

Simplifying the Blood Donor History Questionnaire: Progress Report

**Blood Products Advisory Committee Meeting
June 14-15, 2001**

Joy L. Fridey, MD, MBA
on behalf of the
**AABB Task Force to Redesign the Blood
Donor History Questionnaire**

- **Retrospective**
- **Current state of affairs**
- **Task Force plans for change**
- **Where we are**

1953:

**“DONOR RECORD CARD”
INTRODUCED BY AABB**

1953 Donor Eligibility Questions Itemized “yes - no” Format

Malaria

Syphilis

Jaundice

Tuberculosis

Brucellosis

Upper Respiratory Diseases

Skin Diseases

Allergic States

Bleeding Abnormalities

Convulsions*

Heart Disease

Diabetes*

Drug addiction*

Inoculations/vaccinations*

Alcoholism*

Surgery

Dental extractions

Transfusions

Previous Blood Donation

Weight Loss

Pregnancy

AABB Technical Methods and Procedures, 1953

*In times of national emergencies, may omit these items.

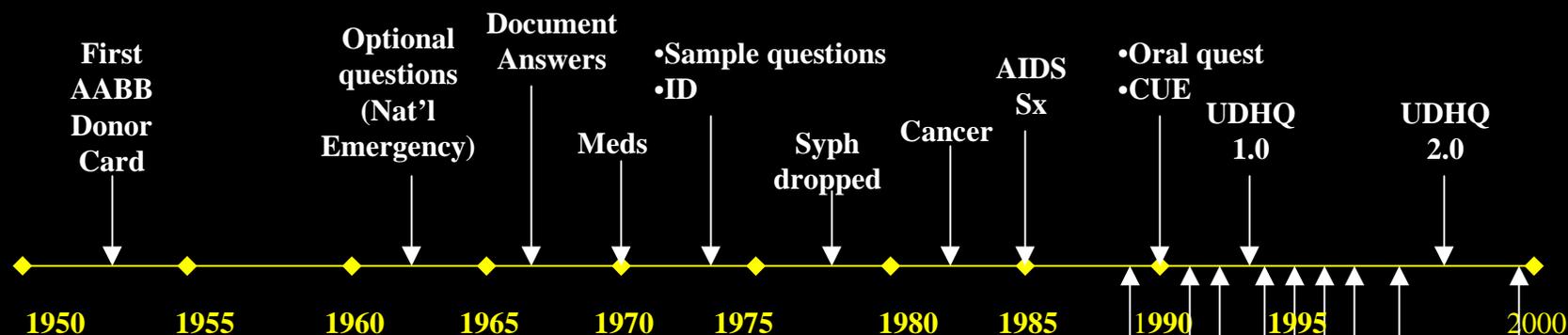
(AABB Technical Methods and Procedures, 1962)

White: No longer in use

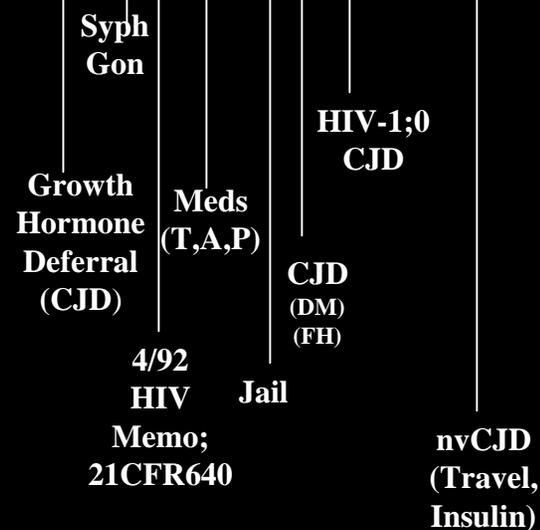
Yellow: In use

Blood Donor Eligibility Questions: Chronology

AABB



FDA



Blood Donor Qualifying Information: A Half-Century Review



Structure of Questions on UDHQ

Single item: 24

Compound: 14

Multi-item: 8

**Source of Required/Recommended
Donor Information:**

AABB: 20 Items

FDA: 50 Items

“Wish List” from FDA’s Constituents

- 1. Shorter questionnaire for all donors**
- 2. Abbreviated questionnaire for repeat donors**
- 3. Questions: easier to understand, less intrusive**
- 4. Less repetition (written, oral)**
- 5. Self-administered questionnaire**
- 6. Validation of questions by proposing agency prior to recommending/requiring**

Attempts to Cope

- **1992: AABB/BCC Uniform Donor History Card**
- **Multi-item and compound questions appeared**
- **1998: AABB reorganized questions**
- **By end of 1999, FDA approval of several abbreviated versions**
- **2000: FDA asks industry to form a multi-agency task force, under aegis of AABB**

Donor History Questionnaire: Task Force (DHQTF)

- **American Association of Blood Banks (AABB)**
- **American Blood Resources Association (ABRA)**
- **American Red Cross (ARC)**
- **America's Blood Centers (ABC)**
- **Centers for Disease Control and Prevention (CDC)**
- **National Center for Health Statistics (NCHS)**
- **Department of Defense (DOD)**
- **Food and Drug Administration (FDA)**
- **Ethicist**
- **Statistician**
- **Research survey design specialists**

Ex officio: Canadian Blood Services

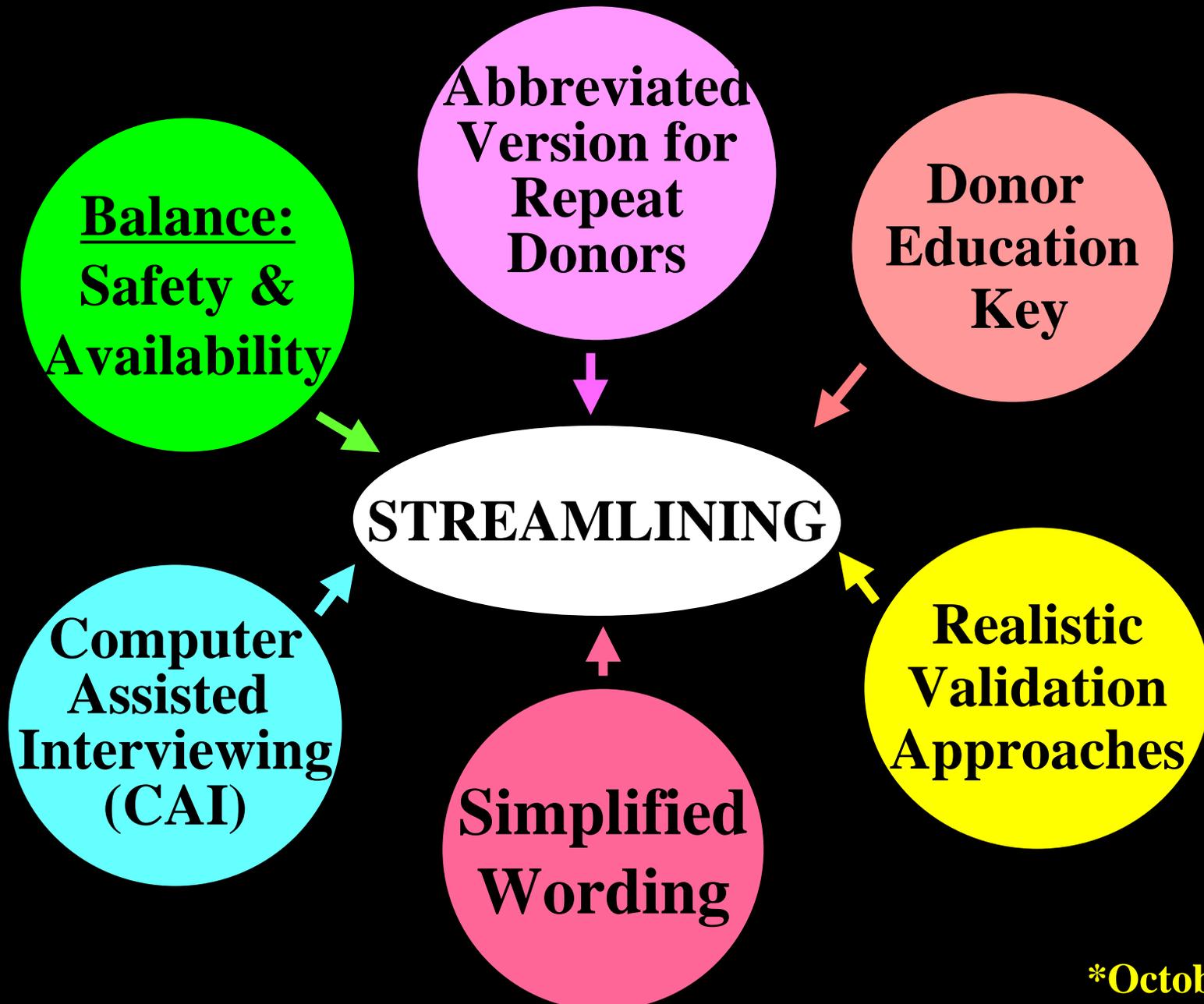
DHQ TASK FORCE: PARAMETERS

- **Research: conduct focus groups and pilot studies; major initiatives not expected.**
- **No research funds available from FDA**
- **Heavy reliance on participation of blood collection establishments and Task Force members**
- **Work mainly through conference calls, ecommunication**
- **Proposal due in 2001**

CHALLENGES

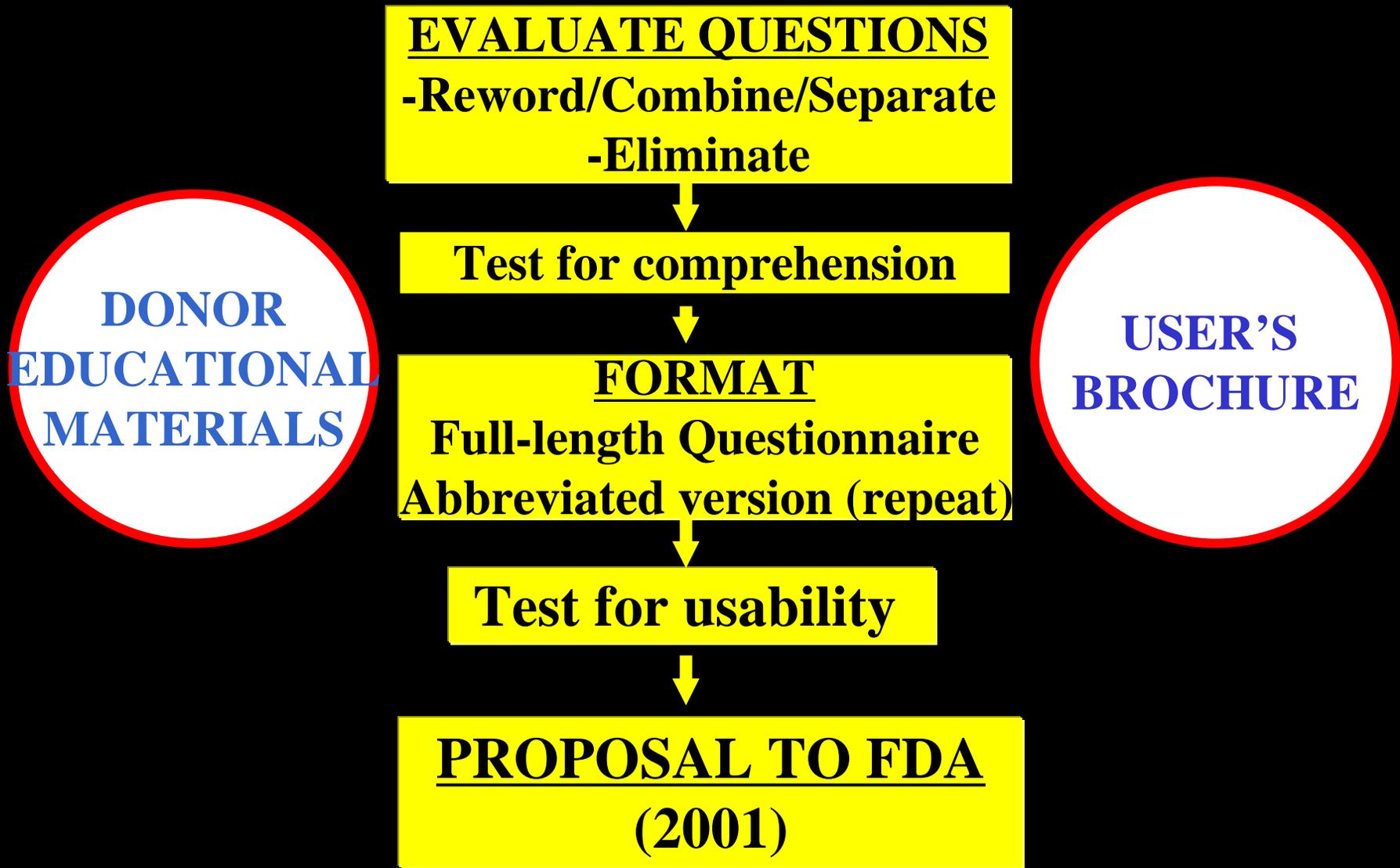
- 1. Communication**
 - **Intraorganizational**
 - **Interorganizational**
- 2. Managing expectations of end users**
- 3. Resources (time, money, people, organizations)**
- 4. Validating within the parameters**
- 5. Change**

Recurring Themes of the AABB/FDA Conference*



*October 2000

TASK FORCE ACTION PLAN



Activities of Task Force to Date

- Kick-off conference call: June 21, 2000
- Developed, executed survey of AABB Institutions (to identify problematic questions)
- Co-organized the 10/00 AABB/FDA Workshop on Streamlining the Donor Questionnaire
- **Developed simplified questions and proposals for elimination of some questions**
- Refined research approach for evaluating changes; conducted focus groups
- Worked with FDA on xeno, malaria questions

HOW

- **12 all-Task Force conference calls**
- **14 conference calls by 6 subcommittees**
- **3 face-to-face meetings**
- **Hundreds of emails**

“Simplify”

..to make simple or simpler: as

a) to reduce to basic essentials

b) to diminish in scope or complexity:

STREAMLINE

c) to make more intelligible: CLARIFY.

...Webster's New Collegiate Dictionary

Simplify Fewer items

Wisdom of the Past

“The questions must be asked in non-medical terms.”

AABB Technical Methods and Procedures, 1962

Simplification

- = **Better donor comprehension**
- = **More accurate, relevant information**
- = **Improved safety**
- = **Fewer errors**
- = **Fewer discarded units**

Our approach to simplifying...

- 1. What is the target information of the question?**
- 2. What is the simplest way a question can be stated?**
- 3. Take cues from FDA E&A Reports, AABB surveys**
- 4. Use published* and project-specific focus group information**
- 5. Utilize judgment, experience of Task Force members**
- 6. Leverage experience of health survey experts**

***Orton S, Transf. 2000;40:1407-1413**

Approach to simplifying.....

1. Task Force subcommittees

- Survey design specialist input**

2. Entire Task Force review, revisions

3. Focus groups (S. Orton, Holland Labs, ARC

Proposed Revisions (In General)

- **Use of less ethereal phraseology**
- **Break up many compound questions**
- **Medications: list of required inquiries**
- **Health conditions: focus on most germane**
- **Eliminate some non-FDA questions**
- **Self-administered questionnaire**

Specific Modifications to Retained Questions

Question 2

Current:

In the past 8 weeks have you given blood, plasma or platelets here or anywhere else?

Proposed:

In the past eight weeks have you given blood, platelets, or plasma?

In the past 16 weeks have you given double red cells?

Question 4

Current:

Are you feeling well and healthy today?

Proposed:

Are you feeling well today?

Questions 5, 6, 7

Current:

5. In the past 12 months have you been under a doctor's care or had a major illness or surgery?
6. Have you had chest pain, heart disease, recent or severe respiratory disease?
7. Have you ever had cancer, a blood disease, or a bleeding problem?

Proposed:

- Have you ever had any type of cancer, including leukemia?
- Have you ever had any problem with your heart and/or lungs?
- Have you ever had a bleeding condition or a blood disease?
- Have you had any medical condition listed on the Medical Deferral List? **[FOR LOCAL USE]**

Question 8

Current:

Have you ever had yellow jaundice, liver disease, viral hepatitis, or a positive test for hepatitis?

Proposed:

Have you ever had hepatitis?

Question 9

Current:

Have you ever had malaria, Chagas' disease or babesiosis?

Proposed:

- Have you ever had malaria?
- Have you ever had (a) Chagas' disease?
(b) Babesiosis?

Question 10 - Medications

Current:

10A -Tegison

10B -Soriatane

10C -Aspirin...in past 36 hours

10D -Accutane, Proscar, Propecia

10E -Past 4 weeks, any pills or medications?
(1. Special inquiry about bovine insulin)

Proposed:

- Are you taking any medications on the Medication List?



Donor will be given a list with the FDA- req'd med inquiries on it

- Are you currently taking an antibiotic or any other medication for an infection?

- In the past 36 hours have you taken aspirin or anything that has aspirin in it?

MEDICATION DEFERRAL LIST

Please DO NOT DONATE if you have taken any of these medicines IN THE PAST MONTH:

- PROSCAR (FINASTERIDE)
- PROPECIA (FINASERIDE)
- ACCUTANE (ISORETINOIN)

Please DO NOT DONATE if you have taken any of these medicines in the PAST THREE YEARS:

- SORIATANE (ACTITRETIN)

Please DO NOT DONATE if you have EVER TAKEN any of these medicines:

- TEGISON (ETRETINATE)
- GROWTH HORMONE FROM HUMAN PITUITARY GLANDS
- INSULIN FROM COWS (BOVINE, OR BEEF, INSULIN)

IF YOU WOULD LIKE TO KNOW WHY WE NEED TO DEFER YOU FOR TAKING THESE MEDICINES, PLEASE KEEP READING:

- **If you have taken or are taking Proscar, Propecia, Accutane, Soriatane, or Tegison, your donated blood could contain significant levels of these medicines and possibly cause birth defects in fetuses.**
 - **Proscar is for prostate gland enlargement**
 - **Propecia is for baldness**
 - **Accutane is for severe acne**
 - **Soriatane and Tegison are for severe psoriasis**
- **Growth hormone from human pituitary glands was prescribed until 1985 for children with delayed growth. The hormone was obtained from human pituitary glands, which are found in the brain. Later, a few people who took this hormone developed a rare nervous system condition called Creutzfeldt-Jakob Disease (CJD, for short). CJD has not been associated with growth hormone preparations available since 1985.**
- **Insulin from cows (Bovine, or beef, insulin) is an injected material used to treat diabetes. If this insulin was imported into the US from counties in which “Mad Cow Disease” has been found, there is a rare chance it could contain material from infected cattle. (Bovine insulin has not been known to transmit “Mad Cow Disease.”)**

Questions 11 and 12

Current:

11. In the past four weeks have you had any shots or vaccinations?
12. In the past 12 months have you been given rabies shots?

Proposed:

- In the past four weeks have you had any shots or vaccinations?
- Eliminate 12

Question 13

Current:

Female Donors: In the past 6 weeks, have you been pregnant or are you pregnant now?

Proposed:

Female donors: Are you pregnant?

Question 14

Current:

A. In the past 3 years have you been outside the United States or Canada?

B. Have you visited or lived in the United Kingdom (names of countries) from 1980-1996? If so, have you spent a total of six months or more from 1980-1996?

Proposed:

A. No changes

**B. Between 1980 through 1996, did you spend time in the United Kingdom that adds up to six months or more?
<names of countries>**

Question 15 - CJD/vCJD

Current:

- A. Have you ever received human pituitary derived hormone?
- B. Have you ever received a dura mater (or brain covering) graft?
- C. Have you or any of your blood relatives ever had Creutzfeldt-Jakob disease or have you ever been told that your family is at an increased risk for Creutzfeldt-Jakob disease?

Proposed:

- A. Will be removed from the card proper and added to the “Medications Deferral list”
- B. No change
- C. Have any of your relatives ever had Creutzfeldt-Jakob disease?

Question 16

Current:

In the past 12 months have you had close contact with a person with yellow jaundice or viral hepatitis, or have you been given Hepatitis B immune globulin (HBIG)?

Proposed:

- In the past 12 months have you come into contact with blood or saliva from, or had sexual contact with, a person who has hepatitis?**
- In the past 12 months have you been given hepatitis immune globulin (HBIG)? (Note: this is not the same as the Hepatitis B vaccine)**

Question 18

Current:

In the past 12 months have you received blood or had an organ or a tissue transplant or graft?

Proposed:

- **In the past 12 months have you had a blood transfusion or received clotting factor concentrates?**
- **In the past 12 months have you had a transplant such as organ, tissue, or bone marrow?**
- **In the past 12 months have you had a graft such as bone or skin?**

Question 19

Current:

In the past 12 months have you had a tattoo applied, ear or skin piercing, acupuncture, accidental needlestick, or come into contact with someone else's blood?

Proposed:

- In the past twelve months have you had a tattoo applied or or ear or skin piercing (including acupuncture)?**
- In the past 12 months have you had an accidental needlestick or come into contact with someone else's blood?**

Question 20

Current:

- A. In the past 12 months have you had a positive test for syphilis?
- B. In the past 12 months have you had or been treated for syphilis or gonorrhea?

Proposed:

- A. Eliminate
- B. No change

Questions 21 and 22 (Money-sex)

Current:

21. In the past 12 months have you given money or drugs to anyone to have sex with you?

22A. At any time since 1977 have you taken money or drugs for sex?

22B. In the past 12 months have you had sex, even once, with anyone who has taken money or drugs for sex?

Proposed:

- In the past 12 months have you had sex with a prostitute or anyone else who takes money or drugs or other payment for sex?
- Since 1977 have you ever received money, drugs, or other payment for sex?

Question 23

Current:

A. Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?

B. In the past 12 months have you had sex, even once, with anyone who has used a needle to take drugs not prescribed by a doctor?

Proposed:

- **Have you ever used needles to take drugs, steroids, or anything else not prescribed by your doctor?**
- **In the past 12 months have you had sex with anyone who has ever used needles to take drugs or steroids, or anything else not prescribed by their doctor?**

Question 24

Current:

Male donors: Have you had sex with another male, even once, since 1977?

Proposed:

Male donors: Since 1977 have you had sex with another male?

Question 25

Current:

Female donors: In the past 12 months have you had sex with a male who has had sex, even once, since 1977 with another male?

Proposed:

Female donors: In the past 12 months have you had sex with a male who has ever had sex with another male?

Question 26

Current:

- A. Have you ever taken clotting factor concentrates for a bleeding problem such as hemophilia?**
- B. In the past 12 months have you had sex, even once, with anyone who has taken clotting factor concentrates for a bleeding problem such as hemophilia?**

Proposed:

- **Covered in revised question 18**
- **Part B: In the past 12 months have you had sex with anyone who has hemophilia or has used clotting factor concentrates?**

Question 27

Current:

A. Do you have AIDS or have you had a positive test for the AIDS virus?

B. In the past 12 months have you had sex, even once, with anyone who has AIDS or has had a positive test for the AIDS virus?

Proposed:

- Have you ever had a positive test for the HIV/AIDS virus?**
- In the past 12 months have you had sex with anyone who has HIV/AIDS or has had a positive test for the HIV/AIDS virus?**

Question 30 - Africa

Current:

- A. Were you born in, have you lived in, or have you traveled to any African country since 1977?
- B. When you traveled to <countries> did you receive a blood transfusion or any other medical treatment with a product made from blood?
- C. Have you had sexual contact with anyone who was born in or lived in any African country since 1977?

Proposed:

- A. Capture question: Have you ever been in Africa?
- B. (If “yes” to A): While you were there, did you receive a blood transfusion or any other exposure to blood?
- C. Have you ever had sex with anyone who was born in or lived in Africa?

Question 31

Current:

In the past 12 months have you been in jail or prison?

Proposed:

In the past 12 months, have you been in juvenile hall, lock-up, jail, or prison?

Proposal to Eliminate Specific Questions

None of these questions are required or recommended by FDA

Three categories:

- 1. Not in AABB Standards or FDA documents**
- 2. In AABB Standards; no FDA recommendation or requirement**
- 3. AABB response to FDA regulation or recommendation that does not specifically call for a question**

Category 1 Questions Recommended for Elimination

(No AABB Standard, no FDA recommendation)

3. Have you for any reason been deferred or refused as a blood donor or told not to donate?

Rationale for Eliminating:

- 1. Non-specific - picks up many previous minor and temporary deferrals.**
- 2. Focus group and 2000 AABB survey of blood centers suggest this question is particularly irksome to donors due to reiteration of reason for previous deferrals at every subsequent donation.**

Category 1 Questions Recommended for Elimination

(No AABB Standard, no FDA recommendation)

28. Are you giving blood because you want to be tested for HIV or the AIDS virus?

Rationale for Eliminating:

- 1. Currently not asked of almost 50% of blood donors**
- 2. 1999 data from three US blood centers, representing 210,000 donors show, that only 0.01-0.03% answered “yes.”***
- 3. Information is posted at blood centers, per FDA**
- 4. Many centers include this in donor educational materials**
- 5. Message will be reinforced in revised educational materials**

*** D. Triulzi, ITXM
J. Gorlin, MBCM
J. Fridey, BBSBRC**

Category 2 Questions Recommended for Elimination
(AABB Standard, no FDA recommendation)

12. In the past 12 months have you been given rabies shots?

Rationale for Eliminating:

“We can find no compelling medical, epidemiological, or public health justification for this question. Specifically, 1) Rabies is not spread by the bloodborne route; rather, after entering through a break in the skin or across a mucosal surface the virus replicates in muscle cells and spreads via peripheral nerves to the central nervous system; 2) the reported incubation period varies from a few days to more than six years, although 75% of persons become ill in the first 90 days following exposure; and 3) post-exposure treatment would not require injection of any live virus material.”

- Mary Chamberland, MD, MPH
- Charles Rupprecht, VMD, PhD
Chief, Rabies Section
Division of Viral/Rickettsial Diseases
CDC
1/31/2001 email to Joy Fridey, MD

Category 2 Questions Recommended for Elimination **(AABB Standards, no FDA recommendation or reg)**

13. In the past 6 weeks have you been pregnant, or are you pregnant now? (Note: proposal is to eliminate “In the past 6 weeks.”)

Rationale for Eliminating:

- 1. Consultation with OB-GYN liaison to the AABB Blood Bank/Transfusion Services Standards Committee: no medical indication to inquire about pregnancy in past 6 weeks. Anemia would be detected through predonation hemoglobin screening; prospective donors with infected episiotomies/C-sections would be symptomatic.**
- 2. AABB BBTS Standards concurs with recommendation.**

Category 2 Questions Recommended for Elimination

(AABB Standard; no FDA recommendation/reg)

17. In the past 12 months have you taken (snorted) cocaine through your nose?

Rationale for Eliminating:

- 1. Eliminated from AABB BBTS Standards, 20th. Ed. due to lack of supporting evidence.**
- 2. REDS data do not show intranasal cocaine use to be an independent risk factor for HCV infection.**

Category 2 Questions Proposed for Elimination

(AABB Standard; no FDA recommendation/reg.)

20A. In the past 12 months have you had a positive test for syphilis?

Rationale for Eliminating:

- 1. Donors will be asked about treatment for syphilis or gonorrhea in the past 12 months.**
- 2. Consistent with approach to hepatitis inquiry, focusing on actual clinical diagnosis vs. test results.**
- 3. 12/12/91 FDA memo (“..Recommendations for Donor Deferral ...Based on the Results of Syphilis Testing”) applies to blood center tests. Our interpretation: deferral based on test results obtained at blood centers, not testing done at non-blood center facilities. Memo does not require that a question be asked.**

Syphilis test question (20A), Rationale for Eliminating (cont'd)

4. Syphilis testing of donors is standard. If donor has been exposed, current tests would detect treated or current infection.

5. Given that highly sensitive syphilis assays are in use, asking if a donor has had a positive test for syphilis is a non-specific and insensitive approach for identifying donors at risk for previous or current syphilis infections.

6. Individuals are more likely to know whether they have had syphilis vs. just a reactive test result.

Category 3 Questions Proposed for Elimination

(AABB question in response to FDA document; FDA question not recommended/required)

- 1. Have you ever donated or attempted to donate using a different name (or another name) here or anywhere else?**

Rationale for Eliminating:

- 1. Current question based on 21 CFR 606.160(e) April 1999: “A record shall be available from which unsuitable donors may be identified so those products from such individuals will not be distributed.” Refers to having and maintaining deferral databases. Unclear how *this* screening question addresses that issue.**
- 2. The ability to link/access donor records a local issue, dependent on technological capabilities and donor identification systems of each center.**
- 3. AABB BBTS Standards Committee concurs with recommendation to eliminate.**

Category 3 Questions Proposed for Elimination
(AABB question in response to FDA document; FDA question not recommended/required)

29. Do you understand that if you have the AIDS virus you can give it to someone else even though you may feel well and have a negative AIDS test?

Rationale for Eliminating:

- 1. Question was based on 4/23/92 FDA memo stating that “donors should be informed that there is an interval during early infection when the HIV antibody test may be negative although the infection may still be transmitted.” This information is covered in many centers’ educational materials already, and will be reinforced in the revised educational materials.**
- 2. Question is complex and long**
- 3. AABB BBTS Standards concurs with recommendation to eliminate.**

Category 3 Questions Proposed for Elimination

(AABB question in response to FDA document; FDA question not recommended/required)

32. Have you read and understood all the donor information presented to you, and have your questions all been answered?

Rationale for Eliminating:

- 1. Based on 4/23/92 FDA memo stating “information should be *written in language* that assures that the donor understands the definition of high risk behavior and the importance of self-exclusion.” A fundamental goal of this project is to comply with this guidance.**
- 2. Unclear how the current question addresses the letter and spirit of the 4/92 memorandum.**
- 3. Most of the question content is embodied in donor card consents; blood centers would be asked to include the question elements in their consents**

Where We Are

- **Awaiting funding for NCHS one-on-one cognitive interviews (validation for comprehension)**
- **Submitted preliminary proposal for FDA conceptual, policy input**
- **Awaiting feedback from FDA**

What's Next?

- **Pass first FDA hurdle (BPAC, others) June, '01**
- **Perform one-on-one cognitive interviews**
- **Refine wording based on above**
- **Reformat questionnaire - compare with current version (donor input)**
- **Abbreviated questionnaire for repeat donors**
- **Revise educational materials**
- **Develop "User's Brochure"**
- **Submit final proposal to FDA**

Task Force Deliverables

- 1. Easier-to-understand “full-length” questionnaire in simplified format; some questions/items eliminated**
- 2. Abbreviated questionnaire for repeat donors**
- 3. Educational materials, “User’s Brochure”**
- 4. Recommendations for streamlining the screening process**

Why is this Effort Different from any Other Effort?

1. The FDA has requested that constituents and “industry” come together to solve key donor questionnaire issues.
2. The FDA has become an integral and engaged contributor to the effort.
3. There is a groundswell of support for this effort.
4. This approach, which embraces validation as a vital element, is essentially the first of its kind for developing donor screening materials.