60-day Public Comment
2025 National Blood Collection and Utilization Survey

PUBLIC COMMENTS:

COMMENTS/RESPONSES

1. Anonymous

Comment: The NBCUS has been a ridiculously excessive unfunded burden on hospital transfusion services. The hours required to properly answer are grossly underestimated, and the questions are poorly constructed to be readily answerable without a great deal of manual labor for parsing the data. The agency should work with the major software vendors to create reports that will provide the data that is requested. That would be so much more efficient and accurate for everyone involved.

Response: The hourly burden estimate is based on previous years' surveys. We recognize that there might be variability in the level of effort required to gather information in order to respond to this survey. We also understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection.

2. Terumo Blood and Cell Technologies

Comment: Terumo Blood and Cell Technologies (Terumo BCT) appreciates the opportunity to submit comments to the Centers for Disease Control and Prevention (CDC) proposed data collection. We commend CDC for assuming management of data collection and publication of the National Blood Collection and Utilization Survey (NBCUS).

Since 1964, Terumo BCT has been a national leader and American medical device manufacturer providing blood collection and processing technology for the majority of blood suppliers in the US. We are committed to unlocking the power of blood and cells which enable an innovation pipeline supporting expanded treatment options for

conditions including sickle cell disease, blood cancers and rare diseases. Our outcomes-driven and patient-centered approach to product innovation has transformed the use of blood components in life-altering therapies for patients and their families worldwide.

With this in mind, we have outlined thoughtful recommendations to enhance the 2025 NBCUS and its role as a vital public health tool in enriching the nation's blood supply.

Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility

Relevant medical devices and blood products including, anticoagulants in blood bags and storage solutions, albumin, source plasma, transfusable blood components were identified by the Trump Administration in its first term as essential medicines and critical inputs necessary to minimize shortages and reduce foreign dependence.

Given this significant classification of blood components, we believe that the NBCUS is an invaluable tool providing insights into the sustainability of the US blood supply. The blood supply is highly sensitive – dependent on an aging donor base, requiring sophisticated inventory management, and needing constant optimization to address fluctuations in demand during unexpected events. As an independent and trusted entity dedicated to collecting and disseminating data regarding the country's public health, we believe that the CDC is uniquely positioned to execute the NBCUS. The NBCUS is critical to the industry's understanding of trends in blood utilization and transfusion medicine. The NBCUS is also used by organizations around the world to quantify and predict blood product needs.

Terumo BCT Recommendation:

- The CDC should continue executing the NBCUS in 2025 and in subsequent years.

Enhance the quality, utility, and clarity of the information to be collected

Terumo agrees with the CDC's proposed changes for the 2025 NBCUS including the addition of questions collecting information about bacterial transfusion-transmitted infections found in blood, length of time any blood shortage lasted, cold storage platelets, pathogen reduced cryoprecipitate units.

Terumo BCT Recommendations:

- Prehospital Transfusions – Add a question that collects information about the distribution of blood products intended for prehospital transfusions. The US is experiencing an increase in use of blood products in the prehospital setting which significantly improves survival for trauma and severely bleeding patients by providing blood when and where its needed.

Response: Thank you for this comment. The question "During 2025, did your institution distribute blood products for transfusion in the pre-hospital setting?" (Yes/No) will be included in the upcoming survey in both Section B and Section C.

- Low Titer O Whole Blood (LTOBW) – Add questions that collect information regarding the distribution of LTOWB. LTOWB is emerging in the US as the preferred blood products for prehospital and in severe hemorrhage as it provides red cells, plasma (clotting factors), and platelets in a single, balanced product, simplifying logistics and offering faster, more effective treatment.

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

For example, the survey could include the following question: How many units of low titer O whole blood, red blood cells, platelets and cryoprecipitate did you distribute to pre-hospital transfusion services.

- Annual Collection and Publication of NBCUS – Transition the NBCUS from a biennial to an annual cycle. This shift would align the NBCUS with other critical federal benchmarks, such as the Behavioral Risk Factor Surveillance System (BRFSS), which the CDC already conducts annually to capture volatile health data. Providing annual data would eliminate the current two-year "blind spot," allowing for more precise resource allocation and faster integration of safety innovations.

  Furthermore, an annual cadence would provide policy makers and hospital systems with the real-time financial and utilization metrics necessary for accurate budgeting and emerging preparedness.

  Response: Resources are not currently available to conduct the NBCUS annually; however, we will consider your recommendation for its feasibility in the future.

- Streamline collection and analysis of data to ensure timely publication of study reports. For example establish digital data reporting or artificial intelligence to facilitate data analysis.

  Response: We understand that automated data reporting would be beneficial and will continue to explore possibilities of streamlining data collection in the future. We aim for timely publication of study reports and will continue exploring opportunities to enhance this turnaround time.

In closing, Terumo BCT recognizes the importance of the NBCUS to track the strength and sustainability of the US blood supply with extended applicability to global blood trends in transfusion medicine. Given that blood supply disruptions can occur rapidly during disasters, we believe that continuous improvements in data collection, timely monitoring, and publication are essential to ensuring availability of this life-saving public health resource. Thank you for your consideration of our proposal. Please do not hesitate to reach out to me directly if you have any questions, janet.johnson@terumobct.com.

3. Circulate

Comment: Circulate appreciates the opportunity to comment on the proposed 2025 National Blood Collection and Utilization Survey (NBCUS). Circulate is an independent, nonprofit organization founded by major U.S. blood operators to enhance the resiliency of the nation's blood supply, support national security, and provide accurate, real-time data about the national blood supply. We applaud CDC's continued leadership in taking on the 2025 NBCUS and recognize the essential benefit NBCUS has brought to the blood and transfusion industry and stakeholders, both public and private, since 2013.

As CDC and HHS/OASH consider the scope and methodology for the 2025 iteration, Circulate respectfully offers the following considerations:

- **Opportunity to leverage existing datasets.** Circulate urges CDC to consider the value of incorporating pre-existing, automated, standardized data sources to support the development of portions of the NBCUS. Circulate maintains a continuously refreshed, highly granular dataset with donation, component, and inventory information contributed directly by blood operators.

- **Reduced burden through a standardized, re-queryable dataset.** Circulate's offering is built around our continuously maintained dataset of standardized, and re-queryable data. All data processing is performed within Circulate's data ecosystem, thus reducing the reporting burden on blood operators compared to traditional survey methods. Utilizing portions of this dataset in conjunction with the development of the 2025 NBCUS would allow CDC to rely less on manual data entry, enhance consistency in classifying data elements, and improve overall analytic consistency. Additionally, the ability to re-query historic and current data enables more sophisticated longitudinal analysis and quality assurance than what is possible through static survey submissions alone. This would improve the applicability and long-term value of NBCUS outputs while easing administrative workload for respondents and federal teams.

- **Successful pilot collaboration with CDC**. During the 2024 Advancement of Blood and Biotherapies (AABB) Annual Meeting, Circulate and CDC representatives jointly presented on national blood supply dynamics. This collaboration prompted both

organizations to assess data quality, methodology, and comparability, and led Circulate to implement several technical enhancements that remain active in our dataset today. Because NBCUS relies on aggregated reporting that cannot always be validated or broken down into component-level detail, complementary use of standardized operational data could strengthen analytic depth and interpretability.

- **Alignment with federal recommendations for real-time, comprehensive blood supply data.** The 2020 Advisory Committee on Blood and Tissue Safety and Availability's (ACBTSA) Report to Congress, Adequacy of the National Blood Supply, highlighted persistent challenges with decentralized, manual, and inconsistent data collection across the blood sector, noting that: *"The absence of comprehensive national data accounting for supply and utilization impedes the ability of blood centers, hospitals, and policymakers to take data-driven actions… There is no single source of information with real-time data on blood supply and demand. The blood community currently monitors changes in supply through a manual, decentralized, imprecise process that gathers data from different reporting organizations."* Circulate was founded as a direct response to these concerns and represents a concrete pathway toward achieving the federal government's stated goals of consistent, real-time, and standardized national visibility.

- **Support for BARDA's 2022–2026 Strategic Plan.** Circulate's capabilities also advance BARDA's objective to "enhance and sustain response-ready support services," particularly through the availability of near–real-time data relevant to emergency preparedness and continuity of operations throughout major shocks to the blood supply.

- **Public–private partnership.** Circulate represents the possibility of a public–private partnership in which nonprofit governance, industry expertise, and standardized data practices come together to advance national health and security goals. By leveraging the existing contributions and technical infrastructure developed collaboratively with the country's major blood operators, Circulate can offer the federal government an efficient, scalable, and trusted partner in enhancing the quality and utility of the NBCUS. A closer alignment between Circulate and federal agencies would also create new opportunities for knowledge-sharing, joint validation efforts, and coordinated responses during crises thus reducing silos and strengthening the collective capacity of the blood community.

By incorporating data or analytic outputs from Circulate's existing infrastructure whether for validation, triangulation, or directly into specific elements of the survey CDC could reduce respondent burden, enhance NBCUS, and strengthen national preparedness. Access to a dataset that reflects the U.S. blood supply in real time also provides a unique opportunity to inform the resiliency, planning, and readiness framework that is so critical to national security.

Circulate welcomes the opportunity to meet with CDC, HHS/OASH, or relevant project teams to discuss these suggestions in greater detail and to explore potential pathways for partnership.

Response: Thank you for these comments. We understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection.

4. America's Blood Centers

Comment: America's Blood Centers (ABC) is the national organization bringing together community-based, independent blood centers. Our member organizations operate more than 700 blood collection sites in more than 1,100 communities, providing close to 60 percent of the U.S., and a quarter of the Canadian, 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. All ABC U.S. members are licensed and regulated by the U.S. Food and Drug Administration (FDA).

ABC applauds the Centers for Disease Control and Prevention (CDC) for its continued support of the National Blood Collection and Utilization Survey (NBCUS). Since 2013, the CDC, in close collaboration with the Office of the Assistant Secretary for Health (OASH), has conducted the NBCUS, a biennial survey that is crucial for understanding and managing the blood supply in the United States. The NBCUS captures data on blood collection, processing, and testing; blood and blood component transfusions; modification of components; and prices paid by hospitals for blood components.

The NBCUS data and resulting publications provide the most comprehensive information currently available on blood collection and utilization in the United States. They are used by private organizations, such as hospitals, blood collectors, and testing and device manufacturers, as well as government agencies to track blood donor trends, ensure blood safety, understand utilization, and plan for disasters, emergencies, and future needs.

I. **ABC recommends an alternative focus for the additional questions CDC is proposing to add to the NBCUS.**

CDC is proposing to add new questions to the NBCUS, including items on "information about bacterial transfusion-transmitted infections found in blood, length of time any blood shortage lasted, cold storage platelets, [and] pathogen reduced cryoprecipitated units." However, ABC has several concerns regarding this proposal. Regarding the measurement of blood shortage duration, it is unclear how hospitals would reliably track and define the duration of blood shortages, particularly given variability in shelf-life management and dynamic inventory flows. Additionally, the term "cold storage" should be revised to "cold-stored platelets," as this represents a specific and emerging product

category. Furthermore, cold-stored platelets and pathogen-reduced cryoprecipitated units are currently under-implemented, raising questions about their inclusion in a national utilization survey at this time.

ABC recommends CDC consider an alternative focus for these additional questions. Greater value may be gained by including questions on whole blood utilization, as well as the utilization of products in the prehospital setting.

Response: Regarding cold-stored platelets, thank you, this is reflected in the current version of the survey**.** While these products may currently be rarely used in the United States, we believe that understanding baseline implementation numbers are important to tracking use over time.

II. **ABC strongly recommends the NBCUS include questions addressing the quantity of whole blood transfused and discarded in the hospital setting and the total number of whole blood units converted into packed red blood cells (pRBCs) as a method to reduce wastage.**

As noted in the Notice of Proposed Data Collection, the Office of Management and Budget (OMB) is "interested in comments that will help…enhance the quality, utility, and clarity of the information to be collected" through the NBCUS.

Whole blood has had a positive impact on the resuscitation of patients who are at risk in hemorrhagic shock.1 However, whole blood may pose inventory challenges to blood centers, as it requires additional manufacturing steps and has shortened expiration dates when compared to red blood cells. The expiration date for whole blood units is up to 35 days from collection, and as few as 21 days when leukoreduced, whereas the expiration date for red blood cells is up to 42 days.2 Additionally, unlike group O red blood cells that may be transfused to any blood group, group O whole blood contains ABO associated antibodies that may illicit a transfusion reaction in non-group O patients. To mitigate transfusion-related acute lung injury (TRALI), male blood donors are preferred.3 Given these challenges, it is important to understand the number of whole blood units transfused and discarded in the hospital setting.

To provide greater value to the blood community and the U.S. government, and to more fully understand and address the evolving needs for whole blood units for donors the U.S. blood supply, ABC recommends adding questions to the NBCUS to determine:

1. The total number of whole blood units transfused in the hospital inpatient setting;
2. The total number of whole blood units transfused in the hospital emergency and trauma departments;

3. The total number of outdated units of whole blood discarded in the hospital inpatient setting;
4. The total number of outdated units of whole blood discarded in the hospital emergency and trauma departments;
5. The total number of leukoreduced whole blood units transfused in the hospital inpatient setting vs. the total number of non-leukoreduced whole blood units; and
6. The total number of whole blood units converted into packed red blood cells (pRBCs) to mitigate wastage.

Response: Regarding whole blood transfused and discarded (comments 1 and 3), please note that C2b addresses allogenic whole blood units transfused and outdated. Regarding comments 2, 4-6, we agree that these questions may be of interest for the operations of a blood center. However, we feel the public health benefits would not outweigh the response burden placed on participants. We will consider these for future surveys.

III. **ABC strongly recommends the inclusion of questions addressing the quantity of whole blood, red blood cells, thawed plasma, and liquid plasma transfused and discarded in the pre-hospital setting.**

Research studies suggest that, for hemorrhaging trauma patients, each minute of delay in administering a unit of whole blood increases the odds of 24-hour and in-hospital mortality by 2%.4 Additionally, ABC's survey data, outlined in ABC's May 2025 report, A Vital Resource: Community Blood Centers and the *Growth of Prehospital Blood Programs*, shows that since 2022, there has been a consistent upward trend in the number of community blood centers providing blood and blood products as part of pre-hospital transfusion programs across the United States. In 2022, there were 18 ABC member blood centers supporting a pre-hospital blood program, and in 2024, that number rose to 34 with 2 blood centers in the process of, and 4 considering, starting a program. This 89% increase in participating community blood centers over just two years highlights blood centers' commitment to expanding the availability of blood products and improving patient outcomes.

The report also highlights a dramatic increase in the supply of specific blood products for pre-hospital use, particularly Low Titer-O Whole Blood and Type-A Liquid Plasma units. According to the report's underlying survey results in 2023, ABC members collected and distributed approximately 15,000 products in support of prehospital programs. In 2024, that number rose to over 32,000 products, including low titer group O whole blood, group O red blood cells, A liquid plasma, and AB liquid plasma.

While the report demonstrates a substantial increase in the use of blood products in the pre-hospital setting, community blood centers still face challenges. For example, managing separate blood inventories for pre-hospital use adds complexity to blood center

operations. Additionally, the risk of unused products expiring coupled with the logistical challenges of rotating inventory to prevent wastage contribute to hesitancy among some blood centers.

Given the importance of, and increase in, transfusions in the pre-hospital setting, and the challenges faced by some blood centers, ABC urges adding questions to the NBCUS to determine:

1. The total number of whole blood, red blood cells, thawed plasma, and liquid plasma units transfused in the pre-hospital setting;
2. The total number of outdated units of whole blood, red blood cells, thawed plasma, and liquid plasma discarded in the pre-hospital setting; and,
3. The total number of patients received by hospitals who have been transfused in the prehospital setting.

As noted above, the NBCUS is the only source of comprehensive data on blood collection and usage available for both public and private stakeholders. It supports benchmarking and surveillance, ongoing research, regulatory needs, disaster planning, and national security concerns. As such, the addition of questions relating to pre-hospital blood transfusions and whole blood use in the hospital setting is essential to continuing the collection of timely, comprehensive data of use to all stakeholders.

Response: Thank you for this comment. The question "During 2025, did your institution distribute blood products for transfusion in the pre-hospital setting?" (Yes/No) will be included in the upcoming survey in both Section B and Section C.

IV. ABC strongly recommends the inclusion of the following additional fields and data elements in the NBCUS.

The NBCUS should include:

1. A field for the number of prophylactically supplied antigen-negative or phenotype-matched red blood cell units transfused, such as K-, E-, c-, Fy(a-), Jk(a-);
2. A data element to capture the number of antigen-negative red blood cell units issued or transfused for therapeutic purposes in patients with existing clinically significant alloantibodies;
3. A field to report the annual number of platelet units issued and transfused that were HLA-selected (HLA-matched, HLA-compatible, or antigen-negative) or crossmatch compatible; and,
4. A field to report the number of washed red blood cell units and washed platelet units issued and transfused, particularly in light of the sunsetting of the COBE instrument, to better anticipate operational and clinical resource needs.

Response: We agree that these questions may be of interest for the operations of a blood center. However, we feel the public health benefits would not outweigh the response burden placed on participants. We will consider these for future surveys.

ABC appreciates the opportunity to comment on the Notice of Proposed Data Collection. If you have any questions or require additional information, please contact Justine Coffey, Director of Regulatory Affairs and Public Policy (jcoffey@americasblood.org).

5. Mitchell Berger

Comment: In reference to the above information collection, I recommend that the 2025 National Blood Collection and Utilization Survey (NBCUS) include questions on emergency planning and preparedness among blood establishments. Even though various NBCUS reports reference the importance of the survey and blood supply for emergency preparedness and response, it does not appear the survey itself directly asks about blood collection center/establishment emergency preparedness efforts.[1] While hospitals likely are captured on other surveys and included in hospital emergency preparedness plans, blood establishment emergency preparedness efforts remain unclear.

Based on NBCUS and other materials[2] survey questions could include:

- Has the blood center developed or updated a continuity of operations plan within the past year?
- Has the blood center during the past year contacted their state, local or territorial emergency management and public health agencies to discuss the importance of the blood supply (as recommended by the AABB Disaster Task Force)?
- Has the blood center during the past year participated in state, local or territorial emergency planning and response activities such as exercises or training (as recommended by the AABB Disaster Task Force)?

Such questions can emphasize to blood centers the importance of considering emergency preparedness in their work and establish a baseline for Disaster Task Force partners, including HHS, to use in their planning and outreach. Thank you for considering this input.

Note/Disclosure: I am submitting these suggestions solely in my personal/private capacity. The views expressed are mine only and should not be imputed either to other individuals or to any public or private entity.

Response: We agree that these are important considerations in blood center operations; however, we believe that this survey is not the most appropriate forum for assessing this information. These data would be better pursued by the AABB task force.

6. AABB

Comment: The Association for the Advancement of Blood and Biotherapies (AABB) appreciates the

opportunity to provide comments in response to the notice issued by the Centers for Disease
Control and Prevention (CDC) regarding the 2025 National Blood Collection and Utilization Survey (NBCUS).

AABB is an international, not-for-profit association representing institutions and individuals
involved in transfusion medicine and biotherapies. 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 optimize patient and donor care and safety. AABB individual membership includes physicians, nurses, scientists, researchers, administrators, medical laboratory scientists and technologists, and other health care providers.

AABB commends CDC for its sustained dedication to collecting and analyzing data on blood
availability and utilization through the NBCUS. We value CDC's engagement with the blood community and its efforts to ensure that the survey instrument remains current, effective, and
reflective of evolving needs.

The proposed collection of information is necessary and will have practical utility. The
NBCUS is a critical tool for helping the blood community, healthcare organizations, and policymakers understand patterns related to blood collection, utilization, shortages, and emerging
practices. The information can be used by all stakeholders to guide decision making, support
strategic planning, and strengthen national preparedness and security.

The agency's estimate of the burden of the proposed collection of information is too low.
CDC estimates that each respondent will spend approximately 3.5 burden hours completing the
questionnaire. The data are not easily extracted from laboratory information systems, medical
records, or blood establishment computer systems. Thus, blood collectors and hospitals often
need to use time consuming, manual processes to sort, run, clean, and look up different data
required to complete the survey.

Response: The hourly burden estimate is based on previous years' surveys. We recognize that there might be variability in the level of effort required to gather information in order to respond to this survey.

CDC could minimize the burden on respondents by allowing and encouraging electronic
data submissions. Specifically, we encourage CDC to explore opportunities to leverage automated exports from platforms such as laboratory information systems and blood establishment computer systems. Additionally, CDC could consider a consolidated reporting
mechanism for multi-hospital systems.

Given the increasing complexity of transfusion practice, CDC may wish to consider a tiered or
modular reporting approach, in which a core set of essential data elements is collected from all
respondents, with optional supplemental modules for specialized practices (e.g., prehospital
transfusion, Low Titer O Whole Blood (LTOWB), granulocytes, neonatal transfusion). This approach could preserve data quality while minimizing respondent burden and supporting more
targeted analyses.

Response: Thank you for these comments. We understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection. CDC currently works with respondents who may provide data for numerous facilities, so that they are able to submit survey data through a consolidated mechanism. Respondents can contact nbcus@cdc.gov directly to discuss this option once the survey links have been received.

AABB has several recommendations to enhance the quality, utility, and clarity of the information to be collected.

- **General Comment.** The NBCUS is critical to understanding trends in transfusion practice,
  particularly as care extends beyond traditional hospital settings. Prehospital blood transfusion programs are expanding, making it essential to capture data on the quantity and variety of blood products being obtained, transfused, and discarded in these settings. We encourage CDC to collect data from both blood collectors and hospitals, as program structures vary: some are hospital-run, some involve blood collectors working directly with EMS agencies, and others involve all three partners. In some models, blood collectors have direct visibility into how products are used, while in others this information primarily resides with hospitals. If possible, it may

be helpful to distinguish air EMS from ground EMS, as these settings differ substantially in scale, logistics, product mix, and inventory risk.

- **B2c.** Consider adding a line to capture LTOWB, as the number of these products has
  increased over the past couple of years and has an impact from collections through the end
  user.
  Response: We agree that these questions may be of interest for the operations of a blood center. However, we feel the public health benefits would not outweigh the response burden placed on participants. We will consider this for future surveys.
- **B2o.** Consider asking (1) the average number of granulocytes collected per unique patient,
  and (2) if donors were given steroids and/or G-CSF for granulocyte collection.
  Response: We agree that these questions may be of interest for the operations of a blood center. However, we feel the public health benefits would not outweigh the response burden placed on participants. We will consider this for future surveys.
- **B4.** "People" may be construed as 1 person presenting multiple times in 2025 counted as 1.
  Do you intend to capture the number of 'prospective donors' that presented to donate? **Response:** This question intends to capture individual donors (individuals should be counted only once). Please note that first-time versus repeat donors and their donations are captured in question B6.
- **B8.** Consider adding a category for donors who did not disclose their ethnicity.
  Response: Thank you, this change has been made.
- **B10.** Consider changing instructions for each question from "and outdated" to "or outdated."
  Response: CDC is asking for all three; therefore, we believe that "and" is most appropriate.
  B11. Consider asking whether institutions distributed the following products for prehospital
  transfusion: (1) red blood cells (RBCs), (2) LTOWB, (3) whole blood, (4) plasma or (5) other.
  Response: Thank you for this comment. The question "During 2025, did your institution distribute blood products for transfusion in the pre-hospital setting?" (Yes/No) will be included in the upcoming survey in both Section B and Section C.
- **B15.** Consider adding percentage of inventory that applies to each bacterial risk control
  strategy.
  Response: This can be statistically estimated.
- **B16.** We appreciate that CDC defines the term "shortage" for the purpose of this question.
  While some blood collectors and hospitals use a 24-hour supply to define shortage, this

definition may not align with how shortages are operationally defined by blood collectors or
hospitals, particularly across different product types and geographic contexts. Clarification
— or acknowledgment of this limitation — would improve interpretation of the data.

Additionally, this definition may not capture the data that the survey is intending to gather.
Blood centers take many measures to reduce their inventory before actually getting to less
than a 24-hour supply. It may be helpful for CDC to revise the question to ask if facilities had a shortage that resulted in a specific product being allocated.

Response: CDC understands the limitations in variability as it relates to the definition for "shortage." In previous years we have defined "shortage" differently; however, feedback among internal and external partners has indicated that defining shortage as less than a 24-hour supply is the most broadly applicable criteria for assessing this response.

- **General Comment.** Consider adding therapeutic collection procedures as a distinct, well-defined category to enhance reporting accuracy and ask respondents to report data about:
    - Testosterone Replacement Therapy (TRT)
    - Hemochromatosis Whole Blood (WB)
        - For hemochromatosis WB, it would also be helpful to know if all individuals are accepted and only those units collected from qualified individuals are manufactured into transfusable products with the other collections being discarded, or if only units from patients with hemochromatosis who qualify as an allogeneic blood donor will be eligible for donation.

  Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C2b.** Consider adding lines for facilities to report:
    - Imported LTOWB for transfusion
    - LTOWB near end of shelf-life that were further manufactured into RBCs for
    - transfusion
    - LTOWB discarded as LTOWB

  Response: We agree that these are important questions; however, we feel they are beyond the public health scope of the survey and the public health benefits would not outweigh the response burden placed on participants. We will consider these for future surveys.
- **C3b.** Consider adding a query regarding percentage of O+ and O- that were transfused to
group O patients.

Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.

- **C4.** Consider asking how many requests were received for directed RBC or directed whole
  blood units. Consider adding a query as to whether the institution crosses directed units into general inventory to prevent discard or if the units maintain their directed status until end of shelf-life.
  Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C5a.** For apheresis platelet units, include cold stored platelets versus room temperature
  stored platelets
  Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C5c**. Consider adding a query regarding percentage of AB plasma that is transfused to AB
  patients.
  Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C5d.** For cryoprecipitate, consider splitting pre-pooled cryo pools from individual units
  either transfused as a single unit or pool just prior to transfusion. Then the follow up
  question regarding pool size will apply only to the pre-pooled units or pools intended for
  adult patients.
  Response: The survey currently includes instructions regarding pooled products; this allows for standardized comparisons year by year.
- **C5d.** Is the reference to “pathogen reduced cryoprecipitated individual units transfused”
  referring to “pathogen reduced cryoprecipitated fibrinogen complex”? If so, consider asking
  for size of pool in addition to number of units transfused.
  Response: The language has been changed to “pathogen reduced cryoprecipitated fibrinogen complex” for clarity.
- **C5d.** For the question related to granulocyte units transfused, consider asking if dose of
  granulocyte transfusions were greater than target dose of ~0.6x10^9/kg.

Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.

- **C6c.** For the second answer, consider revising the language to read "Satellite aliquot bags or Pedipacks attached via sterile docking/welding to full-size unit." The reference to
"Pedipack" may be interpreted as 4 bags aliquoted at one time to about 70mL per aliquot
from the full-size unit, but there are other multiple aliquot bag systems available.
Response: We appreciate this suggestion and understand there may be variability dependent on facilities. The question is consistent with previous survey iterations and will enable comparison across survey years.
C6d: Consider revising the question to read, "For neonatal patients, does your facility
attempt to use aliquots from the same full-size unit for every transfusion until the unit is
exhausted?"
Response: We appreciate this suggestion but believe the question currently confirms to Plain Language standards.
- **C8**. For some hospitals, it is not feasible to identify product ages at transfusion since it
would be a fully manual process.
Response: CDC understands that some questions in this survey are not readily available for all facilities to answer. This question is not required and we understand that some hospitals may omit this item.
- **C10.** In addition to asking about the number of RBC and plasma units transfused in the
different settings of care, consider asking about the number of units of whole blood units that were transfused in the different settings.
Response: We agree that this information may be of interest; however, we feel it is beyond the public health scope of the survey and the public health benefits would not outweigh the response burden placed on participants. We will consider these for future surveys.
- **C10**. Consider asking respondents to report the number of units transfused to outpatients
versus inpatients within each care setting.
Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C.10.** Consider inserting a row for the number of units transfused in hematology/oncology,
rather than grouping hematology/oncology with inpatient medicine. Increasingly, hematology/oncology patients receive blood transfusions in the outpatient setting.

Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.

- **C21b.** Consider adding two questions after the general question related to the number of
  RBC units transfused to individuals with sickle cell disease:
  1. "How many RBC units were transfused to individuals as part of an RBC exchange?"
  2. "Does your institution have a policy on matching antigens for RBC transfusions
     for sickle cell disease patients, regardless of antibody status?"
     a. No
     b. Yes, for C/c, E/e, K
     c. Yes, for C/c, E/e, K, and others

  Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.
- **C23.** The term "sample collection errors" is general and may be interpreted in multiple ways. Consider asking respondents specifically about wrong blood in tube, which is objective and commonly tracked.
  Response: The question is meant to capture various sample collection errors tracked at an institutional level, not solely limited to wrong blood in tube.
- **General Comment.** Consider asking transfusion services the question about shortages of
  each blood product (B16). As noted above, a 24-hour supply - the proposed definition of
  shortage - may not align with a hospital's definition of a shortage. For example, for some
  hospitals, a 24-hour platelet supply may represent normal daily inventory. A clear metric
  might be: "During 2025, on how many days did your facility experience a platelet shortage
  that caused a delay of more than eight hours between receipt of a transfusion order and
  administration of platelets to a patient?"
  Response: CDC understands the limitations in variability as it relates to the definition for "shortage." In previous years we have defined "shortage" differently; however, feedback among internal and external partners has indicated that defining shortage as less than a 24-hour supply is the most broadly applicable criteria for assessing this response.
- **General Comment.** Consider asking questions about distributing or transfusing low yield
  platelets, and whether these units are pathogen reduced or conventional platelets.

Response: We agree that this information may be of interest; however, we feel that the public health benefits do not outweigh the response burden placed on participants. We will consider this for future surveys.

Thank you for the opportunity to provide comments on the 2025 NBCUS. If you have any questions or need additional information, please contact me at lmstone@aabb.org.

7. Vitalant

Comment: We are pleased to provide comments to the Centers for Disease Control and Prevention (CDC) on the proposed information collection project titled the 2025 National Blood Collection and Utilization Survey (NBCUS). As one of the nation's largest nonprofit blood and biotherapies healthcare organizations, Vitalant plays a vital role in ensuring the health and safety of patients and our community every day. In addition to collecting and providing blood to hospitals, we also provide comprehensive reference laboratory and transfusion medicine services, unique coagulation testing, cell therapy manufacturing and Human Leukocyte Antigen (HLA) services, and work on the forefront of science and healthcare through the Vitalant Research Institute and Vitalant Innovation Center. Vitalant collects eleven percent of the nation's blood supply for patients across twenty-eight states.

1) Evaluate whether the proposed collection information is necessary for performance of the functions of the agency, including whether the information will have practical utility.

The proposed collection of NBCUS information is both necessary and highly valuable. The data serves an essential role in enabling the blood community, healthcare institutions, and policymakers to understand and monitor national trends in blood collection, utilization, and discards. These insights support informed decision-making, strategic planning, and public health preparedness—indicating that the information collected has clear and practical utility.

2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used.

The agency's burden estimates appear reasonable and aligned with actual operational experience. For example, approximately **40 hours** are required to extract data **for 22 hospitals** from a single laboratory information system (LIS), and another **40 hours** to extract enterprise-level data from a single blood establishment computer system (BECS). These figures reflect a low burden relative to the value of the resulting dataset. However, the overall utility of the data could be enhanced by reducing the

two-year lag between collection and publication, thereby improving its timeliness.

3) Enhance the quality, utility, and clarity of the information to be collected.
Several improvements would strengthen data quality and usability:

- **Develop a standardized glossary** to ensure consistent interpretation of terms across organizations. For example, clarification is needed on whether "procedure" refers to collection attempts or only successful collections. Plain language.
    - Numerous questions regarding what to include and exclude in the quantities
      throughout the survey:
        - If we draw Platelet Quad units, do they fall under Triple or get excluded?
          Response: The survey intends to capture total allogeneic apheresis platelet units (via question B2g_1); platelet quad units should be included in total platelet units but would not be separately tracked.
        - Do we count Jumbo Plasma as 2 equivalent plasmas or 1?
          Response: Jumbo Plasma would be counted as 1 if distributed as 1 unit but counted as >1 if distributed as more than one unit.
        - Some questions refer to Allogeneic/Directed only while others do not. Do
          we then include Therapeutic, Autos, Research, etc. in the more generic
          questions?
          Response: The survey intends to only capture data on blood collections that are intended for transfusions as blood products, these may include autologous, directed, or allogenic donations.
        - Does deferral qty only includes deferrals preventing a needle stick on the
          current visit?
          Response: For B5, deferrals are intended to reflect instances where a blood donation was not conducted due to the presence of a deferral criteria; low hemoglobin or low hematocrit, example deferral criteria, would only be ascertained by a needle stick to assess those levels.
        - What types of deferral reasons fall into High-risk behaviors. What types of
          deferrals fall into Other non-medical reasons? How do we ensure these are
          consistent across blood centers?
          Response: For the 2025 survey, the included high-risk behavior deferral criteria include specific definitions. Any deferrals that are not captured under the categories specified in the survey are reported as other non-medical reasons.

        - What is Outdate? Products expired on our shelves and were not sold for
          research? Do they include outdates credited?
          Response: The survey intends to only capture data on blood collections that are intended for transfusions as blood products. The survey is not intended to capture data related to research.
- **Data Difficulty:** Hard to pull data at this level of detail.
    - We are unable to provide deferrals by Phlebotomy Group. We lose Intended phlebotomy for deferred donors.
      Response: The survey does not capture data related to phlebotomy groups.
    - It is difficult for us to pull some data accurately such as Platelet Singles, Doubles, and Triples.
      Response: CDC understands that some questions in this survey are not readily available to answer for all facilities; questions related to platelet singles, doubles, and triples are not required.
- Remove outdated or low-value questions that do not contribute meaningful insight into current operational or clinical trends.
  Response: During every survey cycle, CDC assesses the response rate for each question from the previous survey cycle along with the public health importance of that variable. The current survey reflects questions that are retained due to their public health value.
- Add questions capturing pre-hospital blood use and discard data—an increasingly relevant area, particularly for trauma systems and EMS agencies.
  Response: Thank you for this comment. The question "During 2025, did your institution distribute blood products for transfusion in the pre-hospital setting?" (Yes/No) will be included in the upcoming survey in both Section B and Section C.
- Improve visibility into utilization and discard patterns across all major blood components, including:
    - Whole blood (transfused and discarded)
    - Red blood cells (transfused and discarded)
    - Plasma (transfused and discarded)

  Response: This information is currently captured in questions C2-C5.
- Circulate has brought together a group of blood centers (Vitalant, American Red Cross, OneBlood, and Gulf Coast) to clearly define NBCUS questions to more consistently report comparable results. Many steps including code maps, clean definitions, etc. have been implemented to align the large blood centers. They may be a resource to help drive consistency.
  These additions would provide a more comprehensive and actionable picture of national blood use.
  Response: CDC defers to respondents on how they leverage various partnerships to provide accurate and complete responses to the survey.

4) Minimize the burden of the collection of information on those who are to

respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submissions of responses.

The burden on respondents can be significantly reduced through streamlined processes and centralized data entry mechanisms:

- Allow and encourage electronic data submission, leveraging automated exports from LIS and BECS platforms.
  Response: We understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection.
- Reduce duplicative reporting for multi-hospital systems. For example, because Vitalant serves 30 hospitals on the same LIS, receiving separate surveys for each facility is inefficient. A consolidated reporting mechanism—such as the spreadsheet provided by the NBCUS team—should be standard practice.
  These improvements would preserve data quality while reducing labor demands on participating organizations.
  Response: CDC currently works with respondents who may provide data for numerous facilities so that they are able to submit survey data through a consolidated mechanism. Respondents can contact nbcus@cdc.gov directly to discuss this option once the survey links have been received.

5) Assess information collection costs.

Information collection costs are modest relative to the value of the resulting national dataset. Current estimates indicate:

- Forty hours of labor to extract and compile required data for a multi-hospital system
  using a single LIS.
- Forty hours of labor to compile BECS-derived data across an enterprise system.

Given the operational importance of NBCUS data and the potential enhancements outlined above, the associated costs are reasonable and justified.

8. <u>Cerus Corporation</u>
Comment: Cerus appreciates the opportunity to comment on the Centers for Disease Control and Prevention's (CDC's) proposed data collection methodology for the 2025 National Blood Collection and Utilization Survey (NBCUS).

Cerus develops and supplies pathogen reduction technologies used across the U.S. blood system and works closely with blood centers, hospitals, and public health partners to support the availability and safety of blood components for patients. From this vantage point, we view the NBCUS as a core element of the national health data infrastructure and strongly support its continuation.

Value and necessity of the NBCUS

The NBCUS remains the only comprehensive, nationally representative source of data spanning blood collection, distribution, utilization, and shortage trends, as well as an important tripwire for the detection of emerging safety considerations. The information generated by this survey has unique and demonstrated utility in informing public policy, emergency preparedness, and industry best practices, including during recent periods of acute stress on the blood supply.

Independent or privately funded surveys—while useful for targeted insights—cannot replicate the scope, consistency, or authority required to assess national infrastructure or guide system-wide improvements. A trusted, federally led effort is essential to ensure continuity and comparability of data, transparency, and actionable insights for both public and private stakeholders.

Burden considerations and opportunities for improvement

Cerus acknowledges concerns that have been voiced regarding the time and effort required to complete the NBCUS. Experience from prior surveys indicates that estimates have often understated the actual burden of effort required, particularly for facilities with complex operations, limited staff, and/or limited access to automated reporting systems.

At the same time, we believe the appropriate response is not to scale back data collection, but to modernize how data are gathered. CDC's assumption of primary responsibility for NBCUS data collection presents an important opportunity to work with blood centers, hospitals, and major software vendors to enable standardized, automated reporting where feasible. CDC's experience with other national surveillance systems, including the National Healthcare Safety Network (NHSN), may offer useful lessons as NBCUS continues to evolve.

CDC is well positioned to leverage its convening authority to gather stakeholders for a national discussion about new approaches to reduce the burden of manual data entry, improve accuracy, and ultimately enhance the quality and timeliness of the data.

As data collection becomes more automated and standardized, CDC could also consider increasing the frequency of NBCUS data collection and accelerating analysis and public reporting. Annual national reporting on blood safety and availability is the norm in other industrialized countries, including the United Kingdom's Serious Hazards of Transfusion (SHOT) reports and the French government's ANSM hemovigilance system. More timely data would enhance the practical utility of the survey for policymakers, healthcare systems, and industry stakeholders, particularly during periods of supply disruption or rapidly evolving clinical practice. Increased cadence and faster dissemination would ultimately increase the survey's value and better justify the effort required.

Response: The hourly burden estimate is based on previous years' surveys. We recognize that there might be variability in the level of effort required to gather information in order to respond to this survey. We also understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection.

Data modernization, resiliency, and patient care
The proposed updates to the 2025 NBCUS—particularly the inclusion of questions related to shortages, bacterial transfusion-transmitted infections, and newer blood products—reflect the evolving realities of transfusion medicine and should strengthen the survey's relevance. As infectious risks evolve, including emerging or residual transfusion-transmitted infections, the ability to assess mitigation strategies at a population level further underscores the value of comprehensive, timely NBCUS data.

Comprehensive, nationally coordinated data capabilities are necessary to strengthen the resiliency of the U.S. blood supply and protect hospitals' ability to provide consistent patient care. Compared with other countries, the U.S. lacks a fully integrated national hemovigilance system capable of linking collection, utilization, adverse events, and outcomes across the blood supply chain. This gap limits our collective ability to optimize patient care, proactively identify risks and unmet needs, and respond efficiently to emerging challenges.

While the NBCUS is not itself a hemovigilance system, it represents, alongside the NHSN, a strong foundation for moving toward such an ideal system. The UK and French systems noted above are excellent models that could be considered for adaptation by CDC. Continued modernization, improved timeliness, and expanded analytical capability can help bridge current knowledge gaps and support a more comprehensive, data-driven approach to safeguarding patients and strengthening the blood system.

Quality, Utility, and Clarity of the Information to be Collected

To ensure the 2025 survey provides the most actionable insights for public health preparedness, the interpretability of utilization data must reflect the meaningful distinctions found in modern clinical practice. In response to the request for ways to enhance the survey's practical utility, we recommend the following refinements to the data collection framework:

1. Component Attributes: The survey should distinguish between labile blood components with different processing profiles.
    - **Irradiation Status:** Distinguish between irradiated and non-irradiated units for both red blood cells (RBCs) and platelets.

- **Pathogen Reduction:** Ensure distinct line items for pathogen-reduced apheresis platelets and pathogen-reduced, cryoprecipitated fibrinogen complex.
- **Platelet Source:** Maintain the distinction between apheresis platelets and whole-blood derived platelets to track shifting collection trends.

Response: The survey currently captures these in questions C7b, C27b, C5d, and C5a.

2. Standardization of Definitions: Accuracy in reporting is often hindered by ambiguous nomenclature. We recommend two specific clarifications to improve data quality:
   - **Define "Units" for Pooled Products:** Whole-blood derived platelets and cryoprecipitated AHF are frequently transfused in pools; we recommend the CDC provide a standardized definition of a "unit" within the survey instructions. This will ensure that data from diverse facilities can be accurately aggregated for assessment and comparison.

   Response: The survey provides instructions on inclusion of individual units and pooled product.

The implementation of these refinements will ensure that the NBCUS evolves alongside the clinical landscape it seeks to measure.

Conclusion

Cerus supports CDC's continuation and stewardship of the NBCUS and encourages ongoing efforts to improve efficiency, clarity, timeliness and analytic value through automation and collaboration with system stakeholders. Investments in new technologies and automated data collection approaches will help balance respondent burden while maximizing the survey's contribution to resilience of the nation's blood supply.

Thank you for the opportunity to comment. Cerus stands ready to engage further with CDC on data-driven approaches that strengthen availability, safety, and resilience for patients and caregivers who depend on blood and blood components.

9. **Aliyah Brock**

   Comment: I support the 2025 National Blood Collection and Utilization Survey because it provides important data that helps ensure a safe and reliable blood supply in the United States. I encourage the CDC to keep the survey questions clear and consistent so results are accurate. Reducing the time burden on hospitals and blood centers through clear instructions and electronic reporting could also improve participation and data quality.

Response: Thank you for your comment. We understand that automated, real-time data upload would be beneficial and will continue to explore possibilities of streamlining data collection.

10. **Anonymous**

Comment: I DO NOT support the 2025 National Blood Collection and Utilization Survey. Its is a waste of tax-payer resources. I would discourage the CDC to focus on infectious disease study and reduce time spend on collecting irrelevant data. This places burden on hospitals and blood centers and cause a decline in participation and data quality.

Response: Thank you for your comment.