

# Better testing, better care – the role of the laboratory in improving outcomes

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***Mike Hallworth***  
***Shrewsbury, UK***

**WEQAS Annual Conference**  
**Cardiff Bay, 28 November 2018**

CARDIFF  
**2Q18**

ANNUAL  
CONFERENCE

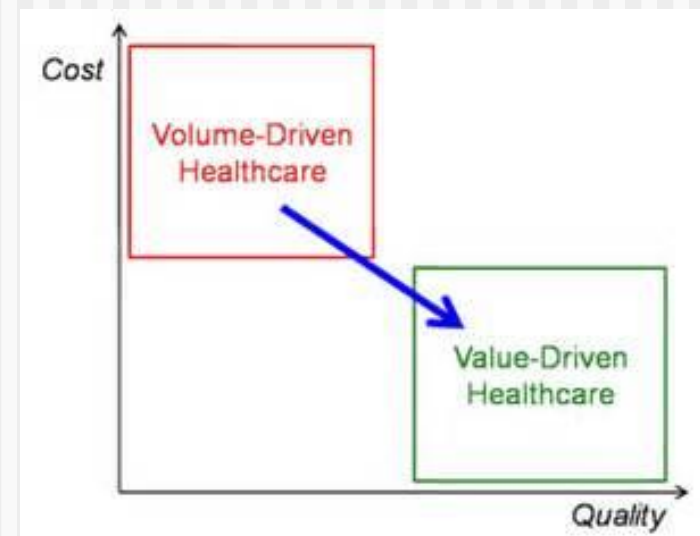
# Outline

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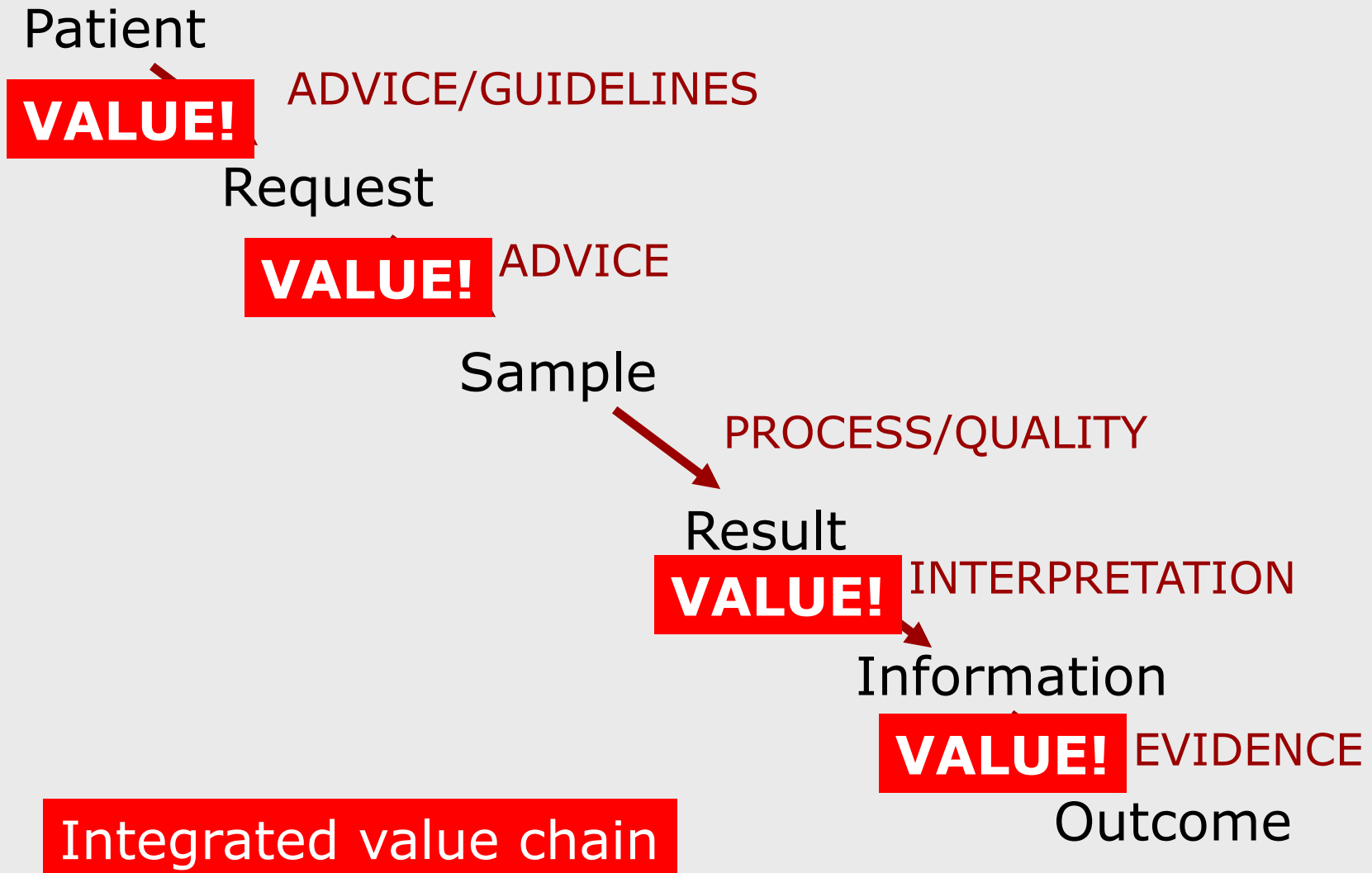
- Introduction
- Linking lab testing to outcomes
- Example: diagnostic error
- What needs to change?

# Volume to value

- Focus on improving the value of laboratory services



# Laboratory medicine



# Health outcomes

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$$\text{VALUE} = \frac{\text{Outcome}}{\text{Cost}}$$

Porter ME: What is value in health care? NEJM 2010; 363: 2477-81

**120** assays available and more are coming

Ferritin AFP CA 242 CEA Total PSA 17-OH Progesterone  
CK-MB LP-PLA2 Troponin I Myoglobin NT-proBNP Progesterone Cyclosporine A  
Tacrolimus, FK 506 Digoxin TSH(3rd Generation) T<sub>4</sub> T<sub>3</sub> FT<sub>4</sub> FT<sub>3</sub> HA HAIP N-P C IV  
Laminin C-Peptide NSE Insulin free HCG PAPP-A Chag FSH LH  
HCG/β-HCG EBV EA IgA EBV EA IgM EBV CA IgM PCT IgM IgA IgE  
Intact PTH Calcitonin Osteocalcin Vitamin B<sub>12</sub> Ferritin FA Toxo IgG Rubella IgG  
HBsAg Anti-HBs CA 72-4 H.pylori IgG β<sub>2</sub>-MG IGF-1  
Cortisol ACTH CA 125 CA 19-9 CA 15-3 Angiotensin I D-Dime  
FT<sub>3</sub> TG T<sub>3</sub> CA 50 Glycine Proinsulin Estradiol Estri Pro  
gesterone Testosterone EBV VCA IgA EBV VCA IgG 25-OH Vitamin D SCCA  
Rubella IgM CMV IgG HSV-1/2 IgG HSV-2 IgG GAD 65 HSV-1/  
IgM Anti-HBe Anti-HCV free Testosterone Anti-HBe Syphilis  
CYFRA 21-1

**Tumor Markers**  
**Bone Metabolism**  
**Inflammation**  
**Drug Monitoring**  
**Hepatic Fibrosis**  
**EBV**  
**Thyroid**  
**Cardiac**  
**Glycometabolism**  
**Kidney Function**

## MORE ASSAYS FOR LABS INFINITE VALUE FOR PATIENTS



### MAGLUMI™ 800

- Throughput: Maximum 180 tests/hour
- Onboard capability: up to 40 samples
- Reagent position: 9
- Sample and reagent continuous loading
- Compact size

# Outline

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- Introduction
- Linking lab testing to outcomes
- Example: diagnostic error
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# Outcomes research

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- Outcomes: “results of medical interventions in terms of health or cost” (Bissell)
  - Clinical
  - Operational
  - Economic

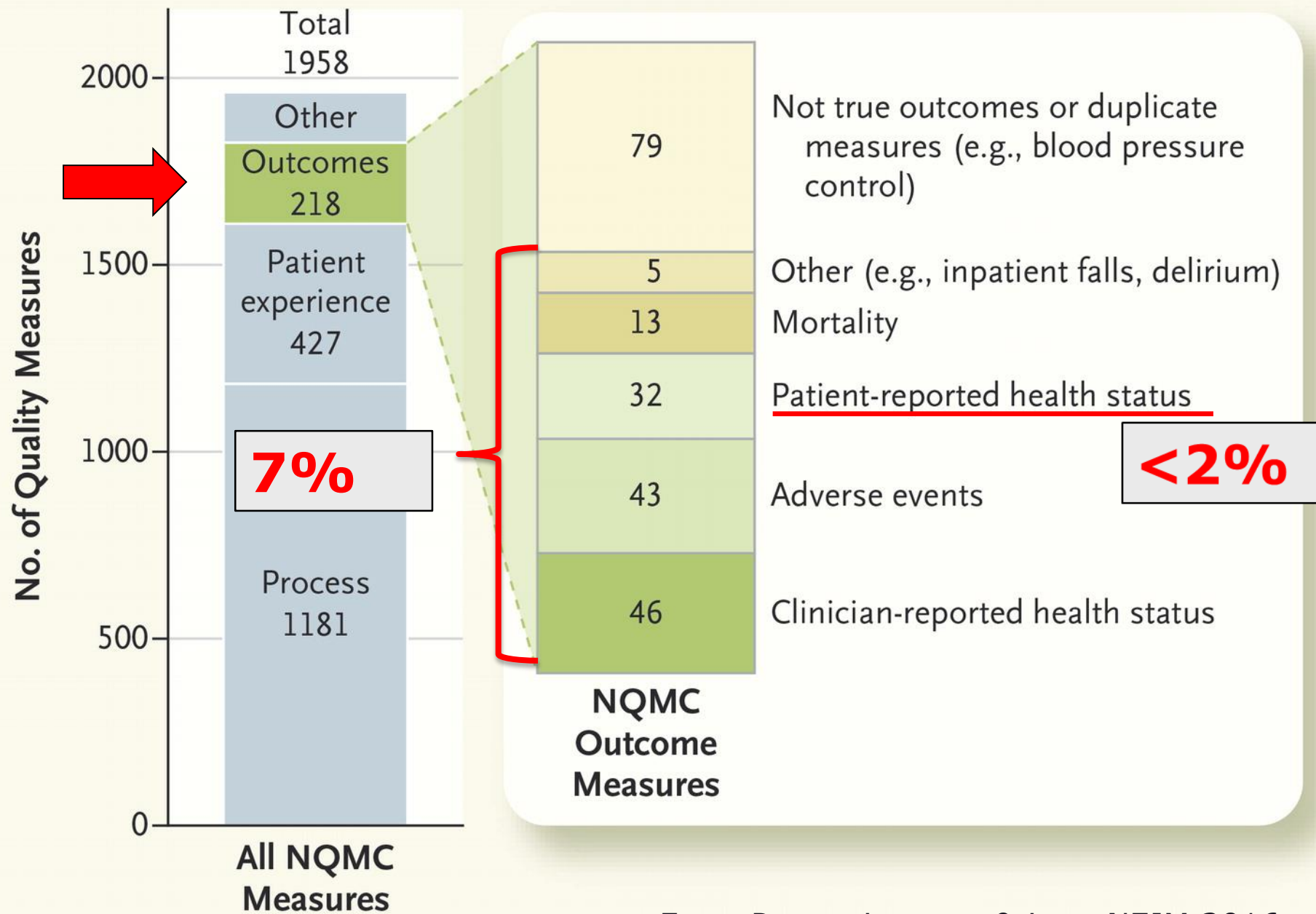


# Quality Indicators

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- National Quality Measures Clearinghouse





From Porter, Larsson & Lee; NEJM 2016

# International Health Rankings (Commonwealth Fund, 2017)

	AUS	CAN	FRA	GER	NL	NZ	NO	SWE	SWZ	UK	US
<b>Overall rank</b>	<b>2</b>	<b>9</b>	<b>10</b>	<b>8</b>	<b>3</b>	<b>4</b>	<b>4</b>	<b>6</b>	<b>6</b>	<b>1</b>	<b>11</b>
<b>Outcomes</b>	<b>1</b>	<b>9</b>	<b>5</b>	<b>8</b>	<b>6</b>	<b>7</b>	<b>3</b>	<b>2</b>	<b>4</b>	<b>10</b>	<b>11</b>

# Assessment of performance in health care

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- 'Quality' defined as compliance with evidence-based guidelines
- Outcome measurement led by specialty groups/societies – don't tend to look at whole process
- Overwhelming focus on clinical status not functional status
- No consensus on measures





'Let a thousand flowers bloom'

Anselm Kiefer, 1999

- 
- “We predict that a time will soon come when it will be hard to believe that measurement of outcomes that mattered to patients was rare in 2016 – and organizations that measured them each did it in their own way”

# International Consortium for Health Outcomes Measurement

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# ICHOM is gaining the support of the health care community

ICHOM's Sponsoring Partners\*

## PLATINUM



## GOLD

Carl Bennet AB



## SILVER



## BRONZE



## COFOUNDERS

\*As of July 1, 2015





# ICHOM Standards completed

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- Breast cancer
- Cataracts
- CKD
- Cleft lip and palate
- Colorectal cancer
- Coronary artery disease
- Craniofacial microsomia
- Dementia
- Depression & anxiety
- Heart Failure
- Hip and knee OA
- Hypertension
- Inflammatory Arthritis
- IBD
- Low back pain
- Lung cancer
- Macular degeneration
- Older people
- Overactive bladder
- Parkinson's disease
- Pregnancy and childbirth
- Prostate cancer
- Stroke



ICHOM

# ICHOM Standards in preparation

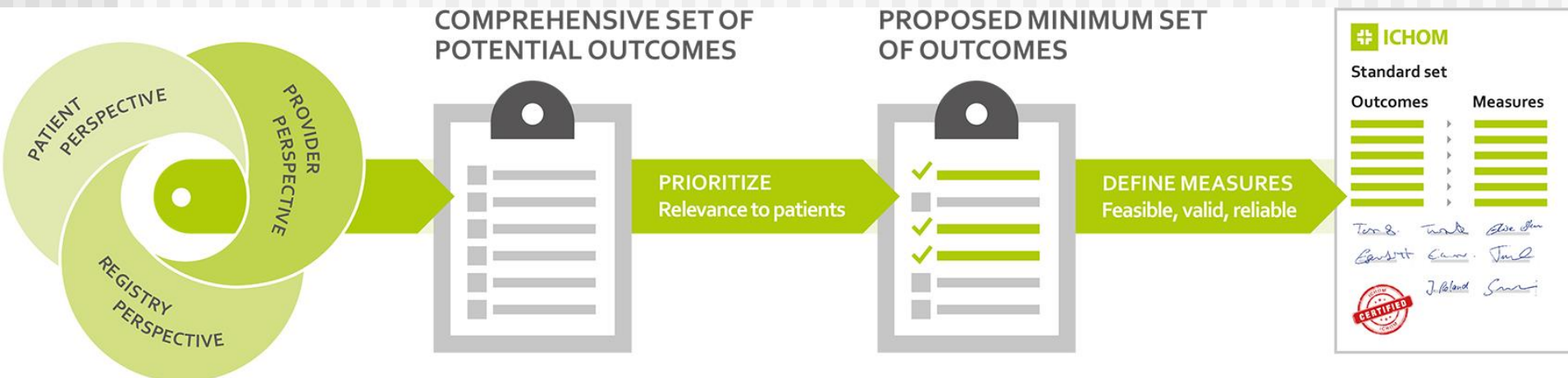
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- Current standards cover 54% of global disease burden
- Adult overall health
- Atrial fibrillation
- Congenital upper limb anomalies
- Diabetes
- Facial palsy
- Hand/wrist conditions
- Hypertension
- Oral health
- Paediatric overall health



ICHOM

# ICHOM method



## Example: HEART FAILURE



ICHOM

# Example: CORONARY ARTERY DISEASE



ICHOM

- 
- The need for an outcomes research agenda for clinical laboratory testing

Lundberg G. JAMA 1998; 280: 565-6

- “clinicians and laboratorians should all be concerned about the effects of that laboratory test and whether the performance of it was useful for the patient or for the public’s health,”

# Outcome studies differ from studies of prognostic accuracy

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- Studies of prognostic accuracy ask:  
“Does the result of the test predict an outcome of interest?”
- Outcome studies ask:  
“Is the use of the test associated with improved outcomes?”

# High sensitivity TnI on presentation enables early safe discharge

- Admission hs-cTnI of 1.9 ng/L (Architect) used to stratify patients:
  - $\leq 1.9$ : discharge *unless* high-risk of ACS or sample taken within 1h of pain
  - $> 1.9$ : admit to CDU for 2<sup>nd</sup> cTnI
- Admissions fell from 60.9% to 38.4%
- Mean LOS fell from 23h to 9.6h
- Follow up:  
Negative Predictive Value for major adverse cardiac event:
  - at 30 days = 99.6%
  - at 9 months = 98.4%



# Challenge: Connecting Laboratory Testing to Outcomes



Demonstrating the value of lab tests on health outcomes is reliant on linking the test with processes that directly impact outcomes.

# The problem with getting evidence of added value

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- “In order to improve outcomes, a laboratory test must be appropriately ordered, conducted, returned with results on a timely basis, correctly interpreted and affect a decision for further diagnosis and treatment”
- Lewin Group report on The Value of Laboratory Screening and Diagnostic Tests for Prevention and Health Care Improvement, 2009

# Systematic evaluation of immunoassay POCT to define impact on patients' outcomes

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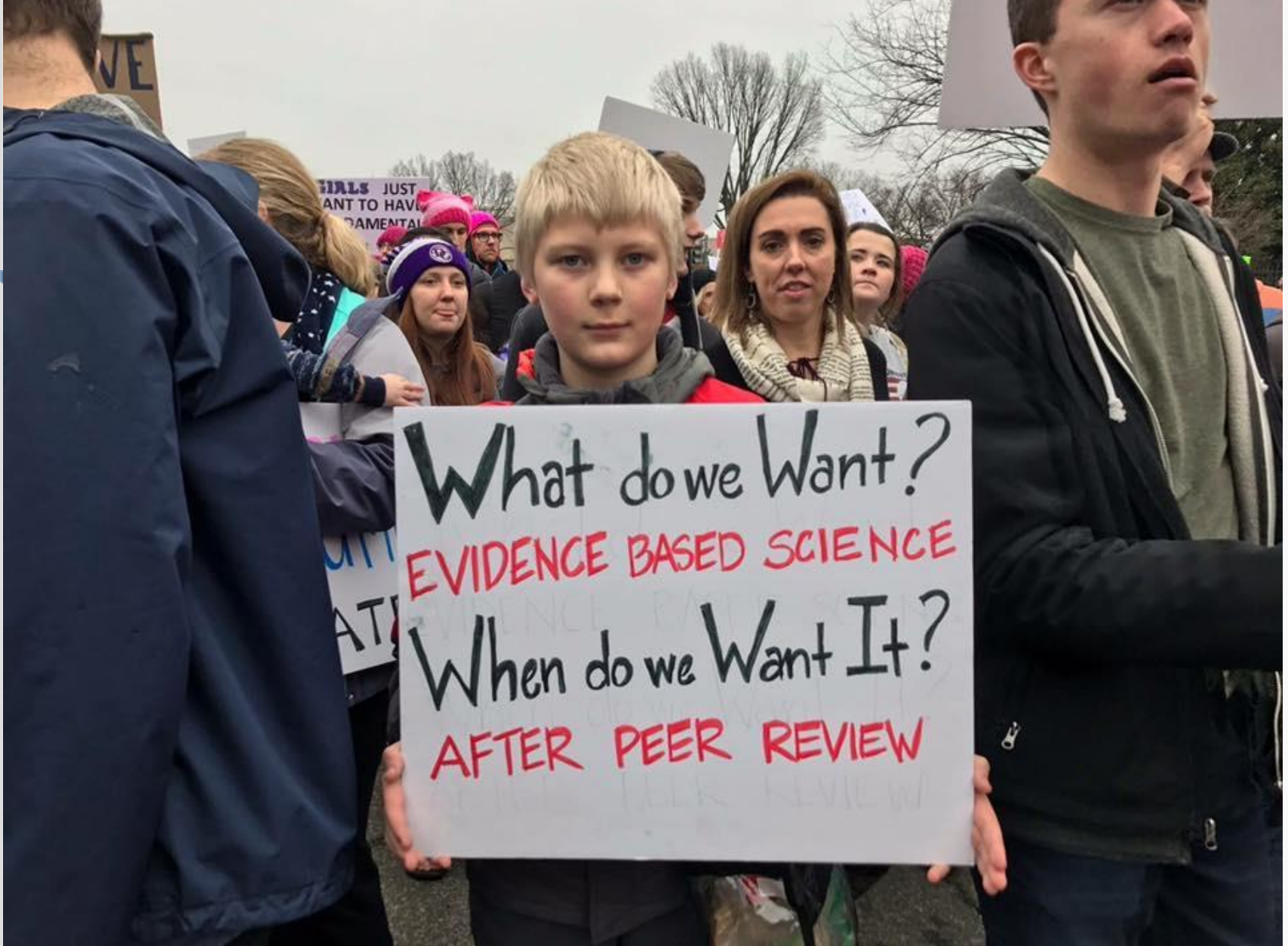
- 116 papers studied
  - 51 looked at clinical impact
  - Most showed decreased result turnaround time
- BUT**
- “insufficient evidence to define an improvement in clinical outcome”
  - “POCT for immunometric markers ... have potential to improve patient outcome, though this aspect is inadequately recorded in current clinical studies”

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To demonstrate the link between a testing strategy and an outcome:

- The test needs to be **used appropriately**
  - better utilization, communication and interpretation
- The study design must be rigorously defined and properly implemented – **better evaluations related to specific clinical decisions**





**Women's March 21 January 2017  
@RaphaelShephard**

# Outline

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- Introduction
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- Example: diagnostic error
- What needs to change?

# Medical error in the US

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- Estimated 251 454 deaths 2013
- Compare: (CDC data for 2013)
  - 611 105 deaths from cardiac disease
  - 584 881 deaths from cancer
  - 149 205 deaths from chronic respiratory disease



## ECRI Institute's Top 10 Patient Safety Concerns for 2018

1

Diagnostic errors

2

Opioid safety across the continuum of care

3

Internal care coordination

4

Workarounds

5

Incorporating health IT into patient safety programs

6

Management of behavioral health needs in acute care settings

7

All-hazards emergency preparedness

8

Device cleaning, disinfection, and sterilization

9

Patient engagement and health literacy

10

Leadership engagement in patient safety

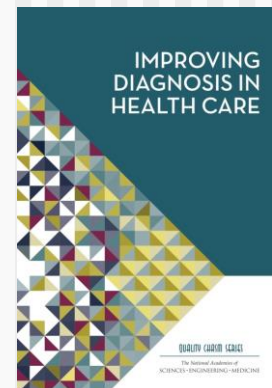
MSI 30

# Diagnostic error

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- Estimated 5% of US adults seeking OP care each year experience a diagnostic error
- Contribute approx 10% of patient deaths and 6-17% of adverse events in hospitals

(Improving Diagnosis in Health Care,  
Health & Medicine Division, National Academies 2015)



# Diagnostic error

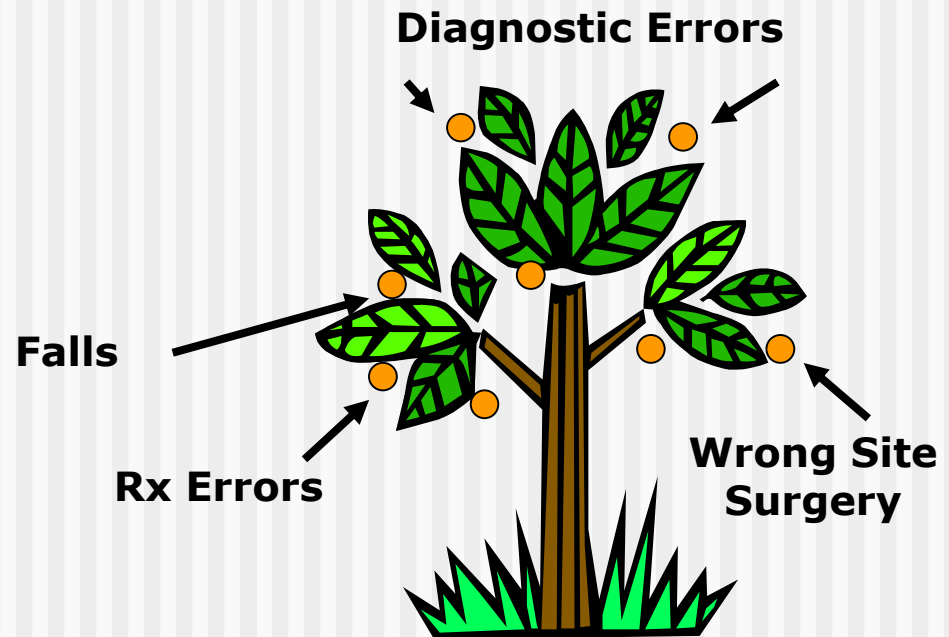
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- NAM report definition
  - “a failure to establish an accurate and timely explanation of the patient’s health problems or a failure to communicate that explanation to the patient”

# Diagnostic Error

- Diagnostic errors = misdiagnosis, missed diagnosis, or delayed diagnosis<sup>1</sup>

<sup>1</sup>Graber, M. L. et al, "Diagnostic error in internal medicine," *Archives of internal medicine*, vol. 165, July, 2005.



# Value

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**Value** = Delivered **benefits** – delivered **harm**  
(undesirable effects  
of testing)

Epner PI, Gans JE, Graber ML

When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine.

BMJ Qual Saf 2013; Epub 2013 Aug 16 doi: 10.1136/bmjqs-2012-001621

# Lab-related causes of diagnostic error

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- Inappropriate test ordered (overuse)
- Appropriate test not ordered (underuse)
- Appropriate test result misapplied
  - Knowledge deficit
  - Failure of synthesis
  - Misleading result
- Appropriate test result delayed/missed
- Appropriate test result inaccurate

(Epner et al BMJ Qual Saf 2013)

# Analysis of malpractice claims – US

Ann Intern Med 2006; 145: 488-496

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## Faulty process leading to missed diagnosis:

- Failure to order diagnostic/lab test 55%
- Inappropriate/inadequate follow-up 45%
- Failure to obtain adequate history/exam 42%
- Incorrect interpretation of diag test 37%
- Failure to refer 26%
- Provider did not receive test results 13%
- Tests ordered but not done 9%
- Tests performed incorrectly 8%

- 
- Improving diagnosis and reducing diagnostic errors: *the next frontier of laboratory medicine*

Plebani M, Lippi G

Clin Chem Lab Med 2016; 54: 1117-8



# Lab-related causes of diagnostic error

---

- Inappropriate test ordered
- Appropriate test not ordered
- Appropriate test result not used properly
  - Knowledge deficit
  - Failure of synthesis
  - Misleading result
- Appropriate test result delayed/missed
- Appropriate test result wrong/inaccurate



**UTILIZATION**

(Epner & Astion, 2012)

# Lab Tests Driving Waste in Healthcare

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- “First, Do No Harm”:
  - Washington Health Alliance 2018 report on waste and low value health care services
- Examined 47 common treatment approaches known to be overused
- 1.3 million patients received these services
- 47.9% deemed to be low value
- 36% of healthcare spend went on low value procedures

# Key drivers of overuse

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- 11 of 47 procedures accounted for 93% of the low-value services and 89% of the estimated wasteful spend

# Top 11 wasteful procedures

(descending order of volume)

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1. Too frequent cervical cancer screening in women
2. Preop baseline lab studies prior to low-risk surgery
3. Unnecessary imaging for eye disease
4. Annual ECGs/cardiac screening before low-risk surgery
5. Prescribing antibiotics for acute upper respiratory/ear infections
6. PSA screening
7. Population-based screening for vitamin D deficiency
8. Imaging for uncomplicated back pain in the first 6 weeks
9. Preop ECG/CXR/pulmonary function tests before low-risk surgery
10. Cardiac stress testing
11. Imaging for uncomplicated headache



“New tests provide ever more information, yet without wisdom we risk making well people sick rather than making sick people well.”

Dr Jessica Watson, BMJ 27 July 2017

# Systematic reviews

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- Van Walraven (1998)
  - JAMA 280; 550-558
  - Rates of inappropriate testing 4-95% !
- Zhi et al (2013)
  - 1997-2012
  - 34 009 citations
  - 493 selected for review
  - 42 included in review

# Useful definitions

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- 1. **Utilization**: The number of tests ordered
- 2. **Appropriateness**: the fraction ordered **correctly**
- 3. **Overuse**: the fraction ordered **incorrectly**
- 4. **Underuse**: the fraction of tests that **should have been** ordered that were ordered

# Zhi et al (2013)

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- 42 studies
  - 38 investigated overuse
  - 8 investigated underuse
  - 4 both
- 31 objective/11 subjective criteria
- 20 looked at >1 test

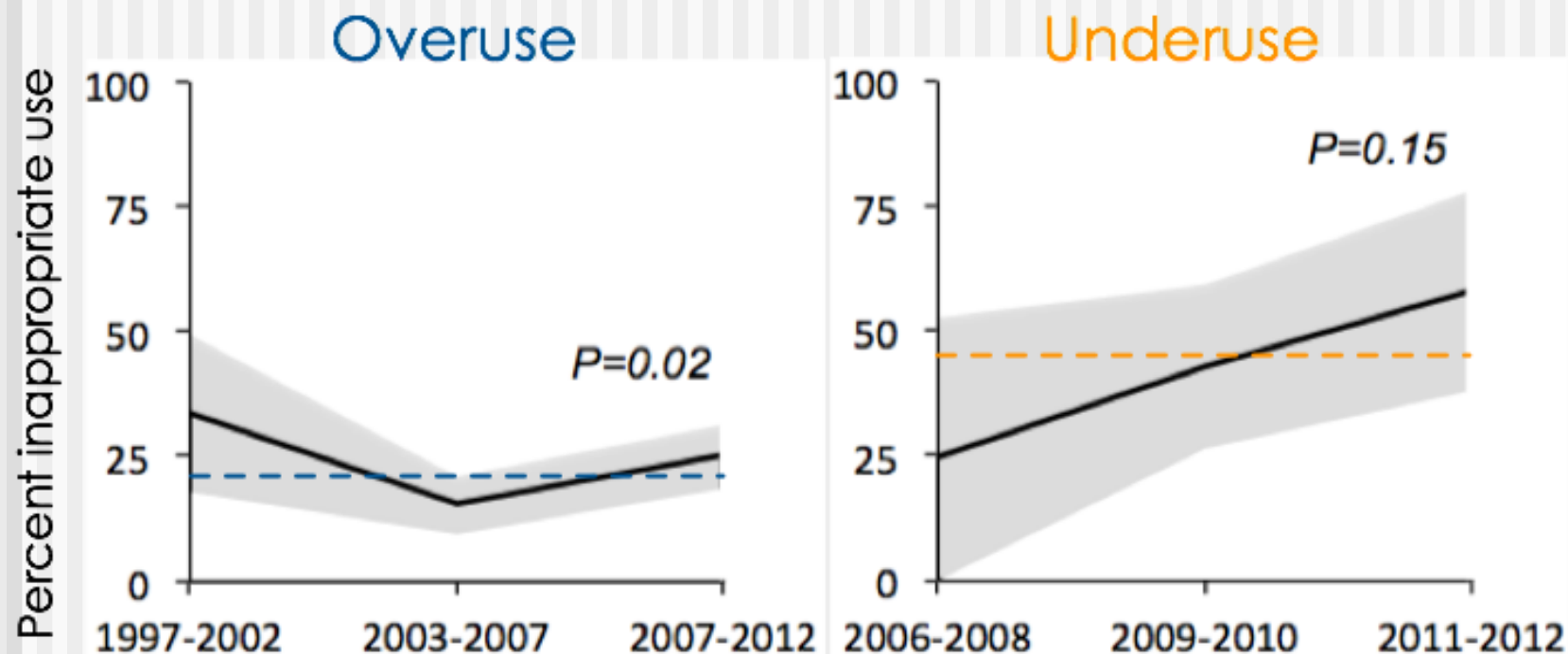


# Zhi et al (2013)

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- Overall mean rate of inappropriate **overuse** = **20.6%** (95% CI 16.2 – 24.9%, n=114)
- Overall mean rate of **underuse** = **44.8%** (95% CI 33.8-55.8%, n= 18)

# Results: overuse vs. underuse



Note,  $P$ -values uncorrected for multiple possible binnings

Zhi et al, 2013

1 May 2018

## Callum [REDACTED] 'discharged with salts' before death

**A boy with an undiagnosed life-threatening illness was discharged from hospital with re-hydration salts hours before his death, an inquest heard.**

Callum [REDACTED], eight, died after a cardiac arrest on 3 March 2017 - less than 24 hours after leaving Worcestershire Royal Hospital.

Dr [REDACTED] told the inquest there was "a high chance" a blood test would have detected his illness.


Callum, from Redditch, Worcestershire, had been suffering from Addisonian crisis ...the inquest heard on Monday.

Registrar Dr [REDACTED] told Worcestershire Coroner's Court she discharged Callum after diagnosing gastroenteritis. He was sent home from the hospital with Dioralyte.

She said: "Sadly, we know that had they [the tests] been done, there's a high chance we'd have picked up that he had an adrenal insufficiency."

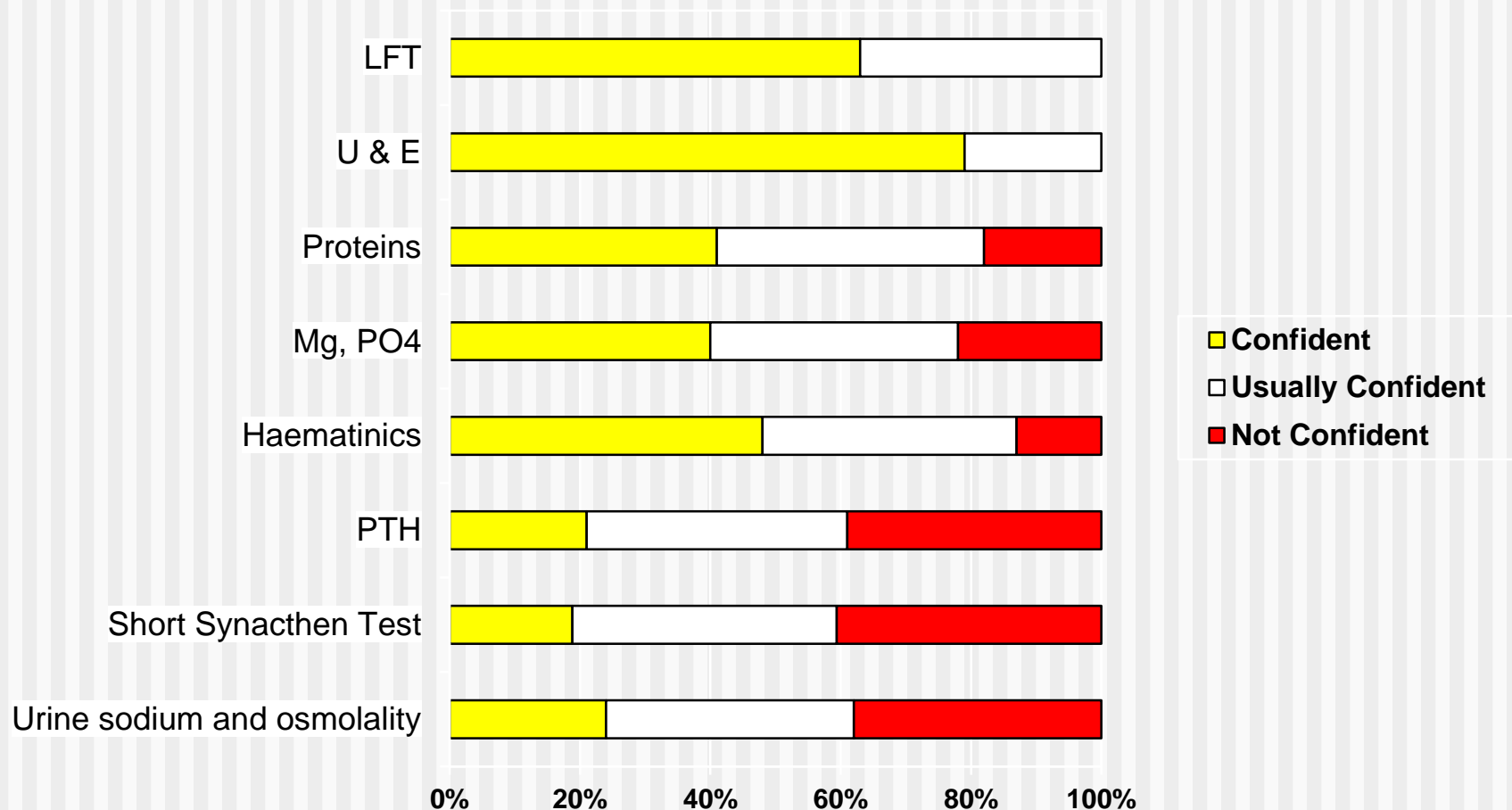
# Lab-related causes of diagnostic error

## INTERPRETATION

- Inappropriate test ordered
  - Appropriate test not ordered
  - Appropriate test result not used properly
    - Knowledge deficit
    - Failure of synthesis
    - Misleading result
  - Appropriate test result delayed/missed
  - Appropriate test result wrong/inaccurate
- 

(Epner & Astion, 2012)

# UK junior hospital doctors: “How confident are you in *requesting* laboratory tests?”



(Khromova & Gray, 2008)

# Do users understand tests?

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- Primary Care Physicians' Challenges in Ordering Clinical Laboratory Tests and Interpreting Results  
JABFM 2014; 27: 268-274
- Physicians order tests in 31% of patient encounters
- 14.7% report uncertainty about ordering
- 8.3% report uncertainty about interpreting

---

If a disease has a prevalence of 1 in 1000, and the test to detect it has a false-positive rate of 5%, what are the chances that a patient with a positive test actually has the disease?

In a 2014 study, almost half of doctors studied said “95%”

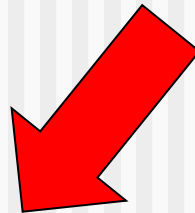
Actual answer = <2%!

# Lab-related causes of diagnostic error

---

- Inappropriate test ordered
- Appropriate test not ordered
- Appropriate test ordered
  - Knowledge deficit
  - Failure of synthesis
  - Misleading result
- Appropriate test result delayed/missed
- Appropriate test result wrong/inaccurate

**COMMUNICATION**



(Epner & Astion, 2012)



## ECRI Institute's Top 10 Patient Safety Concerns for 2017

- 1 Information management in EHRs
- 2 Unrecognized patient deterioration
- 3 Implementation and use of clinical decision support
- 4 Test result reporting and follow-up
- 5 Antimicrobial stewardship
- 6 Patient identification
- 7 Opioid administration and monitoring in acute care
- 8 Behavioral health issues in non-behavioral-health settings
- 9 Management of new oral anticoagulants
- 10 Inadequate organization systems or processes to improve safety and quality

MS17077

# International Health Rankings (Commonwealth Fund, 2014)

	AU	CH	CA	DE	FR	NL	NO	NZ	SE	UK	US
<b>Overall rank</b>	<b>4</b>	<b>2</b>	<b>10</b>	<b>5</b>	<b>9</b>	<b>5</b>	<b>7</b>	<b>7</b>	<b>3</b>	<b>1</b>	<b>11</b>
<b>Safe care</b>	<b>3</b>	<b>4</b>	<b>10</b>	<b>6</b>	<b>2</b>	<b>7</b>	<b>11</b>	<b>8</b>	<b>5</b>	<b>1</b>	<b>7</b>
<b>\$ Per capita 2011</b>	3800	5643	4522	4495	4118	5099	5669	3182	3925	3405	8508

# Safe Care measures

	AU	CH	CA	DE	FR	NL	NO	NZ	SE	UK	US
Safe care rank	3	4	10	6	2	7	11	8	5	1	7
Delayed abnormal results	7%	5%	11%	5%	3%	5%	10%	8%	9%	4%	10%
Incorrect diagnostic test	4%	3%	5%	2%	3%	6%	4%	5%	3%	2%	5%

(Commonwealth Fund, 2014)

# NEWS SOUTH WEST WALES

Home World UK England N. Ireland Scotland Wales Business Politics Health Education Sci/Environment Technology Entertainment & Arts

Wales Politics North West North East Mid South West South East Newyddion

6 July 2012 Last updated at 17:59

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## Baby painkiller murder: Mother Michelle Smith gets life



Michelle Smith will serve at least 12 years

**A mother has been jailed for life after being found guilty of murdering her baby daughter with adult painkillers.**

Michelle Smith, 34, of Swansea, who denied poisoning Amy in 2007, will serve at least 12 years.

Amy had been taken to hospital, but she died later, and the drug dihydrocodeine was found in her blood.

Smith walked into a police station in January and said: "I did it", before retracting her confession minutes later, Swansea Crown Court heard.

The jury had been out since Wednesday, and Smith broke down as it delivered its verdict.

### Related Stories

**Murder trial mum blames hospital**

**Baby 'poisoned on day of visit'**

**Baby drug test lab 'foolproof'**

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**Social care costs cap wins favour**

**Seventh arrest in terror probe**

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Is this island nation really the world's beer and cannabis capital?

### Most Popular

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On the third visit, Smith told doctors Amy had been sleepy and only managed a small feed that day, and was quickly found to have breathing problems again.

Michelle Smith  
Confession that jury as told she made at Neath police station

Intensive care

She was tested, a urine sample taken, and was ultimately sent back to the same paediatric intensive care unit in Cardiff.

Meanwhile the urine sample had tested positive for an as yet unidentified drug. Sent away to a specialist lab and identified as dihydrocodeine (DHC), the finding, unaccountably, was not passed to Amy's doctors at the time, the court heard.

her father-in-law saying she was going "to give myself up".

The jury heard that more than four years after Amy's death she walked into Neath police station and told an officer: "I did it. I did it. I killed Amy."

She signed a police officer's notebook confirming what she had said but only five minutes later retracted her "confession".

More on This Story

Related Stories

- Murder trial mum blames hospital 29 JUNE 2012, SOUTH WEST WALES
- Baby 'poisoned on day of visit' 25 JUNE 2012, WALES
- Baby drug test lab 'foolproof' 20 JUNE 2012, WALES

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# Notification of critical results

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“Urgent physician notification of critical results, both qualitative and quantitative, has become the standard of care because of **high impact on patient welfare**”

Global trends in critical value practices and their harmonization

Kost GJ and Hale KN

Clin Chem Lab Med 2011; 49: 167-176

# Review of clinical negligence cases involving GP test result management

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- 50 cases analysed
  - 48%: failure to notify pt of abnormal result
  - 36%: test result not actioned by GP
  - 16%: test deemed necessary but not ordered

Baylis et al BMJ Open Q 2018: 7.e000463

# Proper systems to ensure results are actioned

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- Electronic systems for acknowledgement of results
- ?Lab follow up of critical results which have not been viewed/actioned



# Diagnosis Detection and Follow Up: Unrepeated Creatinine

7,218 lab orders placed for patients with an abnormal creatinine not repeated after 90 days

```
graph TD; A[7,218 lab orders placed for patients with an abnormal creatinine not repeated after 90 days] --> B[3,465 total labs repeated within 90 days (48%)]; B --> C[1,768 abnormal results (51%)]; C --> D[1,624 New CKDs identified]
```

3,465 total labs repeated within 90 days (48%)

1,768 abnormal results (51%)

1,624 New CKDs identified

# Information overload

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- Survey of 2590 primary care physicians
- Median number of alerts (path/Xray) per day: 63
- 86.9% felt number of alerts excessive
- 69.6% reported more alerts than they could effectively manage
- 29.8% reported having missed results leading to care delays
- Singh et al. JAMA Intern Med 2013; **173**: 702-4

# Outline

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- Introduction
- Linking lab testing to outcomes
- Example: diagnostic error
- What needs to change?

# What needs to change?

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- Better evaluations
- Better education
- Better teamwork

# Philosophies of value of medical tests (Bossuyt)

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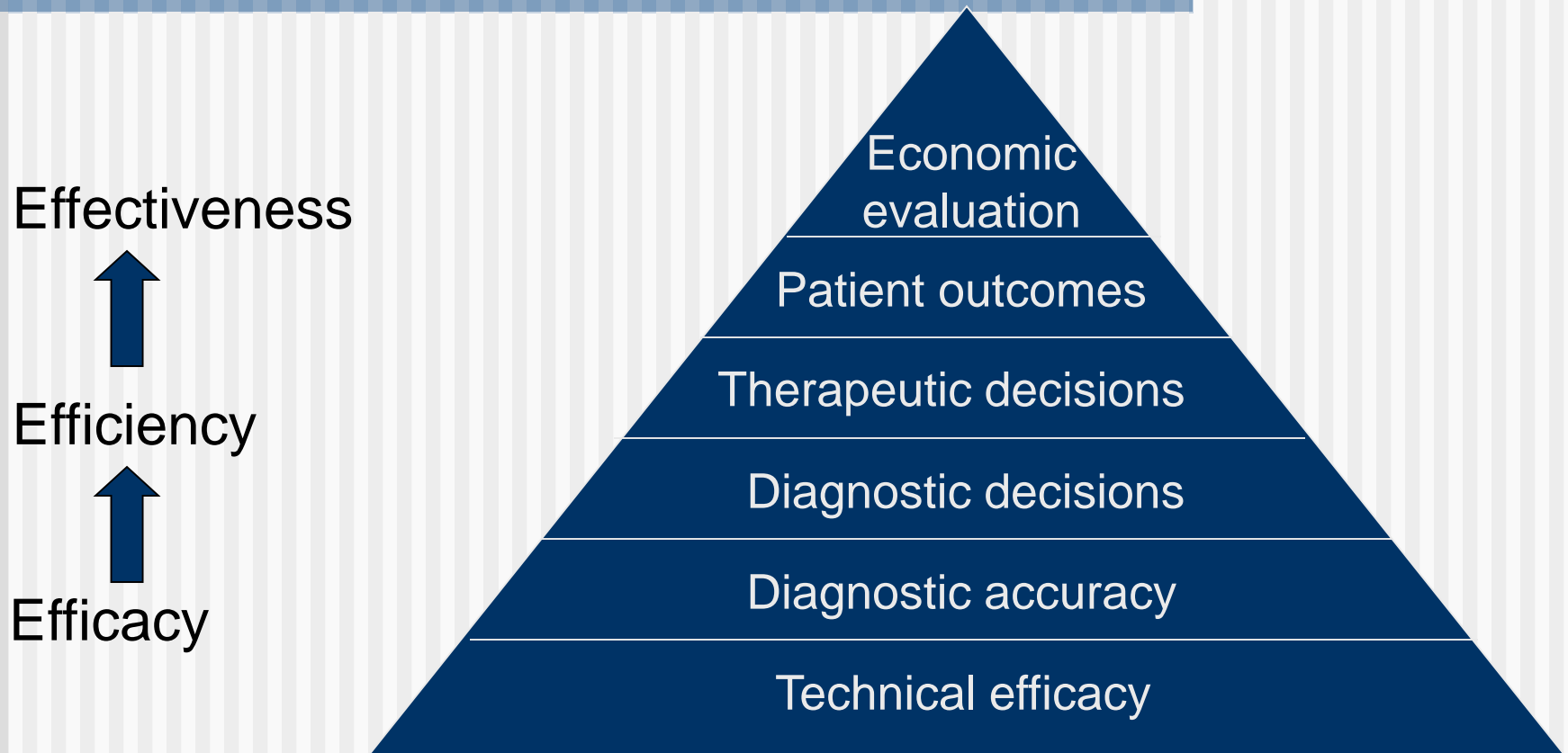
## ■ Essentialism:

The theory that the **value** of a marker or a medical test should be determined by the **'trueness'** of its **results**

## ■ Consequentialism:

The theory that the **value** of a marker or a medical test should be determined by the **value** of its **consequences**

# Evaluation of diagnostic tests



# Components of test evaluation

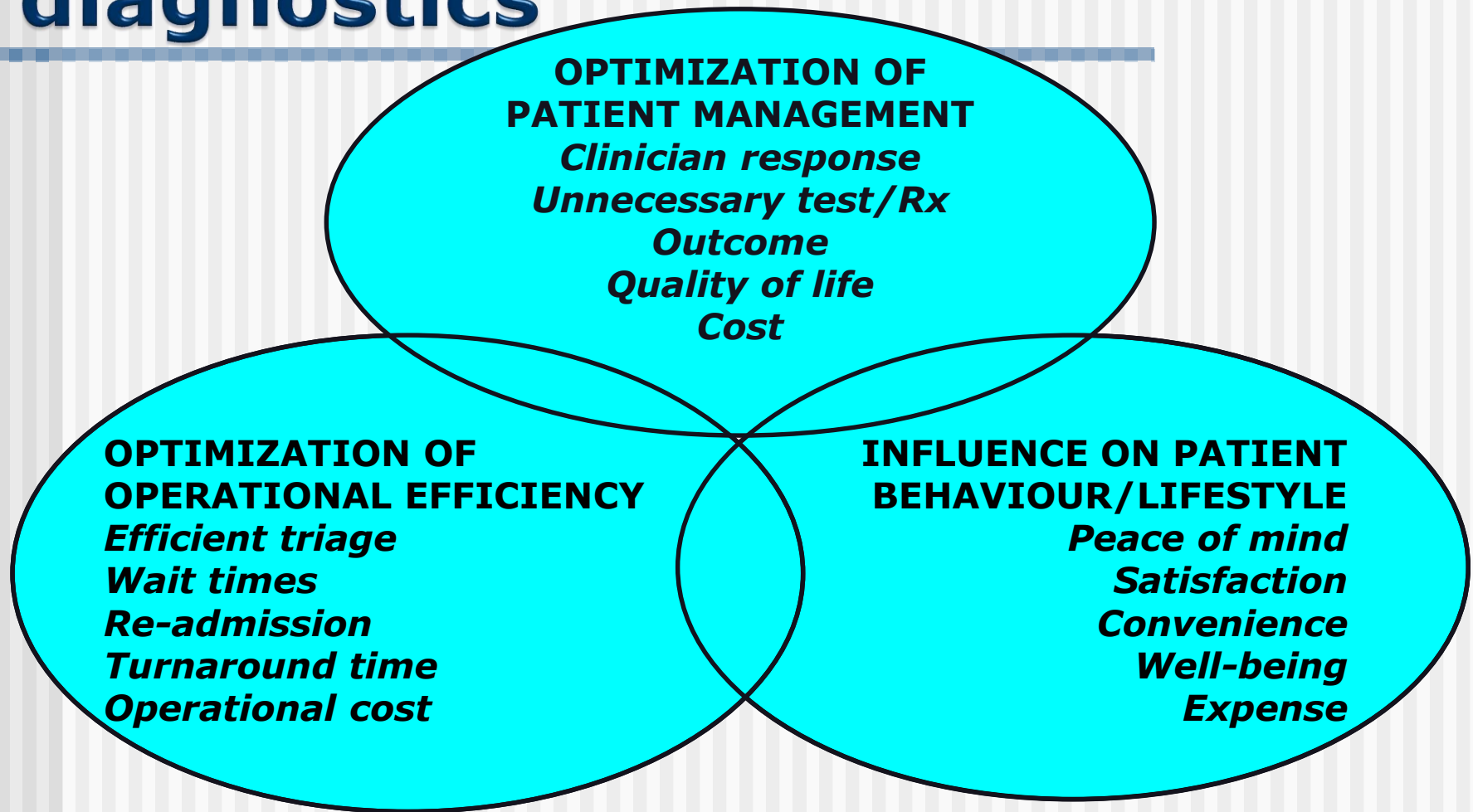
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- Analytical performance
- Clinical performance
- Clinical effectiveness
- Cost effectiveness
- Impact of testing on patient, organization, society

"From biomarkers to medical tests – the changing landscape of test evaluation". Horvath et al, EFLM Test Evaluation Working Group. Clin Chim Acta 2014; 427: 49-57



# Framework for assessing the value of laboratory diagnostics



(Anonychuk et al, 2012)



# Biomarker development targeting unmet clinical needs

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- 1. Identify the unmet clinical need
  - What is the clinical management problem and desired outcome?
- 2. Verify the unmet need for a biomarker
  - Is there an existing solution?
- 3. Validate the intended use
  - Would the biomarker contribute to the solution?
- 4. Assess the feasibility
  - Would the biomarker solution work in practice?
  - What is the optimal setting for the test? – POCT/central

# Improving diagnosis

- Recommendation 1a:
  - ...health care organizations should ensure that health care professionals should have the appropriate knowledge, skills, resources and support to engage in **teamwork in the diagnostic process...**



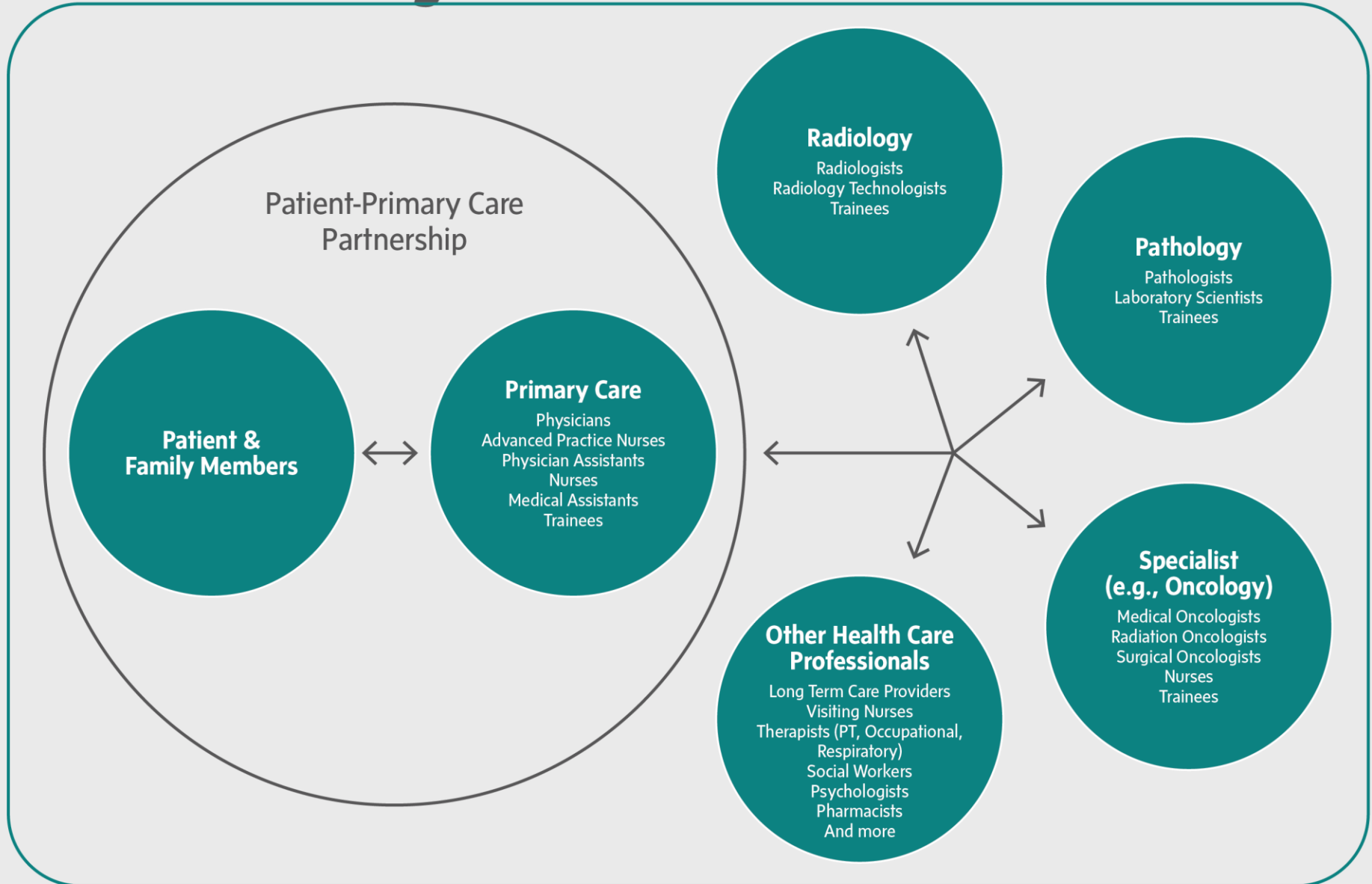
# Patients' views on top 4 causes of medical errors

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- 1. Physicians not spending enough time with patients 72%
- 2. Overwork, stress or fatigue of health professionals 70%
- **3. Failure of health professionals to work together or communicate as a team 67%**
- 4. Understaffing of nurses in hospitals 65%

Views of Practicing Physicians and the Public on Medical Errors  
Blendon et al, NEJM 2002

# Diagnostic Team Members



# Improving diagnosis

- Recommendation 1b:
  - Health care organizations should **partner with patients and their families** as diagnostic team members and facilitate ... engagement in the diagnostic process...

# Improving diagnosis

- Recommendation 1b (cont):
  - To accomplish this, they should:
    - Provide patients with opportunities to learn about the diagnostic process
    - ...

# Patients' Expectations of the Benefits and Harms of Treatments, Screening and Tests

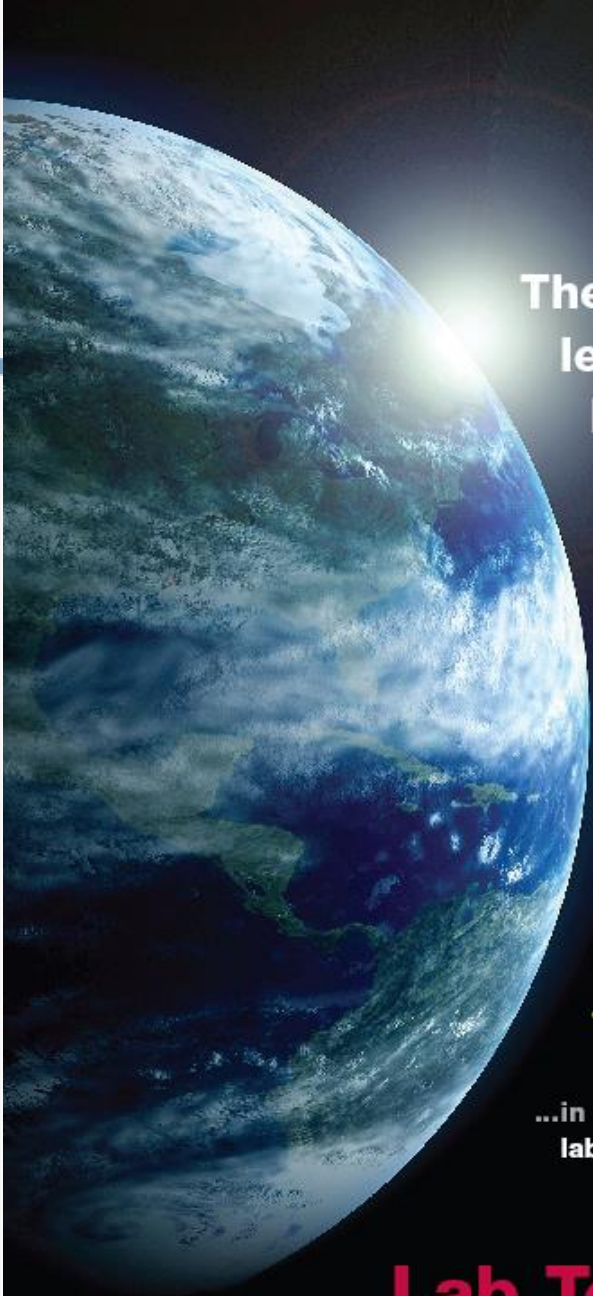
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## ■ Benefits

- 32 studies
- Overestimation of benefit in 65% of 34 outcomes with data available
- In further 17 outcomes (no data provided) authors concluded benefits overestimated in 88%

## ■ Harms

- 13 studies
- Underestimation of harm in 67% of outcomes



**The world is  
learning about  
lab tests...**

**...in English**

[labtestsonline.org](http://labtestsonline.org)  
[labtestsonline.org.uk](http://labtestsonline.org.uk)  
[labtestsonline.org.au](http://labtestsonline.org.au)

**...en español**

[labtestsonline.es](http://labtestsonline.es)

**...auf Deutsch**

[labtestsonline.de](http://labtestsonline.de)

**...po polsku**

[labtestsonline.pl](http://labtestsonline.pl)

**...magyarul**

[labtestsonline.hu](http://labtestsonline.hu)

**...in italiano**

[labtestsonline.it](http://labtestsonline.it)

**Lab Tests Online®**

A Global Standard for Patient Education



# The vision

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- 21st century medicine needs a flexible information resource:
  - that facilitates **selection of the right test** on the right patients at the right time,
  - with **results delivered in a timely fashion** to the right place
  - accompanied by context-specific **interpretation**
  - linked to **guidance on agreed action** to be taken (where appropriate)
  - with **validated patient-oriented clinical and economic outcome measures**

# Call to action...

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- Agree definition and validation of effectiveness measures – a “common currency” for outcomes
- Benchmark existing and new biomarkers in specified situations using commonly accepted outcome measures
- Improve utilization of new and existing biomarkers

# Changing role of lab medicine

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## ■ From:

- Specimen-centred
- Clinical testing
- Lab. performance
- Provider of results

## ■ To:

- Patient-centred
- Clinical decision-making
- Patient outcomes
- Partner in care