XVIII Convegno Nazionale degli Ufficiali Medici e del Personale Sanitario della Croce Rossa Italiana
Verona, 22 – 25 Settembre 2016
Palazzo della Gran Guardia

Point-of-Care Testing: lo stato dell'arte

Piero Cappelletti

SIPMeL

Definizione

BOX 1

Laboratory investigations by POCT take place:*[1]

- Outside the laboratory
- In the immediate vicinity of the patient
- Without sample preparation and generally without pipetting steps. The test material is usually whole blood.
- With measuring instruments intended or used for single samples
- With "ready-to-use" reagents
- Without the necessity of in-depth medical technical qualification for operating the instrument
- With rapid availability of the results
- With the immediate deduction of therapeutic consequences from the results

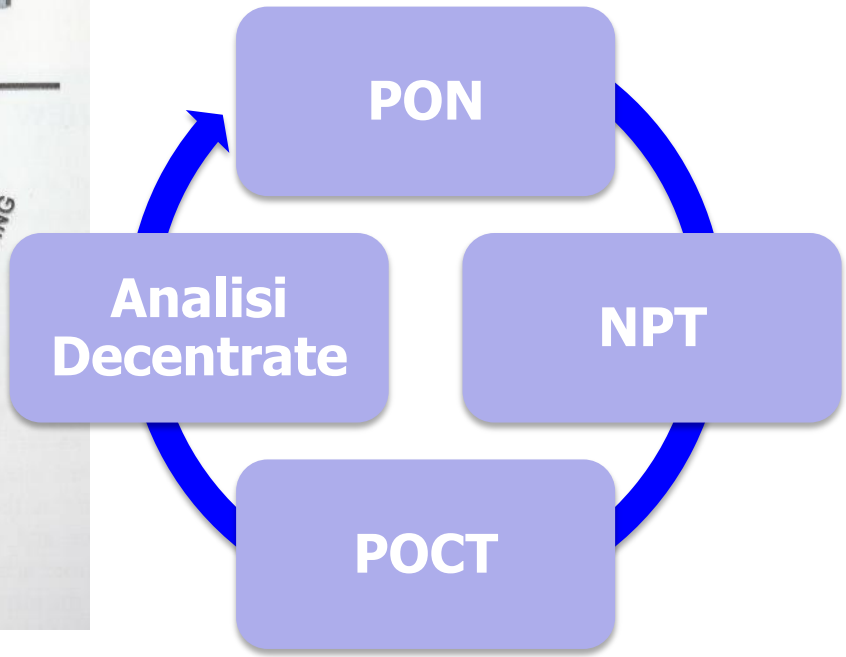
R Junker et al 2010

Point-of-care testing is defined as testing at the point of patient care, wherever that medical care is needed.

GJ Kost 1995

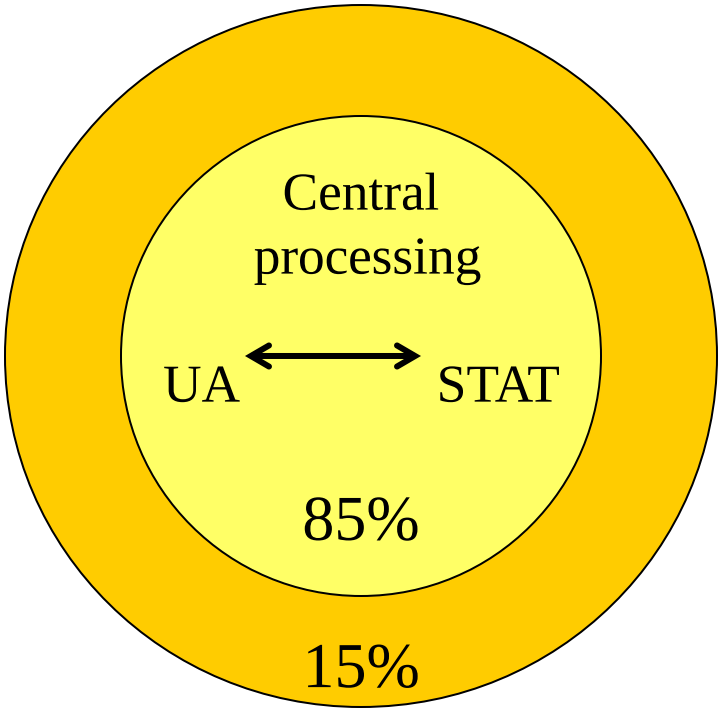
Denominazione

Curtis et al 2015

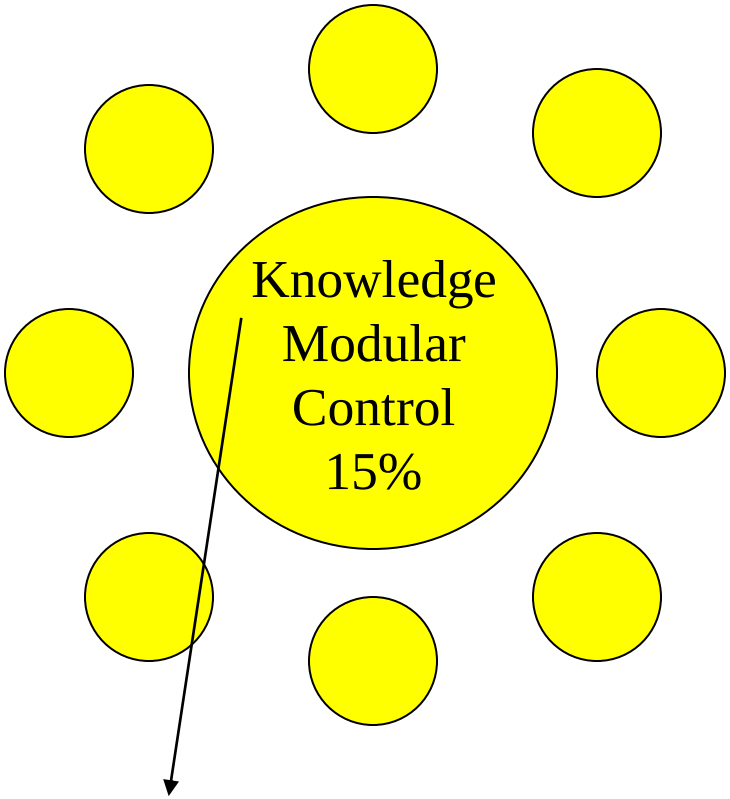


Diffusione

2000 Consolidated



2020 Distributed



Quality, trends, outcome

R Felder 1999

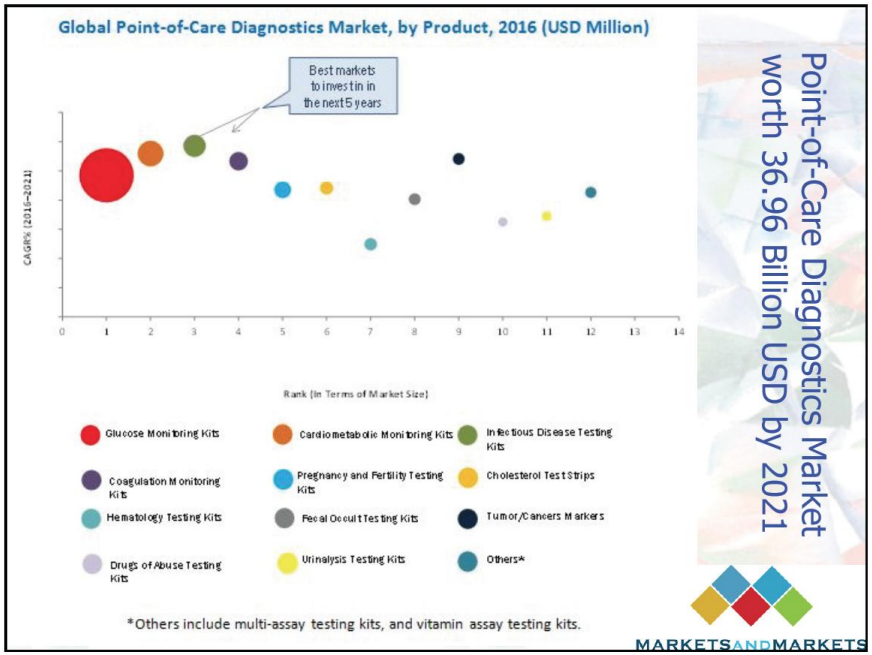
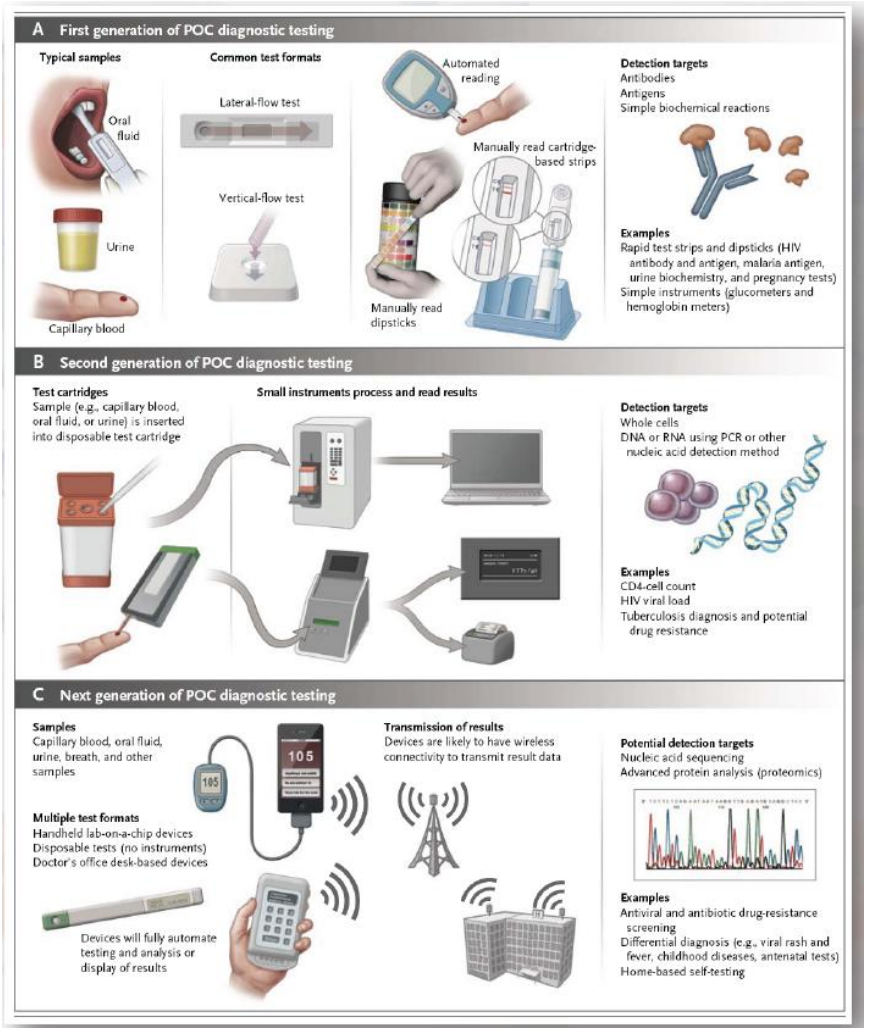


Table. Some opportunities for the use of PoCT.

Setting	Application	Potential Benefit
Home	Management of long term conditions e.g. diabetes, heart failure, anticoagulant monitoring Early detection of complications e.g. infection in patients on chemotherapy	Better awareness of condition Motivation to manage condition Avoid need to attend hospital Avoid cost of transport Avoid time off work
Community pharmacy	Management of long term conditions Health checks	Person/patient convenience Better access to relevant population
Retail health clinic	Patient initiated testing e.g. flu test, strep A test, pregnancy test, cholesterol	Patient convenience Greater acceptance by patient Reduce need to visit GP Use when GP centre closed
Paramedical vehicle	Pre-hospital testing e.g. cardiac markers, blood gases Manage inter-hospital transport	Faster triage through ED Earlier intervention Reduce risks of inter-hospital transport
Urgent care centres	Urgent care for non-life-threatening conditions Rule-out testing	Avoid need to attend hospital ED Use when GP centre closed
Emergency room	Testing for rapid triage and treatment	Reduced length of stay in ED
Operating room	Monitoring operative procedures	Reduce post-operative care requirement Convert to day care
Intensive care	Monitoring vital parameters	Improve mortality and morbidity Reduce length of stay

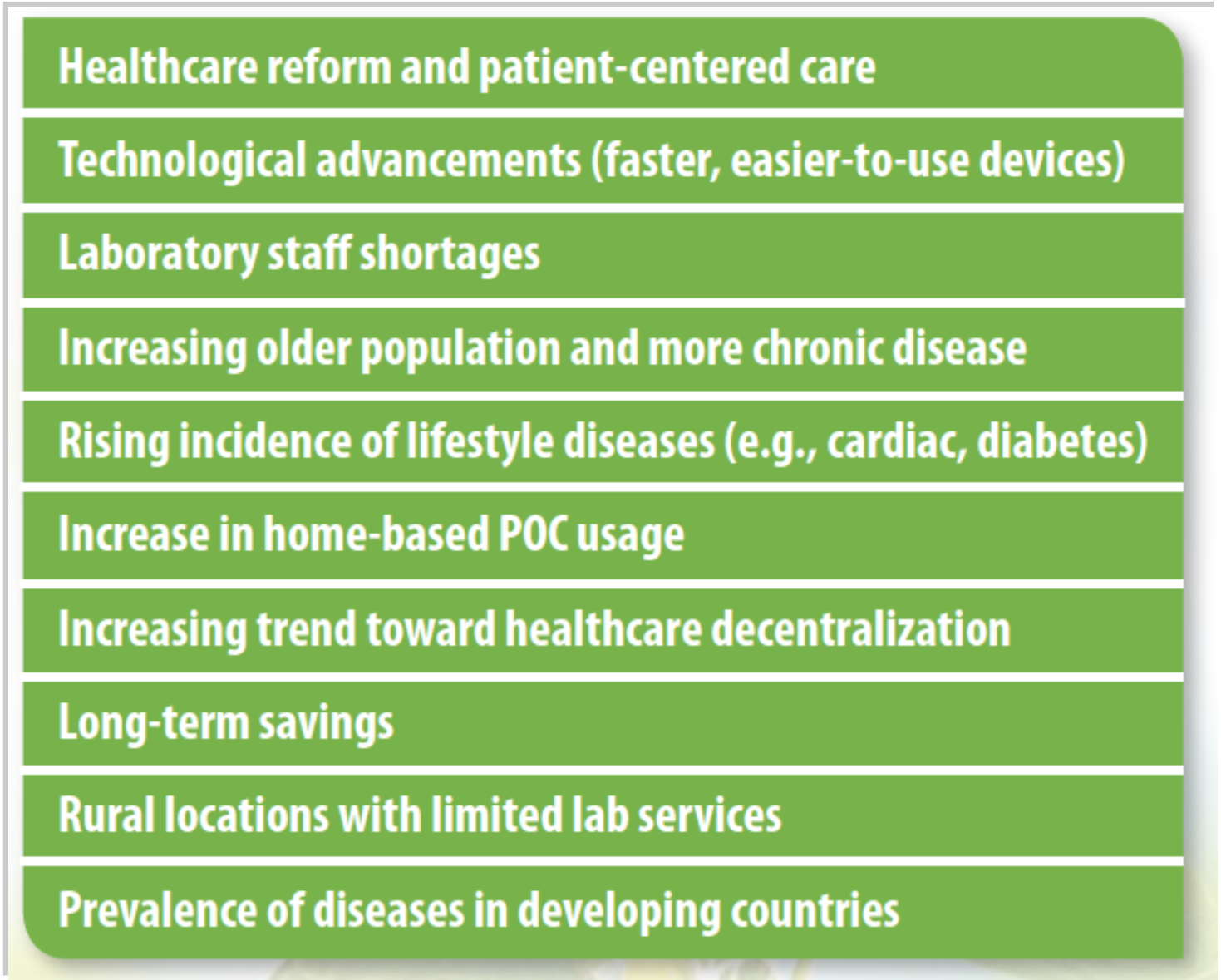
GP,general practitioner; ED,emergency department.

A St Jhon 2010



IV Jani, TF Peter 2013

Motivazioni



K Futrell 2015

POCT: where is the evidence?

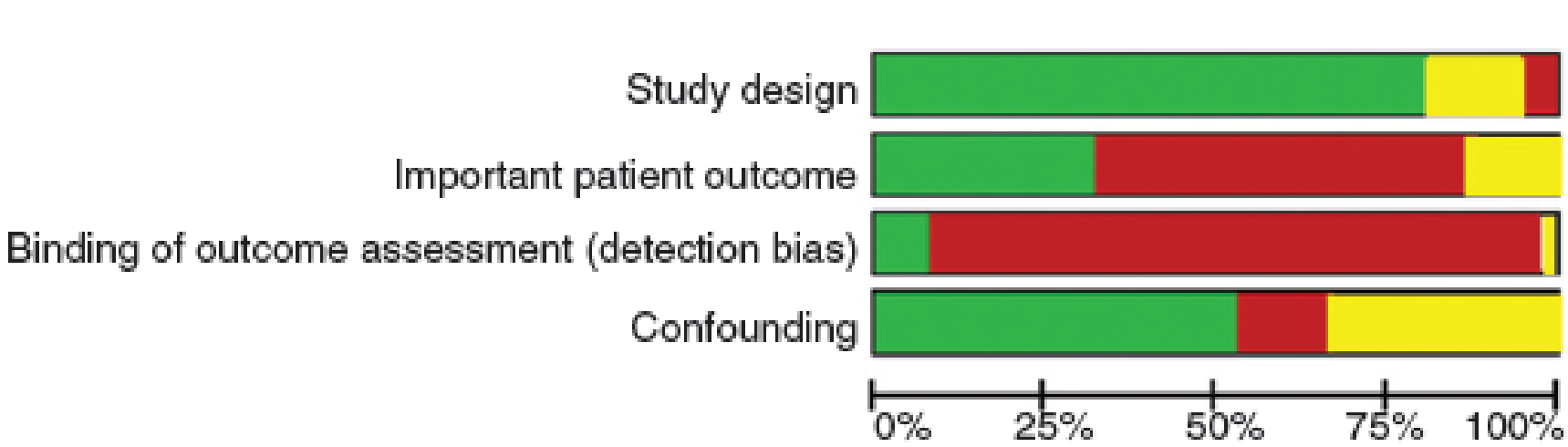


Figure 2 Risk of bias.
Red, high risk of bias; yellow, unknown risk of bias; green, low risk of bias.

V Pecoraro et al 2014

POCT: where is the evidence?

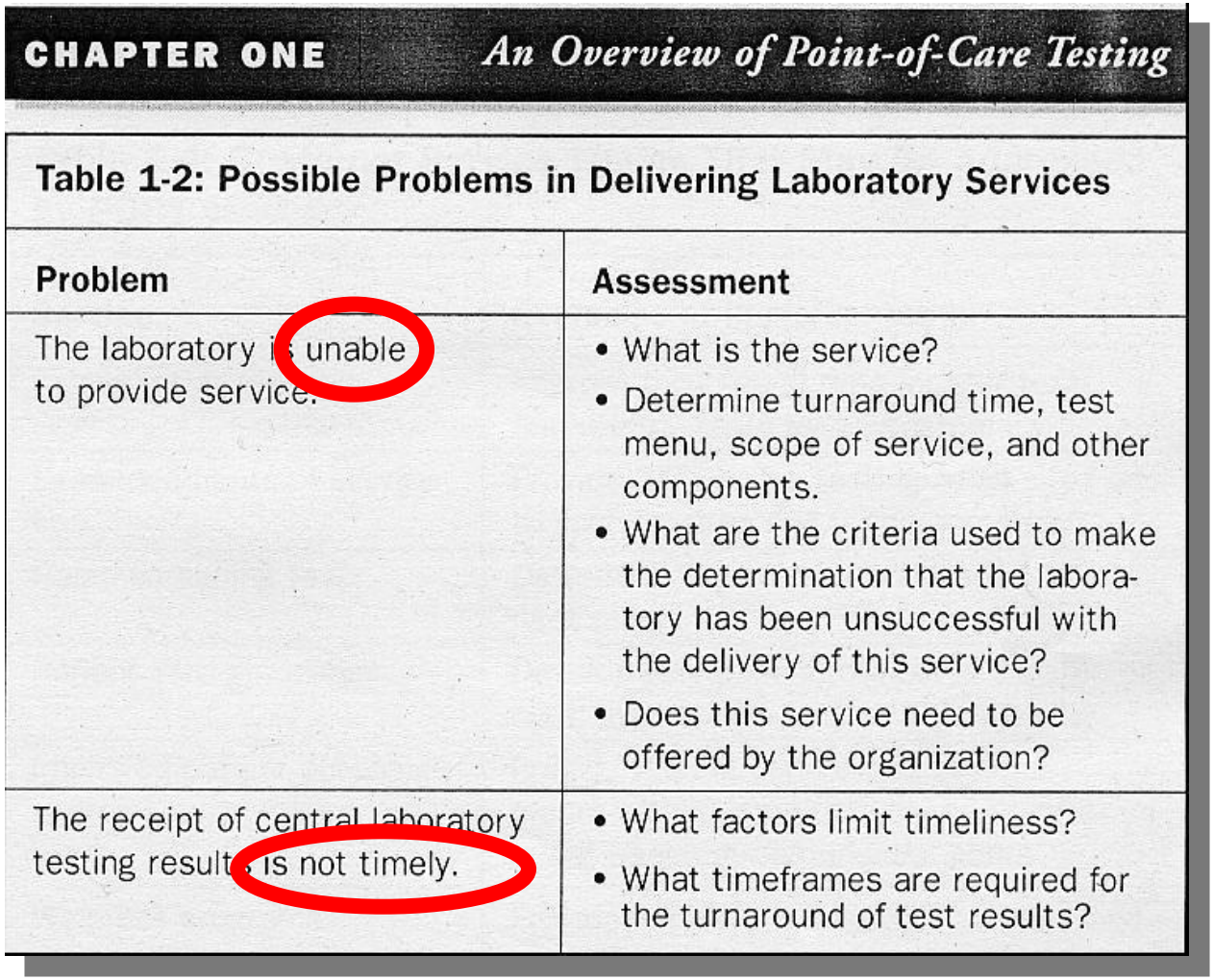
The value of POCT in disaster care setting remains poorly defined because of the infeasibility of conducting controlled trials. However, the extrapolation of POCT studies from traditional setting to disaster care has merit. We propose three value propositions … cardiac biomarkers, AKI injiuries markers, multiplex pathogen detection …

NK Tran et al 2015

Quando il POCT

- ***Only tests affecting key clinical decision ...***

JR & K Lewandrowsky 2015



CHAPTER ONE *An Overview of Point-of-Care Testing*

Table 1-2: Possible Problems in Delivering Laboratory Services

Problem	Assessment
The laboratory is unable to provide service.	• What is the service? • Determine turnaround time, test menu, scope of service, and other components. • What are the criteria used to make the determination that the laboratory has been unsuccessful with the delivery of this service? • Does this service need to be offered by the organization?
The receipt of central laboratory testing results is not timely.	• What factors limit timeliness? • What timeframes are required for the turnaround of test results?

GJ Kost 1995; CP Price, IM Hicks 1999

Caratteristiche dei device

1. Simple to use.
2. Reagents and consumables are robust in storage and usage.
3. Results should be concordant with an established laboratory method.
4. Device together with associated reagents and consumables are safe to use.
5. Connectable

A St John, CP Price 2014

Table 1. The ASSURED guidelines that indicate the features that should be designed into all PoCT devices.

- **A**ffordable – for those at risk of infection
- **S**ensitive – minimal false negatives
- **S**pecific – minimal false positives
- **U**ser-friendly – minimal steps to carry out test
- **R**apid & **R**obust – short turnaround time and no need for refrigerated storage
- **E**quipment-free – no complex equipment
- **D**elivered – to end users

Quality and Risk Management

- Testing site neutrality
- Risk Assessment
- Training e Formazione

- Quality Assurance
  - **Internal Quality Control**
  - Correlation samples with central laboratory
  - External Quality Assurance (EQA)
  - Outcomes evaluation (review of medical records)
- **IQCP – EP23**

Errori in POCT

Table 2. Modified Kost Point-of-Care Testing (POCT) Error Classification

Phases/Steps in POCT Process	Step-by-Step Defects
1. Preanalytic phase	
a. Test ordering	Excessive/mistimed orders
b. Patient/specimen identification	Wrong patient/wrong specimen; erroneous patient/specimen information entry
c. Specimen collection	Inappropriate/inconsistent specimen type, volume, or application to testing surface/chamber
d. Specimen evaluation	Attributes degrading patient ID/collection quality not recognized
2. Analytic phase	
a. Method calibration	Omitted, nonprotocol, or misentered calibration
b. Specimen/reagent interaction	Patient-related native interference, specimen-related nontarget influences, specimen-reagent matrix effects
c. Result generation	Results outside method's validated range
d. Result validation	Lack of quality control and/or other performance monitors
3. Postanalytic phase	
a. Report formatting	Absent/inappropriate units, reference intervals, machine output; mistaken human transmission/transcription
b. Critical value reporting	Criticality not recognized, not brought to decision maker's attention, not documented for retrieval
c. Other result reporting	Report communication failed/delayed; lost to retrieval
d. Report recording/retrieval	Lack of correlation between initially generated/finally recorded result

FA Meier, BA Jones 2005

Table 1. Sources and Amplifiers of Point-of-Care Testing Error

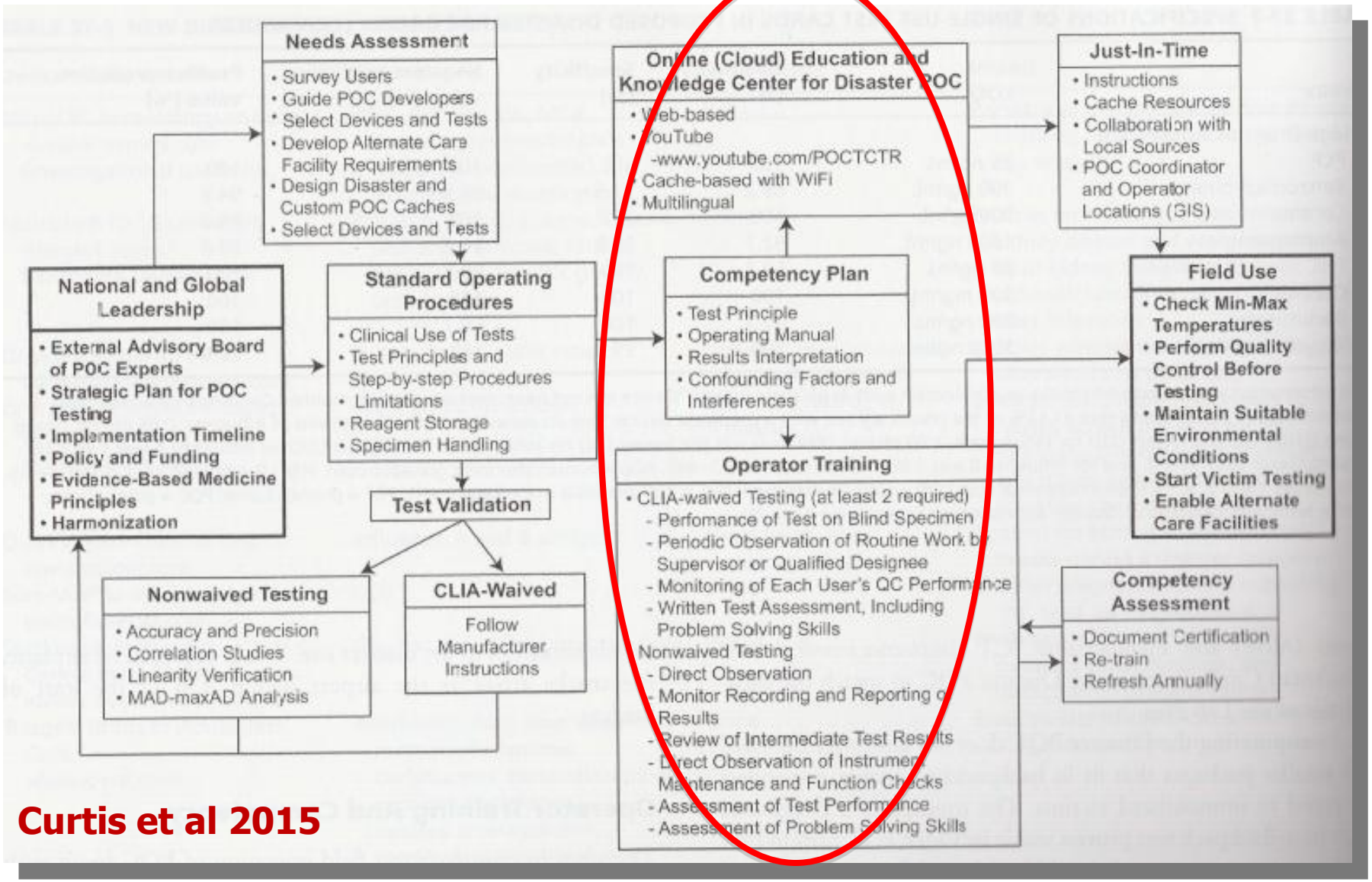
Sources
Operator incompetence
Nonadherence to procedures
Use of uncontrolled reagent/equipment
Amplifiers
Incoherent regulation
Rapid result availability
Immediate therapeutic implications

MJ O'Kane 2011

Table 3. Breakdown of POCT quality errors by phase in the analytical process.

	N	%
Preanalytical	72	32
Analytical	147	65.3
Postanalytical	6	2.7

POCT implementation flowchart



Curtis et al 2015

Esiti ed evidenze

Medical outcomes

- fewer admissions
- decreased mortality
- decreased morbidity
- **shorter length of stay**
- decreased readmission rate
- improved quality of life

L Larsson 1999

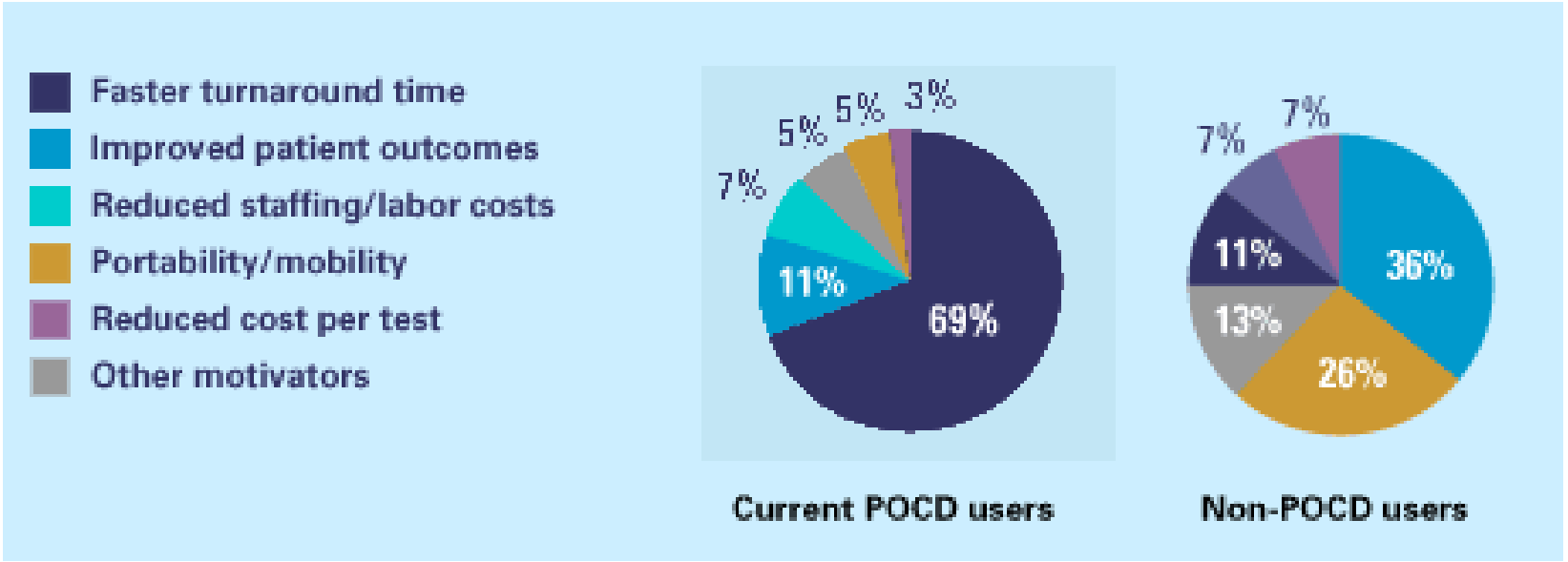
Service outcomes

- patient and staff satisfaction
- blood conservation
- decreased pre and post-analitycal errors
- **faster TAT**
- diminished requests

P St-Louis 2000

Rapidità (TAT)

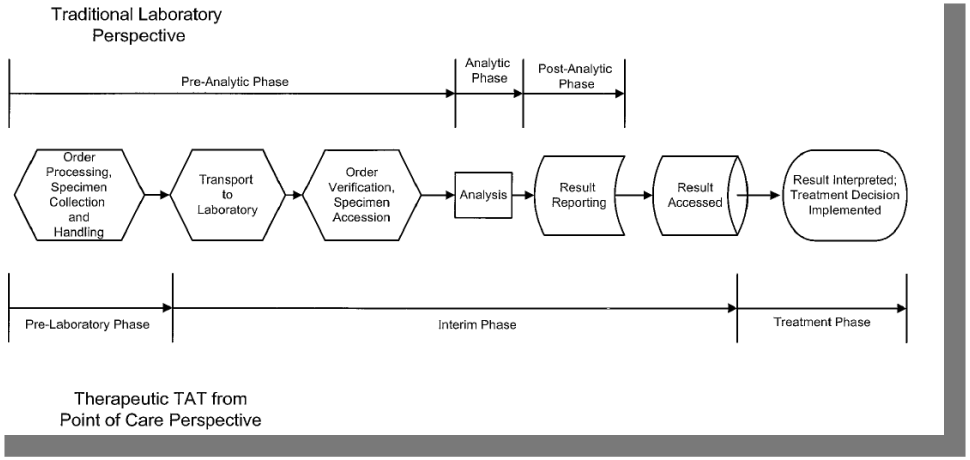
Top Five Motivators for Adopting Point of Care Technology



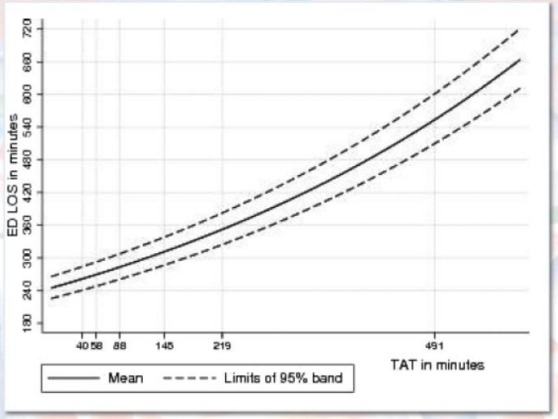
Source: Science Advisory Board Survey, Nove

Therapeutic TAT

ML Kilgore, SJ Steindel, JA Smith 1998



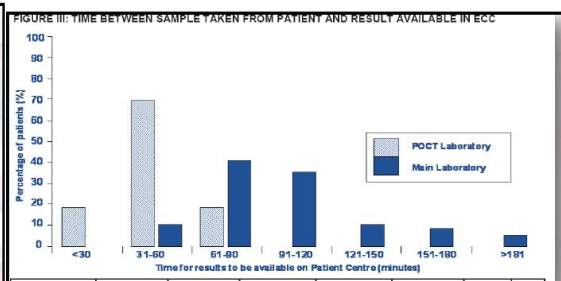
TAT e LOS in ED



- 30' TAT = 17' LOS
- TAT/LOS = 0.19
- TAT & test n° ➔ 10% ED LOS variability

Li et al 2015

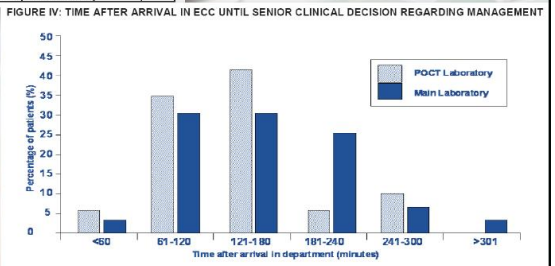
Pts complexity (age>70y; time to discharge; test n°); day & hours of access



PoCT – Results available in mins	Time<30mins	31-60mins	61-90mins	91-120mins	121-150mins	151-180mins	>180 mins
PoCT number of patients (and %)	3pts = (17%)	12pts= (66%)	3pts = (17%)	0	0	0	0
Main Laboratory		4pts=(13.8%)	12pts=(41.3%)	10pts=(34.5%)	3pts=(10.4%)		

Clinical Decision Making

MN. Illahi,
R Lapworth,
P Bates 2012



Senior decision minutes	Time<60 mins	61-120 mins	121-180 mins	181-240 mins	241-300 mins	> 300 mins
PoCT Lab (pts)	1 = 5.6%	6 = 33.3%	8 = 44.4%	1 = 5.6%	2 = 11.1	__
Main Lab (pts)	1 = 3.5%	9 = 31%	9 = 31%	7 = 24.1%	2 = 6.9%	1 = 3.5%

Condizioni per esiti favorevoli

TABLE 6-1 POCT DECREASES TAT AND LOS, BUT HAS NOT BEEN SHOWN TO IMPROVE PATIENT OUTCOMES

Test	Outcome
Cardiac markers	↓ TAT ↓ LOS ↓ Hospital admission rates
B-type natriuretic peptide	↓ TAT ↓ LOS ↓ Hospital admission rates ↓ Overall treatment costs
D-dimer	↓ TAT ↓ LOS ↓ Hospital admission rates
Drugs of abuse	↓ TAT ↓ LOS ↓ Central laboratory test burden
Pregnancy	↓ TAT ↓ LOS
Urinalysis	↓ TAT ↓ LOS ↓ Central laboratory test burden
HIV	↓ TAT ↑ Rates of testing acceptance

HIV = human immunodeficiency virus; LOS = length of stay; POCT= point-of-care testing; TAT = turnaround time.

JR & K Lewandrowsky 2015

... only with systematic workflow changes ...

Nichols et al 2000

... management algorithms ...

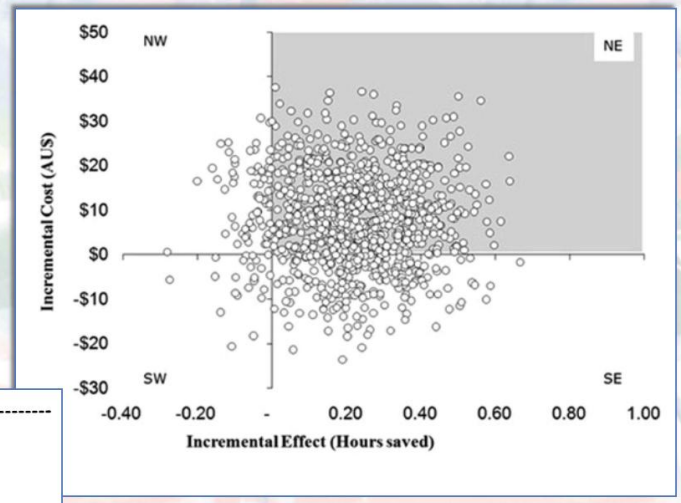
Despotis et al 1997

... prescribing behavior ...

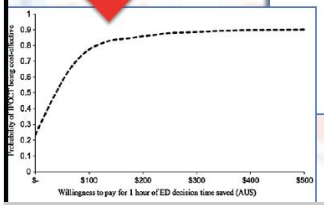
IV Jani, TF Peter 2013

Evidenze economiche e POCT

POCT cost-effectiveness



113 $ Aus



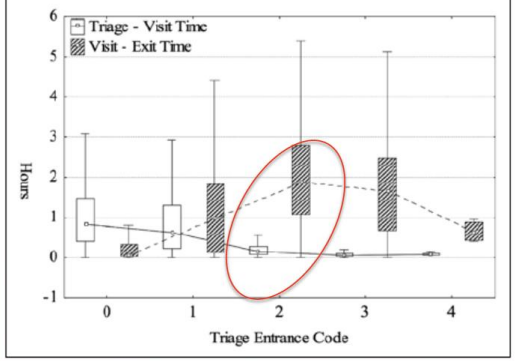
Asha et al 2014

Costo analisi in ED

Tab. VII. Triage codes weights, patients and equivalent patients.

Triage Code	White	Green	Yellow	Red
$Weight_{TriageCode}$	1	1,5	2	2,5

Fig. 6. Box plots (min, 25th, 50th, 75th centiles and max) of the waiting times distributions for the Triage – 1st visit and 1st visit – patient's exit time (0: White codes, 1: Green codes, 2: Yellow codes, 3: Red Codes, 4: Black codes - dead at ED arrival).



Tab. VI. Per patient (structure) cost.

Structure	Cost per patient
Emergency Department	€ 126.69
Observation and Short Hospitalization	€ 426.96

Cremonesi et al 2010

Costo/h x paziente cod. giallo: 148,52€

sits per year

Operation time
Recovery time

Economic	
Resource utilisation	Cost per QALY
Intermediate outcomes	Emergency admission rate
	Length of stay in Emergency Department
	Blood product utilisation
	Clinic costs
	Cost per episode

A St John, CP Price 2013

Speed for Quality?

- The results of the principal components analysis also suggest that clinicians are willing to trade off some degree of **accuracy for timeliness** and ease of use

ML Kilgore et al 1998

- To tolerate complacency for inaccurate point-of-care test results would **undermine** long-standing fundamental principles of medical practice and laboratory science

GJ Kost 1999

Roots, development and future directions of laboratory medicine

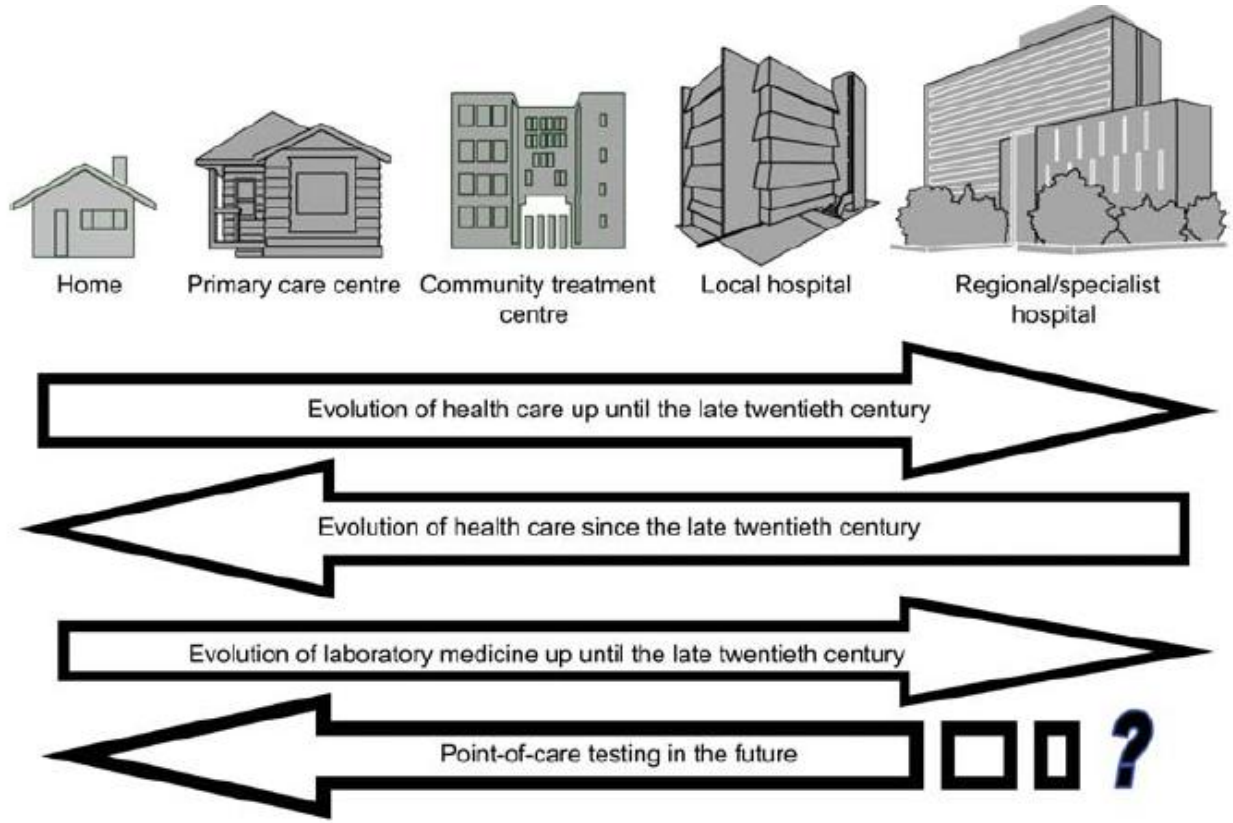


Figure 2 Illustrating the parallel evolutions of the delivery of healthcare and laboratory medicine.

CP Price 2010

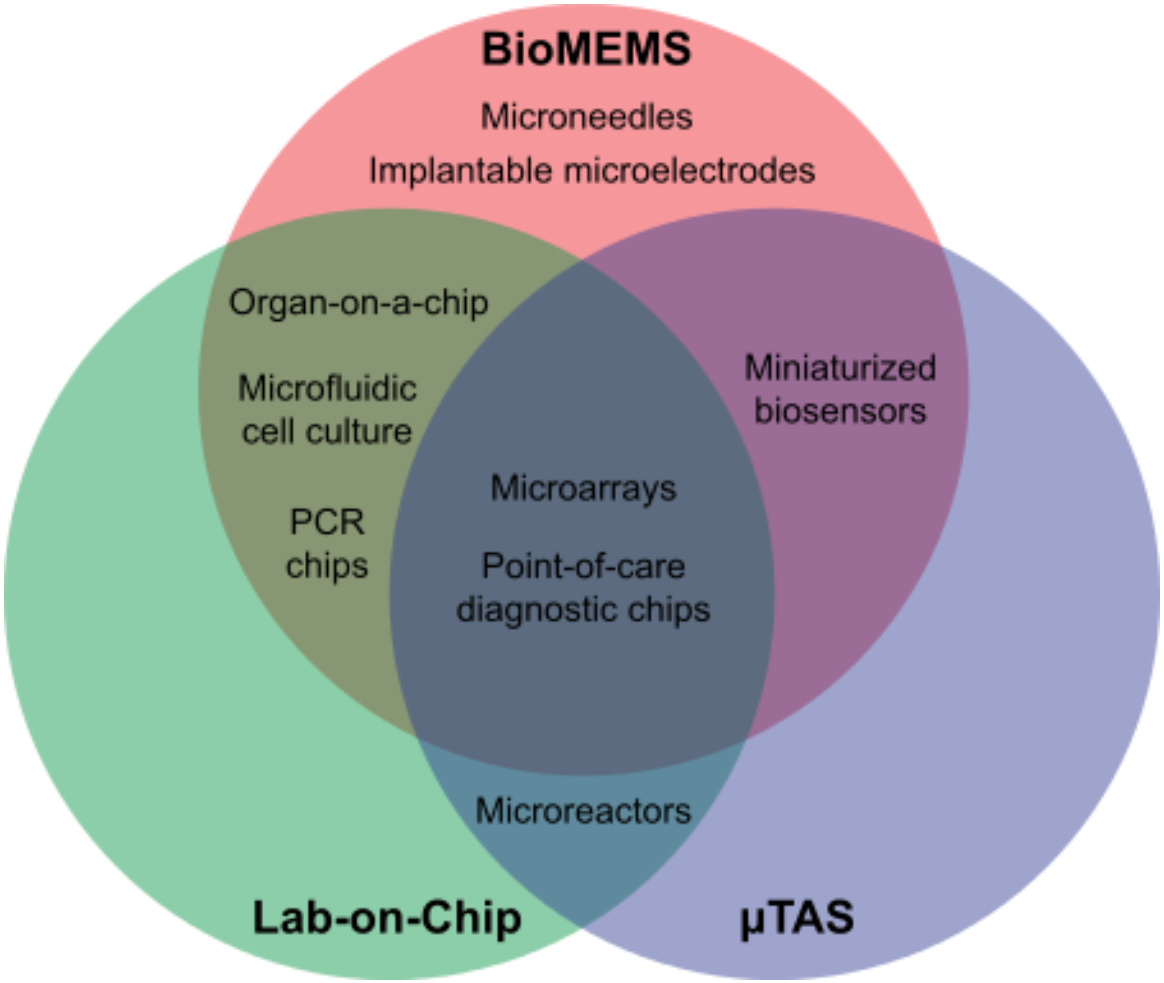
Disaster POCT Needs Assessment

- Handhelded devices
- Multiplexity (patients)
- Robustness (T, vibration, humidity, impact shock)
- Priority: clinical sensitivity, TAT, clinical specificity, battery operation

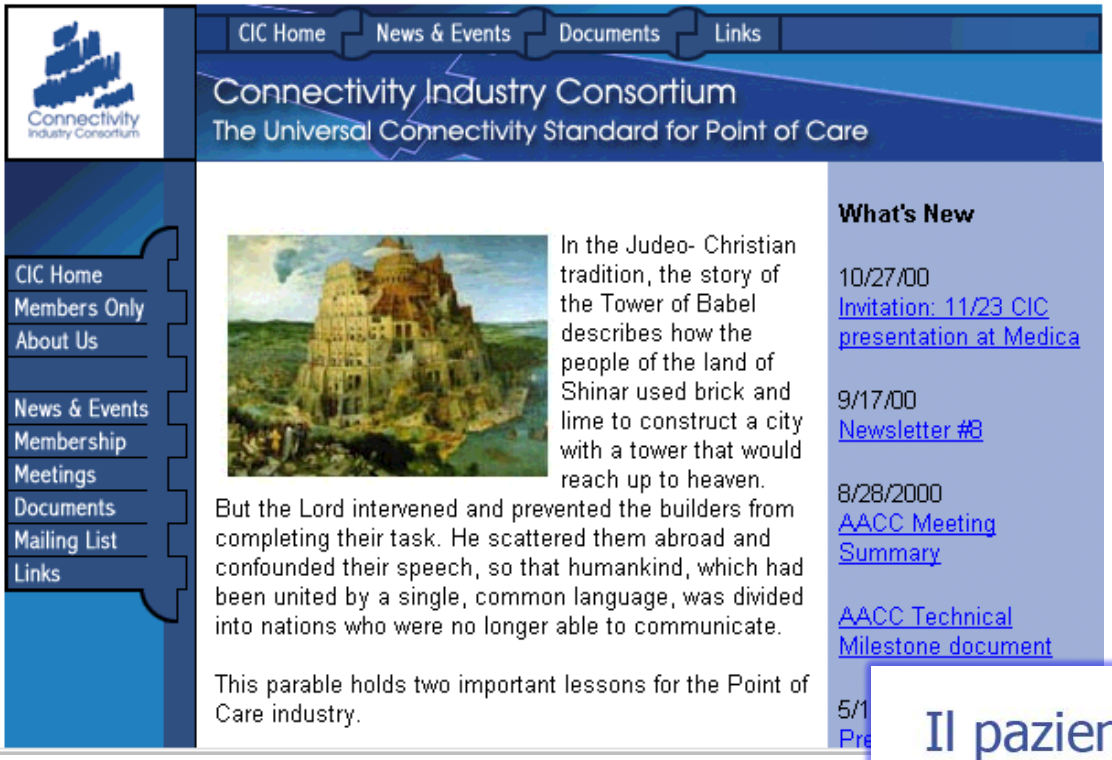
Kost et al 2015

- Sampling method: cassette, mechanical, multiple, disposable
- At patient-side
- First responder
- Priority: pathogens, CBC, chemistry (…), O_2 sat, ABO group … ; upgrade (pandemics)
- Characteristics: risk, effort, time

Innovazione tecnologica



PB Luppa 2015

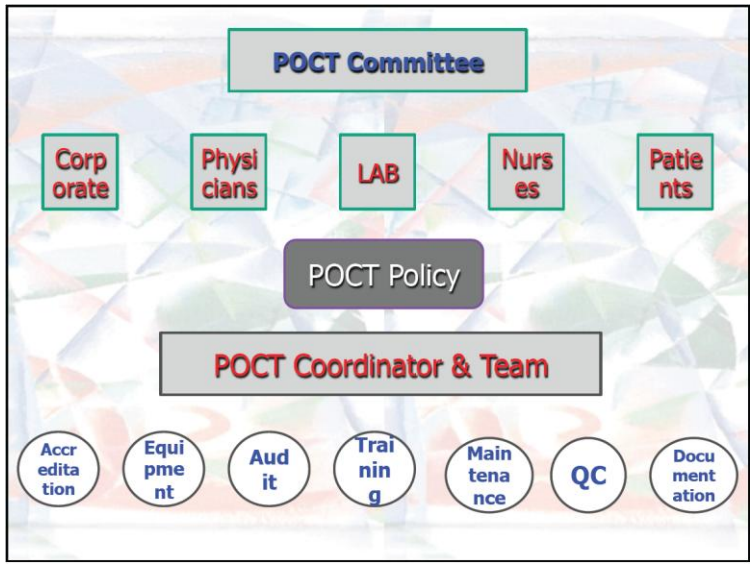


Connetivicty

Wired
Wi-fi
Bluetooth
Infrared
GISs

CLSI Standards

- POCT01-A2 *Point-of-Care Connectivity*
- POCT02-A *Implementation Guide of POCT01 for Health Care Providers*
- POCT04-A2 *Point-of-Care In Vitro Diagnostic (IVD) Testing*
- POCT05-A*Performance Metrics for Continuous Interstitial Glucose Monitoring*
- POCT07-A Quality Management: *Approaches to Reducing Errors at the Point of Care*
- POCT08-A *Quality Practices in Noninstrumented Point-of-Care Testing: An Instructional Manual and Resources for Health Care Workers*
- POCT09-A *Selection Criteria for Point-of-Care Testing Devices*
- POCT10-A2 *Physician and Nonphysician Provider-Performed Microscopy Testing*
- POCT11-A2 *Pulse Oximetry*
- POCT12-A3 *Point-of-Care Blood Glucose Testing in Acute and Chronic Care Facilities*
- POCT13-A2 (FORMERLY AST04-A2) *Glucose Monitoring in Settings Without Laboratory Support*
- POCT14-A (FORMERLY H49-A) *Point-of-Care Monitoring of Anticoagulation Therapy*
- POCT17-ED1 *Use of Glucose meters for Critically Ill Patients*



Standard ISO

Per i POCT in generale, lo **standard di riferimento** è ISO 22870:2006[39], il quale fornisce specifici requisiti applicabili ai POCT in connessione con lo standard ISO 15189:2012 *Medical laboratories – particular requirements for quality and competence*[41]. I requisiti ISO 22870:2006[39] si applicano ai POCT in ospedale, clinica o ambulatorio di un'organizzazione sanitaria e quindi non si occupano del *self-testing*, comunque esso si declini (farmacie, ambulatorio del medico, *home testing*, ecc.). Un recente lavoro italiano[42] illustra i rapporti tra i due standard, tenendo conto delle diverse revisioni degli stessi, ed è guida utilissima per l'accreditamento dei POCT.

Riv Ital Med Lab (2016) 12:14–25
DOI 10.1007/s13631-016-0106-x

RASSEGNA

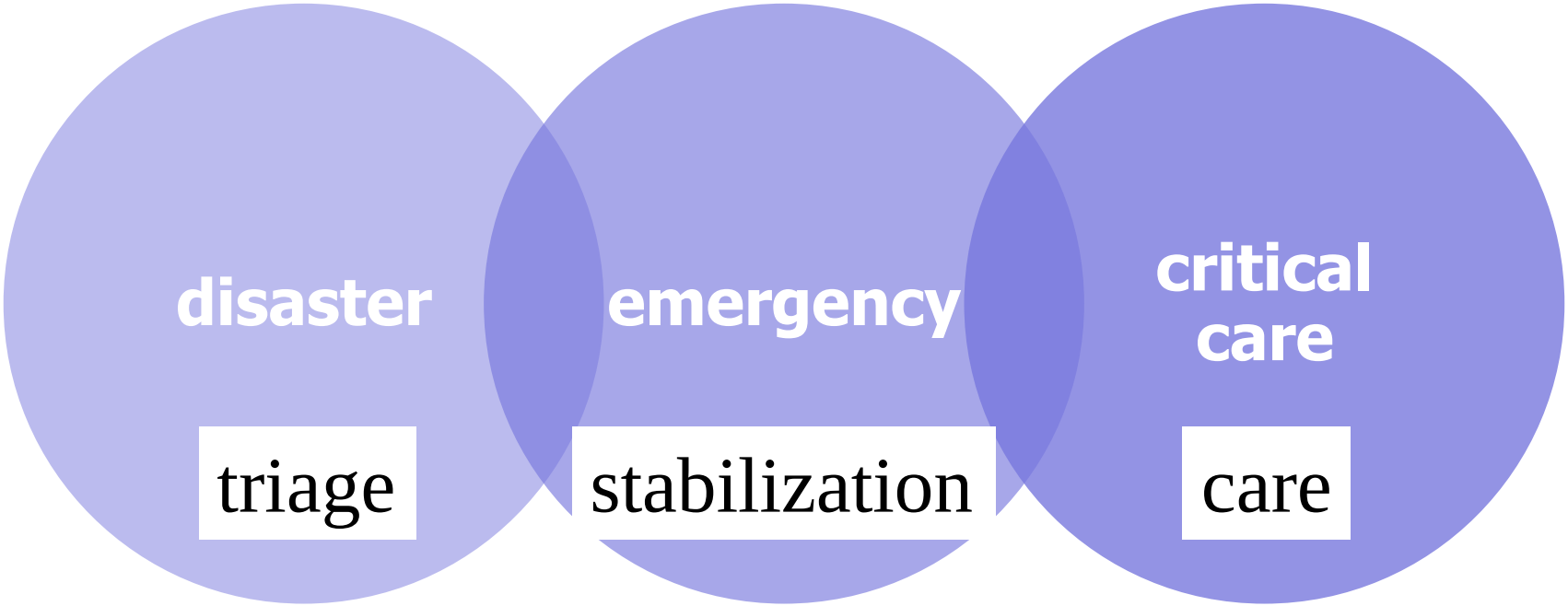
PoCT e diagnostica decentrata. UPDATE 2016 Posizione SIPMeL del GdS Point of Care Testing

PoCT and diagnostic system. UPDATE 2016 Position paper of SIPMeL GdS Point of Care Testing

Pasquale Coppolecchia[1] · Cettina Drago[2] · Luca Rossi[3] · Rossana Colla[4] · Renato Tozzoli[5] · per il GdS PoCT della SIPMeL

Ricevuto: 17 novembre 2015 / Accettato: 13 gennaio 2016 / Pubblicato online: 4 febbraio 2016

POCT continuum



POCT devices: handhelded, robust, multiplex, connected, harmonized

Tran et al 2015

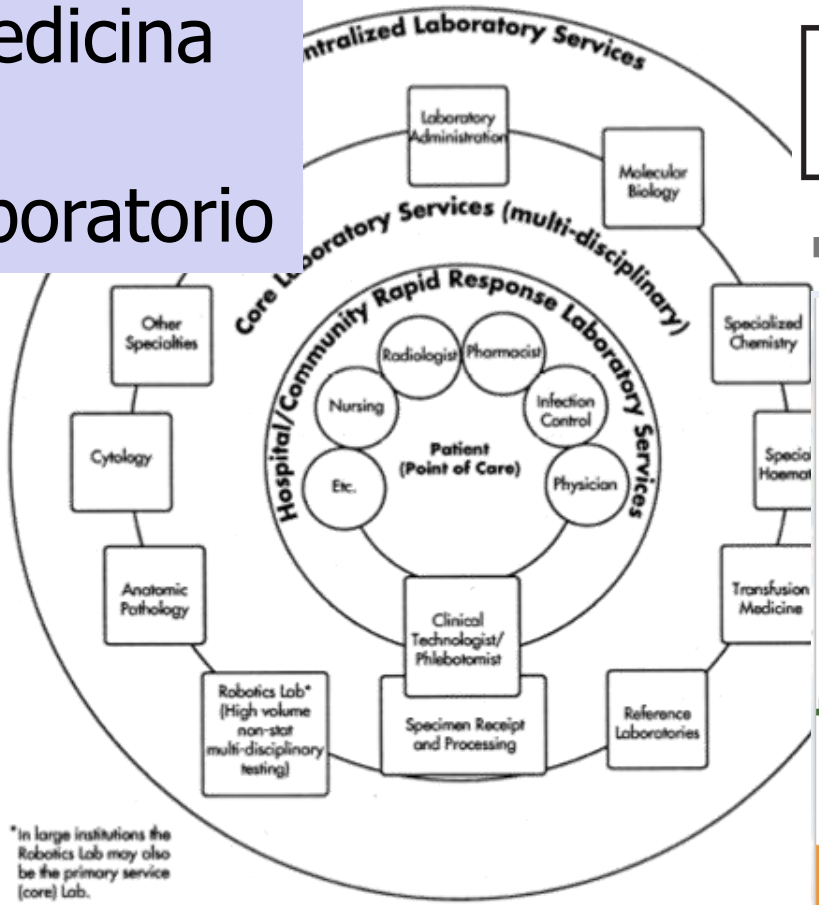
Small-world Network Shared Resources

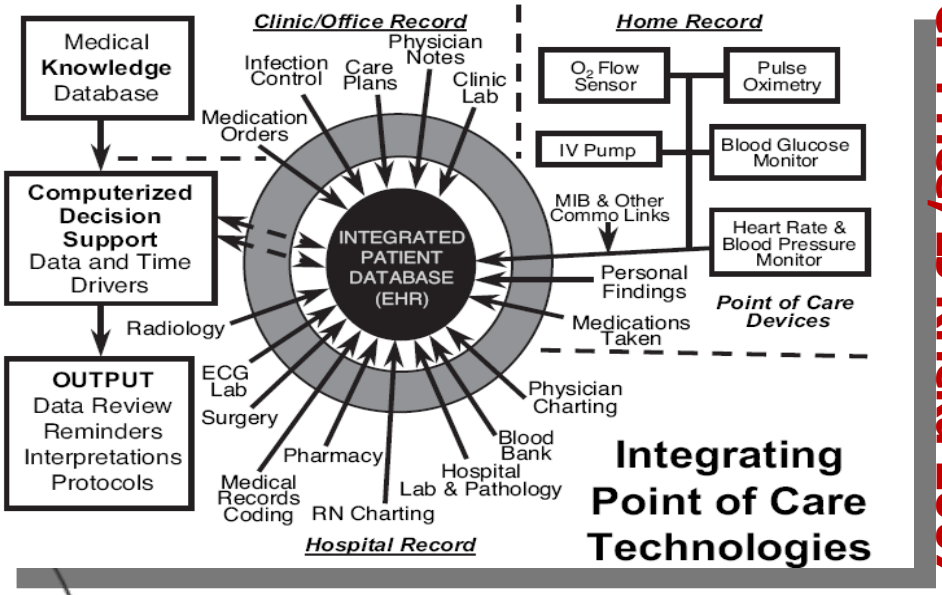
Disaster POCT

Kost et al 2015

Un nuovo mondo

POCT è una modalità della medicina di laboratorio





CP Price, LJ Kricka 2007

Richardson et al 1999

Il futuro della Medicina di Laboratorio

P Cappelletti 2012