Evidence-based Laboratory Medicine

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Content

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• History
• Challenges
• Steps
• Appraising evidence
• Tools
• Criticism
• Barriers
“......although the laboratory represents a small percentage of medical centre costs, it leverages 60-70% of all critical decisions, e.g. admission, discharge and drug therapy.”

Forsman RW. Clin Chem 1996;42(5):813-6
History

EBM – McMaster University Canada – Guyatt et al

• “Kaozheng”: practicing evidential research – used in interpretation of ancient Confucian texts
• 4th century: Plato described clinical guidelines
• 17th century Paris: bleeding therapy for cholera – higher mortality
• 18th century: 1769 Morgagni used autopsy to study disease
• 19th century Paris: philosophical origins

Past 30 years – a lot of interest in EBM
Evidence-based medicine (EBM)

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

Integration of BEST RESEARCH EVIDENCE with CLINICAL EXPERTISE and PATIENT VALUES

EBLM

- About diagnostic tests – relationship between a biomarker and pathology of disease
- Less clinical and more about rational use of resources
- Diagnostic performance or comparing tests
- Laboratory medicine an integral part of practice of medicine
Challenges

- >30 000 biomedical journals published annually
- >17 000 new medical books annually
- >6000 articles per day on internal medicine
- Systematic reviews: many studies inadequate and misleading
- Need minimal standards (critical appraisal)
Challenges (2)

- Increasing healthcare costs – payers want evidence
- General public more educated and want best tests (Dr Google)
Why do we need EBLM?

Pressure to do more:
• Increasing population
• Ageing population
• Chronic diseases
• New tests / technologies
• Budget constraints
• Management culture
• Rationalization
• POCT
• Private providers
• Public expectation

Pressure to do less:
• Budget constraints
• Management culture
• Public sector constraints
• Rationalization
Steps in EBLM process

• Formulate answerable question
• Track down best evidence
• Critically appraise evidence
• Implement policy based on evidence
Outline of the evidence-based laboratory medicine process

- **Ask**
  - Convert information needs into answerable, clinically relevant questions

- **Find**
  - Track down the best evidence for answers

- **Appraise**
  - Critically appraise the evidence for validity and usefulness (rate strength)

- **Act**
  - Apply results of this appraisal in laboratory practice

- **Audit**
  - Evaluate (audit) performance
## Structured PICO & CAPO question formulation

<table>
<thead>
<tr>
<th>PICO</th>
<th>CAPO</th>
<th>Question</th>
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<tbody>
<tr>
<td><strong>P: Patient population</strong></td>
<td>C: Case</td>
<td>What are the patient characteristics, symptoms and demographics? Consider the condition that may be present.</td>
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<tr>
<td>I: Intervention</td>
<td>A: assay or laboratory procedure</td>
<td>Which laboratory medicine procedure or strategy is considered?</td>
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<tr>
<td>C: Comparison</td>
<td>P: Predicate (reference standard)</td>
<td>What is the reference standard or predicate method?</td>
</tr>
<tr>
<td>O: Outcome</td>
<td>O: Outcome</td>
<td>What is the endpoint of interest?</td>
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<tr>
<td>Phase I</td>
<td>Phase I. Do patients with the condition have different test results compared with normal controls? (Diagnostic Sensitivity)</td>
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<tr>
<td>Phase II</td>
<td>Do patients with specified test results have a higher probability of the condition compared with patients with other results for the test? (Specificity)</td>
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<td>Phase III</td>
<td>Among patients having the same pre-test probability (that is, the same clinical presentation), does the test distinguish those who have the condition from those who do not? (Positive and Negative Predictive Values)</td>
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<tr>
<td>Phase IV</td>
<td>Do patients who have the test performed have better outcomes compared with those who do not? (Prognosis or Risk Stratification)</td>
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Articles

Systematic reviews:
• Valuable EBLM tool
• Concise summary of best available evidence from primary studies
• Explicit methods to critically review and synthesize evidence
• Do not always produce a definite answer

Metaanalysis:
• Statistical methods to combine results of numerous studies
• Results presented in a graphic form as odds (or risk) ratio with 95% CI
• No effect: RR 1
• NB Bias
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Risk Ratio 95% CI

Favors Treatment
Favors Control
Standard Meta-Analysis
Bias

- **Population** bias – how as population selected?

- **Verification** bias – gold standard?

- **Review** bias – if not blinded to results underestimate test accuracy

- **Publication** bias – positive results

- **Language** bias
Evidence-based laboratory medicine at the core of continuous quality improvement
Tools for continuous quality improvement

1. Clinical guidelines
   • Systematically developed statements to assist clinician and patient decisions for specific clinical circumstances
   • Consistency of care – decided by experts
   • Translation of research
   • Lot of time and effort
   • Poor evidence – poor quality
Tools for continuous quality improvement (2)

2. Care maps

- Optimum steps in process of care with standards for each step to allow comparison to best practice
- Grid with readily obtainable outcome measures
- Relies on good-quality evidence
- Do they optimize and improve care?
- Benchmarking
Tools for continuous quality improvement (3)

3. Assessment of outcomes

• Effectiveness of care
• May suggest review and updating of guidelines
• Clinical audits
Criticism of EBLM

• EBM is outrageously exclusionary” and even “microfascism” in the way it sifts knowledge

• By anointing only a small sliver of research as best evidence and discarding physician judgement and more than 90% of the medical literature, patients are forced into a one-size-fits-all straight-jacket

• The best EBM should be integrated into medicine, not be at odds with it

US News, September 11, 2006
Barriers

• Translating results into everyday practice a major challenge

• Finding information

• Accessibility and user friendliness of results

• Guidelines must be relevant, easy to use, widely disseminated and updated

• Educational tools
Potential solutions

• Information overload and public more knowledgeable and demanding

• Need best available evidence for appropriate use of lab tests

• Critical appraisal of evidence

• Team work and clinical liaison

• Advise on use of tests – demand management

• Interpretative comments
Conclusion

- Develop a clinical question
- Locate the evidence
- Diagnostic performance
- Appraise
- Develop clinical pathway
- Audit
DEMAND EVIDENCE AND THINK CRITICALLY