KAISER PERMANENTE

Kaiser Permanente Medical Center, San Francisco
Northern California Region
********** **********

Work Instruction

Title:	**TQ-Transfusion Service Quality Monitors**	**WI Number** SFOWI-1213 **Revision:** 6
Department: Immunohematology **Area:** 2425 Geary Blvd SFO Hospital Lab	***Document is in the Final Approval Process. 2 - approvals are required***	
Type of Document: Work Instruction		**Review Period -** 340 **Days**

PURPOSE

To monitor critical quality indicators by systematic collection and analysis of data for the purpose of improving service and patient care.

QUALITY INDICATORS

Blood Administration Audit (Monthly)
Review QC documentation and maintenance/repair record (Monthly)
Specimen and Requisition Problems Audit (Monthly)
Blood Supplier Audit (Monthly)
Product Issue Audit (Monthly)
Variance Log Indicators (Quarterly)
Adverse Events (Quarterly)

GOALS

A. To ensure that quality indicators perform at expected standards.
B. To capture problems or identify potential problems or unhealthy trends from the data collected which can then be promptly addressed and corrected.

METHOD OF DATA COLLECTION

A. Staff documents all data or problems on the appropriate forms.
B. Data is collected daily, or at specified interval or when it occurs:
    1. Daily – Daily QC, Blood Supplier Audit, Product Issue Audit
    2. Specified Interval – Maintenance, Non-daily QC, Blood Administration Audit
    3. When it occurs - Variance Log, Specimen and Requisition Problems
C. Supervisor or designee reviews and analyzes and in some of the audits, also categorizes the data at specified intervals:
    1. Monthly - Review QC documentation and maintenance/repair record, Variance Log, Blood Supplier Audit, Product Issue Audit, Blood Administration Audit

DATA SUMMARY and REPORT

A. Problem, discrepancy or potential nonconformance identified through audits is investigated with formulation of corrective/preventive action. Information is shared with staff in monthly meetings.

B. A report of the data summary is prepared monthly and/or quarterly by the Supervisor/designee or ALAD (Assistant Laboratory Administrative Director) and submitted to the Medical Director, and hospital oversight committees for review i.e. Quality/RISK Management, Tissue and Transfusion/Blood Utilization Committee (TNT/BUC) and Medical Executive Committee (MEC).

PROCEDURE

NOTE: Responsible Reporting Form (RRF) will be filed for any occurrence discovered in the audit process that may have adversely impacted patient care/safety.

A. Blood Administration Audit (Monthly)

1. A CLS will follow a unit of blood product from dispense to transfusion using AF0001 Blood Administration Checklist for documentation.
2. The CLS will audit critical steps outlined in the NCAL Regional Adult Blood Administration Policy which include the following:
    a. Is the blood product pick-up form appropriate and has adequate patient's identifiers?
    b. Is the bedside check done correctly prior to transfusion?
    c. Is the first 15 minutes of the transfusion procedure done correctly by RN?
    d. Is documentation complete, i.e. MD's transfusion order, nurse's blood administration, informed consent?
3. Supervisor will review each audit and perform follow up if there is any discrepancy with nursing and present findings for discussion in subsequent TNT meetings.

B. Review QC documentation and maintenance/repair record (Monthly)

1. Daily QC is reviewed the next day by the supervisor or designee. Any discrepancy will be noted on the QC log itself and documented on a Variance Log.
2. Non-daily QC/maintenance and completed Daily QC logs are reviewed monthly by the supervisor or designee.
3. The supervisor will summarize the data every month on the BF0009 Quality Control Summary Log which is reviewed by the ALAD and the Medical Director.
4. The data is also compiled and reported quarterly on the Quality Management Quarterly Report.

C. Specimen and Requisition Problems Audit (Monthly)

1. BB Staff documents all specimen labeling and requisition errors as they happen on the BB Specimen Problem Log (Access Database).
2. Specimens and requisitions that do not meet the requirements specified in SFOWI-0079 Blood Bank Specimen and Requisition protocol are unacceptable for testing.
3. Supervisor or designee analyzes the data and summarizes the problems into the following categories:
    a. Mismatched Name/MRN
    b. Name spelling error
    c. Unlabeled

d. Name cutoff
e. Illegible
f. MRN error
g. Missing initial/signature/NUID
h. Date/Time missing or error
i. QNS
j. Misidentified
k. Hemolyzed
l. Hemolyzed/QNS - Used for DBCK only
m. No requisition
n. Other (Specify in comment)

4. The summary report is presented to the hospital TNT committee each month.

D. Blood Supplier Audit (Monthly)

1. The blood supplier is assessed on the 5 following criteria:
   a. Daily Inventory received timely – inventory should arrive before 11am same day
   b. Number of units returned to supplier – number of incorrect products received that must be returned
   c. Appropriate delivery containers used – the products must be packaged and delivered in appropriate containers and packing materials that maintained proper shipping temperature for the specific component e.g. ice-packs with RBCs, dry ice with frozen products, gel-packs with platelets.
   d. Products received are in satisfactory condition – products have adequate segments, have no 'particulate' matter, are not hemolyzed, clotted or lipemic, are not discolored, are not leaking, face label is legible and intact, no more than two unique donor identifiers, RAD-SURE sticker indicates Irradiated, etc.
2. A dayshift CLS checks blood products inventory, fills out BF0012 Daily Inventory Control and places orders using the online ordering system.
3. Non-daily inventory product orders are documented on AF0035 Blood Component Ordering Log.
4. BB staff record the quality data daily on AF0038 Blood Supplier Audit form:
   a. Each morning, a BB staff will review AF0035 for timely STAT delivery of the products ordered the day before and document the number of orders not received timely on the form.
   b. The BB staff who receives the morning shipment of blood products checks to make sure that the delivery meets criteria and document on AF0038, including any problems encountered.
      i. The daily delivery should arrive no later than 11:00 a.m. Use a check mark to indicate timely delivery or write the time of receipt if after 11:00 a.m.
      ii. Write "0" to indicate no products were returned to BCP. Otherwise, document the number of units returned and indicate the donor unit numbers returned on the shipment receipt.
      iii. Use a check mark to indicate correct shipping containers and appropriate packing materials used. Otherwise, write "N" in the box and document the number of units rejected and the unsatisfactory condition in the comment section.
      iv. Write "0" if products received are in satisfactory condition or document the number of units rejected and the unsatisfactory condition

in the comment section.

5. Staff writes Variance Log and contacts blood supplier to resolve urgent issues/problems. Supervisor will follow up with blood supplier as needed.
6. Recurring issues will be reported to Regional Practice Leader.
7. Supervisor reviews, analyzes and submits the audit data monthly to ALAD and the Medical Director for review. The acceptable threshold is >90%.
8. A quarterly summary report is submitted to MEC for review.

E. Product Issue Audit (Monthly)

1. The computer system generates a Transfusion Log every day that captures all the blood products dispensed on the day before.
2. BB staff performs the following daily:
   a. record the total number of transfused units indicated on the Transfusion Log
   b. record the number of units not posted or missing yellow Product Chart Copy (PCC):
      i) Units transfused in LIS but missing PCC or
      ii) PCC indicated dispensed but not documented in LIS
   c. record the number of units or components dispensed which were not requested on the pick-up slip.
   d. record the number of occurrences in which the Patient's name and MRN on the pick-up slip do not match the retained yellow PCC.
   e. record the number of occurrences in which the unit# or blood component on the Transfusion Log do not match the yellow PCC.
   f. select one transfused unit for trace back:
      i) record '1' if the unit dispensed has a BB requisition with ordering MD on file
      ii) record '2' if the unit dispensed has a BB requisition without ordering MD on file
      iii) record '3' if the unit dispensed has no BB requisition on file
   g. select 3 requisitions to make sure CLS initials for:
      i) Label check
      ii) History check
   h. record any corrective action taken:
      i) complete a Variance Log if appropriate. Supervisor will follow-up the error if needed.
      ii) any errors connected to patient or unit information must also be corrected on the white PCC. Retrieve copy from nursing unit or chart room.
3. Supervisor or designee will compile the data for monthly reports submitted to Quality/Risk Management and a quarterly summary submitted to MEC. The acceptable threshold is >90%.

F. Variance Log Indicators (Quarterly)

1. The Variance Log AF0015 is used internally to document any concerns or problems (nonconformance, near-miss, complaints, etc) which includes:
   a. description of the event
   b. investigation of the cause
   c. the corrective/preventive action; discussion with staff involved with event
   d. outcome/follow up
2. The Variance Log is reviewed firsthand by the supervisor who will perform

follow up if necessary.

3. The data is collected and categorized each month by the ALAD who prepares a quarterly summary report:
    a. Inadequate /barrier communication (COMM)
    b. S.O.P. not followed (SOP)
    c. Equipment limitations/malfunction/missing calibration or maintenance (EQIP)
    d. Defective/contaminated material and control/reagent (REAG)
    e. Mislabeled recipient sample/requisition (MISR)
    f. Mislabeled blood products (MISB)
    g. Unacceptable storage/transport condition (STOR)
    h. Fail to notify/quarantine nonconforming units (QUAR)
    i. Incorrect/missing testing/reaction strength/reaction result in computer (INCR)
    j. Incorrect selection of blood components (INCB)
    k. Incorrect issue of blood products (INCI)
    l. Special needs not met (SPEC)
    m. Clerical errors (CLER):
        i) wrong procedure or component code
        ii) wrong unit status/data entry
        iii) wrong/no unit details/report
        iv) wrong/missing patient data/testing results/tech ID
    n. Patient Transfusion HX in CIPS not checked (HIST)
    o. Double Check Policy not followed (DBCK)
    p. TAT not met (TAT)
    q. Misfiled/lost requisition/specimen/product (MISF)

4. Root cause analysis is used to investigate the causes of nonconformances relating to products, processes and the quality system.
5. Significant variances and proposed corrective/preventive action are discussed with employees in subsequent staff meeting.
6. Staff is encouraged to participate in the development of solutions.

G. Emergency Release Audit

1. Every Emergency Release is reviewed using TF0008 Urgent Requirement for Blood and Components Checklist for the following:
    a. Completion of the Emergency Release of Donor Blood Form
    b. Timely dispense
    c. Tests completion and TAT
    d. Documentation of emergency dispense time in the computer system.
2. Discrepancy is followed up as necessary and may be written up on a Variance Log.

H. Massive Transfusion Audit

1. Every Massive Transfusion is reviewed for the following:
    a. Indication
    b. Blood product usage and wastage
2. In addition, the Medical Director reviews each case for appropriate MTP initiation and present findings at the TNT/BUC.
3. The collected data is reported monthly at the TNT/BUC.

I. Adverse Events

1. Every Transfusion Reaction workup is reviewed for completion using TF0009 Transfusion Reaction Workup Checklist and categorized.
2. Discrepancy is followed up as necessary.
3. The categories are tallied and reported quarterly on the Quality Management Quarterly Report.

J. Blood Product Wastage

1. BB Staff documents all blood product wastage after disposition on the BB Product Wastage Log (Access Database).
2. The data is compiled monthly and presented at the TNT/BUC.

REFERENCE

A. AABB, Standards for Blood Banks and Transfusion Service, current edition, Bethesda, MD.

B. CAP Checklist for Transfusion Medicine, current version, Northfield, IL.

Associated Documents:

External Documents

Associated Quality System Documents - None

Document Revision History:

Revision: 6	**Date Created:** 01/24/2013 **Date of Last Revision:** 07/05/2019	**Last Approval Date:** 05/23/2019

Document Author: Cara H Lim/CA/KAIPERM	**Document Manager:** Richard Chui/CA/KAIPERM

Reason for Change:

Revision:	Sec/Para Changed	Change Made:	Date
1	N/A	Initial Issue of Document	1/24/13
2	Approver Procedure A. Data Summary and Report. A.	New BB Medical Director. Changed Blood Administration Audit from bi-monthly to monthly. Revised.	9/23/13
3	Procedure D.1.b. Procedure D.1.d. Procedure D.1.e. Procedure D.4. Procedure D.5.	Revised. Changed daily inventory delivery from within 4 hours to before 10am. Revised. Added examples of appropriate packing materials. Revised. Added more conditions to evaluate products. Revised. Added instructions on how to document audit data. New. Added instructions to file VL to reflect current practice.	11/18/13
4	Whole document Procedure C.1. Procedure C.3. Procedure D.2. Procedure D.5. and 6. Quality Indicators and Procedure G, H, I, J.	Changed QUEOC to MEC (Medical Executive Committee). Changed from manual log documentation to electronic documentation using Access database. Added 4 new categories: QNS, Hemolyzed, Hemolyzed - Used for DBCK only, and Other. Revised instructions from faxing to online blood product ordering. Added supervisor follow-up and report of recurring issues to Regional Practice Leader. Added new sections for Emergency Release Audit, MTP Audit, Adverse Events and Blood Product Wastage.	11/25/16 12/30/16
5	Approver	Change of Lab Director and Transfusion Service Director	4/25/19
6	Procedure C. Specimen and Requisition Problems Audit (Monthly) Procedure D. Blood Supplier	Added 'No requisition' category per current practice. Changed Daily Inventory Delivery Time from 10am to 11am per	5/30/19

	Audit	agreement with Vitalant (formerly BCP) effective 11/30/17.	

Notification List:

Approvals:

First Approver's Signature

Name: Sarah C Cherny/CA/KAIPERM
Title: Transfusion Service Medical Director

Second Approver's Signature

Name: Elizabeth M Hosfield/CA/KAIPERM
Title: Chief of Pathology; CLIA Director

Document History Section