Towards patient-centered laboratory medicine – using lab testing to reduce diagnostic error and improve patient outcomes

Short Course 74109
AACC Annual Meeting, Philadelphia, PA.

Wednesday August 3, 2016
1030am – 1200pm

Mike Hallworth
(Shrewsbury, UK)
Danielle B Freedman
(Luton, UK)

Towards Patient-Centered Laboratory Medicine

Mike Hallworth

AACC Annual Meeting
Philadelphia, PA, 3 August 2016

AACC Better health through laboratory medicine.

Speaker Financial Disclosure Information

Grant/Research Support:	None
Salary/Consultant Fees:	Elsevier
Board/Committee/Advisory Board Membership:	None
Stocks/Bonds:	None
Honorarium/Expenses:	Tosoh Bioscience
Intellectual Property/Royalty Income:	None

AACC

Outline

- Introduction
- Understanding value
- Improving outcomes, reducing harm
- Towards better evaluations
- Vision and call to action

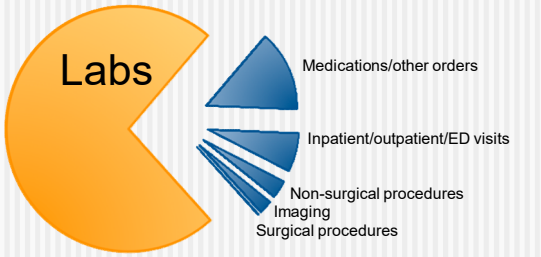
4

Importance of lab medicine

- Single highest-volume medical activity
- Patient safety – fast, accurate diagnosis
- Essential to clinically cost-effective delivery of care
- Often the principal basis for costly downstream care
- Spans primary/secondary care
- Added value at pre- & post-analytical phases

5

Throughput



Ramy Arnaout 2015

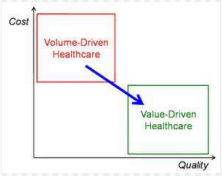
Laboratory medicine - cost

- Global IVD market valued at $44 bn in 2011, growing at a rate of 7.8% from 2011 to 2016
- 3-5% of healthcare costs

7

Volume to value

- Focus on improving the value of laboratory services



8

Clinical chemistry

Sample

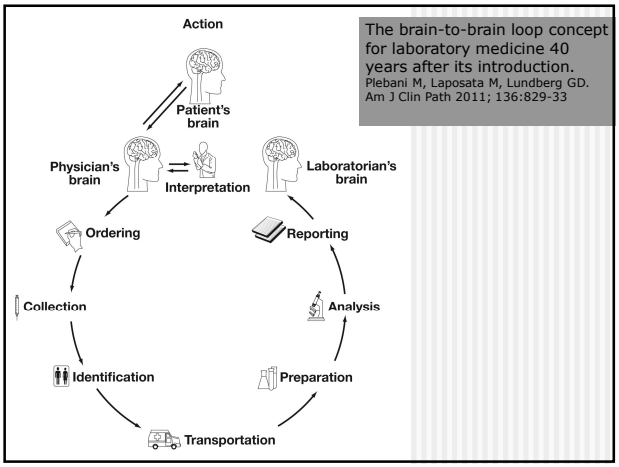
PROCESS/QUALITY

Result

Laboratory medicine

Patient
VALUE! ADVICE/GUIDELINES
Request
VALUE! ADVICE
Sample
PROCESS/QUALITY
Result
VALUE! INTERPRETATION
Information
VALUE! EVIDENCE
Outcome

Integrated value chain



The brain-to-brain loop concept for laboratory medicine 40 years after its introduction.
Plebani M, Laposata M, Lundberg GD.
Am J Clin Path 2011; 136:829-33

Outline

- Introduction
- Understanding value
- Improving outcomes, reducing harm
- Towards better evaluations
- Vision and call to action

12

Value can be defined in clinical and economic senses

- Clinical value
  - Diagnostic accuracy
  - Predictive value
  - Clinical utility in decision-making
  - Improved health-related outcomes

  Usually not country or health care system specific
- Economic value
  - Economic efficiency and effectiveness compared to standard process of care

  Depends on the setting in which the test will be used

The 70% claim

(Hallworth, Ann Clin Biochem 2011; 48: 487-8)

- "70% of critical medical decisions depend on laboratory data"
- "70% of all medical decisions depend on laboratory data"
- "70% of diagnoses depend on laboratory data"
- ……where is the evidence?

14

The Value of IVD Testing in Medical Practice

- Rohr UP et al.
- PLoS One 2016; 11: e0149856

- Survey of 79 oncologists/cardiologists:
- "75% of patients underwent IVD testing, testing that led to a substantial clinical decision in 66% of these patients."

15

IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management & Outcomes

- Formed May 2012
- Chair M Hallworth
- Objectives:
  - To evaluate the available evidence supporting the impact of laboratory medicine in heathcare
  - To develop the study design for new retrospective and prospective studies to generate evidence-based data to support IFCC promotional activities to the healthcare community and the public
- Report in Clin Chem April 2015

16

Health outcomes

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

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

17

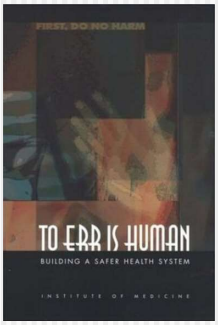
Outcomes research

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

IoM 1999

Health system outcomes

- Safety
- Timeliness
- Effectiveness
- Equity
- Patient-centredness



Philosophies of value of medical tests (Bossuyt)

- 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

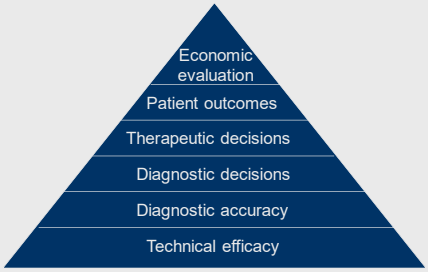
Two views of tests:

	Essentialist	Consequentialist
Key value	Truth	Usefulness
Focus	Results	Consequences
Emphasis	Validity	Utility
Statistics	Accuracy	Health Outcomes

- 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,"

Evaluation of diagnostic tests

Effectiveness
↑
Efficiency
↑
Efficacy



Marshall & O'Brien, 2003

Questions for lab tests (Bossuyt)

- Is the test trustworthy? (efficacy)
  TECHNICAL PERFORMANCE
- Is the test meaningful? (efficiency)
  CLINICAL PERFORMANCE
- Is the test helpful?
  CLINICAL EFFECTIVENESS

Chain of inquiry for valuation of lab tests (The Lewin Group)

Technical validity	Clinical validity	Clinical utility
Ability to measure the analyte accurately and reliably	Ability to detect and predict the disorder that is associated with an analyte measurement	Clinical effectiveness – the balance of risks and benefits associated with using the test in routine practice
Accuracy – analytical specificity – analytical sensitivity Precision Robustness	Clinical sensitivity Clinical specificity Positive predictive value Negative predictive value	Intermediate/surrogate outcomes Health outcomes (mortality, morbidity, quality of life) Adverse effects of diagnostic use Adverse effects of treatment

Value

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

Outline

- Introduction
- Understanding value
- Improving outcomes, reducing harm
- Towards better evaluations
- Vision and call to action

27

Improving lab performance

- Quality assurance ✓
- Standardization/harmonization ✓
- Process optimization ✓
- Method development ✓
- Reference intervals ✓
- Outcome studies ??

28

Outcome studies differ from studies of prognostic accuracy

- 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:
  - ≤1.9: discharge *unless* high-risk of ACS or sample taken within 1h of pain
  - >1.9: admit to CDU for 2nd 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%

Ford, C: personal communication 2016

30

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.

(R. Christensen)

The problem with getting evidence of added value

- "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

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

Medical error in the US

- 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

Makary MA, Daniel M (JHMI): *BMJ* 2016;353:i213934

Diagnostic error

- 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

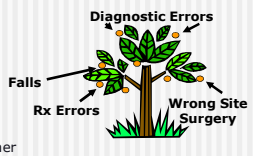
(Improving Diagnosis in Health Care,
Health & Medicine Division, National Academies 2015)

35

Diagnostic Error

- Diagnostic errors are defined as misdiagnosis, missed diagnosis, or delayed diagnosis[1]
- Diagnostic errors occur in 10-15% of cases,[2] with more than 50,000 DxE in primary care and 40-80,000 annual deaths in hospitals[3]
- One in twenty adults in outpatient settings experience a diagnostic error annually[4]

[1]Graber, M. L. et al, "Diagnostic error in internal medicine," *Archives of internal medicine*, vol. 165, July, 2005.
[2]Berner, E. S., & Graber, M. L, "Overconfidence as a cause of diagnostic error in medicine," *American Journal of Medicine*, vol. 121, 2008, S2-S23.
[3]Newman-Toker DE. Measuring Diagnostic Errors in Primary Care - Invited Commentary. *JAMA Internal Medicine* 2013 February 25
[4]Singh, H., Meyer, A. N. D., & Thomas, E. J, "The frequency of diagnostic errors in outpatient care: estimations from three large observational studies involving US adult populations." *BMJ Quality & Safety*, 2014



P. Epner

36

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

(Epner & Astion, 2012)

37

Analysis of malpractice claims – US

Ann Intern Med 2006; 145: 488-496

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

39

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)

40

IoM report 2015

- Goal 2:

Enhance health care professional education and training in the diagnostic process

- Appropriate use of diagnostic tests

41

Lab-related causes of diagnostic error

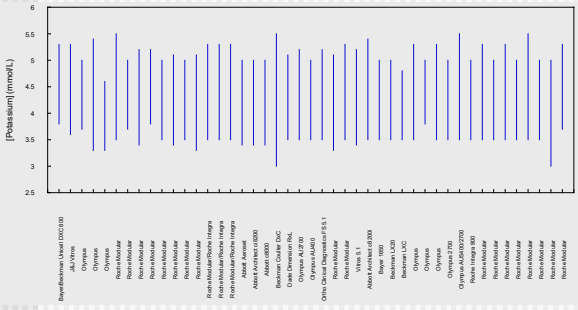
INTERPRETATION

- 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)

42

Potassium reference ranges
(data from UK Pathology Harmony)



Reference range harmonization

- UK Pathology Harmony project
  - www.pathologyharmony.co.uk
- Pediatrics – CALIPER

(**CA**nadian **L**aboratory **I**nitiative in **PE**diatric **R**eference intervals)

"Closing the gaps in Pediatric Laboratory Reference Intervals: A CALIPER Database of 40 Biochemical Markers in a Healthy and Multiethnic Population of Children"
Clin Chem 2012: 58; 854-868

Lab-related causes of diagnostic error

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

COMMUNICATION

(Epner & Astion, 2012)

45

BMJ Qual Saf 2011; 20: 194-199

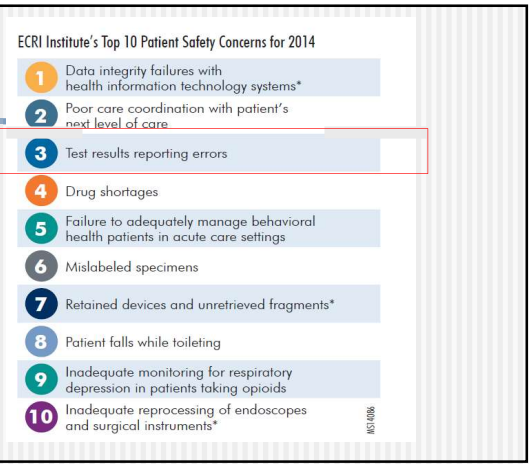
Error management

PRESS RELEASE

The safety implications of missed test results for hospitalised patients: a systematic review

Joanne Callen, Andrew Georgiou, Julie Li, Johanna I Westbrook

http://qualitysafety.bmj.com/content/20/2/194.full.pdf+html



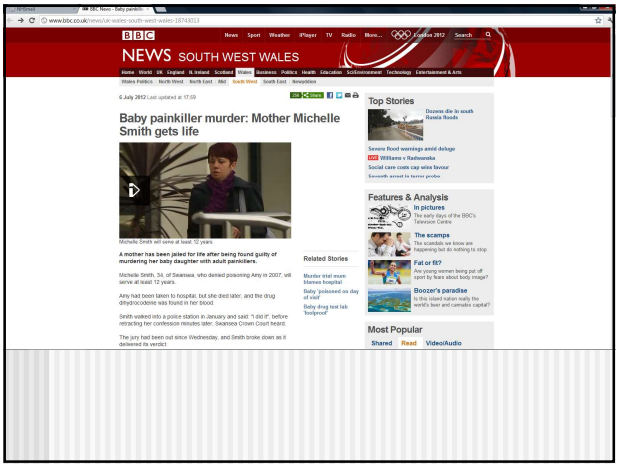
International Health Rankings (Commonwealth Fund, 2014)

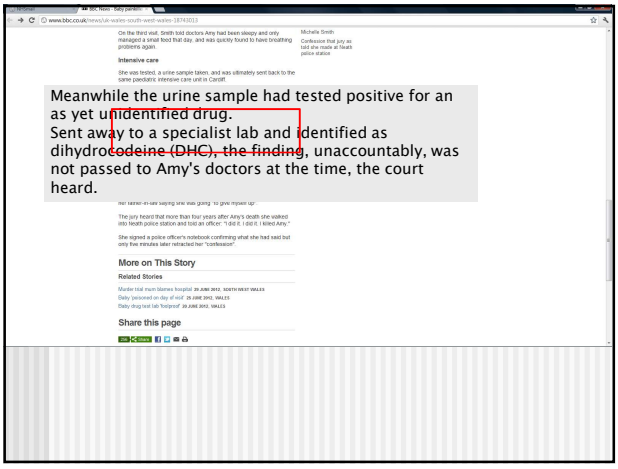
	AU	CH	CA	DE	FR	NL	NO	NZ	SE	UK	US
Overall rank	**4**	**2**	**10**	**5**	**9**	**5**	**7**	**7**	**3**	**1**	**11**
Safe care	3	4	10	6	2	7	11	8	5	1	7
$ Per capita 2011	3800	5643	4522	4495	4118	5099	5669	3182	3925	3405	8508

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)





Rory Staunton (1999-2012) – missed sepsis

The Rory Staunton Foundation for Sepsis Awareness
www.rorystaunton.com

Malpractice Concerns

- From 2004-2008, 22 malpractice claims were specifically related to receipt and transmittal of test results → **$16 million in incurred costs**
- 14 related to missed diagnosis of cancer. Most of these cases (83%) were high severity → death or permanent disability
- The vast majority of the diagnosis-related cases (92%) occurred in the ambulatory setting

Anuj Dalal,
Brigham & Womens' Hospital,
Boston MA

Proper systems to ensure results are actioned

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

Notification of critical results

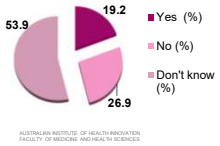
"Urgent physician notification of critical results, both qualitative and quantitative, has become the standard of care because of high impact on patient welfare"

Global trends in critical value practices and their harmonization
Kost GJ and Hale KN
Clin Chem Lab Med 2011; 49: 167-176

Perceptions of missed test results

MACQUARIE University

In the past year I have missed an abnormal result that led to delayed patient care



In the past year a colleague has missed an abnormal result that led to delayed patient care

AUSTRALIAN INSTITUTE OF HEALTH INNOVATION
FACULTY OF MEDICINE AND HEALTH SCIENCES

Andrew Georgiou

Information overload

- 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

CBSNews.com / CBS Evening News / CBS This Morning / 48 Hours / 60 Minutes / Sunday Morning / Face the Nation

CBSNEWS Video US World Politics Entertainment Health MoneyWatch SciTech Crime

By MICHELLE CASTILLO / CBS NEWS / March 5, 2013, 1:16 PM

Too many electronic health record alerts may be leading doctors to skip them

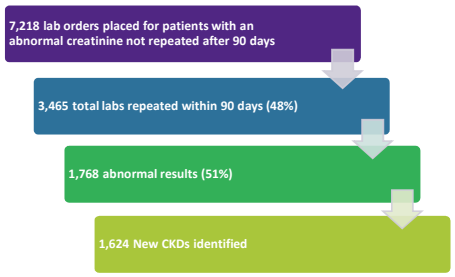
Your doctor may be more likely to ignore your test results if they come electronically.

A new study published in the JAMA Internal Medicine on Mar. 4 revealed that doctors receive about 63 electronic health record (EHR)-based alerts each day, which are supposed to let them know about abnormal patient results. And, almost one-third of the doctors surveyed - about 30 percent - admitted that they had missed some results because of too many alerts.

"If you're getting 100 emails a day, you are bound to miss a few. I study this area and I still sometimes miss emails. We have good intentions, but sometimes getting too many can be a problem," Dr. Hardeep Singh, chief of health policy, quality, and informatics at the Michael E. DeBakey Veterans Affairs Medical Center, in Houston, told TIME.

24

Diagnosis Detection and Follow Up: Unrepeated Creatinine



M Kanter / Kaiser Permanente

59

Resources

- CLSI Guideline GP47:

"Management of Critical- and Significant-Risk Results"

December 2015

http://shop.clsi.org/GP47.html

- NHS England:

"Standards for the communication of patient diagnostic tests on discharge from hospital"

March 2016

https://www.england.nhs.uk/patientsafety/wp-content/uploads/sites/32/2016/03/discharge-standards-march-16.pdf

Outline

- Introduction
- Understanding value
- Improving outcomes, reducing harm
- Towards better evaluations
- Vision and call to action

61

WG-Test Evaluation

Clinica Chimica Acta 427 (2014) 49–57

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Special report

From biomarkers to medical tests: The changing landscape of test evaluation

Andrea R. Horvath [a,b,*], Sarah J. Lord [b,c,1], Andrew StJohn [d], Sverre Sandberg [e], Christa M. Cobbaert [f], Stefan Lorenz [g], Phillip J. Monaghan [h], Wilma D.J. Verhagen-Kamerbeek [i], Christoph Ebert [j], Patrick M.M. Bossuyt [k], For the Test Evaluation Working Group of the European Federation of Clinical Chemistry Laboratory Medicine

"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

Components of test evaluation

- 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

EFLM EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Cyclical framework for the evaluation of *in vitro* medical tests

Key components of the test evaluation process are driven by the purpose and role of using a test in the clinical pathway.

Horvath, EFLM WG-TE

Define the purpose and role of the biomarker in the clinical pathway

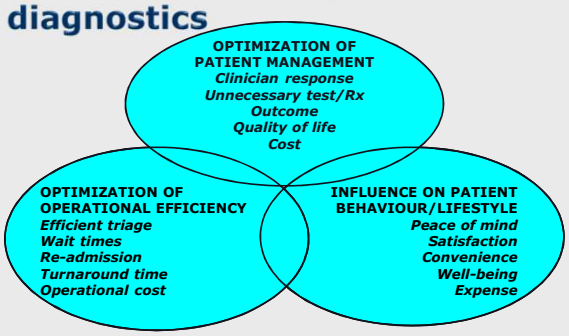
- **Test Purpose:**
  - Describes the intended clinical application of the test and how the test information will be used to improve clinical management in practice
    - SCREENING
    - DIAGNOSIS
    - PROGNOSIS
    - MONITORING
- **Test Role:**
  - How the test will be positioned to alter the existing clinical pathway in a specific condition/target population
    - TRIAGE
    - REPLACEMENT
    - ADD-ON

Horvath, EFLM WG-TE

Evaluation – asking the questions

- PICO format
  - Identify the clinical need
- **P**opulation – which patients?
- **I**ntervention – what test?
- **C**omparator – what are we doing now?
- **O**utcome – how do we measure success?
  - - DIRECT: clinical outcomes?
  - - INDIRECT: surrogate outcomes?

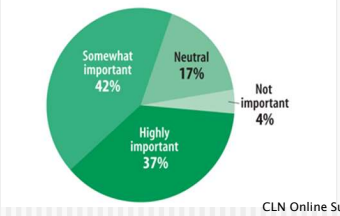
Framework for assessing the value of laboratory diagnostics



(Anonychuk et al, 2012)

Factors influencing physician test utilization:

Utilization of new tests before diagnostic or prognostic utility has been firmly established:



CLN Online Survey July–August 2012
(CLN September 2012)

Design of tumour biomarker monitoring trials

- EGTM Monitor Working Group

- 4 phase model based on drug evaluation
  - Phase 1: Characterisation of marker
    - (kinetics, correlation with tumour burden)
  - Phase 2: Sensitivity, specificity, predictive value
  - Phase 3: Assessment of effectiveness of biomarker-guided intervention by measuring patient outcome in randomized trials
  - Phase 4: Audit of long-term effects after the biomarker has been introduced into the patient pathway

Sölétormos et al, Clin Chem 2013

Outline

- Introduction
- Understanding value
- Improving outcomes, reducing harm
- Towards better evaluations
- Vision and call to action

71

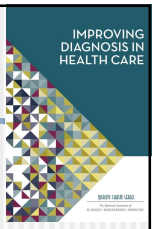
The vision

- 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 arms…

- Agree definition and validation of effectiveness measures – a "common currency" for outcomes
- Benchmark existing and new biomarkers in specified situations using commonly accepted measures of clinical effectiveness
- Improve utilization of new and existing biomarkers –
  - optimum testing strategies based on presenting complaint
  - support of effective requesting
  - timely and appropriate result transmission
  - availability of consultation and interpretation
  - audit of effectiveness in practice – *work your data*

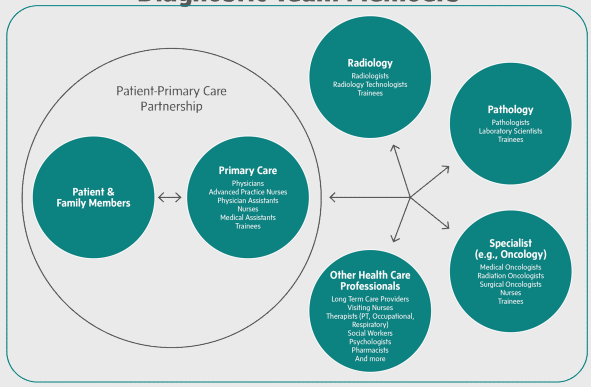
Improving diagnosis



- Recommendation 1:
  - …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…

74

Diagnostic Team Members



The National Academies of SCIENCES • ENGINEERING • MEDICINE

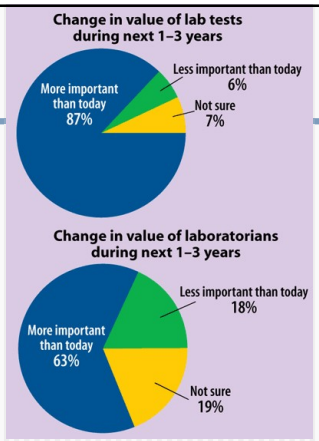
SOURCE: National Academies of Sciences, Engineering, and Medicine. 2015. *Improving Diagnosis in Health Care*. Washington, DC: The National Academies Press.

75

Changing role of lab medicine

- From:
  - Specimen-centred
  - Clinical testing
  - Lab. performance
  - Provider of results
- To:
  - Patient-centred
  - Clinical decision-making
  - Patient outcomes
  - Partner in care

76



AACC CLN Survey
November 2010

- "Here is our opportunity to be welcomed as participants in the diagnostic process. The [IoM] committee is saying, it's time for you to suit up. The score is tied 3-3 in the bottom of the ninth, and we're sending the pathologist to the plate. Don't strike out. You're going to have to swing the bat"
- Mike Laposata (Galveston)
- CLN January 2016

78

The future…

- "Never make predictions, especially about the future…"

  Yogi Berra

- "The best way to *predict* the future is to *shape* it"

  Willi Brandt

79

References

- Special issue eJIFCC January 2015
  www.ifcc.org
- IFCC Task Force report

  "Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine": Hallworth MJ et al.
  Clinical Chemistry – April 2015
  (doi:10.1373/clinchem.2014.232629)

80

81

Working with physicians - *how to improve utilization and ensure effective interpretation of laboratory tests*

Dr Danielle B. Freedman
Director, Pathology
Luton and Dunstable University Hospital, UK

AACC Aug 2016, Philadelphia, USA

Speaker Financial Disclosure Information

- Grant/Research Support: None
- Salary/Consultant Fees: None
- Board/Committee/Advisory Board Membership: None
- Stocks/Bonds: None
- Honorarium/Expenses: None
- Intellectual Property/Royalty Income: None

Question 1

How much is spent in the US on unnecessary testing and procedures ?

a. $ 1.5 billion
b. $ 3.0 billion
c. $ 6.8 billion
d. $ 18.0 billion

17.4 % of US GDP was spent on health care in 2009

$65 billion per annum on > 4.3 billion laboratory tests

Outline

- Factors *influencing* test ordering by clinicians
- Strategies for *modifying* clinicians ordering patterns
- Implementing policies to *improve* laboratory utilization, result interpretation and thereby improve patient outcome

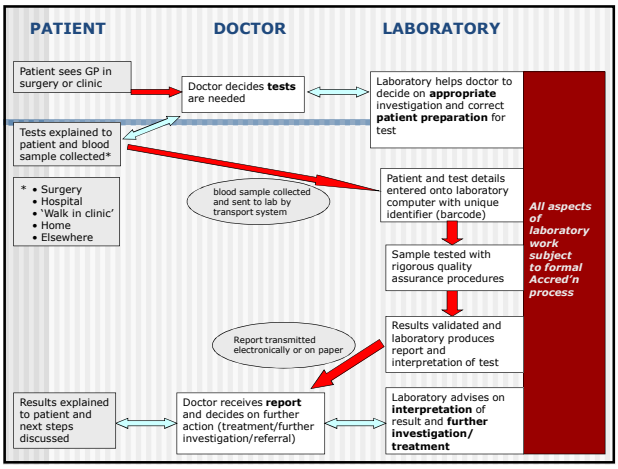
Laboratory medicine - cost

- Global IVD market valued at $49 bn in 2012, growing at a rate of 7% from 2012 to 2017
- 3-5% of healthcare costs

Laboratory Medicine
what is the service?

RIGHT .....patient
test
sample
time
result
decision
action
price

OUTCOME



IBD and IBS – UK (pop. 60m)

Bloating / distension, abdominal pain, altered bowel habit – common

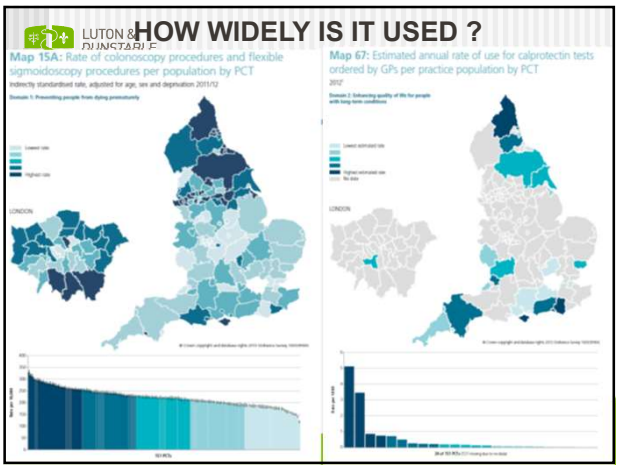
Clinical exam / history alone not always reliable – **DIAGNOSTIC DILEMMA**

coeliac, somatisation, infective, gynae pathology.

? IBD

Patients per year

- Ulcerative Colitis 120,000
- Crohn's 60,000
- IBS (avg incidence 15%) 9 million



CALPROTECTIN: CLINICAL USE

- Distinguishes functional (IBS) symptoms from organic symptoms (inflammatory) - **>95% sensitivity and specificity**
- Normal result excludes IBD and **requirement to scope**
- Sigmoidoscopy tariff = **$790,** Colonoscopy **$1040**
- Faecal calprotectin testing = **$70**
- Luton experience (patients referred where diagnosis of organic versus functional disease uncertain):
  - In secondary care, – 70% reduction in Endoscopy
  - Potential saving **$68,000 per 100 patients**

Question 2

What most determines a clinician's test ordering?

1. Fear of litigation
2. Cost of test
3. Evidence based guidelines
4. Patient went to *Lab Tests Online*
5. Watched an episode of '*House*' last night

Lab-related causes of diagnostic error

- Inappropriate test ordered (overuse)
- Appropriate test not ordered (underuse)
- Appropriate test result not used properly
  - Knowledge deficit – wrong interpretation
  - Misleading result
- Appropriate test result delayed/missed
- Appropriate test result wrong – RARE!

(Epner & Astion, 2013)

Wrong test choice accounts for up to 50 – 60% of missed / delayed diagnoses (Plebani, 2010)

Analysis of malpractice claims – US

Ann Intern Med 2006; 145: 488-496

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%

Types and relative frequency of errors in the different phases of the TTP

Phase of the TTP	Relative Frequency (%)
Pre-pre-analytic	46 – 68.2

Wrong test choice accounts for up to 50 – 60% of missed / delayed diagnoses

Approx 30% of total laboratory medicine errors have direct impact on patient care, and 2 -7% cause an adverse event.

Plebani Ann Clin Biochem 2010,47:101-110

Primary care in Ordering Clinical Laboratory Tests and Interpreting Results

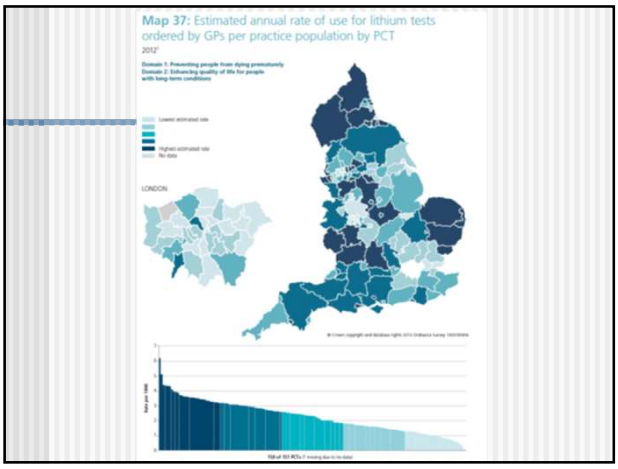
Physicians order tests in 31% of patient encounters

14.7% report uncertainty about ordering

8.3% report uncertainty about interpreting

Potentially affects 23 million patients pa

Hickner et al JABFM 2014; 27: 268-274



Preventing overdiagnosis

- "Medicine's much-hailed ability to help the sick is fast being challenged by its propensity to harm the healthy"
- "Too many people are being overdosed, overtreated and overdiagnosed"

  Moynihan et al, BMJ 2012

5% of healthy patients get abnormal test results

Some Causes of Overutilization

- Patient pressure
- Duplicate requesting
- Lack of understanding of the diagnostic value of a test
  - "just in case"
- Ordering 'wrong' test
- Failure to understand the consequences of overutilization
- Defensive testing
- Perverse financial incentives (more tests = more revenue)
- **"Availability creates demand "**

Consequences of Overutilization

- Increased resource utilization
- Incorrect diagnosis and treatment
- Incorrect test ordering delays diagnosis
- Increased length of stay
- Patient alarm
- Contribute to blood loss

In the UK

- Laboratory investigations £2.5 billion / year (i.e. $3.6bn)
- Approximately 4% of total NHS expenditure
- Annual increase in workload 8-10%
- 25% of pathology tests unnecessary
  - Department of Health Independent Review of Pathology Services 2009
- BUT same amount of under requesting?
- *Local audit July 2012 – Inpatients 34% "inappropriate"*

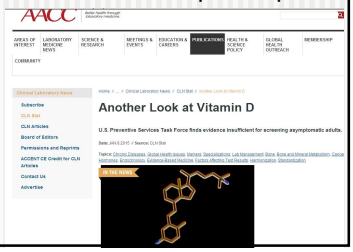
Studies outside the UK

- 4.5 – 95% inappropriate lab use
  Van Walraven JAMA: 1998 (US)
- 5.1%
  Weydert Arch Pathol Lab Med: 2005: 129: 1141-1143 (US)
- 21% (No reason and low yield)
  Pal et al JMGIMS: 2009: 14: ii: 40-46 (India)
- **30% "Consensus" estimate**
  AACC Webinar 26th Oct 2010
- 30% Repeat testing
  van Walraven Clin Chem 2003;49:12 (Canada)

Unnecessary testing

- Australia – Vit D requests increased by **4,600 %** from 2002/3 to 2011/12 !!
- 73,000 requests to 3.5million requests pa

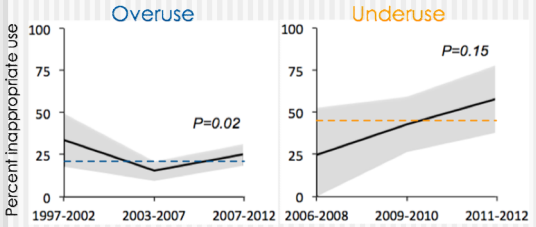
Vasikaran S:
Ann Clin Biochem
2013: 50: 283-4



Zhi et al (2013)

- 1997-2012, 42 studies
- 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

Arnaout—CAP—091614

Reviewing of results in ER at the Luton & Dunstable Hospital

	2010	2012	2014
Not reviewed within 1 hour	50% *	71%	
Not reviewed within 2 hours	26%		
Not reviewed within 3 hours	14%		
Never reviewed	10%	10%	7.4% $130,000

* 89% were outside the reference interval

When Less is More

Repeat testing of critical values can delay treatment and waste resources

In the US:

- CAP Q probes : 61% of all labs repeat critical results
- Delays of 17-21 minutes due to re-testing[1]

In Europe:

- Repeat testing causes delays in result communication by 35-42 mins

Is there any evidence for repeating critical vlaues?

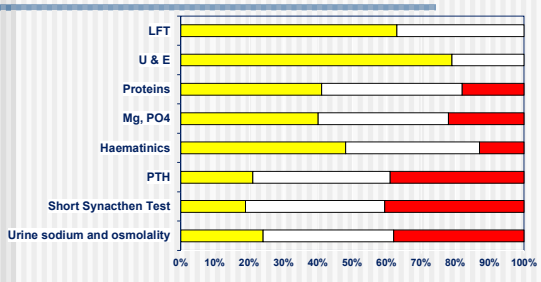
- Audit of 2,308 repeated tests:
  99.3% of specimens no difference in the results[2]

1. *Arch Pathol Lab Med. 2014: 138: 788-93*
2. *Clin Chem Lab Med 2014: 52: 1739-45*

THE GLOBE AND MAIL

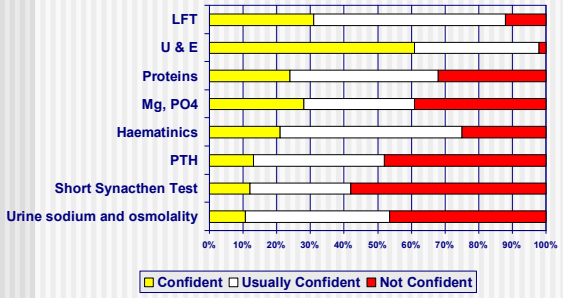
- Wendy Levinson
- **Fewer tests, less treatment sometimes makes good medicine**
- Contributed to The Globe and Mail
- Published Friday, Feb. 21 2014, 7:46 AM EST
- Last updated Friday, Feb. 21 2014, 7:49 AM EST
- Physicians' professional responsibility, and calling, is to provide the highest quality of care for patients. We base our care on scientific evidence to guide our recommendations to patients. ***Choosing Wisely Canada*** is a campaign to help physicians and patients engage in a conversation about tests, treatments and procedures that are not needed and to support them in making smart and effective choices to ensure high quality care. ***Choosing Wisely Canada*** is not about cost cutting or rationing.

UK junior hospital doctors: "How confident are you in *requesting* laboratory tests?"



(Khromova & Gray, 2009)[10]

How confident are you in *interpreting* laboratory tests?



Questions *Oxford ,2010*	Answer Options	Correct Answer	% Correct
1. Which of the following blood groups would it be unsafe to transfer to a man of blood group O Rhesus positive?	O Rh positive O Rh negative A Rh positive	A Rh positive	77
2. **In a patient on Warfarin in whom there is no, or only minor bleeding, at what INR would you consider administering Vitamin K?**	3 5 7 8 10	8	36
3. The following test result would confirm a diagnosis of iron deficiency:	A low serum iron Both a low serum iron and low transferrin A low serum ferritin	A low serum ferritin	61

Neglect by hospital staff contributed to man's death

Derby Telegraph

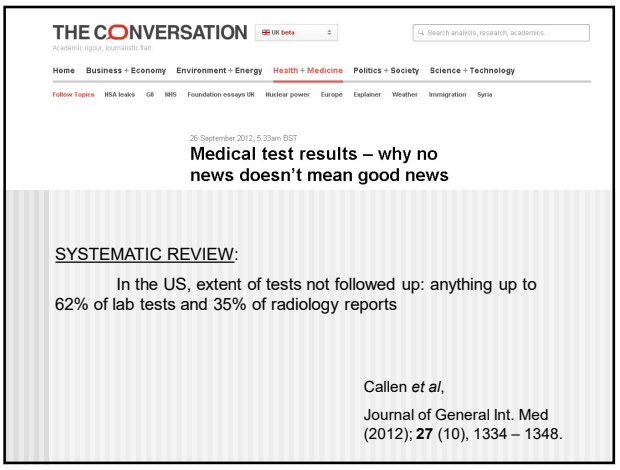
By **This is Derbyshire** | Posted: May 13, 2011

Ripley-born Mr Walters, 83, was admitted to the hospital after fracturing his hip dancing at a care home.

A series of failures – including a **misreading of blood tests**, a lack of communication and medics' **refusal to put him on a drip** – played a part in his death.

Dr Hunter, Coroner for Derby and South Derbyshire, said: "No-one should die in similar circumstances to Mr Walters. "No effective treatment was offered." He said the hospital's errors amounted to "gross failures" which "constitute neglect".

The **blood test results clearly showed he was dehydrated** and was one of several "simple checks" that should have acted as a warning.



26 September 2012, 5.33am BST

Medical test results – why no news doesn't mean good news

SYSTEMATIC REVIEW:

In the US, extent of tests not followed up: anything up to 62% of lab tests and 35% of radiology reports

Callen *et al*,

Journal of General Int. Med (2012); **27** (10), 1334 – 1348.

The Problems

- Too many tests
- Different names
- Different units
- Different reference intervals
- Different alert limits
- Inconsistent guidelines

The UK National Laboratory Medicine Catalogue

UK implementing an England-wide model for EHR presented with an initial pathology catalogue derived from a multiplicity of sources:

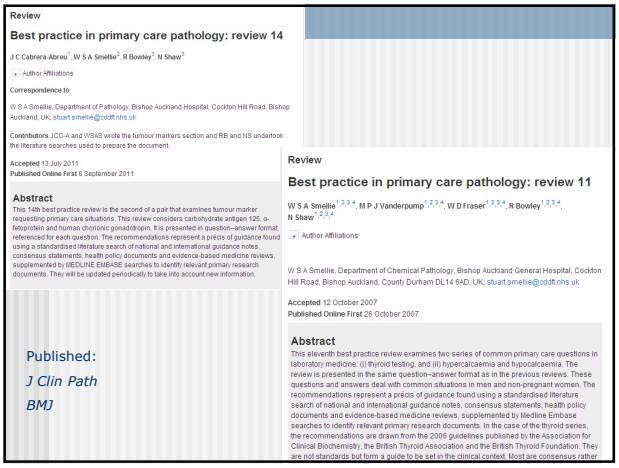
- Duplications
- Inconsistent naming formats
- Ambiguity. Unclear what the lab response to a request should be
- Not fit for purpose of applying national codes (SNOMED)

Example: Vitamin Ds

Taken from Editorial Tool used by content reviewers. Copyright Dept of Health.

Strategies for Changing Physician Behaviour in Ordering Lab Tests

- *Bandolier* Review of 49 articles between 1966 and 1998
- Strategies that don't work by themselves
  - Physician consensus building
  - Test guideline dissemination
  - Traditional education
  - Utilisation audits
  - Inform physicians of lab test charges



Review

Best practice in primary care pathology: review 14

J C Cabrera-Abreu[1], W S A Smellie[2], R Bowley[3], N Shaw[3]

Author Affiliations

Correspondence to

W S A Smellie, Department of Pathology, Bishop Auckland Hospital, Cockton Hill Road, Bishop Auckland, UK; stuart.smellie@cddft.nhs.uk

Contributors JCC-A and WSAS wrote the tumour markers section and RB and NS undertook the literature searches used to prepare the document.

Accepted 13 July 2011
Published Online First 6 September 2011

Abstract

This 14th best practice review is the second of a pair that examines tumour marker requesting primary care situations. This review considers carbohydrate antigen 125, α-fetoprotein and human chorionic gonadotropin. It is presented in question–answer format, referenced for each question. The recommendations represent a précis of guidance found using a standardised literature search of national and international guidance notes, consensus statements, health policy documents and evidence-based medicine reviews, supplemented by MEDLINE EMBASE searches to identify relevant primary research documents. They will be updated periodically to take into account new information.

Review

Best practice in primary care pathology: review 11

W S A Smellie[1,2,3,4], M P J Vanderpump[1,2,3,4], W D Fraser[1,2,3,4], R Bowley[1,2,3,4], N Shaw[1,2,3,4]

Author Affiliations

W S A Smellie, Department of Chemical Pathology, Bishop Auckland General Hospital, Cockton Hill Road, Bishop Auckland, County Durham DL14 6AD, UK; stuart.smellie@cddft.nhs.uk

Accepted 12 October 2007
Published Online First 26 October 2007

Abstract

This eleventh best practice review examines two series of common primary care questions in laboratory medicine: (i) thyroid testing, and (ii) hypercalcaemia and hypocalcaemia. The review is presented in the same question–answer format as in the previous reviews. These questions and answers deal with common situations in men and non-pregnant women. The recommendations represent a précis of guidance found using a standardised literature search of national and international guidance notes, consensus statements, health policy documents and evidence-based medicine reviews, supplemented by Medline Embase searches to identify relevant primary research documents. In the case of the thyroid series, the recommendations are drawn from the 2006 guidelines published by the Association for Clinical Biochemistry, the British Thyroid Association and the British Thyroid Foundation. They are not standards but form a guide to be set in the clinical context. Most are consensus rather

Published:
J Clin Path
BMJ

The Association for Clinical Biochemistry & Laboratory Medicine
Better Science, Better Testing, Better Care

The Royal College of Pathologists
Pathology: the science behind the cure

December 2015: *www.rcpath.org*

National Minimum Retesting Intervals in pathology:

- Clinical Biochemistry [see previous]
- Haematology – general, coag, transfusio
- Immunology
- Microbiology
- Virology
- Cellular Pathology

IBMS INSTITUTE OF BIOMEDICAL SCIENCE

National Minimum Re-testing Interval Project:
A final report detailing consensus recommendations for minimum re-testing intervals for use in Clinical Biochemistry

	E5	Hypothyroid - monitoring of treatment.	The minimum period to achieve stable concentrations after a change of dose of thyroxine is 2 months and TFTs should not normally be assessed before this period has elapsed. Patients stabilised on long-term thyroxine therapy should have serum TSH checked annually. An annual fT4 should be performed in all patients with secondary hypothyroidism stabilised on thyroxine therapy.	Association for Clinical Biochemistry, British Thyroid Association and British Thyroid Foundation (2006) UK guidelines for the use of thyroid function tests. Association for Clinical Biochemistry, British Thyroid Association, British Thyroid Foundation July 2006.

National Minimum Re-testing Interval Project:
A final report detailing consensus recommendations for minimum re-testing intervals for use in Clinical Biochemistry

SP7	C-Reactive Proteins (CRP)	Not within a 24 hour period following an initial request with the exception of paediatric requests	Hutton et al. Ann Clin Biochem 2009; **46**: 155-158.

ACADEMY OF MEDICAL ROYAL COLLEGES

Protecting resources, promoting value: a doctor's guide to cutting waste in clinical care

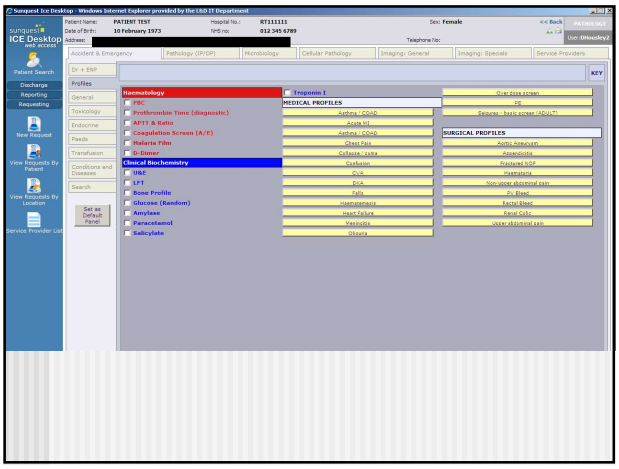
UK: " *Do not Do"*

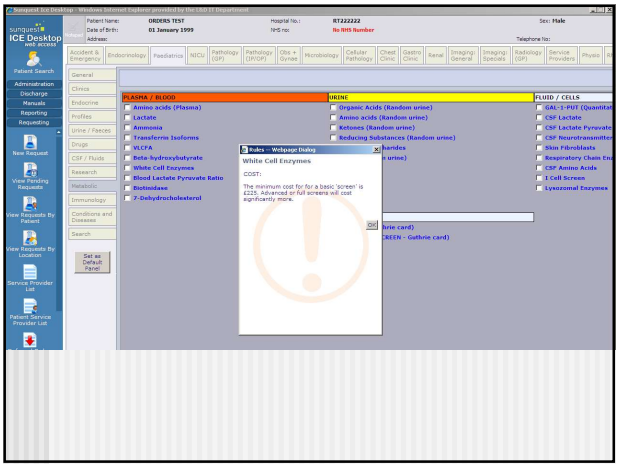
[NICE April 2014]

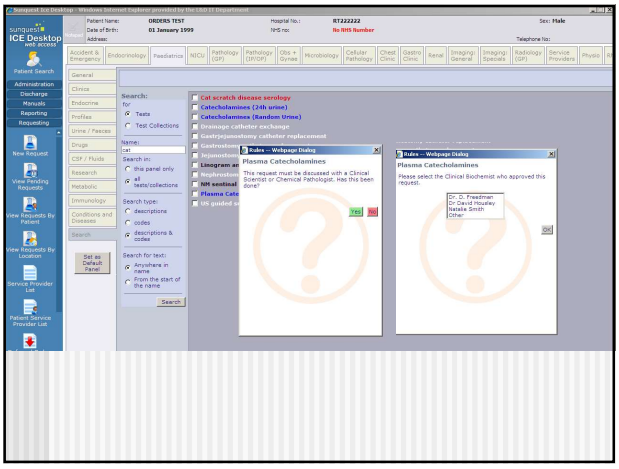
US: "*Choosing Wisely"*

[NEJM 2014]

November 2014


Sunquest Ice Desktop - Windows Internet Explorer provided by the LSD IT Department
ICE Desktop
Patient Name: PATIENT TEST
Date of Birth: 10 February 1973
Address:
Hospital No.: RT111111
NHS no: 012 345 6789
Sex: Female
Telephone No:
Haematology
Troponin I
MEDICAL PROFILES
SURGICAL PROFILES
Clinical Biochemistry
U&E
LFT
Bone Profile
Glucose (Random)
Amylase
Paracetamol
Salicylate
Malaria Film
D-Dimer
Coagulation Screen (A/E)
Prothrombin Time (diagnostic)
APTT & Ratio
FBC


Sunquest Ice Desktop - Windows Internet Explorer provided by the LSD IT Department
ICE Desktop
Patient Name: ORDERS TEST
Date of Birth: 01 January 1999
Address:
Hospital No.: RT222222
NHS no: No NHS Number
Sex: Male
Telephone No:
PLASMA / BLOOD
URINE
FLUID / CELLS
Amino acids (Plasma)
Lactate
Ammonia
Transferrin Isoforms
VLCFA
Beta Hydroxybutyrate
White Cell Enzymes
Blood Lactate Pyruvate Ratio
Biotinidase
7-Dehydrocholesterol
Organic Acids (Random urine)
Amino acids (Random urine)
Ketones (Random urine)
Reducing Substances (Random urine)
Rules -- Webpage Dialog
White Cell Enzymes
COST:
The minimum cost for for a basic 'screen' is £225. Advanced or full screens will cost significantly more.
OK
CSF Lactate
CSF Lactate Pyruvate
CSF Neurotransmitter
Skin Fibroblasts
CSF Amino Acids
I Cell Screen
Lysozomal Enzymes


Sunquest Ice Desktop - Windows Internet Explorer provided by the LSD IT Department
ICE Desktop
Patient Name: ORDERS TEST
Date of Birth: 01 January 1999
Address:
Hospital No.: RT222222
NHS no: No NHS Number
Sex: Male
Telephone No:
Search:
Tests
Test Collections
Cat scratch disease serology
Catecholamines (24h urine)
Catecholamines (Random Urine)
Drainage catheter exchange
Gastrojejunostomy catheter replacement
Rules -- Webpage Dialog
Plasma Catecholamines
This request must be discussed with a Clinical Scientist or Chemical Pathologist. Has this been done?
Yes
No
Rules -- Webpage Dialog
Plasma Catecholamines
Please select the Clinical Biochemist who approved this request.
Dr. O. Freedman
Dr. David Moseley
Deirdre Smith
Other
OK

Change in number of tests sent for urine toxicology screening (including drugs of abuse) per month after request vetting.

Fryer AA, *et al. J Clin Pathol* 2013;**66**:62–72.

Providing cost information on laboratory test ordering:

- Controlled clinical trial:
  - Johns Hopkins Hospital displayed fees for 61 random lab tests in CPOE
- Outcomes:
  - Active arm (3.72 → 3.40 tests per patient = 8.59% decrease).
  - Control arm (1.15 → 1.22 tests per patient = 5.63% increase).

Feldman et al; JAMA 2013; 173 (10), 903 – 908

CDS Rules to reduce repeat measurements of iCa, Mg and NT-proBNP

Moyer et al Clin Chem 2016

- CDS pop-up alerts for repeat
  - iCa – 24hrs
  - Mg 48 hrs
  - NT-proBNP 1 hospitalization

Test	Percentage decrease in 90 days
iCa	48
Mg	39
NT-proBNP	28

No increase in adverse patient outcomes

The Five Rights of Clinical Decision Support (CDS)

1) The right information……
   - **Alert includes previous patient test results and EBLM**
2) To the right person……
   - **Requestor is making a potentially misinformed decision about lab testing**
3) In the right CDS intervention format
   - **Interruptive alert**
4) Through the right channel
   - **CPOE**
5) At the right time in the workflow
   - **At the time of ordering**

130

Barriers to guideline adherence

Misra & Barth, Ann Clin Biochem 2013, Cabana JAMA 1999

- Lack of awareness
- Lack of familiarity with content
- Lack of agreement
- Inertia of previous practice
- External barriers, eg Financial constraints, time, patient reluctance

Summary of intervention strategies to improve physician ordering behaviour

(*Freedman DB eJIFCC 2015 26: 15-30)*

- Guidelines, education and audit of adherence, outcomes
- Use of Formularies
- Standardize nomenclature, units, profiles and ref intervals
- Electronic order systems (CPOE)
- Diagnostic algorithms, reflex and reflective testing
- Minimum retesting intervals
- Request vetting and restrictions
- Feedback to users – activity data, appropriateness and costs
- **Multiple interventions**
  - **MUST stay in place otherwise behaviour will drift back to the unwanted condition**

Case: 65y/o F c/o tingling and cramps

- Initially GP requested Bone profile

  Adjusted Calcium 7.2 mg/dL (9-11)

- Subsequently GP requested PTH and Vitamin D

  PTH Low
  Vitamin D Normal

- Discussion with GP – patient on Omeprazole (PPI) for 3yrs
- Magnesium 0.60 mg/dL (1.8-3.6)

Case: 65y/o F c/o tingling and cramps

Hypomagnesaemia

- Cardiac dysrhythmia, including ventricular fibrillation

Emergency Admission $2400

plus

Stay on CCU $1200/day

Reflective Testing

Add additional tests and/or comments – discretionary or based on clinical judgement of laboratory clinician in the interpretation of results

Oosterhuis, Clin Chem Lab Med 2011

- Reflective testing resulted in more adequate actions compared with controls [42% vs 27%]

Reflective Testing

Verboeket-van de Venne et al
Ann Clin Biochem 2009

- 53% GP's- positive influence of adding tests and comments on patient management
  - Earlier diagnosis and treatment of anaemia, thyroid disease or renal disease
  - Earlier referral to a specialist

- GP referral to Dr.Freedman June 2015

51 yr old Male, c/o 2 year history of excessive somnolence

PMH	Obesity , Asthma
DH	Salbutamol, Seretide inhaler
FH	CHD – father MI age 42 years old,Obesity
SH	Non smoker, no alcohol
c/o	Migrainous Headaches 6 month history of nocturia Weight gain – 60kg in 2 years ?Sleep Apnoea
O/E	Obese BMI 62 BP 150/93 Bilateral gynaecomastia, Very little body hair

Investigations by GP

Test (units)	Result	Reference Range
U&E	Normal	
Free T4 (ng/dL)	0.55	0.7-2.0
TSH (uU/mL)	1.5	0.5 – 4.8

Question 2

- a) Would you reflectively add tests ?
- b) Which tests would you add ?

Q 3 What are your front line TFT's?

1) FT4
2) TSH
3) FT4 & TSH
4) Other

Prevalence and incidence of hypopituitarism in an adult caucasian population in northwestern Spain

- Prevalence 45.5/1000
- Annual Incidence 4.2/100,000
- L&D population approx 320,000
  5 cases of hypopituitarism in 3 months

  L&D annual incidence = 6.25/100,000
  Higher than average!

Regal M, Paramo C, Sierra SM, Garcia-Mayor RV. 2001. Prevalence and incidence of hypopituitarism in an adult caucasian population in northwestern Spain. *Clin Endocrinol*. 55 (6): 735-40.

Efficiency and effectiveness of reflex and reflective testing in four biochemical scenarios

Biochemical scenario	NND	Number of new diagnoses
Hypovitaminosis D*		
Reflex	1.1	81
Reflective	1.1	124
Hypomagnesaemia†		
Reflex	2.3	137
Reflective	2.4	62
Hypothyroidism‡		
Reflex	19	153
Reflective	–	0
Hyperthyroidism§		
Reflex	2.9	59
Reflective	4.7	6

Srivastava et al. Ann Clin Biochem 2010; 47: 223-227

NND, number needed to diagnose
*25-hydroxy-vitamin D < 50 nmol/L
†Magnesium <0.70 mmol/L
‡Serum free thyroxine <11.0 pmol/L
§Serum free thyroxine >22.0 pmol/L

ACB National Audit of Reflective Testing 2011

John Monaghan, Derby UK

23-year-old female with Amenorrhoea. Gonadotrophins and hormones were normal over the previous 12 months but no clinical details.

No urine or serum pregnancy test had been carried out.

LH **<0.5** uU/mL
FSH **<0.5** uU/mL

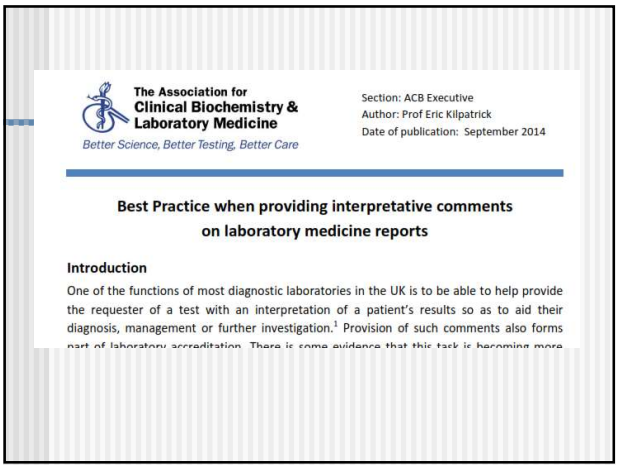
Q 4 Would you add serum HCG ?

ACB National Audit of reflective testing results 2011

54-year-old male with no clinical details on the form nor any previous results.

Request was for urea and electrolytes but the sample was noted to be lipaemic.

Q 5 Would you add TG/lipids ?



The Association for Clinical Biochemistry & Laboratory Medicine

Better Science, Better Testing, Better Care

Section: ACB Executive
Author: Prof Eric Kilpatrick
Date of publication: September 2014

Best Practice when providing interpretative comments on laboratory medicine reports

Introduction

One of the functions of most diagnostic laboratories in the UK is to be able to help provide the requester of a test with an interpretation of a patient's results so as to aid their diagnosis, management or further investigation.[1] Provision of such comments also forms

Low HDL cholesterol …….

A Ballantyne, DG Housley and DB Freedman- ACB FOCUS 2015

Case 88y/o F

- Referred to Eye clinic for sight deterioration
- Bilateral central retinal vein occlusion secondary to hypertension BP 180/100

Total Cholesterol (mg/dL)	80
Triglycerides (mg/dL)	50
HDL-C (mg/dL)	<25

- Q6 Would you add any tests ?

Patient's view of the laboratory

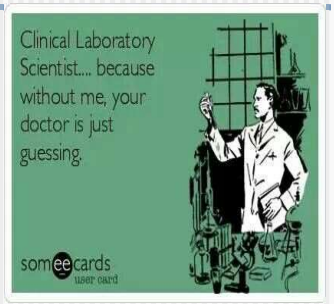
Samples in

↓

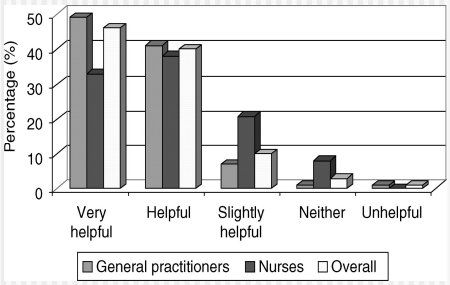
Results out

Other views of the laboratory

The reality

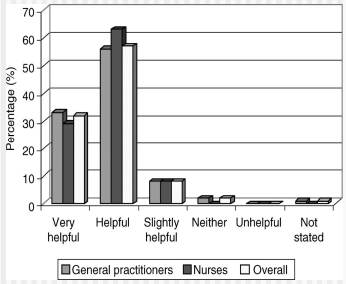


Are endocrine comments useful to GPs?



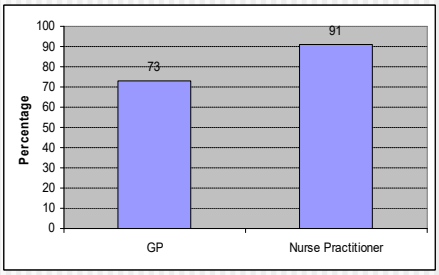
IM Barlow Ann Clin Biochem 2008; 45: 88–90

Are TFT interpretative comments useful to GPs?



IM Barlow Ann Clin Biochem 2008; 45: 88–90

TFT comments affecting patient management



Percentage feeling comments (very) frequently helped /influenced patient management

IM Barlow Ann Clin Biochem 2009; 46: 85–86

UK National Audit of Interpretive Comments

Kilpatrick & Freedman, ACB UK annual Survey Ann Clin Biochem 2011

- **Aim** To assess extent, process of interpretative comments.
  Impact on patient outcome
- **Method**
  Email questionnaire from ACB office using 'survey monkey'

  England, N Ireland, Scotland and Wales
  71% response rate

Question 1

Which of the following tests carried out in your lab?

Analyte	No comments	With comments
U+E, LFT, Bone Glucose	27.9%	70.6%
Lipids	18.8%	79.7%
HbA1C	29.9%	60.6%
TFTs	8.0%	88.3%
Gonadotrophins	7.2%	86.2%
Endo dynamic function tests	8.0%	84.1%

Analyte	No comments	With comments
PTH	13.3%	74.8%
Cortisol/SST	6.5%	87.7%
Drugs of Abuse/Toxicol	18.2%	47.7%
Antiepileptics	38.2%	56.6%
Cats	4.6%	51.9%
Tumour markers	17.6%	69.9%

Question 2

	Computer – **all** reports	Human sees all reports	Human sees 'rules'
U & E, LFT, Bone	11.3%	6.1%	82.6%
TFTs	7.9%	13.5%	80.2%
Gonadotrophins	18.9%	48.0%	44.1%
Cortisol /SST	15.2%	67.2%	21.6%
Dynamic function	5.6%	70.2%	20.2%
PTH	6.1%	58.8%	33.3%
Drugs of Abuse / Toxicol	15.5%	63.1%	23.8%
Cats	6.2%	64.2%	22.8%

Vignettes

- In particular comments on endocrine results from primary care, resulting in referral to endocrinologist to confirm diagnosis and provide treatment. Low calcium results from primary care – comments suggesting add magnesium, resulting in discussion and management/magnesium replacement provided to patient in community, rather than admission to Hospital for investigation.
- Preventing invasive investigation in child with an isolated very high alk phos by advising to wait for isoenzymes (laboratory added) to exclude THP of infancy (subsequently confirmed).

- Pointing out on many occasions that a raised serum potassium level is most likely due to Pseudohyperkalaemia when the platelet count or white cell is significantly raised and to confirm by measuring potassium in a lithium heparin sample.
- GP patient with ALT >2600 U/L, who had taken paracetamol overdose, but presented to GP with a completely different clinical history and had not mentioned any suicide attempt. After Clinical Scientist discussed result with GP and suggested the possibility of paracetamol overdose, the GP called the patient back and the patient admitted taking a large amount of paracetamol. The GP arranged for patient admission.
- High Prolactin seen in GP patient receiving anti-psychotic medication. Prevented further extensive investigation regarding ? prolactinoma.

A National Survey of Interpretative Reporting in the UK

Kilpatrick & Freedman Ann Clin Biochem 2011 : 48 : 317-320

"..... national survey has shown that the addition of interpretative comments into clinical biochemistry reports is widespread throughout the UK "

".....many respondents made specific comments stating that GPs wanted more interpretative comments and found this an invaluable part of the laboratory service "

What Experts Say.....

Anand Dighe, Director, Core Lab Massachusetts Gen Hospital, 2011

"…. Our job description is not just to turn out ten million test results per year. Our job is to help clinicians order and interpret tests.

The test result is just the starting point "

Dighe and colleagues surveyed physicians when the lab first included the interpretive comments:

Physicians said the comments had prevented a misdiagnosis in 71% of cases and that they wouldn't even look at the results until the interpretation was back because it just wasn't worth their time without it.

What Experts Say.....

Prof Mario Plebani, University of Padua, School of Medicine,2011

Interpretive comments include :

"... any additional information on the lab report that may help a clinician to better interpret information from the lab "

" The increase in number of tests and their complexity have highlighted the difficulties in data interpretation encountered by GPs and physicians receiving lab results"

Adult male – cloudy urine

Urine microbiology = NAD

Urine protein = NAD

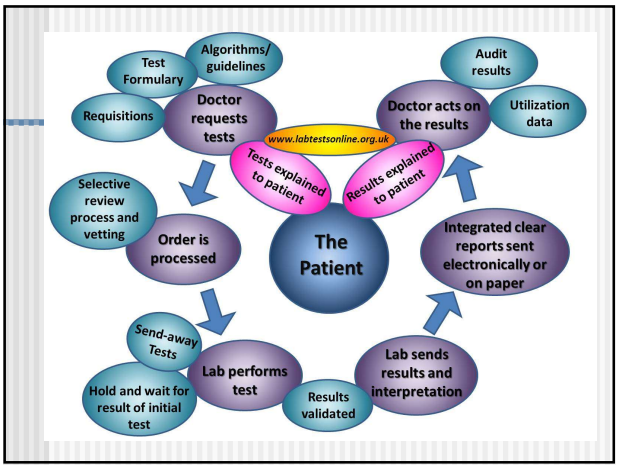
Comment – The urine on examination appeared milky rather than 'cloudy'. We have added a triglyceride which is raised (1.3 mmol/L) and we therefore suggest causes of chyluria are explored.

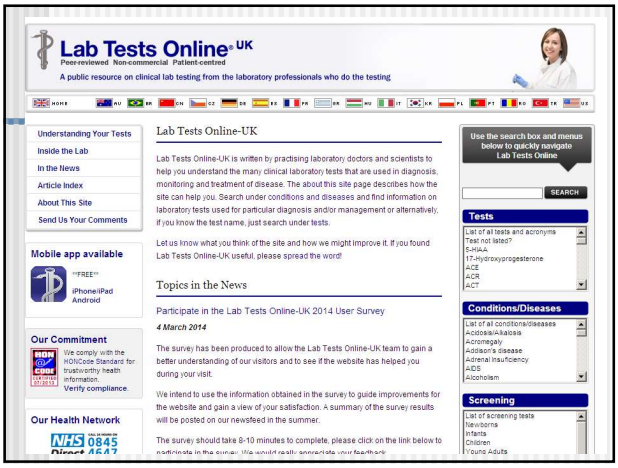
Follow-up. Two separate specimens received from each ureter. Left ureteric sample = triglyceride of 1.1 mmol/L and right sample = undetectable triglyceride.

Comment – Results indicate that chyluria persists and is related to the left renal tract.

Patient underwent lymphangiography that confirmed an anatomical link between the lymphatic system and left kidney.

Further investigations confirmed this was due to filariasis.


Test Formulary
Algorithms/ guidelines
Requisitions
Doctor requests tests
www.labtestsonline.org.uk
Tests explained to patient
Results explained to patient
Audit results
Doctor acts on the results
Utilization data
Selective review process and vetting
Order is processed
The Patient
Integrated clear reports sent electronically or on paper
Send-away Tests
Lab performs test
Hold and wait for result of initial test
Results validated
Lab sends results and interpretation

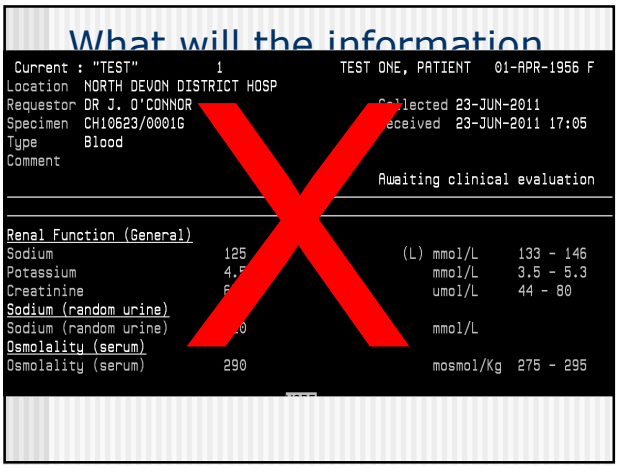

Lab Tests Online UK
Peer-reviewed Non-commercial Patient-centred
A public resource on clinical lab testing from the laboratory professionals who do the testing
Understanding Your Tests
Inside the Lab
In the News
Article Index
About This Site
Send Us Your Comments
Mobile app available
iPhone/iPad
Android
Our Commitment
Our Health Network
Lab Tests Online-UK
Lab Tests Online-UK is written by practising laboratory doctors and scientists to help you understand the many clinical laboratory tests that are used in diagnosis, monitoring and treatment of disease. The about this site page describes how the site can help you. Search under conditions and diseases and find information on laboratory tests used for particular diagnosis and/or management or alternatively, if you know the test name, just search under tests.
Let us know what you think of the site and how we might improve it. If you found Lab Tests Online-UK useful, please spread the word!
Topics in the News
Participate in the Lab Tests Online-UK 2014 User Survey
4 March 2014
The survey has been produced to allow the Lab Tests Online-UK team to gain a better understanding of our visitors and to see if the website has helped you during your visit.
We intend to use the information obtained in the survey to guide improvements for the website and gain a view of your satisfaction. A summary of the survey results will be posted on our newsfeed in the summer.
The survey should take 8-10 minutes to complete, please click on the link below to
Use the search box and menus below to quickly navigate Lab Tests Online
SEARCH
Tests
Conditions/Diseases
Screening

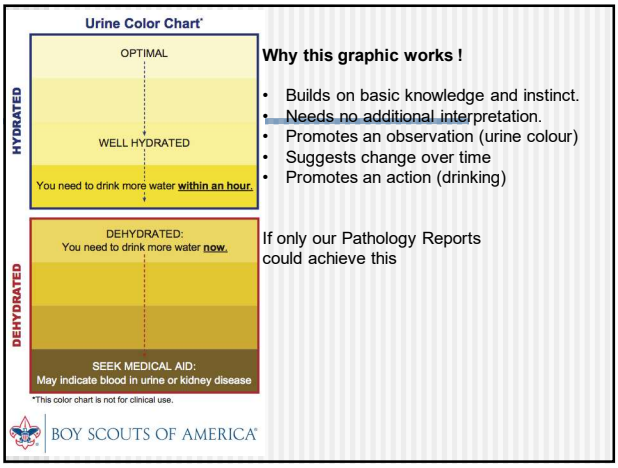

68TH AACC ANNUAL
SCIENTIFIC MEETING & CLINICAL LAB EXPO
July 31 - August 4, 2016
Philadelphia, PA • USA
REGISTER NOW!
AACC
Lab Tests Online
Empower Your Health. Understand Your Tests.
A program of AACC
Lab Tests Online Wins Digital Health Award
Lab Tests Online was announced as a winner of the Digital Health Awards, an awards program that honors the world's best digital health resources. READ MORE
DIGITAL Health AWARDS
WINNER
SPRING 2016

What will the information

```
Current : "TEST"          1              TEST ONE, PATIENT   01-APR-1956 F
Location  NORTH DEVON DISTRICT HOSP
Requestor DR J. O'CONNOR                      Collected 23-JUN-2011
Specimen  CH10623/0001G                       Received  23-JUN-2011 17:05
Type      Blood
Comment
                                              Awaiting clinical evaluation

Renal Function (General)
Sodium                    125                 (L) mmol/L     133 - 146
Potassium                 4.5                     mmol/L     3.5 - 5.3
Creatinine                81                      umol/L     44 - 80
Sodium (random urine)
Sodium (random urine)     20                      mmol/L
Osmolality (serum)
Osmolality (serum)        290                     mosmol/Kg  275 - 295
```

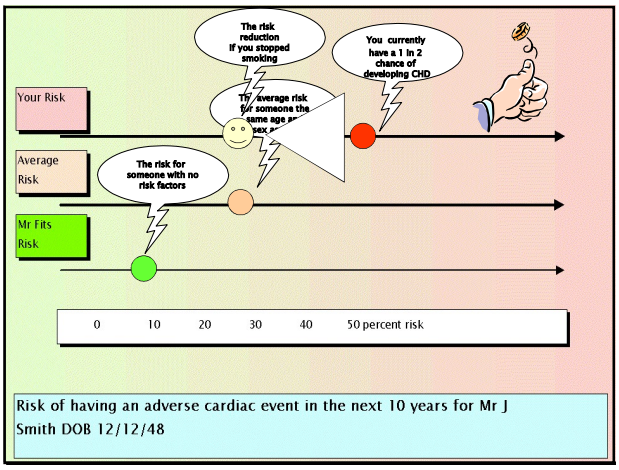




Why this graphic works !

- Builds on basic knowledge and instinct.
- Needs no additional interpretation.
- Promotes an observation (urine colour)
- Suggests change over time
- Promotes an action (drinking)

If only our Pathology Reports could achieve this



References

- Special issue eJIFCC January 2015
  www.ifcc.org
- IFCC Task Force report

  "Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine": Hallworth MJ et al.
  Clinical Chemistry 2015 ;61;589-599