**Laboratory Utilization:**
The right test, in the right patient, at the right time

Kristin Fiebelkorn, MD, has no relationships with commercial companies to disclose.

**Objectives**
At the end of this presentation, the participant will be able to:
- Describe the role that prevalence plays in the positive predictive value of a test
- List the reasons why physicians order unnecessary tests
- List the risks of performing unnecessary tests
- Describe the strategies that may be used to effectively manage laboratory utilization

**Pathology & Laboratory Medicine**
A pathologist is a physician who specializes in the diagnosis and management of human disease by laboratory methods.

All lab tests you will ever order on a patient have been validated and interpreted under the direction of a pathologist.

**Laboratory Utilization Review**
- What it is NOT:
  - Gate keeping, bean counting, barrier to care
- What it IS:
  - Process ensuring the right test is performed to answer the clinical question
  - Stewardship of resources – but only in the context of what is necessary for care
  - Pathology & Laboratory Medicine as part of the health care team caring for a patient

**Some statistics**
- 75% of physicians surveyed in 2014 said that the frequency of unnecessary medical tests and procedures is a somewhat or very serious problem.
- Studies have estimated that approximately 20% to 50% of laboratory tests may not be appropriate

Why do providers order unnecessary tests and treatments?

- Old or outdated practice
- Confusion about correct test to order
- Misunderstanding of test performance in a given clinical situation
- Order error – human or automated (order sets)
- Patient/parent request or insistence
- Fear of litigation

In response, the Choosing Wisely® campaign was developed.

- Called upon leading medical specialty societies and other non-physician organizations
- Identification of tests or procedures commonly used in their field the necessity of which should be questioned and discussed.
- Initiation of a dialogue not only among providers, but also between providers and patients.

• Choosing Wisely® aims to promote conversations between providers and patients by helping patients choose care that is:
  - Supported by evidence
  - Not duplicative of other tests or procedures already received
  - Free from harm
  - Truly necessary

• Recognizing that patients need better information about what care they truly need in order to have these conversations with their providers, Consumer Reports is developing patient-friendly materials and is working with consumer groups to disseminate them widely.

  Choosing Wisely® recommendations should not be used to establish coverage decisions or exclusions. Rather, they are meant to spur conversation about what is appropriate and necessary treatment. As each patient situation is unique, providers and patients should use the recommendations as guidelines to determine an appropriate treatment plan together.

“Things Providers and Patients Should Question”

- Not meant to regulate, and not intended to guide reimbursement.

- Intended to initiate discussion about the need for these frequently ordered tests or treatments that may not be utilized appropriately.
Choosing Wisely®

Lists for physicians/providers
Example: American Academy of Pediatrics

Materials for patients
And more…

Choosing Wisely®

Materials for patients
Example: Pediatric antibiotic utilization

Choosing Wisely®

Materials for patients
Example: Pediatric antibiotic utilization

Choosing Wisely®

Materials for patients
Example: Pre-OP labs

What about laboratory tests?

• What is appropriate lab test utilization?
  – The right test
  – On the right specimen
  – In the right patient
  – At the right time
Why do we order lab tests?

<table>
<thead>
<tr>
<th>Indications for testing</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening</td>
<td>Testing to detect asymptomatic abnormalities</td>
</tr>
<tr>
<td>Diagnostic</td>
<td>Testing performed to ensure prior &quot;normal&quot; test results remain within reference interval</td>
</tr>
<tr>
<td>Prognostic</td>
<td>Testing to determine response to specific therapy, including adverse events and monitoring of therapeutic drug levels</td>
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What is the risk of unnecessary testing?

- Test result may be misinterpreted
- Patient may be misdiagnosed
  - May not receive appropriate therapy
  - May receive inappropriate therapy (with possible adverse effects)
  - May carry an incorrect diagnosis in their medical record that can impair long term appropriate care

What is the risk of unnecessary testing?

- Increased patient/parent anxiety
- Mandates expensive follow-up investigations
- Contributes to iatrogenic anemia
  - Not only in our littlest patients

Statistics, reference ranges, and false positive results

- Normal reference ranges are calculated with 95% confidence intervals
- This means that values for 1 out of 20 normal individuals will be outside of the reference range
- Risk of false positive results increases with increasing number of tests, especially when not indicated

Prevalence, positive predictive values, and false positive results

- What about "yes/no" tests?
- The likelihood that a positive test indicates disease (PPV) depends heavily on prevalence
Sensitivity (TP/TP+FN) = 100%  
Specificity (TN/TN+FP) = 99.5%  

Positive predictive value = TP/TP+FP  

True Positive  
False Negative  
False Positive  
True Negative  

Prevalence, positive predictive values, and false positive results  

- What does this have to do with lab utilization?  
- By choosing testing based on history/physical and other findings, you are altering the "prevalence" by selecting which patients are tested (increasing pre-test probability)  
  - If H&P and findings support the possibility of the diagnosis, less risk of false positives  
  - If H&P and findings DO NOT support the possibility of diagnosis, more risk of false positives  
  - Examples:  
    - JC virus CSF PCR on:  
      - Healthy immunocompetent young woman with headache and normal imaging  
      - HIV patient with CD4<50 and abnormal imaging  
    - RSV testing in July vs. January  

Johns Hopkins, Osler Service:  

Never order a laboratory test unless you know what you are going to do with the results.  

Another way to put it:  

Never order a laboratory test unless you can answer the question:  

How will the results of this test alter the management of my patient?  

Types of lab utilization issues  

- Tests that are outdated/should no longer be performed on any patients  
- Tests that are used in inappropriate clinical situations  
- Tests that will not alter management of the patient  
- Tests that are run too frequently  
- Tests for rare possible diagnoses when there is a much more likely diagnosis  

FIRST, DO NO HARM:  
Importance of method and specimen type  

- If the wrong test is ordered for the patient’s condition, or the wrong specimen type is tested, it is likely that the result will be misinterpreted.  
- Delayed diagnosis, leading to delay in therapy  
- Less sensitive test or wrong specimen → if negative, condition is inappropriately ruled out → failure to treat  
- Less specific test or wrong specimen → if positive, patient is labeled as having a condition she does not  
  - Treated for the wrong condition (including side-effects)  
  - Stop looking for diagnosis (may miss the right diagnosis)  
  - Long-term labeled with a disease inappropriately  
    - Inappropriate/unnecessary therapy  
    - Insurance implications
What can we do?

- Education (limited effectiveness on its own)
- Communication with Pathology (case by case basis)
  - Always good, but insufficient time and personnel to address ALL testing in this way
  - Best for infrequent/unalusual tests requiring review of medical record and consultation
- This is our current method of utilization review at UHS – reference “sendout” test review with special focus on tests with high frequency of order errors
  - Pathology resident
  - Clinical pathology faculty (Drs. Fiebelkorn & Furmage)
- Laboratory Formulary
  - UHS Lab Formulary specifically addresses reference lab “send out” tests at this time

Why would a lab test not be on the formulary?

<table>
<thead>
<tr>
<th>Type</th>
<th>Utilization review</th>
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</table>
| High volume use | Requires extraordinary effort to keep a test on the formulary.
| Non-formulary | Requires extraordinary effort to keep a test on the formulary.
| High volume use | Reviewed by Laboratory Utilization Advisory Subcommittee.
| Non-formulary | Reviewed by Laboratory Utilization Advisory Subcommittee.

What do you need to know about SOFT/SCC conversion?

- The laboratory information system (LIS) is changing for all inpatient and outpatient clinical lab areas
  - Thousands of man/woman hours over 18 months to make this conversion
- Go live date is midnight, Friday, November 6, 2015
- Why? All support for the old LIS (Cerner) will be discontinued at the end of 2015
- Will this affect my results? No, nothing has changed in Sunrise
- Are there any other changes? Yes. There are new processes (Soft ID and Soft SITX) for the collection of specimens and transfusion of blood. This will ensure positive patient identification and decrease errors.
- What if I have a question? The lab will have phone numbers available for specific inquiries closer to the live date. A pathologist will also be able to direct your question anytime to the appropriate person for resolution.
What can we do?

• Who is “we”, anyway?
  – Clinical Providers
  – Laboratory Providers
  – IT
  – UHS Administration

• Laboratory Utilization Advisory Subcommittee (LUASC)

LUASC Mission

To implement an evidence-based, cost-effective approach to laboratory testing that supports the missions of UHS and UTHSCSA as the academic health center of South Texas

• Vision/Goals:
  – To systematically and scientifically evaluate current and new laboratory tests to develop a formulary that is cutting edge, evidence based and cost effective
  – To review laboratory utilization data to ensure that use is appropriate to the most current scientific evidence and to our patient populations.
  – To systematically and periodically review all CPOE laboratory order sets for appropriateness in accordance with Joint Commission requirements.

What if I have questions?

• Please call before ordering/collecting specimen if you are unsure
  – We are happy to help – this is our job.

• It is ALWAYS easier than trying to handle an incorrectly ordered test or incorrectly collected specimen afterwards.

• You can call…
  – The laboratory (collection requirements, etc.)
  – A pathology resident (provide coverage of all clinical laboratory areas, and there is always a pathology resident on call)
  – A pathology attending…

Current LUASC Activities

• Review proposed changes in testing at UHS
• Review requests for addition or removal of tests from formulary
• Refinement of formulary procedures, integration into Sunrise ordering information
• Review of order sets for appropriateness
• Continued identification of potential areas of inappropriate utilization (including data collection and evaluation)
• Genetic testing utilization and support
• Point of care testing utilization and compliance

Laboratory Medicine:
Lab Directors at UHS

- Russell Higgins, M.D.
  Hematology/Clinical Lab Section Director
  UHS Laboratory Medical Director (effective 8-1-15)
  Cell: 210-771-8804

- Kristin Fiebelkorn, M.D.
  Immunology & Virology Lab Section Director
  Division Chief for Clinical Pathology (eff. 8-1-15)
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- Wieslaw Furmaga, M.D.
  Chemistry/Clinical Lab Section Director
  Cell: 210-837-1268

* Supervise the majority of reference lab test review
Reference lab testing tips

- Be as clear as you can in your order request, especially if it is an unusual test (indication for test, special instructions)

- We are required by law to refer testing only to CLIA certified laboratories (not research labs)
  - Also constrained by reference lab contracts

- Need enough volume (serum, especially CSF) to send test
  - You’d be surprised how much it takes for 20 PCRs
  - You’d be surprised how little is left after cell counts, glucose, protein, cultures, other studies, etc.

- “Send to the CDC” – they don’t just test anything
  - Approval from CDC before we can send, requires case form, etc.

- When in doubt, call