Demonstrating the Value of Laboratory Medicine

Making the case for a value proposition

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The value proposition for laboratory medicine

Dr Andrew St John, ARC Consulting, Perth, Western Australia
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2014 - present

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Laboratory Medicine at the centre of the Healthcare system

Laboratory Medicine is part of the multi-disciplinary team at the centre of healthcare

With this influence comes responsibility!
Laboratory Medicine: The Process

1. Patient
2. Need for Laboratory Medicine
3. 4a Pre-analytical
4. Laboratory Medicine Phases
5. 4c Post-analytical
6. 4b Analytical
## Laboratory Medicine: Three Phases

<table>
<thead>
<tr>
<th>Pre-Analytical</th>
<th>Analytical</th>
<th>Post Analytical</th>
</tr>
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<tbody>
<tr>
<td>Test selection</td>
<td>Specimen processing</td>
<td>Data into knowledge</td>
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<td>Clinical reporting</td>
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<td>Result validation</td>
<td>Clinical follow-up</td>
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- 46-68% Lab errors*  
- <10% Lab errors  
- 18-47% Lab errors*  

* Plebani M. *Clin Chem Lab Med* 2006; **44**: 750-9
Laboratory Medicine: Quality Ladder
Laboratory Medicine: Quality Ladder

1. Analytical Quality

2. Pre-analytical Quality

3. Post-analytical Quality

4. Quality Management / Lab Accreditation

5. Adding Value
Adding Value to Laboratory Medicine

Continuous laboratory quality improvement

Develop

Improvement in efficiency and cost effectiveness

Improvement in clinical outcomes

‘Adding Value’

Adding Value occurs largely ‘outside’ the laboratory. It is a professional responsibility shared with national and international bodies.
Laboratory: Improving Clinical Effectiveness

Expanding contribution from laboratory medicine specialists

- National screening programmes
- Clinical risk assessment
- Rapid diagnosis
- Direct to right medical team

- Improve patient outcomes
- Support clinical users
- Manage point of care testing
- Monitor response to therapy
- Facilitate further testing or therapy

- ‘Hands on role’
- Clinical validation, interpretation
- Clinical advice, audit

Successful contribution is predicated on a high quality laboratory service
Laboratory: Improving Clinical Effectiveness

Highly trained laboratory professionals

Clinical risk assessment
Rapid diagnosis
Direct to right medical team

Improve patient outcomes
Manage point of care testing
Monitor response to therapy
Facilitate further testing or therapy
Clinical validation, interpretation
Clinical advice, audit

‘Hands on role

Successful contribution is predicated on a high quality laboratory service

How do we demonstrate our competence for these responsibilities?
Current demands on healthcare delivery including laboratory medicine

• Improving quality and patient safety
• Containing costs
• Delivering value-for-money
Limitations arising from our current concepts of Laboratory Medicine
Laboratory Medicine: The Process
Laboratory Medicine: The Process

Phases:
1. Doctor
2. Need for Laboratory Medicine
3. Pre-analytical
4a. Pre-analytical
4b. Analytical
4c. Post-analytical
Laboratory Medicine: Three Phases

Pre-Analytical | Analytical | Post Analytical

Test selection | Specimen processing | Data into knowledge
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46-68% Lab errors* | <10% Lab errors | 18-47% Lab errors*

* Plebani M. *Clin Chem Lab Med* 2006; **44**: 750-9
Can we further reduce errors without ‘revolutionising’ our practice?

Proposal: Laboratory Medicine: Value Ladder
Proposal: Laboratory Medicine: Value Ladder

1. Increased efficiency: automation and POCT
2. Cost effectiveness
3. Clinical Laboratory Management
4. Evidence-Based Laboratory Medicine
5. Delivering Value through the Value Proposition
So what is the Value Proposition in Laboratory Medicine?
Value in healthcare

- Value defined as “Health outcomes achieved per dollar spent”

- “Cost reduction without regard to the outcomes achieved is dangerous and self-defeating, leading to false “savings” and potentially limiting effective care”
Value of Pathology Campaign in Australia
How can we improve the evaluation and determine the economic impact of tests?
Test evaluation – poorly performed!

• Barriers to complete test evaluation
  • Frequently complex intervention
  • Indeterminate outcomes
  • RCTs not always possible
  • Cost
Cyclical framework for the evaluation of in vitro medical tests.

This framework illustrates that the key components of the test evaluation process are driven by the purpose and role of using a test in the clinical pathway.
How can we improve the evaluation and determine the economic impact of tests?

Tests could be considered as a form of a Value Proposition as used in business.
Definition of a value proposition:

“A clear, simple statement of the benefits, both tangible and intangible, that the company will provide, along with the approximate price it will charge each customer segment for those benefits”.
Components of a commercial value proposition

• Identify the customer
• Understand what the customer values
• Define the product or service
• Identify the benefits of the product or service to the customer, including cost
• Identify the benefits of the product or service to the customer, including the competition
• Present the proof to substantiate claims
<table>
<thead>
<tr>
<th>Commercial Value Proposition</th>
<th><strong>Laboratory Medicine Value Proposition</strong></th>
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<tbody>
<tr>
<td>Identify the customer</td>
<td>Key points:</td>
</tr>
<tr>
<td>Understand what the customer values</td>
<td>• Clinical pathway</td>
</tr>
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<td>Define the product or service</td>
<td>• Need for change</td>
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<tr>
<td>Identify the benefits of the product or service to the customer, including cost</td>
<td>• Multiple stakeholders (&amp; Silos)</td>
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<td>Identify the benefits of the product or service to the customer, including the competition</td>
<td>• Economics increasingly important</td>
</tr>
<tr>
<td>Appraise proof to substantiate claims</td>
<td>• Measuring what we implement</td>
</tr>
<tr>
<td></td>
<td>• Laboratory to drive process</td>
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# Commercial & Lab Med Value Proposition

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<tr>
<td>Identify the customer</td>
<td>Who are the customers and the relevant stakeholders?</td>
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<tr>
<td>Understand what the customer values</td>
<td>What is the unmet need?</td>
</tr>
<tr>
<td>Define the product or service</td>
<td>What is the care pathway?</td>
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Target Population & Setting

Potential Benefits: TP, TN, Improved health, Operational & Economic outcomes

Potential Harms: FN, FP, Impaired health, Operational & Economic outcomes

Management Decision

- Therapeutic intervention
- Other intervention

Current Test(s)
- Diagnosis
- Monitoring
- Prognosis

New Test(s)
- Specify position & role; (add-on, replacement, triage)

Clinical Pathway Mapping

Outcomes
- Potential Benefits: TP, TN, Improved health, Operational & Economic outcomes
- Potential Harms: FN, FP, Impaired health, Operational & Economic outcomes
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<td>What is the test and its utility/ies?</td>
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<td>What are the benefits of using the test?</td>
</tr>
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<td>What are the resource requirements?</td>
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| Identify the benefits of the product or service to the customer, including the competition | What is the **impact on outcomes**?  
What change in **practice** is required to deliver these outcomes?  
What change in **process** is required to deliver these outcomes?  
What change in **resource requirement** is likely?  
**Who is accountable** for delivering this value proposition?  
What are the **translation challenges**?  
What are the **implementation metrics**? |
<p>| Appraise proof to substantiate claims |  |</p>
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<td>What is the evidence of <strong>clinical effectiveness</strong>? What is the evidence of <strong>cost effectiveness</strong>?</td>
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Challenges when using a test as an intervention

- Unmet Clinical Need
- Clinical Setting
- Test Result
- Clinical Decision
- Clinical Action
- Health Outcome

Resource Investment
Resource Disinvestment
Practice Change
Process Change
Budget or Financial Silos – Inhibit innovation and change in practice

- Medical specialties
- Surgical specialties
- Pediatrics
- Geriatrics
- Lab Medicine
- Radiology
- Pharmacy
- Emergency Dept.

Organisation

Patient Pathway
Validation of a high-sensitivity troponin I in a 2-h diagnostic strategy to assess 30-day outcomes in emergency-department patients with Possible acute coronary syndrome
### Steps in the Value Proposition for use of high-sensitive Troponin assays

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<tr>
<th>Step</th>
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<td>1.</td>
<td>Unmet clinical need</td>
</tr>
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<td>2.</td>
<td>Test</td>
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<td>3.</td>
<td>Patient population</td>
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<td>4.</td>
<td>Test intervention utility</td>
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<td>5.</td>
<td>Outcome</td>
</tr>
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<td>6.</td>
<td>Location where test is performed</td>
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<td>7.</td>
<td>Quality of evidence available</td>
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<td>8.</td>
<td>Part of the care pathway in which the test will be used</td>
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<td>Stakeholders involved in delivering/receiving care identified in care pathway</td>
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<td>10.</td>
<td>Benefits/disadvantages to each stakeholder in relation to outcome identified above</td>
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<td>Resource/activity contributed by each of service lines involved in care pathway with and without test intervention</td>
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<td>Implementation plan including metrics for monitoring appropriate adoption</td>
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**Key Steps** in the Value Proposition for use of high-sensitive Troponin assays

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| 9.   | Stakeholders involved in delivering/receiving care identified in care pathway  
Patient  
ED Physician  
Cardiologist  
Hospital/Healthcare provider  
Payer/Insurer  
Laboratory |
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<th>10. Benefits/Disadvantages to stakeholders involved in delivering/receiving care identified in care pathway –</th>
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| **Patient** – greater satisfaction through less time spent in ED  
**ED physician** – can process more patients through rapid discharges  
**Cardiologist** – may receive more referrals (false positives?)  
**Hospital/Healthcare provider** – may have to invest in redesigned ED to assist with redesigned protocol but will be able to meet ED discharge targets  
**Insurer/Payer** – reduced costs through more rapid discharges  
**Laboratory** – has to meet rapid TAT targets; test may cost more. |
Key Steps in the Value Proposition for use of high-sensitive Troponin assays

12/13. Resource/activity contributed by each of service lines involved in care pathway with and without test intervention

   The economics of the new intervention:
   • Significant financial benefits of increased ED capacity because of more rapid discharge of non ACS patients
     versus
   • Increased costs due to more referrals to cardiologists of patient with abnormal troponin results; and possibly more expensive tests including hs Troponin.

14. Implementation plan including metrics for monitoring appropriate adoption

   Making sure that what is planned is implemented
   Modifying implementation plan to facilitate adoption
   Achieving the right balance of investment/disinvestment
Summary

• Laboratory Tests can also be considered as a form of a Value Proposition

• The concept requires careful identification of all the steps and stakeholders in the patient care pathway where the test is used.

• Greater efforts are required in the economic assessment of the complete care pathway, and with implementation and audit.

• The Laboratory has to develop greater collaboration with clinicians and with other key healthcare stakeholders.

• And there is the opportunity for the Laboratory to take leadership on how the test is used and generate the value proposition.