Right Patient, right result, right time! So we're done - right?

Mike Hallworth

Shrewsbury, UK

@mike_hallworth

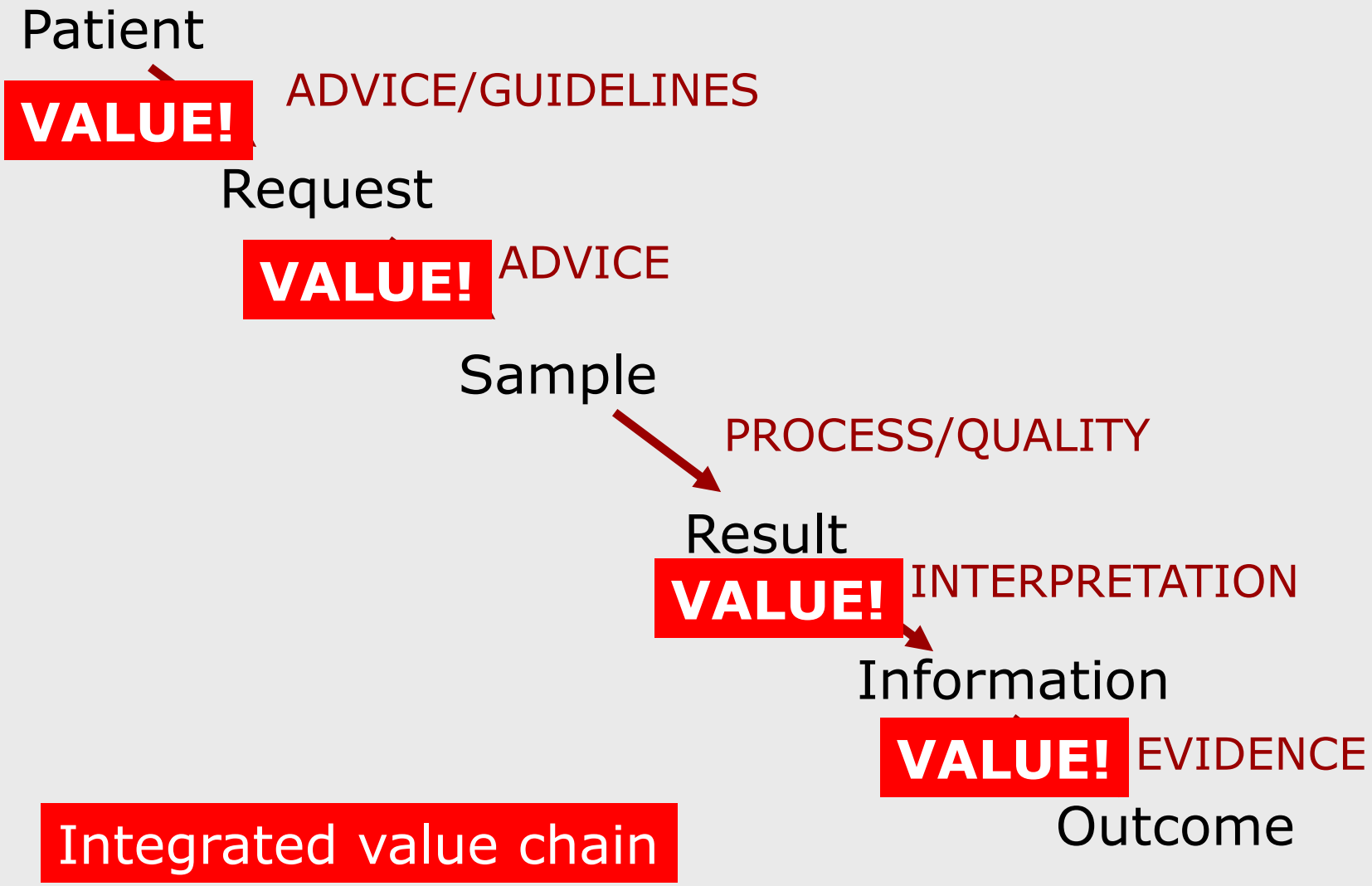
Clinical chemistry

Sample

PROCESS/QUALITY

Result

Laboratory medicine

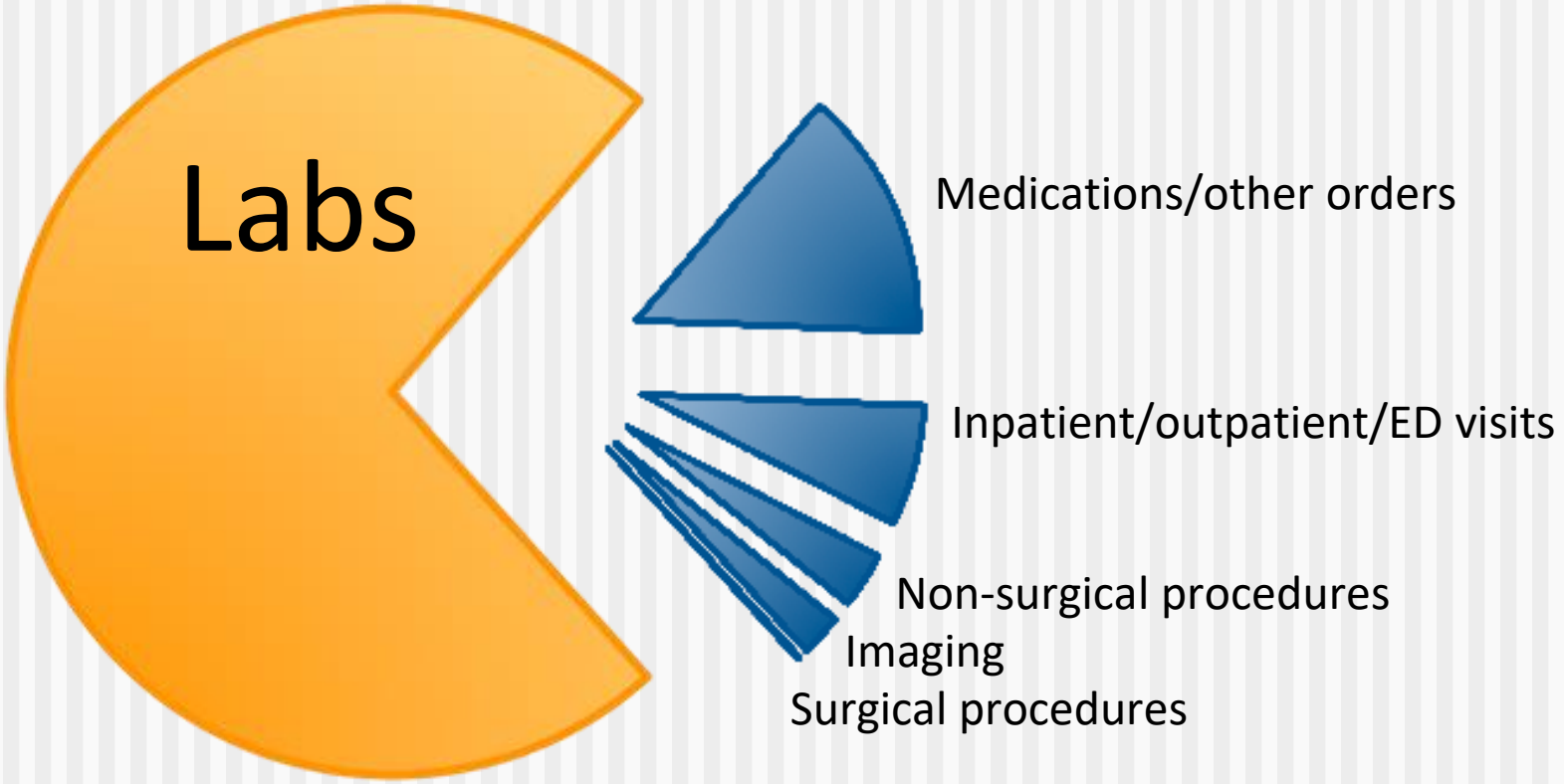


Integrated value chain

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

Throughput



Ramy Arnaout 2015

Philosophies of value of medical tests (Bossuyt)

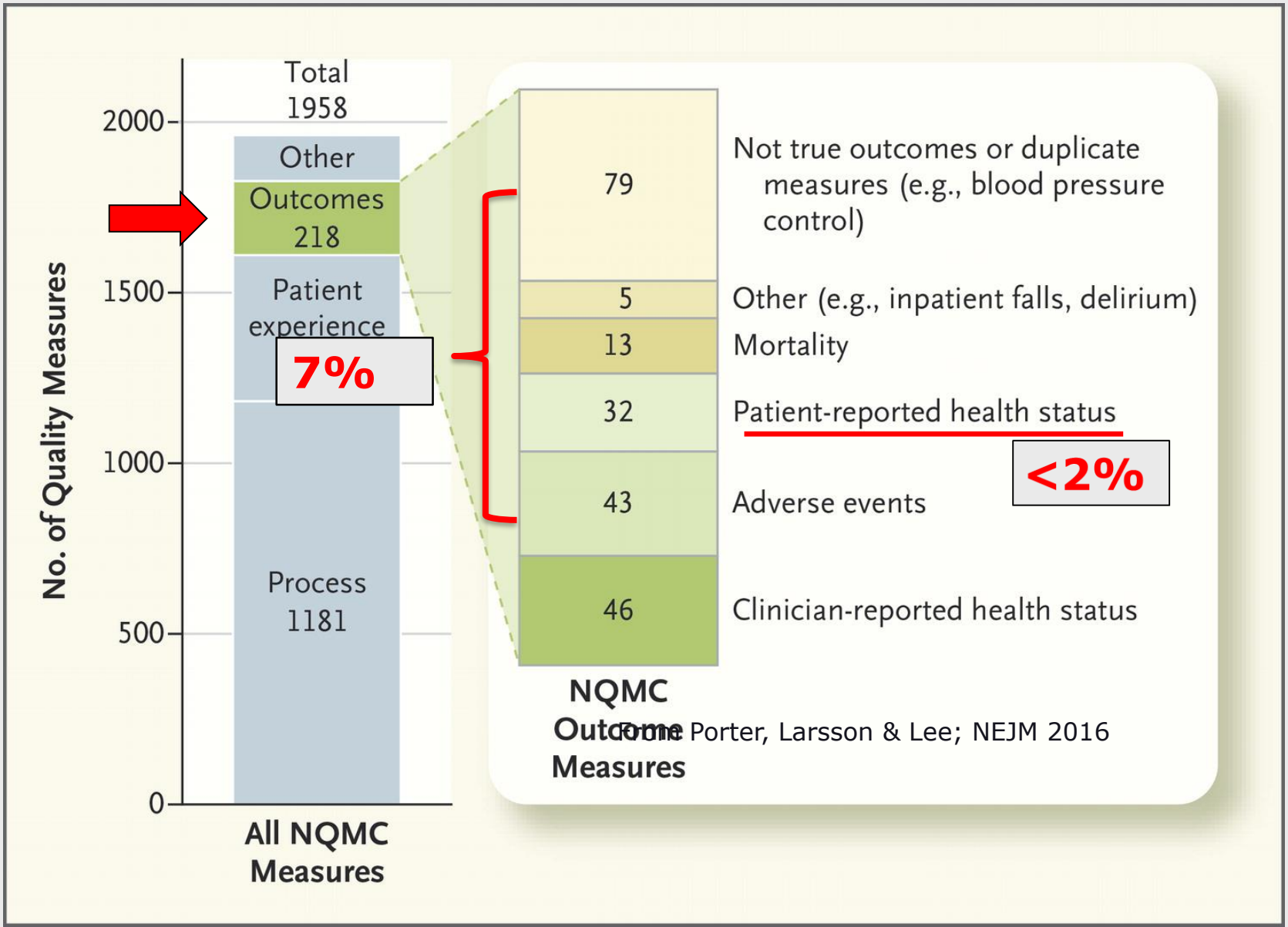
- Essentialism:

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

HEALTHCARE QUALITY MEASURES
National Quality Measures Clearing House: USA (1998-2018)



Assessment of performance in health care

- '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

From Porter, Larsson & Lee; NEJM 2016

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 for lab tests

- "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

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:i213911

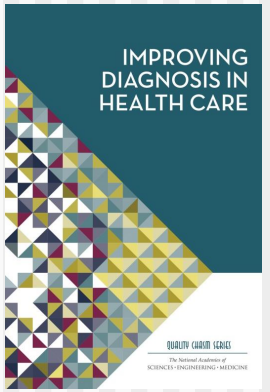
ECRI Top 10 Patient Safety Concerns 2017-2022

- 2017: #1 Test result reporting and follow-up
- 2018: #1 Diagnostic error
- 2019: #1 Diagnostic stewardship and test result management thru EHRs
- 2020: #1 Missed/delayed diagnoses
- 2022: #5 Cognitive biases and Dx error

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)



Diagnostic Error

- Diagnostic errors are defined as:
  - misdiagnosis
  - missed diagnosis
  - or delayed diagnosis

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

Lab-related causes of diagnostic error

- Inappropriate test ordered
- Appropriate test not ordered
- 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)

Lab-related causes of diagnostic error (postanalytical)

- Inappropriate test ordered
- Appropriate test not ordered
- 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

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%

Estimated proportions of errors in phases of the total testing process (Plebani, 2010)

PHASE	EXAMPLES OF ERROR	ESTIMATED PROPORTION OF ERRORS
Pre-preanalytical	Test ordering, patient ID, patient prep, sample collection, sample quality, transportation and storage	46-68%
Preanalytical	Sample sorting, centrifugation, labelling separation	3-5%
Analytical	Sample analysis	7-13%
Postanalytical	Validation, interpretation, TAT, critical value reporting	13-20%
Post-postanalytical	Interpretation, delayed reaction, lack of follow-up or referral	25-46%

- 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

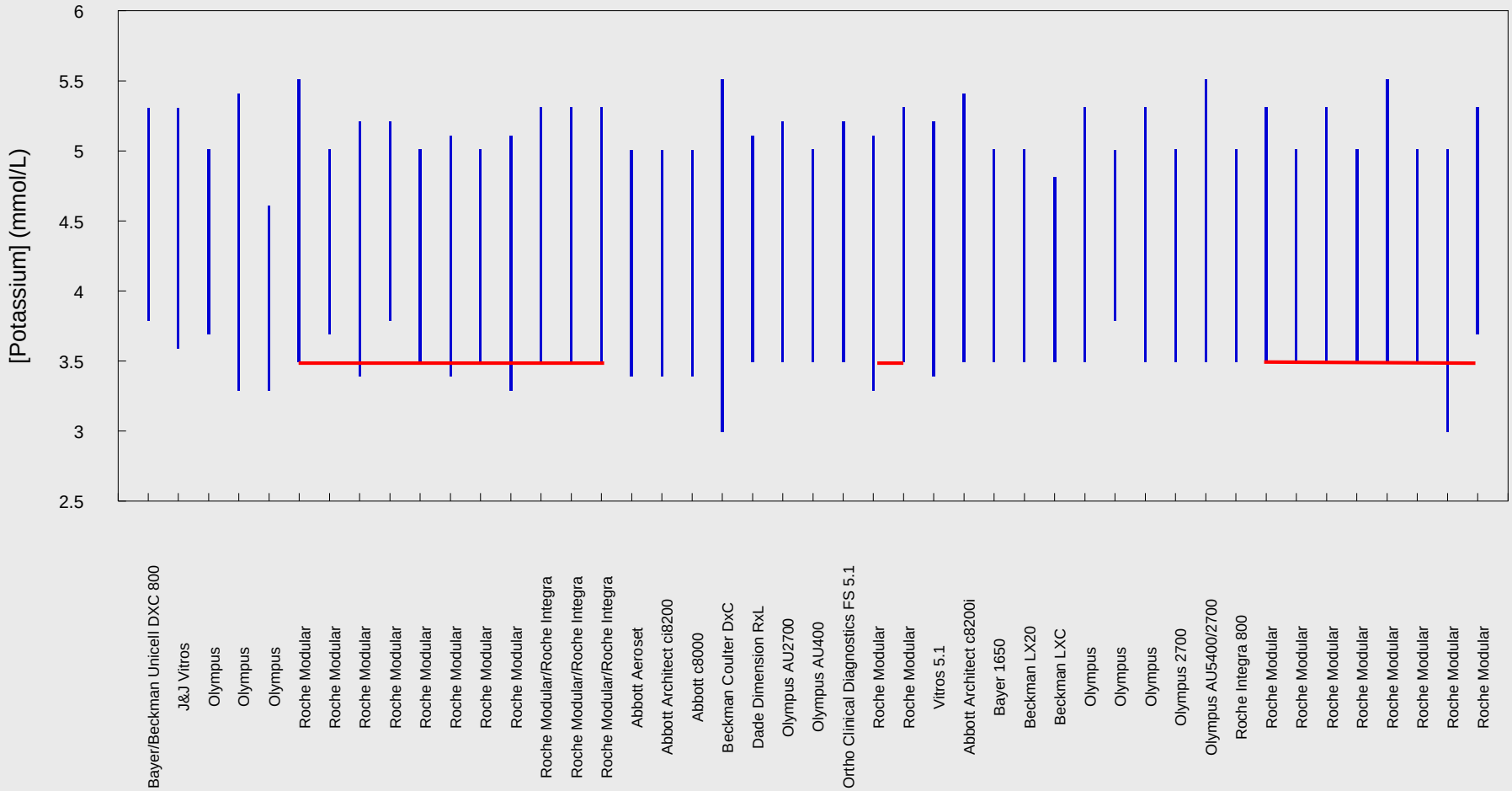
INTERPRETATION

- 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)

Potassium reference ranges

(data from UK Pathology Harmony)



Creatinine reference ranges
(CALIPER database; Abbott Architect)

- 0 – <15 days: 29-82 umol/L
- 15 days – 2 yr: 9-32 umol/L

Reflex and Reflective Testing

Reflex testing:

- Tests added automatically (computer generated)
- Or defined by protocols/guidelines (using “rules”)

Reflective testing:

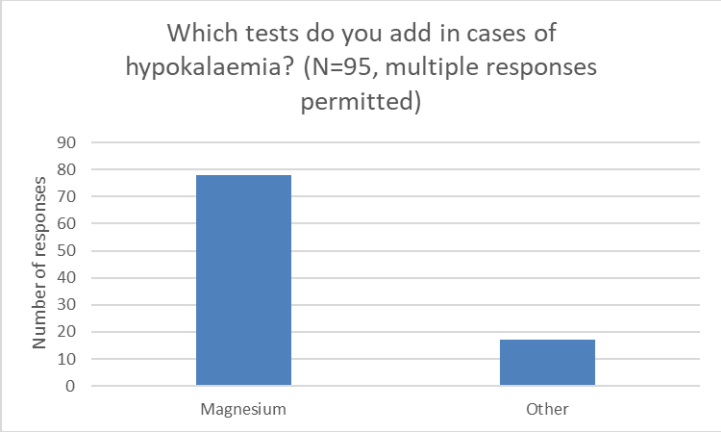
- Tests added after patient review based on clinical judgement at discretion of lab specialist (and discussion with requesting physician)

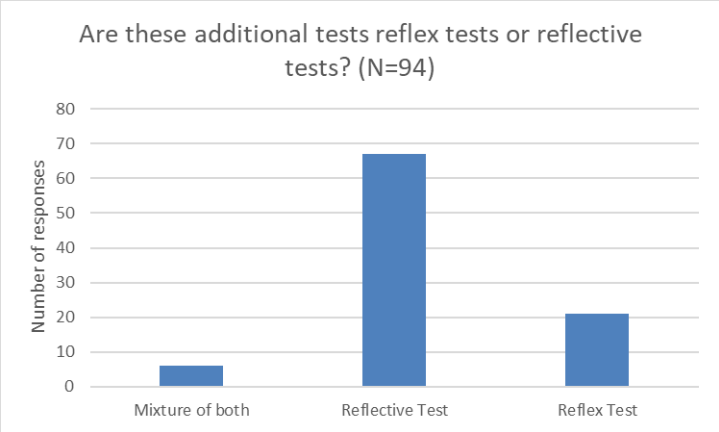
UK National Survey 2016 - add Mg test?

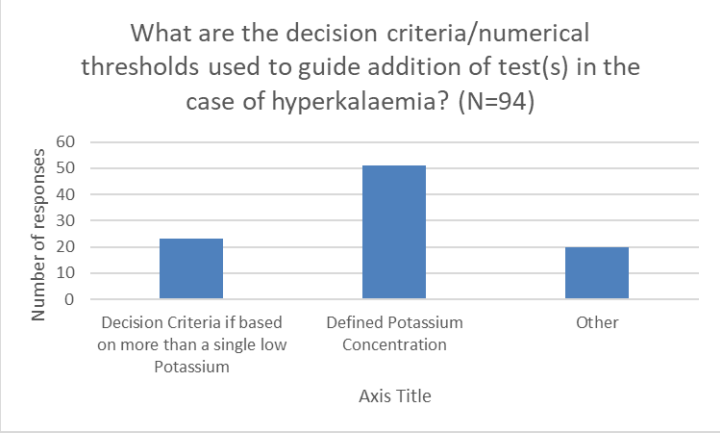
	When calcium low	When potassium low
Added	80%	57%
Reflex	25%	26%
Reflective	75%	74%
Interpretative comments	67%	68%

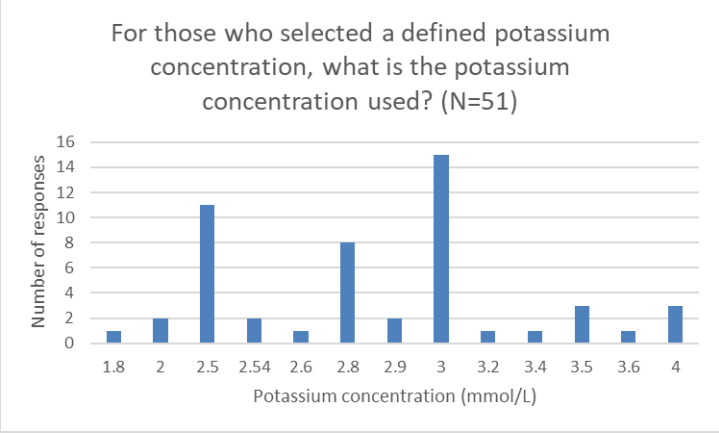
(McKeeman et al, 2020)

EFLM Survey: Hypokalaemia









(preliminary data from 2022 survey – EFLM Post-analytical Working Group
Kindly supplied by Dr D B Freedman)

Macroprolactin

	When total prolactin is high
Added	77%
Reflex	35%
Reflective	65%
Interpretative comments	96%

(McKeeman et al, 2020)

And on the individual level..

- 12.6.2008
- 28 year old man on medical ward
- “Tired and faint”
  - Na 128 mmol/L
  - K 4.9 mmol/L
  - Urea 8.7 mmol/L
  - Creat 89 umol/L

28 year old man (contd)

- Duty biochemist adds plasma cortisol
- Cortisol = 68 nmol/L

- Telephoned to ward - ? Addison's
- "Oh, we've sent him home…!"

ACB Best Practice Guidelines (2014)

Reflective testing:

☐ When the reflective test has obvious relevance to the initial test(s) requested and/or to the medical condition being investigated or diagnosed then the additional tests can be performed without necessarily contacting the requestor or patient. However, this general principle might first need to be agreed with the service commissioners and users.

☐ If the reflective test could lead to the identification of a disease not originally considered by the requester or unrelated to the initial test(s), then consent should be sought from the patient, usually via the test requester.

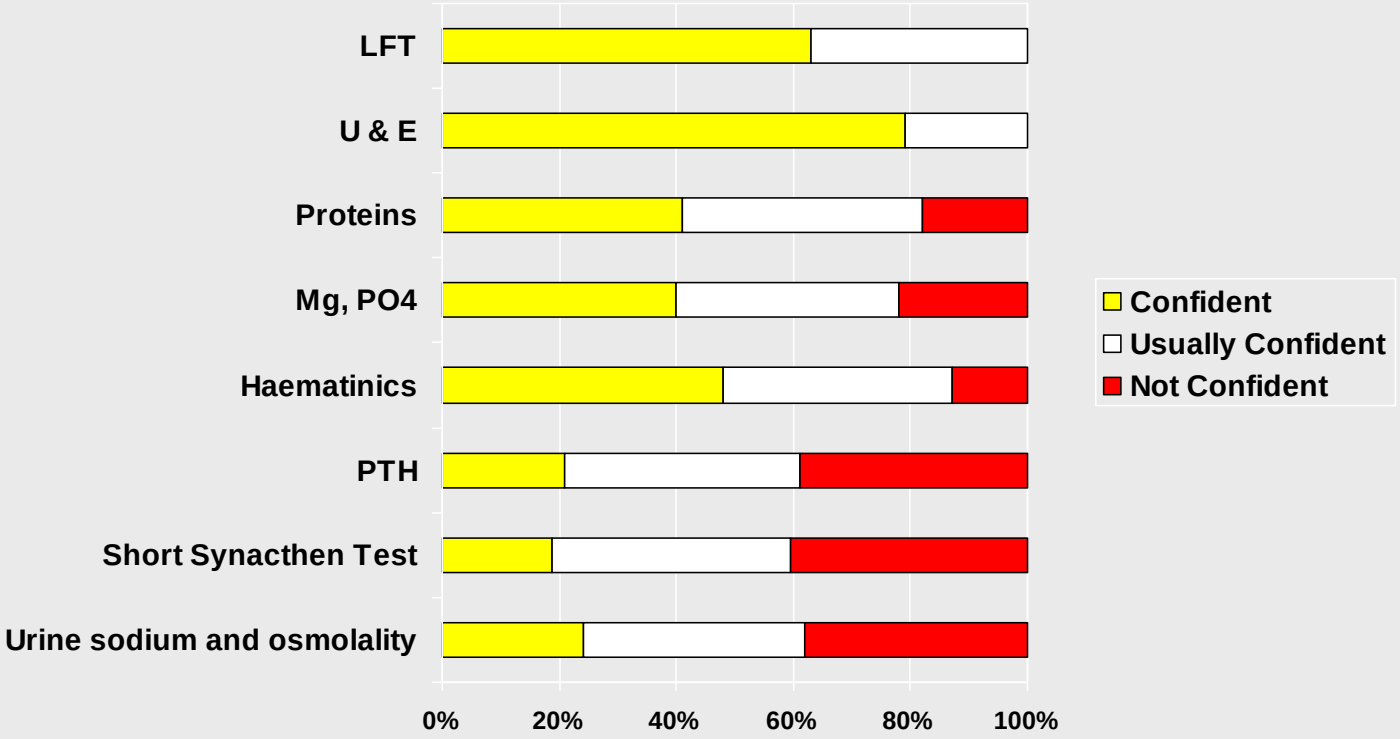
(Kilpatrick, 2014)

Do users understand tests?

- Primary Care Physicians Challenges in Ordering Clinical Laboratory Tests and Interpreting Results

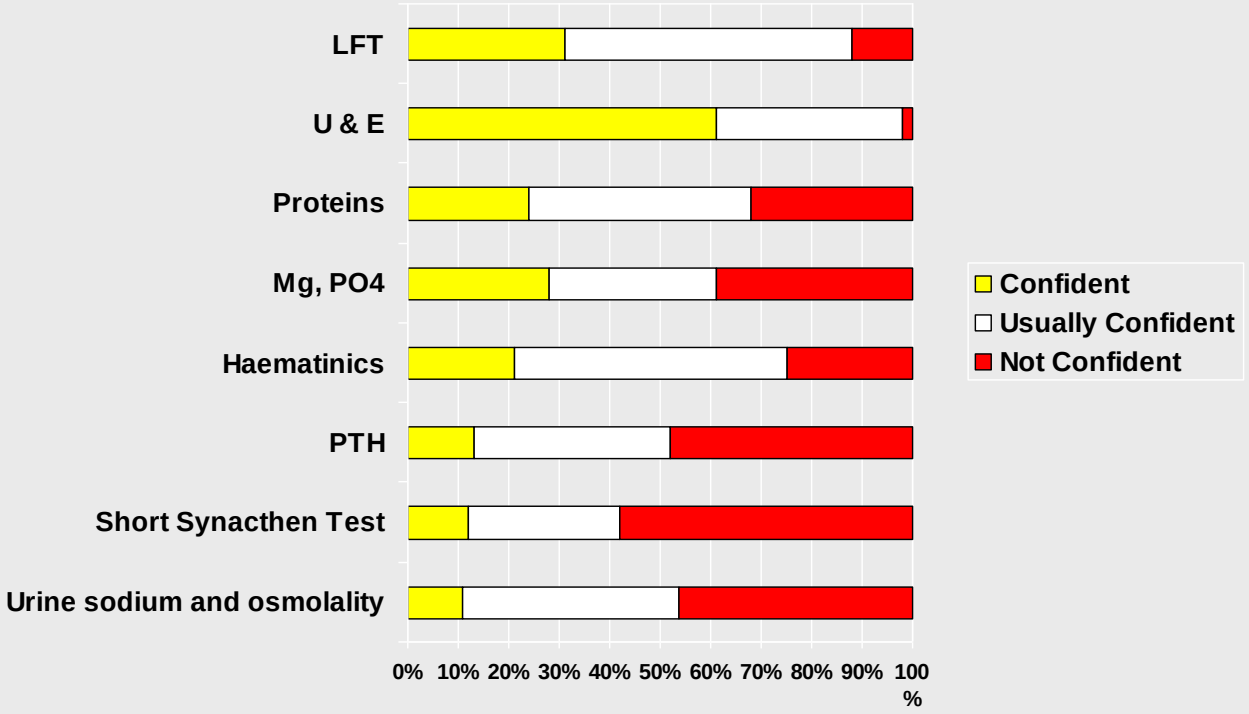
  JABFM 2014; 27: 268-274
- Physicians order tests in 31% of patient encounters
- 14.7% report uncertainty about ordering
- 8.3% report uncertainty about interpreting

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



(Khromova & Gray, 2008)

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



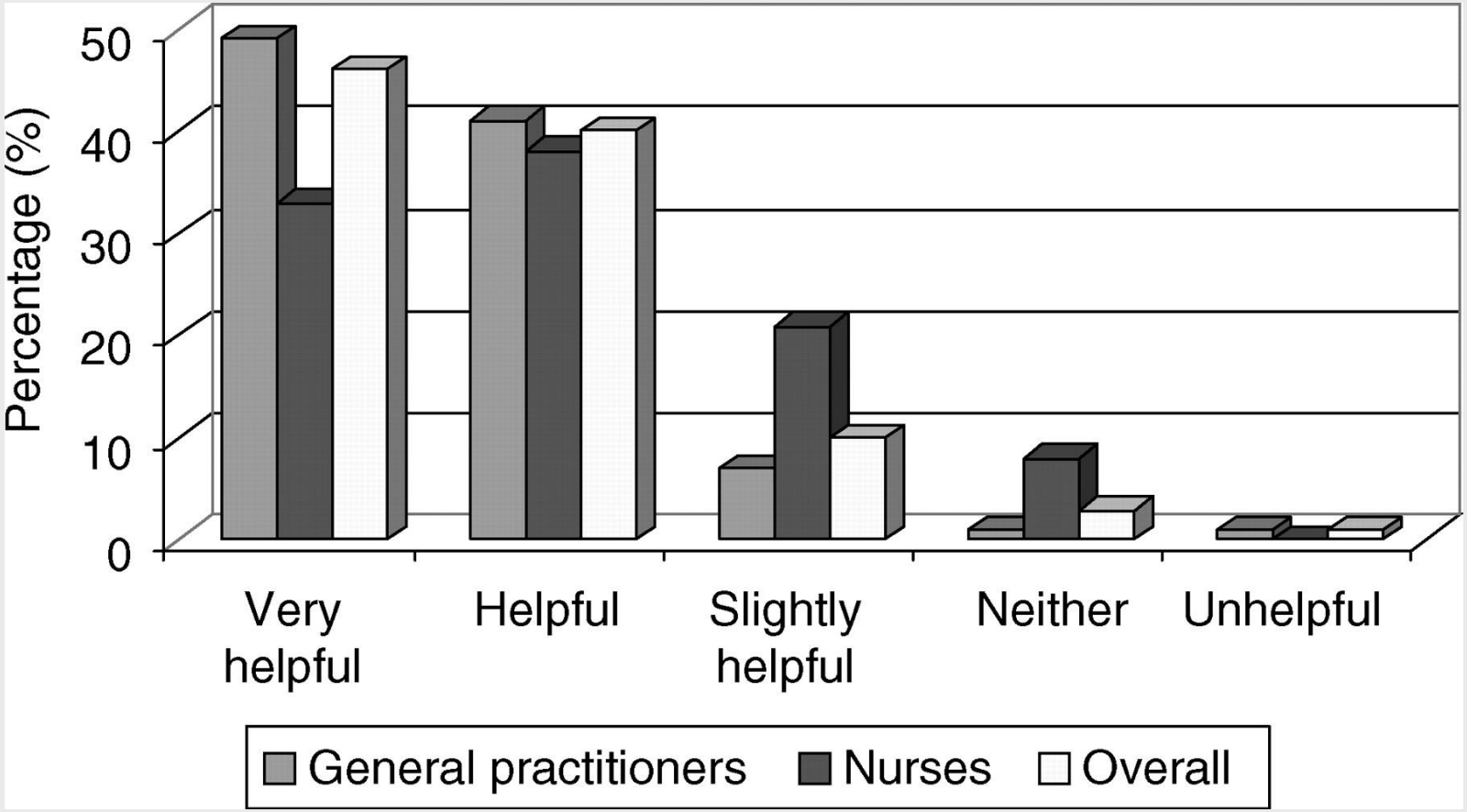
(Khromova & Gray, 2008)

Interpretative comments on reports

- "…interpretative comments include "any additional information on the lab report that may help a clinician better interpret information from the lab"
- "…increases in the number of tests and their complexity have highlighted the difficulties in data interpretation encountered by GP's and physicians receiving laboratory tests"

(Plebani, Clin Chim Acta 2009: 408: 46-51)

Are endocrine comments useful to primary care?



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

Coagulation Interpretations

Physician survey of a lab Medical Interpretative Service (USA)…”

	Yes%	No%
Were the interpretations useful?	98	2
Did the interpretation reduce the time to diagnosis?	59	41
Did the interpretation reduce the number of lab tests?	72	28
Did the interpretation help prevent a misdiagnosis?	72	28

(Laposata M et al. Arch Pathol Lab Med 2004:12)_

ACB Best Practice Guidelines (2014)

Clarity in providing interpretative comments:

- Clarity and lack of unintentional ambiguity
- Comments should add clinical value- stating potential implications of results, further investigations that may address differential diagnosis
- Usefulness depends on knowledge of recipient, i.e. specialists unlikely to benefit
- Identity and designation of person making the comment should be clear on the report

(Kilpatrick, 2014)

Understanding testing

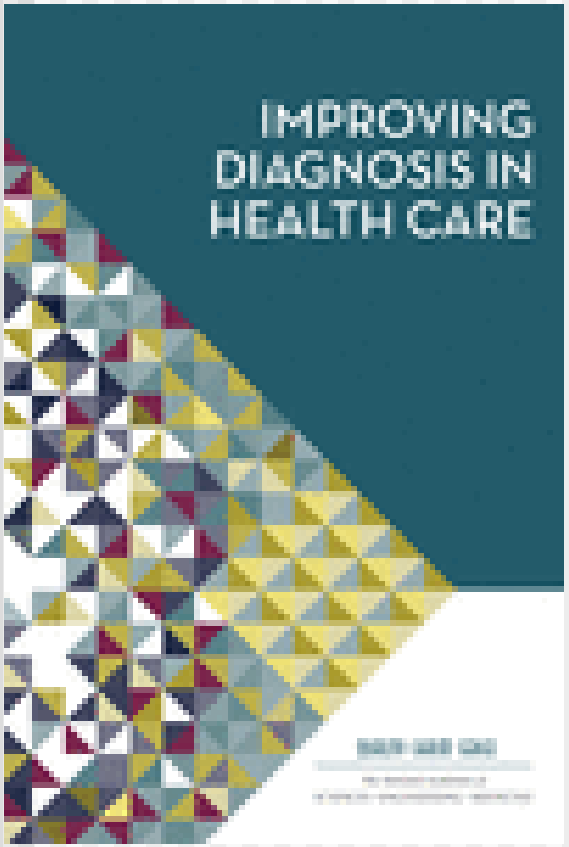
If a disease has a prevalence of 1 in 1000, and the test to detect it has a false-positive rate of 5%, what are the chances that a patient with a positive test actually has the disease?

Daniel Morgan, Washington Post, 5 Oct 2018

“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

IoM report 2015 (USA)



- Goal 2:

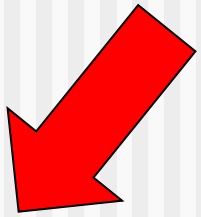
Enhance health care professional education and training in the diagnostic process

- Appropriate use of diagnostic tests

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)

International Health Rankings (Commonwealth Fund, 2014)

	AU	CH	CN	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	CN	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)

6 July 2012 Last updated at 17:59

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.

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Murder trial mum blames hospital

Baby 'poisoned on day of visit'

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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.

Intensive care

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

Michelle Smith

Confession that jury as told she made at Neath police station

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".

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Murder trial mum blames hospital **29 JUNE 2012, SOUTH WEST WALES**
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Baby drug test lab 'foolproof' **20 JUNE 2012, WALES**

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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"

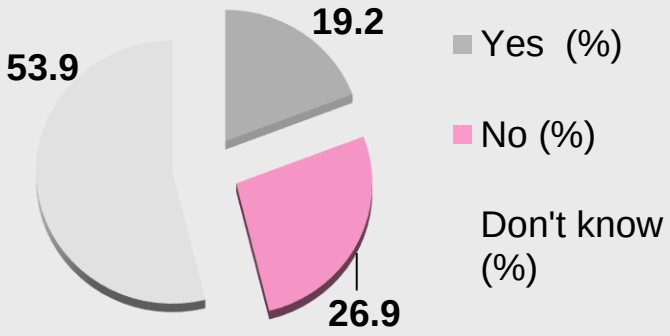
Global trends in critical value practices and their harmonization

Kost GJ and Hale KN

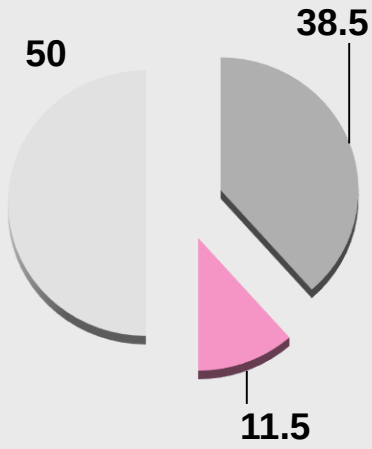
Clin Chem Lab Med 2011; 49: 167-176

Perceptions of missed test results

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



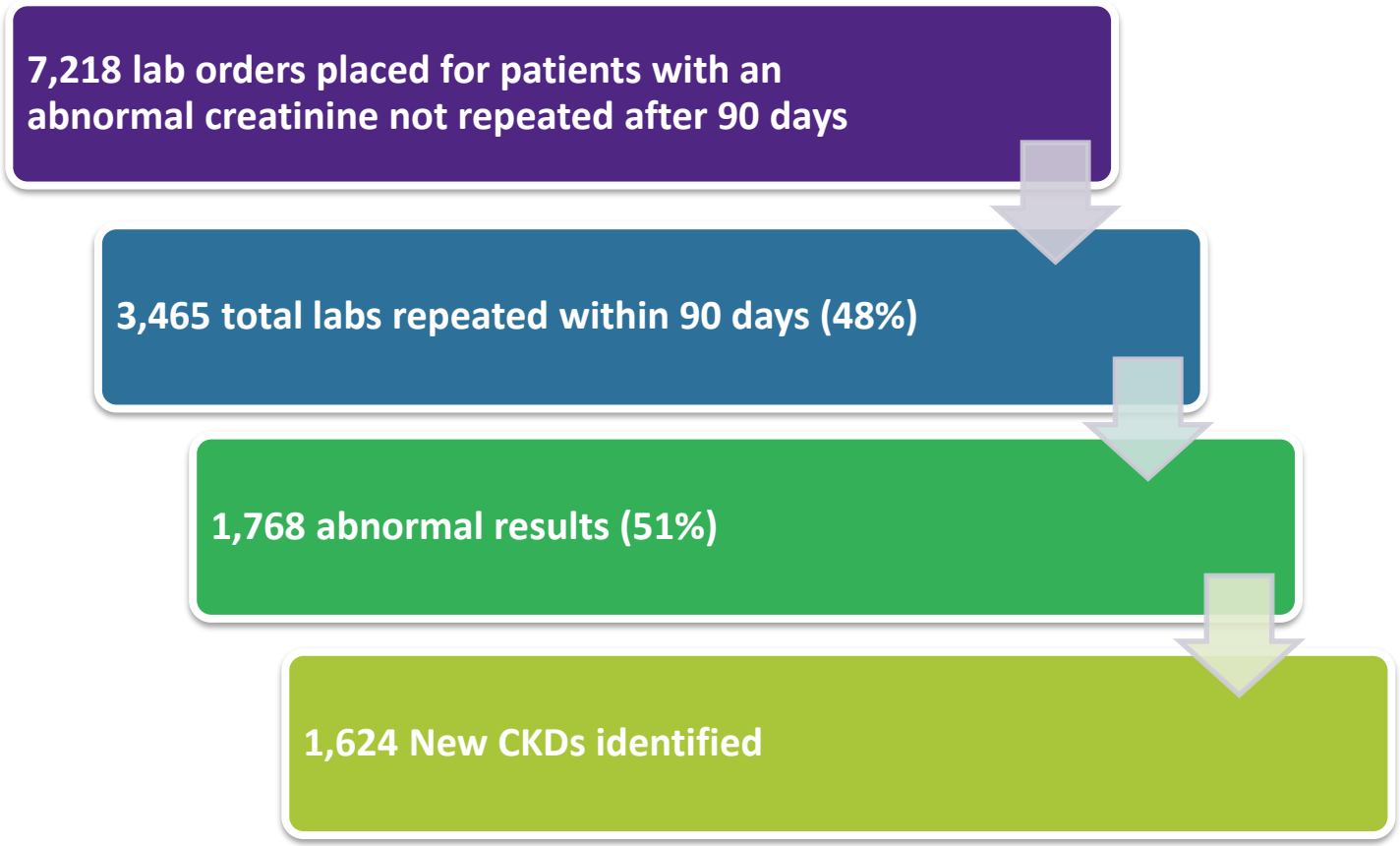
AUSTRALIAN INSTITUTE OF HEALTH INNOVATION FACULTY OF MEDICINE AND HEALTH SCIENCES

(Andrew Georgiou)

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

Diagnosis Detection and Follow Up: Unrepeated Creatinine



M Kanter / Kaiser Permanente

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

Alert thresholds

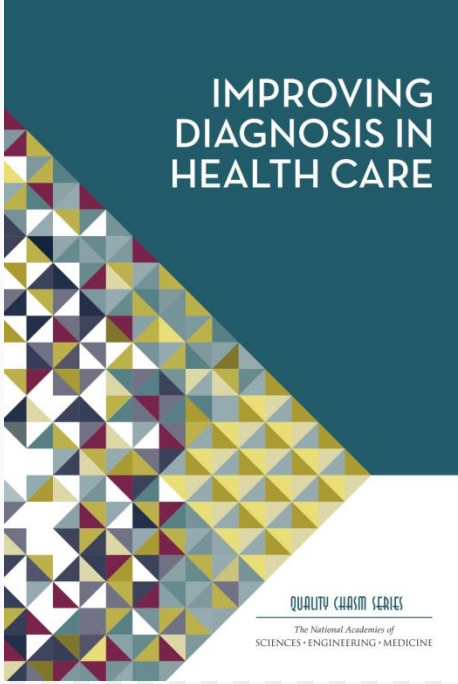
Evidence level	Na- low	Na- high	K- high
4: Individual institutions	115-125	150-160	6.0-7.0
3: Surveys of labs/clinicians	120-125	155-160	6.0-6.5
2: Prof. body recommendations	120	155-160	6.0-6.5
1: Clinical outcome studies	120	155	6.2-7.0

What alert thresholds should be used to identify critical risk results: a systematic review of the evidence.
Campbell CA, Georgiou A, Westbrook JI, Horvath AR.
Clin Chem 2016; 62: 1445-57

Streamlining urgent notification

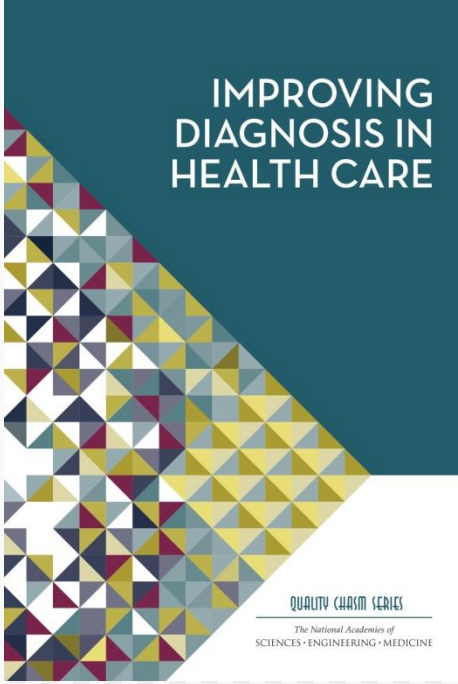
- Corinne Fantz, Emory Healthcare (Atlanta):
- Previous notification limits
  Potassium <3.0 or >6.0 = 230 calls/week
- After adjusting limits in line with peer group
  Potassium <2.7 or >6.1 = 122 calls/week
- Arch Pathol Lab Med survey reported 6.1 min for inpatient and 13.7 min for outpatient calls –at both ends!!

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

- 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

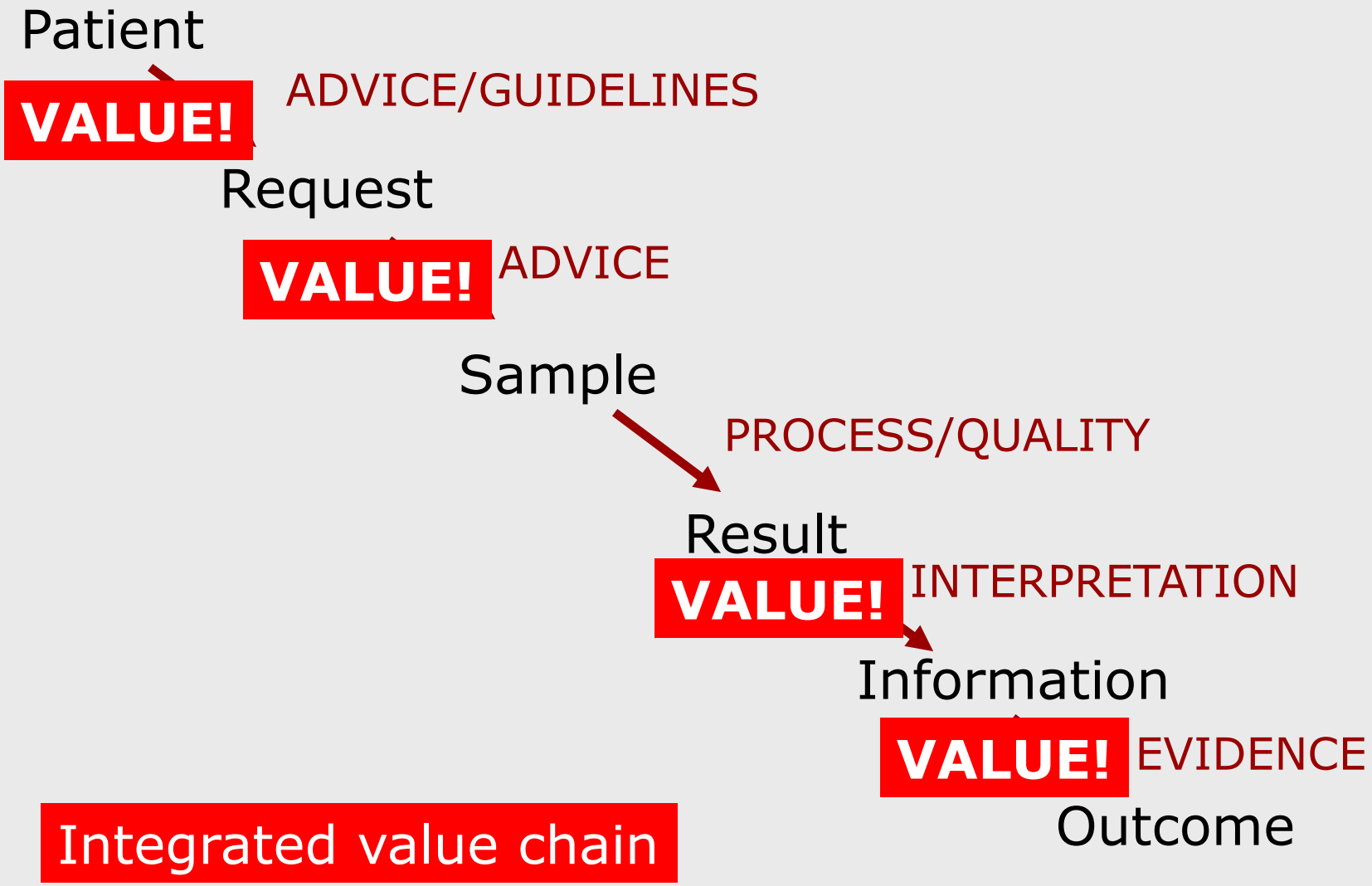
Hoffman TC, del Mar C. JAMA Intern Med 2015

LAB TESTS ONLINE UK

Your Trusted Guide

Peer Reviewed • Non-Commercial • Patient Centred

Laboratory medicine



Integrated value chain

Improving lab performance

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

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

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