2005 IQLM Conference

Evaluation of Laboratory Quality Indicators

IQLM Quality Indicators Workgroup

Department of Health and Human Services

IQLM Quality Indicators Workgroup

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POSTER HANDOUT

LABORATORY QUALITY INDICATOR EVALUATIONS
- BLOOD CULTURE CONTAMINATION
- PATIENT IDENTIFICATION
- TEST ORDER ACCURACY & APPROPRIATENESS
- ADEQUACY & ACCURACY OF SPECIMEN INFORMATION
- CRITCAL VALUES REPORTING
- ROUTINE ADULT LIPID SCREENING
- CLINICIAN SATISFACTION WITH LABORATORY SERVICES

REFERENCES

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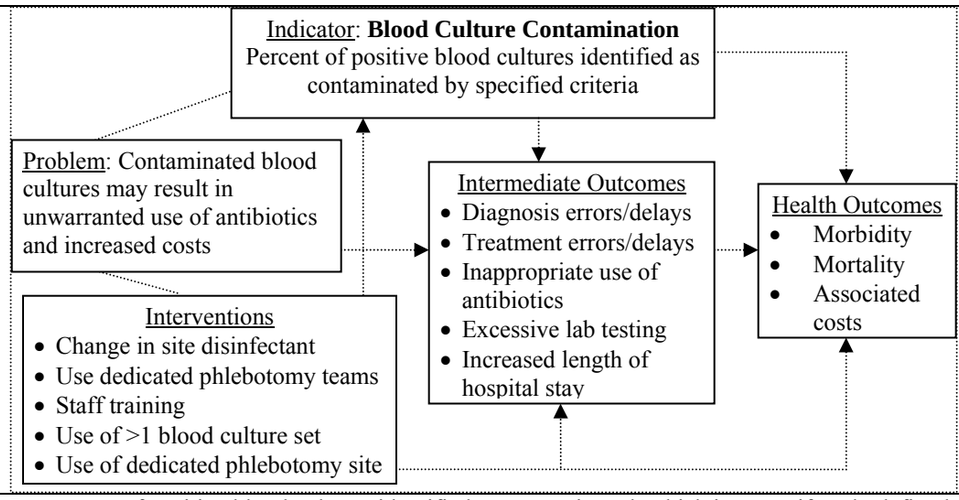
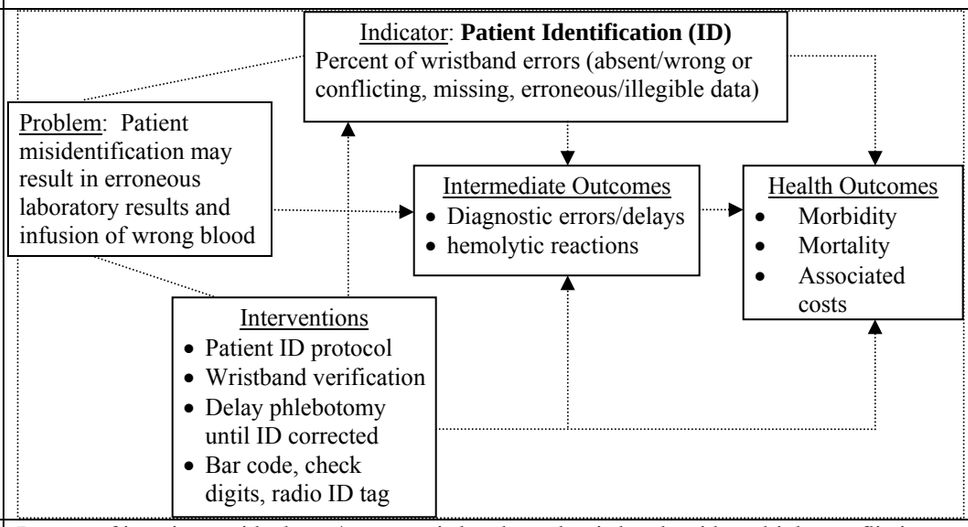
IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Blood Culture Contamination** (ASM, CAP, CLSI)
Conceptual Framework	
Definition	Percentage of positive blood cultures identified as contaminated, which is not uniformly defined. Useful criteria for determining if a microorganism is a contaminant include: • Identity of the organism • Presence of the microorganism in a single blood culture when multiple cultures drawn • No growth of the same microorganism as found in blood from another normally sterile site • Patient symptoms
Population/Care Settings	All patient populations/care settings with blood culture results.
Rationale/Evidence	False positive results are routine in blood cultures, and the trade off of sensitivity for specificity is often considered justified because of the risk of failing to detect an active infection. Thus, controlling blood culture contamination is necessary to reduce undesirable clinical outcomes (i.e., associated with inappropriate use of antibiotics, excessive laboratory testing, and associated costs including longer and more costly hospital stays and laboratory and pharmacy charges.) Published studies have demonstrated that several measures may significantly reduce false positive rates, and contamination is affected by various factors including: • Type of skin disinfectant used • Method of draw • Site from which culture is drawn • Blood culture volumes • Dedicated phlebotomy teams for collecting blood culture specimens
IOM Domains	Safety, Effectiveness, Timeliness, Efficiency
Numerator Description	Number of positive blood cultures identified as "contaminated," which is not uniformly defined. Criteria used to define if a microorganism is a contaminant include: • Identity of the microorganism • Presence of the microorganism in a single blood culture when multiple cultures are drawn • No growth of the same microorganism as that found in the blood from another normally sterile site • Patient symptoms Also, data can be collected to identify possible sources of contamination, which may include: o method of draw (e.g. 2 needle, direct needle into broth) o type of disinfectant used o definition of contaminate o site from which culture drawn (e.g. IV catheter vs. dedicated venipuncture site) o blood culture volumes
Denominator Description	Total number of positive blood cultures drawn
Data Sources	Primary source is laboratory results. Additional sources for numerator include laboratory, infection control, and medical records. Information on possible sources of contamination is generally survey-based.
IMPORTANCE	
HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their	• Average blood culture contamination rate is about 2.5% (range 1-5%), and in many teaching hospitals it exceeds 6%; American Society of Microbiology (ASM) standards indicate it should not exceed 3%. • Positive blood culture result can be false 20-50% of time. • Physicians rely heavily on blood culture results to diagnose and monitor febrile patients. • Erroneous results from blood culture contamination can have serious patient outcomes due to false positive results, including: o administration of excessive antibiotics

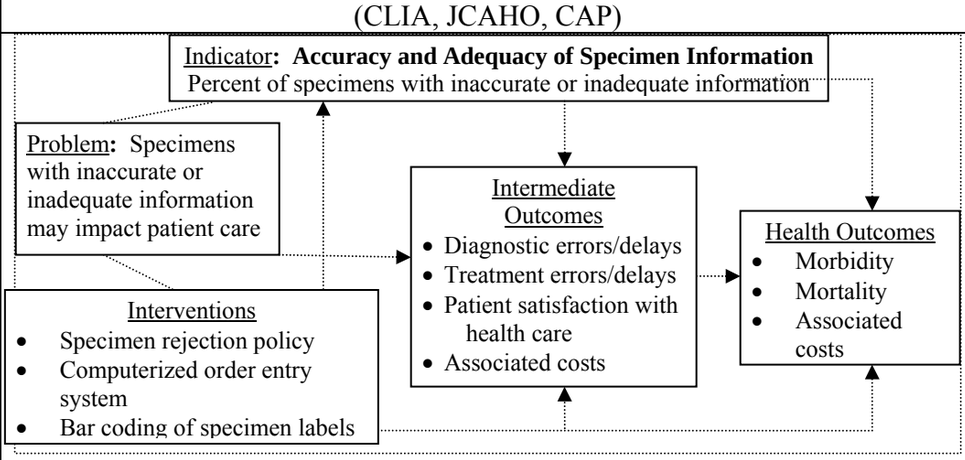
associated costs	o excessive length of hospital stays (average 4.5 days longer) o associated costs
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	Average blood culture contamination rate is about 2.5% (range 1-5%), and in many teaching hospitals it exceeds 6%; American Society of Microbiology standards indicate it should not exceed 3%.
• **Actions taken to improve performance and evidence of effectiveness**	• Studies showed significant reduction in blood culture contamination rate from: o changing site disinfectant o using dedicated phlebotomy teams o staff training o bottle top decontamination before use • Conflicting results as to collection of higher blood volume per culture reducing contamination rates • Contamination rates were also influenced by o number of blood culture sets drawn o site from which blood culture drawn (separate, dedicated phlebotomy site vs. intravenous catheter) influenced results.
SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• Published studies, reviews, and clinical practice guidelines (e.g. CLSI, ASM) have demonstrated that reducing blood culture contamination rates improves quality of care and reduces healthcare costs. • Physicians acting on a potentially contaminated blood culture must choose to either ignore a potentially life-threatening result, or fight an infection that may not exist, including unnecessary and potentially harmful and costly care (e.g. administration of antibiotics, extending patient hospital stay, and more tests).
• **Indicator**	• No evidence found directly linking reduction in percent contaminated blood cultures to changes in health outcomes. • Studies showed direct evidence of increased hospital stays, cost, and separation from family resulting from blood culture contamination.
Reliability/Validity	• Non-standardized definitions of "contamination" cannot consistently and accurately represent this concept, and produce credible results over time and across multiple organizations. • Study results comparable for pre- and post-interventions among variables and facilities.
FEASIBILITY	
Explicit specifications and standardized data requirements	Criteria for what constitutes "contamination" have not been uniformly or consistently defined (see the Numerator Description), preventing standardized implementation and production of accurate and comparable results.
Implementable (for large numbers)	• Main data sources (laboratory results and medical records) are accessible and timely. • Numerous health care organizations (e.g., CAP, ASM), hospitals, and medical centers have measured blood culture contamination rates, conducted studies of variables associated with blood culture contamination, and the outcomes related to health and cost. • No standardized data sources are available across laboratory testing sites.
Reasonable cost/benefit of measurement	• No information found estimating measurement cost, however measurement requires relatively minor modification to current practice. • Financial costs associated with blood culture contamination include: o 20% increase in laboratory charges o 39% increase in IV antibiotic charges o False positive episodes led to: ▪ 50% longer hospital stays (4 days) ▪ 44% increase in laboratory charges ▪ 82% increase in pharmacy charges
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• Results of studies easily understood and of clinical and economic significance to users (physicians, laboratory personnel, medical centers, insurers) who act on indicator • Blood culture contamination is universally identified by microbiologists and physicians as an area of concern. • Best practice guidelines (e.g. ASM) include identification of blood culture contamination rates for internal quality improvement. • Studies have shown significant costs associated with blood culture contamination. • Not a quality measure in AHRQ's National Healthcare Quality Report.
Health care system control	• Interventions for controlling blood culture contamination rates can be operationalized into actions addressing processes and/or outcomes under control of health care systems, including physicians, laboratories, nursing and other personnel, pharmacies, and insurers.

IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Patient Identification** (CAP, JCAHO, AABB)
Conceptual Framework	
Definition	Percent of inpatients with absent/wrong wristbands, and wristbands with multiple, conflicting, erroneous, missing or illegible data
Population/Care Settings	All hospital inpatients
Rationale/Evidence	• Identification errors may result in inappropriate treatment or extended hospital stay. • Patient misidentification is a major contributor to acute hemolytic reactions as a result of infusion of ABO-incompatible blood [studies indicate that 40%–50% of transfusion fatalities result from improperly identifying the patient or the blood components].
IOM Domains	Safety, Effectiveness, Timeliness and Efficiency
Numerator Description	Hospital inpatients with wristbands errors include: • absent wristbands • wrong wristbands • multiple wristbands with conflicting data • wristbands with erroneous, missing or illegible data
Denominator Description	All hospital inpatients
Data Sources	Survey instruments with data collected from patient wristbands and patients
IMPORTANCE	
HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs	• Except for transfusion medicine, no evidence was found relating wristband errors to intermediate or health outcomes, or associated costs, however improving the accuracy of patient identification is one of JCAHO's 2005 National Patient Safety Goals. • Several studies have implicated wristband error as a major contributor of acute hemolytic reaction and the resulting morbidity, mortality and associated health care. • Several studies indicate that 40%–50% of transfusion errors and transfusion-related fatalities result from errors in properly identifying the patient or the blood components; annual U.S. estimate of 360 transfusion errors based on extrapolation of New York state data (1990-1999). • Several studies involving from 143 to 712 hospitals have documented prevalence of wristband errors and absent wristbands at 2.1%–5.7%.
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	• Wristband error rate in 204 hospitals (median number of beds, 99) was <1.0% in 8%, 1.0%–3.9% in 27%, 4.0%–9.9% in 35% and ≥10.0% in 29% of institutions. • Wristband error rate in 712 hospitals (median number of beds, 265) was <1.0% in 25%, 1.0%–3.9% in 41%, 4.0%–9.9% in 24% and ≥10.0% in 9%. • Wristband error rate of 217 hospitals was ≤0.3% in 10%, ≤3% in 50% and ≤11 in 90% of institutions.
• **Actions taken to improve performance and evidence of effectiveness**	• No evidence of effectiveness found for strategies to reduce patient identification errors. • Identification technologies potentially reducing patient identification errors include o wristband identification bracelets o biometric identification systems o check digits o bar codes o radio frequency identification tags o point-of-care label printers and scanners • A fail-safe system, physically preventing the possibility of error, was effective in detecting otherwise undiscovered errors in transfusion practice such as misidentification of blood recipients.

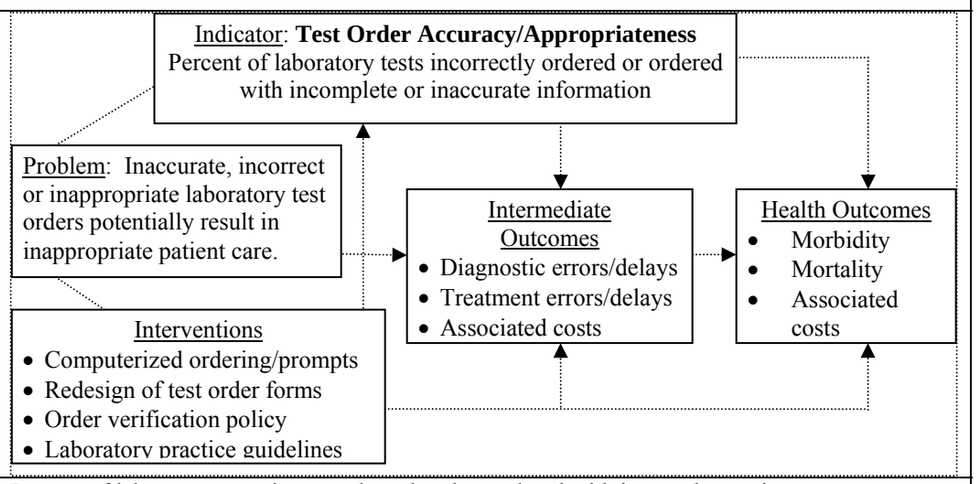
SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• Patient misidentification is a major contributor to acute hemolytic reactions as a result of infusion of ABO-incompatible blood [studies indicate that 40%–50% of transfusion fatalities result from improperly identifying the patient or the blood components]. • No evidence found relating wristband errors to actual patient misidentification events that resulted in adverse intermediate or health outcomes. • Wristband errors may be associated with patient identification errors linked to health/intermediate outcomes such as: o diagnostic/treatment errors or delays o acute hemolytic reactions
• **Indicator**	• No evidence found demonstrating improvement in wristband error rates positively impacts health outcomes of individuals or populations. • There is indirect support for utility of this indicator as a measure of intermediate (acute hemolytic reaction) and health (morbidity and mortality) outcomes.
Reliability/Validity	Wristband data errors have not been consistently defined, therefore, this indicator may not consistently and accurately produce credible and reproducible results over time and across multiple organizations. Despite differences in study design, three multi-hospital studies have provided comparable results for • Wristband error rate of 2.7%–5.7% in studies published in 1993–2000 • Relative prevalence for the different types of wristband errors: o absent wristbands: 49.5%–71.6% o wristbands with missing data: 9.1%–17.5% o multiple/conflicting wristbands: 3.7%–18.3% o wristbands with erroneous data: 6.7%–8.6% o wristbands with illegible data: 3.5%–7.7% o wrong wristbands: 0.5%–1.1%
FEASIBILITY	
Explicit specifications and standardized data requirements	Lack of consistent and precise definitions for wristband errors prevents producing accurate and comparable results.
Implementable (for large numbers)	Several multi-institutional studies have examined the frequency and type of wristband errors involving: • 2,464,000 inpatients in 712 hospitals • 451,000 inpatients in 204 hospitals • 1,757,730 inpatients in 217 hospitals
Reasonable cost/benefit of measurement	• No information was found addressing costs associated with monitoring for this indicator. • No information was found directly relating a reduction in wristband error to any health benefit. • A 2-year multi-institutional study showed that continuous monitoring of wristband errors resulted in reduced wristband error rates.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• Accurate identification of patients is recognized as essential for specimen collection for laboratory testing in regulation and accreditation standards. • Improve the accuracy of patient identification is one of JCAHO's 2005 National Patient Safety Goals. • Several studies found patient misidentification as a major contributor to acute hemolytic reactions as a result of infusion of ABO-incompatible blood. • Wristband error monitoring may be used for internal quality improvement efforts. • This indicator is not noted as a quality measure in the AHRQ's National Healthcare Quality Report.
Health care system control	• Written checklists to guide administration of transfusions has been shown to be related to fewer errors in patient identification. • There is evidence for effectiveness of wristband monitoring to decrease wristband error rates. • Phlebotomists may refuse to perform phlebotomy on a patient when a wristband error is detected.

IQLM QUALITY INDICATOR EVALUATIONS

<table>
<tr><td>INDICATOR NAME
(Primary Sources)</td><td>Accuracy and Adequacy
of Specimen Information
(CLIA, JCAHO, CAP)</td></tr>
<tr><td>Conceptual Framework</td><td> 
</td></tr>
<tr><td>Definition</td><td>Percent of all specimens sent to the laboratory with inaccurate or inadequate information on the specimen container (e.g., no label, illegible or no patient information, no tissue source for surgical specimens, no relevant clinical information)</td></tr>
<tr><td>Population/Care Settings</td><td>All patients and sites with specimens sent for laboratory testing</td></tr>
<tr><td>Rationale/Evidence</td><td>• Inaccurate or inadequate specimen label information may result in identification errors, and potentially affect laboratory test results and patient outcomes.
• No data were found relating inaccurate or inadequate information on a specimen label to intermediate or health outcomes and associated costs.</td></tr>
<tr><td>IOM Domains</td><td>Safety, Timeliness and Efficiency</td></tr>
<tr><td>Numerator Description</td><td>Number specimens received within a given time period with inaccurate or inadequate information which may include specimen label problems including the following: no label, illegible, incorrect or missing patient name or unique patient identifier number, no tissue source for surgical specimens, no collection date, incorrect/missing demographic information, discrepant information with test requisition.
Terms not specifically defined: “inaccurate,” “inadequate,” and “clinician”</td></tr>
<tr><td>Denominator Description</td><td>Total number of specimens received in the laboratory</td></tr>
<tr><td>Data Sources</td><td>Laboratory information systems</td></tr>
<tr><td colspan="2">IMPORTANCE</td></tr>
<tr><td>HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs</td><td>• No evidence found related to intermediate or health quality outcomes, or associated costs.
• Limited evidence found on prevalence/incidence for specimen labeling deficiencies.
• Evidence found limited to specific specimen types detailed below.
<table>
<tr><th>Specimen type</th><th># hosp.</th><th># specimens</th><th>% inadequately labeled</th></tr>
<tr><td>Surgical</td><td>417</td><td>1.0 million</td><td>1.2–2.2%[a]</td></tr>
<tr><td>CBC[b]</td><td>703</td><td>7.9 million</td><td>0.023%[c]</td></tr>
<tr><td>Chemistry</td><td>453</td><td>10.7 million</td><td>0.024%[c]</td></tr>
<tr><td>Phlebotomy</td><td>210</td><td>830,000[d]</td><td>0.015%[e]</td></tr>
</table>
[a] Some deficiencies label and requisition; [b]Complete blood count; [c]Inadequately labeled specimen and inadequately completed requisition reason for specimen rejection; [d]Number of phlebotomies; number of specimens not provided; [e]Rate rejected per successful phlebotomy.</td></tr>
<tr><td>POTENTIAL FOR IMPROVEMENT
• Evidence of variation in quality</td><td>• No evidence found addressing overall variation of specimen labeling deficiencies
• Only distribution information about deficiencies and rejection rates, including requisition information for:
o CBC specimens (rejection rate 0.45%; 10th percentile 1.25%; 90th percentile 0.12%)
o chemistry specimens (rejection rate 0.35%; 10th percentile 1.35%; 90th percentile 0.06%)</td></tr>
<tr><td>• Actions taken to improve performance and evidence of effectiveness</td><td>• Limited evidence of effectiveness found for actions to decrease the rate of specimens with inaccurate or inadequate information.
• Type of specimen collection personnel impacted specimen rejection rates. Non-laboratory personnel were 1.6–4.1 times more likely to be associated with rejected CBC specimens compared to laboratory personnel. Non-laboratory hospital personnel were 1.8–3.5 times more likely to be associated with rejected chemistry specimens than laboratory personnel.
• Use of a quality improvement monitor for specimen rejection did not result in better performance; nor did the length of time such a monitor was in place.</td></tr>
</table>

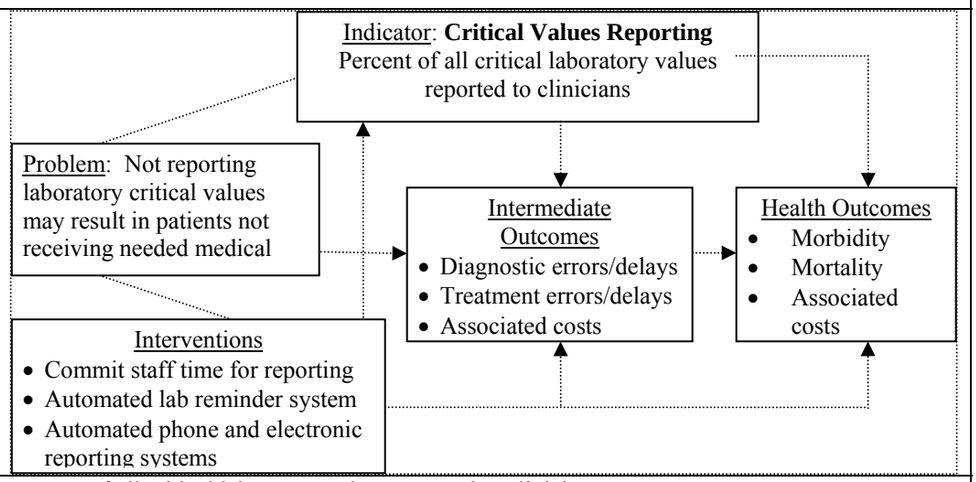
SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• No evidence was found relating specimen labeling deficiencies to any intermediate or health outcome, or associated costs. • Specimen labeling deficiencies may impact clinical processes and/or outcomes which may be associated with intermediate outcomes such as: diagnostic errors/delays, treatment errors/delays, and patient satisfaction with health care • JCAHO 2005 National Patient Safety Goals include accurate specimen labeling • No evidence was found demonstrating that improvement in this indicator positively impacts health care processes or outcomes relating to health, or is associated with recognized quality of care measures.
• **Indicator**	• Non-standardized definitions of specimen information "accuracy" and "adequacy" cannot consistently and accurately represent these concepts and produce credible results over time and across multiple organizations. • However, three studies of rate of specimen rejection due to inadequately labeled specimens produced comparable rates (0.015–0.024%) even though rejection rates were for different specimen types and were based on different criteria.
Reliability/Validity	• Non-standardized definitions of specimen information "accuracy" and "adequacy" cannot consistently and accurately represent these concepts and produce credible results over time and across multiple organizations. • However, three studies of rate of specimen rejection due to inadequately labeled specimens produced comparable rates (0.015–0.024%) even though rejection rates were for different specimen types and were based on different criteria.
FEASIBILITY	
Explicit specifications and standardized data requirements	Criteria for what constitute a specimen with "inaccurate" or "inadequate" information are available (see Numerator Description); however, they have not been uniformly or consistently defined, preventing standardized implementation and production of accurate and comparable results.
Implementable (for large numbers)	• No standardized data sources available across laboratory testing sites. <u>Studies</u> • A 1994 study monitored accuracy and adequacy of specimen information involving 417 hospital laboratories for surgical pathology specimens only • Three studies monitored the rate of specimen rejection due to inadequately labeled/unlabeled specimens o CBC analysis in 703 laboratories in 1995 o chemistry analysis in 453 laboratories in 1997 o outpatient phlebotomies involving 210 institutions in 2002 <u>Regulations</u> • JCAHO includes requirement for surgical specimen labeling (Requirement 1A) • CLIA requires laboratories to establish and follow written policies and procedures to ensure positive identification of a patient's specimen and an ongoing mechanism to monitor, assess and correct problems identified.
Reasonable cost/benefit of measurement	• No information found addressing costs or benefits associated with this indicator • Additional work resulting from rejected specimens for a single test for unspecified reason was estimated to take 16–37 paid minutes.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• Monitoring for accuracy and adequacy of specimen information may be used for internal quality improvement. • The laboratory is required by law to establish and follow written policies and procedures that ensure positive identification from the time of collection or receipt of the specimen through completion of testing and reporting of results. • JCAHO 2005 National Patient Safety Goals include accurate specimen labeling • Reducing the rate of inadequately labeled specimens is expected to reduce specimen rejection rate. Three CAP studies found inadequate labeling of specimens as a cause of specimen rejection in 5.1%, 6.7%, 5.8% and of all rejected cases for the following rejection rates: 0.45% of CBC specimens, 0.35% of chemistry specimens, and 0.026% of outpatient phlebotomies, respectively. • Not a quality measure in AHRQ's National Healthcare Quality Report.
Health care system control	• No evidence found of effectiveness for actions to decrease inaccurate or inadequate specimen labeling information. • Laboratory interventions suggested to improve performance include: effective implementation of specimen rejection policy, computerized order entry system, bar coding of specimen labels

IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Test Order Accuracy and Appropriateness** (CAP)
Conceptual Framework	
Definition	Percent of laboratory tests incorrectly ordered or ordered with incomplete or inaccurate information.
Population/Care Settings	All patient populations having laboratory tests ordered and all health care settings and providers where laboratory testing is ordered or performed
Rationale/Evidence	• Laboratory test order errors delay diagnosis and treatment, consume resources, and cause patient inconvenience. • However, limited evidence was found relating accuracy and appropriateness of test ordering to intermediate or health outcomes. • Indirect evidence for adverse impact due to blood loss caused by inappropriately ordered laboratory tests.
IOM Domains	Safety, Effectiveness, Timeliness and Efficiency
Numerator Description	Tests ordered inappropriately or incorrectly may include: • redundant tests ordered within defined time windows • tests ordered with incorrect or inadequate information • tests ordered not meeting specific testing guidelines Terms not specifically defined: • "incorrect or inadequate information" • "testing guidelines"
Denominator Description	Number of all tests ordered
Data Sources	Laboratory information systems, hospital information systems, and medical records
IMPORTANCE	
HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs	• Limited evidence found for prevalence/incidence of inaccurate or inappropriate test orders and associated medical/health quality problems or outcomes. • In a study of test ordering accuracy, 1.9% of ordered tests showed physician name discrepancies. • Two studies found redundant test ordering rates of 1.5% and 1.2% and a third study found 28.2% of tests were ordered earlier than a pre-defined time interval. • No evidence found for the seriousness of indicator-related health outcomes. • Indirect evidence that excessive laboratory testing may be a primary cause of anemia and resulting transfusion in preterm infants, and that excessive phlebotomy may cause up to half of RBC transfusions. • Although several studies provided evidence for laboratory charge reductions resulting from interventions to reduce test utilization, no cost data have been presented.
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	• In a study of thyrotropin (TSH) test orders, a median of 1.5% were duplicate orders within 7 days of the first test. • In a study of outpatient test ordering accuracy, with a median of 1.0%, 1 or more tests were not ordered in laboratory computer. • In a study of test ordering accuracy 1.9% of ordered tests showed physician name discrepancies.
• **Actions taken to improve performance and evidence of effectiveness**	Several single-institution studies related various interventions to decrease test over-utilization with decreases in laboratory charges and conflicting evidence for decreasing hospital length of stay (some studies showed a reduction in length of stay while others showed no effect). Interventions included: • computerized prompts when ordering tests • computerized displays of impact on charges and length of stay

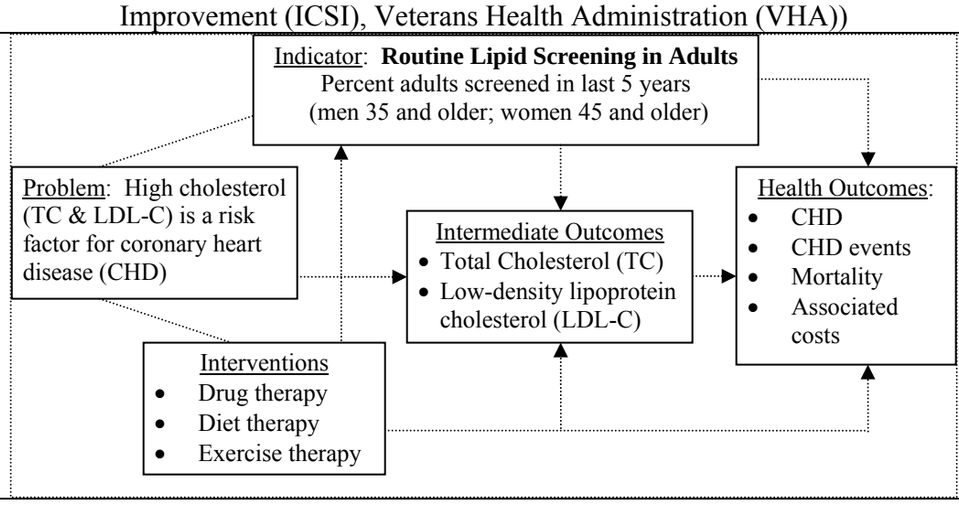
	• administrative changes • test requisition redesign • educational initiatives • implementation of practice guidelines
SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• Limited evidence was found relating test order accuracy or appropriateness with intermediate or health outcome, or associated costs. • Conflicting evidence for impact of decreasing test over-utilization on hospital length of stay; some studies showed a reduction in length of stay while others showed no effect. • Indirect evidence for adverse impact of laboratory test over-utilization in causing anemia that contributed to the need for blood transfusions.
• **Indicator**	Limited evidence demonstrating an association between this indicator and recognized quality of care measures or that improvement positively impacts health outcomes of individuals or populations.
Reliability/Validity	• Given the non-standardized definitions, this indicator cannot consistently and accurately produce credible results over time and across multiple organizations. • Most data on interventions to improve test utilization, however, showed a positive impact despite the limitation resulting from nonequivalent metrics and incomparable study settings.
FEASIBILITY	
Explicit specifications and standardized data requirements	Criteria for what constitute an "inaccurate" or "inappropriate" test order have been provided (see the numerator description); however, there is variation in the definition of these terms preventing standardized implementation and production of accurate and comparable results.
Implementable (for large numbers)	• Most studies addressing laboratory test utilization relate to single facilities with varying definitions of test order appropriateness and accuracy. • A study of inpatient test ordering accuracy in 577 hospitals involved 224,000 completed tests and 225,000 test orders. • A study of outpatient test ordering accuracy in 660 hospitals involved 115,000 outpatient test requisitions. • A study involving 502 hospitals and 221,000 TSH test orders, examined duplicate tests defined as being performed within 7 days of the first test.
Reasonable cost/benefit of measurement	• No evidence found on indicator measurement costs. • Intervention studies directed towards over-utilization of laboratory tests have consistently shown modest charge reductions of the order of 4–27%. Although not determined in most studies, impact on costs is expected to be much smaller.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• On the basis of information found from 3 CAP studies, monitoring for test order accuracy may be used for internal quality improvement. • Several interventions alone and particularly in combination were consistently successful in reducing the rate of laboratory test over-utilization as well as laboratory charges. • Computerized order entry and clinical decision support are recognized by AHRQ as a patient safety practice with medium strength of evidence regarding impact and effectiveness for medication errors and adverse drug events primarily related to the ordering process. This could apply to laboratory test ordering. • Not a quality measure in AHRQ's National Healthcare Quality Report.
Health care system control	• To decrease test order inaccuracy, a policy requiring staff to check written orders against computer orders could be instituted. • To decrease the rate of duplicate test orders, limit test ordering for each patient to fewer clinicians. • Interventions to decrease laboratory test over-utilization include o computerized prompts o displays of previous results and probability of abnormal results o displays of charges and length of stay o requisition redesign o implementation and promotion of practice guidelines o educational interventions o clinician feedback.

IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Critical Values Reporting** (CAP, CLIA, JCAHO)
Conceptual Framework	
Definition	Percent of all critical laboratory values reported to clinicians • Critical laboratory values are defined as results requiring immediate notification to the clinician for necessary patient evaluation or treatment. • No standard list has been developed of laboratory tests for which critical values exist. • Due to variation in test methods, patient population, and individual patient characteristics, no universal definition of critical value limits for any laboratory test has been defined.
Population/Care Settings	All patients with laboratory tests with critical values in all health care settings.
Rationale/Evidence	• No studies found effects of critical values reporting on patient outcomes, however reporting of critical values has been shown to influence patient therapy. • Every facility is required by CLIA to have a system for identifying and reporting "imminent life-threatening test results, panic or alert values." • JCAHO 2005 National Patient Safety Goals include timely communication of laboratory test critical values (Requirement 2A). • Although no cost data specific to the indicator were found, based on average time for notification, a large hospital laboratory estimate of slightly less than one full-time equivalent would be required.
IOM Domains	Safety, Effectiveness, Timeliness and Efficiency
Numerator Description	Number of critical values in the denominator successfully reported to a clinician within a given time period. Terms not specifically defined: • "successfully reported" • "clinician" • "time period"
Denominator Description	Number of laboratory test critical values (i.e. results requiring immediate clinician notification for necessary patient evaluation or treatment) • No standard list of laboratory tests included • Critical value limits for each laboratory test are not uniformly defined. • The terms "immediate" and "necessary patient evaluation or treatment" are not uniformly defined.
Data Sources	Laboratory information systems
IMPORTANCE	
HEALTH **Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs**	• No evidence found addressing the overall percentage of critical values reported, or its relationship to intermediate or health quality outcomes, or associated costs. • Total critical values frequency of 0.1% of reported laboratory test results. • As there is no common definition for critical limits for each test, for many tests these limits o vary by several-fold and o are institution-specific • Reporting of critical values is considered important because they may represent life-threatening situations, and ensure clinicians are promptly notified.
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	• No evidence found addressing overall variation or substandard performance of percentage of critical values reported • In a CAP Q-Probes survey of laboratory critical values policies and procedures, critical values were reported for o 95% of positive blood cultures o 91% of positive cerebrospinal fluid cultures o 96% of toxic therapeutic drug levels

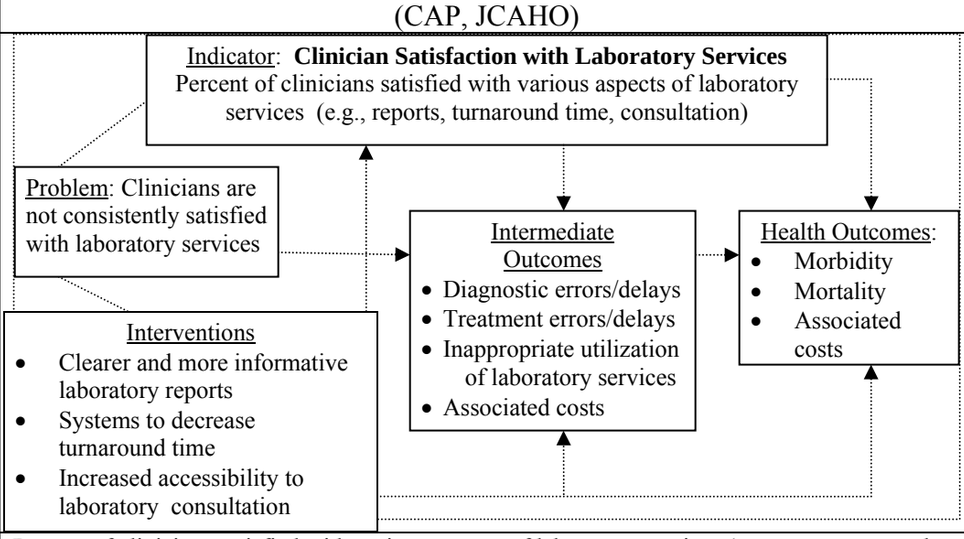
	• 2001 survey of hospital coagulation laboratories, 0.8% of hospitals did not report critical values.
• **Actions taken to improve performance and evidence of effectiveness**	• No evidence found of effectiveness of actions to improve critical values reporting, or that ongoing monitoring increased the rate of critical values reporting over time. • Laboratories not currently measuring critical values reporting can implement a monitoring program. • Actions can be taken by laboratories measuring critical values to successfully report a higher proportion.
SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• No evidence was found relating reporting of critical values to any intermediate or health outcome, or associated costs. • In a single study surveying nursing supervisors and physicians, greater than 60% of staff interviews and medical record reviews indicated critical values resulted in a change in therapy. • JCAHO 2005 National Patient Safety Goals include timely communication of laboratory test critical values (Requirement 2A).
• **Indicator**	No evidence was found demonstrating that improvement in critical values reporting positively impacts health care processes or outcomes relating to health, or is associated with recognized quality of care measures.
Reliability/Validity	Non-standardized terms and definitions for critical values reported (see Numerator and Denominator Descriptions) cannot consistently and accurately represent these concepts, and produce credible results over time and across multiple organizations.
FEASIBILITY	
Explicit specifications and standardized data requirements	Critical values reported have not been uniformly or consistently defined (see Numerator and Denominator Descriptions), preventing standardized implementation and production of accurate and comparable results.
Implementable (for large numbers)	• Critical values reporting has been implemented by a large number of hospital laboratories. • CLIA regulations require critical values reporting protocols. • Organizations that have used critical values reporting include CAP and JCAHO. • JCAHO 2005 National Patient Safety Goals include timely communication of laboratory test critical values (Requirement 2A). • No standardized data sources are available across laboratory testing sites.
Reasonable cost/benefit of measurement	• No information found addressing costs or benefits associated with this indicator • Information on critical values reporting system time requirement estimates include: o Critical values calls took an average of 6 minutes for inpatients and 14 minutes for outpatients o Slightly less than one full-time equivalent would be required for notification of critical values in a large hospital laboratory.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• Critical values reporting may be meaningful to hospital clinicians since in one study: o critical values resulted in changes in patient therapy more than 60% of the time o 95% of physicians surveyed found critical values lists valuable • As currently implemented, critical values reporting is used for internal quality improvement. • No evidence found linking critical values reporting to outcomes leading to improvement in health care. • JCAHO 2005 National Patient Safety Goals include timely communication of laboratory test critical values (Requirement 2A). • Not a quality measure in AHRQ's National Healthcare Quality Report.
Health care system control	• A system of critical values reporting can be operationalized into actions addressing processes under the control of the health care system. • Critical value reporting verification can be documented using the laboratory information system.

IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Routine Lipid Screening in Adults** (U.S. Preventive Services Task Force (USPSTF), Institute for Clinical Systems Improvement (ICSI), Veterans Health Administration (VHA))
Conceptual Framework	
Definition	Percent of adults with an up-to-date cholesterol screen (i.e., total cholesterol (TC) and high-density lipoprotein cholesterol (HDL-C) in the last 5 years)
Population/Care Settings	All men 35 and older; all women 45 and older; in various clinical and community settings
Rationale/Evidence	• Cholesterol is a major risk factor for coronary heart disease (CHD), which increases with TC and LDL-C. CHD affects almost 1/4 of the U.S population, accounted for more than 700,000 deaths and an estimated cost of more than $368 billion in 2004. • Although there is no evidence associating adult lipid screening rates with improvement in health outcomes, there are data addressing the effectiveness of 2 intermediate steps: o screening to detect lipid disorders o lipid disorder treatment (drug therapy) to reduce CHD events
IOM Domains	Effectiveness, Equity
Numerator Description	Individuals from the denominator with documentation (test results and date) of cholesterol screen, which must include TC and HDL-C, in the last 5 years.
Denominator Description	Men age 35 and older and women age 45 and older (does not include those who do not have medical provider encounters).
Data Sources	Medical records (charts or administrative data) with 5-year history for patients demonstrating TC and HDL-C test levels and dates or with CPT-4 codes (administratively). National data sources: CDC's Behavioral Risk Factor Surveillance System (BRFSS); National Health Interview Survey (NHIS)
IMPORTANCE	
HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs	• No evidence found relating adult lipid screening rate to intermediate or health outcomes, or associated costs. • There is substantial evidence that the higher the level of blood cholesterol, the greater the risk of CHD such that the incidence of CHD is proportional to TC and LDL-C. • High cholesterol (hyperlipidemia) affects more than 65 million Americans (17% of adults aged 20 and over for 1999-2002) and is more prevalent in older age groups. • CHD, which includes heart attack and heart failure, affects 65 million people, almost 1/4 of the U.S. population, and remains a leading cause of death accounting for more than 700,000 deaths and cost exceeding $368 billion in 2004.
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	• 1998 U.S. adult cholesterol screening rates (past 5 years): age 18 and older: 67%; 18-44: 53%; 45-64: 81%; 65+: 87%. • Almost 3/4 of adults with high cholesterol do not have it under control, and more than 3/4 are not taking medication for their condition (1999-2000)
• **Actions taken to improve performance and evidence of effectiveness**	• No evidence of effectiveness found for actions to increase adult cholesterol screening. • General awareness and healthcare provider activities include education and outreach efforts such as: o establishing a process to identify those needing cholesterol screening o making educational brochures available at time of visit • Drug therapy for lipid disorders reduces the relative risk for CHD events and CHD mortality by approximately 30%, with reduction depending on underlying risk of those being treated.

SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• A broad base of evidence indicates LDL-C and TC levels are directly related to CHD incidence and risk. • Total excess risk from lipid disorders depends on the presence of other risk factors, however increased risk for CHD events associated with cholesterol levels is continuous with no clear "cut-off" separating normal from abnormal. • Serum cholesterol contributed an estimated 38% of total risk factor reduction (including blood pressure and smoking) in CHD incidence of 7-11% and 430,000 fewer deaths over the 1980-1990 period. • Cholesterol levels can be reduced by lifestyle modifications (diet low in saturated fat, losing excess weight, increasing physical activity), and drug therapy.
• **Indicator**	• No evidence found demonstrating improvement in adult lipid screening rates positively impacts health care processes or outcomes, however it is a nationally recognized quality of care measure. • There is substantial indirect evidence supporting routinely screening men aged 35 and older and women aged 45 and older for lipid disorders. • Screening can detect cholesterol abnormalities and lead to treatment before heart disease develops or worsens. • No data found to inform the appropriate frequency of screening.
Reliability/Validity	As defined, adult lipid screening consistently and accurately measures the desired concept and events across mutliple participating organizations over time using medical records (charts or administrative data) of TC and HDL-C testing (CPT-4 codes: 80061, 83718, 83719, 83721). National data sources documenting this measure include CDC's Behavioral Risk Factor Surveillance System (BRFSS) and National Health Interview Survey (NHIS)
FEASIBILITY	
Explicit specifications and standardized data requirements	This indicator definition, specifications, and data requirements are sufficiently standardized, detailed, precise, understandable and implementable to produce accurate and comparable results.
Implementable (for large numbers)	• Implementation requires access to patient records for at least 5 years; entities likely to have sufficient access include primary care settings and health care systems. • Indicators representing the percent of adults with lipid screening have been implemented by the VHA and HMOs participating in NCQA HEDIS measures for patients with diabetes, national surveys (BRFSS and NHIS) • This indicator as defined is a recommended measure of ICSI's lipid screening in adults health care guideline.
Reasonable cost/benefit of measurement	• No evidence found on indicator measurement costs. • Hyperlipidemia screening evidence: One study estimated for every 418 adults screened (LDL-C), if detection followed by pravastatin treatment for 5 years, one death in 5 years could be prevented, comparable to or less than the number needed to be screened for high blood pressure. • Hyperlipidemia treatment evidence: LDL-C lowering is cost-effective for primary prevention for those at higher risk for CHD, but not at lower risk. Cost effectiveness is highly dependent on drug prices.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• There is general agreement in the medical community for the need to lower blood cholesterol to reduce the incidence of CHD due to the congruence of many types of scientific evidence. • Indicator is related to the U.S. National Cholesterol Education Program's (NIH) recommendation for a fasting lipoprotein profile at least once every 5 years (adults age 20 and over), and is listed as a measure in AHRQ's National Healthcare Quality and Healthcare Disparities Reports (percent of all adults age 18 and over).
Health care system control	Lipid screening tests are ordered by health care professionals, however no effectiveness evidence was found for interventions to increase adult screening rates.

IQLM QUALITY INDICATOR EVALUATIONS

INDICATOR NAME (Primary Sources)	**Clinician Satisfaction with Laboratory Services** (CAP, JCAHO)
Conceptual Framework	
Definition	Percent of clinicians satisfied with various aspects of laboratory services (e.g., test turnaround time, accessibility, communication)
Population/Care Settings	All clinicians ordering and using laboratory test results in their practice in all health care settings
Rationale/Evidence	• Clinician (customer) satisfaction is considered an element of laboratory service quality. • No evidence was found to relate clinician satisfaction to intermediate or health outcomes and associated costs.
IOM Domains	Not applicable
Numerator Description	Number of clinicians surveyed satisfied with specific aspects of laboratory service including: test turnaround time, resolution of telephone inquiry, quality of professional interaction, follow up of clinical contacts, pathologist accessibility and responsiveness to problems, diagnostic accuracy, staff courtesy, communication of relevant information and of significant abnormal results, specimen submission process, content, clarity and format/style of test report. Terms not uniformly defined: • "clinician" • "satisfied" (assessed using various rating scales) • specific aspects of laboratory service above
Denominator Description	Total number of clinicians surveyed
Data Sources	Clinician surveys
IMPORTANCE	
HEALTH Prevalence/ Incidence and seriousness of indicator-related medical/health quality problem(s) and their associated costs	• No evidence found to relate clinician satisfaction rates to any intermediate or health outcome, or associated costs. • The following clinician satisfaction rates have been reported: o 95% overall surgical consultation process o 53%–90% various aspects of reference laboratory telephone services o 53%–91% various aspects of anatomical pathology services o 78% hospital blood transfusion services o 79%–90% chemical pathology services (communication with laboratory, turnaround time, reporting format)
POTENTIAL FOR IMPROVEMENT • **Evidence of variation in quality**	Wide variation in clinician satisfaction with various aspects of laboratory services within and among institutions, however substantial variation in the questions, rating scales, and clinician population.
• **Actions taken to improve performance and evidence of effectiveness**	There is no evidence of effectiveness found for actions to increase clinician satisfaction with laboratory services. Suggested interventions to improve performance on this indicator include: • clearer, more informative laboratory reports • systems to decrease turnaround time increased accessibility to laboratory consultation

SCIENTIFIC ACCEPTABILITY	
Strength of Evidence • **Quality Problem**	• No evidence was found relating clinician satisfaction to any intermediate or health outcome, or associated costs. • To the extent that specific aspects of clinician satisfaction measures variables that can be linked to intermediate outcomes, they may affect o diagnostic errors/delays o treatment errors/delays o inappropriate utilization of laboratory services, and associated costs.
• **Indicator**	No evidence was found demonstrating that improvement in the indicator positively impacts health care processes or outcomes relating to health of individuals, or is associated with recognized quality of care measures.
Reliability/Validity	• The same survey has not been administered over time to the same clinician populations; therefore accuracy and reproducibility of indicator results over time and the degree to which they are subject to random error cannot be evaluated. • Several studies of clinician satisfaction with various laboratory services show comparable satisfaction rates.
FEASIBILITY	
Explicit specifications and standardized data requirements	Criteria for what constitutes clinician satisfaction and the relevant aspects of laboratory services have not been uniformly or consistently defined (see Numerator Description), preventing standardized implementation and production of accurate and comparable results.
Implementable (for large numbers)	• No standardized data sources available across laboratory testing sites. • Monitoring of clinician satisfaction with various aspects of laboratory services has been done by a large number of laboratories • No information was found providing estimates of effort and cost of abstracting and collecting data.
Reasonable cost/benefit of measurement	No information was found addressing costs or benefits associated with this indicator.
USEFULNESS	
Comprehensible and relevant to users, decisionmakers, and stakeholders	• Surveying clinician satisfaction of laboratory services is used for internal quality improvement; this has been done by many organizations and has been reported by several investigators. • Not a quality measure in AHRQ's National Healthcare Quality Report.
Health care system control	• No evidence was found of effectiveness for actions to increase clinician satisfaction with laboratory services. • Laboratory interventions suggested to improve performance include: o clearer, more informative reports o systems to decrease turnaround time o increased accessibility to laboratory consultation

IQLM Quality Indicators Workgroup
IQLM 2005 Conference Poster
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