**Purpose:**

Describe how audits are used to assess organizational effectiveness, system efficiency, process effectiveness, business performance, risk management, and conformance to requirements.

**Policy:**

Harborview Medical Center Transfusion Services Lab (HMC TSL) audit plan includes internal and external audits, tracing, and process or element audit. The interconnectedness of the TSL department’s process and other areas of the hospital are taken into consideration in the design of the audit plan. Quality Assurance coordinator will employ one or a combination of several auditing strategies during the data-gathering phase of the audit.

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| **Segment Audit** |
| **Type of Audit** | **Action** | **Related Document(s)** |
| Process | QA coordinator or designee will: 1. Randomly select RBC unit numbers to be audited from current inventory list.
2. Confirm availability of segments for testing by physically matching the selected unit numbers with corresponding segments sequestered in plastic bags.
3. Complete the audit form and submit to QA coordinator for review.
4. If during the audit, it was discovered that there are units missing their corresponding segments, attempts should be made to sequester the segments if RBC bags are still available in inventory.
5. Generate a Quality Improvement (QIM) report.

Note:This audit is performed bi-annually (5-6 Segments) | Segment Audit FormSample and Unit Segment Management ProcessReceiving Blood Products into InventoryQuality Process- Occurrence Reporting  |
| **Process Control ( Tracer Audit)** |
| **Type of Audit** | **Action** | **Related Document** |
| Systems and document control | QA coordinator or designee will:1. Select a routine order for type and crossmatch from the CPOE order rack,2. Assign selected order to a CLT for accessioning and perform direct observation on:* Order entry
* Sample acceptability check
* Inventory Management
* Component Preparation
* Issuing
* Returning
* Billing, crediting
* Quality Control
* Equipment Management

4. Document results of the direct observation and interview method on the Tracer Audit form. 5. Using the same order, assign a MLS to perform the following:* Pre-transfusion testing
* ABO/Rh
* Front and reverse type
* Antibody Screen
* BAD file
* ABO type specific product
* CXM results consistent with AB Screen
* All results properly entered in Sunquest
* Blood product allocation / Issue
* Product release in SQ/LIS

4. Document the results of the direct observation on the Tracer Audit form.5. Review audit related documents * Policies or practices and procedures
* Quality control documentation of reagents and equipment
* Deviation form, QIM, PSN report generated if specimen was rejected.
* Training documentation of the CLT and MLS who were assigned to complete the order.

6. Document any missing or incomplete process on the comment section of the Tracer audit checklist7. Finalize the audit results by completing the questions on the summary section of the Tracer Audit checklist.Note:This audit is performed bi-annually using 2-3 routine patient orders per audit. | Tracer Audit Form |
| **Blood Transfusion Administration Audit** |
| **Type of Audit** | **Action** | **Related Document** |
| Process and document Control | Evaluation of the nursing personnel compliance to established blood administration protocol.QA coordinator or designee will select a routine order for crossmatch that is ready for issue. Alert the transfusionist that a tracer audit will be performed on the blood component from the time of issue to the time first VS data is taken. * Performed by TSL-QA coordinator or Transfusion safety Officer
* Evaluation of the overall administration process and transfusionist compliance to the existing Nursing protocol.
* Assessment of the Transfusion Administration Process form will be used to compile objective evidence collected.
* Using the ORCA system, review all audit related documents
* Physician’s order to transfuse
* Inclusion of signed consent for transfusion in the patient’s chart
* Verify accessibility of the current on line copy of the Blood Administration procedure by asking transfusionist to access and print copy the policies in the intranet for you. Copy of the print out will be attached to the audit checklist for review.
* Document or record on the form any discrepancies with existing protocol and verbal affirmations if transfusionist was notified of the discrepancies.

*Note:* Performed randomly up to 4 different patient care areas per year. | Assessment of the Transfusion Administration Process FormIntranet / on-line Blood Administration Nursing Policies |
| **Vital Signs Audit** |
| **Type of Audit** | **Action** | **Related Documents** |
| Vital Signs/ORCA chart documentation – External audit | Weekly Infusions Vitals Report [Amalga] containing patient information of all blood transfusion episodes from previous week is generated by the HMC – QI department and sent via E-mail to QA Coordinator.QA coordinator or designee will use the data to:* Create a spreadsheet by filtering all transfusion episodes with missing or incomplete Vital signs:
* 15 minutes prior to start of transfusion
* 15 minutes after start of transfusion
* 15 minutes at end of transfusion
* Provide details of transfusion episode including:
* Name of transfusionist
* Unit start and end time
* Blood component type
* Blood component number
* Number of pooled units if applicable
* Determine the compliance rating for each patient location by dividing the number of missed or incomplete episode by the number of completed transfusion performed.
* Using the completed spreadsheet, disseminate the compliance rating of each patient care area to respective nurse managers via E-mail.
* Document incidents that involve blood administration that do not have any vital signs taken, before, during and after transfusion.
* Summarize the audit data using the VS audit tool and report any compliance issues to Transfusion Safety Officer.

Note: Questions about the data should be referred to: (pergamit@uw.edu). | ORCA Chart Vital Signs Audit and Feedback Form Weekly Infusions Vitals Report [Amalga] |
| **Chart Audit** |
| **Type of Audit** | **Action** | **Related Document** |
| Document control – External Audit | Using completed Blood Product Release forms, QA coordinator or designee will randomly select patient records with known completed transfusion. * Using the patient’s MRN, access patient record in ORCA.
* Select PATIENT encounter date closest to or inclusive of transfusion date.
* Change search criteria to include the most number of viewable documents ( #999), this will enable you to look up as many encounters as needed.

Search patient’s record under CLINICAL NOTES- sub folder:1. **CONSENT/LEGAL**

The Informed consent Manual listed the following as valid consent for transfusion:* UH-0173 – used for surgical and other “invasive” procedures. This form includes consent for anesthesia and blood products.
* UH1148- used for blood administration not associated with a procedure.
* UH2063 – used for blood refusal or partial consent (ie: selected components).
* UH2224 – used for “medical” treatment and testing. This form is designated for “non-invasive” treatment.
* UH2225- used for general refusal of treatment.

**Note:** * **UH0173** – is valid for the duration of inpatient stay; will require a new consent if and when patient was discharged and re-admitted.
* **UH1148** – is valid for one year from the time of consent (date of signature).
* **Massive transfusions may or may not require a “signed” consent form.**
* UH2226 – used if proceeding with treatment under the “implied consent: emergency exception; completed before the treatment if possible. This is not actually consent, but signed by the attending physician and a second physician to document clinical agreement that there is an emergent need to proceed with treatment when express consent cannot be obtained.
* If the treatment does not require a consent form, you may document the consent discussion and the patient’s or surrogate’s agreement on the “comment section of the audit form (usually found in a progress note).
* Include specific documentation of the patient’s capacity, if indicated.
1. **Physician’s TRANSFUSION ORDER**

**Verify if the transfusion order contains information on the following:*** Dose
* Rate
* Attributes or special processing if required
* Check for Pre-transfusion medication if any
1. **Two-Person verification check before component transfusion: Audit performed on the Transfusion Records scanned into ORCA:**
* Date
* Time
* Transfusionist
* Witness
* Assessed Reaction/ Non-reaction to transfusion
 | Blood Product Release FormTransfusion Chart Audit FormInformed consent Manual – HMC Intranet |
| **TSL Quality Improvement (QI) Documentation Audit**  |
| **Type of Audit** | **Action** | **Related Document** |
|  **Document Control - Internal Audit** | On a monthly basis, QA coordinator or designee will review compiled Quality Improvement Monitoring (QIM) forms with the objective of identifying potential risk or gaps in performance. 1. **Data Analysis**
* Quantify the data to show process activities of the different areas.
* Categorize and summarize the data findings.
* Revisit the area if something appears to be missing or if clarification is needed.
* Evaluate the non-conformance under the following areas:
* Blood product entry into SQ system (BPE)
* Blood product Processing (BCP)
* Blood product Label Check (BLC)
* Blood product Issue (BPI)
* Component selection and compatibility testing
* Patient testing- including reference laboratory procedures
* Routine Quality Control log reviews
* Investigation of adverse reactions
1. **Reporting audit results**
* Use various statistical techniques to report process improvement and quality control data. (I e: standard statistical tools such as run charts, pie charts, Pareto diagrams and/ or bar graphs).
	+ - Use the notes taken during the audit to serve as basis for the report and include the details of the observations if necessary.
		- Perform immediate follow-up on reports of nonconformance or failure to meet requirement which resulted in a negative, significant impact
		- Document action taken on the final report
		- Submit report to TSL Manager for discussion at monthly staff meetings.
 | QIM Form |
| **Transfusion Reaction Audit** |
| **Type of Audit** | **Action** | **Related Document** |
| Process and Documentation Audit | On a weekly basis, QA coordinator or designee will review previous week’s data on Transfusion Reaction work-up. The audit will include assessment of report for completeness. The existing electronic database will be updated with the information of Transfusion reaction episodes and will reflect the following:* Patient demographics
* Date of suspected transfusion reaction report
* Accession numbers of samples implicated
* Date of completed result
* Type of suspected reaction
* Kind of associated component
* Associated Blood product Identification
* Underlying patient condition

The main objective of the audit is to compile information in case the transfusion reaction episode is implicated on a product recall or lookback. Patient’s chart with transfusion reaction work-up documentation and the Sunquest computer system is used for the collection of pertinent transfusion reaction data. |  |
| **Trauma and MTP Response Log Audit** |
| **Type of Audit** | **Action** | **Related Document** |
| Process and Documentation audit  | On a monthly basis, the QA coordinator or designee will review previous month’s trauma and MTP response log for completeness. The objective is to track down incomplete logs wherein Uncrossmatched and Universal type blood products were issued and presumed transfused to patients. Data from this log is used for the Massive transfusion audits therefore the completion of the log is critical. The result of this audit is discussed as part of the monthly staff meeting QA report. The Portable and Trauma log audit includes the following elements:* Responding Tech ID
* Response date and time
* MTP activation (if applicable)
* MTP activation date and time (if applicable)
* Blood sample for Type and screen collection date and time
* Portable refrigerator return time (if applicable)

**Note:**QI reports are generated for each log that was deemed incomplete and missing information resulted in a subsequent FDA Blood Product Deviation Reports.Corrective action is taken by TSL or QA manager up to and including retraining and review of SOPs involving trauma response. | Portable Refrigerator Response Log Transfusion Service Internal Audit-Trauma and MTP Response Log |
| **Component Storage and Blood Warmer Audit**  |
| **Type of Audit** | **Action** | **Related Document** |
| Documentation and Temperature monitoring system audit  | On a monthly audit, the QA coordinator or designee performs a manual review of all documents pertaining to:* Equipment validation
* TEMP TRAK system quality control audit for each shift
* Equipment’s Out-of- service documentation
* Return to service Calibration documentation
* Scheduled preventative maintenance

Temp Trak QA report will be generated by auditor and reconcile with the daily QC audit. All alarms and equipment that are out of service should have proper documentation and will have corresponding data on the monthly QA log. A Quality Improvement report is generated and a QI tracking number will be indicated on the monthly Storage review file.  | Monthly QC review formQI Report |

**References**

Standards for Blood Banks and Transfusion Services, Current Edition. American Association of Blood Banks, AABB Press, Bethesda MD

Silva, M.Vengelen-Tyler, V.Quality Toolkit and Case Studies: Solutions for Common Problems, AABB Press, Bethesda MD, 2011.

Russell, J.P.ed. The ASQ Auditing Handbook, 4th Edition.