CHAPTER 14 CLINICAL CENTER ULTRASOUND TESTING

14.1 Ultrasound Staff Certification Requirements

Sonographers are required to complete the HFM Study training session at the University of Alabama at Birmingham to be HFM Study certified sonographers (Held 11/4-5/09 and 3/10-11/10). If there is a personnel turnover or additional sonographers need to be certified they need to come to UAB for HFM Study ultrasound training. There is no provision for HFM Study certified sonographers to train local site sonographers. Sonographers will be required to demonstrate proficiency performing preoperative upper extremity mapping sonograms and postoperative AV fistula evaluation sonograms as per HFM Study ultrasound core protocol. Sonographers will be required to perform at least 3 pre-operative mapping sonographic studies and at least 3 postoperative AV fistula sonographic evaluation studies with evaluation by Dr. Robbin or Dr. Umphrey for sonographer certification. Two of these studies are performed at the UAB training courses, and the final preoperative and postoperative ultrasound will be to demonstrate proficiency at the sonographers local institution with local equipment.

The preoperative mapping ultrasound will be performed (in most cases) prior to the patient's enrollment in the HFM study. Therefore, it is possible that the preoperative ultrasound was performed by a non-HFM certified sonographer. Each laboratory has agreed to follow the HFM preoperative study protocol, and thus the protocol should be followed for each preoperative examination even if not performed by an HFM certified sonographer. However, every effort should be made to have an HFM certified sonographer perform all studies, as they have precise training in optimal preoperative mapping techniques and methods to ensure reproducibility.

14.2 Performing the Ultrasound Test

Preoperative ultrasound mapping will (in general) be performed prior to the patient being enrolled in the study. Sonographers will follow the HFM Study ultrasound preoperative imaging protocol and (optimally) complete a preoperative mapping worksheet at the time of examination. Once the patient is enrolled in the HFM study, the worksheet should be faxed to the US Core, and the images transmitted to the US Core. Every attempt should be made to expedite the transmission of images and worksheet as soon as possible after enrollment, within 24 hours of enrollment if at all possible. The goal will be for the US Core to be able to evaluate the images prior to surgery in nearly all cases. If the HFM preoperative worksheet was not filled out at the time of the ultrasound, optimally an HFM certified sonographer will fill out the preoperative worksheet and fax it to the US Core. The US Core will fill out the preoperative mapping worksheet if the worksheet is not filled out by the ultrasound laboratory. The US Core will assess the images for adherence to the HFM Study US imaging protocol.

Postoperative sonographic evaluation of AV fistulas will be performed as per the HFM Study US imaging protocol by an HFM certified sonographer with completion of the postoperative sonographic worksheet, which will be faxed to the US Core. Please see the pre-operative sonographic mapping and postoperative AVF imaging and performance protocols and worksheets in the MOP.

No blinding is necessary for the completed preoperative worksheets. However, the ultrasound laboratory personnel should fax the completed postoperative worksheets to the US Core, to avoid

any potential bias from other study personnel seeing the results of the postoperative research ultrasounds, unless otherwise specified by the protocol.

14.3 Policy for Unblinding Ultrasound Results

The ultrasounds obtained 1 day, 2 weeks, and 6 months after AVF creation as well as those obtained prior to any procedure or cannulation of the fistula are not part of usual care at any institutions participating in the HFM Study and are obtained exclusively for research purposes. By contrast, the ultrasounds obtained preoperatively (for mapping) and 6 weeks after fistula creation are, in some study institutions, obtained routinely as part of standard clinical care. For ultrasounds obtained routinely at the institution as part of standard clinical care, or for those ordered by a treating physician because of a particular concern or finding, the local ultrasound interpretation should be incorporated into the medical record and transmitted to ordering clinicians as for any clinical study. The results of ultrasound studies obtained only for the purposes of research, ("research ultrasounds") should *not be communicated to the study participant, study team or participant's physicians, including their nephrologists and surgeons during the course of the study except under the rare circumstances outlined at the end of this policy.*

The rationale for this approach to managing ultrasound data is that the clinical value of research ultrasound data is unknown, and the reporting of these ultrasounds to the clinical care team may modify care thus interfering with the ability to follow the natural history of fistulas or evaluate factors that impede their maturation.

Some centers have adopted the HFM ultrasound protocols (i.e., ultrasound technique and components) for preoperative mapping and/or postoperative clinical ultrasounds performed at their institutions. The sonographers at these centers will be able to differentiate research ultrasounds from clinical care ultrasounds because the research ultrasounds will be ordered as "HFM research". Centers that retain institution-specific ultrasound protocols will order the institutional ultrasound when a clinical care ultrasound is necessary; the research ultrasounds will be ordered and performed according to the HFM protocols.

In brief, the possible abnormalities that can be seen at the preoperative mapping and postoperative AVF USs fall into 2 categories. The first category contains findings that are potentially life or limb threatening, and if seen at ultrasound at any time should be reported to the study PI: 1) large pseudoaneurysm and 2) brachial or radial artery occlusion.

The second category contains findings that may impede fistula maturation, such as draining vein stenosis or occlusion, but are not life or limb threatening. These findings are not reported to the PI as per the rationale extensively discussed in the HFM protocol.

Under the rare circumstance that a sonographer has concerns that an abnormality observed on a research ultrasound is life or limb threatening, he or she should immediately call the study PI or, if the PI is unavailable, the study participant's surgeon or nephrologist. If they are unavailable, a vascular surgery consultation should be immediately obtained. Sonographers also may call the US Core if they have questions regarding their findings or the above policy.

An unblinded HFM research ultrasound (i.e., one that is not obtained for clinical purposes) is

documented in the Diagnostic Study Form 424, Q.6. The Form 424 is entered in addition to the Form 216 (Local Ultrasound Imaging and Transmission).