POCT accreditation

A practical approach

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Southwest London Pathology (SWLP)

SWLP

- **X4 NHS Trusts in Southwest London**
- **Hub is based at St George's Hospital**
- **100s of specialities including Majors Trauma**
- **Serving a population of > 2.5m people**
- **>10000 POCT service users**
- **Community POCT services**

Accreditation: Why?

- Maximise patient safety and improve patient outcome
- Increase the service users' confidence in the service
- Good way to demonstrate competence in the laboratory
- Mitigate risks, errors, and litigation
- Service/laboratory recognition: National & Worldwide
- Instrumental for continual service improvement
- Business development and service growth
- Boost laboratory staff morale and confidence
- Mandatory
- Prestigious!.

ISO15189

- **Organisation of management**
- **Personnel**
- **Equipment**
- **Purchasing of inventory: Analysers and reagents**
- **Process control : IQC, EQA**
- **Document Control**
- **Information Management**
- **Risk management**
- **Assessment :EQA and interlaboratory comparison**
- **Process improvement**
- **Service satisfaction**
- **Facilities and safety**

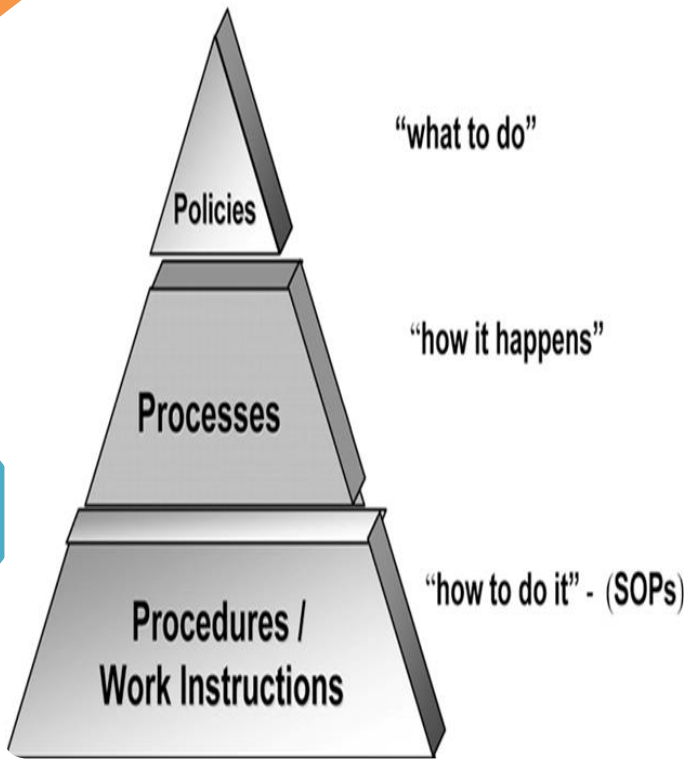
ISO 22870…

Now Incorporated in 15189:2022

- **POCT governance: POCT committee**
- **POCT policy and guidelines**
- **POCT meetings**
- **User training and competency assessment**

POCT accreditation

- The aim is to review the 12 areas of ISO15189.
- Self-assessment
- Identify the gaps.
- Action plan!



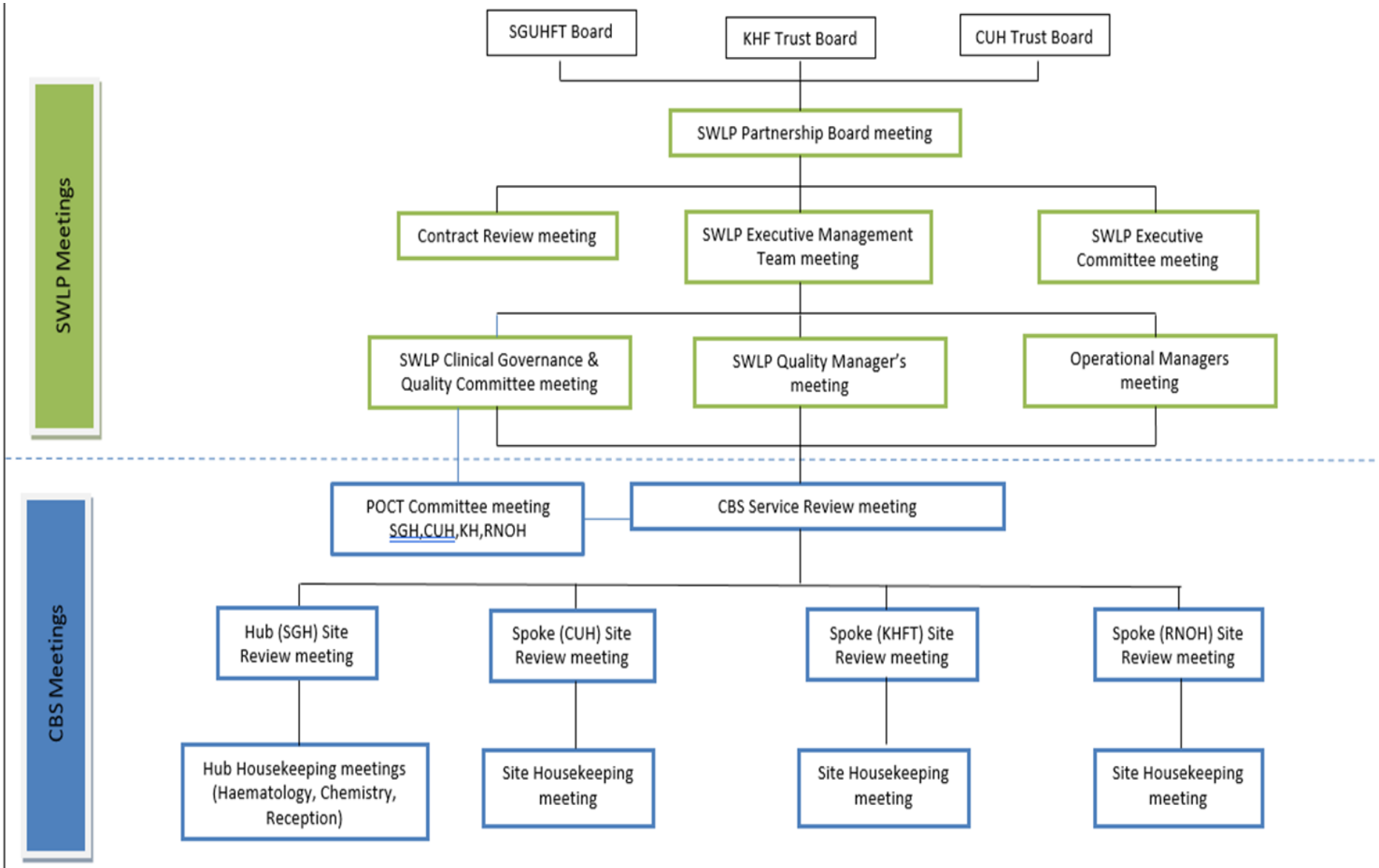
POCT governance: POCT committee??

- No longer mandatory in 15189:2022
- Committee meetings! AMR
- Representation from all stakeholders
- Accurate record of meetings including actions
- Process for introducing new POCT services.
- Reports to Trust Clinical Quality & Governance Committee, Laboratory Quality Meetings, Laboratory Clinical Governance Meetings, and contract meetings.

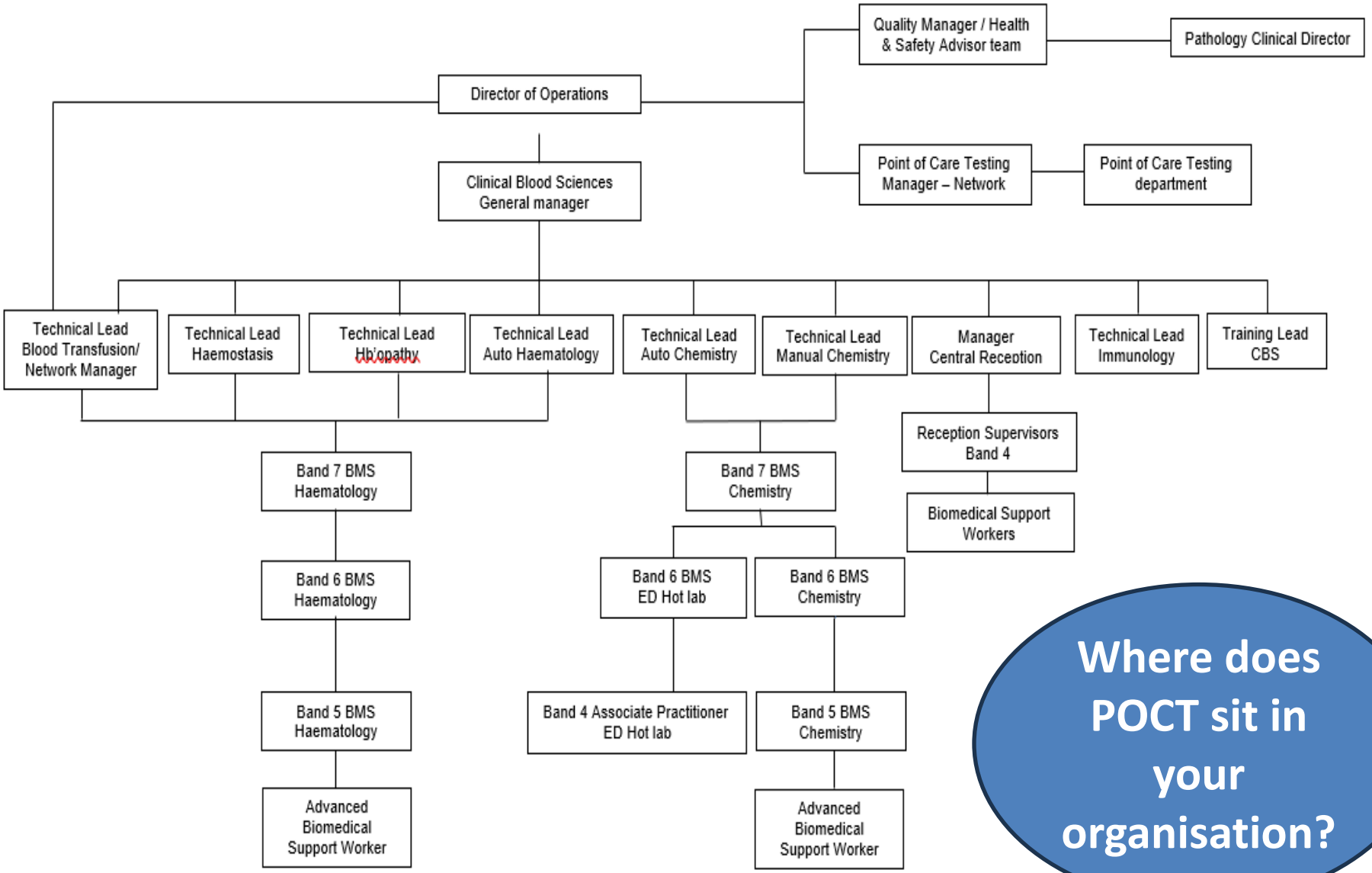
POCT Policy and Guidelines:

- Is POCT covered in your quality manual?
- Safe and effective management and use of POCT systems
- Fit for their intended purpose
- Competent users
- Correct patient
- Quality results >>> (EPR).
- Primary and secondary care settings

Organisation:



Organisation: Departmental organogram



Where does POCT sit in your organisation?

SWLP POCT team

- POCT clinical lead
- General Manager
- POCT manager – Network Lead
- POCT Quality Manager- Network
- POCT coordinators: x1 per site
- POCT Specialist Biomedical Scientist
- POCT clinical Scientist - Network
- POCT IT systems administrator
- POCT implementation specialists
- POCT trainer and training facilitator
- POCT Associate practitioner
- POCT Advanced Biomedical Support workers

A stand-alone Pathology Discipline

Gap Analysis:

POCT ISO 15189 Self Assessment Report

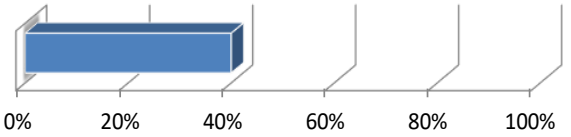
Area Details	
Site	
Service	SWLP
Department / Laboratory	POCT
Operations Manager	Haval Ozgun
Quality Manager	Faye Browne
Telephone	
Fax	
email	

Assessment Details	
Date of Self Assessment	
Assessor(s)	

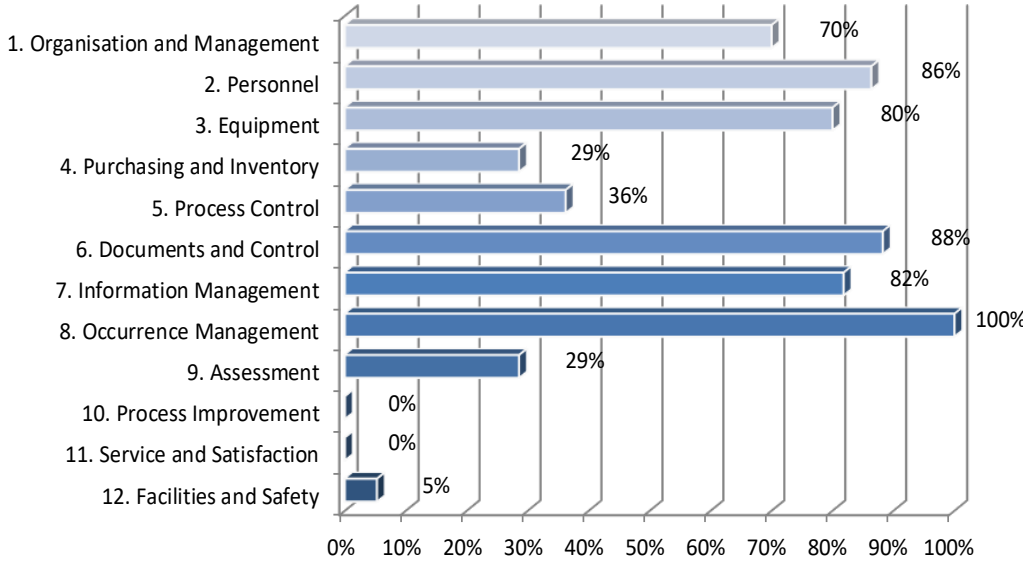
Action Log Summary	
Status	**Count**
Compliant Requirements	65
Actions Outstanding	29
Action Progress	**84%**

Total Compliance

Overall Progress **40%**



Quality System Essentials - Point by Point Compliance



4. Management Requirements - Point by Point Compliance **Overall Compliance 41%**

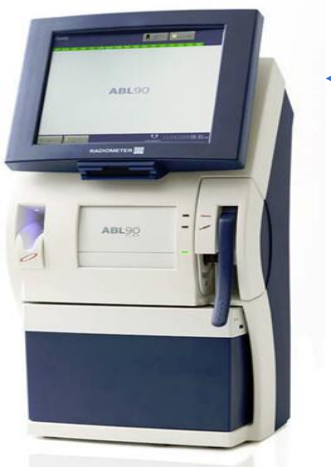
Technical Assessment:

- V & V: Acceptance criteria
- System suitability report
- IQC performance review: IQC reference ranges
- MOU
- EQA review: Dashboard
- Training & Competency: Records/policy/ plan
- Results interface: End to End validation
- Reagents: Acceptance and Storage
- Observation of users' interactions with the analysers

Technical Assessment:

IT - Middleware - EPR

Users should be able to confirm the patient's ID prior to performing the test



Patients' demographics ADT feed

Patient's demographics

Patient's results

AQURE: POCT middleware

Supported remotely by the Radiometer IT team

Trust IT controls the messaging between the application and the hospital system(s)

Trust Integration Engine (TIE)

Electronic availability of results.

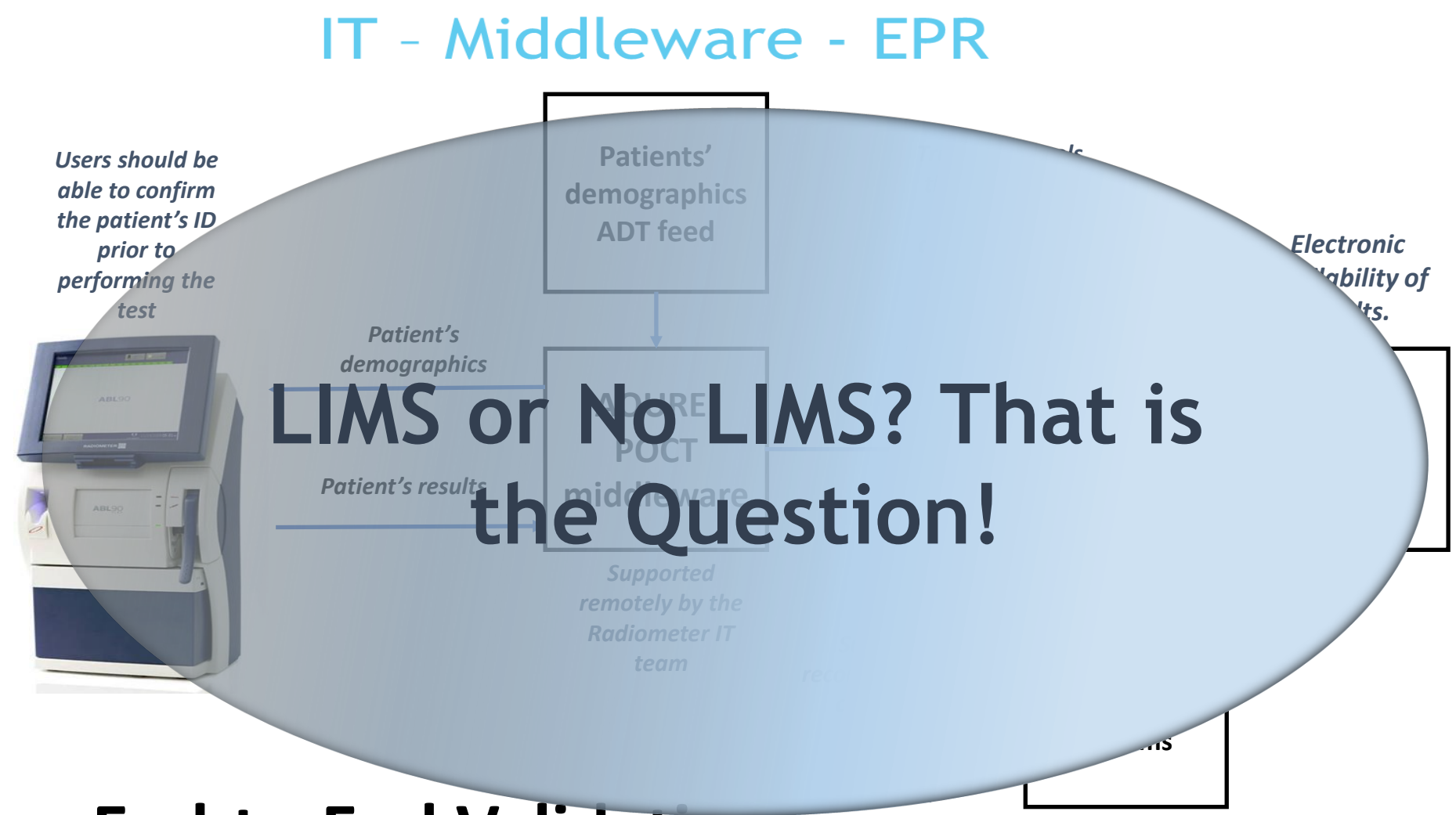
Electronic patients records (EPR)

Such as GP records, infection control and hospital informatics system.

Other downstream systems

End-to-End Validation

Technical Assessment:



LIMS or No LIMS? That is the Question!

End-to-End Validation

QMS Assessment:

- Quality manual & POCT policy
- Roles and responsibilities: JDs
- Governance: Meetings (Departmental, quality, and AMR)
- Risk management
- Communication: Pathology handbook, POCT Webpage
- Audit: Schedule to cover all aspects of POCT (Clusters!)
- Document control: Hard and electronic copies
- Risk management: Reporting and Management of incidents
- POCT Personnel: Induction, Appraisal, training records
- User feedback: User survey, Annual Management Review (AMR)
- Service level agreements, Supplier review, Contract review etc..

POCT Audits:

- Designing your audit schedule:
- Risk-based approach / UKAS Findings
- Service clusters: Adult, Paediatric and Neonatal
- Acute: ED, ITU, Labour, theatres
- Non-acute: Medical wards, outpatients
- Staff number and turnover
- Number of incidents raised
- Must be based on and with reference to a standard.

POCT Audits:

Designing your audit schedule:

1	2	3
• Known Issues – Incidents • Non-conformances raised in the last 2 years • No re-audit performed • UKAS findings	• No Issues • Non-conformances raised in the last 2 years • No issues were identified at the reaudit • UKAS recommendations	• No Issues • No Non-conformances raised in the last 2 years

POCT Audits:

Vertical Audit	Witness Audit	Horizontal Audit
5.1.5 Training 5.1.6 Competence 5.3.1 Equipment 5.3.2 Reagents and Consumables 5.4 Pre-examination 5.5 Examination 5.6 Ensuring Quality of Examination Results 5.7 Post-examination 5.8 reporting of Results 5.9 Release of results	4.3 Document Control 5.1.5 Training 5.1.6 Competence 5.5 Examination 5.6 Ensuring Quality of Examination Results	4.13 Control of records 4.14 Evaluation and Audits 4.15 Management Review 5.2 Accommodation and Environmental Conditions 5.3.1 Equipment 5.3.2 Reagents and Consumables 5.4 Pre-Examination Processes 5.6 Ensuring Quality of Examination Results 5.7 Post Examination Processes 5.8 Reporting of Results 5.9 Release of Results

Outcome:

Findings	Recommendations
Mandatory resolution with evidence 3 Months timeframe Use to inform audit schedules	Not mandatory to act on Use as a guide for service improvement They may be raised in surveillance visits

Quality Manual incorporating POCT POCT policy and guidelines Pathology user hand book Management of personnel POCT committee and departmental meeting minutes Quality Policy POCT annual Management Report	Induction checklist Management of Personnel Staff training folder Training policy Appraisal policy and records POCT End -user training policy and procedure
POCT Management of Materials Temperature monitoring charts and documents Reagent acceptance logs The management and oversight of POCT reagents. Middleware SOP, verification reports.	Document control policy Qpulse POCT process and quality records policy SOPs Procurement and management of equipment SOP POCT management of materials SOP Examination SOP Training policy and SOP
Identification and Control of Non-conformities Rick and incident management policy Quality reports Examples of incidents including serious incidents and impact on patients. Documentation of remedial actions, root cause analysis, and preventative actions.	EQA report (dashboard) / Discussions in POCT meetings Investigation of EQA failure AMR V&V reports IQC reviews with clinical sign-offs MoU calculations Referral laboratories N/A
Audit schedule, reports, findings, dealing with non-conformance. Evidence of halting patient testing / withholding results when QC and or Calibrations fail: AQURE!! Witness audits: End-to-end investigation of non-conformances. POCT Internal Audit Procedure/Audit Action Plans Quality reports	POCT committee meeting minutes Monthly POCT departmental meetings User survey / Service review meetings/ SLAs Monthly POCT activity reports Fortnightly POCT operational meetings Site-specific service review meetings User handbook
Temperature audits, premises audit Health and safety audits First aid box / Nominated first aid staff/fire wardens / corporate health & Safety and environmental policies.	Review of suppliers document / MES contract review minutes Procurement and management of equipment policy Verification and validation document Change control documents All relevant SOPS Asset register: Service reports

ISO15189:20222

What's new?

ISO15189:20222

What's new?

- **Risk management**
  - Risk analysis, control, Appetite/acceptability, monitoring.
  - Risks that can impact on patient care and outcomes
  - Business continuity and contingency plans: Evidence of testing and effectiveness?

- **Service agreements:**
  - POCT service level agreements which define service specifications and KPIs.
  - Contract meetings!

POCT SLAs

Southwest London pathology hosted by
St George's University Hospitals NHS Foundation Trust Situated at Blackshaw Road, Tooting, London, SW17 O0T

And

Croydon University Hospital

For the Provision of Point of Care Testing services

(Blood gas and ketone analysis services)

Period covered:

From **01/01/2021 – 01/10/2025**

SOUTH WEST LONDON PATHOLOGY HOSTED BY
St George's University Hospitals NHS Foundation Trust Situated at Blackshaw Road, Tooting, London, SW17 O0T

And

St. George's Hospital NHS Foundation Trust – Diabetes department

For the Provision of Point of Care Testing services

Period covered:
From **01/08/2021 – 01/10/2025**

SOUTH WEST LONDON PATHOLOGY HOSTED BY
St George's University Hospitals NHS Foundation Trust Situated at Blackshaw Road, Tooting, London, SW17 O0T

And

St George's Hospital NHS Foundation Trust

For the Provision of Thromboelastograpghy (TEG6) analysers

Period covered:
From 01**/05/2020 – 01/10/2025**

Lessons and Recommendations:

- Harmonisation of POCT
- Understand the standard …. Purchase a copy.
- UKAS is ***not*** an advisory body!
- Use your existing QMS
- Extension to Scope
- Choose no more than 2 services to start with
- If multiple sites: Start with one site
- Detailed and evidenced Gap analysis
- Team engagement: Everyone has a role!
- Engage with service users
- A project plan and progress tracker
- Pre-assessment: Do not hide anything!
- Application & Assessment: Act on findings and recommendations
- Maintain the accreditation: Surveillance visits

Questions?


Obrigado
감사합니다
Gracias
Merci
شكرا لك
Thank you
Danke
謝謝
Ευχαρι