

Point of Care

A holistic (clinicians) perspective

Dr S Omar
Veripath



What is Point of Care (POC)?

- A laboratory diagnostic test performed at or near the site where clinical care is delivered..

Point of Care testing. Nichols et al. Clin Lab Med 27 (2007)

- Some other definitions of POC by :

- CAP
- Joint commision on accreditation of healthcare organisations
- Wikipedia

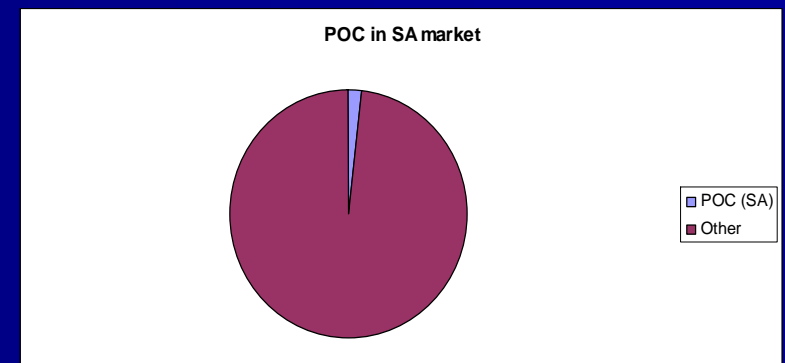
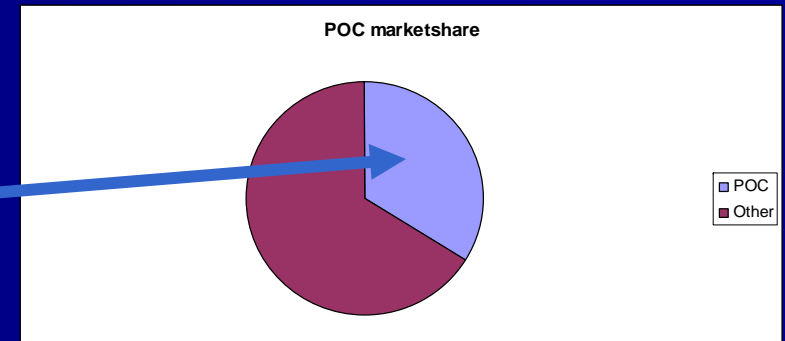
...Resident training in Point of Care testing. Campbell et al. Clin Lab Med 27 (2007)

- All have some common concepts:

- Used at/near patient
- No permanent dedicated space (lab) required
- Entire process, collection, analysis and result review are at the/near patient care point

How big is it internationally?

- 7 Billion US dollars worldwide
- 30 -34% of the in vitro diagnostics market internationally
- Growth rate of 9%
- Locally – Distributors estimate the market share at perhaps 1-2%



How is it regulated in US?

- Federal regulation
- **CLIA' 88**
 - Min standards
 - Validation
 - QC
 - Categories of tests – waived tests
- **“CLIA Waived tests”** – tests cleared by FDA for home use.
 - Simple and accurate
 - Likelihood of erroneous result is negligible
 - No reasonable risk of harm

Practically – how is it done?

- Laboratory adopts a waived test only policy
 - Enrol in CLIA programme
 - Pay fee (for some support)
 - Follow manufacturers instructions



Current clinical laboratory improvement amendments waived category tests available

- Diabetes testing
 - Glucose
 - Ketone
 - Hemoglobin A1c
- Hemoglobin
- Reproductive testing
 - Human chorionic gonadotropin (pregnancy)
 - Luteinizing hormone and Fern Test (ovulation)
 - Follicle-stimulating hormone (menopause)
- Renal function
 - Urine dipstick
 - Microalbumin
- Infectious disease
 - Streptococcus*
 - HIV
 - Helicobacter pylori*
 - Influenza A and B
 - Mononucleosis
 - Respiratory syncytial virus
 - Trichomonas*
 - pH and amines (bacterial vaginosis)
- Occult blood
- Drugs of abuse testing
- Therapeutic drug monitoring (lithium)
- Lipids
 - Cholesterol
 - High-density lipoprotein
 - Low-density lipoprotein
 - Triglycerides
- Brain natriuretic peptide
- Liver function
 - Aspartate aminotransferase
 - Alanine aminotransferase
- Coagulation (prothrombin time/international normalized ratio)
- Tumor markers (bladder tumor-associated antigen)

40 tests -
CLIA waived

But, really the menu is larger than you imagined –
With just this...



FBC + 3 part Diff



You can achieve :

Routine tests

- Urea, Cr, electrolytes
- Full blood count with platelets (3 prt diff), ESR
- Glucose
- Liver function test (complete)
- Amylase
- CMP
- Lipogram
- HBA1C
- Microalbuminuria
- CRP, Procalcitonin
- INR
- PSA and AFP

Emergency testing

CKMB	Methadone
Myoglobin (M)	Opiates
Troponin (Trp)	PCP
BNP	Cannabis (THC)
D-Dimer(Dd)	Antidepressants (TAD)
INR	P02
Paracetamol	PC02
Amphetamines	pH
Metamphetamines	Oximetry
Barbiturates	Lactate
Benzodiazepines	BHCG
Cocaine	HIV elisa/ rapid

Extra nice to have's

- Hep B
- Hep C
- Skin allergy testing
- Hb only
- WCC only

And there is more, if you're willing to look

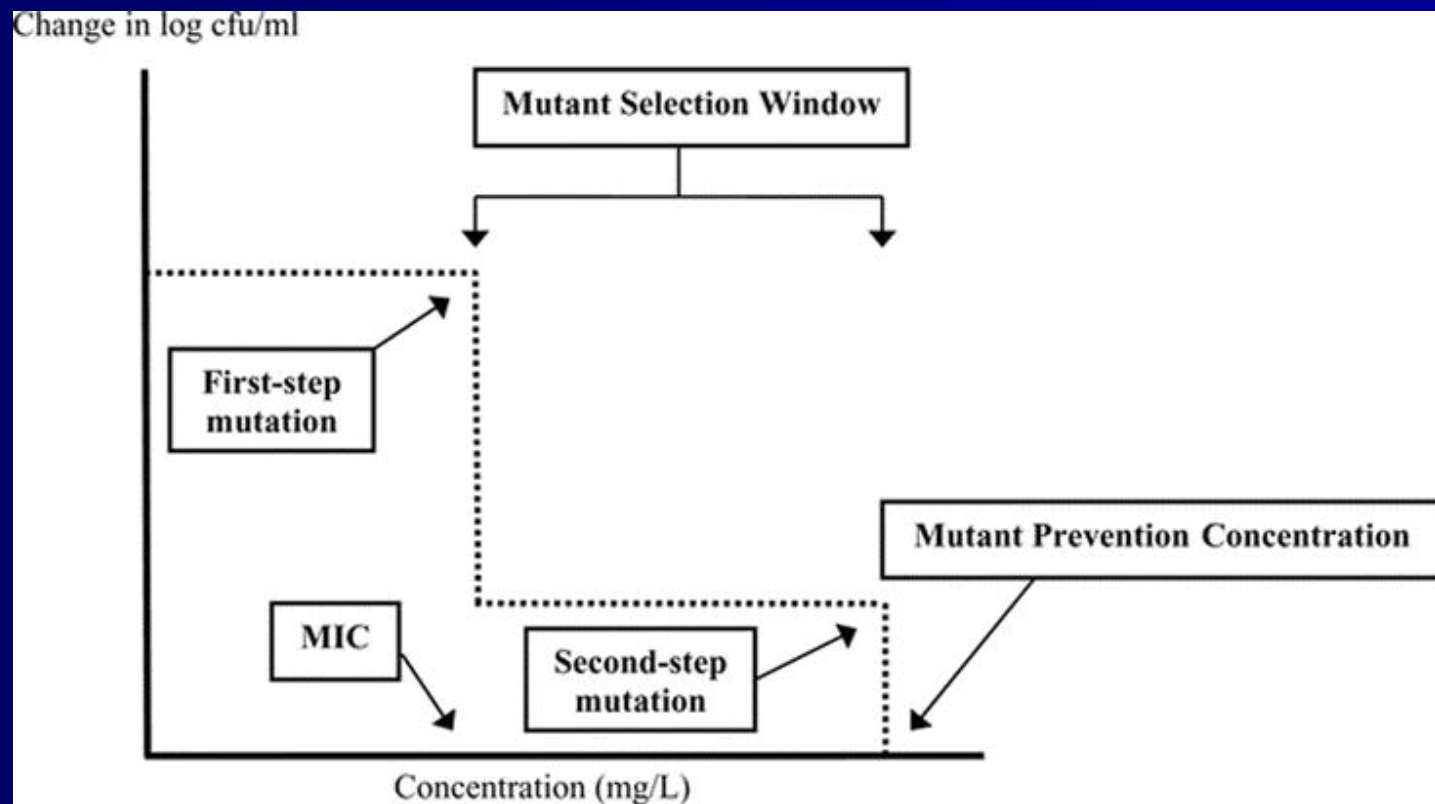
Summary – what's available on POC?

- 30 common tests account for ~68% of all requested codes in SA's private sector....Pretorius C ,SAMJ;97(1)2007
- The POC profile shown covers 95% of these 30
- In addition there are at least another 10 codes available on POC
- POC can therefore accurately cover ~70% of requested tests

Is it necessary? **No doubt!**

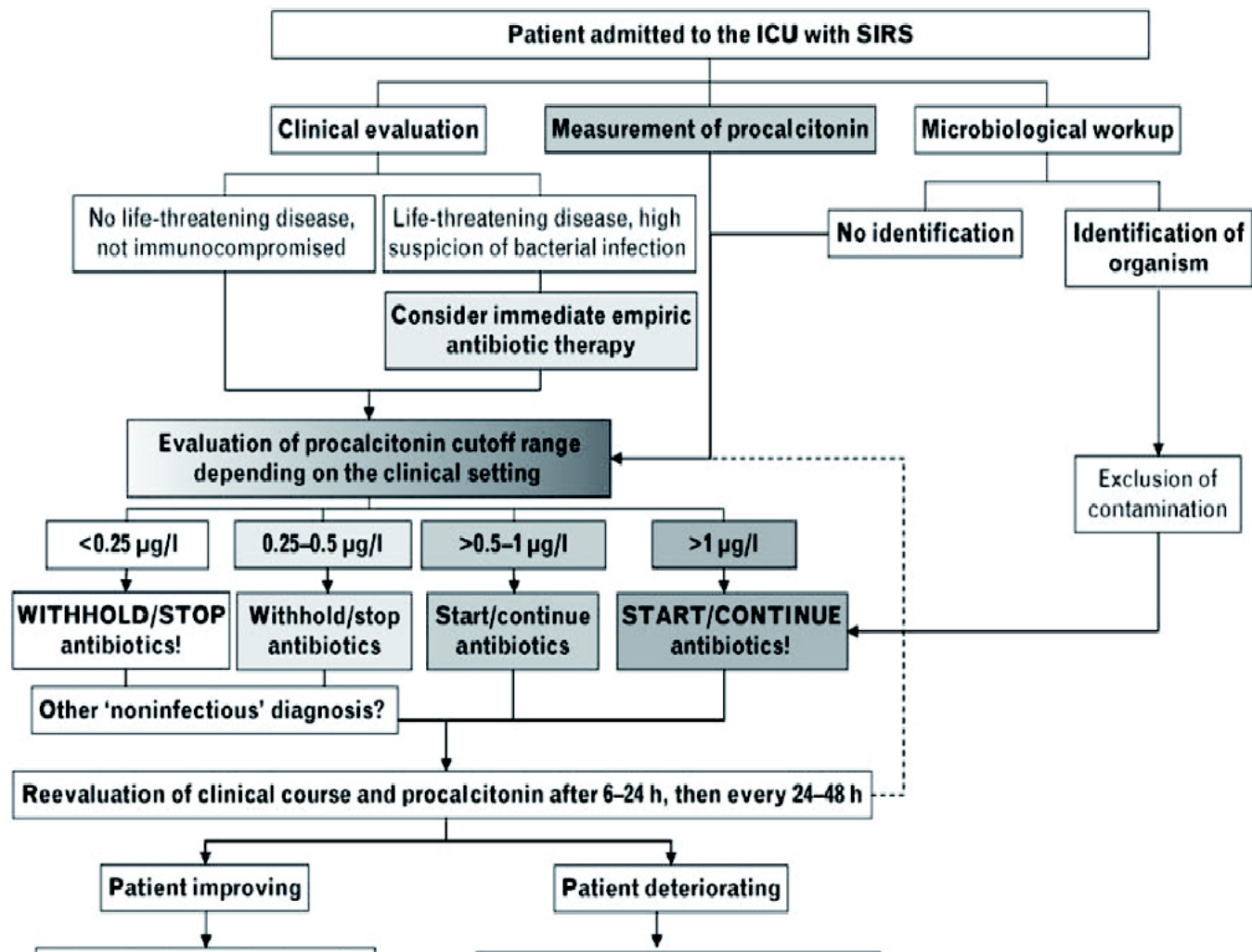
- There is growing evidence that a better, more rapid diagnosis can lead to better outcomes.
 - From the onset of hypotension, each hr delay for A/B over the ensuing 6 h → ↓ survival by 8%
 - Inadequate A/B Rx → poorer outcomes. You need to know the renal function for the correct dose
 - IHD – Early intervention saves lives and heart muscle
 - PE – earlier detection is more amenable to fibrinolysis
 - Paracetamol hepatotoxicity can be prevented if treated earlier

Underdose, and it costs lives and money!



Inflammatory marker protocol

Yes it works!



Where's the evidence for POC?

Point-of-care versus central laboratory testing: an economic analysis in an academic medical center. Tsai et al. Clin Ther. 1994 Sep-Oct;16(5):898-910

- POC TAT – 8 min v.s 59 min Lab
- Therapeutic TAT – 8min vs 1h 25min

~20% of patients had treatment delayed

Point of care testing: randomised
controlled trial of clinical outcome. Kendall et
al. BMJ. 1998 Sep 19;317

- 1728 patients presenting to ER
- POC vs Lab
- Decisions were made earlier with POC
 - POC Haematology tests -74 min earlier
 - POC chemistry tests – 86min earlier

Improving access to diagnostics: an evaluation of a satellite laboratory service in the emergency department.

Leman et al. Emerg Med J. 2004 Jul;21(4):452-6

- 1065 pt's -Academic hospital ER
- POC vs Lab

- Time to results significantly faster
- Time to discharge significantly faster
- Time to therapy faster... $p=0.06$

A randomized trial to assess the efficacy of point-of-care testing in decreasing length of stay in a pediatric emergency department. Hsiao et al. *Pediatr Emerg Care*. 2007 Jul;23(7):457-62

- Paediatric emergency dept
- 225 patients
- 65.0 minutes less time to results ; $P < 0.001$)
- 38.5 minutes ($P < 0.001$) less time in the ED.

The Evidence is there

It is cost effective! – We need to act now!

Examples of improved outcome from POC

Faster decision making	Chest pain, Drug O/D
Faster Rx	Drug O/D
Improved adherence to Rx	Diabetes
Reduced Cx rate	Diabetes
Faster optimization of Rx	Anticoagulation
Reduced Re-operation rate	Parathyroidectomy
Improved patient satisfaction	↓travel, ↓cost, ↑ownership of ds

Point of Care testing. BMJ;322;1285-1288

Economic outcomes of POC

- ↓ no. of clinic visits
- ↓ hospital LOS
- Fewer unnecessary admissions
- Less inappropriate Rx
- ↓ blood and blood product use
- Improved quality of life

It saves us money (and lives)

Point of Care testing. BMJ;322;1285-1288

POC lab vs Conventional Lab

Advantages and disadvantages of [point of care](#) testing

Advantages	Disadvantages
Quality of care can be improved by immediate results in some settings	Non-laboratorians may have difficulty with required quality control, documentation, and similar functions essential for reliable testing
Point-of-care tests may improve efficiency of care in some settings, reducing costs	Usually higher unit cost of testing than central laboratory method
Point-of-care tests can save labor in following up results with patients (eg, by telephone)	Usually more personnel time per test than central laboratory testing
Patients can learn their results immediately and not be lost to follow-up	For many routine visits, tests unavailable at point-of-care may also be required, necessitating multiple collections
Point-of-care tests can improve patient flow through busy clinics and emergency departments	Testing may be difficult to add to workload of personnel with existing responsibilities, causing potential errors caused by multitasking

Win- win for all Hospital



- Receives an **exceptional 24 hour diagnostic service** that is self driven.
- Enables **appropriate admissions** that will utilize resources – Pharmacy, theatre etc.
- Prevents **holding up of beds** by overnight admissions of uncertain diagnosis.

Overall benefit for the hospital.

Emergency Department or practice



- Rapid, accurate diagnosis.
- 24 hour self service.
- Improves patient TAT in casualty
 - No waiting room that is bursting at its seams
- Improves appropriate referral and admission.
- Marketing points for Casualty/ practice
 - Drugs of abuse screening while you wait etc

Overall benefit for the Casualty

Medical funder

- ↓ no. of clinic visits
- ↓ hospital LOS
- Eliminates unnecessary admissions
- Reduces further testing
- Less inappropriate Rx
- ↓ blood and blood product use
- Improved quality of life



Overall benefit for the funder –most obvious

What is the cost?

- Example... Tsai et al
 - ~15 years ago
 - Chemistry profile
 - Seven tests
 - 22% less at Lab (vs. POC)

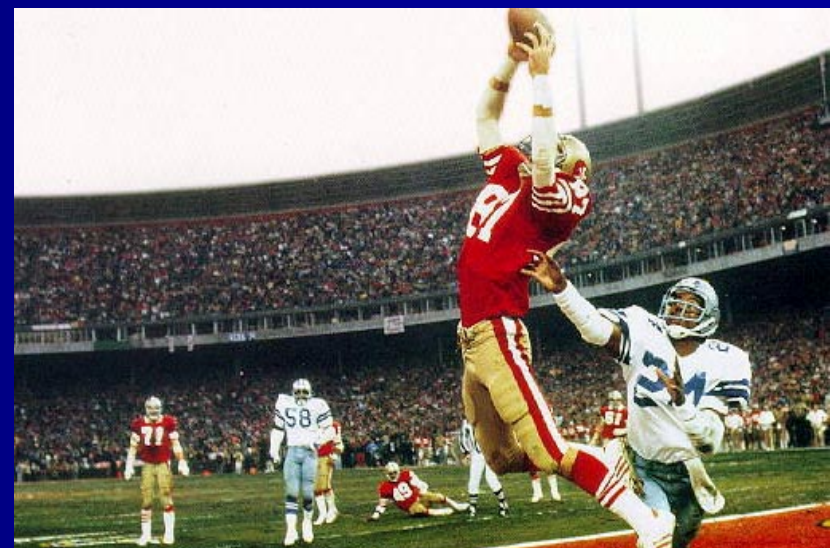
But we don't want to pay more!!



What do we know?

- There are proven indirect cost savings.
- Is it viable to fund these POC on the same tariff codes as conventional tests? **Yes**

We save indirectly
It costs no more
Where's the catch?



We have to open doors!

- CLIA Waived tests" –
- tests cleared by FDA
 - Simple and accurate
 - Likelihood of erroneous result is negligible
 - No reasonable risk of harm
- If a Laboratory **adopts a waived test only policy**
 - Enrol in CLIA programme
 - Pay fee (for some support)
 - Follow manufacturers instructions

We need to reimburse all above at Pathology rate



How can we start?

POC tests in the ICU – ABG, electrolytes, lactate etc

- The ICU clinicians daily fee -includes interpretation of chemistry and gas results
- These results have an immediate benefit (no value in historical data on blood gases)
- Phlebotomy and POC test often performed by ICU staff
- Only cost that need to be considered is the instrument and test.
- If a hospital took over this cost –
 - Cost saving?
 - Hospital could include ABG's as part of ICU/HCA daily tariff.
 - Value of this must be carefully considered.
- If a Pathologists opinion is required – Billing code for this

Thank you

