Influencing Clinical Outcomes

Mike Hallworth
The problem

- All of us believe laboratory medicine has a role in patient care
- Lots of anecdotes, little hard evidence
- We take refuge in the “70% claim”
  - ‘Laboratory medicine data influences 70% of clinical decisions’ – or similar
- Evidence for this is also poor
Editorial

The ‘70% claim’: what is the evidence base?

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IFCC Taskforce on the Impact of Laboratory Medicine on Clinical Outcomes (TF-ICO)

- Established following proposal by CPD, reporting to EB
- Objectives
  - To evaluate the available evidence supporting the impact of laboratory medicine in health care
  - 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
Who are we?

Mike Hallworth (UK)  Flor Vanstapel (BE)  Trefor Higgins (CN)  Eric Kilpatrick (UK)  
Corinne Fantz (US)  Sherry Faye (Beckman Coulter)  S V Rana (IN)  
Wenzhe Li (US)

Plus Christoph Ebert (Roche – not pictured)
What are we doing?

First project:
- First project:
- Proposed Special Report – Clin Chem
  “Measuring the current and future role of laboratory medicine in influencing clinical outcomes’
- Summarize the problems
- Identify solutions
- Propose a plan..
The problems

- ‘Outcomes’ = ‘results of medical interventions in terms of health or cost’ (Bissell, quoted by Bruns, 2000)
- Question is not:
  - “Does the test result predict an outcome of interest?”
- But:
  - “Is the use of the test associated with an improved outcome?”
- Differentiate diagnostic accuracy and clinical utility
  - (factors such as physician inaction, result misdirection, time etc. interfere)
Solutions

- More, better-targeted research
- Specific guidance on trial design and interpretation
- Checklist for suitable outcome studies
Areas of work

- Review existing work
  - Lewin Group, AHRQ, CER etc
- Role of the lab in defining and monitoring standards of care
  - Guidelines (CHD, diabetes as paradigms)
- The role of the lab in preventing misdiagnosis (incl overdiagnosis) -
  - Work with P Epner/ITSRI project (“Improvements in Tests Selection and Results Interpretation”)
  - “Diagnostic Error in Medicine” conference
Areas of work (2)

- Defining lab quality markers associated with patient outcomes (turnaround/LOS etc)
- Producing/summarizing checklists for outcome studies suitable for RCTs
- Describing alternatives to RCTs for diagnostic tests
  - How can IT/EMRs help?
- Examples in targeted fields of well-conducted outcome studies
How can you help?

- What have we missed?
- What can your Task Force/Working Group contribute?

  - All comments/contributions gratefully received:
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  - Or via IFCC Office