

Computer-Based Blood Donor Screening: A Status Report

Louis M. Katz, Paul D. Cumming, and Edward L. Wallace

There is a substantial literature suggesting that computer-assisted interviewing has advantages over face-to-face and written self-administration of interviews in venues eliciting sensitive information similar to that sought in blood donor history screening. We review some of the recent developments in blood donor history screening, the evidence suggesting that automated interviews should be useful, and the experience to date using computer interviews for blood donation. These data

suggest that automated computer-assisted interviewing increases the elicitation of behaviors associated with the risk of transfusion-transmissible infection in donors, improves donor and staff satisfaction, and reduces errors and omissions that frequently accompany traditional interviewing methods. Food and Drug Administration–cleared systems for computer-assisted self-interview of blood donors are briefly described.

© 2007 Elsevier Inc. All rights reserved.

ASSURANCE OF A safe supply of allogeneic blood and blood products is the primary driver of activity in blood services. Interventions with extremely high cost-benefit ratios are now common. For example, introduction of nucleic acid testing in minipools for HIV and HCV in the late 1990s reduced the risks of transmission of these pathogens in transfused, tested allogeneic blood to 1:1.8 million and 1:1.6 million, respectively, leaving only small test-negative window period risks for these agents.¹ Small infectious risks remain, as evidenced by 2 blood recipients recently infected with HIV from a nucleic acid–tested whole blood donation.² There are, in addition, a host of other infections—protozoan, bacterial, viral, and prion—which are transfusion-transmissible for which no tests are currently available.³ Protection of the allogeneic blood supply from traditional transfusion-transmissible diseases (TTD); from emerging or reemerging TTDs; and particularly from the window period residual risks for HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV) depends on the effectiveness not only of laboratory screening of volunteer blood donors but also on efforts to minimize the recruitment and phlebotomy of high-risk donors.

High-risk volunteer donors are persons who (i) have a history of TTDs or have engaged in behaviors, especially sexual practices or parenteral drug use, known to be associated with TTDs and/or have close contact with others with TTDs; (ii) have traveled to or resided in locations where TTDs are prevalent; or (iii) have risky health histories, for example, prior infection, recent transfusion, or receipt of plasma derivatives associated with an appreciable incidence of infection. Screening is the

process by which blood collecting organizations identify and defer high-risk donors to avoid introducing TTDs into the allogeneic blood supply. It is a multistep process involving recruitment of safe donors, provision of up-to-date donor education materials, checking for in-force prior deferrals, a mini-physical examination with elements focused on stigmata of parenteral drug use, and a health history interview preceding phlebotomy. Like laboratory testing, donor history screening has improved substantially in recent years because of efforts by the blood community to recruit, identify, and retain low-risk donors and by more active federal involvement and regulation of the whole blood and blood products collection and distribution process. As a result, the prevalence of HIV, HBV, and HCV infections among first-time blood donors are 3%, 14% and 13%, respectively, of those in the US population.⁴ There remains room for improvement, as evidenced by the finding that 2% of volunteer whole blood donors reported deferrable high-risk behaviors on an anonymous postdonation survey.⁵

From Medical Affairs, Mississippi Valley Regional Blood Center, Davenport, IA; Talisman Ltd., Vienna, VA; and Center for Management Systems, Naples, FL.

This study was supported by The National Heart Lung and Blood Institute Small Business Innovation Research grant no. HL072635 (Paperless Quality Donor System with Decision Making).

Address reprint requests to Louis M. Katz, MD, Executive Vice President, Medical Affairs, 5500 Lakeview Parkway, Davenport, IA 52807.

0887-7963/07/\$ - see front matter

© 2007 Elsevier Inc. All rights reserved.

doi:10.1016/j.tmr.2006.08.001

BRIEF HISTORY OF BLOOD TESTING AND DONOR SCREENING

Forty years ago as many as 1 in 4 transfused patients developed viral hepatitis. In the late 1960s, some 69% of all open heart surgery patients at the National Institutes of Health Clinical Center acquired hepatitis from transfused blood.⁶ Introduction of the first generation hepatitis B surface antigen (HBsAg) test in 1970 reduced the rate to 7%.⁶ Movement toward an all-volunteer whole blood supply in the 1970s further increased public confidence in the safety of allogeneic transfusion.⁷ The transfusion-AIDS crisis in the early and mid 1980s, however, destroyed that public trust. Although new or additional blood tests for HIV, HBV, and HCV introduced in the mid to late 1980s and early 1990s constituted major advances in protection of the allogeneic supply, all were traditional serologic tests with substantial seronegative window periods associated with residual risk of transfusion-associated infection (~1:225 000; 1:50 000, and 1:3 300 for HIV, HBV, and HCV, respectively).⁸

As public confidence in the safety of the allogeneic blood supply fell in the early 1980s, in the absence of effective laboratory screening for HIV and posttransfusion non-A and non-B hepatitis, the transfusion medicine community began serious efforts to recruit and screen low-risk donors using nonlaboratory methods. By 1983, evidence from the Centers for Disease Control that HIV was a TTD convinced the American Association of Blood Banks (AABB), American Red Cross, and the Council of Community Blood Centers (now America's Blood Centers) to initiate education and questioning of blood donors about their behaviors and experiences that were epidemiologically associated with HIV infection. Gay organizations were asked to discourage members from donating. Donors were given information about recognized risks and asked to self-defer if they self-identified as having risk⁹ (men having sexual contact with multiple male partners, IV drug use, Haitian origin, hemophilia treatment with factor concentrates manufactured from large paid donor pools, and sexual contact with persons with these characteristics). For reasons of assumed donor sensitivity and uncertainty about the magnitude of the AIDS threat, the 3 organizations initially did not recommend using direct questions regarding donors' sexual practices.⁹ In 1985, after introduction of the first serologic test for HIV, some blood service

organizations began direct questioning of male donors for male-to-male sexual activity, whereas other blood-collecting organizations introduced the test without amending their health history screening.⁹ Direct questioning of donors for HIV risk was not formally required in the United States until February 1991.

Throughout the early AIDS era, the US Food and Drug Administration (FDA) worked cooperatively with the principal organizations and professional associations of the whole blood and blood products sector to regulate the transfusion medicine community through consensus. This changed abruptly in 1992 when the FDA imposed strict regulations (current good manufacturing practices [cGMP]), similar to those required of pharmaceutical manufacturers, on the blood collecting community. Among cGMPs was development of health history questionnaires including FDA-mandated questions on high-risk behaviors to be asked of every donor at every donation.

HEALTH HISTORY QUESTIONNAIRE

A primary goal of appropriate donor recruitment and screening is to select and retain donors whose characteristics predict a low incidence and prevalence of TTDs. Retrospective studies of blood donors infected with HIV or hepatitis viruses have repeatedly shown many to have recognizable behavioral risks, which, when disclosed, justify their deferral.¹⁰⁻¹² Within the past several years, effort has been expended to standardize the donor history questionnaire (DHQ) and to secure approval for it from the FDA. American Association of Blood Banks, which authored the first uniform DHQ (UDHQ) in 1993 developed, through its Interorganizational UDHQ Task Force, new long and short form UDHQs and submitted them to the FDA for approval. In 2004, the FDA approved the new long form UDHQ as a substitute for the old UDHQ or for any of the many customized health history questionnaires previously approved by the FDA for use in individual collection facilities.¹³ To date, however, the FDA has withheld approval for the new short form UDHQ, intended for frequent repeat donors, pending review of findings from ongoing studies of its performance.

Current health history questionnaires used in the blood community include facility-specific DHQs and a mix of AABB's old and new UDHQ. All, as a condition of facility licensure, are approved by

the FDA and supported by standard operating procedures (SOPs) that describe how each step in the donor interview is to be conducted and how various responses by donors to each question are to be treated, including criteria for acceptance or temporary and indefinite (ie, permanent) deferrals.

In recent years, the blood community has used donor education materials and the health history questionnaire as the initial means of protecting the blood supply from emerging and potential TTDs, for which tests are not available. For example, in 2002, the FDA mandated inclusion of additional questions intended to identify donors with past activities, residence, or travel suggesting the possibility of exposure to variant Creutzfeldt-Jakob Disease. In 2003, more questions were added about exposure to smallpox vaccine (vaccinia), severe acute respiratory syndrome, and West Nile Virus.¹⁴ As a result, the number of questions on the original AABB UDHQ increased to 61. The new long form UDHQ consists of 49 questions that were redesigned with input from cognitive scientists, using focus groups and cognitive interviews, to improve the ability to elicit the targeted information.

MODES OF ADMINISTERING THE DHQ

Historically blood-collecting organizations have administered the DHQ by having their staff ask each donor the questions in a face-to-face interview (FTFI) or using written donor self-administered questionnaires (WSAQ). Eligibility or deferral is determined based on the responses to each question. Staff is guided by current SOPs or, when directed by organizational SOPs, by consultation with the facility medical director or a trained designee. More recently, some organizations have adopted various computer-assisted donor interviews ranging from staff administered questionnaires, with the staff entering donor responses into a system, to more complex computer-assisted donor self-interviewing (CASI) systems using text, often with combinations of audio and/or visual prompts. This array of methods to administer the donor health history has prompted questions about their comparative effectiveness and efficiency. When selecting a mode, blood-collecting organizations have the task of evaluating 3 considerations: safety, efficiency, and costs. Each screening approach has certain advantages and disadvantages in each of the 3 dimensions.

Of the 3 modes, FTFI, WSAQ, and CASI, the latter varies the most. In its simplest form, CASI is conducted on a stand-alone computer with text questions displayed for reading on the monitor and answers entered by the respondent using a keyboard, keypad, or mouse. Audio presentation of the interview questions can accompany eye-readable text to improve understanding over text only. Further enhancements of the basic CASI system include pictures illustrative of the content of the question; response inputs via touch screen; inclusion of back, help, and skip commands to improve accuracy and completeness of responses, staff review modules for assessment of completed DHQs, direct printing of the DHQ with provision for signatures, and electronic transfer of final interview data to other associated computer systems.

EFFECTIVENESS OF THE 3 MAIN INTERVIEWING MODES

Survey interviewing is a common technique in behavioral research. Consequently, behavioral researchers have a long-standing interest in evaluating the ways these interviews are conducted, especially their effects on the accuracy of subject responses to interview questions. Since the late 1960s, survey researchers have investigated the relative effectiveness of various forms of computer-assisted interviewing, primarily CASI or audio CASI (A-CASI), as alternatives to FTFI and WSAQ for eliciting accurate responses to interview questions. In 1996, Weisband and Kiesler¹⁵ reported a meta-analysis of 39 comparative studies from the social sciences, computer sciences, and medical literature between 1969 and 1994. They found that computer-assisted interviewing was significantly more effective than FTFI and WSAQ, especially when the information sought was judged socially sensitive or stigmatizing. In 1998, Turner et al,¹⁶ studying adolescent high-risk sexual, drug use, and violent behaviors, reported them to be admitted up to 17 times more frequently when subjects were interviewed via A-CASI than by WSAQ. The following year, Richman et al¹⁷ reported a meta-analysis of 61 comparative studies conducted between 1967 and 1997. A key finding of this study was that "computer instruments reduced social desirability distortion (ie, increased frank, accurate responses) when...used as a substitute for face-to-face interviewing, particularly when...asking respondents to reveal highly sensitive behavior,

such as whether they used illegal drugs or engaged in risky sexual behavior.” Computer-assisted interviewing was significantly more effective than WSAQ when computer respondents were (i) assured anonymity, (ii) alone, and (iii) allowed to skip and backtrack on the computer. More recent literature supports these findings. Cooley et al¹⁸ reports that using touch-screen A-CASI (AT-CASI) to obtain sensitive information on sexual and illicit drug behavior from patients 15 to 39 years of age at a sexually transmitted disease clinic was more effective than traditional interview techniques. Johnson et al,¹⁹ in a recent study comparing the effectiveness of CASI with WSAQ to elicit information on high-risk sexual behavior in a general population, reported similar findings.

A few studies have actually involved blood donors. In 1992, Locke et al²⁰ reported a cross-over study that compared the effectiveness of the traditional written questionnaire plus FTFI with a CASI system using the standard American Red Cross health history questionnaire. Among 272 donors, the CASI system identified 12 reporting behaviors associated with HIV risk or symptoms compatible with AIDS, none of whom were identified when interviewed first by written questionnaire and FTFI. In 1993, the American Institutes for Research (AIR) conducted an extensive, complex cross-over study, contracted for by the FDA, comparing the effectiveness of existing WSAQ and/or FTFI interviewing with an AT-CASI system developed by AIR for donor interviewing.²¹ Of 7015 donors in the study, 27 (1.09%) of 2468 donors interviewed via computer were deferred for risky behavior, whereas only 23 of 4547 interviewed traditionally (0.51%) were rejected for similar reasons ($P = .00553$). The authors conclude that use of the computer alone would have identified more deferrals than the comparator interviews. FDA officials deemed the study inconclusive because study procedures did not permit determination of whether the observed outcome was the result of greater sensitivity of AT-CASI to identify high-risk behavior or lower specificity. More recently, Sellors,²² in a randomized cross-over study of donor deferral rates conducted at 133 blood clinics in Canada, compared a handheld computerized health history questionnaire with a written questionnaire. They found that 43.7% of deferrable donors were identified by the CASI but not by the written

questionnaire. In 2005, Katz et al²³ reported results of a before-and-after study of donor deferrals for high-risk behaviors among 2739 first-time blood donors at the Mississippi Valley Regional Blood Center. They found that only 1 of 890 (1.12 per 1000) such donors interviewed by FTFI between 2000 and 2001 was deferred, whereas 19 of 1849 (10.28 per 1000) donors interviewed using an audiovisual touch-screen CASI (AVT-CASI) between 2001 and 2002 were deferred, a significant difference ($P = .017$; odds ratio, 9.15; 95% confidence interval, 1.3-183.8). In a similar study using essentially the same system at another regional blood center, Cumming et al²⁴ found that with a combination of FTFI and WSAQ, the rate of deferrals of first-time donors for high-risk behavior was 5.8 per 1000, whereas after installation of an AVT-CASI system the rate increased to 11.2 per 1000, a 93% increase.

These data demonstrate that CASI is more effective than FTFI in eliciting positive responses to sensitive questions. It also appears CASI is more effective than WSAQ in this respect, although less so than when compared with FTFI. Behavioral researchers and others infer that the difference between FTFI and the other 2 modes of interviewing arises in part from privacy differences and from reduction of social desirability distortion (the tendency of respondents to provide information biased toward what they perceive as the socially accepted or desirable answer).^{15,17} Because CASI and WSAQ are quite similar in the privacy provided each interview subject, these researchers offered the following possible reasons why people disclose more when using a computer: computer interfaces create in respondents an inattention to audience; they provide for immersion in the immediate task along with invulnerability to criticism; they foster an impression that responses “disappear” into the computer; they give a sense of comfort leading to a less wary attitude; and there are other misattributions that cause respondents to be careless about their responses. Whatever the underlying mechanism(s), the weight of available evidence indicates that CASI is more effective than WSAQ in eliciting accurate answers to sensitive questions.

To what extent does the observed increased deferral of donors admitting to high-risk behavior by CASI actually protect blood safety? This depends mainly on the incidence (early, test-negative

infections) of TTDs among donors admitting such behavior to the computer but withholding the information when using other interview formats. From studies by Petersen and Doll,¹⁰ Conry-Cantilena et al,¹¹ and Murphy et al,¹² we can conclude that the elicited behaviors are useful indices of TTD risk, so the donors should be deferred. The studies that would be required to actually demonstrate a decrease in risk to transfusion recipients are too large to accomplish and unlikely to be undertaken.

OTHER CONSIDERATIONS

CASI systems have other characteristics that enhance their appeal for blood donor screening: (i) increased donor and staff satisfaction, (ii) potentially improved understanding by less literate donors when audio and/or visual prompts are incorporated, (iii) reduced donor and staff errors, and (iv) reduced staff time.

Donor and Staff Satisfaction

Blood bankers are acutely concerned with donor reactions to the screening interview. When interviewing of blood donors on their sexual, drug, and other socially sensitive behaviors was introduced, the intrusive nature and complexity of information sought during the interview provoked one blood banker to label the interview a “donor interrogation.”²⁵ To date, all studies of CASI systems for donor screening have included surveys assessing donor reactions to the interview format. Locke et al,²⁰ in their early study, reported that although donors believed CASI interviewing was as effective as FTFI for screening, they found it more private (39% vs 7%) and more likely (61%) to elicit honest responses. The AIR study reported that 53.5% of the donors preferred CASI for interviewing, whereas 64.4% felt it would yield more honest answers.²¹ More recently, Zuck et al²⁶ reported that 40% of the donors participating in a pilot study of an early version of an AVT-CASI system found the computer preferable, whereas 36% preferred the FTFI mode. Sixty-seven percent of donors believed donors would be more truthful when interviewed via AVT-CASI, although only 7% thought FTFI would yield more truthful information. Katz et al²³ reported that 68% of donors preferred the CASI system, whereas only 10% preferred the FTFI. In addition, 92% of donors were very satisfied with the privacy

provided by the system, and 68% felt it would elicit more truthful answers. One study, Sanchez et al,²⁷ has questioned increased donor satisfaction with and preference for CASI interviewing. Thirteen percent of the blood donors they surveyed about their hypothetical reaction to CASI screening stated such a system would either discourage them from donating (5.2%) or that they were unsure (8.0%). None of the donors in the study had actually used CASI screening, prompting Gillespie,²⁸ in an editorial commenting on the studies of Sanchez et al and Katz et al, to emphasize the importance of differentiating real and projected behavior and the importance of studying actual behavior in any scientific field. From these and similar studies,²⁹⁻³¹ it is reasonable to conclude that most donors and interviewees are more satisfied with CASI than FTFI. Moreover, as Katz et al²³ demonstrated, blood center staffs believe AVT-CASI is faster, personally more satisfying, and less likely to induce staff errors.

Donor Understanding

Comprehension of questions on the screening interview is essential. When donors fail to understand a question and answer it erroneously, the interview has failed. The ability of donors to understand medical and health-related questions is of particular importance for WSAQ and CASI because both assume donor literacy. There is substantial evidence that this assumption is overly optimistic. Wilson,³² in a summary of findings from 10 studies on literacy and health, concluded that most adults with poor literacy are adept at disguising their inability and disinclined to ask for help. The author cites the 1993 National Adult Literacy Study, which found that the average American reads at the eighth to ninth grade level, whereas most medical information found on the Internet is written at the 12th grade level. In an analysis of medical literacy among a randomly selected sample of 18 to 45 old-year-old adults in Baltimore, Al-Tayib³³ found that 28% had a literacy level of grade 8 or less and 12% of grade 6 or less. Eighteen percent of the study’s participants with some college or a 2-year degree (sometimes cited as the prototypic blood donor) were reading at an eighth grade level when responding to a WSAQ on drug use, sexual behavior, and sexually transmitted diseases, which are topics also queried among donors.

Table 1. Computer-Assisted Self-Interviewing Systems for Blood Donors*

System characteristics	QDS	HCID	IDM	5D
1. Standard or configurable system and installations	Standard across all centers: Mississippi Valley (begun in 2001), West Tennessee, Mid-south, LifeShare, Dartmouth-Hitchcock Medical Center; all 100% QDS except some LifeShare buses; more than 1,000,000 completed interviews	Configurable: Gulf Coast; 450000 completed donor interviews	Configurable; Community Blood Center-Dayton, May 2006; Blood Systems, Inc, expected January 2007	Configurable; Blood Center of Iowa, expected fall 2006; Blood Center of Wisconsin, expects implementation of 1 donor center and 1 mobile pilot by the end of December 2006
2. Questionnaire	2 Options: AABB UDHQ (61 questions) or AABB new long form version UDHQ (49 questions); English and Spanish versions available	AABB UDHQ (49 questions, 1 local question); English and Spanish versions available	AABB UDHQ; English and Spanish versions available	2 Options planned: AABB UDHQ (61 questions) and AABB new long form version UDHQ (49 questions); capable of handling all Latin-based character set languages
3. Equipment	Sahara Touch-It tablet computers with Windows printers	Panasonic Toughbook CF-73 touch screen laptops for mobiles; HP/Compaq MX 2000 MT minitowers for donor centers	Pentium PC, min 256 RAM, Windows XP (Celeron and W2K OK); PDAs/handhelds planned for 1stQ 2007 revision with ELO touch screens (mouse/keyboard optional); Motion LE1600 Tablet PCs (Celeron/wireless); review with 17-inch monitors, bluetooth scanners, signature pads, keyboard/mouse	Pentium PC, min 256 RAM, Windows XP; CASI workstation: ELO or Dell Touchscreens (optional keyboard/mouse); UareU fingerprint scanners, signature pads, keyboard/mouse; staff review workstation: 17-inch monitors, keyboard/mouse
4. Operational locations	Fixed sites and mobile	Fixed sites and mobile	First fixed sites and then to mobiles	Fixed sites and mobile planned
5. Software: Donor interview	CASI with audio and visual prompts and finger touch-screen or stylus inputs; responses for each question: Yes, No, and "???" ; Back, Next	CASI with touch-screen, audio, and visual prompts not in use; responses for each question: Yes, No, Skip, Review Answers, Quit	CASI with touch-screen, audio, and visual prompts; responses for each question: Yes, No, Not Sure, Back, Next	CASI with audio and visual prompts available and finger touch-screen or stylus inputs; responses for each question: Yes, No, Help, Back, Next, Request Assistance

Staff review	Symbol and color-coded donor responses to all questions on single screen; requires review and resolution of missing or aberrant responses; provides decision aids; prints completed donor interview record for signatures	Highlights donor response to each question; requires review/ resolution of missing or aberrant responses; prints completed donor interview record for signatures	Requires review and resolution of each missing or aberrant response; electronic signature capture; no hard copy of donor interview	Requires review and resolution of each missing or aberrant response; electronic signature capture; no hard copy of donor interview (can be generated)
Database	Database to store information on all donor and staff actions for each interview and review	Database to store information on all donor and staff actions for each interview and review	Oracle database to store information on all donor and staff actions for each interview and review	Database to store information on all donor and staff actions for each interview and review
6. Training required	Donors, none; staff, 2-3 h; release 2.03 (vital signs and electronic signature capture), 1 h additional; phlebotomy 1 d additional	Donors, none; staff, 2-3 d, including physical and phlebotomy modules	Donors, none; staff, 5 4-h sessions with a short refresher course	Donors, none; planned staff, 1 d for reviewers and up to 3 d for system administrator, including physical and phlebotomy modules
7. Other features:				
Communications	Upload data to blood bank computer system; LAN and WAN; satellite WAN being developed	LAN (WAN option not used); 1-way interface to blood bank computer system and 2-way in testing	LAN and WAN; data encrypted; mobiles with server (laptop) updated overnight; mobile equipment will communicate wirelessly with mobile server	LAN and WAN; data encrypted; mobiles with server (laptop) updated overnight; mobile equipment will communicate wirelessly with mobile server
Technology Implementation	Web CBE-30 as standalone or with wired and wireless local area and WAN configurations	Client-server; Web version in development CBE-30 as standalone or with wired and wireless local area and WAN configurations	Client-server: JBoss and Java CBE-30	Web; Client-Server for staff review CBE-30 as stand-alone or with wired and wireless local area and WAN configurations
Updates	Additional and modified questions distributed within 1 wk; survey research module expected to be released this summer or fall; Internet version awaiting FDA approval	Questions controlled by blood center; have installed local questions within 1 workday	Questions controlled by blood center; can add donor survey questions	Questions controlled by blood center; can add donor survey questions

Abbreviations: RAM, random access memory; PDA, personal digital assistant. Manufacturers: Sahara, TabletKiosk, Torrance, CA; Panasonic, Panasonic Corp of North America, Secaucus, NJ; HP, Hewlett-Packard, Palo Alto, CA; Compaq, Hewlett-Packard; Pentium, Intel, Santa Clara, CA; Windows XP, Microsoft, Redmond, WA; ELO, Elo Touch Systems, Menlo Park, CA; Motion, Motion Computing Inc, Austin, TX; Dell, Dell Inc, Round Rock, TX; Uare U, Digital Persona, Redwood City, CA; Oracle, Oracle Corp, Redwood Shores, CA; JBoss, division of Red Hat, Atlanta, GA; Java, Sun Microsystems, Santa Clara, CA.

*Information on in this table was provided by vendors with confirmation by end users of configurations in use, except for the Haemonetics system, which was not yet in use at the time of compiling the information. Thanks to Paul Sullivan at MVRBC, Judith Woll at Community Blood CenterDayton, and Susan Rossman at Gulf Coast Regional Blood Center for their “in-use” system descriptions.

The recent revision of AABB's UDHQ is the prime example of effort by the blood services community to adapt donor screening to reasonable levels of adult literacy. After focus groups and cognitive interviews, many medical terms in the original UDHQ were eliminated or modified in the new questionnaire to improve donor comprehension. The potentially iterative nature of a FTFI might seem ideal to assess and reinforce comprehension, but that depends on adequate staff sensitivity, intuition, patience, and training to perceive and remediate donor misunderstanding of the content and intent of questions. CASI systems can include audio to mitigate literacy issues and/or "Help" and "Skip" alternative responses along with the usual "Yes" and "No" choices for each question providing donors with assistance when needed. Some CASI systems include visual prompts illustrating the activity or subject matter to improve donor comprehension (Table 1).

Error Reduction

Donor and staff errors and omissions on screening interviews result in the collection, distribution, and transfusion of unacceptable donations. Donor errors, particularly donor failure to admit to high-risk behaviors, are thought to endanger the blood supply. Also troublesome are errors and omissions recognized and reported to the collecting organization after donation (postdonation information [PDI]). Errors resulting in labeling and making available for distribution nonconforming blood products are transmitted to FDA as blood product deviation reports (BPDRs), and summarized annually by the agency.³⁴ The donor interview process is responsible for 75% of all BPDRs, occurring at a rate 11 times that of the next largest category. The frequency of such errors may be, in part, a function of the screening method used by the collecting organization. Cumming et al,²⁴ in their recent study at a regional blood center, found that in the first year after implementing an AVT-CASI system, the elicitation of information resulting in donor deferrals increased substantially. First-time donor PDI reports to FDA increased by 269%, compared with those during the previous FTFI-WSAQ interview, whereas repeat donor PDIs increased by 79% and then declined substantially. The hypothesis is that AVT-CASI may have more effectively prompted donors' subsequent recall of information requested during

the interview. Goldman et al,³⁵ in a 2005 study of 870 Canadian donors (94% repeat) found that (i) blood donors' ability to recall questions immediately after completing their paper DHQ was poor, (ii) recall was particularly poor when items were part of a list, and (iii) recall was improved when using the AABB UDHQ and further improved by using AVT-CASI.

CASI systems have an advantage over FTFI and WSAQ for error reduction. Properly designed CASI systems include programed quality checks and staff alerts for aberrant or incomplete donor responses, incomplete staff reviews, omission of donor and staff signatures (when done electronically), and failure to properly file donor health history records when transferred to electronic data repositories. By automating the screening process wherever possible and embedding programed checks on human error, CASI systems substantially reduce staff errors in the screening process.

Three recent studies indicate the extent to which CASI systems are effective in this respect. Gordon et al,³⁶ in assessing the effects of loss of their center's computer equipment to disaster, found the frequency of omissions on the donor record form quadrupled (.25% vs 1%) when computer-assisted interviewing fell from 98% to 30%. Katz et al³⁷ reported a 61% decline in staff-related screening errors after introduction of an AVT-CASI system. Cumming et al²⁴ reported staff errors and omissions decreased by 69% after AVT-CASI introduction at another regional blood center. Thus far, there have been no studies comparing CASI systems to WSAQ in this respect. However, data processing procedures for donor screening via WSAQ are essentially the same as those for FTFI, so it is reasonable to expect that error reduction would be similar when CASI is substituted for WSAQ.

Staff Time Required

CASI donor screening requires less staff time than FTFI. In their study, based on an AVT-CASI version of the original UDHQ, Katz et al,²³ reported a decrease in staff time per interview of 5 minutes (68%), whereas total interview time for donors increased from 7.4 to 11.2 minutes, compared with the previous FTFI. Interestingly, despite the increased total time, 87% of donors perceived that the time needed for CASI was favorable, compared with FTFI. More recently, the

same authors reported a further 38% reduction in average staff review time when using the CASI version of the new UDHQ (1.77-1.09 minutes).³⁷

Cost of Quality

There is a dearth of literature addressing the tradeoff between system costs and the value of quality improvements in donor screening realized when CASI reduces staff errors and omissions. Cunningham³⁸ has estimated the costs of staff errors that occurred during donor screening at the Indiana Blood Center in 2003. This study evaluated “hidden costs (of errors) to the blood center, including costs associated with documentation of the error upon discovery; initial evaluation and investigation of an error; lost product costs; labor expenses; and quarantine and resolution of quarantine of the involved products.” The estimated annual cost of such errors was \$87280, and the study “provided compelling evidence that automated donor screening processes should be considered.”

AVAILABLE CASI SYSTEMS FOR BLOOD DONOR SCREENING

Four vendors presently offer proprietary CASI systems for blood donor screening in the United States: Talisman Medical Systems Ltd, Vienna, VA (Quality Donor System) referred to hereafter as “QDS”; Healthcare ID Inc, Buffalo Grove, IL, (DONOR-ID), referred to hereafter as “HCID”; Information Data Management, Rosemont, IL (Prelude), referred to hereafter as “IDM”; and Haemonetics’ 5D Information Management Division, Edmonton, Alberta, Canada (eQue), referred to hereafter as “5D.”

Characteristics of the 4 systems, as described by vendors and, where installed and in use, verified by customers, are summarized in [Table 1](#). Of the 4 systems, 2 are operational (QDS and HCID) in blood centers; the third, IDM, is being installed at present; and the fourth, 5D, is scheduled for first installation in fall 2006. All systems can use the new AABB long form UDHQ with English and Spanish versions available. Beyond this, they differ in several respects. QDS is a standardized system with the vendor responsible for installation and maintenance of all screening questions, all audio and visual prompts, and all additions and changes thereto. With HCID, IDM, and 5D, the user is responsible for installation of the UDHQ questionnaire, selecting pictures for visual display,

recording audio prompts, providing the Spanish translation, and making future changes in system content. Thus, QDS is a “turnkey software” system in that it relieves center management of the tasks of installing and maintaining system content, whereas HCID, IDM, and 5D allow management to modify questions on the UDHQ, addition of local questions if desired, and the choice of developing audio and visual prompts.

All vendors use commercially available, off-shelf computer equipment specified by brand name and model number for purchase by the user. Described generically, QDS uses finger touch-screen tablet computers with Windows (Microsoft) printers for all fixed sites and mobiles; HCID uses touch-screen laptop computers for mobiles and standard desktops for fixed sites; IDM uses standard desktop computers with personal digital assistant (PDA)/handhelds planned for early 2007, touch-screen monitors, stylus-only tablet computers, wireless scanners, and electronic signature pad; and 5D uses standard desktop computers with touch-screen monitors, fingerprint scanners, and signature pads for fixed sites. Mobiles are planned but as yet undefined. Typically, installation, validation, and implementation require weeks or months before center screening is fully automated. In general, implementations have been sequential with fixed donation sites preceding mobile operations.

All systems permit the donor the alternative of answering, skipping, or requesting help on each question. In addition the donor can backtrack and revise responses to previous questions. When the interview is completed, each system shifts to its staff review mode, highlighting those questions that require further staff interaction with the donor. Each highlighted question must be resolved by further donor explanation satisfactory to staff or by a deferral decision. Staff is constrained in the review by center SOPs directing further inquiry and deferral decisions. After, and only after, all highlighted questions have been adjudicated, the systems produce the donor record for staff and donor signature. QDS and HCID produce printed output for signature, whereas IDM and 5D display the final interview on the monitor, to be signed electronically on a signature pad. An imminent release of QDS provides for touch-screen input of donor and staff signatures.

No formal donor training time is required with any of the systems because operation of each

system is self-evident. QDS, for which the vendor retains responsibility for system maintenance, requires 2 to 3 hours for center staff familiarization with system setup and the staff review procedure. HCID, IDM, and 5D, because each assigns responsibility for software maintenance and process changes to center staffs, vary the requirement with HCID using 2 to 3 days of staff training. IDM uses 5 sessions of 4 hours each together with a short refresher course, and 5D allots 1 day for reviewers and up to 3 days for system administrators.

The means by which data are communicated among stations of the screening systems and from the screening system to the blood bank computer system or other data repository is important in minimizing staff time to update system records and avoid errors in communication between systems. All systems can operate on a local area network (LAN), whereby a single server holds all system software and services multiple clients on the network. At present, one center using QDS operates its fixed and mobile sites on wireless LANs. All other centers use stand-alone stations, each of which holds the full complement of software. The advantage of a LAN is that only the server is involved in system changes and validations, whereas with standalone stations, each station is involved, increasing staff time for implementation and maintenance. Although the QDS 510(k) covers electronic data transfer, at present, centers using the system prefer manual entry of selected interview data into the main blood bank computer system. IDM, HCID, and 5D, on the other hand, produce electronic donor records that can then be transferred directly to the main system. IDM does not produce a printed donor record; 5D can generate the hard copy if required.

QDS software is web-based, whereas HCID and IDM are client-server based and 5D is web-based with client-server for staff review. The main difference between the 2 is that with web-based software, only the computer servers need be updated and validated for system changes, whereas with client-server software, both servers and stations must be updated and validated. A wide area network (WAN) using a single server to service multiple geographically dispersed stations has advantages over standalone or LAN software (see section below on system extensions).

All center system installations in the United States, whether consisting of standalone stations,

LANs, or WANs must be submitted to the FDA for review and clearance. All 4 proprietary systems are FDA 510(k) cleared. Centers are permitted to install them using a changes being effected-30 days (CBE-30) license supplement that allows FDA 30 days to object before implementation.

Additions or changes in QDS interview questions are the responsibility of the vendor staff who develop required revisions or those requested by users and transmit them to center staff for installation and validation. This change process requires 1 week, based on experience with smallpox vaccination, severe acute respiratory syndrome, West Nile symptoms, and variant Creutzfeldt-Jacob disease guidances. Gerber et al,³⁹ using a QDS system, describe making such a change in 10 stand-alone stations within 3 days. HCID, IDM, and 5D leave center staff responsible for changes for which there is no reported experience to date.

EXTENSIONS OF PRESENT CASI SYSTEMS

Available technology offers several opportunities for improvement in present AVT-CASI screening systems. Chief among these are (i) Internet donor interviewing, (ii) WAN and wireless communications, (iii) archival databases, and (iv) staff decision aids.

Internet Interviewing

Use of the Internet for e-mail communication is commonplace in the United States and already in use by blood centers for donor recruitment. An obvious next step for blood centers, strongly supported by sponsoring organizations interested in minimizing employee donation time, is to screen donors at home or work via the Internet. Smith and associates first suggested doing this some years ago.⁴⁰ A system for Internet interviewing has been developed for QDS and pilot-tested at the Mississippi Valley Regional Blood Center.⁴¹ The interview is conducted via a secure Internet server requiring password-protected broadband access, audio capability, and a printer at the donor's computer. Donors access and complete the interview without providing personal identifiers. An encoded bar code printout with a unique identifier is produced for donors to present to the donation site. Screening staff ask the donor 3 additional questions to verify authorship of the printout, that nothing material has changed since its completion and that it was completed in a private setting. The

staff then scans the bar code to decode the interview, insert the donor identification, complete the staff review, and print the donor card for signatures. Most donors participating in the pilot study reported the system allowed for adequate privacy, felt the Web site was easy to access, that instructions were easy to follow, and audio and video quality was very good. Thirty-nine percent were interviewed at home, 58% at work, and 3% elsewhere. Sixty-one percent stated a preference for the Internet interview, 35.6% were neutral, and 3.4% preferred the on-site interview. A prior approval supplement for implementation has been submitted to FDA. In addition to assisting organizations sponsoring blood drives by decreasing donor time at the blood drive, the system is expected to increase donor satisfaction. Furthermore, because Internet donor interviewing is anonymous until staff review, the interview site remote, and the interview totally private and under donor control at all times, it may increase the accuracy of elicited information. As Fielding et al⁴² discovered in a recent test of postdonation telephone interviewing of blood donors, traditional on-site WSAQ for donor screening can lead to underreporting of high-risk behavior, probably because of social desirability bias and embarrassment considerations, factors that may be minimized when donors are interviewed remotely.

Wide Area Networks

Typical blood center organization includes a headquarters containing the blood bank computer system and principal collection site, multiple widely dispersed satellite collection sites, and mobile collection operations used to service donors at workplaces, schools, churches, and other convenient locations. A CASI system for such a center typically consists of several interviewing stations at each fixed and mobile collection site, either standalone or on a LAN, each of which contains the full complement of screening software including a database capable of storing donor interview data. Data are returned to the main site in portable computers on portable media or over phone lines. This process is inefficient. If activity data are required from screening terminals, staff must extract the data from each station computer or LAN servers and collate and transmit them to headquarters. Implementation of system changes is similarly complicated. Construction of a WAN

simplifies all this as each site station becomes part of the center-wide electronic network. WANs allow transmission of encrypted data to and from the headquarters' central server, site servers, and each station and mobile unit. Consequently, little or no staff time is needed for daily up- and downloading of data, for collation and communication of data to and from system-wide databases, or for making system changes, which are confined to the WAN central server. Because much US blood is collected on mobile operations in suburban and rural areas where no wired WANs are available, QDS, IDM, and 5D have WAN capability including data encryption. At present, QDS is testing a WAN system using satellite communication between headquarters and mobile units as part of its system now installed at West Tennessee Regional Blood Center.⁴³

Archival Databases with Online Communication

Given WAN capability with a CASI screening system, a center can install and maintain a central database containing the historical record of every donor's previous interviews, with the information accessible for staff review during subsequent interviews. For example, centers report that FDA inspectors cite them for inconsistent donor travel histories. A WAN configuration on a CASI system will permit staff at any collection location to access a donor's travel history during the staff review for comparison with the current information, allowing resolution of any discrepancies. Real-time access to historical data can prevent inappropriate collections, facilitate timely discovery and action on postdonation information, and prevent unnecessary deferrals when complicated donor histories have been previously evaluated and found acceptable.

Decision Aids

Decision aids consist of a variety of supplementary tables, flow charts, and instructions, detailing for staff how to evaluate aberrant or unclear responses to interview questions. They range in complexity from simple checklists to complex flow charts involving multiple supplementary questions leading to a variety of decision outcomes. Normally, such checklists or flow charts are included in the center's printed SOPs for staff guidance on handling responses to each question in the interview. American Association of Blood Banks, as part of development of the new long form UDHQ,

has produced a set of decision aids consisting of flow charts and tables to assist screening staff in their response to aberrant answers. These lists and flow charts can be incorporated into CASI systems for use by staff when consultation or guidance is needed during review, as has been done with QDS and IDM.

CONCLUSIONS

Computerized health histories and donor screening increase the accuracy and efficiency of the blood donation process. Presumably this translates into transfusion safety, although direct measurement is difficult, given low rates of donor infection. Given that 75% of BPDRs reported to FDA involve the donor interview, decrements in

errors and omissions by themselves justify broader implementation of CASI systems and are consonant with the blood community's adoption of cGMPs. The enhancements being developed for present systems will provide further process improvements that mesh nicely with the emphasis on current good manufacturing practices in blood banking and the use of electronic health records more broadly.

ACKNOWLEDGMENT

The authors thank Talisman staff Chantell Murphy for her literature research; Philip S. Abrams, PhD, for his advice on architecture and other computer systems technology; and Joseph C. Johnston for general comments on the manuscript.

REFERENCES

1. Jackson BR, Busch MP, Stramer SL, et al: The cost-effectiveness of NAT for HIV, HCV and HBV in whole-blood donations. *Transfusion* 43:721-729, 2003
2. Phelps R, Robbins K, Liberti T, et al: Window-period human immunodeficiency virus transmission to two recipients by an adolescent blood donor. *Transfusion* 44:929-933, 2004
3. Dodd RY: Emerging and newly recognized transfusion-transmissible infectious diseases. Overview of current blood borne diseases. Presentation before the Advisory Committee on Blood Safety and Availability Committee, January, 2005
4. Dodd RY, Notari EP: Epidemiology of blood borne infections for the period January-December 2005. Reported 3/29/06 from The ARCNET Data Center. Personnel communication with PD Cumming. Current prevalence rates for HIV, HBV and HCV for US population obtained from: *Morbidity and Mortality Weekly*, June 54 (24) 1. Hepatitis B Fact Sheet October 25, 2005; www.cdc.gov/hepatitis. Hepatitis C Fact Sheet October 25, 2005; www.cdc.gov/hepatitis
5. Williams AE, Thomson RA, Schreiber GB, et al: Estimates of infectious disease risk factors in US blood donors. *JAMA* 277:967-972, 1997
6. Schmidt PJ: The national blood policy: A study in the politics of health. Paper presented at the 22nd meeting of the Secretary's Advisory Committee of Blood Safety and Availability, Washington, DC, 2004
7. Department of Health, Education and Welfare: Fed Regist 42:11018-11023, 1977
8. Dodd RY: The risk of transfusion-transmitted infection. *N Engl J Med* 327:419-421, 1992
9. Leveton LB, Sox HC, Stoto MA: HIV and the blood supply: An analysis of crisis decisionmaking. Washington, DC, Institute of Medicine, National Academy Press, 1995
10. Petersen LR, Doll L: HIV Blood donor study group: Epidemiologic, laboratory and donation characteristics. *Transfusion* 31:698-703, 1991
11. Conry-Cantilena C, VanRaden M, Gibble J, et al: Routes of infection, viremia, and liver disease in blood donors found to have hepatitis C infection. *N Engl J Med* 334:1691-1696, 1996
12. Murphy EL, Bryzman SM, Glynn SA, et al: Risk factors for hepatitis C virus infection in the United States blood donors. *Hepatology* 31:756-762, 2000
13. FDA/CBER Draft guidance for industry-acceptable full-length donor history questionnaire and accompanying materials for use in screening human donors of blood and blood components. April, 2004
14. See FDA/CBER Draft guidances for industry dated: January 9, 2002; December 30, 2002 (corrected February 4, 2003); and September 16, 2003
15. Weisband S, Kiesler S: Self disclosure on computer forms: meta-analysis and implications. *Chi* 96; ACM 0-89791-777-4/9/04
16. Turner CF, Ku L, Rogers SM, et al: Adolescent sexual behavior, drug abuse and violence: Increased reporting with computer survey technology. *Science* 280:867-873, 1998
17. Richman WL, Weisband S, Kiesler S, et al: A meta-analysis study of social desirability distortion in computer-assisted questionnaires, traditional questionnaires, and interviews. *J Appl Psychol* 84:754-775, 1999
18. Cooley PC, Rogers SM, Turner CF, et al: Using touch-screen audio-CASI to obtain data on sensitive topics. *Comput Hum Behav* 17:285-293, 2001
19. Johnson AM, Copas AJ, Erens B, et al: Effects of computer-assisted self-interviews on reporting of sexual HIV risk behaviors in a general population sample: A methodological experiment. *AIDS* 15:111-115, 2001
20. Locke SE, Kuwaloff HB, Hoff RG, et al: Computer-based interview for screening blood donors for risk of HIV transmission. *JAMA* 268:1301-1305, 1992
21. American Institute for Research: Increasing the safety of the blood supply by screening donors more effectively, executive summary. FDA, 1993 (contact 223-91-1002)
22. Sellors JW, Hayward R, Swanson G, et al: Comparison of deferral rates using a computerized versus written blood donor questionnaire: A randomized, cross-over study. *BMC Public Health* 2:14 (Published online 2002 August 21), 2002
23. Katz LM, Cumming PD, Wallace EL, et al: Audiovisual touch-screen computer-assisted self-interviewing for donor

health histories: Results from two years experience with the system. *Transfusion* 45:171-180, 2005

24. Cumming PD, Watlington N, Schifano JV, et al: Regional scale impacts of an audiovisual touch-screen computer-assisted self interviewing (AVT) system. Abstract of presentation submission 06-AB-862-AABB, AABB 2006 annual meeting. *Transfusion* 46s:A14-020C, 2006 (abstr)
25. Sayers MH: Duties to donors. *Transfusion* 32:465-466, 1992
26. Zuck TF, Cumming PD, Wallace EL: Computer-assisted audiovisual health history interviewing: Results of the pilot study of the Hoxworth Quality Donor System. *Transfusion* 41:1469-1474, 2001
27. Sanchez AM, Schreiber GB, Glynn SA, et al: Blood-donor perception of health history screening with a computer-assisted self-administered interview. *Transfusion* 43:165-172, 2003
28. Gillespie TW: The "crisis" of blood donation. *Transfusion* 45:128-129, 2005
29. Lautenschlager GJ, Flaherty VL: Computer administration of questions: More desirable or more social desirability. *J Appl Psychol* 75:31-314, 1990
30. Erdman HP, Klein MJ, Greist JH, et al: A comparison of two computer-administered versions of the NIMH diagnostic interview schedule. *J Psychiatr Res* 26:85-95, 1992
31. Thornbery J, Bhaskar B, Krulewitch CJ, et al: Audio-computerized self-report interview use in prenatal clinics. *Comput Inform Nurs* 20:46-52, 2002
32. Wilson JF: The crucial link between literacy and health. *Ann Intern Med* 139:875-878, 2003
33. Al-Tayyib AA, Rogers SM, Gribble JN, et al: Effects of low medical literacy on health survey measurements. *Am J Public Health* 92:1478-1482, 2002
34. FDA/CBER: Blood products deviation reports (errors) by manufacturing systems/functions. <http://www.fda.gov/cber/biodev/bpdrfy05.htm>
35. Goldman M, Ram S, O'Brian S: The blood donor screening questionnaire: Is it effective? AABB 2005 bulletin board. *Transfusion* 45s:SP202, 2005 (abstr)
36. Gordon EC, McLain DW, Block B, et al: Impact of computer assisted health history system on omissions on donor records. AABB 2005 bulletin board abstract. *Transfusion* 45s:A7, 2005 (abstr)
37. Katz LM, Wallace EL, Cumming PD: AABB UDHQ: New versus old. Presentation at annual meeting AABB, 2005. *Transfusion* 45s:2214, 2005
38. Cunningham KJ: Cost of quality for donor screening documentation errors. AABB Annual Meeting 2003; Poster session AP 126. *Transfusion* 43:171A, 2003 (abstr)
39. Gerber LE, Holdorf LA, Sullivan PE, et al: Audio versus manual implementation of new questions. *Transfusion* 43s:A63, 2003 (abstr)
40. Smith JW, Forsberg JE, Gilcher RO: Innovations in blood donor screening and blood collection. *Curr Hematol Rep* 1:129-133, 2002
41. Katz LM, Schifano J, Scott E, et al: Internet donor health history interviewing. Presentation at annual meeting AABB, 2005. *Transfusion* 45s:S201, 2005 (abstr)
42. Fielding R, Lam TH, Hedley A: Risk-behavior reporting by blood donors with an automated telephone system. *Transfusion* 46:289-297, 2006
43. Schifano J, Scott A, Watlington N, et al: The adventures of implementing a satellite base wide area network. Abstract of presentation submission 06-AB-156-AABB, AABB 2006 annual meeting, 2006 (abstr)