DISCLOSURES:

Relevant Financial Relationship(s)
None

Off Label Usage
None
Laboratory Test Utilization Definition

• A strategy for performing appropriate laboratory and pathology testing with the goal of providing high-quality, cost-effective patient care

• Laboratory tests including anatomic pathology:
  • $60 - $70 billion; ~4% of healthcare costs
  • Conventional wisdom is that 20 to 40% of laboratory testing is unnecessary
  • 20-25% increase annually in molecular/genetics
  • Molecular / Genetics is 15% of laboratory costs; anticipated to reach 25% soon
  • Largest growth: proprietary tests, genetic tests, and test bundling
How does utilization fit into our current healthcare environment?
Healthcare Funding – Reality Check

- Medicare – bankrupt by ~2020; unsustainable
- Commercial Payers – commercial market is shrinking; aging population; increasing costs of chronic illness as part of their portfolio; can’t tolerate more cost shifting
- Employers – shifting healthcare costs will squeeze already narrow margins and overall economic survival
- Consumers – cost-shifting to patients is increasing
- Providers – consolidation of practices and systems

**Conclusions**: continued squeeze on fee for service; can’t depend on volume increases to pay for healthcare; payments will decrease; will see switching to value-based payments
Oncology – How will it change?

• Survey done in April 2012 of community oncology practices
  • 19% closing
  • 35% struggling financially
  • 31% had been acquired or establishing a contract with a hospital system
  • 11% had merged
• High and rapid growing costs – top target for payers
• Financial incentives to adhere to treatment pathways are emerging

ACO’s and oncology

• Prediction is that CMS will implement bundled payments for oncology by 2015 or 2016
• “Global payment” to cover all or significant parts of the care cycle
• Patient management fee
• Rewarded or penalized according to adherence to care pathways
• Share in or assume risk for cost savings
• Payers and hospitals are in a battle regarding this model
Do we have utilization issues in medicine – including hematology?
Geographic Variation in Patient Care

The percent of cancer patients receiving chemotherapy during their last two weeks of life varies widely among hospitals. Read more in "End-of-Life Care for Medicare Beneficiaries with Cancer is Highly Intensive Overall and Varies Widely."
A Bone Marrow Study

*Patient comes to Mayo; outside work-up; straight forward diagnosis of a myeloproliferative neoplasm: primary myelofibrosis*

**Laboratory assays performed:**

- BM morphology
- Immunohistochemical stains
- Flow cytometry
- T-cell gene rearrangement studies
- Cytogenetic karyotype
- BCR-ABL1 FISH
- MDS FISH
- Gene array analysis
- JAK2 V617F
- JAK2 exon 12 sequencing
- MPL exon 10 sequencing
# Utilization: Heme-Associated Assays

<table>
<thead>
<tr>
<th>Assay</th>
<th>Utilization Guideline</th>
<th>MCR Data</th>
</tr>
</thead>
<tbody>
<tr>
<td>JAK2 V617F</td>
<td>Blood and bone marrow are equal</td>
<td>1624 ordered over 3 yrs</td>
</tr>
<tr>
<td>JAK2 exon 12</td>
<td>Only possible PV and JAK2V617F is negative</td>
<td>42% over-ordered 10% under-ordered</td>
</tr>
<tr>
<td>MPL exon 10</td>
<td>Only possible MPN with equivocal morphology</td>
<td>38% over-ordered 5% under-ordered</td>
</tr>
<tr>
<td>Chromes - lymphoma staging</td>
<td>Only useful if unexplained cytopenias</td>
<td>31% over-ordered</td>
</tr>
<tr>
<td>MDS FISH</td>
<td>Only if &lt;20 metaphases or cytogeneticist needs</td>
<td>68% over-ordered</td>
</tr>
<tr>
<td>KIT 816V - blood</td>
<td>Negative in SM; use only if heme-associated SM</td>
<td>95% over-ordered</td>
</tr>
<tr>
<td>B- and T-cell lymphoma FISH - blood and marrow</td>
<td>Only to follow morph and flow studies</td>
<td>73% over-ordered</td>
</tr>
<tr>
<td>T-GR – blood and marrow</td>
<td>Only in context of T-cell phenotyping studies</td>
<td>43% over-ordered</td>
</tr>
<tr>
<td>B-GR – blood and marrow</td>
<td>Almost never useful</td>
<td>98% over-ordered</td>
</tr>
<tr>
<td>PML-RARA FISH</td>
<td>Not useful in follow-up APL</td>
<td>27% over-ordered</td>
</tr>
<tr>
<td>CLL FISH</td>
<td>Only useful in CLL</td>
<td>15% over-ordered</td>
</tr>
<tr>
<td>Plasma cell FISH</td>
<td>Not useful if no monotypic plasma cells</td>
<td>13% over-ordered</td>
</tr>
</tbody>
</table>

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Why do we have laboratory utilization issues?
Why Do We Have Utilization Issues?

- Realities of practice
- Knowledge gap
- Marketing
- Litigation fear
- $$$ incentives

Providers

- Lab systems and processes
- Ordering systems
- Test names
- Test bundles
- $$$ incentives
- Patents

Clinical Labs

- Fee for service
- $$$ incentives
- EMR / IT
- Coding systems

Health Systems

- “More” is better
- Google
- Dissatisfaction with healthcare
- Marketing
- Societal demands

Patients

Utilization

Providers

Clinical Labs

Health Systems

Patients
Why Do We Have Laboratory Test Utilization Issues?

• Knowledge gap between clinicians and how to use today’s increasingly complex laboratory assays

• Patients with particular diseases may not see that disease subspecialist

• Clinical knowledge, when a test is ordered, is incomplete. The clinician is compelled to order everything as it may be the only chance to get that information.

• Initial laboratory and pathology studies can help narrow the diagnostic choices and testing needs. But if laboratories don’t have a review and ordering process in place, clinicians have no choice but to order excess testing.

• Fee for service does not encourage appropriate use
How do we address laboratory utilization issues?
Utilization Management Tools

- Provide clinician education – albeit little lasting impact
- Obsolete certain tests
  - Examples: Bleeding time, band counts, etc.
- Establish gatekeeper functions
  - Identify tests that require laboratory review
- Restrict the frequency of specific tests
  - Focus on hospitalized patient
- Review admission and treatment templates
  - Look for redundancies and test frequency
- Use order entry pop-ups and online decision support tools
- Use physician profiling or report cards as feedback
- Develop a test formulary for complex and hi-cost tests
Test Names Contribute to Utilization Mistakes

- BCR/ABL, Translocation 9;22, FISH (D-FISH)
- BCR/ABL, p190, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Monitoring Assay
- BCR/ABL, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay
- BCR/ABL, p210, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Quantitative, Monitoring Chronic Myelogenous Leukemia (CML)
- BCR/ABL, Tyrosine Kinase Inhibitor Resistance, Kinase Domain Mutation Screen
Get Rid of Bad Tests and Quack Laboratories

• Tests that should be obsoleted
  • RBC folate
  • Bleeding times

• Quack tests from bad laboratories: Tests with no or minimal clinical validation or scientific validity
  • Random allergy tests
  • Nutritional screening
  • Hair tests for allergies
  • Etc.
Unbundle Your Laboratory Tests

• Bundling is defined as having multiple tests associated with a single test order

• Bundling tests frequently combines a standard but cheap assay with a more expensive but less proven test, i.e., overbundling

• Bundling of tests is common in all medical areas

• Overbundling is a contributing factor to high priced laboratory testing
Unbundle Your Laboratory Tests

Flow cytometry: Mayo uses a triage approach

• 8 antibodies to screen for B-cell clonality, increase in blasts, and abnormal T-cell phenotype

• Results drive whether to stop or to add more disease specific antibodies

• 80% of our flow requests stop at the triage step

• Integrate with morphologic features, previous or concurrent studies, and any provided or known clinical history

• Don’t use the “shotgun” approach with every possible antibody
Cost Depends on Number of Antibodies Used

Flow Cytometry
Total Allowed Payment ($) for Code 88185 per Patient Visit

Cost drivers

Mayo

Data source: commercial insurance payer, 2009 calendar year

Copy of slide Tait JF, Astion ML, Mandel AN, Bryt AB, unpublished data University of Washington, and CareCore National Inc.
Send-and-Hold Process

• Offer “Send-and-Hold” tests to be sure that the right specimens get drawn, but requests are then reviewed in the lab or driven by initial test results.

• Be clear that labs and clinicians know how long a specimen will be held (i.e., validated) for those cases in which an incorrect decision gets made.

• Build systems that allow for sequential testing as part of an algorithmic process.
Send-and-Hold Examples

- Flow cytometry in a lymphoma staging
  - Wait for bone marrow morphology
- Cytogenetics in a lymphoma staging
  - Wait for bone marrow morphology
- T-cell gene rearrangements for cytopenia
  - Wait for flow cytometry results
- AML molecular prognostics (cytogenetic negative)
  - Wait for cytogenetic results
- Plasma cell FISH in a MGUS evaluation
  - Wait for flow cytometry results
Laboratory Test Algorithms and Guidelines

- Four types of algorithms:
  - **IT-driven**: Clinical input and information drive what testing gets ordered or not
  - **Laboratory-driven**: Laboratory results drive subsequent test selection. Testing is performed by laboratories using available specimens; specimens are shared between labs
  - **Pathologist-driven**: Review of pathology findings determine next steps in testing algorithms; cancel or add appropriate next steps
  - **Genetic Counselor-driven**: Review of genetic test requests require genetic experts with laboratory knowledge; make phone calls to add or cancel testing
The Patient

Order is processed

Lab performs test

Lab sends results

MD requests tests

MD acts on the results

MD interprets test

Manual solution: In the lab

IT solution: Time of order

Utilization efforts

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What did Hematology and Hematopathology do at Mayo?
Questions

• Can we design a system in which all ancillary tests on bone marrow specimens are ordered by the hematopathologist based on a combination of clinical information and morphologic observations?

• If we can, will this reduce unnecessary testing and the associated costs?
Collaboration

• Between laboratory divisions:
  • Laboratory Genetics
  • Hematopathology
  • Anatomic Pathology

• With clinicians
  • Expertise
  • Experience
  • Endorsement
Method

• Identify opportunities
• Review practice data and literature
• Derive recommendations
• Achieve consensus
• Final guidelines approved
• Design process and implement
• Audit and adjust algorithms
Collaborative Process for Optimizing Test Utilization

1 Patient Evaluated

2 Differential Diagnosis Generated

3 Tests Ordered

4 Morphology Review

5 Differential Diagnosis Refined

6 Algorithm Consulted Test Order Refined
Progress!

• Complete
  • Lymphoma staging bone marrows
  • Chronic lymphocytic leukemia
  • Evaluation of plasma cell proliferative disorders
  • Chronic myeloid leukemia diagnosis & follow up
  • Evaluation of myeloproliferative neoplasms
  • Evaluation of myelodysplastic syndromes
  • Acute myeloid leukemia
  • Acute promyelocytic leukemia diagnosis & follow up

• In progress
  • Eosinophilia/mast cell disorders
Myeloproliferative Neoplasm: A Diagnostic Approach to Bone Marrow Evaluation

Clinical suspicion of myeloproliferative neoplasm

Bone marrow testing begins with:
- #5434 Hematopathology Consultation
- #8506 Chromosome Analysis, Hematologic Disorders, Bone Marrow
- #31155 JAK2 V617F Mutation Detection, Bone marrow
- #89006 BCR/ABL, mRNA Detection, Reverse Transcription-PCR (RT-PCR), Qualitative, Diagnostic Assay
- OR #90578 BCR/ABL, Translocation 9:22, FISH (D-FISH)

Bone marrow morphology: MPN?

No

No further testing

Negative for JAK2 V617F Mutation

- Complete blood count (CBC)
- #80173 Erythropoietin (EPO), Serum

Not supportive of PV

ET

PMF

MPN, not otherwise specified (ET or PMF)

Yes

Positive for JAK2 V617F Mutation

- Complete blood count (CBC)
- Clinical findings
- Bone marrow features
- #80173 Erythropoietin (EPO), Serum

Positive

PV

Equivocal

Clinical and morphologic suspicion of MPN

High

#60024 MPL Exon 10 Mutation Detection, Bone Marrow

Negative

No further testing

Low

Negative

No further testing

Positive

ET

PMF

MPN, not otherwise specified (ET or PMF)

Legend

PV: Polycythemia vera
ET: Essential thrombocythemia
PMF: Primary myelofibrosis
MPN: Myeloproliferative neoplasm
## Algorithm and Guideline Impact on Test Ordering in Hematopathology: 1st Half 2013

<table>
<thead>
<tr>
<th>Assay</th>
<th># tests canceled</th>
<th>Cost Savings</th>
<th>Assay</th>
<th># tests canceled</th>
<th>Cost Savings</th>
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<tbody>
<tr>
<td>Chromosomes</td>
<td>246</td>
<td>118421.94</td>
<td>CHIC2 FISH</td>
<td>1</td>
<td>313.49</td>
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<tr>
<td>BCR-ABL FISH</td>
<td>48</td>
<td>13333.92</td>
<td>B-GR</td>
<td>6</td>
<td>4237</td>
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<tr>
<td>PCPD FISH</td>
<td>102</td>
<td>53707.08</td>
<td>T-GR</td>
<td>9</td>
<td>6355</td>
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<tr>
<td>CLL FISH</td>
<td>7</td>
<td>4803.89</td>
<td>JAK2 V617F</td>
<td>79</td>
<td>40132</td>
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<td>B-lymphoma FISH</td>
<td>11</td>
<td>7548.97</td>
<td>JAK2 exon 12</td>
<td>18</td>
<td>6606</td>
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<tr>
<td>T-lymphoma FISH</td>
<td>5</td>
<td>3431.35</td>
<td>MPL exon 10</td>
<td>2</td>
<td>980</td>
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<tr>
<td>MDS FISH</td>
<td>38</td>
<td>24320.76</td>
<td>KIT</td>
<td>19</td>
<td>13015</td>
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<tr>
<td>AML FISH</td>
<td>43</td>
<td>46817.97</td>
<td>PCPD (chromes / PCPD FISH)</td>
<td>96</td>
<td>96761.28</td>
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<tr>
<td>ALL FISH</td>
<td>6</td>
<td>4137.36</td>
<td>CSF Flow studies</td>
<td>132</td>
<td>42768</td>
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<tr>
<td>Imatinib FISH</td>
<td>13</td>
<td>8192.34</td>
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</tbody>
</table>

**First Half 2013 summary:** 881 tests canceled; cost savings = $495,883.35
## Chromosome Analysis (CCA) – Utilization Review

<table>
<thead>
<tr>
<th></th>
<th>Original</th>
<th>Post-Utilization Implementation</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>% of total BMs with CCA</td>
<td>CCA abnormalities per 100 BM</td>
</tr>
<tr>
<td><strong>Mayo Rochester</strong></td>
<td>51%</td>
<td>20</td>
</tr>
<tr>
<td><strong>Hospital C</strong></td>
<td>95%</td>
<td>21</td>
</tr>
</tbody>
</table>

$600,000 annual cost savings
Standardizing Physician Practices: Good Medicine or Bureaucracy?

• Anything **might** work and nothing **always** works!

• Attempts to standardize clinical processes seldom achieve better than 50% success rate. Why?
  • if standardization is expected every time
  • if you fail to recognize whether the patient is “usual” or “special”

• Standardization must focus on the “usual” patient – (~80% of the time) – and allow exceptions for the “special” patient

• The important thing is whether the standard is **considered** all of the time - not whether the standard is **used** all the time

• Standardization fails when you fail to recognize the **artisan** approach to medical care
Questions & Discussion