most part simply aren't available to do that stratification, and that is one of the problems.

Back to the last slide.

[Slide.]

At the last meeting, there was a very elegant presentation of the revised Uniform Donor History Questionnaire by Dr. Joy Friday and discussion and review of that revision, and BPAC voted unanimously that the final FDA-approved version of the UDHQ is suitable to screen donors of allogeneic whole blood and blood components for transfusion.

The task that remains is to integrate this revised questionnaire with FDA's current thinking represented in the draft guidance, and that is the charge for today.

The draft guidance was made available in April of 2002 and comments were due and received by June 21st of this year.

[Slide.]

Looking specifically at some of the elements, 12 comments to the docket were received with respect to the draft guidance. The most frequently commented element was the self-administration aspect for new donors with the

exception of the audio-assisted computer self-administration.

Eight comments referred to this. There was also a split. Some of the comments argued that, in fact, for even the risk questions, that the evidence didn't support use of oral questioning for high-risk questions, and some of them reflected some confusion about the intent of the guidance and whether or not we were potentially recommending that blood centers currently using self-administration for medical portions of the questionnaire would have to go back and change their current procedures.

We also included in the guidance that new or modified questions should be highlighted in some way, so that repeat donors, who have seen the bank of questions before, would have some way of recognizing that a question was new and being aware of that, because I think some prior data indicate that in the scanning of the questionnaire, sometimes each individual question isn't looked at in tremendous detail for repeat donors who may have donated many times before.

The current thinking reflected in the guidance removes the recommendation for oral

administration of the high-risk behavior questions for repeat donors. This had six comments largely supportive of that position.

FDA recommended that there be secondary measures to assure donor understanding. FDA didn't say specifically what these measures should be. Potentially, they could run the gamut from asking a donor at the end of the process whether they understood the questions, which is commonly in place now, to other means to assess understanding and comprehension, readability of the questions.

Also included were adequate instruction of staff and of the donors, assistance as needed with the process, and quality assurance of the process through internal SOPs, and special provisions for audio and visual administration of the questionnaire and particularly for audio computer-assisted technology, which has become popular in the larger general population in high-risk surveys, and the literature tends to be very supportive that this is an elegant way to obtain at-risk information.

[Slide.]

To tackle today's topic, our first speaker will be Dr. John Boyle from Schulman, Ronca, and

Bucuvalas. The title of his talk is Administering the Blood Donor Screening Questionnaire: Issues Related to Sensitive Information. I must say John has put together a very extensive review of the current literature and look forward to his presentation.

The next talk is entitled Beyond Literacy: Collecting Accurate Medical Information. This is a review of the literacy aspects of the discussion, and again, I think also a very excellent collection of current knowledge about literacy factors. The presenter is Vickie Virvos, who is an educator with Enlightening Enterprises in Richmond.

Finally, I will return with questions for the committee and I will give a little preview of the questions now.

[Slide.]

1. Does the committee agree that audio-CASI procedures, that is, audio computer-assisted self-interview, that these procedures are as accurate as direct oral questioning for eliciting blood donor medical/behavioral histories? Yes or No.

2. Does the committee believe that for first-time donors, self-administration procedures

other than audio-CASI are as accurate as direct oral questioning for the entire donor questionnaire? Yes or No.

3. If not, for procedures other than audio-CASI, are the following portions of the donor questionnaire appropriate for self-administration to first-time donors?

Specifically, we have highlighted the routine medical questions, which, in fact, are frequently self-administered in blood centers today.

The next component is HIV/AIDS high risk questions, yes or no, and the complex medical or travel, and I would include in there those with complicated scientific or medical terminology.

We look forward to your deliberations and thank you.

DR. NELSON: Thanks very much.

Dr. John Boyle, who is a former valuable member of BPAC, will review the literature.

Presentation

John Boyle, Ph.D.

DR. BOYLE: Thank you. It is great to be here again. Alan and the FDA did an extensive search for people who had served on BPAC of

professional survey researchers that served on the Uniform Donor History Questionnaire and who lived or actually had an office within three blocks of this facility, and my name just rose right to the top of the list.

While we are waiting, what I was asked to do was to address the issue of sensitive information in interview settings and specifically, some of the issues here, what about self-administered, what about interviewer-administered, what about audio-CASI, what do we know, what does the literature know or tell us about the likelihood of getting a better report of sensitive information as in the HIV/AIDS risk behavior sections.

[Slide.]

What we did was do a review of the methodological journals in survey research for articles on the reliability of survey measures by mode of interview.

Secondly, we did a review using Medline for articles on validity and reliability in health surveys. We took in references in articles from either source. We added transfusion and other areas in this literature.

We reviewed over 50 articles. Although that list is probably not exhaustive of everything in this, it will provide you a broad overview of what the literature has available.

I believe for those members of the committee, we provided an annotated listing of 20-plus articles, so if you had a chance to read them on the plane or would like to read them later, you can go back to the source documents.

[Slide.]

The first thing that I really want to impress upon the committee, because I think it is something, if you are not survey research, you are not necessarily that well aware of it, an interview is not a test.

The donor screening interview is a key element in the protection of blood safety, but interview data does not have the fixed properties of a biologic test, such as specificity and sensitivity.

Interview data is subject to a variety of observational errors. That means non-sampling errors.

Finally, there are multiple sources of observational errors that may vary with the content

and context of the interview. While this is true in survey research, it should be true in other interviewing settings, such as the donor interview.

[Slide.]

How much does what somebody tells you in an interview vary from what you think you know about reality? If you compare what we did in a reverse records check of people who reported themselves as victims of crimes, to what they would say subsequently in a survey, you can see that the agreement rate is anything from 48 percent to 90 percent.

So, in the case of burglary, a uniform donor screening of burglary, about 90 percent will tell you that that indeed has happened in the past 12 months. If you should ask about rape, however, it will be about two-thirds, and assault, 48 percent.

So, you do not have--and don't take these rates as being true of everything, just take these rates as indicative that people, for a variety of reasons, do not reply to an interview in a way that it matches what other measures of truth necessarily are.

[Slide.]

We are not talking about rape or physical assault in these things. Let's talk about things we are. We had the opportunity to do a test/retest of a national sample of this happens to be men, they happen to be in their 50s to 60s, and we asked them whether their doctor had ever told them they had had hepatitis.

Six months later, we went back to the same sample and repeated the same question. It was embedded in a larger health survey. Now, the tools block this down here a little bit, but the reporting consistency is 97.3 percent. So, if you are interested in psychometrics, that is really great.

On the other hand, about 1 out of 5 persons who positively reported that they had hepatitis, and answered the follow-up questions, when was it first diagnosed and what kinds of hepatitis do not report that consistently at two points in time.

So, you have some sense on at least the hepatitis question, and this is a telephone interview with experienced monitored interviews in the midst of a health survey, not affected by setting and other issues, presumably very private,

you had this kind of issue about whether or not it gets reported. So, the question is why.

[Slide.]

There are whole sources of error in AIDS behavior research, and it is true of all research. Some come from the respondent, like recall, ability to comprehend, motivation, threat or approval of the particular question.

Some come from the instrument, the terminology, the question structure, the order effects. Some from the mode, channel capacities, length and pace, privacy, interviewer behaviors as it relates to the mode, and finally, some from the interviewer, the personal characteristics and how that interacts with the respondent, the ability or willingness of the interviewer to follow rules, and finally, training and control.

I am supposed to be talking about mode here because we are talking about several different modes, but the bottom line is mode interacts with respondent, with instrument, and interviewer, so there is a lot of stuff going on here. When you change mode, you have to be aware of how these other things contribute to the error measurement.

[Slide.]

I will skip this one. This is just technical, it is how mode works.

[Slide.]

Very quickly, the two principal concerns about mode in observational error. The bottom one, effects on disclosure, the biggest concern is that there is underreporting of sensitive information and how that relates to mode.

The second area is the effect of mode on respondent comprehension - understanding, attention and recall, reporting accuracy.

In terms of the issues before this committee, the biggest issue will be does an interviewer's presence asking questions, possibly in an open setting, is that going to contribute to an underreporting of sensitive behavior because of issues related to privacy.

On the other hand, will an interviewer, interacting with respondent, give them better understanding, greater attention and better reporting accuracy in those settings. Those are effectively the two big questions.

[Slide.]

In terms of the comprehension, what we know is respondents may not understand a word, but

are unwilling to show ignorance. They may try to simplify a difficult question, they may try to answer what they think is the spirit of the question rather than the exact words.

They may overlook parts of a question. They may have response categories that don't fit their experience, but maybe they are not willing to ask how to do it.

The question order may affect the way they answer questions, and questionnaire burden may cause respondent to answer without thinking.

[Slide.]

Let's talk about some of the things that might be on a donor history questionnaire. There was a study done-- this is qualitative--by NCHS some years ago where they asked, tell me if you have heard of the term and definitely know what it is, you have heard of the term and are pretty sure you know what it is, or you have never heard of the term and you are not sure what it is.

The important issue is probably not that diverticulitis is not recognized by about half of the people in this particular study, but terms like hepatitis are not recognized and they don't feel familiar, they are not sure what it is, for 1 out

of 5, and if you stick the old "or jaundice" on it, it doesn't really improve things, because 1 out of 5 don't really know what jaundice is.

Even in areas like anemia, you have got 10 percent. Fortunately, syphilis and diabetes are pretty well recognized. But the familiarity of terms is an issue.

[Slide.]

A real life example in a survey that I monitored where somebody tried to get at sexual preferences, and the question was: "Are you bisexual?" And the answer was, "Yes, my husband is the only man in my life."

Now, let me point out in terms of our issues, on a self-administered questionnaire, the person would have checked "bisexual." One of the advantages of the interviewer-administered questionnaire is the opportunity, whether it is right or wrong we have to discuss, but the opportunity of interviewer to interact, to potentially correct or at least make notes of this type of issue.

Now, you are going to say to me, John, we don't use words like bisexual in our instrument. You know, we use things like xenotransplantation,

because we all know it is all about a warrior princess.

But moving on to simpler terms.

[Slide.]

Let's take really simple terms. Let's talk about the word "weekday." This was tested. What is meant when I say weekday, we are open weekdays 9:00 to 5:00? Half said it is Monday through Friday. Another third said it is every day of the week. Then, 12 percent weren't sure, and the other people picked sort of more bizarre choices, but the bottom line is even a term like weekday, if we don't test it, we assume everybody understands it, has the source for error.

[Slide.]

Part of the issue why follow-up is good, this is very complex, but let me simply say we used to ask in transportation studies, "While driving this vehicle, how often do you wear your shoulder belt - all the time, most of the time, some of the time, or rarely?" And then someday, because the data did not match observational studies, we asked, "When was the last time you didn't wear the belt?"

Of the people who say they wear the belt all the time, that is your first column there, what

you see is 4 percent of them say they didn't wear it today, and another 6 percent said not within the past week. So, 10 percent who wear it all the time didn't wear it at sometime during the past week.

Now, the nice thing is you get a nice metric up here. Today, 4 percent, 32, 64, 75. It is not that people are stupid, it is not that people are lying to you. It is simply the fact that people are answering in their own metric and how they understand the question.

If you put these two pieces together, how often do you usually wear, and when was the last time you didn't wear the belt, and I take all the time and take all those people who didn't wear it within the past 12 months out, and we created a variable called all the time minus, it actually matches observational data, but you have to take those steps to be able to get something approaching reality.

[Slide.]

We will skip the irritable bowel question, but part of the issue is if your response categories are yes or no, you get a different answer than if you ask frequency, so it is important if you are trying to get at certain

issues.

[Slide.]

In terms of the communication of response, what you have to ask yourself is the question embarrassing to the respondent, is the response sensitive or threatening, how private is the interview setting, how confidential is the response, and does the purpose of the question justify any embarrassment or threat to the respondent.

Now, why do we have to do that?

[Slide.]

What you see is even two decades ago, the public felt that institutions in our society were asking unnecessarily personal information, and when asked do they limit their questions to what they really need to know or do they ask for too much personal information, we are not surprised when we see that credit bureaus ask too much, but 24 percent of the public say hospitals ask too much unnecessary information, and 11 percent say their private doctors do.

[Slide.]

Moreover, what we find is that the public is not very convinced about the confidentiality of

this information. When asked whether the Census Bureau protects the privacy of their personal data, the good news is 14 percent of the public are very confident that it does. The bad news is, is that almost half say not at all or not too confident about that, and that is the Census Bureau, who ranks relatively high.

[Slide.]

And how does this impact? We don't know how it impacts upon reporting, but we do know that it impact very markedly on willingness to participate, which presumably will translate, so concern about privacy, low to high, willingness to participate in the census, low to high, impacts dramatically.

If we say that that is likely to translate also into issues of accuracy of reporting and full disclosure, then, we may have a problem.

[Slide.]

So, then, how embarrassing are these questions, we ask. Going back to some stuff from NCHS, we asked people how they rated how embarrassing certain conditions where, and it was from definitely embarrassing at 1.0, somewhat embarrassing 2.0, and not at all embarrassing at

3.0.

Looking at the means, everybody agrees anemia and hay fever are not very embarrassing to report. On the other hand, syphilis is really not a good thing to report. But if you look at something like hemorrhoids, cirrhosis, but let's also look at hepatitis, and, of course, some of these people don't understand what hepatitis is, but nonetheless, the bottom line is that many of the things you would like to know about, people recognize as embarrassing conditions, hence, they will be subject to sensitivity issues.

[Slide.]

Let's skip this one. Move on.

[Slide.]

Now, from some data. In the National Fertility Survey, they had some data on doing the questions about the number, well, actually, various sex questions, self-administered versus interviewer-administered.

What we are looking at is the number of sex partners in the past year. It was 1.7 self-administered, it was 1.4 interviewer-administered. Number of sex partners in the past five years, 3.9 versus 2.8.

Condom use in the past 30 days, 46.7 percent self-administered, 35 percent interviewer-administered. Since these were women, this was the condom use of their partner.

If you look at the odds ratio what you really is across all of these, they vary in terms of the absolute rates, that self-administered gives a higher rate than interviewer-administered, which suggests if you believe that more reporting of a sensitive behavior is better reporting, then, it suggests that self-administered gets higher reports.

[Slide.]

Looking at another study, this is a study that deals with what was always viewed for some years as very sensitive, and this has to do with questions that are race related. Attitudes about African-Americans.

Would not vote for a political candidate who is African-American. Ten percent face to face, 22 percent self-administered by mail.

Would not want a close relative or family member to marry. There is really no difference here.

Favor equal opportunity in education and

training for African-Americans, 30 percent to 22.

Favor spending more money on preschool and early education for African-Americans, 60 to 39.

Strongly oppose special preferences in hiring and promotion for minorities, 30 to 38 percent.

So, there is difference on these questions, not all of them, but many, always in the direction of the self-administered getting a higher report of what would be viewed as less socially acceptable behaviors.

[Slide.]

One of the things that we have been asked to address is the issue of face to face versus audio-CASI. For those of you who have heard this blow by you several times and don't know what audio-CASI is, basically, it's computer-assisted self-administered, which means the questionnaire is on your computer, and you are given the computer, and you are answering all the questions on the computer, but so that people don't really know the questions you are answering, you have got headphones on and you are listening to the question and only the answers go onto the screen, so people don't see what it is you are responding to. That

is audio-CASI.

[Slide.]

We asked in a survey about mental health symptoms.

[Slide.]

First, we asked the questions in person or with one sample we did it in person. What we found was major depressive episodes in the past year, 7 percent. Generalized anxiety, 1.6. Panic attacks, 2.0, and agoraphobia, 1.6.

Let's compare it to what you get with the same type of sample audio-CASI.

[Slide.]

Fifteen percent, 6 percent, 4 percent, and 2 percent. The bottom line is that you have got a 2 to 1, you have got almost a 3 to 1, you have got a 2 to 1, and here no difference, but in each of the cases, what you find is higher reporting of sensitive symptoms or symptoms of sensitive conditions by audio-CASI rather than in person.

[Slide.]

Why do we get higher prevalence of sensitive items in self-administered questionnaires regardless of whether or not they are paper and pencil or they are audio-CASI?

The sources are interviewer-induced error. This involves the interaction between the interviewer and the respondents. The interviewer contributed error, this is where the interviewer actually makes the error, and the privacy of the response, which is the interaction between the question, the interviewer, the setting, and the respondent.

[Slide.]

Once again, how would an interviewer per se affect a response? We saw differences between self-administered and interviewers in terms of the race questions. Let's look at some race questions. These are a little bit older.

[Slide.]

White respondents asked by white interviewers if they would mind if a relative married a Negro. Obviously, by our language, we are about 25 years old. But 25 percent would not mind.

Believe Negro and white students should go to the same school, 56 percent.

Would not mind if Negro of the same class moved into the block, 66 percent.

Finally, they should play together freely,

84 percent.

[Slide.]

If the white interviewer is responding to a black interviewer, what you see here is a higher rating in all of these, most dramatically on the issue if a relative would marry, it goes from 26 to 72 percent, which basically means that the characteristics of the interviewer is interacting with the respondent and the question and affecting response. You have got an error term floating around out there.

[Slide.]

In addition to the interviewer who because of his gender, because gender impacts, his socioeconomic status, age, the way they dress, their race, all of this can impact upon a respondent and their answers without the interviewer ever intending to do anything.

Now, let's talk about when we get to the issue of how the interviewer actually behaves. Studies have been done monitoring telephone interviews, and telephone interviewers know they are being monitored, which looked at exactly how interviewers follow rules, who do they deliver the question, do they read it exactly as written.

Fifty-six percent closed, 51 percent restricted open and open-ended questions, only 30 percent read it exactly as written. Minor changes. Major changes 7, 4, 8, and they didn't even read it, 1, 1, and 16.

Interviewers, even when they are being monitored, may not follow rules.

[Slide.]

In another study that was done where they actually observed interviewers in role-playing exercises, mock interviews, the same thing. Did they read it exactly as written? Experienced interviewers, 67 percent. New interviewers, 66.9. New interviewers at the end of training. 66.4. In other words, it is really not an issue of training, it is really not an issue of experience, interviewers don't always do what they are told even when they are being observed.

[Slide.]

But the interviewer gives you the opportunity to probe responses. The good news is about 80 percent probed properly when observed, and under observation, about 1 out of 5 couldn't do the probes properly.

[Slide.]

Let us go back to another issue in terms of paper, audio-CASI, and this is from the National Survey of Adolescent Males, and this is where a lot of the audio-CASI data comes from.

They were asked about any male to male sex ever, 1.5 percent paper self-administered, 5.5 percent audio-CASI. Needless to say, very significant odds ratio.

Male to male anal sex ever, 1 percent, 2 percent. It is not significant. So, a lot of what is happening here is stuff other than male to male anal sex.

Sex with a prostitute, 0.7, 2.5 percent. Very significant.

Street drugs with a needle, 1.4, 5.2.

Shared needle ever, 0.1 to 1.1.

Needless to say, on many HIV risk factors, it is fairly clear that self-administered does not give the same level reporting as another form of self-administered, audio-CASI. However, let me put a caveat here.

The biggest difference here occurs among adolescents. Once you move to the older group, the difference between paper self-administered and audio-CASI drops dramatically, in many cases

becomes nonsignificant.

[Slide.]

Another thing that is being used is telephone-CASI compared to a telephone interviewer, and respondents were asked how they preferred it in terms of protecting their privacy. Forty-nine percent said telephone-CASI was better, 11 percent telephone interviewers, 40 percent were indifferent. Getting honest answers, respondents, 73 percent said the telephone-CASI was better than the telephone interviewers at getting honest answers.

Asking sensitive topics, 66 percent thought telephone-CASI was better compared to 23 percent. However there is a tradeoff here. Easier to use, 30 percent said the telephone-CASI was easier to use, 59 percent said the telephone interviewer was.

Easiest to change answers, 1 percent to 61 percent.

So, like everything, there are tradeoffs here in terms of what you are getting. One form is viewed as more private, the other one is viewed as easier to use and easier to change.

[Slide.]

Why is the prevalence of sensitive items usually higher in audio-CASI than self-administered?

Audio-CASI guarantees by its technology greater privacy of questions. You are listening. Nobody can see what the question is. In terms of the self-administered questionnaire, I don't know from the literature whether we are sitting in a group filling these out, whether we are sitting in private cubicles where the people are coming around, you don't know.

The audio-CASI guarantees that. It guarantees greater privacy of responses. You are putting this in. Nobody can see or hear what you are doing. It is not setting dependent. You can do this in a crowded area and people listening and so on, whereas, the paper is going to depend upon exactly the setting.

Also, there is no data on this, but novelty may be a factor and legitimacy may be a factor, that is, it is complicated, it's expensive, maybe that means it is more important.

[Slide.]

How does this stuff affect the donation process, because there is a small literature on

this. This is a case of at-risk potential donors who left the donation process as a function of the health history and reason for leaving.

Current health history only, currently health history plus behavioral questions, and current health history plus comprehension questions.

What this shows, there is no differences in the rates, the base rates all about the same, no differences in the potential deferred for medical, very little for not specified, and most of it comes in from the AIDS risk, and it comes in from current health history plus behavioral questions.

However, what this doesn't tell you is whether or not these behavioral questions, if they have been added in a self-administered rather than a non-donor administered form, would have had the same effect. In most research we do, the more questions we ask about a sensitive behavior, the higher rate we get.

So, it is inconclusive, but interesting.

[Slide.]

In another study, we looked at the HIV deferral rate for 100,000 donations before and after direct oral questions were implemented at

four blood centers in 1990 to 1991. You can see the rate per 100,000 before the DOQ and note that it varies dramatically from a low of 67 to a high of 477, after DOQ, where it varies from a low of 253 to a high of 555.

The odds ratio is such that in two cases, it is not significant and in two cases it is significant. Now, the interesting fact here is introducing direct oral questioning affects the likelihood of deferral in two out of four facilities. What is interesting among other things is the two that it does, it brings the rate up more in the range of those before, so I am not convinced that I am not dealing with something like a demonstration effect, a Hawthorne effect where by introducing the things, you are changing something in someplace rather than others, but the authors concluded you can't say that adding direct donor questions necessarily increases the reporting of deferrable conditions. It does in some places, in other places it doesn't, and we don't know why.

[Slide.]

Looking in the same study at the actual cases of HIV seropositive donations per 100,000 before and after, the bottom line is that in none

of these cases is it significant.

[Slide.]

In another study, there was a study of direct questions versus indirect questions in terms of deferrals of 6 to 8 blood centers, and what you found basically is this is all donors logged in, all deferrals, and then the rate of deferral based on customary HIV screening, there is basically no difference between these, positive answers to oral HIV risk, which was not done here.

What you see is a higher rate in direct questions than it was indirect, refusal to give answers to additional questions, which would get you deferred, no difference between direct and oral, but if you add these together, if you add additional questions, you get a higher rate of deferral. Unfortunately, it doesn't tell you whether or not if you added these questions in a self-administered versus an oral, you would get these differences.

[Slide.]

So, to finally add up, we asked in one of the studies, we asked donor reaction to the additional oral questions, and this is both indirect and direct, but let's just look at direct.

Were they easy to understand? Yes, 90 percent said yes. Was the privacy good to excellent? 82 percent said yes. Obviously, 1 out of 5 said it wasn't.

Would it stop high risk donors? Only 17 percent said it would, would or might stop them. Well, 79 percent said it will or might.

Did it cause embarrassment? Seven percent who went through the direct questioning said yes, it caused them embarrassment. And would it stop them from donating? Very few said it would, but 1 to 2 percent said that it would.

So, bottom line, from the standpoint of the donors going through the oral questioning, what they tell us is 7 percent say--I am sorry, starting up here--1 to 2 percent they would not donate again as a result, 7 percent said it caused embarrassment. About 80 percent thought it would stop high risk donations, 20 percent did not think it would. Almost 20 percent said the privacy in which they did it was not good or excellent, and almost everybody said it was easy to understand.

[Slide.]

What about the staff reaction? Same questions basically. Let's just talk about direct.

Did they understand? Ninety-seven percent of staff said yes, they understood. Was the privacy adequate? Well, they tended to agree, 80 percent said it was adequate, 20 percent said it wasn't adequate.

Would it screen out high risk? Staff was more likely to think it will screen out, but only 64 percent thought it would.

Are donors honest? Eighty-four percent said they were. Twenty-seven percent of the staff said donors minded the questions, and 24 percent of the staff thought that this would decrease returns.

[Slide.]

Probably more of concern if we moved to oral questioning on total basis, based upon this survey, only 81 percent of the staff said the donors understand the need to ask these questions. Only 83 percent, after extensive training, said the training for the staff was adequate.

The one you should be most concerned about is only 78 percent of the staff who administered it said they were comfortable asking the questions. If people are not comfortable asking the questions, don't expect the answers to be the ones that you are trying to get.

[Slide.]

Finally, the issues that should be addressed from these donation studies. Findings suggest that additional questions identify additional at-risk donors. The question is how many questions can you ask.

It is not clear that removal of these donors reduces HIV seroprevalence in the donation at least from one study.

There are serious issues of training adequacy for donors, the interviewing role may not be comfortable, and privacy may not be adequate for direct questions.

[Slide.]

From the literature, there is no consensus on the best method to collect sensitive information. The limitations of the data is there is a limited number of studies, most are opportunistic, comparison is always between one or two modes.

There is limited control over interactions between mode, interviewer, respondent, instrument, and setting, and there are different results for subgroups, which I have not gone into here - older versus younger, race related. All of these produce

different results in terms of modes.

[Slide.]

Finally, I am forced to answer the question about what is at least the direction of the findings. Self-administered questionnaires tend to result in higher reported levels of sexual activity, drug use and depression, which is only one of a series of mental health behaviors, than interviewer administered questions.

Increased privacy in interview settings, like audio-CASI, will increase reporting rates of sensitive behaviors, but audio-CASI is not so much a technology as a technology that helps achieve a goal, and that is privacy.

Finally, perceived confidentiality of survey will affect reporting rates of sensitive behaviors. If people understand why it is necessary and are assured and believe that the data is treated confidentially, they will report more honestly.

My conclusion basically is--if somebody asked me to vote, and they don't because I am no longer here--is the data basically says that interviewer administered questionnaires, unless you really control the setting, introduces errors that

are likely to reduce the correct and accurate reporting of sensitive behaviors compared to self-administered under appropriate circumstances.

This does not say that the interviewer or donor historian cannot achieve in concert with the process a higher rate. The respondent has to be assured of why this is being done, they have to be convinced that it is valuable, they have to be convinced that it is confidential and will be used in the right way. They have to be able to answer questions.

All of these things can be part of the process in a very valuable role for the interviewer or donor historian in the process, however, the literature, at least my conclusion is, basically says if you have to choose between the two, the interviewer administered way introduces more error in a field setting than it can contribute in terms of improving understand and comprehension.

Thank you.

DR. NELSON: Thank you.

Questions? Dr. Allen.

DR. ALLEN: In the blood donor setting, there is a complex set of interactions going on in that there may be social pressure to donate, there

may be altruistic reasons for donating, and so on, as opposed to just a person who is agreeing to participate in a survey to collect information.

Do you have any sense in that kind of a setting where there may be other reasons for wanting to move through the process and donate, why a person may give less accurate information on one methodology or another in terms of collecting the information?

DR. BOYLE: The reason that I started with sort of the general survey research information and then brought in the limited number of studies we do have from the blood setting is I found the results remarkably similar.

We don't have the kind of extensive study to know the differences in terms of whether or not the people who are less likely to respond honestly don't even come in. We do know from other settings we don't allow interviewers who know respondents in a community to be part of the setting because we know that affects it. So, in a small community, if everybody knows each other, then that setting is likely to make issues of privacy and accuracy of reporting more of a problem.

But what you are seeing up here is the

literature is limited because most people do not fund methodological studies, and in addition to that, the complexity of the dimensions are such that we are working by analogy.

I think the analogy from the data that we were seeing from the blood centers makes it similar to what we see in other setting, but in most other settings, we do it by telephone or by mail or in other ways where it is almost by definition a more private setting than in a bustling blood collection center.

DR. ALLEN: Second question, and that is with the complexity of the medical and social information that is being collected. I most often donate either where there is at least in part a self-administered questionnaire or it is totally interviewer administered, and I, over a period of years, actually more than a decade, have been concerned that the interviewers tend to present information so quickly, even though it is being read, the questions are fairly complex, they are multiple part, there are lots of medical terms and what I will call medical jargon in there.

I am a physician. I find it hard to listen and understand everything even though I have

been donating for 30-some years.

Is there evidence that the audio-CASI or even self-administered questionnaires can elicit the information accurately, is that a better way of doing it perhaps given the complexity and the precision that is required here?

DR. BOYLE: There is two very different questions. One is the whole issue of attention to the questionnaire and the way that it is done. When we monitor telephone interviewers, what you see happen in terms of quality control is when they start the first interviews, up to maybe 40 interviews, you see a constant improvement in quality control and reading the questions correctly, and so on, and after you get to about 50 interviews, it starts dropping off partly because they are familiar with it, they are not listening as much, they think they knew it all, and they are worried about production rates, so they start moving it along. They are not as interested, they are bored, and so on.

From the standpoint of the respondent, the respondent who is hearing this for the first time or the second maybe, is more likely to spend more attention, in my impression, than an interviewer

who has done it over and over and over again, from doing something on the order of 400 telephone interview surveys a year, you hear the respondents being much more thoughtful in terms of the responses than interviewers who have heard it all.

So, I would expect, don't know, but would expect that that would translate into the type of setting that you are talking about, as well, unless you have extraordinary monitoring of those health interviewers.

DR. SCHMIDT: In your study of this literature, I wonder if anybody has used this technique where they are listening to the questions by earphones and they are looking at the computer monitor which says yes or no, but the computer monitor also gives them a picture.

So, if you are talking about jaundice, you see what it is they are saying, and we used to talk about sex questions and using stick figures, but the opportunity to amplify the question with a picture exists.

Has that been used in studies?

DR. BOYLE: I think there will be some people commenting later on perhaps about that. The literature is new enough and the techniques are new

enough that I certainly don't have a lot to report to you on that, but certainly it is an obvious application and a way to improve understanding through that methodology.

DR. DOPPELT: I was going to ask a related question. The conclusion you came to seem to be based mostly on the differences in response for questions to which the person has an answer, they just may not feel comfortable giving the answer, and the question is comparing the interviewer versus the self-administered, when the person doesn't understand the question like the jaundice or, you know, at least with an interviewer, you have a chance to say, well, you know, jaundice means you are yellow or something.

DR. BOYLE: One of the issues that is probably true I think across the board, at least in the survey research industry, is that we insist that the interviewers read only what is on the screen. That may involve follow-up probes, and so on, but when the interviewer is supposed to explain to somebody what something is, they are as likely to make an error in that description by making it too broad or too narrow or leave something out that you really don't know necessarily what is going on.

From the data you saw about interviewer following rules, even under observation, you worry about that. Clearly, if you have interviewers or technology that can flip you to an explanation about what is or what are the symptoms or whatever, you can improve the knowledge and comprehension of the respondent, but unless you have people who are knowledgeable enough and controlled enough to give the same and correct answers each time, you do not want to have somebody who is paid, I don't know, 12, 14 dollars an hour giving explanations about what hepatitis is or other things to a respondent if you want an accurate response. That would be my general response.

When we move to the technology, whether it is CADI or CAPI OR CASI, we are basically, you know, under hepatitis, you put you are not sure, and then it brings up data on here is a description of a person, here is a description of symptoms, and these things have all been standardized, so that people who are experts agree that these are good probes, you are much further down the line.

But I would prefer a technology that provides that in a standardized fashion than watching interviewers. I have listened to over 50

hours of well-trained field interviewers doing surveys when they knew that it was being taped, and they say things like "Now about your drug use, oh, no, I can tell you are a nice person, you wouldn't answer yes to any of these questions," this is a Census supervisor.

So, my concern is if you can control the interviewer and the interviewer setting, they have an opportunity to be value-added, but they have to be very good, very well trained, and very controlled, or they simply introduce sort of uncontrolled error.

Yes.

DR. LEW: I wanted to comment, though, on the single study or the larger study looking at blood donors, and I was impressed with that study, that I don't know if it is really powered to give you the answers, because if you notice, at the one center that has the most donors, it was highly significant that there was an increase, in fact, the two centers that had lots of donors, it was very significant that if you were giving the oral questions, people were more likely to admit to them than in the written.

I think I would like to distinguish

between a written questionnaire versus the audio-CASI, which is very new and has a lot of potential.

Also, I was impressed that even though the other two smaller donor centers didn't statistically have significance, all of them showed at least a trend I would say that, you know, face-to-face interviewing got more answers that would suggest a donor should not donate.

Now, their bottom line was maybe the questions aren't good, and if you can comment on that. Again, I am very impressed that at least in those centers, if you ask face to face, it does make a difference to be able to exclude people who might be at risk.

DR. BOYLE: Oh, I believe that some of the contributors to that research or at least the organizations may even be present here may be able to provide more detail on that than I can.

DR. WILLIAMS: John, one mechanism that has potential application in the blood donor setting is computer-assisted self-interview without the audio component. There may not be data to directly correlate, but would you equate that closer to a paper questionnaire or would it carry

many of the potential benefits of the audio-CASI?

DR. BOYLE: It has many advantages over the paper questionnaire in terms of comprehension because you have the opportunity to have the follow-up screens where you can ask the question have you traveled outside of the United States in the past whatever years.

If yes, then, it takes you to the continents. If yes, it takes you to the countries where you are much more likely to get an accurate answer to your question than the question that says have you been to the British Isles including Wales, the Isle of Mann, and so on, on a questionnaire.

The opportunities of CAPI to get more accurate answers, I mean I think are demonstrable even without data. It allows you to answer, to get more specific questions, to provide information, yet not expand the interview link by any notable amount.

In terms of privacy issues, you do not have the same level of privacy as audio-CASI where you are hearing the questions and nobody can see on the screen what the question is. So, I think in terms of privacy, it is probably comparable to a self administered because whether you are sitting

at a computer screen or you are sitting there with your questionnaire in front of you, depending upon the setting where you are cheek by jowl together or you are sitting by yourself, that tells you what the privacy is.

You probably will generate some novelty effects. It will also increase the sense of the legitimacy, which is equated with the level of effort you make to get these answers, but the big advantage of CAPI is it would allow you to ask better questions and get better answers than you can do in any self-administered, any paper and pencil format.

DR. FITZPATRICK: Based on the lack of any difference in serological testing at those sites, do you think we need to do something to study the effectiveness or see if the oral questions are actually accomplishing anything?

DR. BOYLE: Well, that is a very good question. I mean when in point of fact you get higher rates of deferral, but you don't get higher seroprevalence, the question is whether or not the additional deferrals you are getting are reducing risk.

It is one study. I would hate to hang my

whole hat on it, but it is the obvious question you ask at the end of the day there.

DR. LEW: If I could just comment on that, because I also thought about that. I don't think the study was designed adequately to even address that question, because if you look at it, they took historical data, and we know that the trend is going down, et cetera, they could have done a better job to really address that question.

DR. FITZPATRICK: My question was do you think it is worthwhile, is that enough evidence to promulgate more research into that area though.

DR. BOYLE: Well, let's put it like this. When I was on the committee, I promulgated research for everything, but particularly as it relates to the donor screening questionnaire, because you are doing, you know millions of them a year, it is a burden on the respondent, it is a burden on the facility, it impacts upon presumably donation, so it better have a good response in terms of risk.

At the same time, it covers issues that may not be picked up by other forms of testing. So, in terms of the amount of money that is being spent now, spending a fraction to improve the quality of the risk protection afforded by the

process would seem to be a very valuable and very important and very significant thing to do, and then I wouldn't have to stand up here and sort of say I have got an apple here and a melon here and an orange here, so I conclude we could actually have some critical tests.

DR. SCHMIDT: I would think that some of these studies benefit from being repeated after the American public is exposed to donor voting techniques, computer assisted, because in my day to day life I almost never run into a situation where I have to answer computer assisted questions, so for many donors coming in, blood donors, this would be pretty unique, but I think in a couple of years they will be more used to it except in Florida, of course.

DR. NELSON: The next presentation, Victoria Virvos is going to talk about the literacy issues.

Presentation

Victoria Virvos

MS. VIRVOS: Good morning.

[Slide.]

Let me start off just by saying I want to give you just a little bit about my background only

because I come from a very different perspective of everyone pretty much in this room. I am a educator 24 years, I am a bright person, but in this environment, which is out of my realm, I feel very illiterate. I think this is a real good issue because as we look around and as we think about this whole piece, and it goes way beyond literacy, the bottom line is this.

We are talking a very complex question that has lots of different pieces to it, and we are trying to boil it down and say yes or no, and I am saying that from the start because when I was first asked to come and present, one of the first things I did was I went and I called some of my friends who are reading experts, and I was trying to get information about literacy.

I want you to know I spent so much time talking to people who are very bright and well versed in their area, and they could not give me a specific answer. So, as we look at this information, what I want you to understand is this. The bottom line is at the end, I will tell you in my professional opinion the answer to the question that is being asked, but I will also tell you that it's a very complex issue.

So, having said that, if we would please start with the transparencies, the first one on the considerations.

[Slide.]

There are some issues here as you look at answering the question of whether or not first-time donors should be allowed to actually do a self-administered questionnaire.

I am not going to go over all of these, but I want you to understand, if any of you are interested, you find me and I will talk at great length, but in order to put this in a context and do it within a relatively reasonable amount of time, I tried to really limit this, but when you are talking about that, one of the first things we need to do is look at what is the definition of literacy, because I will tell you my definition of literacy was very different from what the current definition of literacy is.

The second thing is when you look at the literacy, and we will go over this, but then there are different levels or scales of literacy, so I am suggesting that you can look, and the information that I will share with you, what you need to understand is that depending on what scale you are

in, can change depending on the environment, and so on and so forth.

So, again, all of this is to say we are taking complex information, trying to make is very simplistic.

You now have also an area of functional literacy, and again, it is connected, but it is a different component.

You have health literacy, and this is an issue I think really that for me personally, I really want you to think about this because if you take people, such as yourselves, who are embedded in this, this is your life, your health literacy is going to be very different from mine.

If you take the general public who is going to be the type of person who is donating blood, you need to understand they may not be at the same level of health literacy as some of you are, not because they are stupid people, but because they have other lives.

I will also tell you I would invite any one of you--and this is not meant to be unkind, it is meant to be very honest--come into my world and see whether or not you would have the same level of literacy if you were talking to me as an educator.

So, when I looked at this, I was looking really from the point of view of people, not necessarily those of you who are just immersed in this whole health issue.

You have got readability issues, and I think you mentioned, and it has major implications, now again, I am not suggesting one or another thing, but I am saying that the whole readability issue, you could give me a lot of what has been discussed on paper, and I can read it, and not necessarily make any sense out of it.

But then you have got characteristics of adult learners, and again, this is an issue I think for some of you that you are missing the boat, and the reason is this. Adult learners--and what I looked at specifically was information as it relates to adults--and I think the point of all of this is what looks good, makes sense on paper in this scientific environment, is very different when you take it into the real world and you deal with adults.

So, having said that, let's just quickly start with the whole literacy issue.

[Slide.]

If you look at the top, personally, this

was my interpretation of literacy. If you look at the second one, this is the current definition. When they took that current definition, because it is way beyond just being able to read and make sense out of something that is written, because you are going to have information presented in lots of different ways.

[Slide.]

The study that was done and this whole data that I am giving you is the most comprehensive, up-to-date, and I am saying that because it is also onboard for 2002 to actually be updated, so what I am giving you is recognized in terms of literacy to be the most up-to-date.

What this organization and the whole literacy survey, what they did was they created three literacy scales.

[Slide.]

These are the three scales that will affect whether or not someone is at a certain level of literacy, and if you will just take a moment and read over those.

The bottom line is literacy, it is not just being able to read something and make sense.

[Slide.]

These are five levels. What NALS did was they looked at and they said bottom line is you don't have just literate or illiterate people. Wouldn't that be nice if we could do that, but literally, it is a continuum. Again, I mean this sincerely. If you look at me in different areas of my life, sometimes I will be at one level, another time I will be at a different level depending on the environment and what is expected of me.

Now, again, I am saying, and being very honest with you, if I go somewhere and there is a computer, I don't care what level you want to call it, I am illiterate, and I say this upfront because does it not make sense to some of you that again we are not all on the same level, and it has nothing to do with my degree or my level of intelligence.

A lot of it has to do with the environment meaning if I am in an environment with auto mechanics, I am going to be at a different level. Again, if you come into my world of education, if I looked and if I was talking to every one of you just one on one, and I said something like you need to know about me, something you need to know is that I do have a learning disability and truly, I actually have ADD as a result of, too, and I have

problems at times trying to focus.

See, I can talk and talk and talk. You could look at it on paper, but it is going to affect whether or not you understand if your background is not educational in nature. In this environment, if I stopped in the middle of this, and if I said does everyone understand or do you have any questions, and if you are sitting next to someone in this room that you deem to be important, crucial to your career or whatever else, I will guarantee the majority of you in this room may not have any idea of what I just said, but ain't going to raise your hand because you don't want to appear to be stupid.

So, I can go into a blood donation center, which I did last week as a matter of fact, and I was asking the people in this center about the whole idea of the self-administered and what they thought, and so on, and so forth, and I asked this one lady, I said do you believe that is a good idea, and she said yes.

I said, well, tell me how do you know if people, what if I am doing this writing, answering, and I don't understand. She said, well, you can ask someone. I said what if I don't know what to

ask, and she just looked at me and she said I never thought about that.

Now, again, I am giving you a broad overview, but if you look at the different levels, Level 1, 21-23 percent of American adults scored in this level. Now, again, I need to be upfront with you. That doesn't tell you one thing, I mean it really and truly does not tell you a lot, and I also don't want you to make some assumptions based on that, because--if you will go to the next slide, please--

[Slide.]

See, Level 3 from literacy experts is considered functional literacy, and what that means if you are trying to be successful in today's labor market, you need to be at at least Level 3, but I go back to what you need to know is going to change depending on your occupation and your environment.

My father would have been in Level 1. My father was one of the brightest men I knew, but my father came over from Greece, and his English was very limited. So, you see where a lot of people who will fall into the first category may be people in this country who do not have English as their primary language.

[Slide.]

This is another way that you can look at this. Personally, I found it a little too simplistic, but I just wanted to again put it in here because I thought it might be helpful for some of you.

[Slide.]

The issue of readability. Now, again, remember that literacy is really big. Let's now look at readability, because this, to me, if you do chose to go towards the whole idea of a self-administered inventory questionnaire, you are going to have to really think about the readability issue.

[Slide.]

These are some current formulas that are used, and I am not here to tell you which is right or which is wrong or if one is better than the other, but I am going to tell you that what I found fascinating is that the results will vary depending on which formula you use.

So, my question to you will be if you choose to do this, which formula are you going to use and how are you going to make that decision, because what might make sense to me as an educator

may not make sense to the general public.

If you look, one of the formulas will return a score two to three grades lower than other formulas, so again it depends. There is a lot of variability when you look at the different types of formulas that you are even going to use.

[Slide.]

To me, this, I believe, is even more critical, and if you will look over that, you can have a readability formula on some literature and come up with one, if you will, grade level. You can take the same literature, change the length of the sentence, some of the words that you use, take out some of the abbreviations, maybe look at how it is formatted, possibly put some pictures in there, look at the writing style of the author, and get a completely different readability grade level.

[Slide.]

Most formulas really look at two factors, and that is the number of syllables and the number of words in a sentence, but what I wanted you to see with the slide before, there are too many variables.

If you again look at just the number of syllables and the number of words in the sentence,

I believe, if you will go to the next slide, wonderful example, that this might make no sense at all, but if you do a readability formula, depending on which one that you use, it will come out with the grade level because of the number of syllables and so on, and it makes no sense.

[Slide.]

I know this is simplistic sounding, but I want you to understand, in essence, that is what I feel like sometimes is being asked, it is say too complex in the real world.

[Slide.]

If you look at the second statement, that the reading level, the readability piece, it predicts, if you look at it more for prediction, most of them look at how people will answer, getting 50 percent correct answers on a comprehension test.

What that means in English is this. If I have something that is scored at a ninth grade level, what it means is if you have reasonable reading ability, you should be able, when you read something at a ninth grade level, if you are a ninth grader, to answer 50 percent of the questions on comprehension correctly.

Now, again, I go back to if I am going to be getting blood, I don't like that.

[Slide.]

These are some things that again I want you to think about as you make some decisions. The first is adults typically, if you look at all of the adults across the country, typically will read at an eighth grade level. That is if you take everyone together, add them up, and so on, that many adults read at least one to two grade levels below their last school grade completed.

So, you can't look at someone who has finished high school and assume they would be on a grade 12. There was some fascinating information on the whole idea of health. Again, I am saying this because of recently having quite a bit of experience with my mother who was in the hospital and talking to physicians, reading material, being competent in my world, but in a health environment not being able to make a great deal of sense.

What I have found through some of the readings that I have done is that for a lot of people in this country, when it is health related, the literacy level is a lot lower than most people realize.

Again this is not meant to be unkind, it is meant to be honest. Many physician in the room and in this country, they might say something, it makes great sense to them, but if the consumer does not understand, what you are going to find is comprehension goes down. Again, it is not because they are stupid people, it is because they don't understand what is being said.

So, what was recommended really is that information be written at a fifth grade or lower reading level. Now, that sounds to me really low, but I will also tell you, if your ultimate goal is for people to be able to comprehend what it is that they are reading, you need to look at the people to whom the information is directed.

The reading ability of a person does not always match his or her educational level. That is why I am not really spending time talking about the blood donors that you currently have because to me this goes way beyond that, and what their academic level is may not necessarily have anything to do with the understanding of questionnaires.

As a general rule, it is better to write a document that is below the reading skill level of the intended audience. Again, this goes back to if

you want people to be able to give you accurate, honest information.

[Slide.]

This bottom line in conclusion. If you were to ask him for my professional opinion should self-administration of the donor history questionnaire for first-time donors be allowed, I would say you will make whatever decision you choose. I personally believe it is not right, and it is not right for a variety of reasons.

I would also ask you to really think about that if you are doing this self-administration, if you choose to do that, I would make sure that you look at how it is written, I would make sure that you look at what words are being used, I would make sure that you look at what happens from the moment people walk into the environment, because I will tell you, and again it goes back to just working with people, that if you want first-time donors to be repeat donors, I believe really and truly that you need to have the human interaction one on one.

Does that mean that that is perfect? I am not suggesting it does mean that, but I am going to tell you, and it has been fascinating for me just to look at some of the reactions because again,

keep in mind my background is behavior, I can't turn it off, but it is amazing to me where sometimes there is information that people are giving facially, I mean it is very blatant, and other people will miss it.

If you want some people behind this whole idea about having human interaction, Daniel Goldman, you are familiar with him I am sure, who has written a lot of books on the whole emotional intelligence, one of the things that comes out loud and clear in a lot of his books is if you take two people with the same skill level, the ones who are more successful in this life are the people who have people skills, and I think we are forgetting that in this whole quest.

Again, it is to be scientific, but you can't remove the human piece out of this because you are dealing with people. The other thing I want you to really think about is Eric Jensen, who has spent a great deal of time looking not just at the brain research, but with learners and people, he has got a lot of information that pretty much says that people let you know what state. You will have learner states. They will let you know what state they are in, in very blatant terms.

As a teacher, when I am giving information, I will tell you I might ask people do you understand. They can nod their heads, but they are nonverbally giving me very different information.

It was fascinating, last week, when I was in a blood donation location, that will remain nameless, someone passed out, literally fainted, and I asked one of the people, I said could you not tell that this person was having some problems, I mean because someone does not raise their hand and say excuse me, the fact of the matter is if we look at if we expect people to give us all of this information, you see where we are going to lose sight of information people are giving us that might be more non-verbal.

I go back to--again, if any of you are interested, I will be more than happy to talk to you about this, but when you look at some of the research on adult learners, one of the things that you will find that is loud and clear in the literature--again, this is pretty much how I make my living--is that for most people who are adults, when they are successful on the job, it is even more difficult for them to ask for help. If I go

off of my job into a donation environment, and I am in an environment and I am looking at this information, and I believe I am supposed to know everything, it is very uncomfortable for me to raise my hand or go ask someone for some help.

So, does it make sense that if you need help, you should ask for it, yes, but in the real world, I go back to that is questionable. So, all I am going to ask for those of you in this room who are in a decisionmaking position, just keep in mind that we want to do what is right, but we also want to understand that when you are looking at donors, particularly your first-time donors, and if you want to make them ultimately become repeat donors, we need to realize that we can't become elitist and have expectations that everyone is on the same playing ground in terms of the knowledge of health issues.

Thank you.

DR. NELSON: Thanks.

Questions?

DR. DOPPELT: We have in our packet this donor questionnaire. Have you read this?

MS. VIRVOS: Yes, sir, I have.

DR. DOPPELT: At what grade level do you

think this is?

MS. VIRVOS: I have no clue. I will also tell you this, I was--

DR. DOPPELT: I mean you talk about sentence length, and so forth. I mean they are not very long. They are all pretty short.

MS. VIRVOS: That is relatively new. If you remember the one prior to that, was so convoluted. But to answer your question, I am not sure, and the reason I am not sure is because even if you had little words, you need to understand that because some of the medical terms, I mean you have got so many medical terms there that even if you had single syllable words, it is going to impact.

So, to answer, I don't know the answer. I don't know the answer, and I don't know that there is truly a reading formula that will be able to get at not just the number of syllables and the length of the sentences, but also tie into the whole comprehension piece.

To me, that is something you need to really think about is I might be able to read something, have it in my hand, I may not be able to comprehend enough to give a correct answer.

DR. EPSTEIN: Could I ask you to focus specifically on the question of audio-CASI, because we made a distinction in our draft guidance between a presumed equivalence of audio-CASI to a face-to-face interview versus other forms of self-administered questionnaire, and I am concerned that in your general conclusion that a self-administration, a general questionnaire to first-time donors is not appropriate, you haven't focused on whether there is any useful distinction to be made for audio-CASI versus other formats.

I think that that is very important for the committee because it is sort of the focal point of the questions that the members will be asked.

MS. VIRVOS: I understand. I will acknowledge that, and the reason I did not focus on that was because I was asked specifically to talk about the self-administration of the donor questionnaire and I am not that familiar with that other piece.

DR. EPSTEIN: So, if I could sort of focus this point, the opinions that you have provided would be largely applicable to a person reading the questionnaire.

MS. VIRVOS: No. Let me say this.

Because you can take the computer piece, in essence, it is going to be some of the same information, because it's on a computer, because I have headphones on, and I am hearing the words does not help me comprehend any better.

So, if you are looking at reading it or having headphones and having the information on a screen, and we are still going over the same words, and I can't understand it in print, then, even if I hear it, the comprehension personally I think will still be--

DR. EPSTEIN: Well, let me press that point. Are you suggesting to us that the professional literature indicates that auditory literacy is different or not different from written literacy? You are suggesting that there is no difference.

MS. VIRVOS: No, I am not suggesting that. What I am saying is we are looking beyond. You can read it, you can hear it, you can see it, but if I don't understand it, it doesn't matter. It is the same thing in a one-on-one interview. If you talk to me and even if I am able to look at the information in front of me, if I cannot comprehend the information because I do not understand the

words, you see, to me what you are looking at, you are looking at apples and oranges.

I want to look at more of the comprehension piece. If I am sitting in front of a computer or if I am doing a self-administered--again, this is where I might disagree with some of you--I will tell you this. If I am watching you and if you show me on your face you do not understand, then, I would stop. Whether or not I am supposed to, I know I would stop and say you look like you have a question, but if I am in a room by myself and I am doing this, no one is going to be able to even pick up on that.

DR. EPSTEIN: Again, just to try to clarify matters, you might argue that there may be no ultimate difference in comprehension, but it is conceivable that there might be differences in honesty of reporting.

In other words, your argument would tend toward a conclusion that the use of computers or computer-plus audio may not alter comprehension, but one could still potentially have a useful difference in accuracy or honesty of responses unrelated to comprehension in other words.

MS. VIRVOS: But how can I be accurate in

my response if I don't understand?

DR. EPSTEIN: No. I am saying that the percent of respondents who comprehend might not be different, but among the subset who do comprehend, there might be differences in accuracy of reporting based on the medium.

DR. NELSON: You are saying that you won't be able to detect non-comprehension as well in a self-administered questionnaire as you would with a personal interview, isn't that right?

MS. VIRVOS: That is one of the things I am saying.

DR. NELSON: Isn't that what you are saying?

MS. VIRVOS: Yes, sir. The other issue is this. Again, please understand I don't come from your background, so I could probably say it in a more eloquent way and have you understand better, but I can't, this is me, but I will tell you that when you have face-to-face human interaction, my experience has been that people are more honest when they feel a connection to the person.

DR. NELSON: Well, I think there are two issues. One is honesty and the other is comprehension, and I think, as I understand it, you

may be focusing on the comprehension issue, Dr. Boyle was focusing on the honesty issue related to privacy and the fact that the human interaction has a down side as well as an up side.

MS. VIRVOS: Yes.

DR. NELSON: And the down side is if it is your next-door neighbor, you may not be as honest if it were the computer even though the computer could probably be linked to 10 million people, people think it is more private.

MS. VIRVOS: I go back to what I really do believe is this. I believe that there is not a simple answer to this, that it doesn't matter which method you choose, there are going to up and down sides to everything that you choose.

DR. NELSON: Well, the endpoint is validity, in other words, can we get valid answers to the questions we are asking, and there is multi-components that I think we have to weigh.

Another thing, as I understand it, the committee is being asked is should the whole questionnaire be self-administered in some form or another or should it be part self-administered and part direct questions, and when you come to travel to various places, it changes commonly, I can see

that that is a problem.

DR. FITZPATRICK: Just as an educator, one of the things that isn't evident from the literature today or the discussion today, but we have talked about a little bit in the past, what difference do you think it would make, or do you think it would make a difference, for those places that provide the donor some sort of education about the questions prior to giving them the questionnaire, and there are sites that provide a videotaped explanation of the importance of questions and what some of them mean, and then provide them the questionnaire, there are some places that stand before a group and do the same thing, and then provide them the questionnaire for self-administration?

I know you probably didn't evaluate that, but do you think that could make a difference?

MS. VIRVOS: My first response would be yes. My second response would be depending on, because it goes back to the comprehension piece, that the video, whatever other literature is going to be supplemental, needs to be at a level that I can understand.

Again, so, yes, I am saying that could

help, but I am also suggesting to you it is not that simple. It is taking complex medical information and trying to put it into a level where people can comprehend even if they don't have a health background.

DR. ALLEN: I want to thank you for your presentation and the information. I think it is very helpful for us because it does provide a totally different perspective. I commend you also for going to a blood collection center and doing direct observation.

Did you get a chance to observe any questioning of donors in the process, or have you yourself donated blood and gone through that?

MS. VIRVOS: I have donated blood, I have gone through that. I also, because I had traveled last year, I had to wait a year to donate blood, so I was asked some of those questions one on one.

I will tell you that--again, this is my honest response--if I had not been so involved with the focus groups when we were trying to look at the questions and rewrite them, so that more people could understand them, based on the explanation that I got from the person who was helping me, I don't know that I would have been as successful in

answering them, but I will also tell you, having said that, if I had had the opportunity to read without even a human being around, and asked, you know, go to someone if I needed help, I will tell you what I would have done, is I would have probably very sweetly, because my mama taught me to do that, I would have smiled, and when that person turned his or her back, I would have left the center, not to return, because people don't like feeling incompetent, and it had nothing to do with the individuals in the room. I am saying it has to do if I am successful on my job, when you put me in another environment, and I am not successful, what a lot of us will do is we will try not to go back into that environment.

Personally, I want to make it so that the blood donation process is open to all people, because I think really and truly as we look at some of the people coming up through schools today, we have got a lot of people who are doing more traveling and they are not just going to normal places, and so I personally believe your pool is going to be smaller and smaller and smaller.

That is why to me--again, I do realize we are looking at first-time donors, and that is

really what I tried to focus on, but in the back of my mind, what I also want to do is I want to make those first-time donors be repeat donors.

DR. NELSON: Other questions?

If there is no other discussion, there were three groups that wanted to make comments at the open public hearing.

First is America's Blood Centers. Mary Townsend.

Open Public Hearing

DR. TOWNSEND: Thank you. I did want to clarify I am speaking for the AABB Task Force, not for ABC.

I want to refer you to the written comments that you have in your packet. I don't want to take your time to tell you who AABB is because you know who we are. The members of the AABB Interorganizational Task Force to redesign the Uniform Donor History Questionnaire, which is a mouthful, the members are listed in there.

I just want to mention that we had membership from many blood organizations, as well as from the government agencies, from the military, survey design experts, a statistician, and an ethicist.

As you know from the presentation to this advisory committee three months ago, the Task Force have completed an extensive process to redesign and simplify their donor questionnaire. We appreciate the unanimous endorsement that you gave us three months ago.

The Task Force members unanimously support the use of self-administered questionnaires, or SAQs. The concept of the self-administered format was the fundamental principle underlying the Task Force's redesign effort. The Task Force requests that all donors be permitted to self-administer the questionnaire.

There is a considerable body of survey design literature that supports the use of SAQs over face-to-face interviews. First, to address the concerns about SAQs in first-time donor use, a study by Mayo that is referenced showed that, in general, first-time and occasional donors were actually more likely than frequent donors to pay attention to self-administered questions.

Furthermore, a precedent for allowing donor self-administration of a questionnaire has already been established in 1998 when the American Red Cross received FDA approval for such an

approach, and you will be hearing from the Red Cross in a moment about their experience.

In other non-Red Cross blood centers, it is common practice for both first-time and repeat donors to self-administer all the questions on the questionnaire except for the HIV high-risk questions. This practice has been in place many years, and there is no evidence that by now prohibiting self-administration of the questionnaire by first-time donors, an improved donor qualification process would result.

Indeed, the primary, if not the sole, reason that donors are not permitted to self-administer the high-risk questions is that FDA currently prohibits this practice. At the time these questions were first introduced, it may have been prudent to require that staff administer these questions, but there is no evidence that this is still a valid concept.

A CDC-sponsored interview study of HIV-positive blood donors at major blood centers throughout the United States between 1988 and 1998 showed that among 425 HIV-positive first-time donors interviewed, approximately 20 percent expressed privacy concern as one reason that they

did not self-defer even though they knew that they should.

Outside of the blood donor screening area, there has been considerable evidence of this response anonymity effect that was described by John Boyle in which respondents are reluctant to admit to an interviewer that they have engaged in illegal or embarrassing activities.

Examples also cited include studies by Aquilino demonstrating greater likelihood to discuss a history of depression and admit to illegal use of drugs and alcohol in self-administered questionnaires compared to other modalities, and Tourangeau showing a significantly increased likelihood to report a number of sexual partners, sexually transmitted diseases, and condom use in SAQs as opposed to face-to-face interviews. In fact, Tourangeau concluded that increasing the privacy of data collection via self-administration is the approach most widely believe to improve accuracy of answers to sensitive questions.

It is particularly relevant to this discussion to note that the cognitive interviews performed for the Task Force by Paul Beatty and his colleagues at the National Center for Health

Statistics assumed a self-administered survey, and they were done using participants who had never donated blood, that is your equivalent of the first-time donor.

So, when we talk about taking this donor questionnaire into the real world, it was done, the studies have been done by the committee, by the Task Force. These studies offer reassurance that a SAQ would be effective in a blood donor screening milieu.

A final argument against use for SAQ is that the interview process itself, as Dr. Boyle has already shown, may serve as a vehicle for introducing errors into data collection. Interviewers may inject such errors by reading questions too quickly, which we have all heard about, or with little discussion, thereby resulting in failure to trigger an appropriate or accurate response.

Vocal inflections can also have the same effect. This can be avoided by having individuals read the questions themselves, an approach that has been shown to improve response and focus inaccuracy. Even well-trained interviewers can start to anticipate responses to questions that

have little response variation and may introduce unintended variables into question administration. The SAQs appear to reduce the unintended effects of interviewer on the answers to the questions.

Finally, we would like to address FDA's concerns about donor literacy. Data from the REDS study show that the vast majority of donors have a high school education or greater, whatever that means, and literacy therefore should not be an issue for many donors.

I want to remind that you donor screening does not occur in a vacuum. The Task Force realizes that donor screening is a process including donor education, questionnaires, and interaction with the donors after this questionnaire is completed.

Even if a donor has literacy problems or reading problems for that matter, and those of us who are getting older understand that, the FDA is aware that the donor receives careful attention through the donation process. Simply observation alone can determine that someone is inattentive and does not appear to be reading the questions.

In such situations, the staff will intervene and administer questions if necessary.

The User Brochure developed by the Task Force emphasizes that blood center staff should invite inquiries from donors and be available in the event that the donor is having problems.

The Task Force also took a common sense approach of embedding quality assurance tools within the new questionnaire to demonstrate donor attentiveness and understanding by designing the new questionnaire to detect when somebody is just, quote "checking" the boxes.

It is worth noting that FDA representatives to the Task Force were involved in the very rigorous discussions that led to the Task Force taking these additional measures. The Task Force does not endorse oral administration of the questionnaire for all first-time donors in the unlikely event that an isolated donor may be illiterate. The means to determine if someone is having difficulty reading the questions already exist in current screening practice and, further, has been built into the new questionnaires.

Again, I want to remind the committee that this does not occur in a vacuum. We are not talking about handing a person a donor screening implement, having them fill it out, turn it back,

and say okay, let's go.

If the User Brochure instructs the screener to interact with the donor upon completion of that instrument. For example, on the travel question, if a donor checks yes, they have traveled out of the United States, then, the donor screener sits down and discussed the travel pattern and history with the screener.

I want to remind you that these are capture questions and they are aimed at capturing activity that then will be elicited and discussed by the screener. I also want to remind you that the Task Force, in designing this new questionnaire, has already a great deal of time and effort to already address sentence length, word choice, use of abbreviations, the layout of the document, formatting of the document, and overall organization of the content.

I want to remind you that we are talking about the new questionnaire, not the old, complicated, complex one.

Blood centers around the United States are still awaiting FDA's response to the questionnaire redesign proposal that was submitted to FDA in March. The Task Force would like to assist the FDA

review process in any way possible, and would not like to see the process further delayed by any possible impasse over the issue of donor literacy.

As an alternative to the very prescriptive requirement to orally administer the questionnaire, to detect a very small number who may have a literacy or reading problem, the Task Force would like to offer several suggestions.

One is that FDA recommend that blood centers develop a mechanism for determining if first-time donors have literacy or other reading problems. Another approach utilized in the plasma industry is simply to ask donors to read aloud selected items from the educational material or the questionnaires to demonstrate literacy.

We would emphasize that we would like to have as much flexibility as possible for the blood centers.

In closing, the Task Force would again like to emphasize its firm conviction, based on survey design literature and expertise, and the evaluation project of the National Center for Health Statistics, that the blood donor questionnaires should be self-administered by all donors.

Thank you for your time.

DR. NELSON: Thank you.

Comments or questions?

DR. LEW: Just a quick one. You mentioned the CDC study that 20 percent of people who were HIV-positive who donated said there were privacy concerns, but what we don't know is how many people, because they were confronted with questions face-to-face, as we saw with the other studies, they actually admitted that they did, and then they deferred.

DR. TOWNSEND: And I don't believe that was addressed in that study.

DR. LEW: That's right, so it could be that many more people, because of the face-to-face, actually said no, I have this risk, I am not going to donate. Also, you didn't give the other 80 percent of why people continued to donate, was it comprehension?

DR. TOWNSEND: To be honest with you, I don't have that study. That data was provided to us, I believe by Mary Chamberland, who is not here.

DR. FITZPATRICK: Are we to infer from your comments that since you submitted it to FDA in March, there has been no dialogue between you and

FDA?

DR. TOWNSEND: Not that I know of. Kay? That is correct.

DR. FITZPATRICK: Second, in the studies and the activity that was done in developing the Uniform Donor History Questionnaire, were there instances when you provided the questionnaire to a group, and then repeated it at some later date with that same group to determine the validity and honesty of the answers and the questions?

DR. TOWNSEND: No.

DR. FALLAT: I think it the questionnaire that you were using is the one that we have in front of us?

DR. TOWNSEND: Yes, that is the new questionnaire.

DR. FALLAT: Is that the one that you were using?

DR. TOWNSEND: Right.

DR. FALLAT: It seems to me curious that there is no column that says "don't understand" or "not sure." Has that ever been considered, and wouldn't that be an important column to add to respond to the understanding or illiteracy question.

DR. TOWNSEND: No, actually, that is covered in the User Brochure. As I said, this is not done in a vacuum. Donors will be handed this questionnaire and will be instructed what to do, and one of the instructions is if you are not sure about an answer, leave it blank, and they can also mark on it.

At the end, the donor sits down with the screener and they go over this questionnaire together if there are any questions. So, these are capture questions simply to see where the screener needs to put the emphasis, which we believe is a better use of screener time, talking one-on-one with the donor about where their issues are, where their questions are, and the rest of the stuff that is easily understood could be answered.

DR. FALLAT: Do you have any data on the number of people or the number of questions and the kinds of questions that were left blank then?

DR. TOWNSEND: No, the testing of this was not done on the whole instrument. The testing of these questions was done question by question in donor interviews, looking at the content of the question itself.

The Task Force had limited funds and our

emphasis was on developing better questions, and the studies were done in developing better questions. Although we would have liked to have taken the whole questionnaire at the end and tested it as a whole, we were unable to do that. Kay, am I correct? Yes.

DR. NELSON: The next is Dr. Peter Page from the American Red Cross.

DR. PAGE: Thank you. The American Red Cross is a member of the American Association of Blood Banks and supports the statement that they just made. They and others earlier this morning referred to some data the Red Cross has collected in the past and presented to the FDA, which I will now review with you on the SAHH or Self-Administered Health History.

[Slide.]

I will first describe the process. It provides standard written informational materials. We have a brochure that we call What You Must Know Before Donating Blood, which relates risk behavior in relation to blood safety. The donors later sign that they have read and understood that brochure.

Each presenting donor is provided instructions for completing the Self-Administered

Health History in a confidential setting.

The donor completes the questions on what we call the Blood Donation Record, and then the health historian, the Red Cross staff person assesses the donor's comprehension by asking four questions orally.

[Slide.]

The health historian reviews the Blood Donation Record for any "yes" responses to questions. They review it for legibility and they review it for completeness to ensure that all questions have an answer.

The health historian then reviews with the donor orally and documents information for any and all "yes" responses, and it is the health historian, the staff person, that then determines the donor eligibility.

[Slide.]

The procedure for verifying donor comprehension. After the donor has completed the form and answered all the questions, the health historian asks each donor four things. He asks the donor: Do you have any questions? Do you understand all of the questions on the form? Would you like someone to go over the questions you

answered with you? Do you feel that your form was completed in a confidential manner?

If there are any "no" responses, then the staff will perform a staff-administered health history for that presenting donor.

[Slide.]

We compared Self-Administered Health History with Direct Oral Questioning or DOQ. This was a study in which we had four parts. We assessed donor call back, otherwise also known as post-donation information, exemplified by a donor developing a fever a day or two after the donation and calling back to make sure we are aware of that, something that was referred to in an earlier presentation today on another subject.

We also assessed donor deferral rates for the high-risk questions in self-administered versus direct oral questioning. We looked at the confirmed positive viral marker rates, and then there was a survey of donor and staff regarding satisfaction.

The next slide describes the sequence and the size of the study.

[Slide.]

There were nine study regions of Red

Cross's 36 blood regions around the country, and there were 5 control regions that were selected for a similar urban-rural mix.

The study began in January of 1996 and both the study and the control group for six months used Direct Oral Questioning, so we have comparison of the study regions and the control regions doing the same things at the same time in the beginning.

Then, the study region, nine of them, for a year used Self-Administered Health History for over 2 million donations, and then the control regions stayed with Direct Oral Questioning for 800,000 donations.

So, we have the Self-Administered Health History data, which we can compare historically to the same regions earlier, and we can also compare it to, at the same time, the other control regions. Both comparisons were done.

The next slide shows the conclusions.

[Slide.]

The donor call back rate or post-donation information was statistically significantly greater with the Self-Administered Health History, but not a large difference.

The deferral on high-risk questions had a

statistically significant increase overall and depending on whether you looked at the other regions at the same time or the same regions historically, it was a 42 to 57 percent increase in deferrals for high-risk questions or people who didn't donate and we don't have a test result on.

We looked at the infectious disease marker rates and for HIV and hepatitis B surface antigen, there was no difference and no change.

For hepatitis C and syphilis, there was an increase, however, historically from the early part to the latter part, but the same increase was observed in the control regions.

For HTLV, in three of the nine study regions, there was an increase, and the same increase was not observed in control regions. The increase was small.

We concluded that Self-Administered Health History is comparable to Direct Oral Questioning.

[Slide.]

The donor and staff satisfaction surveys showed the donor processing time decreased an average of 4 minutes and up to 8 minutes, an issue that has been a complaint from many donors that it takes so long to donate.

There was a sense that particularly the older donors were less embarrassed, and the staff felt that donor comprehension was good. Some staff members felt that donors would be more honest in not having to verbalize some sensitive information. This is based upon surveys of staff and donors.

[Slide.]

This slide is a copy of a letter we received from the FDA in 1998.

[Slide.]

This slide summarizes the key points that the FDA has accepted this data and accepts us including Self-Administered Health Histories as an alternative to direct oral questioning in our procedures.

[Slide.]

My last slide just states that since that approval, we have screened over 5 million first-time donations using this process.

Thank you.

DR. NELSON: Do you have any sense of the issue raised by the previous speaker about the proportion where there were real significant comprehension problems with the questionnaire when you went to the self-administered from the oral?

DR. PAGE: I don't have with me, and don't know if we have, data about the number of times the donors answers "yes" to one of the four questions trying to determine whether they understood it or not, and I don't have data as to how many questions are left unanswered in self-administered to bring to the person, but that is data that we could prospectively collect.

DR. SIMON: I may have missed it, but this includes now the high-risk questions or does not?

DR. PAGE: Yes, all questions.

DR. SIMON: All questions.

DR. PAGE: The only questions necessarily asked are the ones do you have any questions, do you understand the questions, do you want somebody else to go over it with you, and do you feel it was done in a confidential manner.

DR. STUVER: Do you have any sense of if there were any differences between the two methodologies with respect to whether they were first-time donor or repeat donor?

DR. PAGE: No. This study was done to study the acceptability or a similarity of direct oral and self-administered, and this study did not provide out first-time from repeat. This was done

six to seven years ago.

DR. NELSON: Twenty, 30 percent of donors are first-time?

DR. PAGE: That's correct, about 20 percent in general were first-time, or 20 percent of donations are from first-time donors.

DR. NELSON: So, you would probably have several hundred thousand.

DR. PAGE: Five million since then. Oh, but in the study--

DR. NELSON: In the study.

DR. PAGE: In the study, it would have been several hundred thousand, yes.

DR. KOFF: Peter, can you mention what the four questions that were asked that were used to judge comprehension?

DR. PAGE: They are: one, do you have any questions; two, do you understand all of the questions on the form; three, would you like someone to go over the questions you answered with you; and, four, do you feel that your form was completed in a confidential manner.

DR. KOFF: Those really don't sound to me like they are really getting to the question of comprehension. They are getting to perception maybe

of comprehension, but have there been any studies using SAHH actually trying to get a handle on how much comprehension actually occurred? Have you done anything in that direction?

DR. PAGE: Not that I am aware of specifically, but this is not a field that I have been close to over the years.

DR. LEW: That is something I wanted to ask myself. I am just amazed that we are now jumping into this, 5 million people already using this, and yet, there is some important questions about comprehension and validity of using the self-administered test, but we are jumping into it without any prospective studies, I mean studies to actually look at it and make the decision if this is the right thing to do.

I am also impressed with one of the slides that was shown. A fifth of all people, 20 percent don't know what hepatitis means. If you look at the new questionnaire, you know, have you ever had it, et cetera, and the way this is set up, your system, you only kind of pursue those questions where people answer yes.

Many people, when they see a word they don't understand, oh, no, I didn't have that

disease, and they are just going to check off "no." It is hard to believe that we are doing this to millions and millions of people without stronger testing to make sure it is the right thing to do.

DR. PAGE: We do ask them if they have any questions, but if--

DR. LEW: I would like to ask the people who do these studies that have these questionnaires, with a box saying "I don't understand, actually make people more honest, because if you don't have that option, and you have to say "yes" or "no," well, no one wants to look dumb, and they may say "no," but if they said "don't understand it," and it's a standard question, they feel comfortable saying "I don't understand."

DR. PAGE: I think the intent is to permit them to leave the question unanswered until they interact with a staff person, who can then handle it verbally with them.

DR. LEW: Most people would like to complete a test, that's my guess.

DR. NELSON: There are actually some data from the REDS study, which follows up donors who have markers, and how often has the issue been

comprehension as opposed to socially desirable responding.

DR. SIMON: I would just like to try to put in context, following on the last comments, actually, the interview given by an interviewer has not been validated or studied to any greater extent than the self-administered.

This has simply not been an area that has received attention or study until really the Task Force, as far as I know, well, there was some other work done by Donna Mayo, and there have been sputterings of efforts over the years, but I think a lot of the attention is being focused now is because this is the first time that we have really looked at it. Maybe Harvey has on that same point.

DR. KLEIN: It is a point that I think has been made, but perhaps this committee needs to have reemphasized, and that is to the best of my knowledge, none of the questions on any of the donor questionnaires ever used has ever been validated.

Yet, we collected 15.1 million units of whole blood and components last year, so we have what is clearly a non-validated system in place.

Many of the questions vary dramatically

from center to center. This is no standardization. To be brutally frank, some of the questions on risk behavior and geographical exclusion that have been accepted verbatim as given by the FDA are literally incomprehensible.

I have a high school degree and I was reasonably high up in my high school class, and when I donate blood, I have to read them several times. So, I think sort of like the HTLV-3 assay, that was anti-HTLV-3, that was licensed in 1985, it is not the same assay that we are using today.

I hope that we will clearly see this as a starting point and start to validate this kind of questionnaire, but looking at what we are currently using, I don't think we should be in any way satisfied that we are stepping off of a very comfortable and a very useful questionnaire into an abyss. We are not. This is clearly a step in the right direction whether it is applied as a self-administered or as one that is administered by a screening nurse.

DR. FITZPATRICK: I was just curious, in the light of you seeing very little significance and difference in serological testing between groups or PCR testing I am assuming since some of

this was done after NAT, but seeing an increase in 42 to 56 percent of your deferrals, why would you choose to increase your deferrals over what you were seeing as benefits?

DR. PAGE: Those deferrals were the high-risk deferrals, and we don't have a sample on them to know what their viral positive marker rate is, but I would say that if there is any question about their suitability or answering "yes" to a question, it would have been best not to have collected, which is what happened when there was self-administered health history.

Am I understanding your question?

DR. FITZPATRICK: Well, a large number were repeat donors, though, that would have been self-deferring for the first time even though they had donated previously.

DR. PAGE: Presumably. I don't know the proportion that were first-time versus repeat in that group.

DR. FITZPATRICK: So, you would have available the data to look at to see if you were--

DR. NELSON: I doubt very much that the data would answer this question just because the proportion with markers is small enough, and the

denominator is so large, and the number of diffused is deferred. Additional deferrals is probably a fairly small number of the total.

DR. PAGE: The number deferred for those high-risk questions is a relatively small proportion of the overall deferrals. I don't have it at hand, but that's available.

DR. NELSON: I don't think the data are going to be adequate, but it would be interesting if you, in fact, could measure markers in that group without taking a unit. That is I think difficult for you to do.

DR. PAGE: A possibility is to the fingerstick and put a drop on the filter paper, which can then be analyzed for some of those markers. It has been considered, but I don't believe done.

DR. NELSON: Well, they separately do a hematocrit, so there is a fingerstick part of it, before the unit is taken.

DR. PAGE: It could be done, and ELISA testing can be done on such blood on filter paper.

DR. LEW: If I could just add a comment that I guess on the study that you showed, that was based on that study, that you could use that

questionnaire, I guess I have concerns are those populations truly comparable between the controls and the test group, because if you look at it, it looked to me that the controls only donated twice over that time period. There were I think 400,000 and then 800,000 donations, and then the actual test group, there was only 500,000, but they donated two million times.

There were some differences in HTLV-3. Again, I just don't know the data, so I don't know if those are truly comparable in that study.

DR. PAGE: You are astute to notice that there is not the same ratio of sample sizes in the study and the control group, and that was related to not every study started on January 1st, and not every study stopped on June 1st, but they were all done during that period of time.

One might have done it for three months, another one might have done it for five months.

DR. LEW: And then the other last thing is that I agree that we don't have a validated system with the oral. It is just that we are calling this the standard because it has been used forever, and I think a good point is brought up. We need to start validating these tests.