



Advancing Transfusion and
Cellular Therapies Worldwide

Via Electronic Mail

May 24, 2021

The Honorable Rachel Levine, MD
Assistant Secretary for Health
Office of the Assistant Secretary for Health
U.S. Department of Health & Human Services
Mary E. Switzer Building
330 C Street SW, Room L600
Washington, DC 20024

RE: Agency Information Collection Request (ICR); 60-Day Public Comment Request, National Blood Collection & Utilization Survey (NBCUS) (OS-0990-0313)

Dear Dr. Levine,

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to “improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide.” AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

AABB commends the Department of Health and Human Services (HHS) for its longstanding and ongoing commitment to collecting and analyzing data on blood availability and utilization through the NBCUS. We appreciate the agency’s willingness to engage with private-sector partners to continuously improve the tool. We also appreciate HHS’ interest in capturing information on the impact of the COVID-19 pandemic on the blood supply.

As AABB noted in previous comments submitted to HHS, we believe that the establishment of a national data infrastructure that monitors real-time data on the blood supply chain from vein to vein – or from donor to patient – is critical to health system resiliency and preparedness in the United States and is essential to ensuring the adequacy of a safe blood supply before, during, and after public health emergencies. The National Blood Collection & Utilization Survey (NBCUS) is limited. The NBCUS is voluntary and therefore, the data are not comprehensive. Additionally, the NBCUS collects retrospective data and does not reflect real-time responses. The sharp fluctuations in supply and utilization were particularly challenging during the COVID-19 pandemic, and the absence of real-time data limited the ability of blood donor centers, hospitals, clinicians, the broader health care community, and policymakers to take data-driven actions to ensure that the blood supply was continuously sufficient to meet patients’ needs.

In addition, the value of the NBCUS’ findings is limited by timeliness. We encourage HHS to make the results of the 2021 NBCUS available as soon as possible. The results from the 2017 NBCUS were not

published until 2020, which reduced the utility of the data. The outdated data are not useful tools for forecasting demand and current management of blood inventories.

Despite these shortcomings, and in the absence of a comprehensive, real-time data infrastructure, we believe that the NBCUS provides important information on trends related to blood availability and utilization and offer feedback on the NBCUS instrument for 2021.

General Feedback

1. HHS' estimated burden for completing the NBCUS is far too low. Clean and accurate data takes time to collect and are essential to the validity of the NBCUS report. HHS estimated average burden per response of 4 hours does not take into consideration the significant time spent running reports and exporting, manipulating, and tallying data from several systems. AABB members – including community-based blood collectors, hospital-based blood collectors and hospital transfusion services - believe completing the survey will take close to 20 hours, with some facilities reporting that it will take more time to complete the survey.
2. AABB recommends that HHS accompany product names with the associated industry standard product codes, as managed by ICCBA, to facilitate the completion of the survey.
3. HHS can reduce burdens associated with completing the survey and enhance response rates by including qualifying questions for questions with historical poor response rates. For example, some hospitals with donor centers are unable to complete questions pertaining to units imported, distributed and types of deferrals, since this information is not available in their systems. Having main questions on whether these data are collected and then pre-populating their responses with “N/A” or “0” can reduce response time.
4. We encourage HHS to expand the COVID specific monthly metrics question to the first quarter of 2021 in order to capture the impact of the pandemic on the blood supply and COVID-19 Convalescent Plasma (CCP) use.
5. AABB recommends that HHS create a new, separate 2020 section that captures collection and utilization rather than relying on supplements to sections B and C. Adding a new section for 2020 data may help data aggregation since the questionnaire format is different compared to 2021.
6. Regarding the age of red blood cell (RBC) units, some clinicians noted that the data may not capture facilities using Citrate Phosphate Dextrose Adenine (CPDA), which could underestimate RBCs issued toward the end of shelf-life. HHS may consider asking blood collectors and transfusion services about their use of CPDA or highlighting this point as a limitation of the data.

Section B

1. We encourage HHS to clarify instructions on which facilities should complete each section of the survey, and what information should be included in the related responses. For example, hospital blood collectors were confused about whether information from their transfusion services should be captured in Section B or Section C.
2. Various factors have caused many blood providers to consider whole blood derived platelets, which may not be captured by question B2f. AABB recommends that HHS work with the blood community to develop questions that explore current practices and trends related to whole blood derived platelets.
3. With respect to question B7, it is critical to understand whether different methods of blood collection - such as apheresis platelets, whole blood collection, and apheresis RBCs - are preferred by different donor age groups. We encourage HHS to work with the blood community to develop survey questions that explore whether different age groups prefer different collection methods.

4. For question B8, we encourage HHS to work with HHS' Office of Minority Health and the blood community to revisit and update the terms used in the question to ensure that they are as inclusive as possible. Additionally, it is important to have a more comprehensive understanding of donor demographics to evaluate the availability of antigen negative blood. Therefore, we encourage HHS to work with the blood community to develop questions that further delineate people of color, rather than referring collectively to donations from "All minority donors (including African-American, Hispanic, Asian, Pacific Islander, American Indian)."
5. In question B9, we appreciate HHS adding a reference to the Severity Grading Tool for Donor Adverse Events developed by AABB Donor Hemovigilance Working Group (footnote page 11). We encourage HHS to use this same reference when defining "severe donor adverse event" in the glossary to ensure that the term is used consistently throughout the survey. Additionally, please update the link in the footnote to: https://www.aabb.org/docs/default-source/default-document-library/resources/severity-grading-tool-for-donor-adverse-events.pdf?sfvrsn=ff563263_4.
6. We recommend that HHS clarify in question B10f that blood collectors should report all units of CCP distributed, including units collected under the EUA, units collected and distributed for clinical trials and units disseminated under emergency Investigational New Drug (eIND) application.
7. We recommend that HHS revise questions B15 and B16 to include all options for bacterial risk control strategies made available by the FDA in its guidance entitled "Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion."¹ For example, the current survey questions do not enable facilities to note that they are using rapid testing. Additionally, FDA's guidance goes into effect on October 1, 2021, and blood collectors are changing their strategies throughout the year. If HHS is interested in learning how the FDA's guidance is changing practices, we encourage the agency to ask questions related to pre- and post-implementation of the guidance.
8. We recommend that HHS add questions to capture new technologies and products, such as pathogen reduced technology (PRT) cryoprecipitate (question B10i) and cold-stored platelets (question B2), included in providers' inventories.
9. We encourage HHS to revise question B17 to capture shortages of specific blood products. Instead of asking a general yes/no question, HHS may consider asking respondents to indicate blood shortages related to individual blood components (i.e., RBCs, platelets, cryoprecipitate, etc.).
10. AABB appreciates HHS' desire to understand the impact of the pandemic on blood availability and utilization. However, members reported that it may be difficult for blood collectors to extract retrospective data to respond to questions SB3, SB4, and SB5.

Section C

1. Currently, questions C5 – C6 specifically address pediatric blood transfusions, whereas questions C2 – C4 are generic. Please specify that questions C2- C4 pertain to adult as well as pediatric transfusion to avoid confusion with pediatric only questions.
2. We recommend reducing the burden associated with completing the survey by incorporating logic related to pediatric/neonatal populations into question C1. For example, having the following responses to question C1 - (1) yes, adult only; (2) yes, both adults and pediatric/neonates; (3) yes, pediatric/neonates only; (4) no - can then lead to customizable questions based on whether a hospital transfuses adults, adults and pediatric/neonates, or only pediatrics/neonates.

¹FDA, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry (September 2019, Updated December 2020) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance>.

3. We encourage HHS to define aliquots as adult equivalent standard units in every question that intends to capture transfusions provided to pediatric/neonatal patients. Currently, this information is captured in a footnote in question C6b (page 33) and is not obvious to participants completing individual survey questions. Also, the footnote is associated with question C6 but participants may need the information to accurately answer questions C2 – C6.
4. When formatting the sub-questions under C5a, we encourage HHS to include a space between whole blood-derived platelets and apheresis platelet units. As formatted in the draft, participants may not see apheresis platelet units.
5. In question C5a under “Outdates,” the textbox for directed platelets to intended recipients should be labeled “number of units outdated.”
6. We recommend that HHS further refine the CCP questions in question C5c to have hospitals separately report units of CCP transfused and outdated under the EUA, units transfused under clinical trials and units transfused under emergency Investigational New Drug (eIND) application.
7. In question C5c under “Outdates,” the textboxes for Group AB plasma and CCP should be labeled “number of units outdated.”
8. Transfusion services responding to question C5c will know the total number of outdated units but may not necessarily know the ABO type of the outdated units. Therefore, they may not be able to respond to the question asking for the number of units of Group AB plasma that were outdated.
9. In question C6b under Neonatal Transfusions, we encourage HHS to clarify whether reconstituted whole blood should be included in the count of whole blood.
10. For question C8, transfusion services may not be able to specify the age of the RBCs or platelets transfused, as many do not track this information.
11. In question C12, we encourage HHS to specify whether the “4 or 6 unit” example is referring to whole blood-derived/equivalent units or apheresis platelets. Also, “degree of bleeding” is not relevant for prophylactic platelet transfusions because the patients are not bleeding.
12. We recommend that HHS ask hospitals the same question related to shortages of specific blood components that is being asked of blood collectors (question B17).
13. For question C13, we suggest that HHS clarify that hospitals should report the dollar amount that reflects the cost of acquiring blood and should not include the costs associated with hospital-based procedures that occur after the unit has been received (i.e., irradiation). It is possible that hospitals would pool their cost data rather than submitting the cost of acquiring each product (e.g. leukoreduced RBCs). When HHS analyzes the responses to question C13, we suggest that the Agency clarify that the cost information does not account for these hospital-based procedures and services.
14. For question C21, we suggest that HHS clarify the definition of “electronic system for tracking transfusion related adverse events” or provide examples of such a system. Does HHS intend for the term to include electronic medical records, eQMS, Patient Safety Network, hemovigilance reporting, or all of the above?
15. We recommend that HHS revise questions C24 to include all options for bacterial risk control strategies made available by the FDA in its guidance entitled “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion.”² For example, the current survey questions do not enable facilities to note that they are using rapid testing. Additionally, we recommend that HHS allow participants to select all strategies that apply.

² FDA, Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion: Guidance for Industry (September 2019, Updated December 2020) available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/bacterial-risk-control-strategies-blood-collection-establishments-and-transfusion-services-enhance>.

16. With respect to questions C24 – C26, FDA’s guidance goes into effect on October 1, 2021, and blood collectors and hospitals are changing their strategies throughout the year. If HHS is interested in learning how the FDA’s guidance is changing practices, we encourage the agency to ask questions C24 – C26 related to pre- and post-implementation of the guidance.
17. With respect to question C26, we suggest HHS add a question to understand the proportion of PRT-treated apheresis platelets transfused in comparison to the total number of platelets transfused.
18. We encourage HHS to add a question that captures the total number of CCP recipients in 2020 and 2021, which will enable the agency to understand the number of patients that received CCP as well as the ratio of CCP units per patient.
19. For question C25c, we encourage HHS to include definitions for the terms “confirmed positives,” false positives,” and “indeterminate results” that are consistent with AABB’s Association Bulletin 04-07, “Actions Following An Initial Positive Test for Possible Bacterial Contamination of a Platelet Unit.”³
20. As HHS is aware, it is important that hospitals properly utilize and conserve group O RBCs. We encourage HHS to add a question that asks hospitals to note whether they have adopted policies and protocols that are aligned with AABB’s Association Bulletin #19-02 entitled, “Recommendations on the Use of Group O Red Blood Cells.”⁴
21. Under Supplemental Section C, we encourage HHS to collect data on discards that occurred during 2020, as this information is essential to understanding the impact of the COVID-19 pandemic on the blood supply.

Survey Glossary

1. We encourage HHS to use the definition of “severe donor adverse event” included in the footnote on page 11 (the Severity Grading Tool for Donor Adverse Events developed by AABB Donor Hemovigilance Working Group) in the glossary definition of the same term. It is confusing to have two different definitions in the survey.
2. We encourage HHS to clarify the definition of “distributed” by considering the role of hospital-based blood collectors. Does the term refer to selecting units in the blood bank or labeling a unit and moving it from the production side to being available for transfusion?
3. We encourage HHS to include a definition of “prepared” in the glossary, and to account for the role of hospital-based blood collectors. For example, does “prepared” refer to a manufacturing step, does it refer to the mechanical preparation (and not infectious disease testing) or does it refer to the entire process from collection to labeling (so that a donor who is deferred due to a test result would not have their units counted as prepared, even though they were filtered/prepared and awaiting labeling when the result came back)?
4. We encourage HHS to include in the glossary that there are various acceptable “outdates” associated with various products, especially platelets. Clarification of the day of expiration might address some confusion associated with the FDA guidance entitled “Bacterial Risk Control Strategies for Blood Collection Establishments and Transfusion Services to Enhance the Safety and Availability of Platelets for Transfusion.”
5. We encourage HHS to include in the glossary distinct definition for “fill rate for blood collectors”.
 - a. Definition of fill rate used by blood collectors:

³ AABB Association Bulletin #04-07, Actions Following An Initial Positive Test for Possible Bacterial Contamination of a Platelet Unit, October 14, 2004, *available at* https://www.aabb.org/docs/default-source/default-document-library/resources/association-bulletins/ab04-07.pdf?sfvrsn=7dd90f74_4.

⁴ AABB Association Bulletin #19-02, Recommendations on the Use of Group O Red Blood Cells, June 26, 2019, *available at* <https://www.aabb.org/docs/default-source/default-document-library/resources/association-bulletins/ab19-02.pdf>.

- i. Standard and emergent/STAT orders are time-sensitive; the clock begins when the order arrives in the blood center and stops when the order leaves the blood center.
- ii. Fill rate for standard orders: The percentage of standard orders received that are fully completed within 8 hours.
- iii. Emergent/STAT orders: The percentage of emergency/STAT orders received that are fully completed within 2 hours.

Thank you for the opportunity to provide feedback on the 2021 NBCUS. If you have any questions or need additional information, please contact Srijana Rajbhandary at srajbhandary@abb.org or 240-333-6608.

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB