- **CLINICAL CENTER ULTRASOUND PROCESSING**

15.1 Documenting Your Local Ultrasound Facilities

Details regarding the US scanner which will be used for the HFM Study ultrasounds at each site will be documented in Form 313 (Ultrasound Facility Form) and entered into the database. If there is any change in ultrasound equipment during the study, this information should be sent to the US Core and an inquiry sent to the DCC through the database to update the Form 313. If new sonographers are to participate in this study they will need to undergo training at the University of Alabama at Birmingham and perform the appropriate certifying preliminary sonographic exams.

15.2 The Baseline Ultrasound

The baseline preoperative mapping ultrasound maps out the arteries and veins of the arms to assess whether suitable anatomy for AVF placement is present. The sonographers will be checking for the presence of stenosis and thrombus and measuring brachial artery blood flow rate, as well as identifying suitable veins for AVF placement. This will be a bilateral or unilateral examination, according to preference of the clinical center. Note that if the patient is enrolled with a planned AVF surgery, a preoperative mapping ultrasound of that particular arm (not just the contralateral arm) must have been performed.

- If done before patient consent

  The preoperative mapping ultrasound imaging protocol has been given to each individual center, and the PIs have stated that the individual vascular labs will follow the protocol for preoperative mapping ultrasounds.

- If done after patient consent

  If the patient has already been consented into the study, every effort should be made to have an HFM Study US Core certified sonographer perform the preoperative ultrasound mapping study.

  The preoperative ultrasound must be transmitted and read by the core for adequacy prior to AVF placement. It is strongly encouraged to have the US core assess the study prior to surgery for adequacy. Sending the preoperative mapping US study to the core the same day the patient is enrolled, and subsequent postoperative fistula ultrasounds the same day the ultrasound is performed is strongly encouraged. *If an adequate preoperative mapping ultrasound has not been performed, the patient may not continue in the study (exclusion criteria).*

15.3 Post-Operative Ultrasounds

See Section 4.4.1 of the Protocol and Figure 15.1 at end of chapter.

<u>Ultrasound Scheduling Principles and Rules</u>

1. Scheduled target US at 1 day post-op, and 2, 6, and 26 weeks. (3, 15, 16)

2. After first cannulation US, all US exams stop. (1, 2, 4, 5, 7, 8, 10, 11, 13)

3. If no prior intervention, pre-cannulation US for any first cannulation between 10 and 26 weeks (≥ 10 weeks and 26 weeks). (2)

4. If first intervention before first cannulation
    a. Remaining normally scheduled USs before 26 weeks are omitted.
    b. Pre-first intervention US if intervention between 10 and 26 weeks (13, 14), unless the intervention is a declot. If the fistula is thrombosed, a pre-intervention US should not be performed.
    c. Pre-first cannulation US before 26 weeks (4, 5, 7, 8, 10, 11, 13). If no first cannulation by 26 weeks, US at 26 weeks (6, 9, 12, 14). There should be 4 weeks between the first intervention ultrasound and the 26 week ultrasound.
    d. If first intervention is after 26 weeks, do an US prior to cannulation (15).

5. An additional pre-intervention US is done for the first intervention only, and only if that occurs during weeks 11-26 (13, 14), except for the following scenarios:
    a. If only a fistulogram was performed (not a fistulogram and angioplasty), the ultrasound performed prior to the fistulogram needs to be read by the US Core, but does not count as the pre-first intervention ultrasound, as an angioplasty was not performed. Note that this will not be known before the procedure, as the decision to do an angioplasty is made at the time of fistulogram. There may be multiple interventions before cannulation.
    b. If a DRIL procedure is performed, a pre-intervention ultrasound should be performed and read by the US Core. However, this ultrasound does not count as the pre-first intervention ultrasound.

- **Day 1: Within one calendar day of AVF placement**

    The perioperative ultrasound will be to assess for immediate complications, and to measure brachial artery blood flow rate as a potential very early predictor of AVF maturation.

1. At the time of consent, or any time before the vascular function tests are done, you know that early ultrasound cannot be done within 2 days post-op, do not enroll the subject.

2. If you enroll a subject thinking that you can get the early ultrasound within 2 days post-op, and things change after consent is signed such that early ultrasound is not possible within 2 days, you do NOT drop the subject. Instead, get ultrasound on day 3 if possible. If you cannot get the ultrasound on day 3, no ultrasound until 2 weeks.

- **2 weeks postop**

    The 2-week ultrasound will be to assess for surgical complications and patency. Measures of AVF diameter and blood flow rate (among others) will assess whether the 2 week ultrasound can be used as a potential early predictor of AVF maturation

- **6 weeks postop**

  The 6-week ultrasound is to determine the status of AVF development at 6 weeks, preferably prior to any cannulation. The 6 week ultrasound will be correlated with physical examination, and eventual AVF maturation, and may prove to be an early predictor of AVF maturation.

- **Prior to first cannulation between 10 and 26 weeks**

  An ultrasound shortly before or, failing that, within 2 weeks after first cannulation will determine ultrasound parameters close to ascertainment of clinical maturation.

- **Prior to surgical or endovascular fistula revision between 10 and 26 weeks**

  If surgical or endovascular fistula revision is scheduled for AVF evaluation and treatment, an ultrasound should be performed prior to the procedure to determine the AVF status, and if potential reasons for AVF non-maturation such as stenosis are present.

- **26 weeks postop, if AVF has not been abandoned, cannulated or undergone a surgical revision by then**

  In these circumstances, an ultrasound should be performed at 26 weeks to evaluate the current status of the AVF, and changes that have occurred since the prior ultrasound at week 6. If an intervention occurs after 26 weeks, an ultrasound should be obtained prior to cannulation (if this occurs).

15.4 Scheduling the Day 1, Two-Week and Six-Week Ultrasounds

When the AVF surgery is scheduled, the within one calendar day, 2 week and 6 week ultrasound dates can be determined and scheduled. To avoid technical issues due to bandage placement and vasospasm, the former should preferably be scheduled on the day after surgery. However, a day-of-surgery examination may be performed if, despite prior consent and current encouragement, a patient is unwilling or judged unlikely to return due to logistical issues such as distance and scheduling conflicts with dialysis. It may be easiest to wait until the surgery has been performed to actually schedule the ultrasounds, according to local preference. The DCC will be monitoring the centers for performance of the ultrasounds.

15.5 How to Find Out if an Angioplasty or Surgical Intervention is Scheduled in the Next 5 Days and Schedule an Extra Ultrasound

Due to differences in local relationships and logistics, clinical centers will adopt local procedures for this purpose. *These are appended to this manual.*

15.6 Using the Follow-Up Imaging for Clinical Indication Form 424

This form details the reason for imaging.

15.7 Submitting Images to the Core

- **Completing the Form 216**

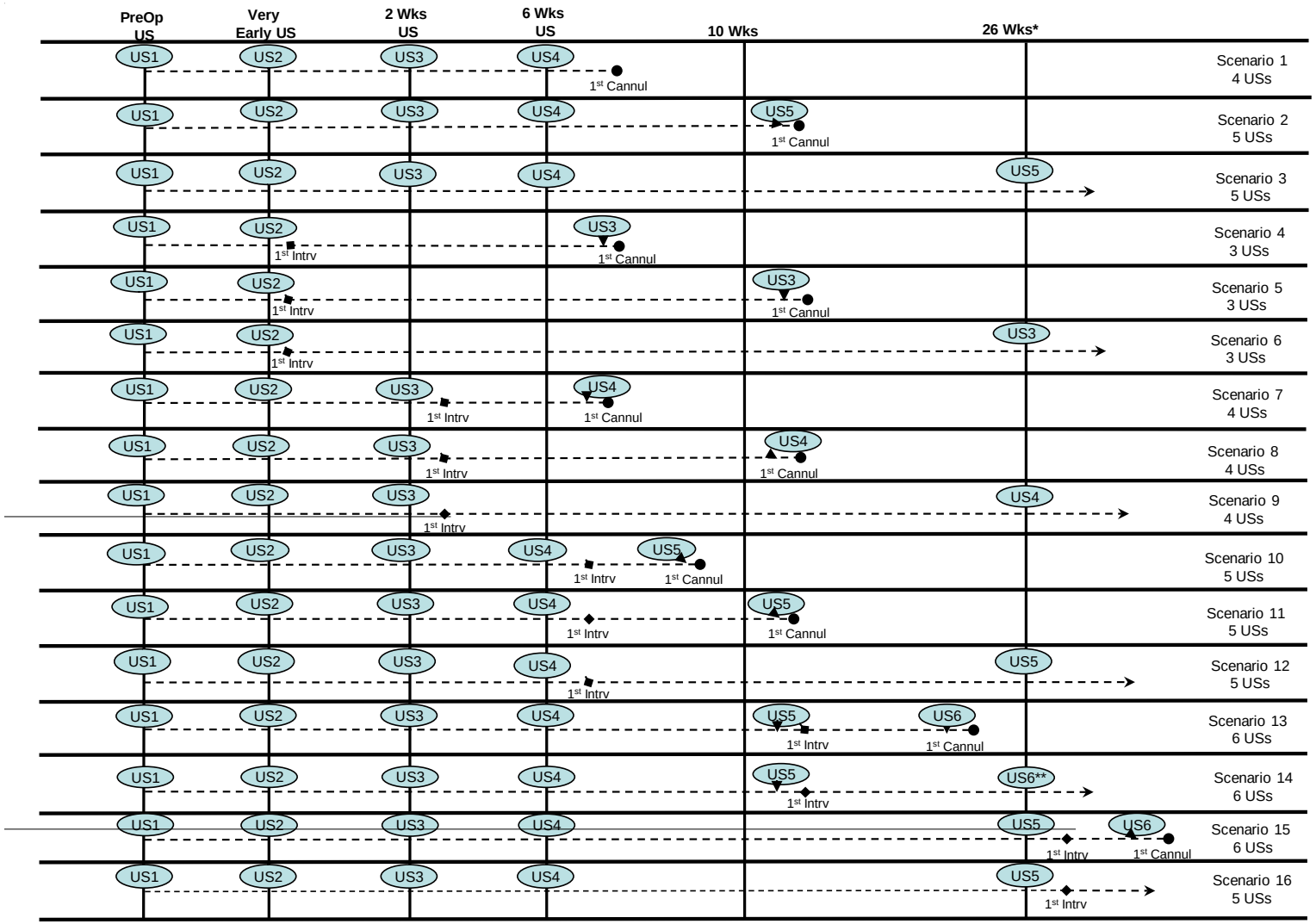
  Form 216 details the subject name, date of ultrasound study, US scanner equipment manufacturer, and name of sonographer

- Image transmission

  The US Core will receive images directly from the clinical site. A CD, DVD or thumb drive containing the images will either be express mailed to the UAB Core, or submitted electronically in a secure HTTPS electronic transfer. This process will be individualized for each center. If the images are mailed, ship images to:

Dr. Michelle Robbin, MD
619 S 19TH Street, JTN 358
Birmingham, Al 35249
205-934-7978 (phone)
205-975-7213 (fax)

Figure 15.1



- If no cannulation has occurred by 26 weeks, a 26-week US is done. This US will be final, unless first cannulation is planned after a post-26 week intervention (see Scenario 15).

** There should be 4 weeks between the pre-intervention US and the Week 26 US

Note: A pre-intervention US is done before the first intervention only.