

# Standards for microbiology laboratories

Brian I. Duerden

*Inspector of Microbiology and Infection  
Control*

*Department of health*

**Why an Inspector?**

**Infection is different.....**  
**(from other medical and**  
**pathology disciplines).....**

***.....it spreads!***

# *The Challenge*

How to protect individuals and  
the population overall against  
infection

# Getting Ahead of the Curve

- Emphasis on Health Protection
- Emerging threats
  - Infections, chemicals, radiological
  - Natural events
  - Deliberate release and bioterrorism
- Priorities identified
- Health Protection Agency to be created
- NHS responsibilities to contribute to HP
- Microbiology standards - Inspector

# Inspector of Microbiology

- Conceived January 2002
  - *Getting Ahead of the Curve*
- Formulated July 2003
  - *Job description and advert*
- Appointed October 2003
- Commenced January 2004

# Inspector of Microbiology

- Champion & promote high quality clinical & public health microbiology
  - all labs in NHS contribute to surveillance
  - promote standards & quality
  - identify gaps in specialist & reference micro.
  - achieve adherence to SOPs
  - protocols to reduce the risk of loss/misuse
  - compliance with security
- Links with devolved administrations and internationally

# Relationship with CPA

## ■ Standard A2

– Needs and requirements of users

- Determine the needs and requirements
- Specify as objectives
- Regular review

# Who are users (stakeholders)?

- Commissioners & funders; clinicians
  - PCTs, NHS Trusts/FTs
  
- SofS, Gvt, DH, NHS (ultimate funder)
  - CMO, Inspector of Microbiology
  - RDsPH, SHAs
  - HPA

# Form of requirement

- Legislation
  - Health Bill 2006
- Ministerial statement in Parliament
- DH Policy publication
  - Getting Ahead of the Curve
  - Winning Ways
- CMO statement
  - *C. difficile* surveillance

# ***Vision and Goal***

**An integrated and cohesive, quality assured microbiology and virology service to support clinical care of patients with infection and for health protection.**

# Delivered by

- Microbiology and Virology services in
  - NHS Trusts
  - the HPA
  - Universities
  - the private sector
- *Working in partnership*
- Accredited
- Qualified and trained staff
- Quality assured through inspection

# Requirements of laboratories

- Agreed SOPs and algorithms
  - Contributing to development and evaluation
- Safety and biosecurity
  - HSE and HO requirements
- 24/7 access to local service and expert support from regional/national network
- Outbreak investigation, look-back exercises

# Requirements of laboratories (2)

- Reports to CCDC, RE, CDSC for routine surveillance programmes
- Contribute to enhanced and sentinel surveillance
- Provide samples to reference laboratories
- Food, water and environmental coverage
- Immediate local support for deliberate release or other incidents
- Training .....range of professional groups

# Algorithms and SOPs

- Pre-laboratory
  - What specimens from which patients
- Pre-analytical
  - What investigations – agreed range of agents
- Analytical SOPs
  - Standardised, quality controlled
- Post-analytical
  - Interpretation; reporting to clinicians
  - Reporting to HPA – surveillance, outbreaks
  - Refer isolates to reference laboratories

# Health Care Standards

- Healthcare Commission (CHAI)
- Seven domains
  - ***Safety***
  - Clinical and Cost Effectiveness
  - ***Governance***
  - Patient Focus
  - Accessible and Responsive Care
  - Care Environment and Amenities
  - ***Public Health***

# Accreditation required!

- Ministerial Statement, HoL, July 2003
- Healthcare Commission
  - Criterion in annual health check
- Health Bill 2006
  - Code of Practice for Infection Control

Laboratory support from an accredited  
laboratory

# Who provides Quality Assurance for Microbiology?

- CPA & UKAS
- HSE
- NEQAS
- Professional bodies
  - training
  - qualification CPD
- ***All contribute to the quality package monitored by the Inspector and the HC***

# Expectation of accreditation

- Quality of laboratory work and professional interpretation
- Quality of patient care
- Fulfilling Public Health/Health Protection functions

# Role of the Inspector

- Ensure that it happens
  - With all stakeholders
  - Develop a networked, consistent service
  - Working to agreed standards
- Ensure that the clinical and public health requirements are reflected in HC inspections and in performance management by Strategic Health Authorities

# How?

- Work with key stakeholders
  - Microbiology/virology services
  - Users & recipients of services
  - Standards and accreditation bodies
  - Health & safety and Security
- Develop standards with ownership
- Establish inspection criteria with HCC to reflect the standards
- Ensure consistency