Point of Care Testing – current and emerging quality perspectives

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Londonderry
N. Ireland
Total POCT Market: Revenue Forecast (US)
2006-2016 ($ Million)
Largest Segments in the 2009 US POCT Market (as % of total market):

- Infectious Disease 18%
- Glucose 16.4%
- Blood Gas & Electrolyte 15.7%

Largest Segments in the 2016 US POCT Market (as % of total market):

- Infectious Disease 21.9%
- Cardiac Biomarkers 17.6%
- Coagulation PT 13.7%
Diverse role of POCT

• Use by health care professionals

• Use by patients [glucose, PT/INR,pregnancy]

• Use in different settings e.g. ICU, home
Themes

• Quality of the POCT process

• Quality of the care pathway which incorporates POCT i.e. are patient outcomes improved?
Patient safety

‘To err is human: Building a Safer Health System’

Institute of Medicine 1999

Medical error – 98 000 deaths per year in US

• Laboratory tests?
• POCT??
Central Lab Testing

- Test ordering
- Patient preparation
- Correct sample, patient
- Transport to lab
- Lab sample preparation
- Analyser preparation
- Analysis
- verification
- verification
- Report issue
- Critical result communication
- Clinical action
Test ordering

Patient preparation

Correct sample, patient

Transport to lab

Lab sample preparation

Analyser preparation

Analysis

verification

Report issue

Critical result communication

Clinical action
Errors - sources and amplifiers
Meier FA, Jones BA. Arch Pathol Lab Med 2005;129:1262

Latent conditions:
• Operator competence
• Non adherence to procedures
• Uncontrolled instruments

Amplifiers:
• Rapid result availability
• Immediate therapeutic implication
• Incoherent regulation
Governance failure

CMS survey [2001]:

• 19% operators untrained
• 32% no SOP available
• 25% did not follow SOP
Frequency of POCT error

- Little information available – difficult to investigate
- Central lab error rate 0.085 - 0.6%
- POCT error rate: 0 – 0.65%
Error rates in POCT

• ~ 400 000 POC tests [glucose, BG/electrolytes, pregnancy, ketones, DoA, urinalysis]

• 2 acute / 1 non acute hospital sites

• Accredited service
<table>
<thead>
<tr>
<th>Test type</th>
<th>Number of tests</th>
<th>Number of defects</th>
<th>Defect, % of total tests</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood gas/electrolytes</td>
<td>22,687</td>
<td>119</td>
<td>0.52</td>
</tr>
<tr>
<td>Blood gas/electrolytes/troponin I</td>
<td>5,809</td>
<td>10</td>
<td>0.17</td>
</tr>
<tr>
<td>Pregnancy</td>
<td>8,879</td>
<td>14</td>
<td>0.158</td>
</tr>
<tr>
<td>Glucose</td>
<td>303,389</td>
<td>71</td>
<td>0.02</td>
</tr>
<tr>
<td>Drugs of abuse</td>
<td>247</td>
<td>1</td>
<td>0.4</td>
</tr>
<tr>
<td>Hb A1c</td>
<td>1,236</td>
<td>8</td>
<td>0.65</td>
</tr>
<tr>
<td>Urinalysis</td>
<td>64,370</td>
<td>2</td>
<td>0.003</td>
</tr>
<tr>
<td>Blood ketones</td>
<td>1,087</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
## Sources of Error

<table>
<thead>
<tr>
<th></th>
<th>POCT ¹</th>
<th>Central Lab ²</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-analytical</td>
<td>32 %</td>
<td>87.6%</td>
</tr>
<tr>
<td>Analytical</td>
<td>65.3%</td>
<td>11.1%</td>
</tr>
<tr>
<td>Post - analytical</td>
<td>2.7%</td>
<td>1.3%</td>
</tr>
</tbody>
</table>

¹ Clin Chem 2011; 57:1267-71  
² Ann Clin Biochem 2008;45:129-134
## Impact of POCT errors

<table>
<thead>
<tr>
<th>Severity</th>
<th>Actual Impact</th>
<th>Potential Impact</th>
<th>Stat testing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 [least]</td>
<td>51.2%</td>
<td>2.7%</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>48.4%</td>
<td>77.8%</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>0%</td>
<td>1.3%</td>
</tr>
<tr>
<td></td>
<td>4</td>
<td>0%</td>
<td>14.7%</td>
</tr>
<tr>
<td></td>
<td>5 [worst]</td>
<td>0%</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

1 Clin Chem 2011; 57:1267-71
2 Clin Chem 1997;43: 1345-51
How to minimise POCT defects?

• Instrument design / engineering
• Assay design
• Ensure assay performance is appropriate to purpose
• Operator training
• Better governance
• Regulation
POCT – The quality of the care pathway
POCT and care pathways – a paradigm shift

• Need to demonstrate clinical benefit – ultimate quality measure

• May need to restructure care pathway to achieve benefit – ‘disruptive technology’
Self monitoring of blood glucose in Type 2 DM

• Supported by ADA guidelines since 1987
• Clear evidence of benefit lacking
• It depends what you do with the results!
ESMON Study Design

Invitation to participate

Randomisation

Baseline Data 3 mths 6 mths 9 mths 12 mths

Non Monitoring

Monitoring
Efficacy of self monitoring of blood glucose in patients with newly diagnosed type 2 diabetes (ESMON study): randomised controlled trial

Maurice J O’Kane, consultant,1 Brendan Bunting, professor,2 Margaret Copeland, trial manager,3 Vivien E Coates, professor,3 on behalf of the ESMON study group
doi:10.1136/bmj.39534.571644.BE

New Type 2 DM patients randomised to SMBG or non SMBG groups

**HbA1c**

<table>
<thead>
<tr>
<th>Time (months)</th>
<th>Monitoring</th>
<th>Control</th>
<th>P value</th>
<th>Mean difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>8.8 (2.1)</td>
<td>8.6 (2.3)</td>
<td>0.68</td>
<td>−0.33 (−0.77 to 0.51)</td>
</tr>
<tr>
<td>3</td>
<td>7.2 (1.1)</td>
<td>7.1 (1.2)</td>
<td>0.50</td>
<td>0.18 (−0.47 to 0.23)</td>
</tr>
<tr>
<td>6</td>
<td>7.0 (0.9)</td>
<td>7.0 (1.1)</td>
<td>0.82</td>
<td>0.04 (−0.27 to 0.35)</td>
</tr>
<tr>
<td>9</td>
<td>6.9 (0.8)</td>
<td>7.1 (1.4)</td>
<td>0.30</td>
<td>0.19 (−0.16 to 0.54)</td>
</tr>
<tr>
<td>12</td>
<td>6.9 (0.8)</td>
<td>6.9 (1.2)</td>
<td>0.69</td>
<td>0.07 (−0.25 to 0.38)</td>
</tr>
</tbody>
</table>
Structured Testing programme study
Polonsky *et al.* Diab Care 2011;34:262-67

Patients

- Active Control group
- Structured testing group
Structured Self-Monitoring of Blood Glucose Significantly Reduces A1C Levels in Poorly Controlled, Noninsulin-Treated Type 2 Diabetes

Results from the Structured Testing Program study

Diabetes Care 34:262–267, 2011

William H. Polonsky, PhD

[Diagram]
Anticoagulant monitoring

- 5%-10% of over 65y on anticoagulant
- Narrow therapeutic range
- Potential for patient self testing and dosing

How does this compare with usual care?
Meta-analysis: Effect of Patient Self-testing and Self-management of Long-Term Anticoagulation on Major Clinical Outcomes

Hanna E. Bloomfield, MD, MPH; Ange Krause, MD; Nancy Greer, PhD; Brent C. Taylor, PhD, MPH; Roderick MacDonald, MS; Indulis Rutks, BS; Preetham Reddy, MD; and Timothy J. Wilt, MD, MPH


22 trials, 8413 patients of patient self testing [PST] alone or in conjunction with self–dose adjustment.
Figure 4. All-cause mortality in PST or PSM versus usual care studies.

<table>
<thead>
<tr>
<th>Study, Year (Reference)</th>
<th>Events/Total, n/n</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PST or PSM</td>
<td>Usual Care</td>
</tr>
<tr>
<td><strong>Long-term trials (≥12 mo)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sidhu and O’Kane, 2001 (39)</td>
<td>0/51</td>
<td>4/49</td>
</tr>
<tr>
<td>Menéndez-Jándula et al, 2005 (11)</td>
<td>6/368</td>
<td>15/369</td>
</tr>
<tr>
<td>Fitzmaurice et al, 2005 (35)</td>
<td>5/337</td>
<td>11/280</td>
</tr>
<tr>
<td>Körtke et al, 2001 and 2007 (13, 14)</td>
<td>94/488</td>
<td>142/442</td>
</tr>
<tr>
<td>Siebenhofer et al, 2008 (17)</td>
<td>15/99</td>
<td>11/96</td>
</tr>
<tr>
<td>Matchar et al, 2010 (24)</td>
<td>152/1465</td>
<td>157/1457</td>
</tr>
<tr>
<td>Soliman Hamad et al, 2009 (18)</td>
<td>1/29</td>
<td>1/29</td>
</tr>
<tr>
<td><strong>Short-term trials (&lt;12 mo)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beyth et al, 2000 (23)</td>
<td>21/163</td>
<td>26/162</td>
</tr>
<tr>
<td>Fitzmaurice et al, 2002 (27)</td>
<td>0/30</td>
<td>1/26</td>
</tr>
<tr>
<td>Gardiner et al, 2005 (30)</td>
<td>1/44</td>
<td>0/40</td>
</tr>
<tr>
<td>Christensen et al, 2007 (32)</td>
<td>1/50</td>
<td>0/50</td>
</tr>
<tr>
<td>Dauphin et al, 2008 (15)</td>
<td>1/33</td>
<td>0/34</td>
</tr>
<tr>
<td>Sawicki, 1999 (10)</td>
<td>1/90</td>
<td>1/89</td>
</tr>
</tbody>
</table>
• ‘Compared with usual care, PST with or without PSM is associated with significantly fewer deaths and thromboembolic events ..... without increased risk for a serious bleeding event, for a highly selected group of motivated adult patients ...’
Conclusions

• Defect rate may be higher than central lab testing
• Operator factors important
• Robust governance and regulation essential
• Clinical impact of POCT must be established