Clinical Microbiology and Infection Control - molecular technology and quality control in microbiology laboratories

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Microbiology service

- Basic requirements
  - Reliable service
  - Accurate results
  - Interpretation and advice

- Underpins patient safety

- Depends upon
  - Quality control (internal process control)
  - Quality assurance (external system check)
Traditional approach

- External quality assurance
  - Challenge analytical capability
  - Externally provided QA samples
  - Result is what matters!

- UK NEQAS – essential part of quality system (>30 years)

- Internal quality control
  - Individual laboratory responsibility
Is this enough?

- Changes in
  - Laboratory practice
    - Science replacing art!
    - Genetic and chemical analyses
    - Automation, commercial systems and kits
    - Concerns for sensitivity, specificity, PPV, NPV
  - Management and organisation
  - Cross-specialty methodology

- Demands standardisation and QC of processes, with formal records
Traditional bacteriology

- Culture on media; identify by phenotype; sensitivity test by culture
- QC – *an inexact science*
  - Growth and identification of a reference strain
  - Susceptibility of a ‘control’ strain
Virology

- Less reliance on microscopy (EM) and tissue culture – both rarely used
- Antigen detection & molecular methods
  - Automation; commercial reagents and kits
- QC essential for validity and reliability
  - Standardised material
  - Every run/analysis
  - Records retained
Microbiology

- Automated virology tests in ‘microbiology’
- Equipment/systems shared with other pathology specialties
- Molecular testing for
  - Bacteria, virulence factors, resistance determinants
- Roll out from specialist and reference laboratories
HCAI drivers

- MRSA screening – rapid (PCR) or conventional
  - All elective admissions by March 2009
  - All admissions by March 2011
- *C. difficile* diagnosis
- Norovirus
- Real time typing?

...*how to implement in clinical practice?*
QC...not just an internal issue

Accreditation (CPA/UKAS) - 17 years on
- Basic requirement of commissioners
- Pathology Modernisation
  - Standard for plurality of providers
- Health Act 2006 Code of Practice
  - Requires HCAI support from accredited lab
- Commissioning guidance for TB services
- Public Health Bill 2007- lab reporting

.....an external marker of quality
Standardised QC

- Each step of analysis
- QC material in every run
- Record result with QC material for inter-run comparisons
- QC materials to be standardised and generally externally sourced

A very different approach from traditional microbiology!
POC testing

- Who is responsible?
- Who does the QC and QA?
- Accreditation?
- Links to laboratory systems?