

# POCT

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POCT

What Should we talk  
about?

**NHS**

**HEART of  
ENGLAND**  
NHS Foundation Trust

# GOOD HOPE HOSPITAL





# HEARTLANDS HOSPITAL





# SOLIHULL HOSPITAL





# BIRMINGHAM CHEST CLINIC



# POCT Drivers

- Definitions
- International / National Drivers
- Recent Health Care Trends
- Key POCT Documents
- Local drivers

# Early POCT



# What is POCT ?



DB2010(03)

*“...any analytical test performed for a patient by a healthcare professional outside the conventional laboratory setting.”*



ISO 22870:2006

*“...testing that is performed near or at the site of the patient with the result leading to possible change in the care of the patient.”*

# What is POCT ?



The Royal College of Pathologists  
Pathology: the science behind the cure

*“An analytical test undertaken by a member of the healthcare team or by a non-medical individual in a setting distinct from a normal hospital laboratory.”*

## **Other terms**

- near patient testing (NPT)
- bedside testing
- extra-laboratory testing
- disseminated / decentralised lab testing.

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# Examples of POCT

- analysers and kits for HbA1c (DCA 2000 x 3)
- FBC (4)
- bilirubinometers
- blood gas analysers (28 Radiometer & 6 Bayer)
- blood glucose meters (320 Abbott Optium, 10 PXP)
- cardiac testing: BNP, troponin (withdrawn)
- D-dimer (Clearview Simplify + Roche HS232)
- cholesterol tests (support in community)
- coagulometers (Roche CoaguChek x 20)
- electrolyte analysers
- MRSA screening tests
- pregnancy tests
- rapid test kits for infectious disease markers
- urinalysis test strips. (Bayer 8SG + Stratus/
- fetal fibronectin

# Drivers

## **International / National**

- International Standards Organisation (ISO)
- Department of Health (DH) Reviews
  - Carter Reviews 1 & 2 (Aug 2006 & Dec 2008)
  - Darzi Review (2008). High Quality Care For All
  - Transforming Community Services (TCS)
- Medicines and Healthcare Products Regulatory Agency (MHRA) – formerly MDA
- Royal College of Pathologists (RCPATH)
- The Joint Working Group on Quality Assurance (JWGQA)
- Clinical Pathology Accreditation Ltd. (CPA)
- UK Accreditation Service (UKAS)

# Top 10 Tips

## Point Of Care Testing

- 1** **Involve your local hospital laboratory**  
Your local hospital pathology laboratory can play a supportive role in providing advice on a range of issues including the purchase of devices, training, interpretation of results, troubleshooting, quality control, and health and safety.
- 2** **Management**  
Many people will be involved in the creation, implementation and management of a POCT service. It is vital that an appropriate POCT co-ordinator is identified and a POCT committee established.
- 3** **Health and safety**  
Be aware of the potential hazards associated with the handling and disposal of body fluids, sharps and waste reagents outside of a laboratory setting.
- 4** **Training**  
Training must be provided for staff who use POCT devices. Only staff whose training and competence has been established and recorded should be permitted to carry out POCT.
- 5** **Always read the instructions**  
... and be particularly aware of situations when the device should not be used.
- 6** **Standard operating procedures (SOPs)**  
SOPs must include the manufacturer's instructions for use.
- 7** **Assuring quality**  
The analysis of quality control (QC) material can provide assurance that the system is working correctly.
- 8** **Results**  
Results should be reviewed by appropriately qualified staff with particular reference to the patient's history.
- 9** **Record keeping**  
... is essential and must include patient results, test strip lot number and operator identity.
- 10** **Maintenance**  
In order that devices continue to perform accurately they must be maintained according to the manufacturer's guidance.

# Recent Health Care Trends

## 1<sup>st</sup> Carter Review (Aug 2006)

- Pro-POCT
- Growing demand
- Focus of services – Community
- Enhanced accessibility
- Use of POCT
  - To change skill set e.g. Phlebos doing POCT testing
  - For new care pathways
  - In combination with lab services
- IT links / connectivity
- Pathology support – extension into community

# Recent Health Care Trends

## Darzi Review (June '08) “High Quality Healthcare for All”































- Quality at the heart
- Emphasis on prevention – vascular risk assessment
- Services commissioned to meet local needs
- More choice & more focus on “Patient Experience”
- Coalition for better health (3<sup>rd</sup> sector) = partnerships
- SHA to promote innovations – prizes + funds
- More PBC & better QUOF
- NICE approved drugs funded
- Improved care - long term conditions

# Recent Health Care Trends

## 2nd Carter Review (Dec 2008)

- POCT providers – clinical audit & clinical governance
- POCT providers should be accredited
- POCT accessibility of community base services
  - Darzi: moving services out of hospitals
- POCT in poly clinics and pharmacies
- Helps make services responsive to users
- POCT facilities part of pathology network
- GPs should invest in POCT

# Quality Dashboard

Clinical Outcomes	Patient Satisfaction	Staff Satisfaction
• Mortality 	•National survey data 	•Response rate to survey 
•MRSA numbers 	•Local survey data 	•Leadership satisfaction score 
•C'Diff numbers 	•Number of SUIs  •Number of near misses 	•Positivity score from survey 
•Harm: ❖ Falls  ❖ Tissue sores ❖ Medication errors	•Waiting times :  ❖ Non admitted ❖ Admitted emergency (breaches) ❖ Admitted elective	•Staff turnover 
•Length of stay 	•Number of complaints 	•Sickness 
•Local clinical outcome measures 	•Recommender index 	
•Increased use of POCT 	•Directly bookable 	
Cost/Value for Money		
•Operating Surplus 	•OP surplus per wte 	•Spend on temporary staffing 
Transformation - Continuous Improvement measures		
•% discharges at weekend 	•Productivity benchmark measures 	•Number of patients in hospital > 50 days and > 10 days 
•% discharges before 1pm 	•World Class Ward – yes or no? 	•Reduction in “rework” 
•Weekly discharge target 		

# NHS Litigation

- Level 1
- *Level 2*
- *Level 3*



# Care Record Service Compliance

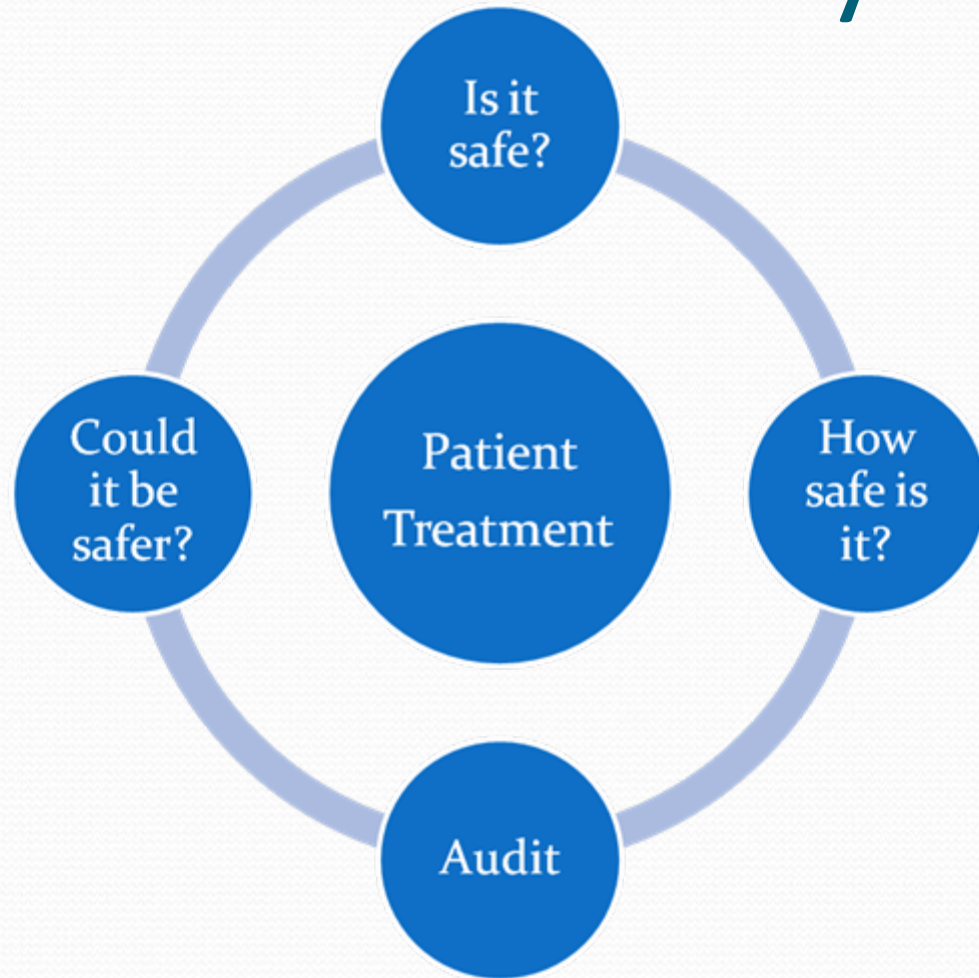
- Functionality Grade

All Trusts need to develop their strategy approach  
to achieving CRSC system functionality  
2009

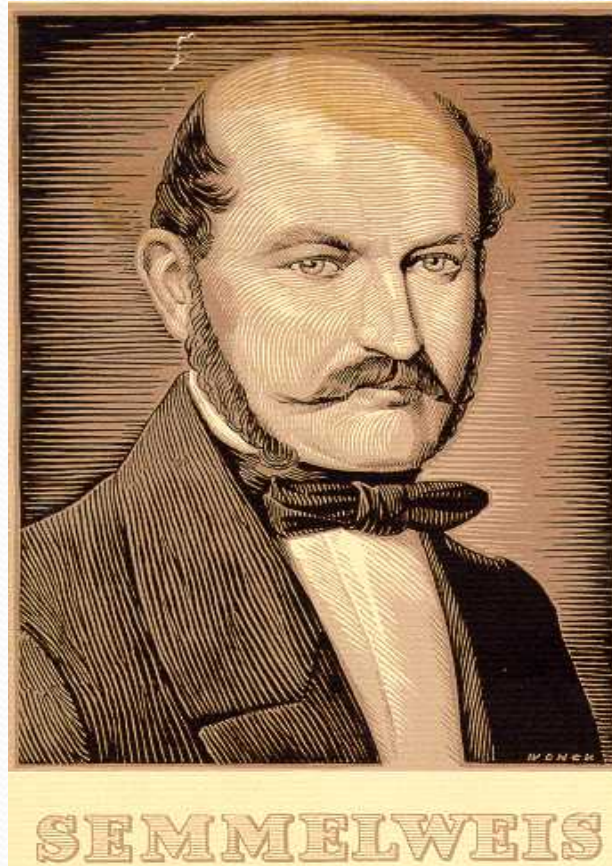


Fully implemented their CRSC system  
2012

# National Patient Safety Strategy



# The Ignaz Patient Safety Value



# The Ignaz Patient Safety Value



- Childbed Fever
- Chlorinated lime Solution

# The Ignaz Patient Safety Value

## Systems

- Assessment of current systems
- Are any changes required to maintain or improve safety

## People

- Are there enough adequately trained staff
- What skills are required to operate safely

# The Ignaz Patient Safety Value

## Measurement

- Are current measurements adequate and what are their values
- What measurements are required and what are their target value

## Point of Care

- Systems
- People
- Measurement



Care Quality  
Commission

# History of Key POCT Documents

- 1989 - Revised '92 & '99. Guidelines for Near Patient Testing. IBMS/ACB/JWGQA
- 2002- MHRA. Management & use of *in vitro* diagnostic devices. DB 2002(03).
- 2004 – RCPATH. Guidelines on point-of-care testing.

# History of Key POCT Documents

- 2006 – ISO 22870. Point-of-Care-Testing (POCT): Requirements for quality and competence.
- 2010 – MHRA. Management & use of IVD Point of Care Test Devices.
- 2010 – CPA. Additional Standards for Point-of-Care Testing (POCT) facilities

# What do they say?

- Guidelines for NPT = advisory notes / guidelines
- “Management and Use of IVD Point of Care Test Devices”. MDA Bulletin 2002
  - Supportive role for Pathology
  - Questions before implementation
  - Blueprint for management & organisation of POCT
  - POCT Co-ordinator
  - Multi-disciplinary POCT committee
  - Revised & updated in 2010 (with case studies)

# ISO 22870:2006

- Point-of care testing (POCT) – requirements for quality and competence.
- Only 11 pages – used in conjunction with ISO 15189
- Applies to POCT hospital, clinic or ambulatory care
- Does not apply to self-testing
- Requirements
  - QMS
  - Governing body – ultimately responsible
  - Health professional grouping (med advisory committee)
  - POCT management group (POCT committee)
  - Quality manager

# CPA – POCT standards

- Launched Apr 2010 & apply from 01/11/10
- Based on ISO 22870
- Additional to CPA Med Lab Stds (ISO 15189)
- 20 additional standards
- Separate assessment (and fee!)
- Assessed by vertical and examination audits
- Multiple POCT sites listed (10 % sample)
- POCT accreditation recorded on CPA website

# CPA / ISO 22870 - specifics

- QMS as for ISO
  - Quality policy, doc control, audits, NCs, continuous quality improvement, AMR etc.
- Validation & comparability data with lab methods
- Verification
- Regular review of EQA / IQC
- Training & competency records
- Permanent record in medical record
- Results distinguished from lab results

Compliance requires POCT fully integrated in lab QMS

Much easier (but not essential) with connectivity

# Role for Pathology

- **Pre-2002:** Pathology acted as advisors providing information to users via leaflets and policies (no enforcement)
- **2002 – present:** Pathology acts in partnership with users with involvement in training & support (some control)
- **2010+:** Accredited POCT fully integrated into lab QMS

Pathology has total control (& responsibility) for POCT

- **Are users ready for pathology to have control ?**
- **Do we have the resources ?**
- **What are the penalties if POCT isn't accredited?**

# Local Drivers

## What Drives POCT locally

- Cost savings
  - Market testing
  - Consolidation of suppliers & service contracts
  - MSC
- Consolidation of equipment
  - Maintenance
  - Service contracts
  - Spares & consumables

# Local Drivers

- Quality concerns
  - Incidents
  - Litigation
- Income generation
  - Primary Care support
  - Beta testing
- Quality, Innovation, Productivity, Prevention (QUIPP)
  - Reconfiguration
  - Alternative patient pathways

# Financial Consolidation

## POCT breakdown @ HEFT

Blood Gas £265K

Blood Glucose 988 K strips per annum = £225K

HbA1c £50K                      Dipsticks/Readers £30K

15 Haemocues - ?    D-dimer strips ?

12 Coagucheks - ?    HCG tests ?

FBC £20K

5 Cardiac readers - £25 K

Total = ? Estimated > £0.75 million

# Financial Consolidation

Who manages the budget ?

Who ensures value for money ?

Who is responsible for cost savings ?

Where is the incentive for innovation & efficiency savings ?



# Joined up POCT

Quality, Innovation, Productivity, Prevention  
(QIPP agenda)

POCT projects fit neatly into the QIPP agenda

Quality – Improved management of POCT

Innovation

- Reconfiguring patient pathways to improve patient experience e.g. one stop clinics

Productivity – Reducing length of stay

Prevention – Use of POCT for screening e.g. CHD

# Community POCT

## Why get involved with community POCT?

- Income generation
- Improve links with pathology users (customers)
- Establish role in supporting community testing
- Enable dis-intermediation (QUIPP)
  - i.e. cut out the middle man (person). Remove steps from clinical pathways / avoid hospital visits.
- Transforming Community Services –DH initiative
  - Many trusts are now service providers for some community services therefore responsible for any POCT within the service.

# Future Challenges

- Financial climate
- CPA POCT Stds / ISO 22870 compliance
  - Comparability of results
  - Connectivity
  - Technical validation
- Training & competency records (NHSLA / ISO)
- New technology – patient barcodes / RFID
- Fragmentation of PCTs
- Increasing demand
- Expanding repertoire – molecular

# Questions

