The Evolving Role of Point of Care Testing

Rosy Tirimacco
Chair IFCC PoCT Task Force, Glucose PoCT WG, IFCC General Conference, KL 2013
Point of Care Testing

- Point of Care Testing (PoCT) is diagnostic testing performed at or near the site of patient care.

- A test which will result in an action leading to an improved health outcome.
Where Is PoCT Performed

- Home and community environment
- Community pharmacy
- Primary Care
- Disaster and Pandemic Scenarios
- Rural and Remote
- Paramedical vehicles
- Hospitals – ED, ICU, operating rooms
# Advantages & Disadvantages

## PoCT Advantages
- Simpler sample collection
- Simpler pre-analytical process
- Faster test results available leading to more timely treatment
- Removes pathology access barriers
- Increased patient satisfaction

## PoCT Disadvantages
- Increased workload
- Potential errors due to lack of expertise and quality control
- Potentially incompatible to local laboratory method used
- Increased Cost
- Inadequate storage of results
Something to Consider

- Although PoCT may not be as accurate when compared to traditional laboratory testing its value in offering faster results in conventional and unconventional settings cannot be ignored.
## Reasons for Using PoCT

<table>
<thead>
<tr>
<th>Reasons for ordering test</th>
<th>Setting</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rule in or rule out disease</td>
<td>Primary care</td>
<td>D-dimer</td>
</tr>
<tr>
<td>Rule in or rule out diagnosis</td>
<td>Emergency department</td>
<td>Troponin</td>
</tr>
<tr>
<td><strong>Treatment guide/monitor</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decide on drug dosage</td>
<td>Primary care</td>
<td>Blood glucose</td>
</tr>
<tr>
<td>Assess efficacy</td>
<td>Operating room</td>
<td>Parathyroid hormone</td>
</tr>
<tr>
<td>Monitoring compliance</td>
<td>Primary care</td>
<td>HbA1c</td>
</tr>
<tr>
<td><strong>Patient-related factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guidance and reassurance</td>
<td>Home</td>
<td>International normalised ratio</td>
</tr>
<tr>
<td>Convenience</td>
<td>Home</td>
<td>White cell count</td>
</tr>
<tr>
<td><strong>Physician-related factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Guide therapy</td>
<td>Primary care</td>
<td>Natriuretic peptide</td>
</tr>
<tr>
<td>Avoid adverse event</td>
<td>Imaging suite</td>
<td>Pregnancy test</td>
</tr>
<tr>
<td><strong>Policy/organisation factors</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reduce unnecessary referrals</td>
<td>Primary care</td>
<td>Natriuretic peptide</td>
</tr>
<tr>
<td>Manage long term care</td>
<td>Home</td>
<td>Telehealthcare system</td>
</tr>
</tbody>
</table>

Price CP, St John, Point of Care Testing: Making Innovation Work for Patient-Centered Care, AACC Press ISBN 978-59425-143-6
The Changing Health Care Practice Environment

- Increasing numbers of elderly
- More chronic disease
- Workforce shortages
- Medical cost pressures
- Increased demand for patient safety
- Increased demand for optimal and equitable outcomes
- Rapidly evolving therapeutic possibilities
- New technology – diagnostic, information and communication
Healthcare Reforms

- Commitment to patient-centred care – emphasis on primary care
- Improve access to care
- Better patient experience
- Improved quality of care
- Encouraging patients to ‘take charge of their disease’ – enhance understanding and awareness of their disease
The Aim of Health Care

- Reduce the overall burden of disease
- Improve life-expectancy
- Reduce overall CVD mortality rates
- Achieve the greatest disability free survival rates
- Improve equity of access to achieve equality of outcomes
- Improve efficacy
- Improve cost effectiveness
Implications of the Changing Practice Environment

- Demand for:
  - Increased efficiency
  - Throughput
  - Cost effectiveness
  - Greater accountability for processes of care and outcomes
  - Removal of barriers/impediments to EBC
  - Demonstration of Quality Improvement

- Need to embrace new ways of delivering care
  - Team based, multi-disciplinary care
  - Role re-definition
  - One-stop care (clinic or home based delivery, local capacity)
  - Care process integration and re-engineering/redesign
  - Data collection, analysis and feedback integrated into the process of care
Implications for Medical Testing of the Changing Practice Environment

Where appropriate any test that can be done at POC should be considered if the following conditions are met:

- Safety
- Reliability
- Quality
- Cost effectiveness
- Improved outcome – patient (clinical or satisfaction), health system
- Improved efficiency – doctor, patient, health system
- Reduced global cost
Traditional Limitations to POCT

- Technology – accuracy, precision, reliability
- Knowledge and training
- Quality assurance
- Accountability – ordering, reporting, data management
- Cost – capital, consumables, staff
- Connectivity
POCT Opportunities

- Technological Advances
  - Increased range of tests
  - Improved accuracy, precision, reliability and cost
  - Improved operational systems

- Interconnectivity
  - For networked instrument management – software, technical support, inventory management, cost accounting
  - For networked data management

- Outcomes based uptake
Potential Economic Outcomes

- Reduced number of clinic visits
- Reduced length of hospital stay
- Earlier discharge from hospital
- Fewer unnecessary hospital admissions
- Better optimised drug treatment
- Less inappropriate use of drugs
- Improved quality of life
What Can PoCT Achieve?
Australian Population Density

<table>
<thead>
<tr>
<th>Country</th>
<th>Area km²</th>
<th>Population</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>7,659,861</td>
<td>20,434,176</td>
</tr>
<tr>
<td>Sth Aust</td>
<td>978,810</td>
<td>1,600,000</td>
</tr>
<tr>
<td>France</td>
<td>547,030</td>
<td>60,742,000</td>
</tr>
<tr>
<td>Germany</td>
<td>357,021</td>
<td>82,400,996</td>
</tr>
<tr>
<td>Italy</td>
<td>301,230</td>
<td>58,742,000.00</td>
</tr>
<tr>
<td>Spain</td>
<td>499,542</td>
<td>43,484,000</td>
</tr>
</tbody>
</table>

Source: [www.abs.gov.au](http://www.abs.gov.au)
Prevalence of Chronic Disease per 1,000 Population* within Australia

Data Sources:
Heart Failure Data - Clark, Driscoll & Stewart 2005;
Spatial Unit - ABS ASGC Census Collection Districts 2001
Pathology - Rosy Tirimacco (SA Health)

* Natural Breaks (Jenks) Classification

Feb 2010
Country Health SA Services

- Population: 450,000 (28% of total)
- 980,000 square km
- Age profile: 14% > 65 years
- Emergency Care: 66 hospitals providing 24/7 cover
- Catchment populations: 1500 - 30,000 per hospital
- On-site Laboratories (on-call only after-hours) - 10
- Significant shortage of doctors and nurses in primary care and hospitals.
  - ~420 doctors (30 % overseas trained)
  - > 3000 nurses
- Significant shortage of Medical Specialists
Integrating Service Provision

- Rural hospitals
- Rural doctors, nurses and allied health
- Rural specialists
- Pathology service
- Pharmaceutical supply
- Tertiary specialists and cardiology services
- Ambulance service
- Aeromedical and retrieval services
- Medical ICT services
- Medical administration and clinical governance

RFDS Base, Pt Augusta
Statewide 30 Day AMI Mortality 2001-10

[Graph showing mortality rates from 2001 to 2010 with specific percentages indicated for each year.]
Task Force Members

Full Members
- Adil Khan  Member CA
- Gerry Kost  Member US
- Pascal Pernet  Member FR
- Trevor Allison  Corp. Rep./Siemens
- Rolf Hinzmann  Corp. Rep./Roche

- Anne Skurup  Corp. Rep./Radiometer

Corresponding Members,
- Joan Pearson  Association for Clinical Biochemistry

Corporate Corresponding Member
- Andrei Malic  NOVA BIOMEDICAL CORPORATION
IFCC PoCT Task Force

Terms of Reference

- To promote quality in the use, performance, interpretation and reporting of POCT across the full spectrum of clinical chemistry and laboratory medicine
- To create a forum for high level discussion on a wide range of POCT related topics
- To provide international leadership for developing the clinical practice of POCT in Laboratory Medicine
Task Force Objectives

O Creation of a communication network for specialists who are expert in POCT. To include other POCT specialist groups; expert individuals in IFCC Full, Affiliate and Corporate Members; regulatory agencies and users of POCT

O Definition, implementation, evaluation and reporting of a range of defined POCT projects. To include projects that address quality in POCT performance, the appropriate clinical use of POCT, connectivity and the cost effectiveness of POCT. Projects should complement rather than duplicate projects being undertaken by other POCT specialists

O Preparation of educational support material for those using or considering the use of POCT

O Creation of a library of publications that document the clinical effectiveness of POCT and the impact on clinical outcomes. To include clinical chemistry, haematology, microbiology and other disciplines of laboratory medicine, as appropriate
Proposed PoCT Working Groups

- How should Glucose Meters be Evaluated for Critical Care
- Use of PoCT HbA1C for screening (diagnosis?) of diabetes
Environmental Stress Testing

- Address labelled and off-label use in the context of different environmental use cases such as disaster scenarios.
- Define how PoCT systems should be evaluated for environmental stress.
- Develop guidelines for use of PoCT systems subject to a variety of real world conditions.
- Define how reagents and devices should be transported and what quantitative monitors should be used for manufacturer compliance.
Our Planned Tasks

- “Thinking of Introducing PoCT – Things to Consider” – educational document directed at scientists starting our in this area and non-scientists.
- Clinical use cases for PoCT devices and criteria for selection and implementation
- Analytical control of PoCT – internal quality control, external quality control, correlation with central laboratory
Planned Tasks

- Advice for PoCT quality systems
- Performance validation for decision-making domains
- Harmonisation for PoCT devices/user interfaces procedures, quality control
What will be our recipe for Success!

- Integration of all stakeholders involved with PoCT:
  - Doctors
  - Nurses
  - Laboratory scientists
  - Consumers
  - Industry
- Work together to create a safe environment for PoCT
Currently running a survey to determine the uptake of eQA programmes for PoCT blood glucose

Potentially a significant knowledge gap regarding the importance of enrolling glucose meters in an eQA programme

If you haven’t done so already please participate https://www.surveymonkey.com/s/IFCCglucoseEQ A
It could be argued that as clinicians we have a duty of care to utilise benefits of PoCT particularly in rural and remote areas with poor access to traditional pathology.

For any PoCT queries contact rosy.tirimacco@health.sa.gov.au
"You can go home now. The virus was in the diagnostic computer."