

SP101

ABERRANT RESPONSES ON DONOR INTERVIEWS

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The donor health history questionnaire is a product of reconciliations among opposing aims. Precision in wording is mandatory for blood safety reasons; yet questions must be understandable by donors ranging widely in general and medical literacy. Generality in question wording aids in the capture of occasional, but important, events at the cost of screening of numerous unimportant ones. Specificity in wording has the advantages of aiding donor understanding and memory recall while limiting the volume of unrelated responses, but risks failing to detect important though remotely related events. Large numbers of questions ensure essential coverage at the expense of potential loss of donor attention and satisfaction.

Given a proposed questionnaire, it is useful to assess the extent to which it will reconcile among these opposing aims. Recently the Uniform Donor History Task Force (TF) of the American Association of Blood Banks (AABB) submitted to the US Food and Drug Administration (FDA) a Proposed Uniform Donor History Questionnaire (UDHQ) for approval by that agency as a standard for the blood services industry. While the important aspects of the full-length questionnaire, and its alternate abbreviated form and associated materials, have been tested using focus groups and cognitive methods, its effectiveness has yet to be tested on a large sample of blood donors.

Time constraints and regulatory considerations prevent on site large scale testing of the UDHQ in one or more blood centers prior to its approval by the FDA, so other testing alternatives must suffice. One alternative, not considered by the TF, is to examine outcomes from donor responses to existing health history questions similar to those on the proposed UDHQ on blood center questionnaires approved by the FDA. We report here results of a preliminary study of such conducted in Y2002 at the Mississippi Valley Regional Blood Center (MVRBC). At the time MVRBC was using the then current version of the AABB Uniform Donor History Questionnaire, hereafter MVRBC questions. The time period was post implementation on new variant CJD but pre implementation of smallpox, SARS and West Nile Virus donor questions.

Study Method. From June 1 to August 17, 2002 detailed outcomes from health history interviews of 8,527 blood donors responding to as many as 52 MVRBC questions were recorded by the Quality Donor System™ (QDS), a computer-assisted audio-video touch screen donor self interviewing system installed at MVRBC. QDS includes a special computerized research database system that records every action (Yes/No answer, Skip or Help) by every donor on every question on the interview together with staff revisions and comments on deferrable interview outcomes and other unusual results.

Of the 52 questions on the MVRBC questionnaire 46 are similar to ones on the proposed UDHQ. The study universe consisted of 573 (6.7%) new donors and 7,954 (93.3%) repeat donors the vast majority of whom were middle income literate persons. Initial and final aberrant responses and donor deferrals for all 52 questions were recorded and examined including staff comments ultimately printed on donor health history cards.

Study Results. As shown on Table 1, a total of 8,527 donor interviews were recorded on the QDS research database. Only 1,352 (15.9%) donors answered acceptably all questions on the interview; 7,174 (84.1%) donors initially answered aberrantly one or more questions. Aberrant answers occurred with approximately the same frequency among new and repeat donors. Ultimately only 296 prospective donors were deferred as a result of study interview outcomes.

In all 376,832 questions were answered by donors during the study. Initially, donors answered aberrantly 18,146 (4.8%) of these; however, after staff review of donors' initial aberrant responses, 2,700 (0.7%) of these responses were revised acceptable leaving a total of 15,446 (4.1%) final aberrant responses. Among the initially aberrant responses later revised by staff were 548 Skip or Help responses (0.15%) leaving 2,152 (0.57%) responses that were the result of donor errors in responding to questions on the interview.

Table 2 is a detailed summary of study findings by interview question. Included with the text of each question are a) the number of initially aberrant responses to that question, b) the number of final aberrant responses after staff review and c) the number of donor deferrals. Final aberrant responses as a percentage of initial aberrant responses and deferrals as a percentage of final aberrant responses are also included.

Questions eliciting the largest numbers of initial and final aberrant responses were those asking about widely occurring general or specific events (e.g., Q#3...been deferred or refused as a blood donor; Q#5...under a doctor's care; Q#10C...aspirin in past 36 hours; Q#10E...taken pills or medication; Q#s14A&B...travel outside US or Canada). Of these four (Q#s 5, 10E and 14A&B) resulted in substantial numbers of donor deferrals, although the percentages of each were low relative to the numbers of final aberrant responses. Conversely, some specific questions (e.g. Q#15C...blood relatives had CJD; Q#19...tattoo, ear or skin piercing; Q#23A...used a needle, even once) produced relatively few initial and final aberrant responses but substantial numbers of actual deferrals with high numbers of deferrals as percentages of final aberrant responses.

As anticipated and determined with the aid of QDS Reviewer comments, questions dealing with residence or travel outside the US, especially those involving Mexico, Central American and Europe accounted for 206 (53.6%) of the 384 final aberrant responses judged deferrable. This, however, is an overstatement of the actual percentage of donors deferred as a result of residence or travel outside the US, since many deferrable responses to the residence and travel questions were duplicated on similar questions.

Discussion. Table 2, together with staff comments on deferrable and other unusual donor aberrant responses, provide a basis for comparing selected MVRBC interview questions with similar ones proposed for the UDHQ. Exhibit 1 shows study results from two MVRBC questions, Q#s 4 and 5, that are similar to Q#1 on the UDHQ. MVRBC Q#4 is an exceedingly general question, as is Q#1 of the UDHQ. MVRBC Q#4 captured very few initial and final aberrant responses and no deferrals apparently because prospective donors who feel ill fail to present. MVRBC Q#5 is a similar general question but with more specific content. It captured a large number of initial and final aberrant responses resulting in a substantial number of deferrals (14). While 10 of the 14 deferrals would have been detected ultimately by other questions on the MVRBC questionnaire, 4 might not. Staff comments indicate these 4 were unusual, complex cases relating to recent surgery, accidents and medical diagnoses not likely to be covered by other interview questions. Apparently, the specific

component of MVRBC Q#5, "...under a doctor's care or had major surgery..." induced donor recall of deferrable events that otherwise might have been overlooked.

Exhibit 2 compares a single MVRBC question with two virtually identical questions on the UDHQ. In this case the MVRBC question applied to two distinctly different types of donors, red cells and platelets, having markedly different minimum required times between donations. Under MVRBC standard operating procedures (SOPs), platelet donors require a minimum time interval between donations of 2 weeks while for red cell donors the minimum is 8 weeks. Since the same question is asked of both types of donors, numerous initial and final aberrant responses but few deferrals result from this usage. Staff comments evidence that virtually every aberrant response was the result of a platelet donor presenting to donate platelets within the acceptable minimum time interval not recognized by the question. The same result is likely from the UDHQ question. It would seem that the introduction of a second question specific to platelet donors, with both questions prefaced by such phrases as, "Whole blood donors, in the past 8 weeks...etc" or "Platelet donors, in the past 2 weeks...", would relieve staff of the necessity of reviewing and revising numerous initially aberrant responses that serve no purpose other than to reduce by one the number of questions in the interview.

Exhibit 3 provides a comparison of an approach using a multiple number of specific questions to detect legitimate drug usage that is unacceptable for donation with one proposed for the UDHQ that employs an off-question list of such drugs. Specific questions on proscribed drug usage have the advantage of stimulating donor recall and staff inquiry into the specifics of donor drug usage at the cost of adding numerous interview questions to the questionnaire, the vast majority of which do not apply to most donors. Off listing of proscribed drugs, on the other hand, means that every donor must review the list of such drugs while answering only Yes/No to the single question, have used or are now using one or more of the proscribed items. Other conditions being equal, the numbers of aberrant answers to the UDHQ question should approximate the cumulative results experienced by MVRBC. Staff and donor time saving through off-questionnaire listing of proscribed drugs, however, is unlikely since every donor must scan the list and every aberrant response to the UDHQ question must be followed by stepwise questioning by staff of the specifics of aberrant usage together with assessment of deferment requirements as set forth in the SOP supporting the UDHQ question. Thus, the issue here is: Are donors more or less likely to recall and admit to legitimate drug usage that is unacceptable for donation when presented with specific questions regarding each drug or when asked to scan and identify such drugs from a single extensive list?

Conclusion. This preliminary study of health history interviews of MVRBC blood donors is limit in applicability to blood donors in general because of the under representation of new donors (7% versus a probable national average of 20%) and it is suspected that the educational level and cultural behavior patterns of repeat donors at MVRBC are well above the national average thereby biasing study results. The study does raise questions, however, regarding the structure and content of some questions on the proposed UDHQ. It also suggests the need for a similar large-scale study of donor responses to the UDHQ, one more likely to identify comprehension and inclusion/representativeness problems than previous methods. Such a large scale study conducted subsequent to FDA approval of the UDHQ with the understanding that if major shortcomings are found revision would follow seems the most rational approach for creation of a more effective and efficient questionnaire.

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Table 1. Summary of donor responses to interview questions at MVRBC Period: June 1 to August 17, 2002

Numbers of Donors by Donor Categories	Number of Donors	Number Answering all Qs OK	Number Answering 1+Q Aberrant	Percent Answering all Qs OK	Percent Answering 1+Q Aberrant	Number of Donors Deferred
1.1 First time donors	573	63	509	11%	89%	na
1.2 Repeat donors	<u>7954</u>	<u>1289</u>	<u>6665</u>	<u>16%</u>	<u>84%</u>	<u>na</u>
1.3 All donors	<u>8527</u>	<u>1352</u>	<u>7174</u>	<u>16%</u>	<u>84%</u>	<u>296</u>

Numbers of Questions	Numbers	Percentage
1. Total interview questions	376,832	100%
2. Final total aberrant answers to interview questions	<u>15,446</u>	<u>4.1%</u>
3. Final total acceptable answers to interview questions	<u>361,386</u>	<u>95.9%</u>

Answered Aberrantly by Donor Categories	Answered Yes	Answered No	Answered Help	Answered Skip	Totals
1.1 First time donors	1100	75	72	7	1254
1.2 Repeat donors	<u>15530</u>	<u>893</u>	<u>282</u>	<u>187</u>	<u>16892</u>
1.3 All donors	<u>16630</u>	<u>968</u>	<u>354</u>	<u>194</u>	<u>18146</u>

Numbers of Questions Answered Aberrantly by Donor Categories	Totals	Totals	Totals	Totals	Revised Aberrant Answers	Remaining Aberrant Answers
Yes answer changed to No	1316				1316	
Yes answer left as Yes	<u>15314</u>					15314
Total	<u>16630</u>					
No answer changed to Yes		952			952	
No answer left as No		<u>16</u>				16
Total		<u>968</u>				
Help answer changed OK			259		259	
Help answer changed N-OK			<u>95</u>			95
Total			<u>354</u>			
Skip answer changed OK				173	173	
Skip answer changed N-OK				<u>21</u>		21
Total				<u>194</u>		
Total aberrant answers revised					<u>2700</u>	
Total aberrant answers left						<u>15446</u>

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Table 2. Analysis of interview outcomes and staff comments from 8,527 blood donor interviews at Mississippi Valley Regional Blood Center June 1 to August 17, 2002.

Question Number	Question	Numbers of Aberrant Responses		Responses Final as % of Initial	Number Deferrals	Responses Deferrals as % of Final
		Initial	Final			
1	Have you ever donated or attempted to donate using a different (or another) name here or anywhere else?	216	184	85%	0	0.00%
2	In the past 8 weeks have you given blood, plasma or platelets here or anywhere else?	1073	785	73%	2	0.25%
3	Have you for any reason been deferred or refused as a blood donor or told not to donate blood?	2791	2765	99%	4	0.14%
4	Are you feeling well and healthy today?	82	2	2%	0	0.00%
5	In the past 12 months have you been under a doctor's care or had a major illness or surgery?	1581	1273	81%	14	1.10%
6	Have you ever had chest pain, heart disease, recent or severe respiratory disease?	453	393	87%	4	1.02%
7	Have you ever had cancer, a blood disease or a bleeding problem?	296	269	90%	26	9.67%
8	Have you ever had yellow jaundice, liver disease, viral hepatitis or a positive test for hepatitis?	51	27	53%	0	0.00%
9	Have you ever had malaria, Chagas disease or babesiosis?	19	14	74%	0	0.00%
10A	Have you ever taken etretinate (Tegison) for psoriasis?	6	0	0%	0	0.00%
10B	In the past three years have you taken Acetretin (Soriatane)?	18	1	6%	1	100.00%
10C	In the past 36 hours have you taken aspirin or anything that has aspirin in it?	1645	1448	88%	6	0.41%
10D	In the past month have you taken Isotretinoin (Accutane) or finasteride (proscar or Propecia)?	15	2	13%	1	50.00%
10E	In the past 4 weeks have you taken any pills or medications?	4877	4625	95%	26	0.56%
10E1	Since 1980, have you ever injected bovine (beef) insulin?	26	20	77%	19	95.00%

Question Number	Question	Numbers of Aberrant Responses		Responses Final as % of Initial	Number Deferrals	Responses Deferrals as % of Final
		Initial	Final			
11	In the past 4 weeks have you had any shots or vaccinations?	200	166	83%	3	1.81%
12	In the past 12 months have you been given rabies shots?	10	0	0%	0	0.00%
13(d)	Female donors: In the past 6 weeks have you been pregnant or are you pregnant now?	6	3	50%	0	0.00%
14A	In the past three years have you been outside the US or Canada?	1508	1449	96%	20	1.38%
14B	Since 1980, have you ever lived or traveled in Europe?	1491	1468	98%	54	3.68%
14B1	From 1980 through 1996, did you spend time that adds up to 3 months or more in UK?	71	47	66%	46	97.87%
14B2	Since 1980 have you received a transfusion of blood, platelets, plasma, cryoprecipitate, or granulocytes in UK?	35	18	51%	18	100.00%
14B3	Since 1980 have you spent time that adds up to 5 years or more in Europe, including the UK?	48	28	58%	27	96.43%
14C	From 1980 through 1996, were you a member of the US military, a civilian military employee, or a dependent of a member of the US military	204	170	83%	20	11.76%
14C1	From 1980 through 1990, did you spend a total of 6 months or more associated with a military base in Belgium, Germany or Netherlands?	34	28	82%	15	53.57%
14C2	From 1980 through 1996, did you spend a total of 6 months or more associated with a military base in Spain, Portugal, Turkey, Italy, Greece?	12	8	67%	6	75.00%
15A	Have you ever received growth hormone made from human pituitary glands?	9	0	0%	0	0.00%
15B	Have you ever received a dura matter (or brain covering) graft?	4	0	0%	0	0.00%
15C	Have any of your blood relatives had CJD?	36	19	53%	19	100.00%
16	In the past 12 months have you had close contact with a person w/yellow jaundice or viral hepatitis or have you been given Hepatitis B Immune Globulin (HBIG)?	79	9	11%	0	0.00%

Question Number	Question	Numbers of Aberrant Responses		Responses Final as % of Initial	Number Deferrals	Responses Deferrals as % of Final
		Initial	Final			
18	In the past 12 months have you received blood or had an organ or tissue transplant or graft?	14	5	36%	1	20.00%
19	In the past 12 months have you had a tattoo applied, ear or skin piercing, acupuncture, needle stick or come in contact with someone else's blood?	58	30	52%	30	100.00%
20A [SSAS]	In the past 12 months have you had a positive test for syphilis?	7	1	14%	0	0.00%
20B [SSAS]	In the past 12 months have you had or been treated for syphilis or gonorrhea?	2	0	0%	0	0.00%
21 [SSAS]	In the past 12 months have you given money or drugs to anyone to have sex with you?	1	0	0%	0	0.00%
22A [SSAS]	At anytime since 1977 have you taken money or drugs for sex?	2	0	0%	0	0.00%
22B [SSAS]	In the past 12 months have you had sex, even once, with anyone who has taken money or drugs for sex?	3	1	33%	1	100.00%
23A [SSAS]	Have you ever used a needle, even once, to take drugs that were not prescribed by a doctor?	19	19	100%	19	100.00%
23B [SSAS]	In the past 12 months have you had sex with anyone who used a needle to take drugs not prescribed by a physician?	5	1	20%	1	100.00%
24 [SSAS]	Male donors have you had sex, even once, with another male since 1977?	0	0	0%	0	0.00%
25 [SSAS]	Female donors, in the past 12 months, have you had sex with a male who had sex, even once, since 1977 with another male?	3	0	0%	0	0.00%
26A [SSAS]	Have you ever taken clotting factor concentrates for a bleeding problem such as hemophilia?	9	0	0%	0	0.00%
26B [SSAS]	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?	3	0	0%	0	0.00%
27A [SSAS]	Do you have AIDS or have you had a positive test for the AIDS virus?	2	0	0%	0	0.00%

Question Number	Question	Numbers of Aberrant Responses		Responses Final as % of Initial	Number Deferrals	Responses Deferrals as % of Final
		Initial	Final			
27B [SSAS]	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?	3	0	0%	0	0.00%
28 [SSAS]	Are you giving blood because you want to be tested for the AIDS virus?	18	0	0%	0	0.00%
29 [SSAS]	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?	797	12	2%	0	0.00%
30A	Were you born in, have you lived in, or have you traveled to any African country since 1977?	157	147	94%	0	0.00%
30B	When you traveled to these countries did you received a blood transfusion or any other medical treatment with a product made from blood?	6	0	0%	0	0.00%
30C	Have you had sexual contact with <u>anyone</u> who was born in or lived in any of the listed African countries since 1977?	10	6	60%	0	0.00%
31 [SSAS]	In the past 12 months have you been in jail of prison?	7	2	29%	1	50.00%
32	Have you read and understood all the donor information presented to you and have all your questions been answered?	124	1	1%	0	0.00%
Totals		18146	15446	85%	384	2.49%

SSAS--Socially sensitive and stigmatizing question.

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Exhibit 1. Comparison of wording of general capture questions and possibility of overlooked deferral conditions.

Comparable Examples:

Mississippi Valley Regional Blood Center Experience:

	Numbers of Aberrant Responses		Number of Deferrals
	Initial	Final	
Question No. 4: Are you feeling well today?	82	2	0
Question No. 5: In the past 12 months have you been under a doctor's care or had a major illness or surgery.	1581	1273	14

Uniform Donor History Questionnaire:

Question No. 1: Are you feeling well and healthy today?

Observations:

Question 4 from MVRBC is very general eliciting few aberrant responses and no deferrals.

Question 5 from MVRBC is a general yet specific question eliciting many responses leading to 14 deferrals of which 4 were for reasons not otherwise captured by later questions on the MVRBC questionnaire nor would they have been by any question on the proposed UDHQ.

Comment

Capture questions worded too generally are unlikely to accomplish their intended purpose of identifying medical causes warranting donor deferral that are not covered by other questions on the questionnaire. In the example MVRBC prospective donors presenting for donation obviously felt well enough to donate and stated so on Q#4 even though some (4 on Q#5) had medical conditions (e. g., recovering from recent surgery, accidents or medical diagnostic procedures results from which were as yet unknown), deemed sufficient reasons to warrant deferral yet not covered by other questions on the questionnaire.

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Exhibit 2. Comparison of single questions serving multiple types of donors.

Comparable Examples:

Mississippi Valley Regional Blood Center Experience:

	Numbers of Aberrant Responses		Number of Deferrals
	Initial	Final	
Question No. 2: In the past 8 weeks have you given blood plasma or platelets here or anywhere else?	1073	785	2

Uniform Donor History Questionnaire:

Question 8: In the past 8 weeks have you donated blood, platelets or plasma?

Question 9: In the past 16 weeks have you donated a double unit of red cell using an apheresis device?

Observation:

MVRBC staff comments on aberrant responses to Q #2 indicate that the vast majority are previous platelet donors who must be questioned further to determine if they meet the MVRBC requirement of a minimum 2 week interval between platelet donations.

Comment:

Platelet and plasma donors differed from red cell donors in purpose and frequency of permissible donation. Questions separating the two by introductory phrases such as: "Platelet donors, in the past 2 weeks...etc" or "Whole blood donors, in the past 8 weeks...etc." would reduce substantially the number platelet donors having to be interviewed by staff in order to revise initial aberrant responses.

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Exhibit 3. Comparison of multiple question approach vs. single question with extensive SOP follow-up.

Comparable Examples:

Mississippi Valley Regional Blood Center Experience:

	Numbers of Aberrant Responses		Number of Deferrals
	Initial	Final	
Question No. 10A: Have you ever taken etretinate (Tegison) for psoriasis?	6	0	0
Question No. 10B: In the past three years have you taken Acetretin (Soriatane)?	18	1	1
Question No. 10D: In the past month have you taken Isotretinoin (Accutane) or Finasteride (Proscar or Propecia)?	15	2	1
Question No. 10E1: Since 1980, have you ever injected bovine (beef) insulin?	26	20	19
Question No. 15A: Have you ever received growth hormone from human pituitary glands?	9	0	0
Question No. 10E: In the past 4 weeks have you taken any pills or medications?	4877	4625	26

Uniform Donor History Questionnaire:

Question No. 4: Have you ever taken any medications on the Medication Deferral List?

Observations:

MVRBC Question 10A, 10B, 10D, 10E1 and 15A endeavor to identify drugs warranting review and possible donor deferral. Aberrant responses to these questions are few, only Q#10E1 involves substantial deferral possibilities.

UDHQ Question 4 is specific to drugs on the accompanying list. As such it is meant to capture the same aberrant responses as were captured by the first five MVRBC questions. MVRBC Question 10E, however, is very general. As a consequence it captured many aberrant responses. Examination of staff comments on deferrals from Q #10E indicate most aberrant responses would have been captured by other questions on the interview. However, a few deferrals might not have been captured (e. g., Claritin or Lipitor) which, though not causes for deferral, led to identification of underlying medical problems warranting donor deferrals.

Comment:

Questions on specific medications are likely to elicit few aberrant responses while general questions produce many. The task in question wording is to secure a balance between specific wording that is sufficiently general to identify related medical conditions warranting further inquiry and possible deferral while avoiding excessive generality that results in extensive staff review in order to identify the few exceptional cases. The UDHQ question, with its attendant SOP list of drugs warranting possible deferral, is likely to minimize staff review at the risk of lack of sufficient generality needed to capture exceptional cases.

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