



**Department of Veterans Affairs  
Office of Inspector General**

**Office of Healthcare Inspections**

**Report No. 15-01043-247**

## **Healthcare Inspection**

# **Alleged Unsafe Blood Transfusion Practices Battle Creek VA Medical Center Battle Creek, Michigan**

**May 25, 2017**

**Washington, DC 20420**

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## Table of Contents

	<b>Page</b>
<b>Executive Summary</b> .....	i
<b>Purpose</b> .....	1
<b>Background</b> .....	1
<b>Scope and Methodology</b> .....	5
<b>Patient Case Summary</b> .....	7
<b>Inspection Results</b> .....	9
Issue 1. Unsafe Transfusion Policy and Practices .....	9
Issue 2. Failure to Report Blood Transfusion Adverse Reaction .....	10
Issue 3. Peer Review Committee Procedure Issues .....	11
<b>Conclusions</b> .....	11
<b>Recommendations</b> .....	12
<b>Appendixes</b>	
A. Veterans Integrated Service Network Director Comments .....	13
B. Battle Creek VA Medical Center Director Comments .....	14
C. Office of Inspector General Contact and Staff Acknowledgments .....	17
D. Report Distribution.....	18

## Executive Summary

The VA Office of Inspector General (OIG) conducted a healthcare inspection in response to a complaint received in 2014 about unsafe blood transfusion practices at the Battle Creek VA Medical Center (BCVAMC) in Battle Creek, MI. Specifically, the complainant alleged that a patient experienced an adverse reaction because of the unsafe transfusion practices of a BCVAMC hospitalist. Veterans Integrated Service Network (VISN) staff initially conducted a review of the matter, but the OIG determined that the VISN review was inadequate, necessitating this OIG healthcare inspection.

We substantiated that a BCVAMC hospitalist contributed to a patient's adverse reaction by engaging in unsafe transfusion practices. The patient's pre-transfusion medical issues and chest x-ray findings indicated that the hospitalist should have reassessed the need to transfuse 3 units of packed red blood cells and monitored the patient's clinical status, including hemoglobin levels, more closely. The hospitalist did not document the need (initially or after each transfusion) to transfuse 3 units of packed red blood cells. The increase in blood volume from 3 units of transfused blood contributed to the patient experiencing a potentially life threatening adverse reaction due to circulatory overload.

A lack of guidance in the BCVAMC policy, which did not support the AABB<sup>1</sup> recommended standards for single unit transfusions, likely contributed to the hospitalist's unsafe transfusion practices. Although not directly related to the patient's case, unit staff also identified communication barriers that may have affected professional clinical collaboration.

BCVAMC policy requires providers to report blood transfusion related adverse reactions, including circulatory overload, to the Blood Usage Review Committee for analysis to help prevent similar adverse reactions from occurring in the future. Because providers did not report this patient's adverse reaction, the Blood Usage Review Committee did not analyze the circumstances surrounding the event. In addition, we found that the Transfusion Officer on the committee was also the physician who ordered and supervised the majority of transfusions, presenting a potential conflict of interest between committee responsibilities and professional responsibilities.

Additionally, we found that the Peer Review Committee did not follow all Veterans Health Administration peer review policies and procedures. We provided BCVAMC leaders a summary of our findings.

We recommended that the BCVAMC Director ensure that:

- BCVAMC managers update the medical center blood transfusion policy to align with AABB blood transfusion guidelines.

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<sup>1</sup> Prior to 2005, the AABB was known as the American Association of Blood Banks but is now known only by its acronym. The AABB is the organization that establishes and publishes transfusion and cellular therapy procedures and guidelines.

- Providers follow medical center policy and report transfusion adverse reactions to the Blood Usage Review Committee for review.
- The Transfusion Officer who is appointed to the Blood Usage Review Committee has no conflict of interest between committee and professional responsibilities.
- For level 2 and level 3 peer reviews, the Peer Review Committee provide recommendations to supervisors of non-punitive and non-disciplinary actions, that supervisors discuss and follow up with providers, and that Peer Review Committee minutes include documentation of actions and of supervisory follow-up as required by the Veterans Health Administration.

## Comments

The Veterans Integrated Service Network and Facility Directors concurred with our recommendations and provided acceptable action plans. (See Appendixes A and B, pages 13–16 for the Directors' comments.) We will follow up on the planned actions until they are completed.



JOHN D. DAIGH, JR., M.D.  
Assistant Inspector General for  
Healthcare Inspections

## Purpose

The VA Office of Inspector General (OIG) conducted a healthcare inspection to assess the merit of an allegation made in 2014 by a complainant regarding unsafe blood transfusion practices by a hospitalist<sup>2</sup> at the Battle Creek VA Medical Center (BCVAMC), Battle Creek, MI.

## Background

BCVAMC provides tertiary psychiatric care, primary and secondary medical care, and extended and long-term care to veterans in the western and lower Michigan peninsula. BCVAMC has 276 total beds and includes a Community Living Center and Residential Rehabilitation Treatment Program. Community based outpatient clinics are located in Benton Harbor, Lansing, and Muskegon, MI, and a Health Care Center is located in Wyoming, MI. BCVAMC is part of Veterans Integrated Service Network (VISN) 10.

**Blood Transfusions.** Hemoglobin (Hgb) is a red blood cell protein that carries oxygen from the lungs to body tissues.<sup>3</sup> Patients diagnosed with anemia have a reduced number of circulating red blood cells, which lowers Hgb levels.<sup>4</sup> Symptoms of anemia occur when low Hgb levels in the blood cannot meet the oxygen needs of the body<sup>5</sup> resulting in fatigue (the most common symptom), dizziness, and headache.<sup>6</sup> Causes of anemia include illnesses that affect the production of red blood cells in the bone marrow as well as blood loss for any reason.<sup>7,8</sup> Providers may treat anemic patients with blood transfusions.

Because blood transfusions may pose health risks to patients, transfusion benefits must outweigh the risk of injury.<sup>9</sup> Some risks may be life threatening such as transfusion-related acute lung injury and circulatory overload.<sup>10,11</sup> Blood components

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<sup>2</sup> A hospitalist is a practitioner (physician, nurse practitioner or physician assistant) who is engaged in clinical care, teaching, research, and/or leadership in the field of hospital medicine.

[https://www.hospitalmedicine.org/Web/About\\_SHM/Hospitalist\\_Definition/About\\_SHM/Industry/Hospital\\_Medicine\\_Hospital\\_Definition.aspx?hkey=fb083d78-95b8-4539-9c5b-58d4424877aa](https://www.hospitalmedicine.org/Web/About_SHM/Hospitalist_Definition/About_SHM/Industry/Hospital_Medicine_Hospital_Definition.aspx?hkey=fb083d78-95b8-4539-9c5b-58d4424877aa). Accessed on August 17, 2016.

<sup>3</sup> Hemoglobin is a red blood cell protein that carries oxygen from the lungs to body tissues and carbon dioxide from the tissues to the lungs. Merriam Webster. <http://www.merriam-webster.com/dictionary/hemoglobin>. Accessed May 4, 2016.

<sup>4</sup> Venes, Donald, M.D., M.S.J, ed. *Tabor's Cyclopedic Dictionary* 20<sup>th</sup> ed. Philadelphia, PA: F.A. Davis Company; 2005.

<sup>5</sup> Ibid.

<sup>6</sup> U.S. Department of Health and Human Services, National Heart, Lung and Blood Institute.

<https://www.nhlbi.nih.gov/health/health-topics/topics/ida/signs>. Accessed October 19, 2016.

<sup>7</sup> Venes, Donald, M.D., M.S.J, ed. *Tabor's Cyclopedic Dictionary* 20<sup>th</sup> ed. Philadelphia, PA: F.A. Davis Company; 2005.

<sup>8</sup> Mayo Clinic Tests and Procedures Blood Transfusion. <http://www.mayoclinic.org/tests-procedures/blood-transfusion/basics/why-its-done/prc-20021256>. Accessed May 17, 2016.

<sup>9</sup> American Society of Hematology, Transfusion guidelines: when to transfuse,

<http://asheducationbook.hematologylibrary.org/content/2013/1/638.full>. Accessed May 17, 2016.

<sup>10</sup> Circulatory overload is an increase in a patient's blood volume, usually caused by transfusion or infusion of excessive amounts of fluid.

such as blood plasma, platelets, and red blood cells are used in transfusions. Red blood cell transfusions are the focus of this inspection.<sup>12</sup> Providers order red blood cells as packed red blood cells (PRBCs), which are administered to patients in unit increments.<sup>13</sup>

Transfusion Associated Circulatory Overload. Patients who cannot tolerate the increased blood volume from transfusions are at risk of developing an adverse reaction known as transfusion associated circulatory overload (TACO). The risk for TACO increases in patients with pre-existing cardiac illnesses, such as congestive heart failure (CHF), or when the volume of fluid consumed is greater than the volume eliminated (positive fluid balance).<sup>14</sup> In patients with CHF, the heart cannot pump blood effectively, slowing the flow of blood out of the heart. As a result, blood returning to the heart backs up, causing congestion in body tissues and pooling of fluid in the lungs and extremities.<sup>15</sup> Providers must be cautious when assessing transfusion patients with cardiovascular issues, as anemia symptoms for these patients can include symptoms such as chest pain or shortness of breath, which may also be indicative of a worsening cardiac condition.<sup>16,17</sup>

Patients developing TACO typically experience symptoms within 6 hours following a blood transfusion. These symptoms may include increased difficulty in breathing, hypertension, increased heart rate, cough, orthopnea,<sup>18</sup> and hypoxia.<sup>19</sup> Arterial blood gas<sup>20</sup> and oximetry tests both measure hypoxia. Oximetry tests determine the oxygen saturation of blood.<sup>21</sup> Blood oxygen saturation (O<sub>2</sub> saturation) percentages are considered abnormal if below 90 percent<sup>22</sup> and, per facility policy, if below 90 percent on

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<sup>11</sup> Merck Manual Professional Version Online, Complications of Transfusion, <http://www.merckmanuals.com/professional/hematology-and-oncology/transfusion-medicine/complications-of-transfusion>. Accessed May 3, 2016.

<sup>12</sup> Mayo Clinic Tests and Procedures Blood Transfusion, <http://www.mayoclinic.org/tests-procedures/blood-transfusion/basics/why-its-done/prc-20021256>. Accessed May 17, 2016.

<sup>13</sup> The Internet Pathology Laboratory for Medical Education, <http://library.med.utah.edu/WebPath/TUTORIAL/BLDBANK/BBPROD.html>. Accessed May 17, 2016.

<sup>14</sup> National Healthcare Safety Network Hemovigilance Module: Adverse Reaction Definitions taken from NHSN Biovigilance Component: Hemovigilance Module Surveillance Protocol v2.1.2. *AABB Center for Patient Safety Quick Reference Guide*. January 2014.

<sup>15</sup> American Heart Association, Types of Heart Failure, [http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Types-of-Heart-Failure\\_UCM\\_306323\\_Article.jsp#.WBdVbKqa3L8](http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Types-of-Heart-Failure_UCM_306323_Article.jsp#.WBdVbKqa3L8). Accessed June 29, 2016.

<sup>16</sup> American Society of Hematology, Transfusion Guidelines: when to transfuse, <http://asheducationbook.hematologylibrary.org/content/2013/1/638.full>. Accessed May 17, 2016.

<sup>17</sup> UpToDate, <http://www.uptodate.com/contents/heart-failure-beyond-the-basics>. Accessed January 11, 2017.

<sup>18</sup> Orthopnea is shortness of breath when lying down, that is relieved by sitting up (cannot breath lying down).

<sup>19</sup> Hypoxia is an oxygen deficiency in the body's tissues.

<sup>20</sup> Arterial blood gas tests measure how well the lungs are able to move oxygen into the blood and remove carbon dioxide from the blood and are typically ordered when patients have worsening respiratory symptoms.

<sup>21</sup> Venes, Donald, M.D., M.S.J, ed. *Tabor's Cyclopedic Dictionary* 20<sup>th</sup> ed. Philadelphia, PA: F.A. Davis Company; 2005.

<sup>22</sup> Mayo Clinic Symptoms Hypoxemia, <http://www.mayoclinic.org/symptoms/hypoxemia/basics/definition/sym-20050930>. Accessed October 31, 2016.

room air, may indicate respiratory issues related to the transfusion.<sup>23</sup> Treatment for TACO, recognized as a common adverse reaction to blood transfusion,<sup>24</sup> includes the administration of diuretic medications<sup>25</sup> and oxygen.

Clinical Practice Guidelines for PRBC Transfusion. According to AABB<sup>26</sup> guidelines, transfusions are indicated at different Hgb blood levels depending on the patient's condition and a provider's clinical assessment.<sup>27</sup> Clinical guidelines for men suggest a normal hemoglobin range of 13.8 to 17.2 grams per deciliter (g/dL).<sup>28</sup> BCVAMC applies a comparable normal range of 13 to 16g/dL. According to AABB, PRBC transfusions may be indicated for patients with cardiovascular conditions when Hgb levels are 8g/dL or less.<sup>29,30</sup>

For patients not actively bleeding, AABB guidelines recommend a single unit PRBC transfusion followed by a clinical assessment of the patient's condition.<sup>31</sup> Research has shown that liberal transfusion strategies, such as ordering 2 or 3 units for every patient, do not always produce superior patient outcomes and "may expose patients to unnecessary risks."<sup>32</sup> One unit of PRBCs typically increases a patient's Hgb level by 1g/dL.<sup>33</sup> Thus, single unit transfusions are often enough to relieve patients' symptoms, and patients may not need a second unit. The single unit strategy involves strict adherence to a restrictive transfusion threshold, which includes clinical symptom assessment and/or hemoglobin tests. When a patient develops symptoms that may either be an indicator of transfusion overload or disease progression, such as with cardiovascular disease, providers must use clinical judgement to advocate the best management for their patients and limit the patient's exposure to the possibility of adverse reactions, such as TACO, due to multiple transfusions.<sup>34</sup>

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<sup>23</sup> Medical Center Memorandum 115p-1003, *Blood Transfusion*. February 2014.

<sup>24</sup> Roubinian NH, Murphy EL, Transfusion-Associated Circulatory Overload (TACO): prevention, management, and patient outcomes. *International Journal of Transfusion Medicine*, Vol. 3 pp. 17–28. April 24, 2015. <https://www.dovepress.com/transfusion-associated-circulatory-overload-taco-prevention-management-peer-reviewed-fulltext-article-IJCTM>. Accessed May 4, 2016.

<sup>25</sup> Diuretics are medications that reduce fluid volume in the body by increasing urination.

<sup>26</sup> Prior to 2005, the AABB was known as the American Association of Blood Banks but is now known only by its acronym. The AABB is the organization that establishes and publishes transfusion and cellular therapy procedures and guidelines.

<sup>27</sup> AABB, *Red Blood Cell Transfusion: A Clinical Practice Guideline*, July 2012.

<http://annals.org/article.aspx?articleid=1206681>. Accessed May 4, 2016.

<sup>28</sup> U.S. National Library of Medicine, Medline Plus, *Hemoglobin*. <https://medlineplus.gov/ency/article/003645.htm>. Accessed on August 31, 2016.

<sup>29</sup> Mark Fung, Eighteenth Edition, *Technical Manual*, Bethesda, Maryland: AABB 2014, p. 501.

<sup>30</sup> American Society of Hematology, Transfusion guidelines: when to transfuse. <http://asheducationbook.hematologylibrary.org/content/2013/1/638.full>. Accessed May 5, 2016.

<sup>31</sup> Mark Fung, Eighteenth Edition, *Technical Manual*, Bethesda, Maryland: AABB 2014, p. 610.

<sup>32</sup> American Society of Hematology, Transfusion guidelines: when to transfuse, <http://asheducationbook.hematologylibrary.org/content/2013/1/638.full>. Accessed May 17, 2016.

<sup>33</sup> Robert Weinstein, *2012 Clinical Practice Guide on Red Blood Cell Transfusion*, adapted from "Red Blood Cell Transfusion: A Clinical Practice Guideline from the AABB." *Ann Intern Med*. 2012; 157: pp. 49–58.

<sup>34</sup> American Society of Hematology, Transfusion guidelines: when to transfuse. <http://asheducationbook.hematologylibrary.org/content/2013/1/638.full>. Accessed May 5, 2016.

Veterans Health Administration and BCVAMC Policy. Veterans Health Administration (VHA) requires facilities to establish Transfusion Utilization Committees, policies, and procedures to promote safe transfusion practices and to monitor transfusion usage and adverse outcomes.<sup>35</sup> The policy also requires staff to collect data on adverse reactions resulting from blood transfusions, such as circulatory overload, and report the data to a Transfusion Utilization Committee for further review and evaluation. The goal is to minimize the risk of transfusion-related adverse events and outcomes.

The Blood Usage Review (BUR) Committee is the designated BCVAMC Transfusion Utilization Committee. According to BCVAMC policy, providers who confirm a transfusion-related adverse reaction must complete a blood transfusion reaction report and provide the report to the BUR Committee for review.<sup>36</sup> The BCVAMC's BUR Committee members include the Hematology Section supervisor, who acts as the Chair; a Transfusion Officer appointed by the Chief of Staff; the Laboratory Director; the Chief of Ancillary Services; the Patient Safety Manager; a Nurse Manager; the Chief of Quality Resource Services; and the Clinical Laboratory Manager. In addition to reviewing transfusion-related adverse reactions, the committee may also refer cases for peer review evaluation.<sup>37</sup>

**Peer Review for Quality Management.** VHA defines peer review as an organized process carried out by an individual health care professional and a selected committee of professionals to evaluate the performance of another professional. Although this process sometimes identifies organizational system issues, the primary goal is overall improvement of care through a review of individual provider decisions and case management of a patient's care. Information gathered during the process concerning the individual provider and specific BCVAMC system quality assurance practices is confidential and generally protected by Title 38 of the United States Code (USC), section(§) 5705.<sup>38</sup>

The BCVAMC must follow specific VHA requirements to complete the process correctly and ensure that providers gain insight into quality assurance and patient care practices. To ensure this process functions appropriately, a clinical professional in the same medical field (a peer) reviews the identified provider's episode of care decisions and assigns a level of performance.<sup>39</sup>

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<sup>35</sup> VHA Directive 2009-005, *Transfusion Utilization Committee and Program*, February 9, 2009. This Directive was in effect during the time frame of the events discussed in this report; it was rescinded on September 11, 2015 and replaced with VHA Directive 1185. The 2015 Directive contains the same or similar language regarding the establishment of a Transfusion Utilization Committee.

<sup>36</sup> Medical Center Memorandum 115p-1003, *Blood Transfusion*, February 2014.

<sup>37</sup> BCVAMC MCM 9621, *Blood Usage Review Committee*, October 2012. This policy was in place at the time of our review and was replaced by BCVAMC MCM 9621, *Blood Usage Review Committee*, December 2014. Both policies have the same or similar BUR Committee requirements.

<sup>38</sup> VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010. This Directive expired June 30, 2015 and has not yet been updated.

<sup>39</sup> VHA Directive 2010-025.

The determination of a Level 1 peer review result indicates that most experienced, competent providers would have managed the case in a similar manner. A Level 2 result is an indication that the peer reviewer has determined that most experienced, competent providers might have managed the case differently. A Level 3 determination indicates that most experienced, competent providers would have managed the case differently.<sup>40</sup>

Once clinical peers assign a level, the Peer Review Committee (PRC), with input from the reviewed provider, evaluates the review and establishes a final level. When a peer-reviewed provider's actions are determined to be level 2 or level 3, the PRC makes recommendations to the provider's supervisor for non-punitive, non-disciplinary actions to discuss and follow up with the provider. The supervisor must report to the committee when follow-up actions with the provider are complete.<sup>41</sup>

**Allegations.** On November 10, 2014, OIG received an allegation that, in 2014, a patient experienced an adverse reaction because of unsafe transfusion practices employed by a BCVAMC hospitalist.

Initially, the OIG Hotline Division requested that the VISN conduct a review of the complainant's allegation and submit a response. OIG determined the VISN's response to the allegation was insufficient and initiated this inspection on November 11, 2015.

## Scope and Methodology

We initiated our review in November 2015 and completed our work in November 2016. To determine the merit of the allegation, we interviewed the complainant and conducted a site visit January 5–7, 2016. We interviewed nursing staff, the Nurse Manager, the Nurse Practitioner, and the Physician Assistant assigned to the unit where staff administered blood transfusions to the patient. We also interviewed the Chief of Staff, the Associate Chief of Staff, the BUR Committee Chairperson, and the hospitalist, who was also the Transfusion Officer.

We reviewed BCVAMC and VHA policies and procedures, and AABB guidelines. We assessed whether BCVAMC system issues existed relating to transfusion practices, and we reviewed the BUR Committee and PRC procedures and meeting minutes for fiscal year 2015, as these committees' responsibilities included addressing transfusion adverse reactions and provider actions.<sup>42,43</sup>

VHA Directive 2010-025, *Peer Review for Quality Management*, June 3, 2010, cited in this report, expired June 30, 2015. We considered this policy to be in effect, as it had not been superseded by more recent policy or guidance. In a

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<sup>40</sup> VHA Directive 2010-025.

<sup>41</sup> Ibid.

<sup>42</sup> Medical Center Memorandum 115p-1003, *Blood Transfusion*, February 2014.

<sup>43</sup> BCVAMC MCM 11-1066, *Peer Review for Quality Management*, October 2012.

June 29, 2016 memorandum to supplement policy provided by VHA Directive 6330(1),<sup>44</sup> the VA Under Secretary for Health (USH) mandated the "...continued use of and adherence to VHA policy documents beyond their recertification date until the policy is rescinded, recertified, or superseded by a more recent policy or guidance."<sup>45</sup> The USH also tasked the Principal Deputy Under Secretary for Health and Deputy Under Secretaries for Health with ensuring "...the timely rescission or recertification of policy documents over which their program offices have primary responsibility."<sup>46</sup>

We **substantiate** allegations when the facts and findings support that the alleged events or actions took place. We **do not substantiate** allegations when the facts show the allegations are unfounded. We **cannot substantiate** allegations when there is no conclusive evidence to either sustain or refute the allegation.

We conducted the inspection in accordance with *Quality Standards for Inspection and Evaluation* published by the Council of the Inspectors General on Integrity and Efficiency.

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<sup>44</sup> VHA Directive 6330(1), *Controlled National Policy/Directives Management System*, June 24, 2016, amended January 11, 2017.

<sup>45</sup> VA Under Secretary for Health Memorandum, *Validity of VHA Policy Document*, June 29, 2016.

<sup>46</sup> *Ibid.*

## Patient Case Summary

In 2014, a male in his 60s with diabetes, chronic kidney disease, and a history of CHF arrived at the BCVAMC's Urgent Care Clinic. After an assessment, the Medical Officer of the Day (MOD) admitted the patient to BCVAMC with acute renal<sup>47</sup> injury and anemia.

According to the patient's electronic health record (EHR), over the next few days, the patient received treatment including the administration of intravenous (IV)<sup>48</sup> fluids. His renal condition improved, but his anemia worsened, and he began having difficulty breathing. On the day of admission (Day 1), a respiratory therapist recorded the patient's baseline O<sub>2</sub> saturation level on room air (without supplemental oxygen) at 95 percent.<sup>49</sup> Upon examination, the MOD noted that the patient had no rales or crackles<sup>50</sup> and no fluid in the lungs. On Day 3, due to increasing shortness of breath, rales in his lung bases, and a decrease in his O<sub>2</sub> saturation level to 86–88 percent, the MOD ordered oxygen supplementation at a low level of 1 Liter/minute (L/m). According to the EHR, the patient's O<sub>2</sub> saturation level returned to 94 percent.

On Day 4, a nurse noted that the patient appeared more tired and lethargic, and the MOD ordered an Hgb blood test, cardiopulmonary consult, and a chest x-ray. The MOD also increased the patient's oxygen to 2 L/m. A nurse noted in the EHR that the patient's fluid intake, which included IV fluids, and output (generally urination) showed that the patient was taking in about twice the amount of fluids as he was eliminating from his body.

On Day 5, the hospitalist described the patient's lungs as clear, and a nurse again noted that the patient's fluid output was less than his fluid intake. On that date, the patient's Hgb was between 7 and 8 g/dL, and the hospitalist recommended a PRBC transfusion. The patient signed the necessary consent forms, and the hospitalist ordered 3 units of PRBCs and an Hgb blood test to be done following administration of the third unit.

On the morning of Day 6, prior to the first transfusion, a radiologist performed a chest x-ray and noted that the chest x-ray results revealed radiographic findings most consistent with pulmonary edema<sup>51</sup> and recommended clinical consideration for acute CHF. He also reported that the chest x-ray showed a notably enlarged heart and increased bilateral pleural effusions<sup>52</sup> since the patient's last chest x-ray done

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<sup>47</sup> Renal refers to or pertains to the kidney.

<sup>48</sup> Intravenous refers to the administration of fluids or medications directly into veins.

<sup>49</sup> Normal values of O<sub>2</sub> saturations range between 94–100 percent.

<sup>50</sup> Crackles and rales are sporadic abnormal breath sounds.

<sup>51</sup> Pulmonary edema is an abnormal buildup of fluid in the lungs, which leads to shortness of breath. It is often caused by CHF because the heart is unable pump the blood efficiently, and blood backs up into the veins that take blood through the lungs. <https://medlineplus.gov/ency/article/000140.htm>. Accessed August 16, 2016.

<sup>52</sup> Pleural effusion refers to a collection of fluid in the pleural (lung membrane) space that can be seen and detected only by an x-ray, <https://radiopaedia.org/articles/pleural-effusion>. Accessed June 6, 2016

approximately 2½ weeks prior to admission, and that the findings needed the provider's attention. A cardiopulmonary consult was scheduled for Day 7.

The patient received the first unit of PRBCs shortly before noon on Day 6. A nurse acknowledged the presence of bilateral pulmonary effusions prior to administering the blood but noted the hospitalist's instructions that it was "ok to administer with effusions." After the completion of the first unit approximately 3 hours later, the hospitalist documented the radiologist's chest x-ray findings in a progress note. He assessed the patient and found crackles at the patient's lung bases, indicating fluid in the lungs. The hospitalist ordered an immediate, one-time IV diuretic dose, an IV diuretic every 8 hours, and the discontinuation of the IV fluids previously ordered for the patient's renal condition. During the time the patient received the transfusion, his O<sub>2</sub> saturation level remained in the 90s.

About 1 hour after the first unit had infused, a nurse began administering the second unit of PRBCs and again documented the hospitalist's instructions that it was "ok to transfuse with effusions." During the second transfusion, the patient's O<sub>2</sub> saturation level remained above 90 percent. Approximately 3 hours after the completion of the second unit, a nurse noted scattered crackles at the patient's lung bases and administered an IV diuretic ordered by the hospitalist. However, the hospitalist did not assess the patient. According to a nursing assessment, the blood transfusion did not affect or worsen the patient's respiratory status at that time. A respiratory therapist assessed the patient and determined the patient's O<sub>2</sub> saturation level was 89 percent. The respiratory therapist increased the patient's O<sub>2</sub> to 4 L/m and, after several minutes, the patient's O<sub>2</sub> saturation level increased to 92 percent. On the post-transfusion assessment, a nurse noted that the patient had pleural effusions; but, other than the drop noted by respiratory therapy immediately after the transfusion, the O<sub>2</sub> saturation level remained above 90 percent at 2, 4, and 6 hours after the transfusion, indicating no circulatory overload.

Around midnight on Day 6, a nurse began administering the third unit of PRBCs. At that time, the patient's O<sub>2</sub> saturation level was 97 percent; 15 minutes later, the saturation level was 96 percent. An hour later, a nurse called a respiratory therapist because the patient began having difficulty breathing. The patient's O<sub>2</sub> saturation level had dropped to 89 percent. The respiratory therapist described the patient as sitting up in bed in a tripod position (leaning forward and resting on hands), rather than lying down, taking shallow gasping breaths, and complaining that he could not breathe. The respiratory therapist gave the patient an inhalant treatment specifically ordered by the physician every 2 hours as needed for shortness of breath and discussed the patient's condition with the nurse. At that time, the patient was attentive and able to work with the respiratory therapist to use the inhalant, but the therapist reported that the patient was also very anxious and that anxiety might be contributing to the patient's condition.

A nurse measured the patient's O<sub>2</sub> saturation level upon completion of the third transfusion and found it had increased to 95 percent. About 15 minutes after completion of the third unit, the MOD, responding to information concerning the patient's condition, ordered immediate doses of both an IV diuretic for shortness of breath and an

IV medication for the patient's anxiety. A nurse administered both medications shortly after receiving the orders.

After receiving the additional medications, a nurse documented that the patient was experiencing an increase in shortness of breath, an increase in oxygen demand, high blood pressure, and anxiety. A respiratory therapist, responding to a request to assess the patient 2 hours after the patient received the diuretic and anti-anxiety medication, found him sitting in a tripod position, appearing to be in increased respiratory distress as compared to the previous assessment. The MOD transferred the patient to the Special Needs Unit for closer monitoring and immediately ordered a higher dose of an IV diuretic, a blood pressure medicine for the patient's hypertension, and arterial blood gases to assess the patient's respiratory status. The MOD documented the patient's blood pressure, which was higher than the previous measurement. According to the EHR, blood gases drawn showed that the patient was hypoxic.<sup>53</sup> In response, the MOD placed the patient on a bi-level positive airway pressure<sup>54</sup> device, increased the O<sub>2</sub> to 5 L/m, and continued diuretic treatment and close monitoring. A nurse documented on the post-transfusion assessment note that the patient experienced circulatory overload within 6 hours after the transfusion and the MOD had been contacted.

The MOD documented that despite the IV diuretic administered, the patient had trouble breathing after the transfusion of 3 units of PRBCs. The MOD assessed the patient's deteriorated clinical state as respiratory failure secondary to worsening CHF. Later in the morning of Day 7, the hospitalist resumed care of the patient, ordered additional doses of an IV diuretic and anti-anxiety medications, and added respiratory medications to the patient's treatment. A chest x-ray done that morning showed bilateral changes throughout the lower lobes, indicative of decreased lung function and collapse. The patient's Hgb value on Day 7 was between 11 and 12 g/dL.

Over the next several days, the patient's respiratory condition stabilized, and on Day 12 he was transferred to the VA Ann Arbor Healthcare System for further renal work-up. The patient's hospital discharge summary described the patient's CHF as getting worse after the patient received 3 units of blood. A nephrology consult completed at Ann Arbor on Day 13 indicated the patient "received three units of PRBCs on [Day 6], with subsequent TACO and respiratory distress."

## Inspection Results

### Issue 1: Unsafe Transfusion Policy and Practices

We substantiated the allegation that a hospitalist engaged in unsafe PRBC transfusion practices, which resulted in a patient experiencing an adverse reaction.

<sup>53</sup> Hypoxia results from a lower than normal concentration of oxygen in arterial blood causing shortness of breath, which, if the condition continues, may cause brain damage or death.

<sup>54</sup> A bi-level positive airway pressure device, also known as a BIPAP, provides ventilator assistance to patients with respiratory insufficiency.

The patient's Hgb level of <8 g/dL supported the decision for the hospitalist to administer a PRBC transfusion. However, according to AABB clinical practice guidelines, a transfusion of one unit of PRBCs would likely have increased the patient's Hgb level to >8 g/dl, above the AABB recommended level to transfuse patients with a cardiovascular condition such as CHF. The patient's deteriorating respiratory condition, positive fluid balance, and pre-transfusion chest x-ray suggested the presence of heart failure and identified the need to closely monitor the patient's clinical condition and assess the patient for further transfusions. However, rather than take the single unit approach recommended by the AABB, the hospitalist ordered 3 units of PRBCs for transfusion, increasing the patient's risk of experiencing TACO.

After transfusion of the first unit, the hospitalist acknowledged the chest x-ray findings. He also detected fluid in the patient's lungs and adjusted the patient's plan of care by discontinuing the IV fluids and giving the patient an IV diuretic. However, the hospitalist did not discontinue the remaining two transfusions or order an Hgb level to assess whether the patient needed additional units. According to the EHR, after the third unit, the patient experienced circulatory overload, or TACO, which required transfer to the Special Needs Unit for closer monitoring and additional treatments.

An additional factor that may have contributed to the hospitalist's unsafe transfusion practices was the lack of guidance in the BCVAMC transfusion policy. The policy did not follow the AABB guidelines and recommendations regarding single unit transfusions.

Though not directly related to the patient's case, staff identified communication issues, citing possible language and cultural barriers that may have contributed to a lack of professional collaboration.

## **Issue 2: Failure to Report Blood Transfusion Adverse Reaction**

Though not an allegation, we found that providers did not follow BCVAMC policy when they failed to report a blood transfusion adverse reaction to the BUR Committee.

BCVAMC policy requires that the attending provider discuss the patient's condition with the Transfusion Officer and complete a blood transfusion reaction report when a blood transfusion adverse reaction occurs. This process of completing a report should occur regardless of whether the attending provider is the Transfusion Officer or another provider.<sup>55</sup>

Additionally, BCVAMC policy requires the Transfusion Officer and the Laboratory Director perform intensive evaluations of all transfusion reaction reports and present the results to the BUR Committee for further analysis. The committee is required to meet

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<sup>55</sup> BCVAMC MCM 115P-1003, *Blood Transfusions*, February 2014.

quarterly and review all identified transfusion adverse reaction reports to minimize the risk of similar transfusion adverse events from occurring.<sup>56,57</sup>

The MOD's EHR progress note stated the patient's symptoms resulted from the transfusion of 3 PRBC units. However, we found no documentation that the MOD or hospitalist (Transfusion Officer) discussed or completed a transfusion reaction report.

In addition, the BUR Committee meeting minutes that would have documented reviews of any events that occurred during the time period covered by the Case Summary above, did not include and did not identify the patient who developed an adverse reaction after receiving 3 units of PRBCs.

According to the hospitalist's supervisors, the hospitalist (who served as the Transfusion Officer on the BUR Committee) ordered and performed the majority of the transfusions. Both supervisors told us that this fact might have been a conflict of interest for the hospitalist, affecting the decision not to report adverse transfusion reactions to the BUR Committee.

### **Issue 3: Peer Review Committee Procedure Issues**

Although not an allegation, we found that the BCVAMC PRC did not follow all VHA peer review policies and procedures regarding documentation of committee recommendations for actions and follow up by supervisors.<sup>58</sup> We provided BCVAMC leaders a summary of our findings.

## **Conclusions**

We substantiated the allegation that a BCVAMC hospitalist engaged in unsafe PRBC transfusion practices that resulted in a patient's adverse reaction. We found that the hospitalist ordered 3 units of PRBCs for transfusion and did not monitor the patient's clinical status, including hemoglobin levels, between units. The radiologist's interpretation of the patient's chest x-ray the morning just prior to the transfusion noted that the patient's condition was consistent with acute CHF and noted the existence of bilateral pleural effusions and an enlarged heart. Aware of this cardiopulmonary condition after the transfusion of the first unit, the hospitalist did not order an Hgb test to assess whether the patient needed the second or the third unit. Furthermore, the hospitalist did not change the number of units ordered and did not order Hgb tests between the administration of the second and third unit. The patient experienced TACO, an adverse reaction to the PRBC transfusions. A lack of guidance in the BCVAMC policy also likely contributed to the hospitalist's unsafe transfusion practices.

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<sup>56</sup> BCVAMC MCM 9621.

<sup>57</sup> Ibid.

<sup>58</sup> VHA Directive 2010-025.

Although not directly related to the patient case, staff identified some communication barriers that may have negatively affected professional collaboration on the unit. These issues may need further investigation by the BCVAMC leadership staff.

Neither the hospitalist nor the MOD followed BCVAMC policy to report the blood transfusion adverse reaction and to complete a transfusion adverse reaction report. The BUR Committee had no documentation of the adverse reaction and, as a result, did not conduct the necessary analysis to help prevent potential similar events from recurring. The Transfusion Officer on the committee ordered and supervised the majority of transfusions, which presented a potential conflict of interest between committee responsibilities and professional responsibilities.

Additionally, we found that the PRC did not follow VHA policy regarding documentation of committee recommendations for actions and follow-up by supervisors.

## Recommendations

1. We recommended that the Battle Creek VA Medical Center Director ensure that Battle Creek VA Medical Center managers update the blood transfusion policy to align with AABB blood transfusion guidelines.
2. We recommended that the Battle Creek VA Medical Center Director ensure that providers follow Battle Creek VA Medical Center policy and report all transfusion adverse reactions to the Blood Usage Review Committee for review.
3. We recommended that the Battle Creek VA Medical Center Director ensure that the Transfusion Officer who is appointed to the Blood Usage Review Committee has no conflict of interest between committee and professional responsibilities.
4. We recommended that the Battle Creek VA Medical Center Director ensure that for level 2 and level 3 peer reviews, the Peer Review Committee provide recommendations to supervisors of non-punitive and non-disciplinary actions, that supervisors discuss and follow up with providers, and that Peer Review Committee minutes include documentation of actions and of supervisory follow-up as required by the Veterans Health Administration.

## VISN Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

**Date:** March 7, 2017

**From:** Director, Veterans in Partnership (10N10)

**Subj:** Healthcare Inspection—Alleged Unsafe Blood Transfusion Practices,  
Battle Creek VA Medical Center, Battle Creek, Michigan

**To:** Director, Bedford Office of Healthcare Inspections (54BN)  
Director, Management Review Service (VHA 10E1D MRS Action)

1. Thank you for the opportunity to review the draft report regarding the Healthcare Inspection – Alleged Unsafe Blood Transfusion Practices at the Battle Creek VA Medical Center.
2. I concur with the report and Implementation Plans submitted by the Battle Creek VA Medical Center.

Robert P.  
McDivitt 282600

Digitally signed by Robert P. McDivitt 282600  
DN: dc=gov, dc=va, o=internal, ou=people,  
0.9.2342.19200300.100.1.1=robert.mcdivitt@va.  
gov, cn=Robert P. McDivitt 282600  
Reason: Concur  
Date: 2017.03.09 16:11:53 -05'00'

## BCVAMC Director Comments

**Department of  
Veterans Affairs**

**Memorandum**

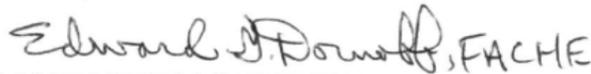
**Date:** March 7, 2017

**From:** Director, Battle Creek VA Medical Center (515/00)

**Subj:** Healthcare Inspection—Alleged Unsafe Blood Transfusion Practices,  
Battle Creek VA Medical Center, Battle Creek, Michigan

**To:** Director, Veterans in Partnership (10N10)

1. The facility concurs with the report.
2. No additional comments.



(original signed by Edward G. Dornoff, Associate Director, for:  
Mary Beth Skupien, Ph.D.)

## Comments to OIG's Report

The following Director's comments are submitted in response to the recommendations in the OIG report:

### **OIG Recommendations**

**Recommendation 1.** We recommended that the Battle Creek VA Medical Center Director ensure that Battle Creek VA Medical Center managers update the blood transfusion policy to align with AABB blood transfusion guidelines.

Concur

Target date for completion: April 30, 2017

BCVAMC response: The blood transfusion policy is under review and is being rewritten to include alignment with AABB blood transfusion guidelines.

**Recommendation 2.** We recommended that the Battle Creek VA Medical Center Director ensure that providers follow Battle Creek VA Medical Center policy and report all transfusion adverse reactions to the Blood Usage Review Committee for review.

Concur

Target date for completion: April 30, 2017

BCVAMC response: Clarification of adverse action reporting is included in the draft of the medical center policy regarding blood utilization. Templates include instructions for providers for reporting to Blood Usage Review Committee in the event of suspected reaction. There have been no adverse reactions since January 2016. Suspected reactions are reported to the Transfusion Utilization Committee (formerly the Blood Usage Review Committee) members and included into the quarterly Transfusion Utilization Committee minutes.

**Recommendation 3.** We recommended that Battle Creek VA Medical Center Director ensure that the Transfusion Officer who is appointed to the Blood Usage Review Committee has no conflict of interest between committee and professional responsibilities.

Concur

Target date for completion: April 30, 2017

BCVAMC response: On January 8, 2016, a new Transfusion Officer with no conflict of interest was appointed.

To ensure that no conflict arises in the future, the following statements will be added to the Transfusion Utilization Committee policy:

- **Transfusion Officer:** A physician with knowledge and experience in blood banking or hematology, actively participating in the review program that monitors and addresses transfusion practices. When the Transfusion Officer is the attending provider for a transfusion, the data from that transfusion will be reviewed by the Associate Chief of Staff for Medical Service.
- **Associate Chief of Staff for Medical Service:** The Associate Chief of Staff for Medical Service is responsible to ensure that all providers are periodically reoriented with respect to their individual responsibilities and reviews transfusion data in cases where the Transfusion Officer was the attending provider.

**Recommendation 4.** We recommended that the Battle Creek VA Medical Center Director ensure that for level 2 and level 3 peer reviews, the Peer Review Committee provide feedback to supervisors of non-punitive and non-disciplinary actions, that supervisors discuss and follow up with providers, and that Peer Review Committee minutes include documentation of actions and supervisory follow-up as required by the Veterans Health Administration.

Concur

Target date for completion: June 30, 2017

BCVAMC response: At the conclusion of each Peer Review Committee meeting, the Risk Manager sends out specific case information and a follow-up form for the Service/Discipline Chief to discuss with the provider for level 2 and 3 peer reviews. During this meeting, the Service/Discipline Chiefs reviews with the provider the non-punitive recommendations from the Peer Review Committee. The form is routed to the Chief of Staff for review then back to the Risk Manager for the Peer Review file. This has been the practice of the Battle Creek VAMC since June 1, 2016.

The above information will be reflected in the Peer Review Committee Meeting Minutes beginning March 22, 2017 and we will monitor compliance by reviewing the Peer Review Committee Meeting Minutes for at least 3 months.

## OIG Contact and Staff Acknowledgments

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<b>Contact</b>	For more information about this report, please contact the OIG at (202) 461-4720.
<b>Contributors</b>	Emorfia Valkanos, RPh, Team Leader Nancy Barsamian, RN, MPH Elaine Kahigian, RN, JD Thomas Jamieson, MD Roneisha Charles, BS

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