

SP99

## **AUTOMATING DONOR DEFERRAL DECISIONS**

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In reviewing aberrant donor responses to the health history questionnaire center staff are required to follow FDA approved standard operating procedures (SOPs) consisting of a series of follow-up questions and deferral criteria to determine whether the donors should be accepted or deferred. Most questions on present donor history questionnaires and their related SOPs, including those on the AABB proposed Uniform Donor History Questionnaire (UDHQ), are well structured suggesting that the staff review and decision process could be partially automated on a computer-assisted donor self interviewing system such as the Quality Donor System<sup>TM</sup> (QDS) now installed at the Mississippi Valley (MVRBC), Lifeblood/Mid-South and West Tennessee Regional Blood Centers. We report here a result of a preliminary investigation of this potential and its implications.

Study Method. Between June 1 and August 17, 2002 we conducted a study of initial and final aberrant donor responses by 8,527 blood donors to the 52 UDHQ questions then on the MVRBC's questionnaire. The questionnaire was administered using the QDS system which recorded in the system's research database every action taken (Yes/No, Skip, Help) by every donor on each question on every interview, including staff actions on every aberrant response together with staff comments on each deferral. (For further information on the study see SP101.) Results from the study, together with preliminary analyses of the logical structure of each interview question and its follow-up questions and deferral criteria as set forth in its SOP were the basis for assessing the potential for automating donor review and decision processes.

Study Results. All 52 questions and their SOPs on the then current MVRBC interview were examined and categorized as: a) open-ended with little or no automation potential, b) open-ended but having decision aid potential, and c) well structured with automation potential. As shown on Table 1, six of the questions and their SOPs were judged too open-ended for automation, five were considered candidates for decision aids, and the remaining forty-one deemed possible to automate. Examples of each the three types of questions are shown on the table. Questions 4 and 6 are so open-ended that any attempt to design an automated set of supplementary Yes/No questions that could determine the particular reason for each and every aberrant answer would be an exercise in futility.

Other questions on the interview, such as Questions 11 and 10E, while too open-ended for efficient automation, are candidates for automated decision aids. In the QDS system every donor response to each interview question is presented to the reviewing staff member on a separate screen with aberrant responses high-lighted for special review and, if necessary, deferral decision. Exhibit 1 illustrates the logical structure for staff review of aberrant donor responses to Question 11, while Exhibit 1A shows the form of a proposed

decision aid for the question. The aid is a computerized version of the printed listing available to staff members directing them as to how each type of shot or vaccination is to be treated. The advantage of such an automated decision aid lie in its immediate availability to staff on the reviewer's computer screen thereby avoiding the necessity of staff having to search the printed SOP every time an aberrant response to this question is encountered. Such decision aids can take almost any form (lists, maps, illustrations, etc.) that are part of the related SOP and essential to donor clarification and staff assessment of aberrant responses. The benefit of decision aids lies in the improved effectiveness and efficiency they are able to impart to the staff review process.

Most questions and their related SOPs on the MVRBC history questionnaire were judged capable of being automated. For the most part the questions are specific and well structure as are the supplementary questions and deferral criteria set for in the SOPs. This appears to be true as well of the present version of the proposed UDHQ. Evidence of this is found in the draft Donor History Questionnaire Users Brochure which contains proposed flow charts for assessing aberrant responses to each question. The UDHQ brochure, however, does not include proposed standardized SOPs, since center SOPs for assessing aberrant responses to each question are expected to vary somewhat from center to center. .

Exhibit 2 uses the logical structure of MVRBC's SOP for assessing donor responses to Question 9. It illustrates how an aberrant response to this multi-topic question could be parsed to permit use of a set of Yes/No supplementary questions with defined actions for each outcome. On a computer-assisted interview system such as QDS, which includes automated decision capabilities, the set of supplementary questions would be presented to each donor immediately following an aberrant response to the interview question. The donor would then answer each supplementary question, results from which would be recorded on the interview record. These results, together with the initial aberrant answer, could be presented for staff review and verification following conclusion of the donor interview.

Exhibit 3 illustrates a somewhat more complex case posed by Question 2 from the MVRBC interview. The added complexity is occasioned by several factors: a) three different types of allergenic blood donors at MVRBC (whole blood, platelet and plasma) with different required minimum time intervals between donations, b) possible shifting of donors from one type donation to another on successive presentations and c) maximums on the number of platelet donations permitted per donor per week and per year. While somewhat more complex, SOPs for this question are well structured permitting complete rendition of the supplementary questions and decisions within the proposed structure for automating the SOP.

In a related study of initial and final aberrant responses to MVRBC donor history questions (see SP101) it was discovered that a number of donors answer aberrantly and erroneously to even the most specific interview question. This is a substantial problem for full automation. If the SOP review process is automated and there exists no further check on the decision outcome these erroneous responses may result in unnecessary donor

deferrals. MVRBC Question 3 illustrates the problem. In the SP101 study six women answered Yes to the pregnancy questions but only three were or had been within the designated time. The other three had been pregnant but were inattentive as to the time criteria. One possible way of reducing the frequency of such errors would be to include within the structure of the automated SOP a confirmatory routine parsing the interview questions by asking it again in a different way. Such routines will help correct inattentive responses.

Study Discussion and Conclusions. Results of this preliminary study indicate that SOP follow-up questions and deferral criteria for aberrant responses to approximately three-quarters of all donor history questions are technically capable of being automated. Other considerations, however, appear to limit the extent to which this assessment and deferral process can be fully automated. First, is the need to include within the automated assessment procedure cut-outs to staff review when unusual donor responses present conditions that fall outside the logic of the automated review and decision process. Second, all erroneous aberrant donor responses are unlikely to be detected and corrected even if confirmatory routines are included. Third, full automation of deferral decision processes, without subsequent staff review, is unlikely to be acceptable to center managements or the FDA.

What, then, are the potential advantages of automating donor deferral decisions? Such processes can serve as a further aid to staff performing interview reviews. Results from the automated assessment process made available to staff would provide them with recommended outcomes consistent with center SOPs. Staff would then verify reasons for the recommended outcome with the donor and accept or revise the outcome depending results from the verification process. Thus, automation would serve both as a guide for staff actions and a control on such when actions taken were inconsistent with center SOPs. Automation will provide improved process control and documentation of donor screening activities in compliance with cGMP requirements.

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**Table 1.** Estimated numbers of donor health history questions employed by MVRBC decision processes on aberrant answers to which a) could Not be automated, b) could be assisted by decision aids, or c) could be automated on a computer-assisted interviewing system together with examples of each.

	Total Number	% of Total
<b>Questions whose aberrant decision processes could not be automated</b>	<b>6</b>	<b>11.5</b>
<i>Examples</i>		
Q 4. Are you feeling well and healthy today?		
Q 6. Have you ever had chest pain, heart disease, recent or severe respiratory disease?		
<b>Questions whose aberrant decision processes could be assisted by decision aids</b>	<b>5</b>	<b>9.6</b>
<i>Examples</i>		
Q 11. In the past 4 weeks have you had any shots or vaccinations?		
Q 10E. In the past 4 weeks have you taken any pills or medications?		
<b>Questions whose aberrant decision processes could be automated on computer-assisted systems</b>	<b>41</b>	<b>78.9</b>
<i>Examples</i>		
Q 9. Have you ever had malaria, Chagas disease or babesiosis?		
Q 2. In the past 8 weeks have you given blood, plasma or platelets here or anywhere else?		
Q 13(d). Female donors: In the past 6 weeks have you been pregnant or are you pregnant now?		
<b>Total Number of Questions</b>	<b>52</b>	<b>100.0</b>

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**Exhibit 1.** Decision structure for determining if a prospective donor is eligible make a present donation based on history of shots or vaccinations.

**Interview Question** In the past 4 weeks have you had any shots or vaccinations?

**Interview Question Answers**

No → Proceed to next interview question.

Yes → Mark for Supplementary Staff Administered Interview Questions and proceed to next question.

**Supplementary Staff-Administered Interview Questions**

No. 1: What shots or vaccinations have you had in the past 4 weeks?

Donor Response No.1 → Names shot or vaccination type.

Staff → Calls up Shots and Vaccinations Decision Aid (SVDA) (Exhibit 1A) and determines:

Acceptable → Proceed to next supplementary staff interview question.

*Not Acceptable* → Defer donor as indicated on SVDA.

No. 2: What other shots or vaccinations have you had in the past 4 weeks?

Donor Response No.2 → Names shot or vaccination type

Staff → Refers to SVDA and determines:

Acceptable → Proceed to next supplementary staff interview question.

Not Acceptable → Defer donor as indicated on SVDA.

No. 3-N: What other shots or vaccinations have you had in the past 4 weeks?

Donor Response No.3-N → Repeat No. 2 if named otherwise:

Staff → Terminates supplementary interview process and revises interview question response to:

No → if all donor responses to supplementary questions acceptable, otherwise

Yes → if donor is to be deferred.

**Exhibit 1A.** Decision aid for staff determination of the acceptability of shots or vaccinations received by donors in the 4 weeks preceding donation.

**Interview Question** In the past 4 weeks have you had any shots or vaccinations?

**Description** The decision aid, illustrated below, consists of a computer generated table of vaccinations or biologicals (shots) that donors might have received during the four weeks preceding the health history interview.

**Procedure** Decision aid is used in staff decision making upon interviewing the donor whose QDS generated donor health history interview record is flagged as requiring a supplementary staff interview because of an aberrant answer to the interview question regarding shots or vaccinations during the past 4 weeks

#### **Form of the Decision Aid**

### **MISSISSIPPI VALLEY REGIONAL BLOOD CENTER DEFERRAL PERIODS FOR VACCINES AND BIOLOGICALS**

<b>VACCINES</b>	<b>DEFERRAL PERIOD</b>
Anthrax Vaccine	None
BCG Vaccine (attenuated)	Prophylaxis for TB--2 weeks Cancer Chemotherapy --5 years.
Cholera vaccine (killed)	None
Diphtheria Toxoid	None
Hemophilus Influenza Type B Vaccine (killed)	None
Hepatitis A Vaccine (inactivated) HAVRix	None
Hepatitis B Vaccine (inactivated) Engerix HepataVax, Recombivax, TwinRix	48 hours post injection
Influenza virus vaccine (inactivated)	None
Lyme Disease	None
Measles Virus Vaccine (live) Rubeola	2 weeks
Meningitis vaccine	None
Meningococcal polysaccharide vaccine (killed)	None
Mumps virus vaccine (live)	2 weeks
Plague vaccine (killed)	None
Pertussis vaccine (killed)	None
Pneumococcal polysaccharide vaccine	None

## BIOLOGICALS

### VACCINES

### DEFERRAL PERIOD

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Polio virus vaccine (inactivated-injection)	None
Polio virus vaccine (live-oral)	2 weeks
Rabies vaccine (killed)	Pre-exposure (prophylaxis)None Post-exposure--1 year
Rocky Mountain Spotted Fever	None
Rubella virus vaccine (live)	4 weeks
Smallpox vaccine (attenuated)	2 weeks or until scab has fallen off, whichever is longer
Tetanus Antitoxin (equine)	2 weeks
Tetanus Toxoid	None
Typhoid Vaccine (killed)	None
Typhoid Vaccine (oral-live)	2 weeks after last dose (series of 4 capsules)
Typhus (killed)	None
Varicella-Zoster vaccine (live) Chicker Pox	4 weeks
Yellow fever vaccine	2 weeks
Measles, Mumps, Rubella MMR	4 weeks
Coccidioidin	None
Histoplasmin	None
Mumps Antigen	None
Spherulin	None
Tuberculin	None
Other vaccine	Consult Charge Nurse
Anti-rabies serum (equine)	1 year
Diphtheria Antitoxin	2 weeks
Hepatitis B immune globulin (HBig)	1 year
Human Immune Globulin (Gamma Globulin)	If exposed to Hepatitis B--1 year
Human Pituitary -Derived Hormones Growth Hormone	Permanent
Rabies Immune Globulin	1 year
Rho (D) Immune Globulin	None
Varicella-Zoster Immune Globulin (Vzig) chicken pox	4 weeks
Other Biological	Consult Charge Nurse

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**Exhibit 2.** Algorithm structure for determining if a prospective donor is eligible to make a present donation based on having had malaria, Chagas disease or babesiosis

**Interview Question** Have you ever had malaria, Chagas disease or babesiosis?

**Interview Question Answers**

No → Proceed to next interview question.

Yes → Proceed to Supplementary Interview Questions.

**Supplementary Interview Questions**

No. 1: Have you ever had malaria?

No → Proceed to Supplementary Interview Question No. 2.

Yes → Proceed to Question No. 1.1.

No. 1.1: Do you have malaria today?

No → Proceed to Question No. 1.2.

Yes → Mark donor for deferral and proceed to the next interview question.

No. 1.2: Have you had malaria or malaria symptoms during the past three years?

No → Proceed to Supplementary Interview Question No. 2.

Yes → Mark donor for deferral and proceed to next interview question.

No. 2: Have you ever had Chagas disease?

No → Proceed to Supplementary Interview Question No. 3.

Yes → Mark donor for permanent deferral and proceed to next interview question.

No. 3: Have you ever had babesiosis?

No → Change Interview Question Answer to NO and proceed to next interview question.

Yes → Mark donor for permanent deferral and proceed to next interview question.

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**Exhibit 3** Algorithm structure for determining if a prospective donor is eligible to make a present donation based on required minimum time intervals required by different types of blood donations

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

**Interview Question Answers**

No → Proceed to next interview question.

Yes → Proceed to Supplementary Interview Questions.

**Supplementary Interview Questions**

No. 1: Are you planning on donating whole blood today?

No → Proceed to Supplementary Interview Question No. 2.

Yes → Proceed to Whole Blood Screening Questions?

No. 2: Are you planning on donating platelets today?

No → Proceed to Supplementary Interview Question No. 3.

Yes → Proceed to Platelet Screening Questions?

No. 3: Are you planning on donating plasma today?

No → Refer for staff help as an unusual donation form.

Yes → Proceed to Plasma Screening Questions?

**Whole Blood Screening Questions**

No. 1: Was your previous donation (or donations) whole blood?

No → Proceed to next whole blood screening question.

Yes → Was your donation made 56 days (8 weeks) or more before today?

Yes → Proceed to next whole blood screening question.

No → Defer donor.

No. 2: Was your previous donation (or donations) platelets or plasma?

No → Change interview question response to NO and proceed to next interview question.

Yes → Was your donation made 7days (1 week) or more before today?

Yes → Change Interview Question Answer to NO and proceed to next interview question.

No → Defer donor.

**Platelet Screening Questions**

No. 1: Have you already donated platelets 2 times in the past week?

Yes → Defer donor.

No → Proceed to next platelet screening question.

No. 2: Have you donated platelets 24 times or more in the past year?

Yes → Defer donor.

No → Proceed to next platelet screening question.

No. 3: Was your previous donation (or donations) whole blood?

No → Proceed to next platelet screening question.

Yes → Was your donation made 56 days (8 weeks) or more before today?

Yes → Proceed to next platelet screening question?

No → Defer donor.

No.4: Was your previous donation (or donations) platelets?

No → Proceed to next platelet screening question.

Yes → Was your donation made 2 days or more before today?

Yes → Proceed to next platelet screening question?

No → Defer donor.

No. 5: Was your previous donation (or donations) plasma?

No → Change Interview Question Answer to No and proceed to next interview question.

Yes → Was your donation made 28 days (4 weeks) or more before today?

Yes → Change Interview Question Answer to No and proceed to next interview question.

No → Defer donor.

### **Plasma Screening Questions**

No. 1: Was your previous donation (or donations) whole blood?

No → Proceed to next plasma screening question.

Yes → Was your donation made 56 days (8 weeks) or more before today?

Yes → Proceed to next plasma screening question?

No → Defer donor.

No. 2: Was your previous donation (or donations) platelets?

No → Proceed to next plasma screening question.

Yes → Was your donation made 2days or more before today?

Yes → Proceed to next plasma screening question.

No → Defer donor.

No.3: Was your previous donation (or donations) plasma?

No → Change Interview Question Answer to NO and proceed to next interview question.

Yes → Was your donation made 7days (1 week) or more before today?

Yes → Change Interview Question Answer to NO and proceed to next interview question.

No → Defer donor.

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**Exhibit 4** Algorithm structure for determining if a prospective female donor is eligible donate at present based on response to the interview question regarding pregnancy.

**Interview Question:** Female donors: In the past 6 weeks have you been pregnant or are you pregnant now?

**Interview Question Answers**

No → Proceed to next interview question.

Yes → Proceed to Confirmatory Questions.

**Confirmatory Questions for Deferral**

No. 1: Are you pregnant Now?

No → Proceed to next Confirmatory Question.

Yes → Defer donor.

No. 2: Were you pregnant on {computer determined data 6 weeks prior to present date}?

No → Proceed to next Confirmatory Question.

Yes → Defer donor.

No.3: Then, isn't it correct that you were Not pregnant on or after {computer determined date 6 weeks prior to present date}?

No → Refer to staff.

Yes → Change Interview Question Answer to NO and proceed to next question?

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