

Discussion: A key point is that most publications do not differentiate between hospitalization for vascular access or non–vascular access related admissions. The indications for hospitalizations and their categorization is most accurately defined and determined a priori in prospective studies. Furthermore, most "access days" do not accurately count days an access is in use or in place. Often, the vascular access in place at a given time point (e.g. end of the month), is taken to be the access used for the entire time period. Thus, if a patient was using an AVF for the first 25 days of a month then required a catheter, only the catheter would be counted and may have 30 or 31 days erroneously attributed to its use for that month. The impact would be to increase the access days attributed to catheters and may minimize the severity of an outcome, such as catheter-related infectious hospitalization (e.g. the denominator would increase, reducing the rate/1000 catheter days). This highlights the importance of prospective tracking of vascular access creations/insertions and removals or censoring in a prospective electronic manner.

4. Complication Free Days (CFD)

This term has not been previously applied to the hemodialysis vascular access literature but is common in other literature, such as in the field of cardiology.

Complications include "serious vascular access events" and are comprised of any one of the following: access thrombosis, radiological or surgical intervention to facilitate or maintain patency, VA-related infections (see below for these definitions). Each event counts for 1 complication day. For example, if a graft had 2 angioplasties and 1 thrombolysis from the time of creation to 6 months (183 days), that graft would have 180 complication free days.

Often, these complications or serious vascular access events may be associated with extended problems, such as hospitalizations or need to use catheters with their accompanying risks. This can be described as CFD-extended. For example, in the above graft example, suppose the graft got infected after the last thrombolysis and required surgical resection of a graft component and 3 days of hospitalization. The "CFD-extended" would be 176 days (2 angioplasties + 1 thrombolyisis + 1 surgical revision + 3 hospital days).

In another 6 month example: in a patient who had a fistula created but failed to mature, requiring ligation of collateral vessels to faciliatate maturation and also requiring a central venous catheter for 6 weeks and developed CVC-related bacteremia, the fistula would have

181 CFD (1 day for ligation + 1 day for infection) and 139 CFD-extended (6 weeks or 42 weeks with a catheter, 1 ligation and 1 infection).

The ideal vascular access is one that provides adequate dialysis without complications; such an access would have extended patency with low maintenance and costs. While this "ideal" access might be achieved in a few, providing the most *appropriate* access for an individual can be a realistic expectation for all patients. The most appropriate access will be different for each patient and should consider important aspects of the patients clinical and life circumstances. One indicator for appropriate access is determining how many complications a patient may encounter with their access. Thus, an important measure is how many "complication free days" (CDF) a patient may have in a given timeframe using their access.

CFD and CFD-extended will allow a somewhat standardized comparison between vascular access types (given evaluation within similar time periods).

5. Access Abandonment

Determining the last day an access is used or is no longer available (similar to patient death but can be considered "access death") is important for determining outcomes and denominators for event rates. Access abandonment is synonymous with final fistula or graft loss and access unsalvageable loss. It is defined as a fistula or graft that can no longer be used for 1 or 2 needle, prescribed dialysis as it may be unable to provide adequate flows and/or is deemed unsafe for the patient, and the associated problem cannot be corrected by any intervention, including medical, surgical, or radiological interventions or rest. See appendix to confirm access abandonment.

Arteriovenous Accesses

1. Description of Arteriovenous Accesses

A. Arteriovenous Fistula—an autologous arteriovenous access created by a connection of a vein to an artery (e.g. cephalic vein joined to radial artery) where the vein serves as the accessible conduit. Common locations include the forearm (radiocephalic) and upper arm (brachiocephalic and brachiobasilic). Other less common combinations may exist, such as the ulnar-basilic fistula. When less commonly created vascular access are studied, a clear description of their surgical anastomosis is suggested.

1. Primary Fistulas [6]:

a. ***radiocephalic fistula***: the preferred first option for creation of AVF. There are 3 types of radiocephalic fistulas: (1) radiocephalic AVFs constructed near the "anatomical snuffbox", (2) radiocephalic AVFs at the wrist, transposed or direct, and at the wrist (the most common type of AVF created), and (3) proximal radio-cephalic AVF which is transposed and looped.

b. ***brachiocephalic fistula***: comes in two configurations, direct or transposed. The direct, non-transposed brachiocephalic AVF is the preferred AVF to be placed if a radiocephalic AVF cannot be placed or has failed.

c. ***basilic vein transposition (brachial-basilic) fistula***: the third preferred option for AVF creation. The basilic vein is routinely transposed because of its depth and consequently, only a short segment is available for cannulation. This type of AVF can be constructed in one or two steps.

2. Secondary Fistulas [6]: An AVF constructed after a failed AVF or AVG, and utilizes the conversion of an arterialized outflow vein to a direct or transposed AVF.

B. Arteriovenous Graft—An artificial prosthetic segment used to connect an artery and vein for hemodialysis use. AVGs can be placed in the upper and lower arm, and thigh regions. They can be made of a variety of synthetic materials and have a variety of configurations.

2. Arteriovenous Fistula and Graft Patency Definitions

A major problem with AVFs is the high frequency of primary failures, either due to lack of maturation or early thrombosis. In AVGs patency is threatened by progressive stenoses and frequent thrombosis. Time-dependent clinical outcomes, such as access patency, can be measured with a variety of outcomes (e.g. time to occlusive thrombosis or time to complete access abandonment), and are important vascular access measures that can be determined with Kaplan-Meier survival curves or life-table analysis. Anatomical patency is determined by imaging techniques. Our group recommends the following terminology when referring to vascular access and anatomical patency.

A. Time-dependent patency definitions

a. Primary Unassisted Patency: the time of access creation or placement until any first intervention (endovascular or surgical) to maintain or restore blood flow, first occurrence to access thrombosis, or reaching a censored event (death, transfer to another hemodialysis unit, transfer to peritoneal dialysis, transplantation, and end of study period) [4]. It can be additionally calculated at 30 and 90 days, and at 6, 12, 18, and 24 months. Recent studies from clinical trials [7,8] and large observational studies have also adhered to this definition [9]. These clinical studies have considered access procedures to include endovascular interventions such as angioplasty, thrombolysis, thrombectomy, or surgical revisions.

b. Cumulative Survival (or secondary patency): the time of access creation or placement until access abandonment or achievement of a censored event (death, transfer to another hemodialysis unit, transfer to peritoneal dialysis, transplantation, and end of study period), and includes all surgical and endovascular interventions [5]. The definition of access abandonment should be standardized. We suggest a checklist to be verified by the investigator in order that this “hard outcome” of access abandonment cannot be altered (see appendix).

c. Post-intervention Primary Patency: the time from the index procedure until the next access thrombosis or reintervention. Post-intervention primary patency ends with a re-intervention anywhere within the access circuit, from the arterial inflow to the superior vena cava-right atrial junction. It can follow a standard time to event Kaplan-Meier analysis with

a censoring event (death, transfer to other unit or peritoneal dialysis, transplant, end of study period) and can be additionally calculated at 30 and 90 days, and at 6, 12, 18, and 24 months [4], to allow for cross-study comparison.

Discussion: The definitions and reporting of patency in AV access studies have differed significantly. Many studies have excluded primary failures in the analyses of patency while other studies report patency only at specific time points (i.e. 6 months or 1 year). Standards for reporting patency have to date only been published from vascular surgeons and interventional radiologists, and not from nephrologists [5,10]. Valid comparisons describing patency can only be made if the definitions are universally used by all specialties in a consistent manner.

B. Anatomical patency definitions

1. Hemodynamically Significant Stenosis: K/DOQI defines hemodynamically significant stenosis as >50% reduction of normal vessel diameter (graft or draining venous system) accompanied by one or more hemodynamic, functional or clinical abnormalities, not explained by other reasons, which include [11]:

Surveillance measures [12]

- Decreased blood flow (blood pump or intra-access flow)
- Elevated static or derived venous pressure
- Elevated negative arterial pre-pump pressures that prevent acceptable blood flow
- Elevated access recirculation
- Unexplained decreases in measured amounts of hemodialysis delivered
- Abnormal duplex ultrasound (flow and/or stenosis)

Monitoring measures

- Persistent extremity swelling
- Prolonged bleeding after needle withdrawal
- Altered pulse or thrill in the fistula or graft
- Altered bruit in the fistula or graft

A reduction in diameter measurement on its own is insufficient to define a clinically significant lesion and should not be intervened upon based on a single criteria. The clinical abnormalities suggested by K/DOQI are non-specific. We recommend that consistent terminology (i.e. ≥2 consecutive dialysis sessions where ≥1 surveillance measure(s) and ≥ 1 clinical monitoring measure(s)) are observed and documented, in addition to a reduction in diameter to be deemed hemodynamically significant. This definition, as well as any other previously published definition needs validation.

2. Complete Occlusive Access Thrombosis: an absence of bruit or thrill, using auscultation and palpation, throughout systole and diastole at least 8 cm proximal to the arteriovenous

anastomosis [13]. An occlusive access thrombosis indicates loss of anatomic, hemodynamic, and clinical patency. This differs from an incomplete or non-occlusive thrombosis that may be suspected, particularly when clots are observed such as at the time of cannulation. In these cases, a weak bruit or thrill may still be present.

3. Terminal Access Thrombosis: similar to the definition for complete occlusive thrombosis with the addition that patency cannot be restored such that the access can no longer be used for dialysis following surgical or radiologic intervention, such as thrombolysis. Terminal thrombosis fits the criteria required for access abandonment (above).

4. Time to Thrombosis: a term is applied to an AVF or AVG that` refers to the time from date of access creation, to date of thrombosis. Time to thrombosis is analyzed by the Kaplan Meier method with censoring for patient death, transfer to another unit or modality, or end of study.

Discussion: Previously, time to thrombosis was calculated from a variety of start times, such as from the time of access creation, after 1 month or after successful use of the access (and sometimes referred to as functional patency). Currently, there appears to be no clear consensus on this definition. We recommend standardization of definitions to indicate a start time as the time of access creation. During interventional trials, time to thrombosis may be an important outcome. In these cases, it is important to clearly define the index date from which the start time is derived. In most cases, it would be the date of randomization or start date of study intervention/medicine. We suggest that when only the first thrombotic episode is calculated, a proportion should be described, in addition to a survival analysis, depending on the description required. This allows for comparison across studies and is clinically relevant.

Furthermore, one access can contribute to several thrombotic episodes. If multiple thromboses are counted, we recommend reporting of a rate (e.g. X thrombosis/1000 access days). The denominator "access days" would be the number of days the access (AVF or AVG, as appropriate) was in place from creation to the end of desired time period of evaluation.

3. Vascular Access Maturation Definitions

The functionality of an AV access is a critical concept, both in defining clinical research and patient outcomes, and one that has been met with a variety of definitions for "failure" of permanent access in the literature. The below definitions will encompass the following terms previously used in the literature: primary failure, failure to mature, early failure, late failure, and mature fistula. These definitions specifically refer to new fistulas and those used for new cannulation. They do *not* apply to fistulas that have been used for >6 months and subsequently develop a problem that requires intervention. A comprehensive definition should include an indication of who evaluates the fistula, defined timeframes, and criteria for functionality.

Suggested definitions for "failures and successes" of permanent accesses pertain to their functional patency, such that they can be used for dialysis. This will be based on time frame

since access creation as the pathophysiology and etiology of failure varies, and often coincides with time.

Lastly, a distinction must be made between whether a fistula is suitable for dialysis and whether it is successfully used for dialysis. Whether a fistula is suitable for dialysis attempts to define aspects of the fistula that encompasses surgical technique, its development, facilitation, and maturation to the point that is deemed "suitable" for consistent 2 needle cannulation at prescribed dialysis blood flows. An equally critical aspect of fistula success, is whether it can be cannulated with 2 needles and successfully used to provide dialysis at prescribed flow rates.

While we cannot assume that all cannulators are experts, in order to determine the "cannuation readiness" of a fistula, first cannulations should be performed by experienced cannulators; otherwise, it will be impossible to determine whether the fistula was unsuccessfully cannulated because it was too frail or due to poor cannulation technique of the operator, causing the fistula to "blow". In addition to experienced cannulators, the appropriate needle size and blood pump rate for initial fistula uses must be determined by experienced personnel (nephrologists or nurse), to limit cannulation injury and the fistula "blowing".

We therefore assume in the following definitions that an expert cannulator is performing the first cannulations, with appropriately determined dialysis parameters, such that failures are due to the fistula itself rather than failure of the cannulating or dialysis technique. This is an acknowledged limitation of the definitions; we recommend documentation as to reasons for unsuccessful cannulation (e.g. fistula too deep, fistula too frail, inexperienced cannulator, etc).

A. Immediate Vascular Access Failure—an access that has either no appearance of or a loss of bruit or thrill within 72 hours of creation as determined by a health care provider skilled at assessing AVF or AVG (e.g. surgeon, nephrologist, hemodialysis nurse, vascular access coordinator). This is usually due to technical sources of failure (e.g. intra-operative thrombosis). In addition, an access that is lost due to iatrogenic reasons, for example, emergency ligation of a fistula or graft due to steal syndrome will also be included, even though an initial or apparent bruit or thrill may be present.

B. Early Dialysis Suitability Failure [14]—an access that, despite radiological or surgical intervention, cannot be used successfully for dialysis by 3 months following its creation. See below for definition of "used successfully for hemodialysis". Early failure is usually due to stenosis or presence of accessory or collateral veins. For this reason, accesses should not be deemed a failure unless surgical or radiological intervention has failed to correct these problems. A high success rate for use for dialysis has been reported following intervention [14].

C. Late Dialysis Suitability Failure—an access that, despite radiological or surgical intervention, cannot be used successfully for dialysis by 6 months following its creation [15]. While the study by Dember et. al. used a timeframe of 120–150 days following access

creation only 2% of patients had interventions [13], making it difficult to ascertain whether or not a permanent access would have been suitable for dialysis if they were intervened upon to facilitate its use. See below for definition of "used successfully for dialysis". Six months has previously been used and allows for time for further maturation following facilitative intervention.

D. Fistula Used Successfully for Hemodialysis (FUSH)—A fistula is deemed successfully used for dialysis if it can be used with two-needle cannulation for two thirds or more of all dialysis runs for 1 month *and* deliver the prescribed dialysis within the prescribed time frame. Typically, in North America, this would be defined, in patients who receive conventional intermittent hemodialysis 3 times a week with duration of 3.5 to 4.5 h, blood flow rates of 300 to 450 ml/min, and dialysate flows of 500 to 800 ml/min. The blood flow rates, duration, and frequency may vary to achieve a target sp-Kt/V of 1.2. A *minimum* criterion for successful use of a fistula for conventional hemodialysis would be 2-needle cannulation for 2/3 runs within a month at an average blood flow rate (total blood processed over duration of hemodialysis) of 300 ml/min in a 3.5-hour HD session [13,15]. For short daily and nocturnal dialysis, the criteria requiring 2 needle cannulation for 2/3 runs within a month is necessary to adequately deliver prescribed dialysis (e.g. a fistula can be deemed successful if it can adequately deliver prescribed nocturnal dialysis at a blood flow rate of 250 ml/min for 7 hours). The above criteria also apply to arteriovenous grafts.

Discussion: The lack of uniform definitions reporting AVF maturation, function, and suitability exists in the literature and makes it extremely difficult to compare outcomes of different studies. Furthermore, very few studies clearly defined readiness for cannulation. Huber et. al [16] had criteria for cannulation in their prospective study that includes: an estimated vein diameter of 6 mm or more and a suitable wall thickness, although no objective criteria were used for the latter. There are no specific studies that define and validate criteria determining when a fistula is suitable for cannulation.

E. Cannulation Failure—Often, an access is deemed suitable for dialysis by expert evaluation (experienced nephrologists, nurse, vascular access coordinator) yet even the expert cannulator is unsuccessful at achieving 2 needle cannulation for a variety of reasons, including an access that is too fragile, located too deep, otherwise inaccessible, or other reasons. Cannulation failure is defined as the inability to place and secure 2 adequately sized dialysis needles to provide prescribed dialsysis.

F. Cannulation Injury—

- **a.** *Minor cannulation injury* – an injury that may result in bleeding infiltration and swelling that may be treated with conservative measures such as ice and rest for 1–2 days but cannulation can be re-attempted for the next dialysis session. The access should be successfully re-cannulated with 2 needles in ≤ 7 days [17]. Note that even a minor cannulation injury may require the use of a temporary catheter.
- **b.** Major cannulation injury- an injury that results in significant bleeding infiltration and swelling that requires recovery for >7 days [17].

c. Severe cannulation injury - an injury that results in significant bleeding complications that requires one of: blood transfusion, emergency room visit, hospitalization, radiological or surgical intervention.

4. Surgical and Procedural Definitions

Frequent access-related complications and problems continue as barriers to successful dialysis treatment. In AVFs, interventions to promote maturation are frequently required. While in AVGs, interventions to treat stenoses and thromboses are common. It is therefore important to have tools to salvage and maintain permanent accesses in order to improve the success and longevity of AV accesses. We recommend the following in reference to vascular accesses procedures and interventions.

A. Hemodialysis Access Circuit—the vascular access from the created arterial anastomosis (AVF or AVG) up to the superior vena cava-right atrial junction.

B. Angiogram—a contrast venography evaluating the access circuit, often referred to as a fistulogram when specifically interrogating an AVF or AVG. An angiogram is indicated to determine the patency and/or adequacy of the superficial and deep venous systems, including central veins of the hemodialysis access circuit and to evaluate for possible significant stenosis, collateral or accessory vessels. A digitally subtracted angiogram (DSA) is the gold standard to evaluate the hemodialysis access circuit. Recently, it has been demonstrated that in patients with advanced chronic kidney disease, AVF can be evaluated and salvaged successfully using small contrast volumes with a low incidence of contrast-induced nephropathy[18,19].

Note: While “fistulogram” is often used in reference to venogram of an AVG, this should be avoided to limit confusion. Trainees are often unaware of a patient’s true access and the use of “fistulogram” in reference to a graft may cause confusion. This is also the case when vascular access research is multidisciplinary, involving nephrologists, surgeons, radiologists, and nurses. For this reason, we recommend standardized terminology and the use of the term “angiogram” when referring to venogram of either an AVF or AVG (e.g. “angiogram” of a fistula or “angiogram” of graft).

C. Radiological Endovascular Intervention—When discussing endovascular interventions to salvage AVFs and AVGs, there are three primary procedures:

1. **Balloon angioplasty**: the intraluminal balloon dilatation at any level of the hemodialysis vascular circuit.
2. **Stent deployment**: the placement of a self-expanding or balloon expandable stent at any level of the vascular access circuit. The stents can be either covered or non-covered metallic, nitinol, or other material stents.
3. **Pharmacologic thrombolysis**: the infusion of a thrombolytic agent to lyse the thrombus located at any level of the hemodialysis vascular circuit.
4. **Mechanical thrombectomy**: the use of a mechanical device to fragment or macerate a thrombus located at any level of the hemodialysis vascular circuit.

5. **Pharmacomechanical thrombolysis and thrombectomy**: the combination of pharmacologic and mechanical techniques to clear the hemodialysis access circuit of any thrombus.

C. Procedure Success-Stenosis—The following refers specifically to the success of intervening on a stenotic lesion and will be followed by "stenosis". Procedural success is defined as the treatment success of the target stenotic lesion and it can be anatomic, hemodynamic or clinical as defined below:

a. **Anatomic Success-stenosis:** determined *during* the index procedure and will be defined as the achievement of an immediate post-procedure residual stenosis of less than 30%, measured at the narrowest point of the lumen, as indicated by direct visualization or measurement at the end of the procedure.

b. **Hemodynamic Success-stenosis**: the resolution of a pre-procedural indicator of a hemodynamically significant stenosis. Procedural indicators per K/DOQI guidelines may include any one of the following[11]:

    1. Decreased blood flow→improved intra-access blood flow by >20%
    2. Elevated static or derived venous pressures→normalized venous pressures
    3. Elevated negative arterial pre-pump pressures that prevent increasing to acceptable blood flow→normalized pre-pump pressures and return to baseline blood flow
    4. Elevated access recirculation using urea concentrations→no access recirculation
    5. Elevated access recirculation using dilution techniques (non urea-based) →<5% access recirculation
    6. Unexplained decreases in the measured amount of hemodialysis delivered (Urea reduction ratio, Kt/V) →resumption of dialysis adequacy as measured by urea kinetics
    7. Abnormal duplex ultrasound→return to baseline duplex ultrasound (or intra-access doppler flows >4–500 ml/min (AVF), >600 ml/min (AVG) and/or <30% residual stenosis
    8. Physical findings of persistent swelling of the extremity→reduction or resolution of swelling
    9. Prolonged bleeding after needle withdrawal→normal bleeding time
    10. Altered characteristics of pulse or thrill in the access→stronger pulse and continuous thrill
    11. Altered characteristics of bruit in the access→return to low pitched systolic and diastolic bruit

c. **Clinical Success-stenosis:** previously defined as the resumption of normal dialysis for at least one session after the index procedure [5]. This is a definition used by radiologists and is unsatisfactory for nephrologists.

   To be clinically successful, the intervention must allow resumption of normal dialysis with two-needle cannulation and prescribed blood flows for 2/3 runs within the month following the intervention. If such a definition were not met, the patient would continue to be dependent on their catheter such that the intervention would be deemed a clinical failure.

d. **Functional Success – stenosis:** successful 2 needle cannulation following an intervention that provides the prescribed dialysis and allows for catheter removal.

Note: Similar definitions can be added for interventions for other indications, which would be added as a descriptor. For example, if a fistula was failing to mature due to the presence of collateral vessels, successful ligation could be indicated and defined as follows:

Functional Success – ligation: successful 2 needle cannulation following ligation that provides the prescribed dialysis and allows for catheter removal.

D. Surgical Intervention—

1. **Thrombectomy**: surgical removal of thrombus from the hemodialysis vascular circuit.
2. **Patch angioplasty**: surgical revision of a venous outflow stenosis with a prosthetic or autogenous patch
3. **Surgical revision**: surgical correction of an abnormal aspect of the access, such as the resection of a stenotic area with an end-to-end anastomosis of the vessel. This can be done at different levels [4]:
   a. Arterial anastomosis area.
   b. Intra-graft anastomosis area.
   c. Venous anastomotic area (for AVGs).
   d. Venous outlet.
   e. A combination of any the previous sites. Other corrective maneuvers include a jump graft that can be placed at any level to bypass a long segment of stenosis.

Hemodialysis Catheters

Central venous catheters are the most common vascular access used among incident hemodialysis patients [20]. However, catheters are associated with the greatest risk of adverse events, which include infection, catheter dysfunction from thrombosis, occlusion of a central vein, and inadequate blood flow leading to poor dialysis adequacy [21–23]. This section covers terminology that can be standardized to catheter type, infection, and patency.

1. Catheter Types

Catheters are often referred to either as permanent or temporary. While temporary catheters are intended for short-term use (≤ 2 weeks) and often non-tunneled[4]; many non-tunneled catheters are used longer than initially anticipated. We discourage the use of describing catheters as “temporary” or “permanent”. Indeed, the majority of catheters should be temporary and should be cuffed and tunneled to be used as a bridge access only to allow time for placement and maturation of an AVF or AVG [24]. We recommend the description of the catheter in terms of its site of placement, as “tunneled” or “non-tunneled” and “cuffed” or “non-cuffed”, to allow for a quick estimation of the catheter’s risk of infection, rather than duration of use, which is not reliable. For a clinical patient specific example: Patient X has a right internal jugular tunneled, cuffed catheter, inserted under fluoroscopy under sterile conditions on X date. For a research example: the rate of TPA use for tunneled, cuffed catheters was X/1000 catheter days, or the proportion of incident non-tunneled, non-cuffed catheters was 25%.

A. Non-tunneled Catheters—A percutaneous dual-lumen venous catheter that is not tunneled subcutaneously, usually intended for temporary access (≤2 weeks) [4].

B. Tunneled Catheters—A percutaneously inserted dual-lumen venous catheter that is tunneled subcutaneously, usually intended for longer usage (>2 weeks) [4].

2. Definition of Catheter Infections

Bacteremia is a frequent complication of catheter use in hemodialysis patients [23,25,26]. Catheter-related bacteremia occurs more commonly in non-tunneled dialysis catheters than cuffed, tunneled catheters [27]. Several prospective studies have devised a classification system for defining catheter infections based on different levels of confidence [28–30].

A. Catheter Related Bacteremia—

1. Definite
    a. The same organism grown from at least 1 percutaneous blood culture and from a culture of the catheter tip[31]; or
    b. a blood culture drawn from a catheter that has a ≥ 3-fold greater colony count of microbiologic isolates than those drawn from a peripheral vein[31].
2. Probable: Positive blood cultures obtained from a catheter and/or a peripheral vein in a symptomatic patient when there is no clinical evidence for an alternative source of infection[31].

Discussion: The definitions above are similar to those published by the Intravenous Guideline Subcommittee of the Infectious Disease Society of America (2001) and the Public Health Agency of Canada (1997) [31,32]. Definitions related to catheter infection should be unified and kept as simple as possible so that they are easily applicable to practicing physicians. In the clinical setting, catheter tip cultures are not uniformly available due to the fact that in most instances it is impractical to remove the catheter for diagnostic purposes only. Furthermore, peripheral vein cultures are usually undesirable as it may traumatize

vessels which should be protected for future AVF creation. Indeed, strict criteria such as the differential time to positivity of blood cultures drawn from the catheter compared to that detected from a peripheral vein, or criteria based on quantitative cultures are expensive and used primarily for research rather than clinical purposes.

B. Catheter Exit Site Infection—

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

Discussion: These are similar to the definitions published by the Public Health Agency of Canada, 1997, and the Intravenous Guideline Subcommittee of the Infectious Disease Society of America[31,32]. We did not include the measurement of "within 2cm of the exit site", as stated in the Infectious Disease Society of America guidelines. Instead, for purposes of unity and simplification, we used the term, "at the exit site" as was used in the Canadian guidelines. We also simplified the Canadian guidelines, by eliminating the 3rd qualifier, "possible" exit site infections, due to the lack of clear differentiation between "Possible" and "Probable" exit site infections.

C. Catheter tunnel infection—

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

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

Discussion: This is similar to the definition published by the Public Health Agency of Canada, 1997[31,32]. The same issues discussed under an explanation of the exit site definition apply to this definition.

3. Catheter Patency Definitions

Catheter dysfunction, often recognized by decreased blood flow, can occur immediately after placement or after sustained use. It is most commonly due to an intramural or extramural thrombus. Furthermore, prolonged catheter use can produce vascular stenosis, often of the central vein. The following definitions refer to common terminology used to define catheter patency and vascular stenosis.

A. Primary catheter patency—the time period commencing from catheter insertion to the time of first intervention for that same catheter. First intervention includes the administration of thrombolytic therapy, mechanical thrombectomy, or fibrin sheath stripping.

Discussion: This definition is similar to those recommended by the Society for Vascular Surgery and the American Association for Vascular Surgery in their published reporting standards, 2002 [4]. However, we feel that once a catheter is exchanged or removed a removal date should be assigned to the discharged catheter and a new insertion date be assigned to the newly inserted catheter. If there is no intervening fistula or graft use, the catheter days would continue in the given patient. The advantage of this approach is careful accounting of catheter days used and the number of catheters used, to keep accurate documentation of complications and costs associated with catheter use. The location of catheter removal and re-insertion should be carefully documented.

B. Cumulative (secondary) catheter patency—the time period commencing from catheter insertion to the time of exchange or removal of that same catheter for any reason, including the time after the use of interventions to maintain catheter function. Interventions include the use of thrombolytic therapy, mechanical thrombectomy, or fibrin sheath stripping. The number of interventions can be represented numerically in brackets after the time period is provided. Example: Cumulative or secondary catheter patency of 4 months, [2 interventions].

Discussion: The published reporting standards for this definition by the Society for Vascular Surgery and the American Association for Vascular Surgery previously used the term, "assisted primary catheter site patency" [4]. We wanted to maintain consistency with AVF and graft definitions. Use of "cumulative patency" or "secondary patency" is less confusing than "assisted primary patency" Once primary patency is lost, everything else is either cumulative or secondary. The word "site" was removed to refocus the definition on the catheter, as opposed to the venous site of insertion. Providing both the number and word, "interventions", makes it more comprehensive.

C. Continuous catheter site—the time period commencing from initial catheter insertion to the time of catheter site abandonment for any reason, including the time period after continuous catheter exchanges. The catheter site refers to the initial vein of insertion, even if catheter exchange was performed through a new tunnel. The number of total catheters used in the same site should be provided in brackets after the time period is provided. Example: Continuous catheter at the right internal jugular vein site use of 12 months, [3 catheters].

Discussion: The published reporting standards for this definition by the Society for Vascular Surgery and the American Association for Vascular Surgery previously used the term, "Secondary catheter site patency" [4]. We modified this term such that the focus is on the initial and continued use of a specific venous insertion site. In addition, the definition is more comprehensive with the specification of the word "catheters" after the number is provided.

D. Catheter dysfunction—the first occurrence of either (1) peak blood flow of 200 ml per minute or less for 30 minutes during a dialysis treatment, (2) mean blood flow of 250 ml per minute or less during two consecutive dialysis treatments, or (3) inability to initiate

dialysis owing to inadequate blood flow, after attempts to restore patency have been attempted.

Discussion: This conservative definition was recently utilized in a large, multicenter, randomized-controlled trial, and included specific parameters [33]. The KDOQI 2001 vascular access working group defined catheter dysfunction as "failure to attain and maintain an extracorporeal blood flow sufficient to perform hemodialysis without significantly lengthening the hemodialysis treatment" [34]. The Work Group considered sufficient extracorporeal blood flow to be 300 mL/min. However, a study published in 2006 reported that a BFR of <300 may deliver adequate dialysis in patients weighing <70 kg [35].

E. Catheter thrombosis—catheter dysfunction occurring after a successful first usage, without a mechanical cause.

- **a.** Intrinsic catheter thrombosis: when the thrombus forms and is attached to the internal or external surface of the catheter lumen. Thrombi present intra-lumenally or at the catheter tip and a fibrin sheath thrombus are included in this category.
- **b.** Extrinsic catheter thrombosis: when the thrombus is caused by the presence of a catheter, but is formed on the wall of a vein, or atrium. Intra-atrial, mural and central vein thrombi are included in this category.

Discussion: These are definitions published by Dr. Gerald Beathard, 2001, and utilized by K/DOQI guidelines for vascular access, 2001 [34,36]. The main limitation is that a definitive diagnosis cannot be made without radiography. Intraluminal thrombus can be surmised with exclusion of mechanical causes and aspiration of clot; extrinsic catheter thrombosis may not be detected until the extrinsic thrombosis is quite large.

F. Cumulative thrombolytic use—the number of thrombolytic instillations/1000 catheter days.

Conclusions

Vascular access dysfunction remains a major cause of morbidity and mortality in hemodialysis patients and the research in this area currently lacks well-designed multicenter observational studies and randomized-controlled trials. In order to advance the quality of clinical care and research in hemodialysis vascular access dysfunction we have proposed uniform definitions relating to vascular access dysfunction to be used when conducting and publishing clinical studies and for patient care.

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Appendix

Final fistula or graft loss = access abandonment = unsalvageable loss

Definition: this access can no longer be used for 1or 2 needle, prescribed dialysis as it may be unable to provide adequate flows and/or is deemed unsafe for the patient, and the associated problem cannot be corrected by any intervention, including medical, surgical, or radiological interventions or rest.

Please check the following:

	Yes	No
The fistula/graft does not have a pulsation (even with augmentation) at the anastamosis or the access body		
The fistula/graft does not have a palpable thrill at the anastamosis or the access body		
The fistula/graft does not have an audible bruit anywhere along the anastamosis or body (up to 10 cm from the anastamosis)		
A radiological intervention such as angioplasty, thrombolysis, stenting, embolization or other will not salvage the access to be useable		
A surgical revision will not salvage the access to be useable. Note: A revision means that it is a revision of the current access and not a surgical procedure that will effectively create new access		
A reasonable effort has been made to improve the condition of the access in order for it to be used; for example, adequate elevation and time for rest of an infiltrated fistula		
The access is viable but there are complications that require the abandonment of the access e.g. high cardiac output failure or severe steal syndrome		
Other, indicate:_____		
I confirm that the fistula or graft is officially abandoned for further use and is not safely salvageable		

Assessment by:
- ☐ Principal Investigator
- ☐ Primary Nephrologist
- ☐ Vascular Access Coordinator/Nurse
- ☐ Dialysis nurse familiar with patient's vascular access

This assessment should NOT be made by the study coordinator

Date: _____

Signature of PI: _____

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