Rapid Surveillance of Blood Donors

General Research Protocol for Survey #2

Overview and Aims:

In preparation for events such as bioterrorism and pandemics that may threaten the U.S. blood supply, the U.S. Food and Drug Administration (FDA) is initiating a project to develop rapid deployment data collection tools at participating blood centers. The primary aim of this study is to develop survey- and questionnaire-based data collection tools that are:

- validated, and;
- flexible enough to respond to numerous situation types, and;
- representative of U.S. blood donors, and;
- able to be implemented quickly.

The proposed surveillance system will provide the FDA improved quantitative estimates needed to evaluate policy options for maintaining safe blood supplies and protecting public health during national emergencies and transfusion-transmissible infectious disease epidemics.

Roles and Responsibilities

Five Blood Centers (BCs) will each select a random sample of their eligible blood donors for web-based survey participation. Four BCs are responsible for contacting via email the selected donors to invite them to respond to the web survey. One BC will provide the selected email addresses to NORC and NORC will send the email invitations.

NORC will develop the web survey, will collect the respondent data directly, and will do all necessary cleaning and editing. The demographic information[1] for the respondents will be collected on the survey so that no matching to the original Blood Center data is required.

NORC will further aggregate the respondent data so an individual's information cannot be identified and the BC cannot be identified. NORC will transmit the respondent data and population tabulations to FDA.

AABB and NORC are responsible for drafting the final report.

[1] The demographic information includes age category, gender, state of residence, apheresis or whole blood donor, and first time or repeat donor.

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Purpose: Utility of Data for Quantitative Risk Assessment.

The data collected through this survey will improve FDA's ability to estimate the risk of potential exposure or infection of donors with a transfusion transmitted disease agent and to potentially estimate the impact of risk reduction measures on the safety and availability of blood. The delivered data will improve the ability to estimate the risk by informing FDA of the potential number of blood donors exposed or infected. These data will likely play an important role in reducing the uncertainty of risk estimates during the occurrence of an emerging infectious disease (EID) or other public health situation (where uncertainty is high) that may threaten blood safety and availability. In the absence of specific information about the exposure of blood donors, FDA adds appropriate uncertainties to the risk estimate based on available information, which during an EID or public health situation may be extremely limited. The delivered data provide FDA and stakeholders with more and better information that can improve our ability to characterize the impact of risk reduction measures, for instance, by more accurately estimating the number or percentage of blood donors who may be deferred because of exposure or infection. Ultimately, the delivered data will improve the quality of data and scientific information available to FDA and stakeholders for decision-making during times of great uncertainty and expands FDA collaborations with blood collecting organizations in better managing risks to the blood supply and protecting public health.

Methods

The Blood Center (BC) or NORC will contact a representative sample of active donors using email to invite the donor to complete a web survey.

The demographic information for each respondent will be collected on the web survey and will include the following information: gender, age in categories, state of residence, an indicator of the type of donation as either "Whole Blood" or Apheresis" and an indicator of either "first time" donor or "repeat" donor. For analysis, each BC will provide NORC with aggregated summary data, without identifiable information, for these demographic variables over all blood donors. NORC will further aggregate the data from all Blood Centers so that no individual or Blood Center is identifiable.

NORC will collect the respondents' survey data. No personally identifying information will be maintained in this file.

The number of completed surveys will be sufficient for making valid inference. The minimum number of completed surveys is 1,000 donors for each Blood Center.

Sample Selection

Each Blood Center has its own protocol for defining the sample frame and selecting the sample. In all cases, the donors to be subject to sampling are restricted to allogeneic donors (DONTYPE = 'H') at least 18 years of age who have made at least one successful donation in the calendar year 2014.

For all Blood Centers:

1. The sample frame will be constructed to avoid, as much as possible, the chance of including the same individual more than once in the frame.
2. The selection is done using random sampling
3. Replicates, i.e. random subdivisions of the sample, will be created to allow additions to the sample if the response rate is lower than expected.

Survey Development and Administration

NORC will generate the web-based survey. The questions for the survey are provided in Attachment 1.

Either the BC or NORC will contact the selected donors via email in order to enlist their response to the survey. In a rapid deployment there may not be any follow-up and we expect that only one request is made.

If possible, it would be useful to know how many of the selected email addresses were invalid – i.e. bounced back.

Data and Tabulations Provided to NORC

The individual donor's responses to the survey questions, with the demographic information, will be collected by NORC. Note that there is no personally identifying information on this file.

Aggregated population and respondent counts are used for analysis ---e.g. allowing post-stratification to improve overall estimates of prevalence. However, the individual tabulations provided by each BC will not be published or provided separately. The tabulations provided to NORC/AABB will be used to create overall tabulations of number of donors, aggregated across all BCs to a geographic level such that no individual BCs data can be identified.

Consent

The methodology employs only survey techniques and recruitment and participation in web-based surveys are a part of everyday life. The research presents no more than minimal risk of harm to subjects.

In some cases, the BC may have received prior consent from their donors to be contacted for surveys.

Additionally, the documentation of consent will be included in the opening section of the web-based survey. The first screen seen when going to the web will contain the following:

> Thank you for your past blood donations to [*BC name inserted here]* and for the precious gift you so generously shared.
>
> We are asking you to complete a short survey about your outdoor activities and for some donors, domestic travel in the summer months. The outdoor activities and travel history of donors is important because of potential exposures to specific viruses, bacteria, and parasites that are present in ticks in regions of the U.S.
>
> We are asking about your outdoor activities and summer domestic travel in order to characterize blood donors in general and not specifically to characterize you. In fact, your responses will be anonymous and combined with other donor responses, but your responses will assist us and federal public health scientists in determining the potential U.S. population exposure to tick-borne diseases that have emerged over the past few years.

All Americans whether or not they are blood donors need to exercise caution when outdoors in areas where ticks are present

Your participation in this survey will help to assure a safe and adequate supply of blood for your neighbors and for you.

Will you participate in this follow up survey?
___ Yes (continue to questions) ___ No (Go to last screen)

Protection of Human Subjects

Research is confined to web-based surveys. The only contact made with a selected donor is to invite participation in a web-survey, through email. No blood donors will be approached in person as part of the study.

The survey questions are provided in Attachment 1. The question content reflects a donor's potential exposure to specific viruses, bacteria, and parasites that are present in ticks in regions of the U.S. Answers to the questions are categorical in nature (i.e. no free text).

Individuals may refuse participation with no consequences for not participating.

Risks and Risk Mitigation

The initial email contact will provide advance notice of the type of data to be collected from the web-survey and the measures taken to protect their confidentiality. An example is provided below:

You have been selected at random from adults who donated blood in 2014. The [**insert Blood Center**] thanks you for your past donation and invites you to participate in this short survey about your outdoor activities and for some donors, domestic travel in the summer months.

The outdoor activities and travel history of donors is important because of potential exposures to specific viruses, bacteria, and parasites that are present in ticks in regions of the U.S.

We are asking about your outdoor activities and summer domestic travel in order to characterize blood donors in general and not specifically to characterize you. In fact, your responses will be anonymous and

combined with other donor responses, but your responses will assist us and federal public health scientists in determining the potential U.S. population exposure to tick-borne diseases that have emerged over the past few years.

All Americans whether or not they are blood donors need to exercise caution when outdoors in areas where ticks are present.

Participation is voluntary but your participation in this survey will help to assure a safe and adequate supply of blood for your neighbors and for you.

The questions should only take about 5 minutes to complete.

Your responses will be kept confidential and not disclosed to third parties. If you have any questions about the study, please call our toll free line at **xxx-xxx-xxxx** or send an email to **xxxxx**

Participants will assent by completing the web-survey questionnaire.

The respondent data are stored at NORC on a secure server. There is no personally identifying information and potential identifiers such as age and location are suitably aggregated into classes or regions so that there is minimal risk of identification. Only individuals on the research team will have access to any of the individual information gathered from the survey. Only the minimum amount of information necessary to achieve the objectives of the study will be collected

The data will not be used for any purpose other than stated, namely to provide the final data product to FDA. Once the data have been further aggregated and tested and the project finalized, NORC will destroy the individual respondent data.

<u>Benefits</u>

Participation in the survey does not directly benefit the individual respondent

The benefit to the society as a whole is expected to be

- an improved quality of data and scientific information available to FDA for decision-making and

- collaboration between FDA and blood collecting organizations which will result in better management of risks to the blood supply in order to protect public health.