



LEIDS UNIVERSITAIR MEDISCH CENTRUM

How to assure the quality of POC testing?

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Outline

I. Evolution of healthcare delivery and laboratory medicine

II. Rationale for POCT

III. Essential Requirements for rationalized POCT

- ✓ POCT policy & management structure
- ✓ POCT and its place in the clinical pathway
- ✓ An informed business case
- ✓ Tips for successful POCT
- ✓ A POCT implementation plan
- ✓ Role of lean thinking

IV. How to assure the quality of POCT?

V. Innovative POCT technology example

VI. Concluding thoughts

I. Evolution of healthcare delivery and laboratory medicine



Evolution of healthcare up until the late 20th century

Development of more patient-centered care

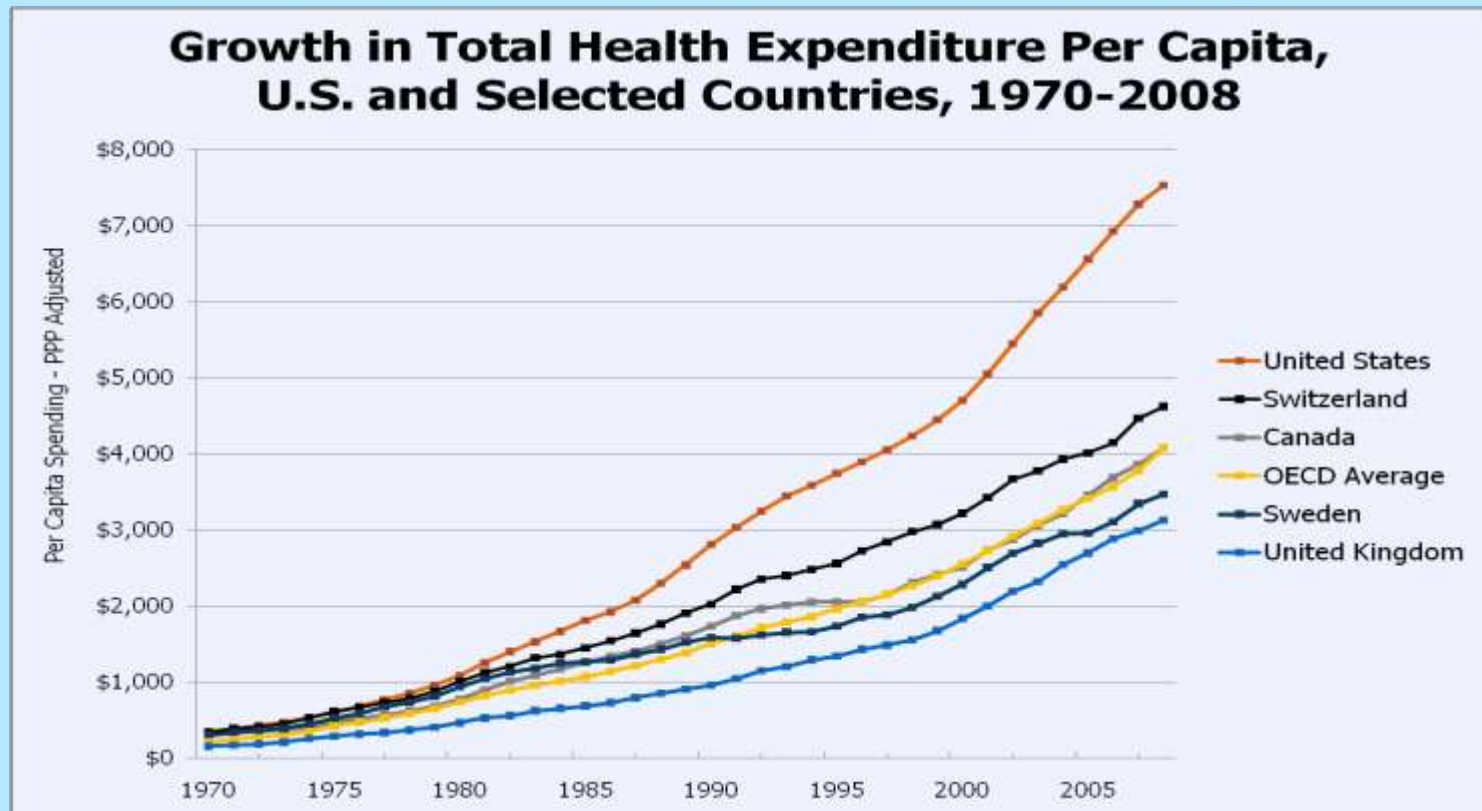
Evolution of laboratory medicine up until the late 20th century

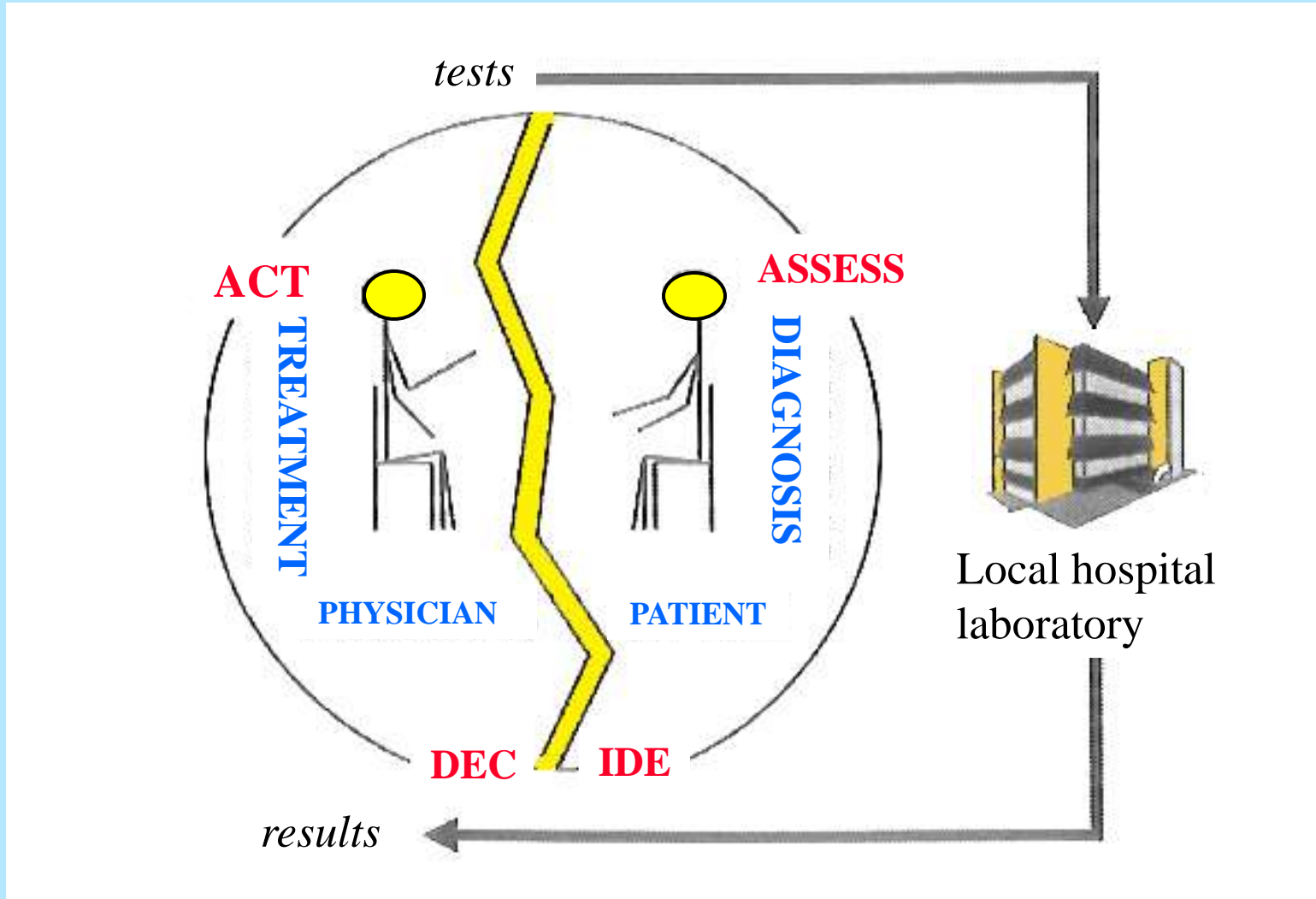
Point-of-care testing for the future



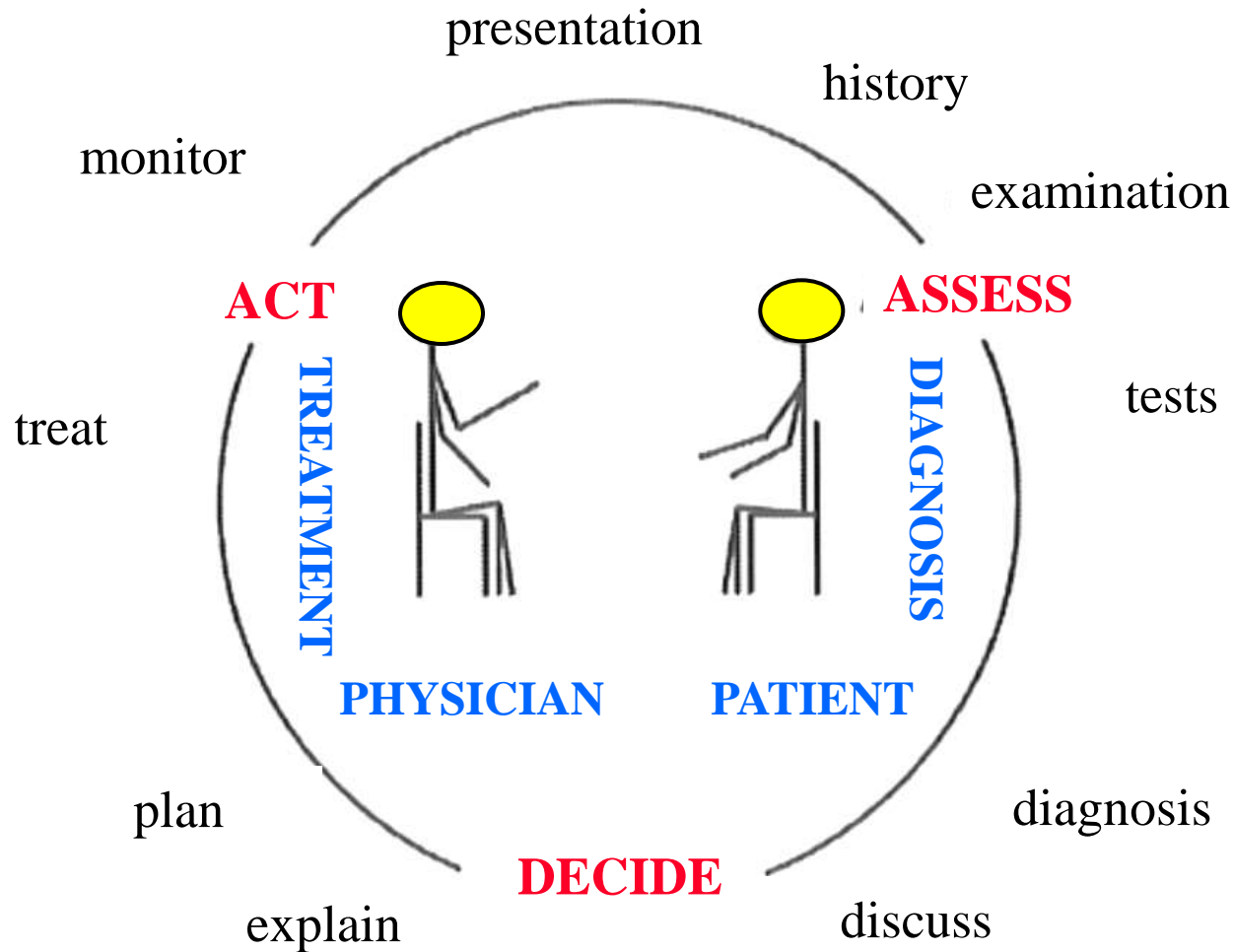
Healthcare trends

- Patients with chronic disease ↑
- Health care professionals ↓
- Costs ↑





POCT can improve physician-patient interaction



II. Rationale for POC testing

POC tests have clinical value only if they are
clinical effective

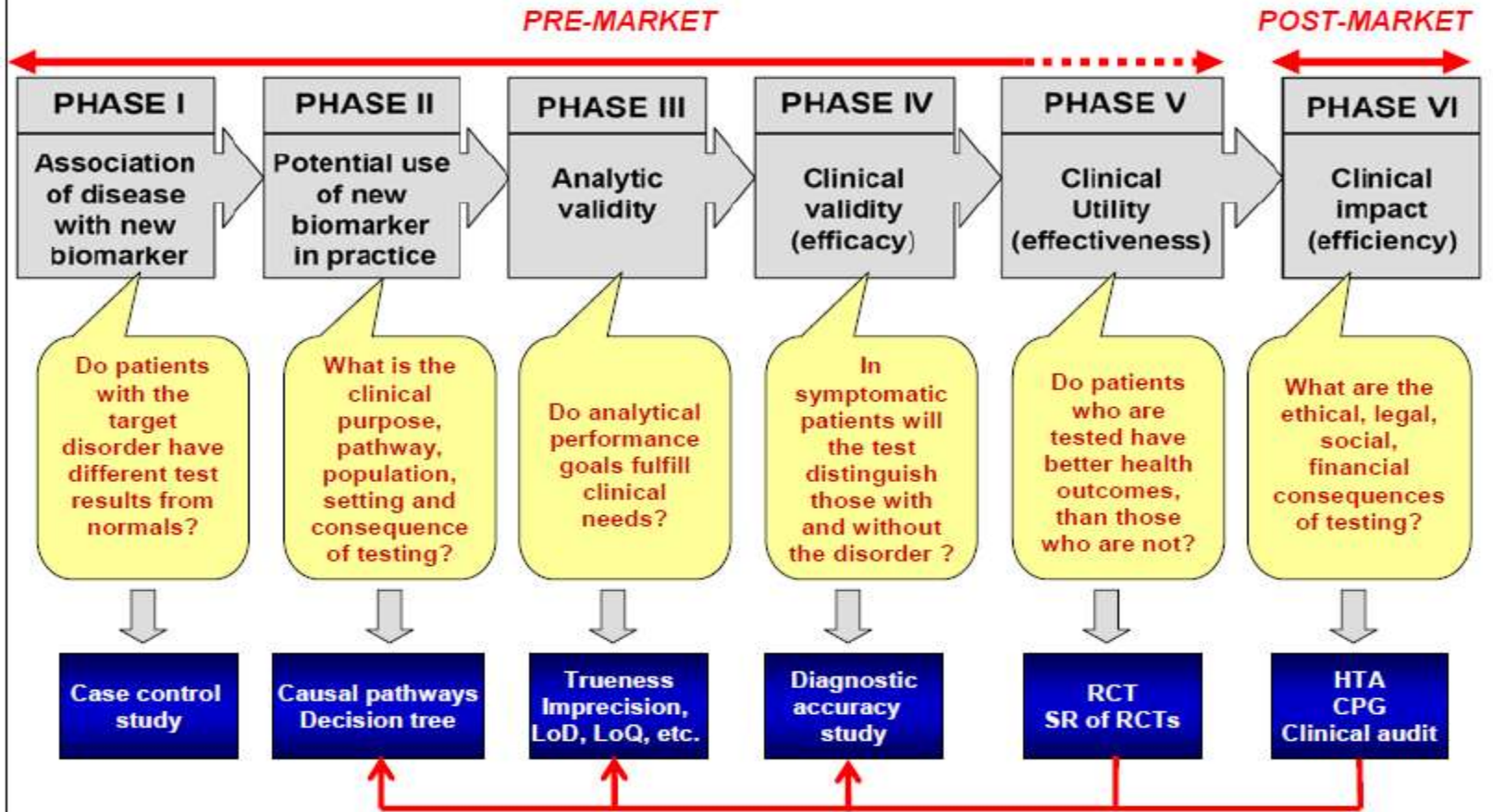
&

improve patient-centered or organizational or
economic outcomes.

- **Analytical validity:** the ability of *an assay* to conform to technical specifications and to correctly detect or measure a particular analyte.
- **Clinical validity:** the ability of *a medical test*
 - to yield results that are correlated with a particular clinical condition/physiological site in accordance with target population and intended use;
 - to be “fit for purpose”.
- **Clinical effectiveness:** the ability of a medical test to direct clinical management and to improve patient outcomes.

Medical Test Evaluation framework

Diagnostic test evaluation



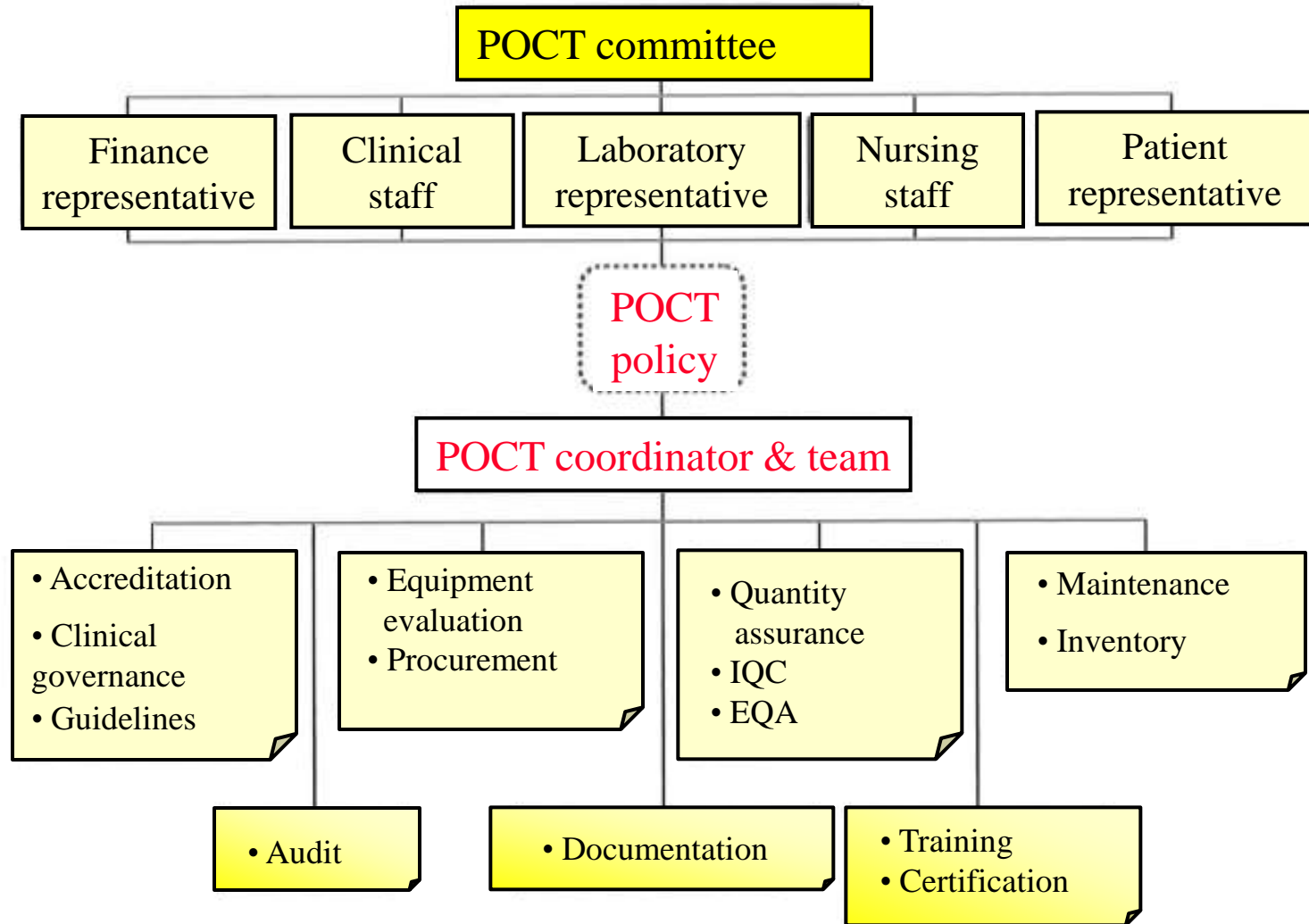
Outcome measures of POC tests

Outcome measure		Test purpose	Medical Test
<i>Clinical</i>	<i>Process</i>		
Reduced antibiotic use	Reduced need for laboratory tests	Rule out UTI	Urinalysis
Early detection of renal Disease	Advise the patient at the clinic visit	Rule out albuminuria	Urine albumin creatinine ratio
Faster and earlier diagnosis	Reduced clinic visits and use of echocardiography	Rule out a diagnosis of heart failure	Natriuretic peptide
Reduced complication rate	Reduced non-attendance at the clinic and reduced clinic visits	Screening for infection	Chlamydia
Increased period within the therapeutic window and reduced complication rate	Reduced clinic visits and reduced hospitalization	Self-monitoring and self-dose adjustment	INR
Improved glycemic control indicated by HbA1c	Reduced clinic visits	Primary care management of diabetes	HbA1c in primary care
Faster triage to therapeutic intervention	Reduced length of stay in ED	Rule out acute coronary syndrome	Troponin I or T in ED
Faster diagnosis and treatment	Reduced clinic visits	Rule out DVT	D-dimer in primary care

III. Essential Requirements for rationalized POC testing

- POCT policy & management structure
- Its place in the clinical pathway
- An informed business case
- Tips: consider
 1. Standardization
 2. Communication
 3. Improvement (process!)
 - Performance indicators
 4. Integration
 5. Positive attitude
- A POCT implementation plan

A typical hospital management structure for the organization of POCT



POC testing and its place in the care pathway

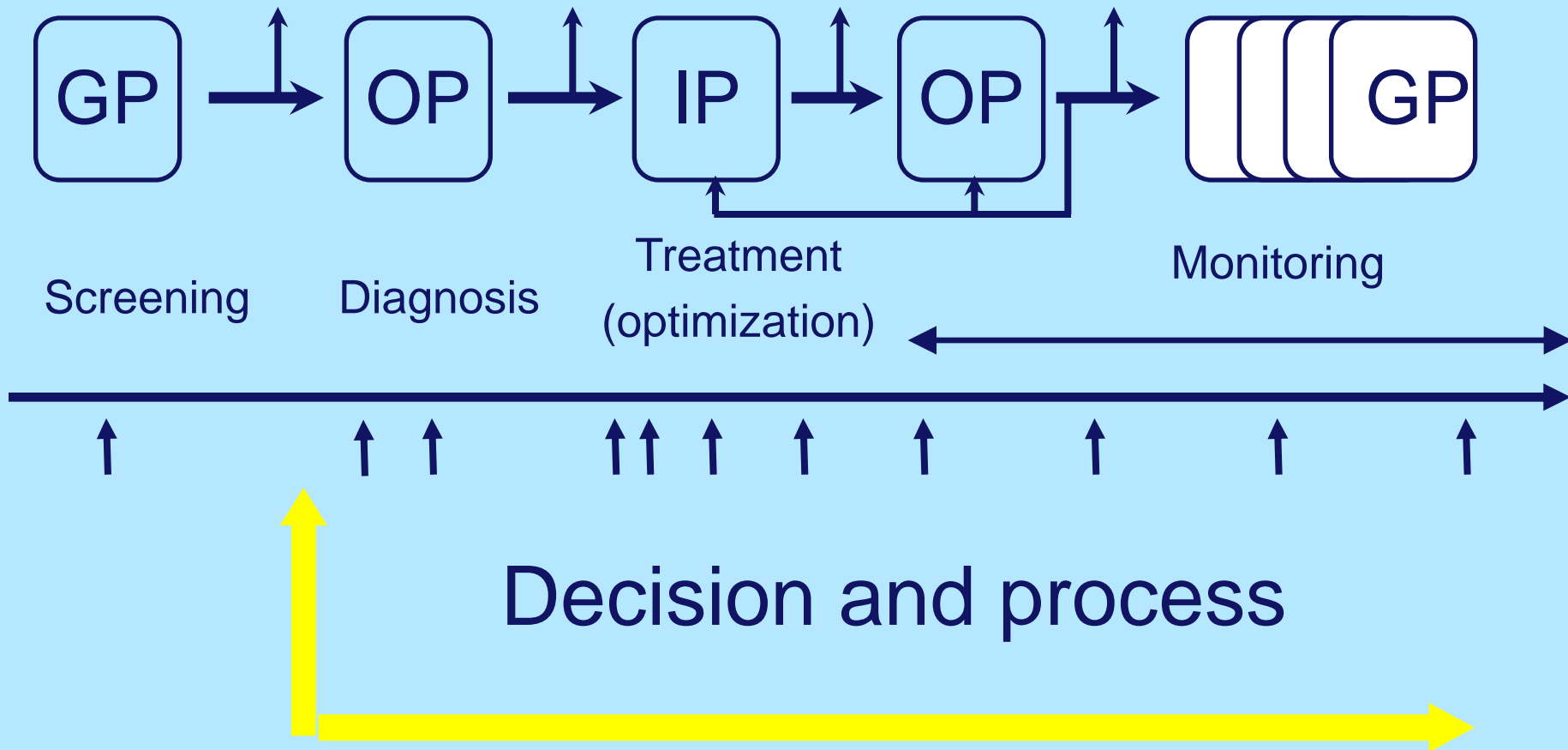
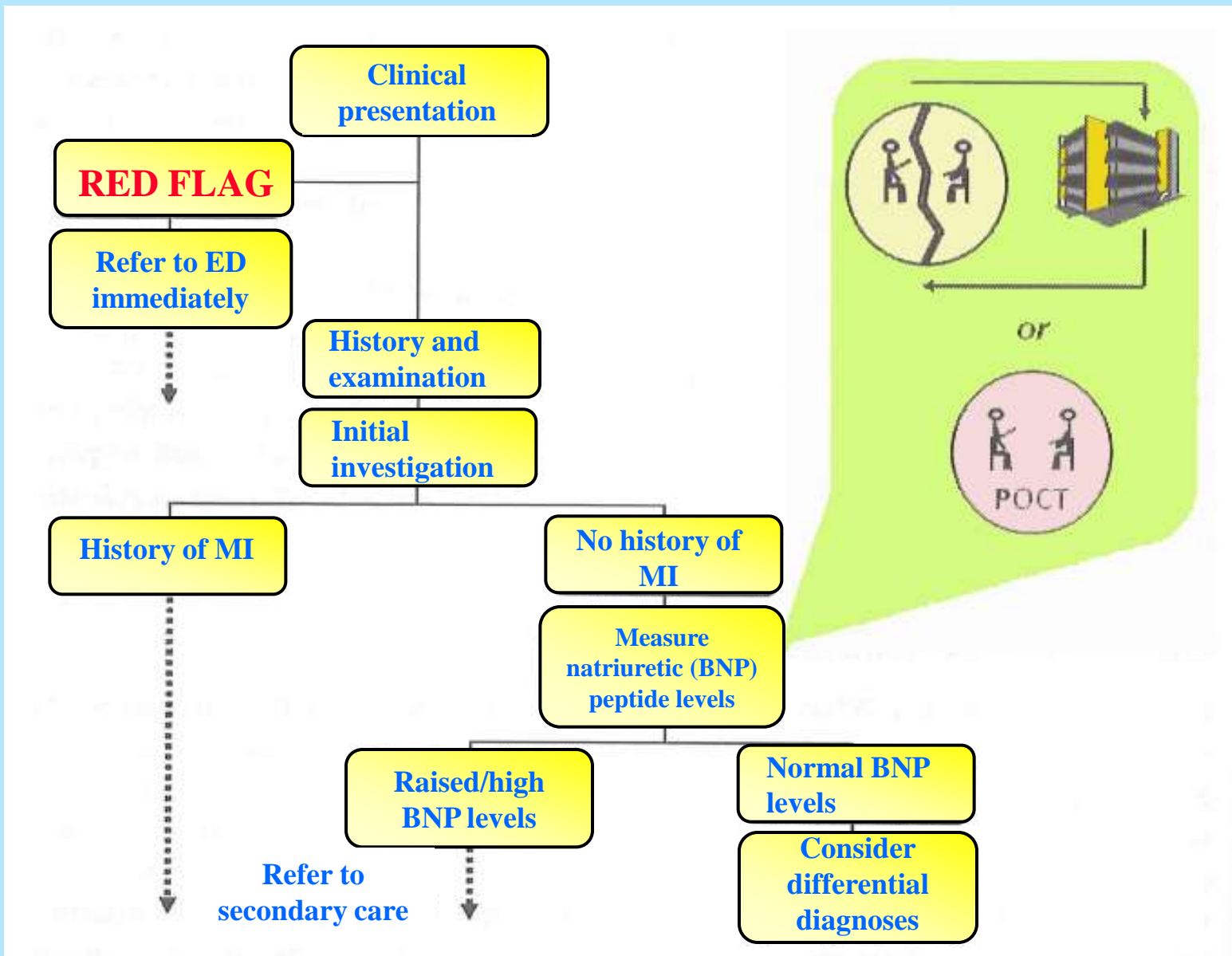
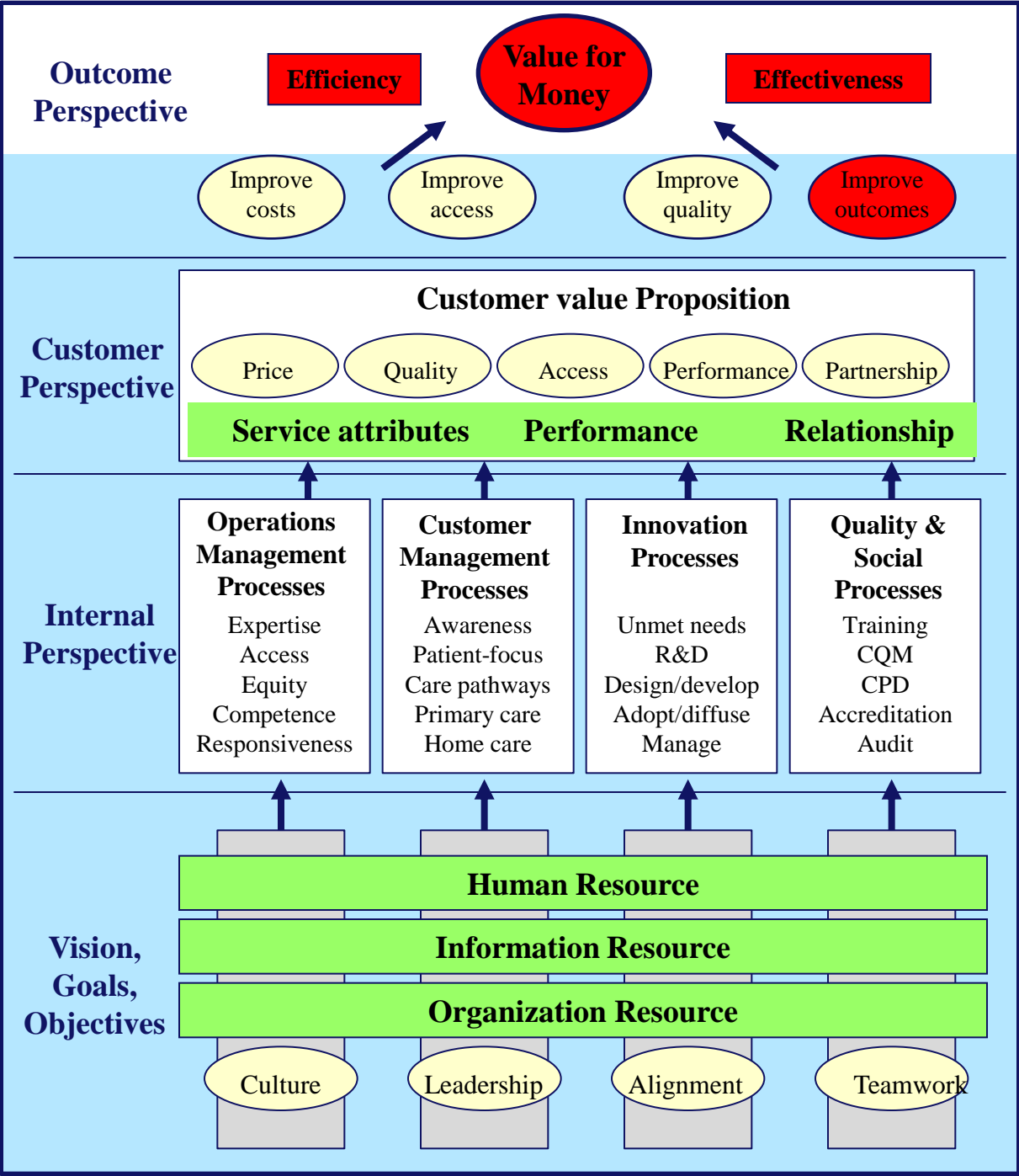


Diagram that illustrates where POCT may be of value in the diagnostic phase for primary care

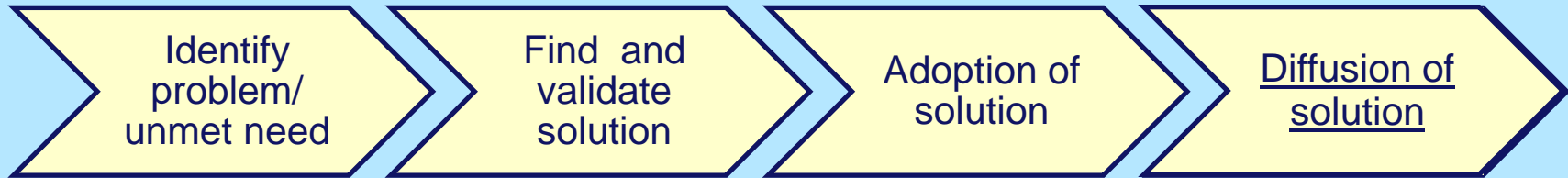


Value Strategy Proposition map



POCT, AACC press,
with permission from
Andrew St John

Developing an informed business case



Identified as part of:

- (i) strategic planning e.g. excessive length of stay,
- (ii) continuous quality improvement/audit e.g. clinic missed
- (iii) outcomes review e.g. number of HbA1c results >7.0%

Technology evaluated for:

- (i) relevant repertoire of tests
- (ii) analytical performance assessed by relevant user group
- (iii) **improved outcome shown**
- (iv) economic assessment shows benefit

Technology assessed for:

- (i) quality of evidence of effectiveness
- (ii) value-for-money
- (iii) robustness of business case
- (iv) feasibility of adoption
- (v) potential unintended consequences
- (vi) return on investment

Performance management:

- (i) establishment of implementation programme
- (ii) resource reallocation programme
- (iii) benchmarking to monitor performance
- (iv) revise according to experience

Key features of a POCT implementation plan

Identify unmet need and potential solution

Validate solution in pilot study

Redesign care pathway

Identify new performance metrics for new process

Identify new performance metrics for patient outcome

Identify new performance metrics for resource utilization

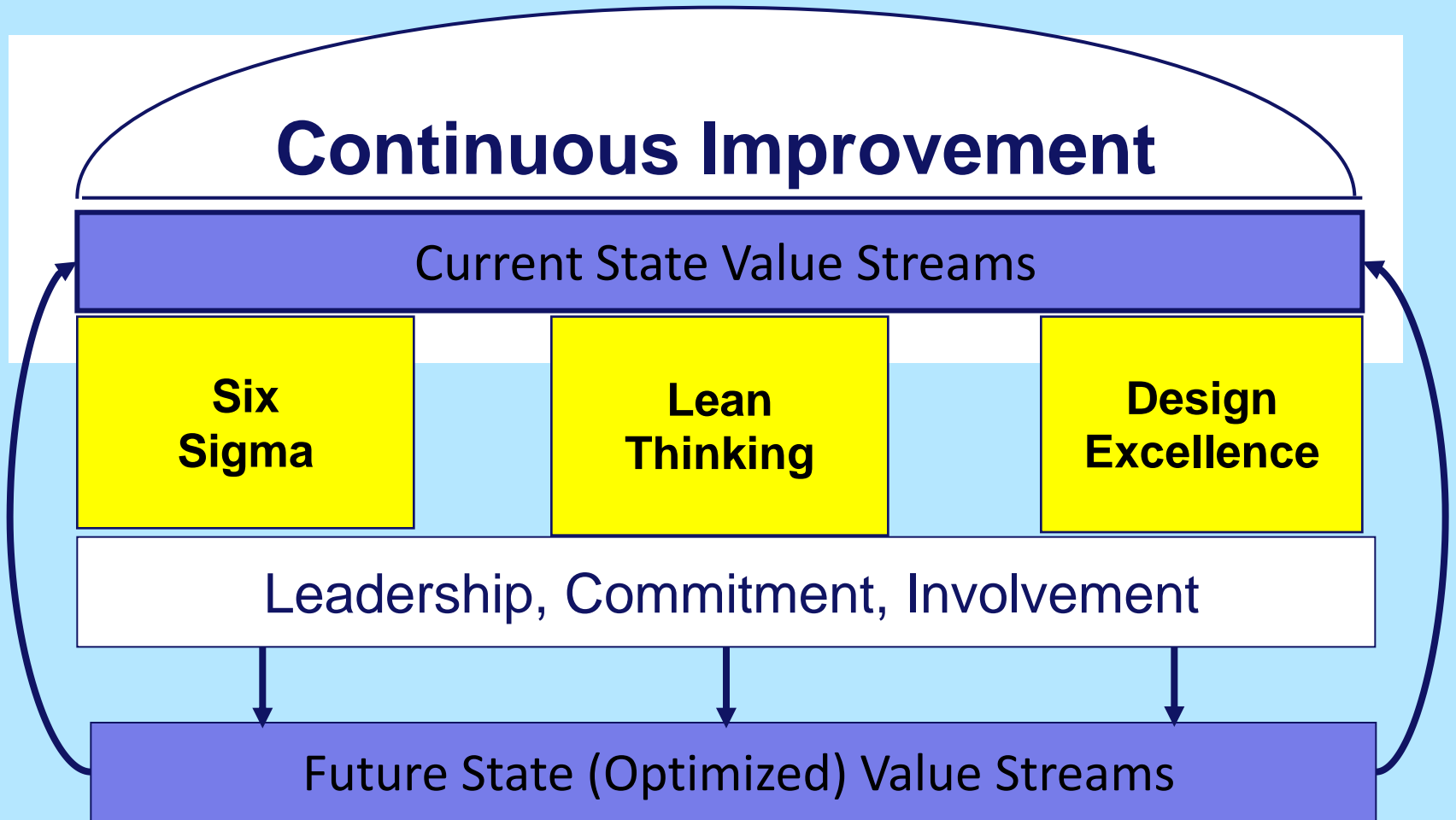
Train staff and assess competence

Commence implementation

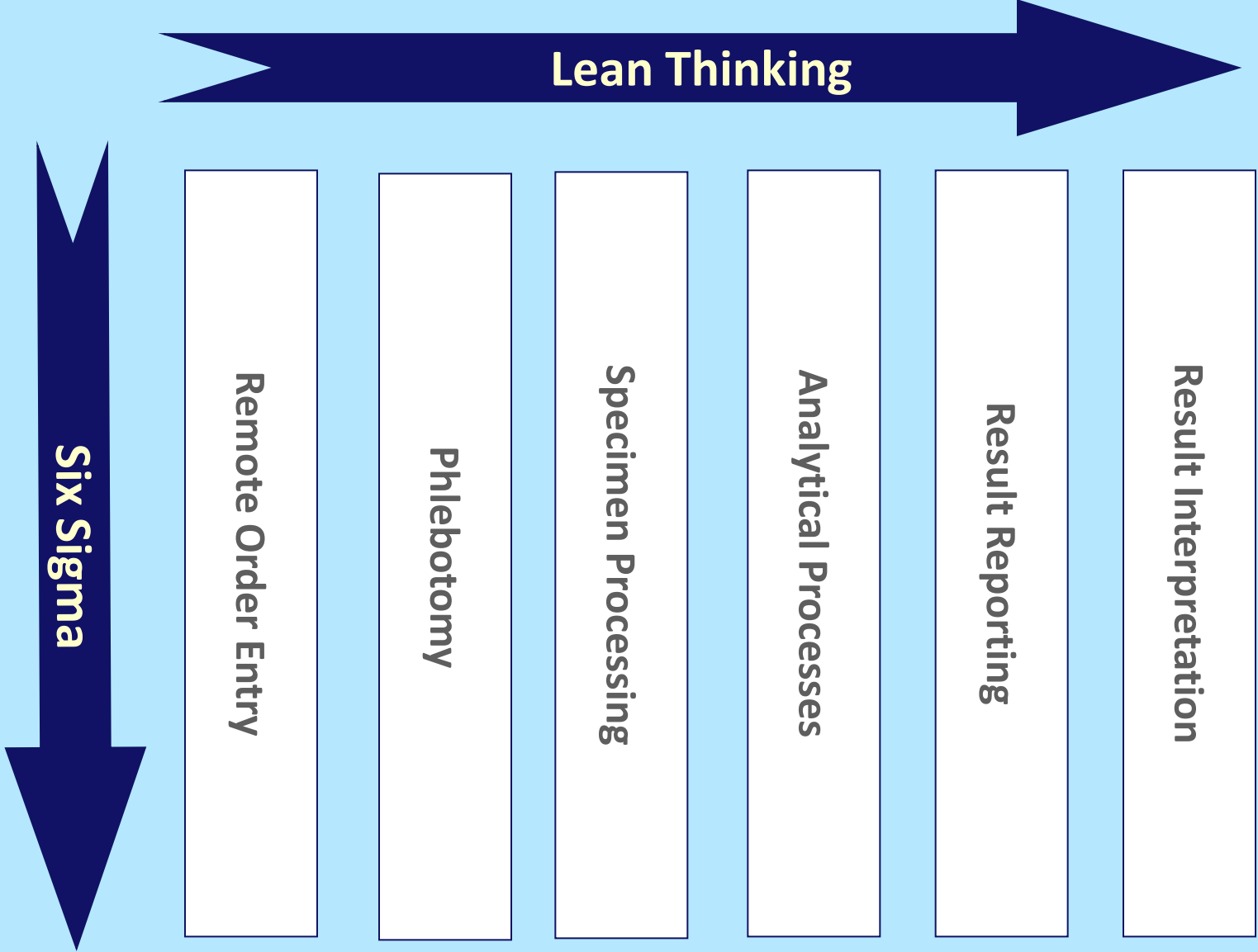
Monitor performance against metrics and review

Adjust practice if required and continue

Continuous improvement



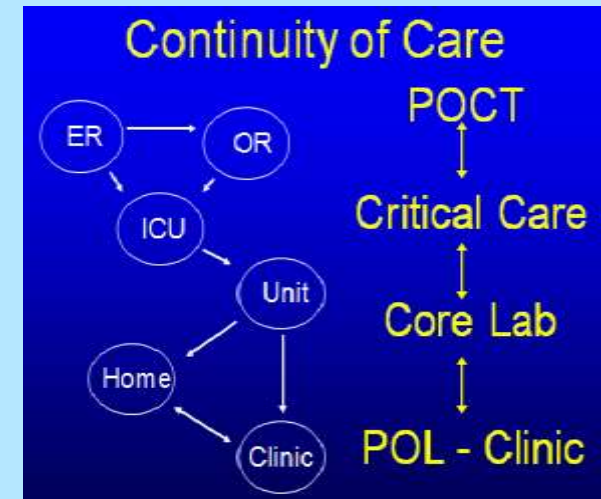
Relationship between Lean Thinking and Six Sigma



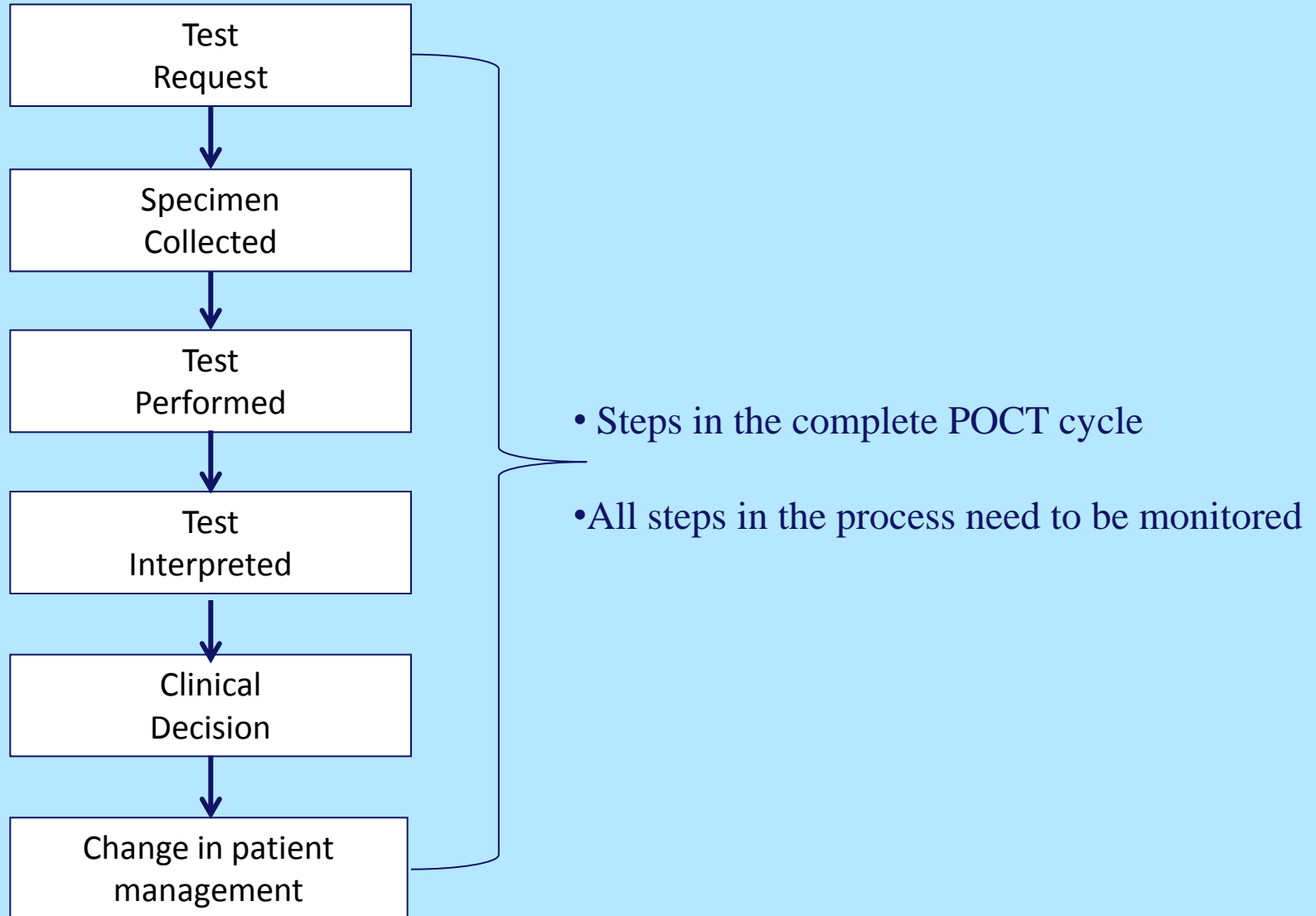
Tip #1 Standardize

Standardize instrumentation and methods across the institute of the healthcare provider

1. Minimize number of different devices
2. One policy can be shared amongst sites/wards
3. Central management system (i.e. oversight and data management)
4. Share reference intervals
5. Same methodology, clinical limitations
6. Simplifies training and competency.



IV. How to assure the quality of POC testing?



Guidelines

- TNO guideline (voluntary)
- IVD 98/79/EC directive (obliged)
 - Manufacturers → CE mark
- NEN-en-ISO 22870 POCT guideline – requirements for quality and competence



GLUCOSE



Average glucose of 9,0 mmol/L and uncertainty

- Due to biological variation → 8,0 – 10,0
- With TE_a criterion of 7% → 7,2 – 10,8
- With TNO criterion of 15% → 6,6 – 11,4
- With ISO criterion of 20% → 6,1 – 11,9

Performance Indicators

1. Successful QC

- a. Number of errors where wrong QC analyzed
- b. QC documentation
- c. QC statistics compared to hospital statistics
- d. Percent of QC that fail
- e. QC outliers with comment
- f. Failed QC with appropriate action (patients not tested)

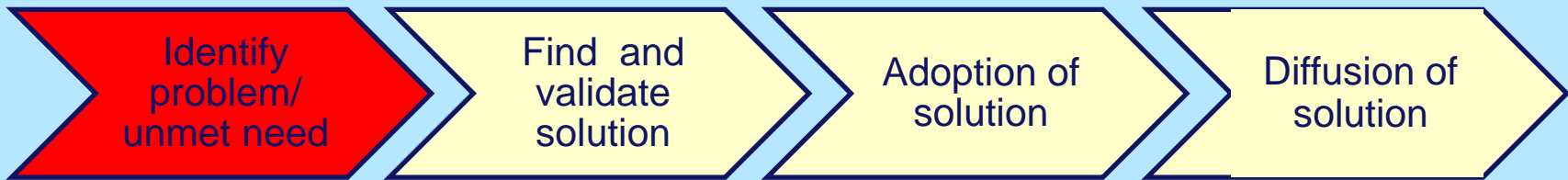
2. Utilization (number of tests/site or device)

- a. Tests analyzed vs tests reported
- b. Single lots of test and QC in use at any time

3. Compliance

- a. Untrained operators
- b. Clerical errors or data entry errors
- c. Medical record entry with reference ranges
- d. Expired reagents
- e. Refrigerator temperature monitored
- f. Proficiency testing successful
- g. Action plan response to site compliance deficiencies

V. Innovative POCT technology example



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Renal transplant patients

- Unmet clinical need: early detection of kidney rejection
- First year: 20 visits of outpatient clinic



Most important parameters to be measured:

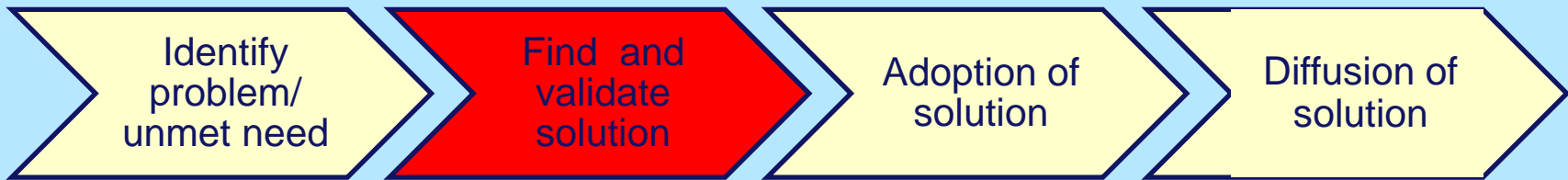
- Creatinine (renal function)
- Blood pressure



Need for handheld device for measuring creatinine **at home**

Innovative POCT technology

- a whole blood creatinine self-management example



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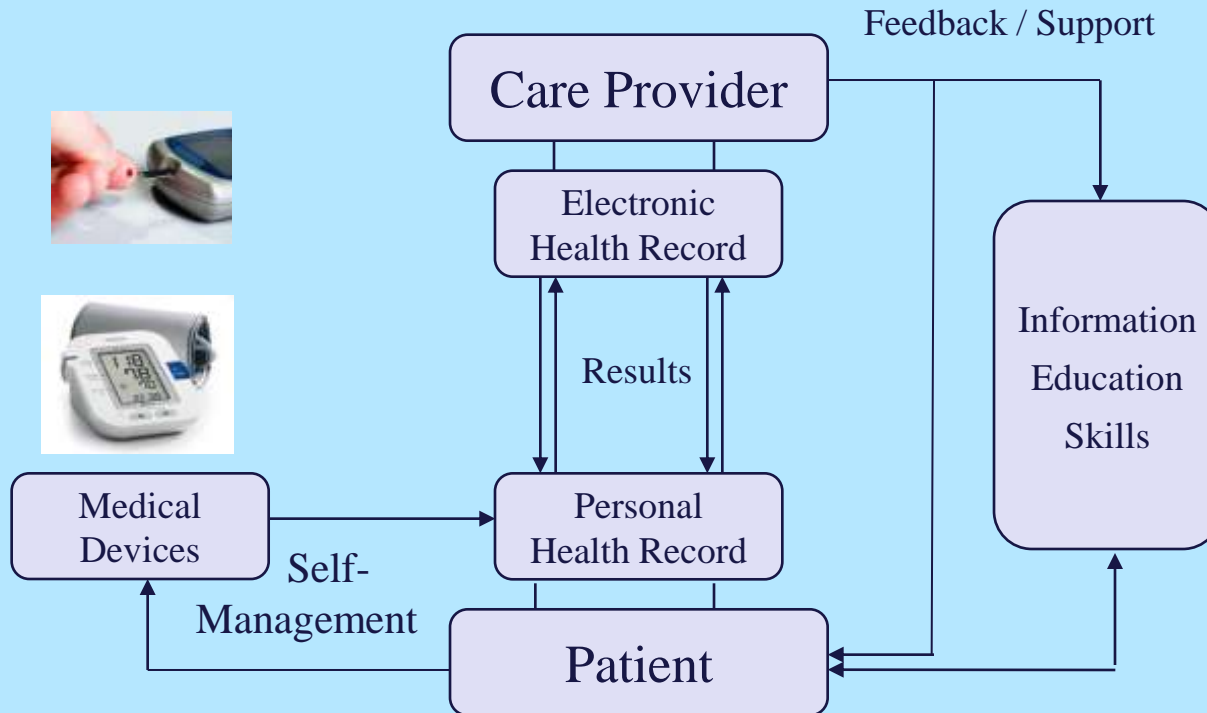
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Point-of-Care Creatinine analyzer Nova StatSensor®



Disease / Selfmanagement Infrastructure

- Creatinine StatSensor example



Content

Technical

Organizational

Financial

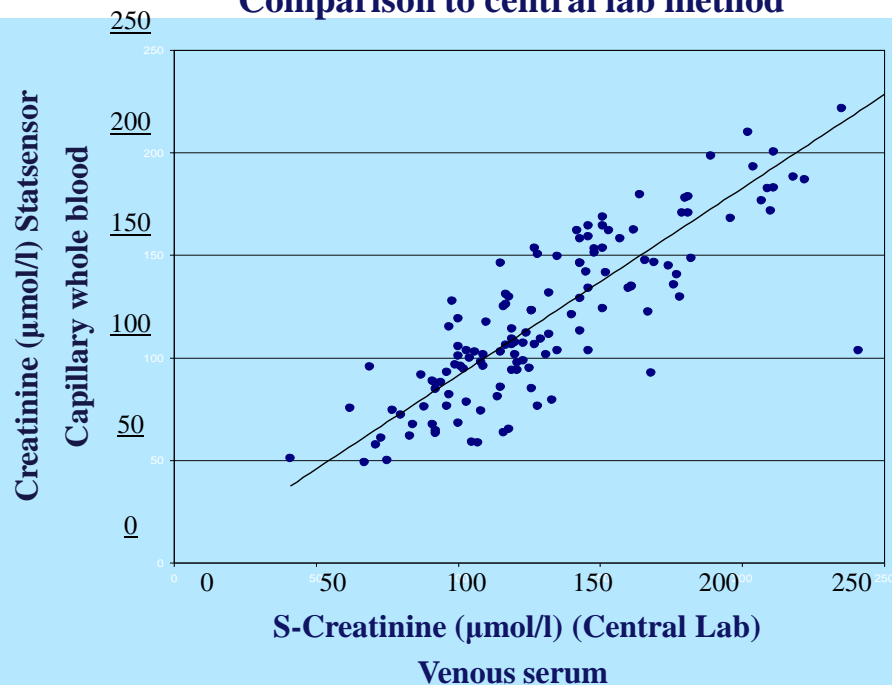
Social

Scientific

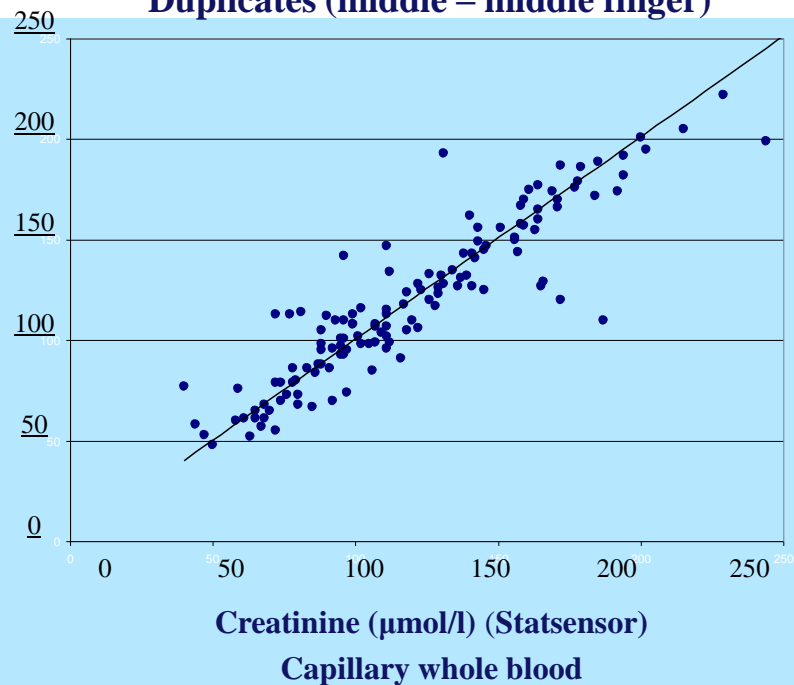
Boundary Conditions

Analytical validation of Nova StatSensor®

Comparison to central lab method



Duplicates (middle – middle finger)



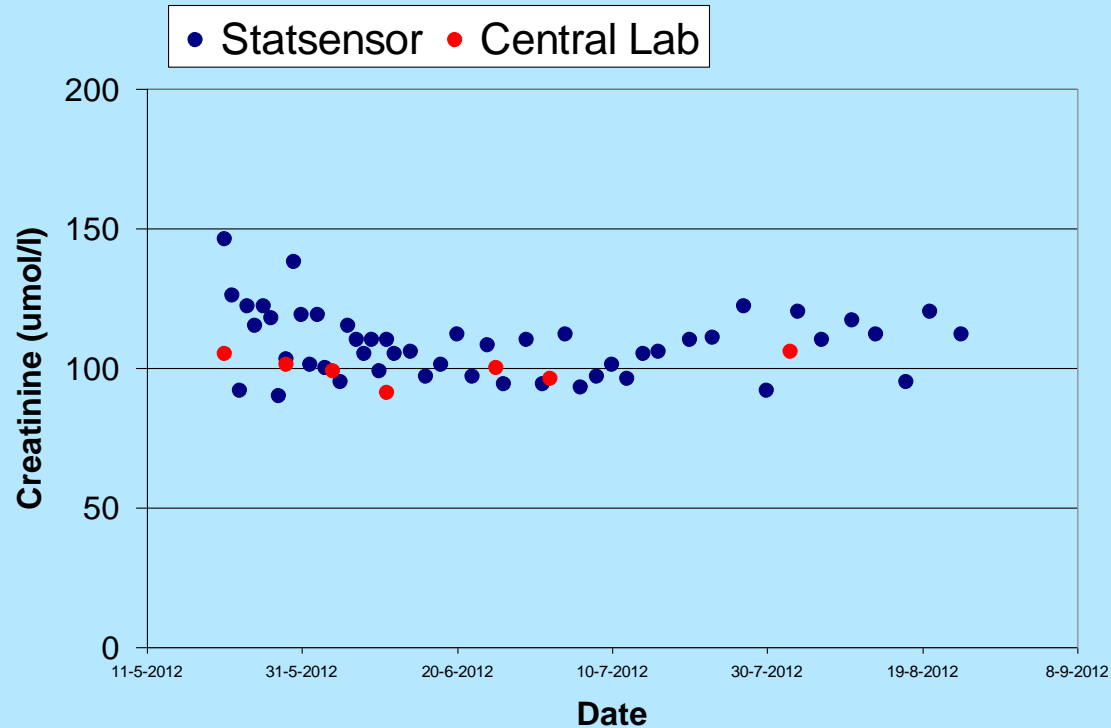
Critical difference / Reference Change Values (RCVs):

- 35% for StatSensor in fingerprick
- 23% for Statsensor in heparinized venous whole blood,
- 15.5% for the central lab method

RCVs were calculated as $2.8 * (CV_a^2 + CV_b^2)^{1/2}$.

CV_a = analytical CV; CV_b = intraindividual biological CV. ; $CV_b = 5,3\%$; (C. Ricos et al. Scand.J.Clin.Lab.Invest 1999;59:491-500)

Home measurements: more frequently



First weeks after transplantation:

- Creatinine Outpatient clinic: 1 x / week
- Creatinine Home measurements (Statsensor): 7 x / week

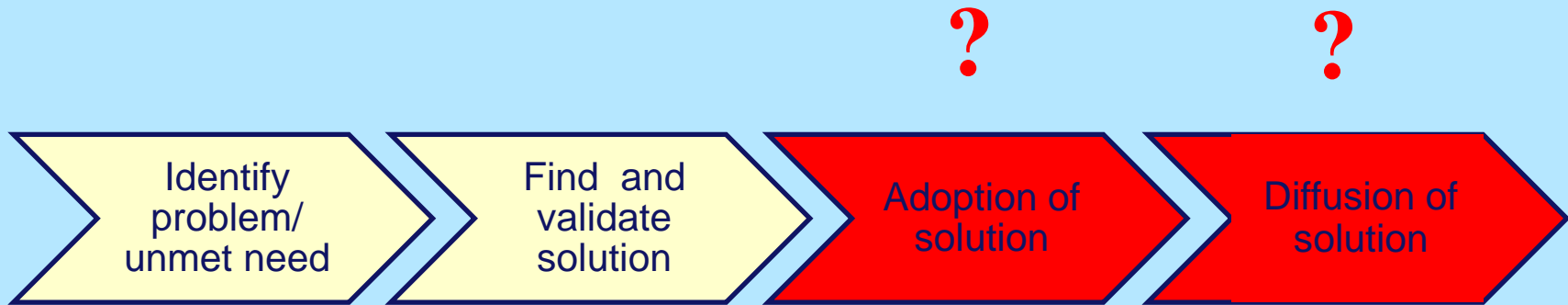
Analytical Performance!

- High (pre)analytical variation > desirable imprecision
 - High RCV (2.25 increase compared to central lab method)
- ⇒ for clinical use central laboratory method can not be replaced by the Statsensor

Clinical utility???

- More measurements (daily)
- Earlier identification of trends (necessary for detection of rejection)?

Innovative POCT technology & developing an informed business case



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VI. Concluding Thoughts

1. Consider POCT only if it is **the** justified solution to fulfill unmet clinical needs.
2. Develop an informed business case.
3. **Standardization of instrumentation and methods** across the institute of the healthcare provider, and **effective communication** are fundamental to building a successful POCT program.
4. Best way to motivate is to **engage operators**, communicate not just the policy but the reason for the policy – **the Why!**
5. Quality improvement at the point of care should be linked to institutional improvement plans.
6. Most important tips for successful POCT include **integration into the patient care pathways**, and promotion through a positive institutional culture.

POCT Success

Good management is the art of making problems so interesting and their solutions so constructive that everyone wants to get to work and deal with them.

Paul Hawken, Growing a Business