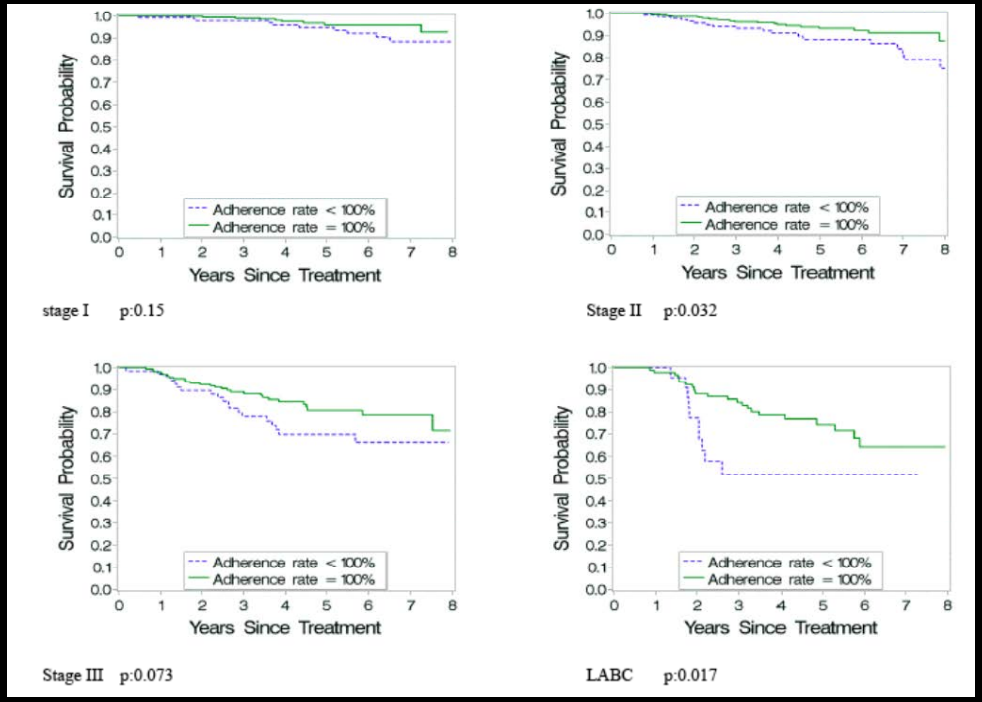
Where Lab Medicine Creates Value In Healthcare: Getting Out of the Lab To Help Clinicians Achieve Better Patient Outcomes

Lee H. Hilborne, MD, MPH, FASCP, FCAP, DLM(ASCP)^{CM}
Medical Director, Care Coordination, UCLA
Senior Medical Director, Quest Diagnostics
Senior Health Services Researcher, RAND
Past President, ASCP

We Have To Focus On Patient Outcomes To Be Relevant To The Value Equation

- **Outcomes matter to patients, payers, government, and others**
  - **Often influenced by externalities and more limited data**
- **The Donabedian quality model relates outcomes to structure (what we have in place) and process (what we do)**
  - **Structure and process are the usual focus of initiatives**
  - **They are more under the control of the individual**



Med Care. 2009;47:217-25.

We Have Seen A Huge Push To Demonstrate Clinical Utility

- **Analytic validity**
  - **How well a test performs in the lab**
  - **How well does the test measure the properties or characteristic(s) it is intended to measure**
- **Clinical validity**
  - **Diagnostic accuracy**
  - **The accuracy with which a test predicts the presence or absence of a clinical condition or predisposition**
- **Clinical utility**
  - **The usefulness of the test and the value of the information to medical practice**
  - **Test can be used to guide treatment or provide other benefit**

Most literature focuses on Clinical Validity

We must continue to push the envelope as we think and work "Beyond the Lab"

- Our health care system is moving to a new model that maximizes efficiency, with changes to delivery and reimbursement approaches.

- Doing the right thing for patients will always be what is most important, requiring the right diagnostic insights
  - That depends on our laboratories **and laboratorians**
  - We must make sure that our services have clinical utility

- Laboratory professionals must lead when it comes to diagnostic services
  - Advance patient-centered care
  - Improve overall healthcare quality
  - Reduce unnecessary utilization

- And we will be regarded (and rewarded) as much for what we don't do as what we do actually do

As Healthcare Evolves, Are We Properly Positioned to Respond?

- **Given the changes likely in medicine…**
- **How does pathology and laboratory medicine fit in?**

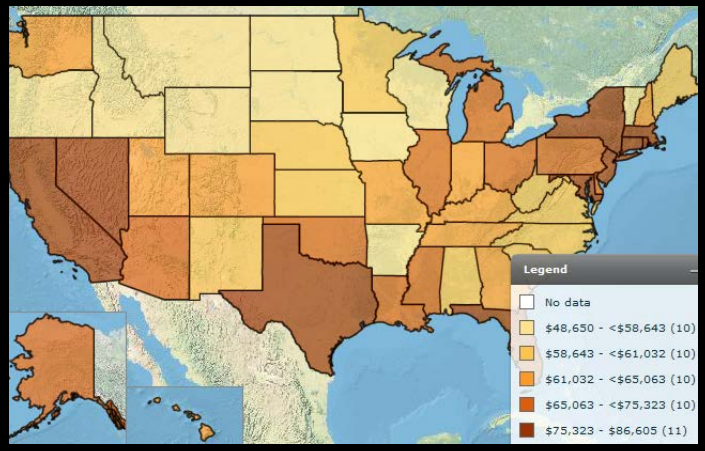
- **What do we do about change?**
  - **Influence our environment when possible**
  - **Change ourselves to respond to the environment when needed**

- **If we cannot get where we need to be from where we are now, how must we change to get there?**
  - **Maybe we can't get there from here, but we can get there**
  - **ASCP looked at these issues**
- **We will return to this in a bit**

Three Healthcare Facts

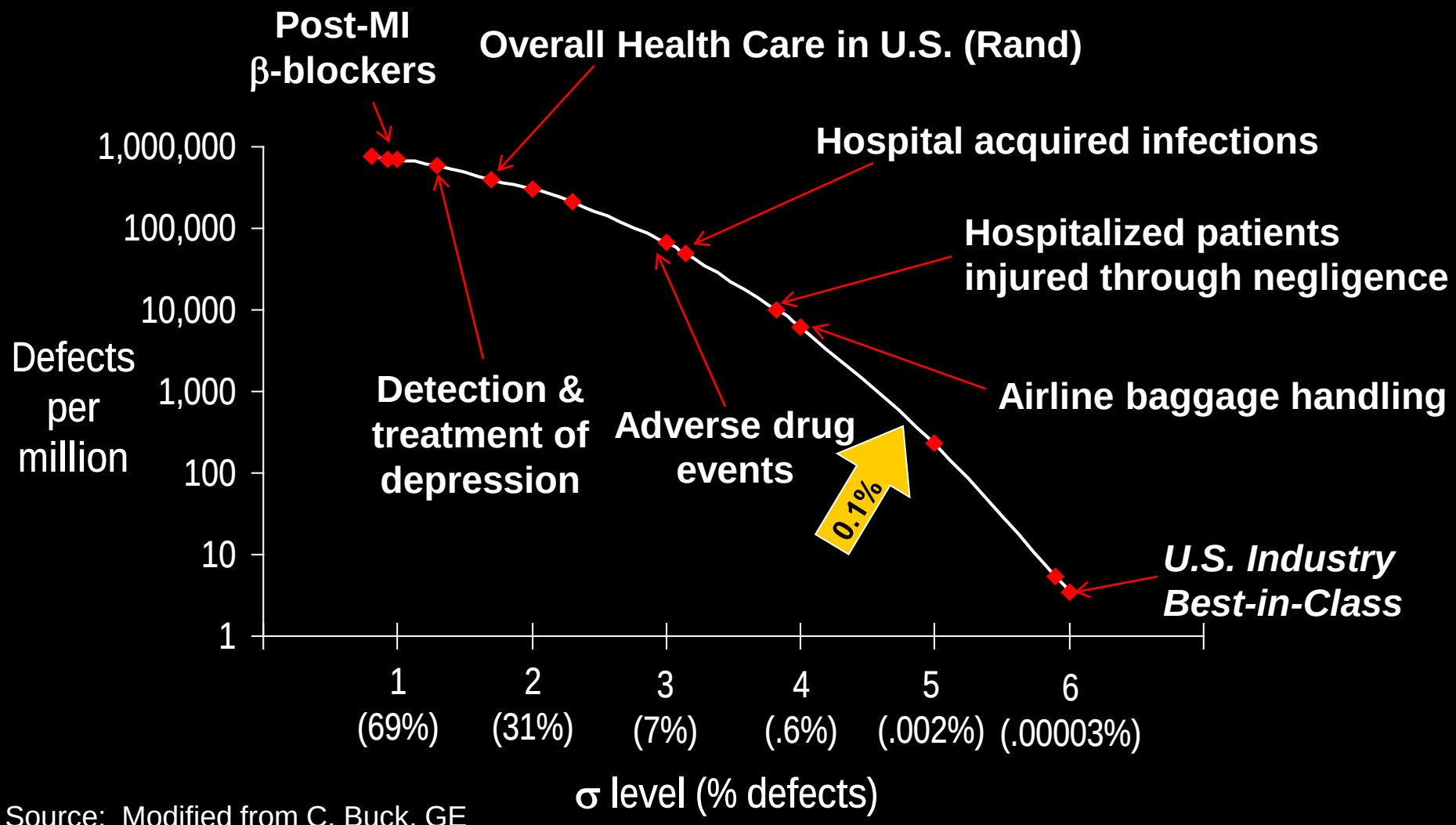
- **Treatments vary widely in value**
- **Clinical intuition and professional consensus are poor at telling which is which**
- **We do some treatments that have little, no, or negative value and fail to do some treatments that have high value**

- **State per capita Medicare spending in the last two years of life varies nearly two-fold**
- **Similar variation is seen in other areas**
  - **Ambulatory care**
  - **Hospital care**
  - **Procedures**



Dartmouth Atlas, 2010

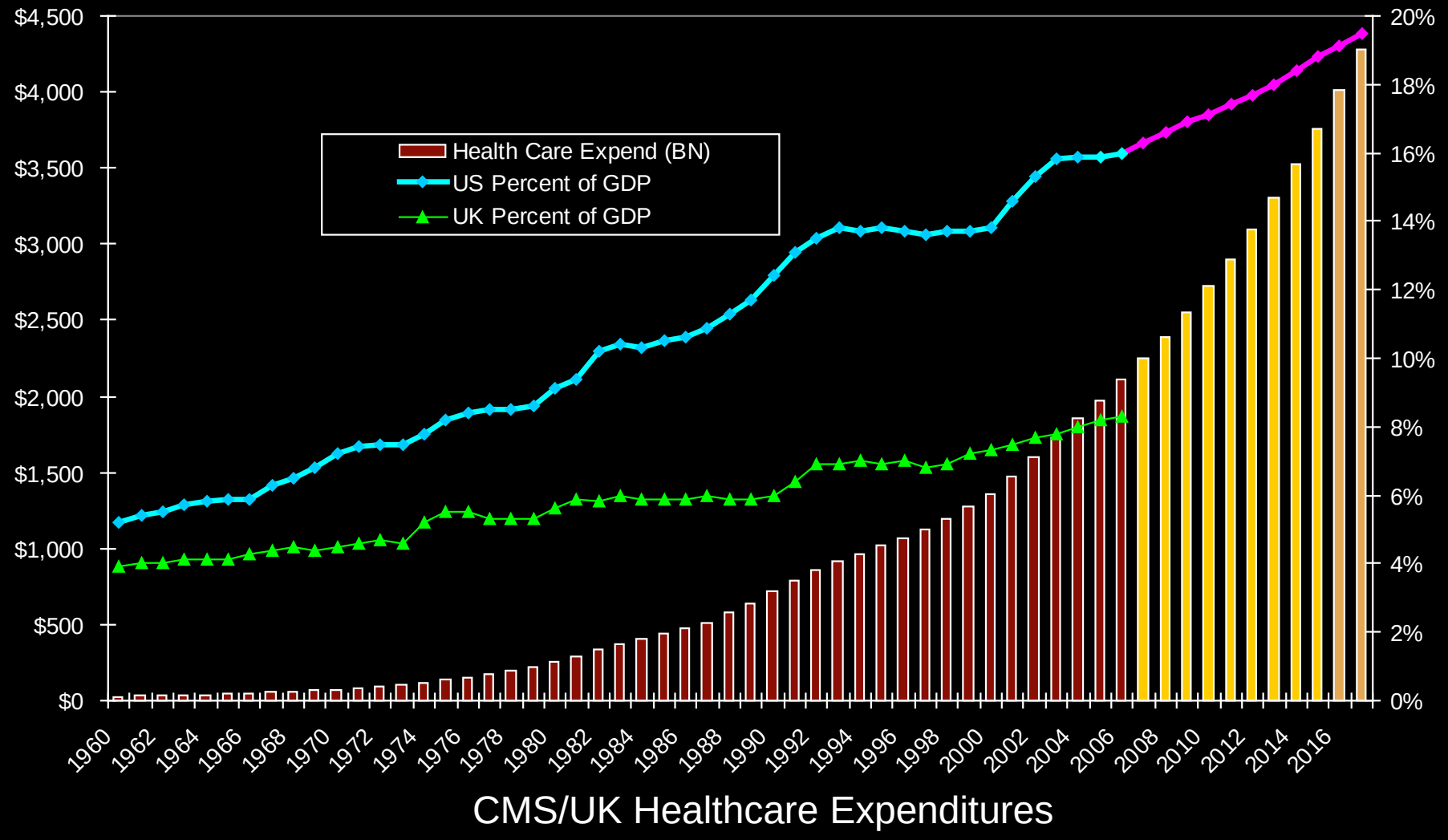
And Comparative Data Show Quality Defects Occur at Alarming Rates



Source: Modified from C. Buck, GE

Laboratory Medicine Is Among The Best

Cost/Resource Use Are Key Drivers For Demand for Healthcare Value In The US

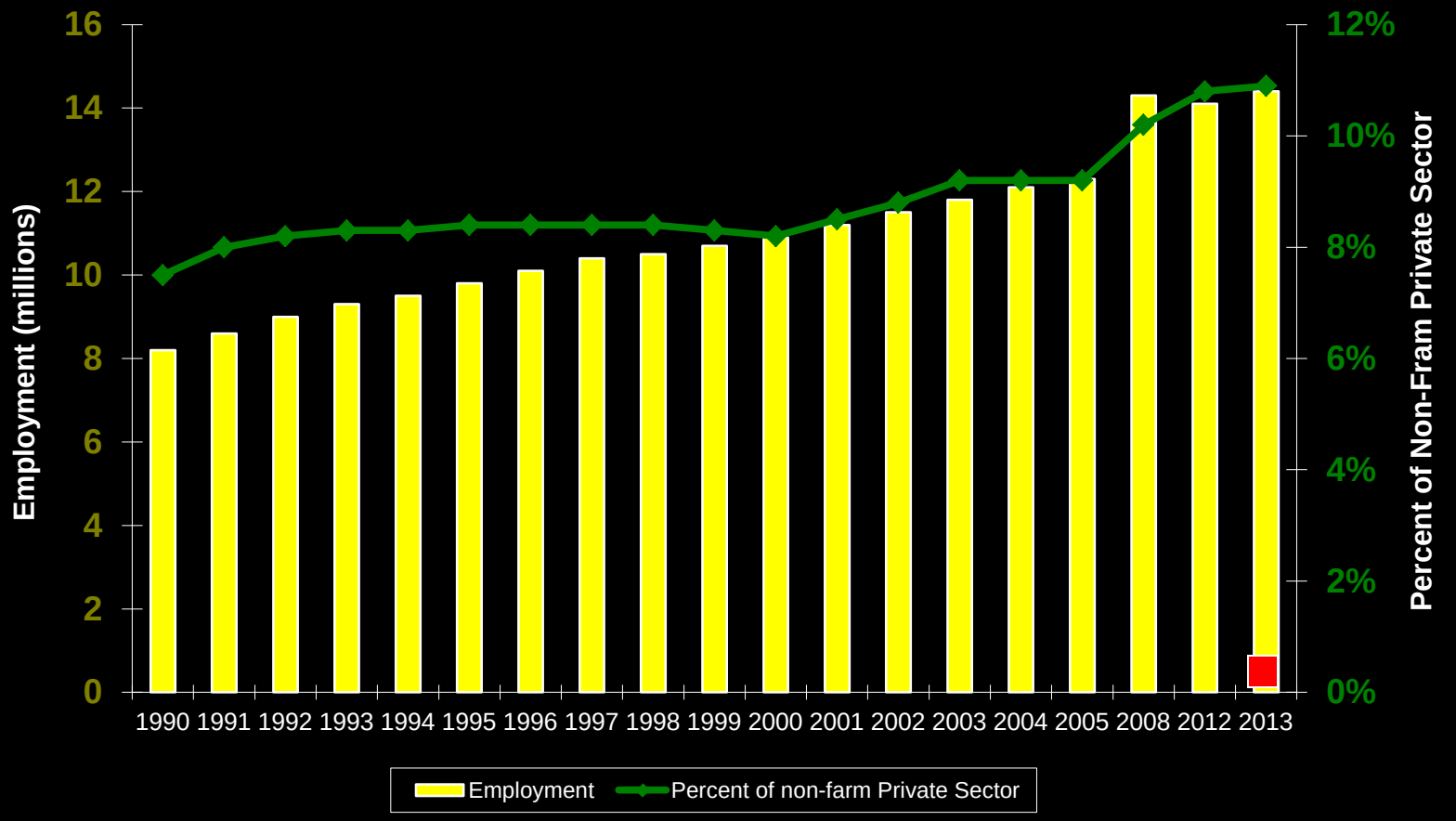


CMS/UK Healthcare Expenditures

Sources: CMS (US), OECD and ONS (UK)

The Rising Proportion of the Workforce in Health Care is Partly to Blame

Laboratory Medicine Is Only A Small Part

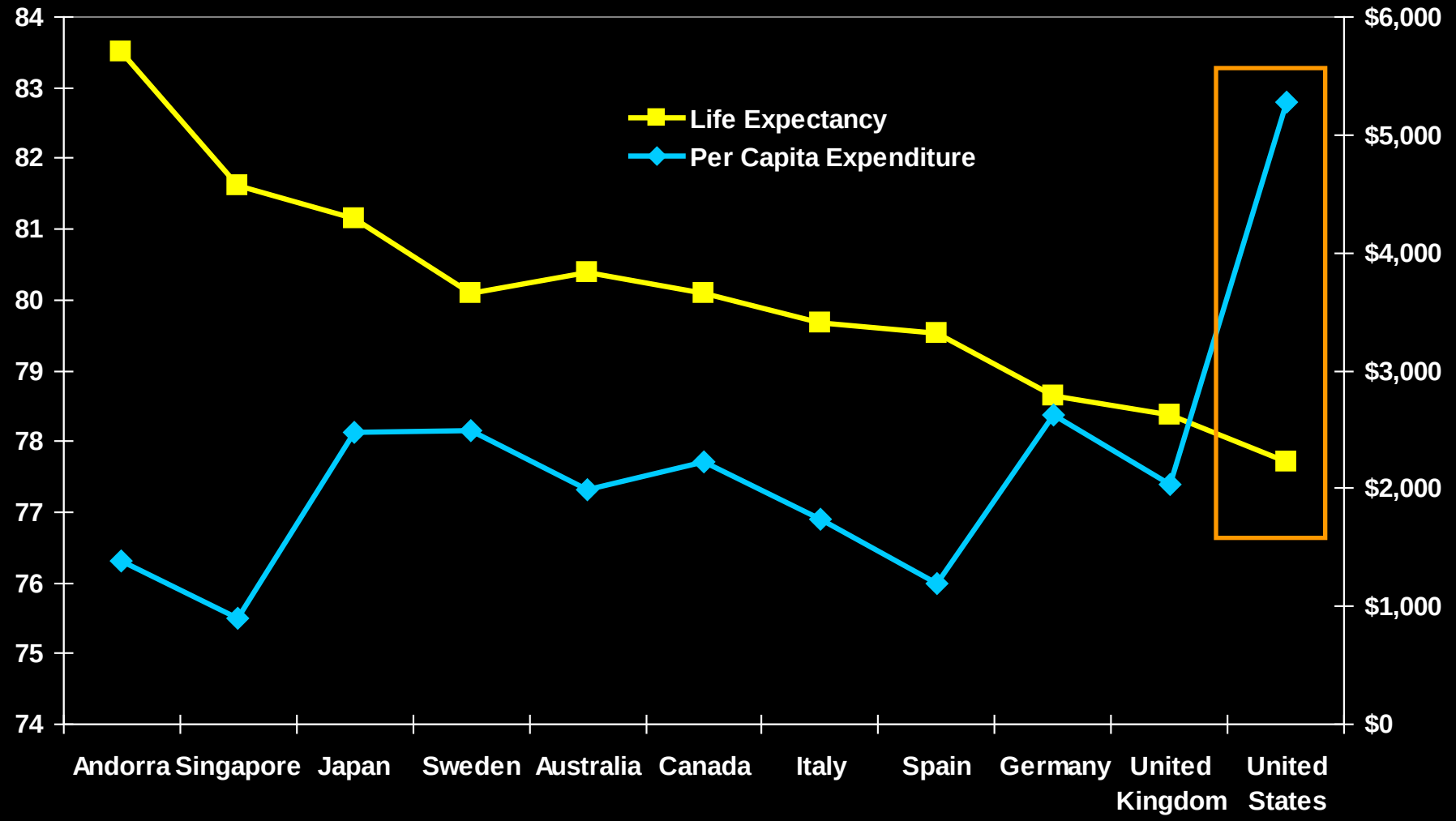


Kaiser Family Foundation, Trends and Indicators in Changing Health Care Marketplace, 2006

Approximate lab personnel

High Cost Doesn't Necessarily Mean Good Outcomes

The US Spends More On Care But People Don't Live Longer



For laboratory medicine to create value…

- **Let's not reinvent the wheel**
  - **What's important to us must be the same as what's important to all of medicine**
- **We need to speak the same language as our clinical colleagues**
- **Smart people already defined where we want to be for quality**
- **The Institute of Medicine identified the six quality domains**
  - **Safe**
  - **Effective**
  - **Patient-centered**
  - **Timely**
  - **Efficient**
  - **Equitable**

Laboratory diagnostics are among the most critical components when clinicians care for patients

- **Important in >70% of clinical decisions**
- **Comprise only 2-4% of healthcare expenses (US, Medicare)**

- **Consider 24 common clinical outpatient conditions with explicit evidence for a specific course of evaluation or treatment**

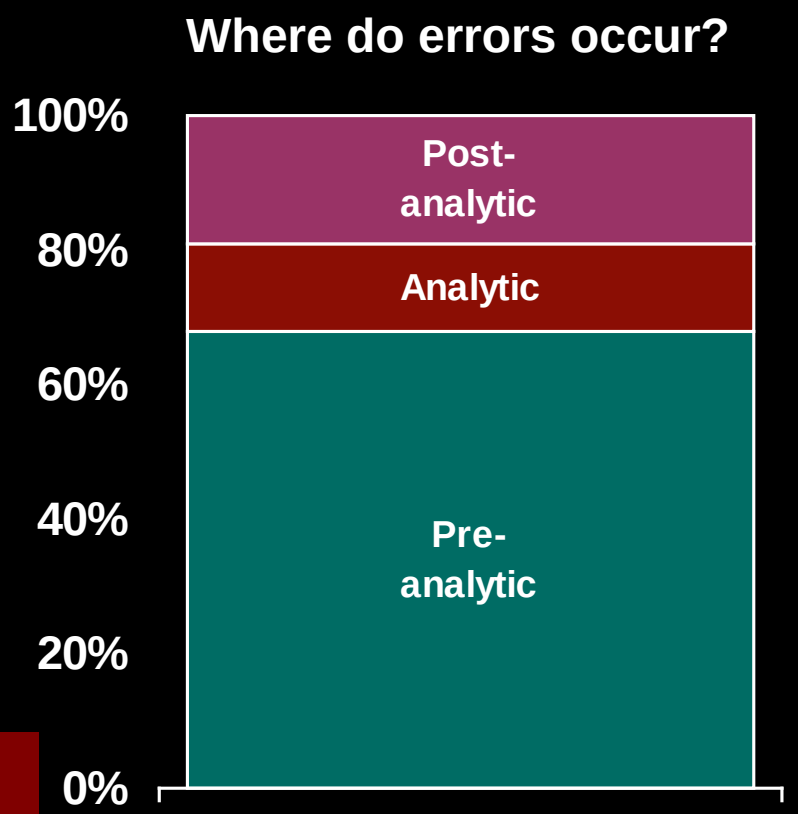
- **n how many of these common conditions are laboratory tests part of the diagnosis or monitoring?**
  - **Involved in Diagnosis: 50%**
  - **Involved in Treatment Monitoring: 38%**
  - **Involved in Diagnosis or Treatment: 63%**

- **No other specialty touches so many clinical situations that impact patients**

Although opportunities exist to improve service in all three phases of the total testing process

- **Pre-analytic**
- **Analytic**
- **Post-analytic**

- **Most opportunities exist outside the analytic phase**

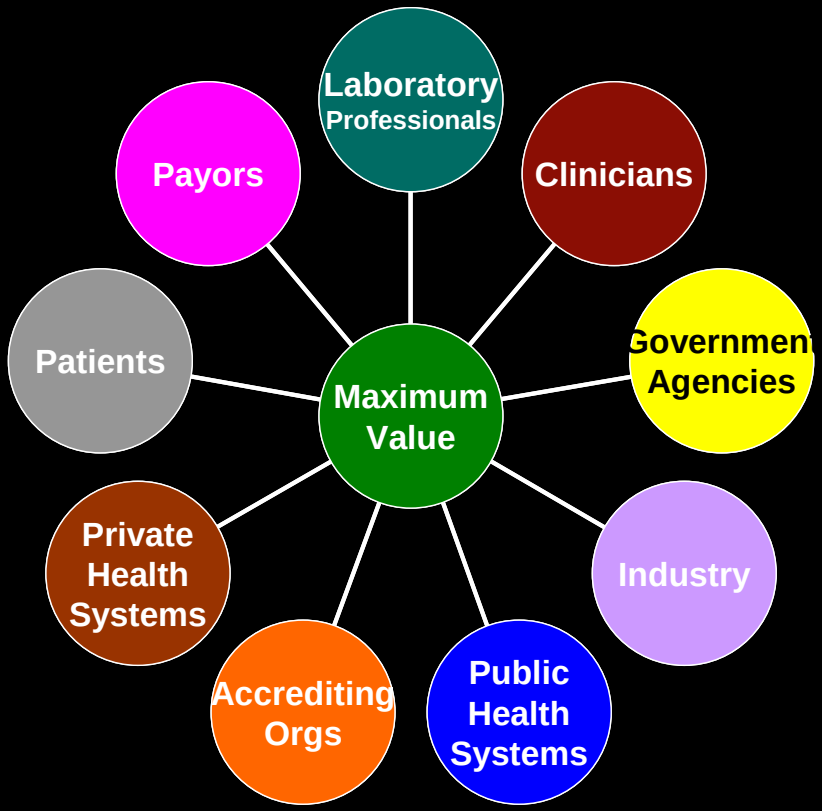


Laboratorian's Comfort Zone

(Plebani, 1997)

So Laboratory Medicine Creates Value in Healthcare

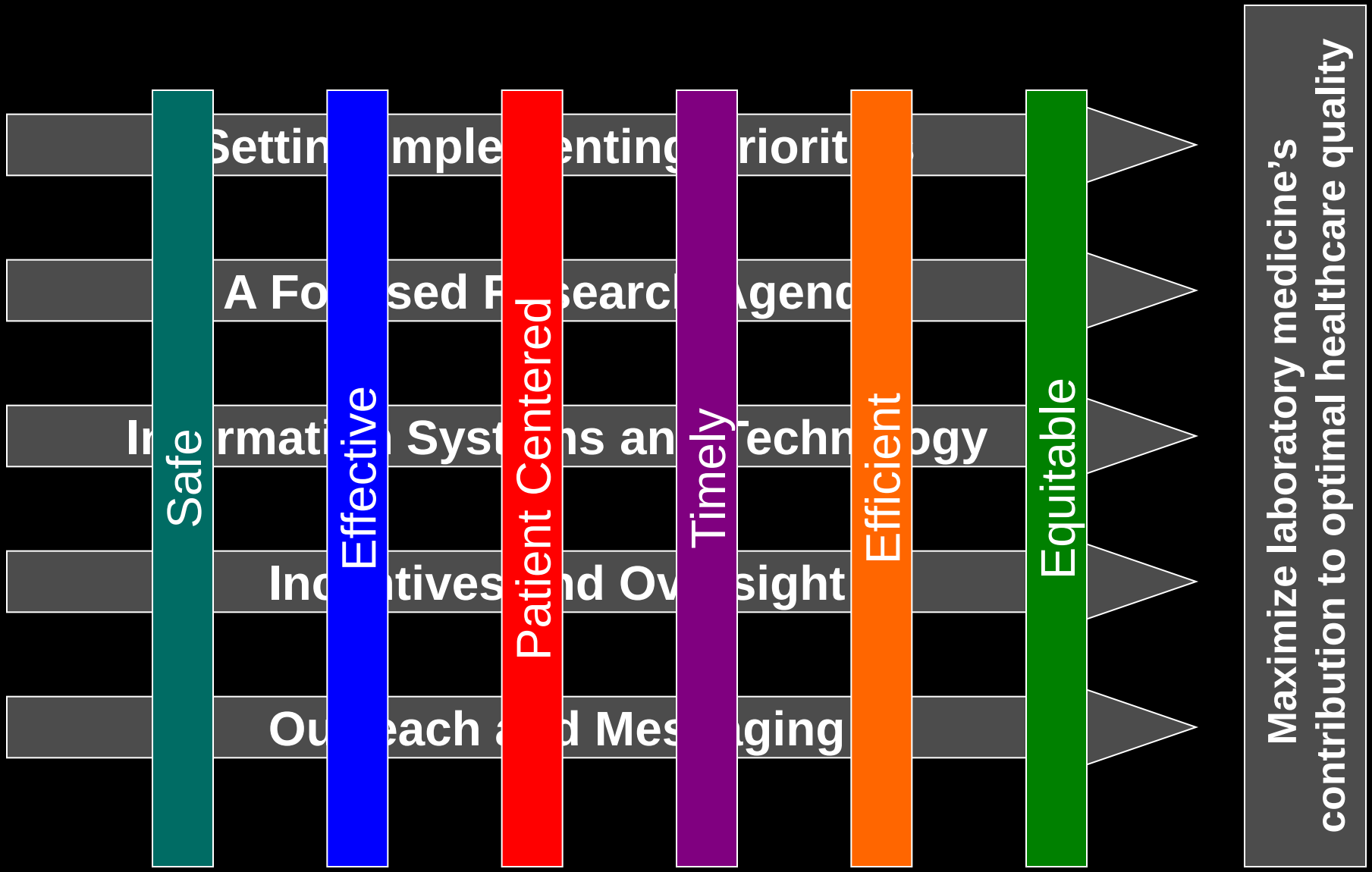
- When we maximize laboratory medicine's contribution to optimal healthcare quality OVERALL
- That's only going to happen when we think "beyond the lab"
- And reach outside the lab to help clinicians achieve those better patient outcomes



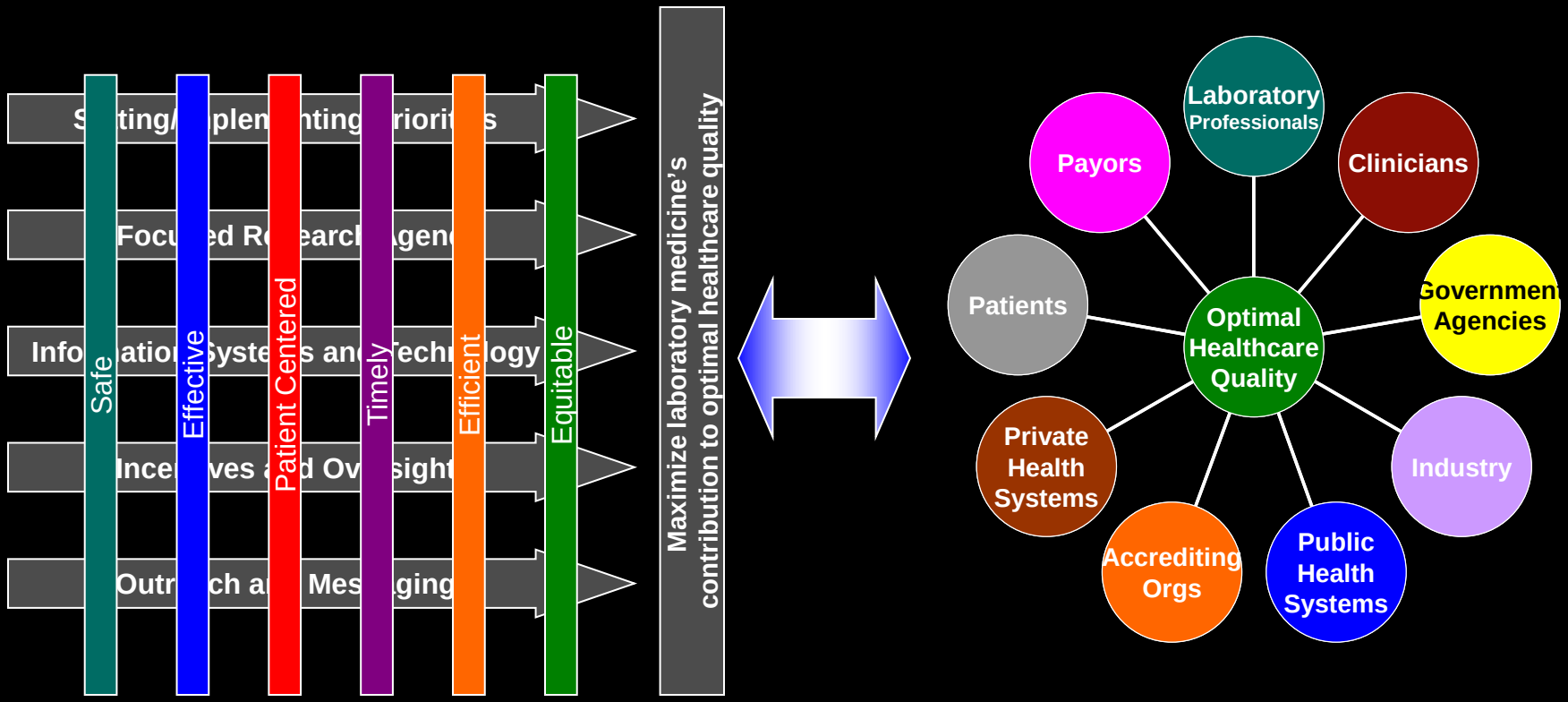
CDC Developed a Conceptual Model For Lab Medicine Based on an HHS Framework

With A Goal To Reach A Vision We Can All Support

And Overlay The IOM Quality Domains



If This Roadmap Framework Is Right, How Do We Engage All Stakeholders To Make It Happen?



Subgroups Provided Initial Thoughts To Better Define The IOM Domains In A Laboratory Context

- **Safe**
  - **Fully integrate lab results into patient care**
  - **Lab testing helps and does not harm patients**
- **Effective**
  - **Evidence-based decision making guides use**
  - **Results guide care via effective decision making**
  - **Tests performed have clear clinical utility**
- **Patient Centered**
  - **Lab services reflect patient preferences, values**
  - **Patient values incorporated into the interpretation of laboratory findings**
  - **Laboratory tests, facilities, information, and resources are designed with the primary focus on the patient**

Subgroups Provided Initial Thoughts To Better Define The IOM Domains In A Laboratory Context

- **Timely**
  - **Results reach providers (and patients) at or before when they are needed**
  - **“Outputs” are effective “inputs” to subsequent patient care processes**
- **Efficient**
  - **Eliminate waste (e.g., repeats, redundant services, ineffective technology)**
  - **Billing and reimbursement schemes facilitate, rather than discourage, appropriate testing**
- **Equitable**
  - **All patients have equal access to appropriate and necessary laboratory services**

So What Do We Do With This Information?

- **The laboratory has been a leader in quality measurement**
  - **We started before other discipline even thought about it**

- **Frankly, we do a better job within the laboratory than most any other part of medicine**
  - **But we have more work to do**
  - **Understand and champion not just analytic and clinical validity, but particularly clinical utility**
  - **Focus on improving operations even more**
  - **Particularly focus on the pre and post analytic aspects of laboratory medicine**
  - **Develop appropriate indicators for our services**

Let's Go Back To This Discussion: As Healthcare Evolves, Are We Properly Positioned to Respond?

- **Given the changes are likely in medicine…**
- **How does pathology and laboratory medicine fit in?**
- **What do we do about change?**
  - **Influence our environment when possible**
  - **Change ourselves to respond to the environment when needed**
- **If we cannot get where we need to be from where we are now, how must we change to get there?**
  - **Maybe we can't get there from here, but we can get there**
- **ASCP looked at these issues**

We Surely Are Seeing Momentous Trends

For the healthcare system

- **Continued cost pressures**
- **Workforce shortages**
- **Increased demand for transparency**
  - **Quality**
  - **Patient Safety**
  - **Cost**
- **Standardization of clinical care**
  - **Evidence based practice**
- **Globalization?**

For the laboratory

- **The laboratory viewed as a commodity**
- **Explosion in molecular and genetic medicine**
- **Migration of laboratory services away from the laboratory**

Let’s look at a few of these issues

System: Cost pressures

- **We must continue to show added value**
  - **Getting to the right answer quickly through lab services**
  - **Elimination of expensive invasive diagnostic procedures and tests without clinical utility**
- **Demonstrate value of professionals in the laboratory**
  - **The future requires us to be recognized**
  - **Be at the table when decisions are being made**
  - **Make sure we are seen as a partner in new care models**
- **To address cost pressures we must**
  - **Respond to our environment by managing costs**
  - **Change ourselves to provide better value to the system**

System: Workforce Shortages

- A global challenge, particularly for certain classes of workers
- Salaries have increased to attract workers in a global market
- Some alternatives to trained workers will continue to emerge
  - But professions that continue to show value in improving safety and quality will survive
- There will need to be better training opportunities and incentives to attract people to the health professions

- To address workforce shortages we must
  - Respond to our environment by increasing recruitment and retention of laboratory personnel
  - Continue to change ourselves by gaining new skills in new areas of diagnostic medicine

System: Increased Demand For Transparency

- These pressures will increase
  - The lab is well positioned to provide data and information to our colleagues and those with oversight responsibility
  - The lab has years of experience with data monitoring and quality improvement – these skills are needed in other parts of the healthcare system
  - Laboratory professionals must embrace a culture of safety

- To address transparency demands we must
  - Respond to our environment by working with colleagues to assure they achieve quality aims
  - Continue to change ourselves
    - Become increasingly comfortable with sharing data and responding to findings
    - Add additional management concepts to our certification exams and training

System: Globalization

- **Right now this is something to monitor**
- **Medical tourism hasn't really caught on to any great extent**
- **But image based (and interpretative) specialties can be easily outsourced, especially as bandwidth expands**
  - **The major obstacle right now is regulation not technology**
  - **Outsourcing can be local, regional, national, or global**

- **To address globalization demands we must**
  - **Respond to our environment by improving services so people will outsource to us, not from us**
  - **Continue to change ourselves by adding local value to diminish the incentives to outsource**

Laboratory: Viewed As A Commodity

- **Competitive bidding: a cost saving measure aimed at the laboratory**
  - **There are initiatives in other disciplines as well**
  - **Experts have said this is a bad idea**
- **Implies lab services can be done on a production line –there's no professional service**

- **To address the push for competitive bidding we must**
  - **Respond to our environment**
    - **Make sure regulators and customers understand the value we provide**
    - **Provide quality services at competitive prices**
  - **Continue changing ourselves by adding local value that demonstrates essential services that cannot be provided at a distance**

Active Involvement In The Choosing Wisely Campaign Is A Strategy To Raise Value

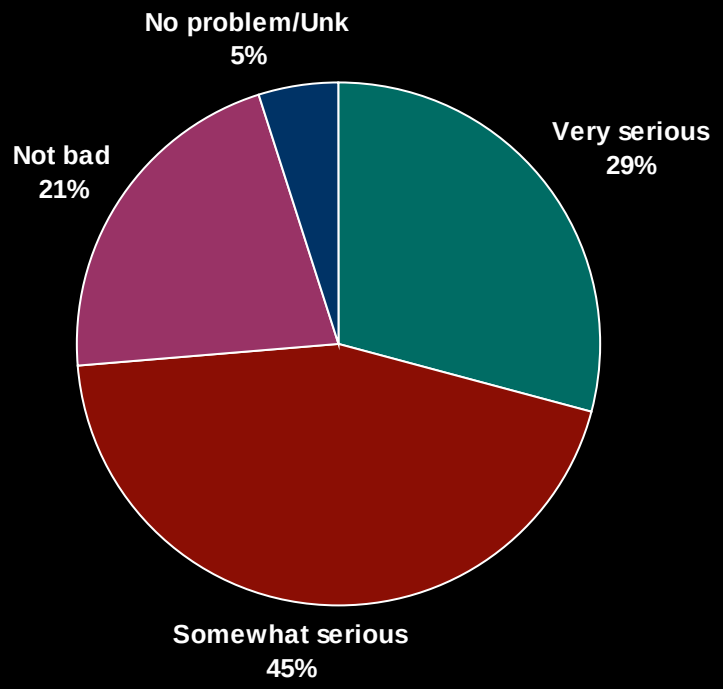
Choosing Wisely: An ABIM Foundation initiative to help physicians and patients engage in conversations to reduce the overuse of tests and procedures and support physician efforts to help patients make smart and effective care choices.

Choosing Wisely®
An initiative of the ABIM Foundation

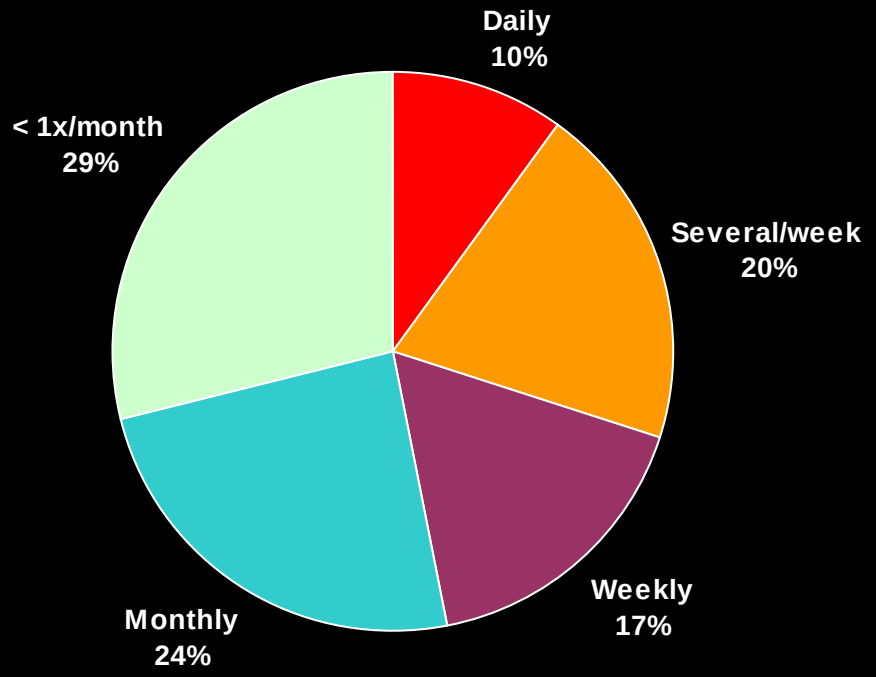
Consumer Reports®

AARP®

How is it working? Here's Some Initial Feedback Published Last Quarter

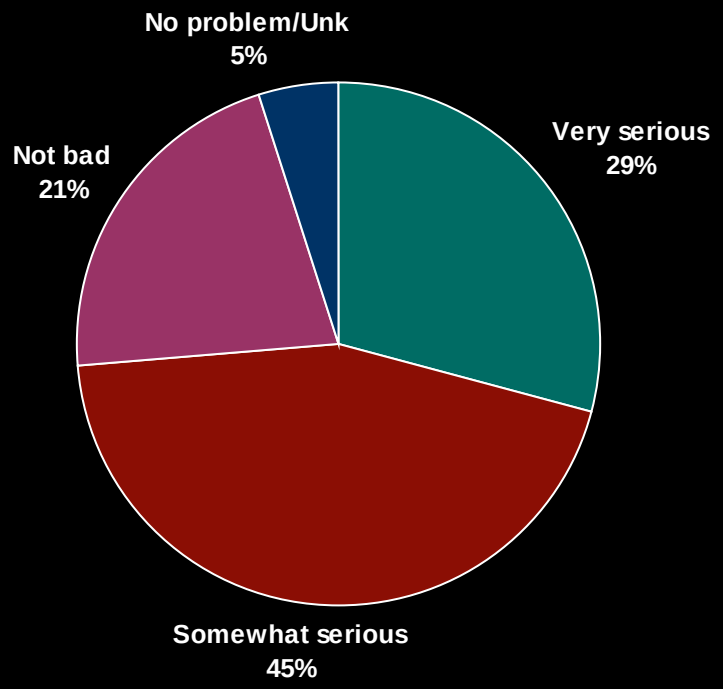


How serious a problem is unnecessary tests and procedures?

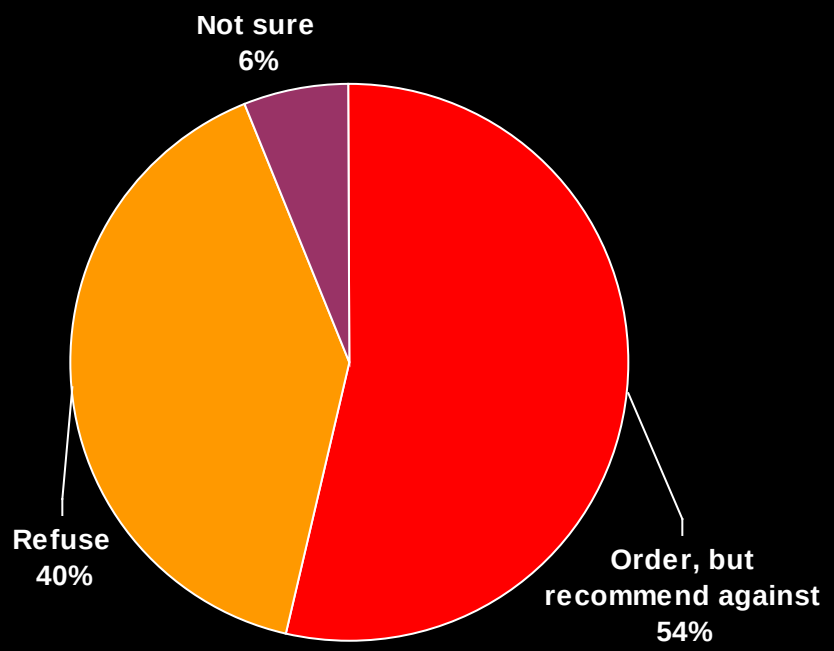


How often do patients ask for an unnecessary test or procedure?

How is it working? Here's Some Initial Feedback Published Last Quarter

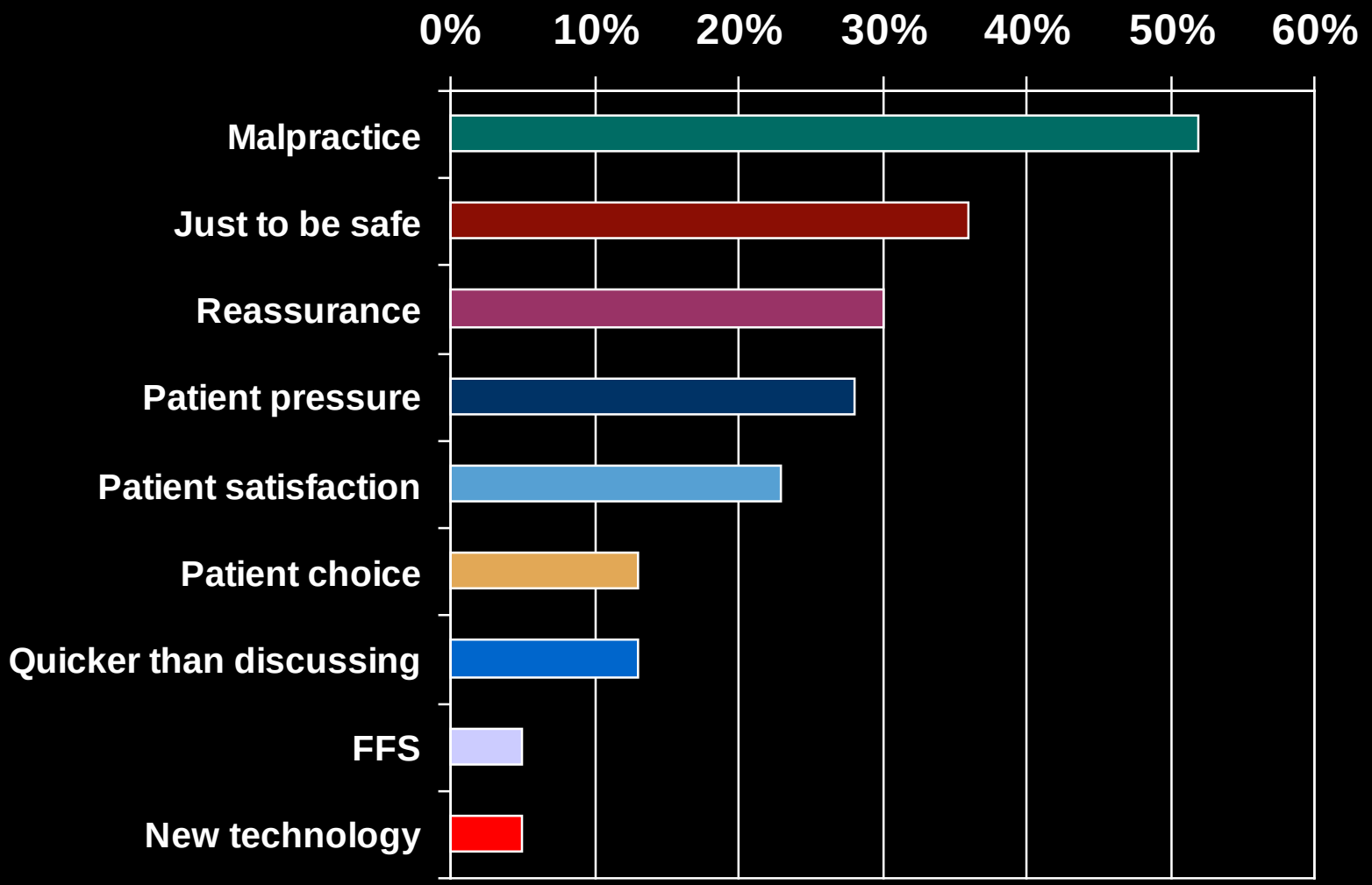


How often do patients follow your advice and avoid a procedure?



What would you do if a patient asked for a test you knew was unnecessary?

Why Do Doctors Order Tests They Think Are Not Necessary?



Many organizations on board and new ones are joining and increasing recommendations

ABIM Foundation

American Academy of Allergy, Asthma & Immunology

American Academy of Clinical Toxicology

American Academy of Dermatology

American Academy of Family Physicians

American Academy of Hospice and Palliative Medicine

American Academy of Neurology

American Academy of Ophthalmology

American Academy of Orthopaedic Surgeons

American Academy of Otolaryngology–Head and Neck Surgery

American Academy of Pediatrics

American Association of Blood Banks

American Association of Clinical Endocrinologists

American Association of Neurological Surgeons

American Association for Pediatric Ophthalmology and Strabismus

American College of Cardiology

American College of Chest Physicians

American College of Emergency Physicians

American College of Medical Toxicology

American College of Obstetricians and Gynecologists

American College of Occupational and Environmental Medicine

American College of Physicians

American College of Radiology

American College of Rheumatology

American College of Surgeons

American Gastroenterological Association

American Geriatrics Society

American Headache Society

AMDA—Dedicated to Long Term Care Medicine

American Psychiatric Association

American Society of Anesthesiologists

American Society of Clinical Oncology

American Society for Clinical Pathology

American Society of Colon and Rectal Surgeons

American Society of Echocardiography

American Society of Hematology

American Society of Nephrology

American Society of Nuclear Cardiology

American Society of Plastic Surgeons

American Society for Radiation Oncology

American Society for Reproductive Medicine

American Thoracic Society

American Urological Association

Commission on Cancer

Consumer Reports Health

The Endocrine Society

Heart Rhythm Society

National Physicians Alliance

North American Spine Society

Robert Wood Johnson Foundation

Society for Cardiovascular Angiography and Interventions

Society of Cardiovascular Computed Tomography

Society for Cardiovascular Magnetic Resonance

Society of Critical Care Medicine

Society of General Internal Medicine

Society of Gynecologic Oncology

Society of Hospital Medicine

Society for Maternal-Fetal Medicine

Society of Nuclear Medicine and Molecular Imaging

Society of Thoracic Surgeons

Society for Vascular Medicine

There Are Many Dimensions to Appropriate Test Utilization

- Our laboratories constantly contribute to improved care and reduced cost.
- In hospitals, lab professionals serve on many committees and task forces.
- Center appropriate test utilization on good patient care; include cancellation of inappropriate tests and addition of appropriate tests for optimal outcomes.
- Five tests that ASCP recommends for *Choosing Wisely* are one dimension of appropriate test utilization.
- Patients should learn firsthand about these tests, so they can make informed choices.

Five initial tests were selected for lab medicine to be illustrative of common situations we confront.

- An ASCP review panel examined hundreds of options based on both the practice of pathology and evidence available through literature.
- And selected ASCP's 5 initial tests for Choosing Wisely.
  - We only were allowed to have five!
- Common situations
  - Tests with merit in some circumstances but are not appropriate in others
  - Tests with no clinical utility
  - Tests that have been generally replaced by better tests
  - New and emerging diagnostics
- This is the beginning

Choosing Wisely®

An initiative of the ABIM Foundation

Here Are The Five First Tests

1. **Do not perform population-based screening for 25-OH-Vitamin D deficiency.**
2. **Do not perform low-risk HPV testing for cervical disease.**
3. **Avoid routine preoperative testing for low-risk surgeries without a clinical indication.**
4. **Only order Methylated Septin 9 (SEPT9) on patients for whom conventional diagnostics are not possible.**
5. **Do not use bleeding time to guide patient care.**

Although there is only one primary lab organization involved…

- Many of the organizations shown earlier have developed recommendations that involve laboratory testing
- Laboratory testing is so critical to the practice of medicine
- That’s why other organizations talk about testing appropriateness

There are lots of examples in other organizations' recommendations.

American Academy of Allergy, Asthma, and Immunology (AAAAI)
•Don't perform unproven diagnostic tests, such as IgG testing or an indiscriminate battery of IgE tests, in the evaluation of allergy

Endocrine Society and AACE
•Don't routinely measure 1,25-dihydroxyvitamin D unless the patient has hypercalcemia or decreased kidney function
•Don't prescribe testosterone therapy without known deficiency

American Academy of Ophthalmology
•Don't perform preoperative medical tests for eye surgery unless there are specific medical indications

Commission on Cancer
•Don't perform surgery to remove a breast lump for suspicious findings unless needle biopsy cannot be done

Society of Hospital Medicine
•Don't perform repetitive CBC and chemistry testing in the face of clinical and lab stability

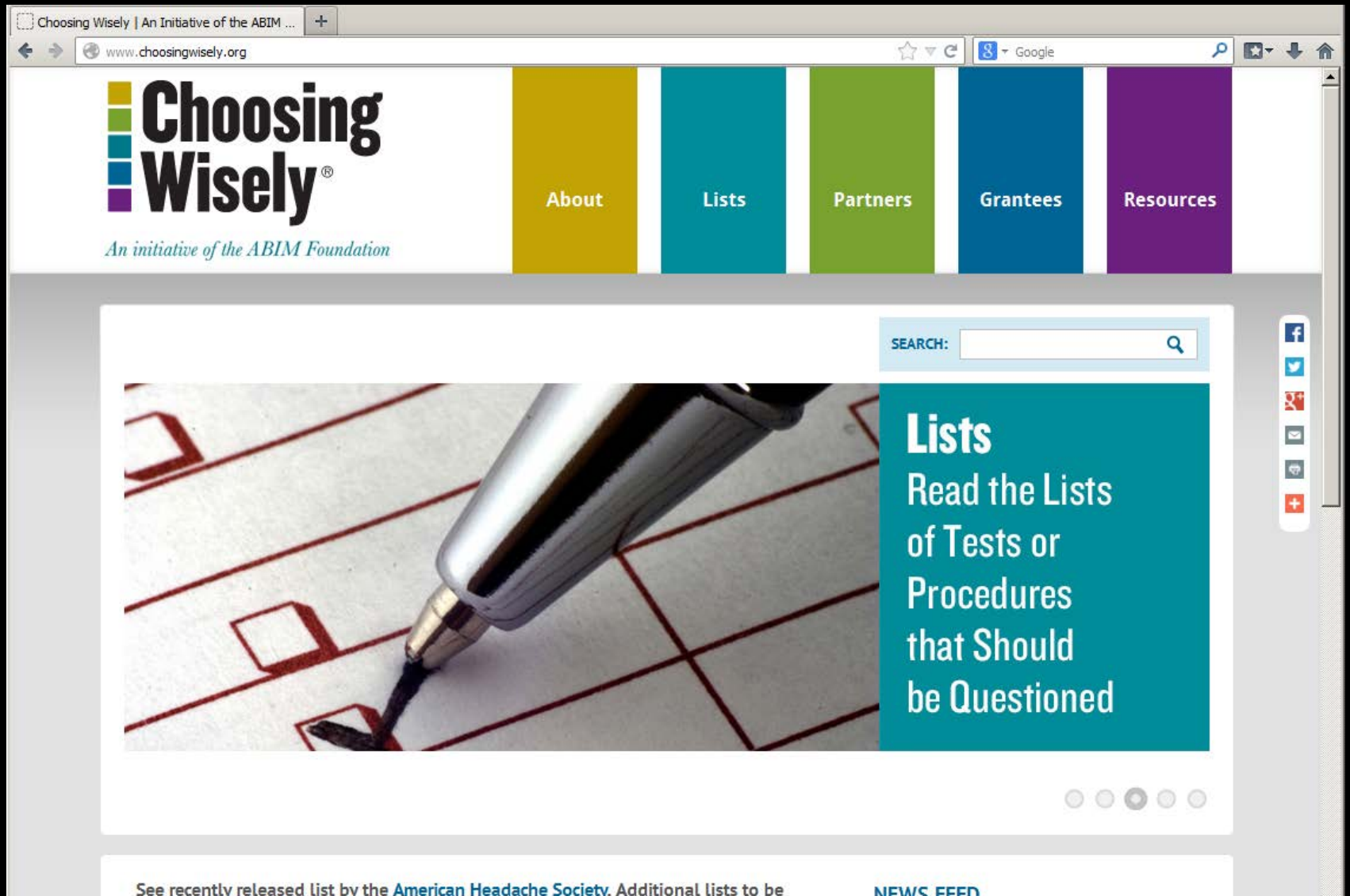
American Academy of Family Physicians
•Don't perform Pap smears on women younger than 21 or who have had a hysterectomy for non-cancer disease
•Don't screen women younger than 30 years of age for cervical cancer with HPV testing, alone or in combination with cytology
•Don't screen women older than 65 years of age for cervical cancer who have had adequate prior screening and are not otherwise at high risk for cervical cancer
•Don't routinely screen for prostate cancer using a prostate-specific antigen (PSA) test or digital rectal exam

Society of General Internal Medicine
•Don't perform routine general health checks for asymptomatic adults
•Don't perform routine pre-operative testing before low-risk surgical procedures

American Academy of Clinical Toxicology
•Don't order heavy metal screening tests to assess non-specific symptoms in the absence of excessive exposure to metals

American Congress of Obstetrics and Gynecology
•Don't perform routine annual cervical cytology screening (Pap tests) in women 30–65 years of age

You can review the entire list at choosingwisely.org



Laboratory: Molecular and Genetic Medicine

- An exploding domain for laboratory professionals
- We must make sure we remain the masters of this diagnostic field
- As personalized medicine increases, the lab becomes as important in many diseases as pharmaceutical services

- To address the explosion in molecular and genetic medicine we must
  - Respond to our environment
    - Develop guidelines for appropriate use of services
    - Help clinicians and patients “Choose Wisely”
    - Work with local colleagues and drug developers
  - Continue to change ourselves
    - Get additional training in molecular and genetic medicine
    - Add molecular diagnostics and genetics to our training programs and certification exams to a greater extent

Laboratory: Movement Of Services Outside The Laboratory

- **Point of care diagnostics are here to stay**
- **POC instruments offer respectable quality with rapid turnaround and acceptable price**
- **Political environment makes obtaining a waiver pretty easy**

- **To address the migration of testing outside the central lab we must**
  - **Respond to our environment**
    - **Assure timely services**
    - **Provide quality oversight and training for POC testing**
    - **Develop guidelines for use of POC services**
  - **Continue to change ourselves**
    - **Assume a more professional, consultative role**
    - **Integrate lab services into clinical care**

More pressure for improved quality practices

- **Assuring appropriate test selection**
- **Value in avoiding repeat testing when results are already available**
- **Demonstrating value added in clinical practices**

- **When patients, physicians and hospitals have a choice (price being equal), laboratory selection will be based on service quality, not analytical quality**
  - **Most providers “assume” analytical quality**
  - **Not entirely unreasonable – we all play by the same rules**
  - **Service is what providers actually see**
  - **Responsiveness, clinical consultation, ease of use**

Technologists' roles will evolve

- **Less focus on analytic skills**
  - **Technical experts will always be valued, in fact it's likely in the immediate future the demand for genetics will grow**
  - **But there will be new, better ways (e.g., NIPT)**
  - **Manual technical skills are being replaced by automation**
  - **The technical "winners" will be those who can achieve comfort at the interface between technology and automation**

- **More focus on oversight and consultation**
  - **Be the professionals that guide healthcare in "Choosing Wisely" when it comes to genetics**

We Need To Recalibrate Our Approach

- We are still in the driver's seat
- But we need to be proactive
  - Hopefully there's still a driver's seat
  - If there is, we need to sit in it!
- Focus on clinical utility
  - Engage in *Choosing Wisely* and other programs
- Extend outside the laboratory to make sure others know who we are and what we do
- Leverage our strength through our specialty organizations and our broader networks
- Let's discuss!