Point of Care Testing

What has that got to do with me?

Dr Mairiead MacLennan- Chair
Dr Sarah Glover
Mr Charlie Houston

Healthcare Science National Delivery Plan

CURRENT SITUATION

Roll-out and clinical governance of POCT (specifically in relation to quality control, application of MHRA guidance and overall healthcare science involvement) varies across NHS boards. This has significant implications for patient safety and patient flow.

OUR AMBITIONS

We want to:

- reduce unnecessary variation within and across NHS boards
- improve patient experience by reducing unnecessary secondary referrals
- reduce repeat testing and associated costs
- improve patient flow, access and monitoring.

DELIVERABLE 2

To achieve our ambitions, NHS board healthcare science leads will work with medical directors and clinical teams to develop a local implementation plan that ensures clinical governance and effective roll-out of point-of-care testing. This will be achieved by the end of 2017 in acute services and the end of 2018 in primary care, with full implementation by the end of 2020.

ACHIEVING DELIVERABLE 2

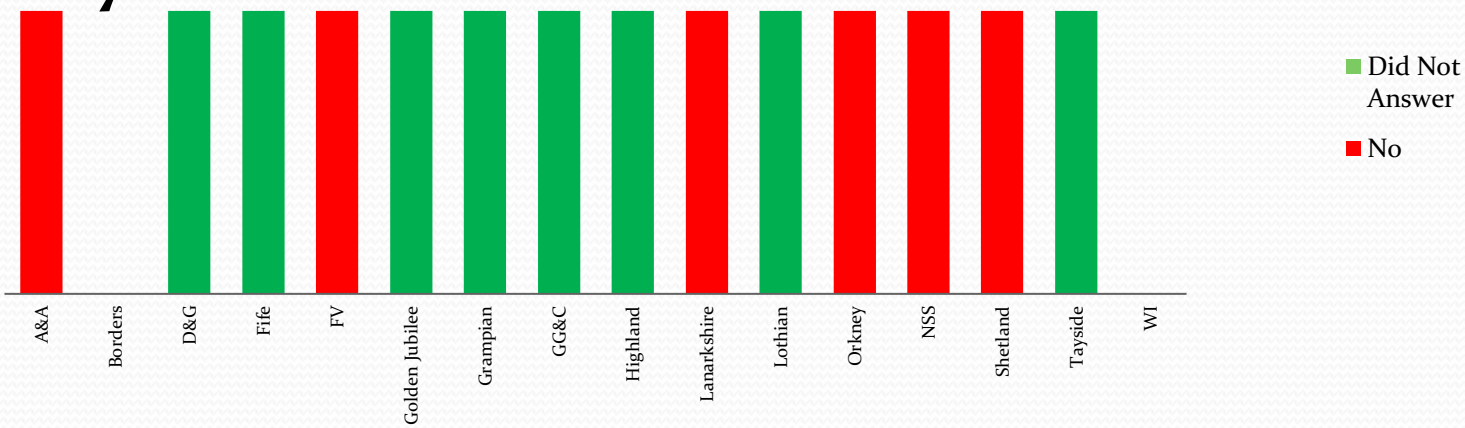
NHS boards will:

- participate in the national POCT programme on the use of POCT in primary and secondary care in Scotland (as described by the Scottish Medical and Scientific Advisory Committee (Scottish Government, 2011)), implementing local plans to ensure cost-effective implementation and governance of POCT systems and sharing knowledge across boards on how POCT technology benefits patient-pathway outcomes.

National healthcare science leads and NHS board healthcare science leads, managers and heads of services will:

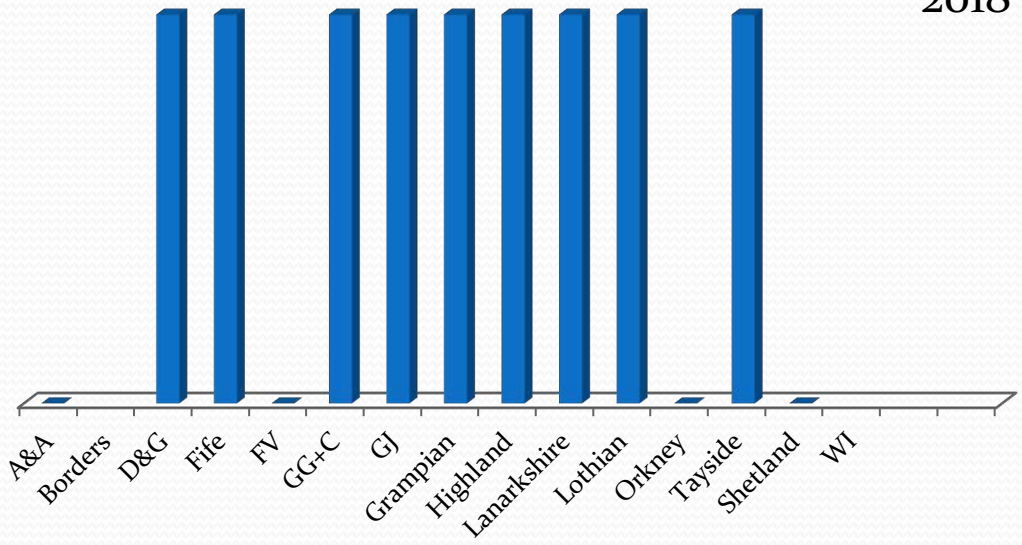
- work across disciplines to instigate whole-system improvements in the delivery of POCT in acute and secondary care settings.

2017



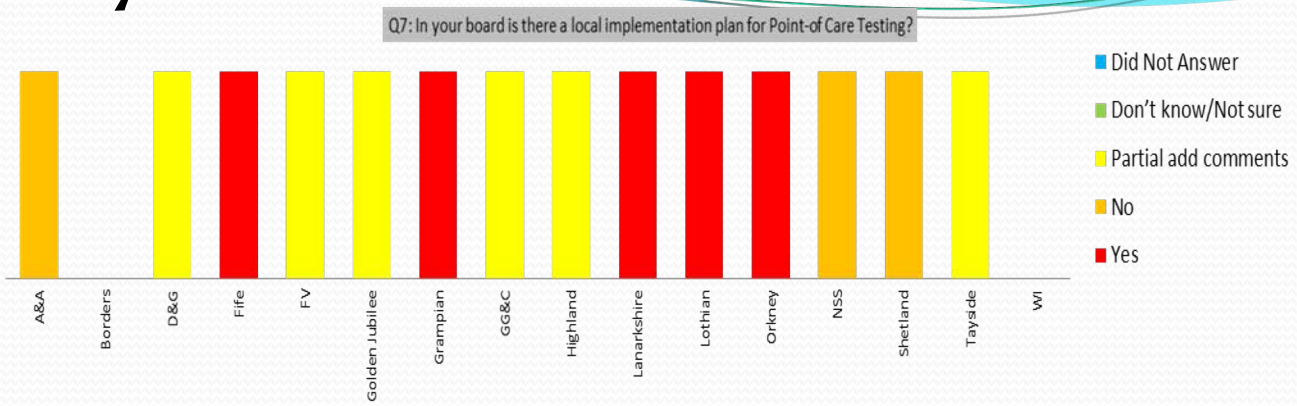
Do you have a POCT committee

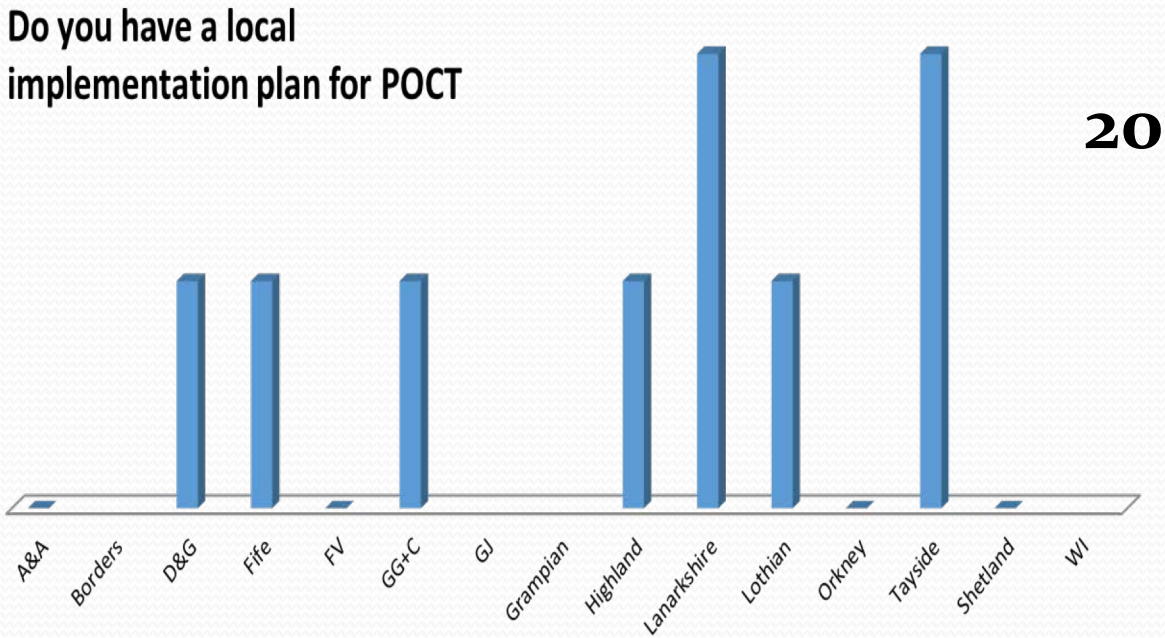
2017 – 8 boards
2018 – 9 boards



2018

2017


Q7: In your board is there a local implementation plan for Point-of Care Testing?
Did Not Answer
Don't know/Not sure
Partial add comments
No
Yes
A&A
Borders
D&G
Fife
FV
Golden Jubilee
Grampian
GG&C
Highland
Lanarkshire
Lothian
Orkney
NSS
Shetland
Tayside
WI


Do you have a local implementation plan for POCT
A&A
Borders
D&G
Fife
FV
GG+C
GJ
Grampian
Highland
Lanarkshire
Lothian
Orkney
Tayside
Shetland
WI

2018

Dr Sarah Glover

Harrogate and District NHS
NHS Foundation Trust

POCT: Achieving UKAS Accreditation
The Harrogate Experience

Sarah Glover
Clinical Scientist & POCT Clinical Lead

Introduction

* Background
* Applying for UKAS ISO Accreditation
* Preparing for UKAS assessment
* The assessment
* Non-conformances
* Surveillance visits
* How our service has improved
* Final thoughts

Background


Staithes
Whitby
Kirkby Stephen
Scotch Corner
YORKSHIRE MOORS
North York Moors & Coast
Scarborough
Hawes
Leyburn
Sedbergh
Thirsk
Helmsley
Pickering
Filey
YORKSHIRE DALES
Yorkshire Dales
Ripon
Ingleton
YORKSHIRE
Malton
Bridlington
Grassington
Knaresborough
Malham
Skipton
HARROGATE
YORK
Wetherby
Haworth
York & Yorkshire Wolds
Beverley
LEEDS
Withernsea
Hebden Bridge
Grimsby
Holmfirth
PEAK DISTRICT
SHEFFIELD

Background

- Harrogate District Hospital

- Ripon Community Hospital

Background

* Hospitals
* Outreach clinics
  * North Leeds
* Community
  * Integrated care teams
  * NY Dental services

POCT Department

* Sub-department of Blood Sciences
* 1.2 WTE Band 3 Practitioner
* 1.2 WTE Band 7 POCT Manager
* POCT Clinical Lead

POCT Accreditation

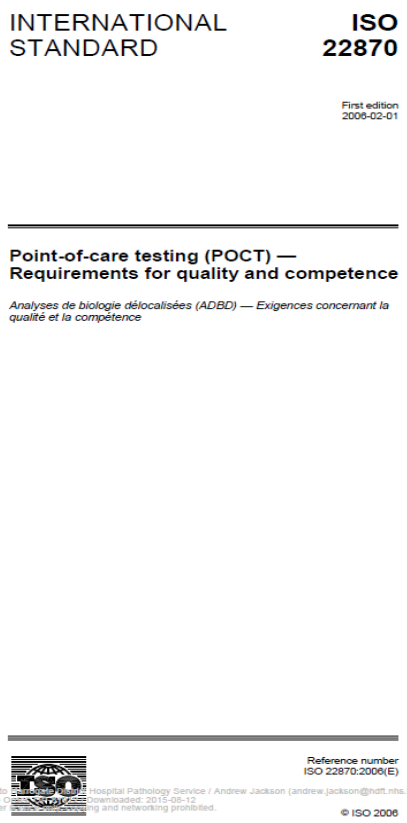
* 2007: Accredited as part of Biochemistry to CPA standards
* 2011: Accredited to CPA POCT standards
  * 2013: Re-assessed surveillance visit

* Jan 2015: Blood Sciences UKAS assessment
* March 2016: POCT UKAS assessment – ISO accredited

* October 2016 and 2017: Surveillance visits
  * Joint BS and POCT

Applying for UKAS ISO Accreditation

* ISO Accredited Pathology lab?
* Governance
* Scope?
  * Devices, locations, service users
* ? Pre-assessment visit
* Gap analysis
* Cost!!
* Application Paperwork



INTERNATIONAL STANDARD

ISO 22870

First edition
2006-02-01

Point-of-care testing (POCT) — Requirements for quality and competence

Analyses de biologie délocalisées (ADBD) — Exigences concernant la qualité et la compétence

Reference number
ISO 22870:2006(E)

Which Services Did We Include?

* 5 GEM 4000 blood gas analysers (ward based)
* 1 EPOC blood gas analyser (patient's homes)
* ~ 60 Abbott FPP blood glucose/ketone meters (hospital wards, community hospital, outreach clinics)
* ~ 30 Sterilab Urilyzer Pro urine dipstick analysers (hospital wards, community hospital, outreach clinics)
* 2 Alere Afinion HbA1c meters (hospital clinics)

What We Excluded!!

* Glucose meters used by community staff
* fFN meter
* INR meter
* Cholestech LDX meter (healthchecks)
* Drager Bilirubinometer
* CO meters

Preparing For The Assessment

* Initial Gap analysis - audits are a good tool
* Risk Assessments
* Updated documentation
* Training programs
  * Evidence of competency
* Committee and governance structure

What Was New For Us?

* Uncertainty calculations
* Reagent acceptance
* Asset management / record keeping
* Traceability
* Some aspects of verification
* Temperature audits

Preparation - What Worked For Us

* Gap analysis
* Task list: assign responsibilities & target dates
* Huddles!!

Task	Who	Due Date	Completed?	Comments
~~Fix access to Analyse IT~~	~~NH~~	~~16/10/2015~~	~~Y~~	~~Analyse IT now working~~
Write POCT method verification documentation and upload to Qpulse	SG	12/02/2018		To be approved on Qpulse and distributed
~~Complete verification documentation and attach to asset register~~	~~SG~~	~~23/10/2015~~	~~Y~~	~~INR still to be done~~
~~Staff Competency documentation & answers~~	~~NH~~	~~Y~~	~~Y~~	~~Done~~
POCT Manager competency sign-off	**EJ/NH**	**14/03/2016**		**Ongoing**
~~Address non-conformances from PXP vertical audit~~	~~NH~~	~~29/02/2016~~	~~Y~~	~~Ongoing~~
New Replacement device checklist to be created,	**CH**	**16/10/2015**		
~~Audit of Blood Gas Results in LabCentre and ICE~~	~~SG~~	~~16/10/2015~~	~~Y~~	~~Done~~
~~Address non-conformances from Blood Gas result audit (LabCentre and ICE)~~	~~NH/CK/SG~~	~~31/01/2016~~	~~Y~~	

Preparation - What Worked For Us

* Communicating regularly with UKAS
  * Interpretation of standards

* Multidisciplinary involvement in preparation:
  * Pharmacy
  * Suppliers
  * Clinical teams

Pre-Assessment

* Assessors requested documentation
* UKAS identified areas to be assessed
  * Devices
  * Locations

liaise with users, clinics etc

create a visit plan

Assessment Days!!!

* Lead assessor - Louise Davison
* 2 Technical assessors
* 2 full days on site
* Moderator- Delia Geary

Format of Assessment

* Opening meeting
* Lead assessor
  * All aspects of quality management system
* Technical assessors
  * visits & audits at locations on & off site
* Feedback & discussion throughout assessment
* Closing meeting

Challenges……

* Ensuring a user is performing a test at time of assessment!
* Expect the unexpected e.g. clinic cancellations
* Evidence
  * can you prove what you say?
* Time pressures - geography
* Running the service during the assessment!!!!

Improvement action Summary (IAS)

Organisation name:	Harrogate and District NHS Foundati
Customer number:	8646
Legacy UKAS Ref(s):	
Project number:	216860-00
Assessment type:	Extension to Scope
Date of issue:	23/Mar/2016

Finding ref	Assessor name	Location	Date finding raised	Clause and description of finding	Accreditation standard	Additional accreditation standards	Agreed/Proposed improvement action	M or R	Evidence required (Y/N)	Evidence due date
216860-00-E00998-001	Louise Davison [E00998]	QMS	22/Mar/2016	4.1 The organisation and management of POCT is not fully defined, e.g. the tiers of management/communication lines between the laboratory and staff performing POCT, and roles and responsibilities with regards the lab assuring themselves that staff performing POCT meet the requirements of the Standards	[HK004123] ISO15189	ISO 22870 4.1	Fully define the organisation and management of POCT	M	Y	14/Jun/2016
216860-00-E00998-002	Louise Davison [E00998]	QMS	22/Mar/2016	5.1.5, 5.1.7 The laboratory have not assured themselves that staff performing POCT meet the requirements of the Standards with regards to performance review, ethics and confidentiality of patient information	[HK004123] ISO15189	ISO 22870 5.1.5, 5.1.7	Training/competency record to be expanded to include specifics on ethics and confidentiality. To review and agree mechanism for meeting the requirements of 5.1.7, and supply evidence of implementation	M	Y	14/Jun/2016
216860-00-E00998-003	Louise Davison [E00998]	QMS	22/Mar/2016	4.1.2.2 The health professional grouping responsible to the Trust governing body for defining the scope of POCT to be made available is not clearly defined. In practice, decisions such as the approval of the new glucose meters cannot be demonstrated to have been made by such a group; in addition records do not demonstrate that the laboratory director or other suitably qualified person was responsible for selecting the chosen POCT devices/reagents.	[HK004123] ISO15189	ISO 22870 4.1.2.1, 5.1.2	Fully define responsibilities, and update appropriate group TOR.	M	Y	14/Jun/2016
216860-00-E00998-004	Louise Davison [E00998]	QMS	22/Mar/2016	4.2.2 The POCT/Pathology quality manual does not fully describe the management of POCT, for example in relation to: - management of data and information (does not include Gemweb and Unipoc - personnel management for staff performing POCT (e.g. induction, performance review) - POCT test requesting processes - ethical conduct including sharing barcodes,passwords, avoidance of collusion for EQA results - POCT user staff suggestions	[HK004123] ISO15189	ISO 22870 4.2.5	Update quality manual to fully reflect the POCT management system	M	Y	14/Jun/2016
216860-00-E00998-005	Louise Davison [E00998]	QMS	22/Mar/2016	4.3 The pathology document control procedure does not fully define the mechanisms for control of POCT documents such as control of distribution of hard copies, control of documents and instructions on the POCT section of the Pathology website. The instruction on the POCT section of the Pathology website are not document controlled. ISO 22870 is not adequately document controlled.	[HK004123] ISO15189	ISO 22870 4.3	Update document control procedure appropriately. Introduce a mechanism to adequately control information on the POCT website. Add 22870 information to Qpulse document master list	M	Y	14/Jun/2016

Non-conformances

* 37 mandatory non-conformances and 2 recommendations
* Main areas were :
  * Training
  * Product verification
  * Communication
  * Audit
  * Governance
* 12 weeks to address non-conformances

Key Issues

* Training
  * Practical evidence of competency
  * Professional responsibilities of users
  * Sample collection: ensuring users are competent
* Verification
  * Comparability between individual POCT devices
  * In-house QC ranges
  * IT verification

Key Issues

* Communication
  * Clear outline of communication channels with users
  * Providing evidence
* Audit
  * Record of audit training
  * Root cause analysis, follow up

Key Issues: Governance

* Very clear roles and responsibilities
  * Procurement of new services
  * Ownership of results
  * Test requesting
* POCT staff management competency assessment & CPD
* Multidisciplinary decision making

Non Conformances - Clearance

* Submission of evidence
* Most NCs cleared with first round of evidence
* All NCs cleared in 3-4 months

Accreditation Granted ☺

Surveillance Visits

* Every year
  * Full assessment every 4 years
* Oct 2016 - 2 days in POCT
  * lead assessor
  * 1 technical assessor
* Identified areas to visit
* Lead assessor followed up on any previous concerns & NCs
* 4 weeks to submit evidence – 4 NCs

Surveillance Visits

* Opportunity to add additional services / amend current services
* Extension to scope (ETS) for any changes
  * New analysers
  * Additional locations
  * Changes to devices / kits
* 2017 – Gem 5000 BG analysers installed
  * Assessed in Oct 2017
* 12 weeks to clear NCs if ETS

How Have We Improved?

* Ensures value for money for the Trust
  * In times of austerity, having a clearly defined quality framework ensures quality is not compromised for financial gain
* Informs users of their responsibilities to ensure the service is clinically & cost effective
* Benchmarked the quality of our service
  * Applying ISO standards to non-accredited areas

How Have We Improved?

* Standardisation & improved efficiency
* We identify issues sooner so fixes are quicker & easier
* Continuous evaluation of service provision
* Improved the quality of the POCT service

Before……

Preparation → Assessment Visit → Accreditation

Phew!

Preparation → Assessment Visit → Accreditation

… and After


Continuous service review:
quality objectives, quality indicators, audits etc
Preparation, visit plan etc
Assessment visit
Evidence for Non conformances
Accreditation
Quality

Main Challenges For Us Now..

* Ever growing service / Ever shrinking NHS budget!!
* Focussing on connectivity
* Working with manufacturers to improve device functionality to help achieve ISO standards

Final Thoughts

* UKAS accreditation – not easy but achievable
* Accreditation is valid for specific devices
* ISO standards provide a good template to work towards in achieving a quality service
  * Which areas will benefit the service most?
* One solution does not fit all
  * There are many way to achieve conformance to the standards

Thank you for your time

Sarah Glover

Clinical Scientist & POCT Clinical Lead

Harrogate and District NHS Foundation Trust

sarah.glover@hdft.nhs.uk

Plans for the Future

- What are the top challenges in a reliable POCT System
- What do you want to see happening in Scotland
- What should a national policy cover
- National POCT coordinator Group- What Role?
- What approach would services find supportive and useful to ensure consistency and to avoid duplication of effort

Plans for the Future

Is the preferred approach:

- Collectively across disciplines across Scotland
- Collectively within disciplines across Scotland
- Collectively across disciplines within boards
- What about ISO 22870