

# **EDCTP Stakeholder Meeting on HIV**

# Online Consultation Feedback

# 1 Introduction

In preparation for the meeting, EDCTP has set up an online consultation to gather views from stakeholders. The end result is expected to be a concrete set of recommendations through an open consultative process that involves a broad range of stakeholders from academia, industry, foundations, non-governmental organisations, civil society, governments and other interested parties working in the field of HIV.

The comments and recommendations will inform discussions at the respective meetings and where appropriate contribute to EDCTP strategy in this field. The feedback from the online consultation is presented in this document as they have been submitted. These will also feature in the final meeting report.

# 2 Online Consultation Feedback

## Dr Eleni Aklillu

Karolinska Institute, Sweden

## Current status of the field

The use a short course of nevirapine to mothers during labor and to newborns post-partum reduces the risk of mother-to-child transmission (MTCT). However, recent data suggest that such short-term successes may be at the expense of resistance and viral failure once treatment is introduced after delivery. ARV Pharmacokinetic studies in Children are scares in Africa. The Dose-treatment response needs to be investigated well. Drug interaction between ARV and drugs used to treat coinfection such as tuberculosis and fungal infections remains challenge. Mentoring adverse events and toxicity during ART is another challenge that often insidious, progressing unnoticed until the patient's health has been seriously impaired. For instance; zidovudine-associated anemia, nevirapine and efavirenz-associated impaired liver function, and didanosine-associated pancreatitis, efavirenz associated/CNS toxicity. Identifying the underlined pharmacologic or pharmacogenetic biomarkers for early identification of susceptible individuals before their health is seriously comprised may improve success ART.

# **Future Directions**

Extensive clinical research is a key.

### The role of EDCTP

Identify key research areas and provide funding.



### Dr Peter U Bassi

APIN Ltd - UMTH

## Current status of the field

- Access to care, ignorance and poverty
- Adherence to ART and Monitoring of ADR is also a problem

#### **Future Directions**

Viral Load and CD4 should be a mosr. All PHP in ART to have pharmacovigilence system in place

### The role of EDCTP

They should introduce fellowship in ART pharmacovigilence to support clinicians in the field. APIN Nigeria has developed a lab for viral load monitoring & this need be sustained through funding and training.

#### Mr CIZA Bonne

Public Health Center of VUGIZO

### Current status of the field

- There a lack of necessary and sufficient funds towards the three PRDs
- Poor implication of Governments and other stakeholders
- Lack of infrastructures, materials, Drugs and other consumables
- Scarcity of competent and skilled personnel
- Lack of good policies, guidelines
- Lack of Awareness within community
- Concentration is mostly focused on treatment than prevention." Prevention is better than cure"
- Lack or poor partnership and network
- Lack of strong and reliable prevention (Vaccines)

# **Future Directions**

- Make necessary and sufficient funds available: Strengthen the Global fund for three PRDs and create further funds resources
- Governments and other stakeholders should be strongly involved
- Define good policies and guidelines
- Make available prevention and treatment services to all in need and provide necessary materials, infrastructures, drugs and other consumables
- Train personnel and transfer knowledge
- Strengthen research for PRDs and advance it to find good prevention(Vaccines)
- Strengthen Collaboration, partnership and network
- Raise Awareness amongst people

### The role of EDCTP

- Funding research work
- Funding projects or initiatives looking for the three PRDs control
- Strengthening partnership, collaboration and network between professionals,
   Governments, Funders, research institutions and other stakeholders
- Training and Knowledge transfer
- Capacity building

Key players: - Governments, WHO, Professionals involved in PRDs control, Research institutions, Various Funders and other stakeholders, Health institutions, People.



# **Prof Francesco Castelli**

Head of the Department of Infectious and Tropical Diseases at the University Hospital in Brescia, Italy

### Current status of the field

Key barriers:

- Qualified human resources
- Socio-cultural aspects
- Infrastructures
- Co-infections

### **Future Directions**

- New training procedures (north-south sandwich programmes)
- Decentralize interventions
- Bed-side laboratory testing for monitoring efficacy and toxicity
- Research on major co-infections (TB, HBV, HCV, malaria)

### The role of EDCTP

Promote and fund research activities, both basic research, operational research and pharmaceutical research. Promote training for clinical researchers and ethical board members.

### **Dr Alex Coutinho**

Executive Director, Infectious Diseases Institute, Uganda

## Current status of the field

- State of the health systems fragmented and stresses
- Lack of linkages between formal health systems and communities
- Insufficient science and technology e.g. for vaccine or microbicides
- Insufficient country investments in resources needed for sustainability

### **Future Directions**

- Microbicides
- Longer acting medications
- Point of care simple screening tests for viral load, CD4, TB
- Devices like PREPEX for circumcision

# The role of EDCTP

EDCTP needs to consult more and make the effort to really understand the state of health or lack of it in hard to reach and hard to stay parts of Africa. Consult:

- African academic institutions
- Centers of excellence in Africa like IDI
- Large NGOs like TASO



### Dr Giovanni Battista Cozzone

Advisor to The Director, National AIDS Center, Istituto Superiore di Sanità, Italy

#### Current status of the field

The major issue in South Africa is access to ART therapy in general and for those that have access, adherence to therapy and quality of counselling.

### **Future Directions**

The development of an effective therapeutic vaccine to offset ART co-morbidities could improve the outcome of ART therapy. The National AIDS Center of Istituto Superiore di Sanità has recently completed enrolment for the phase II study with the Tat therapeutic vaccine in South Africa.

# The role of EDCTP

EDCTP should co-fund the most advanced therapeutic vaccine approaches. Tat therapeutic vaccine is the most advanced in the field. EDCTP should co-fund the future pivotal phase III registration trial in South Africa.

# Prof. Serge Eholié

Service de maladies infectieuses et tropicales du centre hospitalier universitaire de Treichville Côte d'Ivoire

## Current status of the field

- Implementation of the new WHO guidelines
- Increase and sustainability of funds allocated to prevention and treatment of HIV infection
- Early HIV diagnosis and care including PMTC
- Management of non AIDS co-morbidities
- Management of chronic side effects
- Salvage therapy and access to third line drugs
- Access and use of viral load
- Care and treatment of vulnerable population: IDU, MSM, adolescents, prisoners

#### **Future Directions**

- Trials with the new drugs available
- New strategies: induction/maintenance, sequencing
- Assessment of follow-up with less or no CD4 vs viral load as POC (change the paradigm)
- Trials with interferon free regimen (DAA) in HIV/HCV co-infected patients
- Trials with TB/Bedaquilline regimens in HIV/TB co-infected patients
- Assessment and implementation of test and treat strategies

### The role of EDCTP

- Strengthen or create a network with clinicians and biologists, and behavioural sciences
- Develop a South-South and North-South collaboration
- Organise meetings to share the findings of EDCTP

## Dr Barbara Ensoli

National AIDS Center Istituto Superiore di Sanitá (ISS), Italy

## Current status of the field

ISS is present in South Africa with a cooperation program in support of the National Department of Health (NDOH) National Strategic Plan (NSP) on HIV, STIs and TB. Our experience, therefore, mainly relate to South Africa. The main challenges/limitations relate, in our experience, to difficulties in plans implementation and monitoring in the periphery (particularly in rural areas).



### **Prevention:**

## Social/behavioural issues

- Existing social/gender "norms" driving risk behaviours are still a main issue (not only in rural areas)
- Poor/limited consciousness of own HIV/TB status is limiting progresses in behavioural prevention [despite NDOH national campaign for HIV Counselling and Testing (HCT) and TB screening]

## Biomedical intervention

- Male circumcision campaign: existing traditional circumcision practices limit/compromise
  its effectiveness (despite NDOH intervention to offer biomedical support to traditional
  circumcision through the campaign)
- Safety/efficacy of microbicides and PrEP delivery at the population level need to be evaluated prior to/in support of policy decisions (as also indicated in the NDOH Strategic Plan)
- Plans are presently enforced to promote the use of male and female condoms, prevent mother to child transmission, integrate sexual and reproductive health services with HIV counselling; main challenge being the burden of work-load for the public Health System, particularly in the remote/disadvantaged locations
- Research toward development of HIV vaccines in the country is still limited despite programs of the Medical Research Council (MRC) of South Africa in support of research proposals

### Control and treatment:

- Upon the launch of the national plan for antiretroviral therapy (ART) for HIV-infected individuals with CD4+ T cell counts ≤ 350 cells/µl the proportion of HIV-infected patients on therapy is steadily increasing in South Africa
- Main challenge related to the above (as well as with any similar campaigns/interventions in any sub-Saharan country) is sustaining the quality of care delivery and compliance to therapy despite the enormous work-load coinciding with increased access to ART for the population.

### **Future Directions**

## *Interventions:*

- Build on existing efforts to increase access to therapy by sustaining/elevating the quality of care and promoting compliance
- Develop/strengthen Clinical Research capacity toward conduct of HIV clinical trials. Clinical trials add to the country assets by building up on GPC/GCLP and technology transfer/training, by developing clinical, laboratory, and logistic infrastructures as well as human resources and skills, and elevate the standard of healthcare. The GCP/GCLP clinical and laboratory platforms are catalysts for the enhancement of care standards and (if sustained) in time can be rolled-out to other areas
- Lack of sustainability of successful interventions in Developing Countries is a "lesson-learned". A sustainability plan should be incorporated in any intervention plan and should be implemented as part of any intervention.

# **Products:**

- The efforts for development/testing of new vaccine candidates (preventative and therapeutic) should be pursued and be reinforced as these remain the only tools to eradicate HIV/AIDS
- Testing of new combinations of (candidate) therapeutic vaccines and drugs (including new
  drugs) regimens should be supported. Therapeutic vaccines can increase drug efficacy,
  allow reduce drug doses, simplify treatment. This would make "the" difference in
  Developing Countries. On this goal and as part of the cooperative program with NDOH, ISS



is testing Tat vaccine candidate (Ensoli PLoS ONE 2010, Monini PLoS ONE 2012) in HAART-treated patients in a phase II trial in South Africa

• Strategies to evaluate (with controlled studies) the safety and efficacy of microbicides and PrEP when delivered to the population in the Developing Countries are urgently needed.

### The role of EDCTP

- EDCTP should integrate, as by the EDCPT aims, the development of clinical-laboratory platforms for clinical research and clinical experimentation within the public sector
- Integration of interventions with the public sector strategic plans is the key ingredient for success and sustainability of the achievements (and to contribute effectively to global capacity building)
- The key players for EDCTP are, therefore, the Public Health and Research/Academy Institutions. Private-public enterprise and technology transfer should be maximised
- EDCTP, at the same time, should promote and easy the integration and coordination of the NGOs under the umbrella of the Public Governance (to maximise EDCTP intervention, resources and efforts).

#### **Dr Pat Fast**

Senior Advisor, International AIDS Vaccine Initiative (IAVI), USA

## Current status of the field

Challenges abound!

- Scientific: we need long-acting prevention methods that are safe, acceptable and simple to administer such as a vaccine or perhaps long-acting topical or systemic PrEP.
- Clinical Trials: we need large clinical research platforms where relatively simple large (or perhaps huge) trials can be conducted, with nested intense scientific investigations in a subset of participants who are at risk.
- Operational and financial: We need to apply what we know-- everyone in Africa should be tested for HIV and many should be frequently retested; effective counselling (especially couples counselling where applicable) must be provided and treatment must be prompt and accessible for the long term. Structural interventions such as cash transfer and improved educational opportunities for youths must also be pursued.

### **Future Directions**

The definition of extremely potent and broadly cross-reactive monoclonal antibodies may lead to the most rapid interventions, using direct gene transfer to bypass the need to induce these rare antibodies with vaccines. Long-acting PrEP and topical PrEP are likewise near-term opportunities for intervention. Operational combination prevention using expanded male circumcision, couples counselling and early treatment may prove highly effective in some circumstances. Phase 1 and 2 vaccine trials in Africa remain of critical importance to identify suitable candidates for efficacy testing in the region. The next set of efficacy trials may be ready to begin within 5 years.

### The role of EDCTP

EDCTP is nearly unique in valuing capacity building-- many others look only to the general population in the highest-incidence areas. Identifying and interacting with key populations in somewhat lower incidence countries of East and West Africa and linking them to operational or investigational trials is of paramount importance, both to avoid 'over-researching' a few areas and to demonstrate the value of various interventions in these different populations and regions. An example of this is the important research that EDCTP has supported among the fisherfolk of Lake Victoria. EDCTP's ability to link pharmaceutical companies to African as well as European researchers and non-profits is critically important for sustainable development of many different interventional products. EDCTP's emphasis on promoting the research careers of young African scientists is uniquely valuable--stable research platforms must be created to support the long-term career development of these young clinical research 'stars'.



# **Dr Henry Gabelnick**

Senior Advisor, CONRAD

### Current status of the field

The key problem in the use of either oral or topical PrEP is adherence. When used as directed, there is clear evidence that several products work.

#### **Future Directions**

The development of easier to use products plus counselling that products are ineffective if not used as directed may establish PrEP as a viable tool in HIV prevention.

### The role of EDCTP

EDCTP can aid in the conduct of clinical trials to demonstrate the effectiveness of new products. Some of the key players are the UK MRC, IPM, CAPRISA, SA MRC, and CONRAD.

# Prof. Peter Godfrey-Faussett

Science Adviser, UNAIDS, Switzerland

### Current status of the field

Community engagement, linkage and retention strategies for testing care and treatment; young women's choices and prevention literacy; hidden key populations, particularly MSM and sex workers; easier treatment regimens; better prevention technology, domestic and international funding and prioritisation.

### **Future Directions**

HIV cure agenda is making some progress with understanding of reservoirs and treatment approaches; better systems and linkage/retention will lead to significant reductions in transmission in generalised epidemics, but key populations will need special focus and probably additional interventions such as PrEP.

# The role of EDCTP

More visibility in international policy arena, which is often dominated by US institutions (NIH, CDC, PEPFAR). Trials of PrEP; health systems and community based approaches to testing, linkage and retention; build capacity for viral reservoir testing, point of care viral load assays; trials of cure strategies in acute infection and in chronic infection on long-term suppressive ART.

#### Prof. Tomáš Hanke

Principal Investigator, The Jenner Institute, University of Oxford, UK

### Current status of the field

Funds, accessibility of drugs and availability of promising candidate vaccine platforms and their systematic, co-ordinated testing in efficacy trials.

# **Future Directions**

Prospects for making significant advances in the HIV/AIDS field would greatly enhanced by increased and sustained commitment of funders, and a systematic side-by-side testing of the most promising vaccine platforms in efficacy trials addressing rationally the main roadblocks on the HIV vaccine development. Co-ordination, open-mindedness, maintenance of cohorts.

## The role of EDCTP

EDCTP should stay focused diseases-wise and region-wise. EDCTP should not try to cover too much at the same time.



### **Dr Catherine Hankins**

Amsterdam Institute for Global Health and Development (AIGHD), The Netherlands

#### Current status of the field

- Lack of access to tailored, friendly HIV prevention and ART programmes for key
  populations, particularly men who have sex with men, sex workers, people who inject
  drugs, prisoners, fisherfolk in sub-Saharan African settings including novel programmes
  such as oral and topical pre-exposure prophylaxis (PrEP) strategies
- Structural barriers (legal, social, financial) to provision and uptake of services by key populations
- Suboptimal levels of knowledge of HIV status (how to increase access, uptake)
- Need to strengthen linkages from HIV testing into clinical staging, care, and treatment: how to reduce this big loss to follow-up at this stage in the cascade
- Inadequate social change communications to support healthy sexual choices.

#### **Future Directions**

- Given proof of effectiveness of oral pre-exposure prophylaxis, we need demonstration projects, particularly for key populations with extremely high incidence, in the next 3 years that incorporate novel motivational counselling support to adherence and more accurate adherence measurements
- The impact of treatment scale-up will begin to be seen in further reductions in HIV incidence if we develop new models of service delivery that support high adherence in asymptomatic individuals who meet treatment guidelines.

#### The role of EDCTP

- EDCTP can link European research partners with country research institutions, ensuring that research endeavours meet ethical requirements by having government buy-in to provide standard of care as part of national programmes, against which novel approaches are tested
- EDCTP can broker joint funding with international donors interested in implementation science.

## Dr Hesh Jani

Director General, Instituto Nacional de Saúde

# Current status of the field

The most critical challenge is the overall weakness of the health system, including (but not limited to) issues related to: education and retention of skilled human resources, lack of hard and soft infrastructure, and absence of institutions (and funding) to conduct research around the implementation of interventions.

## **Future Directions**

The area of diagnostics has seen tremendous progress in the last years and several products relevant to HIV medicine are in the pipeline. Timely research on the performance and effective implementation of these new diagnostic technologies may pave the way for significant advances in the field. In addition, advances in study design and accumulating experience over the conduct of effectiveness trials in developing countries open the possibility of conducting high quality implementation trials of a number of promising interventions (e.g. mHealth).

#### The role of EDCTP

EDCTP could direct significant proportion of the funding towards: strengthening the workforce of institutions in developing countries, strengthening the national (and global) framework to support implementation research and evidence-based policy making, and promoting the incorporation of system strengthening activities in clinical research projects. Among the key players are the product developers and national research and policy making institutions.



EDCTP could interact with product developers through product-specific meetings. As for the national institutions in developing countries, regional meetings may be the most effective approach.

## Prof. Walter Jaoko

Deputy Director, Kenya AIDS Vaccine Initiative (KAVI), Kenya

### Current status of the field

A great divide between scientific knowledge and translation of the knowledge into practice. For example, the success story of adult male circumcision and treatment as prevention if implemented would turn the tide of HIV in sub-Saharan Africa, but its implementation is very limited.

### **Future Directions**

The prospects are great if there is funding. African governments have to prioritize this and put a budget line for implementation.

#### The role of EDCTP

EDCTP can fund implementation science. For example, treatment as prevention can be offered through a test and treat strategy beginning with high risk populations and spreading to the general population. Various adult voluntary male circumcision procedures should be tested to evaluate the most cost effective and easy to implement method for wide scale use.

# Dr Assan Jaye

Senior Scientist/Immunologist, MRC, The Gambia Unit

# Current status of the field

Translational challenges in treatment:

- A cure-based research to eradicate HIV reservoir; understanding the nature and homeostasis of reservoir and an approach to activate latency. A multi-targeted approach that includes the role of immune activation in promoting reservoir.
- Can early ART treatment result to cure? a replication of the 'Mississippi child' Status of Prevention Science
- Resolving uncertainty in clinical success of topical and oral PrEP: Need for clinical studies to
  include measures of PK/PD & understanding of impact of hormonal and cyclical changes in
  women as well as immune activation on effect of drug concentrations; ways to address
  delivery system and adherence.
- HIV treatment as Prevention in SSA
   Inadequate health system research on how to improve early entry and retention in care; inadequate health system and monitoring facilities and investments; inadequate resources to cover treatment to both asymptomatic and symptomatic patients.

Gaps in pathogenesis and vaccine development.

- With RV144 Trial and the identification of broadly neutralizing Abs in some infected individual, hope is rekindled that HIV vaccine can harness appropriate CD4 T cells and protective Abs
- There is need to study the correlates of risk in vaccine trials
- The urgent need to understand to develop international consortium on 3 platforms to understand immune and genetic correlates of protection, viz, Elite Controllers, HIV-2 infection and long term sero-discordant couples.

#### **Future Directions**

- Optimization studies for both ART & PrEP effectiveness and delivery
- Supporting health systems research for optimal ART delivery
- Elimination of new infections in children is possible (43% lower in 2011 than in 2003); Optimal PMTCT translational research



- Development of biomarkers for measuring immune activation and use of immune activation modulators in cure research
- Advancing the understanding of the correlates of protection for vaccine design.

#### The role of EDCTP

Supporting the Nodes of Excellence and strategic funding to encourage the harnessing of specific cohort platforms and resources that allow international collaboration.

# Dr Brigitte Jordan-Harder

Senior Technical Adviser, GIZ, Germany

### Current status of the field

- Further reduction of new infections
- Universal access to ART
- Early detection of HIV infection
- · Continuous availability of medicine for treatment
- Adherence and resistance building
- Early diagnose of resistance building
- Availability of affordable tests for monitoring treatment outcomes
- Weak health systems
- Weak research institutions in developing countries
- Limited cooperation between research and development cooperation
- Quality of care and treatment
- Affordable second and third line treatment
- Toxicity of long term ART, pregnancy outcome under ART and mothers' health outcome
- ART of children and health outcomes
- Choice of drug combination for first line treatment in developing countries
- Involvement of civil society in care and treatment
- Adverse effects of access to treatment on behaviour.

### **Future Directions**

- Wide spread and continuous implementation of effective prevention strategies especially those targeting youth
- Implementation of new approaches to increase HIV testing (fee for service; vouchers)
- Health systems strengthening (re-organisation of health service provision; logistic systems
- Development and implementation of new approaches for increased adherence (new counselling approaches; cash transfer for transport and others)
- Monitoring of resistance building
- Testing of drug combinations more robust in regard to resistance building
- Development of methods for virus counts for easy use under field conditions
- Build research capacity not only of individuals but of institutions
- Strengthen cooperation between research and development cooperation to allow more research contributing to development
- Define the role that different groups of civil society can play in the provision of effective ART and develop strategies for their involvement

## The role of EDCTP

EDCTP strategy should foresee funding for identified priority areas but a later review should allow changes following actual development. The strategy should further clarify capacity development and make well defined activities with a respective budget a condition for funding of a submitted proposal. The strategy should include not only researchers, research institutions and ministries responsible for funding research as important stakeholders but also agencies/ministries for development cooperation.

Capacity building initiatives to develop expertise in this field.



#### **Dr Pauline Justumus**

Agence Nationale de Recherche sur le Sida et les hépatites (ANRS), France

### Current status of the field

- Key issues: ART coverage of HIV infected people, HIV information and knowledge of population
- Challenges: ART supply with updated WHO recommendations
- Limitations: Government involvement, country health budget

#### **Future Directions**

• Countries have to continue funding programmes, institutions.

### The role of EDCTP

- Key players are researchers and government members from LMIC
- Interaction between countries, programmes, interventions
- Possibility to get important grants.

#### Prof. Pontiano Kaleebu

Director, MRC/UVRI Uganda Research Unit on AIDS, Uganda

#### Current status of the field

Funding is limited; Some high risk groups have not been reached or lack the required tools; Need to better understanding of social/cultural factors that affect use of known prevention; lack of vaccine or something that will give long term protection that will not be strongly associated with behavioural; Complacency, thinking we now have the tools and treatment. Relaxed prevention efforts and direction of efforts to care and treatment.

### **Future Directions**

If there is increased funding for prevention prospects are good, including increased access to treatment, PMTCT and continued funding of research into new prevention tools. We need to see how combination prevention works, use of ART as prevention and circumcision.

### The role of EDCTP

We need to encourage north-south collaboration but also provide resources to researchers in the south to continue research in prevention and treatment. We need to build more capacity of individuals and institutions. Key players include civil society, research/study populations policy makers, researchers, funders and NGOs.

## Prof. Elly Katabira

Professor of Medicine, Makerere University

#### Current status of the field

Key issues: 1. Commitment and political will by the countries with high HIV burden. 2. Inadequate financial resources contributions by the countries themselves. 3. Inadequate human resources to deliver services. 4. Poor health seeking behaviours.

Challenges: 1. Poor health systems that have been neglected for a long time. 2. Adequately trained health workers and their retention into the services. 3. Inadequate contribution by the people for their health care because of extreme poverty.

# **Future Directions**

1. Health system support to improve the working environment for the health workers. 2. Strengthen research capacity at all levels to provide evidence for appropriate interventions. There is need to build capacity at higher level - e.g, PhD to provide leadership at institutions of higher learning.



### The role of EDCTP

To provide a platform and support for private/public and north/south collaborations in research with the various institutions in sub-Saharan Africa. This will help to create a critical mass of researchers within the region and also help with the retention of these skills within Africa.

# Prof. Marie Laga

Unit of International HIV/AIDS policies, Belgium

### Current status of the field

Key challenges in Prevention:

- In Western world, reducing rate of new infections among MSM
- In Africa: reducing rates of new infections in hyperendemic countries (Eastern and Southern Africa)
- Methods to measure impact/effectiveness of combination prevention Key challenges in ART treatment:
- Sustainable and simple delivery models to keep millions of people on treatment life long
- Replicable models to involve communities in treatment.

## **Future Directions**

Prevention:

- Demonstration projects to integrate biomedical tools in package of combination prevention and learn while doing
- Larger role of self-management of HIV positive patients.

### The role of EDCTP

- EDCTP could play a leading role in reflecting (think tank) on alternative methods to evaluate complex interventions such as combination Prevention
- EDCTP could play a stronger role in translating evidence into policies, and advocating for intensifying prevention, through expert groups and alliances with other key players.

# Prof. Joep Lange

Professor of Medicine/Executive Scientific Director, Academic Medical Center University of Amsterdam/AIGHD, The Netherlands

### **Current status of the field**

A key issue is the identification of as many HIV-infected persons as possible, because those with unknown HIV status are the main drivers of the epidemic. Another key issue is to put as many people as possible on treatment and do this early in the infection: this is good for their own health, but will also allow for task-shifting, a necessity given the shortage of qualified health care workers in sub-Saharan Africa. Another key question is how to best do "combination HIV prevention", using all available tools. A major limitation is of course an increasing need for resources for the scale-up of HIV prevention and treatment, in an era of shrinking resources.

### **Future Directions**

If the money is available major progress can be made with scaling up treatment and combination HIV prevention and stemming the epidemic. Promising new products/interventions are long acting (parenteral) antiretrovirals, broadly neutralizing monoclonal antibodies (for PMTCT; although expensive) and possibly HIV vaccines that elicit broadly neutralizing antibodies (although this may take a little bit longer than five to ten years).

# The role of EDCTP

EDCTP can best contribute most by focusing on the main issues, thus no quibbling about when



to start antiretroviral treatment, but investigate how to best implement treatment as prevention and combination HIV prevention (comparing different approaches and methods). Key players obviously are African research institutions, as well as African governments and in Europe the ANRS, MRC and the Amsterdam Institute for Global Health and Development. Obviously collaboration with other major funders is a good thing, but not at the detriment of innovation and boldness.

# **Dr Tom Lutalo**

Principal Research Officer, RHSP-Uganda Virus Research Institute, Uganda

### Current status of the field

- Demand for and uptake of services e.g male circumcision is still sub-optimal
- Timely entry of diagnosed HIV positive patients into care
- Retention of HIV positive persons in HIV care
- Interventions for key populations e.g. fishing communities (are a mobile population, high risk behaviours, very likely to be lost to follow up from HIV care
- Weaknesses in the health systems e.g. availability of health providers and continuous availability of drugs

### **Future Directions**

- Demand generation for HIV prevention and treatment services—interventions to generate demand e.g. strengthening village health teams. Peer educator programs etc.
- Combination prevention
- Health systems strengthening e.g. health provider training programs

### The role of EDCTP

EDCTP can contribute through

- Provision of funding for research programs that include cohorts and health based studies
- Provision of funding for clinical care and services
- Provision of technical support

## Key players

- NGOs providing HIV prevention, care and treatment services, and research (like Rakai Program) meetings with the organization leaders/ investigators
- Local government health offices—through ministry of health leaders
- Research Institutes like Uganda Virus research Institute with the many players in this field
- Institutional Review Boards

## Prof. Lut Lynen

Head of Department, ITM, Belgium

### Current status of the field

• Failure to correctly identify treatment failure in patients on first line HAART. Failure to address the problem of HIV-co-infections like hepatitis C, visceral leishmaniasis.

#### **Future Directions**

- New rapid tests POC for viral load
- New diagnostic tests for hepatitis C, visceral leishmaniasis
- New treatment strategies for HIV-VL (primary prevention) and new molecules for interferon free treatment for hepatitis C.

#### The role of EDCTP

Support academic institutions and researchers from Europe and SSA to jointly address the problems. Encourage contributions from pharmaceutical companies in drug trials in low-income countries for HCV.



### Ms Siobhan Malone

Program Officer, Bill & Melinda Gates Foundation, USA

## Current status of the field

- Too few effective and acceptable prevention products
- Limited well trained human resources in high burden HIV settings
- Limited government engagement and investment in high burden HIV settings
- HIV prevention and treatment efforts often siloed from overall public health efforts more broadly, especially FP and MNCH.

### **Future Directions**

- Scale up of male circumcision
- HIV vaccine R&D
- SRH-HIV integration
- Cure research

#### The role of EDCTP

- Increase engagement of EU member states in directive funding for the most promising clinical trials.
- Greater collaboration with other clinical trial funders, especially NIH and Gates Foundation.

### Dr Francesco Marinucci

Director, PARTEC Essential Healthcare

#### Current status of the field

- Access to drugs
- Reliable diagnostic services
- Human resources adequately trained
- Fully functional HIV clinics.

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### **Future Directions**

- Point-of-care flow cytometer with high-throughput for reliable, accurate, and cost-effective count of CD4 T-cells
- Multiplex test platforms able to perform diagnostic tests for different infectious/noninfectious diseases
- Integration of existing disease-specific health services into comprehensive health packages.

### The role of EDCTP

EDCTP should support the whole cycle of product development by facilitating research, development, clinical trials, and also production (beta versions) of goods. Key players are research institutions in both South and North regions, implementing partners in the field (NGOs and Government), and industry.

### Prof. Sheena McCormack

Senior Clinical Scientist, MRC Clinical Trials Unit, UK

# Current status of the field

In most countries in SSA the epidemic is generalised, and there is still a large unmet need for treatment. Mobilising HIV negative populations to acknowledge and prioritise the risk of HIV remains a challenge, and this will increase as effective treatment rolls out and communities accept that HIV does not have to be a fatal disease. Access to a sustainable supply of medicines will always be a challenge, and even more so with the new WHO guidelines. Behaviour will determine whether or not new interventions are adopted into policy, and whether or not they are taken up and adhered to - this will be true in all epidemic settings.



Consequently the behaviour of individuals, and the collective, has the potential to accelerate or limit progress.

# **Future Directions**

With respect to topical ARV for prevention, we can anticipate the possibility that there will be a licensed microbicide gel (tenofovir 1%) to be applied before and after sex, and an intravaginal ring continuously dispensing dapivirine in the next 5 years. The latter offers real hope for multi-purpose technology for women. It seems likely, although not proven, that policy makers and communities will find topical delivery of ARV more acceptable than oral ARV when there is a continued unmet treatment need. Several trials exploring the test and treat philosophy are expected to report in the next 5 years as is START which will address the question of individual benefit of starting ARV at higher CD4 counts.

### The role of EDCTP

It is terribly important that Europe continues to contribute to this field. EDCTP 1 encouraged collaboration between countries in Europe and their partners in Africa and there are now several viable platforms with clinical research capacity. EDCTP2 should build on this by funding clinical research that national programmes in Europe are unable to do either because of lack of funding or lack of management. Lack of funding is particularly key in HIV prevention trials as these tend to be costly due to the sample size required. As there is now robust evidence for oral pre-exposure prophylaxis this will complicate the assessment of new candidates and the assessment of multi-purpose technologies aimed at reducing the risk of pregnancy, HIV and other sexually transmitted infections.

Key donors of global health trials are the MRC/DFID/Wellcome Trust in the UK, ANRS, USAID, NIH, the Gates Foundation. Interaction could be facilitated by joint calls or by agreeing a common strategy. To do this, EDCTP needs to be up to date with the scientific and policy developments, including those being developed by WHO/UNAIDS.

EDCTP is already in contact with key players in Europe as they obtained grants in the previous programme e.g. MRC CTU, LSHTM and Imperial College in the UK. International scientific networks include the EU funded networks (CHAARM), NIH funded networks (HPTN, MTN and HVTN), ANRS networks, academic networks (MDP, TaMoVac) and the non-profit organisations (Population Council, CONRAD, IAVI, IPM).

# **Dr Graeme Meintjes**

Associate Professor of Medicine, University of Cape Town

# Current status of the field

- Ascertaining development of ART resistance in patients on ART, factors predisposing to it and how it is compromising success of ART at individual and programme level
- Monitoring transmitted resistance
- Strategies for treating patients failing ART, including third line ART
- Understanding ongoing contributors to mortality in HIV-infected populations
- Strategies needed to minimise time patients spend with CD4 < 200 either prior to or on ART. Also to minimise viraemia on ART
- Role of bacterial infections and drug-resistant bacteria as cause of mortality among hospitalised HIV-infected patients in Africa.

## **Future Directions**

- Strategies to reduce size of viral reservoirs
- Role out of less costly viral load test platforms and assessing their performance
- Role of new ART drugs to be used in patients with multi-drug resistant HIV
- Possibility of a new first-line ART strategies e.g. with dolutegravir which has higher barrier to resistance than efavirenz.

#### The role of EDCTP

• Support ART resistance surveillance



- Support clinical trials on optimal strategies for 1st, 2nd and 3rd line ART
- Contribute funding to research investigating reducing size of HIV reservoirs aiming towards HIV cure
- Support efforts to better understand contributors to ongoing HIV mortality in SSA.

# **Dr Victor Mwapasa**

Associate Professor, University of Malawi, College of Medicine, Malawi

#### Current status of the field

• Poor availability and uptake of female-controlled HIV prevention methods such as female condoms and microbicides.

## **Future Directions**

 The prospects of making significant advances are very high but will need to make microbicides which are easily administered and are culturally acceptable.

#### The role of EDCTP

• Funding public-private clinical research partnerships to accelerate the licensing of highly efficacious microbicides and funding implementation research projects to evaluate strategies for improve uptake of female condom and microbicides.

### Dr Ricardo Pereira

Science and Technology Manager, Fundação para a Ciência e a Tecnologia, Portugal

#### Current status of the field

- Evaluation of interventions in all areas of HIV/AIDS intervention in the last 10 to 15 years
- Country ownership of interventions by host countries.

## **Future Directions**

• Involvement of host countries in development and financing of interventions.

# The role of EDCTP

• EDCTP should stay as it is now, i.e. funding a whole range of actors and interventions. However, it needs to increase its visibility.

## Dr Christina Polyak

Military HIV Research Program (MHRP), Walter Reed Army Institute of Research, USA

### Current status of the field

International prevention efforts to curb the epidemic have made great progress, but we urgently need a vaccine to sustain this progress and end the epidemic. The Army-led RV144 Thai vaccine trial offered the vaccine research field scientific direction to help guide future vaccine development. This trial provided the first evidence in humans that a safe and effective preventive HIV vaccine is possible. Although efficacy was 31.2% at the end of the study, there was a higher early effect (60%) at 12 months. The data from the follow-on immunogenicity studies, funded by NIAID and the U.S. Army, will inform future clinical research by providing insights into the immune mechanisms generated by the RV144 regimen and the effects of an additional boost.

### **Future Directions**

The Pox-Protein Public-Private Partnership (P5) was established in 2010 to advance HIV pox-protein vaccine candidates that have the potential to achieve a broad public health impact. The P5 is planning follow-up clinical studies using a similar vaccine regimen to the RV144 one in Southern Africa as well as Thailand targeting the most common HIV subtypes in those regions (subtype C for Southern Africa, B/E for Thailand).



Concurrently, many research groups including WRAIR are pursuing new vaccine combinations aimed at global protection that will soon be evaluated in clinical studies. MHRP has developed a promising next-generation MVA vaccine in collaboration with the Laboratory of Viral Diseases at NIAID. This vaccine is aimed at global protection (multiple subtypes) and is currently in clinical testing in Africa and Sweden in combination with two investigational DNA vaccines. Collaborative work with Beth Israel-Deaconess Medical Center and Harvard University, Crucell Corporation and MHRP point the way to other novel vaccine combinations that will soon be evaluated in clinical studies.

### The role of EDCTP

The EDCTP can help support collaborative international HIV vaccine research projects. For example, TaMoVac is a Phase II study testing a DNA/MVA prime boost regimen. The prime is a DNA vaccine developed by the Karolinska Institute in Sweden. MHRP is providing the virus vector vaccine, Modified Vaccinia Ankara-Chiang Mai Double Recombinant (MVA-CMDR) for the vaccine boost. MHRP is assisting TaMoVac sites in Maputo, Mozambique and Mbeya and Dar es Salaam, Tanzania.

# Prof. Gita Ramjee

Director, MRC South Africa, South Africa

## Current status of the field

- Prevention: rates of incidence HIV unacceptably high among young women in Sub-Saharan Africa
- Challenges: Pragmatic roll-out of effective prevention strategies with high adherence rates.

#### **Future Directions**

- Rolling out medical male circumcision
- Getting as many people tested a possible know your status campaign
- Early treatment of those infected to prevent transmission
- Integration of HIV and reproductive health for women
- A focussed program on HIV prevention among women
- Promote HIV awareness and risk reduction programs
- A multidisciplinary and integrated programs on HIV prevention, treatment and care
- Identifying high risk groups such as serodiscordant couples for targeted treatment interventions.

#### The role of EDCTP

- Support capacity building programs to encourage scientific innovation.
- Implementation science research on proven technologies including combination prevention.
- Leverage funding to encourage innovation by partnering with other sponsors for high impact scientific breakthrough studies.

### Dr Zeda Rosenberg

Chief Executive Officer, IPM, USA

### Current status of the field

For treatment of HIV/AIDS, key limitations are financial and clinical capacity. In prevention, key limitations are gaps in our understanding of socio-behavioural approaches to enhance uptake of current prevention strategies as well as the need for new prevention technologies that are acceptable to people at high risk of HIV infection.

## **Future Directions**

Promising interventions include vaginal microbicides and multipurpose prevention technologies that address both HIV and pregnancy risk.



#### The role of EDCTP

EDCTP is supporting critical clinical capacity in areas of high HIV incidence and prevalence. Since funding for expensive efficacy trials is scarce, EDCTP support in this area is needed. Additionally, EDCTP can continue to play an important role in capacity building for ethics and regulatory infrastructures as well as post-marketing pharmacovigilance.

#### Prof. Osman Sankoh

Executive Director, INDEPTH Network, Ghana

#### Current status of the field

- Demand for services e.g. male circumcision. (uptake of services still sub-optimal)
- Timely entry of diagnosed HIV positive patients into care
- Retention of HIV positive persons in HIV care
- Interventions for key populations e.g. fishing communities (are a mobile population, high risk behaviours, very likely to be lost to follow up from HIV care
- Weaknesses in the health systems e.g. availability of health providers and continuous availability of drugs.

### **Future Directions**

- Demand generation for HIV prevention and treatment services—interventions to generate demand e.g. strengthening village health teams. Peer educator programs etc.
- Combination prevention
- Health systems strengthening e.g. health provider training programs.

### The role of EDCTP

Key players

- NGOs providing HIV prevention, care and treatment services, and research (like RHSP) meetings with the organization leaders/ investigators
- · Local government health offices—through ministry of health leaders

EDCTP can contribute through

- Provision of funding for research programs
- Provision of funding for clinical care and services
- Provision of technical support.

# Mr Kenly Sikwese

Coordinator, AFROCAB, Zambia

### Current status of the field

- Linkage to care remains very poor or very low especially in stand-alone testing centres
- The idea of providing TDF based fixed dose combination sounds promising. But studies are needed to understand the risks of renal disease or at least scale the monitoring of renal failure risks
- Stigma and discrimination still remains a barrier to accessing services for many. In the rapid increase of treatment, this is being under rated or over looked
- Although treatment is indicated at 350 CD4 cells, the median initiation CD4 level remains low
- The institutional and structural issues such as staffing levels, financial resources, testing/treatment sites, diagnostics, etc. need urgent attention. Huge investments need to be made now to reduce incidence across sub-Sahara Africa
- Improved quality of services e.g. decongesting clinics
- Monitoring skills for treatment failure is urgently needed. The number of PLHIV needing
   3rd line is rising but they are still being initiated late and benefit little from the treatment.

### **Future Directions**

Community led treatment programmes such as the Tete Mozambique provide potential for



expanded access and also provide patient support close to the community in which PLHIV reside. Pipeline drugs such as long acting or low toxic/dosage drugs could also positively impact treatment adherence.

#### The role of EDCTP

One thing EDCTP could do is fund some demonstration projects, document and disseminate good practice across Sub Saharan Africa. Some of the key players that are being ignored are patient groups but play a pivotal role in service delivery from testing to care. The key players are the Universities, Ministry of Health, NACs, NGOs and Community groups are all key players. The classic mistake that donors have made over the years is to meet with each group separately. They must be seen as a 'whole' to promote accountability and transparency.

# **Dr Wendy Snowden**

Director, Product Strategy, ViiV Healthcare Ltd., UK

#### Current status of the field

- Access, testing, initiating treatment much earlier in the disease. Improved options for second and third line ART, generalisible from public health perspective
- Identification in immediate access to treatment for children & infants.

### **Future Directions**

Earlier treatment, but this must be supported by much better access, treatment as prevention. Simply reducing CD4 threshold for ART initiation is not adequate, since already there are many people eligible who do not get treatment. PMTCT is very much more successful, but there are still many infected untreated children in Africa and it is critical to identify them and initiate treatment as early as possible to give them the best chance in life.

#### The role of EDCTP

There are several large, highly experienced trials networks (DAIDS/ACTG, IMPAACT, MRC, INSIGHT, HIVNAT, PENTA) who are capable of undertaking critical research.

## **Prof. Souleymane Mboup**

University Cheikh Anta DIOP, Senegal

### Current status of the field

HIV 2:

- Treatment Trials for optimal HIV-2 therapy
- Immunological and Host genetics studies to understand factors that restrict progression to inform HIV-1 vaccine design
- Serodiscordant cohort: To study differential pathogen and host genetics & immunological correlates of protection
- HIV prevention among sero-negative exposed persons (discordant couples, HIV negative sex workers, MSM), drug users, PMTCT and other special populations
- Mitigation factors against prevention and adherence: epidemiological and social studies; drug resistance factors
- Co-infection and Co-morbidities including NTDs.

# **Future Directions**

- Cure
- PreP
- Gene therapy
- Combination of prophylaxis measures

### The role of EDCTP



- Networks of Excellence
- Capacity building integrated to multicentric studies.

#### Prof. Ana E. Sousa

Instituto de Medicina Molecular (IMM), Faculdade de Medicina de Lisboa

#### Current status of the field

A widely neglected area in HIV/AIDS research is HIV-2 infection in spite of its high prevalence in West Africa. A significant prevalence is also found in several European Countries, particularly Portugal. There are currently no clinical trials involving HIV-2 therapy, even though a significant number of HIV-2 infected individuals will ultimately require treatment, despite the very slow rate of disease progression and reduced viremia typical of this infection.

#### **Future Directions**

HIV-2 represents a unique naturally occurring model of attenuated HIV disease that can provide a better understanding of factors that determine disease progression and the control of the viral reservoirs. This knowledge is essential both for "HIV cure" strategies and "HIV vaccine" design.

The rate of CD4 T cell decline in HIV-2 infection is at least 5 times slower than that observed in HIV-1, with the majority of the HIV-2 infected individuals featuring undetectable viremia, even in advanced stages of CD4 T cell depletion and AIDS. This occurs despite:

- the presence of viral reservoirs comparable to those found in HIV-1 infection;
- a preserved ability of viruses isolated from HIV-2 infected patients to replicate in vitro.

Therefore, the majority of HIV-2 infected patients are able to control the HIV-2 reservoirs in the absence of ART.

### The role of EDCTP

EDCTP is in a unique position to promote clinical studies of HIV-2 infected patients involving West Africa, the relevant European Countries and, possibly, India.

## **Dr Miguel Thomson**

Instituto de Salud Carlos III, Spain

# Current status of the field

The main challenge with regard to prevention is obtaining an efficacious preventive vaccine. One of the main obstacles for achieving this goal is the high genetic diversity of HIV-1 in sub-Saharan Africa (SSA), which requires the elicitation of broader immune responses than current vaccine approaches can achieve. HIV-1 genetic diversity should also be taken into account in research related to antiretroviral (ARV) therapies, in order to determine if there are differences in response to ARV drugs and development of drug resistance mutations in different HIV-1 genetic forms circulating in SSA. Therefore, HIV-1 genetic diversity is a key point to be considered in all research related to the development of effective vaccines and therapies against HIV-1 in SSA.

Another great challenge, in the absence of an effective vaccine, is the prevention of high risk sexual behaviour through public health interventions. Even though a wider access to antiretroviral drugs might contribute to prevention of HIV-1 transmission, this will probably not be sufficient to control de HIV epidemic in SSA considering the recent upsurge of sexually transmitted HIV-1 infections in Western countries with universal access to ARV therapies, associated to an increase in high risk sexual behaviour.

#### **Future Directions**

With regard to vaccines, substantial advances are still needed on the elicitation of broad immune responses in animal models before significant progress in human trials could be reasonably expected. In my opinion, it is not very likely that current vaccine approaches



considered in human trials will be successful to prevent HIV-1 infection in SSA in the next five to ten years. Much more research needs to be done in animal models on the significance of HIV-1 genetic diversity for vaccine development. For this research, it is necessary to obtain reagents derived from the different HIV-1 genetic forms circulating in SSA, such as primary viral isolates or functional envelope clones, to be used in assays to detect vaccine-elicited immune responses and in the development of vaccine immunogens.

With regard to antiretroviral drugs, there are currently therapeutic regimens which have proved efficacious against all major HIV-1 genetic forms. The main challenge in SSA is to make those therapies accessible to all HIV-1 infected people. This will require a major effort on improving the public health systems of SSA countries, including developing health care infrastructures, providing appropriate equipment, establishing collaborations with research and health care institutions from developed countries, and training health professionals on laboratory techniques for monitoring responses to ARV drug therapies and development of ARV drug resistances.

### The role of EDCTP

Focusing on my areas of expertise, EDCTP should continue supporting clinical trials targeted to HIV-1-infected individuals in SSA countries. In these trials, HIV-1 genetic diversity should be included as a major variable in the analysis of the results, in order to determine possible differences in therapeutic responses and development of drug resistance-associated mutations related to HIV-1 variants. Therefore, in these trials, EDCTP should support the participation of research groups focused on the study of HIV-1 genetic diversity to carry out the required analyses and to train researchers from SSA on the appropriate methods. EDCTP should also support training of SSA health professionals on techniques for monitoring response to ARV drug therapies and development of ARV drug resistance.

With regard to prevention, EDCTP should support studies on HIV-1 molecular epidemiology in SSA and the collection of HIV-1 samples aimed at obtaining reagents representative of the genetic variants circulating in diverse areas, to be used in research related to the development of vaccines or microbicides. Large scale prevention trials should include phylodynamic studies, which, through analysis of HIV-1 sequences, provide estimations of the growth of HIV-1 epidemics as well as the effect that preventive interventions could have on controlling them. Therefore, research groups and institutions working on the mentioned fields should be key players and should be actively involved in research projects supported by EDCTP, which, considering that they will require the collection of large numbers of epidemiologically representative samples from different SSA countries and the participation of multiple research groups for their processing, should necessarily have a collaborative, multicentric and transnational character.



# Prof. Thorkild Tylleskar

University of Bergen, Norway

## Current status of the field

New WHO guidelines have been launched last month. In our article Van de Perre P, Tylleskär T, Delfraissy JF, Nagot N. How evidence based are public health policies for prevention of mother to child transmission of HIV?

BMJ 2013; 346: f3763 doi: 10.1136/bmj.f3763 http://www.bmj.com/content/346/bmj.f3763

we argue that these guidelines lack scientific foundation. The views expressed in this article explain what I think.

### **Future Directions**

- Option B implementation research should come high on the agenda
- When it becomes clear that option B does not provide 'elimination' of MTCT, we need to have alternatives. One promising approach is long-acting injectable drugs for post-natal prophylaxis of infants.

### The role of EDCTP

• By funding and coordination of activities with European actors.

# Prof. Philippe Van de Perre

Director INSERM U1058; Head of Dept Bacteriology-Virology University Teaching Hospital, France

#### Current status of the field

In the field of PMTCT, two major challenges:

- How to implement new guidelines to an acceptable extension (knowing that previous recommendation had been poorly applied)?
- How to prevent breastfeeding transmission of HIV (knowing that maternal ARV treatment has little effect in preventing breastfeeding transmission)?

## **Future Directions**

In improving PMTCT and prevention of breastfeeding transmission of HIV:

- Combining maternal ARV treatment and infant PreP
- Use of long acting injectable drugs for PreP in infant (breastfeeding transmission). Two good candidates exist: rilpivirin-LA and GSK 744.

# The role of EDCTP

- Liaise with industry to boost the agenda for evaluating long acting drugs in infants and children
- Political dialogue with UN agencies and PEPFAR
- Co-fund large clinical trials or interventional cohorts.

# Prof Janneke van de Wijgert

University of Liverpool, UK

### Current status of the field

HIV prevention: We still need new HIV prevention tools, especially those that women can use. The field is anxiously awaiting the results of the ongoing tenofovir gel and dapivirine ring efficacy trials, but no matter what the results of those trials are, I think that research in this area should continue. I think that the proof-of-concept for antiretroviral drugs applied topically is strong, and that the main barrier to success is getting users to adhere. Young women are an especially challenging (but important!) group to work with. Research on HIV vaccines should also continue, no matter how difficult.



HIV treatment: it is clear that treating as early as possible is in the best interest of patients (and most likely also of communities at large due to the preventive effect of suppressing viral loads) but it is not easily achieved. How will we identify HIV infections early (we certainly are not succeeding in doing so right now)? How will we maintain good adherence for very long periods of time? How will we handle side effects of ART (including long-term side effects, such as 'accelerated aging') and drug resistance?

STI control: There is strong evidence that the HIV epidemic is fuelled by other sexually transmitted infections (STI) and vice versa, and this is especially true for herpes simplex virus type 2 (HSV2). I think that development of an HSV2 vaccine has never received sufficient attention, and that STI control in general should be strengthened. We need user-friendly rapid diagnostic tests and much more active case-finding and follow-up. We also need better treatments for vaginal infections, such as bacterial vaginosis. Reducing all of these STI/vaginal infection epidemics means indirectly also reducing the HIV epidemic.

#### **Future Directions**

In addition to the above, I think that another important, promising direction of research is the development of vaginal rings that contain hormones to prevent pregnancy and antiretroviral drugs to prevent HIV. Women need to be able to choose between products that will protect them from HIV (and perhaps other STIs) but will either allow or block pregnancy, depending on the woman's choice at that time in her life.

#### The role of EDCTP

We know that 97% of vaginal and rectal microbicides research is and always has been publicly funded; this percentage is lower for HIV vaccine research and drug development; (and hardly any funding has been available for research related to STI control). Key players will therefore continue to be governments, universities, NGOs, and PPPs, and in the HIV vaccine and drug development fields also industry. Having said that, I personally think that individual researchers should not be forced to collaborate with industry. The power balance between these partners is often uneven; conflicts of interest do occasionally arise due to the profitmaking nature of industry; and industry tends to be much more risk-averse than (for example)

## **Dr Jimmy Whitworth**

Head of International Activities, Wellcome Trust, UK

### Current status of the field

- The need to balance basic science and field trials of new vaccines and interventions
- The exceptionally high cost of intervention trials in HIV research.

### **Future Directions**

• The effect of Treatment As Prevention; Multimodal interventions; health systems research are the priorities.

# The role of EDCTP

• Balancing USA inputs as EDCTP is already interacting with the key players in Africa.