Introducing the Ultimate Guide to Laboratory Test Utilization

What's in CLSI's GP 49, How to Use It, and Why It Works

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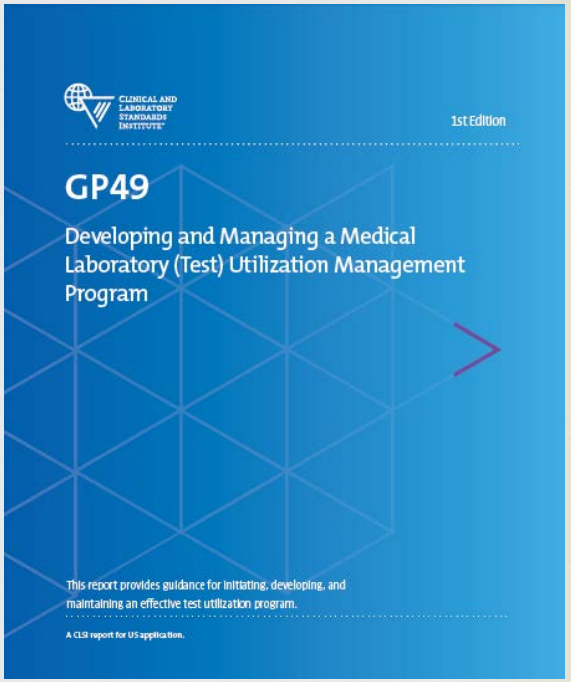
Who, Why, What, How

- Who:
  - Who wrote it: Authors who are Legends
  - Who should do this work locally
- Why:
  - Explanation of the changing workscape
  - Why certain tests need not be performed
- What: To Do. (Good recipes)
- How:
  - CLSI Process – This is a consensus document.
  - Numerous Examples
  - To report your successes.



Text Breakdown

- Foreword/ Introduction
  - Scope/Background/Terminology
- Structure and Function
  - Initial Framework/Organizational Approach/ Program Management
- Strategies and Tactics
  - Causes/Countermeasures
- Analytics and Measures
  - Measures/Analysis/Reporting
- Additional Considerations
  - Problems & Barriers/Elements Needed for Success/Lessons Learned
- Conclusion / Supplemental Appendices

Foreword

- Healthcare is changing.
  - Transaction-Based to Value-Based (Capitated)
- Opportunities for Laboratory Leadership
  - Re-define our role and value in the new system.
  - More actively participate in the pre- and post-analytic space
- Optimizing Testing
  - Addresses under- and over-utilization.

Introduction

- Scope
  - Initiating, developing, and maintaining an effective test utilization committee.
- Rationale
- Risk/Benefits
  - Useful to demonstrate *who* in your system will benefit
- Causes
- International Differences
- Definitions

How to Do it Right (Anything Else Must Be Wrong)

- The correct test is ordered for the correct situation.
- The specimen is collected correctly.
- The laboratory performs the test in a precise, accurate and timely manner.
  - Errors = repeats; untimely results = repeats/less-to-noneffective.
- Test result provides clinically useful information that is interpreted correctly and acted upon (promptly) and appropriately.
  - Activating the *effector arm*
  - Be part of the System

Risks of Under-Utilization

- Incorrect/Delayed Diagnosis
  - Late presentation = advanced disease; more costly to treat.
- Unnecessary hospitalization / increased length of stay
- Increased cost to patient and/or health care organization
- Patient dissatisfaction
  - What should have been done --> Google it.
- Liability exposure or fear of liability
  - A cause of overutilization (Solution = guidelines)

Structure/Function

- Initial Framework
- Commitment and Investment
- Essential Resources
- Organizational Approach
- Program Management

Initial Framework

- Right Sizing
  - No "One Size Fits All"
  - All Politics are Local
- Organizational and Individual Alignment
- Nuts & Bolts
  - Meeting schedule
  - Responsibilities
  - Etcetera

Commitment & Investment

- Resides at all levels:
  - Organizational Leadership
    - More than moral support will become necessary
  - Program Leadership
    - Beware of Becoming a “Heroic Leader”
  - Team Members
    - Committed, Engaged & Active.
  - Clinical and Laboratory Stakeholders
    - Co-Creation is Key

- Time is invested by all
  - Documented and Valued

Essential Resources

- Resources will be needed for:
  - Project management
  - Data collection & analysis
  - Committee meeting preparation and participation
  - Presentations & Meetings
    - Clinical Stakeholders
    - Institutional Leadership
  - Impact analysis
    - Operational and financial
  - Report generation

Organizational Approach

- Engages a wide-range of stakeholders throughout an organization to achieve the desired outcomes.

- Multispecialty Utilization Teams
  - Seek broad-input; respect diverse opinions.
  - Open, collegial exchange -> Informed decision making

- Engagement and Participation
  - I need a hero: Champions are necessary.
  - Clinical:Pathology Dyads can be effective.

- Medical/Financial/ IT Knowledge

- Skill Set to Lead the Team

Motivations & Incentives

- Traditional:
  - Contain and Reduce Healthcare Expenditure.
    - Critical with capitation

- Additional:
  - Implementation of Best Practices (Do Good by doing Right)
    - Improves/Preserves Engagement
    - Improve Patient Care/Experience
    - Decrease Harm (e.g., Iatrogenic anemia)
    - Decreases Unecessary Ancillary Testing (d/t False Positives)
  - Alignment with payors
    - Shared savings
  - Address budgetary gaps.

Sidebar: Positive Predictive Value

- Nuns and Commercial Sex Workers
- Testing and Retesting

Test Specs: 95% Sensitivity/95% Specificity: Good Test, right?

Prevalence of Disease	Positive Predictive Value	Negative Predictive Value
1%	16%	99%
5%	50%	99%
10%	68%	99%
25%	86%	98%
50%	95%	95%

The Team Composition

- Remember to Tailor
  - Composition is dynamic, not static

- Key Members Include:
  - Pathologist & Doctoral-Level Scientist
  - Clinicians & Nurses
  - Administrators
  - Genetic Counselors
  - IT & Data Services
  - Quality
  - Continuous improvement professionals
  - Financial Analysts
  - Statisticians (or someone with equivalent knowledge)

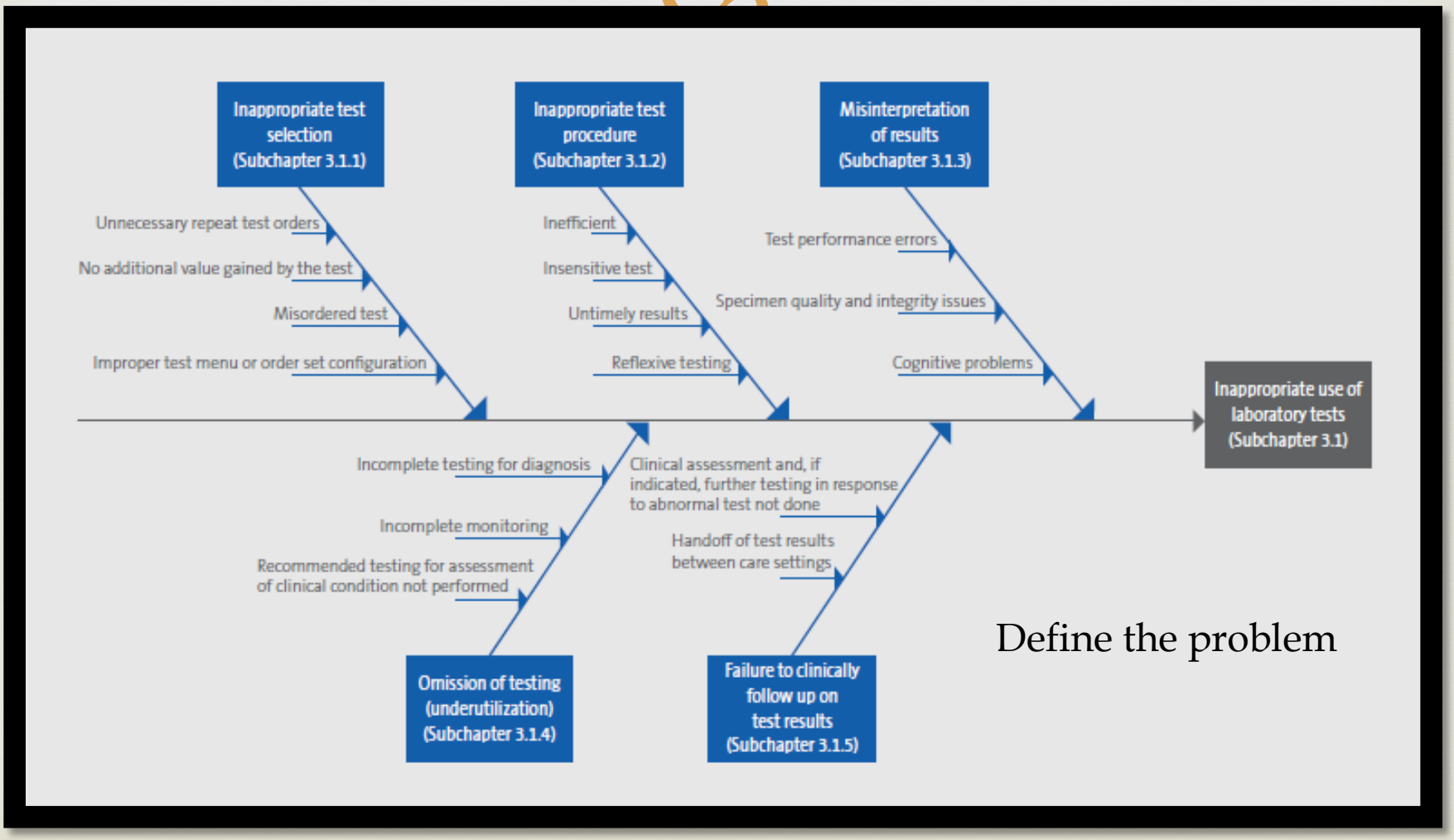
The Team's Work

- To determine: Scope and Goals
- To establish the agenda for meetings
- Prioritize initiatives
- Project management of initiatives
- Collect and analyze data
- Implement proposals and monitor change.
- Track and report impacts (hopefully successes)

- Program management (Lobby for a program manager)

Strategies/Tactics

Now what, again, are we trying to fix ?



Define the problem

Inappropriate Test Selection

- Unnecessary Repeat Orders
  - More frequently than necessary
    - Result will not change within a given time frame.
      - Examples: Lipid panel, HbA1c
  - Results will not change
    - Example: Constitutional genetic tests
  - Provider is unaware of the results
    - Post-analytic issue
    - Ask yourself: How easy is it for my provider to find this result?

Inappropriate Test Selection

- Test Provides No Additional Value
  - Based on the results of another tests
    - Free T3, if TSH is normal; HCV antibody, if HCV RNA detected
  - Based on the inability to interpret due results of another test
    - Free PSA, if PSA <4 or >10 ng/ml.
  - Based on patient demographics, location, time of year, sample type
    - Rapid Strep without pharyngitis; *C. difficile* on formed stool; Influenza when out of season; lipid panel in the ED.
  - Redundancy of results (inches versus centimeters)
    - ESR and CRP; stool calprotectin and lactoferrin

Inappropriate Test Selection

- Misordered Test
  - Technical Problems
    - Inadvertent test selection (i.e. checking the wrong box)
    - Aberrant listing (Numerical/Alphabetical)
      - HIV2 listed before HIV1
  - Cognitive Problems
    - Sound-alike tests
      - Magnesium/Manganese;
      - Crytococcal Antigen vs. Antibody,
      - Anti-thyroglobulin versus thyroglobulin.

Inappropriate Test Selection

- Misordered Test
  - Misunderstandings of Specific Indications
    - Phenochromocytoma (Adults):
      - Blood serotonin (incorrect) vs. urine metanephrine.
    - Allergic Aspergillosis:
      - Galactomannan (incorrect) versus *Aspergillus* IgE
  - Improper Menu or Order Set Configuration
    - One mistake is multiplied and lasts a long time
    - Menu: Listing issues, sound alikes, rarely used tests
      - Consider: Tiered ordering screens (Commonly used; specialty)
    - Order Sets
      - Built in waste, for convenience
      - Consider: optimal algorithmic testing.

Inappropriate Test Procedure

- Inefficient Test Procedure
  - Unnecessary work (overprocessing) -> Delays
    - Example: Working up normal flora in microbiology.
- Insensitive Test Procedure
  - Obsolete test/insensitive -> No diagnositic value -> Additional Testing Needs
- Untimely Result
  - Example: Send-out CSF Gram stain -> poor patient care
- Reflex Testing
  - Reviewing reflex testing to assure appropriateness

Erroneous or Misinterpreted Results

- Test Performance Errors
  - Errors = Repeats; QC = Cost-effective practice
- Specimen Quality/Integrity Issues
  - Problems related to:
    - Specimen Collection: QNS , mislabeling, poorly timed (when applicable) = Repeat
    - Specimen Transport: Compromised integrity -> errors -> patient harm/repeats/ancillary testing.
    - Specimen Processing: As above
  - Problems related to patient condition (e.g., fasting)
- Cognitive Problems
  - Misunderstanding (Consider interpretive comments).
  - Systems-Based Approach

Omission of Testing (Under-utilization)

- Incomplete Testing for Diagnosis
  - Initial
    - Example: Failure to test for both ceruloplasmin and copper for suspected Wilson's disease
  - Reflex:
    - Example: Failure to follow-up a positive HCV antibody test with an HCV RNA assay

- Incomplete Testing for Monitoring
  - Chronic conditions/treatment:
    - Diabetes control.
    - Phenobarbitol: ALT/AST & CBC q 6 months.

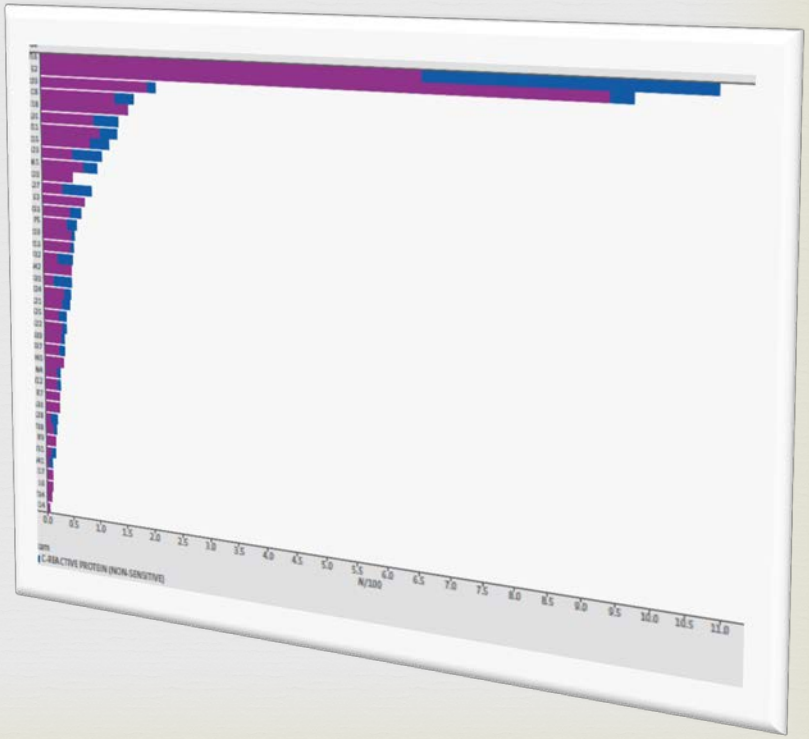
- Recommended Testing for Clinical Condition Not Performed.
  - ER/PR/HER2 not performed on invasive ductal carcinoma.
  - Malpractice issue.

Strategies

- Four Primary Strategies
  - Education and Feedback
  - Test Order Control
  - Appropriate Selection and Application of Laboratory Testing Procedures
  - Utilization of Test Results

Strategies: Education and Feedback

- Prospective (Limited Impact)
  - Clinician, Patient, May Influence Consultation
- Decision Support
  - Passive, Hard Stops, Advanced
- Retrospective
  - Clinician Profiling
    - Compare like practices
  - Inter-Institutional Benchmarking
    - Compare similar institutions



Strategies: Test Order Control

- Use of Test Orders / Order Sets
  - Menu: Configuration is key
    - Remove obsolete tests.
  - Order Sets: Work to standardize within groups
    - Review regularly
- Reflex Testing / Algorithms
  - Work to replace bundling within Order Sets with best practice reflex algorithms
- Limited Availability
  - Tiered testing
  - Privileging / Clinical Consultation Required
  - Lab-Order Only - Hold/Review


Review and approval required
Justification required
Limited to providers on select services
Orderable by all providers

Analytics/Measures

- Performance Metrics to Evaluate Effectiveness
  - Accurately captures relevant clinical and operations effects of the initiative
  - Identifies and excludes clinical and operations outcomes unrelated to the initiative.
    - Example: Don't measure the impact of an initiative to decrease unnecessary influenza test as the season ends.
  - Achieves statistical power
  - Is concise and easy to interpret

Selected Analytical Approaches

- Benchmarking
- Yield Analysis
- Trend Analysis
- Repeat Testing Analysis
- Sequential Testing Rates
- Guideline Conformance
- Variation Analysis

Calculating Cost Savings

- Decreased Operating Costs (Materials & Labor)
- Decreased Patient Care Costs
  - Decreased out-of-pocket expenses
  - Increased patient satisfaction
- Decreased Managed Care Costs
  - (Consider Shared Savings)
- Reduced Specimen Collection Costs
  - Materials; and phlebotomist/nursing time
- Decreased Costs d/t False Positives
  - Repeat testing; possible radiologic studies
  - Additional provider time; lost time from work.

Other Impacts (Difficult to Quantify)

- Increased Patient Satisfaction
  - Fewer phlebotomy
  - Lower costs for phlebotomy/nursing
- Improved Clinical Quality
  - More efficient, timely diagnosis
  - Optimal diagnosis, treatment, and outcomes
  - Fewer false positives
- Improved Value
  - Reduced length of stay
  - Appropriate use of consultations
  - Fewer followups for false-positives

Additional Keys to Success

- Change Management
- Communications
  - Notification / Feedback / Thanks
- Employ Continuous Improvement Tools
- Good meeting practices
- Monitoring and Reporting

Supplemental Appendices

- A. Sample Test Utilization Project Charter
- B. Sample Action Plan Template
- C. Sample Multiple Initiative Utilization Cost Worksheet
- D. Sample Single Initiative Utilization Worksheet
- E. ABIM: Recommendations for Laboratory Testing

Before