THE UNITED REPUBLIC OF TANZANIA NATIONAL AIDS CONTROL PROGRAMME

Research Priorities on HIV/AIDS/STDs o The HIV/AIDS health Sector Strategy
LIST OF ABBREVIATIONS
AIDS-Acquired Immunodeficiency Syndrome
AMREF- African Medical and Research Foundation
ART-Anti Retroviral Therapy
ARV-Anti Retrovirals
AUC- Area under the curve
AZT- Azidothymidine/ziduvudine
BMC-Bugando Medical Center
CD4
CD8
COSTECH- Commission for science and Technology
CPT- Cotrimoxazole Preventive Therapy
CSW- Commercial Sex Workers
DAID
DMO-District Medical Officers
DPS-Director of Preventive Services
EU- European Union
GFATM-Global Fund for Tuberculosis AIDS and Malaria
GOT- Government of Tanzania
GTZ- German Agency for International Development
HBC-Home based care
HSR- Health Systems Research
HTA- High Transmission areas
HCW- Health Care Workers
HISIS- HIV Super Infection Study
HIV- Human Immunodeficiency Virus
KCMC- Kilimanjaro Christian Medical Center
MACP- Mbeya Aids Control Program
MMRP- Mbeya Medical Research Programme
NIH- National Institutes of Health
IEC- Information Communication Education
INH- Isoniazid
IPT- Isoniazid Preventive Therapy
ITM- Institute of Traditional Medicine
OI - Opportunistic Infections
OVC - Orphans and Vulnerable Children
PEP - Post Exposure Prophylaxis
PEPFAR
PMTCT - Prevention of Mother to child Transmission
PMTCT plus-
MTCT - Mother to Child Transmission of HIV
TACAIDS - Tanzania Commission for AIDS
EXECUTIVE SUMMARY
This report is the outcome of a research priority setting workshop organized by the National AIDS Control Programme held from the 13-17th June 2005 at the Tanzania Episcopal center in Kurasini, Dar-es-salaam. The workshop brought together 30 participants from the Ministry of Health, Referral hospitals, Research and academic institutions.

The report is divided into five chapters:
1. Introduction
2. Presentations-research needs
3. Presentations-research updates
4. Priority setting process and methodology
5. Research priorities
6. Conclusions and Recommendations.

This is a third in a series of priority setting workshops. The first workshop was held in 1991 and reflected experiences of the First Medium term Plan (MTP I 1987-1991) and was intended to support the development and implementation of the MTP II (1992-1996) of the NACP. The second workshop was held in September 1999 and was aimed at defining the research priorities within the MTP III objectives. This third workshop is based on the identifying research priorities within the current HIV/AIDS Health Sector Strategy.

Objectives of the workshop
- To identify and prioritize research areas/issues necessary to implement strategies of the National AIDS prevention and control within the health sector strategy
- To select projects which are manageable for five years
- To identify research institutions and partners capable of developing and implementing research activities

Priority Setting Processes
The workshop focused first of all in identifying gaps in research and this information was gained through presentation mainly from NACP staff. This was followed by presentations on ongoing research. The next stage was defining the priority areas within the Health Sector Strategy and evaluate which areas from the last priorities which needed to be taken forward as new research plans. Four groups were formed:
1. Biomedical Research
2. Surveillance and Epidemiological Research
3. Social Behavioral and Communications Research
4. Care and Treatment and Health Services Research
Terms of Reference for the Groups

- Identifying research issues from the Health Sector Strategy
- Identifying research issues from the 1999 priorities.
- Ranking of research issues.
- Generation of research questions for each research topic
- Consensus of research questions in plenary.
- Ranking of research questions

HIV/AIDS/STD Research Priorities
Research priorities were set following the above methodology and key research issues and research questions were outlined. A detailed description of the priorities is in the main text.

Conclusions and Recommendations

GENERAL RECOMMENDATIONS

- Health sector must put in place interventions guided by best practice and innovation
- Research conducted in Tanzania should be of relevance to the local HIV/ AIDS epidemic.
- In the ARV roll out attention needs to be given to the procurement process which is lengthy and could jeopardize the program
- There is a need for M&E systems within the ARV program to monitor drug adherence, treatment outcomes and drug resistance.
- There is a need for establishing linkages between TB and HIV care and involving communities for home based care.
- The issue of disclosure by discordant couples should be given attention.
- There has been a skewed focus in the research activities carried out between 2000-2005. Greater focus has been on Biomedical and Epidemiology research whilst there has been very little focus on Behavioral research.
- 75% of all research carried out between 2000-2005 was carried out within the MTP III research priorities.
- NACP should have some involvement in the Mbeya Medical Research Project.
- It was reiterated that HIV vaccine research is a high priority area for Tanzania.
- There needs to be research on how to effectively communicate/disseminate research findings to the target groups.
- It is important that the package of care for patients after the study is over is clearly defined. There should be advance dialogue with the care and treatment programme.
- It is important to plan interventions in youth that will deter youth from intergenerational sex.
- Capacity building should be an inherent component of the research agenda
The group felt that there was need to focus on research on legal issues related to HIV/AIDs.

**SPECIFIC RECOMMENDATIONS- Biomedical**
- There is need for a functional monitoring system for STI aetiological agents and drug sensitivity patterns within the context of syndromic management of STI’s
- The workshop requested that the report on sensitivity pattern monitoring of *Neisseria gonorrhea* in the zones be disseminated.
- There is need to establish Tanzanian reference values for both adults and children
- There is a need to put efficient QA systems in place
- There is a need to monitor viral dynamics
- The need for simple reliable tests for diagnosis of HIV infection in infants
- What is the optimal timing for Nevirapine administration
- There is need to assess the impact of co morbidities in response to treatment
- There is need for research on the biological determinants of discordance.

**SPECIFIC RECOMMENDATIONS- Traditional Medicine**
- TM remedies in HIV/AIDs need to be carefully monitored.
- There need to be clinical trials of standardized TM formulations
- Tanzania is lagging behind in the field of research of TM remedies for HIV/AIDs

**SPECIFIC RECOMMENDATIONS- Social Behavioral**
- The issue of early sexual debut needs to be given serious attention
- There is a need to promote research in the impact of various forms of media in reducing HIV transmission
- There is need for research in community preparedness for ART roll out.
- There is a need to study the patterns of sexual behavior in people on ART

**SPECIFIC RECOMMENDATIONS- Epidemiology and surveillance**
- Focus should be placed on
  - Drug susceptibility monitoring in HIV/AIDs/STI’s
  - HIV/AIDs/STI’s risk behavior
  - HIV prevalence surveillance

**SPECIFIC RECOMMENDATIONS- Care and Treatment and health services delivery**
- Focus in the area of care and treatment should be placed on
  - Impact of the ART programme
  - Logistical issues around ARV’s
  - Nutrition and ARV’s
Neviripine resistance

**SPECIFIC RECOMMENDATIONS - Nutrition**

- Multivitamin supplementation delays disease progression (improves CD4, CD8 and CD3 T-cell counts)
- Multivitamin supplementation improves hemoglobin levels and maternal weight.
- There is need for research on multivitamins in patients on ART evaluating single vs. multiple RDA’s.
- There is need for research on nutrients (Zn, Se, Fe) in patients on ART.
- There is need to promote locally available nutritional supplements (scientific evidence needed)

**SPECIFIC RECOMMENDATIONS - Voluntary Counseling and Testing**

- Focus should be placed on the following areas:
  - The update of VCT services after the roll out of the ART programme
  - To determine the feasibility of opt out counseling and testing for health care seekers
  - The contribution of VCT services to positive behavioral change
  - To determine factors affecting utilization and provision of the VCT services
  - To understand the role of stigma in VCT services
  - To understand the extent to which VCT services increase counselors workload
  - The impact of stigma and discrimination on the provision of VCT services to PLHA and their families

**SPECIFIC RECOMMENDATIONS - Home Based Care**

- Focus should be placed on the following areas:
  - The effectiveness of ART treatment assistants and treatment adherence to patients receiving ART within the community.
  - The impact of stigma and discrimination on the provision of HBC services to PLHA and their families
  - Factors affecting ART adherence to patients receiving HBC services
ACKNOWLEDGEMENTS

Before going any further, I wish to take this opportunity, on behalf on the Ministry of Health, and on my own behalf, to thank all of the people who attended the workshop to share their perspectives with us and for their contribution both at the workshop and to the completion of the document. I am sure all of you have HIV/AIDS at heart and you are committed to bring the epidemic under control.

This workshop is the third one of its type following the previous two that were held in 1992 and 1999 respectively. The immediate previous workshop, which was held in 1999, at White Sands Hotel, drew participants from research institutions, policy makers and NGOs involved in AIDS activities. For the current workshop, invitations were extended to all health institutions involved in HIV/AIDS research activities in the country.

The task ahead of us is very challenging because the HIV/AIDS epidemic in most parts of our country is still on the increase and the interventions put in place seem to have little impact on the epidemic. Furthermore, the accessibility of the available interventions to our people is still in decimals compared to the needs on the ground. Furthermore, the uptake of some of available interventions is not optimal. We are therefore in a difficult deadlock that is not acceptable given the magnitude of HIV/AIDS in our country and its severe and multiple impacts. Future breakthroughs therefore can only be expected to come from research. Researchers have to intensify their search for more effective preventive interventions as well as perfect the existing curative options and ways to promote uptake of available interventions. At the same time, the search for HIV vaccine must be pursued more vigorously and with better coordination between the developed countries where technology is more advanced, and developing countries which are home to the largest HIV/AIDS burden in the world. Research that is
conducted in our country must therefore aim to provide answers to questions that are present in our own environment and relevant to our local HIV/AIDS epidemic instead of merely addressing issues that are imposed on us by the international community. In that connection, the purpose of this workshop is, among other things, to seek national consensus on the areas where our national research efforts on HIV/AIDS should concentrate and identify national institutions to be involved in the priority research areas. In our discussions in the next four days we should also discuss our capacity constraints with regards to human resources and infrastructure and the ways to address them.

Tanzanian Researchers and Scientists being part of the international scientific community must also continue to work with their international counter-parts in the global efforts to understand the biological characteristics of the AIDS virus in order to get a cure or vaccine for it. I therefore encourage you to consider your involvement in undertaking collaborative clinical trials for vaccines and drugs in joint efforts with international partners. In your deliberations you should also discuss the issue of dissemination of research findings and their use in policy decisions and future programming. This is important because if this does not happen, then all the efforts and resources spent on research can be considered wasted. I am sure none of us is prepared to see this happen.

Dr. Raphael Kalinga
Ag. Director of Preventive Services
CHAPTER ONE: INTRODUCTION

1.0 Historical Background

1.1 The HIV AIDS Health Sector Strategy
   1.1.1. Objectives of the Health Sector Strategy
   1.1.2. Research areas under the Health Sector Strategy
   1.1.3. Research priorities in MTP III and the Health Sector Strategy

CHAPTER TWO: SUMMARIES OF PRESENTATIONS

2.0 WORKSHOP OBJECTIVES
   • To identify and prioritize research areas/issues necessary to implement strategies of the National AIDS prevention and control as stipulated in the Health sector strategy on HIV/AIDS/STI’s.
   • To select projects which are manageable for five years
   • To identify research institutions and partners capable of developing and implementing research activities.

2.1 Over view of the Health sector Strategy on HIV/AIDS/STIs (Rowland Swai, NACP Programme Manager)
   The presentation provided an elaborate account of the Health Sector Strategy on HIV/AIDS/STI’s. The paper focused on the following key areas:
   • The Three ones for HIV/AIDS/STI Response
   • The health sector HIV/AIDS/STI Strategy
   • Care and Treatment Programme
   • Overview of coverage of key Health Sector HIV/AIDS/STI interventions

The three ones for the HIV/AIDS/STI response
   The three ones for the HIV/AIDS/STI response refer to the following key principles
   • One agreed action framework: *National Multisectoral Strategic Framework (2003-2008)*
   • One national coordinating body with a broad multi-sectoral mandate: *Tanzania Commission for AIDS (TACAIDS) (2001)*
   • One agreed country level monitoring and evaluation system: *National M&E Framework for HIV/AIDS (2003)*
The three ones have focused on the institutional framework, coordination and monitoring and evaluation

The health Sector HIV/AIDS/STI Strategy
Health Sector Strategy for HIV/AIDS (2003-2006). Situation and response analysis carried out by NACP with national experts and presented to a stakeholder meeting for review
Focusing on three thematic groups (with NACP staff, national and international experts, stakeholders from NGO, FBO, PLHAs) formulated strategies for (1) Prevention, (2) Care and (3) Cross cutting issues. The strategy was then shared with partners and reviewed in a broad stakeholder meeting. The strategy was then officially launched by the Ministry of Health in March 2003.

The core interventions considered under the Health Sector Strategy fall under three thematic areas which are:
- Prevention,
- Care, treatment and support
- Cross cutting issues.

Prevention
- Treatment and prevention of STIs
- PMTCT
- Condom programming
- Workplace programmes
- Blood safety
- Vulnerable groups
- Youth

Care and Treatment
- Training
- Home based care
- Management of Opportunistic infections
- Antiretroviral treatment
- Nutritional support
- HIV/AIDS/TB interventions

Cross cutting issues
- VCT
- Stigma and discrimination
- Human resources
- Monitoring
- Laboratory services
ART Needs in Tanzania
By end of 2003, there were about 2 million Tanzanians living with HIV, out of which 400,000-500,000 are in need of ART. There are 1.2 million in need of drugs for Opportunistic Infections. To date only about 6,000 Tanzanians are currently on ART and the Government of Tanzania is committed to providing ART to all in need.

National Care and Treatment Plan (2003-2008)
The National Care and Treatment plan was initiated through high level consultations between Government of Tanzania and Clinton Foundation. The plan was developed by a Task Force of 30 Tanzanian experts (NACP, TACAIDS, clinicians, academicians) and 14 US experts. The plan went through a consultative process of regular briefing and review by development partners and stakeholders from all constituencies (Government, NGO, FBO, PLHAs, private sector) and was finally endorsed by Cabinet in October 2003. The plan combines care and treatment to improve the quality of life of PLHA. And aims to provide ART to about 400,000 to 500,000 PLHA within five years between 2003 and 2008 through expansion of care and treatment, strengthening of health care infrastructure and strengthening social support.

Goals of the Care and Treatment Plan
GOAL ONE: To provide quality, continuing care and treatment to as many HIV+ residents of the United Republic of Tanzania as possible.

GOAL TWO: To contribute to strengthening the health care structure of Tanzania, through expansion of health care personnel, facilities and equipment and comprehensive training in the care and treatment of PLWHA

GOAL THREE: To foster information, education and communication efforts focused on increasing public understanding of care and treatment alternatives, reducing the stigma associated with HIV/AIDS, and supporting ongoing prevention campaigns

GOAL FOUR: To contribute in strengthening social support for care and treatment of PLWHA in Tanzania, such as home-based care, local support groups, and treatment Partners

Quick Start Plan of the National Care and Treatment Plan
THREE MAJOR GOALS:
- Establish a care and treatment unit in the NACP
- Expand treatment in already existing sites
- Define systems and processes for a scaled up programme

ART ROLL OUT PROGRESS
91 sites prepared to handle ARV including:
- 4 referral hospitals
- 22 regional hospitals
- 34 District hospitals
- 30 FBO/NGO/PRIVATE hospitals
- 1 military hospital

Table one: 91 sites selected to deliver ART in the first year

<table>
<thead>
<tr>
<th>KCMC</th>
<th>Karagwe</th>
<th>Kyela</th>
<th>Kibaha</th>
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<td>Mount Meru Hospital</td>
<td>Manyoni</td>
<td>Mpanda</td>
<td>Bagamoyo</td>
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<tr>
<td>Babati hospital</td>
<td>Geita</td>
<td>Tukuyu District hospital</td>
<td>Dodoma</td>
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<tr>
<td>Bombo Hospital</td>
<td>Biharamulo</td>
<td>Igogwe Rungwe</td>
<td>Mvumi</td>
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<td>Bariadi</td>
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<td>Kilwa</td>
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<td>Rubya, DDH</td>
<td>Muhimbili National Hospital</td>
<td>Lindi Reg. hospital</td>
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<td>Hanag District hosp</td>
<td>Kasulu</td>
<td>Mwananyamala</td>
<td>Mtwara Reg. hospital</td>
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<td>Haydom</td>
<td>Nzega</td>
<td>PASADA</td>
<td>Tanzania occupational health</td>
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<td>St. Elizabeth</td>
<td>Sikonge</td>
<td>Lugalo</td>
<td>Tumaini</td>
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<td>Kahama</td>
<td>Amana</td>
<td>Hindu Mandal</td>
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<td>Same</td>
<td>Shirati</td>
<td>Mnazi Mmoja, Zanzibar</td>
<td>Agakhan</td>
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<td>Selian</td>
<td>Magu Bukumbi</td>
<td>Temeke</td>
<td>Muhimbili</td>
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<tr>
<td>Mbulu</td>
<td>Makiungu</td>
<td>Morogoro Reg. Hospital</td>
<td>Wete</td>
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ARV roll out capacity building:
Three rounds of training conducted covering 96 sites. A total of 492 health care workers trained, these included the following cadres:
- Medical officers
- Nurses/ counsellors
- Laboratory technicians
- Pharmacists

ARV roll out: Procurement of ART drugs:
Drugs worth 2 billion Tsh procured and distributed – these are enough for 4200 patients in 32 sites. Two tenders worth more than 7 billion Tsh were awarded. These drugs will be enough for 15,000 patients. These drugs arrived in May 2005 and have been distributed.
ARV roll out: Laboratory infrastructure:
All referral and regional hospitals have been supplied with Facs count machines and 38 laboratory personnel have been trained on their use. Laboratory equipment for 10 regional hospitals and 13 district hospitals has been ordered.

ARV roll out: ART programme tools:
The following tools have been developed:
- Guidelines for clinical management of ART
- Training curricular and materials
- Site assessment and accreditation tool
- Monitoring and evaluation frame work and forms

Other services for ARV
STI services
Different training was provided to different Health Care Workers. The training carried out and the number trained is shown below:
Youth friendly services-40
Indent system for STI drugs-192
Syndromic management of STI-390
Syphilis screening in ANC- 400
STI services available in all 21 regions

Voluntary Counselling and Testing
Different trainings on VCT provided:
- Beginners 6 weeks course-122-(cumulative to date 1200)
- Refresher 2 weeks course-120
- Supervisors 2 weeks course-20
- TOT 2 weeks course -25

VCT services were established in 521 sites (481 in public/Faith Based Organizations and 40 sites by AMREF) countrywide. A total of 227,973 clients counselled out of whom 22,121 (9.7%) tested positive and 189,953 tested negative. A National VCT guideline was developed and is in the final stages of production.

IEC
To create treatment preparedness and community engagement for ART the following IEC materials:
- Calenders-60,000 on VCT and care
- ART leaflets-500,000
- Newsletters-100,000
- A TV programme focusing ART under preparation
- Posters-200,000 on nutrition, stigma and services for PLHA
Scaling up of ANC HIV/STI surveillance
Identification of 31 ANC sites in 5 regions (Arusha, Iringa, Mara, Shinyanga, Tabora) Training of 287 surveillance field staff has been carried out. Revision of ANC HIV/STI surveillance protocol. Development of a protocol for HIV drug resistance monitoring has been initiated. Development, printing and dissemination of HIV/AIDS/STI surveillance report number 18. Development of a system for monitoring and evaluation of care and treatment programme.

Home based care services
Implementation of HBC services continued in 70 districts of Tanzania mainland. Up to December 2004 reports had been received from 28 district only. A total number of about 20,000 patients received HBC services (9,150 males and 10,850 female) from these 28 districts.
A total of 71 new HBC providers from the dispensary and Health centre levels had been trained who in turn trained 8,847 family care givers. In total, there are 814 HBC providers, 592 health care providers, 109 providers from Faith Based Organizations, 72 from private sector and 41 from the NGOs. Stakeholder’s sensation meetings on their roles in HBC were held in 5 districts of Iringa (3) districts and Dodoma (2 districts) (WHO/OPEC Initiative supported districts).
A total 15,000 copies of Guidelines for Management of HIV/AIDS for Frontline workers were printed and distributed to the districts.
The Home Based Care Guidelines, Curriculum manuals and leaflets were produced/reviewed and are awaiting printing. A total of 206 HBC drug kits were procured and distributed to the implementing districts.

Condoms
Two parallel systems for condom distribution exist; free public condoms and socially marketed condoms. This intervention is used for control of sexually transmitted diseases and family planning. Condoms numbers in 2004:
- Public sector distribution 21 million
- Social marketing distribution 38.9 million
- A new order of 90 million pieces in process

The Future of Condoms
Planning to procure 60 million pieces during 2005/06 with GF resources
A long term strategy for condom social marketing to be developed.

Conclusion:
Preparations for the start up and rollout of the national ART programme are in place
The success of future scale up will require massive efforts

The following key challenges have been identified.
Major gaps exist in the areas of:

- A skilled health sector workforce
- Sound information systems
- Well managed and regular supply of drugs and other commodities to ensure uninterrupted supplies
- Sustainable funding systems
- ART literacy, stigma, meaning of ARV


**Proposed Research Priorities on HIV/AIDS/STIs to carry from MTP III to the HSS (Bwijo Bwijo)**

**Introduction**

Tanzania initiated the delivery of Anti-retroviral Therapy (ART) in Public Health Facilities in October 2004. Prior to that, only about 2,000 Tanzanians were able to access ARVs. The Government of Tanzania is committed to providing ARVs to all in need.

The National HIV/AIDS Care and Treatment Plan was developed in collaboration with Clinton Foundation and approved by the cabinet in October 2003. The Plan targets to cover about 400,000 - 500,000 HIV infected Tanzanians on ART in a period of 5 years.

91 Sites selected to begin delivering ART - 1st Year

A mix of Public, Private, NGO, FBO hospitals across the country

The number of patients expected to be on ART – 1st Year is about 44,000

Key investigations carried out include:

- Determination of sero-status
- CD4 cells
- Haematology
- Biochemistry
- Viral load*
- Drug resistance tests*
- Sub types*
- Diagnosis of TB and other OIs*
- Treatment of OIs
ARVs:

1st line
- Standard
- Modified

2nd line
Special regimen

Prophylaxis:
CPT and IPT
PEP

Adherence
Strategies that influence adherence
- Patient related
- Clinician/Health team related
- Drug regimen related

Factors that influence adherence
- Patients emotions
- Stigma
- Understanding capability/Communication skills
- Adherence counseling plan
- Adherence Monitoring and follow-up

Priority Research areas that need to be given consideration:

Issues around the administration of ARVs:
- When to start treatment
- Monitoring of Treatment Response including Pharmacodynamics and Pharmacokinetics:

Clinical Laboratory
CD4, Haematology, Biochemistry, Viral Load, Sub types
Drug concentrations:
Peak, Trough, AUC
- Monitoring of drug toxicity
- Drug resistance
  - Primary – community based
  - Secondary – health facilities
- Paediatric issues
- Post Exposure Prophylaxis

Treatment Adherence:
Monitoring of Treatment Adherence including ARVs, CPT, IPT Strategies

Factors

Impact of ART Programme:

- Morbidity and mortality
- Orphans and Vulnerable Children
- Socio-economic
- Opportunistic Infections

Logistics on ARVs:

- Procurement
- Storage
- Distribution
- End user

Surveillance and Epidemiology Research (Dr G Somi)

Tanzania HIV/AIDS Indicator Survey 2003-2004

HIV Prevalence: Key Findings

- 7% of adults are HIV infected;
  - 7.7% of women are infected
  - 6.3% of men are infected
- Highest prevalence in Mbeya (14%), Iringa (13%) and Dar es Salaam (11%)
- 8% of couples are discordant

Response Rate: HIV Testing

Women’s Response Rate by Region

<table>
<thead>
<tr>
<th>Region</th>
<th>Women (%)</th>
<th>Men (%)</th>
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<tbody>
<tr>
<td>Shinyanga</td>
<td>58.0</td>
<td>69</td>
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<tr>
<td>Dar Es Salaam</td>
<td>69</td>
<td>70</td>
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<td>Mara</td>
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<td>Kilimanjaro</td>
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<td>Arusha</td>
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<td>Mwanza</td>
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<td>TANZANIA</td>
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<td>Response Rate</td>
<td>77</td>
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<td>Urban</td>
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<tr>
<td>Rural</td>
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<td>77</td>
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<tr>
<td>Total</td>
<td>84</td>
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</tr>
</tbody>
</table>
HIV Prevalence

Men's Response Rate by Region

HIV Testing Response Rate by Education
Percent eligible women and men tested

HIV Prevalence by Age

HIV Prevalence by Residence
HIV Prevalence by Region

- Kigoma: 2.0
- Manyara: 2.0
- Singida: 3.2
- Mara: 3.5
- Lindi: 3.6
- Kagera: 3.7
- Dodoma: 4.9
- Arusha: 5.4
- Morogor: 5.4
- Tanga: 5.7
- Rukwa: 6
- Shinyanga: 6.5
- Ruvuma: 6.8
- TANZANIA: 7
- Tabora: 7.2
- Mwanza: 7.2
- Kilimanjaro: 7.3
- Pwani: 7.3
- Mtwara: 7.4
- Dar es Salaam: 10.9
- Iringa: 13.4
- Mbeya: 13.8

HIV Prevalence by Education

- Women
- Men
HIV Prevalence by Wealth

- Never in union:
  - Women: 2.8
  - Men: 3.4
  - Total: 9.4

- Currently married or in union:
  - Women: 4.1
  - Men: 3.0
  - Total: 7.8

- Formerly married:
  - Women: 4.6
  - Men: 4.3
  - Total: 10.9

HIV Prevalence by Marital Status

- Never in union:
  - Women: 11.4
  - Men: 9.4

- Currently married or in union:
  - Women: 6.8
  - Men: 4.3

- Formerly married:
  - Women: 4.3
  - Men: 7.7
  - Total: 11.4
HIV Prevalence and Circumcision

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th>Men</th>
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<tbody>
<tr>
<td>Circumcised</td>
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<td>6.5</td>
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<tr>
<td>Not circumcised</td>
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<td>5.6</td>
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HIV Prevalence and Higher Risk Sex

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<td>0</td>
<td>7.9</td>
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<td>1</td>
<td>7.4</td>
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<tr>
<td>2 or more</td>
<td>10.5</td>
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</table>
HIV Prevalence by STIs

Percent among women and men 15-49 who ever had sex

HIV Prevalence and Alcohol Use
HIV Prevalence among Youth

- Urban Women 15-24: 5.5%
- Urban Men 15-24: 5.6%
- Rural Women 15-24: 3.2%
- Rural Men 15-24: 1.8%
- Total Women 15-24: 4.0%
- Total Men 15-24: 3.0%

Both partners HIV negative: 89%

HIV Prevalence in Couples
HIV Prevalence: Key Findings

- 7% of adults are HIV infected;
  - 7.7% of women are infected
  - 6.3% of men are infected
- Highest prevalence in Mbeya (14%), Iringa (13%) and Dar es Salaam (11%)
- 8% of couples are discordant

Age and sex specific prevalence of HIV infection among blood donors, Tanzania, 1996 - 2003
Region specific trends of HIV prevalence among blood donors, Tanzania, 1998-2003
Region specific trends of HIV prevalence among blood donors, Tanzania, 1998-2003

Social and Behavioral Research
Dr Bennet Fimbo

Introduction
• The main aim of this was to review HIV/AIDS situation and trends and discuss them in the context of social behavioral research.
• Review Available data and facts as follows:
Nearly 80% of HIV transmission is through heterosexual relationship in Tanzania. (Surveillance reports)

Early sexual activity (15-17 yrs) especially among girls (BSS)

Sex initiation practices & ceremonies (UNICEF etc)

Poor condom use (BSS & THIS)

Poor Health seeking behaviour (especially for STI management)

Poor utilisation of HIV/AIDS services (especially females in VCT and PMTCT) (project reports)

Contextual issues in communication for Behavior change

The influences on individual behavior

- Culture
- Social
- Gender relationships
- Socio-economic
- Spiritual and Religious beliefs
- Policies
- The social & behavioral factors that influence the long standing differences in HIV prevalence between men and women: Evidence data:
  1. THIS (2003/4): HIV prevalence. 7.7% in women and 6.3% in men
  2. Surveillance Report No. 18 (2003); HIV prevalence 12% in women and 8% in men for blood donors
  3. AIDS cases reported in 2003; 57% women and 43% men

The socio-cultural practices related to different sexual behavior in selected communities: e.g.:
  1. Sex initiation ceremonies/practices and their influence on early sexuality in girls (data from THIS and Behavioral Surveys)
  2.

**Gender studies**

Gender relations and its impact on HIV transmission

Gender relations and health care seeking behaviour

Male dependence in health in the era of HIV/AIDS

Human right perspectives

**Stigma studies**

Magnitude in different social groups, societies or communities.

Strategies to overcome stigma in different community settings (addressing cultural, policy and spiritual issues)

Differences between women and men in stigma issues
Addressing specific behavioural practices

Targeting specific behaviour practices in different societies.
Conducting research on knowledge, attitude and behaviour (KABP).
Addressing specific categories (prevention and/or care and support issues)

Addressing social cultural issues

Responding from the current strategies and initiatives in HIV/AIDS.
Establishment and support of various HIV/AIDS services (HBC, STD, Clinics, PMTCT, ART Access, VCT, etc.)
Challenges: Related to service utilization, sustainable support by community members.
Strategies to overcome social cultural obstacles in communication for behavior change.

Social acceptance of specific terminologies in language and images (the case of USIONE SOO).

Flexibility and elasticity in communication with different communities and specific social groups or target populations.

Identify and study gatekeepers, behavior drivers societies for norms, beliefs, spiritual influences.

Addressing Behavioral Research

Primers of behaviour in different population /social groups.
Risk taking behaviour (among youth, boys and girls).
Health seeking behaviour (among vulnerable populations).

Trends of sexual behaviour among PLHAs (marriages between PLHAs).

Trends and magnitude of cultural (sexual) practices in certain communities (social cleansing, widow inheritance etc).

Unsafe sexual practices among other vulnerable populations (sex workers, youth, particularly girls) and the underlying causes.

Risk taking in relation to different attributes (education, high economic status, marital status, age etc.)

Social behavioural issues
Single marriage (non-polygamous) and extra marital sex and HIV
Polygamy and extra-marital.
Drug use.
Triggers of abstinence and faithfulness.
Rape incidences and their behavioural contexts.

Health and Social services Research
Ms Zabena Msumi

Introduction
Voluntary Counseling and testing
This is a process by which an individual undergoes confidential counselling to learn about his/her HIV status and exercise an informed choice in HIV testing.

Targets for VCT services by 2006
Services started in 1989 in few selected districts
Increase access to VCT services by
Establish 6 VCT sites in each district- 6x121= 726
Establish at least two stand alone sites in every district by 2006 -2x121=242
968 sites by 2006
1600 counsellors trained/upgraded

VCT as entry point to services
This an entry for all services like PMTCT, TB, ANC, STD, HBC and care and Treatment
Patients have to get tested for HIV through VCT and meet eligibility criteria before put on ART
Counseling provides detailed education to a patient about the drugs
Strong HIV preventive tool through behavior change

Activities
Develop National VCT Guidelines
Improve counselor training
Criteria to insure utilization of services
Define counselor specialization
Upgrading counselors to new requirement
In-service supervision as part specialization
Accreditation in counseling services
Review/Develop training materials/guidelines
Develop training modules for upgrading and on going training
Conduct on going supportive supervision
Develop system to avoid burn out
Expand VCT services
Advocate for VCT services

Success of VCT services
VCT expanded throughout the country-520 sites
National Guidelines developed
Counsellors have been trained-1200
National Supervisors were trained
More people are using the services
National team of trainers
National Training curriculum

**Treatment and Prevention of Sexually Transmitted Infections**

*Dr M. Nyanganyi*

Control of STIs through appropriate case management is one of the major promising strategy to reduce HIV transmission.

The Ministry of Health has adopted the syndromic approach.

From 1996 STI control prevention activities have continuously and systematically expanded to cover all 21 regions by 2005.

All public hospitals, health centres and 60% to 70% dispensaries provide STI services.

Guidelines and training materials are in place.

**National Strategies for STIs Control and Prevention**

Training of health care workers on STIs case management using the syndromic approach.

Regular provision of STIs drugs and related supplies for quality STI services.

Training of health care workers in syphilis screening of pregnant mothers attending Antenatal Clinics (Positive cases are treated along with their spouses)

Provision of health education to the community on STIs prevention and control.

Partner notification

Provision of STIs services to sex workers and other vulnerable groups.

Monitoring of the sensitivity patterns of the aetiological agents causing STIs syndromes.

**Proposed Research Priorities**

**Biomedical**
Research Issue: Lack of a functional monitoring system for STIs aetiological agents and drugs sensitivity patterns within the context of syndromic management of STIs.

Develop simple, affordable, sensitive and specific diagnostic tests for common STIs. Determine the aetiological agents causing various STIs syndromes. Monitor the sensitivity patterns of the aetiological agents causing STIs syndromes from time to time. Determine the relationship between STIs Syndromes and HIV acquisition/transmission. Validate the syndromic management of STIs regularly.

Social Behavioral and Communication Research Issues

Research issue: Behaviour responses to STIs (Health Care Seeking Behaviour) The linkage of STIs to behaviour change Knowledge of having STIs and its influence on sexual behaviour What makes people with STIs seek or not seek STIs services? How and why do specific groups respond to STIs infection (women, mobile population, youth, CSWs, etc)

Category 4: Health and Social Services Research Issues

Research Issue: Provision of STIs Services

Factors influence STIs health care seeking behaviour. Mechanisms which can be instituted for availability, affordability and accessibility of STI drugs and supplies in health institutions. Factors which influence compliance of partner notification. The cost-effectiveness of syphilis screening at MCH clinics.

Research issue: Provision of youth friendly health and social services

The magnitude of HIV/AIDS/STIs among the youth. The constraints which youth face in using existing health and social services. The determinants of rural-urban migration among youth.

Laboratory Services
Mr. Khalid

Introduction
Laboratory testing is central to quality care of HIV/AIDS patients
Identify infected cases
Determine eligibility to ART
Monitor treatment efficacy
Monitors treatment safety
Diagnose Opportunistic infections

### Laboratory Capacity Distribution and Test Menu

<table>
<thead>
<tr>
<th>Test</th>
<th>QA/Training Laboratory</th>
<th>Zonal laboratories</th>
<th>Regional laboratories</th>
<th>District laboratories</th>
<th>H/Centre laboratories</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV Diagnosis</td>
<td>+(ELISA Rapid test)</td>
<td>+(ELISA Rapid test)</td>
<td>+(ELISA Rapid test)</td>
<td>+ (Rapid test)</td>
<td>+ (Rapid test)</td>
</tr>
<tr>
<td>HIV DNA PCR</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>CD4 Count</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Chemistry</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>Hematology</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>-</td>
</tr>
<tr>
<td>(TB/STI)</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
<td>+</td>
</tr>
</tbody>
</table>

Tests are widely distributed
Referral
Regional
District
Others
Some tests are relatively new
CD4
New instruments
Quality of Lab tests RESULTS is NOT an issue of the laboratory ONLY

Quality of lab results
Analytical phase variables
Staff competency
Quality of reagents
Testing methods
Remedial measures are underway
Most Pre- and post-analytical errors are uncontrolled by the laboratory

Establishing normal values in Tanzanian population
ART Laboratory test menu
CD4
Some information (publications) on the CD4 normal values
Scarce available data not geographically representative
Geographical variation has been documented
Low lands Vs highlands
Hematology
No established reference values
Currently use normal values programmed in instruments
Chemistry
In-use reference values are based on Western literature

Monitoring of viral dynamics in the era of ART
HIV sub-types
Mapping of circulating subtypes
HIV Drug resistance
Monitor emergency of resistant strains during scaling-up of ART access
Monitor effect of prevention programmes in HIV-DR control

Priority Research Areas
Establish the Tanzanian reference values for both Adults and Pediatrics
Hematology
Chemistry
CD4 cells
Establish the magnitude of laboratory results errors through tracking of different variables
Pre-analytical
Post-analytical
Map circulating HIV sub-types
Emergency of HIV drug resistance strains

The Implementation of Research Priorities
Ms Nancy Msobi
1.0 Introduction:

The need to develop and identify HIV/AIDS/STIs Priority Research issues/areas in Tanzania is very important.

- To keep track to current dynamics of the HIV/AIDS epidemic.
- To enable researchers to consider new areas for operational research
- To respond to emerging research findings and realities of the epidemic in the country.

1.1 Reasons for conducting HIV/AIDS/STI’s related research studies in Tanzania are:-

- To produce and use research knowledge and information as evidence in solving the many complex questions and problems of the epidemic.
- To facilitate the identification and understanding of determinants of HIV spread and
- To support the national response against HIV/AIDS/STIs in the Country

Therefore research information can only be adequately obtained through undertaking multi-disciplinary research


- The NACP focused on eleven priority areas of the MTP 111 that provided a framework for expanded, multi-sectoral response to HIV/AIDS in Tanzania. Research was one of the priority areas and almost each Priority area under MTP 111 had a research component.

1.3 Research objectives under MTP 111

1. To develop better diagnostic and treatment methods for HIV/AIDS
2. To better define risk factors and to develop interventions against HIV/AIDS
3. To monitor the spread of HIV and determine the impact of interventions
4. To evolve and develop innovative methods of mobilizing and involving individuals and communities in HIV/AIDS/STDs control

1.4 Research priorities issues/areas identified were based on four main areas:

1. Biomedical Research
2. Surveillance and Epidemiological Research
3. Social Behavioral and communication Research
4. Health and Social Services Research

- However, Intervention based research was agreed upon to be an area to be covered in all groups as it was envisaged that all the research activities would result in interventions leading to improving and assisting the carrying out of MTP III objectives.

- As a result the priority research topics, the justification for picking them and the research questions under each topic as well as the priority ranking were determined.

- Researchers on HIV/AIDS/STIs/TB working in Tanzania were strongly encouraged to refer to the priority research topics as listed on the booklet titled: Research Priorities on HIV/AIDS/STIs of the MTP-111 (1998 – 2002) Pg. 24-38 when selecting research problems. The full list of research priorities covered under MTP III is appended in Annex 2.

2.1 A REVIEW OF PLANNED AND ONGOING RESEARCH CARRIED OUT BY DIFFERENT RESEARCH INSTITUTIONS

The main aim of this part of the programme was to give an update on ongoing research in the area of HIV/AIDS.

The MUCHS HIVIS project: Planned and on going research activities,
HIVIS BROAD OBJECTIVES
- To optimise the immunisation schedule for DNA vaccine priming with MVA vaccine boosting in the development of HIV-1 preventive vaccine
- To develop expertise and capability to study HIV-1 vaccines in Tanzania

HIVIS OBJECTIVES-TANZANIA
1. To assess the safety of a plasmid DNA-MVA prime boost HIV-1 vaccine among volunteers in Dar es Salaam, Tanzania.
2. To determine immunogenicity of a plasmid DNA-MVA prime boost HIV-1 vaccine among volunteers in Dar es Salaam, Tanzania.
3. To optimise the immunisation schedule for plasmid DNA-MVA prime boost HIV-1 vaccine among volunteers.
4. To build expertise and capability in evaluating HIV-1 vaccines in Dar es Salaam, Tanzania

IMMUNOGENS RELEVANT TO TANZANIA

<table>
<thead>
<tr>
<th>DNA</th>
<th>MVA SWEDEN</th>
<th>MVA TANZANIA</th>
</tr>
</thead>
<tbody>
<tr>
<td>env A,B,C</td>
<td>env E</td>
<td>env A,C,D</td>
</tr>
<tr>
<td>Rev B</td>
<td>Gag A</td>
<td>gag A,C,D</td>
</tr>
<tr>
<td>gag A,B</td>
<td>Pol E</td>
<td>pol A,C,D</td>
</tr>
<tr>
<td>Rtmut B</td>
<td></td>
<td>SAFETY AND IMMUNOGENICITY</td>
</tr>
</tbody>
</table>

THE VACCINE
- Priming with a plasmid having HIV-1 DNA encoding the following genes:
  - env, from HIV-1 subtypes A, B, C
  - rev, from HIV-1 subtype B
  - gag, from HIV subtypes A,B
  - Rtmut (mutated reverse transcriptase), from HIV subtype B
- DNA given at weeks 0, 4 & 12
- Boosting by a Modified Vaccinia Ankara (MVA) vaccine (a live recombinant poxvirus vector vaccine), genetically engineered to express the HIV-1 genes:
  - gp160 (Subtype E), and
  - gag and pol (integrase-deleted and reverse transcriptase nonfunctional, Subtype A).
- MVA at 12 weeks after the last DNA injection
STUDY SUBJECTS

- 60 VOLUNTEERS (45 men, 15 women)
- Principally Police Officers:
  - Have had extensive contact
  - Relatively stable population, easy to follow up
- Other sources:
  - Youths (IDC)
  - Military personnel (Lugalo)
  - NH/MUCHS/UDSM staff & students
  - Women unable to conceive (bilateral tubal ligation, hysterectomy)

Study Design

Randomized, Double Blind, Placebo controlled

<table>
<thead>
<tr>
<th>Arm</th>
<th>Number</th>
<th>DNA immunization</th>
<th>MVA boost</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>20</td>
<td>DNA IM by Bioject</td>
<td>MVA 108 IM</td>
</tr>
<tr>
<td>II</td>
<td>20</td>
<td>DNA ID by Bioject</td>
<td>MVA 108 IM</td>
</tr>
<tr>
<td>IIIa</td>
<td>10</td>
<td>Saline IM by Bioject</td>
<td>Saline IM</td>
</tr>
<tr>
<td>IIIb</td>
<td>10</td>
<td>Saline ID by Bioject</td>
<td>Saline IM</td>
</tr>
</tbody>
</table>
SUBJECTS ELIGIBILITY

- Informed Consent
- HIV negative
- At low risk for acquiring HIV infection
- Healthy
- Other criteria
  - Age, 18-55 years
  - Willing to be HIV tested
  - Able and willing to be followed up etc

PRIMARY ENDPOINTS

- Safety (Local & Systemic AE)
  - Clinical features
  - Standard hematological & Biochemical tests
- Immunogenicity, Magnitude & Quality of
  - Humoral IR
specific binding and neutralizing antibodies against the vaccine.

- Cellular IR
  - Interferon gamma by ELISPOT assay
  - whole blood lymphocyte proliferation assay (FASCIA);
  - intracellular cytokine staining (ICCS) using flow cytometry
  - cytotoxic T lymphocytes (CTL) assays against peptides of the different immunogens

PROGRESS TANZANIA

- Organizational structure in place
  - Includes Community Advisory Board
- Training of personnel
  - HIV & AIDS management; GCP, GLP
- Laboratory infrastructure being developed
  - Training of personnel & equipment (MUCHS & SMI)
- Proposal being developed
  - Submission to NIMR, MUCHS
  - Inputs from WHO-UNAIDS
- Contact with regulatory authorities
  - TFDA
- Contact with the Police initiated
  - Ministry, Police HQ, Regional
  - Volunteers already!!

Progress Sweden
- Phase I trial underway
- Between 16th Feb and 8th June 2005:
  - 30 subjects have received 1st vaccine dose
  - 26 subjects have received 2nd vaccine dose
  - 5 subjects have already received the 3rd vaccine dose
- Recruitment experiences:
  - No need to advertise
  - Mostly general public, by “word of mouth”
  - Altruism & the desire to contribute appear to be the main motives
- Very safe and well tolerated vaccine

WAY FORWARD
- More support needed as a complement to what has been offered to us by donors
- National HIV/AIDS Policy dictates importance of HIV vaccine trials
- Institutional & Government
  - Especially in terms of infrastructure
Office
Clinical Space
Laboratory Space
- Community mobilization
- Set a stage for more HIV vaccine trials in Tanzania
- Impetus from International Community for active participation of developing countries
- Seize the opportunity and develop more Scientific capacity to conduct trials

Tumaini University HIV Research Projects
Irene Kiwelu

Number of Proposals
A. Ongoing (as in June 2005)
1. Malaria ........................................... 8
2. HIV/AIDS and Reproductive Health 20
3. Tuberculosis...................................... 6
4. Parasitic diseases (other than Malaria) 2
5. Ophthalmology................................. 6
6. Non-Communicable disease............ 3
   Total 45

Number of Proposals
1. Malaria........................................... 4
2. HIV/AIDS, TB, STDs ....................... 14
3. Parasitic disease (other than malaria) 2
4. Radiology........................................ 1
5. Ophthalmology......................... 4
   Total 25

Ongoing Research Activities on HIV/AIDS/STDs

Specific aims:
  a) Community Survey:
To describe the structural characteristics, collective efficacy, and youth behavioral risks for HIV in all neighborhoods of Moshi Urban District.

To determine the separate and combined influence of neighborhood structure and collective efficacy on levels of youth HIV risk behaviours.

To select neighborhoods on the basis of these structural and normative factors for participation in an experimental intervention designed to improve child mental health and promote higher levels of collective efficacy.

b) **Experimental Intervention:**

- To assess the impact of the home visitation program on caregiver competence in intervention families.
- To assess the impact of the home visitation program on physical growth, mental health and schooling of preschool children in intervention families.
- To assess the impact of the home visitation program on mental health, schooling and HIV risk behaviours in preadolescent children in intervention families.
- To assess the impact of the child health promotion program on collective efficacy in intervention neighborhoods.
- To assess the impact of the child health promotion program on youth HIV behavioral risks in intervention neighborhoods.

*Duration: 5 years, October 2002 – September 2007*

2. **Positive outcomes for children orphaned by AIDS in six culturally diverse countries (Proposal no. 076)**

**Objectives**

**Aim 1:** Behavioral and emotional adjustment and cognitive development.

- To assess whether life histories and the characteristics of placement, socio-demographics, caregivers and culture are associated with adjustment and learning at base and over time.

**Aim 2:** Health outcomes

To assess whether life histories and characteristics of placement, social-demographics, caregivers, and culture, influence:

a) Measure of health overtime.

b) Baseline biometric, measures of health, reports of illness and numbers of sick drugs.

*Duration: 5 years March 2005 – February 2010*

**Integrated programme to combat HIV/AIDS amongst youth in Tanzania**
Objective (KCMC Component)
To undertake scientific research on contextual factors influencing sexual and reproductive health, knowledge, attitude and practice among youth and parents and operational research on effectiveness of selected interventions.

Duration: 3 years, August 2004 – July 2007

Development, implementation and evaluation of ARV, adherence interventions in the Kilimanjaro Region (Proposal No. 105, Cert. No. 087)

Objectives
The research programme we propose intends to contribute to effective HIV/AIDS – treatment in the broadest sense, by initiating behavioral research that parallels the following necessary sequences of events:

- adequate knowledge of HIV/AIDS → conducting a HIV – test → applying or HAART → adhere to HAART.

Thus, the ultimate goals of the research programme are:

- Increase HIV – testing
- Promote treatment of HIV with HAART
- Optimize adherence to HAART.

Duration: 4 years March 2005 – February 2009

Molecular epidemiology of HIV-1 and primary antiretroviral drug resistance in Tanzania. (Proposal No. 093, Cert. No. 066)

Main Objectives
To establish and use simple and accurate HIV – 1 characterization methods to determine the molecular epidemiology of HIV – 1 and the prevalence of primary ARV drug resistance in relation to HIV – 1 subtypes in treatment of patients in Tanzania.

Specific Objectives
- To determine the circulating HIV-1 subtypes and CRFs and their epidemic spread in Tanzania.
- To evaluate PEIA using HIV-1 characterized samples and determine evolution of HIV-1 subtypes in Kilimanjaro.
- To establish HMA at KCMC.
- To evaluate the use of saliva samples for serological screening and PCR-based HIV-1 sub typing.
To determine the prevalence of primary genetic mutations in RT and PR genes associated with ARV drug resistance between HIV-1 subtype before therapy begins in Tanzania.

To make recommendations if the current ARV can be used by HIV-1 infected individuals and in MTCT prevention in Tanzania.

**Duration:** 3 years October 2003 – September 2006.

**Predictors of virologic failure and resistance among HIV-infected patients treated with fixed dose combination stavudine/Lamivudine/Nevirapine in Northern Tanzania**  
*(Proposal No. 090, Cert. No. 075)*

**Objectives**

- To characterize the point-prevalence of virologic failure and resistance mutations among HIV patients receiving nevirapine-based antiretroviral therapy in Northern Tanzania.
- To identify novel HIV-1 non-subtype B resistance mutations and to determine the effect of subtype on virologic failure among patients at an HIV clinic in Northern Tanzania.
- To determine host factors associated with virologic failure and antiretroviral drug resistance at an HIV/AIDS Treatment Centre in Northern Tanzania.

**Duration:** One year, December 2004 – November 2005.

**Building capacity for antiretroviral clinical research in resource – constrained settings: evaluation of clinical staging criteria of HIV infection in the Kilimanjaro Region of Tanzania**  
*(Proposal No. 060, Cert. 036/054)*

**Objectives**

- To evaluate the utility of clinical staging criteria and simple laboratory testing for predicting CD4 lymphocyte counts, an important immunological parameter of antiretroviral efficacy.

**Duration:** September 2003 – January 2004

**Building capacity for antiretroviral clinical research in resource – constrained settings: prospective surveillance of HIV-infected patients in the KCMC Paediatric HIV Clinic**  
*(Proposal No. 098, Cert. No. 079)*

**Objectives**

- To assist KCMC in developing and maintaining a surveillance system for patients seen in the Paediatric HIV clinic.
To describe clinical, immunological, and virological responses to antiretroviral therapy in the clinic setting and to better understand factors associated with adherence to and tolerance of these medications.

Duration: One year, February 2005 – January 2006

Building capacity for antiretroviral clinical research in resource contrained settings: prospective surveillance of HIV-infected patients in the KCMC HIV clinic (Proposal No. 077, Cert. 079)

Objective

To assist KCMC in developing and maintain a surveillance system for patients seen in the rapidly expanding HIV Clinic. The primary objective of the research component of this project is to describe clinical, immunological, and virological responses to antiretroviral therapy in the medications. It is anticipated that the systematic collection of these data may further provide early clues to predictors of immunologic reconstitution syndromes in a tropical settings.

Duration: One year, August 2004 – July 2005

Building capacity for treatment and care interventions for persons living with HIV/AIDS in poor rural communities: clinical characteristics of HIV home based clients in Kilimanjaro Region (Proposal No. 078, Cert. 057)

Objectives

To assist KIWAKKUKI in developing and maintaining a surveillance system for the clients seen in its HBC program. The primary objective of the research component is to collect and analyze sociodemographic and clinical data from a structured survey instrumented by the home-care providers and from data provided by the home-care providers themselves. This data will help us to better understand the clinical course and adherence to and tolerance to medications of clients. It is anticipated that the systematic collection of these data may provide critical data on the progression of the course of HIV infection, and the sociodemographic and clinical factors associated with disease progression.

Duration: One year, August 2004 – July 2005

Kilimanjaro Reproductive Health Programme (KHRP) Studies: (KCMC-Harvard University Program)

Broad Objectives
To investigate the immediate and underlying causes of reproductive health problems including sexually transmitted infectious (STIs) affecting residents of the Kilimanjaro and other regions in Northern Tanzania.

- To assess the impact of promising interventions to reduce these problems.
- To promote public health programmes that are known to be effective in reducing the burden of reproductive health – related conditions.

**Phase II/IIb Safety and effectiveness study of the vaginal microbicides buffergel and 0.5% Pro 2005/5 Gel (P) for the prevention of HIV infection in women (Proposal No. 089, Cert. No. 072)**

**Objectives**

**Primary Objectives**

- To evaluate the safety of BufferGel and 0.5% Pro 200/5 Gel (P) when applied intravaginally by women at a risk for sexually-transmitted HIV infection.
- To estimate the effectiveness of BufferGel and 0.5% PRO 200/5 Gel in preventing HIV infection among at – risk women.

**Secondary Objectives**

- To estimate the effectiveness of BufferGel and 0.5% PRO 2000/5 Gel (P) in preventing other sexually transmitted infections among women at risk of HIV.

*Duration: Five years (December 2004 – November 2009)*

**Moshi Women’s Health Project**

*(Proposal No. 094, Cert. No. 068)*

**Objectives**

**Primary Objectives:**

- To determine the HIV incidence and evaluate risk factors for seroconversion among high risk women in Moshi, Tanzania.
- To estimate retention in the cohort, and identify efficient retention efforts that will ensure high retention in future microbicide trials.
- To estimate the incidence of the following infections among study participants: Herpes simplex virus type 2, Syphilis, Chlamydial infection, Genital Ulcer, Trichomoniasis, Candidiasis, Bacterial vaginosis.

**Secondary Objectives**

- To assess acceptability of conduction HIV and pregnancy tests on urine samples collected at home of women targeted for future microbicide trials.
- To determine genetic characteristics of HIV-1 isolates among HIV-1 seropositive women.
Expletory Objectives

- To explore if there are vaginal practices that may impact the safety and efficacy of microbicides.

*Duration: Two years, October 2004 – September 2006*

11.3 Phase III Randomised controlled trail on HSV-2 suppression to prevent HIV transmission among HIV discordant couples (*Proposal No. 091, Cert. No. 061*)

**Primary objective**

To measure the efficacy of twice daily acyclovir suppressive therapy in preventing HIV transmission among heterosexual HIV – discordant couples in which the HIV-infected partner is HSV-2 seropositive and has a CD4 cells count of at least 250 cells/mm3.

**Secondary Objectives**

- To estimate the per-contact HIV transmission probability within HIV-discordant couples in which the HIV-infected partner is HSV-2 seropositive.
- To estimate the effect of various factors on the per-contact HIV transmission probability within HIV-discordant couples in which the HIV-infected partner is HSV-2 – seropositive.

**Community study of infertility in Northern Tanzania. (Proposal No. 029)**

**Specific Objectives**

- To estimate the prevalence of primary and secondary infertility.
- To determine the proportions of female, male and couple factors infertility.
- To examine the risk factors of infertility.
- To investigate local perceptions of the causes of infertility.
- To describe treatment options and services that are currently in use, including traditional local healers, medical professionals, and self-treatment. A basic protocol for the recommended treatment of infertility will be developed.
- To analyze the social implications of infertility.
- To assess the demographic implications of infertility.

*Duration: four years, 2002 - 2005*

Kilimanjaro centre for reproductive health and research (KCRHR)

**Goal:**

To improve reproductive health through the strengthening of human and material resources and through the conduct and application of relevant research in reproductive health at national and regional level.

**Long-term Objectives:**

- To implement prevention and management of priority health problems, which include MTCT of HIV, cervical cancer and maternal mortality.
Ensuring that the accrued research findings contribute to the development of regional/national recommended guidelines.

12.1 Component Projects Long-term institutional development (LID) Project Specific Objectives

- To create a core structure of KCRHR with recruitment and specific training of adequate staff.
- To establish Data Management Unit which will facilitate the development of research proposals and research instruments.
- Implementation in KCMC, of the WHO multicountry project on the use of Impact of HAART during Pregnancy and Breastfeeding on MTCT and Mother’s Health (project 2.11.2) with support of KCRHR staff.
- To develop protocol and implementation of cervical cancer project.
- To prepare protocol and identify support for the project on maternal mortality.

12.2 Impact of HAART during pregnancy and breastfeeding on MTCT and mother’s health (HM and MH) – A WHO Multi-Country Study with a carried name, “WHO Kesho Bora Study) (Proposal No. 052)

Specific Objectives
To assess the impact, tolerability and acceptability of a triple antiretroviral (ARV) combination (Zidovudine (ZDV), Lamivudine [3TC] and Nevirapine [NVP] given to HIV-infected pregnant women with CD4 + cell counts below 500 cells/mm3 from the 34 – 36th week of pregnancy to 6 months post-partum. This will be compared with a short-course regimen of ZDV given from the 34 – 36th week of pregnancy to delivery (mother) and during one week post-partum (infant) plus one dose (NVP given at onset of labour and one dose given to the infant. The following endpoints will be assessed.

- The rate of mother to child transmission (MTCT) of HIV measured at 6 weeks and 6 months of age whatever the mode of infant feeding; MTCT rates at 6 months will also be compared in the sub-group of breastfed infants.
- Two years morbidity and survival among HIV-infected mothers.
- Two years morbidity and survival among children born to HIV-infected mother.


Mbeya Medical Research Project
Dr Laurence Maboko

Background of HIV/AIDS Intervention and Research in Mbeya Region

- Established in 1988 with support from GTZ (German Agency for Technical Cooperation) in collaboration with the University of Munich and was known as the Mbeya AIDS Control Programme
- Started as an HIV Reference Laboratory
  - Safety of blood transfusion
  - Sentinel surveillance to monitor the epidemic

**7 main components of the MRACP:**

- MRACP gradually progressed to a comprehensive AIDS control programme
- Behavioural change campaigns
- STD control (syndromic management)
- HIV counselling and testing and Home-based care
- Laboratory services (HIV & STDs)
- Safety of health care systems (Sterilization etc.)
- Prevention of mother-to-child transmission (PMTCT)/PMTCT Plus
- Surveillance and operational research

![Sentinel surveillance among pregnant women age 14-25 in Mbeya Region (n= 12,594)](image)

- The centre is located on the ground of Mbeya Referral Hospital
• Site staffs:
  – 80 Tanzanians
  – 4 Foreigners
• Over the past 8 years the MMRP has evolved to a comprehensive clinical trial centre for vaccines and drugs for HIV, TB & Malaria
• The centre is located on the ground of Mbeya Referral Hospital
• Site staffs:
  – 80 Tanzanians
  – 4 Foreigners
• Over the past 8 years the MMRP has evolved to a comprehensive clinical trial centre for vaccines and drugs for HIV, TB & Malaria

• MMRP evolved from the Mbeya Regional AIDS Control Programme (MRACP) to enable research necessary to better implement existing HIV/AIDS intervention strategies
• 1996 - MMRP was founded by the Mbeya Regional Medical Office, the Mbeya Referral Hospital and the Department of Infectious Diseases & Tropical Medicine at the University of Munich (LMU)
• 2001 - US Military HIV Research Programme (USMHRP) joined MMRP
• 2004 – MMRP collaboration with the National Institute of Medical Research (NIMR), Dar es Salaam
• Additional scientific partners of MMRP are:
  – Muhimbili University College of Health Sciences, Dar es Salaam, TZ
  – University of Cape Town, SA
MMRP Steering Committee

<table>
<thead>
<tr>
<th>Tanzanian Government</th>
<th>US Military HIV Research Program</th>
<th>University of Munich</th>
</tr>
</thead>
<tbody>
<tr>
<td>Andrew Kitua</td>
<td>Deborah Birx</td>
<td>Thomas Loescher</td>
</tr>
<tr>
<td>Donan Mmbando</td>
<td>Francine McCutchan</td>
<td>Hans Nothdurft</td>
</tr>
<tr>
<td>Eleuter Samky</td>
<td>Merlin Robb</td>
<td>Frank v. Sonnenburg</td>
</tr>
</tbody>
</table>

Secretary: Michael Hoelscher, University of Munich

- introduced in April 2004
- meets 2 – 3 times a year
- provides guidance in all major issues

**MMRP - Research objectives**

1. Describe the HIV epidemiological situation in the region and explore different populations for their feasibility to participate in HIV vaccine evaluations
2. Understand the socio-economic background and risk factors for HIV infection
3. Describe the molecular epidemiology of circulating HIV strains
4. Understand the cellular immune-response of HIV infected and uninfected individuals
5. Understand the most prevalent HLA-types in the population
6. Explore the feasibility of different drug regimens and delivery systems for future large scale ARV interventions
7. Establish the appropriate infrastructure in communities that may participate in future phase II, III and IV trials
8. Explore the feasibility of different diagnostic and drug options for diagnosis and treatment of other diseases (e.g. TB and malaria)

**On-going research activities**

**MMRP has established 2 cohorts:**
1. 600 bar-workers in high risk environments for HIV (20 sites along the trans-African highway)
   - Within HIV Super-Infection Study (HISIS)
   - Enrolled Sept – Dec 2000
   - So far, followed up over the past 4 yrs (3 monthly)
2. Population based cohort of ~ 3000 individuals
   - Within Cohort Development (CODE) Project
   - Enrolled Sept – Dec 2002
   - To be followed up for at least 3 years (6 monthly)

HISIS Project /Bar-workers Health Project (BHP)

"Behavioural, Immunological and Virological Correlates of HIV-1 Superinfection (HIV-1+ vs HIV-1++) in Rural Tanzania"

HISIS project - 3 arms

1. Biomedical arm
   - to investigate the prevalence/ incidence of HIV super-infection and response of the immune system

2. Behavioural arm
   - Risk factors for infections (HIV and STDs ) and the population dynamics of the study participants

3. Clinical arm
   - Interaction between STIs and HIV and evaluation of STD drugs

HISIS Primary biomedical objectives:

- Frequency of HIV multiple infections in a high risk cohort
- Frequency and timing of superinfection events
- Dynamics of viral quasispecies after super-infection
- Comparison of cellular and humoral immune response in single and dual infected individuals

HISIS study overview:
• HISIS/BHP = HIV Super-Infection Study/Bar-workers Health Project

• Target group - women working in high-risk environments for STIs/HIV (Bars, Guesthouses, Restaurants and Pome (local brew) shops – along highways

• 20 study sites within 17 HIV High Transmission Areas (HTAs)

• Open cohort - 600 study participants (30 in each of the 20 sites) enrolled Sept – Nov 2000

Among the initial cohort (First 600 participants)

• HIV Prevalence during enrolment (FU0) = 68%

• Cumulative HIV Incidence over the 4 years = 20.8%

• HIV incidence (decreased over the past 4 years)
  –  24 seroconverters in the 1st year
    (Incidence = 14.1 per 100 pyr)
  –  7 seroconverters in the 2nd year
    (Incidence = 4.3 per 100 pyr)
  –  3 sero-converters in the 3rd year
    (Incidence = 2 per 100 pyr)
  –  6 sero-converters in the 4th year
    (Incidence = 3.8 per 100 pyr)
After 48 months (4 years)

- Death rate = 14.6%
- Drop out rate = 25.5%
- Retention rate = 59.8% (74.5% including the dead participants)

Cohort Development (CODE) Project

"Infectious Disease Surveillance (HIV, TB and Malaria) and Cohort Development Among Urban and Rural Adults in Mbeya Municipality, Tanzania"

Sponsored through the US Military HIV Research Program

**Primary objectives:**

Analyze the feasibility, recruitment efficiency, follow-up rates, costs and knowledge for vaccine trials of three distinct cohort development strategies:

- House to house recruiting in a middle class residential area.
- House to house recruiting in a rural population
- Public advertising for study participation

**Secondary objectives:**

- Describe possible endpoints of a vaccine trial
- Describe the HLA distribution in Mbeya region
- Epidemiology of Hepatitis A and B
- Describe the morbidity of recruited population (especially infectious diseases)
- Prevalence and incidence of HIV-1 in an adult urban and rural population
- Risk factors associated with HIV infection

**Prevalence of HIV during enrolment**

<table>
<thead>
<tr>
<th>CODE cohort</th>
<th>HIV-Prevalence</th>
<th>Significance of difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>All participants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Women</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Men</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Cohort overall | 514/3096 (16.6%) | 333/1778 (18.7%) | 181/1318 (13.7%) | p < 0.01  
Mbeya town (Ghana & Advert) | 389/2102 (18.9%) | 257/1211 (21.2%) | 132/891 (14.8%) | p < 0.01  
Rural (Irente) | 125/994 (12.6%) | 76/567 (13.4%) | 49/427 (11.5%) | p = 0.364  
Significance of difference | p < 0.01 | p < 0.01 | p = 0.099 |  

Overall Retention Rates - CODE (all 3 sub-groups)

Primary objective:
• Determine Predictive Values of Urine LAM Elisa in Tanzanian patients with symptoms of PTB
Secondary objectives:
• Determine LAM Elisa sensitivity in Group A (Smear+, Cult+)
• Determine LAM Elisa sensitivity in Group B (Smear-, Cult+)
• Determine LAM Elisa sensitivity in Group D1 (Smear-, Cult-, Chest x-ray +) and Group D2/D3 (Smear-, Cult-, but clinical proof of TB during Follow up)
• Determine LAM Elisa specificity in the control Group C (PTB suspects revealing as Non-TB during Follow up)
• Determine in comparison LAM Elisa specificity in a healthy control Group CC (no symptoms, HIV-)
• Establish a rigorous study concept for evaluation of new TB diagnostics

• The study will include 600-700 consecutive patients presenting with symptoms of pulmonary TB at the TB clinics in Mbeya municipality
• Clearance already obtained from local IRB (May 05) and NIMR/MOH (June 05)
• To start July 2005
• Total duration of the study is 13 months
• Funded by FIND (Foundation for innovative new diagnostics)

2. TB-ERA study

"Study on surrogate markers of drug efficacy, disease activity and relapse in Tuberculosis"

Involves a multi-country partnership with
• 8 African partners (Zambia, Tanzania x 2 sites, South Africa, Senegal, Madagascar, Ethiopia and Gambia) and 5 European partners (United Kingdom x 2, Germany, Denmark and France)
• Funded by EU/EDCTP
• 4-year project
• Approved by local IRB
• Already submitted to NIMR/MOH for approval
• Expected to start in the last half of 2005

The component objectives:
• to run the project effectively and efficiently
• to setup an effective collaborative partnership between the MMRP, the 7 African partners and the 5 European partners for the achievement of the EDCTP call
• Setup two major longitudinal cohorts of 250-350 TB patients and 400-800 contact persons (HIV positive and negative) in Mbeya Region
• Test surrogate marker assays for mycobacterial load and immunologic markers in both cohorts
• Build up a sample bank for clinical material (sera, urines, sputa, mycobacterial isolates)
• Enhance the involvement of the MMRP in the scientific, infrastructure and capacity development activity in research and public health priority areas

3. EMINI Project

"Establishment of the infrastructure to evaluate and monitor the impact of new interventions, including drugs and vaccines for HIV, TB and malaria"
Overall objective:
- Aim of this proposal is to contribute to the overall improvement of health by controlling two of the three major communicable diseases (HIV and TB) and help achieving the outcome criteria set by initiatives such as the WHO 3 by 5 and STOP-TB programmes

Specific objectives:
- the reinforcement of the existing health infrastructure which will improve the health care provision in general and
- the establishment of the capacity to rapidly move new interventions into evaluation, including innovative treatments, vaccines and new diagnostic methods.
- EMINI is an activity that combines intervention, with demographic and disease surveillance and preparation for the evaluation of new interventions in 5-8 selected communities in Mbeya region
- Approval from the local IRB and NIMR/MOH already obtained
- 3 year project
- Expected to start July 2005
- Funded by EuropeAid (EU)

4. Mbeya Anti-Retroviral Adherence (MARVAD) study

"Adherence to HAART among HIV infected persons in Mbeya region, Tanzania: factors for improving compliance and their implications for the treatment outcomes"

STUDY OBJECTIVES:
- To assess correlation between different measures of adherence (self-reporting, interview and pill count)
- To determine the association between adherence patterns measured by each of the three different measures and treatment outcomes [PVL, CD4 count, and Clinical findings (occurrence of OIs, hospitalization and deaths)] over 12 months
- To assess the factors which influence adherence patterns in Mbeya region
- The proposal is ready for submission at the local IRB and NIMR/MOH
- To be conducted in the context of the on-going HIV treatment and care programme at the Mbeya Referral Hospital
- To be funded by MMRP
5. HIV Vaccine Trial

"A phase I/II clinical trial to evaluate the safety and immunogenicity of a multiclade HIV-1 DNA plasmid vaccine, VRCHIVDNA016-00-VP, boosted by a multiclade HIV-1 recombinant Adenovirus-5 vector vaccine, VRC-HIVADV014-00-VP in HIV uninfected Adult volunteers in East Africa”

Sponsored by:
Division of AIDS (DAIDS)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)

Vaccine provided by:
Vaccine Research Center (VRC), NIAID, NIH
Bethesda, Maryland, U.S.A.

Study duration:
• 14 to 16 months per participant

Study clinical sites:
• U.S. Army Medical Research Unit-Kenya and Kenya Medical Research Institute, Kericho, Kenya
• Mbeya Medical Research Program (MMRP) Clinic, Mbeya, Tanzania
• Makerere University-Walter Reed Project Vaccine Research Clinic, Makerere University, Kampala, Uganda

Summary of MMRP cohort data

<table>
<thead>
<tr>
<th></th>
<th>HISIS CODE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Urban 2,000</td>
</tr>
<tr>
<td>Cohort size</td>
<td>600</td>
</tr>
<tr>
<td>Cohort age group</td>
<td>18 - 35</td>
</tr>
<tr>
<td>HIV-Prevalence</td>
<td>69%</td>
</tr>
<tr>
<td>HIV-Incidence</td>
<td>7%</td>
</tr>
<tr>
<td>Recombinant subtype</td>
<td>53%</td>
</tr>
<tr>
<td>Multiply HIV infected</td>
<td>48%</td>
</tr>
<tr>
<td>6 months retention</td>
<td>93.4%</td>
</tr>
<tr>
<td>24 months retention</td>
<td>76.3%</td>
</tr>
</tbody>
</table>

|                  | HIV-19%   |
|                  | 18 – 45   |
| HIV-Incidence    | 1.8%      |
| Recombinant subtype | 39%  |
| Multiply HIV infected | 16% |
| 6 months retention | 90.4%  |
| 24 months retention | 76%   |
|                  | 18 – 45   |
| HIV-Incidence    | 1.5%      |
| Recombinant subtype | 27%  |
| Multiply HIV infected | 8%    |
| 6 months retention | 96.3%  |
| 24 months retention | 89.4%  |
Planned and ongoing VCT and HBC Research Activities
Dr. J. Mbambo

HIV/AIDS PANDEMIC
- Continues to threaten lives of millions of people worldwide
- 40 Million
- 28 million are from sub-Saharan Africa
- 20 Million have died
- Social and Economic burden

Efforts in fighting HIV/AIDS

1. Prevention
   a) Awareness: Health education
      Abstinence for youths
      Fidelity for married couples
      Safe sex
   b) Voluntary testing

2. Care /Therapies

HIV/AIDS THERAPIES

Life prolonging drugs

- Formal/Western/Modern /Conventional ARVs: AZT, 3TC, ddI, d4T, NVP,
- Complementary and alternative (CAM)
  Traditional Medicine (TM)

Traditional medicine (TM)
- Comprehensive term including TM systems of various forms of indigenous medicine, such as Chinese medicine, Ayurveda, Arabic unani, African and Latin american

Traditional medicine therapy involves the use of
- herbal medicines
- animal part/s
- Minerals
- Dietary supplements
- Certain beliefs
In countries with resource-limited settings:
- Limited health care facility
- HIV/AIDS pandemic largely affecting poor third world countries
- Desperate need for care, support and prevention
- Readily available, accessible and affordable alternative
- Effective

- TM have been used for generations, hence their safety and effectiveness are empirically documented
- Up to 80% of people in the poor world rely on TM for their primary health care needs, including HIV/AIDS
- In China, TM accounts for ~ 40% of all health care delivered

Collaboration between Biomedical researchers and Traditional Healers
Collaborative working initiatives :
- TAWG
- THETA
- WOFAK

Collaborative research initiatives: ITM-MUCHS

Experience: ITM- MUCHS study on TM

Objectives:
- To recruit genuine Traditional Healers willing to collaborate with Biomedical Researchers
- To determine socio-anthropological aspects associated with the selection of remedies for treatment of HIV/AIDS
- To monitor the anti-HIV efficacy of the herbal preparations prescribed by THs in patients
- To monitor safety/toxicity in patients laboratory parameters
- To determine chemical profile of the herbal extracts

Methodology

Traditional healers
i) TRADITIONAL HEALERS
- HIV/AIDS knowledge
- Quality clinics
- Record keeping
- Willing to collaborate
- Adherence to ethics

149 THs in Arusha interviewed
7 selected for the study
122 THs in DSM
30(11) selected for the study

Patients
- Recruitment of Research Subjects
- Follow-up and observation of RS for 2 yrs:
  a) **Safety**: Renal function tests (serum creatinine, BUN)
  Liver function tests (ALAT and ASAT)
  Haematological indices (F B P, ESR, Platelet count)
  Allergic reactions
  b) **Clinical progression**
  Serial physical examinations
  Body weight
  Documentation of illness episodes
  Assessment of quality of life
  c) **Virological and immunological indices**
  Viral load
  Absolute counts of CD4+ and CD8+-T- lymphocytes

Results

**Client distribution during recruitment**

<table>
<thead>
<tr>
<th>Sero-status</th>
<th>frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV sero-negative</td>
<td>26</td>
<td>15.9</td>
</tr>
<tr>
<td>Absc. Registration</td>
<td>13</td>
<td>8.0</td>
</tr>
<tr>
<td>Recruited for follow-up</td>
<td>124</td>
<td>76.1</td>
</tr>
<tr>
<td>Total</td>
<td>163</td>
<td>100.0</td>
</tr>
</tbody>
</table>

**Outcome after one year of follow-up**

<table>
<thead>
<tr>
<th></th>
<th>Frequency</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>28</td>
<td>22.6</td>
</tr>
<tr>
<td>Loss of follow-up</td>
<td>25</td>
<td>20.2</td>
</tr>
<tr>
<td></td>
<td>Count</td>
<td>Percentage</td>
</tr>
<tr>
<td>--------------------------</td>
<td>-------</td>
<td>------------</td>
</tr>
<tr>
<td>Still on follow up</td>
<td>71</td>
<td>57.3</td>
</tr>
<tr>
<td>Total</td>
<td>124</td>
<td>100.0</td>
</tr>
</tbody>
</table>

Serum creatinine follow-up for one year (Umol/L)
Percentage of client experienced side effect of traditional medication

<table>
<thead>
<tr>
<th>visit</th>
<th>No</th>
<th>nausea</th>
<th>vomiting</th>
<th>abd. pain</th>
<th>Diarrhea</th>
<th>dizziness</th>
<th>headache</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>124</td>
<td>0.8</td>
<td>1.6</td>
<td>1.6</td>
<td>3.3</td>
<td>0.8</td>
<td>0.8</td>
</tr>
<tr>
<td>2</td>
<td>118</td>
<td>4.2</td>
<td>2.5</td>
<td>1.7</td>
<td>2.6</td>
<td>2.5</td>
<td>2.5</td>
</tr>
<tr>
<td>3</td>
<td>117</td>
<td>0.9</td>
<td>0.9</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0.9</td>
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<tr>
<td>4</td>
<td>109</td>
<td>1.8</td>
<td>0.9</td>
<td>0.9</td>
<td>1.8</td>
<td>2.8</td>
<td>1.8</td>
</tr>
<tr>
<td>7</td>
<td>90</td>
<td>1.1</td>
<td>1.1</td>
<td>2.2</td>
<td>1.1</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>10</td>
<td>83</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
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<td>13</td>
<td>75</td>
<td>1.3</td>
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<td>0</td>
<td>0</td>
<td>1.3</td>
</tr>
<tr>
<td>16</td>
<td>66</td>
<td>0</td>
<td>0</td>
<td>1.5</td>
<td>0</td>
<td>1.5</td>
<td>0</td>
</tr>
</tbody>
</table>

Trend of CD4 count on follow-up

<table>
<thead>
<tr>
<th>CD4</th>
<th>No</th>
<th>Min CD4</th>
<th>Max CD4</th>
<th>Mean</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>121</td>
<td>1</td>
<td>1374</td>
<td>261.69</td>
</tr>
<tr>
<td>1</td>
<td>102</td>
<td>1</td>
<td>1781</td>
<td>295.05</td>
</tr>
<tr>
<td>2</td>
<td>89</td>
<td>1</td>
<td>1150</td>
<td>317.38</td>
</tr>
<tr>
<td>3</td>
<td>83</td>
<td>1</td>
<td>1555</td>
<td>298.02</td>
</tr>
</tbody>
</table>
CD4 4  70  5  1187  300.74
CD4 5  60  7  1316  317.75
CD4 6  33  14 1303  365.03

Relationship of CD4 level on recruitment and outcome of follow-up

<table>
<thead>
<tr>
<th>CD4 Level</th>
<th>Death No(%)</th>
<th>Off follow No (%)</th>
<th>On follow No(%)</th>
<th>Total No</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200</td>
<td>26(92.9)</td>
<td>15(65.2)</td>
<td>26(37.1)</td>
<td>67</td>
</tr>
<tr>
<td>200-500</td>
<td>2(7.1)</td>
<td>6(26.1)</td>
<td>27(38.6)</td>
<td>35</td>
</tr>
<tr>
<td>&gt;500</td>
<td>0</td>
<td>2(8.7)</td>
<td>17(24.3)</td>
<td>19</td>
</tr>
<tr>
<td>Total</td>
<td>28(23.1)</td>
<td>23(19.0)</td>
<td>70(57.9)</td>
<td>121</td>
</tr>
</tbody>
</table>

Preliminary results

Traditional Herbal Remedies Effective against

- Skin conditions
- Diarrhoea
- Cough
- Persistent fever
- Oral thrush
- Herpes zoster
- Effect/stabilize CD4 cell?
- Quality of life

Conclusion

- TM remedies have some effectiveness in the treatment of HIV/AIDS
- TM remedies used against HIV/AIDS should be carefully monitored
Efficacy
Mechanism of action?
Safety: Possible side effects/toxicity

Recommendation
- Formulation of Standardized TM remedies for HIV/AIDS
- Clinical trial of standardized formulations
- Large scale production
- Controlled rational use of these formulations

CHAPTER FIVE: THE PRIORITY SETTING PROCESS
Dr Mwele Malecela

Health and health research
- Health plays a vital role in development
  - not only an outcome, but a co-determinant
  - investment in health yields exceptionally high rates of return
- Not enough is spent on health and health research by many developing countries
- Not enough is spent on health research for the needs of developing countries

Priority setting
- Priority setting is important as it ensures that public funds spent on health research lead to better health for the people.
- It guides donor funded research to deal with priority areas.
- This is especially true with resource poor countries like Tanzania.

Priority setting-Key issues
- Urgency
- Resource allocation
- Avoidance of donor driven research
- Maximizing limited capacity and building capacity
- Avoidance of duplication
- Influencing policy and practice
- Some issues need immediate attention
- Research results needed to inform policy
- Some research is relevant but not urgent.

- Limited resources bring forward the need to prioritize
- Funds should be directed to priority areas
Priority setting allows countries to have their own research agenda
- It is important to consider issues of both global and local relevance but local relevance should be the key factor
- Priority setting reduces donor driven research as a set of national priorities exists.

Key issues in priority setting-capacity
- Does the capacity exist?
- Are there plans to enhance the capacity to carry out this particular research area?

Key issues in priority setting-Duplication
- To avoid several studies dealing with the same issue- a waste of both financial and human resources.
- This takes resources away from other key areas.

Key issues in priority setting-Policy
- Research that is demanded is more likely to influence policy.
- By inference priority research is more likely to influence policy

Workshop objectives
- To identify and prioritize research areas/issues necessary to implement strategies of the National AIDS prevention and control within the health sector strategy
- To select projects which are manageable for five years
- To identify research institutions and partners capable of developing and implementing research activities

Group work-Revisiting the past and planning for the future.
The group work involved examining what has been done so far, what needs to be carried forward from the last set of priorities set in 1999 and finally what needed to be done with reference to the new areas that were presented and the current information on the various subjects that was gained through discussions. Group work followed the following structure:
- What has been done?
  - Refer to
    - Presentations
    - Research inventory
    - Research implementation plan
- What needs to be carried forward?
What needs to be done?
  - Refer to
    - New areas presented
  - Five groups to discuss the gaps
  - Presentations in plenary

GROUP – BIOMEDICAL RESEARCH

Key Biomedical Research Issues

Simple methods:

- In diagnosis of HIV infection in infancy
- Immunological monitoring in children
- Diagnosis of TB and other OI, malignancies.
- In diagnosis to determine causes of fevers in HIV positive cases
- To ensure blood safety (combined antibody antigen assays) as well as improving lab diagnosis
- Alternative Laboratory methods for diagnosis of HIV infection-(not using blood)

HIV characterization in relation to disease progression, vaccine development and ARV drug resistance

3. Simple immunological methods for monitoring HIV disease progression

4. Lack of a national Laboratory capacity Building to undertake essential research (Health systems research).

Good biomedical capacity to undertake TM Research to meet international standards (Health systems research).
6. HIV/STI Vaccine and Microbicide Research and Development efforts.

7. STI etiological agents and drug sensitivity patterns within the context of syndromic management of STIs.

   Biological determinants of HIV discordancy

9. Traditional medicinal treatment and alternative therapies against HIV/AIDS/STIs

10. Locally available nutritional supplements for HIV/AIDS

11. Quality assurance systems in HIV/AIDS/STI laboratory/care, treatment and support

   Normal laboratory reference values in different geographical areas in the country

13. HIV/AIDS among health care workers (care and treatment)

14. Determinants of HIV long-term non-progressors

15. Alternative biomedical preventive measures e.g. PEP, Male/Female condoms, ARV etc.

   PMTCT/ PMTCT Plus research

17. Hepatitis B/C-virus/HSV in relation to HIV/AIDS

18. Drug interaction in HIV/AIDS management e.g. ARVs and traditional medicine

* Capacity building for R & D in the identified biomedical research areas
## EPIDEMIOLOGY AND SURVEILLANCE RESEARCH

<table>
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<td>• Is there a regular system to identify behavioural data to explain observed HIV/STD sero-logical trends?</td>
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<td></td>
<td>• Updating and field testing of operational protocols for systematic and regular behavioural surveillance.</td>
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<td>2. Inadequate of simple affordable and effective models for increasing coverage of national HIV/AIDS/STD Surveillance.</td>
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| 6. Lack of quality assurance measures in various regional and district laboratories. | • Assess the knowledge and skills of labs staff.  
• Upgrading the laboratories to conform to good laboratory practice (GLP).  
• Develop simple affordable tools to be used by district in monitoring quality assurance.                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                      |      |
| 7. Lack of sufficient information on the drug susceptibility monitoring of HIV/AIDS/STI | • What are the diagnostic and therapeutic methods to monitor the ART drug resistance?  
• Determination of HIV resistant strains to specific ART drug.  
• Monitor the sensitivity patterns of HIV strain from time to time.  
• What are the effective methods for monitoring efficacy safety and potency of the affordable ART drugs relevant to Tanzania  
• What are the affordable ART relevant to Tanzania  
• What is the pattern of primary and secondary resistant to ART drugs                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                      |      |
| 8. Inadequate information on factors related to HIV transmission in different groups. | • Factors influencing HIV transmission among different age and population groups e.g youth, institutional, CSW, miners  
   - Social cultural  
   - Social economic  
   - Psychosocial  
   - Biologic  
   - Beliefs and taboos  
• Factors influencing mothers to child transmission of HIV  
• Individual perception of risk of HIV transmission.  
• To what extent does migration contribute to the spread of HIV?                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                      |      |
| 9. Lack of adequate preparations for trials involving vaccines,                  | • What are the necessary preparations/actions that are required to conduct HIV/AIDS vaccine and nutrition trials;  
• What are the different HIV sub-types that are prevalent in Tanzania                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                      |      |
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<td>nutrition and immunomodulators for HIV/AIDS.</td>
<td>and their contribution toward HIV transmission? • What are the indicators to monitor and evaluate vaccine nutritional and other related trials?</td>
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</tr>
<tr>
<td>10. Lack of sufficient information on the efficacy of newly developed HIV/AIDS interventions including ART drugs and nutritional supplements.</td>
<td>• What is the efficacy of ART and nutritional supplements? • Assessment of appropriateness of the newly developed algorithms for treatment of HIV/AIDS in different population groups e.g. - pregnant women - children • To further investigate and conduct large scale trials on the use of vaginal microbicides to prevent STD/HIV in different population groups e.g. CSW discordant couples.</td>
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<td>11. Inadequate information about linkage between HIV/STDs prevalence, incidence, demographic socio-economic and geographic factors.</td>
<td>• What are the explanations for the observed geographical variation in the magnitude and trends of HIV/AIDS/STD • What is the influence of road construction mines, army camps, fishing, plantations etc. in the risk of transmission of HIV/AIDS? • What is the relationship between demographic, socio-economic and geographic factors that contribute to the spread of HIV/AIDS/STDs?</td>
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<td>12. Effectiveness of ARVs impact of ARV in prolonging life and reducing spread of HIV infection.</td>
<td>• What is the change in quality of life in individuals who are on ARV? • What are the survivability of individuals receiving ART? • What is the effectiveness of ART treatment on reduction of mortality and hospitalization?</td>
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SOCIAL BEHAVIOURAL AND COMMUNICATION RESEARCH ISSUES

1. Comparative studies on sexuality in different communities and groups
   - Communities with high, low prevalence and those in the middle.
   - Groups which are high risk and low risk.
   - Cross generational sexual activities.
2. Impact studies of HIV/AIDS on social life and behaviour and different groups including elderly, youth, orphans, professionals.
3. Trends of sexual behaviour in people living with HIV/AIDS.
5. Gender relations and sexuality: Example making sexual related decisions.
6. Institutionalized settings and sexuality.
8. Effective communication to revise current prevalence trends.
9. Disclosure of HIV sero-status to different groups: Children and Adults.
   - Impact of disclosure
   - Effective communication for disclosure
10. Stigma studies.
11. Depression issues in HIV/AIDS.
12. Community support for adherence on ARVs.

CARE, TREATMENT AND HEALTH SYSTEMS

Identification of research areas on care and treatment

1. Efficacy and safety of current recommended ARVs regimens in Tanzania.
2. Determinants of durability of 1st line treatment (regime)
3. To determine the (immunological and virological) response of severely immunocompromised (very low CD4 count) on ARV.
4. Strategy to culturally acceptable and cost effective appropriate measures to adherence of ART and OI prophylaxis

5. Determine magnitude and correlates of primary and secondary resistance

**Identification of research areas on care and treatment**

6. To determine the response of ARV on mothers with pre-exposure to Nevirapine (side effects)

7. Interaction between ARV and other commonly prescribed drugs, traditional medicine, branded food supplements and micronutrient.

8. Objective means of determining ARV adherence in laboratories

9. Pharmacokinetic of ARV by age and by gender

10. Strategies to increase uptake of paediatric age groups in ART clinics.

11. Strategies to enhance use of ART for PMCT among women delivering outside health facilities.

**Identification of research areas on care and treatment**

12. What are simple, cost effective and reliable diagnostic methods for common OIs including TB in children and adults.

13. Feasibility of INH prophylaxis

14. Scaling up of HIV and TB integration


16. Integration of HIV care and HIV prevention (those who are HIV infected and those under ARVs need to be prevented)

17. Research on access to care and treatment for health care workers including post exposure prophylaxis

**Identification of research areas on care and treatment**

18. Research on HIV health related stigma
19. Research on PMCT triple therapy to benefit mother and child (?? Nevirapine)

20. On going research on alternative ARV regimens

21. Research on ARVs response on co morbidities (hepatitis B, C and HIV)

22. Research on effect of nutrition on the pharmacokinetics of ARVs

23. Pilot opt out strategies to invite care and treatment seeking behaviour to ART.

**Identification of researches areas on Health system**

1. * Strategies to roll out ARVs to Health Centres without compromising standards.

2. * Improvement of logistics of procurement and delivery of ARVs and reagents from MSD.

**Group 1**

Research issues

- Discordant couple resistance factors- the biological determinants.
- Community at risk no research in teachers, medical professionals, and MP’s.
- Inventory of medicinal plants and other remedies
- Locally available food supplements
- Alternative remedies for HIV/AIDS
- Impact of HIV/AIDS on the elderly.
- Quality assessment of services for HIV/AIDS in rural Tanzania.

**Group 2**

Research issues-Biomedical research

- Quality assurance
- Reference values
- Lab result errors
Viral dynamics
Simple tests for under 18 months
No 1, No 2, 4, 5, and 6

Epidemiology and surveillance
Scaling up sentinel surveillance-mobile groups eg truck drivers, csw’s and nomads
Innovative methods for identifying risk factors

Social behavioral issues
FGM and male circumscion
Trends of sexual behavior in PLWA
Trends and magnitude of cultural practices
Rape incidence and their behavioral

Health services
Opt in opt out issues
Partner notification after VCT

GROUP - 3

What is missing?

Biomedical Research Issues:
Lack of knowledge and information on HIV/AIDS subtypes and their recombination in some areas of Tanzania.
- Transmission
- Heterosexual, MTCT
- Geographical distributions
- Surveillance

What is missing?
Biomedical Research Issues: cont.

Rationale:

► Prevention and vaccine development
► In relation to recurrence and spread of drug resistance (ARVs)
► Lack of knowledge on the use and timing of NVP is PMTCT.
  - Spectrum of 1 – 72 hours
► Lack of knowledge on affordable and reliable infant HIV test.

Lack of knowledge on:

► Contribution of hepatitis B-virus in HIV/AIDS and impact of an ARV response.

Lack of knowledge on:

► Drug interaction – ARVs and traditional

Surveillance and epidemiology medicine

Lack of knowledge on

► Patients with severely low CD4 count e.g.≤50
► Gradation of CD4 counts.

Social behaviour and communication research

► Gender and sexual related decisions.
► Social behavioral intervention studies in colleges.
► Wealth and education as risk factors for HIV transmission

GROUP - IV

GAPS
(What needs to be done/carried forward)

BIOMEDICAL

1. Simple methods:
● In diagnosis of HIV infection in infancy
● Immunological monitoring in children
● Diagnosis of TB and other OI, malignancies.
● In diagnosis to determine causes of fevers in HIV positive cases
● To ensure blood safety (combined antibody antigen assays)
● Alternative Laboratory methods for diagnosis of HIV infection-(not using blood)
● Improving lab. Diagnosis of HIV using antibody /antigen tests.

2. Lack of national HIV characterization and resistance surveillance system.
   ● Immunological and virological monitoring.

3. Lack of a national Laboratory capacity Building to undertake essential research.

GAPS
(What needs to be done/carried forward) -II

BIOMEDICAL – CONT.

4. Lack of Good biomedical capacity to undertake TM Research to meet international standards.

5. Inadequate HIV vaccine Research and development efforts.

6. Lack of a functional system for STI etiological agents and drug sensitivity patterns within the context of syndromic management of STIs.

SURVEILLANCE

1. Lack of information on trends of HIV infection in special high risk groups like CSWs, 1DUs, people in correctional institutions

2. Behavior surveillance of sexual behavior in relation to ART

SOCIAL BEHAVIORAL AND COMMUNICATION RESEARCH

1. Determinants of discordance and possible interventions to reduce seroconversion rates.

3. Disclosure of HIV serostatus to the children starting with adolescents

**CARE AND TREATMENT**

1. Scaling up effective Care, Treatment and support to reach all eligible Tanzanians.

2. Lack of Preventive measures within the Care, and Treatment strategy.

3. Strategies to scale up uptake by children and adolescents of ARV as well as care and support

4. Care of HIV infected in correctional institutions.

5. Research on access of Care and Treatment for Health Care workers including post Exposure prophylaxis. (Workplace intervention in hospital)

**GROUP 5**

**(A) BIOMEDICAL RESEARCH**

1. Lab Service

   - Infrastructures available in Consultant hospitals only and a few Mission hospitals.

   - There are none in Regional and District hospitals.

   - Lack of reliable HIV and Opportunistic and STIs infection diagnostic methods and clinical methods.

   - Reagents are still a major problem in all hospitals.

   - Governments should have the mandate to source the reagents from manufacturers rather than through MSD.

   - Quality

   - Lab Test reference Manuals should be developed.

   - Capacity to monitor Viral dynamics in ART era -

     - HIV – subtypes

     - HIV drug resistance
- Capacity building for Lab staff

(A) BIOMEDICAL RESEARCH - II

2. Determination of Magnitude of HIV infection among health care workers in different settings

3. To assess nutritional issues and stigmatization influence on HIV/AIDS infected population progression.

4. To observe HIV infected population for health seeking behaviour in relation to progression of HIV.

5. As (in MTP III Document) on No. 6, page 26 and education to Traditional healers.


(A) BIOMEDICAL RESEARCH - III

7. As above, no. 9,p.27. Including
   - adherence and
   - morbidity and mortality

8. Logistics
   - Research on smooth procurement logistics on ART.


10. Monitoring treatment adherence morbidity and mortality.

SOCIAL BEHAVIOURAL AND COMMUNICATION RESEARCH

1. Gender and HIV/AIDS/STD

   Research should be done on social, behavioural biological factors that influence the long standing differences in HIV prevalence between men and women.

2. Behaviour responses to STDs Health Seeking behaviour
   
   ◆ The social-cultural practices related to different sexual behaviour in selected communities (Sex initiation ceremonies /practices and their influence on early sexuality).
All research questions should be continued to address specific behaviour among specific groups respond to STD infection.

SOCIAL BEHAVIOURAL AND COMMUNICATION RESEARCH

3. Inadequate, inappropriate HIV/AIDS/STDs education for different target groups
   - Should be continued because has not been done effectively. As pg. 32.
     - Conduct research on knowledge attitude and behavioural (KABP)

4. Barriers to promotion of safer sex in various target groups.
   - Assess the incidence of rape in the society
   - To be continued as pg. 32.

5. Inadequate involvement of sectors in the multisectoral expanded response.
   - Research on the multisectoral response on HIV/AIDS
   - Investigate the poor commitment and political will.

SOCIAL BEHAVIOURAL AND COMMUNICATION RESEARCH

6. Role of socio cultural and sexual practices in the spread of HIV/AIDS.
   - Research to be done as indicated on pg. 33
   - Research on positive socio-cultural norms and values which encourage positive attitudes and decision making about sexual matters.

Priority Setting Methodology

The Methodology

- Identification of the key research issues
- Generating research questions
- Prioritization of the ensuing research questions
- Identifying multidisciplinary teams to carry out research based on comparative advantages and identification of stakeholders
Stage 1 - Identification of key research issues

- Review of 1999 priorities
- Presentations on state of the art in HIV AID STD research
- Presentation on NACP programme needs
- Discussions and consensus

Stage 2 - Identification of key research issues by discipline

- Review of 1999 priorities
- Presentations on state of the art in HIV/AIDS STD research
- Presentations on NACP programme needs
- Key areas that have not been considered - based on knowledge of the subject
- Discussions and consensus

Stage 2 - Identification of key research issues by discipline

- Generate a list of research areas from which the research question will be generated.
- Presentation of research issues with justification.
- Consideration should be given to:
  - Gender
  - Equity
  - Cost effectiveness of the interventions
  - Influence on policy
  - Poverty
  - Human rights
  - Health reforms

Ranking of research issues
Key issues in ranking

- Urgency of the problem
- What similar research has already been done
  - Is the information available?
  - Does it fit into the local context
  - Do we need more research in this area it feasible to do this research
- Is it feasible to do this research
  - Technical feasibility: HR and organizational capacity
  - Economic feasibility: the costs of carrying out the research and possible source of funds
  - Ethical feasibility
  - Political feasibility: political acceptance of the research
    - Political climate and political will.
- Expected impact of the research
- Will results be used to change policy

Criteria for Ranking

- Relevance: defining the problem in the local context
- Avoidance of duplication
- Feasibility
- Political acceptability
- Applicability
- Ethical acceptability
- Gender issues
- Accuracy of knowledge base
RANKING OF RESEARCH ISSUES

RESEARCH ISSUE: ..........................................................................................................

1. RELEVANCE
   a. 1= Not relevant
   b. 2= Of little Relevance
   c. 3= Relevant but not important
   d. 4= Relevant
   e. 5= Highly relevant

Score.............

2. AVOIDANCE OF DUPLICATION
   a. 1= Several studies exist and information is available
   b. 2= Some studies exist
   c. 3= Some studies have been carried out but information is not available
   d. 4= Very few studies have been carried out in this area
   e. 5= No studies have been carried out in this area

Score.............

3. FEASIBILITY
   a. 1= Extremely difficult
   b. 2= Difficult
   c. 3= Moderate feasibility
   d. 4= Feasible
   e. 5= Highly feasible

Score.............

4. POLITICAL ACCEPTABILITY
   a. 1= Politically unacceptable
   b. 2= Low level of political acceptability
   c. 3= Moderate political acceptability
   d. 4= Reasonable political acceptability
   e. 5= Highly politically acceptable
5. APPLICABILITY (Are the results applicable mainly to policy and practice
   a. 1=Not applicable
   b. 2=Low applicability
   c. 3=Moderate applicability
   d. 4=Reasonable applicability
   e. 5=Highly applicable
Score..................

6. ETHICAL ACCEPTABILITY
   a. 1=Ethically unacceptable
   b. 2=Low ethical acceptability
   c. 3=Moderate ethical acceptability
   d. 4=Ethically acceptable
   e. 5=Highly ethically acceptable
Score..............

7. GENDER ISSUES
   a. 1=No consideration to gender
   b. 2=Little consideration to gender
   c. 3=Moderate consideration to gender
   d. 4=Reasonable consideration to gender
   e. 5=High consideration to gender
Score..............

8. ACCURACY OF KNOWLEDGE BASE
   a. 1=High accuracy of knowledge base
   b. 2=Reasonable accuracy of knowledge base
   c. 3=Moderate accuracy of knowledge base
   d. 4=Very low accuracy of knowledge base
   e. 5=Accuracy of knowledge base highly questionable
   f. Score..............
BIOMEDICAL RESEARCH

Key Biomedical Research Issues and Questions

Lack of simple, reliable and affordable laboratory methods for HIV testing and immunological monitoring of HIV infection at various levels of health care delivery in Tanzania: (39)

- Diagnosis of HIV infection in infancy
- Immunological monitoring in children
- Diagnosis of TB and other OI, malignancies.
- Diagnosis to determine causes of fevers in HIV positive cases
- To ensure blood safety (combined antibody antigen assays) as well as improving lab diagnosis
- Alternative Laboratory methods for diagnosis of HIV infection -(not using blood)
- Immunological methods for monitoring HIV disease progression

Research Questions:

- Determine highly sensitive, specific, simple, rapid and affordable diagnostic/screening tests for blood transfusion services applicable to district health care levels including antibody/antigen combined assays
- Determine simple and rapid confirmatory test combinations for diagnostic testing applicable to district hospital and health centre levels
- Determine highly sensitive and specific HIV diagnostic and confirmatory tests for children below 18 months for use at district hospital levels
- Determine simple and affordable immunological methods for monitoring HIV/AIDS disease progression in adults and children applicable at district hospital levels
- Develop simple, accurate and affordable laboratory diagnostic tests and clinical algorithms for TB, other OIs and malignancies associated with HIV infection
- Develop simple, accurate and affordable laboratory methods (other than microscopy) for determination of causes of fevers in relation to HIV infection, including malaria, bacterial causes of septicaemia, TB, fungaemia and viral agents
• Develop alternative reliable laboratory methods for diagnosis of HIV infection utilising samples other than blood

2. HIV characterization in relation to disease progression, vaccine development and ARV drug resistance (37)

Research Questions:

• Describe the molecular epidemiology of circulating HIV strains in different geographical areas and sub-populations in Tanzania

• Determine the association between circulating HIV strains and vaccine development

• Determine the association between circulating HIV strains and disease progression

• Determine the association between circulating HIV strains and ARV drug resistance

HIV/STI Vaccine and Microbicide Research and Development efforts (40)

Research Questions:

• Determine reliable immunological and virological methods for detection of immunogenicity of candidate HIV vaccines

• Participate and conduct laboratory tests in phase I/II and possibly phase III vaccine trials

• Participate in the development of HIV/STI candidate vaccines including HIV and Papilloma viruses relevant to Tanzania

• Collaborate in the preparation of appropriate cohorts for vaccine trials

• Determine safety, effectiveness and acceptability of macrobicides

STI etiological agents and drug sensitivity patterns within the context of syndromic management of STIs

(34)
Research Questions:

- Determine common aetiological agents
- Develop simple test for common STIs
- Develop simple regimens for STIs
- Monitor sensitivity pattern of STI drugs
- Determine effectiveness of syndromic management

Biological determinants of HIV discordance

(39)

Research Questions:

- Determine possible biological determinants of HIV discordance including HLA relationships (In view of the fact that at one time one member in a long sexual relationship may be infected before passing over the infection to the other and up to 8% of HIV infected and tested couples in Tanzanian are known to be HIV discordant)
- Participate in studies to determine efficacy of intervention measures to prevent transmission of HIV infection among discordant couples

Traditional medicinal treatment and alternative therapies against HIV/AIDS/STIs

(38)

Research Questions:

- Continue evaluate traditional herbal remedies and medicinal plants used by THs on safety and efficacy against HIV/AIDS
- Develop relevant in-vitro bio-assays to enable determination of efficacy of TM against HIV/AIDS
- Standardise active formulations from already established effective herbal remedies for HIV/STIs

Locally available nutritional supplements for HIV/AIDS

(38)
Research Questions:

- Evaluate effectiveness of local nutritional supplements and HIV/AIDS progression
- Formulate standardized locally available nutritional supplements for PLWHA
- Guide local communities to plant and harvest selected nutritional foods

Quality assurance systems in HIV/AIDS/STI laboratory (39)

Research Questions:

- Develop methods for standardization of laboratory methods for HIV diagnosis and research at different levels in TZods in research and clinical laboratories
- Mechanisms for internal and external quality control systems in research and clinical laboratories
- Monitor and evaluate QA performance in HIV labs at all levels

Normal laboratory reference values in different geographical areas in the country (38)

Research Questions:

- Determine normal laboratory reference values in different geographical areas/zones in Tanzania
- Describe the differences of normal laboratory reference values between males and females in different age groups in various parts of Tanzania
- Determine the factors associated with normal laboratory reference values in Tanzania (e.g. altitude, food, genetic etc.)

Determinants of HIV long-term non-progressors (38)

Research Questions:

- Determine the current progression and pattern of HIV infection from the period of infection to AIDS
- Determine association between the progression of HIV infection and:
Demographic characteristics

Locality

HIV subtypes

Food habits

Pregnancy etc.

Institute intervention measures against identified factors that influence HIV progression

Alternative biomedical preventive measures e.g. PEP, Male/Female condoms, ARV etc. (41)

Research Questions:

Conduct efficacy studies of drugs for PEP available among health workers and rape victims

Determine effectiveness of proper and timely condom use against HIV transmission

Develop other methods of biomedical preventive measures e.g. ARV prophylaxis among SWs

12. PMTCT/PMTCT Plus research (43)

Research Questions:

Determine factors that influence mate to participate/not participate in PMTCT plus programmes

Determine the socio-economic impact of PMTCT plus in TZ

Cost-benefit of PMTCT plus in civil servants (under NHIF scheme) in TZ

13. Hepatitis B/C-virus/HSV in relation to HIV/AIDS (38) Research Questions:

Determine the role of HB/CV in HIV disease progression

Determine the role of HSV-2 in HIV infection
Determine the role of HHV-8 in HIV pathogenesis

14. Drug interaction in HIV/AIDS management e.g. ARVs and traditional medicine (37)

Research Questions:

- Determine ARV drug and TM metabolism among Tanzanians
- Determine drug interaction between ARV and other drugs used for HIV related conditions including traditional alternative therapies

* Capacity building for R & D in the identified biomedical research areas
# EPIEMIOLOGY AND SURVEILLANCE

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• Is there a regular system to identify behavioural data to explain observed HIV/STD sero-logical trends?  
• Updating and field testing of operational protocols for systematic and regular behavioural surveillance. |                                                                                   | 8    |
• Evaluation and regular updating of the existing models for national HIV/AIDS/STD. |                                                                                   | 8    |
| 15. Inadequacy of appropriate indicators of HIV and sexual risk behaviour        | • Use of national indicators for measuring risky sexual behaviour.  
• Validation of existing indicators for measuring sexual behaviour.                 |                                                                                   | 12   |
<p>| 16. Inadequacy of innovative methods for identifying risk behavioural factors of HIV/AIDS in the general population. | • Determining the best methods of identifying risk behaviour factors of HIV/AIDS in the general population. |                                                                                   | 10   |</p>
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- Surveillance of sexual behaviour relation to ART |  | 10 |
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- Upgrading the laboratories to conform to good laboratory practice (GLP). |  | 2 |
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- Determination of HIV resistant strains to specific ART drug.  
- Monitor the sensitivity patterns of HIV strain from time to time.  
- What are the effective methods for monitoring efficacy safety and potency of the affordable ART drugs relevant to Tanzania  
- What are the affordable ART relevant to Tanzania  
- What is the pattern of primary and secondary resistant to ART drugs |  | 5 |
| 20. Inadequate information on factors related to HIV transmission in different groups. | - Factors influencing HIV transmission among different age and population groups e.g youth, institutional, CSW, miners  
- Social cultural  
- Social economic  
- Psychosocial  
- Biologic  
- Beliefs and taboos  
- Factors influencing mothers to child transmission of HIV  
- Individual perception of risk of HIV transmission.  
- To what extent does migration contribute to the spread of HIV? |  | 7 |
<p>| 21. Lack of adequate preparations for trials | - What are the necessary preparations/actions that are required to conduct HIV/AIDS vaccine and nutrition trials; |  |  |</p>
<table>
<thead>
<tr>
<th>Research issues</th>
<th>Justifications</th>
<th>Research questions</th>
<th>Rank</th>
</tr>
</thead>
</table>
| involving vaccines, nutrition and immunomodulators for HIV/AIDS. |  | • What are the different HIV sub-types that are prevalent in Tanzania and their contribution toward HIV transmission?  
• What are the indicators to monitor and evaluate vaccine nutritional and other related trials? | 3 |
| 22. Lack of sufficient information on the efficacy of newly developed HIV/AIDS interventions including ART drugs and nutritional supplements. |  | • What is the efficacy of ART and nutritional supplements?  
• Assessment of appropriateness of the newly developed algorithms for treatment of HIV/AIDS in different population groups e.g.  
  - pregnant women  
  - children  
• To further investigate and conduct large scale trials on the use of vaginal microbicides to prevent STD/HIV in different population groups e.g. CSW discordant couples. | 4 |
| 23. Inadequate information about linkage between HIV/STDs prevalence, incidence, demographic, socio-economic and geographic factors. |  | • What are the explanations for the observed geographical variation in the magnitude and trends of HIV/AIDS/STD  
• What is the influence of road construction mines, army camps, fishing, plantations etc. in the risk of transmission of HIV/AIDS?  
• What is the relationship between demographic, socio-economic and geographic factors that contribute to the spread of HIV/AIDS/STDs? | 5 |
| 24. Effectiveness of ARVs, and their impact in prolonging life and reducing the spread of HIV infection. |  | • What is the change in quality of life in individuals who are on ARV?  
• What are the survivability of individuals receiving ART?  
• What is the effectiveness of ART treatment on reduction of mortality and hospitalization? | 1 |
CARE, TREATMENT & HEALTH SYSTEM

1. ARVs AND ART
   □ ART

1. Efficacy and safety
2. Determinants of durability of first line.
3. Immunological and virological response to ART for patients risk very low CD4
4. Interaction of ARVs with other drugs.
5. Pharmacokinetics (P/C)
6. Trials on efficacy, tolerability of alternative ARVs regime.
7. To determine the effect of ART on morbidity, incidence of TB and other OIs, hospitalization rates and survival of HIV infected patients.
8. To determine strategies to ensure sustainability of ART delivery.

2. Adherence
   □ Issue: Inadequate knowledge and experience on adherence

1. Correlates of adherence.
2. Objective means of accessing adherence to ARVs.
3. Influence of alternative ARV regimens on adherence.

3. PMTCT
   □ Issue: Lack of knowledge, inadequate experience and poor PMTCT delivery.

1. Immunological and virological response to ARV following pre exposure to Nevirapine.
2. To determine the feasibility, efficacy and tolerability of triple ART for PMTCT.

13. Resistance
   □ Issue: Lack of knowledge in primary and secondary resistance in Tanzania

1. To track and determine the prevalence and correlates of 1st and 2nd resistance.
7. Diagnosis

- Issue: Lack of simple, reliable, cost effective diagnostic methods for OI including TB in children and adults.
  

6. Prophylaxis OIs

- Issue: Inadequate knowledge and experience in INH prophylaxis.
  
  1. To determine feasibility of INH prophylaxis.

4. ART Delivery System

- Issue: Incomplete roll out of ART delivery in Tanzania.
  
  1. Establish integrated HIV/AIDS and TB care and treatment in correctional institutions.
  2. Barriers to uptake of ART and care and PEP for health care workers.
  3. Develop and pilot strategies to roll out ART to health centres.
  4. To determine feasibility, sustainability and efficacy of logistics of procurement and distribution of HIV related drugs and supplies.
  5. Integrate injection safety and infection control with HIV/AIDS care in health and home based are settings.

5. Home Based Care

- Issue: Inadequate linkage between clinical and home based care and community response
  
  1. To link care and treatment services to home based care service to ensure adherence and psychosocial support.

8. HIV/TB Integration

- Issue: Inadequate integration of HIV/TB
  
  1. HIV/TB integration.

11. VCT and Psychosocial support
Issue: Poor uptake of VCT services and inadequate psychosocial support to PLHA

1. To develop strategies to increase uptake of testing and ART in children.
2. To determine barriers to VCT uptake for health care workers
3. Pilot opt out and counselling and testing for health care seekers to increase access to care, treatment and support.

16. Traditional Medicine

Issue: Lack of knowledge in the use of traditional medicine in the management of HIV/AIDS

1. To establish efficacy, safety and tolerability of traditional medicine in the management of HIV/AIDS.
2. To establish appropriate biomedical capacity to undertake traditional medicine research to meet international standards.

10. Stigma

Issue: Stigma is wide spread and is a deterrent to access to care

1. To determine magnitude pattern and factors promoting HIV related stigma in Health care setting.
2. To determine barriers to care and to develop interventional strategies to promote health seeking behaviour of PLHA.

15. HIV Co morbidities

Issue: Inadequate of knowledge of how co morbidities adversely effect prognosis and response to ART

1. To determine the influence of HIV, Hepatitis B, C and malaria co-morbidities on the immunological, virological response to ART and prognosis.

12. Capacity Building

Issue: Inadequate capacity to deliver and roll out ART efficiently
1. To establish training and other capacity building needs required for efficient ART delivery and home based care.

2. Impact of ART delivery to the capacity building of overall care.

3. Impact of ART delivery to general standards of care.

14. Monitoring and Evaluation

- **Issue:** Lack of validated tools for monitoring and evaluation for ART delivery psychosocial support and home based care.

1. To develop monitoring and evaluation tools for clinical, psychosocial support and laboratory audit of HIV/AIDS management.

9. Integration of Care and Prevention

- **Issue:** Lack of integration of care and prevention

1. HIV prevention care and treatment integration.

2. To integrate syndromic management of STIs into HIV/AIDS care and treatment.

3. Determine the impact of syndromic management of STIs on HIV transmission

**Socio-Behavioural group**

**R1: Comparative studies on sexuality in different communities and groups (45)**

- What are the types of sexualities found in high, moderate and low HIV prevalence communities and groups?

- What are the social and cultural contexts in which sexual activities are shaped and constituted

**Comparative studies…2**

- What are the values and meanings of sexuality associated with the population groups?

- What are the conceptions of sexuality in different communities?

- What are the strategies which would promote mutual faithfulness, abstinence and/or safe sex within communities and groups?

**R2: Impact studies of HIV/AIDS on social life and behaviour of different groups (e.g. elderly, youth, orphans, professionals) (41)**
What are the social, cultural, psychological effects of HIV/AIDS on elderly (especially women), youth, orphans, professionals?

Patterns of sexual behaviour among PLWHA (40)

- What are the patterns of sexual behaviour of PLWHA?
  - Self-disclosure issues and sexuality
  - Their sexual networking
  - Attitudes towards other members of the society
  - Safe/unsafe sex practices

R4: Sexual Behaviours of discordant couples (36)

- What are the socio-cultural factors that influence disclosure of serostatus among couples?

R5: Gender relations and sexuality (41)

- What are the socio-cultural norms and values which influence decision making about sexual matters?
- What are the patterns of sexual negotiations among males and females?

R6: Institutionalized settings and sexuality (41)

- What are the social, cultural and economic factors which influence risky/safe sexual practices in different institutional settings (work-settings, prisons, colleges, barracks, boarding schools etc)?
- What are the strategies which would promote mutual faithfulness, abstinence and/or safe sex within the institutions?

R7: Effective communication to reverse current HIV prevalence trends (44)

- What are the perceptions of different communities on HIV/AIDS messages?
- How can HIV/AIDS messages which are socially and culturally sensitive and appropriate be developed to specific communities and groups?

Effective comm...2

- What are the appropriate approaches for communication in HIV/AIDS?
What are the research methodologies which should be promoted to empower communities develop effective HIV/AIDS interventions?

Effective comm......3

How to re-package and replicate/scale-up successful interventions?

R8: Disclosure of HIV sero-status to different groups (34)

◆ What are the socio-cultural factors which influence use of VCT services?
◆ What are the social, cultural and psychological factors which need to be taken into account in promoting disclosure of sero-status? (in children and adults)

R9: Stigma studies (43)

◆ What are the different types of HIV-related stigma in the various communities and institutions?
◆ What are the cultural and social roots of HIV-related stigma in the different communities and institutions?
◆ What is the impact of stigma on different HIV/AIDS initiatives?

R10: Depression and HIV/AIDS (41)

◆ What are the psycho-social impacts of HIV/AIDS on PLWHA?
◆ What are the psycho-social impacts of HIV/AIDS on families with PLWHA as well as other community members?

R11: Community support for adherence to ARVs (45)

◆ What are the existing social support networks in different communities?
◆ What are the effective/viable social support networks which would support ARV adherence in different localities?
CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

The participants discussed and agreed on the following recommendations that emanated from this workshop. The recommendations have been classified in general and specific categories.

GENERAL RECOMMENDATIONS

- Health sector must put in place interventions guided by best practice and innovation.
- Research conducted in Tanzania should be of relevance to the local HIV/AIDS epidemic.
- In the ARV roll out attention needs to be given to the procurement process which is lengthy and could jeopardize the program.
- There is a need for M&E systems within the ARV program to monitor drug adherence, treatment outcomes and drug resistance.
- There is a need for establishing linkages between TB and HIV care and involving communities for home based care.
- The issue of disclosure by discordant couples should be given attention.
- There has been a skewed focus in the research activities carried out between 2000-2005. Greater focus has been on Biomedical and Epidemiology research whilst there has been very little focus on Behavioral research.
- 75% of all research carried out between 2000-2005 was carried out within the MTP III research priorities.
- NACP should have some involvement in the Mbeya Medical Research Project.
- It was reiterated that HIV vaccine research is a high priority area for Tanzania.
- There needs to be research on how to effectively communicate/disseminate research findings to the target groups.
- It is important that the package of care for patients after the study is over is clearly defined. There should be advance dialogue with the care and treatment programme.
- It is important to plan interventions in youth that will deter youth from intergenerational sex.
- Capacity building should be an inherent component of the research agenda.
- The group felt that there was need to focus on research on legal issues related to HIV/AIDS.

SPECIFIC RECOMMENDATIONS - Biomedical

- There is need for a functional monitoring system for STI aetiological agents and drug sensitivity patterns within the context of syndromic management of STI’s.
- The workshop requested that the report on sensitivity pattern monitoring of *Neisseria gonorrhoea* in the zones be disseminated.
- There is need to establish Tanzanian reference values for both adults and children.
- There is a need to put efficient QA systems in place.
- There is a need to monitor viral dynamics.
- The need for simple reliable tests for diagnosis of HIV infection in infants.
- What is the optimal timing for Nevirapine administration.
There is need to assess the impact of co morbidities in response to treatment
There is need for research on the biological determinants of discordance.

SPECIFIC RECOMMENDATIONS- Traditional Medicine
- TM remedies in HIV/AIDS need to be carefully monitored.
- There need to be clinical trials of standardized TM formulations
- Tanzania is lagging behind in the field of research of TM remedies for HIV/AIDS

SPECIFIC RECOMMENDATIONS- Social Behavioral
- The issue of early sexual debut needs to be given serious attention
- There is a need to promote research in the impact of various forms of media in reducing HIV transmission
- There is need for research in community preparedness for ART roll out.
- There is a need to study the patterns of sexual behavior in people on ART

SPECIFIC RECOMMENDATIONS- Epidemiology and surveillance
- Focus should be placed on
  - Drug susceptibility monitoring in HIV/AIDS/STI’s
  - HIV/AIDS/STI’s risk behavior
  - HIV prevalence surveillance

SPECIFIC RECOMMENDATIONS- Care and Treatment and health services delivery
- Focus in the area of care and treatment should be placed on
  - Impact of the ART programme
  - Logistical issues around ARV’s
  - Nutrition and ARV’s
  - Neviripine resistance

SPECIFIC RECOMMENDATIONS- Nutrition
- Multivitamin supplementation delays disease progression (improves CD4, CD8 and CD3 T-cell counts)
- Multivitamin supplementation improves hemoglobin levels and maternal weight.
- There is need for research on multivitamins in patients on ART evaluating single vs. multiple RDA’s.
- There is need for research on nutrients (Zn, Se, Fe) in patients on ART.
- There is need to promote locally available nutritional supplements (scientific evidence needed)

SPECIFIC RECOMMENDATIONS- Voluntary Counseling and Testing
- Focus should be placed on the following areas:
  - The update of VCT services after the roll out of the ART programme
To determine the feasibility of opt out counseling and testing for health care seekers
■ The contribution of VCT services to positive behavioral change
■ To determine factors affecting utilization and provision of the VCT services
■ To understand the role of stigma in VCT services
■ To understand the extent to which VCT services increase counselors workload
■ The impact of stigma and discrimination on the provision of VCT services to PLHA and their families

SPECIFIC RECOMMENDATIONS-home based care
■ Focus should be placed on the following areas:
  ■ The effectiveness of ART treatment assistants and treatment adherence to patients receiving ART within the community.
  ■ The impact of stigma and discrimination on the provision of HBC services to PLHA and their families
  ■ Factors affecting ART adherence to patients receiving HBC services
## ANNEX I:


#### CATEGORY 1:
**BIOMEDICAL RESEARCH**

<table>
<thead>
<tr>
<th>S/n.</th>
<th>Research issues</th>
<th>Title of Research Projects Implemented</th>
<th>Research Institutions</th>
<th>Funding Agency</th>
<th>Amount Tshs./US$</th>
</tr>
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<tbody>
<tr>
<td>1.</td>
<td>Lack of reliable and affordable laboratory methods for HIV testing at various levels of the Health Care delivery in Tanzania</td>
<td>“Studies of improving the laboratory Diagnosis and Monitoring of HIV Infection.” Project b Prof F. Mhalu et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA-SAREC</td>
<td>SEK 133 (2004)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Establishment of the infrastructure to evaluate and monitor the impact of new intervention include drug and Vaccines for HIV/TB/Malaria.” Dr. L. Maboko et al</td>
<td>TANSWED HIV Project</td>
<td>EU</td>
<td>Euro 3,500,000</td>
</tr>
<tr>
<td></td>
<td></td>
<td>“Final Evaluation of Chemogen Urine LAMELISA as TB Screening test in Patients with symptoms of pulmonary tuberculosis in Tanzania.” L. Maboko et al</td>
<td>TANSWED HIV Project</td>
<td>Foundation for Innovative New Diagnosis (FIND)</td>
<td>Euro 292,742,40</td>
</tr>
<tr>
<td>2.</td>
<td>Lack of knowledge regarding HIV transmission with the Health Care setting.</td>
<td>“Pilot Intervention Project for Prevention of Mother to Child HIV Transmission by Antiretroviral treatment and studies of postnatal transmission by prenatal, perinatal and postnatal antiretroviral treatment in relation to breast feeding in DSM, Tanzania.” PETRA Study Dr C. Killewo et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA SAREC</td>
<td>SEK 5,959,200</td>
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<td></td>
<td></td>
<td>“Preventing Mother to child Transmission on HIV in Dar es Salaam” Dr Corrigan et al</td>
<td>CUAMM-Tanzania PASADA</td>
<td>CUAMM-Tanzania</td>
<td>US $ 80,300</td>
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<tr>
<td></td>
<td></td>
<td>“A Programme for prevention of Mother to Child Transmission of HIV in DSM.” Dr D. Simba et al</td>
<td>MUCHS Harvard School of Public Health</td>
<td>HSPH</td>
<td>US $ 480,000</td>
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<td></td>
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<td>“HIV related Lymphodenopathies Lymphomas.” Project E. Prof E. Kaaya et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA-SAREC</td>
<td>Funded as Above</td>
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<tr>
<td></td>
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<td>“Pulmonary Diseases among patients admitted into the medical wards at MNH.” Project J2 Prof Pallangyo K et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA – SAREC</td>
<td>Funded as above</td>
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<tr>
<td></td>
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<td>“Causes of fever among Febrile Tuberculosis patients readmitted at Muhimbili Medical Wards.” Project J2 Dr R. Josia et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA-SAREC</td>
<td>Funded as above</td>
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<td></td>
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<td>“Clinical Trial of AN 8-Methoxyquinolone (moxifloxacine) to demonstrate Early Bactericidal Activity in Treatment of Tuberculosis.” By N. Sam et al</td>
<td>KCMC/ Tumaini Univ, Kibong’oto National TB Hosp, Intern Union Against TB and Lung Diseases, FRCPATH Univ College, London</td>
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<td>US $ $ 76,800</td>
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<td>4.</td>
<td>Lack of knowledge on factors influencing the progression of HIV infection in Various HIV infected population groups at different health levels.</td>
<td>“Clinical characteristics of smear negative pulmonary tuberculosis: The Association with HIV”. Dr Malekia et al</td>
<td>MNH</td>
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<td></td>
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<td>“Cervic Dysplasia, cancer and other AIDS related malignancies”. Prof E. Kaaya et al</td>
<td>MUCHS, MMRP, MOH, LMU.</td>
<td>European Union</td>
<td>Euro 113,985</td>
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<td></td>
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<td>“Effect of treatment of various Co-infections on viral load and diseases Progression of HIV infected patients” Project J2 Prof K. Pallanyo et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA- SAREC</td>
<td>Funded</td>
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<td>5.</td>
<td>Lack of a functional monitoring system for STI etiological agents and drug sensitivity patterns within context of syndromic management of STI.</td>
<td>“Peripheral Neuropathy in DSM: A study to determine the etiology and characteristics of patient with peripheral Neuropathy admitted to medical wards at MNH. “Prof K. Pallangyo et al</td>
<td>TANSWED HIV Project</td>
<td>SIDA-SAREC</td>
<td>Funded</td>
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<td></td>
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<td>“Renal and Urologic Manifestations Complications of HIV Infections.” Proj J6 Prof F. Mhalu</td>
<td>TANSWED HIV Project</td>
<td>SIDA- SAREC</td>
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<td>“Efficacy of Solanum Incanum in treating”</td>
<td>NACP, Temeke</td>
<td>TACAIDS</td>
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<td></td>
<td>Genital ulcers “Dr M. Nyang’anyi et al”</td>
<td>Municipal Hospital, NIMR</td>
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<td>TSHS 15,540,000</td>
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<td>“Ascertaining safety of Herbal Medicines. Ngetwa and Ngoka in Pre-clinical animal Studies” By Dr P. Mhame et al</td>
<td>NIMR</td>
<td>NIMR</td>
<td>Not funded</td>
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<td></td>
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<td>“A search for Antimicrobial and Antiviral Agents from Tanzania Medicinal plants” By Dr. Shells Mgole Meregesi et al</td>
<td>MUCHS</td>
<td>MUCHS</td>
<td>-</td>
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<tr>
<td>7.</td>
<td>Inadequate national involvement in HIV/STI vaccine research and development.</td>
<td>“Study on feasibility and acceptability of youth for HIV vaccine and microbicides trials.” Project C1. Prof E. Lyamuya</td>
<td>TANSWED HIV Project</td>
<td>SIDA – SAREC</td>
<td>Funded</td>
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<td></td>
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<td>“A pilot Study to optimize trial procedures including the use of Placebo-gel in preparation for the proposed microbicide Development Programme (MDP) 301 placebo controlled Phase 111 trial to evaluate dextrin sulphate and PRO 2000/05 in Prevention of vaginally acquired HIV infection”. By M. Temu et al</td>
<td>NIMR- Muhimbili</td>
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<td></td>
<td>“Evolution of HIV –1 Subtypes in Northern Tanzania: A Retrospective Study” By B. Nyombi et al</td>
<td>KCMC/ Tumaini University, Univ of Oslo, Norway Dep of Microbiology Ulleval, Norway.</td>
<td>Norwegian Research Council</td>
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<td>“Immunological responses in HIV-infected and characterization of Tanzanian HIV-1 Isolates.” By F. Mhalu et al</td>
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| 8.   | Lack of an effective monitoring mechanism for efficacy safety and potency of available drugs in use for treatment prevention of HIV/AIDS. | **MOTHER TO CHILD PROJECT F**  
|      |                                                                                  | **USE OF DRUGS PROJECT M**  
<p>|      |                                                                                  | <strong>Multicentre study – Phase III trial of antibiotics to reduce chorioamnionitis related to perinatal HIV transmission. “G. Msamanga Et al</strong> | MUCHS, Queen Elizabeth Hospital Blantyi Malawi, Zambia University teaching hospital, Lilongwe Central hospital. | HIV Prevention Trials Network USA (HPTN) | Not indicated |
|      |                                                                                  | <strong>A phase 111 trial to determine the efficacy and safety of an extended regimen of Nevirapine in infants born to HIV infected women to prevent vertical transmission during breast feeding.” Prof K. Manji et al</strong> | MUCHS Harvard School of Public Health | HSPH | - |
|      |                                                                                  | <strong>Trial of Vitamins among Children of HIV infected Women” Prof G. Msamanga</strong> | MUCHS Harvard School of Public Health | HSPH | - |
|      |                                                                                  | <strong>Effect of Zidovudane and Lamividane Combination with Chloroquine or Nevarapine in HIV-1 Seropositive Children From Petra Study.”</strong> | MUCHS Univ of Amsterdam, The Netherland | AMC-IATEC BV. (International Antiviral Therapy) | - |</p>
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<tr>
<td></td>
<td></td>
<td>Dr A. Massawe et al</td>
<td>Evaluation Centre) Univ Of Amsredam</td>
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**CATEGORY 2: SURVEILLANCE AND EPIDEMIOLOGY RESEARCH**

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<tbody>
<tr>
<td>1.</td>
<td>Lack of adequate systematic information on the progression of HIV/AIDS/STIs epidemic and behavioural information</td>
<td>“Sexually transmitted diseases (STD) survey among bar and hotel workers in Moshi town, Tanzania.” Dr Sam et al</td>
<td>KCMC, Havard School of Public Health</td>
<td>HSPH</td>
<td>Us $ 30,000</td>
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<td></td>
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<td>“Studies of the Epid. And control of ulcerative sexuality female bar workers in Mbeya Tanzania and their interaction with HIV infection.” By Prof E. Lyamuya et al</td>
<td>MUCHS Harvard School of Public Health Walter Reed Army Institute of Research, USA</td>
<td>HSPH</td>
<td>Us $ 622 000</td>
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<td>“Follow up study for estimation of HIV infection incidence.” Project D Prof J. Killewo</td>
<td>TANSWED HIV Project</td>
<td>SIDA –SAREC</td>
<td>Funded</td>
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<td></td>
<td></td>
<td>“Clinical outcome of female genital discharge syndrome.”</td>
<td>TANSWED HIV Project</td>
<td>SIDA-SAREC</td>
<td>Funded</td>
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<tr>
<td></td>
<td></td>
<td>“Trial of Vitamin in reduction of Vertical Transmission and Progression of HIV infection Among Pregnant Women.”</td>
<td>MUCHS HSPH</td>
<td>HSPH</td>
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<tr>
<td>S/n.</td>
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<td>Institutions</td>
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<td>“Monitoring Progression and Impact of HIV/AIDS in Kisesa ward Magu District” Prof G. Mwaluko et al</td>
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<td>“Monitoring of fertility, mortality and mobility through Demographic Surveillance System.”by G. Mwaluko et al</td>
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<td>“2003 Tanzania HIV/AIDS Indication survey.” BY Kaimu AM et al</td>
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<td>Inadequate information on factors related to HIV transmission in different groups</td>
<td>“Infectious Disease Surveillance and Cohort Development Among Urban and rural Adults in Mbeya.” L. Maboko et al</td>
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<td>“Bar workers Study in order to Determine Immunity to HIV-1 Infection in HIV Frequently exposed individuals as well as determine the current social and”</td>
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<td>Epidemiological situation.” Prof F. Mhalu et al</td>
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<td>Management of Asymptotic Sexually Transmitted Infections STI among Women in HIV Infection.” Proj B Prof E. Lyamuya et al</td>
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<td>Study of Sexuality and STD/HIV Transmission Factors Among Adolescents and Youth Attending a City Reproductive Health Clinic In Dar es salaam.” Proj C1 Prof F. Mhalu et al</td>
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<td>3.</td>
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<td>Making ends meet: An ethnographical study of sexuality and HIV among Tanzania sugar plantations works.” By</td>
<td>KCMC School of Epid. Public health Yale Univ., USA</td>
<td>YALE University</td>
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<td>Management of Asymptomatic Sexually Transmitted Infection among women in HIV infection.” Prof E. Lyamuya et al</td>
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<td>4.</td>
<td>Lack of adequate preparations for trials involving vaccines and immuno modulators for HIV/AIDS.</td>
<td>Police Officers Cohort, Incidence Study Project J1</td>
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<td>Immunological responses in HIV-1 and Characterization of Tanzanian HIV-1 Isolates” Prof F. Mhalu et al</td>
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<td>Behavioural immunological and virologic correlates of HIV-I super infection (HIV-I + VS HIV-I H) in rural Tanzania.” Prof E. Lyamuya et al</td>
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<td>Monitoring of Immune response in I/II Vaccine trials in Sweden and Tanzania.”Proj.J</td>
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<td>1.</td>
<td>“Study on feasibility and acceptability of youth for HIV vaccine in microbicides trials.” Proj C1 Prof. F. Mhalu</td>
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<td>2.</td>
<td>“ Infectious Diseases Surveillance and Cohort Development Among Urban and Rural Adults in Mbeya Metropolitan Region” By L. Maboko</td>
<td>MMRP, Henry Jackson Foundation, USA, Walter Reed Institution of Research, MoH Ludwigs Maximillian Univ, Germany</td>
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<td>“Study of the use of antiretroviral drugs in the management of HIV infection in Tanzania.”By F. Mhalu et al</td>
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<td>“Evaluation of the optimal time to initiate Antiretroviral drugs in Tanzania.” Project M. Prof F. Mhalu et al</td>
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<td>“ Clinical Epidemiology of HSV-2 and the impact of HSV suppressive Therapy to reduce HIV incidence in high risk women ,</td>
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<td>1.</td>
<td>Tanzania.” Debora Watson-Jones</td>
<td>“Evaluation of traditional medicine practice use to manage HIV/AIDS in Arusha and DSM Region.” Mrs F. Uiso et al</td>
<td>TACAIDS MITM Arusha region</td>
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<td>2.</td>
<td>“Observation and Evaluation for safety and efficacy of Traditional Herbal remedies for treatment of HIV/AIDS in Tanzania.” Dr Z. Mbwambo et al</td>
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<td>Muhimbili Inst of Traditional Medicine</td>
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<td>4.</td>
<td>“Mbeya Antiretroviral Initiation study: Randomized trial to compare the use of HAART using generic and original drug combinations.” By L. Maboko et al</td>
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<td>MMRP, MRH, MUCHS, LSHTM, Walter Reed, Army Institute of Research USA. Ludwing - Maximillians Univ., Germany</td>
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<td>6.</td>
<td>Lack of information about the linkage between HIV/STDs prevalence</td>
<td>“Studies on the interaction between HIV infection, Lymphatic Filamasis and Diethyl Carbamazine.” By Nina Nielsen</td>
<td>NIMR, Danish Bilharziasis lab.</td>
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<td>“Studies of the Epidemiology and Control of Ulcerative Sexually Transmitted Infections Among Female Bar workers in Mbeya, Tanzania and Their interaction with HIV infection. Prof E. Lyamuya et al”</td>
<td>MMRP, MRH, MUCHS, LSHTM, Walter Reed, Army Institute of Research USA, Ludwing-Maximilians Univ., Germany</td>
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<td>“Renal and Urologic Manifestations Complications of HIV infections.” Proj K Prof K. Pallangyo</td>
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<td>“Diagnosis of TB in patients co-infected with HIV.” By Dr Deo Mbilima et al</td>
<td>KCMC Univ. of Darham USA</td>
<td>Univ. of Darham USA</td>
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<td>7.</td>
<td>Incidence and socio-economic geographic and demographic factors</td>
<td>“Investigation the role of poverty on environmental degradation and HIV/AIDS: Three selected regions of Tanzania.” By Dr Deo Mbilima et al</td>
<td>Vice President Office,</td>
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<td>“An Intervention Study Among young People in Kahe: A community Health Development Project 2001 – 2006” K. Mnyika K et al</td>
<td>MUCHS, KCMC, Univ of Bergen Norway</td>
<td>Univ of Bergen, Norway</td>
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<td>“Case – Referent approaches for evaluation of Community interventions in Kagera using Data on both aggregated and individual level.” Project D By Prof K. Killewo et al</td>
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<td>“Microbiological and Socio-demographic studies of Acute STDs in relation to HIV Infection and control in Dar es Salaam: Study of sexuality and STD/HIV Transmission among youth and adolescents in DSM.” Proj C1 By Prof F. Mhalu et al</td>
<td>TANSWED HIV Project</td>
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### CATEGORY 3: SOCIAL BEHAVIORAL AND COMMUNICATION RESEARCH

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| 1.  | Gender and HIV/AIDS/STDs | “Male factors influencing participation in Prevention of mother to Child Transmission (PMTCT) of HIV programs in Tanzania, East Africa.” By Dr M. Burke et al  
“Stigma and discrimination related violence against women; a multi-cultural respective.” Dr. J. Mbwambo et al  
“Gender and power relations in the classroom: HIV/AIDS education programme: School as a safe havens or sites of risks: A case study of a Secondary School in Kilimanjaro region.” Melkiory Masatu et al | Dodoma Anglican Church, MUCHS, HSPH, National Centre of HIV Epid and Clinical Research Australia  
MUCHS  
CEDHA – Arusha | National Center of Clinical Research in HIV Epid Aust.  
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CEDHA | Us $ 31,465  
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“Strategies of promoting education about sexuality and reproductive health issues among the youth focusing on literary works.” Project D Prof J.Killewo et al  
“Factors that influence parent child communication regarding Sexual and reproductive Health matters in Kinondoni, District DSM.” By Dr. Hawa Mchomvu et al | TANSWED HIV Project  
TANSWED HIV Project  
Kinondoni Municipal | SIDA – SAREC  
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<td>Inadequate/ inappropriate HIV/AIDS/ STDs education for different target groups.</td>
<td>“Supplementing condom social marketing with education targeting men: Impact on male and female condom update in Tanzania” By Hatzel et al</td>
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<td>“The role of migration and mobility on Sexually transmitted infections in rural villages in Mwanza region. Tanzania”</td>
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<td>“The effect of educative AIDS education Intervention Among Young people in Tanzania: The role of NGOs”.By Sayoko Katsumi</td>
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<td>“Parents attitude and practice towards Sexual and Reproductive Health matters in Korogwe District Tanga” Dr. A. Heller et al</td>
<td>Korogwe District Council</td>
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<td>“ Perception and Practices Towards Prevention of HIV/AIDS infection among Undergraduates of Univ of Morogoro. By Maghanga et al</td>
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<td>“Sexual Educational Research in Kilimanjaro” By Andrimken Uzozie et al</td>
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<td>Barriers to promotion of Safer Sex in various target groups</td>
<td>“ Sexual Risk Behaviours Among Young People in Tabora.” By Dr G.</td>
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<td>“She was being witched and caught an illness similar to AIDS; AIDS and sexuality transmitted Infections causation belief in rural Mwanza.” G. Mshana et al</td>
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<td>By G. Kimaro et al</td>
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<td>“Examining the cultural complex: Ties affecting the spread of HIV/AIDS in rural tribal populations of Tanzania.”Jayne Kulzer et al</td>
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<td>Inadequate involvement of sectors in the multisectoral expanded response.</td>
<td>“CHMT and partners in implementing National AIDS Policy. The case of Moshi district.” By Dr. I. Semali et al</td>
<td>MUCHS Moshi District</td>
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<td>“Baseline Survey of Knowledge, attitude and practice on HIV/AIDS Malaria, Diarrhea diseases among NOREMCO workers in DSM.” By Haugen IL et al</td>
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<td>“Stigma and HIV/AIDS in Tanzania: preventing prevention?” By Nelly Iteba</td>
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<td>“Cost Benefit Analysis of AIDS Prevention Tanzania.” By J. Brent</td>
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<td>“Multi country study on understanding HIV-1 related stigma and discrimination.” By J. Mbwambo et al</td>
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<td>Lack of Indicators for behavioural change</td>
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<td>9.</td>
<td>Role of the media in HIV/AIDS/STDs response</td>
<td>Supplementary Study .” Mark Williams</td>
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**CATEGORY 4: HEALTH AND SOCIAL SERVICES RESEARCH**

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<td>1.</td>
<td>Provision of Medical and Social economic services to meet the needs of PLHAs survivors the worried well families and communities</td>
<td>“The struggle survival: Understanding HIV/AIDS and Orphans programmes in Tanzania” By Amanda Willete et al</td>
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<td>“AIDS orphan and care givers: perceptions of needs and support offered to AIDS orphans” By Razia Rajabu et al</td>
<td>University of Bergen Norway KCMC, UDSM</td>
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<td>“Improved case management for HIV/AIDS: Clinical cost effective case management for HIV/AIDS patients admitted in medical wards in MNH.” By Dr S. Chale</td>
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<td>“AIDS Orphans: Aftermath of losing either or both parents to AIDS as experienced by orphans in Tembeke District, Dar es Salaam, Tanzania.” By Dr. Khalifa Murumbi et al</td>
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<td>“Clinical costs for an outpatient adult AIDS case: Cost saving remedy.” By G. Kamugisha</td>
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<td>“How people living with HIV/AIDS and their families are coping with the disease: Comparisons between rural and urban settings in Mwanza and Mara region, Tanzania.” HonsJorg Dilger et al</td>
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## ANNEX II:

### LIST OF PARTICIPANTS:

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<tr>
<th>S/N</th>
<th>NAME OF PARTICIPANT</th>
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<tr>
<td>1.</td>
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<td>Dr. E. A. Aris</td>
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Mr. Chairman,

Representatives of Donor Agencies,

Workshop participants,

Ladies and Gentlemen

I wish to take this opportunity to thank you all for the 4 days you have taken off from your busy schedules, coming together and formulating our essential research package for the implementation of the Health Sector Strategy for HIV/AIDS/STIs (2003 – 2006).

The National priority setting workshop on AIDS research was deliberately set to look at questions and issues faced by all stakeholders involved in the national response to HIV/AIDS. During the implementation of the HSS III, these issues need to be addressed and questions raised so that answers can be obtained through designed appropriate prevention, Care and Support and impacts for mitigation. In this connection, scientists, policy makers and researchers are challenged in the light of growing demand of the public to transform the basic knowledge into useful and operational concepts. Much effort is still needed to minimize the impact of HIV infection on individuals and the society.

Mr. Chairman,

The research package which has been proposed to all Tanzanian Investigators, their colleagues and associated partners represented here, will be used as a national priority research package areas for combating HIV infection. The research package will particularly
be useful in facilitating a multisectoral national response, development of vaccines and other therapies which will reduce the impact of the disease on individuals and the society. Research which is needed at national level for AIDS prevention and control shall target different behaviour and practices at different environments from district to district, down to community and household level.

Mr. Chairman,

Although we have come to the end of this workshop, our work is not completed, all of us have a responsibility now to start developing research proposals related to the priority identified in the HSS (2003 – 2006), and promote the research package among potential funders and partners. This means researchers from elsewhere should be made to pick up a topic from our Research Priority Agenda for investigation. If they really mean to help us not only themselves.

There is also need to promote operational research at country level and support technically and financially basic research projects.

I therefore do hope that the efforts of the Ministry of Health in collaboration with Research Instructions and other bilateral donors will support research work in response to the AIDS epidemic in Tanzania will continue. Assistance will be needed to continue the identification and co-ordination of material, financial support and facilitation of partnership with external scientific institutions.

On behalf of the Government of Tanzania, I would like to give special thanks to you all who participated so actively and cordially at this workshop. I would also like to give thanks to the National AID Control Programme, the entire National Research Sub-committee for its commitment in organizing this workshop and making it successful.

Mr. Chairman,
Research priority setting is an important milestone for research capability strengthening and for building up national research programmes. In this connection it is my hope that the research package will be out soon and be distributed to all actors for immediate implementation. I am confident that the objectives of the workshop will be accomplished to the full satisfaction of all actors so as to strengthen the National AIDS Control Programme.

I look forward to a successful implementation of the research in relation to the Health Sector Strategy (2003 – 2006)

**Mr. Chairman,**

On this note, I now declare that the National Priority setting workshop on AIDS Research officially closed.

Thank you for your attention.