

EVALUATING NEW LABORATORY TESTS

in the context of NHS commissioning

Christopher P Price

**Department of Clinical Biochemistry,
University of Oxford,
Oxford, UK**

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The National Health Service commissioning

“..the means by which 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 by the tax payer.....”

Department of Health 2006

“Commissioning Care Pathways”

Laboratory Medicine and Commissioning

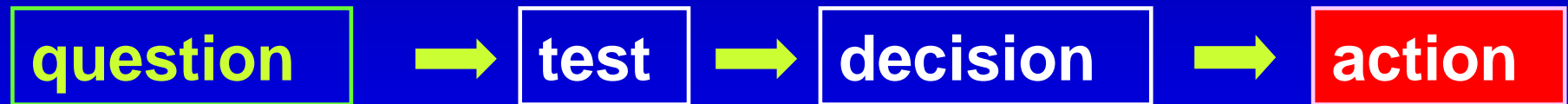
I'm starting from the beginning because.....

- Perception of the role of pathology is poor
- Evidence base is very poor
- Methodology for developing evidence is challenging
- Incentives to develop evidence are absent
- Reimbursement based on cost not value
- Pathologists don't get out enough!!

Laboratory Medicine

why do a test?

PATIENT



OUTCOME

the “appropriate” test

Promoting Health Outcomes

care of individual patients

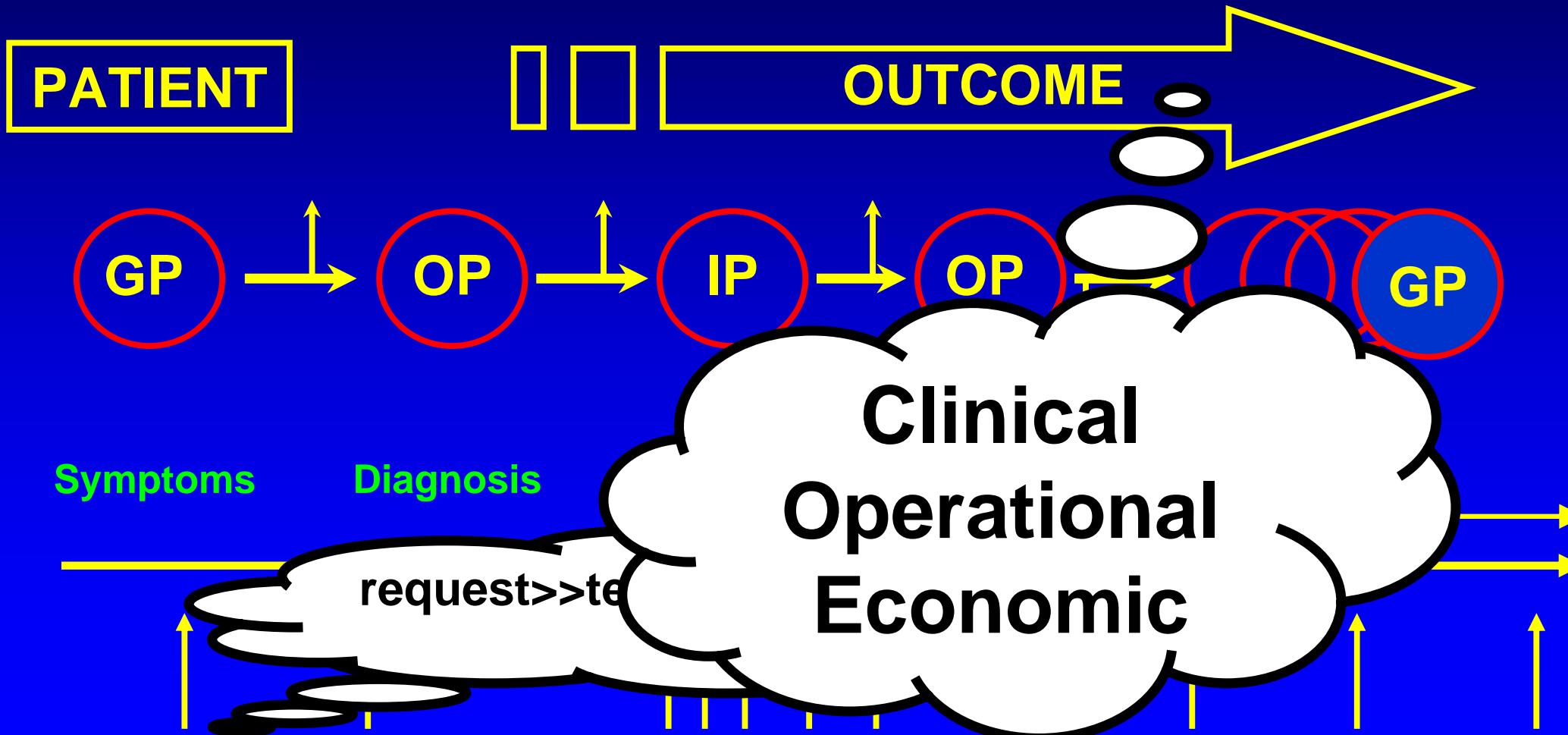
maximisation of benefit

minimisation of risk

reasonable cost

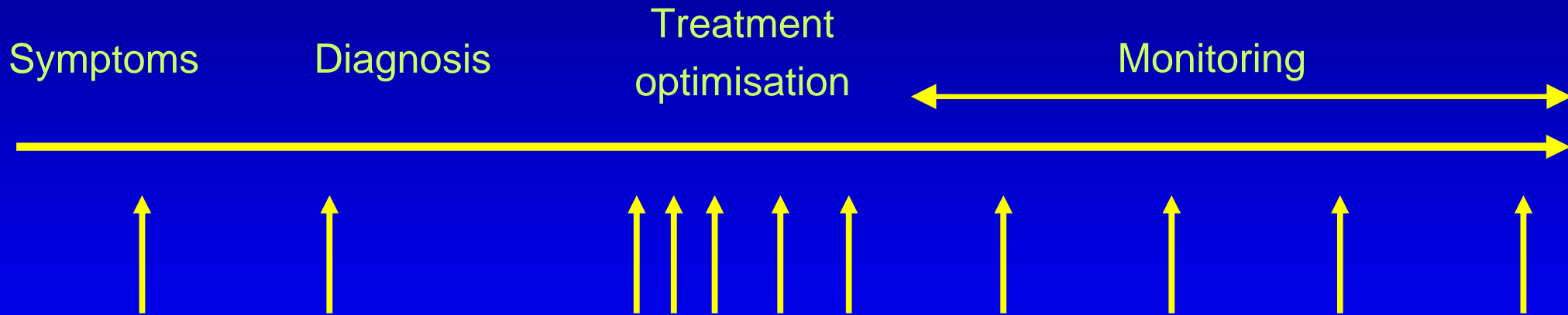
Tests and the Patient Journey

from patient problem to improved outcome



Commissioning Care Pathways

the care pathway and diagnostic tests



How to expedite the care pathway

How to optimise the care pathway

How to maximise the benefit

Laboratory Medicine

the classical research strategy

pathophysiology

analytical method

diagnostic performance

health outcome

Translational Research

Pathology and
identification of
'marker'

Measurement of 'marker'
:analytical variation
:biological variation

Results; affected differ from normals
:relation to disease severity

Patients with certain results more likely to have the
condition

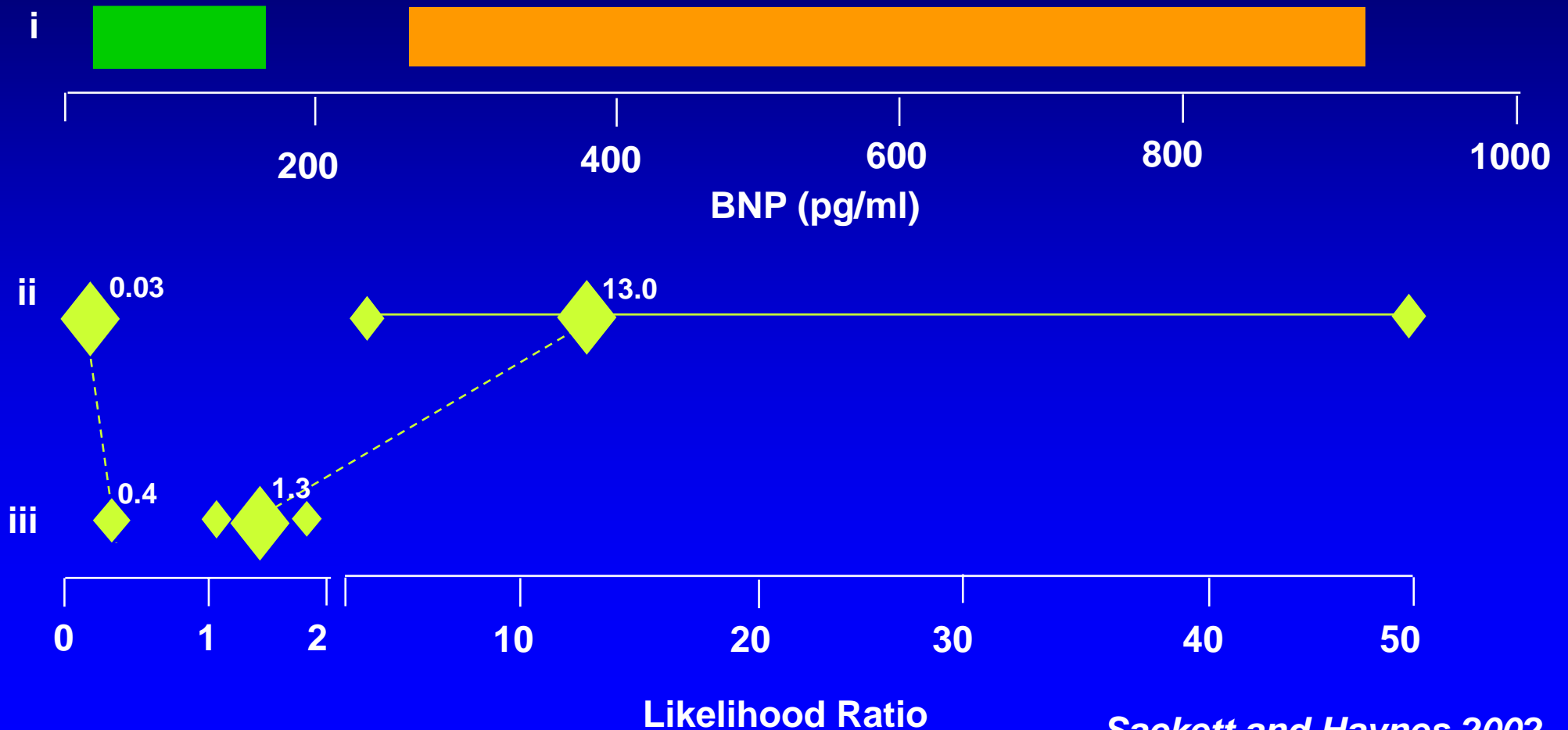
Results differentiate those with disease from those without
disease

**Patients having the test have better outcomes than
those not having the test**

Laboratory Medicine

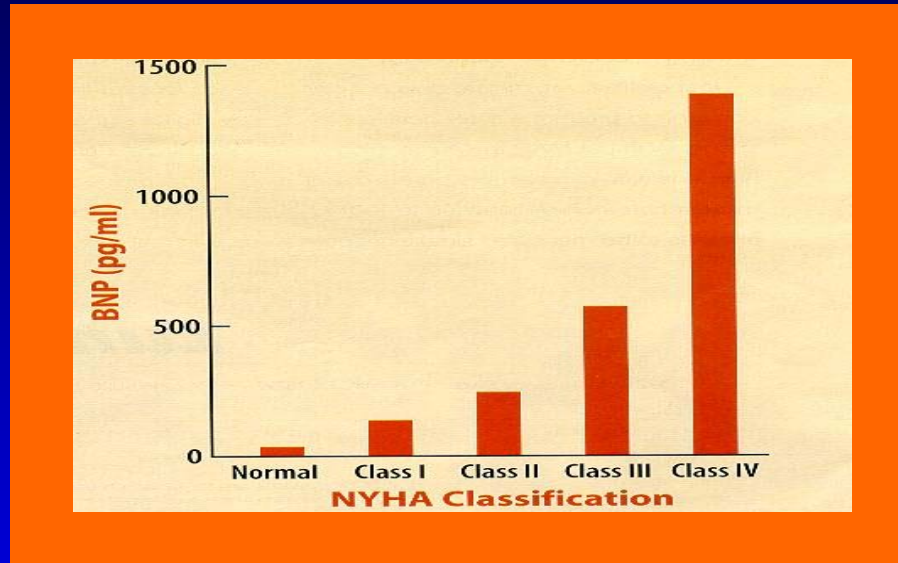
architecture of diagnostic research

BNP in heart failure



Evidence for Making Decisions

Not...



but...

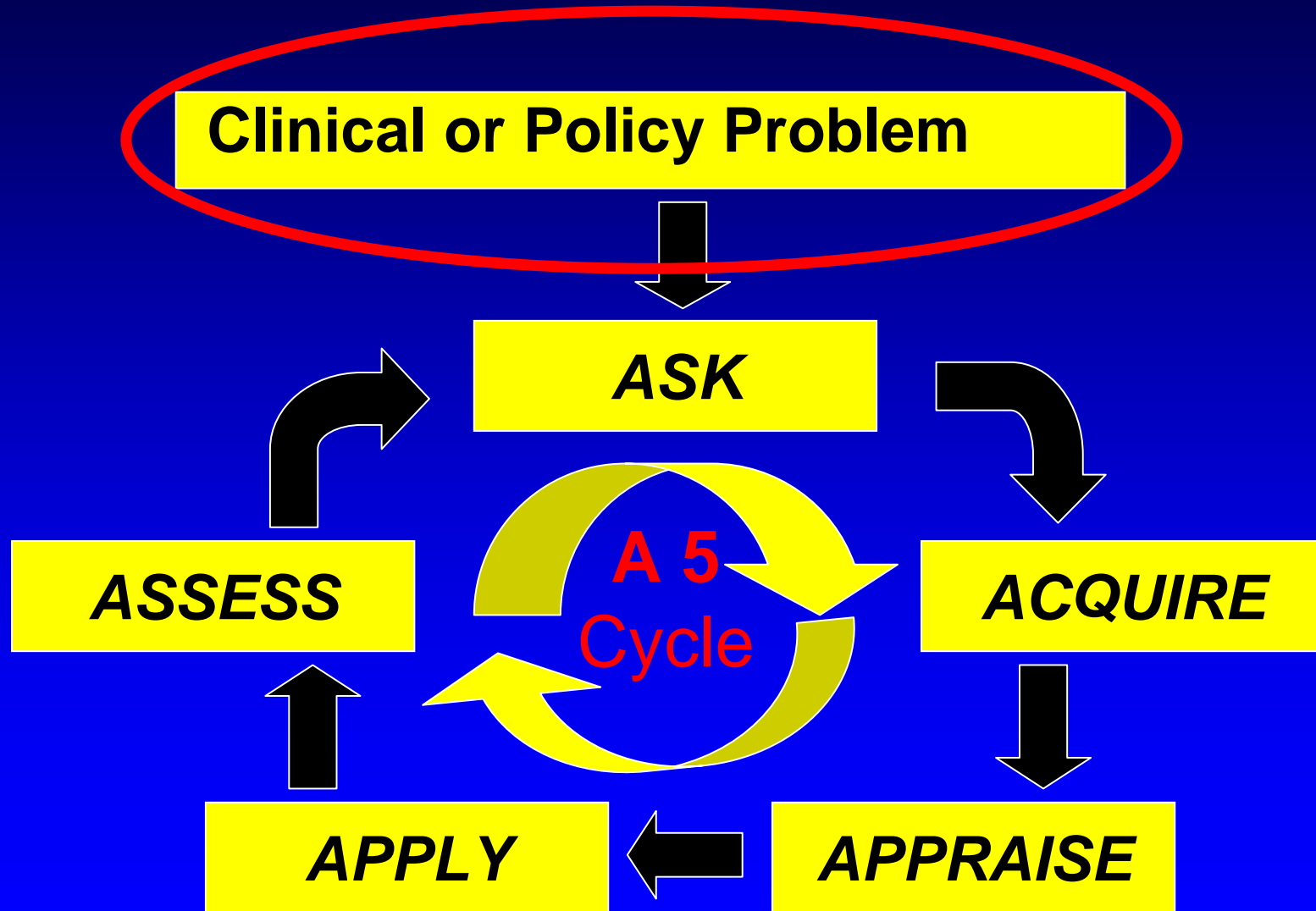
What questions?

What decisions?

What actions?

What outcomes?

The EB(L)M Cycle



Evidence for Making Decisions



New Laboratory Tests

commissioners needs to patient outcomes

- **Need**
- **Question(s)**
- **Evidence**
- **Outcomes**
- **Change management**
- **Implementation plan**

Formulate an Answerable Question the PICO system

- **Population/patient**
- **Indicator/intervention/test**
- **Comparator/control**
- **Outcome**

Formulate an Answerable Question

BNP in primary care

GP: can I use BNP in my practice?

**In patients presenting to primary care
(P) can I use the plasma BNP test (I)
rather than echocardiography (C) to rule
out (O) a diagnosis of heart failure?**

Evidence Based Laboratory Medicine

good quality evidence

explicit clinical question

appropriate spectrum of patients

robust experimental design

measurable reference/outcome

blind comparison with reference/outcome

reference applied regardless of test result

Evidence Based Laboratory Medicine

classification of studies

diagnostic accuracy - rule in
- rule out

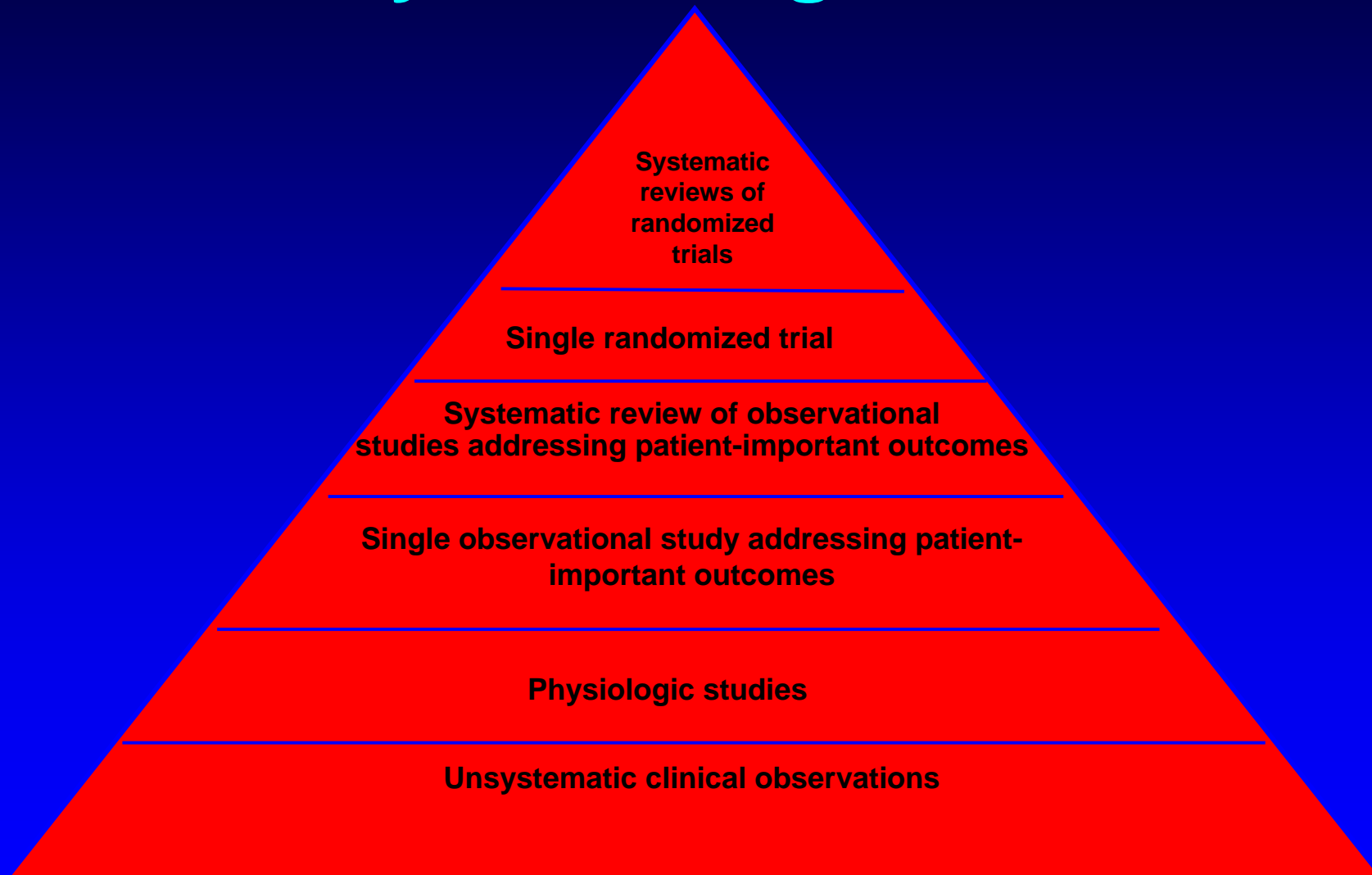
prognostic accuracy

outcome - intervention

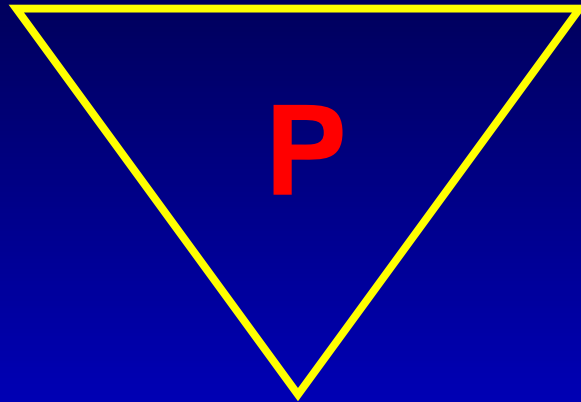
- guided therapy

- monitoring

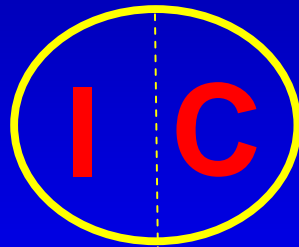
Hierarchy of Strength of Evidence



Critical Appraisal of Evidence

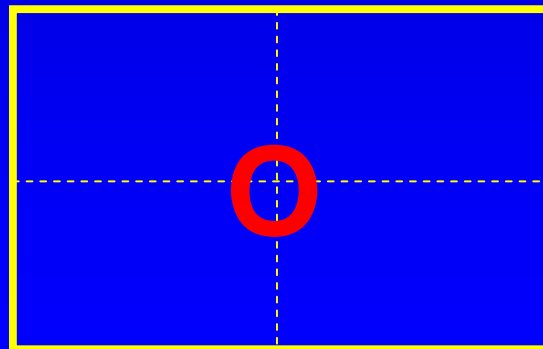


Represent?



Allocation?

Accounted for?



Measured?

blinded?

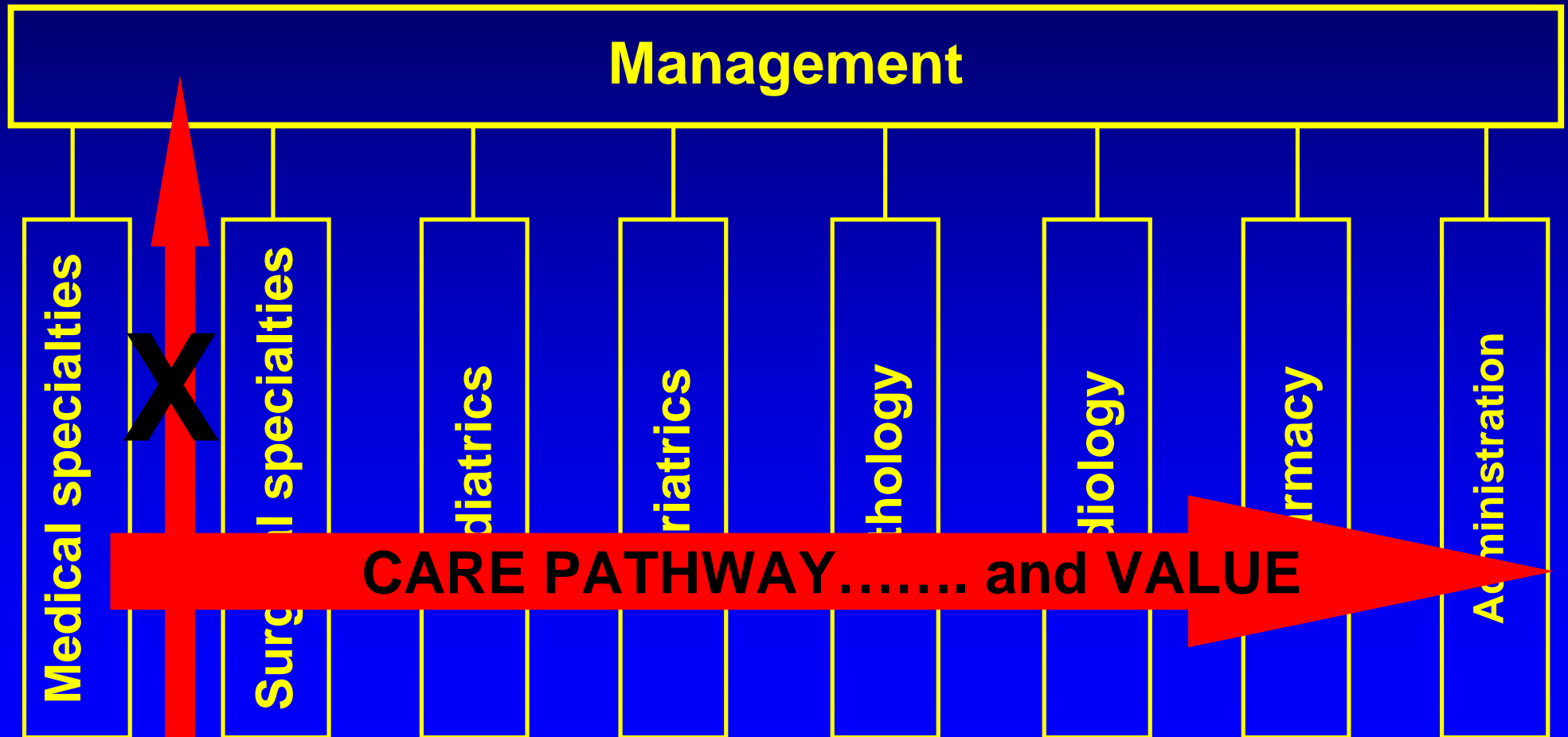
Objective? Jackson et al 2006

Laboratory Medicine and Outcomes

Type of outcome	Clinical	Operational	Economic
Hard	Morbidity Mortality Disability	Time to treatment	Cost/QALY Cost/diagnosis Cost/treatment
Soft	Patient satisfaction	Waiting time	
Surrogate	Complication rate Readmission rate HbA1c	Length of stay	Length of stay

Change Management in Health Care

silo vs care pathway management



Laboratory Medicine

how do we introduce new tests?



Laboratory Medicine practice cycle?



Laboratory Medicine commissioning cycle?



Laboratory Medicine

impact on commissioning of pathways



**Point of care testing: reduces length of stay e.g. cardiac markers in ED
: facilitates care closer to home e.g. HbA1c**

Screening for chlamydia infection reduces complication rates

BNP helps in guiding therapy in heart failure reducing cardiac events

Intraoperative PTH (and imaging) facilitates day case parathyroidectomy

HER-2/neu testing identifies those patients who respond to Herceptin

TPMT identifies those who suffer adverse effects of thiopurine-based drugs