

## Summary of Literature on Alternative Methods of Donor Interviewing

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Thank you for this opportunity to comment on an important aspect of blood donor screening. Talisman Limited is the producer of the Quality Donor System (TM) (QDS), an audio video touch screen computer assisted self-interviewing system (AV-T-CASI) for blood donor screening. QDS and the studies cited below are partially supported by grants from the National Heart Lung & Blood Institute (HL61111). The work is also a priority of DHHS' Advisory Committee on Blood Safety & Availability.<sup>1</sup>

A substantial literature on medical-scientific literacy and interviewing techniques relevant to this discussion has not been addressed in the recent AABB Streamlining report<sup>2</sup> and the CBER draft guidance.<sup>3</sup> This literature shows audio-CASI technologies to be superior to paper and face-to-face interviewing with regard to literacy, truthfulness on socially and legally sensitive questions, clarity, donor satisfaction and likelihood of return and error reduction. We summarized that literature in responsive comments to CBER on June 22, 2002. Below we provide a slightly shorter updated version of the same work<sup>4</sup> with a reference point on potential significance.

Much of this literature extends the work of Turner et al. cited in Reference 4 of the CBER draft guidance but not cited in the document. The Turner work (1998) showed that audio-CASI increased reporting of embarrassing, stigmatizing or illegal behaviors by up to a factor of 17 compared to paper self administered questionnaires (Table 3 adjusted odds ratios) (enclosed).<sup>5</sup> By our count, about one-third of AABB Uniform Donor History Questions fall into these categories.

In a September 1992 JAMA article, Steven Locke and others reported that in a sample of 272 blood donors previously screened and accepted by routine Red Cross written questionnaires or face-to-face interviews 12 donors reported HIV risk behaviors or symptoms when re-interviewed using conventional computer assisted self interviewing (traditional CASI).<sup>6</sup> The problem with printed or electronic questionnaire interviewing is that it presumes donor literacy and illiteracy is a large, often hidden problem in this country. According to Census 2000 over 31 million US residents are foreign born, 52% are from Latin America, and 21 million speak English less than "very well."

People go to great lengths to hide their illiteracy. The American Medical Association web site documents that sixty-seven percent of patients with reading difficulty admit they have never told their spouse about their reading problem (enclosed).<sup>7</sup> If two out of three illiterates can hide their deficiency from their spouses, how then are blood center staff to detect the problem? Isn't it better to use a technology that reduces or eliminates the reading problem?

A most recent article by a Turner group led by A.A. Al-Tayyib (enclosed) provides the best estimate we are aware of as to how great the illiteracy problem may be among blood donors. Based on a sample of 1014 Baltimore MD adults aged 18 to 45 (probably from an STD treatment center) using the Rapid Assessment of Adult Literacy in Medicine (RAELM) instrument, via Table 1 the authors found that 18% of subjects with "Some college or a 2 yr degree" were reading at levels of 8th grade or below. This "Some college or 2 yr degree" group is sometimes cited as typical of blood donors.<sup>8</sup>

In 2001 a Turner group led by P.C. Cooley used touch screen audio-CASI (A-T-CASI) to obtain data on sensitive topics from a sample of 108 subjects who expressed strong preference for A-T-CASI, viewing it as the most private method. The authors conclude A-T-CASI has the potential to "yield more accurate recording of responses."<sup>9</sup>

Our 1999 Hoxworth pilot study on AV-T-CASI published in the December 2001 issue of TRANSFUSION with Thomas F. Zuck, MD as lead author (enclosed)<sup>10</sup> found only two of 400 donors

refusing to use the Hoxworth QDS system. Results from this study have since been corroborated and expanded via studies at the Mississippi Valley Regional Blood Center (MVRBC) led by Louis M. Katz, MD, and Laurie Rogenski, RN. The study information presented below is available in greater detail on the Reference page of Talisman's Web site and has been presented at forums such as the CBER Best Practices workshop this spring but not yet published.<sup>11</sup>

Only one refusal among the first 10,000 donors using the current Web browser AABB UDHQ QDS has been reported by MVRBC. As far as we know, QDS is the only audio-CASI system to employ touch screens or question descriptive color pictures in routine health history screening of blood donors. Standardized donor satisfaction surveys have been conducted at three MVRBC sites and replicated at two of these facilities. Completed surveys from over 1500 donors showed that donors with a preference for one interviewing system or another preferred QDS to traditional face-to-face interviews by a minimum of a factor of four across measures of clarity, privacy, truthfulness, time satisfaction, understanding and likelihood of donating again. For some measures such as clarity and privacy, over 90% of donors prefer QDS to face-to-face screening (presentation enclosed).<sup>12</sup>

MVRBC staffs prefer QDS to manual system alternatives by a factor of three or more when measured by variables of faster for staff, donors more honest, answers more accurate, answers more confidential, fewer staff errors and personal satisfaction. MVRBC also showed that QDS reduces Errors/Omissions by at least 60% (presentation enclosed).<sup>13</sup>

Comprehensive results from the first year of implementation at MVRBC have been accepted by referees for presentation at the fall AABB annual meetings.<sup>14</sup>

An anonymous mail study of blood donors within two months of donation and 34,726 completed instruments reported by the REDS group provides context. The authors note "Individuals who do not respond accurately to questions about infectious disease risk factors at the time of blood donation represent a potential threat to the safety of the blood supply." Results of analyses showed that 1.9% of donors report a deferrable risk unreported at the time of donation. Deferrable risk behaviors were 1.4 times higher for men than women and 1.6 times higher for first time than repeat donors.<sup>15</sup>

In conclusion, it is our belief that donor interviewing should include a verbal or audio component, and that new, unfamiliar, questions in particular must be posed in one of these two modes. We also believe medical-scientific literature supports stronger guidance from CBER encouraging the use of technologies that enhance understanding and honesty, e.g., AV-T-CASI technology.

Paul D. Cumming, PhD  
Talisman Ltd.

Louis M. Katz, MD  
Mississippi Valley Regional Blood Center

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