

Comment on UDHQ Draft Guidance

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These comments apply to “Guidance for Industry: Acceptable Full-Length Donor History Questionnaire and Accompanying Materials for Use in Screening Human Donors of Blood and Blood Components” CBER April 2004. [FDA Docket No. 2004D-0198].

1. **Computer assisted interactive interviews** [p. 5 of draft guidance]

The draft guidance asserts that computer-assisted interactive interviews represent a higher level of risk than other forms of donor interviews, thus requiring a CBE30 prior to implementation rather than the easier and faster Annual Report requirement. The given reason is “concerns that the presentation of questions and information may not be easily readable in all conditions and by all potential users.” This is contrary to our findings documented in [1] and [2] below regarding the Talisman Quality Donor System™ (QDS) – an audio-visual touch-screen computer-assisted self-interview system (AVT-CASI). All donors, first time and repeat, found QDS to be clear (91.8%), private (92.3%) and more likely to elicit more truthful responses (67.7%) than face-to-face interviewing (FTF). Among repeat donors with an opinion, preference for QDS over FTF is extremely strong: 6.7 times as many donors preferred QDS as prefer FTF, 9.5 times as many donors found QDS to be more understandable than those favoring FTF and 14.3 times as many said they were more likely to return with QDS. Because QDS uses audio as well as photographs to supplement on-screen text questions, comprehension as well as literacy issues are addressed better than with other forms of interviewing. Interviews are more consistent than staff-conducted face-to-face interviews because they do not depend on extrinsic variables such as staff pronunciation, speaking speed, regional accents, mood or fatigue. A computer-printed record of donor responses, after compulsory staff review and computer consistency checks, eliminates handwriting and other errors. The second publication [2] documents at least a 60% reduction in reportable errors and a nine-fold increase in donor admissions of risky behaviors compared to face-to-face interviewing. Subsequent and ongoing research, also sponsored by the National Heart Lung and Blood Institute, at two additional blood centers is strongly corroborating these findings. To date over 200,000 donor interviews have been completed with QDS. QDS requires no donor training, only two to three hours of staff training and has been updated to new CBER interviewing requirements in as few as seven days, which is far faster than manual systems.

CBER’s Guidance “Streamlining the Donor Interview Process” [3] refers to the discussion at the Blood Products Advisory Committee meeting of September 12, 2002, in which the committee pointed out that all methods for administering the donor questionnaire were comparable for eliciting information from new donors, but that additional studies were needed to determine the efficacy of various methods to provide a safe blood product. We maintain that the studies just cited clearly establish the superior efficacy of AVT-CASI, as embodied in QDS, to face-to-face interviews of potential blood donors. This research is consistent with other, non-blood-donor studies [4], [5], [6] (referred to in the 2003 Guidance[3]) that demonstrate the superiority of CASI for eliciting admission of risky and socially sensitive and stigmatizing behaviors, as well as improved comprehension among low-literacy interviewees. More recent studies of blood donors cited in [2] reach similar conclusions.

Based on the above, a CASI system, such as QDS, scientifically-proven in blood center production lines to reduce reportable errors along with other benefits discussed above, presents no higher level of risk than other types of interviewing and presents, arguably, lower risk. We therefore propose that implementation of a CASI system that has been scientifically proven in a blood center, be recognized as a minor change from a face-to-face interview, and be accorded the same Annual Report status. This would encourage the use of such systems, instead of discouraging such use like the current draft does.

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2. Standardization

The draft guidance says that adherence to the DHQ procedures would provide adequate measures to meet FDA requirements related to donor eligibility, but does not require manufacturers to implement these requirements. This runs contrary to the established academic and industrial approaches to quality, that recognize the value of standardization of repetitive processes [7 - 9]. Indeed, FDA itself mandates the use of SOPs and cGMPs, which are nothing but localized standards, within each establishment. We propose that the final guidance require the use of the DHQ and associated documents by a specified adoption date, while allowing an exception procedure for those manufacturers who wish to use a different questionnaire, provided it has been validated to the same or higher standards as the UDHQ. This approach is the most likely to optimize quality and hence blood safety and to simplify both adherence to the standard as well as compliance monitoring.

3. Questionnaire format

The new UDHQ questionnaire is presented (in Appendix A of draft guidance) as a multi-page document. We request that the final guidance include clarification permitting the completed questionnaire to be printed in a single-page format if the printed version is produced by a computer self-interviewing system as the final record of the completed interview.

References

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