



October 18, 2021

Office of the Secretary  
Department of Health and Human Services

Re: Document 0990-0313-30D Agency Information Collection Request: National Blood Collection & Utilization Survey (NBCUS)

Dear Ms. Funn:

Thank you very much to the OASH and CDC staff working on the NBCUS for providing responses to ABC's comments, dated May 24, 2021, on the draft 2021 NBCUS. We reviewed the responses received August 26, 2021 and provided our additional comments and clarification in the attachment.

As the critical blood shortage continues in the US, the importance of the NBCUS as a vital tool in assessing ongoing trends in the U.S. blood industry is even more apparent. 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". ABC greatly appreciates OASH and CDC recognition "that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection" (Reference: August 26 OASH/CDC response letter to ABC's NBCUS comments).

To provide greater value to the blood community and the U.S. government for this critical public health benefit, we request 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. Until such time when an automated solution is available, a method to publish a preliminary report of the results minus the analysis after the AABB Annual Meeting needs to be identified and implemented.

ABC looks forward to future collaborations with the CDC focused on the need for a more robust data infrastructure for the blood supply, a critical public health benefit, which reduces the burden on blood centers while leading to more actionable data on issues such as diversity in the blood supply. 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 continue to 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.

We also stand ready to partner on future NBCUS endeavors. Thank you for the opportunity to comment on the NBCUS.

Sincerely,

Kate Fry, MBA, CAE  
Chief Executive Officer

## **ABC New Comments/Recommendations on 2021 NBCUS**

We recommend:

1. The addition of a question to Section C to determine the number of platelet and plasma transfusion recipients. Currently, only the number of RBC transfusion recipients are tracked (in questions C2b-C3a).
2. The inclusion of donors 65+ in the US general population number when calculating the % of Americans who donate blood. Donors 65+ represent 16.5% of the US donor base, and the current calculation includes donors aged 16-64 only.
3. Adjusting the age ranges (referred to in 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?<sup>1</sup>”) to the following benchmarks which are being used by most of the nation’s blood centers. The below alignment (shaded in gray) would be extremely helpful with all blood centers working tirelessly to increase the number of younger donors as the current US blood donor base ages:  
15, 16, 17, 18, 19, 20-24, 25-29, 30-34, 35-39, 40-44, 45-49, 50-54, 55-59, 60-64, 65-69, 70-74, 75-79
4. The addition of the following question: “During 2021, how many **allogeneic whole blood and apheresis red blood cell donors** presented to donate from the following donor age groups? (This includes successful and unsuccessful donations and deferrals).” This new question focuses on **individual donors** where question B7 focuses on **donations**. The age ranges would be the same as listed in recommendation #3.

## **ABC Comments on Responses Received from NBCUS**

### **Section B. Blood Collection, Processing, and Testing**

**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?

#### **Our previous recommendation:**

We recommend adding an additional category: Variable (Low Dose) as many blood centers are now routinely releasing such products for distribution.

**NBCUS response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. As with much of the other data requested in the NBCUS, this is a query to the blood establishment computer system database, and not overly burdensome for the blood center. With the recent implementation of the FDA’s “*Bacterial Risk Control Strategies...to Enhance the Safety and Availability of Platelets for Transfusion Guidance*”, the availability of transfusable platelets in the US is expected to diminish further. Variable (low dose) platelets is one of the alternative products which can help fill the inventory gap. We now recommend instead of adding an additional category to this question, a separate question be created:

## **ABC Comments on Responses Received from NBCUS**

*Of the number of single donor platelets were collected, how many were labeled as variable/low dose?*

**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?

### **Our previous recommendation:**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. As with much of the other data requested in the NBCUS, this is a query to the blood establishment computer system database, and not overly burdensome for the blood center. Plasma is a very generic term and includes transfusable plasma (FFP, PF24, liquid, convalescent) as well as recovered plasma sent for further manufacture. The benefit of an aggregated number is unclear. We recommend rephrasing the question as follows:

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

**Question B2I:** During 2021, how many units of COVID-19 convalescent plasma were collected by your institution? (Count apheresis plus whole blood-derived units).

### **Our previous recommendation:**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** The recommendation for clarification was not to ask collection facilities to differentiate low titer, high titer, and un-titered convalescent plasma units. The intent was to ensure all these categories were included in their answer and prevent inconsistent, inaccurate responses (i.e. some centers might provide only high titer data in their responses). We recommend rephrasing the question as follows:

*During 2021, how many units of COVID-19 convalescent plasma (include low titer, high titer, and un-titered) were collected by your institution? (Count apheresis plus whole blood-derived units).*

## **ABC Comments on Responses Received from NBCUS**

**Question B3.** During 2021, for each product, what was the total number of allogeneic units (non-directed and directed combined) discarded for: (\*indicates a required field)

**Our previous recommendation:**

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.

**NBCUS Response:** The appearance of these questions can be different depending on user interface. Thank you for the suggestion regarding simplifying categories. We will consider this in future surveys.

**Our new comment:** We are providing a clarification for the comment we submitted. Question B3 asks for “Abnormal Infectious Disease Results” data. It does not ask for “*number of repeat reactive and confirmed positive first time and repeat allogeneic donors by infectious disease marker type*”. We could not find the request for these data elsewhere in the survey. We recommend Supporting Statement A under Section 16 be revised as it appears the needed data is not requested in the 2021 NBCUS.

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

**Our previous recommendation:**

We recommend editing the wording, consider: “During 2021, how many people presented/registered to donate? (This includes successful and unsuccessful donations and deferrals).”

**NBCUS response:** We feel that adding the term “registered” may result in misinterpretation by the respondent.

**Our new comment:** In future surveys, recommend reviewing the use of the phrase “presented to donate” as this phrase can be misinterpreted depending on blood center processes. Some donors do “present” to donate but might not be registered because the donor asked a question as to whether they were eligible and found they were not at that time (e.g. travel to malaria risk area one month prior). Use of the word “presented” is noted in other areas of the survey. Please consider in future surveys changing “presented” to “registered” as that is a clearer, more accurate term for this question. We recommend rephrasing the current question as follows to provide further clarity:

*During 2021, how many people presented to donate? (This includes successful and unsuccessful donations and deferrals)*

**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?

**Our previous recommendation:**

Add “Number of donations of” for directed and autologous.

## **ABC Comments on Responses Received from NBCUS**

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** We are providing a clarification of our comments above. For first-time and repeat allogeneic donors, the survey asks for number of donors and donations. For the autologous and directed donors, only the number of donors is asked for. Why are the number of donations in each category not asked for? As with the first-time and repeat allogeneic donor/donations data requested in this question, this is a query to the blood establishment computer system database, and not overly burdensome for the blood center.

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

**Our previous recommendation:**

*Recommend changing to: how many (and what percentage) of your scheduled blood drives were cancelled?*

**NBCUS Response:** Thank you for the suggestion. We will consider this in future surveys.

**Our new comment:** Thank you for considering this edit in the future. The number is only relevant when placed in context. In addition to knowing the number/percentage of drives cancelled, knowing the number of donors this represents would be very beneficial for historical and future planning.

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

**Our previous recommendation:**

Recommend asking “which” products (i.e. cryoprecipitate, type O red cells, etc.).

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants especially if the question is simply asking for a yes/no answer to each type of blood product. It is critical to understand the impact of the pandemic on the blood inventory for future blood industry planning and recovery.

**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.

**Our previous recommendation:**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

## **ABC Comments on Responses Received from NBCUS**

**Our new comment:** We are not clear how the current question is associated with increased response burden. As with the other data requested in the NBCUS, this is a query to the blood establishment computer system's database. Our concern with this question, as well as Question SB2 below which addresses apheresis platelets, is the inconsistency in gathering information. Why ask about collection of one product (RBCs) and distribution of another (apheresis platelets) when both are very relevant for the products especially during these times of blood product shortages?

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

**Our previous recommendation:**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** We are not clear how the current question is associated with increased response burden. As with the other data requested in the NBCUS, this is a query to the blood establishment computer system database. Our concern with this question, as well as Question SB1 above which addresses RBCs, is the inconsistency in gathering information. Why ask about collection of one product (RBCs) and distribution of another (apheresis platelets) when both are very relevant for the products especially during these times of blood product shortages.

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

**Our previous recommendation:**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**ABC Response:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. As the pandemic continues to impact blood centers in 2021 and especially the O inventory, we still feel this is a very relevant question. If this is being considered for future surveys, why would it not be included in the 2021 NBCUS for 2021 fill rates?

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

**Our previous recommendation:**

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

## **ABC Comments on Responses Received from NBCUS**

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this in future surveys.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. As the pandemic continues to impact blood centers in 2021 and especially the O inventory, we still feel this is a very relevant question. If this is being considered for future surveys, why would it not be included in the 2021 NBCUS for 2021 fill rates?

### **Additional comments for Section B (recommended questions to add to the survey):**

#### **Our previous recommendation:**

During 2020, how many (and what percentage of) blood drives were scheduled and then cancelled?

**NBCUS response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. It is critical to understand the impact of the pandemic on the blood inventory for future blood industry planning and recovery. The data was tracked and reported by the blood centers to blood industry organizations.

#### **Our previous recommendation:**

During 2020, did your facility experience a shortage of any blood products?

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants especially if the question is simply asking for a yes/no answer. It is critical to understand the historical impact of the pandemic on the blood inventory for future blood industry planning and recovery. The information was tracked by the blood centers.

#### **Our previous recommendation:**

During 2020, add a question which asks which products were in short supply

**NBCUS response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants especially if the question is simply asking for a yes/no answer to each type of blood product. It is critical to understand the historical impact of the pandemic on the

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blood inventory for future blood industry planning and recovery. The information was tracked by the blood centers.

### **Section C. Blood Transfusion.**

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

#### **Our previous recommendation**

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

**NBCUS Response:** We agree that this information may be of interest for the operations of a blood center. However, we feel that the public health benefits do not outweigh the response burden placed on participants.

**Our new comment:** We feel the public health benefit to acquiring these data does outweigh the response burden placed on participants. It is critical to understand the impact of the pandemic on the blood inventory for future blood industry planning and recovery especially considering the rise in COVID-19 pediatric patients in 2021.