

The Joint Commission's Tracer Methodology Toolkit for the Lab Program



Starting points for tracers:

- Laboratory developed tests
- Critical results
- Emergency release blood products
- Suspected transfusion reactions
- Positive blood cultures
- Autopsies
- Special procedures and special stains
- Point of care testing
- Frozen sections
- Tests with proficiency testing results <100%
- Tissue implants
- New instruments, methods, or tests
- Low volume tests

Below are important items to include in your mock tracers (items in bold are top non-compliance issues)

Employee Files

- **Documentation of education by diplomas, degrees, or transcripts**
- **Documentation of experience to meet CLIA role qualifications**
- State license if required
- Orientation (technical and nontechnical)
- **6 month non-waived competency assessment for new employees**
- **Annual non-waived competency using the 6 methods of evaluation per test system**
- Competency documentation for physicians and mid-level practitioners performing Provider Performed Microscopy Procedures (PPMP)
- Minimum once every two years non-technical competency
- Annual waived competency using two out of four methods per test
- Minimum once every two years performance evaluation
- Blood administration training if applicable
- Flu vaccination/declination

Patient Medical Record

- Order for the test
- Test results including point-of-care testing, PPMP, and waived testing
- **Reference ranges for all quantitative results including waived testing**
- **Name and address of performing laboratory**
- Consent to transfuse
- Order to transfuse
- Documentation of transfusion vitals
- Therapeutic phlebotomy documentation
- Preliminary reports
- Intra-operative reports
- Final reports
- Documentation for critical results notification
- Documentation of tissue transplant

For all specialties/subspecialties:

- Policies and procedures are signed by laboratory director before implementation and when changes are made
- Policies and procedures are signed by laboratory director once every two years. If there are no changes, this can be delegated in writing to the technical supervisor.
- **Proficiency Testing: performance, attestations, staff distribution, and investigations**
- Quality Control
- Calibrations
- **Calibration verifications**
- **Correlations**
- Validation of new instrument, methods, and tests
- In use/open date and expiration date on reagents, QC, and calibrators
- **Temperature charts**
- **Maintenance records for all equipment (including pipettes, centrifuges, refrigerators, scales, and timers)**
- Lot numbers
- Environment of care chapter (eye wash stations, showers, fire extinguishers)
- Surveillance of patient results, quality control results, and maintenance
- Implementation of the National Patient Safety Goals (NPSGs)

For specific specialties/subspecialties Bacteriology, Mycobacteriology, and Mycology

- Media receipt, visual checks, and quality control if applicable
- Susceptibility quality control
- Staining quality control
- Positive blood culture workups – check for timeliness of the workup if not staffed 24/7 in microbiology
- If testing onsite, acid fast stain results are reported within 24 hour of receipt
- CO₂ check of the incubator
- Current antibiogram

Immunoematology

- Suspected and confirmed transfusion reactions
- Emergency released blood products
- RhIG policies, procedures, and administration, if applicable
- Blood warmers and cell salvage maintenance
- Temperature alarm checks
- Blood product acquisition, testing, and disposition records
- Policy for potentially infected blood and blood components
- Blood product deviation reports to the FDA
- System for recording alloantibodies
- Therapeutic phlebotomy or donor center if applicable
- Utilization reports and statistics
- Correlations (tube method if a backup for gel or solid phase)
- Transfusion service director has oversight of blood administration policies, processes, and procedures
- Documentation that the vitals were monitored as required by policy

Coagulation

- The international sensitivity index (ISI) value is specific to the lot of thromboplastin reagent in use
- The normal patient prothrombin time mean is specific to the lot of thromboplastin reagent in use

Cytology

- Workload limits established, recorded, and within all acceptable limits for all primary screeners, including pathologists
- 6 month reassessment of workload limits is completed and documented
- Technical supervisor confirms and documents review of all non-gynecological slides

- Technical supervisor confirms and documents review of specific gynecological slides
- Initial and rescreening results
- Prior negative pap smears
- Annual statistics
- Specimen processing including FNA performance
- Cross-contamination considerations, cell block processing and utilization
- Cytology/tissue correlation

Anatomic Pathology

- Review of surgical specimens
- Blocks and slides are labelled
- Special stain quality control
- Exposure monitoring
- Correlation of intraoperative consultation and final pathology report
- Morgue temperatures and scales
- Waste management
- Autopsy report (preliminary and final timeframes)
- Use of a pathologist assistant

Transplant Safety

- Responsibility for the oversight of the acquisition, receipt, storage, and issuance of tissues is assigned
- State license if required
- FDA registration of suppliers (current and from the timeframe of the tracers)
- FDA registration if distributing
- Temperature and alarm checks
- Tissue logs that include:
 - o Required element of the receipt of all tissues
 - o Reconstitution
 - o Disposition
 - o Dates, times, and staff involved when tissue is accepted, prepared, and issued
- Adverse event policy and investigations
- Record retention

Waived Testing outside of the laboratory

- Quality control (internal and external for kit testing)
- Reference ranges for quantitative test results

TRACER METHODOLOGY 101

The Laboratory Tracer

Laboratory tracers are unique because they do not focus solely on direct patient contact as do tracers in other accreditation programs. Instead, the laboratory tracer evaluates the performance of processes, with particular focus on integrating and coordinating distinct but related processes. The tracer also assesses the interrelationships among departments, programs, services, or units to identify strengths and weaknesses and potential concerns in the relevant processes.

The Joint Commission surveyor will, most likely, begin the laboratory tracer with the test result, and then he or she will follow the entire testing process for that patient from preanalytic to postanalytic processes. The surveyor may visit all areas of your laboratory that affect the delivery of service, including areas where orders are written or recorded, specimens are collected and processed, testing is performed, and results are documented and communicated.

In this month's "Tracer Methodology 101" column, we focus on an individual laboratory tracer that involves information management, analytical procedures, and equipment use.

The Scenario

This tracer was conducted during a laboratory survey at a 120-bed hospital. This organization had purchased the only other hospital in the town and converted it into an ambulatory care center where, among other services, outpatient transfusions were performed. The surveyor selected this tracer from a number of suspected transfusion reaction workups

that had been conducted by laboratory staff over the past 12 months.

The surveyor chose the closed medical record of a 54-year-old man who received chemotherapy and frequently required transfusions. The surveyor reviewed the tracer patient's closed medical record in the presence of the laboratory director, the director of quality management, and the risk manager. On this particular occasion, the physician had ordered two units of packed cells because the patient's hemoglobin was 6.2 grams. The laboratory performed the type and cross-match early in the day with plans to administer the two units at the ambulatory care center later in the day. In addition, the laboratory performed a chemistry profile, thyroid profile, and complete blood count (CBC).

The patient received the first unit of packed cells without demonstrating any signs and symptoms of a suspected transfusion reaction according to the organization's own policy. During administration of the second unit, nursing documented a rise in the patient's temperature of 2.5°F (1.4°C), and a suspected transfusion reaction response was initiated. Nursing contin-



ued to monitor the patient's vital signs, and the patient's temperature continued to rise—with a total increase of more than 4°F (2.2°C)—even though the administration of the blood had been discontinued. As part of the laboratory's protocol, the laboratory was notified of the suspected reaction. The attending physician made the decision to have the patient transferred from the ambulatory care center to the hospital emergency department via ambulance. On arrival at the emergency department, the emergency physician ordered a basic metabolic panel (BMP) and CBC.

The surveyor asked the laboratory director about its policy for receiving orders for stat tests. He also asked the laboratory director to identify staff members who performed the tests and

The Facts on Laboratory Tracers

When to do this tracer: Any laboratory should conduct this tracer when it wants to assess any aspect of its systems and processes. If you choose to conduct mock tracers, in addition to clinical/service groups, consider criteria such as patient sample testing in laboratory sections (for example, hematology, chemistry, biology, or blood bank), policy and procedures that guide testing performance of patient samples, maintenance of laboratory equipment, or pre- and postanalytical procedures.

asked human resources to pull their files so he could later review their competencies, job descriptions, primary source verification of the licenses, and performance appraisals. Coincidentally, the technologist who performed the first CBC prior to the blood administration had worked for the organization for only four months, so the surveyor asked for documentation of her initial orientation and training.

The surveyor then visited the hematology department and asked about instrument maintenance on the hematology analyzer for the day of testing. Staff showed him the daily start-up and shutdown documentation. They were able to identify all lot numbers of reagents used on the analyzer for this time period. This laboratory's policy was to run all three levels of quality control every eight hours. The surveyor reviewed the appropriate quality control records. The first eight-hour period indicated that the normal control level was performed with results that exceeded that laboratory's two standard devia-

tion quality control range. The normal control was repeated, and the technologist had documented appropriate corrective action. The laboratory submitted quality control results monthly to the instrument vendor for interlaboratory comparison. The surveyor reviewed the report for this month, and all data had agreed with peer data. Calibration of this hematology analyzer was performed every six months, and the hematology supervisor was able to show the surveyor the data.

The surveyor was able to talk with the technologist who performed the BMP on the tracer patient during the emergency department visit. The technologist told the surveyor that two levels of quality control material were run every 24 hours for analytes performed on the chemistry analyzer. Typically, quality control was performed on the third shift; however, on the day the tracer patient was tested, a new lot of reagents had been started for glucose, and quality controls had been repeated after calibration of a new lot number.

Each month data from quality control were submitted to the quality control vendor for interlaboratory comparison. The chemistry supervisor located the file and presented it to the surveyor for review. For the particular month when the tracer patient was tested, creatinines were running slightly higher than the peer group. A service call had been initiated on this analyzer, and the surveyor reviewed the report left by the service representative. Apparently, the service representative had to replace a part that he felt had caused a certain amount of carryover between samples and probably caused the elevation noticed when the data were compared to the peer group. As part of the monthly quality control review, a summary of the quality control data, interlaboratory comparison data, and maintenance records was reviewed by the laboratory's administrative director and the medical director. This report included documentation of a discussion of the elevated creatinine results. The medical

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Tips Checklist

Consider the following strategies when conducting a laboratory tracer:

- ✓ ***Focus on issues of particular concern for laboratories and process interfaces with clinical staff.*** Consider those issues of particular concern to a laboratory, such as patient identification, quality control, and communication of critical test results. You can use these specific topics to plan a specialized tracer using a closed medical record.
- ✓ ***Consider your laboratory's past testing activity as a starting point.*** It can be very informative to conduct a tracer of past testing activity, particularly if a pattern of near-miss reports or quality control problems with a particular test have been observed.
- ✓ ***Select the medical record of a patient who received multiple laboratory tests, including tests performed at point-of-care sites.*** This will help you look at multiple processes within your laboratory at one time. Follow the testing from the time of the order to the action taken, if indicated.
- ✓ ***Instead of one person conducting the tracer, consider walking through one as a group.*** Having an informal group discussion as you verbally "trace" through a closed medical record can help laboratory staff to better understand tracers. This is also a good opportunity to discuss possible "workarounds" or other potential problems that could result in a negative outcome.
- ✓ ***Don't forget to consider the beginning and end of a process, not just the outcome.*** For example, while tracking a specimen, make sure that you are following the work done by staff to both collect and then test that specimen. Observe work done with patients. Observe how patient identification is being performed. It is important to remember that tracers can be used to follow an entire process or system, and your goal should be to determine if there are any gaps or potential missteps.

director had determined that this creatinine elevation was not significant enough to consider a look back at patient results. Daily maintenance was reviewed for the day the tracer patient was tested, and evidence was provided for the results of the daily absorbance testing. This analyzer had been purchased by the laboratory since the previous survey, and appropriate documentation was available for the surveyor's review.

In the blood bank, the surveyor had a chance to review the workup of the suspected transfusion reaction. The laboratory had developed a workup form for the technologist to use. For this particular tracer patient, the blood bank technologist had documented a clerical check only. Although the laboratory had a policy requiring a new patient sample to confirm the blood group, Rh type, and direct antiglobulin test, a posttransfusion sample had never been received. The technologist who performed the workup said he waited for a sample but never received one.

After additional discussion, the surveyor learned that the technologist was unaware that the laboratory had blood samples drawn at the time this patient was seen in the emergency department. The laboratory director later said that the technologist could have searched the laboratory information system to locate a sample that would have allowed him to do the required testing. The record also lacked documentation that the laboratory's medical director reviewed this suspected transfusion reaction for six weeks after the reaction, even though the pathologist is available every weekday. Unfortunately, no one in the laboratory realized that the organization had samples from this very patient and his workup could have been completed. As a result, the medical director was unable to make a definitive diagnosis, which nor-

mally would have been included in the patient's medical record.

Sample Tracer Questions

Based on the above scenario, the following are possible questions that could be asked during a laboratory tracer. Use them as a starting point to plan your own tracers. **Note:** *Because the types of questions asked during a tracer can be diverse and depend on the setup at that specific organization, we are providing an online tracer worksheet that includes these sample questions. You can download the worksheet, shown on page 9, and customize it with your own specific tracer questions. Access this tracer worksheet at http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.*

Questions for the laboratory director:

- Can you describe your laboratory process to handle transfusion reactions?
- What training and orientation have been provided to laboratory staff to handle transfusion reactions?
- What data and analysis have you done on the incidence of transfusion reactions in your organization?
- What measures have you introduced, if any, to reduce the incidence of transfusion reactions?
- What initial assessment do you perform for new transfusion patients?

Questions for the laboratory staff:


- What were the specimen collection requirements for the tests performed for this tracer patient? Where were they collected?
- What process did you follow for preparing blood units for this patient's transfusion in an outpatient setting?
- What instructions did you provide to this tracer patient?
- What is your laboratory's policy for ordering a stat procedure?

- How do you verify orders for laboratory testing? How do you determine who is authorized to give those orders?
- What is your quality control process? When is corrective action required?
- What is your quality control process for the BMP? What is your process for accepting and rejecting of a quality control result?
- What is your process when your quality control data reflect a positive or a negative bias based on interlaboratory data? What do you do when your quality control results are higher than acceptable peer data?

Questions for nursing staff:

- What prompted you to suspect a transfusion reaction in this tracer patient?
- What is your policy for addressing a patient exhibiting signs and symptoms of a suspected transfusion reaction?
- What protocol did you follow to address this patient's continued temperature increase?
- What is your assessment process for a new patient?
- Please describe your entire process for administering blood to a patient.

Questions for blood bank staff:

- What is your organization's process for handling a new patient?
- What is your documentation process? How is that documentation reported?
- If you have a question or a problem with documentation or necessary information, what do you do?
- When you did not receive the expected sample, what protocol did you follow? Who did you notify about this situation?
- What process did you follow to document or handle an incomplete diagnosis or test result for this patient? Would your processes for daily review have detected this? 

Mock Tracer Tracking Worksheet: The Laboratory Tracer

Use this worksheet to record notes and areas of concern that you identify while conducting your organization's mock tracers. This information can be used to highlight a good practice or to determine issues that may require further follow-up. "Yes" or "no" indicates whether the staff member interviewed during the tracer answered the question correctly.

Tracer Team Member: _____ Tracer Patient or Medical Record: _____

Staff Interviewed: _____

Unit or Department Where Tracer Was Conducted: _____

TRACER QUESTIONS	YES	NO	FOLLOW-UP NEEDED	COMMENTS OR NOTES
Describe your laboratory process to handle transfusion reactions.				
What training and orientation have been provided to laboratory staff to handle transfusion reactions?				
What data and analysis have you done on the incidence of transfusion reactions in your organization?				
What measures have you introduced, if any, to reduce the incidence of transfusion reactions?				
What initial assessment do you perform for new transfusion patients?				
What were the specimen collection requirements for the tests performed for this tracer patient? Where were they collected?				
What process did you follow for preparing blood units for this patient's transfusion in an outpatient setting?				
What instructions did you provide to this tracer patient?				
What is your laboratory's policy for ordering a stat procedure?				
How do you verify orders for laboratory testing?				
How do you determine who is authorized to give those orders?				
What is your quality control process? When is corrective action required?				
What is your quality control process for the basic metabolic panel?				

Access this entire two-page worksheet at http://www.jcrinc.com/common/PDFs/Pubs/Periodicals/The-Source/TheSource0910-MockTracerTrackingForm_LaboratoryTracer.doc.



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