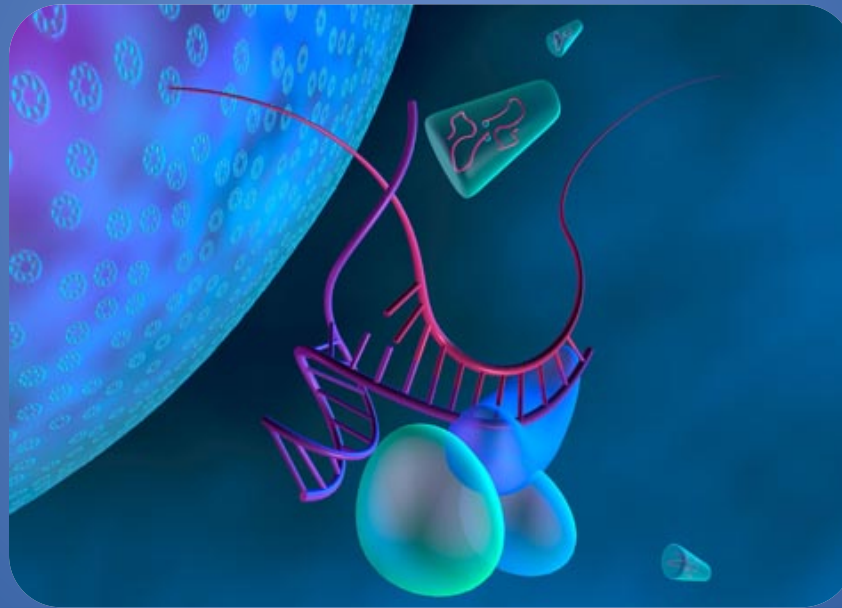


Technology transfer

HIV-1 Molecular Diagnostics:

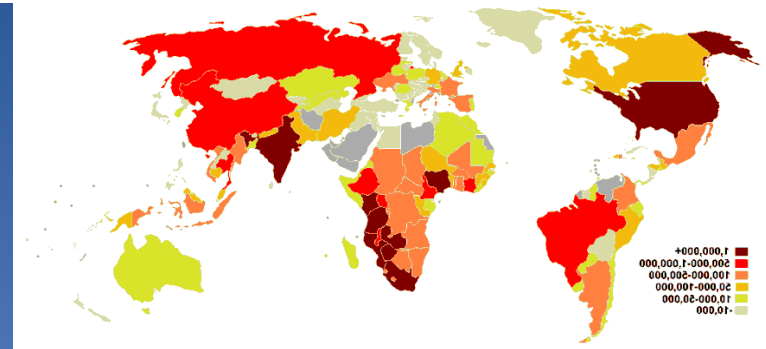
Experiences and lessons learnt



Laura-Lee Boodram
Technical Coordinator Molecular Biology
CAREC
Laboratory Division

11th Meeting of Caribbean
National Epidemiologists and
Laboratory Directors
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Background



- Caribbean prevalence (2nd highest world wide) – 240,000 adults and children living with HIV/AIDS (WHO/UNAIDS 2009 global report)
- Over past 10 year period Caribbean governments have scaled up access to ARV treatment
- Monitoring of patients using ARV treatment essential – clinical decision monitoring, programme evaluation
- Key laboratory services required – HIV viral load testing, CD4 testing, drug resistance testing

CAREC HIV

Laboratory Activities

- Establishment of HIV-1 viral load and CD4 testing capacity at CAREC between 2002 – 2005
- CD4 testing technology transfer: 2006 – 2007. Capacity established in several CMCs
- Initial difficulties with viral load testing : Reliable sample transport/maintaining cold chain from countries to CAREC not easily achievable
- CMCs with high need; able to source funding; established in country capacity for VL testing.

CAREC HIV

Laboratory Activities Cont'd

- 2007: Sample transport difficulties resolved_(mostly) - Use of PPT tube, transport of plasma on wet ice using courier.
- New specimen collection transport and guidelines issued
- CAREC able to expand testing services to OECS countries.



HIV-1 Viral load testing



- Trinidad and Tobago major client. Prevalence HIV/AIDS cases – 20,255 (Sept 2009, NSU TTMOH)
- 2005 – 2010 : 1200 – 1800 annual test requests from all major RHAs
- February 2008: introduction of HIV-1 DNA PCR testing for EID: 200 – 250 test requests per year.
- 2008 – Realignment of CAREC's core functions to support primary surveillance mandate. Transfer of technology initiated for molecular diagnostic testing.

Transfer of technology: the process

Transfer initiated with TTMOH in late 2008, completed July 2010.

Steps in transfer process:

- ✓ Selection of site for new laboratory
- ✓ Selection of testing platform
- ✓ Upgrade site physical infrastructure
- ✓ Purchase equipment and supplies
- ✓ Equipment installation and training of technologists
- ✓ Equipment validation
- ✓ QMS system
- ✓ Monitoring and supervision



Laboratory site selection

EWMSC

- ✓ Central location
- ✓ Space (no. of rooms/layout) and physical infrastructure requiring medium level upgrade
- ✓ Organizational structure (personnel)



Equipment selection

COBAS Ampliprep/Taqman 48 (Roche Diagnostics)

- ✓ Robust, high throughput, automated
- ✓ Backup (Platform already in operation at MRF)
- ✓ Technical and engineering support locally available

Training

- Staff with prior training in Molecular Biology theory/techniques advantageous – learning curve, ease of implementation, trouble shooting
- Problem high staff turnover



Equipment validation

- Switch from COBAS Amplicor to CAPTM48 platform
- >90% concordance between results
- Difficulty: Higher sample volume required for CAPTM48 platform



QMS system

- Documentation:

SOP development: Specimen collection guidelines, specimen receipt, sample storage, test methods, equipment operation, data entry and reporting, general operations, etc.

- IQA, EQA

- Future accreditation



Monitoring and Supervision

- Short term (following implementation):
Issues with sample collection: volumes,
DBS quality; technical queries
- Future:
To be determined at the regional level.