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Jeffrey M. Zirger
Information Collection Review Office
Centers for Disease Control and Prevention
1600 Clifton Road NE, MS H21-8
Atlanta, Georgia 30329

Submitted via https://www.regulations.gov

Re: Docket No. CDC-2025-0882: Notice of Proposed Data Collection Relating to the 2025 National Blood Collection and Utilization Survey

Dear Mr. Zirger:

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.

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 and 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.

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.

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[1] Lammers D, Hu P, Rokayak O, Baird EW, Betzold RD, Hashmi Z, Kerby JD, Jansen JO, Holcomb JB. Preferential whole blood transfusion during the early resuscitation period is associated with decreased mortality and transfusion requirements in traumatically injured patients. Trauma Surg Acute Care Open. 2024 Apr 22;9(1):e001358. doi: 10.1136/tsaco-2023-001358. PMID: 38666013; PMCID: PMC11043766.

[2] 21 CFR 610.53(b).

[3] AABB Standard 5.4.1.3, AABB Standards for Blood Banks and Transfusion Services, 34th ed.

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.

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

The NBCUS should include:

[4]Hosseinpour H, Magnotti L, Bhogadi S, Anand T, El-Qawaqzeh K, Ditillo M, Colosimo C, Spencer A, Nelson A, Joseph,B. Time to Whole Blood Transfusion in Hemorrhaging Civilian Trauma Patients: There Is Always Room for Improvement. Journal of the American College of Surgeons 237(1): 24-34, July 2023. DOI: 10.1097/XCS.0000000000000715.

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.

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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).

Sincerely yours,

Kate Fry, MBA, CAE
Chief Executive Officer