

# A judicious approach to ordering lab tests

Following these guidelines to order fewer tests can improve health care quality and patient experience, while reducing wasteful costs.

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## PRACTICE RECOMMENDATIONS

► Follow US Preventive Services Task Force and professional society recommendations for laboratory testing, including choice and frequency of tests. **(A)**

► Consider the pretest probability of your patient having a disease, and order the most sensitive and specific test to diagnose a new condition. Employ a 2-step approach with a second laboratory test when the first is outside the reference range. **(B)**

► Refrain from ordering routine preoperative testing for patients undergoing low-risk surgeries; these data do not improve postoperative outcomes, can lead to costly testing cascades, and may delay necessary surgical care for patients. **(A)**

### Strength of recommendation (SOR)

- (A)** Good-quality patient-oriented evidence
- (B)** Inconsistent or limited-quality patient-oriented evidence
- (C)** Consensus, usual practice, opinion, disease-oriented evidence, case series

## CASE ►

A 35-year-old man arrives for an annual wellness visit with no specific complaints and no significant personal or family history. His normal exam includes a blood pressure of 110/74 mm Hg and a body mass index (BMI) of 23.6. You order “routine labs” for prevention, which include a comprehensive metabolic panel (CMP), fasting lipid profile, and thyroid-stimulating hormone (TSH) and 25(OH) vitamin D tests. Are you practicing value-based laboratory testing?

*The answer to this question appears in the Case discussion at the end of the article (page 248).*

**V**alue-based care, including care provided through laboratory testing, can achieve the Institute for Healthcare Improvement’s Triple Aim of improving population health, improving the patient experience of care (including quality and satisfaction), and reducing cost:  $Value = (Quality \times Patient\ experience) / Cost$ .<sup>1</sup>

As quality and patient experience rise and cost falls, the value of care increases. Unnecessary lab testing, however, can negatively impact this equation:

- Error introduced by unnecessary testing can adversely affect quality.
- Patients experience inconvenience and sometimes cascades of testing, in addition to financial responsibility, from unnecessary testing.
- Low-value testing also contributes to work burden and provider burnout by requiring additional review and follow-up.

■ **Rising health care costs** are approaching 18% of the US gross domestic product, driven in large part by a wasteful and inefficient care delivery system.<sup>2</sup> One review of “waste domains” identified by the Institute of Medicine estimates that approximately one-quarter of health care costs represent

➤ **Do not order tests just to reassure the patient; unnecessary tests with insignificant results do little to reduce patient anxiety.**

waste, including overtreatment, breakdowns of care coordination, and pricing that fails to correlate to the level of care received.<sup>3</sup> High-volume, low-cost testing contributes more to total cost than low-volume, high-cost tests.<sup>4</sup>

#### **Provider and system factors that contribute to ongoing waste**

A lack of awareness of waste and how to reduce it contribute to the problem, as does an underappreciation of the harmful effects caused by incidental abnormal results.

Provider intolerance of diagnostic uncertainty often leads to ordering even more tests.

Also, a hope of avoiding missed diagnoses and potential lawsuits leads to defensive practice and more testing. In addition, patients and family members can exert pressure based on a belief that more testing represents better care. Of course, financial revenues from testing may come into play, with few disincentives to forgo testing. Something that also comes into play is that evidence-based guidance on cost-effective laboratory testing may be lacking, or there may be a lack of knowledge on how to access existing evidence.

Automated systems can facilitate wasteful laboratory testing, and the heavy testing practices of hospitals and specialists may be inappropriately applied to outpatient primary care.

#### **Factors affecting the cost of laboratory testing**

Laboratory test results drive 70% of today's medical decisions.<sup>5</sup> Negotiated insurance payment for tests is usually much less than the direct out-of-pocket costs charged to the patient. Without insurance, lab tests can cost patients between \$100 and \$1000.<sup>6</sup> If multiple tests are ordered, the costs could likely be many thousands of dollars.

Actual costs typically vary by the testing facility, the patient's health plan, and location in the United States; hospital-based testing tends to be the most expensive. Insurers will pay for lab tests with appropriate indications that are covered in the contract with the provider.<sup>6</sup>

#### **Choosing Wisely initiative weighs in on lab testing**

*Choosing Wisely*, a prominent initiative of

the American Board of Internal Medicine Foundation, promotes appropriate resource utilization through educational campaigns that detail how to avoid unnecessary medical tests, treatments, and procedures.<sup>7</sup> Recommendations are based largely on specialty society consensus and disease-oriented evidence. *Choosing Wisely* recommendations advise *against* the following<sup>7</sup>:

- **performing laboratory blood testing unless clinically indicated** or necessary for diagnosis or management, in order to avoid iatrogenic anemia. (American Academy of Family Physicians; Society for the Advancement of Patient Blood Management)
- **requesting just a serum creatinine to test** adult patients with diabetes and/or hypertension for chronic kidney disease. Use the kidney profile: serum creatinine with estimated glomerular filtration rate and urinary albumin-creatinine ratio. (American Society for Clinical Pathology)
- **routinely screening for prostate cancer** using a prostate-specific antigen test. It should be performed only after engaging in shared decision-making with the patient. (American Academy of Family Physicians; American Urological Association)
- **screening for genital herpes simplex virus infection in asymptomatic adults**, including pregnant women. (American Academy of Family Physicians)
- **performing preoperative medical tests for eye surgery** unless there are specific medical indications. (American Academy of Ophthalmology)

#### **Sequential steps to take for value-based lab ordering**

Ask the question: "How will ordering this specific test change the management of my patient?" From there, take sequential steps using sound, evidence-based pathways. Morgan and colleagues<sup>8</sup> outline the following practical approaches to rational test ordering:-

- Perform a thorough clinical assessment.
- Consider the probability and implica-

tions of a positive test result.

- Practice patient-centered communication: address the patient's concerns and discuss the risks and benefits of tests and how they will influence management.
- Follow clinical guidelines when available.
- Avoid ordering tests to reassure the patient; unnecessary tests with insignificant results do little to reduce patient anxieties.
- Avoid letting uncertainty drive unnecessary testing. Watchful waiting can allow time for the illness to resolve or declare itself.

Let's consider this approach in the context of 4 areas: preventive care, diagnostic evaluation, ongoing management of chronic conditions, and preoperative testing.

#### Preventive guidance from the USPSTF

An independent volunteer panel of 16 national experts in prevention and evidence-based medicine develop recommendations for the US Preventive Services Task Force (USPSTF).<sup>9</sup> These guidelines are based on evidence and are updated as new evidence surfaces. Thirteen recommendations, some of which advise avoiding preventive procedures that could cause harm to patients, cover laboratory tests used in screening for conditions such as hyperlipidemia<sup>10</sup> and prostate cancer.<sup>11</sup> We review the ones pertinent to our patient later at the end of the Case.

While the target audience for USPSTF recommendations is clinicians who provide preventive care, the recommendations are widely followed by policymakers, managed care organizations, public and private payers, quality improvement organizations, research institutions, and patients.

#### Take a critical look at how you approach the diagnostic evaluation

To reduce unnecessary testing in the diagnostic evaluation of patients, first consider pretest probability, test sensitivity and specificity, narrowly out-of-range tests, habitually paired tests, and repetitive laboratory testing.

■ **Pretest probability, and test sensitivity and specificity.** Pretest probability is the

estimated chance that the patient has the disease before the test result is known. In a patient with low pretest probability of a disease, the ability to conclusively arrive at the diagnosis with one positive result is limited. Similarly, for tests in patients with high pretest probability of disease, a negative test cannot be used to firmly rule out a diagnosis.<sup>12</sup>

Reliability also depends on test sensitivity (the proportion of true positive results) and specificity (the proportion of true negative results). A test with high sensitivity but low specificity will generate more false-positive results, with potential harm to patients who do not have a disease.

The pretest probability along with test sensitivity and specificity help a clinician to interpret a test result, and even decide whether to order the test at all. For example, the anti-nuclear antibody (ANA) test for systemic lupus erythematosus (SLE) has a sensitivity of 100% and a specificity of 86%<sup>13</sup>; it will always be positive in a patient with SLE. But when applied to individuals with low likelihood of SLE, false-positives are more common; the ANA is falsely positive in up to 14% of healthy individuals, depending on the population studied.<sup>13</sup>

Ordering a test may be unnecessary if the results will not change the treatment plan. For example, in a female patient with classic symptoms of an uncomplicated urinary tract infection, a urine culture and even a urinalysis may not change treatment.

■ **Narrowly out-of-range tests.** Test results that fall just outside the "normal" range may be of questionable significance. When an asymptomatic patient has mildly elevated liver enzymes, should additional tests be ordered to avoid missing a treatable disorder? In these scenarios, a history, including possible contributing factors such as alcohol or substance misuse, must be paired with the clinical presentation to assess pre-test probability of a particular condition.<sup>14</sup> Repeating a narrowly out-of-range test is an option in patients when follow-up is possible. Alternatively, you could pursue watchful waiting and monitor a minor abnormality over time while being vigilant for clinical changes. This whole-patient approach will guide the decision of whether to order additional testing.

CONTINUED

➤ Reflexively ordering tests together (eg, C-reactive protein with erythrocyte sedimentation rate) often contributes to unnecessary testing.

➤  
**Unnecessary routine preoperative testing and testing sequelae for cataract surgery was calculated to cost Medicare up to \$45.4 million annually.**

■ **Habitually paired tests.** Reflexively ordering tests together often contributes to unnecessary testing. Examples of commonly paired tests are serum lipase with amylase, C-reactive protein (CRP) with erythrocyte sedimentation rate (ESR), and TSH with free T4 to monitor patients with treated hypothyroidism. These tests add minimal value together and can be decoupled.<sup>15-17</sup> Evidence supports ordering serum lipase alone, CRP instead of ESR, and TSH alone for monitoring thyroid status.

Some commonly paired tests may not even be necessary for diagnosis. The well-established Rotterdam Criteria for diagnosing polycystic ovary syndrome specify clinical features and ovarian ultrasound for diagnosis.<sup>18</sup> They do not require measurement of commonly ordered follicle-stimulating hormone and luteinizing hormone for diagnosis.

Serial rather than parallel testing, a “2-step approach,” is a strategy made easier with the advent of the electronic medical record (EMR) and computerized lab systems.<sup>8</sup> These records and lab systems allow providers to order reflex tests, and to add on additional tests, if necessary, to an existing blood specimen.

■ **Repetitive laboratory testing.** Repetitive inpatient laboratory testing in patients who are clinically stable is wasteful and potentially harmful. Interventions involving physician education alone show mixed results, but combining education with clinician audit and feedback, along with EMR-enabled restrictive ordering, have resulted in significant and sustained reductions in repetitive laboratory testing.<sup>19</sup>

**Ongoing management of chronic conditions**

Evidence-based guidelines support choices of tests and testing intervals for ongoing management of chronic conditions such as diabetes, hyperlipidemia, and hypertension.

■ **Diabetes.** Guidelines also define quality standards that are applied to value-based contracts. For example, the American Diabetes Association recommends assessing A1C every 6 months in patients whose type 2 diabetes is under stable control.<sup>20</sup>

■ **Hyperlipidemia.** For patients diagnosed with hyperlipidemia, 2018 clinical

practice guidelines published by multiple specialty societies recommend assessing adherence and response to lifestyle changes and LDL-C-lowering medications with repeat lipid measurement 4 to 12 weeks after statin initiation or dose adjustment, repeated every 3 to 12 months as needed.<sup>21</sup>

■ **Hypertension.** With a new diagnosis of hypertension, guidelines advise an initial assessment for comorbidities and end-organ damage with an electrocardiogram, urinalysis, glucose level, blood count, electrolytes, creatinine, calcium, lipids, and urinary albumin/creatinine ratio. For ongoing monitoring, guidelines recommend assessment for end-organ damage through regular measurements of creatinine, glomerular filtration rate, and urinary microalbumin/creatinine ratio. Initiation and alteration of medications should prompt appropriate additional lab follow-up—eg, a measurement of serum potassium after starting a diuretic.<sup>22</sup>

**Preoperative testing**

Preoperative testing is overused in low-risk, ambulatory surgery. And testing, even with abnormal results, does not affect postoperative outcomes.<sup>23</sup>

The American Society of Anesthesiologists (ASA) Physical Status Classification System, which has been in use for more than 60 years, considers the patient’s physical status (ASA grades I-VI),<sup>24</sup> and when paired with surgery grades of minor, intermediate, and major/complex, can help assess preoperative risk and guide preoperative testing (TABLE).<sup>24-26</sup>

Preoperative medical testing did not reduce the risk of medical adverse events during or after cataract surgery when compared with selective or no testing.<sup>27</sup> Unnecessary preoperative testing can lead to a nonproductive cascade of additional investigations. In a 2018 study of Medicare beneficiaries, unnecessary routine preoperative testing and testing sequelae for cataract surgery was calculated to cost Medicare up to \$45.4 million annually.<sup>28</sup>

**CASE ▶**

You would not be practicing value-based laboratory testing, according to the USPSTF, if you ordered a CMP, fasting lipid profile,

TABLE

## ASA recommendations for preoperative testing: Complete blood count and kidney function<sup>24-26</sup>

Specific recommendations depend on a patient's ASA class and surgery grade.

ASA class <sup>a</sup>	Surgery grade		
	Minor	Intermediate	Major/complex
<b>Complete blood count</b>			
I	Do not routinely offer	Do not routinely offer	Offer
II			
III or IV		Consider for people with cardiovascular or renal disease if any symptoms have not been recently investigated	
<b>Kidney function tests</b>			
I	Do not routinely offer	Do not routinely offer	Consider in people at risk of AKI
II		Consider in people at risk of AKI	Offer
III or IV	Consider in people at risk of AKI	Offer	
<sup>a</sup> ASA class			
I	A normal healthy patient.		
II	A patient with mild systemic disease.		
III	A patient with severe systemic disease.		
IV	A patient with severe systemic disease that is a constant threat to life.		

AKI, acute kidney injury; ASA, American Society of Anesthesiologists.

and TSH and 25(OH) vitamin D tests for this healthy 35-year-old man whose family history, blood pressure, and BMI do not put him at elevated risk. Universal lipid screening (Grade B<sup>3</sup>) is recommended for all adults ages 40 to 75. Thyroid screening tests and measurement of 25(OH) vitamin D level (I statements<sup>3</sup>) are not recommended. The USPSTF has not evaluated chemistry panels for screening.

The USPSTF *would* recommend the following actions for this patient:

- Screen for HIV (ages 15 to 65 years; and younger or older if patient is at risk). (A recommendation<sup>a,29</sup>)
- Screen for hepatitis C virus (in those ages 18 to 79). (B recommendation<sup>30</sup>)

The following USPSTF recommendations might have come into play if this patient had certain risk factors, or if the patient had been a woman:

- Screen for diabetes if the patient is overweight or obese (B recommendation).

- Screen for hepatitis B in adults at risk (B recommendation).
- Screen for gonorrhea and chlamydia in women at risk (B recommendation). Such screening has an "I" statement for screening men at risk.

As noted, costs of laboratory testing vary widely, depending upon what tests are ordered, what type of insurance the patient has, and which tests the patient's insurance covers. Who performs the testing also factors

<sup>a</sup> USPSTF grade definitions:

**A:** There is high certainty that the net benefit is substantial. Offer service.

**B:** There is high certainty that the net benefit is moderate, or there is moderate certainty that the net benefit is moderate to substantial. Offer service.

**C:** There is at least moderate certainty that the net benefit is small. Offer service selectively.

**D:** There is moderate or high certainty that the service has no net benefit or that the harms outweigh the benefits. Don't offer service.

**I:** Current evidence is insufficient to assess the balance of benefits and harms of the service.

into the cost. Payers negotiate reduced fees for commercial lab testing, but potential out-of-pocket costs to patients are much higher.

For our healthy 35-year-old man, the cost of the initially proposed testing (CMP, lipid panel, TSH, and 25[OH] vitamin D level) ranges from a negotiated payer cost of \$85 to potential patient out-of-pocket cost of more than \$400.<sup>6</sup>

Insurance would cover the USPSTF-recommended testing (HIV and hepatitis C screening tests), which might incur only a patient co-pay, and cost the system about \$65.

The USPSTF home page, found at [www.uspreventiveservicestaskforce.org/uspstf/](http://www.uspreventiveservicestaskforce.org/uspstf/) includes recommendations that can be sorted for your patients. A web and mobile device application is also available through the website. **JFP**

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