

# **BACKGROUND:**

Since May 2001 our blood center (BC) has used an Audio-visual touch screen computer assisted self-interviewing (AVT-CASI) system at 10 fixed site and limited mobile operations. The AVT-CASI has also been implemented at two other BC since spring of 2003 creating a user group (UG) of three. During that interval the FDA has produced 3 guidances suggesting 9 new questions be implemented. These changes has been met within the timeframes due to our implementation of the AVT-CASI. The AVT-CASI implementation, training and changes to the manual system occur in parallel.

## **AVT-CASI Vendor Steps**

The AVT-CASI administers the AABB Uniform Donor History Questionnaire (UDHQ) employing audio and visual information. The UG has already agreed to verbatim FDA/AABB question usage and meets via phone to discuss question placement and review suggested photo visuals.

After agreement by the UG on the visuals to be used the corresponding questions are recorded and transmitted to the vendor and integrated with the approved visuals into existing software and completes the vendor validation.

After the vendor validation the software patch is available via the website for BC download and validation.

## **Blood Center Steps**

Because the current AVT-CASI screening systems are stand-alone, each of the 27 systems in use requires patch installation and validation. The installation and patch validation is done over a three-day period for 10 fixed sites sites.

Since the AVT-CASI prints all questions, as each site is updated the modified UDHQ is removed and original blanked side card is returned to use.

The modified manual UDHQ is replaced when updated reprints are available from the printer.

## **Blood Center Steps**

Two versions of the UDHQ are used; a manual version with questions printed for mobile operations and an AVT-CASI version, which is blank on one side to allow for the printing of questions, donor responses and comments from the AVT-CASI at completion of screener review.

Both versions allow for additional questions to be copied from a template to the UDHQ assuring documentation of verbal questioning during any needed transition period.

## **Blood Center Steps**

A single SOP change supports both UDHQ versions facilitating training on the questions and deferrals while the AVT-CASI system changes are being made by the vendor.

The single page UDHQ adopted due to AVT-CASI usage enables modifications and implementation within FDA timeframes for both UDHQ versions.

## **Conclusion:**

While all AVT-CASI changes have been received before the 30-day implementation date, the current main limitation to rapid implementation of the new questions on the AVT-CASI earlier in the timeframe is the inability to upgrade systems via a wide-area network (WAN) in a single process.

However, even with WAN capabilities, center support changes, like SOP updates, staff training for manual UDHQ and donor response review and documentation will prevent implementation sooner than 30 days.