“New Directions in Point of care testing”
Is POCT a new concept? NO
Yesterday's Yardstick for tomorrow's instrumentation
Sequence

- Definition
- Introduction
- Historical background
- Available modalities
- Personal observation
- Future
- Conclusion
Definition

An analytical test undertaken by a member of the health team or by a non-medical individual in a setting distinct from a hospital lab
So what have we gathered from this definition?
A test is performed
- Healthcare team member
  (some medic or paramedic)

- By a totally non-medical person
  - Patient himself
  - Attendant
Where?
Not in the lab
POC Testing Environments

Testing performed at the patient’s side

Hospital Settings
Out-of-Hospital Care
Alternate, Home Settings
Non-instrumental system (strip-based)

- Disposable system or device
Non-instrumental system (strip-based)

Test strip
- Simple analyte type
- Sophisticated multi-analyte reagent strip (with control)
Cartridge based instruments

- Single analysis
- Multiple analysis
Benchtop / Desktop analysis
Simplified definition

POCT means a test performed close to the patient with quick result where patient care is given.
• Rapidity

• validity
Introduction

- Increasing interest
- Not a new concept
- Recent advances
  - Engineering
  - Innovation
  - Miniaturized devices
  - Lab-on-a-chip
  - Micro / nanoscale
- Simplification of blood handling
- Decreased TAT
- Transcription free delivery of reports
Minute to minute
rather
Hour to hour
POCT not a threat rather an opportunity to show our capabilities
Key objectives

- **Results**
  - Quick
  - Reliable
  - Validated

- **Patient proximity**

- **Treatment**
  - Prompt treatment
  - Improving clinical and/or economic outcome

- **Patient reassurance**
How might POCT enhance or affect diagnostic testing

few examples:
- Non-invasive glucose measurement thru ear by INFRATEC DEVICE
- AMI detection (20 min) – Heart FABP
- Triage Cardiac Panel (15 min)
  - CK-MB
  - Myoglobin
  - Troponin I
- Cardio Chek P.A (2 min)
  - Unique POCT tool
  - Lipid profile
  - Diabetic profile
- Nova statsensor Creatinine meter (30 sec)
  - 2 ul blood - fingerstick
  - Creatinine measurement with GFR
• Hemo Cue Albumin System (90 sec)
  - Immunoturbidimetric method (micro albumin)

• TOX / See (15 min)
  - Hand held POCT device
  - 14 most abused drugs (urine sample)

• Toxicological screen - Saliva

• Breath Alcohol meter

• Intrapartum fetal surveillance (oximetry)

• POCT Coagulation meters
Delivery forecast system (pregnancy)

- **Transcutaneous Bilirubin measurement**
  - Based on tissue optics

- **NIRS (Near Infra-red spectroscopy) Tissue Oximetry**

- **Capnometry**

- **Equital Ambulatory Wearable System (physiological)**
  - Heart rate
  - ECG
  - Respiratory rate & effort
  - Temperature
  - Body position
  - Oxygen saturation
  - Impact and fall detection
Point of Care Diagnostics and CLIA-Waived Testing

- **CLIA-Moderate Rapid Test Kits**
  - CLIA-Moderate H. pylori Test Kits
  - CLIA-Moderate hCG Test Kits
  - CLIA-Moderate Mononucleosis (Mono) Test Kits

- **CLIA-Waived Diagnostic Devices**
  - Albumin Analyzers
  - CLIA-Waived Cholesterol Analyzers
  - CLIA-Waived Hemoglobin A1c Analyzers
  - CLIA-Waived Lipid Panel and Triglyceride Analyzers
  - CLIA-Waived Urine Analyzers
  - Glucose Analyzers
  - Hemoglobin Analyzers
  - Ketone Analyzers
  - Microhematocrit Centrifuges
  - Point of Care (POC) Data Management Systems

- **CLIA-Waived Diagnostic Kits and Reagents**
  - Alcohol (Ethanol) Saliva Test Kits
  - Amines Test Kits
  - Bladder Tumor Antigen (NMP22) Test Kits
  - CLIA-Waived Drugs of Abuse Test Kits
  - CLIA-Waived Fecal Occult Blood Test Kits
  - CLIA-Waived hCG Test Kits
  - CLIA-Waived Streptococcus Test Kits
  - Creatinine Test Strips
  - Erythrocyte Sedimentation Rate (ESR) Test Kits
  - Gastric Occult Blood and Gastric pH Test Kits
  - Gastric pH Test Kits

- **Glucose Test Kits**
  - Helicobacter pylori Antibody Kits
  - Helicobacter pylori Urease Test Kits
  - Influenza A, B Test Kits
  - Ketone Test Kits
  - Lyme Disease (Borrelia) Test Kits
  - Menopause and Fertility Impairment (FSH) Test Kits
  - Microalbumin Urine Test Kits
  - Mononucleosis Antibody (MONO) Test Kits
  - Ovulation "Fern" Test Kits
  - Ovulation (Luteinizing Hormone) Test Kits
  - Rapid HIV-1/2 Antibody Tests
  - Vaginal pH and Amine Test Kits

- **Point-of-Care (POC) Diagnostic Devices**
  - Albumin Analyzers
  - Bench-Top Clinical Chemistry Analyzers
  - CO-Oximeter
  - POC C-Reactive Protein (CRP) Analyzer
  - POC Cardiac Marker Analyzers
  - POC Coagulation Analyzers (PT and INR)
  - Point of Care (POC) Creatinine Monitors
  - Point of Care Albumin Creatinine Ratio (ACR) Analyzers
  - Pulse CO-Oximeters
POCT has to be accompanied by POCl
ASCLS recommendations

ASCLS : American Society for Clinical Laboratory Science
POCT Pivotal role

- Instant result sharing
- Software interface enhancing communication
- Decreasing TAT
- Quick decision making
- Intervention
- Revision of treatment
Why has POCT re-emerged?

- New health care trends
- Rising health costs
- To decrease hospital stay
- Movement from inpatient to outpatient or ambulatory settings

All want quick bedside results
Present scenario

- Rapid advances in automation & technology
Is it possible to maintain quality test result?

- While achieving shorter TAT
- Lowering costs through faster discharges
- Personnel shortage
Solution

POCT
Success of POCT

When all futuristic steps are backed by QC & QA
POCT Package

- TQA plan
- POCT ownership
- POCT committee
POCT Quality

Right test with accurate results in shortest possible time
Tailored QC programmes

Check the system as a whole
Switching over to POCT

Not easy
Are we ready for the challenge
A New Horizon for Point of Care Testing

Technology can benefit quality

Laboratory Trends

Profits

Costs

Gulf Coast Point of Care Coordinators
• Cost of instruments / reagents
• Hidden cost of accredited lab support
• Cost of training
• Device management
POCT has changed the

- Testing site
- Technology
- Personnel
• Central lab versus POCT
• Limited number of samples
• Discontinuous nature of testing process
• Pre-analytical quality assurance
POCT Audit

• All POCT results must be able to pass an audit i.e., the results be traced to:
  - The patient
  - The operator
  - The machine or process used
  - Relevant maintenance & QC logs
  - Date & time
  - Current competency record of operator

• All POCT must be quality controlled regularly
QC & QA

- Day to Day QC
- EQA (external quality assurance) monthly
- PT (proficiency testing)
Accreditation

- Better quality
- Efficient POCT services
- Faster diagnosis
- Rapid treatment
How does hospital benefit from POCT

- Ability to process tests on site
- Printed lab style reports
- Saves staff time
- Reduces time spent chasing up / sorting results
- Eliminates transcription errors
- Immediate clinical decision
- May reduce extended length of stay
Where are we today?

- My Hospital
- My POCT
- Tertiary care hospital of Provincial government
On the contrary

Reduction in morbidity and mortality with GDT (goal directed therapy) techniques has improved patient care in conjunction with POCT and EMR (electronic medical record).
Future of POCT

The new directions
Global markets & trends

• POCT market predictions estimate 10 Billion Dollar market by the end of year 2010

• US national science foundation estimates 1 Trillion Dollar annual global market for nano-related services by year 2015
“In the near future a large percentage of diagnostic testing will be done in front of the patients and not in the centralized labs, but this doesn’t mean that high throughput laboratory testing is dead.”

Dr Simon Burnell; Campaign managers at Cambridge
Low time-to-result

- Magnotec Biosensor technology
- Single drop of blood
- Detailed biomarker detection / measurement
  - magnetic nanoparticles
  - measurement of target molecules
  - picomolar concentration
Piezofilm technology

- 30 µl whole blood
- Result: 5 – 10 minutes
Lactate Monitors

- Miniaturized device (ear-clip)
- Nanopotentiostat based German technology
- Result signal reception
  - Wrist watch
  - Cell phone
Temperature detection fabric

- Colour changing fabric
- Standard temperature threshold
- Fruit of
  - 6 years hard work
  - 700000 Pounds
Fitbit

- Miniaturized device
- 3D motion sensor
- Tracks patterns of
  - Physical activity
  - Calories consumed
  - Sleep
- Data uploaded & synchronized
Digital Plaster

- Vital sign monitor
  - Acute care
  - Tele care
  - Chronic disease monitoring
- NSP (Nano sensor protocol)
- Continuous monitoring
- Wireless transmission
  - Temperature
  - Heart rate
  - Respiratory rate
Picolo Express Analyzer

- Specialized POCT instrument
- Wide range of chemistry tests
Photon based Analyzers

- Minimally invasive monitoring
- Critical / emergency care
- Capable of detecting
  - Cardiac biomarkers
  - Metabolites
  - Vitals
Lab in a drop

- Pocket sized PCR device
- Magnetic Nanoparticle technology
- Rapid test
- Sample processing
ABBOT i - stat

- Biosensor & advance micro fluidics technology
- Portable TRUE POCT analyser
- Sample requirement: 65 – 95 ul blood
- Result: within 2 minutes
Living chip

• No more blood draws
• Implantable tiny device
• Early detection
  - Physiologic changes
  - Chemical changes
• Fast
• Accurate
• Non-invasive testing
CONCLUSION