



December 15, 2010

UDHQ Task Force
c/o Scott A. Brubaker, CTBS
Chief Policy Officer
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Via email to brubakers@aatb.org

Dear UDHQ Task Force:

The American Society of Transplantation (AST) Infectious Disease Community of Practice and Organ Donation Advisory Council and the American Society of Transplant Surgeons (ASTS) Scientific Studies Committee thank the AATB for the opportunity to review the donor questionnaires and applaud the effort to standardize the process in an attempt to have a uniform donor history with the goal of minimizing the risk of donor-derived transmissions. The AST and ASTS offer the following comments and recommendations.

One overarching issue relates to how the data will be used and the current evidence available to link the potential answers with risk of disease transmission. This was a topic which was raised in our discussions. Specifically we wondered whether the goal of the questionnaire was to provide guidance regarding optimal donor testing and utilization or whether donors would be excluded on the basis of questions that have a poor predictive screening value. For example, Question # 11 in the adult questionnaire asks about pet exposure; will this lead to specific testing of the donor (i.e. looking for antibody against *T. gondii* if the person owned a cat or looking for LCMV if they had rodent pets) or to exclusion of the donor (i.e. people who owned rodents)? It is possible that, despite the best of intentions, the use of this questionnaire will result in reduced organ utilization that has a greater impact than its reduction on disease transmission.

For many of the questions, there are limited data to clearly inform the level of risk associated with potential answers. Without this data, it may be challenging for clinicians to understand if an answer represents a risk of disease transmission that outweighs the potential benefit of using the organs. Accordingly, we strongly advocate for funding research to assist with validating questions that can be used in surveys, such as the ones submitted.

We have several additional concerns that we would like to make the AATB aware of. First and foremost, we are uncomfortable with the short turnaround time allotted to the public for review of the document and to provide comments on the proposed unified organ/tissue/eye questionnaire. As noted, we very much appreciate the amount of work that has gone into creating this questionnaire. However, we worry that the order and grouping of the questions differs from the current AOPO template questionnaire in use by many OPOs, and may detract from optimal information gathering. We also wonder how much input has been sought from organ transplant professionals, particularly from those professionals directly involved in organ procurement, to obtain their perspective on whether or not the proposed combined questionnaire will meet their needs. We believe it is critical that their input is sought to assess whether or not they think they will be able to use (and in fact choose to use) this new combined questionnaire. There are also concerns about blending donor inclusion/exclusion criteria for organ and tissue donation especially in disparate OPOs where the inclusion/exclusion criteria only allow 25-50% of the organ donors to be acceptable for tissue donation. There are concerns about the defined purpose for the questions and their uniform applicability for organ and tissue donors.

The questionnaire addresses primarily risk for transmissible diseases. Organ function risk assessment history would focus on a variety of other function/disease issues (i.e., kidney stones for the kidney donor, occupational exposures or bronchitis and asthma Rx for lung donor, etc.) that are not included within the risk assessment questions. The questionnaire should clearly identify its purpose.

A final critical question is how AATB plans to address the planned completion of the ongoing CDC effort to update the definitions of so-called high risk behaviours that would identify high-risk donors. To our understanding, the updated definitions are expected to be released in 2011. Accordingly, it is likely that specific questions included in the proposed combined organ/tissue/eye potential donor questionnaire may need to be changed to be consistent with these new definitions. Ideally the questionnaire should be delayed until this document is available so that the questionnaire does not require immediate updating.

In addition to these more global comments, the AST and ASTS have provided several general comments as well as some comments and/or recommendations for individual questions in the combined questionnaire.

General Comments:

1. Make sure all of the questions are written to be comprehensible at an 8th grade level.
2. If time permitted, piloting the order and the framing of the questions prior to implementation would be the preferred approach to optimize accuracy of responses. Partnering with behavioral economists who specialize in this field would be very informative and helpful.
3. The overall look and format of the questionnaire is difficult to follow and read. It starts in a box above with a time frame and then there are separate boxes below with questions and several follow-ups of a., b., c., to which you can answer yes or no. A particular example is page 3, question 12 and 13.
4. The Y/N format will provide inaccurate information. If someone doesn't know about the history, an "unknown" column should be available or provide a Likert scale.
5. For both the >12 and <12 questionnaires, the questions seem to be out of order and not logically ordered. If the goal is to place the high risk/high likelihood of rule out questions up front then that is how we should start but there are basic questions, then high risk, then back to basic.

6. The questionnaire should be carefully reviewed by organ recovery professionals to assure that all of the questions asked are providing truly helpful information. Due to the difficult situation donor families are facing when the questionnaire would be administered, the ability to get accurate information from questionnaires of this length is likely limited.

We had the additional specific comments:

Question or Issue: For > 12 Years	Comment
Question 8: "Did she/he recently have any flu-like symptoms? Symptoms can be a fever, cough, diarrhea, swollen lymph nodes, weight loss or sores in the mouth or on the skin?"	<p>This is the only question looking for current or recent symptoms suggestive of infection. Starting off with "flu-like symptoms" might not be the best question. Suggest a more open-ended question. For instance, if someone has rash or swollen joints or vomiting or conjunctivitis or severe headaches, etc they would answer this question with "NO".</p> <p>REC: more open ended question</p> <p>Did she/he have any recent symptoms of infection particularly with a fever, cough, diarrhea, severe headaches, pink eye, rashes, vomiting diarrhea or sores on their mouth or skin?</p>
Question 11: In the past 12 months, did she/he have any pets?	<p>What is the purpose of this question? Our concern is that donors may be excluded based on certain answers (eg. rodent-type pets as a risk for LCMV) even though the value of this response in predicting disease is unknown</p> <p>If this would prompt testing for LCMV ab or Toxoplasma antibody (cat exposure) could leave in but would ask specifically</p> <p>REC: Consider deleting this question or asking specifically about the pets of interest such as if they had pet rodents (mice, hamsters gerbils)</p>
Question 12: In the past 12 months was she/he bitten or scratched by any animal"	<p>This appears to be getting at risk of rabies. It may be worth doing some discriminatory risk assessment. E.g., asking what type of animal, if it was pet or stray, if the attack was provoked / unprovoked. Was rabies vaccine or immunoglobulin given?</p>
Question 13: West Nile virus	<p>Might be better to ask the symptoms first and then the WNV query</p> <p>REC: Did she/he in the past 4 months have</p>

	<p>flu like symptoms or severe headaches, body aches generalized weakness... that made their doctor concerned for West Nile virus infection?</p> <p>Were they told that they had West Nile virus?</p> <p>If yes when was she/he diagnosed</p>
Question 14: Did she/he have any vaccinations or other shots?	<p>Suggest asking specifically about which vaccines and especially about live vaccines: MMR, VZV, yellow fever etc.</p> <p>Also suggest putting in a time frame such as in the past 2 months...</p>
Question 15: Did she/he get a tattoo? A tattoo can include a touch up of an old tattoo or cosmetic or permanent make-up such as those applied as eyebrows, lips, or eyeliner. If yes, 15a. Were shared or non-sterile instruments, needles or ink used?	<p>Would ask if it was done by a professional or where it was done, more direct than did they use shared inks or needles – would get closer to if done by a professional. Most people do not know about shared inks or needles but know where it was done.</p>
Question 16: In the past 12 months, did she/he have acupuncture, ear or body piercing? If yes, 16a. Were shared or non-sterile instruments or needles used?	<p>Same comment as question #15. Would ask where it was done.</p>
Question 17: In the past 12 months, did she/he live with a person with hepatitis? If yes, what type of hepatitis did that person have? If that person had Hepatitis C...	<p>What if the person did not know what type of hepatitis the potential donor had?</p> <p>Also, too much distance between question #17 and question #34 asking if they had hepatitis. Would suggest linking them together in one place.</p>
Questions 18 and 19	<p>There is inconsistent use of hepatitis (in question 17) and viral hepatitis.</p>
Question 20	<p>Need to explain sexually transmitted, STI and STD during the question</p>
Question 21: In the past 5 years, has she/he been sexually active, even once?	<p>This question says it's going to ask about the people that they had sex with, concern that wording of statement will have family member thinking you are going to ask for names which may shut down the conversation. Would change to: "Need to ask about sexual partners versus who he/she had sex with".</p> <p>Also, title at the top of the question says 5 years, then it asks questions about 12 months and on the next page goes to 5 years again. There is some inconsistency.</p>

Question 25a: receipt of live cells or tissues from animals	Consider putting in some examples
Question 27: Refused as a blood donor	Consider asking if it is known why they were refused and whether it was temporary or permanent
Question 29. Travel outside of the US or Canada	<p>IF the answer is yes might ask specifically about whether or not malaria prophylaxis was taken?</p> <p>Might also consider asking where in the United States the person has lived since there is very different risk for different kinds of endemic infections such as Coccidioides, Babesia, and Dengue.</p>
Question 42	Cardiomyopathy and endocarditis are too complicated and need to be explained in layman's terms.
Question 43	Varicose veins, vasculitis, venous insufficiency, deep vein thrombosis are too complicated and need to be explained in layman's terms.
Question 45	Need examples of toxic substances.
Other issues: Queries about how well the person answering questions knows the donor	Suggest a question that helps to ascertain how well the person answering the questions knows the donor such as "When was the last time you saw or spoke with her/him? Do you live together?" Do you feel comfortable answering these questions or should we speak with someone who might be more familiar with the potential donor?
Other issues: Tuberculosis	<p>Suggest asking specifically about tuberculosis risk. Rec: Asking if she/he ever had a positive test for TB, and if so did they have therapy,</p> <p>Did they have an exposure to anyone with tuberculosis, or work or volunteer in a homeless shelter,</p> <p>We recognize that there is another section on traveling outside the United States or Canada which can help with this and with malaria</p>
Other issues: Encephalitis	Suggest asking specifically about recent symptom cluster of fever, headache, confusion.
Other issues: Question order	
Other issues: HTLV	Suggest asking if donor has ever been found to have HTLV

- Comments in the above tables also apply to the pediatric donor questionnaire. Specific Pediatric Table comments are below

	Comment
Smoking History and Alcohol History Questions	The smoking history and alcohol history questions are maintained with a note that "there is still a need to establish at what age to ask the questions". Is there any value to the transplant centers to have this information on a child age <12 years? If not, suggest removing both questions.
Question 7	Define recently
Question 8	Question is for past 2 months and then asks if she/he have contact with someone who recently had a smallpox vaccination
Question 12: Vaccinations	Since children in this age range are receiving many vaccinations it may be important to specify when they specifically received the live virus vaccinations (MMR, VZV and if appropriate yellow fever or small pox) since those are the ones that would be important for donor transmission

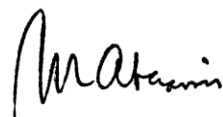
We would be delighted to participate in future discussions on donor surveys for living donors as well.

We hope that you find these recommendations and comments helpful. Like you, we are committed to improving the quality of donor evaluations to reduce the risk of disease transmission. As such, we are available to help provide additional comments or advice as this project moves forward.

Sincerely,



Maryl R. Johnson, MD
AST President



Michael M. Abecassis, MD, MBA
ASTS President