

Strategies and Tactics in Laboratory Stewardship



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Who, Why, What, How



❧ Who:

- ❧ Who wrote it: Authors who are Legends
- ❧ Who should do this work locally

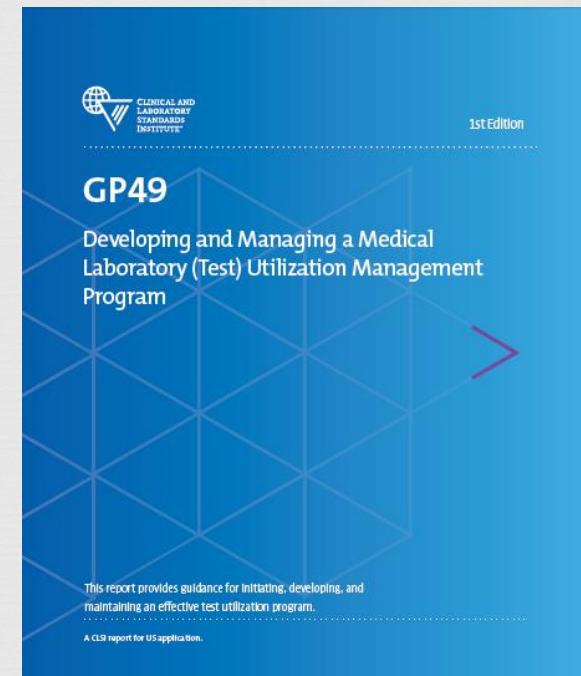
❧ Why:

- ❧ 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.



Your Team Structure/Function

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

Strategies and Tactics are gimmicks that will have limited impact, unless the purpose for the intervention is true and the correct people are engaged.

Initial Framework



❧ Right Sizing

- ❧ No “One Size Fits All”
- ❧ All Politics are Local

❧ Organizational and Individual Alignment

❧ Nuts & Bolts

- ❧ Meeting schedule
- ❧ Responsibilities (ie Action Items)
- ❧ Minutes

Commitment & Investment



- ❧ Resides at all levels:
 - ❧ Organizational Leadership
 - ❧ More than moral support will become necessary
 - ❧ Program Leadership
 - ❧ Beware of Becoming a “Heroic Leader”; Delegate
 - ❧ 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 Alignment



- ❧ Engages a wide-range of stakeholders throughout an organization to achieve the desired outcomes.
 - ❧ You will learn and become more systems oriented.
- ❧ Multispecialty Utilization Teams
 - ❧ Seek broad-input; respect diverse opinions.
 - ❧ Open, collegial exchange -> Informed decision making
 - ❧ You will learn what the laboratory test looks like from another perspective.
- ❧ Engagement and Participation
 - ❧ I need a hero: Champions are necessary.
 - ❧ Clinical:Pathology Dyads can be highly effective.
- ❧ Medical/Financial/ IT Knowledge
- ❧ Skill Set to Lead the Team – Leadership Development

Motivations & Incentives



❧ Traditional:

- ❧ Contain and Reduce Healthcare Expenditure.
 - ❧ Critical with capitation

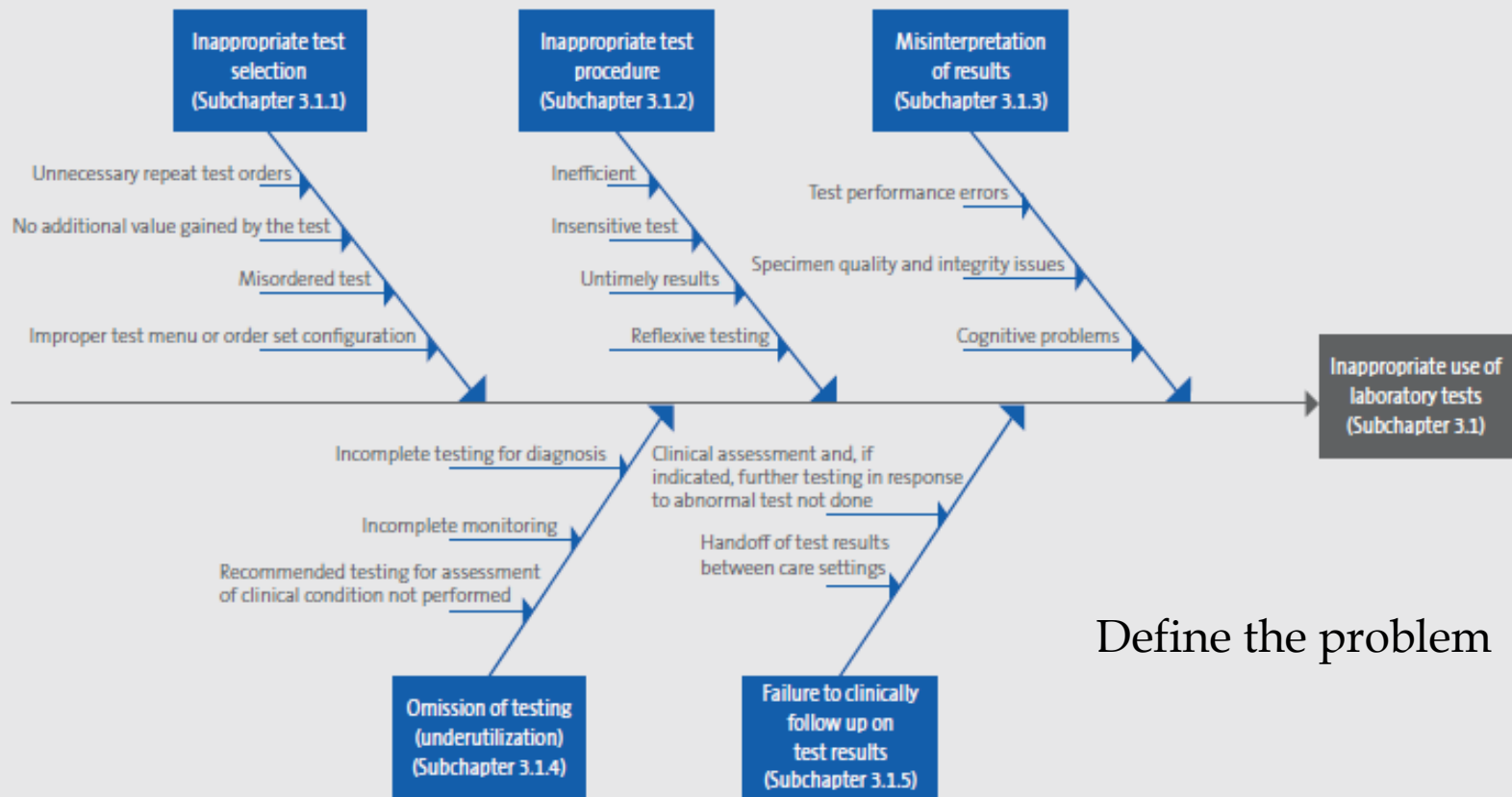
❧ Additional:

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

Strategies/Tactics



Now what, again, are we trying to fix ?



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;
 - ❧ Cryptococcal 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 alike, 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 diagnostic 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.
- ❧ Phenobarbital: 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

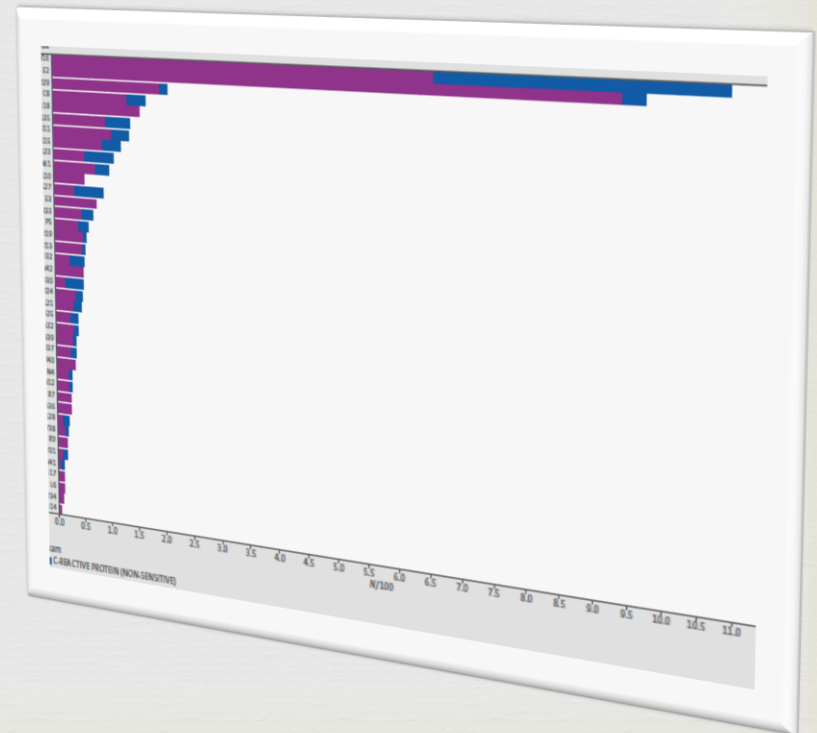
❧ Test Order Control

❧ 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

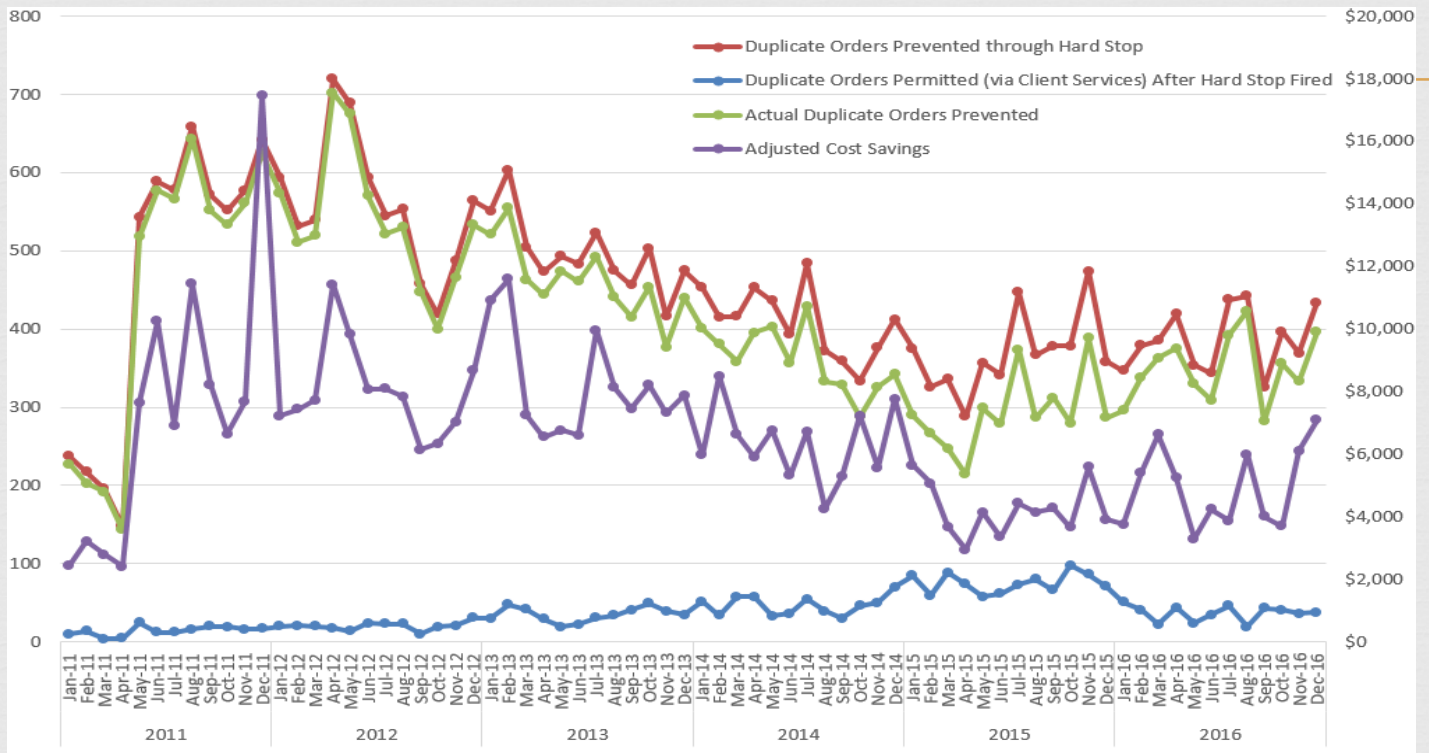


The Cleveland Clinic Experience



Strategies and Tactics
Demonstrated Through
Projects and Outcomes

Hard Stops



2018: 4,225 unnecessary orders prevented;

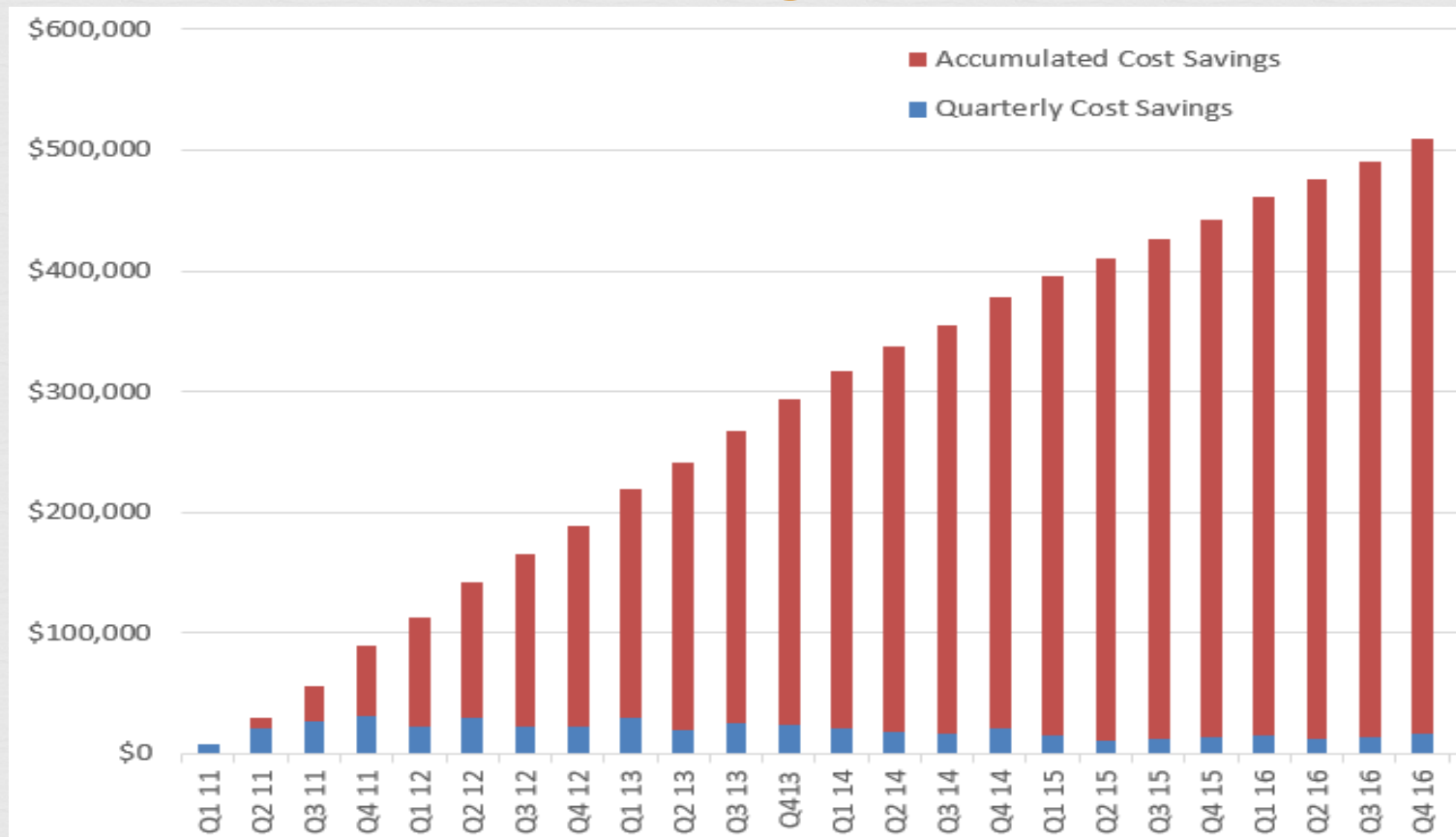
Full Program (1/11-12/18): 38,174 unnecessary orders prevented.

80-95% Success Rate

Unnecessary phlebotomies avoided and blood saved: A lot.

Hard Stop Financials

by Quarter



2018: Cost Avoidance - \$56,122

Total: (1/11 to 12/17): \$578,744

Regional *Smart Alerts*



- ❧ Similar to Soft Stops.
 - ❧ But, with Previous Results Displayed.
- ❧ List includes: 752 of the 1,283 tests on Main.
- ❧ Considerations include:
 - ❧ Non-Cleveland Clinic Practitioners
 - ❧ Practitioner use of Computerized Physician Order Entry-availability
 - ❧ Written orders to unit clerks/nurses
 - ❧ No work-around infrastructure.

Regional Smart Alert

Place orders

New Order Interactions Providers Reports Pending Orders Held Orders Pending Orders Sign & Hold Sign Orders Settings Order Set Pref List

New order: Search

Order mode: Standard New order defaults Not using defaults

During visit (1 Order)

LIPID PANEL BASIC (EU,FV,HL,LK,LU,MM,SP) P Routine, ONCE File

Order Validation

The following information is missing or may need your attention

Warning:

This lab test has been ordered in the last 24 hours; repeat testing is usually not warranted for this analyte within 24 hours.

LIPID PANEL BASIC (EU,FV,HL,LK,LU,MM,SP) was ordered on 9/20/12 at 12:53 PM by provider AGARWAL, RAJESH

If you are ordering LIPID PANEL BASIC (EU,FV,HL,LK,LU,MM,SP) at the same time as other orders, you must first remove LIPID PANEL BASIC (EU,FV,HL,LK,LU,MM,SP) from the order list before you can file the other orders.

Date/Time	Component	Result	Ref Range	Flag
9/20/12 1:58 PM	Triglyceride	333	30 - 149 mg/dL	H
9/20/12 1:58 PM	Cholesterol	222	100 - 199 mg/dL	H
9/20/12 1:58 PM	HDL Cholesterol	55	>55 mg/dL	L
9/20/12 1:58 PM	VLDL-Cholesterol	33	6 - 40 mg/dL	
9/20/12 1:58 PM	LDL Cholesterol	22	60 - 129 mg/dL	L
9/20/12 1:58 PM	Fasting Time	12	hrs	
9/20/12 1:58 PM	TC:HDL Ratio	11.00	1.00 - 5.00	H
9/20/12 1:58 PM	LDL:HDL Ratio	5.00	0.50 - 3.55	H
9/20/12 1:58 PM	Non HDL Cholesterol	6	90 - 159 mg/dL	L

Do you want to accept these orders anyway?

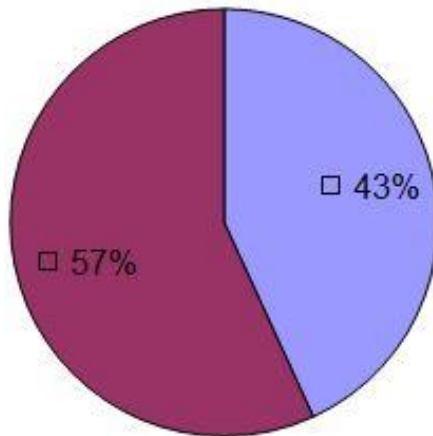
Yes No

Regional Smart Alerts



Monthly calculation of alert compliance

Hillcrest Hospital Lab Soft-Stop
October 2015 Report



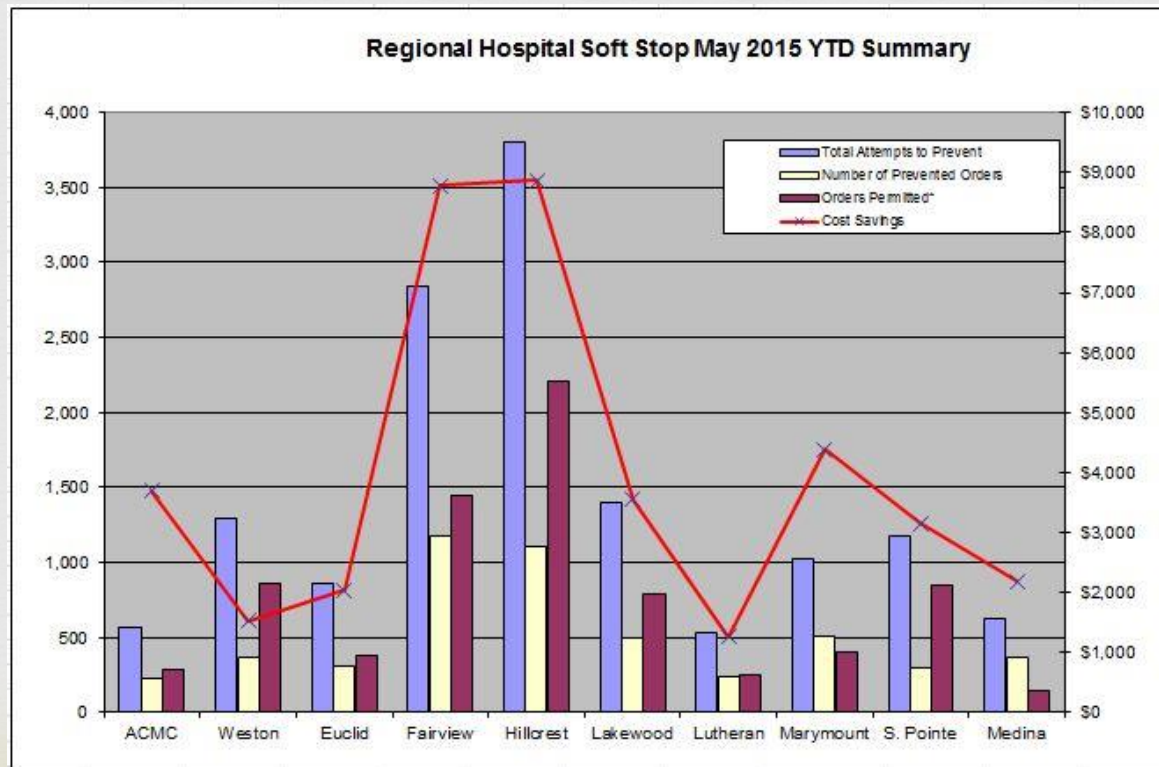
■ Firing without Orders ■ Order placed within 30 minutes of firing

Regional Smart Alerts



9,654 unnecessary tests averted in 2018

Total (10 m 2013 - 2018): 36,421

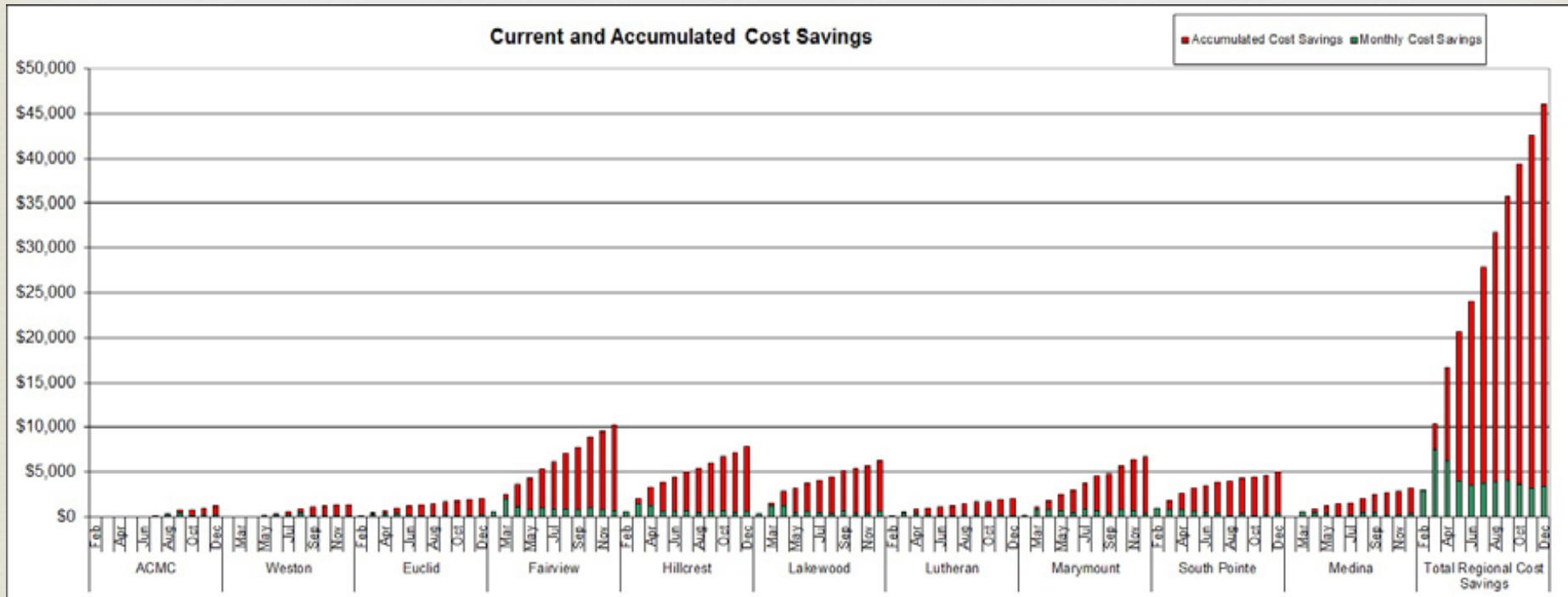


Regional Smart Alert: Cost Avoidance



❧ Cost-Savings, 2018: \$76,100

❧ Total (10m 2013 - 2018): \$287,899



Hard Stop versus *Smart Alert* Comparison

- ❧ One year comparison
 - ❧ Duplicate tests avoided and cost avoidance.
- ❧ The Hard Stop alert was significantly more *effective* than the Smart Alert (92.3% versus 42.6%, respectively; $p < 0.0001$).
- ❧ The cost savings realized per alert activation was \$16.08/alert for the Hard Stop alert versus \$3.52/alert for the Smart Alert.

Optimizing Molecular Genetic Testing



❧ Restricting Testing

- ❧ Specialized tests not on standard menu “Lab Order Only”
- ❧ Restriction to Users Groups

❧ Genetic Guidance

- ❧ Laboratory-Based Genetics Counselor
 - ❧ With Molecular Genetic Pathologist Oversight.
- ❧ Resident/Fellow Involvement
 - ❧ Educational/Not “Thrown to the wolves.”

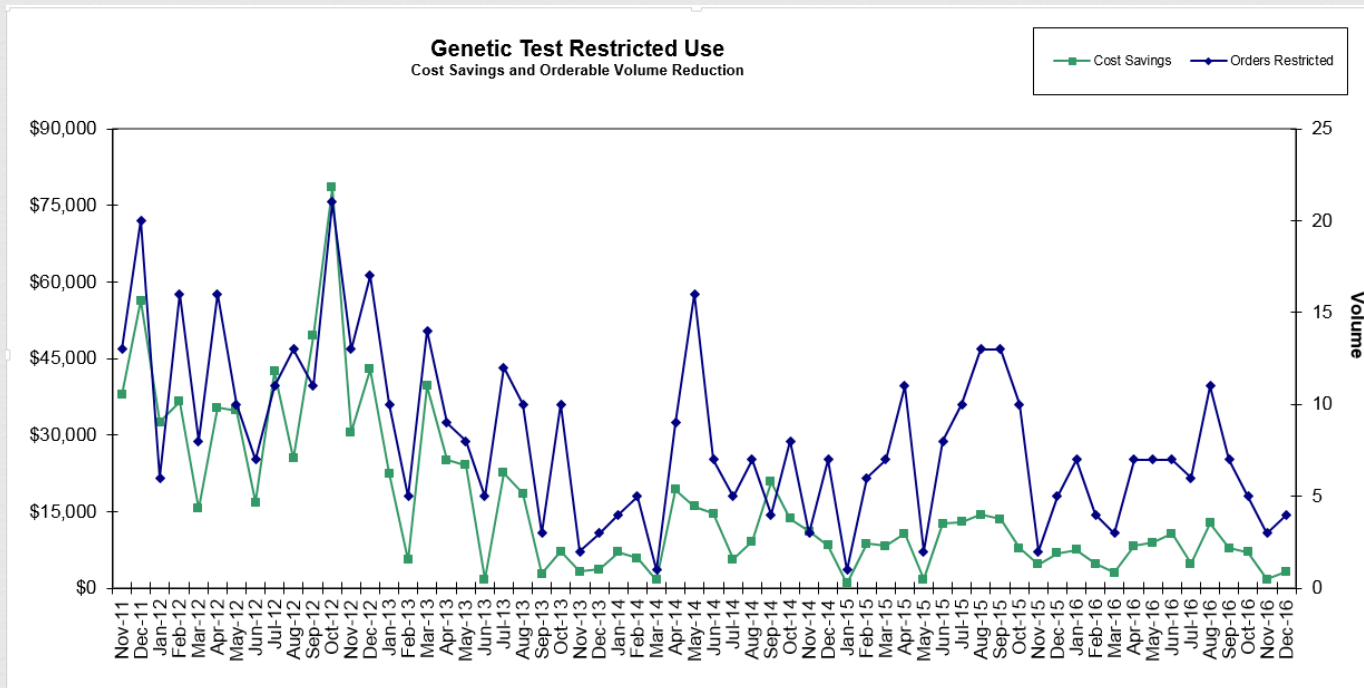
❧ Algorithmic Testing

- ❧ Collaborative Development (Clinician/Pathologist) of Algorithms
- ❧ Extract/Hold -> Sequential Testing
 - ❧ Requires infrastructure & engagement.

Restricted Use Initiative

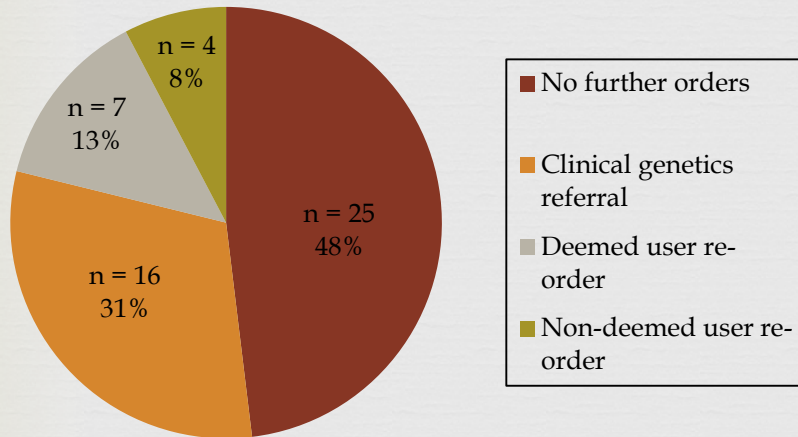


- ❧ Molecular Genetic Tests limited to “Deemed Users.”
- ❧ Inpatient testing requires a Medical Genetic Consult

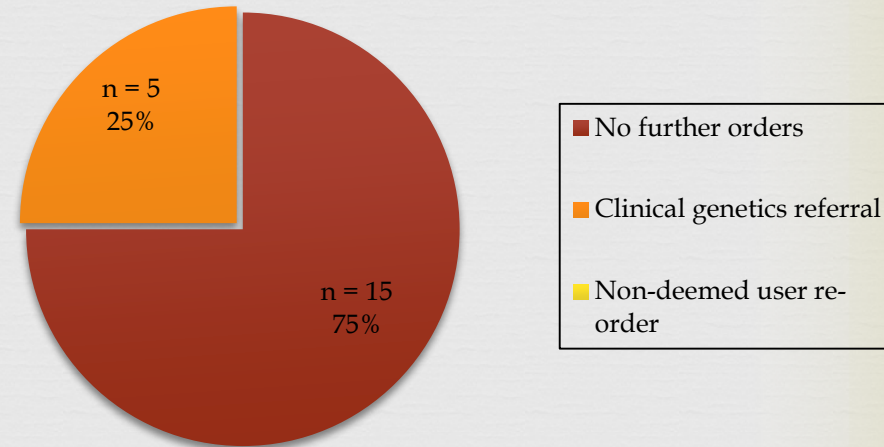


2018: 36 Tests; \$45,45,559 Total (11/11 - 12/18): 601 Tests; \$1,140,218

Follow-up to Restricted Orders



Ambulatory



Inpatient

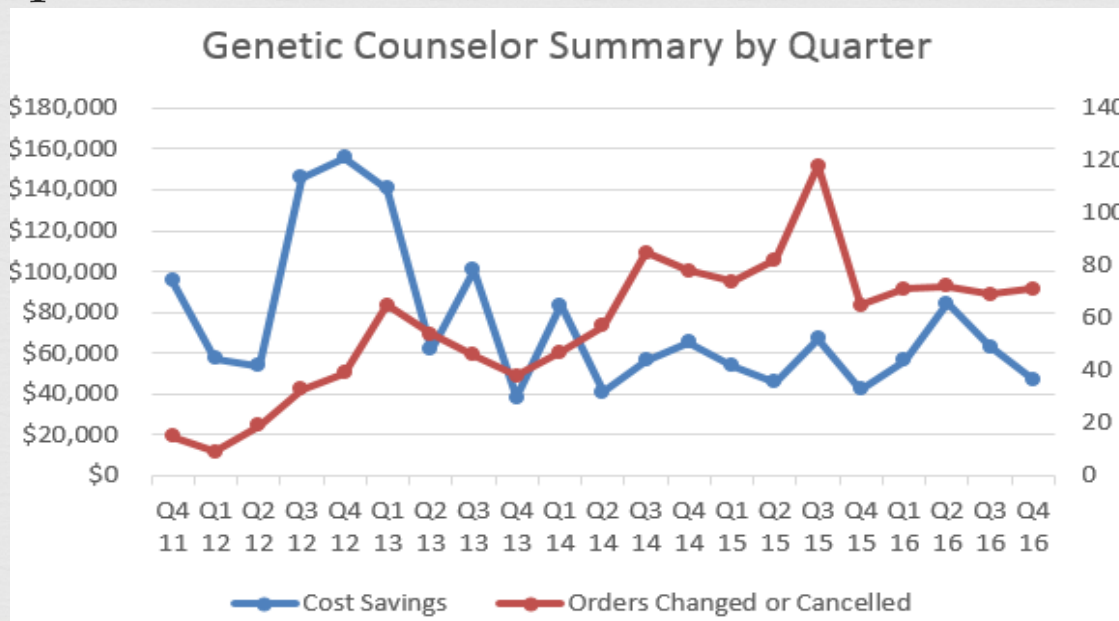
Efficient – Not doing unnecessary testing;

Effective - Directing patients to subspecialists, who need subspecialists

Laboratory-Based Genetics Counselor



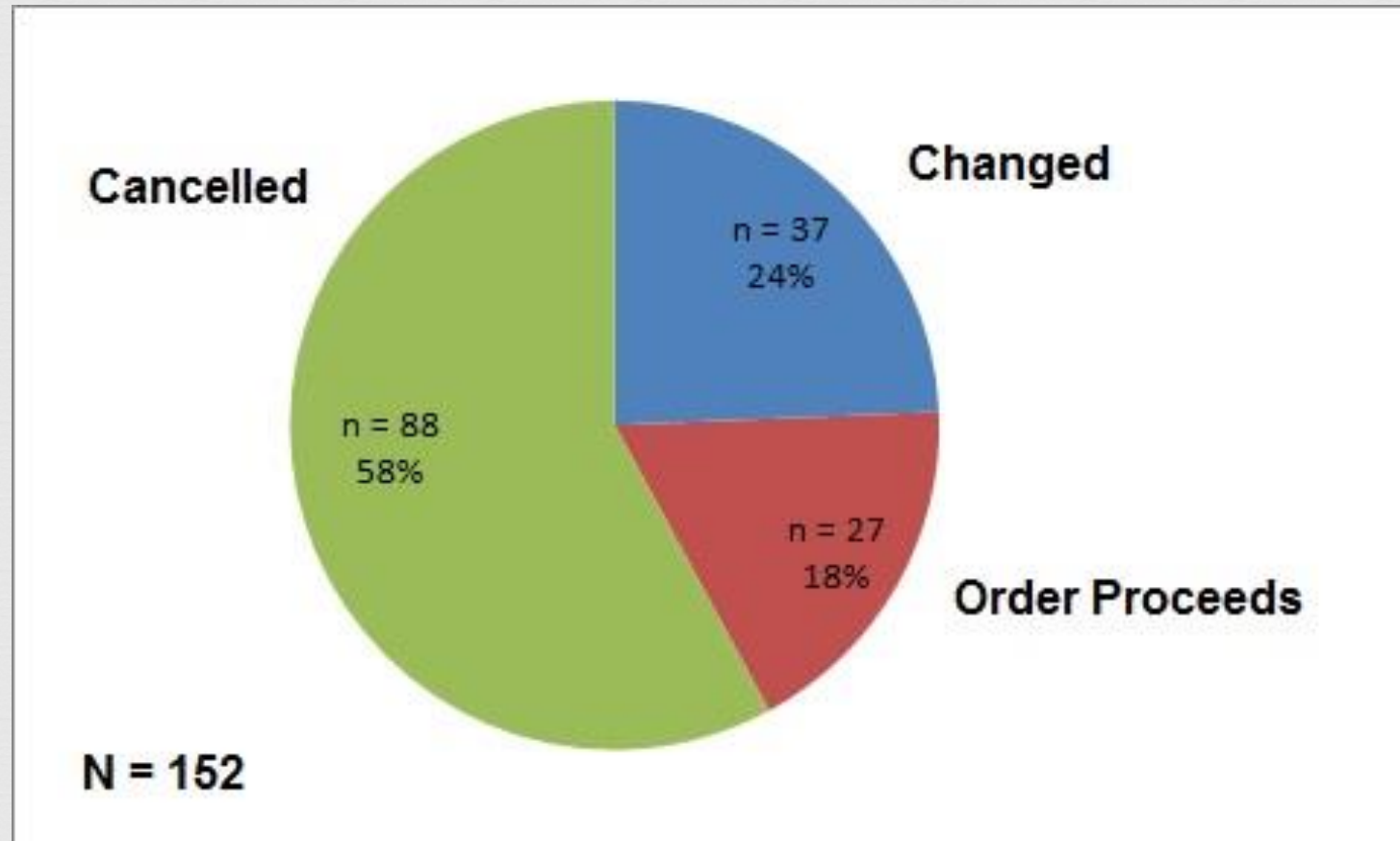
- Pre-Analytic Test Guidance and Post-Analytic Assessment
 - Triage, Decreased panel use and assistance in selecting the appropriate test



2018: 465 tests for \$213,666

Total (9/11 - 12/18): 1,606 tests for \$1,985,082

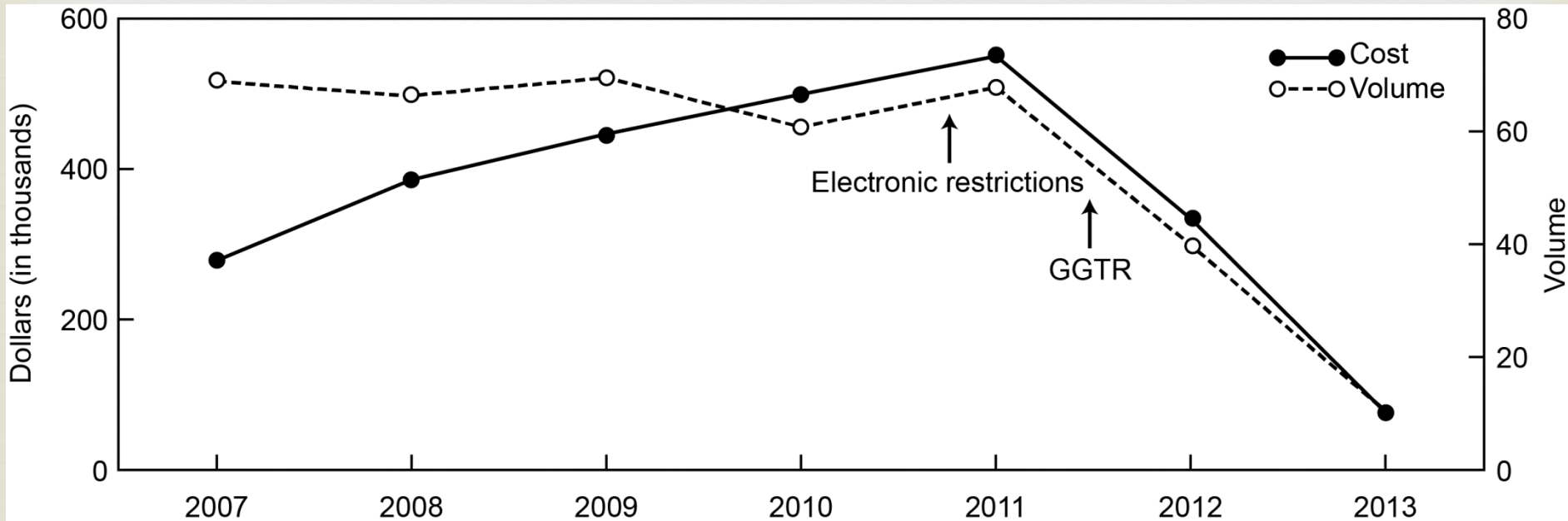
Follow-up of Genetic Counselor Triage



Efficient – Not doing unnecessary testing;

Effective and Patient-Centered - Directing providers to the correct test

Impact of Restricted Use and Genetic Counselor/MGP Triage Interventions



Effective

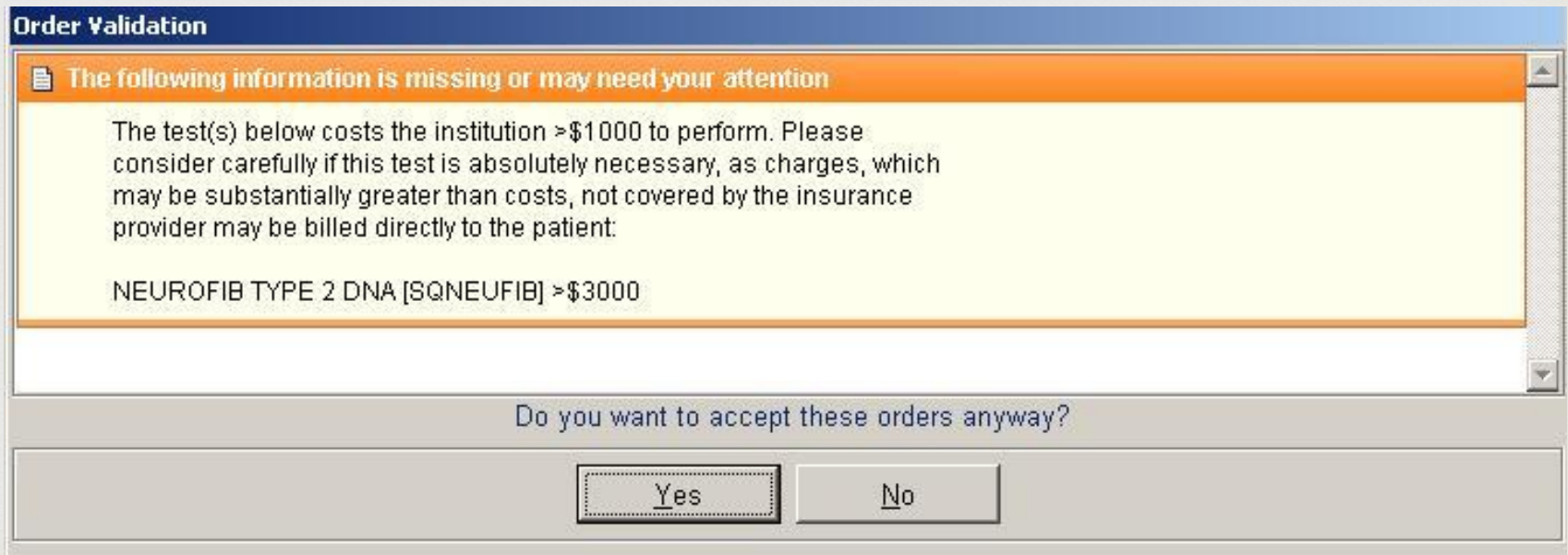
Expensive Test Notification




2018: 467 tests averted; \$352,642

Cumulative (9 m.2013 - 2018):

1,121 tests averted; \$ 1,327,325

A screenshot of a software dialog box titled "Order Validation". The dialog has a blue header bar with the title. Below the header is an orange banner with a document icon and the text "The following information is missing or may need your attention". The main area of the dialog is white and contains a message about a test costing more than \$1000, with a specific example of "NEUROFIB TYPE 2 DNA [SQNEUFIB] >\$3000". At the bottom, there is a question "Do you want to accept these orders anyway?" and two buttons: "Yes" and "No".

Order Validation

 The following information is missing or may need your attention

The test(s) below costs the institution >\$1000 to perform. Please consider carefully if this test is absolutely necessary, as charges, which may be substantially greater than costs, not covered by the insurance provider may be billed directly to the patient:

NEUROFIB TYPE 2 DNA [SQNEUFIB] >\$3000

Do you want to accept these orders anyway?

Extended Hard Stop



- ❧ Time extended hard stop.
- ❧ Went live 11/2014 (after more than a 12 month build).
- ❧ 2015 Expanded to Regional Hospitals
- ❧ *C. difficile* PCR
 - ❧ Once/ 7 days
- ❧ HbA1c
 - ❧ Once/month
- ❧ HCV Genotyping
 - ❧ Once-twice per lifetime.
- ❧ Two Molecular Heme Assays (Once/30 days)

13,023 Duplicate Tests Prevented in 2018; \$70,064 Cost Avoidance

11/2014-2018: 50,997 Duplicate Tests Prevented; \$275,139

Repeat Constitutional Genetic Tests (Once in a Lifetime Testing)

Procedure Name
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 2/22/2016 10:46 AM
PROTHROMBIN GENE PCR [SQPTGENE] ... review result from: 2/25/2016 9:40 PM
HFE (HEMOCHROMATOSIS) [SQHEMDNA] ... review result from: 3/1/2016 6:00 PM
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 2/23/2016 6:11 PM
CYSTIC FIBROSIS SCR139 VARIANT ASSAY [SQCFNGS] ... review result from: 2/10/2016 12:38 PM
CHROM ANALY PERIPH [SQCHRBLD] ... review result from: 9/3/2014 12:30 PM
HFE (HEMOCHROMATOSIS) [SQHEMDNA] ... review result from: 12/10/2014 7:52 AM
HEPATITIS C GENOTYPE [SQHEPGEN] ... review result from: 5/1/2006 1:50 PM
TPMT GENOTYPE (PRO-PREDICTR TPMT BL) [SQPPTMPT] ... review result from: 2/2/2005 5:01 PM
CELIAC ASSOC HLA-DQ GENOTYPE [SQCELIA] ... review result from: 1/28/2016 5:30 PM
MTHFR BY PCR [SQMTHFR] ... review result from: 1/21/2015 8:45 AM
MTHFR BY PCR [SQMTHFR] ... review result from: 10/24/2013 1:00 PM
CELIAC ASSOC HLA-DQ GENOTYPE [SQCELIA] ... review result from: 2/2/2009 5:21 PM
FAMIL MEDITERR FEVER [SQFAMMED] ... review result from: 7/13/2015 7:52 PM
HLA B5701 [SQB5701] ... review result from: 4/18/2014 4:00 AM
PROTHROMBIN GENE PCR [SQPTGENE] ... review result from: 3/17/2016 6:02 PM
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 3/17/2016 6:02 PM
HEPATITIS C GENOTYPE [SQHEPGEN] ... review result from: 5/29/2015 9:52 AM
PROTHROMBIN GENE PCR [SQPTGENE] ... review result from: 3/19/2016 3:44 PM
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 3/19/2016 3:44 PM
HEPATITIS C GENOTYPE [SQHEPGEN] ... review result from: 5/29/2015 9:52 AM
MTHFR BY PCR [SQMTHFR] ... review result from: 2/14/2012 3:37 PM
MTHFR BY PCR [SQMTHFR] ... review result from: 10/26/2015 7:39 AM
HEPATITIS C GENOTYPE [SQHEPGEN] ... review result from: 1/17/2016 4:00 PM
MTHFR BY PCR [SQMTHFR] ... review result from: 1/3/2014 11:43 AM
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 1/27/2014 9:09 AM
MTHFR BY PCR [SQMTHFR] ... review result from: 6/4/2014 2:56 PM
FACTOR V LEIDEN/PCR [SQFVLEID] ... review result from: 9/26/2008 11:06 AM
PROTHROMBIN GENE PCR [SQPTGENE] ... review result from: 9/26/2008 11:06 AM

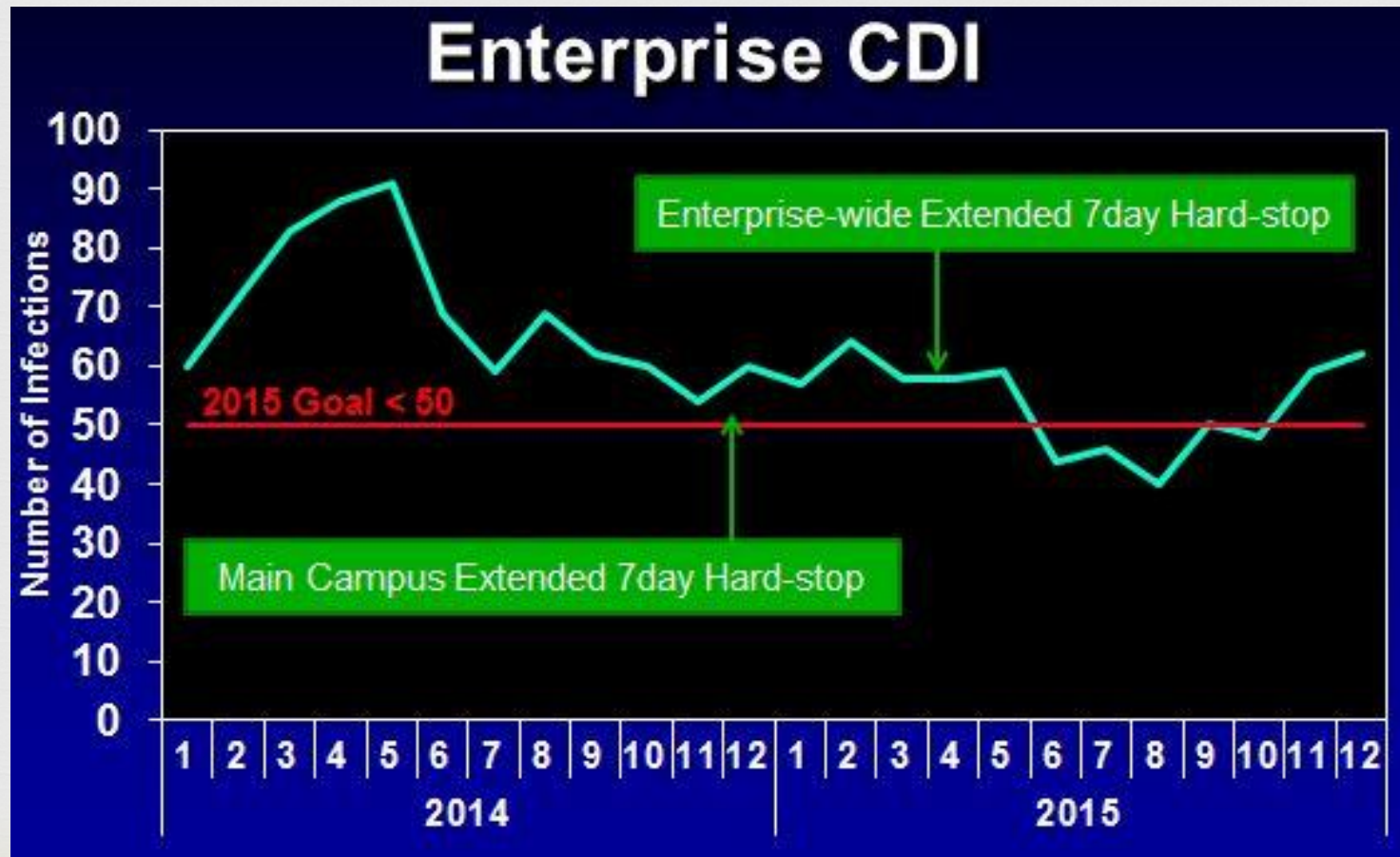
[2018]

350 Tests
\$25,406

[11/2014-12/2018]

1,221
\$158,149

Impact on *C. difficile* Rate



3 Day Rule:

Stool Cultures and O&P Examinations



❧ Limit Ordering of Stool Culture and O&P examinations for patients that are hospitalized >3 days.

❧ 2018

❧ 291 unnecessary orders stopped.

❧ \$9,297 Cost Avoidance

❧ 6/2014 - 2018

❧ 1,148 unnecessary orders stopped.

❧ \$36,795 Cost Avoidance



Duplicate Blood Cultures



- ❧ Initiative discovered under-utilization (ie single draw; single set), which was corrected.
- ❧ Soft Stop notified providers that a blood culture (ie two sets) have been obtained and are in process.
- ❧ Option to continue or stop.
- ❧ 2018: 2,237 blood culture orders stopped;
- ❧ Late 2017-2018: 28,636.
- ❧ 2018: \$27,020; Total: \$28,639.

Education



❧ Graduate Medical Education Initiative

❧ Information on GME Website

❧ Infographic produced.

❧ General

❧ Introduction to the most over utilized tests.

❧ Infographics for Individual Tests

❧ ANA

❧ *C. difficile* testing

❧ TSH

❧ Etcetera,

❧ How to capture impact?



Why reduce inappropriate lab testing?

- Increases patient satisfaction
- Increases patient safety (the more tests performed, the greater the potential for error (i.e. There is a false-positive rate associated with any test that has a specificity less than 100 percent))
- Decreases unnecessary phlebotomy and potentially iatrogenic anemia
- Reduces financial burdens (lower tests = dollar savings) for:
 - hospitals
 - patients
 - third-party payers

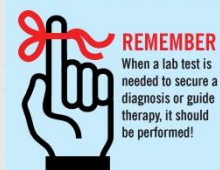
How are we doing this at Cleveland Clinic?



Results since 2010



Patient care *has not* been interrupted or compromised



Want more background on this initiative?
Read Strategies for Appropriate Test Utilization
http://portals.ccf.org/Portals/71/strategies_test_utilization.pdf

An education initiative from the Trench Pathology & Laboratory Medicine Institute, Cleveland Clinic Test Utilization Committee, Education Institute, and Medical Art & Photo

Financial Summary 2018: Ongoing Initiatives

<u>Initiative</u>	<u>Orders Prevented</u>	<u>Cost Savings</u>
1. Hard Stops	4,225	\$ 56,122
2. Restricted Use	36	\$ 45,559
3. Genetics Counselor/ MGP	465	\$ 213,666
4. Regional Smart Alert	9,654	\$ 76,100
5. Expensive Test Notification	467	\$ 352,642
6. Extended Hard Stop	13,023	\$ 70,064
7. Once-In-A-Lifetime Tests	281	\$ 25,406
8. 3 Day Rule Initiative	291	\$ 9,297
9. Daily Orders	0	\$ 0
10. Optimization of Blood Cultures	2,237	\$ 27,027
Total	49,071	\$ 875,876

Accumulated Totals for Entire Program

1. Hard Stops	38,174	\$ 578,744
2. Restricted Use	601	\$ 1,140,218
3. Genetics Counselor	1,606	\$ 1,985,082
4. Regional Smart Alert	36,421	\$ 287,899
5. Expensive Test Notification	1,121	\$ 1,327,325
6. Extended Hard Stop	50,997	\$ 275,139
7. Once-In-A-Lifetime Tests	1,023	\$ 158,149
8. 3 Day Rule Initiative	1,148	\$ 36,795
9. Daily Orders	38,324	\$ 117,951
10. Optimization of Blood Cultures	2,371	\$ 28,639
Total	209,143	\$ 5,935,942

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

Questions?

A black marker is shown drawing a curved line under the word "Questions?". The marker is black with a silver tip and is positioned at the bottom right of the word. The word "Questions?" is written in a cursive, handwritten style on lined paper. The lines on the paper are vertical and evenly spaced.