



The Commonwealth of Massachusetts
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Division of Health Care Quality
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Circular Letter: DHCQ 13-10-601

TO: Acute Care Hospital CEOs
Acute Care Hospital Blood Bank Directors

FROM: Madeleine Biondolillo, MD
Interim Associate Commissioner
Director, Bureau of Healthcare Safety and Quality

DATE: November 8, 2013

SUBJECT: Revised Procedure for Reporting Blood Bank Activity

Background:

In 2010, the Centers for Control and Prevention (CDC) released the first national public health surveillance system to monitor adverse events among patients who receive blood transfusions. The Hemovigilance Module of the CDC's National Healthcare Safety Network (NHSN) was developed with input and support from the AABB and stakeholders within the transfusion community.

NHSN is a secure internet based surveillance system that monitors patient and healthcare personnel safety, used by all Massachusetts acute care hospitals to report healthcare-associated infections. Data entered into NHSN are confidential and protected by CDC's Assurance of Confidentiality through the Public Health Service Act, the Health Insurance Portability and Accountability Act of 1996, and the Patient Safety and Quality Improvement Act of 2005 (PSQIA). All data are guaranteed to be held in strict confidence, are used only for the purposes stated and are never disclosed or released without the consent of the individual or institution.

The Hemovigilance Module provides the rules for surveillance and definitions to ensure that all facilities perform surveillance of adverse events in a standardized way. The goal of this system is to improve patient safety by enabling healthcare personnel to identify trends in their respective hospitals and to allow review and analysis to be performed at the state and national level. Standardization of data collection and analysis will result in better understanding of how to prevent transfusion-related adverse events.

CDC provides NHSN at no cost to hospitals and healthcare facilities, and provides participating facilities with training and ongoing user support, also at no cost. Massachusetts acute care hospitals are experienced using NHSN. As a condition of licensure, all Massachusetts acute care hospitals have successfully reported healthcare associated infection (HAI) to the Department since 2008 and healthcare personnel influenza data using NHSN since last year.

Reporting Requirement:

Massachusetts blood banks and transfusion services subject to 105 CMR 135.000¹ are required to report activities as specified by the Department each month on forms provided by the Department. (105 CMR 135.120).

Beginning June 1, 2014, all licensed blood banks and transfusion services will be required to begin reporting transfusion related adverse events using the NHSN Hemovigilance Module. Prior to that date, blood banks and transfusion services may use NHSN in lieu of reporting on the monthly activity form.

Reporting transfusion related adverse events to NHSN DOES NOT replace reporting patient death or serious *injury* associated with unsafe administration of blood products as a Serious Reportable Event. ² **Unsafe administration includes, but is not limited to, hemolytic reactions and administering: a) blood or blood products to the wrong patient; b) the wrong type; c) blood or blood products that have been improperly stored or handled. All such events should be reported the Clinical Laboratory Program within one business day at 617-753-8439 or 617-753-7014.**

Use of the Hemovigilance Module DOES NOT replace the FDA's mandatory requirements for reporting blood transfusion deaths or blood product deviation reporting.³

Getting Started in NHSN:

All Massachusetts acute care hospitals have used NHSN to report healthcare associated infection data since 2008. Contact the infection prevention department and/or hospital epidemiologist in your facility to learn from their experience and to identify your hospital's NHSN Facility Administrator.

General NHSN information is available at the following link:

<http://www.cdc.gov/nhsn/about.html>

Information on joining the CDC NHSN hemovigilance module can be obtained by visiting the [NHSN Blood Safety Surveillance](#) website.

Reporting to NHSN will provide comprehensive data on adverse transfusion events that will promote the implementation of system-wide improvements resulting in improved patient outcomes and the reduction of healthcare costs.

We appreciate your efforts towards this patient safety initiative.

For NHSN technical assistance please contact:

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¹ [105 CMR 135.000 - Mass.Gov](#)

² [105 CMR 135.000 - Mass.Gov](#)

³ <http://www.fda.gov/biologicsbloodvaccines/safetyavailability/reportaproblem/transfusiondonationfatalities/default.htm>