Applying the Principles of Evidence-Based Laboratory Medicine

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Evidence-Based Laboratory Medicine

“conscientious, explicit and judicious use of current best evidence on medical tests in making decisions about the care of individual patients”

Price and Christenson 2003 from Sackett et al 1996
Evidence-Based Medicine

Patient concerns and values

EBM

Best research evidence

Clinical experience

Guyatt et al 2002
Evidence-Based Medicine

“......trying to improve the quality of the information on which decisions are based.”

“...... is not about mechanisms but about outcomes.”

Glasziou et al 2003
Quality Agenda in Health Care

relevance of laboratory medicine to outcomes

- Safe – avoiding harm
- Patient centred – respecting needs and values
- Timely – minimising delays
- Efficient – avoiding waste
- Equitable – equal quality
- Effective – evidence-based outcomes

Institute of Medicine 2001
Evidence-Based Laboratory Medicine
the context of health care today

Effective  Efficient  Affordable

we secure the best value for patients and taxpayers, meaning (i) the best possible health outcomes, (ii) the best possible healthcare, (iii) within the resources made available........
McKesson and Innosight believe that the only way to make that leap to a healthcare system based on value — one that pays less and generates better outcomes — is through system-wide transformative innovation in all phases of healthcare delivery and financing.
The transformative designation should signal, within the UK and internationally, a product’s strategic importance to the NHS. It should be reserved for the small number of products that have the potential to provide significant benefits in either patient outcomes or NHS costs.
Evidence-Based Laboratory Medicine foundation and evidence requirement

“Do patients who undergo this diagnostic test fare better (in their ultimate health outcomes) than similar patients who are not tested?”

Sackett and Haynes 2002

“The value of a diagnostic test is not simply measured by its accuracy, but depends on how it affects patient health.”

Ferrante di Ruffano et al 2012
Laboratory Medicine Services
why order a test?

PATIENT

question ● test ● decision ● action

OUTCOME
Laboratory Medicine: why we order tests patient benefit and healthcare efficiency
But ..... Utilisation of Tests Varies
slow adoption and variation in use

Atlas of Variation in Diagnostic Services 2013
But ......... Inappropriate Ordering of Tests under-utilisation and over-utilisation

“Ideally no medical decision is made without a reason”

Zhi et al 2013
But ……… Utilisation of Tests
results not acted on, so benefits not delivered?

Use of computer terminals on wards to access emergency test results:
a retrospective audit
Eric Kilpatrick and Stephen Holding BMJ 2001

“The results from 1443/3228 (45%) of urgent requests from accident and emergency and 529/1836 (29%) from the admissions ward were never accessed via the ward terminal”.

The safety implications of missed test results for hospitalised patients:
a systematic review
Joanna Callen, Andrew Georgiou, Julie Li, Johanna I Westbrook BMJ Qual Saf 2011

“A lack of follow-up of test results for inpatients ranged from 20.04% to 61.6% and for patients treated in the emergency department ranged from 1.0% to 75% when calculated as a proportion of tests”.

But .... Ignorance of the Actual Pathway ‘events’ in women receiving chemotherapy

Baker et al. 2017
Perspectives on Outcomes in Healthcare
.... and who is the customer?

outcomes

affordability

ENVIRONMENT
payor, regulator

PURCHASER

PROVIDER

CARER

PATIENT

QUALITY
Quality and Innovation in Medical Interventions
EBLM and the pathway to adoption of a new test
Laboratory Medicine Questions
the classical research evidence development strategy

• biobank mining
• (pathophysiology)
• analytical method
• diagnostic performance

• health outcome
Biomarker Change and Disease Activity
the basic science of laboratory medicine

Kuster et al 2003
The Laboratory Medicine Service Objective answering questions to solve problems

presentation

history

monitor

examination

treat

tests

plan

diagnosis

explain

discuss

ACT

ASSESS

TREATMENT

DIAGNOSIS

PHYSICIAN

PATIENT

DECIDE
Types of Questions

Background questions

- is the test elevated in this condition?
- what is the pathological cause of the elevation?

Foreground questions

- will this help with my diagnosis?
- will this test help my treatment?
Utility of a New Biomarker
how and where will it be used in the care pathway?
Evidence-Based (Laboratory) Medicine Cycle

Clinical/Policy Problem

Ask

Audit

Acquire

Apply

Assess

A5 cycle
Asking the Right Question
formulating an answerable question (PICO)

- Population
- Indicator (test, intervention, etc)
- Comparator
- Outcome
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Patient - characteristics
- signs, symptoms, co-morbidities
- setting
- time

Test - application
- position in care pathway
- decision and action
- process change

Current practice - application
- position in care pathway
- decision and action
- process

Performance:
- e.g. diagnosis
Outcome
- clinical
- operational
- economic

Screening Diagnosis Treatment (optimisation) Monitoring
Identifying the Unmet Needs in Heart Failure diagnostic triage in primary care

- P - breathless patients in primary care
- I - plasma BNP
- C - two cardiologists review
- O - ‘rule-in’ or ‘rule-out’ heart failure
Identifying the Unmet Needs in Heart Failure guided therapy and improved health outcome

- **P** - patients with heart failure
- **I** - plasma BNP
- **C** - current clinical practice
- **O** - achieve target BNP value
Identifying an Unmet Need in Oncology risk of heart failure with chemotherapy

• P - patients on chemotherapy
• I - plasma BNP
• C - two cardiologists review
• O - ‘rule-in’ or ‘rule-out’ heart failure
Evidence-Based Laboratory Medicine
the four stages of service delivery

• assess health care need
  - role and place in the care pathway
• specify services required
  - resource and process needs; expected outcomes
• secure services
  - and performance metrics
• monitor and evaluate outcomes
  - including clinical operational measures
Heart Failure Diagnostic Pathway
prior to access to natriuretic peptide service

15,372 activities

Alan Lewitsky, NHS Improvement 2010
Heart Failure Diagnostic Pathway with access to natriuretic peptide service

15,372 activities

Alan Lewitsky, NHS Improvement 2010
Adopting a New Biomarker
an evidence-based approach

IDENTIFY UNMET NEED

Setting strategic direction and pathway design

Evaluating impact/outcomes

Specifying services

Contracting

A5 cycle
Ask
Audit
Acquire
Apply
Assess

making the business case
Making the Business Case for a Test beginning with the problem

• Identify (and quantify) the unmet need
• Identify the relevant outcome metrics
  - clinical, process and resource
• Impact on clinical decision making
• Impact on/for stakeholders
• Next steps
  - implementation plan
  - performance management
Making the Business Case
the practical questions

- Research question (the unmet clinical need)?
- Is there good evidence available on use of the test?
- Test? *Has it been approved? Is the analytical performance good?*
- Turnaround time? *What is the care pathway need?*
- Decision and action? *Has this been thought through?*
- Process change? *Is it achievable?*
- Outcome expected? *Do we need a pilot? Should we model?*
Quality Metrics and Diagnostic Services resources, process and outcomes

- Analytical quality
- Delivery quality
- Financial quality
- Meeting clinical needs
- Facilitating care pathway
- Improving patient outcomes

PATHOLOGY

PATIENT JOURNEY
Innovation and Continuous Quality Improvement

expected outcomes

Outcomes
- clinical
- operational
- economic

Structure
- staff
- estate
- consumables

Processes
- time
- location
- integration

Donabedian 2003
Performance Management of a Service

- Laboratory service
  - number of tests performed, turnaround time
- Clinical application
  - test utilisation – normals, abnormals, repeats etc
- Change of practice
  - echo utilisation; how many positives and negatives
  - cardiology referrals
- Clinical outcomes
  - diagnoses made, diagnoses missed
- Economic outcomes
  - change in hospital contracts, disinvestment
Adopting a New Biomarker performance management (audit) of adoption

ADDRESS UNMET NEED

- Setting strategic direction and pathway design
  - Ask
  - Audit
  - Acquire
  - Apply
  - Assess
  - A5 cycle

- Collect performance management data
- Specifying services
- Review data against care pathway
- Contracting
- Evaluating impact/outcomes
- Review and revise practice
- Apply revised practice and repeat audit
Evidence-Based Laboratory Medicine
the key points in routine practice

- Making the case for using a test
- Impact on clinical decision making
- Impact on treatment intervention
- Impact on health outcome
- Impact on care process
- Impact on resource requirement
Evidence-Based Laboratory Medicine
the key challenges

problem ➔ evidence ➔ outcome

• clinical need ➔ question + evidence
• appropriate use ➔ decision + action
• effective use ➔ change practice + add value
Thank you!