America's Blood Centers®
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1717 K Street NW, Suite 900, Washington, DC 20006
Tel: 202-393-5725 | Fax: 202-899-2621
www.AmericasBlood.org

May 24, 2021

Office of the Secretary
Department of Health and Human Services
Attn: Sherrette Funn

Re: Document 0990-0313 Agency Information Collection Request: National Blood Collection & Utilization Survey (NBCUS)

Dear Ms. Funn:

America's Blood Centers is North America's largest network of community-based independent blood programs that operate more than 600 blood collection sites, providing nearly 60% of the U.S. blood supply. These blood centers serve more than 150 million people and provide blood products and services to more than 3,500 hospitals and healthcare facilities across North America.

The NBCUS is a vital tool in assessing ongoing trends in the U.S. blood industry. As the only source of comprehensive data on blood collection and usage available for both public and private stakeholders, the report supports benchmarking and surveillance, ongoing research, regulatory needs, disaster planning, and national security concerns. One of the recommendations in the 2020 U.S. Health and Human Services (HHS) "*Adequacy of the Blood Supply-Report to Congress*" is that "we must invest in a data infrastructure that allows us to make the best decisions across the entire blood supply chain, from blood donation to patient care". As such, we provide the following perspective and suggestions:

- We again encourage the CDC to identify opportunities to collect data real-time to further reduce the burden of completing the NBCUS, either through current and/or future changes in the administration of the survey. HHS' current four hour estimated annualized burden to complete the survey is still a significant underestimate and does not take into consideration the time required to collate the vast and varied amount of data requested, which has increased for this survey with the request of 2020 data. As we described in our November 15, 2018 NBCUS comments, it takes ABC members from one day to weeks, median of 25 hours, to complete the survey. The wide range in time is the result of variations in center size and complexity as well as staffing and the sophistication of the available computer reporting resources.

- The projected availability of results for this current survey is not until 2023. To date, the 2019 results have not yet been published on the HHS website, leaving the 2017 report as the most current source of national data on the blood supply. To provide greater benefit to the

blood community and the U.S. government, we request seek methods to facilitate more-timely publication of NBCUS results. Given the importance of the information, coupled with the complexity of gathering the data in support of the information, a solution to fully automate the process must be identified and adopted. Such a tool would greatly improve the turnaround time for survey submission and results availability, improve the quality and utility of the data with standardized definitions, and could provide a mechanism by which the NBCUS could be done more frequently. The availability of real-time data will provide real-time benefit for the entire U.S. healthcare system and national readiness preparedness.

- We also provide in the attachment suggestions on the NBCUS content and organization as well as a request for clarification on the content of specific questions. In particular, we draw your attention to the questions at the end of the attachment focused on improving the diversity of the blood supply. The 2017 NBCUS recognized the importance of this topic, noting that "additional studies to determine effective methods to increase donations among minorities are needed".

- ABC is committed to ensuring that there is an adequate blood supply for individuals with sickle cell disease (SCD) for whom transfusions are lifesaving and prevent complications such as stroke. We request CDC work with the blood community to identify the best mechanism to obtain these data recognizing the current blood center work effort related to the NBCUS.

ABC looks forward to future collaborations with the CDC focused on the need for more robust data infrastructure for the blood supply that reduces burden on blood centers while leading to more actionable data on issues such as diversity in the blood supply. We also stand ready to partner on future NBCUS endeavors. Should you have any questions, please Toni Mattoch (tmattoch@americasblood.org). Thank you for the opportunity to comment on the NBCUS.

Sincerely,

Kate Fry, MBA, CAE
Chief Executive Officer

Comments for the 2021 National Blood Collection & Utilization Survey
America's Blood Centers

Section B. Blood Collection, Processing, and Testing

In addition to collection, processing and testing, this section also covers importing, distribution and product outdating. We suggest changing the title to: *Blood Collection, Processing, Testing, and Inventory Management*

Question B2g: During 2021, from the apheresis collection procedures recorded in B2b, how many platelet units were collected by your institution in each of the following categories?

- *We recommend adding an additional category: Variable (Low Dose)*
- *Many blood centers are now routinely releasing such products for distribution*

Question B2j: During 2021, from the whole blood collection procedures recorded in B2a, how many plasma units were successfully prepared (i.e., separated from a unit of whole blood) by your institution?

- *We recommend a clarification as to whether this includes recovered plasma as well as transfusable plasma*

Question B2l. During 2021, how many units of COVID-19 convalescent plasma were collected by your institution? (Count apheresis plus whole blood-derived units).

- *We recommend a clarification as to titer. Should centers include low titer, high titer, and untitered convalescent plasma units?*

Question B2n. During 2021, what was the average number of cryoprecipitated AHF units per whole blood-derived cryoprecipitated AHF pool?

- *Instead of asking for the average, we recommend asking for the total number of pools produced and how many pools of 10, 5, and/or 2 were made (as centers are now commonly producing multiple pool types).*

Question B2o. During 2021, how many granulocytes were collected by your institution?

- *Is the survey asking about granulocytes collected by apheresis, or derived from a whole blood collection (recommending clarification for survey participants).*

Question B3. During 2021, for each product, what was the total number of allogeneic units (non-directed and directed combined) discarded for (abnormal disease marker results):

- *We recommend changing this to: reactive infectious disease testing results.*
- *In Supporting Statement A, under Section 16, it says one of the types of analyses proposed is "number of repeat reactive and confirmed positive first time and repeat allogeneic donors by infectious disease marker type" This is the only question on donor infectious disease testing results*.

- *We also recommend moving the footnote for this question to the top of the question (so that respondents know how to calculate # of units discarded. Also note: we recommend that the categories be simplified to just whole blood donation and apheresis collections – as a positive infectious disease marker will result in the entire unit (regardless of components produced/collected) being discarded.*

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Question B4. During 2021, how many people presented to donate including successful and unsuccessful donations, and those who were deferred?

- *We recommend editing the wording, consider: "During 2021, how many people presented/registered to donate? (This includes successful and unsuccessful donations and deferrals)*
- *And adding "non-binary" as this is the more current term to the choices; while also keeping "other"*

Question B5. During 2021, how many donors were deferred for the following reasons:

- *We recommend adding "non-binary" and "other" to both "Low hemoglobin or low hematocrit" and "Total presenting donors deferred for any reason".*
- *And adding "scarring" to Tattoo/piercing*

Question B6. During 2021, how many of the following types of donors did your institution successfully collect blood products from and how many donations did they make?

- *Add "Number of donations of" for directed and autologous*

***Question B7**. During 2021, how many allogeneic whole blood and apheresis red blood cell donations combined were successfully collected from the following donor age groups?*[1]

- *Bold "allogeneic" for consistency.*

Question B8. During 2021, how many donations of allogeneic whole blood and red blood cell units were successfully collected from minority donors…?

- *Recommend updating to the currently used language (i.e.* delete *"minority", add "of African descent", "All minority donors (including African American)"*
- Consider changing the question to: *During 2021, how many donations of allogeneic whole blood and red blood cell units were successfully collected from "donors who identify as" …?*

African American or of African descent	Number of donations
Hispanic, Asian, Pacific Islander, American Indian	Number of donations

Question B10a. During 2021, how many units of whole blood intended for transfusion as whole blood were imported, distributed, and outdated by your institution?

- *This question series accounts for unit imported (assumably in addition to a center's collections). But does the distribution/outdate apply to ALL units (collected and imported) – or just imported?*

Question B10f. During 2021, how many units of **apheresis plasma** were imported, distributed, and outdated by your institution?

- *Capitalize the f in Pf24RT24*[4]

Question B10g. During 2021, how many units of **whole blood-derived plasma** were imported, distributed, and outdated by your institution*?*

- *Recommend adding PF24RT24 and COVID-19 convalescent plasma*

Questions B14a and B14b:

- *We recommend revising the questions to add typing RBC antigens using serology at collection facilities (as only molecular typing is covered).*
- *This will give a clearer picture of antigen typing availability in US donor centers to support patients needing extended/prophylactic antigen profiles (as not all collection centers are performing molecular testing but still use serology).*
- *Typed units are essential to support SCD patients as well as other chronically transfused patients.*

B14a. Does your institution type red blood cell antigens using a molecular assay (e.g., genotyping)?

B14a. How does your institution type red blood cell antigens?

Molecular assay (e.g., genotyping)?

Serology

Combination of molecular assay and serology

B14b. How many red blood cell donors were typed using a molecular assay (e.g., genotyping)?

B14b. How many red blood cell donors were typed using the following techniques?

Molecular assay (e.g., genotyping) _____

Serology _____

Combination of molecular assay and serology _____

Consider adding the following question to speak to the availability of diverse donors.

What is your fill rate for RHCE variant red blood cells?

Questions B15a & B15b.

- *Recommend align the choices with the table in* Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion.
- *As it is now, strategies are missing such as secondary sampling*

Question B16. During 2021, how many blood drives were cancelled?

- *Recommend changing to: what percentage of your scheduled blood drives were cancelled?*

Question B17. During 2021, did your facility experience a shortage of any blood products?

- *Recommend asking "which" products (i.e. cryoprecipitate, type O red cells, etc)*

Supplemental Section B: Impact of COVID-19 Pandemic on Blood Collection, Processing, Testing, and Distribution in 2020. *Add "Distribution" so it reads "Blood Collection, Processing and Testing*

- *Recommend adding: Distribution*

Question SB1. During each month in 2020, how many whole blood collection procedures were successfully completed by your institution? Do not count low-volume or incomplete procedures.

- *Consider adding an RBC distribution question here*
- *The section below (on apheresis) includes a question on distribution*

Question SB2. During each month in 2020, how many units of apheresis platelets were distributed by your institution?

- *Consider adding an apheresis collection question here*
- *The section above (RBC) includes a question on collection*

Question SB3. During each month in 2020, what were your fill rates (i.e., percent of orders that were filled in a timely[1] manner) for group O+ allogenic red blood cells?

- *Recommend adding a question about fill rates in 2021 as well (this is a critical issue at the moment)*

Question SB4. During each month in 2020, what were your fill rates (i.e., percent of orders that were filled in a timely[1] manner) for group O- allogenic red blood cells?

- *As above, recommending a question be added for 2021 fill rates*

Additional comments for this section;

- *During 2020, how many (and what percentage of) blood drives were scheduled and then cancelled?*
- *During 2020, did your facility experience a shortage of any blood products?*
- *During 2020, add a question which asks which products were in short supply*

Section C. Blood Transfusion.

- Recommend adding "*in 2021"*

Question C6b. Indicate the total number of units **transfused** to **pediatric** and **neonatal patients** during 2021.

- *Recommend the addition of convalescent plasma to the list of blood components*

Questions C19a & C19b.

- *Revise these questions to include serology testing at hospitals.*
- *Including both molecular and serological typing will give a clearer picture of the availability to perform antigen typing in US hospitals to support patients needing extended/ prophylactic red cell antigen profiles.*
- *Typed units are essential to support SCD patients as well as other chronically transfused patients.*

Questions C25b and C25c.

- *Ensure the choices for each of the below are consistent with the options provided in Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion*

Question C26a. During 2021, did your institution transfuse platelets treated with pathogen reduction technology (PRT)?

- *Recommend deleting – this is already covered in C24.*

Glossary

- *Recommend adding definitions for facility and institution*

Additional Suggestions:

We recommend adding questions to provide visibility of **blood centers** which are receiving requests from hospitals following American Society of Hematology 2020 guidelines for management of sickle cell disease: transfusion support in support of sickle cell patients:

- *Does your institution receive requests from hospitals for extended red cell antigen profile by genotype or serology for all patients with SCD (all genotypes) at the earliest opportunity in their care? An extended red cell antigen profile includes C/c, E/e, K, Jka/Jkb, Fya/Fyb, M/N, and S/s at a minimum.*
- *Does your institution receive requests from hospitals to perform prophylactic red cell antigen matching for Rh (C, E or C/c, E/e) and K antigens over only ABO/RhD matching for patients with SCD (all genotypes) receiving transfusions?*

And the following questions to provide visibility of **hospitals** which are following American Society of Hematology 2020 guidelines for management of sickle cell disease: transfusion support in support of sickle cell patients.

- *Does your institution perform an extended red cell antigen profile by genotype or serology over only ABO/RhD typing for all patients with SCD (all genotypes) at the earliest opportunity? An extended red cell antigen profile includes C/c, E/e, K, Jka/Jkb, Fya/Fyb, M/N, and S/s at a minimum.*
- *Does your institution perform prophylactic red cell antigen matching for Rh (C, E or C/c, E/e) and K antigens over only ABO/RhD matching for patients with SCD (all genotypes) receiving transfusions?*

Additionally (for hospitals):

- *How many units were transfused to patients with sickle cell anemia?*
- *How many patients with thalassemia were transfused?*
- *How many units were transfused to patients with thalassemia?*

Format/Organization

Survey Introduction (Page 1, second paragraph):

- .R*ecommend adding short summary of survey organization. Makes it easier to follow as the timing (from 2021 and 2020) switches back and forth*
- Consider:
    - *The 2021 NBCUS covers the period of collection and utilization from January 1, 2020 to December 31, 2021. Questions were added specifically to gain information on the impact of COVID-19 on the blood supply and utilization in 2020. The survey is divided into four sections:*

- *Section B. Blood Collection, Processing, Testing, and Inventory Management in 2021*
- *Supplemental Section B: Impact of COVID-19 Pandemic on Blood Collection, Processing and Testing in 2020*
- *Section C. Blood Transfusion in 2021*
- *Supplemental Section C: Impact of COVID-19 Pandemic on Blood Transfusion in 2020*

How does a center get a NBCUS number?

- *Should instructions be included – or is that assigned internally at CDC?*

For the series of questions starting with B2a and B2b:

- *We recommend grouping all the questions relating to whole blood collections together, with a section to follow on apheresis.*
- *Going back and forth adds to survey fatigue– and it is easier to concentrate on one collection type at a time.*

When switching from one year to the next (2021 to 2020)
We recommend making the header larger to make the differentiation more apparent.