

## **Supporting Statement A**

### **2021 National Blood Collection and Utilization Survey**

**OMB Control Number 0990-0313 - Revision**

#### **A. Justification**

##### **1. Circumstances Making the Collection of Information Necessary**

This request is for OMB approval of a revised information collection request, the 2021 National Blood Collection and Utilization Survey (NBCUS), OMB No. 0990-0313. For the 2021 NBCUS, minor changes are made to core questions to facilitate usability and two supplemental sections are added to capture information on the impact of the COVID-19 pandemic on the blood supply during the course of 2020. We are not planning to continue the COVID-19 supplemental sections in subsequent surveys.

The Office of the Assistant Secretary for Health (OASH) within HHS is responsible for conducting a biennial cross-sectional national blood products survey. In addition, the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) identified a need to provide national policy makers with current blood supply and demand data. The ACBTSA was established to provide policy advice to the Secretary and the Assistant Secretary for Health. The advice of the ACBTSA is partly dependent on the analysis of relevant blood collection and utilization data, which is also widely distributed to and used by the transfusion medicine and blood banking community. This data collection is authorized by Section 301 of the Public Health Service Act (42 U.S.C. 241) (Attachment A).

The NBCUS is an HHS/OASH funded project conducted biennially. Since 2013, in close collaboration with OASH, the NBCUS has been performed by the Centers for Disease Control and Prevention (CDC), which has the requisite technical and scientific resources to conduct the survey. The response rates for the 2019 NBCUS were 94.3% (50/53) for community-based blood collection facilities, 84.4% (76/90) for hospital-based blood collection facilities, and 76.2% (2140/2808) for transfusing hospitals. Based on the previous three iterations of the NBCUS, we expect an overall response rate of almost 80% across all types of facilities.

##### **2. Purpose and Use of Information Collection**

The objective of the NBCUS is to produce reliable and accurate estimates of national and regional collections, utilization, and safety of blood products – red blood cells (RBCs), fresh frozen plasma, and platelets. This survey will significantly improve the federal government’s capacity to understand the dynamics of blood supply and demand, and to provide a quantitative basis for assessing strategic and regulatory agendas. An important purpose of the 2021 survey is to help the federal government continue to monitor trends in blood availability, which is critical to ensure an adequate supply of safe blood in the United States. In addition to use by the federal government, data collected in this survey will be of practical use to the blood banking and hospital transfusion services communities in the private sector to advance quality standards and procedures. Broad dissemination of the survey findings through publication of reports (2005-2011 surveys) and open access scientific papers in peer review journals (2013-2019 surveys) has significantly benefited not only HHS, but the transfusion medicine community at large by furthering community discussion of key findings. Data from surveys have informed policy across HHS operating and staff divisions.

Each question in the proposed survey relates to the analysis objectives detailed in Section A-16 and lists the questions by survey domains. The general categories of information to be collected are:

- General information
- Blood collection, processing, and testing
- Blood transfusion
- Special procedures and product disposition

### **3. Use of Improved Information Technology and Burden Reduction**

The person completing the electronic survey will be given a unique login and password. Efforts to minimize respondent burden are as follows:

- The survey is divided into two sections (blood collection and blood transfusion) for respondents to complete or skip.
- The survey contains easy to read instructions and skip patterns to avoid having respondents answer unnecessary questions.
- The survey contains a glossary of definitions to assist the respondent.
- A Survey Helpline number will be provided. The toll-free helpline will field inquiries related to the survey and will be available 24 hours a day to answer questions related to the survey.

- For institutions that have not responded, an abbreviated version of the survey containing critical items will be distributed. The survey will be made available both electronically and in paper form.

#### **4. Efforts to Identify Duplication and Use of Similar Information**

The NBCUS has been conducted by HHS/OASH since 2005. Data on blood collection and utilization on a national scale are not available from any other source. While segments of the blood collection industry collect some information, it is often proprietary and not available to the government or the public at large.

#### **5. Impact on Small Businesses or Other Small Entities**

The target population consists of U.S. blood collection facilities and transfusing hospitals. Every effort is made to minimize the burden on small businesses when collecting information.

#### **6. Consequences of Collecting the Information Less Frequent Collection**

The NBCUS is administered biennially. The rapidly changing environment in blood supply and demand makes it important to have regular, periodic data describing the state of U.S. blood collections and transfusions for understanding the dynamics of blood safety and availability. These data have become even more crucial with the need to help ensure patient safety by monitoring and identifying errors in transfusion medicine and related therapies.

#### **7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5**

This request fully complies with 5 CFR 1320.5. There are no special circumstances associated with this data collection activity.

#### **8. Comments in Response to the Federal Register Notice/Outside Consultation**

The 60-day notice for public comment was published in the Federal Register, Volume 86, No. 56, on March 25, 2021, pp. 15953 – 15394 (Attachment B). A total of ninety-nine comments from seven organizations were received. Responses are imbedded in the public comment document (Attachment C).

#### **9. Explanation of any Payment/Gift to Respondents**

Remuneration of respondents is not provided.

#### **10. Assurance of Confidentiality Provided to Respondents**

The Privacy Act of 1974 (5 U.S.C. 552a) does not apply to the proposed data collection since respondents are not human subjects, but institutions; and no patient/donor identifiers are collected. Therefore, no Institutional Review Board review is required. Data identifying institutions will be kept private to the extent allowed by law.

## **11. Justification for Sensitive Questions**

Information on issues of a sensitive nature involving persons is not being sought.

## **12. Estimates of Annualized Hour and Cost Burden**

**12A.** The burden for the NBCUS survey is summarized in the table below. Each institution that is asked to complete the survey is considered to be a respondent. The respondents to this survey are hospitals, blood collection centers and cord blood banks. The number of respondents is 2,266. It is estimated that each respondent will spend about 240 minutes (4 burden hours total; or 2 burden hour/year) completing the questionnaire. The hourly burden estimates are based on 240 minutes from previous years' experience administering the survey and an approximately equal number of questions in the 2021 NBCUS.

### **12A. Estimated Annualized Burden Hours**

<b>Type of Respondent</b>	<b>No. of Respondents</b>	<b>No. Responses per Respondent</b>	<b>Average Burden per Response (in hours)</b>	<b>Total Burden Hours</b>
Transfusing Hospitals	2140	1	2	4,280
Hospital Blood Banks	76	1	2	152
Community-based blood center	50	1	2	100
<b>Total</b>	<b>2,266</b>			<b>4,532</b>

**12B.** The average annualized response burden cost to respondents is estimated to be \$189,528 based on an hourly wage of \$41.82 per hour. The hourly wage estimate is based on the Bureau of Labor Statistics' National Compensation Survey mean hourly wage data for health-related occupations in 2021.

### **12B. Estimated Annualized Respondent Burden Costs**

Type of respondents	Total annual response burden hours	Hourly wage rate	Respondent cost
Hospitals, blood collection centers,	4,532	\$41.82	\$189,528

cord blood banks			
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**13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs**

There is no other capital or start-up costs, and no maintenance or service cost components for this information collection.

**14. Annualized Cost to Federal Government**

All survey operations including survey development, data collection, analysis, and preparation of the final report are contracted to the CDC by OASH. The total cost of this fixed price Interagency Agreement (IAA) is \$242,500 annually.

**15. Explanation for Program Changes or Adjustments**

This collection is being submitted for OMB approval as a revision on a previously approved collection (after three such 3-year approval periods); minor changes were made to some of the survey questions to facilitate usability and all other aspects of the program remain the same. The draft 2021 survey reduces the number of data items collected for sections B (Blood Collection, Processing, Testing, and Inventory Management) and C (Blood Transfusion) to decrease burden time. Supplemental sections were added to both Section B and Section C to capture information on the impact of the COVID-19 pandemic on the blood supply during the course of 2020. Questions on monthly collections, distributions, and transfusions were added to the draft survey for *each month* to understand the month-by-month impact of the pandemic. These data will be valuable, when compared to previous years, for understanding the effects of a major pandemic on the health system. We are not planning to continue the COVID-19 supplemental sections in the 2023 NBCUS. Despite adding the two supplemental sections, the draft 2021 survey is shorter than the 2019 survey. It is estimated that each facility takes an average 4 hours to complete the survey.

**Number of data items collected from facilities during 2013-2021.**

NBCUS Survey section	Number of data items collected				
	2013	2015	2017	2019	2021
Section B (Blood Centers)	98	177	250	246	202
COVID-19 Supplemental Section B	--	--	--	--	26

Section C (Hospitals)	152	187	211	194	181
COVID-19 Supplemental Section C	--	--	--	--	24

**16. Plans for Tabulation and Publication and Project Time Schedule**

The timetable for key activities for the 2021 survey is as follows:

<b>Timeline</b>	
TBD	Receive OMB clearance
December 2021	Finalize NBCUS 2021 in REDCap
February 2022	Confirm contact list and submit REDCap survey to OASH for approval
March 2022	Begin data collection for 2021 survey
July 2022	End data collection
August 2022	Begin data analysis
2023	Publish final comprehensive report

Statistical tabulations of results for each question will be presented. These will be broken down by institution type, services provided, United States Public Health Service (USPHS) region, etc. Selected examples of types of analyses proposed include:

- Analyses of trends in the U.S. blood supply
- Total supply of blood collected in the U.S. broken down by type (e.g., whole blood (WB), allogeneic, WB autologous, WB directed, RBC apheresis, platelets, plasma)
- Total transfusions in the U.S. broken down by type (e.g., WB, RBC, platelets, non-RBC components transfused)
- National estimates of all whole blood and blood component units outdated by blood centers and hospitals
- Component modifications – Irradiation, leukocyte reduction by blood centers and hospitals
- Number of repeat reactive and confirmed positive first time and repeat allogeneic donors by infectious disease marker type

- Rates of confirmed positives and false positives by bacterial testing methods
  - Number of adverse events (e.g., Transfusion-related acute lung injury (TRALI), Transfusion-associated circulatory overload (TACO), Hemolysis, Allergic reactions, etc.)
- After final validation of results a comprehensive report of findings from the survey will be published. The 2005 through 2019 Nationwide Blood Collection and Utilization reports are available at [www.hhs.gov/ash/bloodsafety](http://www.hhs.gov/ash/bloodsafety).

**17. Reason(s) Display of OMB Expiration Date is Inappropriate**

The program agrees to show the expiration date.

**18. Exceptions to Certification for Paperwork Reduction Act Submissions**

There are no exceptions to the certification.