

**Comments by
The American Red Cross
On the
Draft Guidance for Industry:
Streamlining the Donor Interview Process:
Recommendations for Self-Administered Questionnaires
67 FR 19578; April 22, 2002
Docket No. 02D-0080**

The American Red Cross (ARC or Red Cross) is pleased to provide these comments to the Food and Drug Administration (FDA) on the *Draft Guidance for Industry: Streamlining the Donor Interview Process: Recommendations for Self-Administered Questionnaires* (draft guidance). Our views are identified by the draft guidance's section containing the recommendation.

II. BACKGROUND

Under the background section, FDA defines the options available for self-administering the donor questionnaire. Options #1 and #3 contain brief descriptions of the media and how the donor might use it. However, Option #2 does not. Rather, it states that such an option exists:

Audio and/or visual presentation of the questions. The donor reviews the media and documents the answers on a printed form. Your personnel review the answers.

This does not actually contain a description of "Audio." For example, there is no indication of the type of equipment that may be used by a donor. ARC recommends that FDA clarify this option. The description might be revised to read:

Audio and/or visual presentation of the questions. The donor reviews the *questions by listening to a recording or watching a video* and documents the answers. Your personnel review the answers.

III. A. Recommendations for Manual Procedures

Title - ARC believes that FDA intended to make the requirements of this section applicable to all forms of self-administered questionnaires, including the audio and computer-assisted interactive interview. To clarify the applicability, ARC recommends changing the title of

this section from “Recommendations for Manual Procedures” to “Recommendations for *All Self-Administered Procedures*.”

Introductory Paragraph - To be consistent with the intention of making this section apply to all media, we recommend the following changes in the first paragraph of this section:

- Delete the term “manual” in the first sentence, since the guidance’s recommendations for this section will apply equally to audio and computer assisted self-administration.
- Insert the phrase “*listens to and/or sees*” in the first sentence directly after the phrase “as one in which the donor reads...” This change is to explicitly define the broader applicability.
- Delete the phrase “printed answer form” after the phrase “documents his/her answers” since the donor may be assisted by an alternative form of documentation such as a computer.

After the changes noted above, the first sentence would read:

We define the self-administered pre-donation questionnaire as one in which the donor reads, listens to and/or sees the medical health history questions and/or high-risk questions and documents his/her answers.

FDA may find that this change leaves the guidance without a complete definition of the manual self-administered questionnaire. If this is the case, we recommend that FDA include the definitions of each form of the self-administration questionnaire in the previous section, i.e., Section II. Background.

Point #4 – ARC requests that FDA reconsider the recommendation that: “You should not allow new donors to self-administer the donor questionnaire...”

To our knowledge, there are no data demonstrating that a first-time donor is less likely to understand a self-administered questionnaire than repeat donors. Further, many donor centers are examining new technologies and the efforts to simplify the Donor Health History have made considerable progress. Donor centers may have or may be able to develop self-administered questionnaires that are equally comprehensible to first time and repeat donors. Thus, ARC requests that FDA modify this requirement to allow the option for first time donors to use a self-administered questionnaire.

Should the FDA feel that further direction is needed, the Agency could recommend that blood collection centers determine, through pilot testing or other means, that the comprehension of first-time donors is equivalent to that of repeat donors prior to implementation.

Point #5 - Also of major concern is the requirement to “include an evaluation of the donor’s ability to read and understand the language of self-administered questionnaire...”

This requirement is very subjective. It will be interpreted and conducted in a highly variable manner among the blood collection facilities, and similarly be subject to highly variable interpretations by FDA investigators. Is merely asking the donor if they can read the questionnaire sufficient for an “evaluation”? Or, does FDA intend something more rigorous?

Regardless of how carefully donor center staff fulfill this requirement, some donors may misconstrue this form of evaluation. We particularly risk offending qualified donors for whom English is a second language.

ARC also believes this requirement is unnecessary given the full support for donors before, during, and after the questionnaire answering process as required throughout the draft guidance. For example, as defined in Point #6, donor centers must provide options for donors who request assistance, including direct oral questioning.

We believe these activities and all the other practices for aiding donors at the blood donation sites will ensure the donor’s comprehension, or provide other means to complete the questionnaire if uncertainties exist. ARC recommends eliminating this “evaluation” requirement.

Point #7 - This point states that “The instructions and questionnaire must be in a language the donor readily understands.” ARC is uncertain whether FDA believes that all donors must be provided with a translation if English is a second language, or whether the guidance was referring to the donor’s reading/educational level as an indication of their ability to understand the questionnaire.

ARC has translated the donor materials into Spanish. However, having translations available for any possible language that a donor may be more familiar with is unrealistic, and we request that FDA delete this specification. As noted in other sections of this attachment, there are many other provisions for overseeing the donor, providing assistance, and verifying answers so that a translation for each and every language would not be necessary.

Point #9 - This provision requires donor center staff to “administer the new or modified questions to all donors by direct oral questioning or provide all donors with a detailed description of the changes...” How this requirement would be carried out in actual practice and whether it is intended for all forms of self-administered questionnaires is unclear to ARC.

For example, if it has been a year or more since a repeat donor has donated, would we be expected to identify records of previous donations and questionnaires, cross compare them for questions that may have changed since that date, then verbally ask the new or revised questions? Once we've asked the new questions, or provided the required detailed information, would we then ask the donor to switch to filling out the rest of the questionnaire through the manual, audio/visual, or the computer-assisted method?

If this is the intent, ARC's concern is that carrying out this directive will not occur without a significant slow-down in the donation process. Additionally, the potential for the donor to fail to recall the date and location of the last donation exists, so that there would be limited ability to fulfil this requirement if the previous donation was made at a non-ARC donation center.

Job aids might ease some of this activity, but they will not completely eliminate delays. Automation could be considered, but such software will require substantial time to develop, test, and implement. It may be particularly cumbersome to work with automation at a mobile collection site. Moreover, if incorporated into a computer-assisted interactive procedure, automation will not alleviate all delays such as those that may be associated with switching from answering some questions orally to answering others through the computer-assisted procedure.

Additionally, if donor centers highlight new questions, it may appear that the new questions are more important than the previously existing ones. Donors may erroneously believe that if they focus on the new questions, the accuracy of the others is of lesser consequence. We want to be sure that donors treat all questions with an equal level of care and attention.

ARC urges FDA to reconsider and eliminate this requirement.

Point # 10 –ARC believes that quality assurance practices should extend to the self-administered questionnaire. However, this point emphasizes one aspect of quality assurance, i.e., an effectiveness check of the self-administered questionnaire. As a result:

- Donor centers may spend efforts checking the effectiveness of the self-administered questionnaire, when quality assurance of other processes might be more beneficial.
- It appears that the draft guidance requires blood collection centers to continue quality assurance effectiveness checks, even if the effectiveness checks produce satisfactory results. Blood centers may find that they must continue an unnecessary task.
- This point may be unnecessary given validation requirements. Many of the concerns that might be found after implementation, would be identified and resolved before implementation.

Blood Establishments do not object to following quality assurance requirements, but these are fully discussed in other regulations and guidances including the July 11, 1995 *Guideline for Quality Assurance in Blood Establishments* and CFR 820.20, 820.22, and 211.22.

We believe these existing regulations and guidances provide full direction on quality assurance practices, and pertain to the self-administered questionnaire. Thus, there would be no detrimental public health consequence by deleting this point, and we encourage the FDA to do so.

If the Agency still believes a reminder to perform quality assurance steps is needed, point #10 could be amended to do so, but we urge referring to the quality assurance regulations and guidance noted above rather than effectiveness checks. Noting quality assurance specifications within a document designed for a different purpose adds to the difficulty of monitoring all regulatory requirements.

If effectiveness checks are of particular concern to FDA, it would be more appropriate to discuss them in a revision to the 1995 *Guideline for Quality Assurance in Blood Establishments*, so that all the Quality Assurance requirements for blood establishments are retained in one guidance.

III.B. Additional Recommendations for the Use of Audio/Visual Tools

ARC agrees in concept with the goals of this section. However, we note that some requirements tend to be subjective, are unnecessarily detailed, or risk offending the donors who may regard the required form of oversight as intrusive. ARC recommends revision of these points, so that the donor center has greater flexibility to implement the audio/visual tools and establish a more congenial environment for the donors.

Point #3 – This point states that blood collection facilities should:

“Instruct new donors to immediately document answers to questions...and not answer before the recording finishes... instruct the donor to listen to or read the whole question before responding...”

This point comes across as a somewhat heavy-handed approach to guiding donors. Blood donors are volunteers, many make great sacrifices of time and comfort in order to give blood. Donors will be reluctant to return if they do not feel they are treated with a high degree of respect. A more affable approach will help make the donation experience as pleasant as possible for them.

Also, the main concern is that the donors understand the question, regardless of whether they are reading or listening. We recommend the following revised version:

To help the donor hear or read the questions, including any new or revised versions, provide information appropriate for assuring the donor's comprehension prior to response to questions delivered through an audio medium. Such information would include being sure to understand the question before responding, and documenting answers as soon as the question is completely understood.

Point #4 - Similarly, ARC understands FDA's objective, but finds that this point's specificity may be problematic during implementation. For example, if the recording does not pause, the donor may be able to follow along with a written copy of the questions rather than discussing it with the donor center staff.

ARC recommends revising this point to read as follows:

Your system may allow the donor to pause the recording to replay the question, or to ask for clarification. If the donor is not able to pause the recording, make provisions for clarifying the question for the donor prior to recording a response.

Point #5 – This point states that donor centers “should monitor the donor’s attentiveness and be ready to intervene if the donor appears confused or inattentive.” This directive is very subjective, and will be difficult to implement without appearing overly intrusive to some donors.

In addition, the goal of the questionnaire is to obtain the most accurate answers possible. Pilot testing prior to use is likely to identify alternative measures to help ensure the donor is attentive, understands the questions, and answers accurately. Pilot testing may also reveal that the monitoring described in this point may be either unnecessary or of little use in actual practice. Further, Section III.A. provides full guidance on giving the donors adequate instructions and opportunities for questions.

ARC recommends eliminating this point. If there is some lingering concern, the draft guidance could be amended to recommend that the donor center staff remain ready to assist the donor whenever needed.

Point #6 – This point discusses working with multiple donors listening to an audio questionnaire. The main concern is whether the donor can confidentially answer the questions. Thus, the goal is to give all donors adequate privacy when they are answering the questions, regardless of whether there are other donors listening at the same time.

We recommend revising this point to read as follows:

The donor center's SOP should include provisions for self-administration if more than one donor will be listening and/or watching the visual display at one time. The provisions should include determining an appropriate number of donors for joint listening and ensuring privacy when answering the questions.

III.C. Additional Recommendations for Computer-Assisted Interactive Procedures

Point #1 – The draft guidance states that a “New donor may use the computer-assisted interactive procedures provided there is an audio component with the system.”

Similar to our comments on Section III.A., Point #4, ARC requests that FDA reconsider this requirement. In the absence of data to demonstrate there is a reason to differentiate, we ask FDA to revise this recommendation to allow blood collection centers to use the self-administered questionnaire, without an audio component, on all donors.

We would like to point out that this revision would be particularly important for those new donors who may be hearing impaired.

Point #2 – This recommendation contains several provisions, including where to place the printers, review of the answers by the donor and the donor center staff, and signature requirements.

We do not believe that specifying a printer location is needed as long as the donor's responses are kept confidential. ARC recommends that FDA revise the guidance to remind donor centers to ensure the confidentiality of the donor's answers throughout the process rather than include a statement about printer placement.

ARC understands the goal of requiring the donor center staff to review the answers. However, we believe this requirement may not be necessary in the future as technology advances.

ARC recommends allowing greater flexibility by revising the draft guidance to specify that the SOPs should define, using fully tested procedures or technology, how the donor center will ensure that the answers are complete and as accurate as possible prior to signature. Further, we urge establishing this requirement without specifying that the donor center staff must perform the review. This will provide the flexibility to have either the donor center staff review the answers, or take advantage of technology that may be developed in the future to do so.

We also strongly urge FDA to eliminate the requirement to have the donor sign a paper copy. In the future, donor centers would like to have the flexibility to use new technologies that might allow use of electronic signatures, as long as they follow the specifications of CFR

Part 11. If a requirement for a signed paper copy remains in this draft guidance, donor centers may not be able to use such technological advances.

Point #3 – This point contains several validation provisions. However, there are numerous validation provisions already existing in other regulations and guidances, including medical device regulations, and we do not believe there is a need for establishing overlapping requirements in the draft guidance. Thus, we request a revision to avoid the potential for conflicting efforts if an additional set of requirements, terminology definitions, and other specifications result from the duplication.

ARC recommends specifying only that validation should take place, and citing the applicable regulations and guidances. ARC recommends revising this point to read:

You should validate all aspects of your computer system for its intended use. You should perform this validation based on the provisions contained in: References 7 and 10, CFR 820.100, the August 1999 *Guide to Inspections of Quality Systems*, and the Jan. 11, 2002 *Guidance on General Principles of Software Validation: Final Guidance for Industry and FDA Staff*.

Additional Point - Although not mentioned in the draft guidance, Computer Assisted Interactive Procedures are likely to be using computer software that would be defined as Medical Devices. ARC recommends adding a reminder for blood collection centers, where appropriate, to submit such software under Section 510(k) for FDA review prior to use.

Closing

Again, the Red Cross appreciates the opportunity to provide these comments. If there are any questions, please contact Anita Ducca at 703-312-5601

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