

Audiovisual touch-screen computer-assisted self-interviewing for donor health histories: results from two years experience with the system

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BACKGROUND: The donor history interview is an important aspect of blood safety, in part designed to identify unsuitable donors who may present a risk to blood recipients. There is evidence from behavioral science literature that use of computer-assisted interviewing may be superior to face-to-face (FTF) and paper techniques in eliciting sensitive behavioral information of interest to blood collection facilities.

STUDY DESIGN AND METHODS: Audiovisual touch-screen computer-assisted donor self-interviewing with the AABB Uniform Donor History Questionnaire was deployed for routine use in a regional blood center replacing FTF interviews. Donor and staff perception and satisfaction surveys were performed to assess acceptance of the system. Time studies of automated and manual methods were conducted. Rates of deferral of first-time donors for high-risk behaviors and rates of errors and omissions on donor interviewing for the two systems were tabulated and compared.

RESULTS: Donors and staff strongly preferred the automated system in all dimensions assessed. Donor time increased by 4 minutes but staff time declined by 5 minutes per interview. Identification of high-risk behaviors among first-time donors significantly increased. Rates of errors and omissions on donor history forms identified at audit were reduced.

CONCLUSIONS: Both blood donors and collections staff enthusiastically accepted the automated donor interviewing system. A well-designed audiovisual touch-screen donor self-interviewing system is superior to face-to-face interviewing and most likely more effective than paper interviewing.

In December 2001, we reported results of a pilot study of an audiovisual touch-screen computer-assisted donor self-interviewing (AVT-CASI) system for obtaining blood donor health histories at the Hoxworth Blood Center.¹ A donor survey, included as part of the study, showed that the system was an effective means of health history interviewing according to a substantial majority of responding donors. Donors found the system clear and understandable (92%), were comfortable with the process and the privacy provided (95%), and were satisfied with the time required (64%). Among repeat donors who had a preference either for AVT-CASI or for its FTF predecessor, 64 percent preferred AVT-CASI, 90 percent found it more understandable, and 80 percent indicated a greater likelihood of returning when interviewed by the automated system.

Although encouraging, the pilot study lacked robustness in four respects: 1) the study was small consisting of a single installation at which 395 randomly selected donors were interviewed and 277 surveyed; 2) it involved a prototype system lacking a number of technical improvements subsequently added; 3) it used a customized donor health history, results from which could not be

ABBREVIATIONS: AVT-CASI = audiovisual touch-screen computer-assisted donor self-interviewing; FTF = face to face; QDS = Quality Donor System™; SOP(s) = standard operating procedure; UDHQ = Uniform Donor History Questionnaire.

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generalized to blood centers with the AABB Uniform Donor History Questionnaire (UDHQ);² and 4) the short duration prevented assessment of anticipated longer term benefits from computer-assisted interviewing.

Reported here are results from more extensive studies following implementation of a technically updated version of the prototype system, called the Quality Donor System™ (QDS), at the Mississippi Valley Regional Blood Center. QDS was installed sequentially at the center's fixed donation sites in the years 2001 to 2002 during which time more than 50,000 blood donors were interviewed with the system. Comparisons were made between the QDS version of AVT-CASI and FTF interviewing, the system previously used at the center. In all cases, AVT-CASI is the experimental condition and FTF the control. Comparisons included donor and staff opinions about the two methods, times required for donor and staff review, rates of deferrals of first-time donors for high-risk behaviors, and frequencies of errors and omissions detected upon audit of donor history forms.

MATERIALS AND METHODS

The interviewing system

The AVT-CASI system installed at the center consisted of desktop personnel computers running Microsoft Windows 2000 equipped with touch-sensitive screens for recording donor responses. Headphones and a private booth were used to present the audio portion of the interview (Fig. 1) and ink-jet printers produced a completed interview form once all required fields were filled. The donor interview, including audio, text, and illustrative photographs, was programmed in World Wide Web-browser-compatible codes, which will permit interviewing via the Internet if approved by the US Food & Drug

Administration (FDA) Center for Biologics Evaluation & Research (CBER). Upon completion of the interview, donor responses to each question were displayed on a staff review screen (Fig. 2) where colors and icons indicated an aberrant (i.e., requiring staff inquiry or assistance) or acceptable response. Staff further interviewed donors on each aberrant answer, revised initial aberrant responses when warranted, and decided whether deferral was required based on center standard operating procedure (SOP). After staff review, results of the revised interview were printed producing a paper copy of the completed UDHQ questionnaire for donor and staff signatures (Fig. 3), audit, and archiving. Two databases were included in the system: one recorded only donor history and donor card data; the other, a research database, recorded all donor and staff computer interactions and their timing. Results of the donor physical examination and phlebotomy variables were manually recorded on the donor history card during the study.

The health history questionnaire employed by the regional center was the then current version of the AABB UDHQ consisting of 46 questions. The UDHQ interview was incorporated into the AVT-CASI system in May 2001 supplanting the FTF interview. The system was introduced sequentially over a period of months at all fixed collection sites under an FDA-CBER CBE-30 protocol. Throughout the current studies the center continued to employ FTF interviewing on mobiles, data from which were not included in these studies.

From the donor's perspective the AVT-CASI interviewing system used for the current studies was virtually identical to the one described in the pilot study.¹ The interview screen for each question (Fig. 1) contained question text, a photograph of a center staff member and another illustrating the subject of the question, together with touch-screen boxes for donor responses of "Yes," "No," or "???" (help). Two additional boxes, "Next" and "Back," allowed

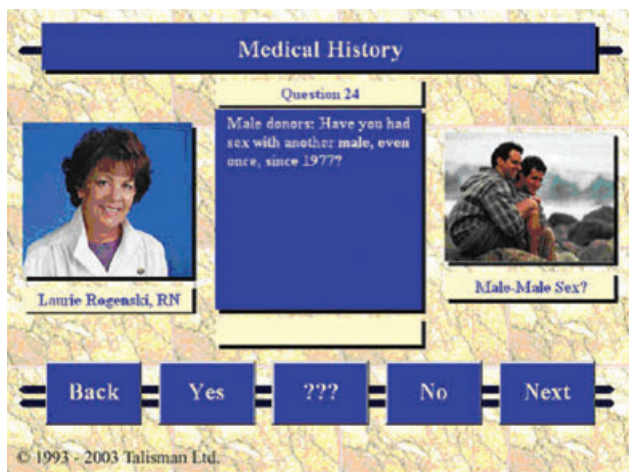


Fig. 1. Sample interview screen (1 of 46) from the QDS employing the AABB-standardized UDHQ.



Fig. 2. Sample staff review screen from the QDS.

Donor ID: 100
Donor Name: TREY

Gender: Female

Session Date: 12/12/2001 5:26:09 PM
Reviewer Login: admin

Y	1	<input type="checkbox"/>	Have you ever donated or attempted to donate blood using a different (or another) name here or anywhere else?
Y	2	<input type="checkbox"/>	In the past 8 weeks, have you given blood, plasma or platelets here or anywhere else?
Y	3	<input type="checkbox"/>	Have you for any reason been deferred or refused as a blood donor or told not to donate blood?
<input checked="" type="checkbox"/>	4	N	Are you feeling well and healthy today?
Y	5	<input type="checkbox"/>	In the past 12 months have you been under a doctor's care or had a major illness or surgery?
Y	6	<input type="checkbox"/>	Have you ever had chest pain, heart disease, recent or severe respiratory disease?
Y	7	<input type="checkbox"/>	Have you ever had cancer, a blood disease or a bleeding problem?
Y	8	<input type="checkbox"/>	Have you ever had yellow jaundice, liver disease, viral hepatitis or a positive test for hepatitis?
Y	9	<input type="checkbox"/>	Have you ever had malaria, Chagas' disease or babesiosis?
Y	10A	<input type="checkbox"/>	Have you ever taken etretinate (Tegison) for psoriasis?
Y	10B	<input type="checkbox"/>	In the past 3 years, have you taken Acitretin (Soriatane)?
<input checked="" type="checkbox"/>	10C	N	In the past 36 hours have you taken aspirin, or anything that has aspirin in it?
Y	10D	<input type="checkbox"/>	In the past month, have you taken Isotretinoin (Accutane) or finasteride (Proscar) (Propecia)?
Y	10E	<input type="checkbox"/>	In the past 4 weeks, have you taken any pills or medications?
Y	10E1	<input type="checkbox"/>	Have you at any time since 1980 injected bovine (beef) insulin?
Y	11	<input type="checkbox"/>	In the past 4 weeks, have you had any shots or vaccinations?
Y	12	<input type="checkbox"/>	In the past 12 months, have you been given rabies shots?
Y	13	<input type="checkbox"/>	Female donors: In the past 6 weeks, have you been pregnant or are you pregnant now?
Y	14A	<input type="checkbox"/>	In the past 3 years, have you been outside the United States or Canada?
Y	14B	<input type="checkbox"/>	Have you visited or lived in the United Kingdom (England, Northern Ireland, Scotland, Wales, the Isle of Man or the Channel Islands) from 1980 to 1996? If so, have you spent a total of six months or more from 1980 through 1996?
Y	15A	<input type="checkbox"/>	Have you ever received human pituitary-derived growth hormone?
Y	15B	<input type="checkbox"/>	Have you received a dura mater (or brain covering) graft?
Y	15C	<input type="checkbox"/>	Have you or any of your blood relatives ever had Creutzfeldt-Jakob disease or have you ever been told that your family is at an increased risk for Creutzfeldt-Jakob disease?
Y	16	<input type="checkbox"/>	In the past 12 months, have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given Hepatitis B Immune Globulin (HBIG)?
Y	18	<input type="checkbox"/>	In the past 12 months, have you received blood or had an organ or tissue transplant or graft?

Y	19	<input type="checkbox"/>	In the past 12 months, have you had a tattoo applied, ear or skin piercing, acupuncture, accidental needlestick or come in contact with someone else's blood?
Y	20A	<input type="checkbox"/>	In the past 12 months, have you had a positive test for syphilis?
Y	20B	<input type="checkbox"/>	In the past 12 months, have you had or been treated for syphilis or gonorrhea?
Y	21	<input type="checkbox"/>	In the past 12 months, have you given money or drugs to anyone to have sex with you?
Y	22A	<input type="checkbox"/>	At any time since 1977, have you taken money or drugs for sex?
Y	22B	<input type="checkbox"/>	In the past 12 months, have you had sex, even once, with anyone who has taken money or drugs for sex?
Y	23A	<input type="checkbox"/>	Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?
Y	23B	<input type="checkbox"/>	In the past 12 months, have you had sex, even once, with anyone who has used a needle to take drugs not prescribed by a doctor?
Y	24	N	Male donors: Have you had sex with another male, even once, since 1977?
Y	25	<input type="checkbox"/>	Female donors: In the past 12 months, have you had sex with a male who has had sex, even once, since 1977 with another male?
Y	26A	<input type="checkbox"/>	Have you ever taken clotting factor concentrates for a bleeding problem, such as hemophilia?
Y	26B	<input type="checkbox"/>	In the past 12 months, have you had sex, even once, with anyone who has taken clotting factor concentrates for a bleeding problem such as hemophilia?
Y	27A	<input type="checkbox"/>	Do you have AIDS or have you had a positive test for the AIDS virus?
<input checked="" type="checkbox"/>	27B	N	In the past 12 months, have you had sex, even once, with anyone who has AIDS or has had a positive test for the AIDS virus?
Y	28	<input type="checkbox"/>	Are you giving blood because you want to be tested for HIV or the AIDS virus?
<input checked="" type="checkbox"/>	29	N	Do you understand that if you have the AIDS virus, you can give it to someone else even though you may feel well and have a negative AIDS test?
Y	30A	<input type="checkbox"/>	Were you born in, have you lived in, or have you traveled to any African country since 1977?
Y	30B	N	When you traveled to <country(ies)> did you receive a blood transfusion or any other medical treatment with a product made from blood?
Y	30C	<input type="checkbox"/>	Have you had sexual contact with anyone who was born in or lived in any African country since 1977?
Y	31	<input type="checkbox"/>	In the past 12 months, have you been in jail or prison?
<input checked="" type="checkbox"/>	32	N	Have you read and understood all the donor information presented to you, and have all your questions been answered?

Accepted Deferred

Signed _____

Comments: Q10C. He took some tablet but not sure about aspirin. Q27B. Don't know Overall Donation Comments: Donor deferred for donation

Fig. 3. Sample 46-question QDS donor form print with socially sensitive and stigmatizing questions indicated by shading. This 46-question version of the questionnaire was replaced in summer 2002 by a version with 52 questions, which include questions to screen for variant Creutzfeldt-Jakob disease. The 52-question version was used through the end of 2002.

donors to move to the next question or return to a prior question for completion or correction. Screens were displayed simultaneously with a verbatim audio presentation of the text.

Research studies

Current studies consisted of two types: 1) surveys of donors following completion of the automated interview and of staff members once they were experienced with the

AVT-CASI system and 2) comparative studies of three prospectively identified outcomes from use of the AVT-CASI and FTF systems conducted at one or more fixed collection sites characterized by approximately 90 percent repeat whole blood or apheresis platelet (PLT) donors. Full implementation of the AVT-CASI system at each fixed collection site occurred within a few days, thereby negating any opportunity for simultaneous collection of outcome measures for both systems at one collection site. Because unmeasured donor differences between sites may have existed, biasing study outcomes, the decision was made to use historic controls from the same sites wherever possible. This was done for two of the three studies: interview time and deferrals for high-risk behavior. Only the errors and omissions study was performed with simultaneous intersite data collection because of the large volume of control and experimental data required. The focus of the latter study was the frequency of staff errors and omissions resulting from administering each of the interviewing methods. Staff training in use of the methods was identical (according to center SOP), so whatever staff related intersite biases that might have existed should have been minimized by the large volumes of data involved in the study.

Other possible study outcome measures were considered, including postdonation information reports and viral marker rates. Differences were either not significant (postdonation information rates and all viral markers, data not shown) or too small to assess significance on reasonable sample sizes (confirmed viral markers). For example, among first-time donors and repeat donors analyzed at the main collection site, no confirmed human immunodeficiency virus (HIV), hepatitis B virus, or hepatitis C virus infection was found among all donors in the interval studied before implementation of the AVT-CASI. Combined confirmed infection rates for those three markers after implementation were 1.6 in 1000 and 0.3 in 1000, respectively, for first-time and repeat donors ($p = 0.083$, Fisher exact). Such large differences in viral marker rates between new and repeat donors are typical of donors as shown by Dodd and others³ with much larger populations.

Donor and staff surveys

Five separate postdonation surveys involving a total of more than 1500 AVT-CASI donors were conducted at the center's main collection site and two satellite sites over a period of several months during the summer and fall of 2001 with a survey instrument virtually identical to that used for the pilot study. Two of the five surveys were site replicates undertaken to determine if donor opinions about the two systems changed upon repeat use of AVT-CASI, especially time required for completion of the interview. In addition 21 of the 22 staff members, then experienced in use of the AVT-CASI system, were sur-

veyed in September 2001 regarding their impressions of the system. Both donor and staff surveys included questions comparing AVT-CASI to the prior FTF interviewing system with a 5-point preference scale. Scores of "1 or 2" were favorable to AVT-CASI, "4 or 5" were favorable to FTF, and "3" indicated no preference for either approach.

Time studies

Time required for donors and staff members to complete the health history interview with the FTF or AVT-CASI systems was deemed important in assessing system effects on donor satisfaction and operational efficiency. FTF time studies were conducted at the center's main collection site, the largest in the regional system. They were carried out by a staff member experienced with the center's FTF interview process immediately before AVT-CASI installation at the site in summer 2001. Two routine half-day collection sessions were selected, morning and afternoon, and 30 FTF interviews consisting of a typical mix of whole-blood and apheresis PLT donors were timed. Individual interview times were recorded, summed, and averaged to determine estimated total time required for a typical FTF interview. AVT-CASI times were derived from data on 1532 consecutive whole-blood and apheresis PLT donor interviews recorded in the AVT-CASI research database at the same collection site as the FTF control immediately following installation of the AVT-CASI system at the site. The database, which created a timed file for each donor interview, allowed determination of time required for the total interview and for each of its three component parts: self-interview, donor waiting, and staff review. Individual times for the three component parts were averaged to obtain estimated mean time required for each part and then totaled to secure estimated total time for a typical AVT-CASI interview.

Deferrals for high-risk behaviors

Analysis of differences in the frequency of donor deferrals for admissions of high-risk behavior was based on first-time donor responses to 15 socially sensitive and stigmatizing questions on the UDHQ. The questions involved are shaded on the donor questionnaire form shown on Fig. 3. Deferrals of repeat donors were not included because of their extremely low frequency. As with the time study, this study was performed with data gathered at the center's largest, fixed collection site. Use of a historic comparison between control and experimental outcomes at a single site was deemed the best means of minimizing whatever intersite biases might have existed. Control data were collected from 890 first-time donors interviewed FTF at the collection site during the 12-month period preceding QDS installation in 2001. Experimental data were collected

TABLE 1. Donor satisfaction survey scores, 2001*

Characteristic	QDS-favorable donors, Scores 1 + 2	QDS-neutral donors, Score 3	QDS-unfavorable donors, Scores 4 + 5	Ratios of numbers of QDS-favorable to QDS-unfavorable donors (1 + 2) to (4 + 5)
A. All donors				
1. Clarity	1379 (91.8)	17 (1.1)	106 (7.1)	13.0
2. Privacy	1388 (92.3)	19 (1.3)	97 (6.4)	14.3
3. Truthfulness	1008 (67.7)	370 (24.9)	110 (7.4)	9.2
4. Time involved	1302 (86.9)	115 (7.7)	82 (5.5)	15.9
B. Repeat donors				
1. QDS vs. staff	968 (68.3)	304 (21.5)	145 (10.2)	6.7
2. Understanding	524 (37.1)	832 (59.0)	55 (3.9)	9.5
3. Likelihood of return	602 (43.6)	723 (52.4)	56 (4.1)	10.8

* Data are reported as number (%).

from 1849 first-time donors interviewed by AVT-CASI at the same site during the 18-month period immediately following AVT-CASI installation. The shorter length of time for collection of FTF data was the result of limited data availability.

Staff errors and omissions

Staff errors and omissions occurring during the interviews were detected by audit of every donor history card upon completion of the donation process. Such errors and omissions resulted in quarantining involved blood units before labeling until errors or omissions were corrected. If uncorrected, quarantined units were discarded. Experimental data on the number and frequency of errors and omissions resulting from AVT-CASI interviews at the center's main collection site during a 1-year period in 2001 to 2002 were compared with control data on the same outcomes from FTF interviewing during the same time period at other fixed collection sites in the center's system.

Statistical analysis

Statistical significance of differences in outcome frequencies was assessed with the two-sided chi-square or Fisher's exact tests and odds ratios as appropriate with computer software (Epi-Info 2002, CDC, Atlanta, GA).

RESULTS

Donor satisfaction

All donors, first time and repeat, found the automated system (sums of 1 + 2 ratings) to be clear (91.8%), private (92.3%), more likely to elicit more truthful responses than FTF interviewing (67.7%), and satisfactory with regard to the time required to complete the interview (86.9%) (Table 1). The latter compared with only 64.0 percent of

donors surveyed in the pilot study.¹ Among repeat donors (Part B), a majority expressed a preference for the AVT-CASI system (68.3%) over FTF interviewing (10.2%) compared with only 40.7 percent versus 23.9 percent in the pilot study. On the remaining two system characteristics, understanding the questions and likelihood of return for subsequent donation, a majority of repeat donors in both studies believed that the two methods were equally effective. Among repeat donors in the two studies, who expressed a preference for one interviewing method or the other, AVT-CASI was preferred on all three characteristics by ratios ranging from 1.8:1 to 9.3:1 in the pilot and 6.7:1 to 10.8:1 in current studies.

In the current study, repeat surveys of donors with previous exposure to AVT-CASI yielded virtually identical results to those obtained from the initial surveys at the same sites (Table 2). Although no marked differences were found between donor responses to the seven survey questions on initial and repeat surveys, on every question on the repeat surveys, time included, responses of donors previously exposed to AVT-CASI were more favorable than those of donors newly exposed to the system. Preference ratios (i.e., the ratio of numbers of donors scoring 1 or 2 on a question to those scoring 4 or 5 across the seven survey variables) ranged from 5.5:1 to 14.5:1 for first exposure donors whereas those for prior exposure donors ranged from 7.9:1 to 20.6:1.

Staff surveys

Results of the staff survey are summarized in Fig. 4. More than three-quarters of staff members surveyed found the AVT-CASI system faster for staff and personally more satisfying and projected that there would be fewer staff errors with AVT-CASI. Only with respect to time required by donors to complete the AVT-CASI interview did staff report the AVT-CASI system at a disadvantage. In all other respects a majority of staff indicated a preference for the computer-assisted system.

TABLE 2. Replicative donor satisfaction surveys: summary comparison of responses to interview questions by donors exposed to QDS at two fixed sites for first-time versus donors previously exposed to QDS (2001)*

Questions	QDS-favorable donors, Scores 1 + 2		QDS-neutral donors, Score 3		QDS-unfavorable donors, Scores 4 + 5		Ratios of numbers of QDS-favorable to QDS-unfavorable donors (1 + 2) to (4 + 5)	
	First exposure	Prior exposure	First exposure	Prior exposure	First exposure	Prior exposure	First exposure	Prior exposure
	A. All donors							
Clarity	692 (91.7)	517 (93.2)	7 (0.9)	8 (1.4)	56 (7.4)	30 (5.4)	12.4	17.2
Privacy	696 (92.4)	518 (93.3)	9 (1.2)	8 (1.4)	48 (6.4)	29 (5.2)	14.5	17.9
Truthfulness	482 (64.4)	382 (69.6)	202 (27.0)	130 (23.7)	64 (8.6)	37 (6.7)	7.5	10.3
Time involved	636 (84.7)	494 (89.0)	68 (9.1)	37 (6.7)	47 (6.3)	24 (4.3)	13.5	20.6
B. Repeat donors only								
QDS vs. Staff	493 (63.7)	404 (73.2)	192 (24.8)	97 (17.6)	89 (11.5)	51 (9.2)	5.5	7.9
Understanding	279 (36.1)	214 (38.8)	458 (59.3)	319 (57.9)	35 (4.5)	18 (3.3)	8.0	11.9
Likelihood of return	320 (42.0)	243 (45.5)	404 (53.0)	274 (51.3)	38 (5.0)	17 (3.2)	8.4	14.3

* Data are reported as number (%).

TABLE 3. Time studies—manual (FTF) and automated (QDS AVT-CASI) donor interviewing

Interview mode	Number	Mean elapsed time (min)				Total donor time	Total staff time
		Self-interview	Wait for staff	Staff review			
AVT-CASI	1532	6	2.8	2.4	11.2	2.4	
FTF	30				7.4	7.4	
Time difference					3.8	-5.0	

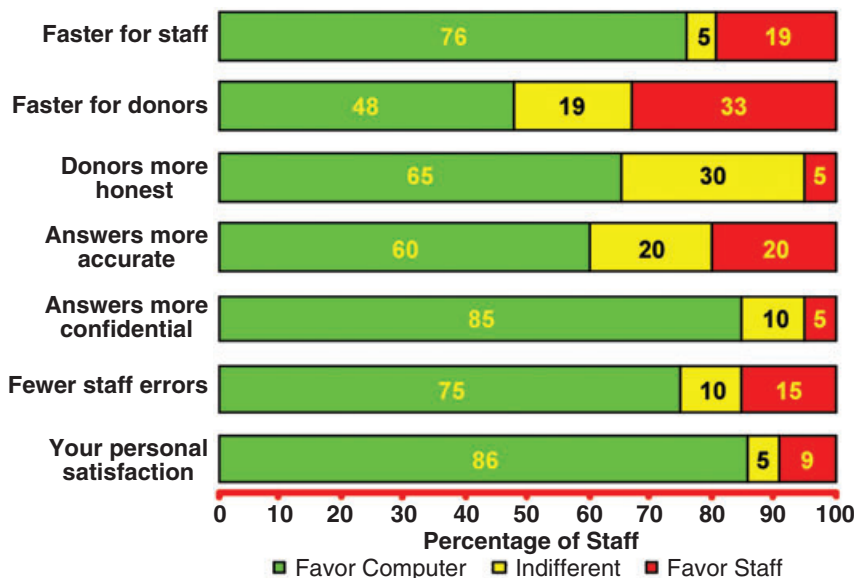


Fig. 4. 2001 QDS staff satisfaction survey results (n = 21 of 22).

Time required

Table 3 summarizes mean times required by donors and staff to complete the AVT-CASI and FTF interviews at the center’s main collection site. Because the FTF interview required donor and staff to be involved constantly throughout the process, the mean time required of

7.4 minutes per interview was the total time required for both donor and staff. AVT-CASI interviewing, however, entailed a donor self-interview with staff involvement only during subsequent review. The mean total time for an AVT-CASI interview was 11.2 minutes divided among time required for donor self-interviewing (6 min), donor waiting for staff to review the interview (2.8 min), and staff review (2.4 min). As a result, the entire AVT-CASI interview required an average of 3.8 minutes more per donor than the FTF, but 5.0 minutes less per staff member.

Deferrals for high-risk behaviors

Table 4 summarizes the numbers and frequency of aberrant responses by FTF and AVT-CASI interviewed first-time donors following staff review of their responses to the 15 UDHQ questions regarding socially sensitive or stigmatizing behavior at the center’s main collection site during the two study periods. During a 1-year period in 2000 to 2001 only one first-time donor interviewed by FTF admitted engaging in such behavior, a rate of 1.12 high-risk first-time donors admis-

TABLE 4. Deferrals of first-time donors for high-risk behaviors*

Period	FTF	AVT-CASI
	May 21, 2000-May 20, 2001	May 21, 2001-December 30, 2002
Number of high-risk deferrals	1	19
Number of total first-time donors	890	1849
Rate per 1000 donors	1.12	10.28

* Deferrals for HIV and sexually transmitted disease, excluding tattoos, body piercing, and other blood exposure. $p = 0.017$; OR, 9.15; 95% CI, 1.3-183.8.

TABLE 5. Errors and omissions* in automated (QDS AVT-CASI) vs. manual (FTF) donor interviews

	Number of interviews		
	AVT-CASI	FTF	Total
Interviews with error or omission	20	250	270
Error-free interviews	13,542	65,934	79,476
Total	13,562	66,184	79,746
Error rate per 1000 interviews	1.475	3.777	3.386
Decline in error rate	61%		

* Errors and/or omissions include missed signatures, questions, vital signs, or documentation of responses or deferral codes. Two-sided $p = 0.00004$ (chi square). OR, 0.39; 95% CI, 0.24-0.63.

sions per 1000 interviews. In the succeeding 18.5-month period in 2001 to 2002 following implementation of the AVT-CASI system, 19 first-time donors admitted to such behavior, a rate of 10.28 admissions per 1000 interviews, 9 times the FTF rate. All but 1 of the AVT-CASI interviewed donors were men who admitted to having sex with men, the exception being a donor who admitted to prior injection drug usage. The difference in rates was significant ($p = 0.017$; odds ratio [OR], 9.15; confidence interval [CI], 1.3-183.8).

Staff errors and omissions

Errors and omissions data are summarized in Table 5. A total of 20 errors and omissions were detected upon audit of the 13,562 donor cards resulting from AVT-CASI interviews at the center's main collection site during the 1-year study period in 2001 to 2002, a frequency rate of 1.5 per 1000, compared with 250 errors or omissions found among 66,184 audited donor history cards from FTF interviews at other center collection sites during the same period, a frequency rate of 3.8 per 1000. This 61 percent decline in the rate of occurrence of errors and omissions resulting from use of the AVT-CASI system was significant ($p = 0.00004$ [chi-square], OR, 0.39; 95% CI, 0.24-0.63).

DISCUSSION

Considerable evidence exists that computer-assisted self-interviewing is superior to other interviewing methods in

eliciting a higher frequency of truthful answers to sexual and other socially sensitive questions and in reducing the frequency of staff errors and omissions during the interview process. CASI effectiveness in securing truthful answers to sensitive questions was established earlier by behavioral science research and summarized in the pilot study publication.¹ Of special interest was the work of Turner and colleagues⁴ who demonstrated improved elicitation of reporting such behaviors with audio-CASI (A-CASI) compared to paper interviews. They reported the admission of high-risk behavior among audio-CASI interviewees of up to 17 times higher than those obtained from self-administered paper surveys. More recent literature supports these findings. Sellors and associates⁵ in comparing a computerized handheld CASI instrument to a standardized paper-and-pencil self-administered questionnaire found a higher incidence of reporting risky behavior with CASI than paper.⁵ Newman and coworkers⁶ reported that audio-CASI elicits more frequent reporting of "stigmatized behaviors" than does FTF interviewing. Cooley and associates⁷ with audio-touch screen-CASI to obtain data on sensitive topics from a sample of 108 subjects found that twice as many subjects preferred audio-touch-screen-CASI as did either those favoring key pads or FTF interviewing, concluding that audio-touch screen-CASI has the potential to "yield more accurate recording of responses." Other investigators including Norris and Galea,⁸ Johnson and colleagues,⁹ Thornberry and colleagues,¹⁰ and Willis and colleagues¹¹ reported similar findings. Williams and Orton¹² provide a good summary of the interplay among behavioral science research, donor interviewing methods, and computer-assisted donor screening concluding its advantages made its "growth inevitable."¹²

A low level of health literacy among a substantial proportion of the US population is a problem receiving increased attention by the medical profession. In a recent article Al-Tayyib and coworkers¹³ based on a probability sample of 1014 Baltimore, Maryland, adults aged 18 to 45 years, with the Rapid Estimate of Adult Literacy in Medicine (REALM) instrument found that 18 percent of subjects with "some college or a 2-year degree," a literacy level often cited as typical of blood donors, were reading at 8th grade or below levels.¹³ In December 2003, the Blood Products Advisory Committee of the FDA accepted the stream-

lined UDHQ encompassing both short and long donor questionnaires and new educational materials aimed, in part, at simplifying the language of the health history questionnaire to improve donor understanding. The problem of low literacy levels and its potential impact on donor understanding of medical information emphasizes the potential value of audio and color illustration, as used in AVT-CASI systems, in presentation of interview questions. In addition a Spanish language version of this system is available, and the system is capable of programming in any language.

Survey results demonstrated a high degree of satisfaction among center donors on first and subsequent exposures to AVT-CASI interviewing. Results from these surveys are broadly consistent with findings from the anonymous Retrovirus Epidemiology Donor Study 1998 mail survey conducted by Sanchez and colleagues.¹⁴ Donors from eight blood centers, none of whom had experienced computer-assisted health history interviewing, were questioned about their attitudes regarding computer-assisted interviewing. Twenty-nine percent of donors with behavioral risks for transfusion-transmitted infections believed that they would be more likely to divulge relevant behaviors. In contrast, 5 percent of donors without such risk thought they would be discouraged from donation. The authors concluded, "(t)he potential for CASI to improve donor screening and increase appropriate self-deferrals should be balanced against the possible loss of reluctant safe donors." No evidence was found in the literature, the pilot study, or the current studies to support such a statement. Unpublished CBER sponsored CASI research on blood donors from more than 10 years ago also provided no reason for concern about losing donors. Only two pilot study donors refused to use the automated interviewing system for reasons of time involved. Only one current study donor refused to use the AVT-CASI system. Because of these studies, the QDS version of AVT-CASI has been implemented at two more regional blood centers with only one donor refusal reported. (P.D. Cumming, personal communication with Marie Broy, RN, of Lifeblood/Mid-South Regional Blood Center, Memphis, TN, and Joseph V. Schifano, CEO, West Tennessee Regional Blood Center 2003, Jackson, TN. After six months or more, Ms. Broy reports one donor refusal to use the QDS [January 19, 2004] and Mr. Schifano [January 20, 2004], none. West Tennessee has been 100% QDS donor screening since the summer of 2003.)

Based on existing evidence, including that presented here, the most effective method for health interviewing of donors would include an audio component to minimize the effects of illiteracy and enhance the perception of privacy, a visual component for improved comprehension, and a touch-screen mode for ease in responding to interview questions in private, all attributes present in the AVT-CASI system used in the current studies.

A major advantage of AVT-CASI as shown by the current studies was its ability to control the interview process thereby ensuring elicitation and recording of all required information before the donor card could be produced and the donor advanced to phlebotomy thus substantially reducing the incidence of interview-related errors and omissions. Center management estimated the reduction in donor processing errors and omissions achieved with AVT-CASI to be approximately 70 percent of the total potential. The remaining approximately 30 percent occur because of inappropriate documentation of the donor examination or history, vital signs, and phlebotomy functions. Enhancements currently being developed for QDS that include these functions should eliminate most residual staff errors and omissions other than staff reviewers' documentation of aberrant responses. Although current studies did not include direct measurement of the value of savings from elimination of staff errors and omissions, Cunningham¹⁵ has estimated an annual direct cost of \$87,280 at their blood center for errors of documentation occurring during donor screening, concluding that automated donor screening should be considered as a means of preventing such errors, with the resultant cost saving to defray the cost of automation.

Improved donor satisfaction with the time required for the AVT-CASI system interview relative to that required during the pilot study can be attributed to technical improvements in the system, especially repeat donor-controllable audio made possible by revised CBER requirements. During the pilot study, donors were required to listen to a complete audio reading of each question plus a 1.5-minute reading of the informed consent agreement. In the current studies, donors who had previously used the system were required to listen to a minimum 2 seconds of audio on each question, during which text and pictures were also displayed, following which they were permitted to answer the question, thus truncating audio, and move to the next question. As shown in Table 6 reduction of the audio requirement and elimination of the informed consent reading requirement reduced total donor time by 3 min even though the number of interview questions increased. The mean time required for a donor to complete the AVT-CASI interview was 3.8 minutes longer than for an FTF interview, yet 87 percent of the donors found this satisfactory. Also shown in Table 6 are results from a study by Ollech and Snowden¹⁶ of time required by a partially self-administered written history questionnaire that reported increased donor satisfaction despite longer actual screening times.

We believe that staff satisfaction with the automated interview was high as a result of two factors: design of the system and center management actions in introducing and implementing QDS. The system was designed to simplify donor and staff use of it. A few screens of instructions

TABLE 6. Average time (min) required for staff-administered donor interviews at three regional blood centers compared with time required for AVT-CASI or paper interviews at the same centers

	Blood Centers		
	Hoxworth* 1999	MVRBC† 2001	Dayton‡ 2002
Number of questions	30	46	22 of 46§
Staff time for manual history	5	7.4	14
Questionnaire media	Custom QDS	UDHQ QDS	Paper
Donor alone	10	6	6
Donor waiting for staff	2	3	NA
Donor with staff	2	2	12
Total donor time	14	11	18
Donor time increase	9	4	4
Staff time saved	3	5	2

* Hoxworth data from center staff study of 25 manually processed donors July 1999 plus QDS machine readable database.¹

† Mississippi Valley Regional Blood Center data from center staff study of 30 donors July 2001 and QDS machine readable database.

‡ Ollech and Snowden.¹⁶

§ 22 of 46 questions are donor self-administered via a paper form.¹⁶

|| "Baseline . . . time . . . from registration to the phlebotomy area . . . was 14 minutes." Probably includes vital signs and may include registration. Vital signs time is often estimated at 5 minutes or less.

with audio at the beginning of the donor module were all the instruction donors needed. The staff module was equally simple requiring only 2 to 3 hours of training. System design also facilitated the addition, deletion, and change in UDHQ questions. New questions required during 2003 were added to the existing system within 7 days. The rate-limiting steps for their implementation were installations on multiple stand-alone stations and retraining staff members in FTF interviewing required in case of equipment failure.

Center management facilitated the introduction of AVT-CASI in advance of implementation by providing staff with a system module and encouraging them to experiment with it in a private setting. This hands-on self-training conveyed to staff the ease of use and potential effectiveness of the system. Several staff members "championed" the system, articulating its purposes: more efficient and effective donor screening. At the same time, management made known its policy of no AVT-CASI-related staff reductions, preferring instead to use the time saved to better manage donors during and after phlebotomy.

Prospective donors who have engaged in high-risk behaviors constitute a risk to the blood supply if infectious donations are missed during serologic or nucleic acid windows, if variant pathogens are not detected by testing when a chronic test negative state may exist, or as a result of testing errors. In addition, there are infections for which no tests are performed (e.g., malaria, babesiosis, and Chagas' disease). Health history interviewing is a primary means of reducing these risks. Williams and coworkers¹⁷ estimated that donors underreport high-risk behaviors by 2 percent. In 2001, Blood Product Deviation reports

recorded some 30,000 such errors of 15,000,000 plus blood donations, a rate of 0.2 percent. The current studies found a significant increase in the frequency with which donors admitted to socially sensitive and stigmatizing behavior when interviewed by AVT-CASI compared with FTF. An analysis was attempted to determine if this was the result of system-enhanced donor memory with pre- and postimplementation frequencies of postdonation information about travel to potentially malaria endemic areas (data not shown). Improved recall was not demonstrated. The phenomenon appears to be the result of a complex of technological and psychological factors inherent in the impersonal, nonjudgmental aspects of computer-assisted self-interviewing in a private setting with audio and visual aids to clearly define the behavioral question.

CONCLUSIONS

AVT-CASI donor interviewing of the type described here has advantages for blood collecting organizations. Interviews are standardized; thus, presentation is identical from interview to interview. Interviews can be presented in any written and spoken language. Simultaneous audio and pictorial presentation may compensate for literacy deficiencies of donors and has been previously demonstrated to increase donor comprehension. Electronic control of interview information reduces donor and staff errors of omission by requiring strict adherence to center SOPs throughout the interview. In addition, electronic transfer of interview information to center backroom systems is technically feasible, a further guarantee of compliance with good manufacturing practice.

At present similar implementations of the QDS are complete or under way at three other regional blood centers with concurrent research being conducted to validate and enhance findings from the current studies.

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