

# Demonstrating the Value of Laboratory Medicine

## Making the case for a value proposition

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Adelaide, South Australia

## The value proposition for laboratory medicine

Dr Andrew St John, ARC Consulting, Perth, Western Australia

# Acknowledgements:

- Dr Graham Beastall, IFCC Past-President (2015,16); IFCC President (2009-2014)
- IFCC Executive Board 2012-2014

2014 - present

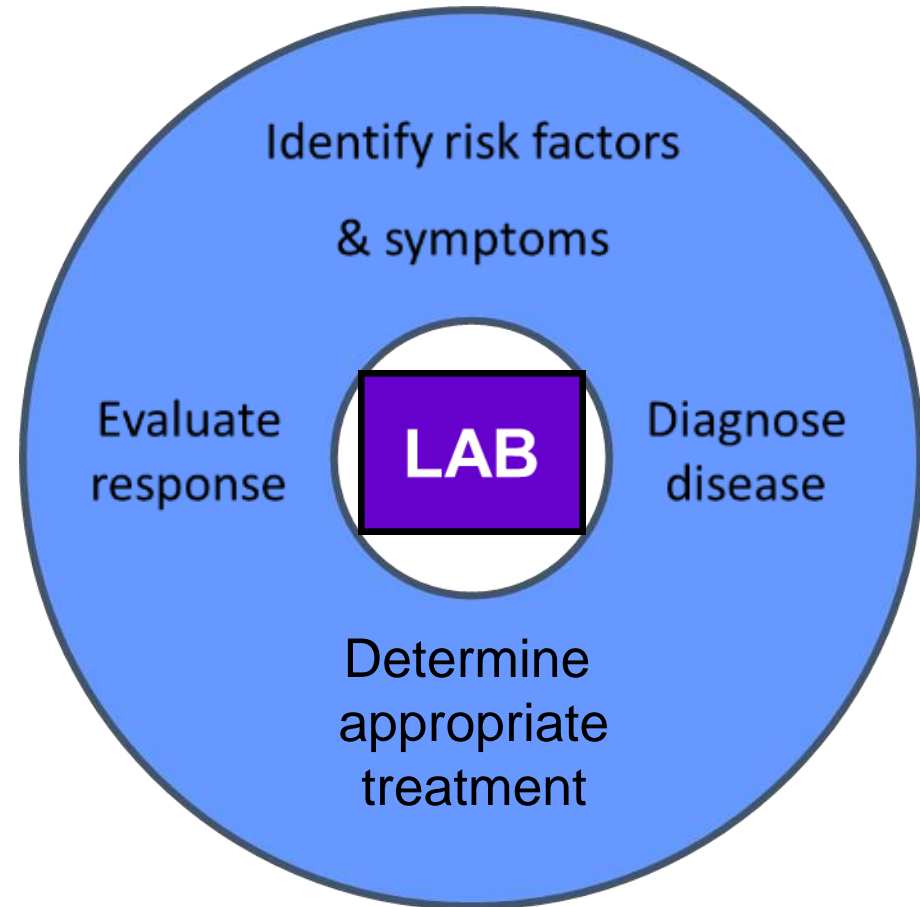
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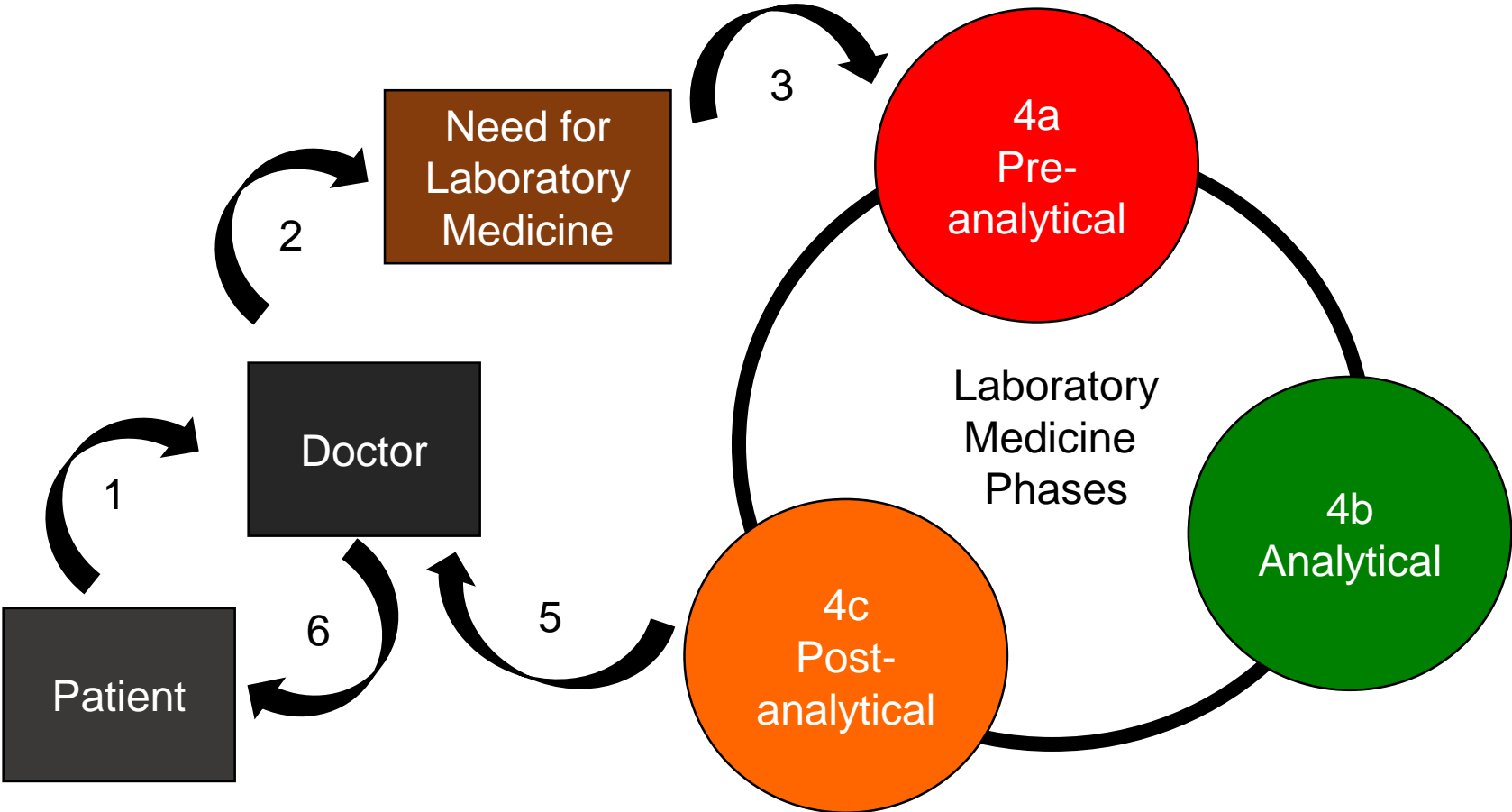
# Laboratory Medicine at the centre of the Healthcare system

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

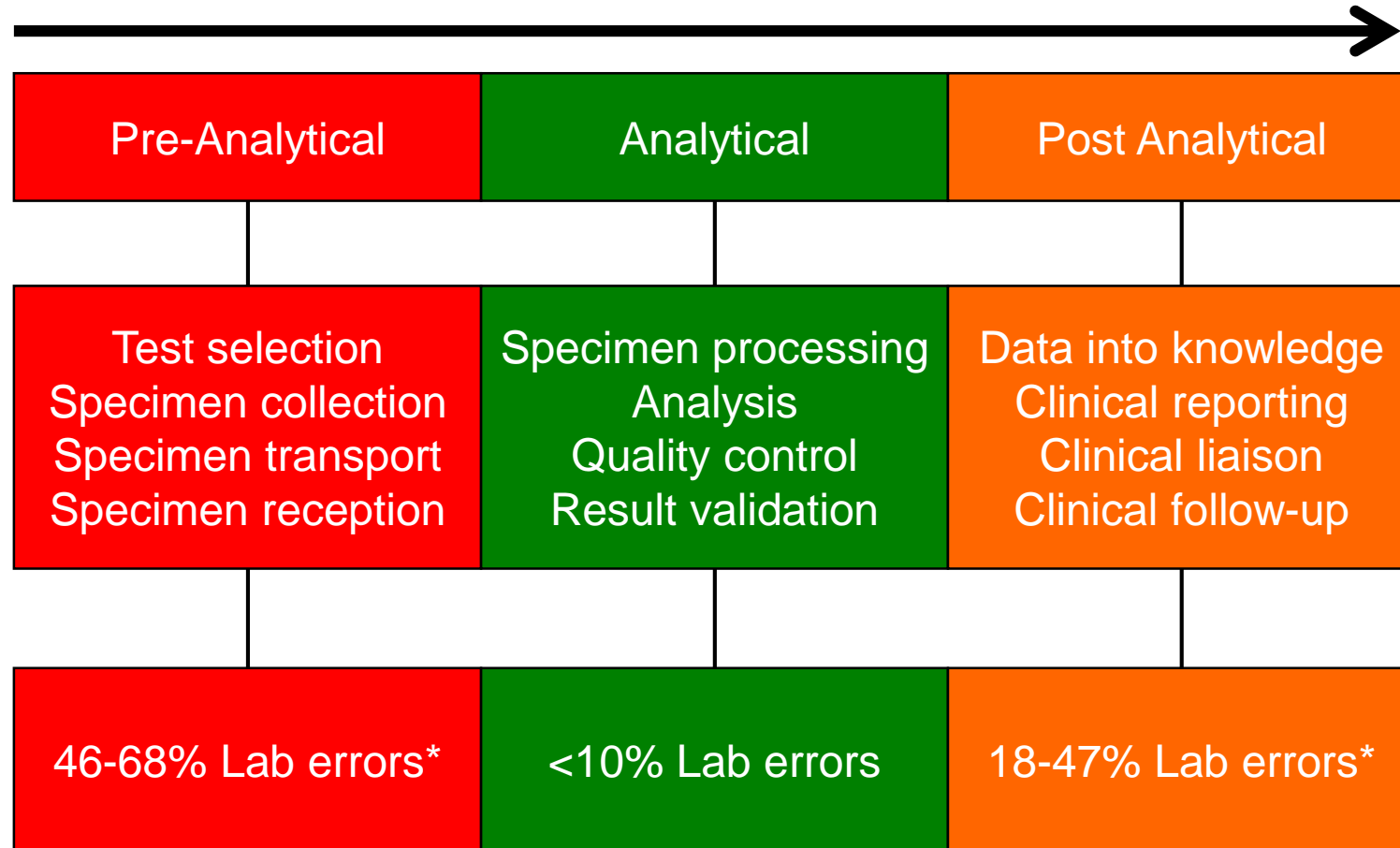
With this influence comes responsibility!



# Laboratory Medicine: The Process



# Laboratory Medicine: Three Phases

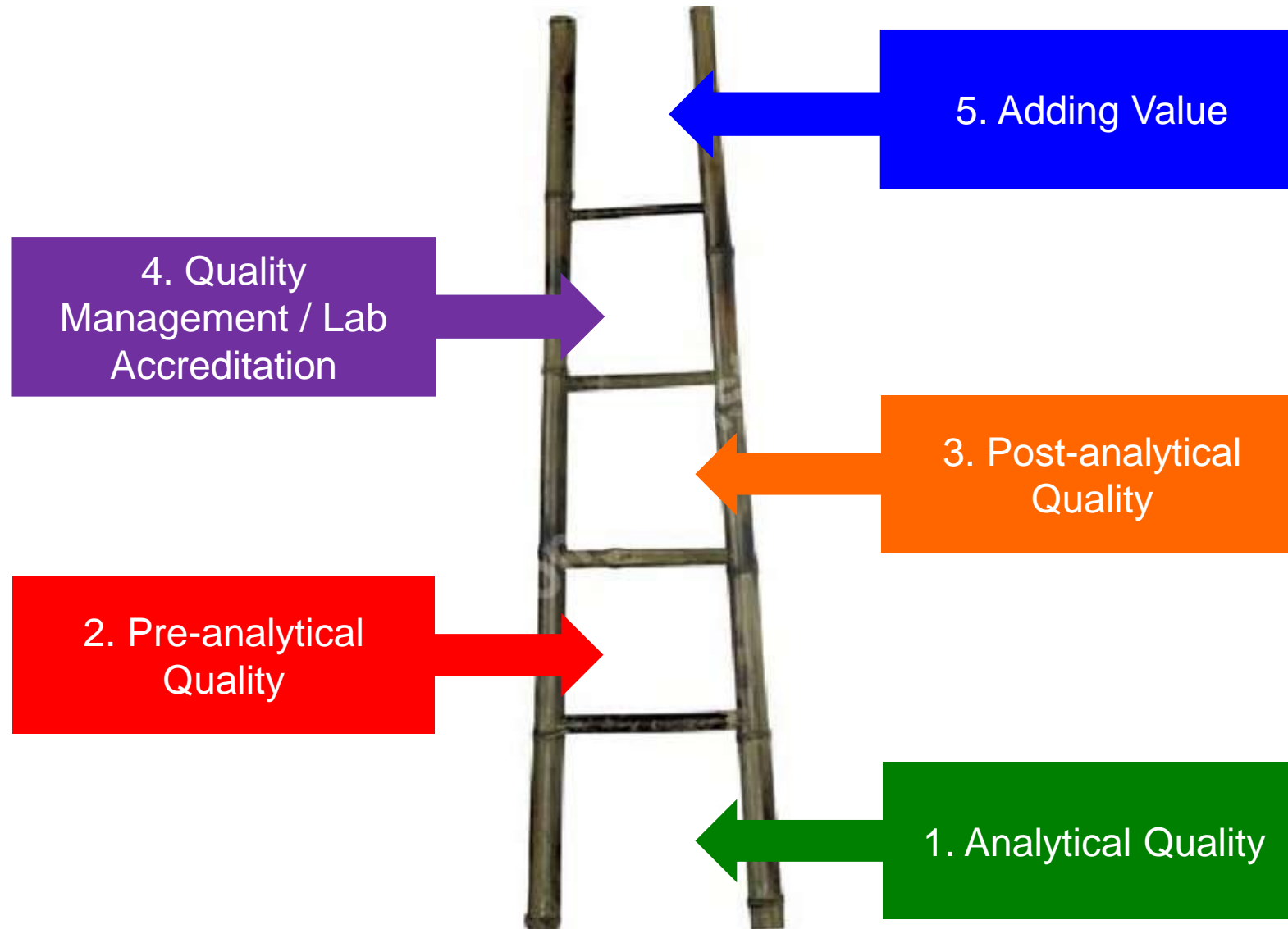


\* Plebani M. *Clin Chem Lab Med* 2006; **44**: 750-9

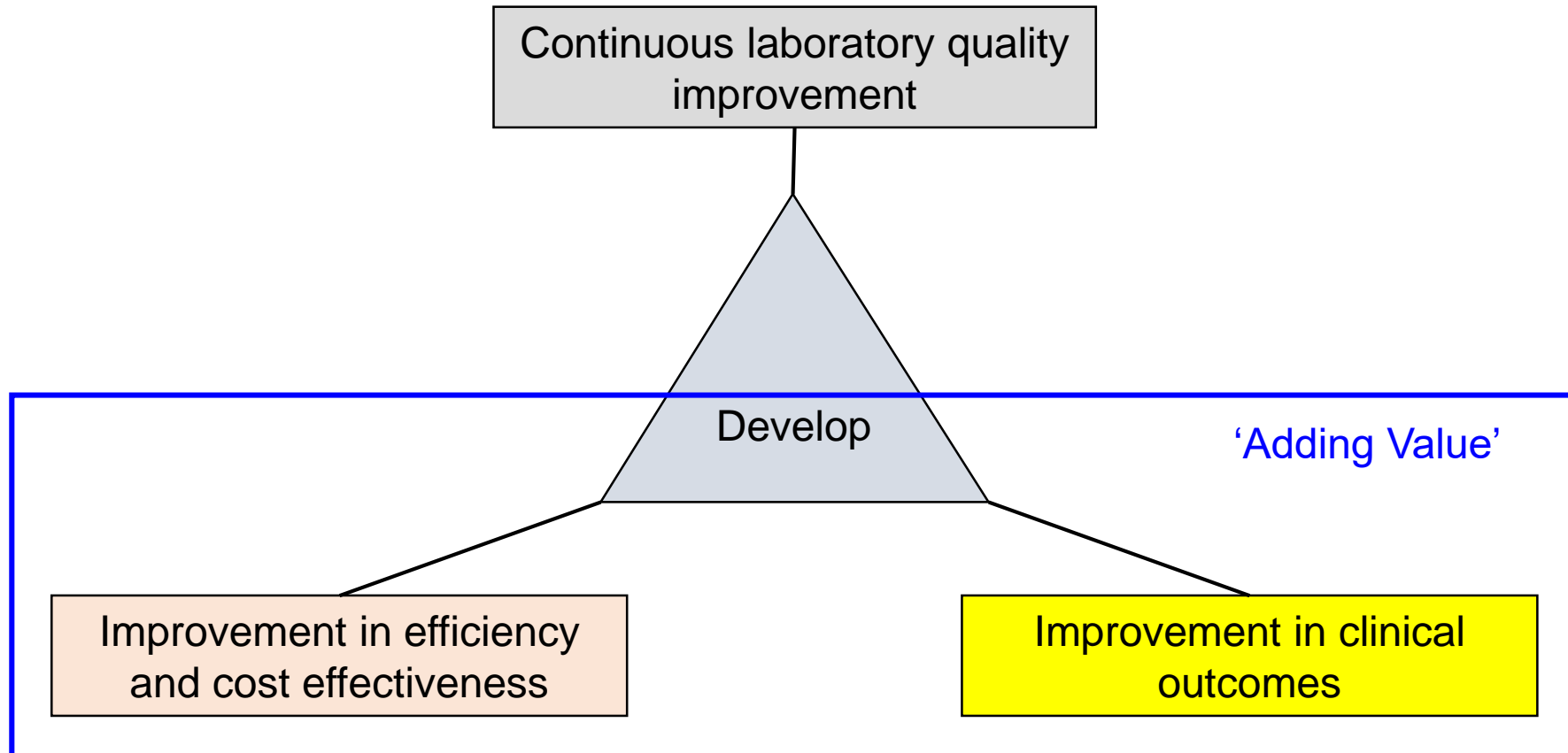
# Laboratory Medicine: Quality Ladder



# Laboratory Medicine: Quality Ladder



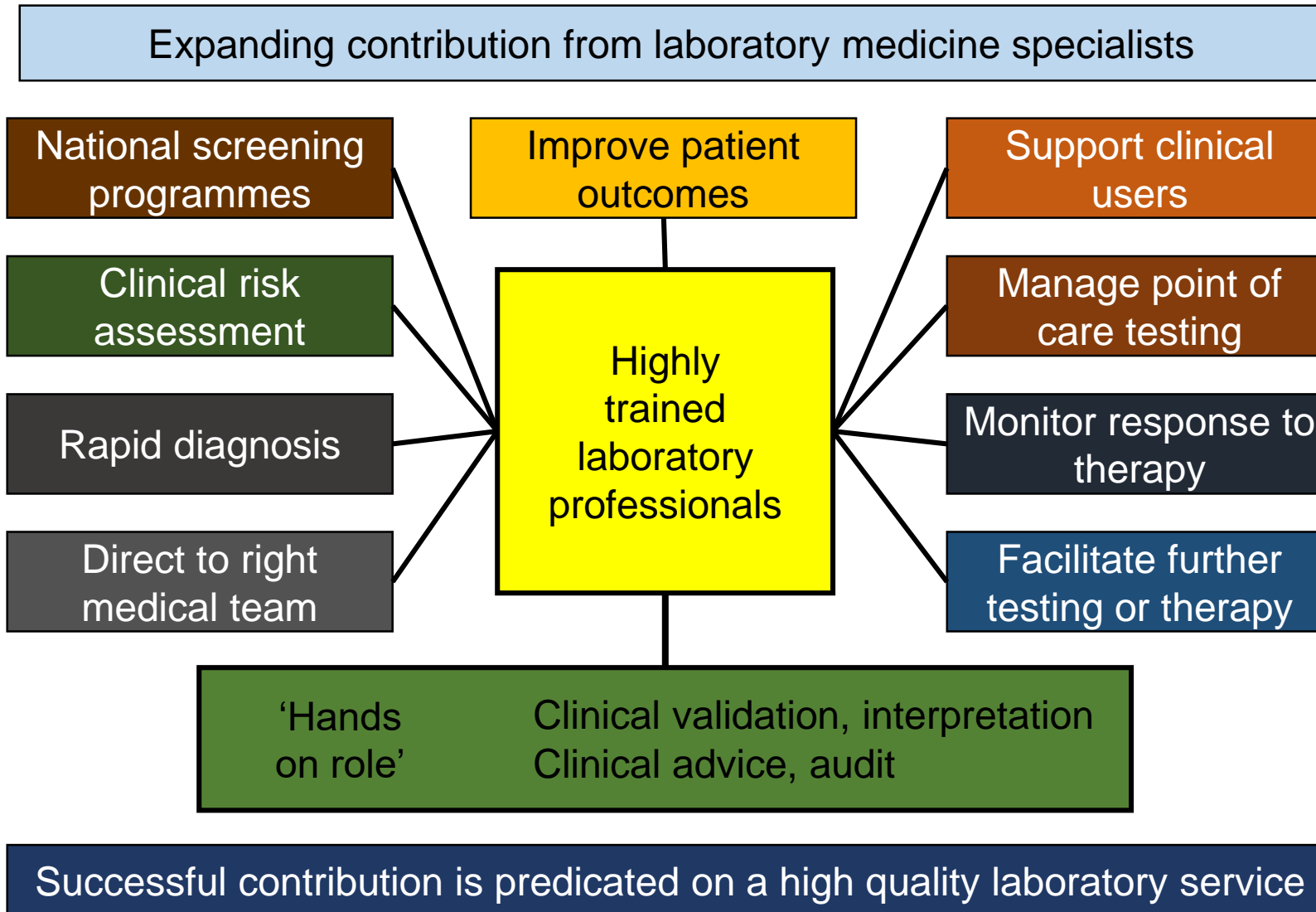
# Adding Value to Laboratory Medicine



Adding Value occurs largely 'outside' the laboratory. It is a professional responsibility shared with national and international bodies



# Laboratory: Improving Clinical Effectiveness



# Laboratory: Improving Clinical Effectiveness

Expanding contribution from laboratory medicine

National screening programmes

Impr

**How do we demonstrate our competence for these responsibilities?**

Facilitate further testing or therapy

'Hands on role

Clinical validation, interpretation  
Clinical advice, audit

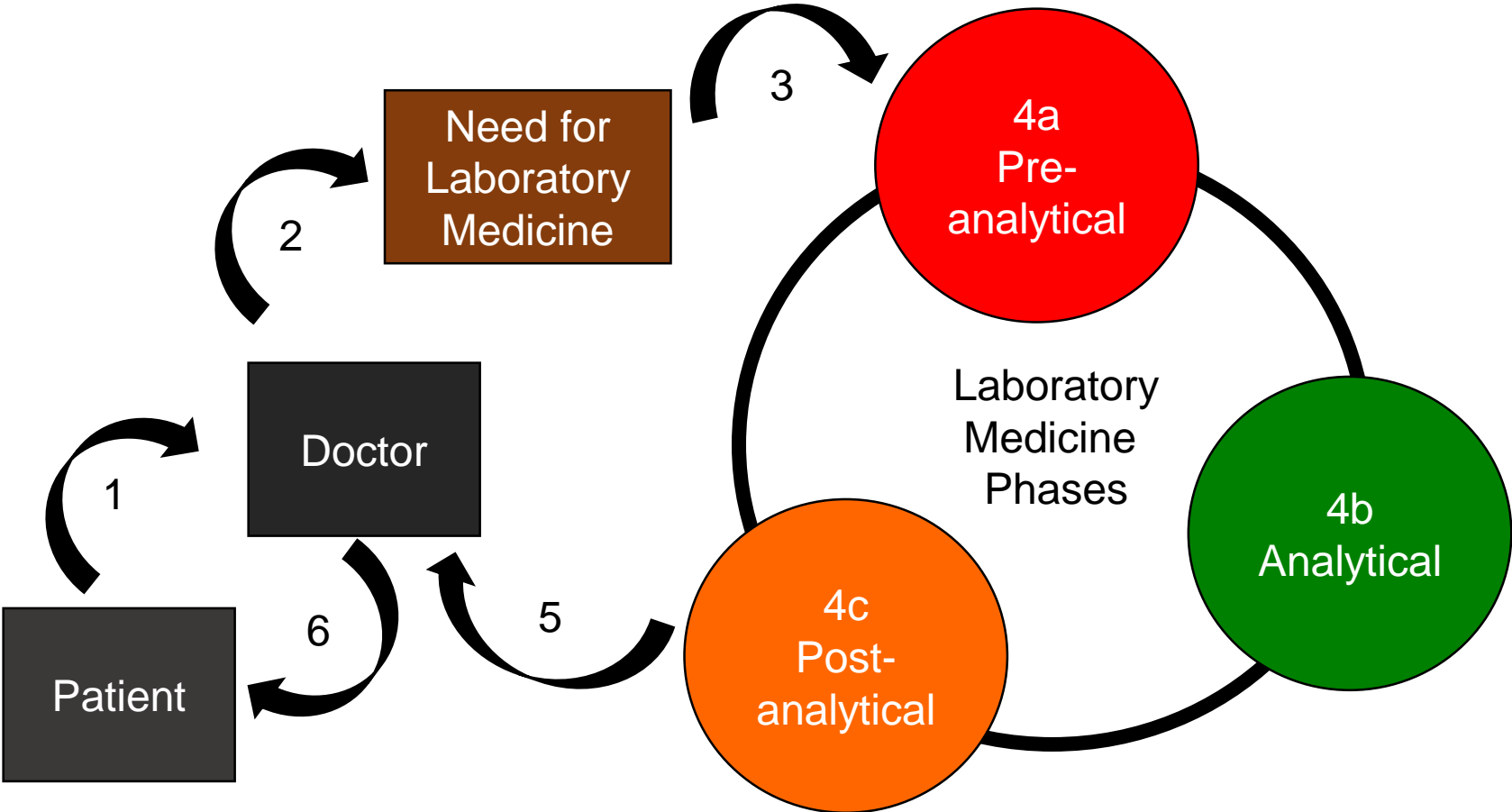
Successful contribution is predicated on a high quality laboratory service

# Current demands on healthcare delivery including laboratory medicine

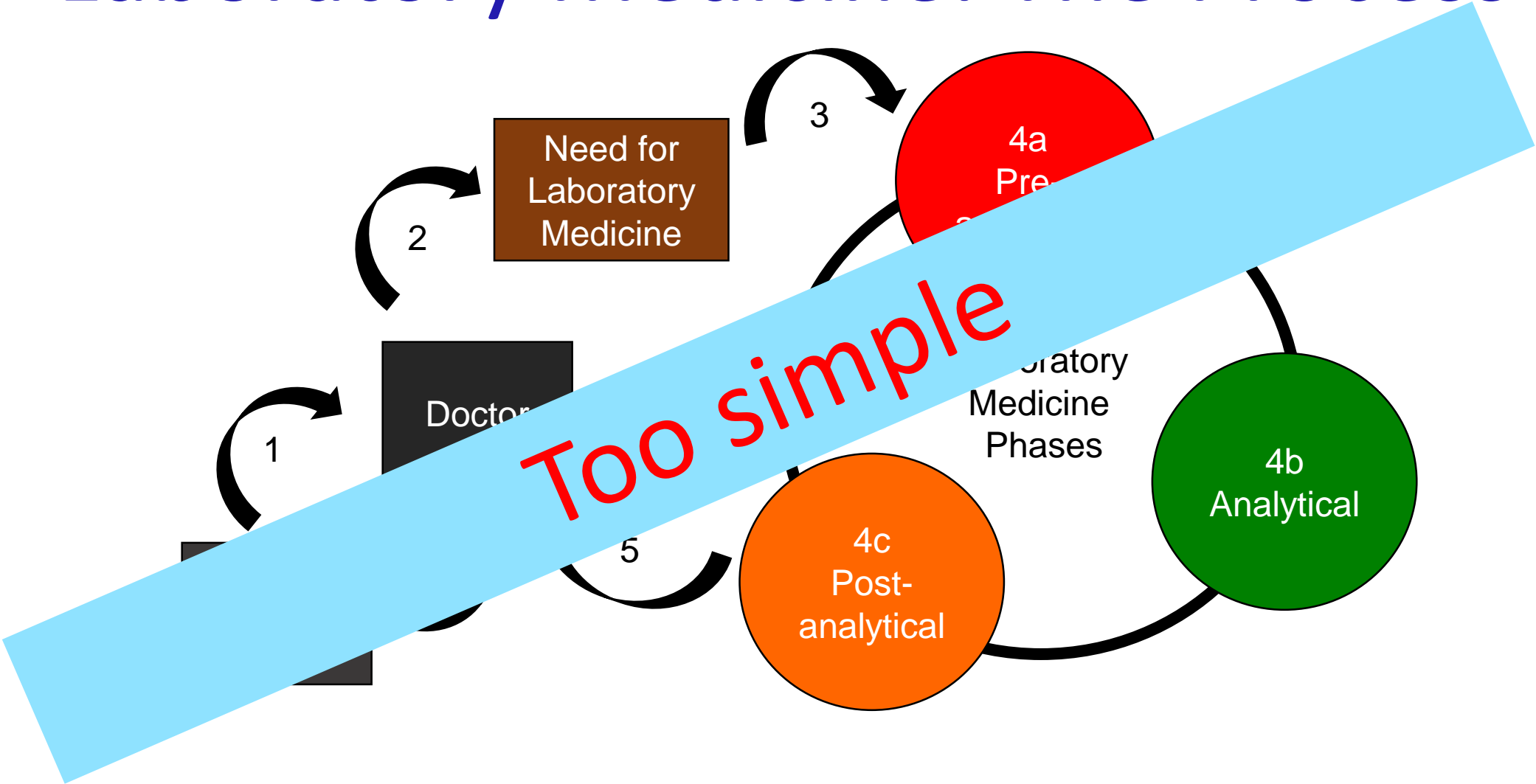
- Improving quality and patient safety
- Containing costs
- Delivering value-for-money

# Limitations arising from our current concepts of Laboratory Medicine

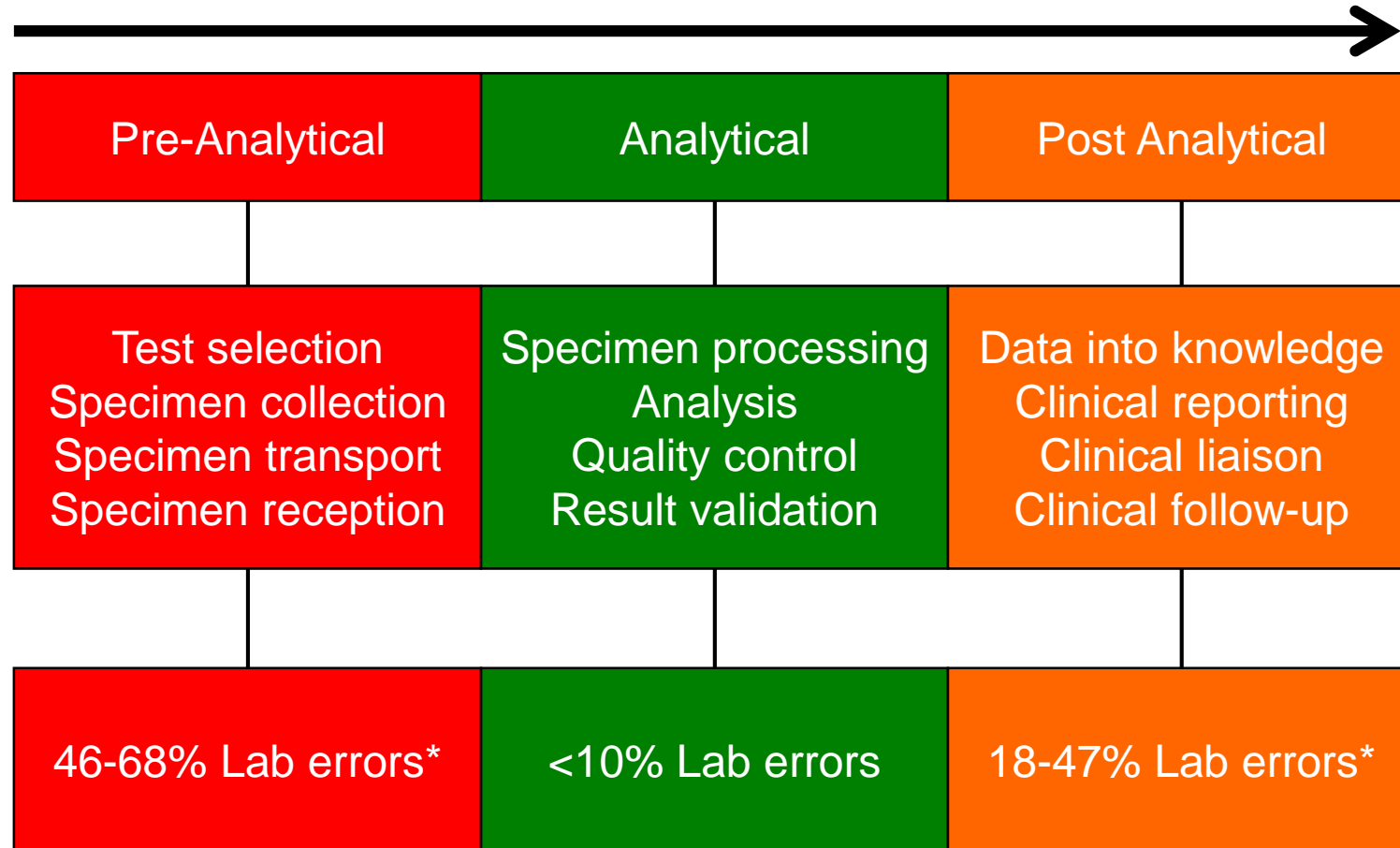
# Laboratory Medicine: The Process



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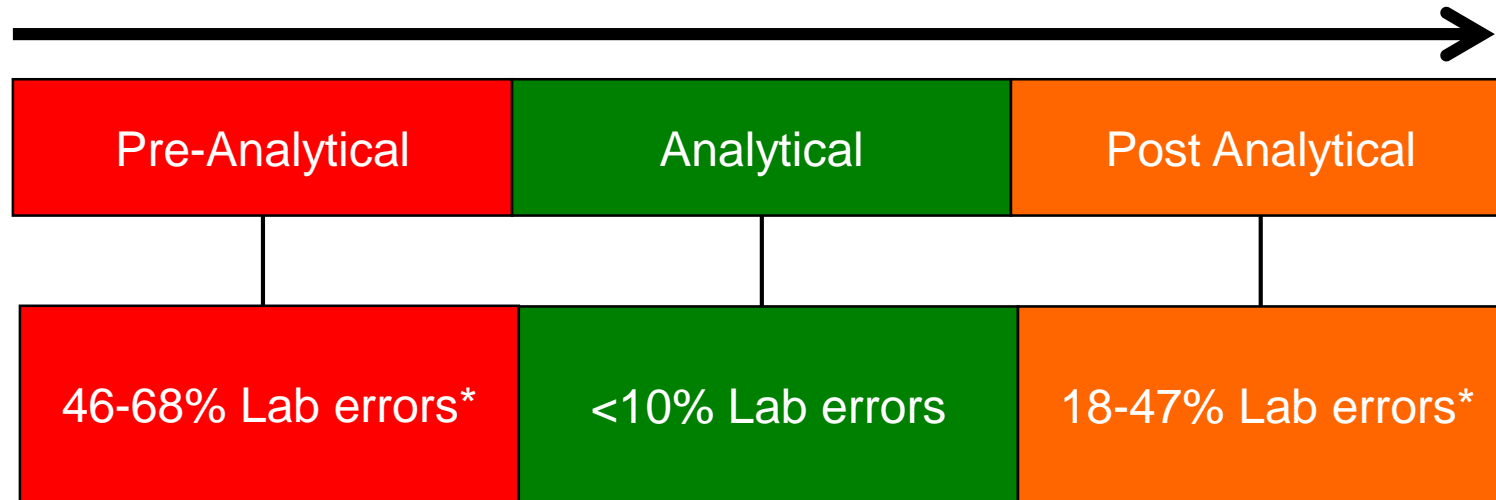


# Laboratory Medicine: Three Phases



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# Reducing Errors in Laboratory Medicine



\* Plebani M. *Clin Chem Lab Med* 2006; **44**: 750-9

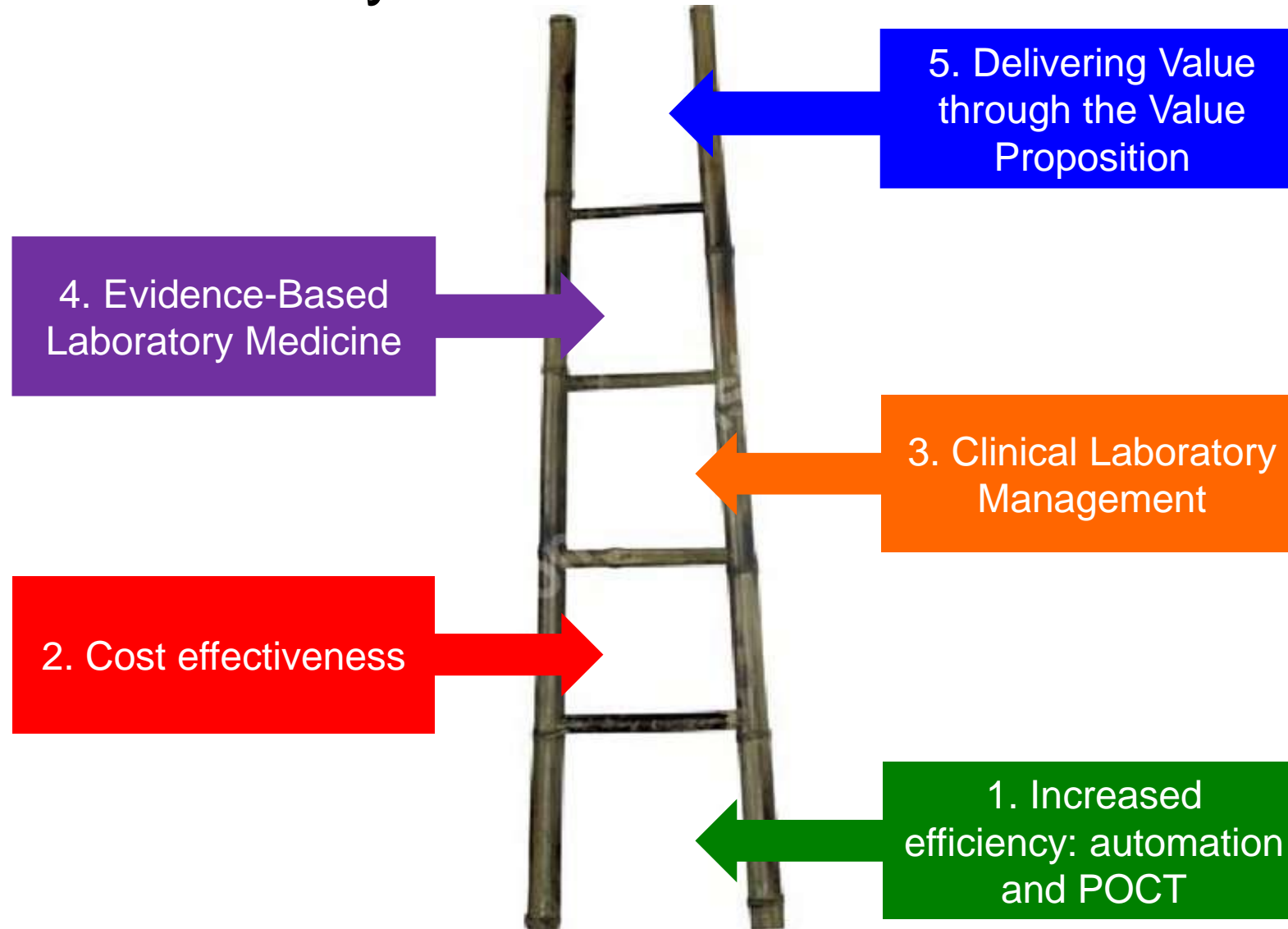
Can we further reduce errors without  
'revolutionising' our practice?



# Proposal: Laboratory Medicine: Value Ladder



# Proposal: Laboratory Medicine: Value Ladder



So what is the Value Proposition  
in Laboratory Medicine?

# Value in healthcare



Perspective  
DECEMBER 23, 2010

## What Is Value in Health Care?

Michael E. Porter, Ph.D.

- ❑ 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





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Invited critical review

## Anatomy of a value proposition for laboratory medicine

Christopher P. Price<sup>a,\*</sup>, Andrew St John<sup>b,1</sup>

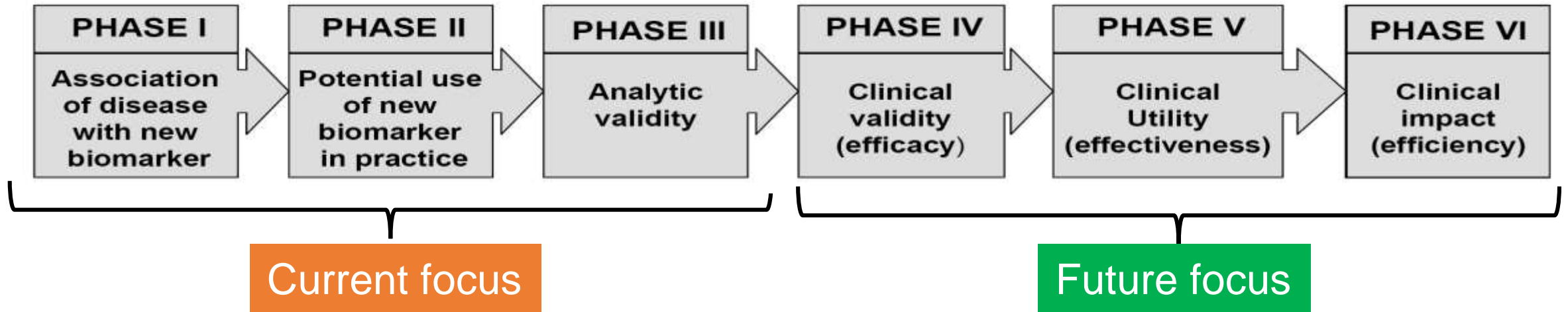
<sup>a</sup> Department of Primary Care Health Sciences, University of Oxford, Oxford, United Kingdom

<sup>b</sup> ARC Consulting, Perth, WA, 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





Special report

## From biomarkers to medical tests: The changing landscape of test evaluation



Andrea R. Horvath<sup>a,b,\*</sup>, Sarah J. Lord<sup>b,c,l</sup>, Andrew StJohn<sup>d</sup>, Sverre Sandberg<sup>e</sup>, Christa M. Cobbaert<sup>f</sup>, Stefan Lorenz<sup>g</sup>, Phillip J. Monaghan<sup>h</sup>, Wilma D.J. Verhagen-Kamerbeek<sup>i</sup>, Christoph Ebert<sup>j</sup>, Patrick M.M. Bossuyt<sup>k</sup>,

For the Test Evaluation Working Group of the European Federation of Clinical Chemistry Laboratory Medicine



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.





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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.***



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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

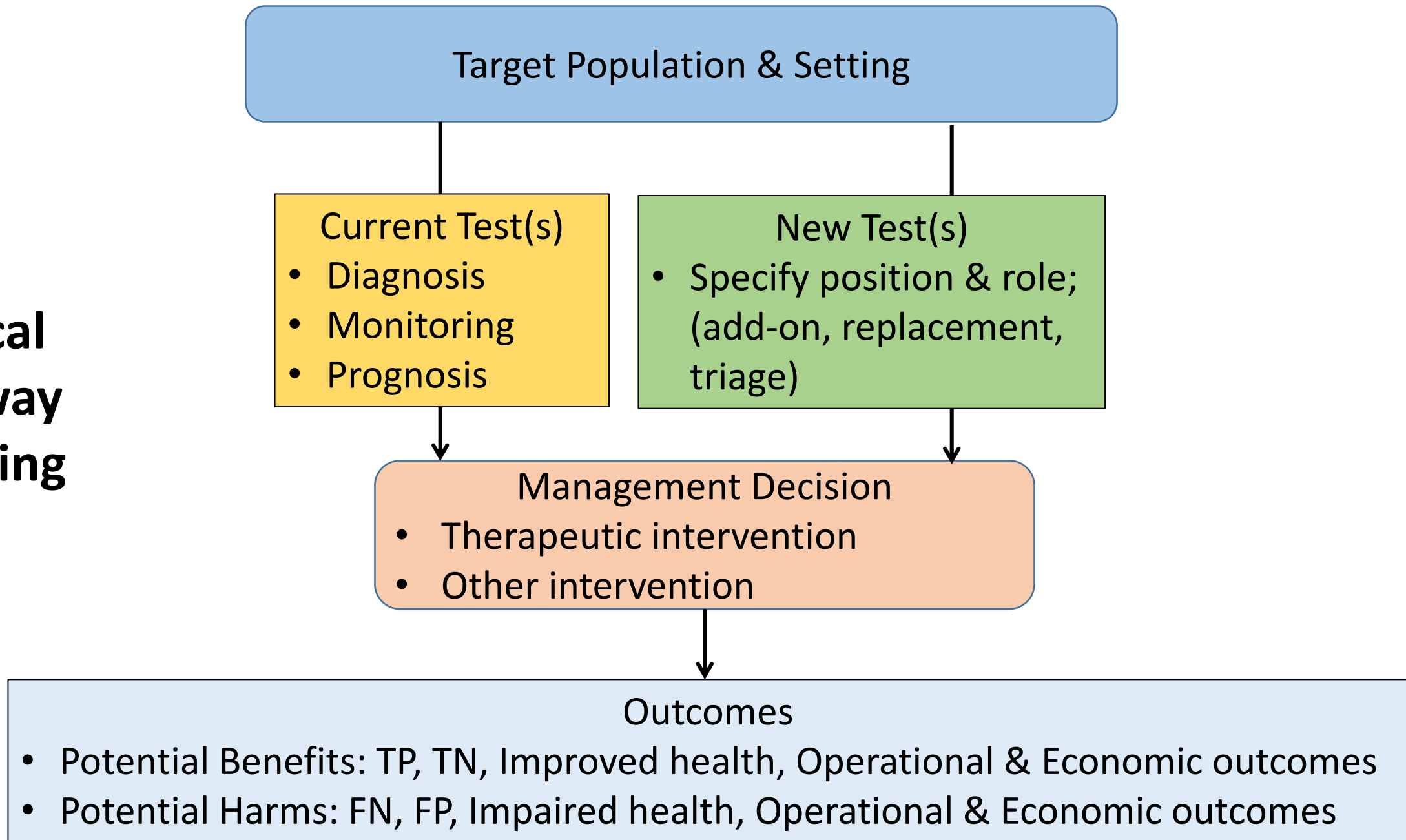
# Commercial & Lab Med Value Proposition

Commercial Value Proposition	<b>Laboratory Medicine Value Proposition</b>
Identify the customer	<p>Key points:</p> <ul style="list-style-type: none"><li>• Clinical pathway</li><li>• Need for change</li><li>• Multiple stakeholders (&amp; Silos)</li><li>• Economics increasingly important</li><li>• Measuring what we implement</li><li>• Laboratory to drive process</li></ul>
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	
Appraise proof to substantiate claims	

# Commercial & Lab Med Value Proposition

Commercial Value Proposition	<b>Laboratory Medicine Value Proposition</b>
Identify the customer	Who are the customers and the relevant stakeholders?
Understand what the customer values	What is the unmet need?
Define the product or service	What is the care pathway?
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	
Appraise proof to substantiate claims	

# Clinical Pathway Mapping



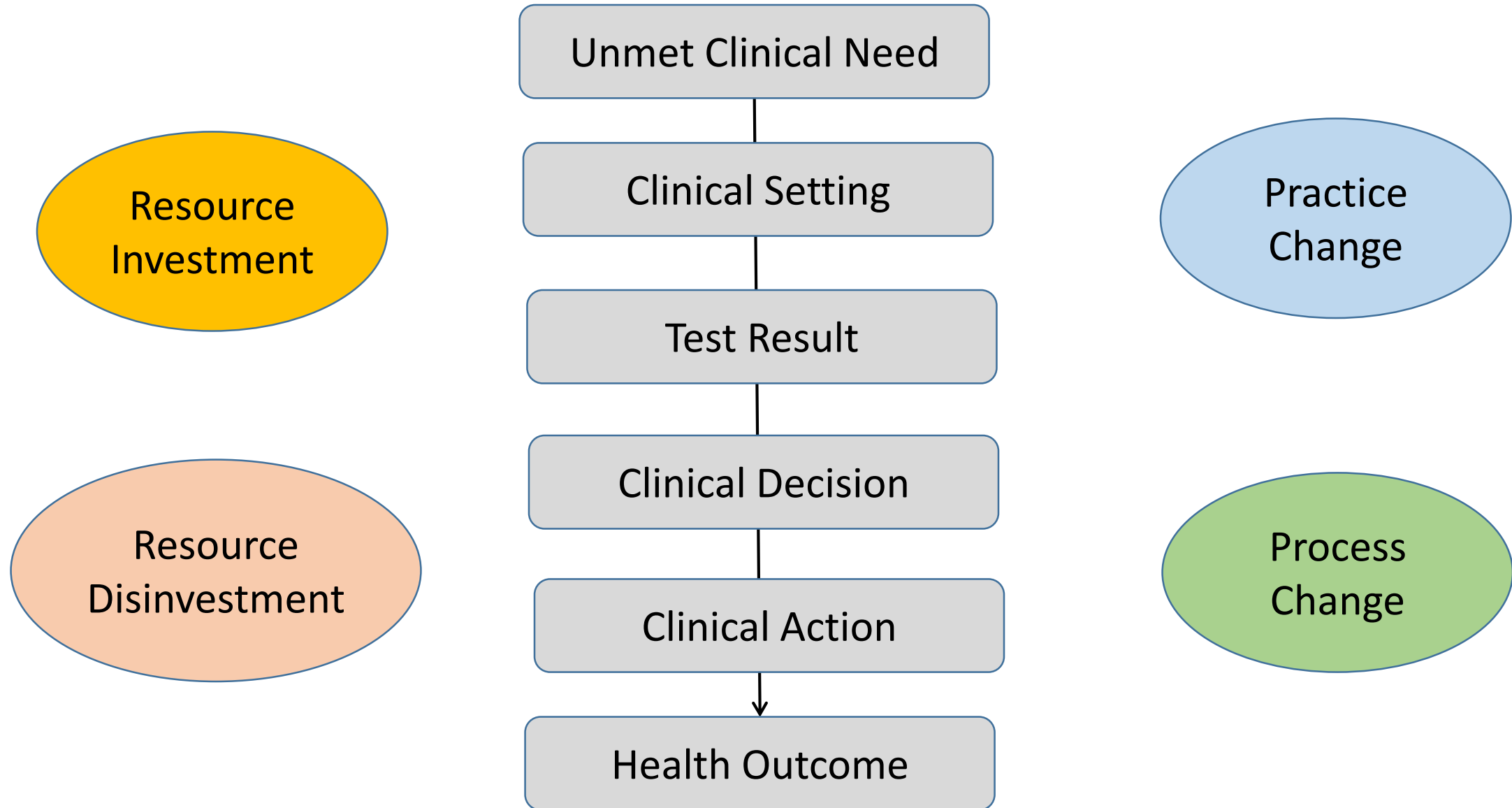
Commercial Value Proposition	<b>Laboratory Medicine Value Proposition</b>
Identify the benefits of the product or service to the customer, including cost	<p>What is the test and its utility/ies?</p> <p>What are the benefits of using the test?</p> <p>What are the resource requirements?</p>
Identify the benefits of the product or service to the customer, including the competition	
Appraise proof to substantiate claims	

Commercial Value Proposition	<b>Laboratory Medicine Value Proposition</b>
<p>Identify the benefits of the product or service to the customer, including the competition</p>	<p>What is the <b><u>impact on outcomes</u></b>?</p> <p>What change in <b><u>practice</u></b> is required to deliver these outcomes?</p> <p>What change in <b><u>process</u></b> is required to deliver these outcomes?</p> <p>What change in <b><u>resource requirement</u></b> is likely?</p> <p><b><u>Who is accountable</u></b> for delivering this value proposition?</p> <p>What are the <b><u>translation challenges</u></b>?</p> <p>What are the <b><u>implementation metrics</u></b>?</p>
<p>Appraise proof to substantiate claims</p>	

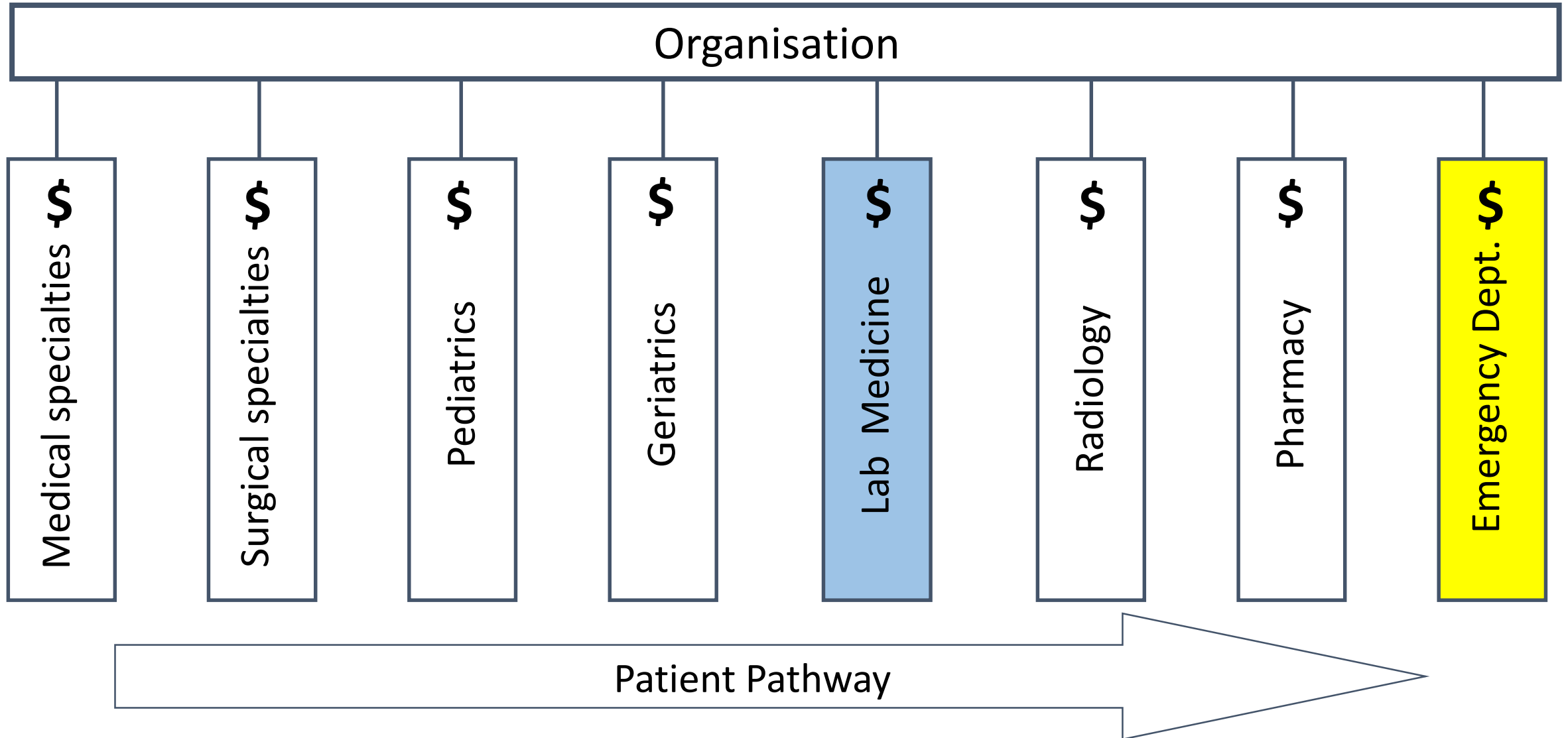


Commercial Value Proposition	<b>Laboratory Medicine Value Proposition</b>
<p>Identify the benefits of the product or service to the customer, including the competition</p>	<p>What is the impact on outcomes?            What change in practice is required to deliver these outcomes?            What change 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>
<p>Appraise proof to substantiate claims</p>	<p>What is the evidence of <b><u>clinical effectiveness</u></b>?            What is the evidence of <b><u>cost effectiveness</u></b>?</p>

# *Challenges when using a test as an intervention*



# Budget or Financial Silos – Inhibit innovation and change in practice



**Myocardial infarction: rapid ruling out in the emergency room**

Patients with symptoms of possible acute coronary syndrome make up a large proportion of people who present to emergency departments, where they undergo lengthy, intensive, and costly assessments.<sup>1,2</sup> Yet few are finally diagnosed with an acute coronary syndrome. Improvements in methods to exclude acute coronary syndrome are needed to reliably reassure and safely discharge low-risk patients who can then proceed to further investigations as outpatients. High-sensitivity cardiac troponin assays are reliable and have low thresholds of detection, but how to take full advantage of this improved precision in clinical care is unclear.<sup>3,4</sup>

In *The Lancet*, Anoop Shah and colleagues<sup>5</sup> report results of a prospective observational cohort study of 5304 patients presenting at emergency departments with suspected acute coronary syndrome. These

despite guideline recommendations.<sup>6,8</sup> Patients with a delayed increase in troponin after the initial test might therefore not have been identified as having an acute myocardial infarction, and missed events might be more common than reported. Furthermore, the median time for the single troponin test was 54 min (IQR 33–85) after presentation to the emergency department. In systems that support very early blood sampling in the emergency department, the threshold of 5 ng/L might not have such a high negative predictive value. In addition, although early presenters represent only a small proportion of all patients (5%), the use of the single troponin test value failed to meet the predefined negative predictive value of 95.5% in these patients, and serial testing should continue in such patients.

Additionally, there are important considerations



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See Online for Article  
[http://dx.doi.org/10.1016/S0140-6736\(15\)00391-8](http://dx.doi.org/10.1016/S0140-6736(15)00391-8)

*Louise Cullen, William Parsonage, Martin Than*

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

1. Unmet clinical need	8. Part of the care pathway in which the test will be used
2. Test	9. Stakeholders involved in delivering/ receiving care identified in care pathway
3. Patient population	10. Benefits/disadvantages to each stakeholder in relation to outcome identified above
4. Test intervention utility	11. Potential risks associated with introduction of test and proposed mitigation strategy
5. Outcome	12. Resource/activity contributed by each of service lines involved in care pathway with and without test intervention
6. Location where test is performed	13. Reimbursement/funding for delivering care pathway with and without test intervention
7. Quality of evidence available	14. Implementation plan including metrics for monitoring appropriate adoption

# Key Steps in the Value Proposition for use of high-sensitive Troponin assays

8. Part of the care pathway in which the test will be used

9. Stakeholders involved in delivering/ receiving care identified in care pathway

10. Benefits/disadvantages to each stakeholder in relation to outcome identified above

11. Potential risks associated with introduction of test and proposed mitigation strategy

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

13. Reimbursement/funding for delivering care pathway with and without test intervention

14. Implementation plan including metrics for monitoring appropriate adoption

# Key Steps in the Value Proposition for use of high-sensitive Troponin assays

8. Part of the care pathway in which the test will be used –

Actually specifying how and where the test will be used in the pathway

9. Stakeholders involved in delivering/ receiving care identified in care pathway

Patient

ED Physician

Cardiologist

Hospital/Healthcare provider

Payer/Insurer

Laboratory

# Key Steps and possible outcomes of VP for use of high-sensitive Troponin assays

10. Benefits/Disadvantages to stakeholders involved in delivering/ receiving care identified in care pathway –

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.