



Advancing Transfusion and
Cellular Therapies Worldwide

Anne Schuchat, MD
Acting Director
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4027

January 27, 2017

Dear Dr. Schuchat:

This letter is to alert you of AABB's concerns, as well as the concerns of several of AABB's institutional members, regarding the recent update of the Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN) Biovigilance Component Hemovigilance Module, which was released in January 2017. Based on feedback received from AABB's members who submit data to the NHSN Biovigilance Component Hemovigilance Module as well as our organization's own review of the revised module, AABB requests that CDC immediately withdraw the NHSN Biovigilance Component Hemovigilance Module that was released in January 2017, reinstate the previous version of the module, and work with stakeholders and users to revise the voluntary reporting system prior to implementing any substantive changes to the system. Additionally, we request the opportunity to meet with CDC to discuss the concerns outlined in this letter.

AABB is an international, not-for-profit association representing individuals and institutions involved in the fields of transfusion medicine and cellular therapies. The association is committed to improving health through developing and delivering standards, accreditation and educational programs that focus on optimizing patient and donor care and safety. AABB membership includes physicians, nurses, scientists, researchers, administrators, medical technologists and other health care providers.

AABB shares CDC's important goals of "improving patient safety, minimizing morbidity and mortality of transfusion recipients, and identifying emerging complications and pathogens associated with blood transfusion." AABB supports CDC's endeavor to obtain high quality, thorough data related to transfusion-associated adverse events to further these objectives. However, we believe the recently released version of the Hemovigilance Module of NHSN (version 8.6) will adversely affect both the quality and quantity of data reported due to fundamental flaws and increased burdens of data entry associated with this most recent version update.

Major hospitals have indicated that they will need to stop entering data into the NHSN Hemovigilance Module due to the changed layout, new requirements and inability to save partially complete records. In addition, in states such as Massachusetts, where reporting under the NHSN Hemovigilance Module is required by state law, the new system amounts to a burdensome, unfunded mandate.

The NHSN Hemovigilance Module is especially onerous because it requires information that is not readily accessible to the professionals in the blood banks who enter the data. For instance, blood bank personnel do not necessarily have access to hospitals' electronic health records, which contain information such as patients' admitting diagnoses (ICD-10 codes), indications for transfusion, comorbid conditions and medical procedures. Even if blood banks are granted access to patients' electronic health records to obtain the required codes, extracting the required information and then entering it into the NHSN Hemovigilance Module is extremely time-consuming. The Module does not permit users to omit these fields. Additionally, users are unable to save records partially entered into the system. This is problematic since users may be called away from data entry in the middle of a record to attend to important patient critical tasks and are then required to restart entering data from the beginning of the record.

Importantly, CDC did not conduct a pilot of the NHSN Hemovigilance Module. Although CDC has already established committees of hemovigilance stakeholders and users, CDC did not consult with either committee prior to designing and implementing the Module. AABB was informed of the changes to the NHSN Hemovigilance Module prior to implementation, but as it was a fait accompli, was not permitted to provide CDC with actionable input related to the new changes. AABB did request that CDC communicate the specific changes to users and stakeholders prior to implementation. In response to AABB's request, CDC provided a general memo to circulate before implementation, but the memo did not include details related to the changes to the system. Although CDC staff have addressed certain software bugs in the system since it was rolled out, AABB and its members are surprised by the number of errors in the programs upon release. Examples of these errors are listed below:

- The Module lists erroneous imputability options for several reaction types. For instance, one imputability option listed for allergic reactions provides, "There are other potential causes present that could explain acute hemolysis, but transfusion is the most likely cause." This option should be corrected since acute hemolysis is never caused by allergic reactions.
- Users are required to enter the "admitting diagnosis ICD-10 code." However, some patients are not admitted since they are outpatients.

AABB believes that routine and regular input from stakeholders and ultimate users of the system is imperative in designing, maintaining and updating a system that encourages voluntary participants to provide valuable information about blood transfusions. Thus, in the spirit of the public-private partnership that was critical to establishing the Hemovigilance Module, AABB respectfully requests that CDC:

1. Withdraw the NHSN Hemovigilance Module that was released in January 2017 and reinstate the last version of the module;
2. Convene the committees of stakeholders and users to determine what proposed changes are workable in today's environment, and to provide continuous feedback as the system is developed, implemented, used and updated;
3. Pilot a new proposed module with current users to ensure that the data requested is accessible to the professionals entering the information into the system, and that data-entry does not take an inordinate amount of time; and

4. Continuously assess the terms and definitions used in the NHSN Hemovigilance Module to ensure that they remain current and consistent with U.S. and international standards for transfusion reactions.

AABB is committed to working with CDC to address the flaws in the NHSN Hemovigilance Module and to promote hemovigilance. We believe that a user-friendly hemovigilance reporting system is imperative to encouraging voluntary hospital participation, collecting data on blood transfusions and ultimately providing data that can inform policies related to patient safety as well as the sustainability of the blood system.

If you have any questions or would like additional information, please contact Dr. Barbee Whitaker, Senior Director, Research, at 301-215-6574 or bwhitaker@aabb.org.

Sincerely,



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