

# Near Patient Testing Point of Care Testing Patient Self Testing

How to implement POCT?  
**= How to create Added Value?**

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# 2 Centuries of Laboratory Medicine

## A history of Mobility

No comfortable transportation -> traffic jams

## A history of Equitable Health Care

No social security -> Welfare State -> Managed Health Care

## A history of Technical Evolution

Flasks and pipets -> automated multi-analyzers -> hand held gadgets  
- transcutaneous - implants

## A history of Communication

Hand-written notes -> HIS -> HIPAA-compliant servers in the cloud

## A history of Patient Empowerment

For the affluent -> for the uneducated -> information & control  
at the touch of a screen

**A history of DRIVERS for POCT**

# POCT Market Place

## Over-the-counter Self-Testing

Lateral Diffusion Tests / Strips

e.g. Pregnancy Tests, glucose, coagulation (INR)

## Prescription Point-of-Care

Primary Care Setting

Nursing Stations

## Emergency & Disaster Settings

**Market driven by commoditization**

**Market driven by customers willing to pay**

# Message #1

**POCT is here to stay**

**If you can't beat them, join them**

## Analysis

### **Old Paradigms in New Territories**

**It is not about threats but about opportunities**

**Not how to preserve the status quo / how to slow down evolution**

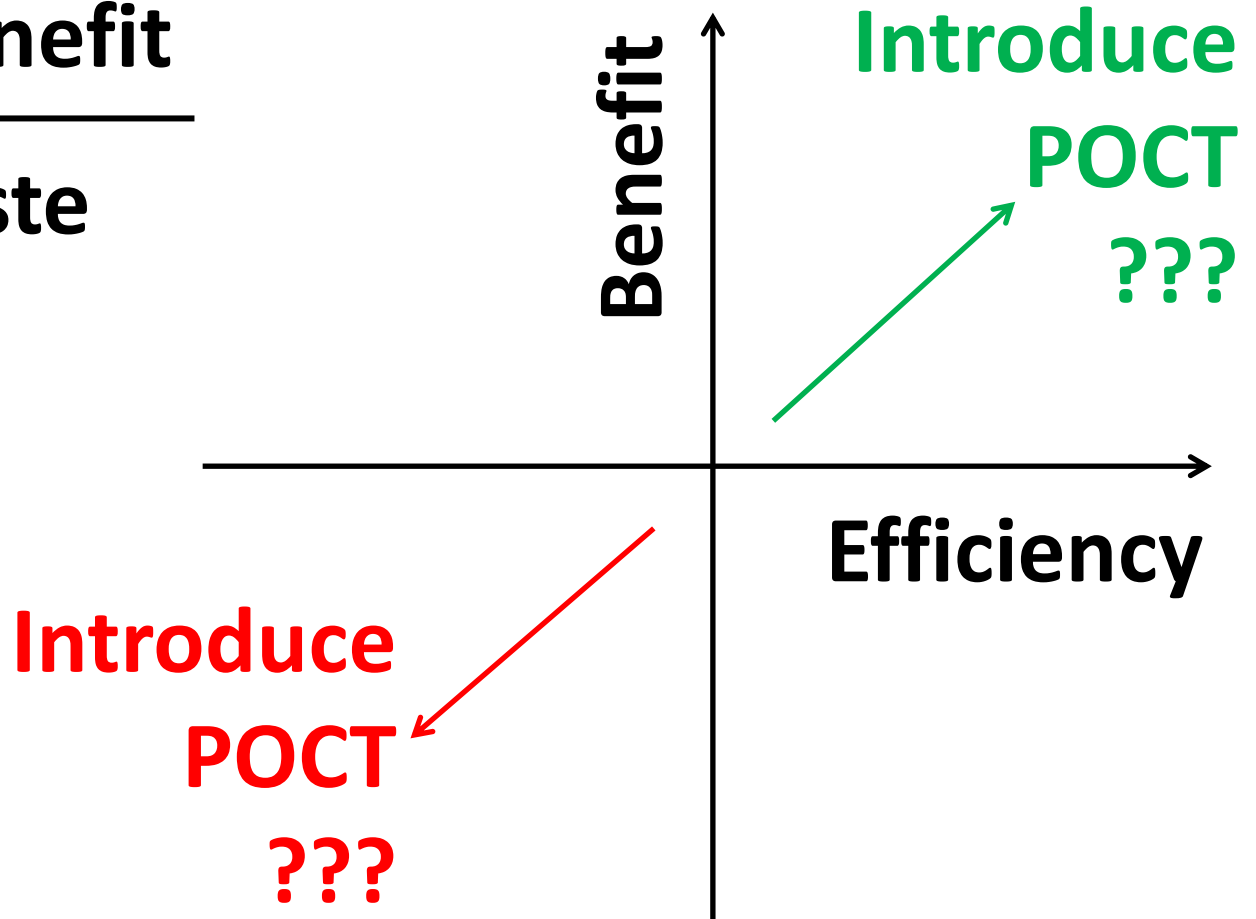
**But how to create **new value** in the **new territory****

# An Easy Recipe for Creating Value

**Create Benefit**

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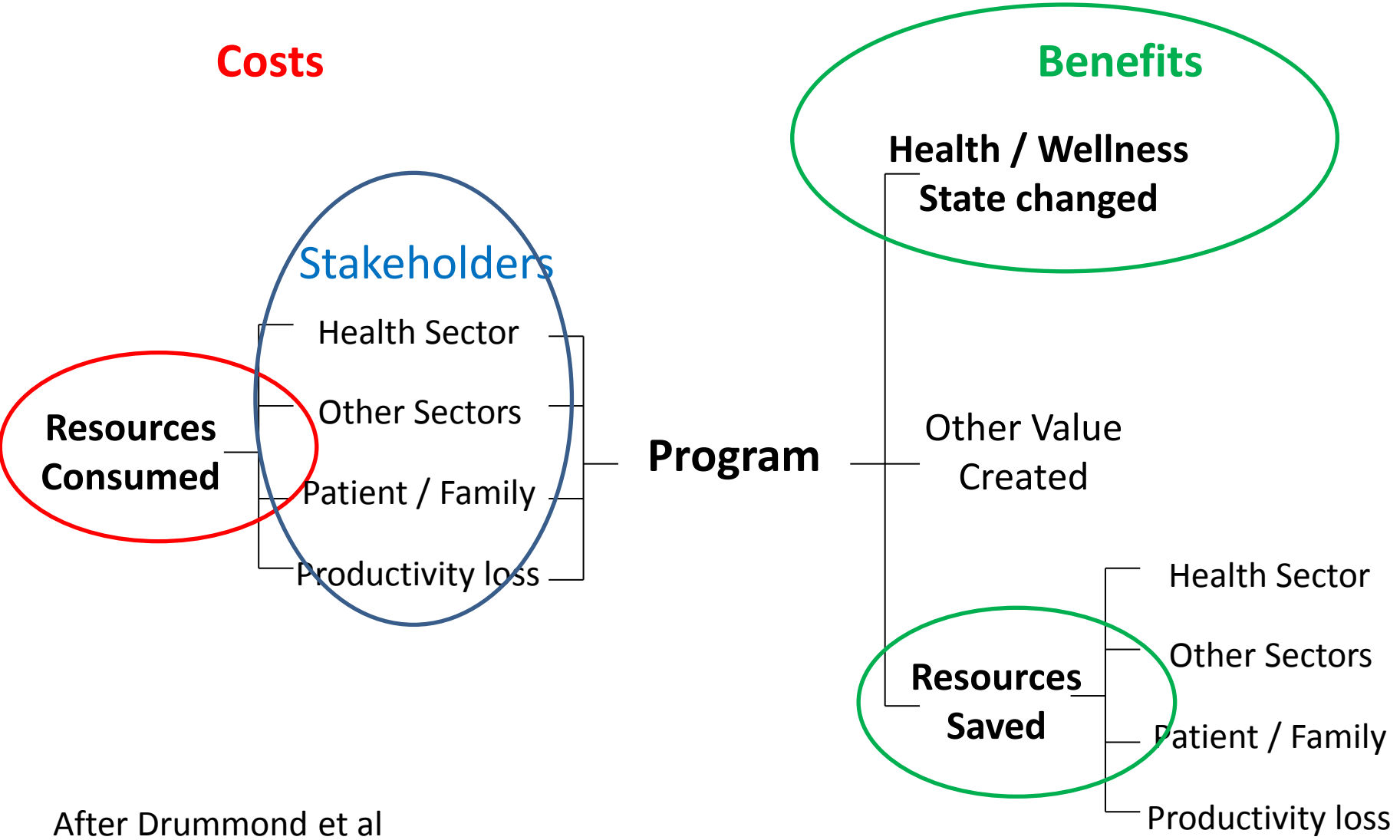
**Cut Waste**



# Where can POCT create **Value** for you?

## Costs

## Benefits



After Drummond et al

# Message #2

**Nowhere in Laboratory Medicine  
the stakeholders come as close together as in POCT**

**Direct Access & Direct Results  
are the appealing factors**

**Industry and Empowered Patient  
drivers for POCT**

## CMIT call for **Proposals to develop POCT Technologies**

Center for the Integration of Medicine and Innovative Technologies

*Posted on April 8 2013*

### **Point of Care Technology Research Center in Primary Care**

... stages of pre-commercial development will be considered ... viable candidates for commercial development ... As number of primary care providers diminishes and need for primary care increases, the fundamental unmet need is **to increase the capacity of providers** to care for more patients without a decrease in the quality of care and without unduly burdening providers.

**Two POC technology-enabled pathways towards this end have been identified:**

- eliminate unnecessary steps and re-work to **increase the efficiency of operations**
- self-monitoring capabilities to the home setting for **patient self-management**



## CMIT call for **Proposals to develop POCT Technologies**

Center for the Integration of Medicine and Innovative Technologies

*Posted on April 8 2013*

**The highest priorities to address needs in **primary care** are:**

- **Clinical laboratory testing:** blood count (WBC differential); electrolytes (K); lipid panel; renal panel (BUN, creatinine, albumin); diabetes screening (HbA1c).
- **Infectious disease:** differentiation viral and bacterial; segmentation into gram positive or negative bacteria.
- **Anticoagulation testing:** INR/PT

# Message #3

POCT broad definition  
is not about new tests  
but about the **logistics** of the **overall Care Process**

The technical **enablers** are

- commoditization
- miniaturization
- communication technology

Also opportunities

for the central lab

Faster accurate diagnostics

Better use of resources

What the marketers **want us to believe**

- capacity and **turn-around gains**
- reduced up-front capital investments

?

## **AAP advises parents not to rely on retail clinics**

The AAP said parents should not rely on retail health clinics to provide primary care services for their children. The policy statement, published in the journal [Pediatrics](#), said although the clinics may be less expensive and more convenient, they do not offer the continuity of care provided by pediatricians. These facilities are "an inappropriate source of primary care for pediatric patients, as they fragment medical care and are detrimental to the medical home concept of **longitudinal and coordinated care**," the group said.

[The Wall Street Journal \(tiered subscription model\)](#)

AAP Smartbrief, published Feb 24 1014

# Message #3

Narrow definition:

POCT is about

optimizing testing at the point of care

**Broad definition:**

POCT is about **optimizing outcome** by

**optimizing laboratory diagnosis at point of care**

not about

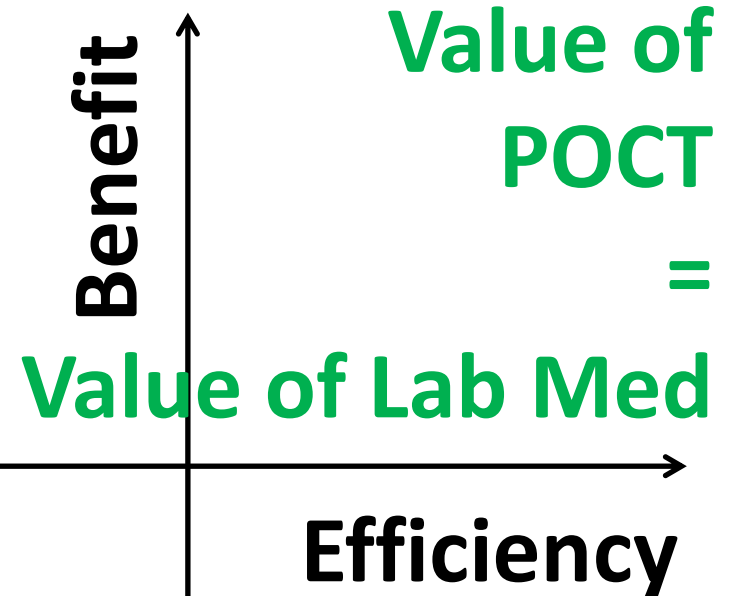
testing at the point of care

# An Easy Recipe for Creating Value

**Create Benefit**

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**Cut Waste**



# Is there Value in Laboratory Medicine?

Diagnosis is a Deliberation Dialogue

Lab Medicine supports this dialogue

Right test, at right time for right patient

Lab stands for Save Results

# The decisive B2B cycle is from patient to patient

Patients

willing to pay for commodity from their own pocket  
Industry has taken notice

Patients self-testing has already started !!!

R) We have to fit expert advice into the B2B cycle

? For over the counter systems  
the point of contact is the pharmacy  
or data are transmitted to physician of choice ?

# The Value in Laboratory Medicine

Diagnosis is a Deliberation Dialogue

Lab Medicine supports this dialogue

Right test, at right time for right patient


Lab guarantees Save Correct Results



## For the **right patient**

- the **right test** at the **right time**
- the **right result on time**
- in the **right format** for  
effective **communication** resulting in  
- the **right answers to patients questions**
- under **comfortable** conditions

Patient's & Physician's B2B:  
Immediacy determines  
effectiveness



= lab medicine's classical quality focus:  
optimize diagnostic power / **logistics**

# Message #4

POCT is

about making the right test **readily available**

## **CAVEAT**

More redundant (poor quality) results introduce  
not a benefit but more medical errors

By scaling up the availability to more settings  
the costs of false positive diagnosis will increase

**R) Without Expert Consult, POCT is not SAVE**

**User has to have direct access to experts**

**Experts have to monitor POCT practice**

# An Easy Recipe for Value creation

**Create Benefit**

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**Cut Waste**

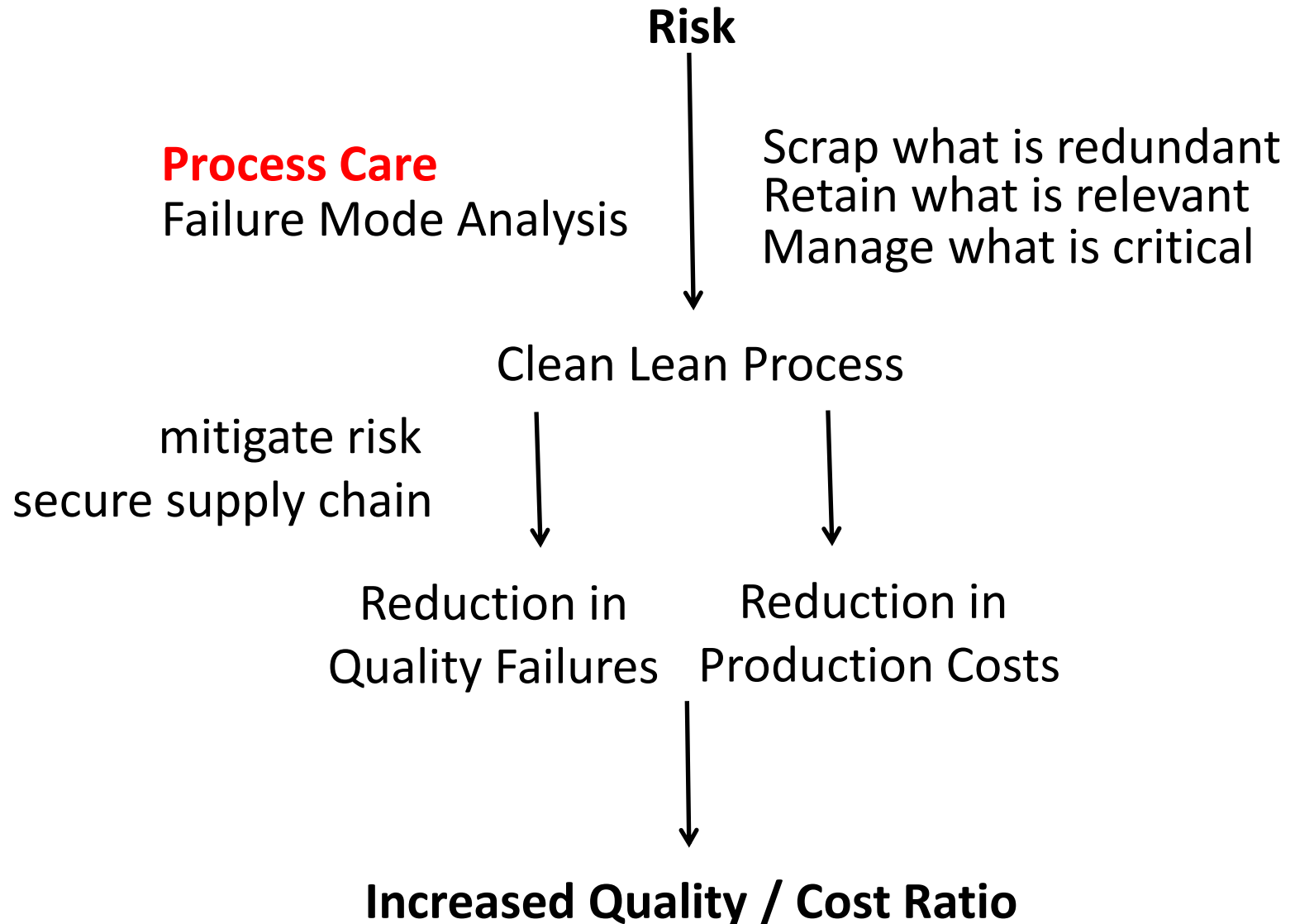
**Toolbox = Process Care**

Scrap what is not needed

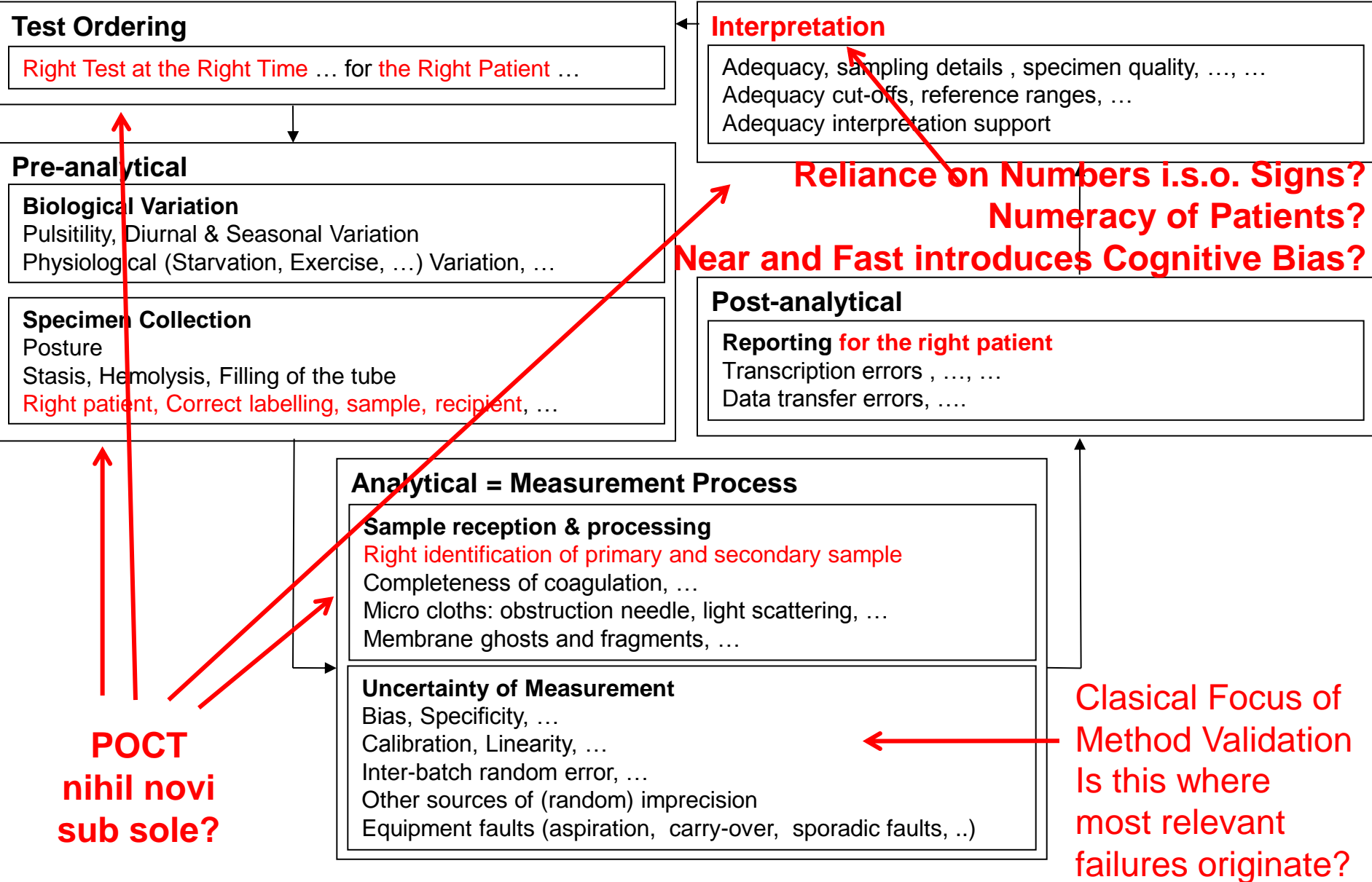
Do what is needed

Manage critical components

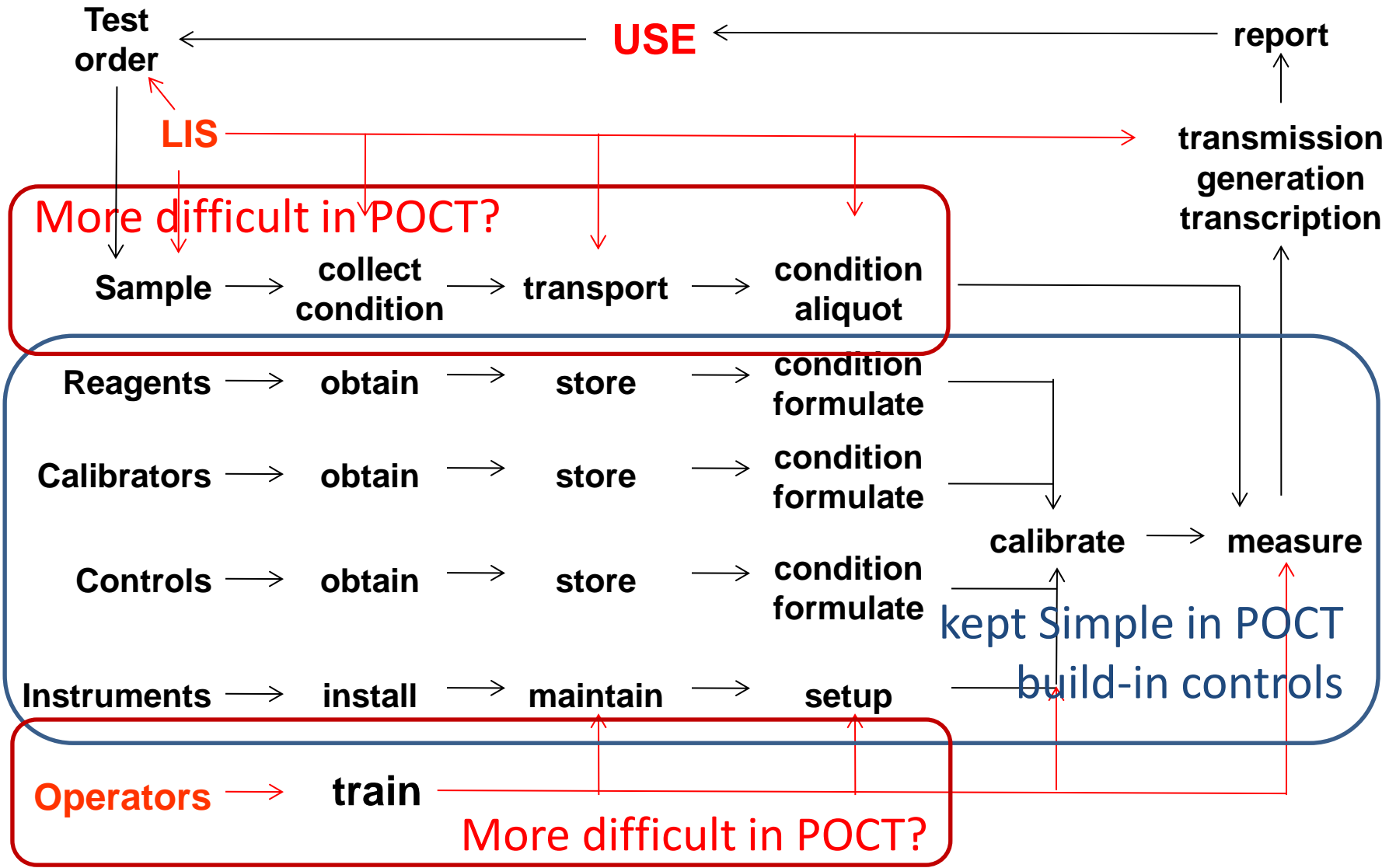
# Risk-Based Quality Management



# Risk Analysis: Failure-Mode analysis: What can cause relevant failures?



# Risk Analysis: GENERIC FAULT TREE in a Medical Laboratory



After ISO/TS 22367:2008

# Message #5

Introducing POCT (or any human activity) is about **organizing fail-safe processes**

Scrap what is not needed

Do what is needed

Manage critical components

# An Easy Recipe for Value creation

**Create Benefit**

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**Cut Waste**

**Toolbox = Quality System**

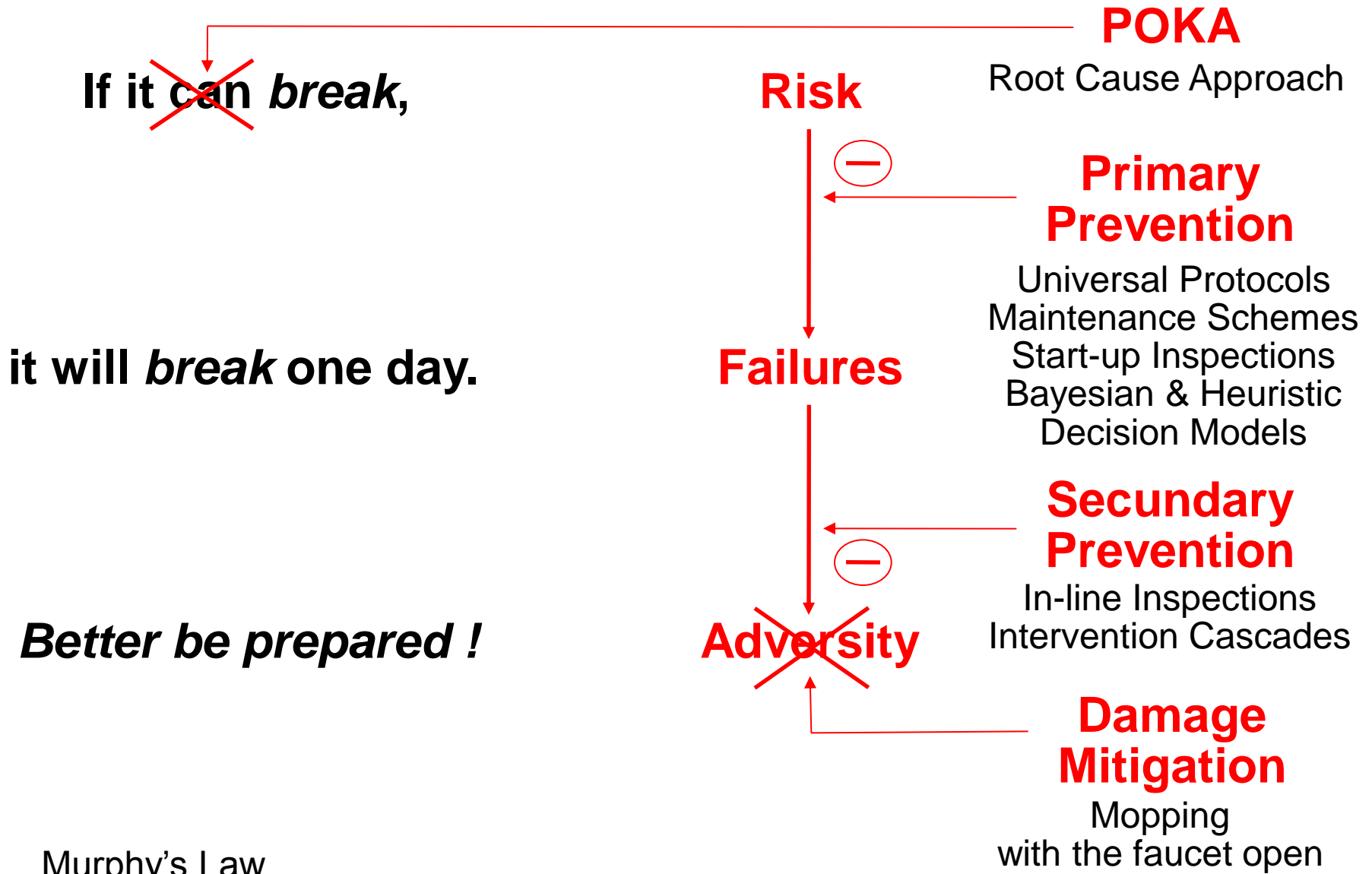
Risk Management & Process Care

Systematic Approach to Systems

Deming-Cycle for Maintenance of Systems



# Quality System = System of Prevention



# COMPONENTS OF QUALITY INVESTMENT

A.V. Feigenbaum

**ADD VALUE**

**CUT LOSSES**

**Investment in CONFORMANCE**

**Costs of QUALITY FAILURE**

**PREVENTION**

**APPRAISAL**

**INTERNAL**

**EXTERNAL**

**Training**  
**Calibration**  
**Maintenance**  
**Lean**  
**DESIGN**  
**for QUALITY**  
**ROOT-CAUSE**  
**APPROACH**

**In- & End**  
**-of-Line**  
**Inspection**

*secondary prevention* →

**Scrap**  
**Rework**

*Damage Control* →

**Adverse Effects**  
**in Patients**  
**Complaints**  
**Customer support**

**NOT-VALUE-ADDING VALUE-RECUPERATING**  
**OPORTUNITY COSTS**  
**The less, the better**

# Message #6

Your Quality System is  
about **optimizing processes & systems**

Scrap what is not needed

Do what is needed

Manage critical components

POCT:

Lack of Consolidation, Increased Overheads,  
Increased Cost Consumables

**from viewpoint of the lab / of end consumer:  
Forbidden Proposition?**

# Standards: Systematic Approach

*Nihil novi sub sole*: ISO 22870 = ISO 15189

Risk Management Principles in POCT

Deming Cycle

Measurement = Knowledge: Validated KPI's

Feedback: Immediacy

Relevance: Stakeholder Buy-in

Additional Focus

**POCT governance: Clinical / Operational**

**Multi-Site System / Interacting Professional Pillars**

# Message #7

POCT comes in different blends

- R) Under development standards for  
Different Organisational Models  
Hospital: ED – outpatients  
Primary Care – Patient Self Testing

## Some of the hurdles

Why is laboratory Medicine different from  
transcutaneous measurement of Hb oxygenation ?  
oxygen saturation at the tip of an indwelling catheter ?  
... saturation \* flow ?

Our clinicians rightfully have a suspicion that  
laboratorians have a hidden agenda

R) The lab has to convince users  
that the lab's involvement =  
managed quality = reduced operational costs

## Application of the Standards: **Waste or Added Value?**

- validation of gadgets  
instead of **valuation of systems**
- quality control and proficiency testing  
instead of **fail-safe designs**
- training & recertification  
instead of **continuous feedback**
- industry provides software for formal compliance  
instead of **development of lean fail-safe & direct systems**

R) **Professional Organisations have to participate in refocusing Quality Standards**

Diagnostics Industry promotes proprietary middle ware instead of adopting **open bidirectional standards**

R) The customer has to speak up

- **pseudo-open systems help monopolies not the customer**

R) Information Technology is capable to solve the problems

- **develop new business models for service industries**
- **patient privacy legislation has to follow**
- **the public has to trust the systems**  
**(overcome Big Brother myth)**



# Some problems specific for the Belgian context

(dated fall 2013)

Standing orders not allowed by reimbursement system

Problem of Standing Orders not unique for lab medicine

R) Optimize the logistics of Care Pathways  
as a win/win for Paying Party, Care Provider & Patient

Financial Risk: Entitlement to reimbursement depends on  
Adherence to Royal Decree & “Praktijkrichtlijn”

R) Either Risk Citation and Restitutive Payments

R) Or Forego Reimbursement

## Some of the hurdles / opportunities

Do physicians want to get involved?

Is there a capacity issue to solve?

Is there a differential diagnostic issue to solve?

Or is it only “me to”?

Information technology is capable

but logistics / applications remain immature

R) Adoption of a **service business model**:

**Distributed expertise:**

**Laboratories catering for Primary Care Physicians**

**Physicians / Pharmacies catering for Patient self-testing**

# Some problems specific to the Belgian context

(dated fall 2013)

No transmural standardized electronic patient files

No standardized electronic patient data exchange protocols

R) **Industry has understood the opportunity** (MS HIPAA cloud)

R) Work in progress, but

**not to be solved at level of countries but worldwide  
(a free market for services lurks in the background)**

# Message #8

## Threats or Opportunities?

A Market not to be Missed

Opportunity

Threat

POCT from the viewpoint of the Laboratory

- POCT: **income** ↓ / **expenses** ↑

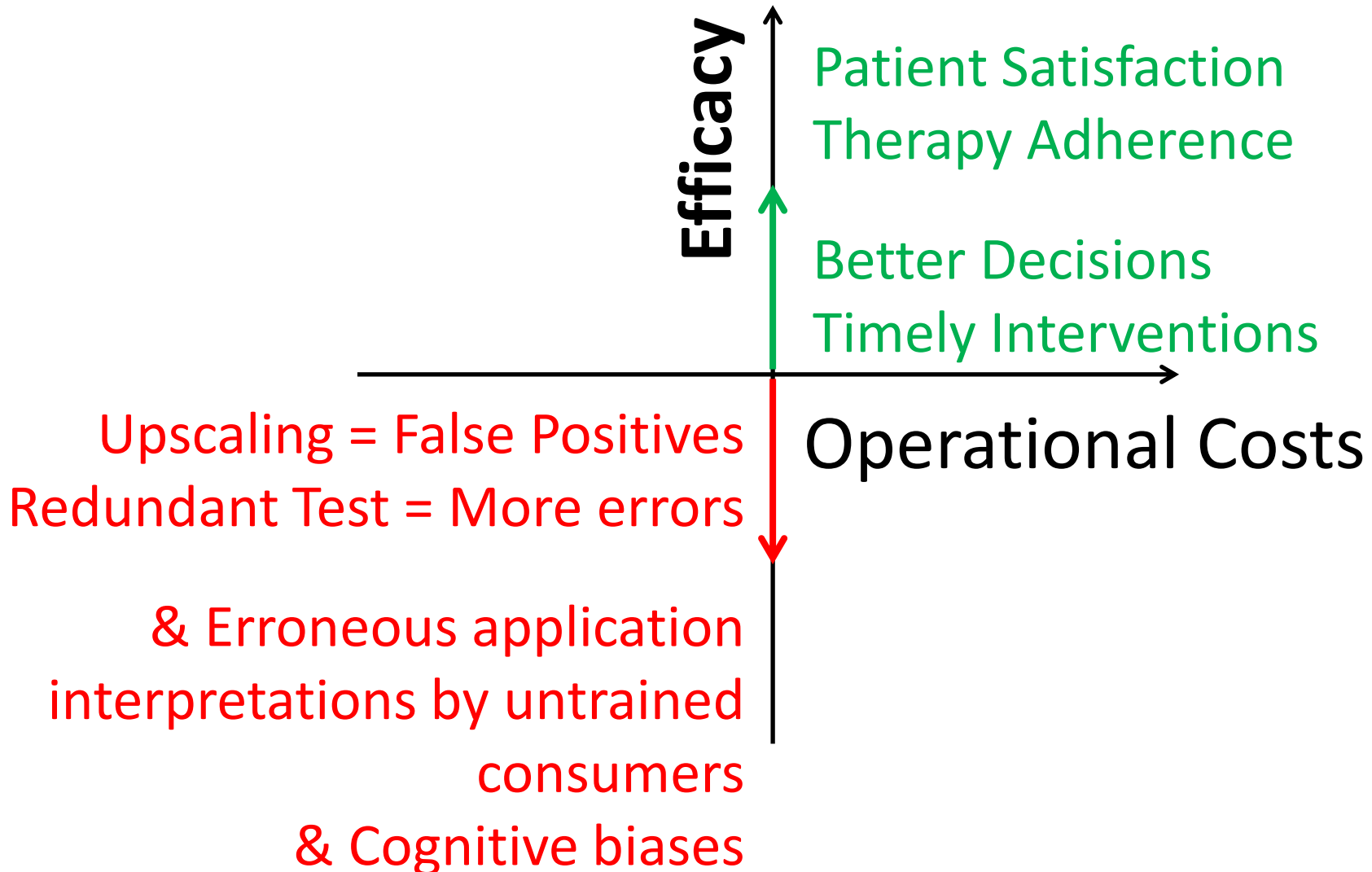
- shift from central lab to POCT

remainder of operations in the central lab more costly

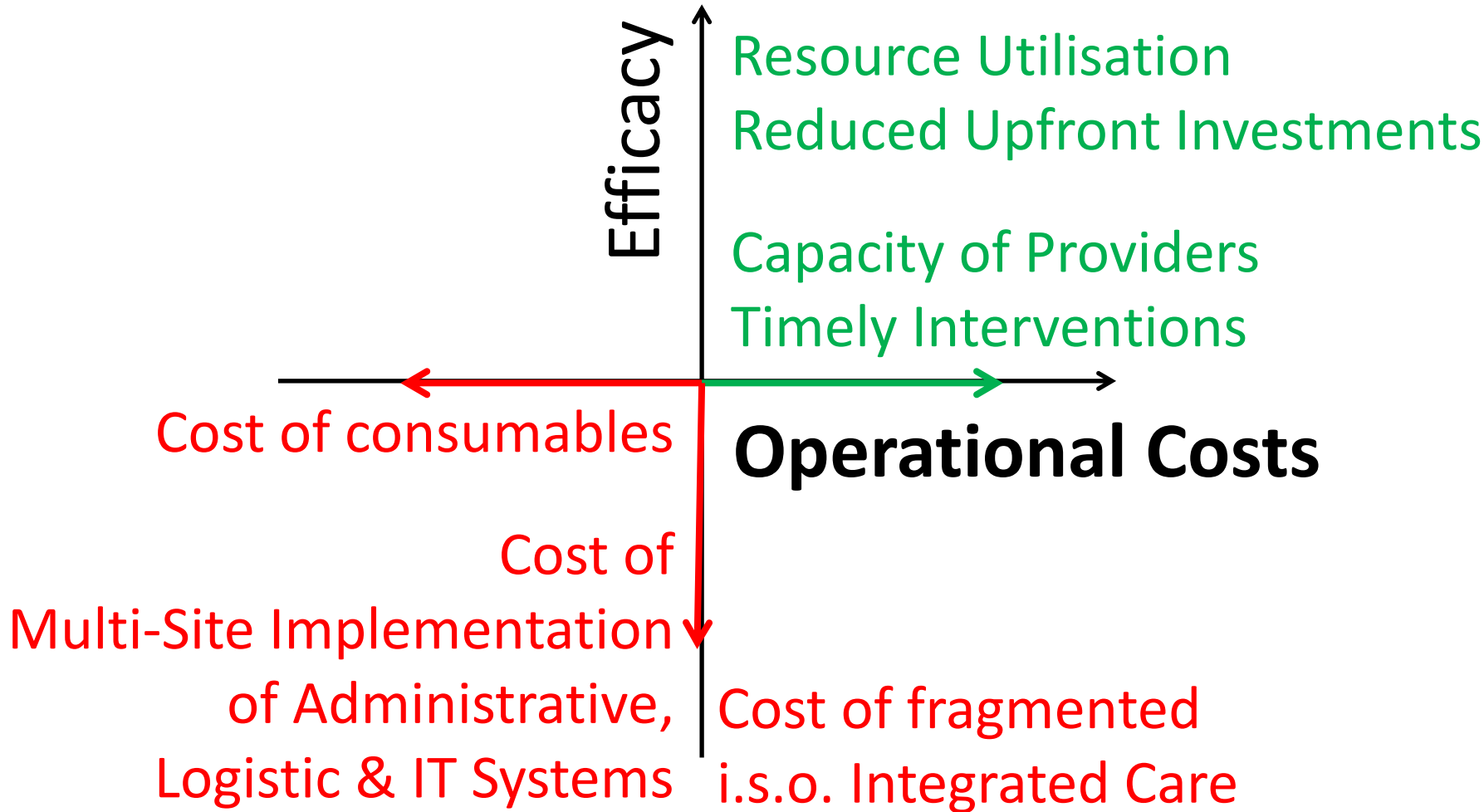
switches in market shares

R) **Get Involved: Primary Care / Transmural Care**  
**Service Business Model**

# Conclusions 1/4



# Conclusions 2/4



# Conclusions 3/4

A Lab Test can only create Value  
in the context of the “**overall care program**”

R) “**System thinking**”

R) Implementing POCT = Process Care =  
“**So einfach wie möglich,  
so kompliziert wie nötig**”

# Conclusions 4/4

## Main Hurdles to Take

- Access to Distributed Expertise
- Informatization
  - Standardized Concentrators (middleware)
  - Shared patient files

## Opportunities for Paying Party, Labs & Industry:

A new Service Industry Business Model

Create value to share

by creating value through networking