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.
  

- Some other definitions of POC by:
  - CAP
  - Joint commision on accreditation of healthcare organisations
  - Wikipedia


- 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

<table>
<thead>
<tr>
<th>Category</th>
<th>Tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Diabetes testing</td>
<td>Glucose, Ketone, Hemoglobin A1c</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td></td>
</tr>
<tr>
<td>Reproductive testing</td>
<td>Human chorionic gonadotropin (pregnancy), Luteinizing hormone and Fern Test (ovulation), Follicle-stimulating hormone (menopause)</td>
</tr>
<tr>
<td>Renal function</td>
<td>Urine dipstick, Microalbumin</td>
</tr>
<tr>
<td>Occult blood</td>
<td></td>
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<tr>
<td>Drugs of abuse testing</td>
<td></td>
</tr>
<tr>
<td>Therapeutic drug monitoring (lithium)</td>
<td></td>
</tr>
<tr>
<td>Lipids</td>
<td>Cholesterol, High-density lipoprotein, Low-density lipoprotein, Triglycerides</td>
</tr>
<tr>
<td>Brain natriuretic peptide</td>
<td></td>
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<tr>
<td>Liver function</td>
<td>Aspartate aminotransferase, Alanine aminotransferase</td>
</tr>
<tr>
<td>Coagulation (prothrombin time/international normalized ratio)</td>
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<tr>
<td>Tumor markers (bladder tumor-associated antigen)</td>
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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

<table>
<thead>
<tr>
<th>Test</th>
<th>Substance</th>
</tr>
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<tbody>
<tr>
<td>CKMB</td>
<td>Methadone</td>
</tr>
<tr>
<td>Myoglobin (M)</td>
<td>Opiates</td>
</tr>
<tr>
<td>Troponin (Trp)</td>
<td>PCP</td>
</tr>
<tr>
<td>BNP</td>
<td>Cannabis (THC)</td>
</tr>
<tr>
<td>D-Dimer (Dd)</td>
<td>Antidepressants (TAD)</td>
</tr>
<tr>
<td>INR</td>
<td>P02</td>
</tr>
<tr>
<td>Paracetamol</td>
<td>PC02</td>
</tr>
<tr>
<td>Amphetamines</td>
<td>pH</td>
</tr>
<tr>
<td>Metamphetamine</td>
<td>Oximetry</td>
</tr>
<tr>
<td>Barbiturates</td>
<td>Lactate</td>
</tr>
<tr>
<td>Benzodiazepines</td>
<td>BHCG</td>
</tr>
<tr>
<td>Cocaine</td>
<td>HIV elisa/ rapid</td>
</tr>
</tbody>
</table>
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
30 common tests account for ~68% of all requested codes in SA’s private sector. 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

Patient admitted to the ICU with SIRS

Clinical evaluation
- No life-threatening disease, not immunocompromised
- Life-threatening disease, high suspicion of bacterial infection

Measurement of procalcitonin
- Consider immediate empiric antibiotic therapy

Microbiological workup
- No identification
- Identification of organism

Evaluation of procalcitonin cutoff range depending on the clinical setting
- <0.25 µg/l
  - WITHHOLD/STOP antibiotics!
  - Other 'noninfectious' diagnosis?
- 0.25-0.5 µg/l
  - WITHHOLD/STOP antibiotics
- >0.5-1 µg/l
  - Withhold/stop antibiotics
  - Start/continue antibiotics
- >1 µg/l
  - START/CONTINUE antibiotics!

Reevaluation of clinical course and procalcitonin after 6-24 h, then every 24-48 h
- Patient improving
- Patient deteriorating

Yes it works!
Where’s the evidence for POC?


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


- 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

- 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

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

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

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Disadvantages</th>
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<tr>
<td>Quality of care can be improved by immediate results in some settings</td>
<td>Non-laboratorians may have difficulty with required quality control, documentation, and similar functions essential for reliable testing</td>
</tr>
<tr>
<td>Point-of-care tests may improve efficiency of care in some settings, reducing costs</td>
<td>Usually higher unit cost of testing than central laboratory method</td>
</tr>
<tr>
<td>Point-of-care tests can save labor in following up results with patients (eg, by telephone)</td>
<td>Usually more personnel time per test than central laboratory testing</td>
</tr>
<tr>
<td>Patients can learn their results immediately and not be lost to follow-up</td>
<td>For many routine visits, tests unavailable at point-of-care may also be required, necessitating multiple collections</td>
</tr>
<tr>
<td>Point-of-care tests can improve patient flow through busy clinics and emergency departments</td>
<td>Testing may be difficult to add to workload of personnel with existing responsibilities, causing potential errors caused by multitasking</td>
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</tbody>
</table>
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**
  - Enroll in CLIA programme
  - Pay fee (for some support)
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*We need to reimburse all above at Pathology rate*
How can we start?

POC tests in the ICU - ABG, electrolyes, 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