B. Collection of Information Employing Statistical Methods

The main objective of the 2013 National Blood Collection and Utilization Survey (NBCUS) is to provide reliable and accurate estimates of national and regional collections, utilization and safety of all blood products. Estimates by United States Public Health Service Region, by hospital surgical volume, and by establishment type (blood center, hospital) will be required. Since most blood collection occurs in blood collection centers and hospital-based blood blanks, while most blood utilization occurs in hospitals, a nationally representative sample of blood collection centers, cord blood banks and hospitals will be required.

B1. Respondent Universe and Sampling Methods

Respondent Universe

The population of inference for the 2013 NBCUS will be all blood collection and utilization facilities in the U.S. The target population for the 2013 NBCUS will consist of all blood collection centers, cord blood banks and all hospitals subject to certain ownership, service and location criteria. Some practical restrictions were also placed on the target population – specifically, hospitals reporting fewer than 100 inpatient surgeries per year were excluded since they contribute little to either collections or blood product utilization.

Sampling Frame and Sample Design

We used the 2012 (fiscal year 2010) American Hospital Association (AHA) annual survey of hospitals and the AABB institutional membership list together to construct a sampling frame that covers virtually all collection, processing and transfusion of blood.

Hospitals on the AHA file were included in the 2013 NBCUS sampling frame subject to ownership, services, location and surgical volume criteria as follows:

1) Ownership – The AHA ownership (CNTRL) must be:

    Veterans Affairs (45) or

    Other non-Federal

    State (12)

    County (13)

    City (14)

    City-county (15)

    Hospital district or authority (16)

    Church operated (21)

    Other (23)

    Individual (31)

    Partnership (32)

    Corporation (33)

AND

2) Services – The AHA primary service (SERV) must be:

    General medical and surgical (10) or

    Surgical (13) or

    Cancer (41) or

    Heart (42) or

    Obstetrics and Gynecology (44) or

    Eye, ear, nose and throat (45) or

Orthopedic (47) or

Children's general (50) or

Children's orthopedic (57)

AND

3) Location – Located within the 50 United States (or the District of Columbia).

AND

4) Surgical Volume – The hospital must conduct 100 or more inpatient surgeries per year.

Hospitals on the AABB member list that could be matched to the AHA file (i.e., hospitals found on both files) were included in the NBCUS frame and sample subject to the information available in the AHA file and the eligibility criteria described above. Of the 6,072 hospitals on the 2010 AHA file, 4,014 were eligible for NBCUS based on the above criteria.

Following the previous 2005, 2007, 2009, 2011 National Blood Collection and Utilization Surveys, we drew a stratified, single stage sample of blood banks and hospitals with equal probability within stratum. Hospitals on the AHA file were stratified separately from hospitals unique to AABB, blood collection centers and cord blood banks, the latter three groups being selected with certainty. We stratified hospitals on the AHA file by size (annual inpatient surgical volume), and selected hospitals in the larger size strata with certainty. Table B1-1 below gives the total population, sample size and sampling rate for the various types of facilities.

Table B1 – 1 Total population, sample size and sampling rate by type of facility			
Type of Facility	**Total Population**	**Sample**	**Sampling Rate (%)**
Hospitals (AHA)			
100-999 surgeries / year	1,577	525	33.0
1,000-1,399 surgeries/year	368	245	66.0
1,400-2,399 surgeries/year	658	658	100.0
2,400-4,999 surgeries/year	831	831	100.0
5,000-7,999 surgeries/year	344	344	100.0
>=8,000 surgeries/year	236	236	100.0
Hospitals (unique to AABB)	35	35	100.0
Blood Collection Centers*	94	94	100.0
Cord Blood Banks	14	14	100.0
Total Facilities	4,157	2,982	71.7

* Institutions such as the American Red Cross will have their central data repository (ARCNET) reporting for all Red Cross centers. Therefore the number of blood centers sampled does not correspond to the total number of blood centers in the United States.

Based on the previous three iterations of the NBCUS, we expect an overall response rate of almost 70% across all types of facilities. Given the overall sample size of 2,982 facilities, we expect a responding sample of about 2,050 facilities.

As with all establishment samples, we anticipate that units on the sampling frame (whether they are sampled or not) can merge with one another, split into multiple units etc. Such events have implications for calculating overall probabilities of selection. We plan to implement procedures that can capture the information relevant to calculating

correct overall probabilities of selection and that also could deal with the phenomenon of sampled units reporting for different organizational levels.

B2. Procedures for Collection of Information

Initial Contact

An introductory letter will be sent from the CEO of AABB (**Attachment K**) to the Director of Transfusion Services of each sampled institution. The letter describes the purpose of the survey, the authority for data collection, and provides a prenotification on the types of information that will be requested on the questionnaire. This will give institutions the opportunity to gather information from 2013 to ease in completing the survey. The introductory letter will have a postage paid tear off section asking for confirmation of the name and contact information of the person who would most likely complete the survey at the specified institution. Verification of the appropriate contact within the selected hospital or blood bank will help increase response rates.

Survey Mailing

Depending upon the type of institution, appropriate sections of the survey instrument (**Attachment F**) along with a prepaid envelope will be mailed. A cover letter co-signed by HHS and AABB will accompany the survey packet. The cover letter will come from a significant HHS official such as the Assistant Secretary of Health and the CEO of AABB. Since a majority of the transfusing hospitals are AABB members, contact from AABB will help ensure participation.

Follow-up

Two weeks after the initial mailing, follow-up will be made to non-respondents with a postcard. The postcard will provide information on the survey and ask again for participation. In addition, the recipients will be provided with the AABB Survey Helpline information. As noted in Section A5, the toll free helpline will field inquiries related to the survey and will be available 24 hours a day. Two weeks after the second mailing a phone call will be made. The phone call will seek to determine obstacles to completing the survey and offer to help in any way possible. Two weeks following the phone call a letter and a copy of the survey instrument will be sent with a request to complete the questionnaire and return it. Frequently, the first copy of the survey goes astray and it is the subsequent mailing that will stimulate action. As a last step, an abbreviated version of the survey containing critical items will be distributed. This critical item questionnaire will be made available both electronically and in paper form.

Monitoring Data Collection and Quality Control

A survey receipt control system will be used to track and monitor distribution of questionnaires and responses, helping to ensure that actions are taken in a timely manner to maximize response rates. All of the sampled institutions will be entered into an MS Access database to track the mailing, receipt and processing of the questionnaires. When a questionnaire is returned, it will be entered into a table that tracks its processing status. Key to obtaining good response rates and complete data in this type of study is developing a rapport with the individual(s) who will be completing the questionnaire and ensuring that the survey gets to the right person who has the knowledge to respond. The use of the tracking system will assist with this process. In addition, institutions that do not

respond will be offered the opportunity to complete the abbreviated version of the survey. This will help obtain critical information from as many institutions as possible. The tracking system will be the vehicle for follow-up of participation status.

Coding schemes will be used to classify original data from source documents into codes that are machine-readable and appropriate for planned analysis. When an unusual response is recorded that does not appear to fit into the existing coding scheme, it will be reviewed by the data manager to determine how best to handle it. The problem will be passed along to the project director if the data manager is unable to resolve it. COED, a proprietary codebook, and machine-edit PC software will be used to create codebooks and define computerized checks. Manual editing will be performed simultaneously with coding. Manual editing of study documents includes checking for illegible answers, incorrectly followed skip instructions, items not answered, responses outside the ranges of acceptable answers specified in the codebook (range check), responses of an incorrect character length, inappropriate responses and inconsistency between answers. In addition, once initial batches of data have been keyed from study documents, a manual edit, or proofreading, of that data will be completed to ensure that all variables have been keyed into the correct record and column positions.

Verification of coding is an important tool that will be used for quality control. The verification sample of at least 10 percent or higher will be a check of the accuracy of coding and will be carried out by independent recoding. Once the discrepancy or error rate falls to an acceptable level, the verification rate will be cut, but will never be lower than 10 percent.

Prepared and coded survey data will then be keyed and verified. Data entry and verification will be performed using customized PC-based commercial software. Data entry programs will be set up to contain checks for completeness of keyed data, including range checks for pre-coded items and skip pattern verification. After the raw data files have been edited and updated, they will be converted into SAS data files.

Weighting

Base weights will be calculated for each unit as the reciprocal of its overall probability of selection. These base weights will then be adjusted for non-response. We will use sampling strata as initial non-response adjustment cells, which can be further refined through the use of Chi-squared Automatic Interaction Detector (CHAID)[1] or other response propensity modeling software to incorporate other variables from the sampling frame that appear related to response propensity. Minimum cell sizes and non-response adjustment factors will be considered in the final non-response cell definition, in order to avoid unnecessarily large increases in variance due to differential weighting. The use of post stratification raking or calibration to adjust the weights to one or more known or estimated population totals available from the sampling frame, the annual AHA survey data file and the AABB member list will be considered. These adjustments have the effect of increasing the precision of estimates, while matching known population counts.

Imputation

All data items will be checked for internal consistency as part of the data cleaning process and as a prelude to imputation. Missing data will be imputed in continuous (i.e., interval or ratio-level) variables via regression or time series models that take into

[1] Kass, G. (1980). An exploratory technique for investigating large quantities of categorical data. *Applied Statistics*, 29, 119-127.

account previously reported data for the same unit (when available), as well as previously and presently reported data for similar, responding units. Separate imputation models will be used for blood centers and hospitals including volume-related variables (e.g., collection, transfusion and/or surgical counts) as predictor variables. Imputation of nominal or ordinal-level variables, to the extent warranted or desired will be achieved through the use of proprietary Westeck or AutoImpute software, which uses a combination of continuous and categorical data modeling, hot-deck imputation and successive iterations to impute such items, while acknowledging questionnaire skip patterns etc. All imputed data items will be checked for internal consistency using the same routines as the data cleaning process and imputation flags will be provided in the analytic dataset to distinguish imputed from reported values.

B3. Methods to Maximize Response Rates and Deal with Non-response

AABB's established relationships in the blood collection and transfusion community, combined with lessons learned from conducting the 2005, 2007 and 2009 NBCUSs, will help enhance participation in the 2013 NBCUS. Announcements have already been made at AABB's Annual Meeting in October 2009 to notify the community of the upcoming survey. Presentations of results from 2007, 2009, and 2011 NBCUS programs were made to further promote the 2013 NBCUS. AABB will use its communication vehicles, distributed daily, weekly and monthly, to help recruit blood centers and member hospitals and to provide updates and information on the 2013 NBCUS. A special section on the AABB website will be dedicated to communication of the 2013 survey as it moves through the 12 month cycle.

For the 2013 NBCUS survey we anticipate that an overall 70% response rate will be achieved. As described in Section B2, the pre-notification letter asking for confirmation of appropriate contact person at each institution, the follow-up postcard at two-weeks after the initial survey mailing, the telephone call at four weeks, and the follow-up letter and survey mailing at six weeks, along with the toll-free helpline will help us achieve the desired response rate.

Despite the methods described above, we still expect some eligible sampled units to be non-respondents. We will deal with non-response and its potential impact on survey estimates through a combination of weight adjustments and non-response bias analysis. As described above (Section B2, Weighting), base weights will be adjusted for non-response using CHAID or other response propensity modeling software to incorporate variables from the sampling frame (other than the sampling strata) that appear related to response propensity.

A non-response bias analysis will then take advantage of the detailed information available for both responding and non-responding sampled units from the annual AHA survey data file and the AABB member list to assess the potential for non-response bias due to both unit (i.e., complete) and item (i.e., item specific) non-response. We will use differences in unit and item response rates across the various detailed data items, both before and after weight adjustments, as a proxy for the potential for non-response bias. We will include a summary of the results of this non-response bias analysis in technical and analytic reports.

B4. Tests of Procedures or Methods to be undertaken

The proposed 2013 survey instrument and data collections procedures are by and large the same as the 2005, 2007, 2009 and 2011 NBCUSs which achieved satisfactory results. Given our success in previous years, we believe our plan to pilot the 2013 survey at two hospitals in the Baltimore-Washington area will be adequate. Consultation was sought from individuals within HHS, blood center staff familiar with center operations, and experts in transfusion medicine.

B5. Individuals consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

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ATTACHMENTS

ATTACHMENT A	Blood Action Plan
ATTACHMENT B	ACBSA Recommendations to the Secretary
ATTACHMENT C	2009 NBCUS Survey Report
ATTACHMENT D	20011 NBCUS Survey
ATTACHMENT E	Justification for Survey Questions
ATTACHMENT F	Flowchart of Sections to Complete
ATTACHMENT G	60-Day Federal Register Notice
ATTACHMENT H	Committee Members List (Confidential)
ATTACHMENT I	BLS National Compensation Survey Hourly Rate for Health Related Occupations
ATTACHMENT J	Critical Items Web Survey
ATTACHMENT K	Pre-notification Letter