Cognitive Evaluation of the Donor Risk Assessment Interview (DRAI):
Results of Interviews Conducted April – December, 2013

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I.   Introduction and Project Background

This report documents findings from a cognitive interview evaluation of the Donor Risk Assessment Interview (DRAI) for a donor greater than12 years old conducted by the Questionnaire Design Research Laboratory at the National Center for Health Statistics (NCHS) in collaboration with the Office of Blood, Organ, and other Tissue Safety, Division of Healthcare Quality Promotion, CDC in collaboration with the American Association of Tissue Banks (AATB). Additionally, the DRAI had been developed by these groups with input from experts from appropriate government agencies such as the Food and Drug Administration (FDA)/Center for Biologics Evaluation and Research (CBER) at the Health Resources and Services Administration (HRSA)/Division of Transplantation, committees representing the United Network for Organ Sharing (UNOS), and professional societies such as the Association of Organ Procurement Organizations (AOPO), Eye Bank Association of America (EBAA), NATCO (the organization for transplant professionals), the American Society of Transplantation (AST), and the American Society of Transplant Surgeons (ASTS).

The DRAI project began in early 2006 with the purpose of creating a uniform donor history questionnaire for organ, tissue, and ocular donation organizations and professional associations in the United States. Assessing donor suitability is a multipronged approach. Laboratory testing is one method for detecting infectious disease and understanding expected organ function, however, laboratory tests cannot detect all aspects of infection and donation quality, and gaps that remain can be addressed by collecting accurate information from a proxy (or proxies) providing information on behalf of the deceased donor.

Part of the rationale in creating a single instrument to be used by all organ procurement organizations (OPOs), eye banks, and tissue banks is to address the lack of standardization among these organizations, which affects quality program review processes. Additionally, the goal of creating a single, standardized instrument is to increase the assurance of safe donation by: 1) optimizing identification of suitable donors, 2) minimizing donor loss due to inappropriate exclusion, 3) accurately identifying an organ donor risk designation, and 4) reducing complexity to facilitate comprehension by a bereaved interviewee.

Development of the DRAI took into account several factors. First, content and format of existing donation questionnaires have never been formally evaluated. As a result, some questionnaires contain questions that are not necessary and can, in fact, inhibit collection of accurate information. Additionally, questionnaires currently used incorporate many long, compound questions or include terminology and word phrases that the general public may not comprehend.   The development of the DRAI, therefore, needed to include a cognitive interviewing evaluation to address these issues.

The Questionnaire Design Research Lab (QDRL) at the National Center for Health Statistics (NCHS) conducted an evaluation of the DRAI. The evaluation used cognitive interview methodology to examine how each question in the DRAI performed, as well as how the questionnaire performed overall. A total of 45 interviews were conducted (in three rounds of 15) between April and December of 2013. This document reports findings from the analysis of those 45 interviews. The next section gives a brief explanation of cognitive interviewing methodology. The final two sections present general findings and specific question-by-question findings, respectively.

II.   Methodology

This section details the methodology used in this research. It begins with an overview of cognitive interviewing, in general, and then discusses how the method was applied in evaluating the DRAI.

a.   Cognitive Interviewing

The aim of cognitive interviewing is to investigate how well survey questions perform when asked of respondents; that is, whether respondents understand the questions according to their intended design and can provide accurate answers based on that intent. As a qualitative method, the primary benefit of cognitive interviewing is that it provides rich, contextual insight into the ways in which respondents 1) interpret a question, 2) consider and weigh relevant aspects of their lives and, finally, 3) formulate a response based on that consideration. As such, cognitive interviewing provides in-depth understanding of the ways in which a question operates, the type of phenomena that it captures, and how it ultimately serves (or fails) the scientific goal. Findings from a cognitive interviewing project typically lead to recommendations for improving a question, or results can be used in post-survey analysis to assist in data interpretation.

Traditionally, cognitive testing is performed by conducting in-depth, semi-structured interviews with a small sample of approximately twenty to forty respondents. The typical interview structure consists of respondents first answering the question being evaluated and then answering a series of follow-up probe questions that reveal what respondents were thinking and their rationale for that specific response. In this regard, cognitive interviews unfold within a narrative format and are often personal and, in comparison to traditional survey interviews, are unique to each respondent. Through this semi-structured design, various types of question-response problems, such as interpretive errors or recall accuracy, are uncovered—problems that often go unnoticed in traditional survey interviews. By asking respondents to provide textual verification and the process by which they formulated their answer, elusive errors are revealed.

As a qualitative method, the sample selection for a cognitive testing project is purposive. Respondents are not selected through a random process, but rather are selected for specific characteristics such as gender or race or other attributes relevant to the type of questions being examined. When studying questions designed to identify persons with disabilities, for example, the test sample would likely consist of respondents with a previously known disability and some respondents with no known disability in order to discover potential causes of false positive or false negative reporting. Because of the small sample size, not all social and demographic groups are represented. Analysis of cognitive interviews does not produce generalizable findings in a statistical sense, but rather, provides an explicit exploration of response processes including patterns of interpretation, which could lead to response error.

Analysis of cognitive interviews was conducted from interviewer notes. The texts of the interviews were collated by question so that comparisons could be made systematically across all respondents. Several levels of analysis were performed. First, distinct occurrences were identified in which respondents experience difficulty or confusion while answering. Additionally, specific instances or patterns of error were also noted and, most importantly, the particular causes of those errors identified.

b.   Donor Risk Assessment Interview Cognitive Interviewing Study

The DRAI cognitive interview study involved three rounds of 15 in-depth, face-to-face, qualitative interviews for a total of 45 interviews. The research question focused largely on identifying response error in the question-response process and understanding *why* the error occurred in order to improve question performance. Question performance was evaluated by comparing the information intended to be captured by the questions against information actually captured. A question that is deemed not to perform well is said to generate response error – that is, respondents do not provide information according to question

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intent. Further, cognitive interviews not only detect response error, but also collect data that illuminate *why* those errors occurred. This information is used to guide question modification and improvement.

The ultimate goal of this study was to create a questionnaire that produces as few response errors as possible. While both false positive and false negative responses were examined, additional emphasis was given to identifying and minimizing the potential for false negative responses because of the nature of questionnaire administration. The DRAI is an interviewer administered questionnaire in which responses of 'yes' are followed up by the interviewer. Therefore, an incorrect answer of 'yes' (i.e., a false positive) can be addressed and eliminated. In addition, supporting tools to the DRAI assist interviewers in determining whether an answer of 'yes' is within scope. These tools include the Implementation Guidance Document, flowcharts for each question, and a document that lists each DRAI question and requirements for screening risk that can be found in relevant regulations, guidance, laws, policy and standards.

However, the questionnaire is structured in a way that an answer of 'no' by the respondent receives no follow-up by the interviewer. As a result, an incorrect answer of 'no' (i.e., a false negative) may go undetected and important aspects of the decedent's medical, behavioral, or travel history will not be captured. During the cognitive interview evaluation, specific attention was given to detecting patterns that may exist among certain questions to produce false negative responses. As with all cognitive interview studies, respondents were selected using a purposive sample. Recruitment strategy varied by round.

Round 1: The central aim of round 1 was to identify basic difficulties respondents may experience in answering questions on the DRAI. Therefore, round 1 included members of the general population who have not lost a loved one. Demographic variation in respondents was sought in order to explore general difficulties that a variety of people may have in answering the questions about a loved one. Table 1 shows a summary of respondents from round 1. Variation in race, age, gender and education is listed.

Table 1: Round 1 Respondent Demographics (n = 15)

	Number	Percent
Race		
Non-Hispanic Black	9	60%
Non-Hispanic White	6	40%
Age		
30-49	5	33%
50-64	7	47%
65 and over	3	20%
Gender		
Women	5	33%
Men	10	67%
Education		
High School or Less	6	40%
Some College	3	20%
Associates or Bachelor's	2	13%
Graduate Degree	4	27%
Relation of Hypothetical Donor		
Spouse	2	13%
Parent	5	33%
Child	3	20%
Sibling	2	13%
Friend	2	13%
Cousin	1	8%

Interviews took place at the NCHS lab in April, 2013. Respondents were asked to think about someone with whom they are close, and answer the DRAI questions in relation to that person. The sample is 60% Black and 40% white. Respondents ranged in age from 30-49 to 65 and over. Two thirds of the sample was male and one third female. Educational levels are broadly represented from those with a high school diploma or less to those with graduate degrees. Moreover, the relationship of the respondents to the "potential" donor is noted. These were important to the extent that respondents may recall information differently for different relationships and because they may have varying levels of knowledge about different people, depending on their relationship to them. This may impact the question-response process.

Round 2: The focus of round 2 was slightly different from round 1. Respondents who had lost a loved one within the past 12 months were recruited in order to begin to examine the effect of grief on the question-response process. Table 2 contains a summary of key respondent demographics, including the relationship of the potential donor to the respondent and the nature of their death process. The sample was largely non-Hispanic Black, older (50-64) and male. There was a wide split on education. Eleven respondents had high school diplomas and four had college or graduate degrees. Most respondents were answering for a parent, a sibling or some other relative. The manner in which their loved one died was also split between the process being long and drawn out or short and sudden. This had a noticeable impact on the way in which respondents interpreted many of the questions, and will be discussed in more detail in the findings section of the report.

Table 2: Round 2 Sample Summary (n = 15)

	Number	Percent
Race		
Non-Hispanic Black	12	80%
Non-Hispanic White	3	20%
Age		
18-29	2	13%
30-49	3	20%
50-64	10	67%
Gender		
Women	4	27%
Men	11	73%
Education		
High School or Less	6	40%
Some College	5	33%
Associates or Bachelor's	2	13%
Graduate Degree	2	13%
Relation of Donor		
Spouse	1	7%
Parent	5	33%
Child	0	0
Sibling	2	13%
Friend	0	0
Other Relative	7	47%
Death Process		
Long & Drawn Out	7	47%
Short & Sudden	8	53%

Round 3: The original plan for round 3 was to aim for the most realistic interview scenario and recruit people who had lost a loved one within the past day or so. This was to be achieved by working with various OPOs to identify families whose loved one had wanted to be a donor but who had been determined to be ineligible. Such families would be told about the cognitive interview study and asked if they were interested in participating. This produced no interviews over a 5-month period. In an effort to complete the study, we recruited respondents in a manner similar to round 2, focusing on recruiting people who had lost a loved one within the past 6 months (in round 2 the timeframe was the past 12 months), and interviewing them in the NCHS lab. People with the shortest time period since their death occurred were recruited first. As a result, demographic diversity was not a priority. Table 3 shows the summary of respondents from round 3, including the date of death of the loved one, the relationship of that person to the respondent, and the nature of the death process. Forty seven percent of respondents in round 3 had lost a loved one 2 months ago or less, 47% had lost a loved one between 3 and 6 months ago and only one (6%) lost a person 7-12 months ago.

Table 3: Round 3 Key Sample Characteristics (n=15)

	Number	Percent
Race		
Non-Hispanic Black	14	93%
Non-Hispanic White	1	07%
Age		
18-29	4	27%
30-49	6	40%
50-64	5	33%
Gender		
Male	5	33%
Female	10	67%
Education		
High school or less	4	27%
Some college	4	27%
Associates or Bachelor's	6	40%
Graduate Degree	1	06%
Date of Death		
2 months ago or less	7	47%
3-6 months ago	7	47%
7-12 months ago	1	06%
Relationship of Donor		
Parent	7	47%
Grandparent	3	20%
Other Relative aunt/cousin)	5	33%
Nature of Death Process		
Short & sudden	7	47%
Long & drawn out	8	53%

Overall, the recruitment modification was productive. The final 15 interviews were completed and, most importantly, the impact of grief was present and accounted for in the question-response process to a degree larger than it had been in round 2.

c. Analysis

Analysis of cognitive interviews includes a multi-stage process involving simultaneous data reduction and theory building (i.e., drawing conclusions). A data entry and analysis software application (Q-Notes) was used to conduct analysis. Q-Notes, developed by the Question Design Research Laboratory, ensures systematic and transparent analysis across all cognitive interviews as well as providing an audit trail depicting the way in which findings are generated from the raw interview data. Without such an analysis, conclusions presented in cognitive interview reports can consist of merely anecdotal reports derived from one or two standout interviews or the general impressions of interviewers.

To conduct the cognitive interview analysis for the DRAI project, original interview text from every interview was first summarized into interview notes. Summary notes specified the way in which individual respondents answered each question, including each respondent's interpretation of questions and key terms, activities and experiences considered by respondents, and any response difficulties and errors. Next, analysis was conducted systematically across interviews, identifying interpretive patterns (including patterns of response errors) across interviews. Findings from this second level of analysis depict the phenomena captured by each question and allows for the assessment of construct validity. The final stage of analysis involved examination of themes by specific subgroups.

III.   Findings

This section provides two levels of findings from the cognitive interview study. First, a discussion of overarching themes and general findings are reviewed. Second, a question-by-question review of findings for specific questions is presented.

a. Overview of Findings

Overall, the questionnaire does a good job of capturing the decedent's medical, behavioral, and travel history. Respondents were generally not confused by the questions and relatively few response errors were detected for the majority of questions. Difficulties that did exist were addressed with the appropriate question revisions following each round of interviews in order to improve the questionnaire. Response error may still occur – no instrument should be expected to be completely absent of measurement error – but is more likely to be false positive error than false negative. The remainder of this report documents the specific nature of any difficulties experienced by respondents and the type of errors that occurred as a consequence.

Cognitive interview findings may be summarized into six overarching themes. First, some of the questions and topics can be sensitive for respondents. Potential outcomes of this can range from respondents feeling uncomfortable or embarrassed to outright refusing to answer. However, respondents did not universally interpret the questions as sensitive. Judging a question to be sensitive is contextually defined and respondents varied in this assessment. Second, some terms that may be thought of as fairly common terms were not necessarily commonly understood by respondents. Third, various questions in the DRAI, while technically different, often end up capturing overlapping information. However, this was not a detrimental aspect of the questionnaire and, in fact, added to its ability to capture a full medical/behavioral/travel history of the decedent. Fourth, the nature by which the potential donor died – whether short and sudden or long and drawn out – has a significant impact on the way in which respondents interpret certain questions. Fifth, grief impacts the question-response process in ways that compromise respondent focus, particularly with regard to the purpose and intent of a specific question or the questionnaire in general. And, finally, medical history is complicated and convoluted. Some of the questions required more knowledge than respondents often have of the decedent's medical/behavioral background. All six of the above factors conspire to make the DRAI a potentially difficult interview for respondents and each is discussed next in more detail.

i. Sensitive topics defined by context

It was hypothesized prior to the study that many questions on the DRAI have the potential to be sensitive, such as questions on the decedent's sexual behavior or use of illicit drugs, and in fact, this was found to be the case. It was not consistently true for every respondent in the sample, but it was for some. When respondents felt the questions were sensitive they demonstrated embarrassment, reluctance or outright refusal to answer the question. However, not everyone had this reaction; some respondents would answer the same set of "sensitive" questions without any compunction at all.

In examining this variation, we found that it was patterned and not idiosyncratic. Sensitive topics are contextual, not universal. Three factors were found to influence the extent to which respondents interpreted certain questions as sensitive. First and foremost, if respondents understood – and could bear in mind – that the purpose of the questions was medical in nature, they felt more comfortable answering questions that they might otherwise deem too sensitive to discuss. Relatedly, the relationship of the respondent to the decedent played a role in whether or not the respondent judged a question to be too sensitive to discuss or answer. Specifically, respondents answering for a parent were more likely to demonstrate embarrassment when answering questions about sexual behavior than those answering for another relative, such as a cousin or aunt/uncle. However, the effect is mitigated by medical contextualization. Those that understood the medical importance and relevance of the questions were more comfortable answering the questions, regardless for whom they were answering. This finding suggests that reminding respondents of the medical purpose of the questions may be an important aspect of the DRAI administration process.

Finally, the age of the decedent played a role in how respondents interpreted the questions, especially the appropriateness of asking certain questions. This is related to sensitivity, but not exactly the same. For example, questions about tattoos, piercings, and jail time in the past 12 months were seen as not applicable to a person in their 70's or 80's, and respondents sometimes expressed amusement at being asked these questions about, say, a grandparent. In this regard, it's important for respondents to understand that because the questionnaire is standardized, all respondents are asked all the questions.

ii. Common terms not so commonly understood

Some terms in the DRAI were not as commonly understood as the questions seem to presume. Examples include "clotting factors," "surgery," "swollen lymph nodes," and "coronary artery disease." When respondents do not know a term, they tend to think it does not apply to them and answer 'no', which likely is the correct answer for rare conditions with unusual names (such as Chagas' disease). But for more common conditions, the risk of a false negative response may be substantial.

Since this pattern emerged early (i.e., in round 1), changes for round 2 included providing short explanations for items with "common terms" that were misunderstood or not known. This strategy seemed to help. In rounds 2 and 3 responses for questions 6d (swollen lymph nodes), 19 (blood clotting factors), 27 (surgery) and 44b (coronary artery disease) showed improvement with regard to respondent understanding.

iii. Overlapping information

Although all the questions in the DRAI are technically different, many elicit similar information. In other words, one piece of information may be captured in multiple places by more than one question. For example, the question asking whether the decedent ever had surgery captured the same information as the question asking whether the decedent ever had any eye problems, procedures or surgery. This duplication constitutes an increased burden on the respondent by increasing administration time and requiring the respondent to give redundant information. Typically, most questionnaires are designed with the goal of

reducing this kind of respondent burden. However, in the context of the DRAI, this phenomenon may be not only acceptable but also desirable to some extent. Asking about health conditions in different ways can prompt respondents to remember important information that they might not otherwise think of. It helps to ensure that a full medical/behavioral history is obtained. A respondent who fails to report cataract surgery in the first question is likely to report it in the second. As a result, no modifications were made to eliminate this pattern.

The following case provides a good example of why capturing overlapping information is beneficial – in this case because respondents have imperfect knowledge of medical issues. This respondent was answering questions about her deceased father who was never diagnosed with hepatitis. She answered 'no' to 14a. (Did he live with a person who has hepatitis), 18g (Did he have sex with a person who had hepatitis/HIV) and 29b (Did he have a positive or reactive test for hepatitis). When she was asked question 30 (Did he EVER have liver disease or hepatitis?) she replied 'no'. However, after a moment of thought she said, "Wait a minute…hepatitis B…is that like liver disease?" Because this was the first instance of the respondent expressing uncertainty about hepatitis after answering three questions about the disease, the interviewer asked the respondent to explain what she was thinking.

Because several questions touch on the topic of hepatitis (14a., 18g., 29b. and 30), this prompted the respondent to think about her sister (even though the questions were about her deceased father) who had a complicated medical story vis-à-vis hepatitis.

In essence the respondent had a disjointed understanding of her sister's condition because doctors gave conflicting stories. One doctor told her sister that she had hepatitis A, another said she had hepatitis B, and still another said that her sister *used* to have hepatitis B but that they no longer see it "in her blood". Confused about what was going on, her sister did nothing about any of it. The experience of her sister caused the respondent to have an unclear understanding of hepatitis in general. While the respondent believed her father didn't have hepatitis, she recalls at question 30 – Did he EVER have liver disease or hepatitis) that her sister did live with her father prior to his death – a fact that she should have but failed to report in question 14a. (in the past 12 months did he live with a person who has hepatitis?). The interviewer was then able to go back and change Q14a. from "no" to "yes". Without multiple questions on hepatitis priming the respondent's memory, this fact may have gone undetected.

iv.   Death process

Perhaps the most impressive finding of this research is that the nature by which the decedent died impacts the manner in which the respondent interprets the questions. Specifically, when the death process has been long and drawn out, respondents tended to think only about medical issues associated with that process when answering certain questions.   This is because a long death process is a different experience from life prior to that phase.   In other words, when death is long and drawn out, it is a different experience from their "normal" life. Some respondents focus on that process while others focus on their loved one's normal life prior to illness. But none considered both ("normal life" and the death process) at the same time when answering the questions.

Questions 4, 5a, 6 and 14 are good examples of how respondents answered the questions differently depending on how their loved one died. Sometimes this served question intent and sometimes it did not. For instance, the Question 6 series is a good example of this pattern serving the question well. The question reads:

> 6. Did she/he recently have any symptoms such as:
>   6a. a fever
>   6b. cough
>   6c. diarrhea

6d. swollen lymph nodes
6e. weight loss
6f. a rash
6g. sores in the mouth or on the skin
6h. night sweats
6i. severe headache
6j. rapid decline in mental ability
6k. seizures
6l. tremors
6m. difficulty walking

The timeframe of "recently" often links the question to the death process, that is, as a question about what the person died from. This was especially true if the decedent's death was long and drawn out. As such, this time period could range from weeks, to months, or even years. But the important point, irrespective of the timeframe being considered, is that the question obtains important and relevant health information about the decedent, which is ultimately the point of the questionnaire.

On the other hand, this pattern does not serve question 5a as well. It asks, "Did she/he take any prescription medication recently or on a regular basis?" When the death process extended over a period of time, respondents tended to include only medication related to that phase of life and neglected to include medications unrelated to the condition from which their loved one died (for example, omitting blood pressure medication if the decedent died of cancer). The same is true for question 14 (In the past 12 months did she/he live with a person who has hepatitis). One respondent answered "no" saying she was thinking of her family members with whom her mother lived prior to becoming ill. She was not thinking of the nursing home that her mother lived in during the last few months of her life. In the latter two cases, important information was not reported because respondents were thinking only of the death process of their loved one.

> v. Grief

One of the more anticipated findings is that grief impacts the question-response process. Respondents experiencing grief can have unpredictable interaction patterns. They often have a difficult time staying on topic and remembering the purpose of the questionnaire. For example, discussion about a condition or illness leads to reminiscing about the decedent's life. This pattern inadvertently turns the interaction between the respondent and interviewer away from a professional, medical/clinical inquiry and into an informal discussion about the decedent's life. This interactional shift is conducive to respondents losing sight of the medical nature of the questions. Once the interaction between the interviewer and the respondent becomes less "medically professional" and more personal in nature, an environment is created that heightens the sensitivity of certain questions. It is socially appropriate – in fact, expected – to discuss sexual activity and drug use with a professional. But it is socially *inappropriate* to do so with an acquaintance, and certainly not with a stranger.

> vi. Imperfect knowledge

Medical histories, conditions, diseases and treatments are often complicated and misunderstood. People have limited understandings of their own personal medical history, much less of someone else's. Further, we found evidence that respondents are sometimes better informants about decedents' everyday behavior patterns than they are for medical histories, per se. For example, questions on smoking and drinking are straightforward for respondents to answer. They understand the terms and concepts, have adequate knowledge about the decedent's behavior, and/or don't perceive the questions as particularly sensitive because they make the link between the topic, its medical implications, and the effect on donation eligibility (e.g., drinking alcohol affects the liver, which may be cause for a rule out). On the other hand, questions

asking about specific medical conditions can be more difficult (e.g., coronary artery disease). Respondents are required to know both the condition and whether or not a diagnosis was made. Questions about sensitive behaviors also function differently from those that ask about non-sensitive behaviors. For example, while respondents were very knowledgeable about decedents' smoking and drinking patterns, they often had less knowledge about sexual behavior and illicit drug use.

b. Question by Question Findings

This section contains a list of all questions on the DRAI. Because of the length of the questionnaire, combined with the one-hour time limit on the cognitive interview (due to respondent burden), not all questions were probed to the same degree. Probing was guided by early findings. Questions that demonstrated response error (or potential for response error) were probed more extensively than those that seemed well understood by respondents and that seemed to capture the intended information.

All filter questions in the DRAI are posed as yes/no questions, so response categories are not listed here[1]. Further, all answers of 'yes' are followed up with questions designed to capture details such as when, why, and/or where? Those are discussed as appropriate, but emphasis in cognitive testing was on the core (filter) questions. Finally, some questions were modified in between rounds of testing, as respondent difficulties were identified and improvements were made to the question. In these cases, each version of the question is presented, along with findings and rationale for question modification.

Introduction: The introduction to the questions confused some respondents in the first round of testing. In particular, the word "gift" was a euphemism they did not immediately understand. In order to clarify the idea, we expanded the term to "gift of donation" (shown in highlight below). The modified introduction read:

> I want to advise you of the sensitive and personal nature of some of these questions. They are similar to those asked when someone donates blood. We ask these questions for the health of those who may receive her/his* gift of donation. I will read each question and you will need to answer to the best of your knowledge with a "Yes" or "No."

No comprehension difficulties were detected in the final two rounds of testing. Respondents understood the purpose of the questionnaire to be assessing the decedent's suitability for donation. To some extent, confusion in the first round may have been due to the fact that those respondents were serving as proxies for someone who was not deceased. Therefore, the interview setting was more artificial than for respondents in rounds 2 and 3 who were serving as proxies for a deceased loved one.

3. Did she/he have any health problems due to exposure to toxic substances such as pesticides, lead, mercury, gold, asbestos, agent orange, etc.?

Extensive probing was not conducted on this question. No one answered 'yes' to this question, and no false negatives were discovered among the answers of 'no.' Probing was initiated in a few cases based on the decedent's occupation (e.g., construction work), and respondents generally understood that the question was asking about toxic exposure.

4a. Did she/he have a family physician or a specialist?
4b. Did she/he use a medical facility such as a clinic or urgent care center?

In round 1 questions 4a and 4b were a single question, which read: "Did she/he have a family physician, a specialist, or visit a medical facility, which can include, for example, a clinic or urgent care center?"
The question was difficult to read (as an interviewer) and came across as two different questions (to the respondents). It was essentially asking two things at once: 'having' and 'visiting' a health care provider are two different things. The question can be interpreted as asking whether their loved one *visited* a doctor recently or whether they had a *regular* doctor they would see when necessary.

The wording was revised to improve the flow ("Did she/he have a family physician, a specialist, or visit a medical facility such as a clinic or urgent care center?"), but the same issues were evident in round 2. Some respondents understood the question to be double barreled and didn't know how to answer or gave two answers. These respondents had something in common: the nature by which their loved one died.
In round 2 interpretations were based on whether respondents' loved one had experienced a drawn out death process or a short, sudden one. A drawn out death process is different from a person's "normal" life, so respondents in this category weren't sure which time period applied. For example, one respondent was thinking of the cancer related to what his father died from. He was not thinking generally about whether his father had a regular GP or place where he routinely went for health care. On the other hand, respondents whose loved one died suddenly saw this question as asking whether they had an established provider. One respondent answered, "She had a family doctor."

In round 3 the question was expanded into 4a (asking about a family physician or specialist) and 4b (asking about using a medical facility). However, question intent was still unclear and the nature of the death process continued to shape respondents' interpretations. For example, respondents in the 'long, drawn out' category sometimes did not know whether the question was asking whether the decedent had a *regular* doctor or whether it was about the doctors they saw in relation to what they died from (e.g., an oncologist).

Additionally, 4b confused respondents when the doctor for which they just answered practices in a clinic. When this was the case, they interpreted the question as "Was the doctor at a clinic?" It was also difficult for people who focus on a specific doctor, not the facility at which the doctor practices. Others go to a particular clinic, and see no particular doctor, only the doctor on duty at the time.

Despite the variety of interpretations, further changes to these questions will not be made. A certain amount of response error was deemed acceptable due to procurement agency access to relevant medical records of the potential donor.

5a. Did she/he take any prescription medication recently or on a regular basis?
5b. Did she/he take any non-prescribed medication or dietary supplements?

There was much packed into the original question (which combined prescription and non-prescription medication) and respondents did not keep track of everything it was asking in round 1. The original question tested in round 1 read, "Did she/he take any medication recently or on a regular basis such as those prescribed, non-prescribed, dietary supplements, etc.?" Because many items are being asked in the question, false negative responses were possible. Respondents simply could not think of everything all at once and would neglect to think of or recall all medications and supplements. In round 2 two questions were created, one for prescription and the other for non-prescription medication.

However, the first question (did she/he take any prescription medication recently or on a regular basis) was still prone to false negatives. Again, the nature of the death process affected interpretations. Those

experiencing a long process answered predominantly for that experience alone and failed to report medications unrelated to that illness.

False negatives were also a risk for those having experienced a sudden death, but for a different reason. Respondents often had difficulty with recall. The question comes early in the interview, before respondents have had time to think and talk about the decedent's medical history, so their memories were not primed to retrieve this type of information. These respondents sometimes had recall issues and did not remember everything their loved one took.

Knowledge was another factor that increased the probably of response error for these two questions. Many respondents had incomplete knowledge of what their loved one took. They often reported that medicines were taken, but they didn't know what kind. As one respondent said, "There were lots of pill bottles around." But the respondent had no idea what they all were. Many times respondents knew the general condition that the decedent had, but not the exact medication that was taken for it. Examples were taking something for "the heart" or a "bad liver." Other times, respondents knew the diagnosis (cancer, Alzheimer's, depression, high blood pressure, high cholesterol), but not the name of the medication, and certainly not the dosage.

It is also worth noting that one respondent had a mother who struggled with serious mental disorders throughout her life and was in and out of institutions. She was on medications for it but the respondent did not report that in question 5a. She only reported allergy medications and antibiotics for a kidney infection. She saw this as a question about physical health, not mental health. It is reasonable to expect that others may do the same.

Similarly, while most respondents reported doctor prescribed medication, some included therapies that were recommended – not prescribed – by the doctor. The example that came up several times was aspirin for a heart condition. But other things were mentioned too, such as vitamin supplements. On the whole, capturing these types of therapies is less troublesome than missing prescribed medicines.

Interpretations of question 5b showed wide variation in what was considered, which probably serves the intent of the question better than narrow interpretations would. For "non-prescribed medication" respondents were thinking of things like aspirin, cocaine and sleep aids. The focus for "dietary supplement" was a little different and included things like vitamins, Gatorade (because it was seen as a healthy thing to drink), weight loss pills and flaxseed in food.

Recall and knowledge issues are inextricably linked to these questions. However, because the questionnaire often captured this information in other places, no further changes were initiated.

6a.-6m. Did she/he recently have any symptoms such as: fever, cough, diarrhea, swollen lymph nodes or glands in the neck, armpits or groin, weight loss, a rash, sores in the mouth or on the skin, night sweats, severe headache, rapid decline in mental ability, seizures, tremors, difficulty walking.

The timeframe of 'recently' is used for all the items that fall under number 6. As one might expect, there were multiple interpretations of what 'recently' meant, ranging from 2-3 months, to 6 months, to 2 years or simply "at the present time". Those are very different lengths of time and one person even said that term was vague (without being prompted). Round 2 revealed that the interpretation of "recently" is influenced by the nature of the death process. Those who experienced a drawn out death process were thinking of that process, regardless of how long it was, from several months to a year or more.

Most of the symptoms in 6a – 6m are common occurrences in everyday life and respondents had no trouble understanding them. However, a few symptoms did pose some variation in interpretation. First, two respondents were not sure how to answer 6c (diarrhea). In both cases the decedent had been very sick

prior to death and wasn't having bowel movements at all. Because this is abnormal, they were not sure if the question should capture this information or if they should stick to a literal interpretation and include only diarrhea (which most respondents understood as loose stool).

As mentioned earlier, some respondents in round 1 did not understand what lymph nodes were in 6d. We added 'or glands in the neck, armpits or groin' and no one expressed confusion on this question in later rounds. The short definition seemed to give enough context for respondents to answer more confidently.

In all three rounds, the question of desired or undesired weight loss came up in question 6e. Most people assumed the question was asking about unwanted weight loss, but a couple included weight loss that had been the result of dieting. To a large degree the intent of the question is interpreted according to whether or not the decedent was ill prior to death. If that was the case, the questions are interpreted with that assumption in mind. If, however, the decedent was not ill prior to death, respondents do not necessarily assume the questions are being asked with illness as a backdrop. The same phenomenon occurred for 6h, night sweats. For example, respondents interpret this differently if a menopausal female with hot flashes was ill prior to death. In short, an answer of 'yes' to these questions for decedents whose death was short and sudden may be false positive errors, but this is not an especially troublesome pattern so no changes to the question were initiated.

In question 6i some respondents were not sure how to interpret "severe" headache. As a result they would qualify their answers. They acknowledged that it was sometimes a difficult judgment to make. They would be able to answer the question, but would indicate their rationale in order to allow the interviewer to decide whether the headaches should count.

Interpretations for 6j varied a bit, but seemed within scope. There were two dominant patterns of interpretation. Respondent thought the question was asking about either deteriorating memory (forgetting where things are) or what they informally termed "dementia" (making up stories).

Sometimes respondents could not see an immediate difference between 6k and 6l, seizures and tremors. But most did not express prolonged confusion – they differentiated it as "freezing up" vs. shaking.

X. Did she/he* have any food or drug allergies?

This question was added halfway through round 2 of testing (which is why it initially lacked a number). No respondents expressed difficulty understanding the concept of having an allergy. No response errors were detected in cognitive testing, but those that do occur may tend toward false positives. For example, one respondent reported a food allergy that the decedent had has a child, but not as an adult. It's unclear whether the question is meant to capture allergies that no longer existed but once did, however, the interviewer can clarify this with the follow-up questions ('what was she/he allergic to?').

7. Did she/he know anyone who had a smallpox vaccination?

All rounds of testing showed that people were very confused about what the smallpox vaccine is. Many respondents assumed that smallpox vaccines are standard in childhood and answered yes. On the other hand, a few correctly questioned whether this is still a vaccine that people are given. A couple respondents interpreted the question as asking whether their loved one knew anyone *who had the disease itself*, not the vaccine for it. Fortunately, the 7a follow-up does a good job of weeding out false positives and no false negatives were found during testing; therefore, no changes to the question were initiated.

It should be noted, however, that this is the single most perplexing question for respondents to answer in the DRAI. It seems incredibly odd to them and their responses often reflect that. For example, one respondent said, "Huh? I do not know the answer to that question. He may have…he was born in 1915.

[Pause] Do we get smallpox vaccines anymore?" Most respondents understood that all questions in the DRAI come with a "to the best of your knowledge" caveat. Question 7 on the smallpox vaccine was the exception to that. To a large extent this may be due to the fact that this information is perceived as unknowable and, therefore, unreasonable to ask. For example, one respondent specifically remarked that she didn't know and would have no way of knowing. "You wouldn't know this about yourself, much less of someone else." This was a common sentiment.

8. In the past 12 months was she/he in lockup, jail, prison, or any juvenile correctional facility?

Respondents understood the intent of the question (that is, people know what it means to be incarcerated), but sometimes felt that it was inappropriate (or sensitive), depending upon the decedent's age. As discussed in the general findings, respondents often wondered why we were asking that question about an elder decedent. It is a common phenomenon that respondents often don't understand that the questions we ask of them are asked of every potential donor regardless of individual characteristics. An important component of the DRAI should be to emphasize to respondents not only that all questions are asked of everyone, but also *why* (e.g., that everyone has a unique story about which assumptions should not be made).

9. In the past 12 months was she/he bitten or scratched by any pet, stray or wild animal?

In round 1 this question was "In the past 12 months was she/he bitten or scratched by any animal?" This was prone to out-of-scope interpretations because respondents did not know what counted as an animal. Several respondents were thinking that mosquitos were part of what was being asked about. The wording was changed to "...bitten or scratched by any pet, stray, or wild animal?" Everyone answered no, and no response error was detected in rounds 2 and 3.

10. In the past 12 months was she/he told by a healthcare professional that they had a West Nile virus infection?

Respondents generally do not know what this infection is, even if they have heard the term. However, no response error was detected. Overall, if respondents have not heard of a rare disease or condition, they answer no, which is most often the correct answer.

11. In the past 12 months did she/he have any shots or immunizations, such as a flu shot, MMR, yellow fever, hepatitis B, etc.?

This question produced some false negatives in round 1. The original wording was, "In the past 12 months did she/he have any shots or immunizations such as MMR, yellow fever, hepatitis B, flu, etc.?" This wording was prone to false negative errors with respondents who did not report the flu shot in particular. This was likely because it was included at the end of the sentence and people only heard the more "serious" vaccines first and didn't pay attention to those at the end. For example, one respondent who answered 'no' was later (during probing) asked specifically about the flu shot and he said, "That did not cross my mind."

The wording was changed to move the flu shot up front as the first example. This did have an impact, as interpretations in round 2 and 3 shifted predominantly to the flu shot because it was very often relevant to their experience. Even though respondents were not thinking of the other examples in the question, this is largely due to the fact that the decedent did not receive any of the other types of vaccines or shots – no response error was detected when respondents were asked about these examples during probing.

12. In the past 12 months did she/he get a tattoo, touch up of an old tattoo, or permanent makeup?
13. In the past 12 months did she/he have acupuncture, ear or body piercing?

These two questions performed in the same manner as question 8 on jail. Respondents understood question 12 to be asking about tattoos and question 13 about piercings. For example, many respondents answered "no" and clarified that any tattoos or piercing occurred longer than a year ago. However, sometimes they felt that it was inappropriate, sensitive, or even amusing, depending upon the decedent's age. As discussed in the general findings, respondents often wondered why we were asking that question about an elder decedent. It is a common phenomenon that respondents often don't understand that the questions we ask of them are standardized – that is, asked of everyone. The same advice applies here as it did for question 8: respondents might need reminding about the standard nature of the questions. For example, prior to question 12 a preamble could be added, such as, "This is a reminder that these are standard questions we ask in every interview. Just answer to the best of your knowledge with a 'yes' or 'no'."

14a. In the past 12 months did she/he live with a person who has hepatitis?
14b. In the past 12 months did she/he live with a person who has tuberculosis?

The main finding for these questions is that respondents did not consider institutional living arrangements when answering.[2] For example, if the decedent had been living in a short or long term care facility prior to death, respondents did not take that situation into consideration when formulating their answer. To some extent this may be because to "live with" implies having a relationship with the cohabiter. Additionally, respondents would have no way of knowing the medical history of other people in an institutional setting and may assume, therefore, that the question would not require thinking about them. As a result, respondents thought only of the living arrangements prior to the decedent falling ill. This is largely applicable only to those who experienced a long, drawn out death.

15. In the past 12 months did she/he come into contact with someone else's blood?

The only source of observed confusion here lies in the definition of contact. "Contact" can vary to include or not include blood literally touching the skin. For example, one respondent discussed how his cousin had worked in a juvenile detention facility where contact with blood would be possible. But he answered "no" to this question because the employees are generally protected with clothing and gloves so that their skin does not touch another person's blood.

Another variation of coming into "contact" with someone else's blood was through blood transfusion. Several respondents thought this was what the question was about. Others did not. Some had to ponder it. For example one person said, "First thing I thought about was if someone cut themselves. The second thing I thought about was blood transfusion." (Neither applied to her deceased loved one, so she answered no.)

Broad interpretations and the false positive responses they tend to create are not seen as problematic for this question, so no changes were made to the wording.

16. In the past 12 months did she/he have an accidental needle stick?

Extensive probing was not conducted on this question. No one answered 'yes' to it, and no false negatives were discovered among the answers of 'no.' The needles respondents were thinking of were intentionally administered by a health care professional or done by the decedents' themselves, for example if they required insulin shots.

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[2] Note that question 14b. was not added until round 3; nothing different emerged for this question.

17. In the past 12 months did she/he have a sexually transmitted infection such as syphilis, gonorrhea, chlamydia, genital herpes, or genital warts?

Extensive probing was not conducted on this question (most occurred in the next question). No one answered 'yes' to this question, and no false negatives were discovered among the answers of 'no'. Respondents were probed on the level of confidence they had in their answers, and most felt they would have known this information, citing the fact that they were very close to the decedent. They confirmed their answer by saying things like, "We're pretty tight." "He would've said he got burned." Or "We talk a lot. He would have dropped that knowledge on me."

The exception to this was when the decedent was a parent. As one respondent put it, "[No.] To the best of my knowledge. My father didn't talk about it. But on the other hand, I don't talk to him about mine either." Another respondent said about his mother, "[No.] She probably wouldn't have told me. She was very private when it came to her health."

18. – 18f. As indicated in the section on general findings, the set of questions on sexual history had the potential to be highly sensitive, especially with respondents discussing parents. For example, one respondent angrily replied to question 18, "That's my mother! How would I know that?" and several others answered the question but refused to elaborate during probing.

However, if respondents had in mind the medical purpose of the questions, they were less likely to be embarrassed or offended – even when discussing a parent. In fact, respondents who either were not talking about a parent or who had the purpose of the questionnaire firmly in mind had no compunction in discussing issues of sexual history or illicit drug use on the part of the decedent.

With this in mind, language was added to the introduction (prior to question 17) of this section to contextualize the reason for asking about sexual behavior and drug use. It reads:

> "As I described before I want to remind you of the sensitive and personal nature of some of these questions. For medical and health reasons, we are required to ask these questions about all potential donors. Next I will ask you about her/his sexual history."

The highlighted text was added to emphasize the medical purpose of the questions vis-à-vis donation. This helped, but the potential for the questions to be sensitive was still present in round 3. This is likely due to the influence of grief. For all questions in the DRAI, grief was found to disrupt the typical question-response process. As discussed earlier, respondents experiencing grief have a difficult time both staying focused on the task at hand and remembering the purpose of the questionnaire. Any opportunity to gently remind them of the medical purpose should be taken.

A note on 18a.-18.g: A couple respondents were confused about the timeframe in round 1 and asked if they should still consider the past 5 years. A note on timeframe was added for clarification: "For the following set of questions, think about the past 5 years".

Additionally, an exploratory question was included as 18h. It read, "In the past 12 months, how many sexual partners did she/he have?" This was not intended to be included in the final version of the DRAI, but sponsors were interested in respondents' ability and willingness to answer the question. Most could answer it as well as any other questions on sexual behavior/activity. One sex partner was the most common answer given because respondents generally believed the decedent to be faithful. However, a couple respondents did answer two partners, knowing that the decedent had romantic involvement with more than one person – but no one answered more than two.

19. In the past 5 years, did she/he receive medication for a bleeding disorder such as hemophilia?

The original wording of this question produced much confusion and response error. The wording of the question in round 1 was: "In the past 5 years did she/he receive clotting factors for a bleeding problem?" People do not know what blood clotting factors are and often conceptualized them as blood thinners. Others simply didn't know the term at all and would say, "I'm not sure what clotting factors are. Is this a pill? I never heard of that term before."

To help clarify the question, the wording was changed in round 2 to "In the past 5 years did she/he receive blood clotting medication for a bleeding problem?" Unfortunately, this did not improve respondents' understandings. Many did not correctly understand what the question was asking. They either thought the question was asking about anticoagulants (medication to *prevent* blood clotting) – "Did you say blood clot?" – or medication due to excessive blood loss (most likely due to an acute injury) – "Like if you have a gash and have to have a blood transfusion."

During probing, it was found that respondents *do* understand the concept once they know what the intent is. For example, they would define it "like hemorrhaging or having a bleeding problem." But the concept was not consistently communicated by the question. Instead, the term "blood clotting medication" was often interpreted as asking about medication to *treat* a blood clot. The question was modified again in round 3 to: "In the past 5 years did she/he receive medication for a bleeding disorder such as hemophilia?" This modification did a much better job at conveying question intent. All of the respondents in round 3 understood what the question was about, describing it as "someone that bleeds a lot", "when the blood does not clot," or "someone who had heavy bleeding." No response error was detected.

20. Did she/he EVER use or take drugs, such as steroids, cocaine, heroin, amphetamines, or anything NOT prescribed by her/his doctor?

Respondents who answered yes were thinking of the substances given as examples in the question (generally cocaine). However, some also included marijuana in their answers.

21a. Did she/he EVER have a transplant or medical procedure that involved being exposed to live cells, tissues or organs from an animal?

Extensive probing was not conducted on this question. It was a rare enough occurrence that most people could not discuss it, other than to repeat or paraphrase the question when asked how they understood it. There was, however, one interpretation that, while reasonable to the respondent, was very much out of scope and yielded a false positive error. This respondent answered 'yes' to the question thinking that his cousin (the decedent) had gone hunting, shot a deer, and upon dressing it was exposed to its internal organs. This kind of mistake is not of deep concern because this type of false positive would be easily detected by the interviewer during the follow-up questions.

21b. Did she/he live with or have sex with a person who had?

No separate issues, apart from those discussed in question 21a, were found for this question. Extensive probing was not conducted on this question.

22. Was she/he EVER told by a physician that she/he had a disease of the brain or a neurological disease such as Alzheimer's, Parkinson's, multiple sclerosis, or epilepsy?

These constructs can be widely defined, sometimes in contradictory ways. For example, one respondent answered 'yes' because the decedent was bi-polar and had been on "anti-psychotic" medicine. To him this

was in scope of the question because this was a "disease of the brain." However, it's unclear whether psychological conditions are meant to be captured by this question. For example, another respondent's loved one also had a mental illness (serious enough to have been institutionalized during her lifetime), but answered 'no' thinking that this question was NOT about mental illness.

In addition to possible false positives, several false negatives may have occurred. In both cases the decedent suffered from "dementia." One respondent did not include this, saying that "Dementia is not Alzheimer's. It's natural, not a progressive disease. It's more like a condition." The other respondent gave similar rationale, suggesting that dementia is not as serious as Alzheimer's. To many, growing old necessarily means losing the ability to remember things. Most respondents understood this question to be asking about serious diseases that occur apart from the aging process.

23. Was she/he EVER refused as a blood donor or told not to donate?

If respondents knew that the decedent had donated blood, they would report this. There was only one respondent who changed her answer from yes to no as she considered different things. When the decedent was healthy, she never tried to donate. But once she was diagnosed with leukemia the decedent was told not to donate – not that she would have anyway. This is a false negative because the respondent incorporates intent to donate into her interpretation of what the question is asking. Interesting, because the wording of the question does not imply intent on the part of the decedent. However, it could be that respondents believe that the only circumstance under which one would be told not to donate would be if he/she actually tried to donate.

24. Was she/he EVER a U.S. military member, a civilian military employee, or a dependent of either?

Respondents generally knew if the decedent had served in the military. There were only two cases that caused some thought/confusion on the part of the respondent. In both cases the concept of 'dependent' created the confusion.

In one case, the decedent's father was serving when the decedent was born, but the respondent chose to answer 'no' because the decedent never lived overseas; her father was always gone and the decedent didn't have much of a relationship to him as a result. The second respondent was simply confused over what 'dependent' meant. She said, "Her [the decedent's] husband was in the military. I don't know if that made her a dependent." The respondent chose to answer 'yes' to this question – which is probably the correct answer – but she had to think about it and wasn't sure of her answer.

In the final version of the DRAI, question 25 will precede this one in order to make for a more logical flow in determining the travel history of the decedent. In addition, this will alleviate the problem of those not understanding the term 'dependent', as any foreign travel by the decedent will be captured one question prior to this.

25. Did she/he EVER travel or live outside the United States or Canada?

If the decedent had military history, this question is repetitious to some respondents. However, they did understand the question and were able to answer it. Moving this question so that it precedes the previous one (question 24) may improve the logical flow.

Most difficulties with this question do not occur around comprehension, but rather around recall. This is especially true for decedents who traveled frequently or to many countries. Under these circumstances response error would not occur in the original question, but it can be difficult or impossible to answer the follow-up questions of "where, when and for how long."

26. Did she/he EVER receive a blood transfusion or other medical treatment outside of the United States or Canada?

Everyone answered 'no' to this question, with only one possible error, depending on the intent of the question. One respondent knew that when the decedent served in active duty he did sustain injury. But the respondent answered 'no' because any treatment received overseas would have been administered on a military base. Clearly this respondent thought that the intent of the question was to capture treatment received from a foreign medical facility or health care provider.

27. Did she/he EVER have any kind of surgery?

There were three issues surrounding this question: Comprehension, knowledge and recall. The original question tested in round 1 ("Did she/he ever have surgery?") had the potential to generate false negative responses, largely due to comprehension of the word 'surgery'. In this round of testing, no actual response error was found; however, the way people thought about the word 'surgery' was fairly extreme. In other words, people thought the question was asking about serious procedures and were not thinking as much about outpatient procedures that are still defined as surgery (mole excision, for example). For serious/extreme surgeries, respondents gave examples such as back surgery, bypass surgery, gall bladder surgery or amputation. One person defined it as "a scalpel going inside your body."

In round 2 the wording was modified to "Did she/he ever have any kind of surgery?" to have people think more broadly about surgery. Rounds 2 and 3 produced mixed results. False negatives generally did not occur in answering yes or no to the initial question, so it performed reasonably well. There was only one exception – one false negative did occur. The respondent answered 'no' but during probing revealed that the decedent had two endoscopies to remove cancer spots on the decedent's lungs. It was unclear why the respondent answered no to this question.

The follow-up questions (what kind, where and when) were more problematic because they require a level of knowledge that respondents often do not have. They frequently have partial information or lack a clear understanding about what procedures were performed and why. For example, one respondent answered 'yes' to question 27 and said, "I guess so. I'm not sure. Probably had to do with cancer…that's all I know."

In addition to knowledge issues, some respondents who answered "yes" did not include all surgeries in the follow up questions, mostly due to recall problems. However, these surgeries were captured elsewhere in the questionnaire. Examples include bunion surgery, laser surgery for glaucoma and bone marrow transplant. Additionally, some procedures were captured that may not be intended, such as tooth extraction and a liver biopsy (that turned out benign). For these reasons, this version performed better in meeting question intent than did the round 1 version.

28. Did she/he EVER use or take growth hormone?

Extensive probing was not conducted on this question. It was a rare enough occurrence that most people did not have a lot to say about it. Everyone answered 'no', with no error detected. In double checking that respondents generally understood the question, they were asked what they thought it meant. They said things like, "it's an enhancement…kinda like steroids," it's "maybe for an undersized person. She [the decedent] wouldn't need that," or "she was already big [300 lbs.], so I don't think she'd want to get bigger."

29a. Did she/he EVER have a positive or reactive test for the HIV/AIDS virus?

Extensive probing was not conducted on this question. It was a rare enough occurrence that most people did not have a lot to say about it. Everyone answered 'no'. To probe whether respondents had a general understanding of the question, they were asked if the decedent ever got tested for HIV. Some did and some

did not get tested. Others didn't know for sure, but assumed the decedent might have been tested during procedures involving other blood work or hospital stays. On the whole, respondents have heard of HIV.

29b. Did she/he EVER have a positive or reactive test for hepatitis?

Extensive probing was not conducted on this question. It was a rare enough occurrence that most people did not have a lot to say about it. All but one person answered no to this question and no response error was detected.

29c. Did she/he EVER have a positive or reactive test for HTLV-I or HTLV-II?

This question was added in round 3. Everyone answered 'no' and almost no one had heard of it, a fact some expressed without being asked. Only one respondent heard of it – the decedent was tested for it among other things before taking a new job – but the respondent did not know what it was.

29d. Did she/he EVER have a positive or reactive test for T. cruzi or told she/he had Chagas' disease?

Extensive probing was not conducted on this question. It was a rare enough occurrence that most people had never heard of it and could not speak to it. Everyone answered 'no' to this question and no response error was detected.

30. Did she/he EVER have liver disease or hepatitis?

This is an example of how respondents often have limited knowledge about medical conditions or diseases. One respondent answered 'yes' and knew only that "His liver was bothering him. It was going bad." The respondent did not know what the formal diagnosis was. The same pattern was observed in other respondents, one who said there was "something going on with her liver." However, response error was not detected because the question asks not just about hepatitis specifically, but also liver disease more broadly.

31. Did she/he EVER have malaria?

Extensive probing was not conducted on this question. Many people had heard of the disease but didn't know much about it. They defined it as something you get in other places such as the "Third World" or "tropical places" or that it comes from mosquitos. Everyone answered 'no' to this question and no response error was detected.

32. Did she/he EVER have cancer?

Most respondents have a fairly clear idea of what cancer is, and when a person is diagnosed with cancer it's a big deal. So this question was straightforward in terms of both comprehension and recall. However, respondents with imperfect knowledge may have a difficult time with the follow-up questions that ask about type, timeframe and treatment. But no response error was found for this question.

33. Did she/he EVER smoke?

This question performed well, as there were no comprehension, recall, or knowledge issues. Most respondents understood this to be asking about cigarettes, but the question also captured marijuana – which is parsed out in the follow-up questions. It also captured regular smokers and light/social smokers. Respondents often provided more detail about the decedents' smoking history and behavior patterns than they could about medical history.

34a. Did she/he EVER have lung disease such as asthma, COPD or emphysema?

Respondents understood the intent of the question to be asking about problems with the lungs. But their lack of specific knowledge made it sometimes difficult to answer. The question also doesn't specify whether a formal diagnosis is required in order to answer 'yes.' So respondents answered in relation to either a formal diagnosis OR simply to the symptoms the decedent had. One respondent saw the decedent wheezing and having trouble breathing the last 12 months of life, but answered 'no' because he thought this question is asking "what do I know that he's been diagnosed with." In this case, the respondent knew much more about the decedent's symptoms than actual diagnosis. Another respondent came to the opposite conclusion and answered 'yes' to this question even though the decedent was never diagnosed. The respondent believed the decedent had either asthma or bronchitis from smoking.

34b. Did she/he EVER have tuberculosis or a positive skin or blood test for tuberculosis?

Extensive probing was not conducted on this question. Two respondents answered yes; all others answered no, and no obvious response error was detected. In other words, no respondents expressed any difficulty with the question.

35. Did she/he EVER drink alcohol?

Similar to the smoking question, most respondents had a clear notion about their loved one's drinking patterns and habits and were willing to speak about them (most answered 'yes'). This included decedents who drank infrequently, moderately and socially, as well as those the respondent described as alcoholic. No response error was detected.

36. Did she/he EVER have diabetes?

Similar to question 32 on cancer, respondents were familiar enough with this disease that they didn't have difficulty answering the question. There was a mix of yes and no answers, and no error was detected.

37a. Did she/he EVER have kidney disease, kidney stones, or frequent kidney infections?
37b. Was she/he* EVER treated with dialysis?

Difficulties can arise in question 37a in relation to respondents' imperfect knowledge of medical issues. This question incorporates several different ideas – disease, condition, infection – that can create some confusion when respondents cannot make these distinctions. And often times, they are less likely to think in terms of disease names and more likely to think about the symptoms exhibited by the decedent.

For example, one respondent who was confused over these distinctions asked, "What do you call it when you're on dialysis? Is that an infection?" Another person said, "He had kidney stones or gall stones. Which are the ones that pass naturally?" This respondent goes on to note whatever it was the decedent had, he passed it naturally – "he never got them lasered out." It is interesting to note that this same decedent had a cancer mass on his kidney, which the respondent did not mention here, but did in question 32 (on cancer). This is an example of how the questionnaire does tend to capture health conditions. Even though they expressed some confusion, both of these respondents answered 'yes' to the question – which is preferable to 'no', since 'yes' prompts the interviewer to collect more information.

However, confusion can sometimes cause a person to say 'no', especially when the health condition is complicated. For example, one respondent did not know what the decedent had or what the diagnosis was, but knew there was some kidney trouble. During probing the respondent noted that one of the decedent's kidneys "wasn't working" and hadn't been for 15 years prior to his death. Additionally, the decedent had been told recently that his remaining kidney was showing decreased functioning, but it never got to the

point of needing treatment. This amounted to a false negative error. The respondent chose 'no' even though the decedent did not have healthy kidneys because there was no diagnosis that the respondent knew of and the decedent did not die from kidney-related disease. (The respondent didn't know exactly what he died from, only that he fainted one day and was found to have a "partially collapsed lung").

Question 37b was added in the second round of testing. Almost all respondents answered no. Those that answered 'yes' knew the type of dialysis treatment received by the deceased.

38. Did he/she EVER have high blood pressure or high cholesterol?

This question did not present many comprehension difficulties for respondents – they generally had heard of and knew what high blood pressure and cholesterol are. There were both yes and no answers, with more respondents answering yes than no. Respondents based their answers on either having a discussion with the decedent about a diagnosis or knowing that the decedent had been taking medication for one or both of the conditions.

However, some of the 'yes' responses were based more on impressions and beliefs than on a known and formal diagnosis. For example, one respondent answered yes not because the decedent had ever been diagnosed with either of these, but because the respondent, himself, believed this to be the case. He thought his father must have had high cholesterol because of his diet. The respondent said his father "ate lots of pork, BBQ, chitlins and pigs' feet." Another respondent said he thought his father had both because his mother and father had been talking about eating better. This goes back to the notion that respondents can often speak more knowledgably about the decedent's behavior patterns than they can about formal diagnoses and medical treatments.

39. Did she/he EVER have heart failure or heart disease, such as weak heart, a heart valve problem or an infection involving the heart?

The question tested in rounds 1 and 2 read: "Did she/he EVER have heart problems or heart disease, such as a weak heart, a heart valve problem or an infection involving the heart?" The concepts and terms in this question were unclear to respondents. As a result, multiple false negative responses were found. One respondent answered no to the question, but probing revealed some heart conditions in the decedent. In not reporting them the respondent said, "Although atrial fibrillation and tachycardia are heart issues…but not these issues." Round 2 confirmed that the question was not clear to respondents. Four false negatives were found. One respondent didn't report congestive heart failure, saying that because it's fluid around the heart, it doesn't count for this question. When asked why she said, "Physical abnormality is what this question is about." Three other respondents had their loved one die of a heart attack but because heart disease was not diagnosed prior to death, they didn't report it.

In round 3 the vague word "heart problem" was deleted and changed to "heart failure," especially to capture people who die of a heart attack (but may have had no prior diagnosis of heart disease). To some extent this helped – two respondents in round 3 had decedents who died of heart attacks (with no prior diagnosis) and both answered yes. However, one person needed help from the interviewer to settle on an answer. Her first response to the question was, "He died of a heart attack. Does that count?" Unfortunately, false positives are still possible, and one was evident in round 3. One respondent answered 'no' but then said, "But he died of a heart attack." When asked why she answered 'no', she explained that there was no prior diagnosis of heart disease. Ultimately, respondents who were prone to response error asked for clarification from the interviewer, so to that extent, the question captures information about heart disease.

All three rounds of testing confirm that the term "heart attack" should be used in place of "heart problems" or "heart failure". Though not a clinical term, per se, it is a term that resonates with respondents.

40. Did she/he EVER have circulation problems of the legs, such as varicose veins, blood clots, leg ulcers or skin discoloration of the feet or ankles?

Respondents did not exhibit extensive comprehension difficulties with this question, and if anything, they were inclined to include more – not less – in their judgments. The clause with the examples encourages respondents to include conditions broadly. For example, one person answered 'yes' because the decedent had surgery on bunions. Another respondent said 'yes' because, "She had big veins. I don't know what it was from. Whether it was medically diagnosed, I don't know." However, it is preferable to have respondents include conditions that may be out of scope than to have them exclude potentially important information.

41. Did she/he EVER have an autoimmune disease such as systemic lupus erythematosis, rheumatoid arthritis, sarcoidosis, etc.?

Most people answered 'no' to this question, and didn't know enough about these conditions to speak about them. One possible source of false positives (several were found) relates to a lack of knowledge of medical conditions. For example, the question sometimes picked up osteoarthritis (which respondents call "regular" arthritis), but this inclusion can be weeded out by the interviewer if necessary. The same is true for lupus – except one person failed to include what she called "regular" lupus. Respondents have the potential to be confused over whether "regular" arthritis and "regular" lupus should be counted here. Also, one person didn't connect the decedent's gout to this question.

42. Did she/he EVER have any eye problems, procedures or surgery?

This question may be prone to false positive answers. Generally this means that it captures information missed by other questions. A good example is surgical eye procedures not being picked up in question 27 (surgery) but being reported here. Other false positives included a few respondents answering 'yes', thinking about the decedent needing glasses for nearsightedness.

43. Did she/he or any of her/his relatives have Creutzfeldt-Jakob disease, which is also called CJD or variant CJD?

Extensive probing was not conducted on this question. Respondents had generally never heard of this disease and had nothing to say about it. Everyone answered no, and no response error was detected.

44a. Is there a family history of diabetes?

Respondents were familiar with the term diabetes. The only complication that arose was in keeping the respondent focused on the decedent. For example, in several cases a false positive was discovered because respondents were thinking of their own family history, not necessarily the family history of the decedent. In other words, they were including people they knew who had diabetes but were no blood relation to the decedent. The concept of family history was thought of in relation to the respondent, not the decedent. Grief has the potential to impair respondents' focus and may contribute to respondents losing sight of whom this question is about. This could be easily clarified in this question and the next. For example, it could read "Did her/his family have a history of diabetes?"

44b. Is there a family history of coronary artery disease, which is a buildup of plaque in the heart's arteries?

The original question in round 1 was: "Is there a family history of coronary artery disease?" In round 1 it was found that 'coronary artery disease' is a term that many people did not know. Similar to question 19 (clotting factors), there was a range of reactions, from respondents not knowing the term at all to having a

misunderstanding of the term. When asked what the term meant some said "I don't know what that is," "never heard of it" or "I think it's more generic." But others thought it referred to things like hypertension, atrial fibrillation, or just generally "heart problems." The question in round 2 was revised to include a short definition to help orient people to its actual meaning. This question performed better in rounds 2 and 3 and is likely to capture more information than less. For example, one person answered 'yes' saying, "I think probably everyone has that. That, to me, is pretty standard because of how we eat." Another person also wasn't sure but also chose to answer 'yes' citing that, "There seems to be that problem…" (she thinks all of her aunts have it, including the decedent).

49. Did she/he EVER have sex with a person who was born in or lived in any country in Africa?

The original question tested in round 1 read: "Did she/he EVER have sex with a person who was born in or lived in Africa?" Some people tended to think of this question as asking exclusively about either the race or nationality of the sex partner. In other words, some white people thought it was asking whether the donor ever had sex with a Black person ("my father wasn't very open-minded"), while others thought it was asking whether the donor ever had sex with someone who wasn't American ("she likes American guys").

For round 2 it was changed to "…a person who was born in or lived in any country in Africa" to help convey the idea that the question is not about a person's race or physical features, but rather about countries. This wording change directed respondent interpretations in the right direction as they focused mainly on someone who was born in another country. For example, one person said, "I don't know if he's ever been with a foreign woman or not." However, no one thought about someone who may now live here but was born in Africa.