Adventures in Laboratory Stewardship

Improving Quality and Care while Lowering Cost

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Medical Director, Medical Operations,
Co-Chair, Laboratory Stewardship Committee
Cleveland Clinic
Speaker Disclosure

None
Opportunities to...

- Improve Quality & Patient Safety
- Enhance Patient Care and the Patient Experience
- Increase Laboratory Efficiency and Effectiveness
- Decrease Cost
- Enhance Your Position on Healthcare Delivery Teams
Addressing the IOM’s Charge

Crossing the Quality Chasm: A New Health System for the 21st Century

The IOM defined quality health care as “safe, effective, patient-centered, timely, efficient and equitable.”

Evidence-based, patient-centered test utilization practices, particularly those deployed through the electronic medical record, are timely and equitable.
Traditional Approaches to Test Utilization

Education with New Test Implementation
- Challenge: Communications that are read.
  - Are these read?

Re-Education
- Challenge:
  - New residents and fellows every year. = Did I already cover this?

Inappropriate orders intercepted upon accessioning.
- Doc-to-doc conversation.
  - Time consuming
  - May be confrontational –
    - (Good time for professionalism and communication skills).
- Specimen already drawn
Substantial Changes

- Electronic Medical Record
  - Computerized Physician Order Entry (CPOE)
    - The decision-maker is at the computer.
  - Clinical Decision Support Tools (CDST)
    - There is an opportunity to unidirectionally interact with the decision-maker in real-time. *(Timely and Equitable)*
    - “Pop-ups” are hazardous.

- Carrots and Sticks (Incentives & Penalties):
  - Meaningful Use
    - An obligation to improve practice with these new tools and systems.
  - MACRA
    - Improvement in medical practice linked to reimbursement.
  - MOC
    - Improvement in medical practice is part IV

- Volume to Value Based Payment System.

- Systems-Based Changes *(Equitable)*.
Patient Care and Safety (Patient-Centered)

- **Over-utilization:**
  - Unnecessary Phlebotomy
  - Iatrogenic Anemia
    - Exacerbates cardiopulmonary compromise
    - Decreases wound healing and ability to fight infections
  - False-Positive Test Results
    - Additional Blood draws
    - Additional Unnecessary Tests

- **Under-utilization**
  - Inadequate Screening
    - Late stage disease presentation.
  - Inadequate Follow-up
    - Missed opportunity for early disease intervention.

Each year, more than 100,000 Americans get the wrong care and are injured as a result.

Patient Experience
(Patient-Centered)

- Pain and Psychological Stress
  - Excessive phlebotomy (One stick or two?)
  - Unnecessary procedures (e.g., transfusions)
  - 0400 wakeups

- Unnecessary work-ups
  - PPV directly related to prevalence of disease
    - Testing normals (as defined by previous testing) means most positives are false positives
    - Daily LFTs -> aberrant abnormality -> Liver ultrasound

- Unnecessary costs
  - Cost of additional phlebotomy
  - Cost of unnecessary tests
  - Cost of follow-up of false-positive results
  - Cost of missing a diagnosis or not following up appropriately
Building the A Team

- Physician / Laboratory Professional Led
- Leadership Support
- Open/ Transparent/ Multidisciplinary
- Active Support/ Partnership Information Technology
  - Clinical Decision Support Tools (CDST) and Computerized Physician Order Entry (CPOE)
  - Interact with (not harass) the physician at the time of order entry.
- Best Practice / Patient Care Focused; Not Cost-Reduction Focused
- Monitoring and Reporting
  - Building credibility and support for your next project.
- Share Successes
Cleveland Clinic Embedded Initiatives

- Pilot: Soft Stop Initiative
- Hard Stop Initiative
- Restricted Use Initiative
- Laboratory-Based Genetic Counseling
- Regional Smart Alerts
- Expensive Test Notification
- Extended Hard Stop
  - Once-in-a-Lifetime Orders
- 3 Day Rule for Stool Cultures/O&F examinations
- Daily Orders Reduction Initiative
Soft Stop Pilot

Trial 1: Quantitative CMV and EBV PCR
- Significant difference in same-day duplicate orders pre- versus post- intervention.  ($p < 0.0001$)

Trial 2: C. difficile PCR
- No significant difference in same-day duplicate orders pre- versus post- intervention ($p = 0.21$)

Why?
- Evidence that CDST Alerts are not read.
## Example of “Pop-Up” Fatigue

<table>
<thead>
<tr>
<th>Date</th>
<th>Test</th>
<th>Patient MRN</th>
<th>User ID</th>
<th>User name</th>
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</thead>
<tbody>
<tr>
<td>9/1/2010 9:22</td>
<td>RETIC</td>
<td>Jane Doe</td>
<td>Doctor</td>
<td>X</td>
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<tr>
<td>9/1/2010 9:22</td>
<td>RETIC</td>
<td>Jane Doe</td>
<td>Doctor</td>
<td>X</td>
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<td>Doctor</td>
<td>Y</td>
</tr>
<tr>
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<td>Jane Doe</td>
<td>Doctor</td>
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<tr>
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<tr>
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</tr>
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<tr>
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<td>A</td>
</tr>
<tr>
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<td>Jane Doe</td>
<td>Doctor</td>
<td>A</td>
</tr>
<tr>
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<td>Doctor</td>
<td>Y</td>
</tr>
<tr>
<td>9/3/2010 14:30</td>
<td>RETIC</td>
<td>Jane Doe</td>
<td>Doctor</td>
<td>Y</td>
</tr>
<tr>
<td>9/3/2010 14:30</td>
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<td>9/5/2010 11:16</td>
<td>RETIC</td>
<td>Jane Doe</td>
<td>Doctor</td>
<td>Y</td>
</tr>
</tbody>
</table>

Repetitive firing of the same CDST suggests the caregiver is not reading the message.
The Hard Stop

The soft stop studies provided evidence to medical operations that a firmer intervention was needed.

They agreed, but...required a “break the glass” scenario in the event that a physician still wanted a duplicate study. (Safe)

Duplicate tests were made available through the laboratory Client Services area.
Warning:
This lab test has been ordered in the last 24 hours; repeat testing is usually not warranted for this analyte within 24 hours. If you feel you need to override the alert please call Lab Client Services (216-444-5733).

HGB A1C was ordered on 5/13/10 at 1:10 PM by provider KNOTT, PHILIP D

<table>
<thead>
<tr>
<th>Date/Time</th>
<th>Component</th>
<th>Result</th>
<th>Ref Range</th>
<th>Flag</th>
</tr>
</thead>
<tbody>
<tr>
<td>5/13/10 1:37 PM</td>
<td>Hemoglobin A1C</td>
<td>7.2</td>
<td>4.0 - 6.0%</td>
<td>H</td>
</tr>
<tr>
<td>5/13/10 1:37 PM</td>
<td>Estimated Average Glucose</td>
<td>160</td>
<td>mg/dL</td>
<td></td>
</tr>
</tbody>
</table>
Hard Stop Proposal

Thirteen tests were selected for a pilot that were thought never to be needed more than once per day.

The list was vetted with the medical staff via Doc.com.

Institute a Hard Stop
- An electronic notification that this is a duplicate order and same day repeated testing for this analyte is usually unnecessary.
- Create a means for the caregiver to still order the test, but with documentation/approval.
Initial Hard Stop List

- Hemoglobin A1C
- CMV Detection, Blood
- Epstein Barr DNA Quant
- Hypercoagulation Diagnostic Interpretive Panel
- *C. difficile* EIA
- FACTOR V LEIDEN/PCR
- PROTHROMBIN GENE PCR
- Uric acid
- IRON + TIBC
- HEP REMOTE PANEL BL
- Lipid PANEL BASIC
- RETIC COUNT
- C-REACTIVE PROTEIN (CRP)

Uric acid removed after clinical input: May be needed more than once per day for during chemotherapy to monitor tumor lysis
Phased Implementation

- **Hard Stop Implementation**
  - **Phase 1:**
    - 12 tests that are NEVER needed more than once per day
  - **Phase 2:**
    - Added 78 tests (total 88)
  - **Phase 3:**
    - “Many more” tests added (>1,200 tests on the same-day Hard Stop list)

- Rapid review/removal process implemented

- One year review disclosed no untoward safety issues (Safe)

- Initially: Physicians only, then -> all
  - (35% of orders were non-physicians in the 1st month)

- Very few caregivers called Client Services to have a duplicate order placed.
  - Reasons for duplicate disclosed educational opportunities in most instances.
# Cost Avoidance Based on Blocked Duplicates

<table>
<thead>
<tr>
<th>Test</th>
<th>Count</th>
<th>Tech Time</th>
<th>Prof Time</th>
<th>Supply Cost</th>
<th>Total Cost</th>
</tr>
</thead>
<tbody>
<tr>
<td>C. Difficile EIA (24219)</td>
<td>31</td>
<td>527</td>
<td>0</td>
<td>128.03</td>
<td>380.99</td>
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<tr>
<td>CMV Detection Blood (24221)</td>
<td>2</td>
<td>16</td>
<td>0</td>
<td>75.28</td>
<td>82.96</td>
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<tr>
<td>C-Reactive Protein (CRP) (23342)</td>
<td>22</td>
<td>44</td>
<td>0</td>
<td>27.94</td>
<td>49.06</td>
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<tr>
<td>HEP Remote Panel BL (23593)</td>
<td>3</td>
<td>30</td>
<td>0</td>
<td>42.72</td>
<td>57.12</td>
</tr>
<tr>
<td>HGB A1C (23607)</td>
<td>9</td>
<td>27</td>
<td>0</td>
<td>15.39</td>
<td>28.35</td>
</tr>
<tr>
<td>Iron + TIBC (23655)</td>
<td>3</td>
<td>6</td>
<td>0</td>
<td>1.11</td>
<td>3.99</td>
</tr>
<tr>
<td>Lipid Panel Basic (23683)</td>
<td>9</td>
<td>117</td>
<td>0</td>
<td>12.6</td>
<td>68.76</td>
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<tr>
<td>Retic Count (23971)</td>
<td>19</td>
<td>19</td>
<td>0</td>
<td>18.43</td>
<td>27.55</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>98</strong></td>
<td><strong>786</strong></td>
<td><strong>0</strong></td>
<td><strong>321.5</strong></td>
<td><strong>696.78</strong></td>
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</table>

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<thead>
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</tr>
</thead>
<tbody>
<tr>
<td>C. Difficile EIA (24219)</td>
<td>11</td>
<td>187</td>
<td>0</td>
<td>45.43</td>
<td>135.19</td>
</tr>
<tr>
<td>CMV Detection Blood (24221)</td>
<td>3</td>
<td>24</td>
<td>0</td>
<td>112.92</td>
<td>124.44</td>
</tr>
<tr>
<td>C-Reactive Protein (CRP) (23342)</td>
<td>12</td>
<td>24</td>
<td>0</td>
<td>15.24</td>
<td>26.76</td>
</tr>
<tr>
<td>HEP Remote Panel BL (23593)</td>
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<td>10</td>
<td>0</td>
<td>14.24</td>
<td>19.04</td>
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<tr>
<td>HGB A1C (23607)</td>
<td>5</td>
<td>15</td>
<td>0</td>
<td>8.55</td>
<td>15.75</td>
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<tr>
<td>Iron + TIBC (23655)</td>
<td>3</td>
<td>6</td>
<td>0</td>
<td>1.11</td>
<td>3.99</td>
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<tr>
<td>Lipid Panel Basic (23683)</td>
<td>6</td>
<td>78</td>
<td>0</td>
<td>8.4</td>
<td>45.84</td>
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<tr>
<td>Retic Count (23971)</td>
<td>6</td>
<td>6</td>
<td>0</td>
<td>5.82</td>
<td>8.7</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>47</strong></td>
<td><strong>350</strong></td>
<td><strong>0</strong></td>
<td><strong>211.71</strong></td>
<td><strong>379.71</strong></td>
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</tbody>
</table>

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<thead>
<tr>
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<th>Count</th>
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<th>Prof Time</th>
<th>Supply Cost</th>
<th>Total Cost</th>
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<tbody>
<tr>
<td>C. Difficile EIA (24219)</td>
<td>20</td>
<td>340</td>
<td>0</td>
<td>82.6</td>
<td>245.8</td>
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<td>CMV Detection Blood (24221)</td>
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<td>0</td>
<td>112.92</td>
<td>124.44</td>
</tr>
<tr>
<td>C-Reactive Protein (CRP) (23342)</td>
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<td>34</td>
<td>0</td>
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<td>37.91</td>
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</tr>
<tr>
<td>HGB A1C (23607)</td>
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<td>0</td>
<td>8.55</td>
<td>15.75</td>
</tr>
<tr>
<td>Iron + TIBC (23655)</td>
<td>2</td>
<td>4</td>
<td>0</td>
<td>0.74</td>
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<tr>
<td>Lipid Panel Basic (23683)</td>
<td>2</td>
<td>26</td>
<td>0</td>
<td>2.8</td>
<td>15.28</td>
</tr>
<tr>
<td>Retic Count (23971)</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>3.88</td>
<td>5.8</td>
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<tr>
<td><strong>Total</strong></td>
<td><strong>57</strong></td>
<td><strong>487</strong></td>
<td><strong>0</strong></td>
<td><strong>290.04</strong></td>
<td><strong>523.8</strong></td>
</tr>
</tbody>
</table>

| Total                            | **202**| **1623**  | **0**     | **823.25**  | **1602.29** |
Hard Stops

2017: 4,563 unnecessary orders prevented;
Full Program (1/11-12/17): 33,949 unnecessary orders prevented.

80-95% Success Rate
Unnecessary phlebotomies avoided and blood saved: A lot.
Hard Stop Financials by Quarter

2017: Cost Avoidance - $54,516

Total: (1/11 to 12/17): $522,622
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.
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,F,V,HL,K,L,MM,SP) was ordered on 9/20/12 at 12:53 PM by provider AGARWAL, RAJESH

If you are ordering LIPID PANEL BASIC (EU,F,V,HL,K,L,MM,SP) at the same time as other orders, you must first remove LIPID PANEL BASIC (EU,F,V,HL,K,L,MM,SP) from the order list before you can file the other orders.
Regional Smart Alerts

Monthly calculation of alert compliance

Hillcrest Hospital Lab Soft-Stop
October 2015 Report

- 57%
- 43%

Firing without Orders
Order placed within 30 minutes of firing
5,507 unnecessary tests averted in 2017
Total (10 m 2013 - 2017): 26,767
Regional Smart Alert: Cost Avoidance

- Cost-Savings, 2017: $41,258
- Total (10m 2013 - 2016): $211,800

![Graph showing current and accumulated cost savings](chart.png)
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

2017: 57 Tests; $67,262  Total (11/11 - 12/17): 565 Tests; $1,094,659
Follow-up to Restricted Orders

Ambulatory

- n = 25
  - 48% No further orders
  - 13% Clinical genetics referral
  - 31% Deemed user re-order
  - 8% Non-deemed user re-order

Inpatient

- n = 15
  - 75% No further orders
  - 25% Clinical genetics referral

Efficient – Not doing unnecessary testing;
Effective - Directing patients to subspecialists, who need subspecialists
Pre-Analytic Test Guidance and Post-Analytic Assessment

- Triage, Decreased panel use and assistance in selecting the appropriate test

Laboratory-Based Genetics Counselor

2017: 223 tests for $244,828

Total (9/11 - 12/17): 1,141 tests for $1,771,416
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

2017: 131 tests averted; $186,849
Cumulative (9 m. 2013 - 2017):
  654 tests averted; $974,683

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?

[Yes] [No]
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.

- **13,140 Duplicate Tests Prevented in 2017; $71,718 Cost Avoidance**

- **11/2014-2017: 37,974 Duplicate Tests Prevented; $205,075**
## Repeat Constitutional Genetic Tests

(Once in a Lifetime Testing)

<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>Review Result</th>
<th>Procedure Name</th>
<th>Review Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>HFE (HEMOCHROMATOSIS) [SQHEMDNA]</td>
<td>3/1/2016 6:00 PM</td>
<td>FACTOR V LEIDEN/PCR [SQFVLEID]</td>
<td>2/23/2016 6:11 PM</td>
</tr>
<tr>
<td>HFE (HEMOCHROMATOSIS) [SQHEMDNA]</td>
<td>12/10/2014 7:52 AM</td>
<td>HEPATITIS C GENOTYPE [SQHEPGEN]</td>
<td>5/1/2006 1:50 PM</td>
</tr>
<tr>
<td>TPMT GENOTYPE (PRO-PREDICTR TPMT BL) [SQPPTMPT]</td>
<td>2/2/2005 5:01 PM</td>
<td>CELIAC ASSOC HLA-DQ GENOTYPE [SQCELLA]</td>
<td>1/28/2016 5:30 PM</td>
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<tr>
<td>MTHFR BY PCR [SQMTHFR]</td>
<td>1/21/2015 8:45 AM</td>
<td>MTHFR BY PCR [SQMTHFR]</td>
<td>10/24/2013 1:00 PM</td>
</tr>
<tr>
<td>CELIAC ASSOC HLA-DQ GENOTYPE [SQCELLA]</td>
<td>2/2/2009 5:21 PM</td>
<td>FAMIL MEDITERR FEVER [SQFAMMED]</td>
<td>7/13/2015 7:52 PM</td>
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<tr>
<td>HLA B5701 [SQB5701]</td>
<td>4/18/2014 4:00 AM</td>
<td>PROTHROMBIN GENE PCR [SQPTGENE]</td>
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<td>MTHFR BY PCR [SQMTHFR]</td>
<td>2/1/2012 3:37 PM</td>
<td>MTHFR BY PCR [SQMTHFR]</td>
<td>10/26/2015 7:39 AM</td>
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<td>MTHFR BY PCR [SQMTHFR]</td>
<td>1/3/2014 11:43 AM</td>
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<tr>
<td>PROTHROMBIN GENE PCR [SQPTGENE]</td>
<td>9/26/2008 11:06 AM</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- **[2017]**
  - 350 Tests
  - $45,183

- **[11/2014-12/2017]**
  - 940
  - $132,743
Impact on *C. difficile* Rate

![Graph showing the impact on *C. difficile* rate with notable reductions after extended 7-day hard-stop implementations on enterprise and main campus.](graph.png)
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.

2017
- 312 unnecessary orders stopped.
- $10,545 Cost Avoidance

6/2014 - 2017
- 857 unnecessary orders stopped.
- $27,497 Cost Avoidance
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?
<table>
<thead>
<tr>
<th>Initiative</th>
<th>Orders Prevented</th>
<th>Cost Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hard Stops</td>
<td>4,563</td>
<td>$54,516</td>
</tr>
<tr>
<td>2. Restricted Use</td>
<td>57</td>
<td>$67,262</td>
</tr>
<tr>
<td>3. Genetics Counselor/ MGP</td>
<td>223</td>
<td>$244,828</td>
</tr>
<tr>
<td>4. Regional Smart Alert</td>
<td>5,507</td>
<td>$41,258</td>
</tr>
<tr>
<td>5. Expensive Test Notification</td>
<td>131</td>
<td>$186,849</td>
</tr>
<tr>
<td>6. Extended Hard Stop</td>
<td>13,140</td>
<td>$71,718</td>
</tr>
<tr>
<td>7. Once-In-A-Lifetime Tests</td>
<td>350</td>
<td>$45,183</td>
</tr>
<tr>
<td>8. 3 Day Rule Initiative</td>
<td>312</td>
<td>$10,545</td>
</tr>
<tr>
<td>9. Daily Orders</td>
<td>38,324</td>
<td>$117,951</td>
</tr>
<tr>
<td>10. Optimization of Blood Cultures</td>
<td>134</td>
<td>$1,619</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>81,517</strong></td>
<td><strong>$841,729</strong></td>
</tr>
</tbody>
</table>

**Accumulated Totals for Entire Program**

<table>
<thead>
<tr>
<th>Initiative</th>
<th>Orders Prevented</th>
<th>Cost Savings</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Hard Stops</td>
<td>33,949</td>
<td>$522,622</td>
</tr>
<tr>
<td>2. Restricted Use</td>
<td>565</td>
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<tr>
<td>3. Genetics Counselor</td>
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<td>$1,771,416</td>
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<tr>
<td>4. Regional Smart Alert</td>
<td>26,767</td>
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<tr>
<td>5. Expensive Test Notification</td>
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<td>$974,683</td>
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<tr>
<td>6. Extended Hard Stop</td>
<td>37,974</td>
<td>$205,075</td>
</tr>
<tr>
<td>7. Once-In-A-Lifetime Tests</td>
<td>940</td>
<td>$132,743</td>
</tr>
<tr>
<td>8. 3 Day Rule Initiative</td>
<td>857</td>
<td>$27,497</td>
</tr>
<tr>
<td>9. Daily Orders</td>
<td>38,324</td>
<td>$117,951</td>
</tr>
<tr>
<td>10. Optimization of Blood Cultures</td>
<td>134</td>
<td>$1,619</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>160,072</strong></td>
<td><strong>$5,060,066</strong></td>
</tr>
</tbody>
</table>
Conclusion

Improvements in Test Utilization can address each issue highlighted by the Institute of Medicine for Quality Health Care

- **Safe**: Interventions that facilitate the right test at the right time.
- **Effective**: Demonstrable results.
- **Patient-Centered**: Employment of best practice guidelines.
- **Timely**: Interventions at the point of order entry.
- **Efficient**: Decreasing waste by not doing unnecessary testing.
- **Equitable**: Interventions are activated for all.

Pathologists and other Laboratorians have an Opportunity in the Era of ACOs, MACRA and Integrated Care.

- Participate in your Laboratory Stewardship Committee today,
- Become active at the systems level in your institution.