Point of Care in Pronto Soccorso

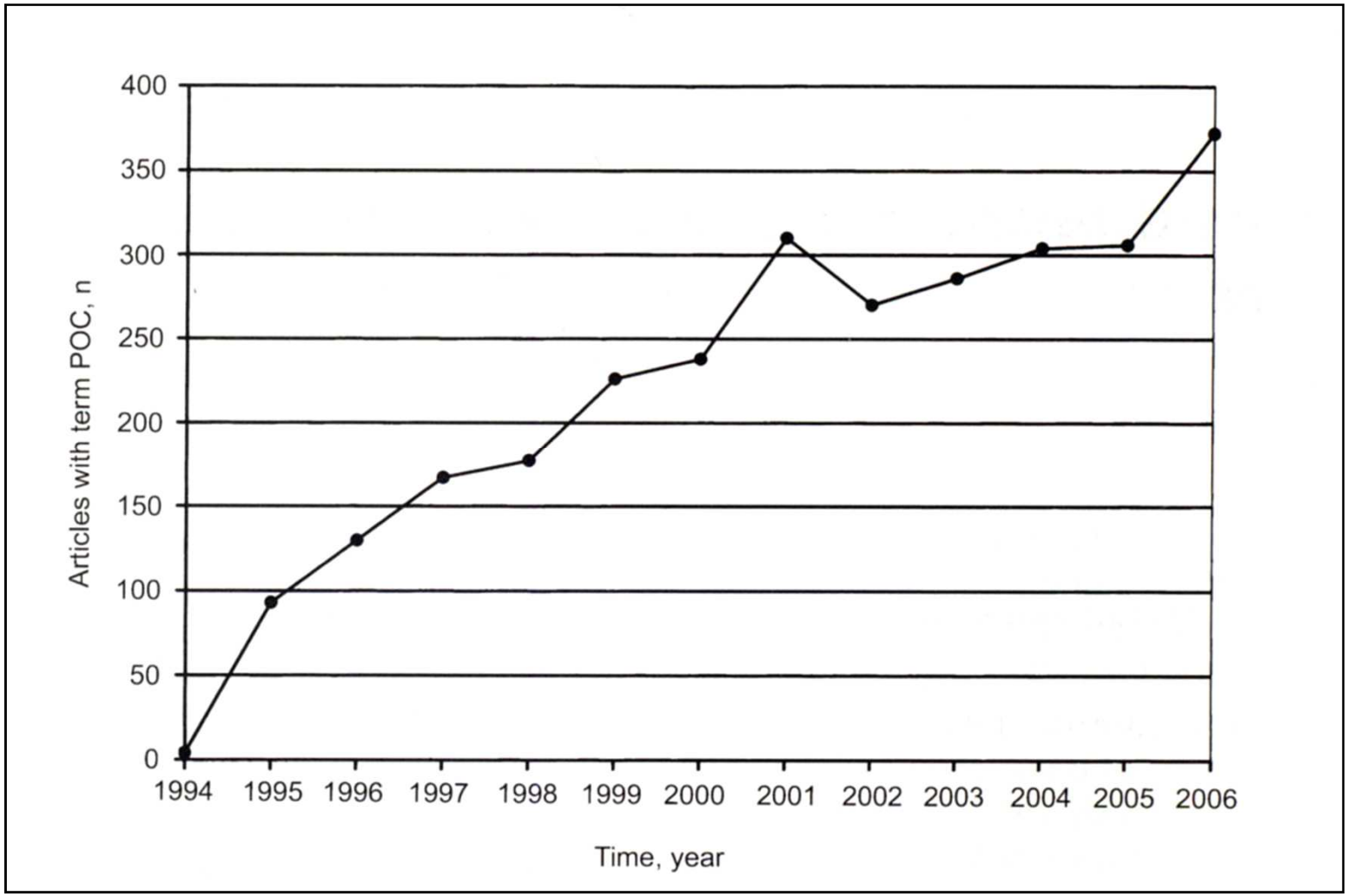
x congresso nazionale
simeu
NAPOLI 18-20 NOVEMBRE 2016

Mario Plebani
University-Hospital
of Padova, Italy

POINT OF CARE TESTING

- The aspect of laboratory medicine known as ***point-of-care testing (POCT)*** has become a significant part of the testing that is performed on patients

- The term “POCT” does not formally show up in the literature until 1994.

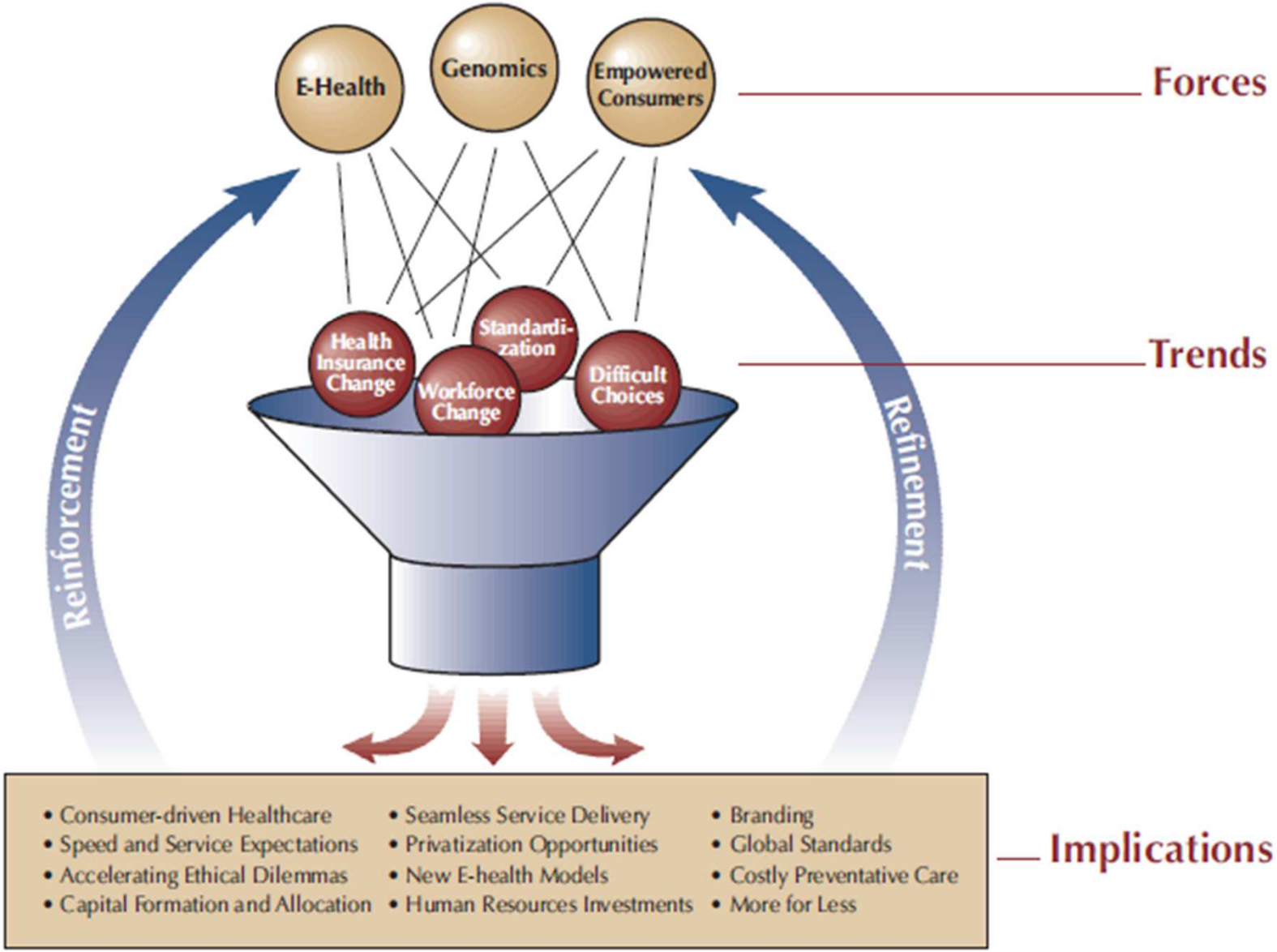


Kazmierczak S, Clin Chem Lab Med 2008;46:1-2

LABORATORY MEDICINE and POCT

One area in which *these trends intersect is the* ***laboratory***, whose role will be much more automated, and much less centralized and less labor intensive. ***Point-of-care testing***, such as handheld blood and saliva analyzers, will be pushed out to the bedside, the clinic and the home.

HealthCast 2010: Smaller World, Bigger Expectations

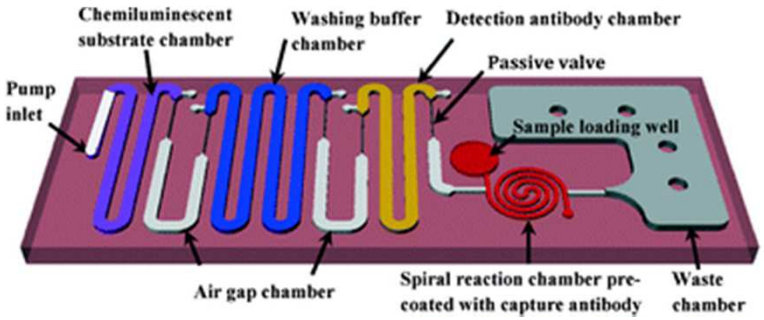

E-Health
Genomics
Empowered Consumers
Forces
Health Insurance Change
Workforce Change
Standardi-zation
Difficult Choices
Trends
Reinforcement
Refinement
• Consumer-driven Healthcare
• Speed and Service Expectations
• Accelerating Ethical Dilemmas
• Capital Formation and Allocation
• Seamless Service Delivery
• Privatization Opportunities
• New E-health Models
• Human Resources Investments
• Branding
• Global Standards
• Costly Preventative Care
• More for Less
Implications

POCT : COSA SIGNIFICA ?

- Point-of-care testing (POCT) is a form of testing in which the **analysis is performed** where healthcare is provided **close to** or **near the patient**.
- Various definitions have been provided in the medical/scientific literature and alternative descriptions include: **near patient testing** (NPT), **bed side testing**, physicians office testing (POL), off site testing, **alternative site testing**, etc.

POCT: RAGIONI di un SUCCESSO

POCT is the paradigm of the so-called "***laboratory on a chip***" systems that utilize ***miniaturization***, micromachining, microfluidics, ***nanotechnology*** and ***wireless communication.***



PREFERENZE DEL PAZIENTE

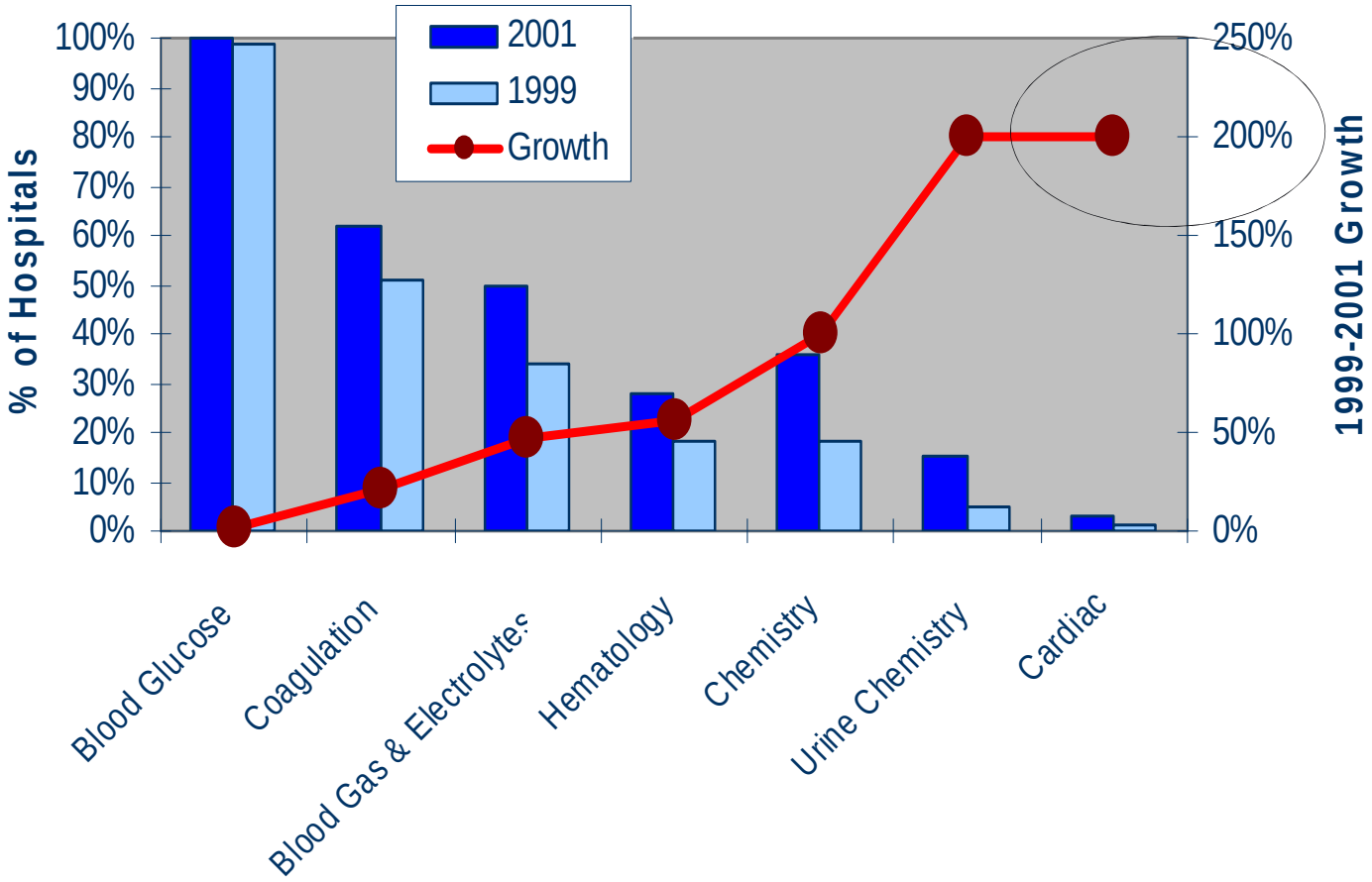
BISOGNI CLINICI

POCT

PRESSIONE DELL'INDUSTRIA IVD

ASPETTI ORGANIZZATIVI

Percentage of Hospitals with POC Instruments by Discipline



MERCATO E CRESCITA

- The global POC diagnostic market reached $13.4 billion in 2010, and is expected to further grow to US$16.5 billion in 2016.

- Hospitals report that they are using significantly more POC tests than in 2007, and 50% of hospitals report they are using significantly more POC test systems.

Abel G Exper Rev Mol Diag 2015

POCT: QUALE CRESCITA?

- Crescita annuale del 7.5% negli ospedali.

- Esami più frequentemente eseguiti in POCT:

  Glucosio, coagulazione, emogasanalisi e HbA1c, ma negli ultimi anni l'incremento più significativo si riferisce ai marcatori cardiaci.

Malone B, AACC Clin Lab News 2015

POCT: VANTAGGI?

POCT offers considerable advantages over central laboratory testing, such as:

- ***fast*** and ***simple specimen handling***,
- ***simpler sample requirement*** (no additives and mostly blood from finger stick; and urine)
- ***no transportation*** is required, and POCT delivers short turnaround time

Why Point of Care Testing?

Advantages of POCT	
1. Simpler pre-analytical process	2. Requires small blood volume e.g. 95 µl
3. Allows bedside testing & portability	4. Provides rapid results
5. Accelerates clinical decision-making process	6. Allows healthcare practitioner to deliver patient-centred care
7. Decreases time to treatment	8. Potential to improve patients outcome

POCT Provides Value

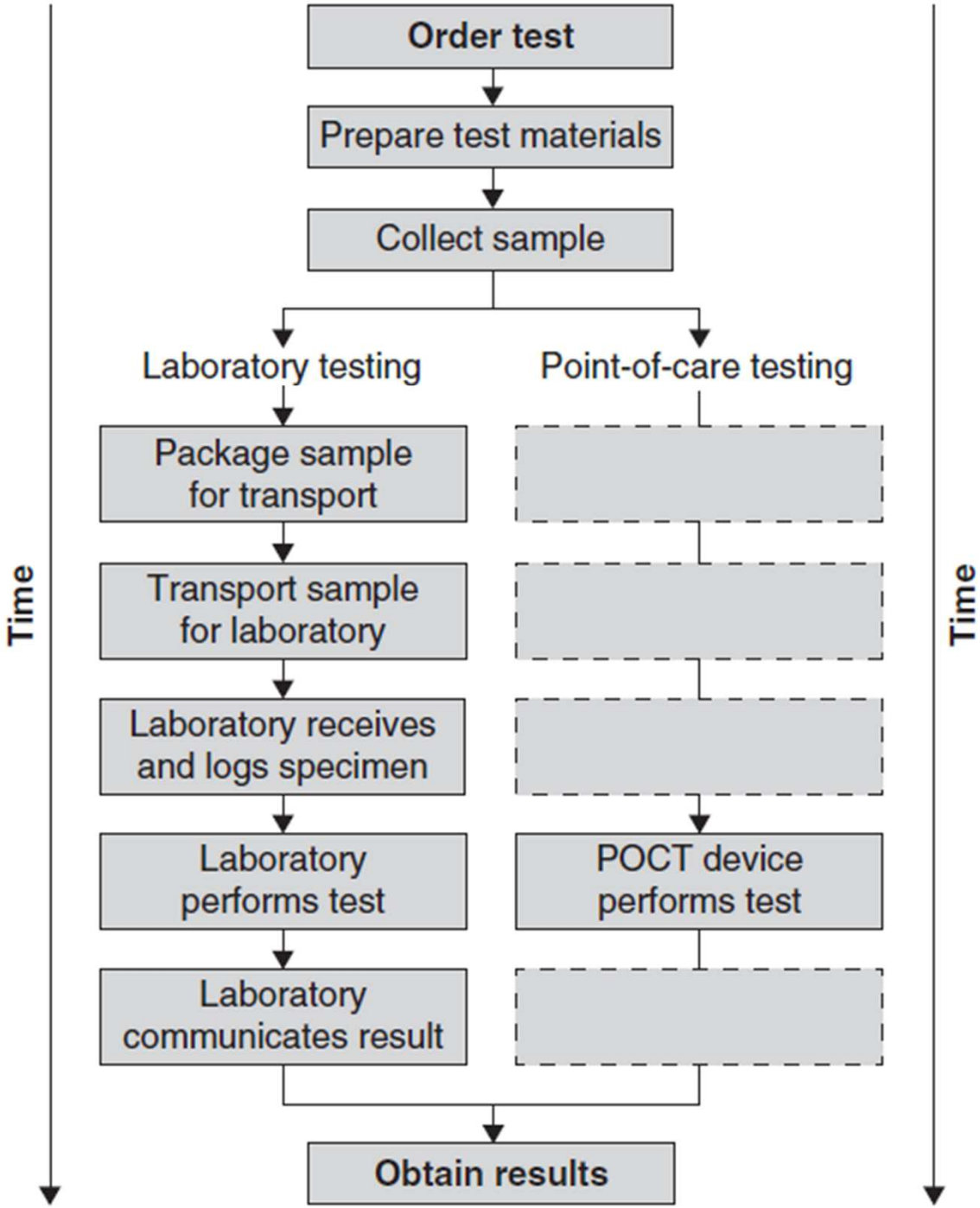
- POCT can provide benefits:
  - Rapid TAT
  - Smaller specimen
  - Rapid delivery of results
  - Early diagnosis. Rapid response

    Improve quality of care while reducing costs

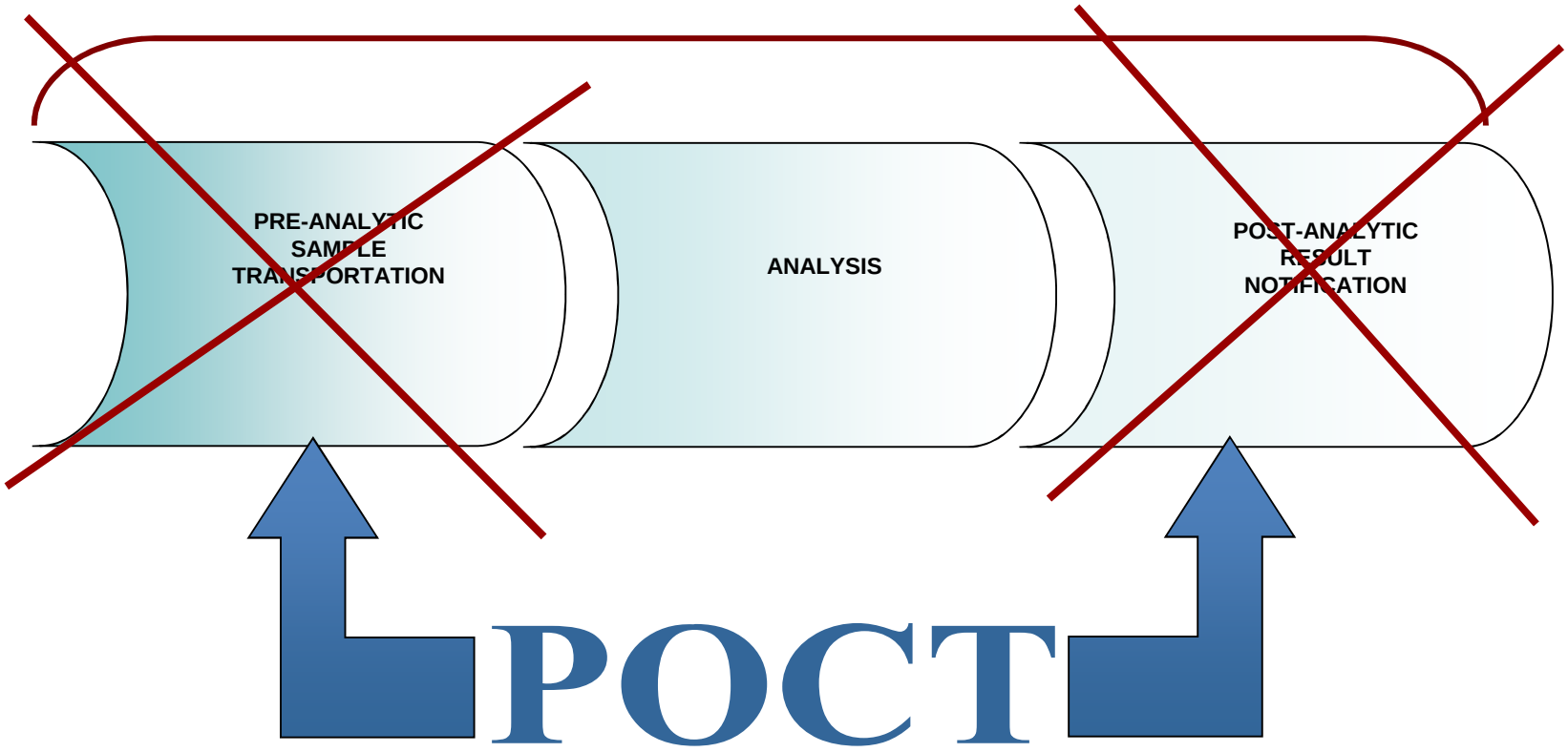
- Also challenges:
  - Less controlled environment
  - Pre-, post-, and analytic phase errors
  - Limited training (procedures/limitations)
  - Failures in instruments, reagents, software

    Increased access to test results vs. potential degradation of quality of results

TURN-AROUND TIME

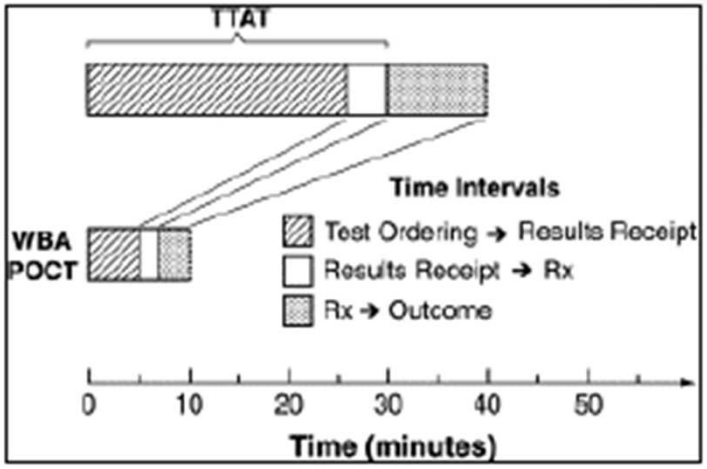

Order test
Prepare test materials
Collect sample
Laboratory testing
Point-of-care testing
Package sample for transport
Transport sample for laboratory
Laboratory receives and logs specimen
Laboratory performs test
POCT device performs test
Laboratory communicates result
Obtain results
Time
Time

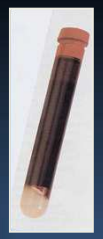
TAT


PRE-ANALYTIC
SAMPLE
TRANSPORTATION
ANALYSIS
POST-ANALYTIC
RESULT
NOTIFICATION
POCT

Vein to Brain Time

- Investigation ordered
- Sample drawn
- Labeled
- Sent to central lab
- Transported to specific lab section
- Specimen entered in analyser
- Time of actual analysis
- Results entered into computer
- Practitioner becomes aware of test results





Intra-laboratory TAT = Laboratory Director Satisfaction

Years 1950-70s

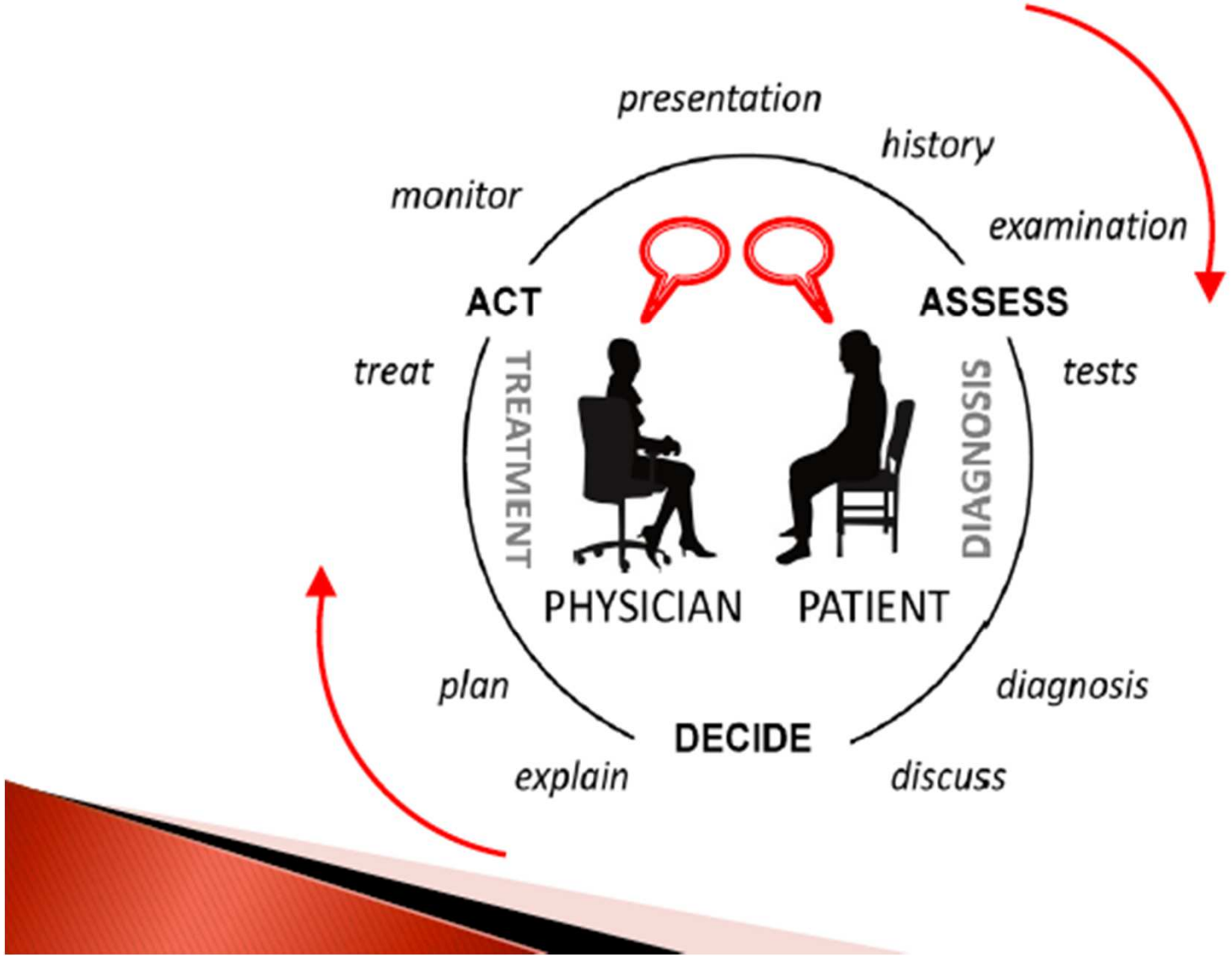
Vein-to-brain TAT = Physician Satisfaction

Years 1970-80s

Therapeutic TAT = Patient Satisfaction

Years 2000

Point-of-Care Testing
what decision? what tests?



POCT and OUTCOMES

Question: Does the faster TAT for POCT lead to ***better outcomes***?

The answer, after 20 years of investigation, is an unequivocal “it depends”.

It depends on the ***analyte*** and the ***testing device***, on the ***reasons for testing***, and on the ***setting*** of the testing, among other variables.

Rainey PM, Ulibarry M Am J Clin Pathol 2014

POCT and CLINICAL OUTCOMES

The **evidence of quality** and the **quality of evidence**

DE GRUYTER DOI 10.1515/cclm-2013-0386 — Clin Chem Lab Med 2014; 52(3): 313–324

Review

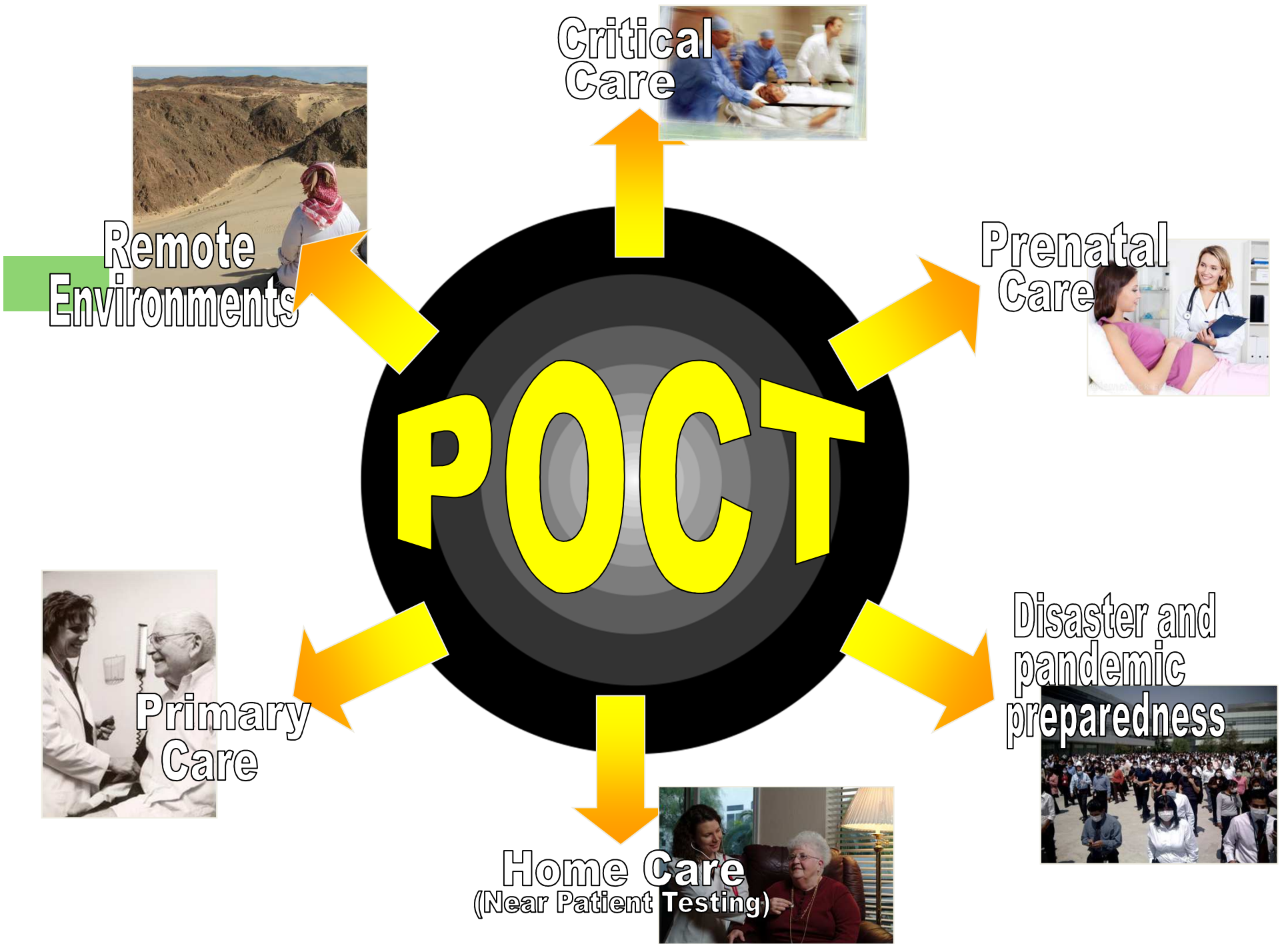
Valentina Pecoraro*, Luca Germagnoli and Giuseppe Banfi

Point-of-care testing: where is the evidence? A systematic survey

in future studies: 1) there is insufficient evidence of the effectiveness of POCT in clinical decision making; 2) the current literature requires further development; and 3) economic analysis exploring whether the potential benefit of POCT justifies the additional cost is needed.

POCT: UTILITA' CLINICA

- L'utilità clinica del POCT è documentata se la ***riduzione del TAT*** e del tempo necessario per la decisione clinica si traduce in ***miglioramenti*** significativi degli ***esiti di salute*** e della ***qualità delle cure***
- Pertanto, non può sorprendere che il gruppo di pazienti che trae maggiori vantaggi dal POCT sono quelli nei quali i ritardi nell'inizio della terapia determinano effetti più negativi sugli esiti di salute


Critical Care
Remote Environments
Prenatal Care
POCT
Primary Care
Disaster and pandemic preparedness
Home Care
(Near Patient Testing)

The NEW ENGLAND JOURNAL of MEDICINE 2013;368(24):2319-24

SOUNDING BOARD

How Point-of-Care Testing Could Drive Innovation in Global Health

Ilesh V. Jani, M.D., Ph.D., and Trevor F. Peter, Ph.D., M.P.H.

- The **rise of POCT** is expected to expand **access** to medical services, **improve health outcomes**, and facilitate the sustainability of disease-control programs.
- The supply of POC tests will directly induces changes, such as **improved patient flow** within clinics.

POCT in Low-and Middle- income Countries

- HIV testing/HIV viral load
- Malaria rapid tests
- NAT-based diagnosis for Tuberculosis
- Drug resistant testing
- Other blood-borm and respiratory infections
- CD4+T Cells

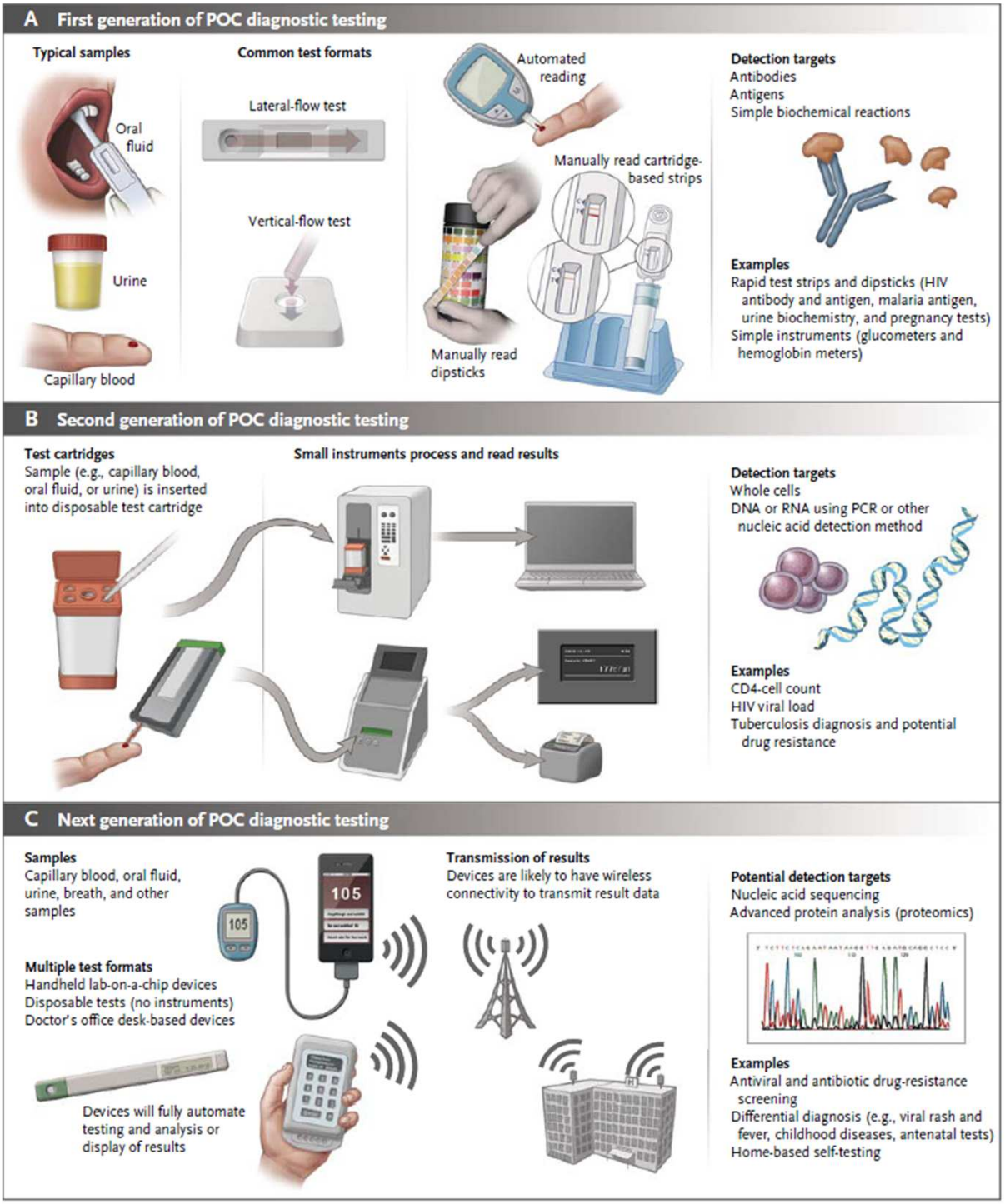
POCT and RESOURCE-POOR COUNTRIES

- In resource-poor countries, POCT may be the only means of delivering advanced testing for epidemiologically important diseases, such as tuberculosis and HIV infection.
- A recent study demonstrated that POC CD4 at the time of HIV diagnosis could improve survival and be cost effective compared with central laboratory CD4 testing.

Hyle EP et al. PLoS Med 2014

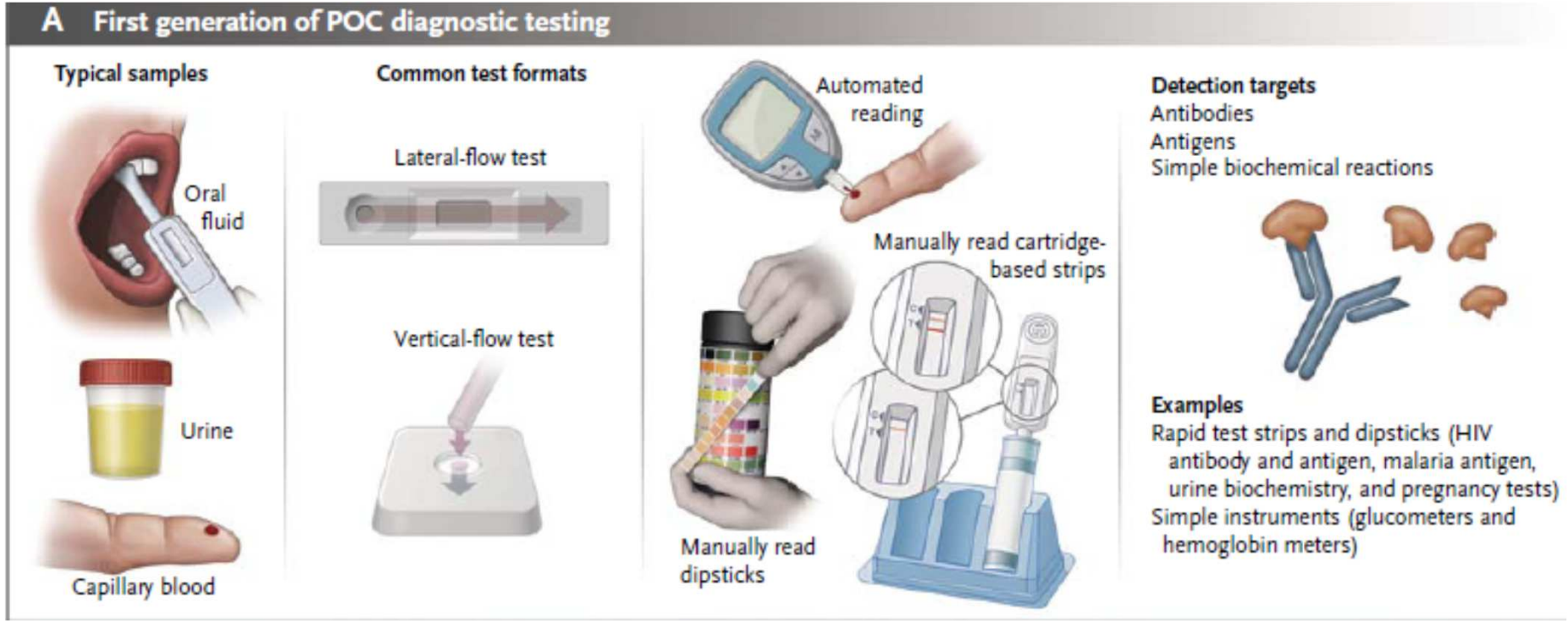
POCT E BENEFICI CLINICI

- Vari studi hanno dimostrato l'utilità del POCT in una serie di aree diagnostiche incluse malaria, HIV, sifilide, gonorrea, INR, D Dimero, fibronectina fetale.
- Questi studi hanno dimostrato la potenziale utilità clinica del POCT che dovrebbe peraltro essere confermata in trials clinici e studi osservazionali.

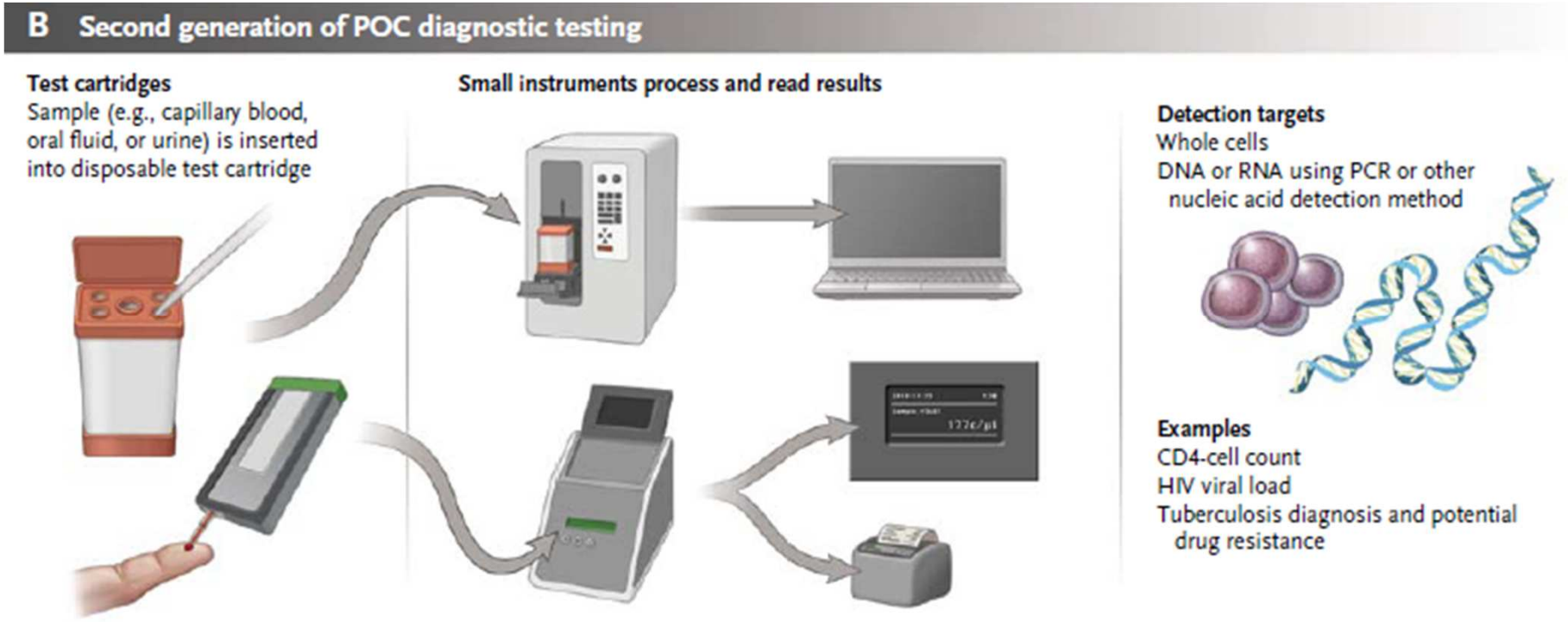


FROM FIRST TO SECOND and THIRD POCT GENERATIONS

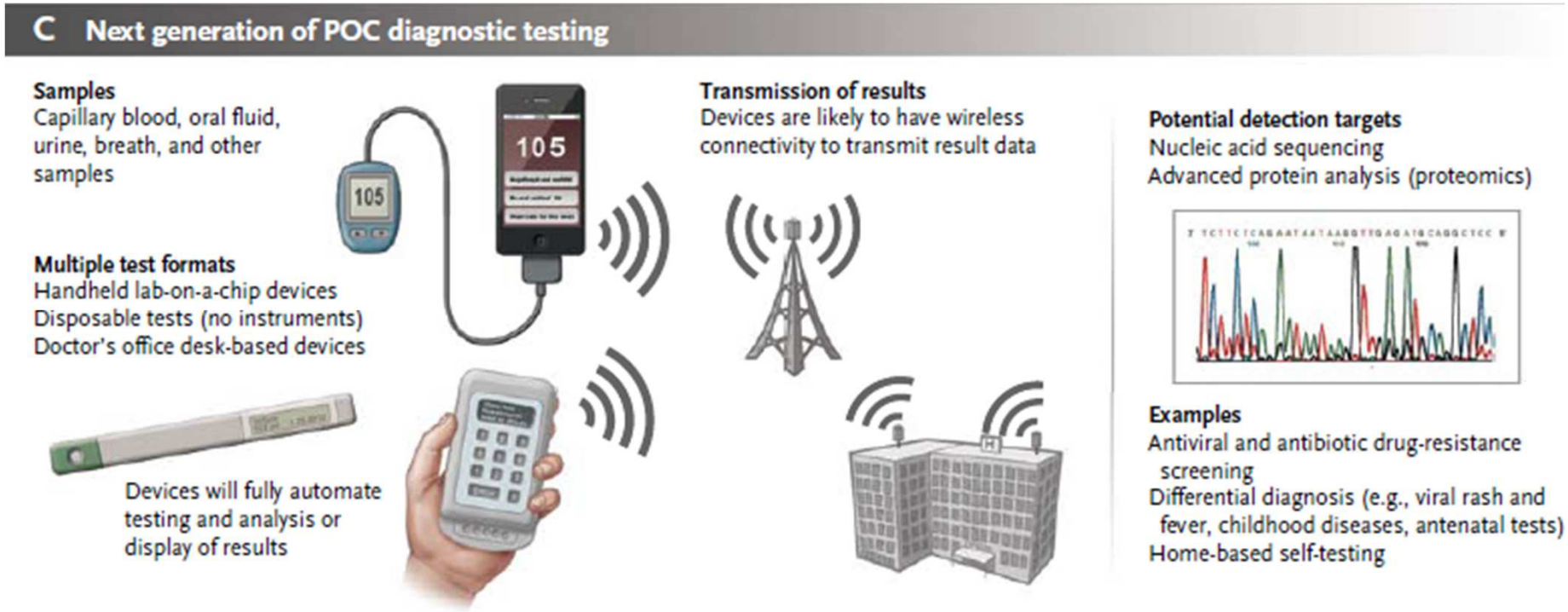
POCT: FIRST GENERATION



POCT: SECOND GENERATION



POCT: THIRD GENERATION



Critical care

Emergency Deparments

Paramedic vehicles

Operating Rooms

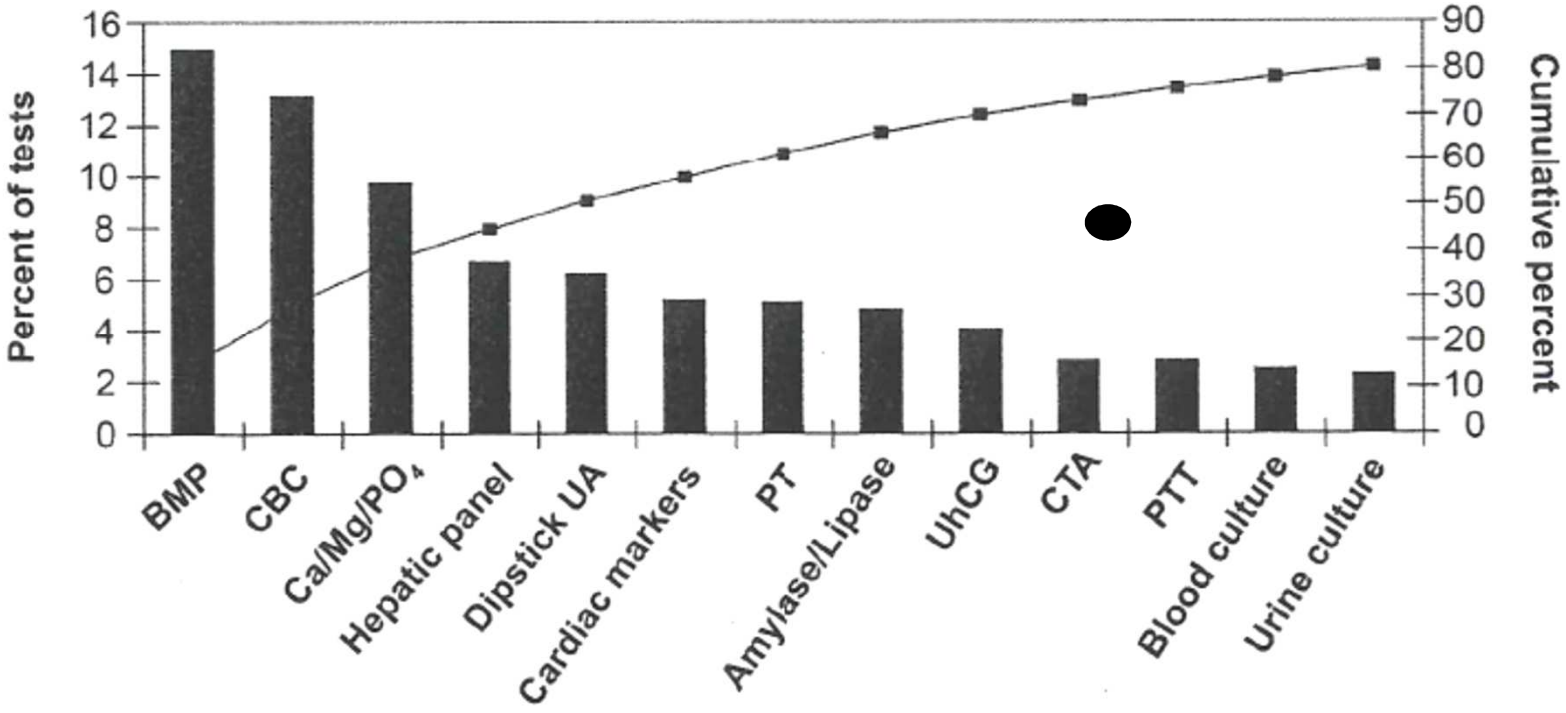
Prenatal Care

Intensive Care Units

POCT in CRITICAL CARE

- Arterial Blood Gases
- Electrolytes
- Glucose
- Lactate
- Lipase
- Hematocrit/Hemoglobin
- Complete Blood Count
- Platelet Count
- TEG
- PT/INR – PTT
- D-dimer
- cTnI/cTnT
- BNP or NT-proBNP
- hCG (blood or urine)
- Dipstick urinalysis
- CRP
- Procalcitonin
- Presepsin (soluble CD 14 subtype)
- Rapid HIV
- Rapid strep A
- Rapid Infwenza A/B?
- Rapid RSV
- Ethanol
- Drug of abuse (DOA), salicylates, acetaminophen

Frequency of common tests requested in the emergency department



Point-of Care Testing. Price CP, St John A, Kricka LJ. American Association for Clinical Chemistry, Inc.

Evolution of the blood gas analyzers: …up to now

Classification:

- **Hands on**
- **Portable**
- **Traditional (bench top)**

POCT:
Navigating between Scylla and Charybdis

POINT-of-CARE TESTING

The ***core principle*** underlying POCT measurement has been described as “ ***reducing turnaround time*** without compromising the ***quality of the information***” on which clinical decisions for patients are based.

Collinson PO, 2006

POCT and ANALYTICAL ISSUES: NOT ALL LABORATORY TESTS ARE EQUAL

- The ***analytical quality specifications*** of POCT should be the ***same*** of centralized laboratory testing.

- For some parameters, this has been achieved, while there are many ***problems with other constituents***

Quality of analysis of electrolytes and cholesterol on central laboratory equipment compared

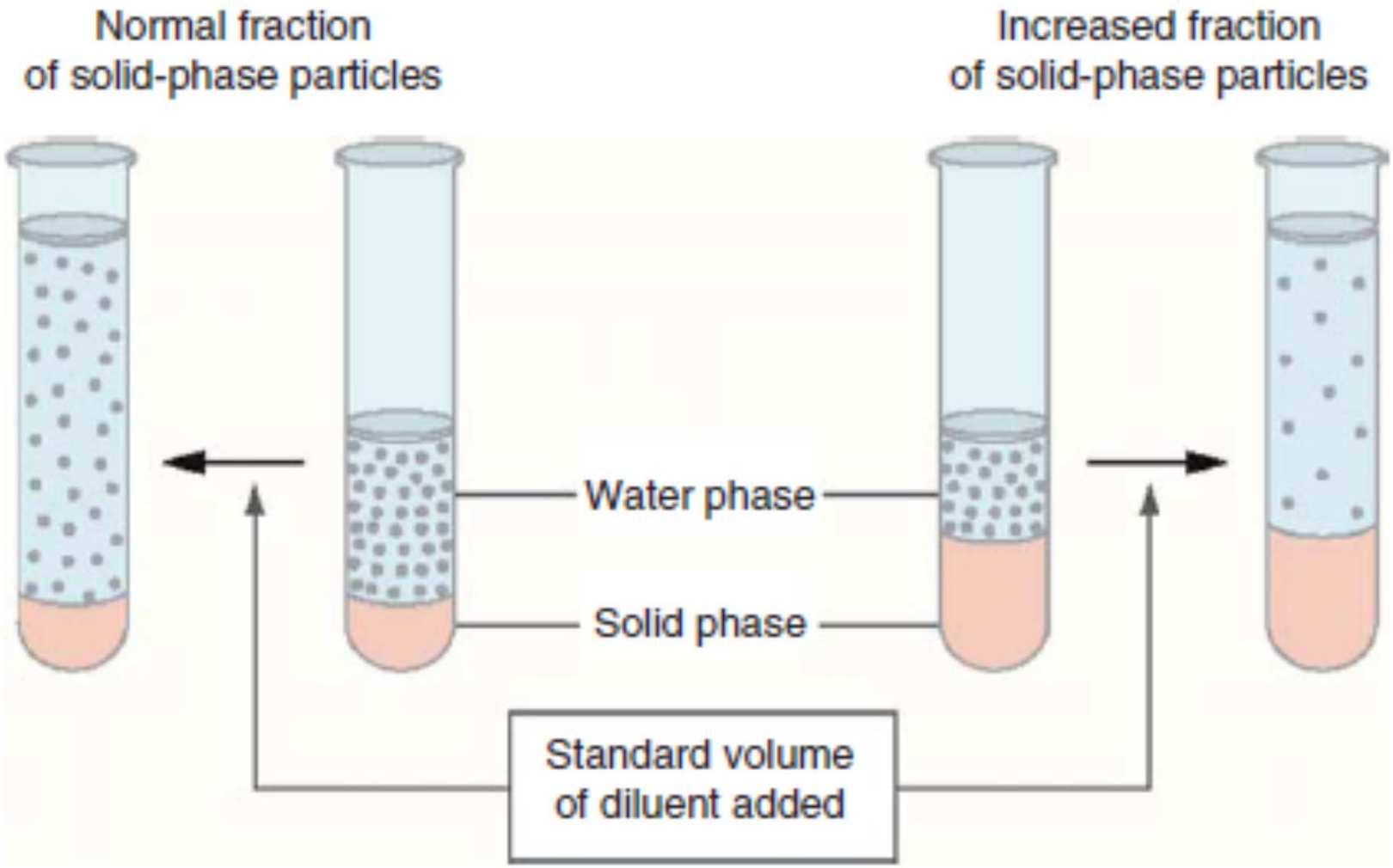
Performance Measured	*Sodium*		*Potassium*		*Cholesterol*	
	SD	*CV%*	*SD*	*CV%*	*SD*	*CV%*
Best central Laboratories	0.6	0.4	0.02	0.5	0.025	0.6
50% of central Laboratories	1.5	1.1	0.07	1.7	0.102	2.5
Best POCT sites	0.3	0.2	0.00	0.1	0.076	1.8
50% of POCT sites	1.0	0.7	0.06	1.6	0.183	4.4

PSEUDOHYPONATRAEMIA

- La determinazione della sodiemia si avvale del principio degli **elettrodi ione-selettivi** (ISE), ulteriormente suddivisi in **diretti** ed **indiretti.**
- I ***metodi indiretti*** prevedono una prediluizione del campione in rapporto da 1:20 a 1:34 per ridurre la quantità di campione e ampliare l'intervallo di determinazione.

PSEUDOHYPONATRAEMIA

- Nei metodi indiretti, è essenziale l'effetto di **spiazzamento dell'acqua** da parte di proteine e lipidi che normalmente contribuiscono al **7%** del volume plasmatico
- Per tali motivi, i metodi sono standardizzati per una prediluizione della concentrazione della **massa di acqua** pari a **0.93 Kg/L (93%).**



Pseudoiponatriemia

Rooney and Schilling *Critical Care* 2014, **18**:692
http://ccforum.com/content/18/6/692

CRITICAL CARE

REVIEW

Point-of-care testing in the overcrowded emergency department – can it make a difference?

Kevin D Rooney[1] and Ulf Martin Schilling[2*]

Il POCT, se utilizzato in modo appropriato, può essere uno strumento utile a ***ridurre il tempo di attesa*** prima delle terapie e migliorare la qualità della cura

Rooney and Schilling *Critical Care* 2014, **18**:692
http://ccforum.com/content/18/6/692

CRITICAL CARE

REVIEW

Point-of-care testing in the overcrowded emergency department – can it make a difference?

Kevin D Rooney[1] and Ulf Martin Schilling[2*]

La riduzione del TAT per i test di laboratorio è utile:

a) Ritardi nell'iniziare la terapia possono *compromettere gli esiti di salute*

b) Questi ritardi rappresentano un fattore determinante nel *processo gestionale clinico*

Rooney and Schilling *Critical Care* 2014, **18**:692
http://ccforum.com/content/18/6/692

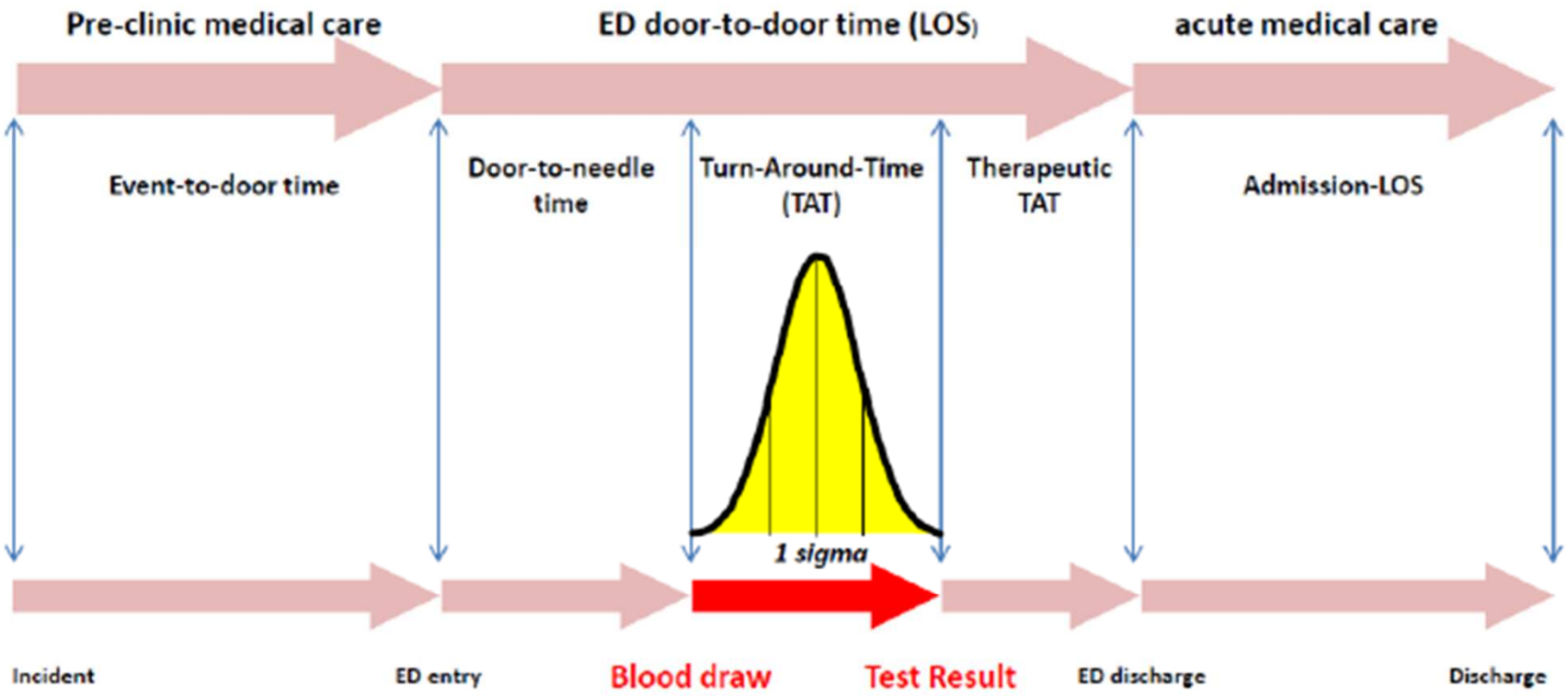
REVIEW

Point-of-care testing in the overcrowded emergency department – can it make a difference?

Kevin D Rooney[1] and Ulf Martin Schilling[2*]

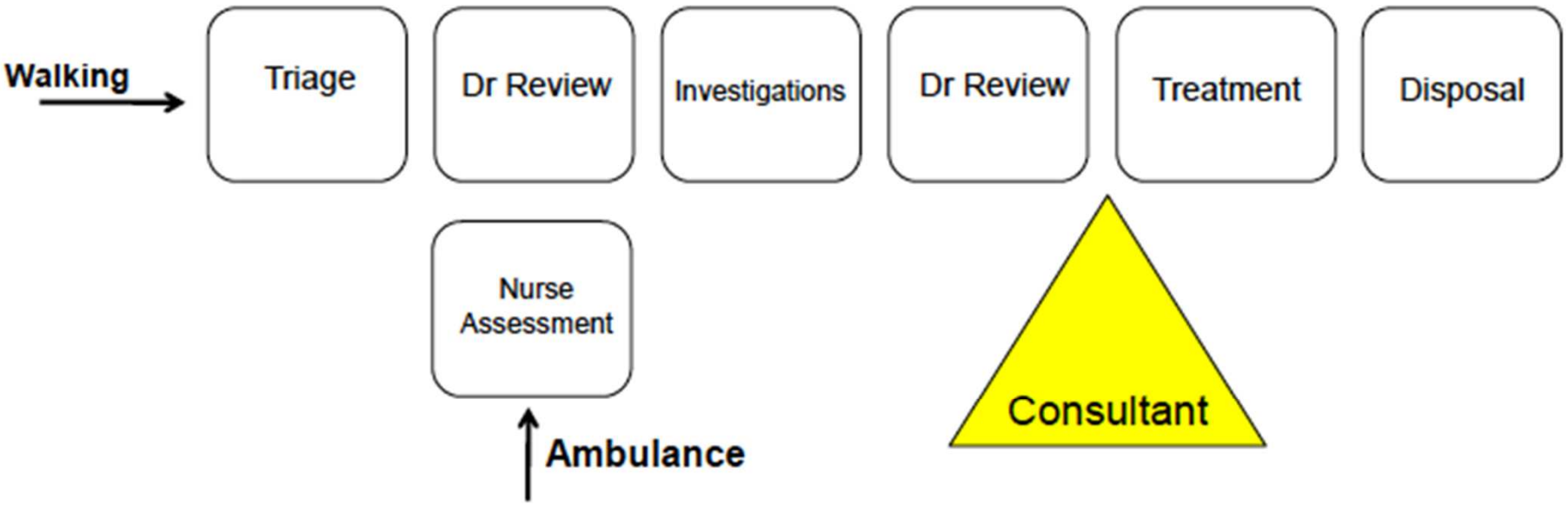
Clinical pathways and *ED logistics* may need substantial *modification to maximize* the clinical and economic *benefits of rapid TATs* provided by POCT.

ED lab process

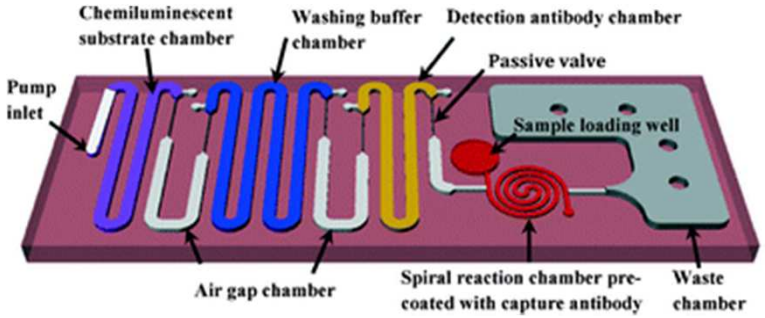


The laboratory process in the ED has a large potential for disruption, because TAT variances determine the time to clinical decision making.

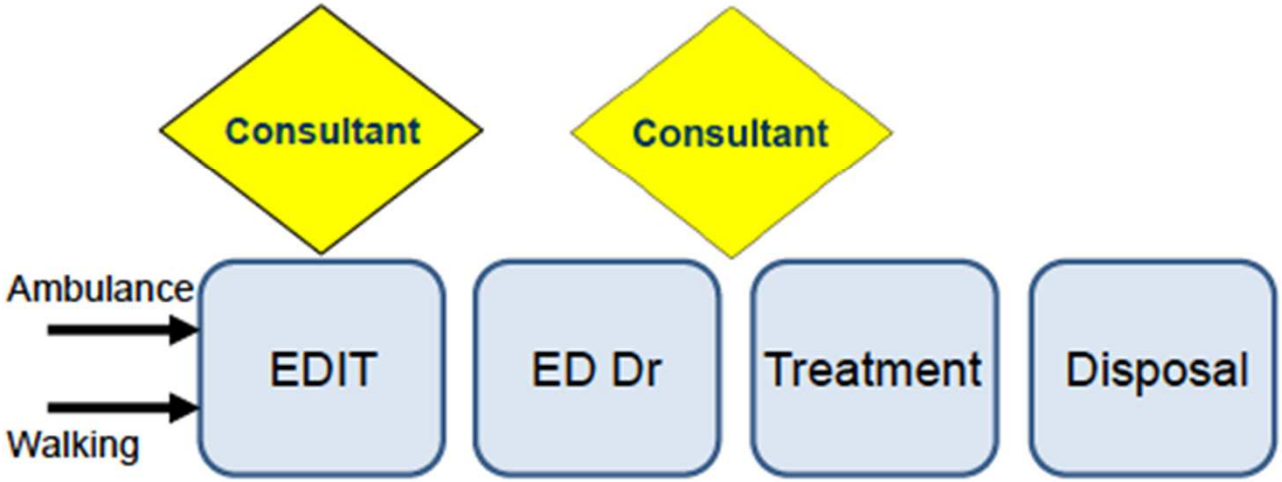
Current System



Jarvis P, 2016



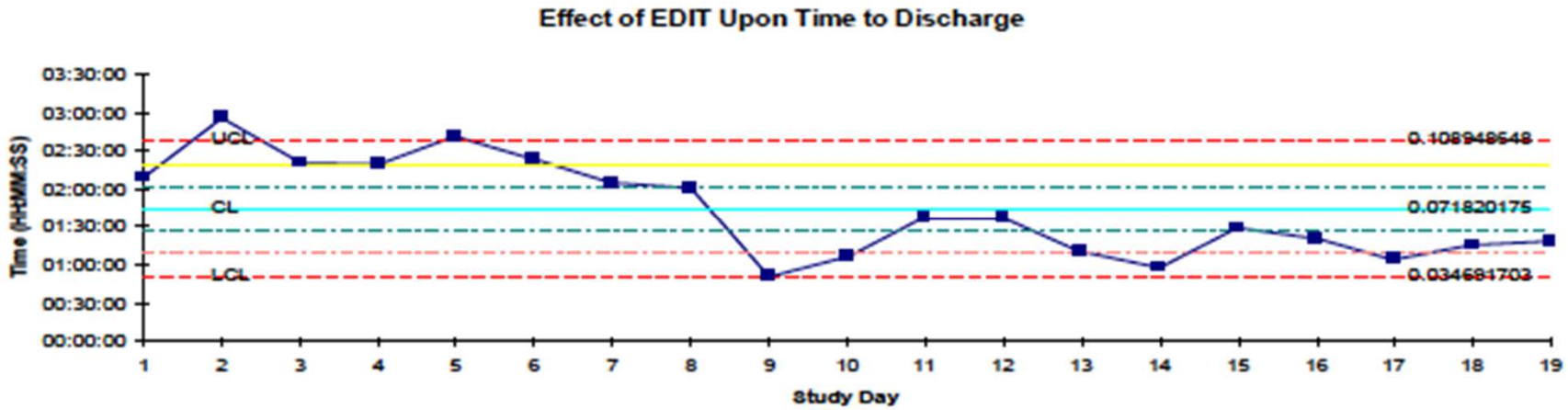
EDIT System



Jarvis P, 2016

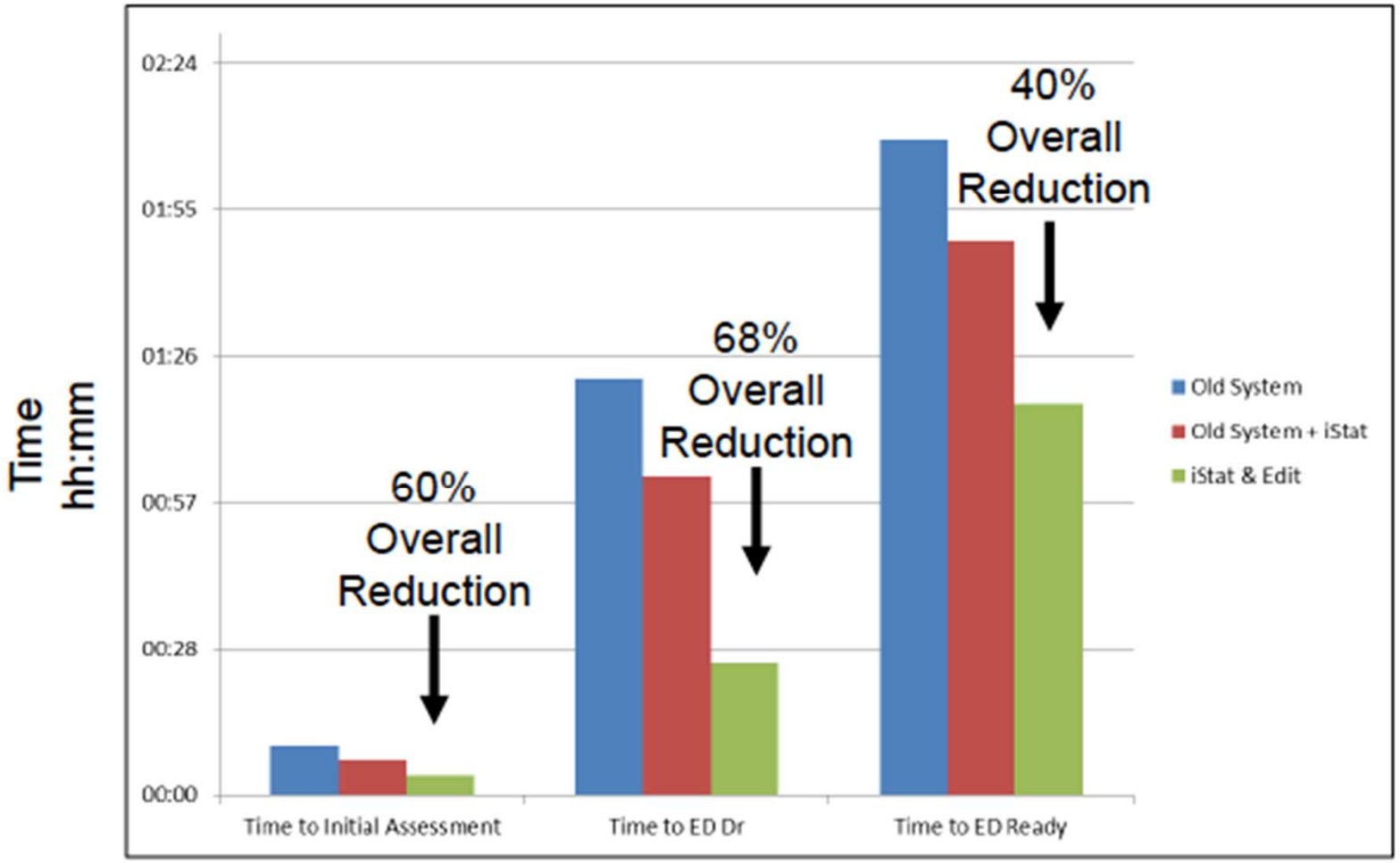
Results

Total ED Journey Time



Median (hh:mm:ss)	02:23:00	01:21:00	p<0.0001
95th Centile	03:59:00	01:34:00	
100th Centile	08:19:00	09:02:00	

Jarvis P, 2016



Effect of the 3 Different Working Models on the Median ED Times

Jarvis P, 2016

Kankaanpää *et al. Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine* (2016) 24:125
DOI 10.1186/s13049-016-0319-z

Scandinavian Journal of Trauma, Resuscitation and Emergency Medicine

ORIGINAL RESEARCH Open Access

Use of point-of-care testing and early assessment model reduces length of stay for ambulatory patients in an emergency department

Meri Kankaanpää[1,2*], Maria Raitakari[3], Leila Muukkonen[3], Siv Gustafsson[3], Merja Heitto[1,2], Ari Palomäki[4], Kimmo Suojanen[1,2] and Veli-Pekka Harjola[1,2]

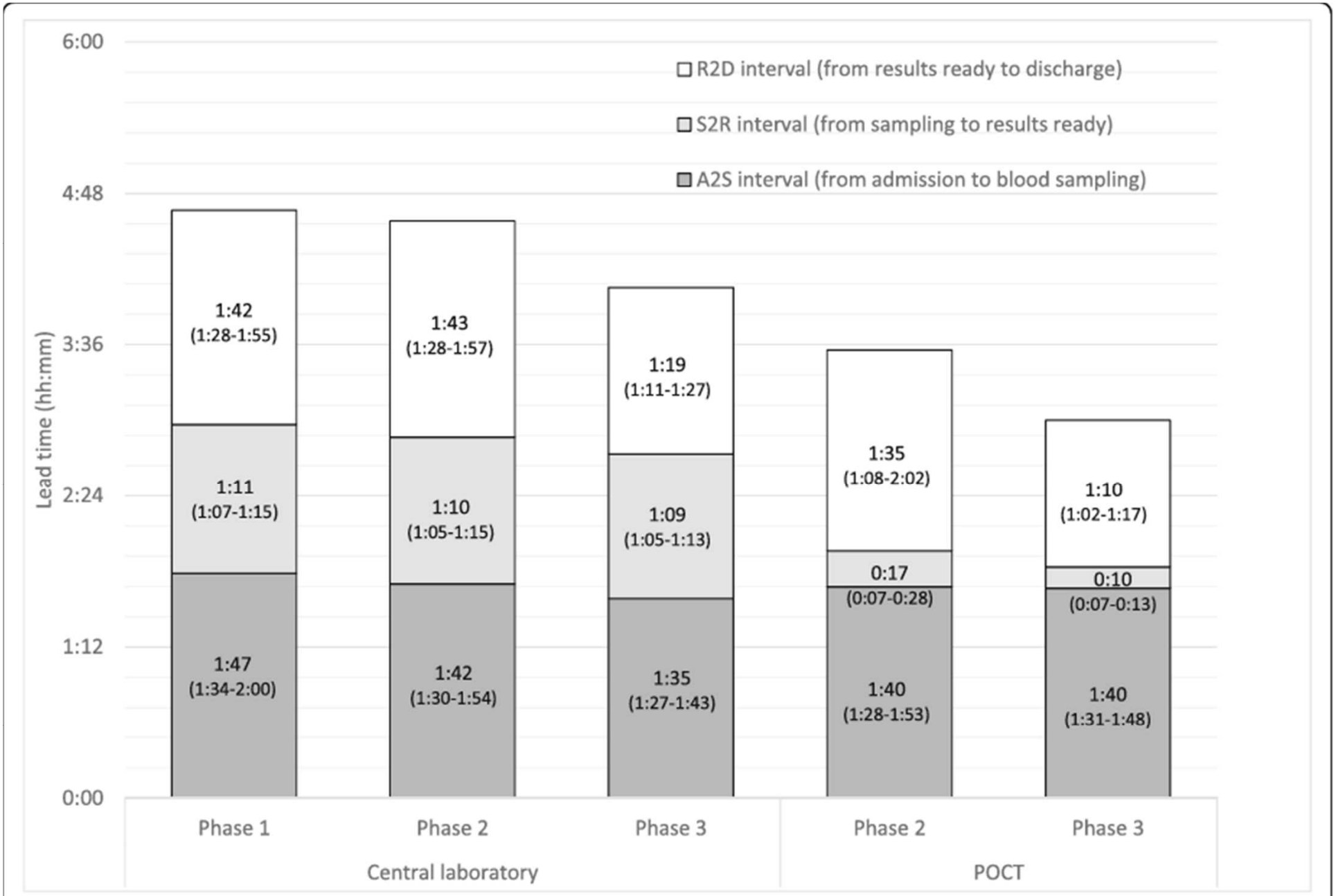


Fig. 2 Patient waiting times from admission to sampling, from sampling to results ready and from results ready to patient discharge in central laboratory and POC groups [Mean Lead Time (95 % Confidence Interval)]

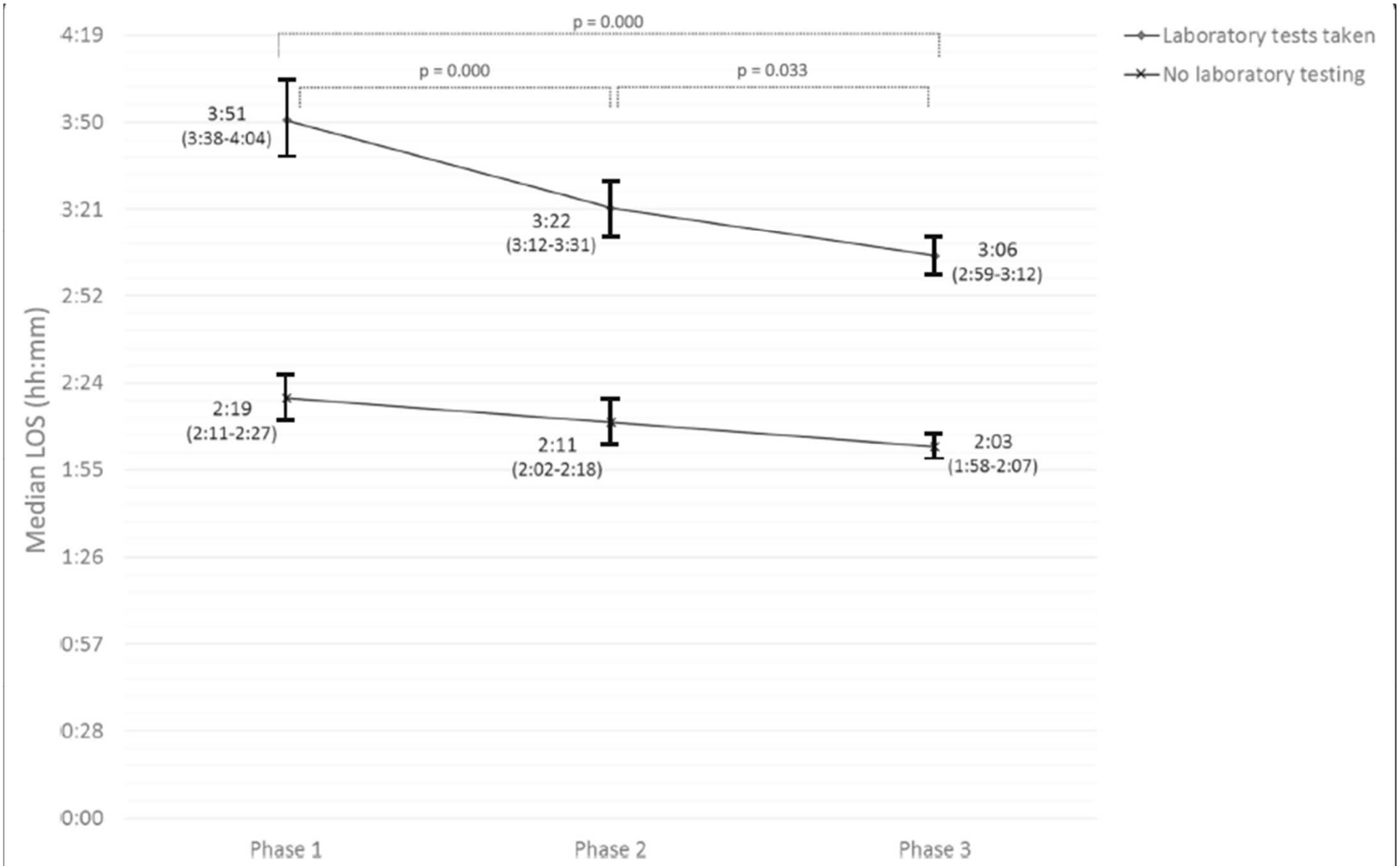


Fig. 1 Median LOS of patient subgroups during different phases of the study [Median LOS (95 % Confidence Interval)]

Table 1 Proportion of patients using POC and central laboratory tests in phase 1, 2 and 3

Patient group	Phase 1		Phase 2		Phase 3	
	Number of patients	% of total	Number of patients	% of total	Number of patients	% of total
No laboratory tests	1120	71 %	933	65 %	2286	68 %
Central laboratory tests only	439	29 %	352	24 %	617	18 %
POCT only	0	–	86	6 %	343	10 %
POCT and central laboratory tests	0	–	27	2 %	105	3 %
Inappropriate use of central laboratory despite availability of tests in POC panel	0	–	44	3 %	5	0.1 %
Grand Total	1559	100 %	1442	100 %	3356	100 %

Journal of Paediatrics and Child Health

doi:10.1111/jpc.13092

ORIGINAL ARTICLE

Utility of early influenza diagnosis through point-of-care testing in children presenting to an emergency department

Jean Li-Kim-Moy,[1,3] Fereshteh Dastouri,[1,3] Harunor Rashid,[1,3] Gulam Khandaker,[1,2,3] Alison Kesson,[2,3,4] Mary McCaskill,[2] Nicholas Wood,[1,2,3] Cheryl Jones,[2,3,4] Yvonne Zurynski,[3,5] Kristine Macartney,[1,2,3] Elizabeth J Elliott[2,3,5] and Robert Booy[1,2,3,4]

Results: Compared with standard testing ($n = 65$), children diagnosed by positive POCT ($n = 236$) had a shorter median hospital LOS by 1 day ($P = 0.006$), increased antiviral prescription (odds ratio 3.31, $P < 0.001$) and a reduction in the time to influenza diagnosis (2.4 *vs.* 24.4 h, $P < 0.001$); however, a negative POCT result ($n = 63$) resulted in delayed diagnosis (44.0 h, $P = 0.001$). POCT did not decrease LOS in ED. Interpretation of reductions in admission and investigations with POCT may be limited by possible confounding. Approximately 4% of influenza patients had a serious bacterial infection; urinary tract infections were commonest (2.7%), but no cerebrospinal fluid cultures were positive. A single positive blood culture was seen among 332 immunocompetent influenza patients.

Conclusions: Influenza diagnosis by POCT was quicker and reduced LOS of hospitalised children, whereas negative results delayed diagnosis. Negative POCT should not alter usual investigations if influenza remains suspected. A controlled prospective study during the influenza season is needed to clarify the direct benefits of POCT.

Table 2 Demographics, clinical details and outcome measures of influenza patients with negative POCT result (POCT-negative) or standard testing (No-POCT)

			Univariate model		Multivariate model	
	POCT-negative ($n = 63$)	No-POCT ($n = 65$)	OR (95%CI)	*P*-value	OR or ratio of mean time (95%CI)	*P*-value
Demographics and clinical details						
Male (%)	60.3	67.7	—	0.39	—	—
Median age in years (IQR)	**5.43 (2.18-5.44)**	**3.49 (0.94-7.79)**	—	**0.009***	—	—
Mean highest temperature in ED (°C)	38.2	38.2	—	0.77	—	—
Mean highest heart rate in ED (per min)	134	143	—	0.08	—	—
Mean highest resp rate in ED (per min)	**30.4**	**34.7**	—	**0.04**	—	—
Mean lowest saturations (%)	96.9	95.9	—	0.14	—	—
Comorbidity present % (*n*)	38.1 (24)	40.0 (26)	—	0.83	—	—
Weekend presentation % (*n*)	27.0 (17)	21.5 (14)	—	0.47	—	—
Daytime presentation 8:00–20:00 h % (*n*)	66.7 (42)	73.8 (48)	—	0.37	—	—
Night-time presentation 20:00–8:00 h % (n)	33.3 (21)	26.2 (17)	—	0.37	—	—
Outcomes						
Median LOS in days if admitted (IQR)	3 (1.5–8.5)	3 (2–4)	—	0.50*	1.25 (0.33–4.69)‡	0.75
Median total time in ED in hours if admitted (IQR)	**4.9 (2.9–6.5)**	**6.0 (4.9–9.8)**	—	**0.03***	0.97 (0.86–1.08)§	0.55
Median total time in ED in hours if discharged (IQR)	2.8 (2.2–4.4)	2.4 (1.9–3.1)	—	0.14*	NP	NP
Median total time to influenza diagnosis in hours (IQR)	**44.0 (18.3–73.1)**	**24.4 (18.1–44.0)**	—	**0.04***	**1.25 (1.10–1.42)§**	**0.001**
Admission % (*n*)	**46.0 (29)**	**81.5 (53)**	**0.19 (0.09–0.43)**	**<0.001**	**0.25 (0.09–0.70)†**	**0.009**
ICU admission % (*n*)	7.9 (5)	4.6 (3)	0.56 (0.13–2.46)	0.44	NP	NP
Antibiotics prescribed % (*n*)	42.9 (27)	53.8 (35)	0.64 (0.32–1.29)	0.22	NP	NP
Antiviral prescribed % (*n*)	23.8 (15)	21.5 (14)	1.14 (0.50–2.61)	0.76	NP	NP
LP performed % (*n*)	4.8 (3)	4.6 (3)	1.03 (0.20–5.32)	0.97	NP	NP
Blood culture performed % (*n*)	**50.8 (32)**	**76.9 (50)**	**0.31 (0.15–0.66)**	**0.002**	**0.31 (0.13–0.78)†**	**0.01**
Urine culture performed % (*n*)	22.2 (14)	26.2 (17)	0.81 (0.36–1.82)	0.60	NP	NP
Invasive urine collection % (*n*)	6.3 (4)	7.7 (5)	0.81 (0.21–3.18)	0.77	NP	NP

Table 1 Demographics, clinical details and outcome measures of influenza patients diagnosed by positive POCT or standard testing (No-POCT)

		Univariate model			Multivariate model	
	POCT-positive ($n = 236$)	No-POCT ($n = 65$)	OR (95%CI)	*P*-value	OR or ratio of mean time (95%CI)	*P*-value
Demographics and clinical details						
Male (%)	58.5	67.7	—	0.18	—	—
Median age in years (IQR)	2.39 (0.96–6.33)	3.49 (0.94–7.79)	—	0.40*	—	—
Mean highest temperature in ED (°C)	**38.6**	**38.2**	—	**0.004**	—	—
Mean highest heart rate in ED (per min)	149	143	—	0.20	—	—
Mean highest resp rate in ED (per min)	35.8	34.7	—	0.53	—	—
Mean lowest saturations (%)	96.6	95.9	—	0.27	—	—
Comorbidity present % (*n*)	28.4 (67)	40.0 (26)	—	0.07	—	—
Weekend presentation % (*n*)	27.1 (64)	21.5 (14)	—	0.36	—	—
Daytime presentation 8:00–20:00 h % (*n*)	63.1 (149)	73.8 (48)	—	0.11	—	—
Night-time presentation 20:00–8:00 h % (*n*)	36.9 (87)	26.2 (17)	—	0.11	—	—
Outcomes						
Median LOS in days if admitted (IQR)	**2 (1–3)**	**3 (2–4)**	—	**0.001***	**4.23 (1.53–11.7)‡**	**0.006**
Median total time in ED in hours if admitted (IQR)	6.1 (4.3–10.2)	6.0 (4.9–9.8)	—	0.74*	NP	NP
Median total time in ED in hours if discharged (IQR)	2.7 (1.7–4.1)	2.4 (1.9–3.1)	—	0.53*	NP	NP
Median total time to influenza diagnosis in hours (IQR)	**2.4 (1.7–4.3)**	**24.4 (18.1–44.0)**	—	**<0.001***	**0.46 (0.42–0.50)§**	**<0.001**
Admission % (*n*)	**50.0 (118)**	**81.5 (53)**	**0.23 (0.12–0.45)**	**<0.001**	**0.18 (0.07–0.48)†**	**0.001**
ICU admission % (*n*)	3.0 (7)	4.6 (3)	1.58 (0.40–6.3)	0.52	NP	NP
Antibiotics prescribed % (*n*)	**33.1 (78)**	**53.8 (35)**	**0.42 (0.24–0.74)**	**0.003**	0.57 (0.28–1.14)†	0.11
Antiviral prescribed % (*n*)	**46.2 (109)**	**21.5 (14)**	**3.13 (1.64–5.96)**	**0.001**	**4.54 (2.00–10.3)†**	**<0.001**
LP performed % (*n*)	4.7 (11)	4.6 (3)	1.01 (0.27–3.73)	0.99	NP	NP
Blood culture performed % (*n*)	**54.2 (128)**	**76.9 (50)**	**0.36 (0.19–0.67)**	**0.001**	**0.38 (0.17–0.86)†**	**0.02**
Urine culture performed % (*n*)	22.9 (54)	26.2 (17)	0.84 (0.45–1.58)	0.58	NP	NP
Invasive urine collection % (*n*)	12.3 (29)	7.7 (5)	1.68 (0.62–4.53)	0.31	NP	NP

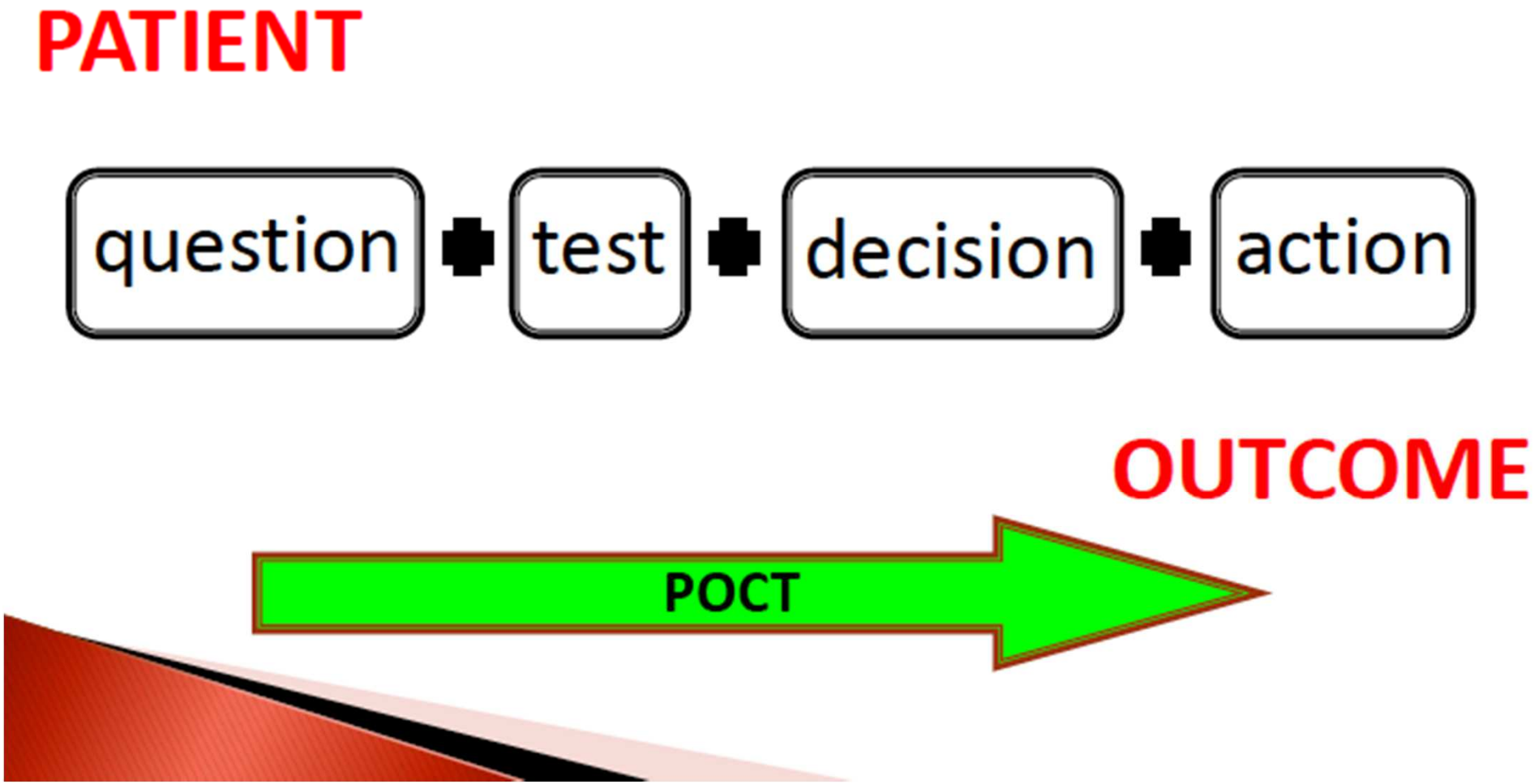
POCT E BENEFICI CLINICI

Per massimizzare i benefici clinici ed economici del POCT, e la riduzione del TAT, è necessario modificare in modo sostanziale i percorsi diagnostici e la logistica dei reparti (specie Dipartimenti di Emergenza).

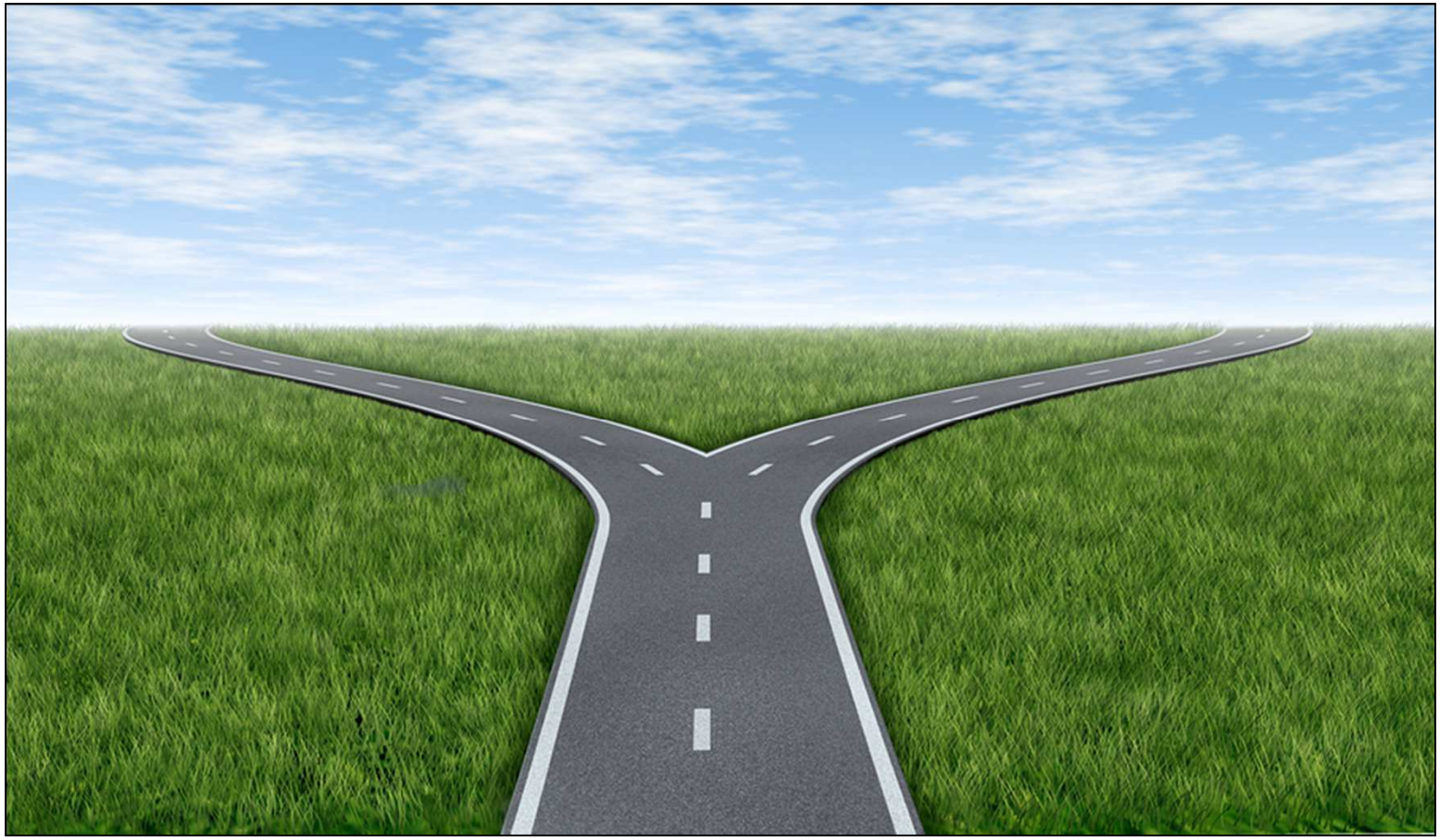
POCT: NEED CHANGES IN HEALTH SYSTEMS

Innovation will be needed in the ***design, operation***, and ***workflow of clinics*** to ensure that testing is accessible and results are ***used in real time*** to guide treatment. POCT may lengthen clinic visits and place extra demands on staffing and space. Bottlenecks at any stage can increase waiting times and result in extra visits by patients, and the benefits of onsite testing may be lost.

Point-of-Care Testing
at the core of patient centred care

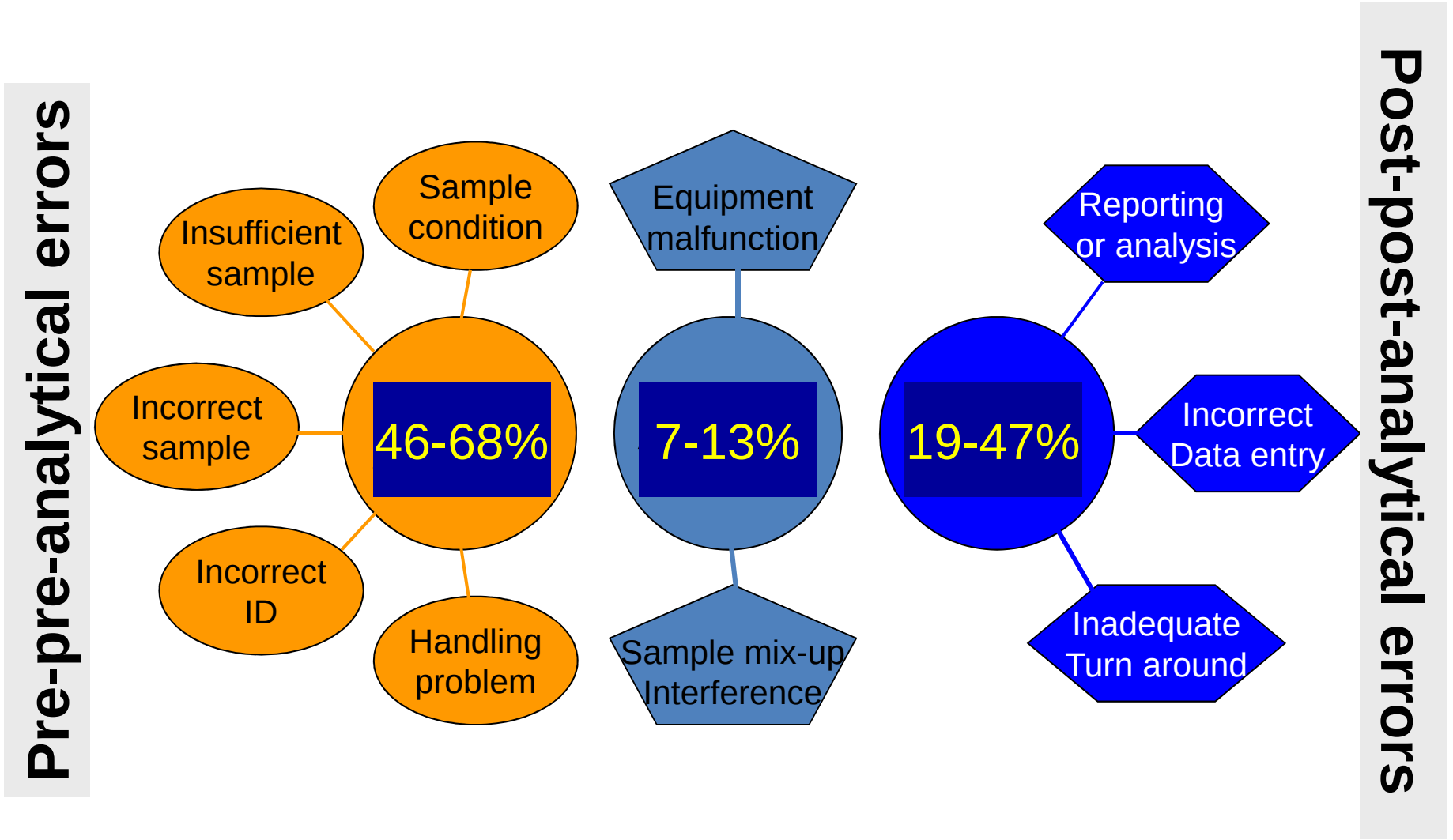


Qual è il rapporto fra ***POCT, qualità***,
e ***sicurezza per il paziente*** ?



Users' view of perfect instrument

Laboratory Medicine Errors



Plebani CCLM 2006

Does POCT eliminate some problematic steps?

- In teoria, il POCT ***elimina alcune delle fasi più problematiche*** del processo, compresa la raccolta del campione (?), trasporto (oh yes!), e consegna dei referti (yes, ma questo non significa più rapido e miglior recepimento).
- Tuttavia, il POCT ***crea altre problematiche per la gestione del rischio clinico***, ed in particolare l'esecuzione di analisi affidata e personale senza specifica formazione in medicina di laboratorio.

Dighe AS et al. 2007

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

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Does POCT reduce the risk of error in laboratory testing?

Mario Plebani *

Department of Laboratory Medicine, University-Hospital of Padova, Via Giustiniani, 2, 35128 Padova, Italy

Phases/steps in POCT process	Step-by-step defects
1. Preanalytical phase	
a. Test ordering	Appropriate/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 compromising patient ID/collection quality not recognized
2. Analytical phase	
a. Method calibration	Omitted, non-protocol, or misentered calibration
b. Specimen/reagent interaction	Patient-related native interference, specimen-related non-target 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. Post-analytical phase	
a. Report formatting	Wrong units, reference intervals; machine output; mistaken human transmission/transcription absent or inappropriate
b. Critical value reporting	Critical results unrecognized, 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	No correlation between initially generated/finally recorded result

Effects of POCT on potential errors in the Total Testing Process: Pre-Analytical Phase

Condizioni latenti	*Potenziale riduzione di errore con POCT*
• Eccessiva richiesta	No
• Tempistica scorretta	No
• Identificazione paziente	No
• Identificazione campioni	Si/No
• Raccolta campioni	No
• Qualità campioni	No

EXCESSIVE ORDERING: NOT ONLY CARDIAC MARKERS

Test panels:

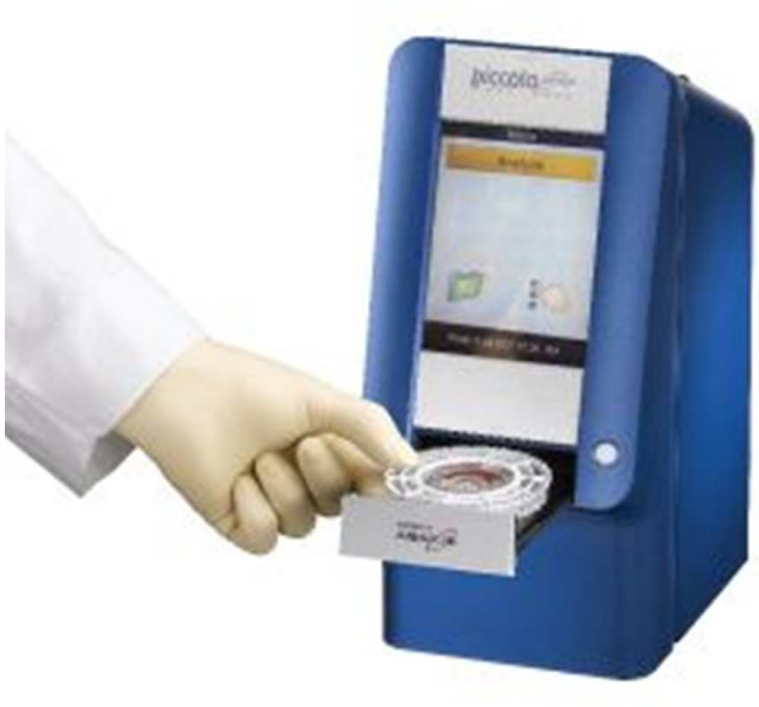
Basic Metabolic Panel

Basic Metabolic Panel Plus,

BioChemistry Panel Plus,

Comprehensive Metabolic Panel,

General Chemistry 13 Panel.



PATIENT IDENTIFICATION

A point-of-care test operator in ***a busy emergency department*** is just liable as a phlebotomist to ***confuse*** Mr. J. Smith, aged 59, with shortness of breath and a new cough, with Mr. J. Smith, aged 70, with acute urinary retention and new onset confusion, when the operator is asked to “get a set of lytes on Mr. Smith” and does not attempt to verify two forms of patient identification.

Jones BA, Meyer FA. Clin Lab Med 2004

Effects of POCT on potential errors in the Total Testing Process: Intra-Analytical Phase

Latent condition for error	*Potential reduction with POCT*
• Method calibration	Not ⬆
• Patient-relative "native interferences"	Not ⬆
• Specimen-related "non target interferences"	Not ⬆
• Specimen-reagent combination-related "matrix effects"	Not ⬆
• Result generation (results outside validated ranges)	Not ⬆
• Result validation (QC)	Yes/Not
• Quality Assessment (EQA, PT)	Not

Table 1. Breakdown of POCT quality errors by test type.

Test type	Number of tests	Number of defects	Defect, % of total tests
Blood gas/electrolytes[a]	22 687	119	0.52
Blood gas/electrolytes/ troponin I[b]	5809	10	0.17
Pregnancy[c]	8879	14	0.158
Glucose[d]	303 389	71	0.02
Drugs of abuse[e]	247	1	0.4
Hb A_{1c}[f]	1236	8	0.65
Urinalysis[g]	64 370	2	0.003
Blood ketones[h]	1087	0	0

[a] Roche Omni S, Roche Diagnostics.
[b] i-STAT, Abbott Point of Care I
[c] Clearview HCG, Inverness Mec
[d] Performa, Inform II and Advan
[e] Nal von Minden-Drug screen.
[f] DCA 2000, Siemens Healthcare
[g] Siemens-Multistix, Siemens He
[h] Abbott Medisense, Abbott Lab

Clinical Chemistry 57:9
1267–1271 (2011)

Quality Error Rates in Point-of-Care Testing

Maurice J. O'Kane,[1*] Paul McManus,[1] Noel McGowan,[1] and P.L. Mark Lynch[1]

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

Effects of POCT on potential errors in the Total Testing Process: Post-Analytical Phase

Latent condition for error	*Potential reduction with POCT*
• Report formatting – *(inappropriated/missed units, reference intervals)*	Not
• Routing	Yes
• Excessive turnaround time	Yes
• Misinterpretation	Not
• Critical value reporting	Not
• Critical value documentation	Not
• Other result reporting	Not
• Report management – *(report verification/preservation, storage and retrival)*	Not

Clinica Chimica Acta 404 (2009) 65–67

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Post-analytical errors with portable glucose meters in the hospital setting

Paolo Carraro *, Mario Plebani

Department of Laboratory Medicine, University-Hospital of Padova, Italy

We found that data obtained were often not reported in patients' files (12.1% of results are missed), the time of blood sampling was recorded in imprecise manner in 7.2% of cases and the glucose concentration was incorrectly reported in 3.2% of results. Although in the post-analytical phase the frequency of incomplete or incorrect data was high, no adverse events were found to be related to this type of error.

Table 3
Number of cases of incorrect transcription of results in the patient records and their frequency expressed as ppm.

	Tests (n)	Incorrect (n)	Frequency (ppm)	Differences>5%	Frequency (ppm)
Surgery	425	14	32,941	3	7059
Internal medicine	1117	35	31,333	3	2686

In the left-hand columns, the cases with an error in concentration of >5%.

Table 4
The kinds of errors in transcription of blood glucose results and their relative frequencies.

Type of error	Relative frequency%	Subtype (relative frequency %)
Single digit error	55	Units digit (79) Dozens digit (17) Hundreds digit (4)
Approximation	34	
Gross error	7	
Digit position switch	4	

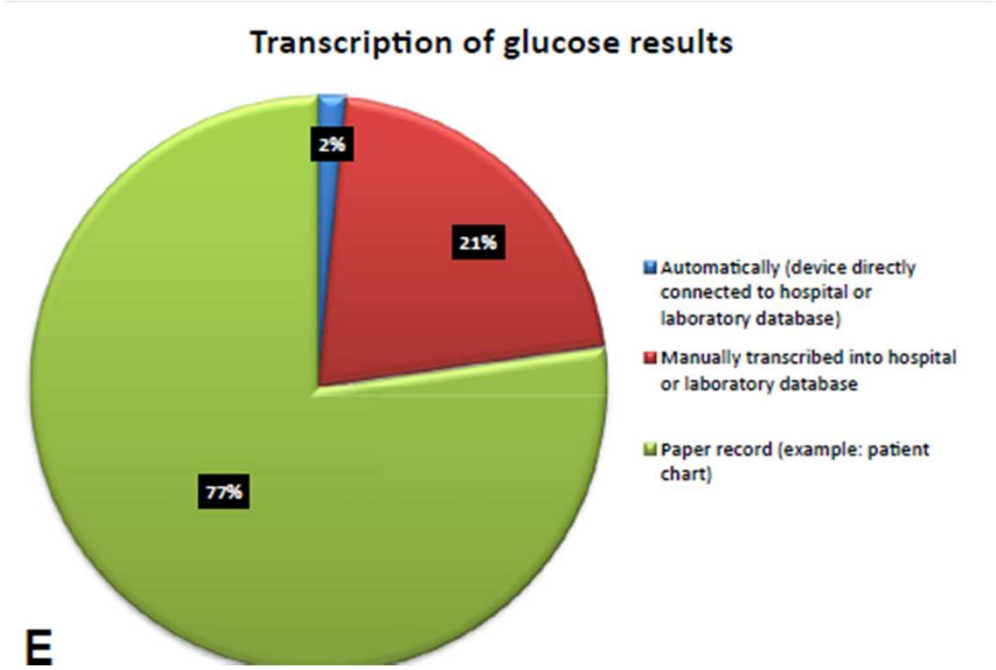
The overall absolute frequency was 3.2% (31,776 ppm).

Pathology (January 2016) 48(1), pp. 51–59

CHEMICAL PATHOLOGY

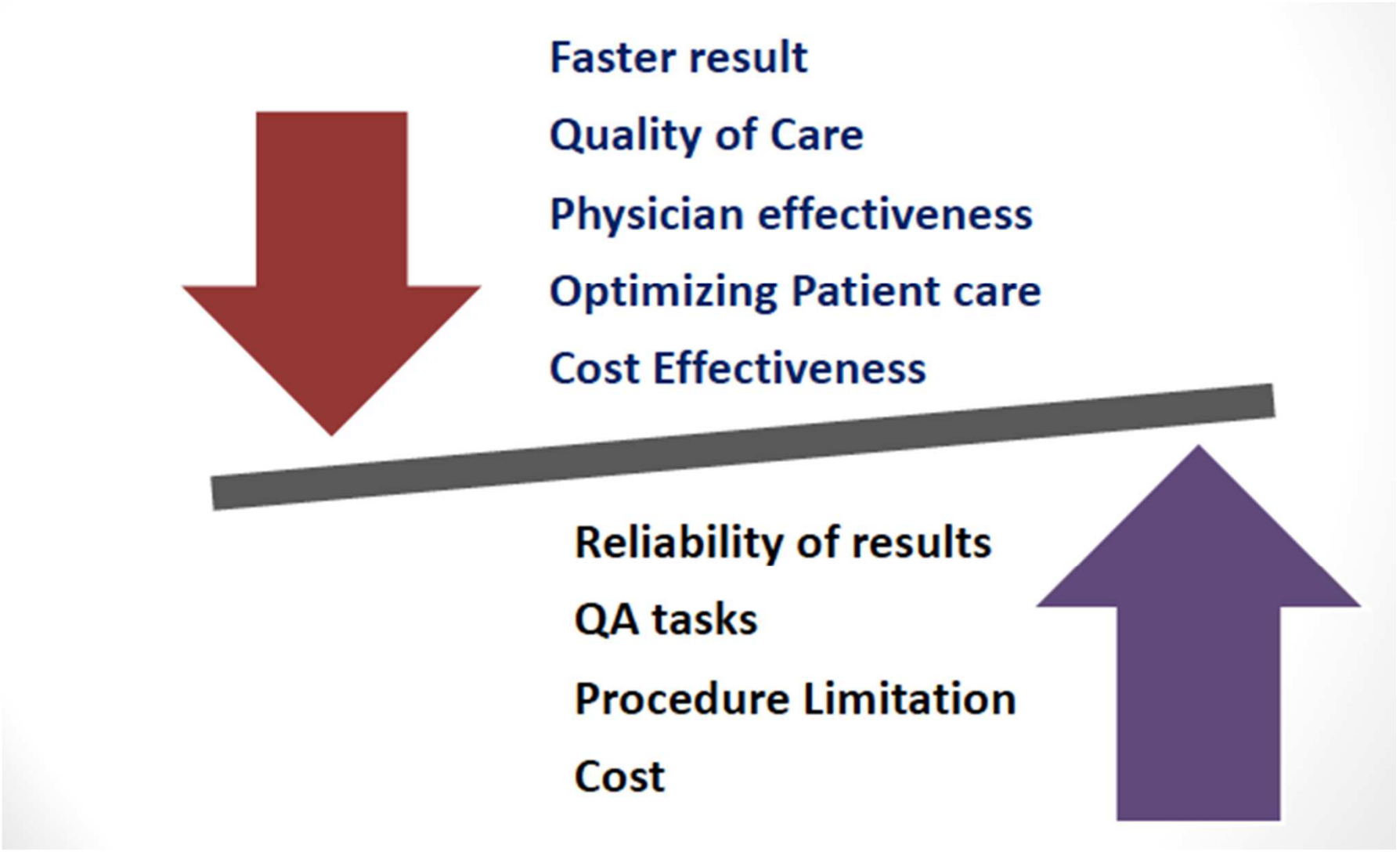
The application of glucose point of care testing in three metropolitan hospitals

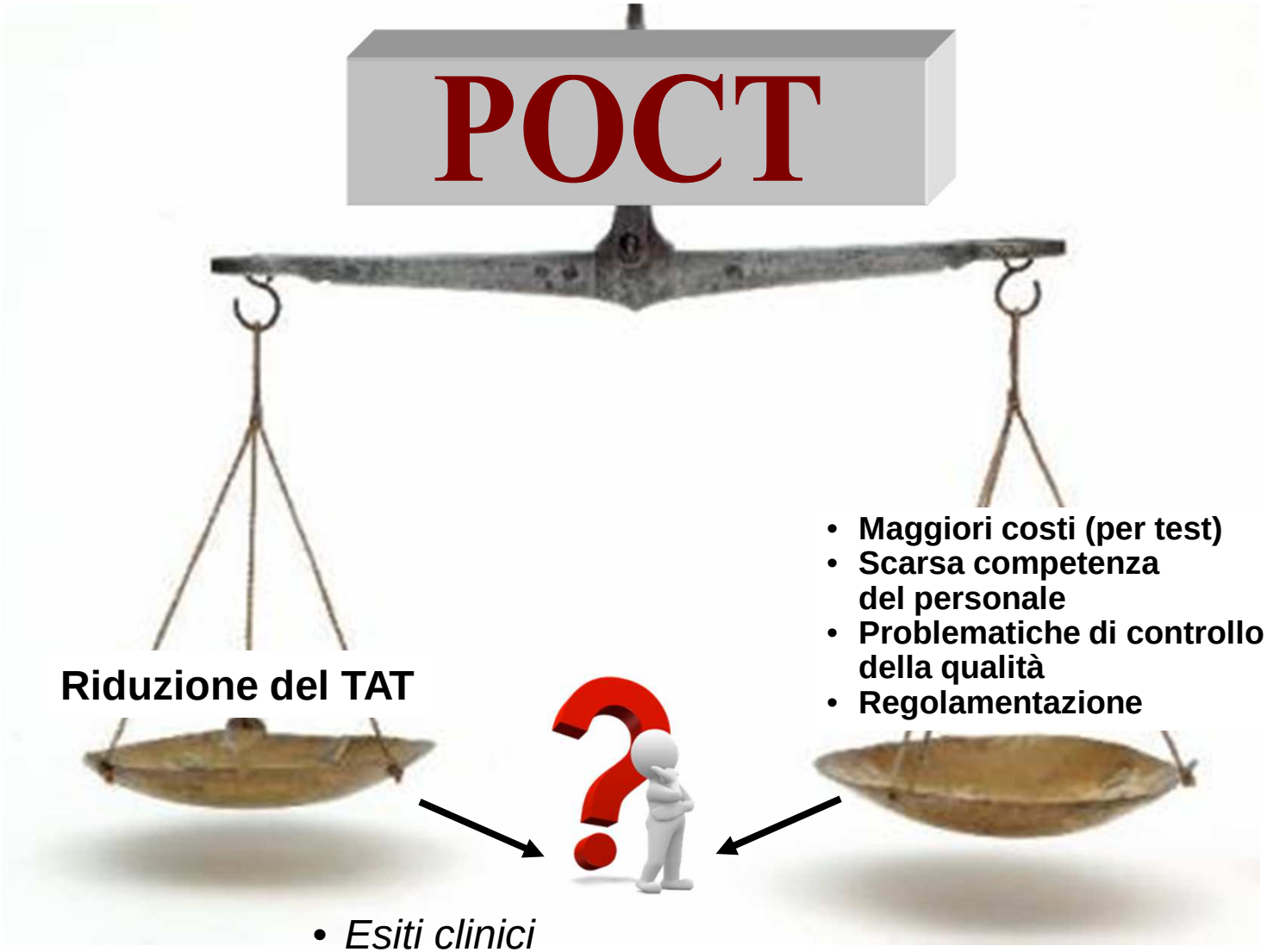
LYNDA SHARP[1], IAN FARRANCE[1] AND RONDA F. GREAVES[1,2]



E

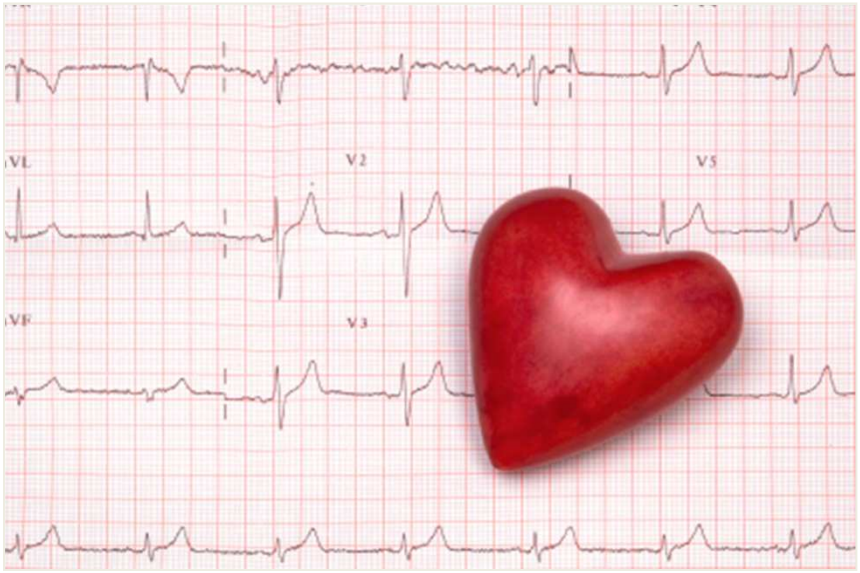
Balancing the desired outcomes with Challenges

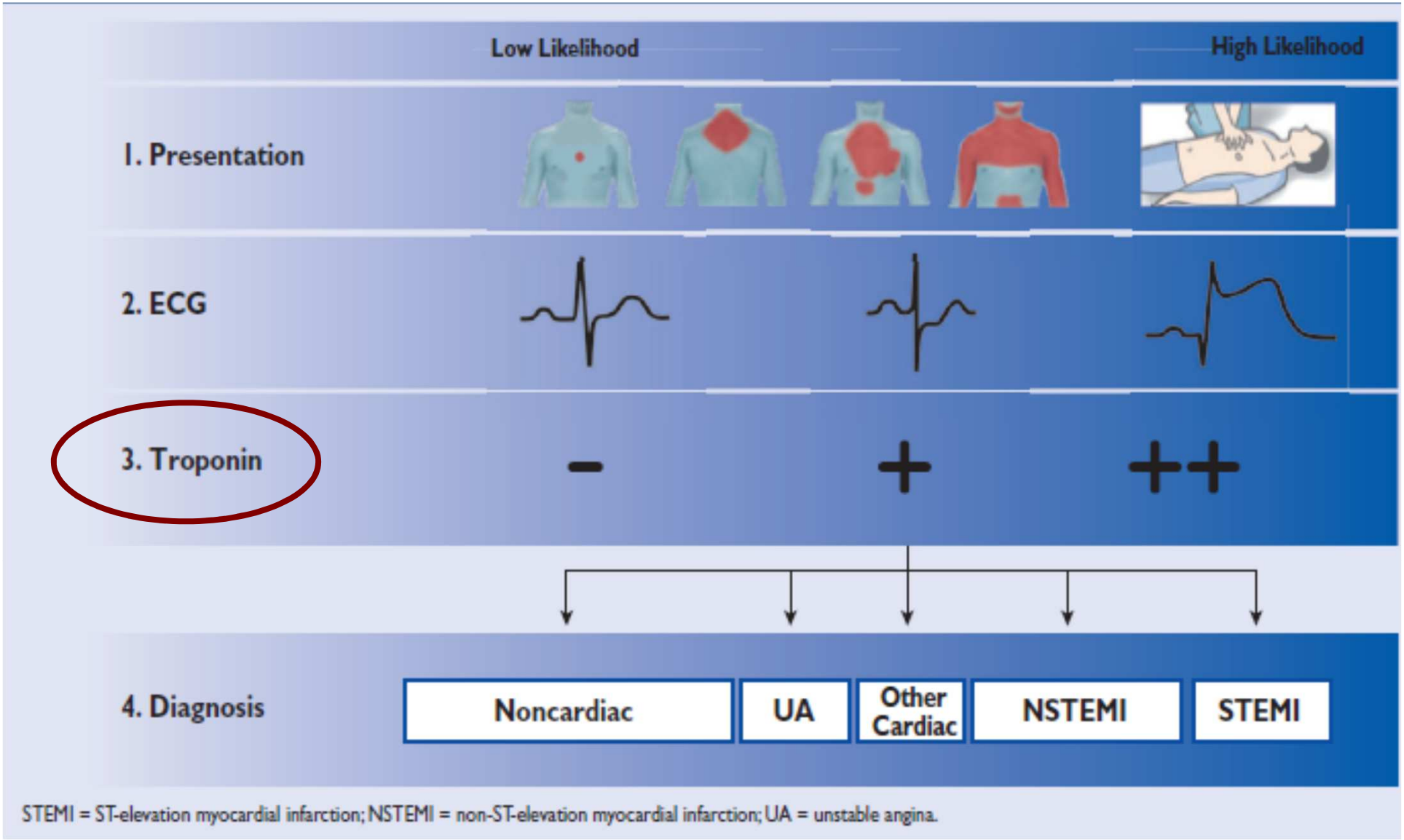




- *Esiti clinici*
- *Costo complessivo della gestione del paziente*
- *Qualità delle cure*
- *Efficienza/efficacia del sistema*

Cardiac Markers: a clear cause for point-of-care testing

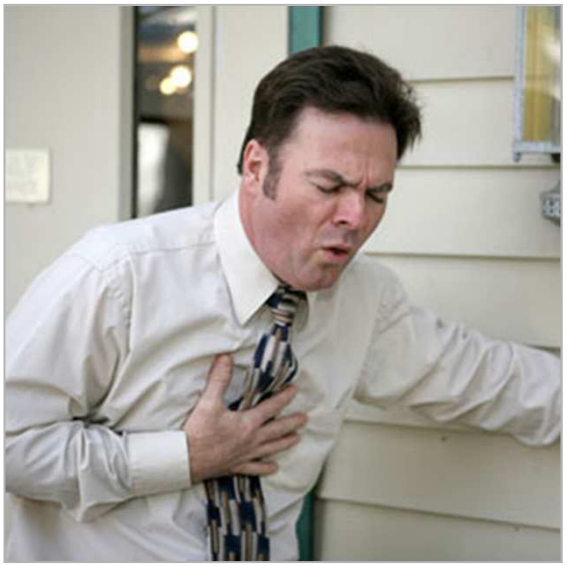




2015 ESC Guidelines for the management of ACS

THE STARTING POINT

Patients with acute coronary syndromes including acute myocardial infarction or other high-risk conditions should be effectively identified by the emergency physician in a ***timely manner*** to initiate specific clinical actions.



THE STARTING POINT

Patients with chest pain who do not have acute coronary syndromes (most patients admitted with chest pain) or alternative high-risk conditions should be ***discharged safely*** and ***prompty***.

CHEST PAIN:
why time is a quality attribute?

ACCELERATED RULE-OUT: BENEFITS

Medical implications of ***accelerated rule-out***:

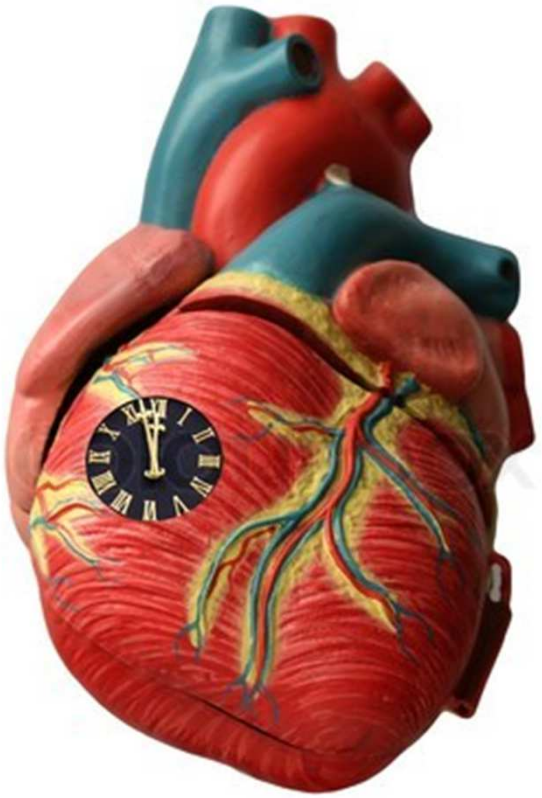
- More rapid relief of patient anxiety
- More rapid indentification of alternative causes of chest pain
- More rapid discontinuation of rhythm monitoring

ACCELERATED RULE-IN: BENEFITS

Accelerated rule-in implications:

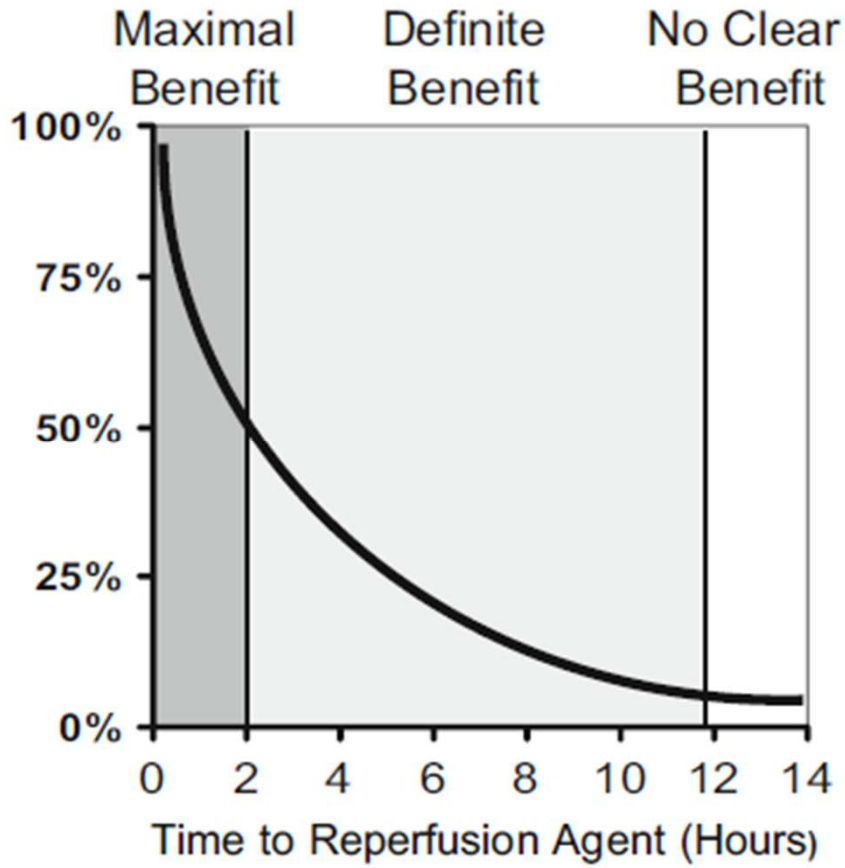
- More ***rapid initiation of*** antiplatelet, anticoagulant and anti-ischemic ***medication***
- More rapid transfer to ***coronary angiography***
- Coronary ***revascularization***, if feasible

TIME IS MUSCLE and
TIME WASTED IS MUSCLE LOST



Our Mantra:

TIME IS MUSCLE and TIME WASTED IS MUSCLE LOST



What is the ***evidence*** that the shorter the trunaround time of laboratory testing, the better the outcomes?

Our Mantra:

TIME IS MUSCLE and TIME WASTED IS MUSCLE LOST

The NACB (2006) noted that patients with STEMI should receive treatment **within 60 minutes** of admission without the use of cardiac biomarkers but recommended an accelerated protocol involving the use of these markers with a **TAT of less than 1 hour**.

The 2001 guideline for management of non-ST-elevation acute coronary syndromes noted that a **rapid (2-hours) rule-out protocol using POC biomarker** testing, ECG, and risk scoring was found to be safe.

VITAL® DIAGNOSTICS

TLC Regulatory Billing & Reimbursement Operations Logistics
Total Lab Care
Laboratory Consulting by Vital Diagnostics

TECHNICAL BULLETIN

Issue: #PF101 *Date: February 1, 2012*

Hospital Outpatient Quality Reporting Programs for Troponin Turn Around Time

CMS-1525-FC "Final Changes to Hospital Outpatient Prospective Payment System (OPPS) Calendar Year (CY) 2012 Payment Rates" published November 30, 2011 included 23 measures for CY 2013 including OP-16.

OP-16 is defined as Troponin Results for Emergency Department acute myocardial infarction (AMI) patients or chest pain (CP) patients (with probable Cardiac CP) within 60 minutes of arrival. Specifically the hospital is to measure whether a Troponin result is received by the treating physician within 60 minutes of the patient arriving in the emergency department (ED). Implementation (monitoring) began January 1, 2012 with first quarter data due into CMS by August 1, 2012. The 2013 OPPS payments will be determined based on the data submitted. ED's are not required to meet this turn around time but must collect the data for submission.

TIME IS MUSCLE and TIME WASTED IS MUSCLE LOST

- **TAT** expectations of the ED physicians exceeded those of the laboratory personnel.
- Most (75%) of ED physicians believed that TAT should be 45 minutes or less;
- Most (82%) laboratorians indicated reasonable a TAT of 60 min.
- No sound evidence is available regarding TAT.

Novis DA et al. Arch Pathol Lab Med 2004

POC methods can provide troponin results more rapidly, potentially accelerating triage and AMI diagnosis

Original Article

A prospective randomized controlled trial of point-of-care testing on the coronary care unit

PO Collinson[1], C John[1], S Lynch[2], A Rao[2], R Canepa-Anson[2], E Carson[3] and D Cramp[3]

Addresses
[1]Department of Chemical Pathology and
[2]Department of Cardiology
Mayday University Hospital
Croydon, Surrey
CR7 7YE, UK
[3]Centre for Measurement and Information in Medicine, City University
London, UK

Correspondence
Dr PO Collinson
Department of Chemical Pathology
2nd Floor, Jenner Wing
St George's Hospital
Blackshaw Road
London SW17 0QT, UK
E-mail: paul.collinson@stgeorges.nhs.uk

Abstract

Background We report the results of a prospective randomized controlled trial comparing point-of-care testing (POCT) with central laboratory testing (CLT) in a six-bed coronary care unit in a district general hospital.

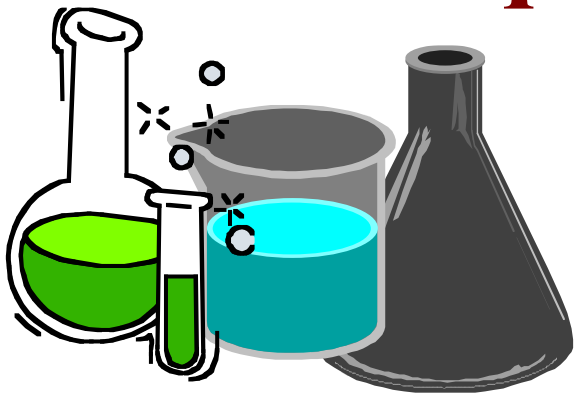
Methods 263 consecutive admissions with chest pain and suspected acute coronary syndrome were randomized to measurement of cardiac troponin T by POCT or CLT only. Patient management was according to a pre-specified protocol utilizing clinical features, electrocardiographic changes and cardiac biomarkers (creatine kinase and cardiac troponin T) to define management. Outcome measures were diagnostic accuracy compared with CLT as 'gold standard', result turnaround time, mortality and length of stay in all patients and those with a protocol-driven early discharge policy.

Results Diagnostic accuracy and mortality was equivalent in the POCT and CLT arm. Overall there was no difference in length of stay. In the pre-specified early discharge group ($n = 64$) there was a significant reduction in median length of non-coronary care unit stay (145.3 h versus 79.5 h) and overall hospital stay (209.3 h versus 149.9 h) in those randomized to POCT.

Conclusion A combination of rapid biochemical diagnosis and structured decision-making reduces length of hospital stay.

Ann Clin Biochem 2004; **41**: 397–404

Not all cardiac troponin assays are created equal



Contents lists available at SciVerse ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Diagnostic performance of four point of care cardiac troponin I assays to rule in and rule out acute myocardial infarction

Vikram Palamalai [a], MaryAnn M. Murakami [b], Fred S. Apple [a,b,*]

[a] Department of Laboratory Medicine and Pathology, University of Minnesota, Minneapolis, MN, USA
[b] Minneapolis Medical Research Foundation and Hennepin County Medical Center, Minneapolis, MN, USA

Conclusion: cTnI is a sensitive biomarker for detection of myocardial injury. The analytical variability that exists between POC cTnI assays demonstrates substantial diagnostic differences for ruling in and ruling out MI in patients presenting with symptoms suggestive of ACS.

NOT ALWAYS FASTER IS BETTER !

Early and late outcome prediction of death in the emergency room setting by point-of-care and laboratory assays of cardiac troponin I

Per Venge, MD, PhD,[a] Claes Öhberg, MD,[a] Mats Flodin, BSc,[b] and Bertil Lindahl, MD, PhD[a,c] *Uppsala, Sweden*

Am Heart J, 2010

POCT for CARDIAC TROPONIN ASSAY

- At the diagnostic cut-off, the laboratory assays identified ***81% or 88%*** of all patients who died of cardiovascular disease during 35 months of follow-up, compared with ***50% or 54%*** for the POCT assays.
- Authors' conclusions: "if a ***clinical suspicion*** of myocardial injury remains despite negative cTnI results with POCT, such results should be ***complemented by results from sensitive laboratory assays***"

THE TAKE-HOME MESSAGE

Several recent studies demonstrated the impact of highly sensitive troponin assays for the prediction of outcome in cardiovascular death.

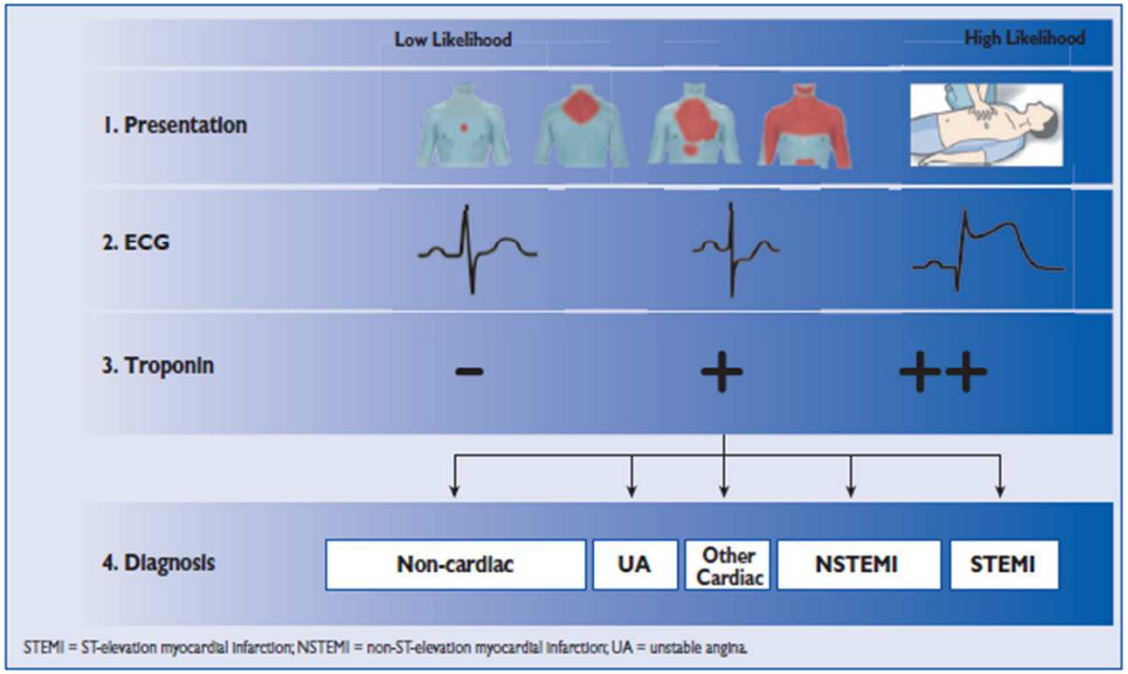
The ***shortcomings of less sensitive POC*** assays of cTnI in this regard have been documented particularly in the ED setting.

European Heart Journal Advance Access published September 11, 2015

European Heart Journal
doi: 10.1093/eurheartj/ehv320

ESC GUIDELINES

2015 ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation



STEMI = ST-elevation myocardial infarction; NSTEMI = non-ST-elevation myocardial infarction; UA = unstable angina.

~50–90% of healthy individuals) assays. High-sensitivity assays are recommended over less sensitive ones.[2,6,8] The majority of currently used point-of-care assays cannot be considered sensitive or high-sensitivity assays.[8,35] Therefore the obvious advantage of point-of-care tests, namely the shorter turnaround time, is counter-balanced by lower sensitivity, lower diagnostic accuracy and lower negative predictive value. Overall, automated assays have been more thoroughly evaluated as compared with point-of-care tests.[2,6,8]

High-sensitivity cardiac troponin I at presentation in patients with suspected acute coronary syndrome: a cohort study

Anoop S V Shah, Atul Anand*, Yader Sandoval, Kuan Ken Lee, Stephen W Smith, Philip D Adamson, Andrew R Chapman, Timothy Langdon, Dennis Sandeman, Amar Vaswani, Fiona E Strachan, Amy Ferry, Alexandra G Stirzaker, Alan Reid, Alasdair J Gray, Paul O Collinson, David A McAllister, Fred S Apple, David E Newby, Nicholas L Mills; on behalf of the High-STEACS investigators†*

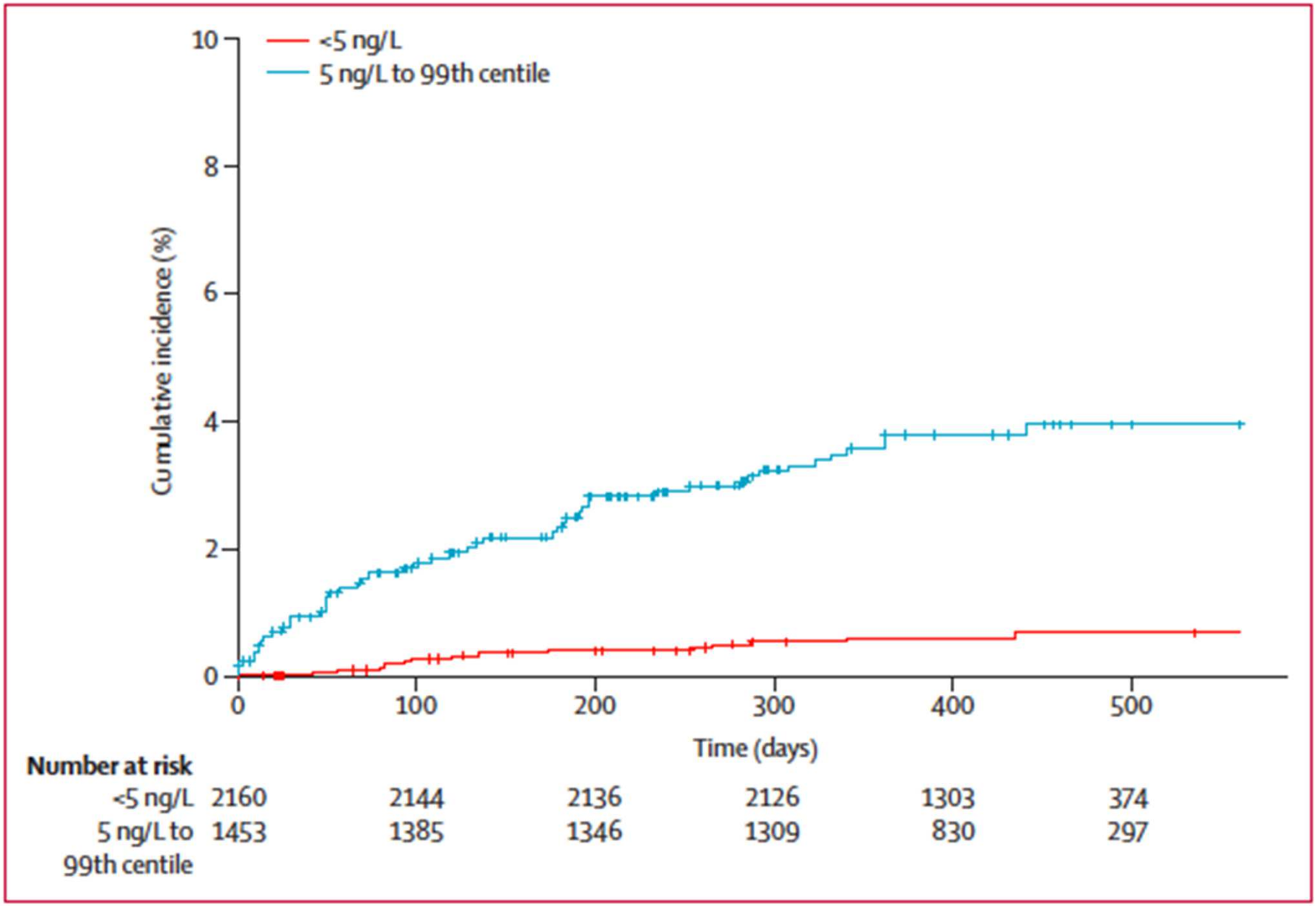
Findings 782 (16%) of 4870 patients in the derivation cohort had index myocardial infarction, with a further 32 (1%) re-presenting with myocardial infarction and 75 (2%) cardiac deaths at 30 days. In patients without myocardial infarction at presentation, troponin concentrations were less than 5 ng/L in 2311 (61%) of 3799 patients, with a negative predictive value of 99·6% (95% CI 99·3–99·8) for the primary outcome. The negative predictive value was consistent across groups stratified by age, sex, risk factors, and previous cardiovascular disease. In two independent validation cohorts, troponin concentrations were less than 5 ng/L in 594 (56%) of 1061 patients, with an overall negative predictive value of 99·4% (98·8–99·9). At 1 year, these patients had a lower risk of myocardial infarction and cardiac death than did those with a troponin concentration of 5 ng/L or more (0·6% *vs* 3·3%; adjusted hazard ratio 0·41, 95% CI 0·21–0·80; p<0·0001).

Interpretation Low plasma troponin concentrations identify two-thirds of patients at very low risk of cardiac events who could be discharged from hospital. Implementation of this approach could substantially reduce hospital admissions and have major benefits for both patients and health-care providers.

	<5 ng/L (n=2160)	5 ng/L to 99th centile (n=1453)	Unadjusted hazard ratio (95% CI)	Adjusted hazard ratio (95% CI)
Myocardial infarction				
30 days	0 (0·0%)	6 (0·4%)		
1 year	6 (0·3%)	19 (1·3%)	0·21 (0·08–0·51)	0·36 (0·13–0·99)
Cardiac death				
30 days	0 (0·0%)	6 (0·4%)		
1 year	6 (0·3%)	32 (2·2%)	0·14 (0·06–0·31)	0·41 (0·17–0·98)
Myocardial infarction or cardiac death				
30 days	0 (0·0%)	12 (0·8%)		
1 year	12 (0·6%)	48 (3·3%)	0·17 (0·09–0·31)	0·41 (0·21–0·80)

Data are n (%) unless stated otherwise. The hazard ratios are derived from a Cox regression model using all follow-up data. The median follow up was 427 days (IQR 371–489 days).

Table 2: **Subsequent myocardial infarction or cardiac death in patients with troponin concentrations below the 99th centile in the derivation cohort**



Number at risk

<5 ng/L	2160	2144	2136	2126	1303	374
5 ng/L to 99th centile	1453	1385	1346	1309	830	297

POCT AS A VIABLE OPTION

POCT is a viable option when clinical laboratories:

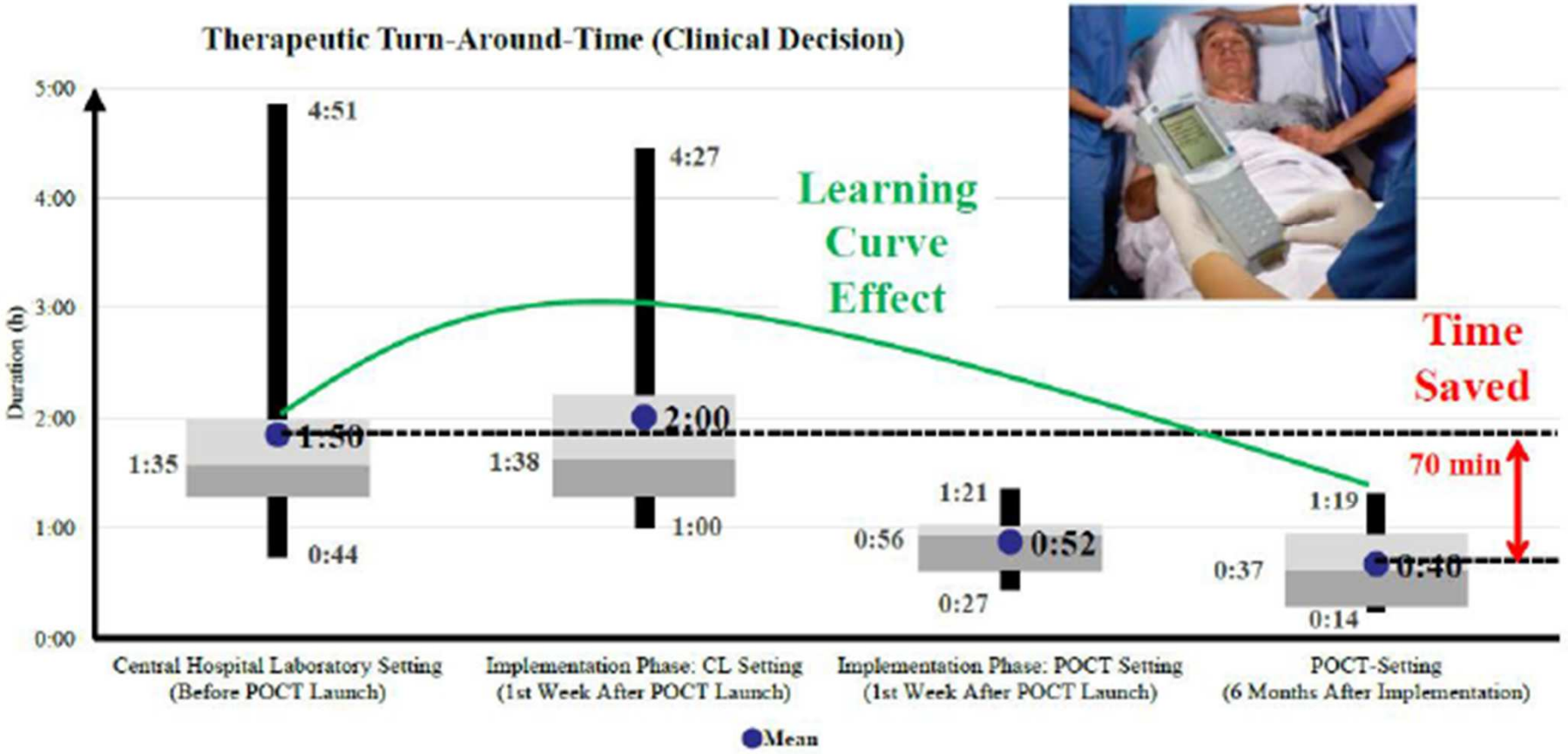
a) Cannot deliver results in the time consensually defined with clinicians (usually within 60 minutes);

b) Close at nights and/or week-ends;

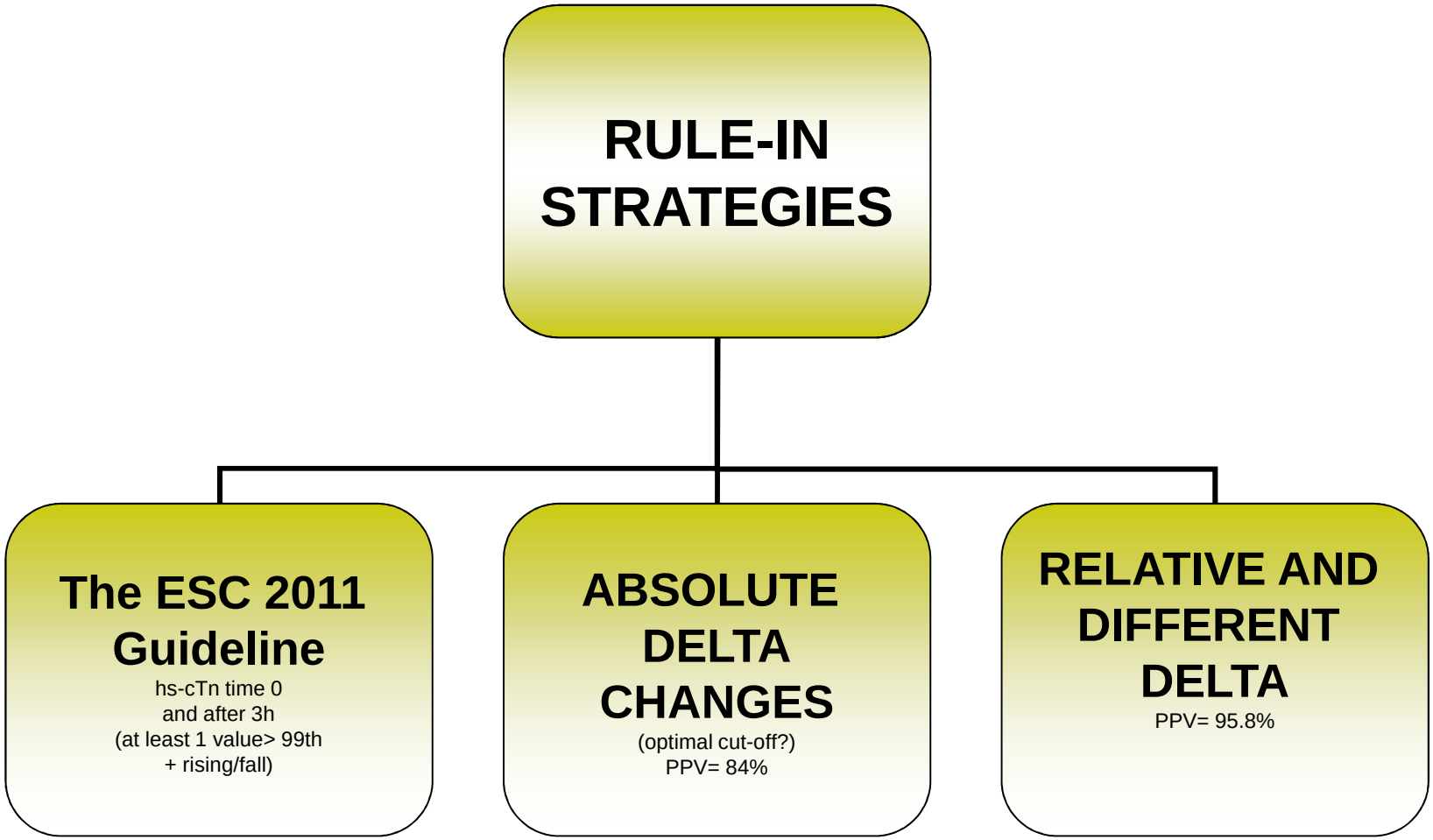
c) Are poorly connected with wards for both sample transportation and result communication;

d) The cost/benefit analysis confirms the value of the option.

Results II


Therapeutic Turn-Around-Time (Clinical Decision)
Duration (h)
5:00
4:00
3:00
2:00
1:00
0:00
4:51
4:27
Learning Curve Effect
Time Saved
70 min
1:35
1:50
0:44
1:38
2:00
1:00
0:56
1:21
0:52
0:27
0:37
1:19
0:40
0:14
Central Hospital Laboratory Setting (Before POCT Launch)
Implementation Phase: CL Setting (1st Week After POCT Launch)
Implementation Phase: POCT Setting (1st Week After POCT Launch)
POCT-Setting (6 Months After Implementation)
Mean

Rule-in strategies


RULE-IN STRATEGIES
The ESC 2011 Guideline
hs-cTn time 0
and after 3h
(at least 1 value> 99th
+ rising/fall)
ABSOLUTE DELTA CHANGES
(optimal cut-off?)
PPV= 84%
RELATIVE AND DIFFERENT DELTA
PPV= 95.8%

TROPONIN ASSAY: SERIAL MEASUREMENTS

- According to the current definition of myocardial infarction, a raise or fall of cTn is necessary for diagnosing ACS.
- The so-called “delta” approach, based on the difference in cTn concentrations obtained in consecutive serial samples, require two firms criteria are satisfied:

  A) *the same molecule should be tested*

  B) *equivalent analytical characteristics*

POCT: A "PERSONALIZED" APPROACH

…..Successful introduction of POC testing for troponin requires not just a comprehensive training and maintenance programme but also an effective initiative to change the **clinical culture** surrounding its use.

Loten C et al. Emerg Med J 2010

POCT and QUALITY

Achieving quality in POCT is incredibly important because *medical decisions are often made immediately* after the test is performed, eliminating any possibility to verify and correct a result.

POCT for cTn: WHY and HOW

- POC methods should be considered if TATs cannot be achieved at an institution per clinical needs;
- POC methods can provide troponin results more rapidly, potentially accelerating triage and AMI diagnosis;
- POC assays may be less sensitive compared to automated central laboratory assays;
- TAT should be measured starting from the patient admission until the result is received;
- According to current guidelines, cTn should be measured at the baseline and after 1 or 3 hours (if high sensitivity assays are used).
- cTn results from different assay methods are not interchangeable and a single method should be used for tracking results

The Good The Bad The Ugly

The Good

High-sensitive POCT assays with analytical performances, cut-off and clinical outcomes equivalent to conventional laboratory assays

The Bad

Semiquantitate POCT assays requiring confirmation and quantitation by conventional laboratory assays

The Ugly

POCT assays in the ED for baseline measurement and further monitoring with conventional laboratory assays

POCT, EVIDENCE and FACTS

Benchè siano ancora assenti prove di efficacia, il POCT *sarà sempre più utilizzato* per permettere l'accesso a servizi clinici, ridurre i disagi ai pazienti, migliorare i percorsi di diagnosi e cura, e soprattutto a facilitare le cure a domicilio.

SOURCES and AMPLIFIERS of POCT ERROR

Sources

- Operator incompetence
- Nonadherence to procedures
- Use of uncontrolled reagent/equipment

Amplifiers

- Incoherent regulation
- **Rapid result availability**
- **Immediate therapeutic implications**

Meier FA, Jones BA, 2005

POCT: CULTURA DELLA SICUREZZA

- ***Assicurare specifiche di qualità basate sulle prove***
- ***Migliorare la competenza degli utilizzatori***, il controllo di qualità e la documentazione dei risultati
- ***Monitorare l'identificazione del paziente***, la qualità dei campioni biologici e dei referti

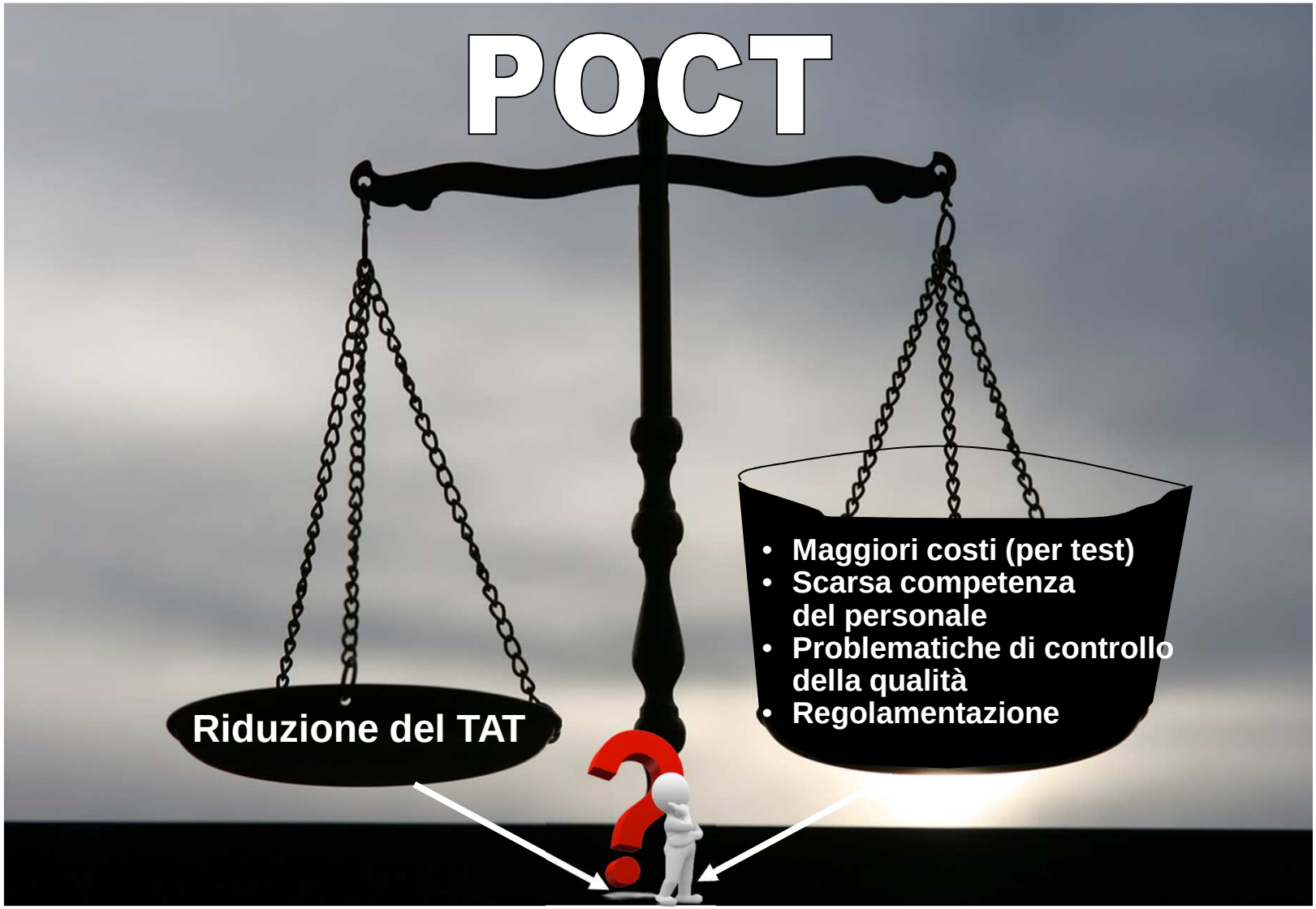
DECALOGO DELLA QUALITA' in MEDICINA di LABORATORIO

1) ***Richiesta*** appropriata
2) ***Tempistica*** appropriata
3) Corretta ***identificazione*** del paziente
4) Corretta ***raccolta*** e ***manipolazione*** del campione
5) Corretta ***procedura analitica***
6) Corretto ***controllo di qualità***
7) Corretta ***validazione*** e ***generazione del risultato***
8) Corretta ***refertazione*** e documentazione
9) Appropriata ***interpretazione*** del risultato
10) Appropriata e tempestiva ***utilizzazione*** del risultato dell'informazione di laboratorio

FESTINA LENTE

Già dalla mia giovinezza ho scelto come mio motto l'antica massima latina ***Festina lente***, "affrettati lentamente".

Italo Calvino. Lezioni americane



- Esiti clinici
- Costo complessivo della gestione del paziente
- Qualità delle cure
- Efficienza del sistema

mario.plebani@unipd.it

Using Studies:
Cambridge Consultants Study 2006