CHAPTER 5 SURGERY DATA COLLECTION

5.1 Preparation for Surgery Data Collection

5.1.1 General Instructions

The key to completing the surgical data collection is to have an involved, engaged surgeon that appreciates the importance of the study and is committed to completing the necessary data forms. The absolute time requirement for completing the forms is actually quite minimal and should not interfere with the day-to-day workload of the surgeon, provided that the forms are available at the appropriate times. The operative data requested is essentially a formal documentation of the procedure and is routine from a surgical perspective. Ideally, the data collections forms should be completed by the surgeon at the completion of the operative procedure along with the other paperwork that is required as part of the routine clinical care (e.g. billing sheets, operative note, perioperative checklist). Accordingly, the appropriate forms (**Form 231 – Details of Surgery**) should be provided to the surgeon at the time of the procedure. The construction of an AVF for hemodialysis access is an elective surgical procedure and, per routine, should be scheduled in advance. Thus, the future operative dates for the study patients can be determined. The surgeon can be alerted to the fact that the patient is a study patient and the importance of completing the forms emphasized. The specific mechanism of providing the surgeon with the appropriate forms may vary per institution, but could include generating a preoperative study packet with the appropriate forms or meeting the surgeon in the preoperative holding room immediately prior to the procedure.

5.1.2 Data Sources

The ideal source of the surgical data is the responsible surgeon and the necessary surgical data should be obtained from the surgeon immediately after completion of the procedure. It is imperative that these data be collected within 24 hrs of the procedure to assure that the data are accurate. There are several data elements on the data collection form and, therefore, any delay will likely reduce the fidelity of the data (e.g. length of anastomosis). There are other potential sources of data to corroborate or help complete the various surgical forms including the billing sheets, anesthesia record, operative notes included in the progress note section of the medical record, the dictated operative notes and clinic notes. Upon completion of any surgical procedure, the responsible surgeon is required to document the procedure in the medical record (either electronic or paper). This is usually documented in the Progress Notes section of the record. Additionally, the surgeon completes a billing sheet which usually lists the specific procedure performed along with the appropriate CPT code (e.g. 36821 – arteriovenous fistula, direct). A complete description of the surgical procedure is dictated by the responsible surgeon within the first 24 hrs after the procedure and this also becomes part of the medical record and billing documentation. A short description of the procedure may also be included as part of the anesthesia record that becomes part of the medical record. Copies of these various notes and dictations can also usually be found in the surgeon's office charts; most physicians maintain office records (independent of the hospital medical record) that contain relevant patient information including operative reports.

5.2 Collected During Surgery

5.2.1 Form 230 – AVF Creation Surgery Notification

The successful creation of an AVF is documented in this form. Additionally, it needs to be documented that a single stage procedure was performed. Occasionally, AVFs will be created using a two stage approach in which the artery and vein are anastomosed to each other during the initial stage and then the vein that comprises the fistula is elevated to a subcutaneous location during the second stage. This is occasionally performed for brachiobasilic or brachiocephalic AVFs in the setting of obese patients. The inclusion/exclusion criteria for the study mandate that only single stage procedures will be performed.

5.2.2 Form 231 - Details of the Surgery

5.2.2.1 Physicians

The surgeons involved with the procedure and their level of involvement are documented in this form. The Attending surgeon is the responsible surgeon and needs to be a member of the study team. It is the Attending surgeon that will also be responsible for completing the form. A Resident surgeon is a surgeon in training. He/she has completed medical school and is involved in a structured training program leading to board certification in a specific discipline. Most of the Resident surgeons in the study will be in General Surgery Residency programs. The General Surgery Residency programs are 5 years long (clinical time exclusive of any research time) and the Residents are commonly described by the Postgraduate Year relative to medical school graduation (PGY1 – first year out of medical school). A Fellow is a surgeon in training that has already completed a Residency leading to board certification. The Fellows in the study may be involved in Vascular, Transplant, or Cardiothoracic Residency programs. Notably, the Fellows are sometimes referred to as Residents of their specific discipline (e.g. Vascular Fellow – Vascular Surgery Resident). Although confusing, the Fellows can be differentiated from the Residents based upon whether they have completed a formal training program.

The level of involvement of the Attending surgeon and the Residents or Fellows is described on the form in an attempt to determine who actually performed in procedure or the critical portions of the procedure. The procedure is broken down into several components for the Attending surgeon including incision, dissection, anastomosis, and closure. It should be documented whether the Attending was “scrubbed” as opposed to just being in the room. Notably, he/she could be “present” in the operating room, but not scrubbed. The Residents and Fellows need to be scrubbed to be considered participants in the procedure.

5.2.2.2 Intraoperative Drugs

The medications administered intraoperatively are documented on this form. Notably, these are medications given specifically as part of the surgical procedure and are usually requested by the surgeon; they are distinctly different than the list of medications that the patients are on preoperatively. Heparin is a blood thinner and is usually administered immediately prior to occluding any blood vessels to prevent the development of thrombus or clot within the vessels during the anastomosis. Protamine reverses the effects of heparin and is given after the anastomosis is completed. If heparinized saline is used

during surgery prior to the creation of the anastomosis, to flush the (clamped) vein and the (clamped) artery used to create the fistula, but is not given systemically, heparin should be recorded as "no" on F231, Q9. DDAVP (desmopressin) and thrombin both help promote the blood to clot and are given after the anastomosis. Topical vasodilators reverse any spasm in the blood vessels. Simple manipulation of the blood vessels (both artery and veins) can induce a significant amount of spasm and, thereby, complicate the construction of the anastomosis. The choice and use of these intraoperative medications is very surgeon-specific and certainly not universal. Similarly, the dosing regimens are not consistent among surgeons although the dosages/delivery regimens do not need to be documented. The use and administration of these medications might not be documented in the dictated operative report. However, they would be recorded on the anesthesia record.

5.2.2.3 Technical Conduct of Operation

The specific details about the operation are recorded on this form in an attempt to identify predictors of successful maturation. Indeed, the specific technical details about creation of AVFs have never been examined in this large of a scale in a multicenter trial.

Three types of anesthesia are used for the construction of AVFs with the choice contingent upon the magnitude of the procedure and surgeon preference. The choices include general inhalation agents, regional field blocks and local field blocks. The general inhalation agents are used more commonly for extensive procedures (e.g. brachiobasilic AVF) that involve the upper arm. They are administered through an endotracheal tube, a laryngeal mask airway or a face mask with the endotracheal tube being the most common. The regional field blocks are used for procedures performed at the antecubital fossa (e.g. brachiocephalic AVF) or more distal on the arm. The regional blocks are performed by the anesthesiologists at the supraclavicular or axillary location. A local field block is commonly used for a radiocephalic AVF and is usually performed by the surgeon. The type of anesthesia should be dictated in the operative note or available in the anesthesia record.

The length of the procedure is defined from the time of the incision to the dressing application. This should be available in the anesthesia record if not recorded by the surgeon. It is important to note that a variety of times are recorded in the medical or anesthesia record (e.g. patient in room, anesthesia ready, surgeon ready, incision, etc…). The time from incision to dressing application most accurately reflects the time required for the procedure and is a surrogate for its complexity.

The future cannulation site of the vein, the artery used for the anastomosis and the vein used for the anastomosis are all recorded in an attempt to determine the specific type of AVF constructed, and, thereby avoid any confusion. The common types of AVF constructed include the radiocephalic, brachiocephalic and brachiobasilic although there are slight variations among these that can lead to confusion. Notably, the cephalic and basilic veins run the length of the arm (both upper arm and forearm) and course along its lateral and medial aspect respectively. They are connected at the antecubital fossa (i.e. elbow) by the median antecubital vein. The brachial artery runs the length of the upper arm and then branches at the level of the antecubital fossa into the radial and ulnar arteries that course over the thenar (i.e. thumb) and hypothenar (i.e. small finger) side of

the forearm. The future site of access cannulation would be the forearm for access procedures using the radial artery at the wrist for the anastomosis. The cannulation site would be the upper arm for any access procedures performed using the radial or brachial artery at the antecubital fossa for the anastomosis. Notably, the radial artery at the wrist is designated as the distal radial artery while the radial artery near the antecubital fossa (immediately after its takeoff from the brachial artery) is designated as the proximal radial artery. It is distinctly unusual to perform an AVF to the ulnar artery although it could be used at both the wrist and antecubital fossa similar to the radial artery. A pair of veins course immediately adjacent to the brachial artery (i.e. paired brachial veins) and they can be used for an AVF although this is rarely performed.

The anastomosis or direct connection between the artery and vein that comprises the AVF can be performed using either sutures of clips (i.e. surgical staples), but the sutured anastomosis is by far the most common. During the anastomosis, both the artery and vein are occluded to prevent blood from obscuring the operative field. This is achieved using either vascular clamps placed on the outside of the vessels, elastic bands wrapped around the vessels (i.e. vessel loops) or an occluding device placed within the lumen of the vessels (i.e. intraluminal occlusion). The length of the anastomosis should also be recorded. Importantly, measuring the length of the anastomosis is not something that is usually performed as part of an AVF procedure. The fact that we want to capture this data will need to be communicated to the surgeon prior to the procedure to insure that it is actually done.

An assessment of the success of the procedure and the likelihood of the AVF maturing into a useable access are recorded on the data sheet. Upon the completion of the anastomosis, there should be a thrill or palpable vibration in the segment of the vein immediately distal to the anastomosis as a result of the underlying hemodynamics related to a large amount of blood flow passing through the low resistance venous circuit. The absence of a thrill is concerning and suggests some sort of problem (e.g. venous outflow obstruction). The extent of the thrill in terms of how far up the arm or forearm that it can be palpated should be recorded. As noted above, the segment of the vein that will be usable for cannulation will span the length of the forearm or upper arm. The length of the vein in the forearm and upper arm can be arbitrarily divided into thirds to facilitate recording the extent that the thrill can be detected. Similarly, the surgeon's impression about the quality of the artery, vein, and likelihood of the AVF being successful in terms of a functional access should be recorded using a simple qualitative scale (i.e. unlikely/inadequate, marginal, likely/adequate, unknown/not assessed). Any specific problems encountered or expected problems should be recorded in text within the space provided on the form. The surgeons should also record whether they were frustrated during the procedure since "surgeon frustration" has been associated with adverse procedural outcome in one of the large, surgical quality improvement studies.

Any new medications (e.g. clopidogrel, aspirin) started after the AVF procedure to facilitate access maturation should be recorded in a fashion similar to the preoperative medications (see **Form 205 – Medication Data Form**). Notably, these are different from the medications given intraoperatively (e.g. heparin, protamine).

All adjunct procedures and additional invasive imaging performed at the time of the AVF should be recorded. Some sort of adjunct procedure will be performed at the time of the

AVF to correct a problem in the inflow artery, vein used for the fistula or the venous outflow track. These adjunct procedures can include either endovascular (e.g. balloon angioplasty or stent) or open surgical procedures (e.g. brachial artery vein patch angioplasty). The need for an adjunct procedure or additional imaging is unusual and suggests that the choice of the artery/vein selected for the AVF were somewhat marginal or that there was a technical problem encountered during the procedure.

5.3 Collected After Surgery

5.3.1 Form 240 – Baseline Drop Out

This form should be completed within two weeks of surgery (or planned surgery date if the patient does not have surgery) for any patient who is not enrolled in the follow-up cohort. Needless to say, every attempt should be made to select patients that will comply with the protocol and complete the study since patients dropping out of the study are problematic from both a statistical and resource standpoint. The primary reason that the patient drops out of the study should be recorded. These include the fact that an AVF was not created in the operating room for whatever reason (e.g. inadequate artery, inadequate vein), the patient did not satisfy the inclusion/exclusion criteria (e.g. age > 80 years, non study surgeon), an alternative mode of renal replacement therapy was initiated (e.g. transplant, peritoneal dialysis), the necessary preoperative imaging was not performed (e.g. vascular function testing), logistical issues prevented continued enrollment (e.g. not available for 2-week ultrasound) or enrollment/consent issues developed. The construction of an arteriovenous graft (AVG) rather than a native AVF may be a common cause of drop out in patients found to have inadequate veins at the time of the surgical procedure. The secondary reason for dropout of the study should be provided using text when a different type of access (not AVF) was created, no access was created, or unusual medical/logistical reasons were identified.

5.3.2 Form 300 - Monthly Follow-up Through Maturity or Abandonment

This form is completed once a month from surgery until 3 months after the study fistula has been abandoned. There are specific questions and sections dealing with access events, fistula cannulation attempts, dialysis adequacy, and cannulation plans. The questions dealing with access events refer to other forms based upon the specific event and/or intervention (re-operation in the early post operative period – **Form 502 Early Perioperative Outcome**, access event – **Form 422 Access Event**, diagnostic procedure – **Form 424 Diagnostic Study**, intervention – **Form 423 Access Intervention)**. These allow for more detailed data collection on the specific access event or intervention.

5.3.3 Form 422 - Access Event

The study affords the opportunity to identify all the access-related events and estimate their complication rates. The specific access-related complications included thrombosis, hand ischemia, infiltration, bleeding, infection, pseudoaneurysm/aneurysm, non-infectious fluid collections, and persistent arm edema. All major complications resulting in the abandonment of the AVF or an intervention are referred to another form for further detailed data collection (**Form 426 – Abandonment**, **Form 423 – Access Intervention**).

Thrombosis or occlusion of the AVF is oftentimes the terminal event for the access. This can occur spontaneously in the case of an AVF that is quite small and fails to mature or it

can occur as a result of a poor needle stick at the time of dialysis. Traditionally, autogenous AVF that thrombosed were abandoned. However, there has been some resurgence in attempts to remediate or salvage these thrombosed native AVFs through either endovascular or open, surgical thrombectomy (i.e. clot removal).

Access-related hand ischemia is a common event that occurs approximately 10% of the time after brachial artery-based AVFs. The phenomenon is referred to by a variety of names with "steal syndrome" being the most common. The underlying pathophysiology is such that the creation of a low resistance, high flow communication between the artery and vein (i.e. the AVF) reduces the blood flow to the hand (i.e. distal to the AVF anastomosis on the arterial tree). Although a misnomer, the AVF allegedly "steals" blood flow from the hand. The access-related hand ischemia can range from mild (i.e. cool hand, slight pain) to severe symptoms (i.e. paralyzed/insensate hand). All patients with severe hand pain, paresthesia, and/or motor strength compromise require some type of remedial treatment to reverse the ischemia. Treatment options include ligation of the access or some type of revascularization to improve the blood flow to the hand.

A poor needle stick at the time of cannulation can result in a hematoma (i.e. blood clot surrounding the access) or direct bleeding through the skin. A large infiltration or hematoma can result in access thrombosis, interruption of the use of the access and/or some type of intervention (i.e. endovascular or open, surgical). Similarly, significant external bleeding can result in the same outcomes. Notably, some bleeding occurs with every dialysis session at the time of the withdrawal of the needles. This is treated with manual pressure or a pressure dressing. It is the intention of the study to identify only "significant" access-related bleeding, particularly those that require a transfusion of blood or blood products and those that require some sort of remedial procedure.

Native AVFs can become infected although this is distinctly quite rare. Indeed, one of the justifications for native AVFs (vs. prosthetic AVFs or grafts) is that they are relatively resistant to infections. The treatment of an infected AVF is contingent upon the severity of the infection in terms of both local and systemic complications. Treatment options range from intravenous antibiotics to access excision and abandonment.

Pseudoaneurysms and aneurysms can develop in AVF. An aneurysm is a circumferential dilation of the AVF while a pseudoaneurysm is essentially a whole in the wall of the AVF that leads to a cavity outside the lumen of the AVF that is contained by the surrounding soft tissue. The later has the appearance of a "bubble" or a weak spot of bicycle inner tube. Dilation of the vein that comprises the AVF is a desired outcome in terms of fistula maturation and ultimate use as a functional access. However, it can be problematic if the vein becomes too large or aneurysmal. The appropriate management of an aneurysmal AVF is somewhat debatable, but most surgeons become anxious when the diameter exceeds 2 cm. The underlying concern is that the aneurysmal AVF will become so large that it will erode through the skin and lead to significant bleeding. The concerns for pseudoaneurysms in terms of rupture risk are similar. Only aneurysms and pseudoaneurysms that require intervention are captured on the data form.

Fluid from the soft tissue may surround or collect around the AVF. This fluid is known as lymph and the collection is known as a seroma. The fluid is straw colored in appearance and is not infectious (i.e. not purulent) or bloody in nature. These non-

infectious, non-hemorrhagic fluid collections are quite rare after an AVF and usually require needle aspiration for diagnosis. The potential outcomes are similar to those seen with infiltration from a poor needle stick.

The placement of an AVF can result in elevated pressures within the outflow veins (i.e. venous hypertension). This venous hypertension can result in the dilation of collateral veins in the arm, chest, neck and breast. In the presence of a central vein stenosis or occlusion, this elevated venous hypertension can lead to arm edema or swelling ipsilateral to the AVF. The arm edema will oftentimes resolve without treatment as a result of the development of additional veins or collaterals. Occasionally, however, the arm edema will be so significant that treatment is necessary. Definitive treatment includes ligating the access or eliminating the central vein occlusion/stenosis.

5.3.4 Form 423 - Access Intervention

All interventions performed on the study AVF are recorded on this form. The interventions are commonly performed to treat access-related complications or to facilitate maturation. Both endovascular and open, surgical interventions are performed for these indications with the choice dictated by the specific problem and the provider (e.g. surgeon, radiologist, nephrologist) preference. Generically, the endovascular options tend to be somewhat less invasive from a patient perspective although also less durable. A record of the procedure and outcome can usually be obtained from the dictated operative or procedure note that is included in the medical record. Note that gathering data is a little bit different from the "real time" scenario in which the surgeon completes the form detailing the technical conduct of the operation (**Form 231 – Details of the Surgery**)

The indication for the intervention should be recorded. Notably, many of the complications necessitating intervention (e.g. thrombosis, access-related hand ischemia) are identified on **Form 422 – Access Event**. Interventions are also indicated to facilitate maturation and/or to improve access function. In this regard, the AVF should be viewed as a complete circuit or loop originating and terminating in the heart. Accordingly, potential problems for remediation include the arterial inflow, the AVF anastomosis, the outflow vein comprising the fistula itself, and the central vein runoff. These account for the arterial inflow stenosis and central vein stenosis as potential indications for intervention although central vein stenoses may also be contributory to elevated venous hypertension and ipsilateral edema. Large venous branches off the main vein that comprises the fistula may inhibit maturation and require ligation. "Superficial" veins that are too deep to cannulate for dialysis may require elevation or "superficialization" as a secondary procedure. This scenario occasionally arises in obese patients undergoing a brachiocephalic AVF. Specifically, the vein that comprises the AVF is sufficiently dilated for cannulation (i.e. > 6 mm), but too deep relative to the skin to be cannulated. Notably, this second stage procedure that comprises the elevation should not have been planned given the inclusion/exclusion criteria for the study (i.e. planned single stage surgery).

The specific interventions for the fistula (including the anastomosis), the arterial inflow, and the central veins are recorded in the form 423. The options for these three anatomic regions are essentially the same. Balloon angioplasty refers to inflation of a balloon

across an area of stenosis. Balloon angioplasty with stent refers to the deployment of stent or wire mesh structure across an area of stenosis. Notably, a "covered" stent may also be used to treat a focal area of bleeding from a bad needle stick or a disrupted AVF resulting from a balloon angioplasty. A thrombosed AVF may be "cleaned out" or thrombectomized using either endovascular or open, surgical techniques. The endovascular thrombectomy techniques commonly involve some type of mechanical means to remove the clot and a chemical means to dissolve the clot. The open, surgical angioplasty entails sewing a segment of vein (or prosthetic material) across an area of narrowing in the AVF as "patch" while a bypass entails interposing a segment of vein (or prosthetic material) to replace a segment of the native vessel.

A variety of procedures are available to treat access-related hand ischemia including simply ligating the access, attempting to narrow the blood flow through the access (i.e. banding), bypass around the AVF (i.e. DRIL – distal revascularization and interval ligation), and resiting the AVF anastomosis more proximal on the arterial tree (i.e. proximalization). A variety of "banding" techniques have been described including narrowing the AVF anastomosis or the proximal portion of the vein comprising the AVF.

5.3.5 Form 424 – Diagnostic Study

All diagnostic imaging studies to evaluate the access are documented on the form. A variety of diagnostic imaging studies are available including a catheter-based fistulogram, catheter-based venogram, catheter-based arteriogram, ultrasound, CT arteriogram/venogram and MRI. The catheter-based procedures and ultrasound will be among the most common. The diagnostic studies are performed for a variety of indications including access–related complications, non-maturing AVFs, and dysfunctional AVFs with the latter including both cannulation difficulties and ineffective dialysis. It is important to note that these are purely diagnostic procedures. Any intervention that is performed as a result of the diagnostic procedure or concomitantly should be recorded on **Form 423 – Access Intervention**. Details of the diagnostic procedure can be obtained from the dictated procedure note or the formal interpretation of the imaging study that is included within the medical record.

Access dysfunction can be suggested during dialysis a number of ways including decreased blood flow through the AVF, elevated venous pressures on the dialysis circuit, inadequate dialysis/clearance (i.e. inability to achieve Kt/V), or excessive bleeding post removal of the cannulation needles. Access dysfunction related to cannulation may occur as a result of an AVF that is too deep, too narrow, or too short in terms of a usable length for both cannulation needles.

The outcome of the diagnostic study or the ensuring recommendations should be recorded. This is easy in terms of a diagnostic procedure and concomitant intervention, but may be more difficult to determine for just a diagnostic imaging study alone. The physician that interprets the imaging study (i.e. radiologist) is usually not the one responsible for treatment decisions. Indeed, the responsible individual will vary depending upon the specific practice and clinical care delivery system. It could be either a surgeon or a nephrologist. It will be important to familiarize oneself with the specific practice. A fall back position is to identify the individual that ordered the diagnostic

imaging study from the requisition form or determine who receives a copy of the dictated report.

5.3.6 Form 426 – Fistula Abandonment

The reason that the AVF was abandoned should be documented. The potential reasons include access–related complications, non-maturing AVFs, and dysfunctional AVFs with the latter including both cannulation difficulties and ineffective dialysis.