

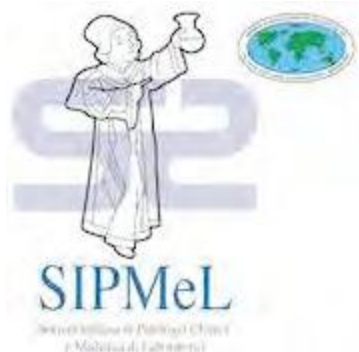


# XVIII CONVEGNO NAZIONALE DEGLI UFFICIALI MEDICI E DEL PERSONALE SANITARIO DELLA CROCE ROSSA ITALIANA

VERONA, 22 – 25 SETTEMBRE 2016  
PALAZZO della GRAN GUARDIA

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

***Piero Cappelletti***



# Definizione

## BOX 1

### Laboratory investigations by POCT take place:<sup>\*1</sup>

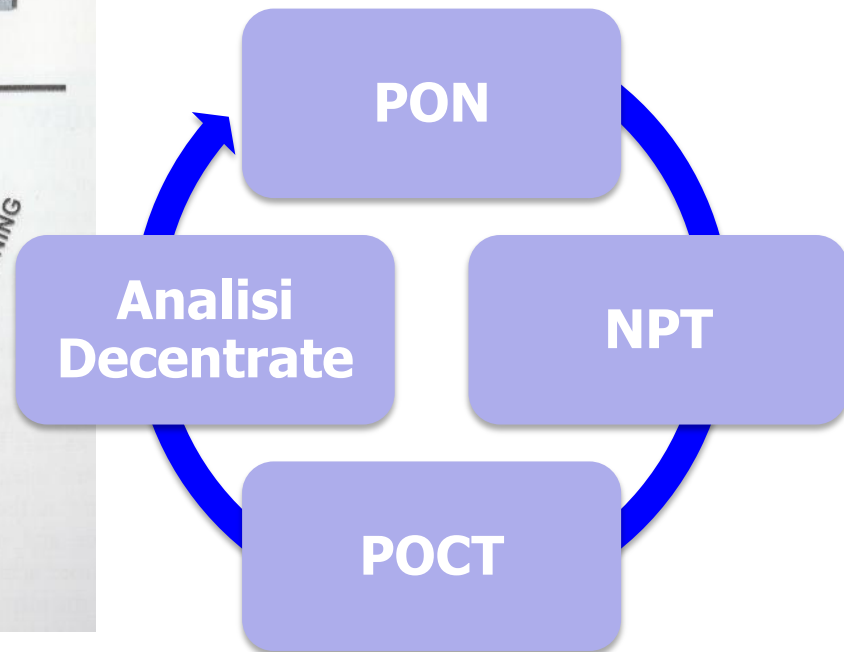
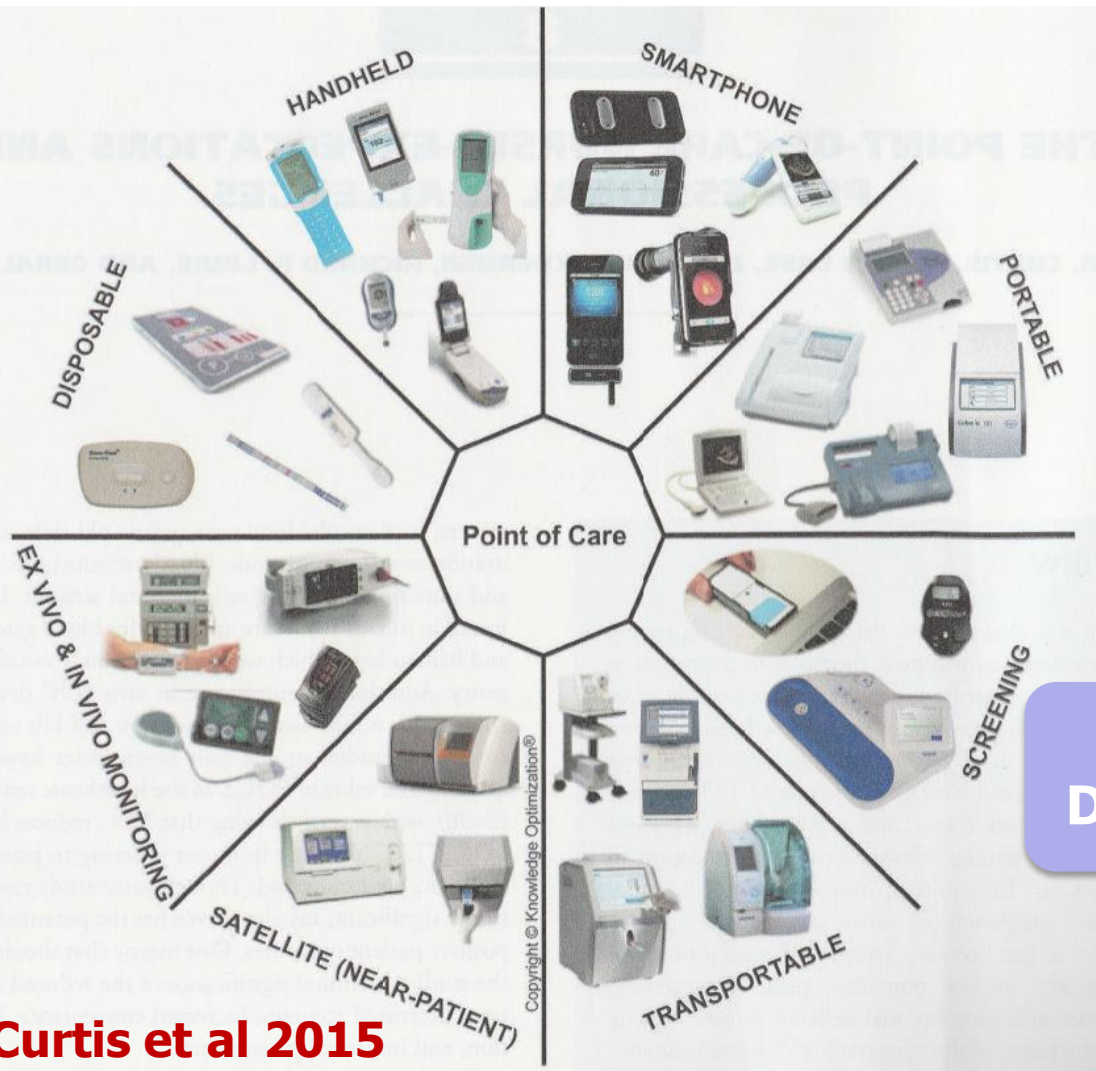
- Outside the laboratory
- In the immediate vicinity of the patient
- Without sample preparation and generally without pipetting steps. The test material is usually whole blood.
- With measuring instruments intended or used for single samples
- With “ready-to-use” reagents
- Without the necessity of 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**

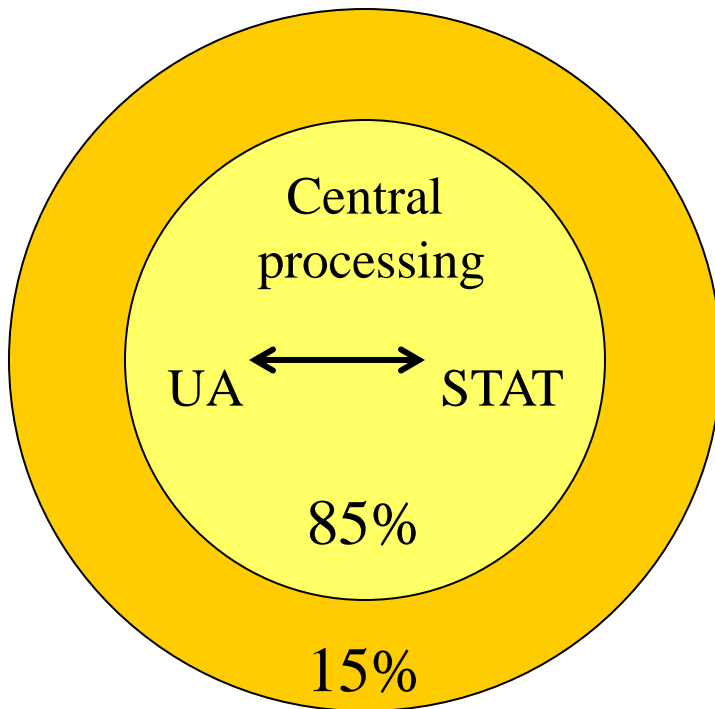
# Denominazione



**Curtis et al 2015**

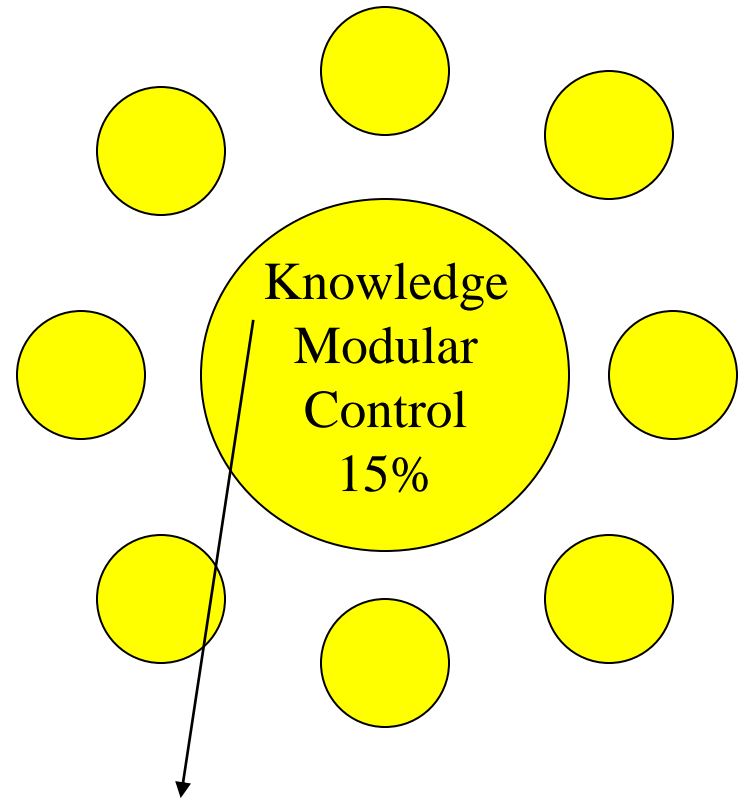
# Diffusione

**2000 Consolidated**



**R Felder 1999**

**2020 Distributed**



Quality, trends, outcome

Global Point-of-Care Diagnostics Market, by Product, 2016 (USD Million)

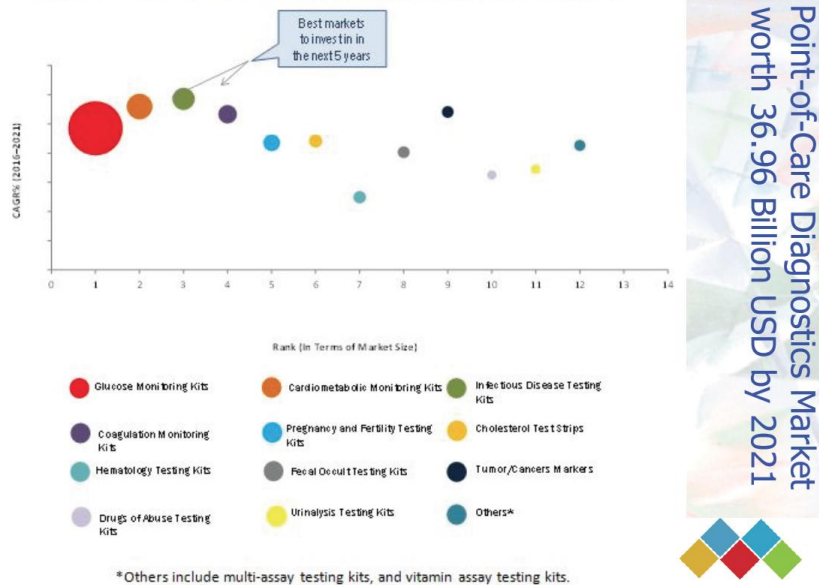
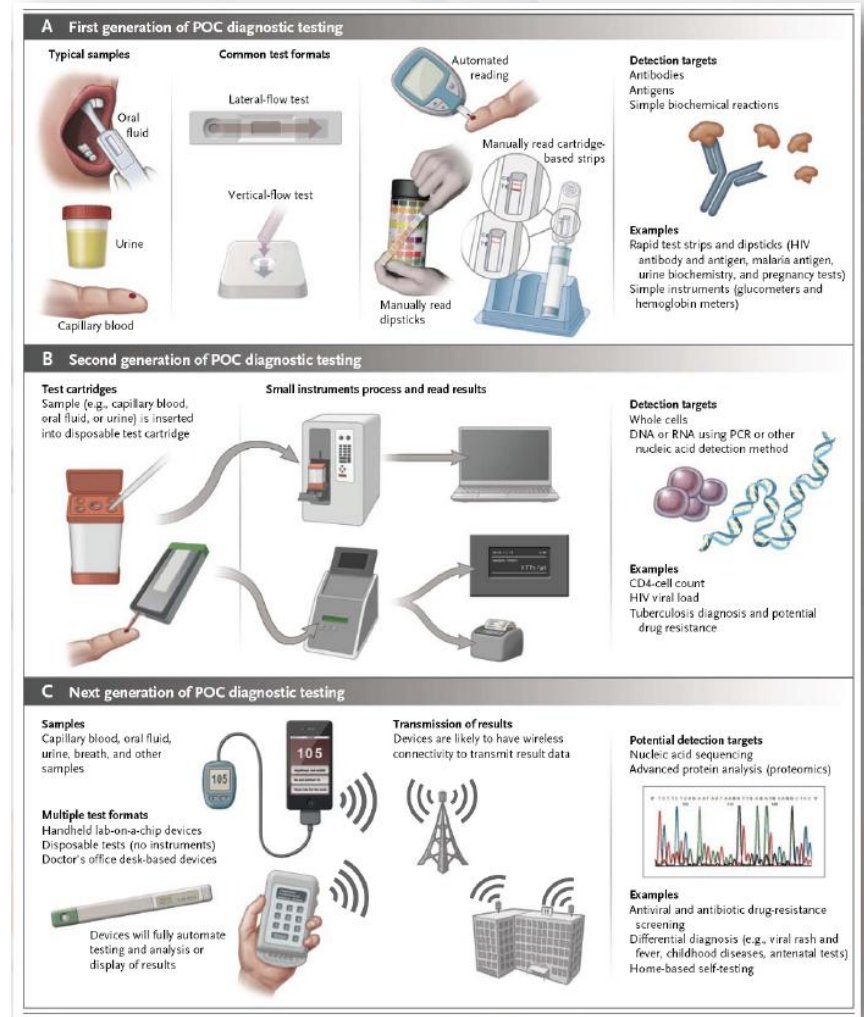


Table. Some opportunities for the use of PoCT.

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.



IV Jani, TF Peter 2013

# Motivazioni

Healthcare reform and patient-centered care

Technological advancements (faster, easier-to-use devices)

Laboratory staff shortages

Increasing older population and more chronic disease

Rising incidence of lifestyle diseases (e.g., cardiac, diabetes)

Increase in home-based POC usage

Increasing trend toward healthcare decentralization

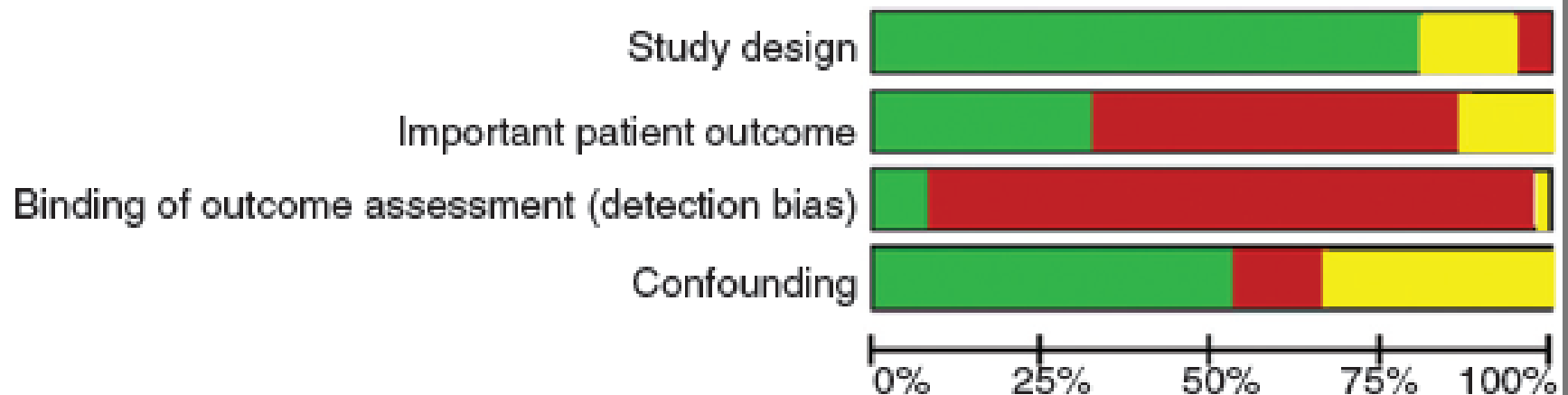
Long-term savings

Rural locations with limited lab services

Prevalence of diseases in developing countries



# 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.

# 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 injuries markers, multiplex pathogen detection ...



# 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.	<ul style="list-style-type: none"><li>• What is the service?</li><li>• Determine turnaround time, test menu, scope of service, and other components.</li><li>• What are the criteria used to make the determination that the laboratory has been unsuccessful with the delivery of this service?</li><li>• Does this service need to be offered by the organization?</li></ul>
The receipt of central laboratory testing results is not timely.	<ul style="list-style-type: none"><li>• What factors limit timeliness?</li><li>• What timeframes are required for the turnaround of test results?</li></ul>

**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

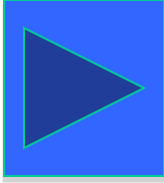
**A St John, CP Price 2014**

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

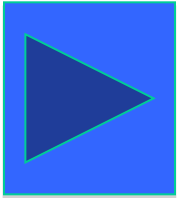
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- Affordable – for those at risk of infection
  - Sensitive – minimal false negatives
  - Specific – minimal false positives
  - User-friendly – minimal steps to carry out test
  - **Rapid & Robust** – short turnaround time and no need for refrigerated storage
  - Equipment-free – no complex equipment
  - Delivered – to end users
-

# Quality and Risk Management

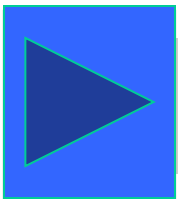


Testing site neutrality



Risk Assessment

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



Training e Formazione

# 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

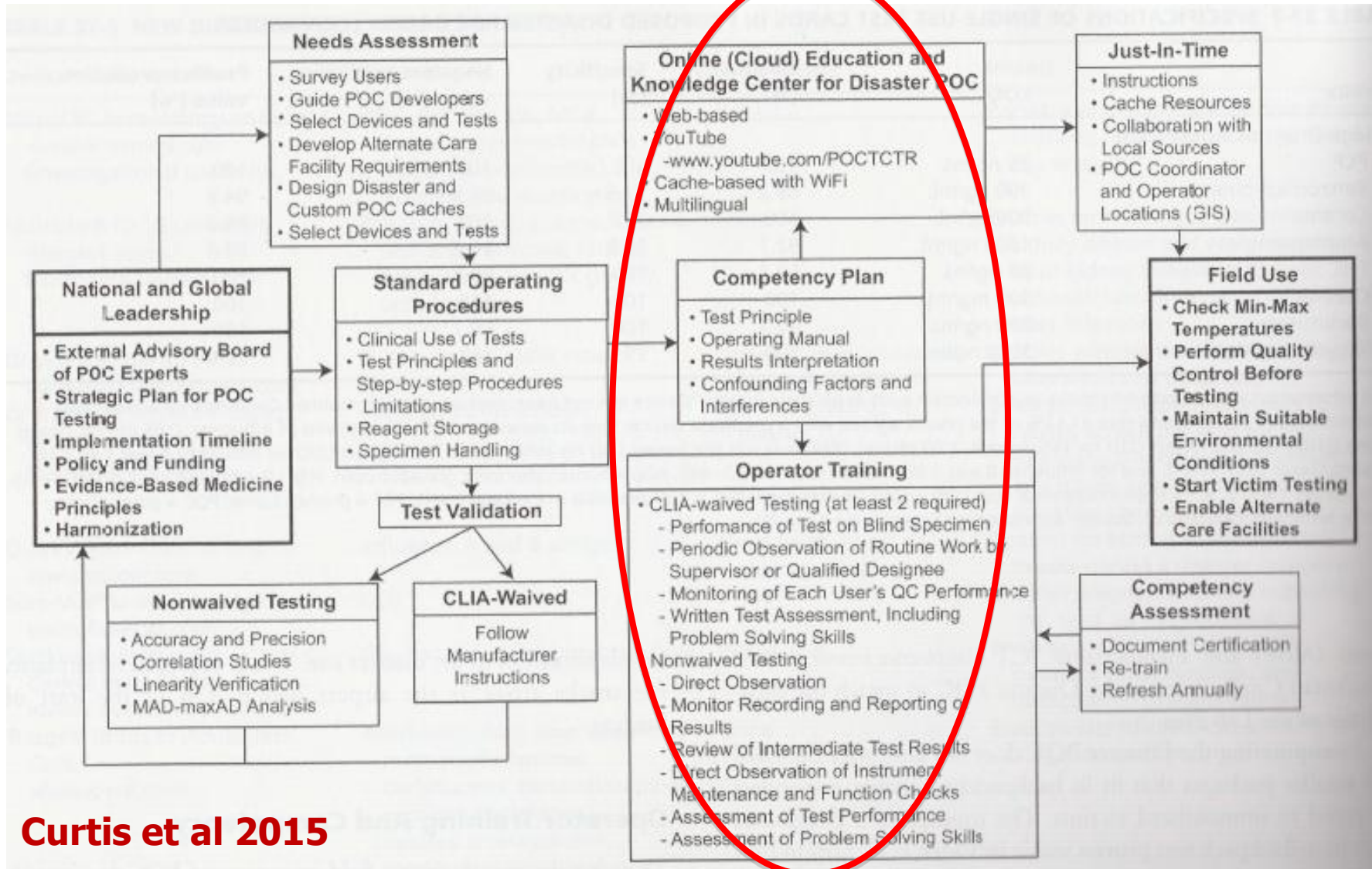
**MJ O'Kane 2011**

**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



# 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

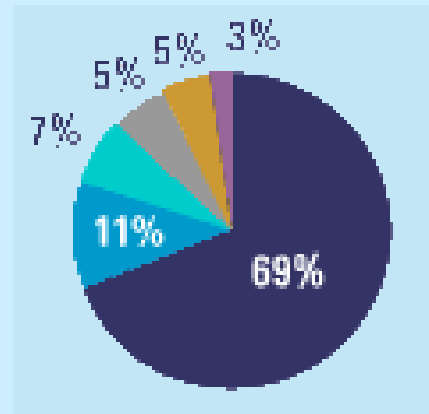
- patient and staff satisfaction
- blood conservation
- decreased pre and post-analytical errors
- **faster TAT**
- diminished requests

**P St-Louis 2000**

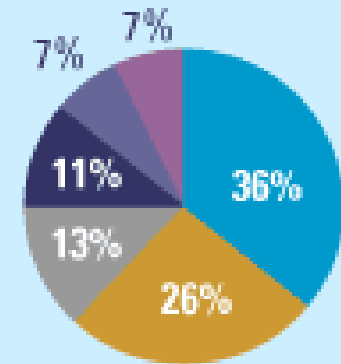
# Rapidità (TAT)

## *Top Five Motivators for Adopting Point of Care Technology*

- Faster turnaround time
- Improved patient outcomes
- Reduced staffing/labor costs
- Portability/mobility
- Reduced cost per test
- Other motivators



Current POCD users

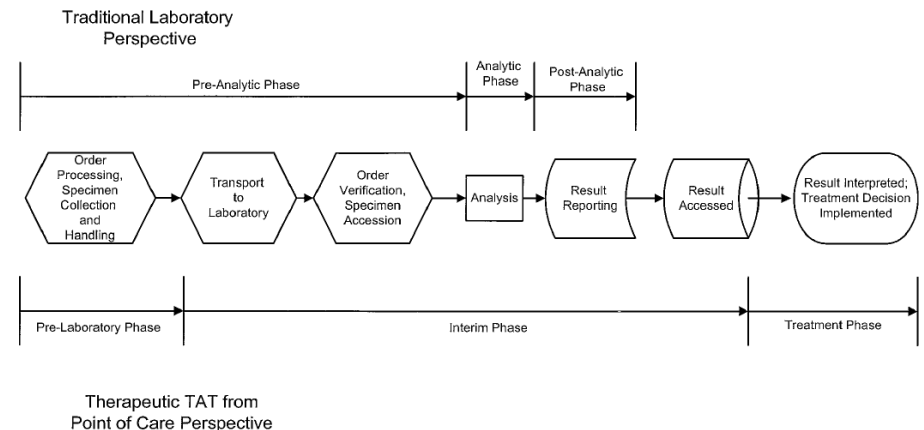


Non-POCD users

Source: Science Advisory Board Survey, Nov 98

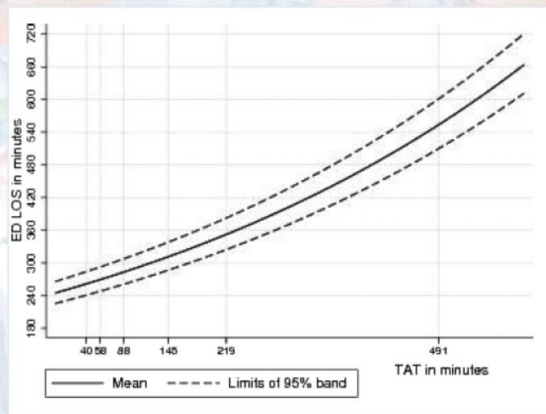
## Therapeutic TAT

**ML Kilgore, SJ Steindel,  
JA Smith 1998**





# TAT e LOS in ED

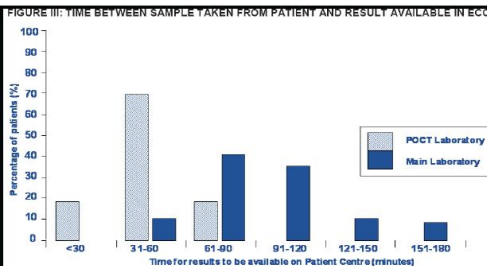


- 30' TAT = 17' LOS
- TAT/LOS = 0.19
- TAT & test n° ➔ 10% ED LOS variability

Li et al 2015

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

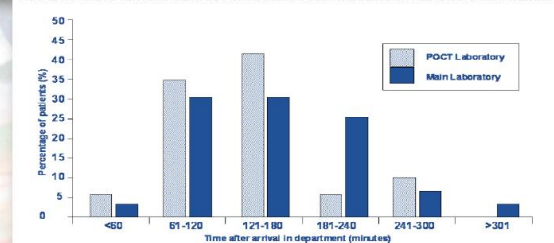
## Clinical Decision Making



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%)		

MN. Illahi,  
R Lapworth,  
P Bates 2012

FIGURE IV: TIME AFTER ARRIVAL IN ECC UNTIL SENIOR CLINICAL DECISION REGARDING MANAGEMENT



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 ...

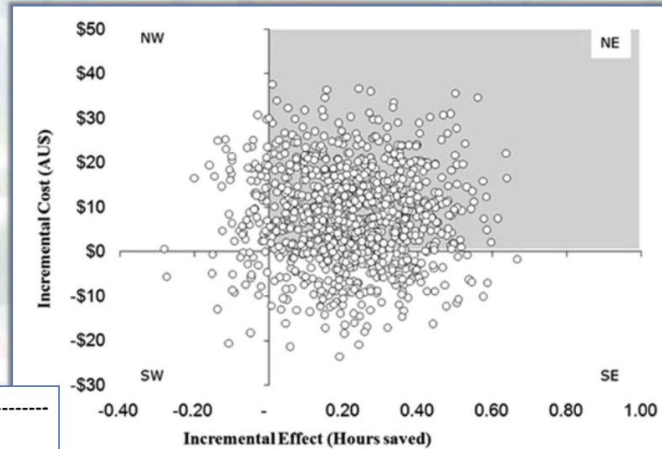
Despotis et al 1997

... prescribing behavior ...

IV Jani, TF Peter 2013

# Evidenze economiche e POCT

## POCT cost-effectiveness

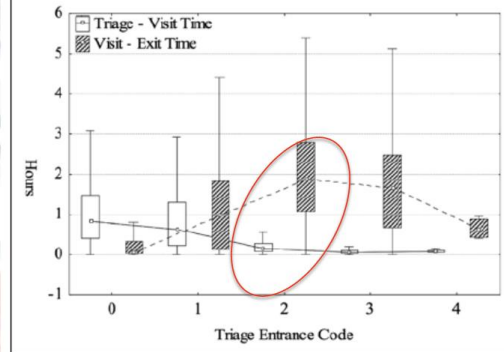


Asha et al 2014

Operation time  
Recovery time

## Costo analisi in ED

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).



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

Tab. VI. Per patient (structure) cost.

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

Cremonesi et al 2010

### Economic

Resource utilisation

Intermediate outcomes

Cost per QALY

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

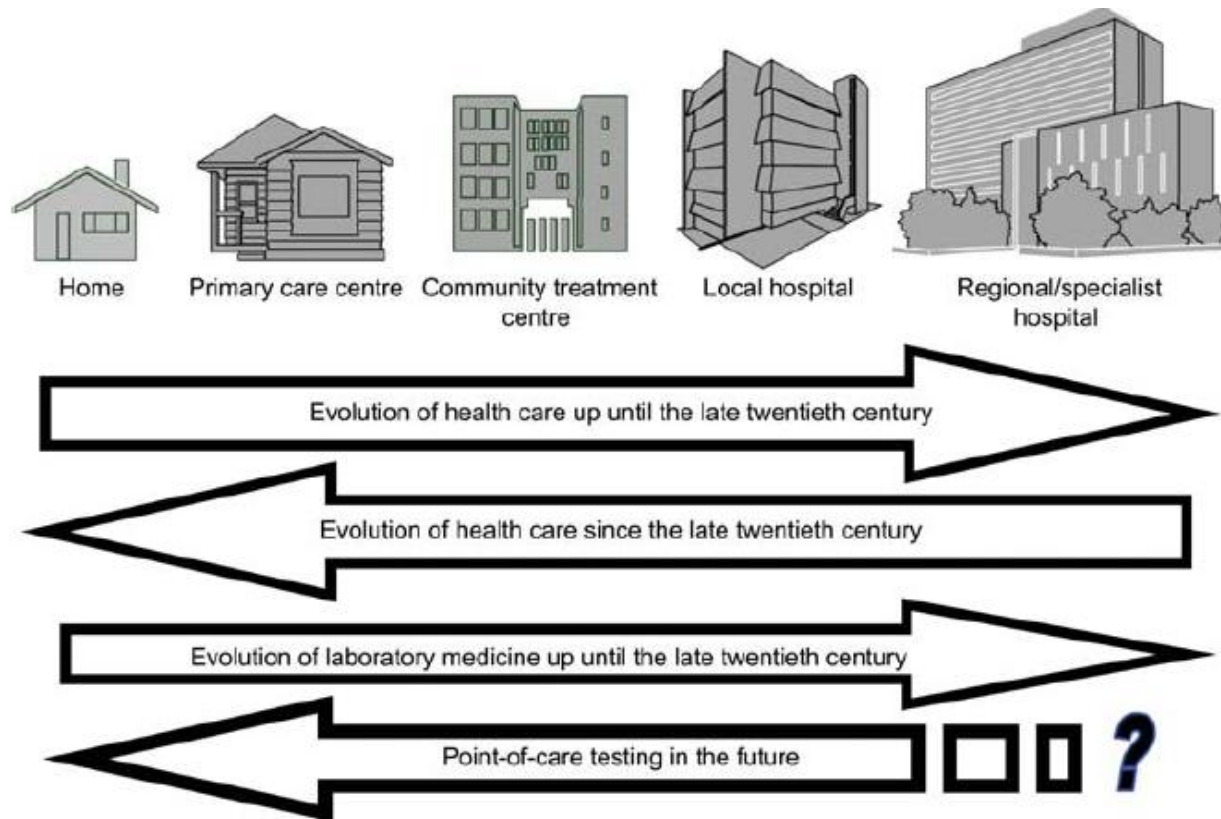


Figure 2 Illustrating the parallel evolutions of the delivery of healthcare and laboratory medicine.

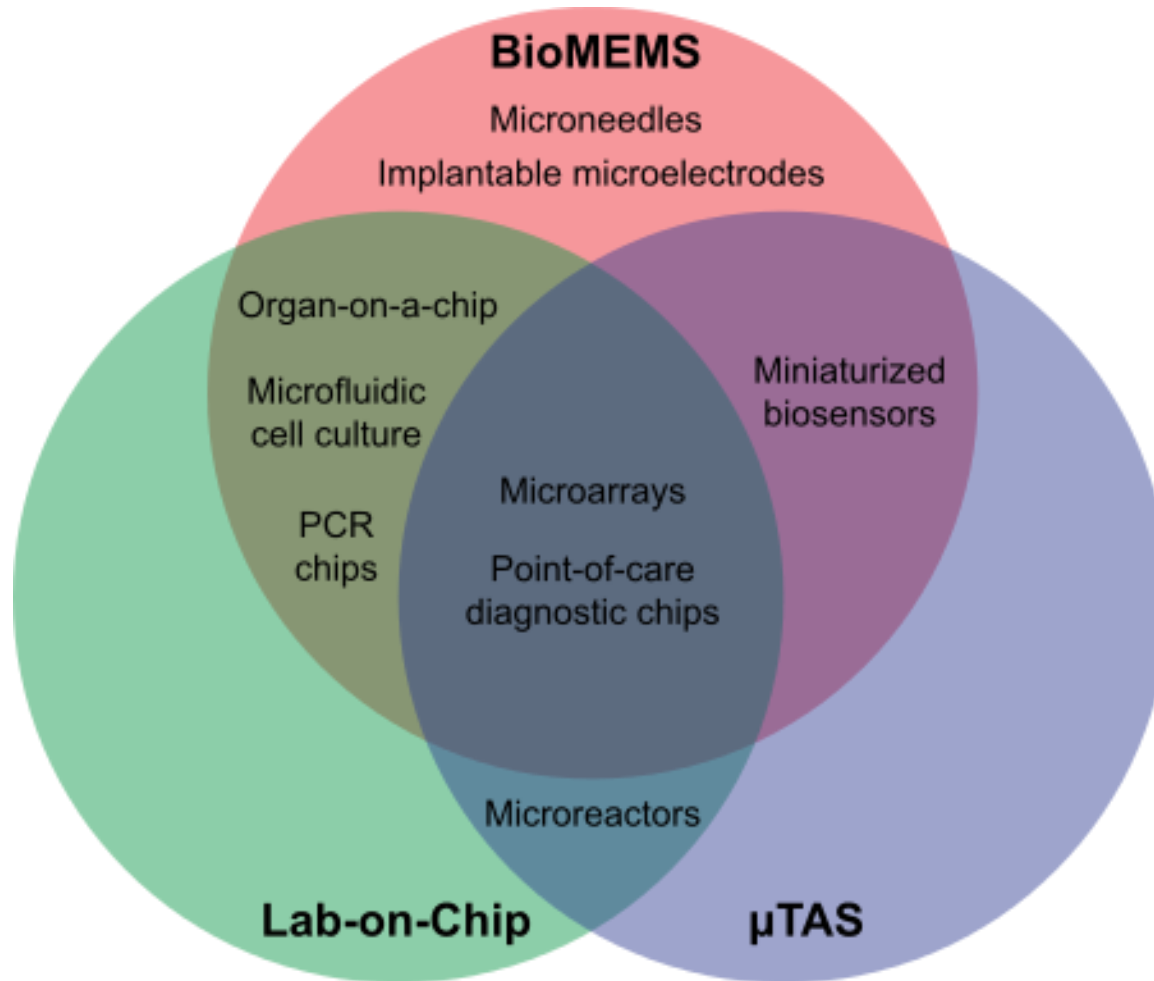
# Disaster POCT Needs Assessment

- Handheld devices
- Multiplexity (patients)
- Robustness (T, vibration, humidity, impact shock)
- Priority: clinical sensitivity, TAT, clinical specificity, battery operation
- Sampling method: cassette, mechanical, multiple, disposable
- At patient-side
- First responder
- Priority: pathogens, CBC, chemistry (...), O<sub>2</sub> sat, ABO group ... ; upgrade (pandemics)
- Characteristics: risk, effort, time

**Kost et al 2015**



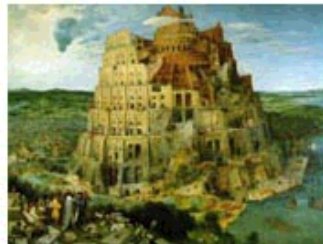
# Innovazione tecnologica





# Connectivity Industry Consortium

The Universal Connectivity Standard for Point of Care



In the Judeo- Christian tradition, the story of the Tower of Babel describes how the people of the land of Shinar used brick and lime to construct a city with a tower that would reach up to heaven.

But the Lord intervened and prevented the builders from completing their task. He scattered them abroad and confounded their speech, so that humankind, which had been united by a single, common language, was divided into nations who were no longer able to communicate.

This parable holds two important lessons for the Point of Care industry.

## What's New

10/27/00  
[Invitation: 11/23 CIC presentation at Medica](#)

9/17/00  
[Newsletter #8](#)

8/28/2000  
[AACC Meeting Summary](#)

[AACC Technical Milestone document](#)

5/1  
Pre

# Connetivicty

**Wired**  
**Wi-fi**  
**Bluetooth**  
**Infrared**  
**GISs**

## Il paziente digitale

Doc Google  
Doc Smartphone  
Doc WD  
(wearable diagnostics)  
Internet of Things





# 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<sup>39</sup>, il quale fornisce specifici requisiti applicabili ai POCT in connessione con lo standard ISO 15189:2012 *Medical laboratories – particular requirements for quality and competence*<sup>41</sup>. I requisiti ISO 22870:2006<sup>39</sup> 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<sup>42</sup> 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<sup>1</sup> • Cettina Drago<sup>2</sup> • Luca Rossi<sup>3</sup> • Rossana Colla<sup>4</sup> •  
Renato Tozzoli<sup>5</sup> • per il GdS PoCT della SIPMeL

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

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POCT Policy

POCT Coordinator & Team

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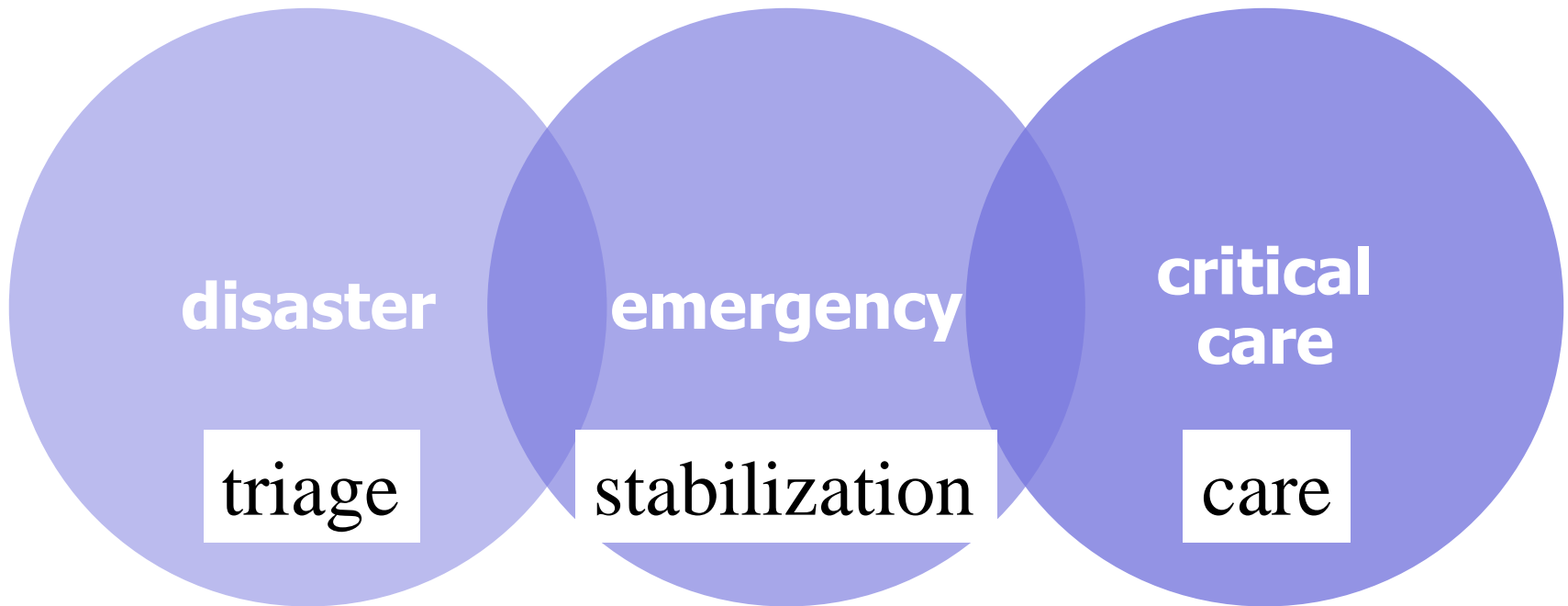
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# POCT continuum



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

# Small-world Network Shared Resources

Emergency  
care

Competency  
preparedness

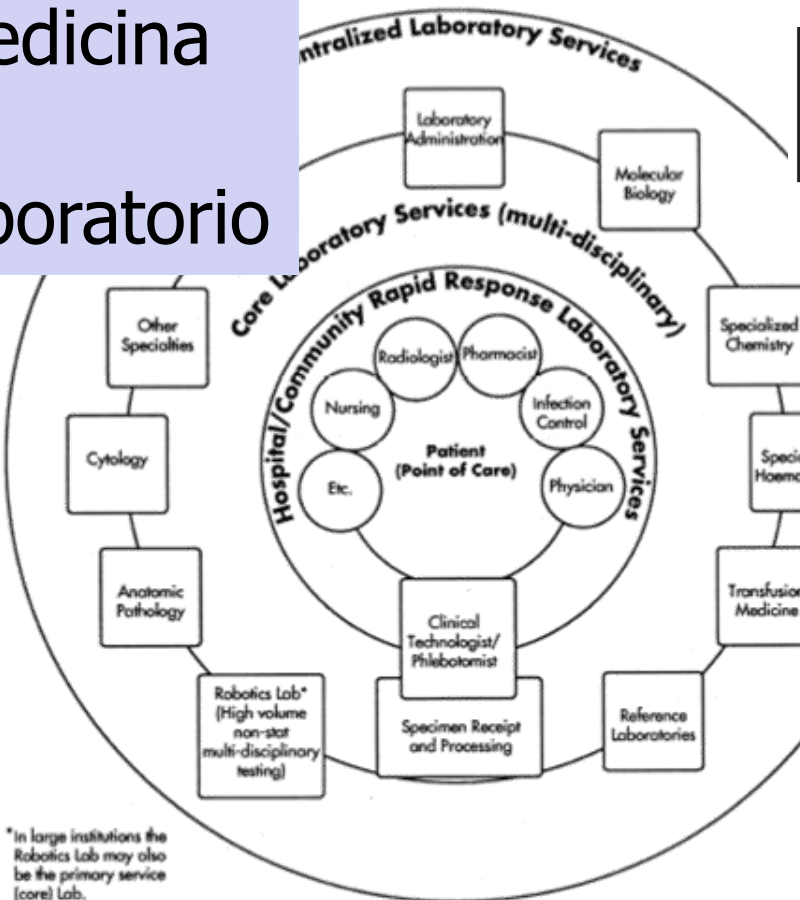
Response  
resilience

Disaster POCT

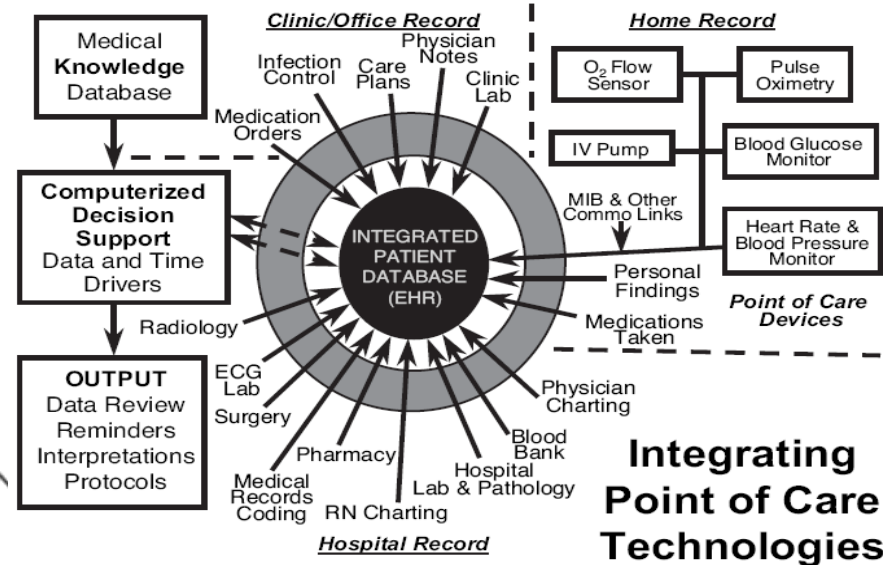
**Kost et al 2015**

# Un nuovo mondo

POCT è una modalità della medicina di laboratorio



\*In large institutions the Robotics Lab may also be the primary service (core) Lab.



**Integrating Point of Care Technologies**

CP Price, LJ Kricka 2007

### 3. The Platform (R)evolution: Defining ecosystems, redefining healthcare

Healthcare IT platforms capture data from disparate sources (e.g., wearables, phones, glucometers), and connect it to provide patients and caregivers a holistic and real-time view of your health.

**Today**

Platforms

Healthcare IT innovations

More platforms are starting to appear—Welltok, TruTrac, Social Wellth

Healthcare IT innovations are allowing providers to deliver a variety of services faster, and for less

**Tomorrow**

Smarter Platforms

Identify Asthma Triggers

Immediate Results

A device connected to your mobile phone can do a finger prick test for immediate results

**41%** of health executives strongly agree that the next generation of platforms will be led by industry players and leaders, not tech leaders.

**Health monitoring:** the #1 reason why 54% of patients use mobile phone apps.

### 5. Workforce Reimagined: Collaboration at the intersection of humans and healthcare

As the digital revolution gains momentum, doctors and healthcare workers are now using machines to be more efficient, provide better care and take on increasingly more complex tasks.

**Today**

Phone Apps

Social Media

Alzheimer's Diagnostic Test

Phone apps are helping doctors and patients calculate the risk of heart surgery

Mental health patients in the UK are using social media to anonymously interact

A software-based Alzheimer's diagnostic test can detect impairments on the hippocampus (the first area of the brain to be affected by the disease) by evaluating your eye movement

**Tomorrow**

Caring Team

Implantable Devices

Real-Time Data

Develop your own caregiving team when you use social media or connect with peers facing similar conditions

Implantable devices collect new levels of data that can better inform a doctor's care plan

Surgeons using wearable devices have real-time access to data from monitoring equipment, so they can make more informed decisions about the patient during a procedure

**66%** of US health systems will offer digital self-scheduling by the end of 2016.

**45%** of health executives strongly agree that within 3 years, companies will need to focus as much on training machines as on training people.

Richardson et al 1999



# Il futuro della Medicina di Laboratorio

Rottura dell'unità spazio/tempo  
Amplificazione dell'interfaccia

“Innovazione distruttiva” ICT & POCT  
Concentrazione/Decentralizzazioni

**Qualità/Sicurezza**  
**Interpretazione/Comunicazione**  
**Traslazione/Trasformazione**

**P Cappelletti 2012**