

# relazioni

## SESSIONE 6

### Technology assessment in microbiologia

Giovedì 4 ottobre 2007, ore 09.00 - 11.00, SALA BIANCA

#### S6.1

#### ASSESSING TECHNOLOGY AND METHODOLOGY IN CLINICAL AND PUBLIC HEALTH MICROBIOLOGY LABORATORIES IN THE UK

**Bevani, V.**

*Evaluations and Standards Laboratory, Centre for Infections, Health Protection Agency, London, NW9 5EQ, United Kingdom.*

Microbiology / virology laboratories in the UK respond to a number of drivers to assure the quality of the work undertaken. Within an overall quality assurance framework, the Health Protection Agency (HPA) assumes a leadership and influencing role in clinical diagnostic and public health laboratories. The talk will describe how the Evaluations and Standards Laboratory (ESL) provides a service to labs in the UK and more widely in Europe and globally on many aspects of quality, focussing on three aspects: the development of national standard methods, assessment of medical and other healthcare related devices, and the use of internal quality control programmes for virology / serology. National Standard Methods, comprising standard operating procedures (mainly for bacteriology), clinical testing algorithms (mainly for virology / serology), overarching syndromic algorithms, and guidance notes are designed to guide clinical diagnostic microbiology and public health laboratories in their laboratory testing regimes. The collection of over 200 National Standard Methods have been drawn up under the curatorship of the HPA over the last ten years by multi professional working groups from professional organizations and laboratory networks from throughout the UK. National Standard Methods are well referenced, regularly updated and represent a good minimum standard for laboratories to comply with; they also help with complying with accreditation requirements. The documents undergo wide consultation with >1000 password holders worldwide and are freely available via the Internet [www.evaluations-standards.org.uk](http://www.evaluations-standards.org.uk). We have a close rela-

tionship with AMCLI and the methods have been translated into Italian and are freely accessible via the Italtbioforma website <http://fad.italbioforma.it/P5.asp>.

The presentation will also describe how the HPA-Microbiological Diagnostics Assessment Service assesses the performance of microbiological *in vitro* diagnostic devices (IVDDs) and associated equipment used to diagnose and manage infection. The UK approach to evaluating medical devices will be described including some of the issues and dilemmas currently facing microbiology / virology in the UK. Another of our remits is developing quality control programmes and supplying quality control reagents to help laboratories monitor the performance of their kits and equipment. The benefits of such a system will be presented, highlighting some interesting findings showing the value of the monitoring.

#### S6.2

#### IL PROCESSO DI VALUTAZIONE DELLE TECNOLOGIE SANITARIE

**Lauria F.N.**

*Ist. Naz. per le Malattie Infettive "L. Spallanzani" Roma*

**Introduzione.** L'evoluzione tecnologica e la crescente complessità dei trattamenti sanitari utilizzati impone la necessità di attuare un sistematico processo di valutazione prima di introdurre una tecnologia nella pratica clinica corrente, considerando le diverse esigenze tecniche, organizzative, di efficacia e di efficienza. Gli esami diagnostici rappresentano la logica estensione dell'esame clinico del paziente: l'uso delle informazioni che derivano da un esame diagnostico è quello di confermare o meno un sospetto clinico ovvero di discriminare tra due diagnosi. Infatti, una prestazione diagnostica è di solito richiesta per: confermare o respingere una ipotesi diagnostica; fornire informazioni circa l'eziologia di una determinata patologia; indicare la presenza di complicanze comprese quelle indotte dalla terapia; fornire informazioni sulla prognosi; monitorare la risposta al trattamento; diagnosticare una patologia nella fase