NATIONAL INSTITUTE FOR MEDICAL RESEARCH

ANNUAL REPORT

JULY 2018-JUNE 2019

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National Institute for Medical Research
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STATEMENT FROM THE CHAIRMAN OF THE COUNCIL

I was honoured to be appointed the Chairman of the National Institute for Medical Reseach (NIMR) Council, an internationally well-renowned health research institute. This is my first Annual report as Chairman. After my appointment I looked forward to instilling the Council's vision for the direction of NIMR and I have not been disappointed in the achievements over the reported year 2018/ 2019.

This report consists of seventy-five (75) projects. The reported projects are not exhaustive of the overall on-going projects as there are also capacity building programmes which include masters and PhD programmes as well as community engagement programmes. The institution also provides technical support for evulations of vertical programme and other health sector interventions on behalf of the Ministry responsible for Health. Research projects generate income and create employment opportunities for Tanzanians. NIMR currently has over 250 staff employed through projects.

Health research has expanded, investments have been made in infrastructure and people, ensuring that we have strong disciplines and a leading position on multi- and inter-disciplinary work. Major research projects describbed in this report give great emphasis to global and national health priority-led research and promote a focus on collaboration across disciplines, universities, sectors and continents, we are well positioned for the future.

I would like to thank all Council members and Council Committee members for their support and time taken in oversight and insightful ideas in running NIMR.

I believe that this annual report will enlighten many to the contribution of research to the health sector. I wish you an enjoyable read.

Dr Deodatus Mtasiwa
Chairman of the Council

MESSAGE FROM THE DIRECTOR GENERAL

The 2018/19 Annual Report provides an insight into the researchers who work every day at NIMR providing evidence and recommending solutions to improve on health service provision and outcomes. The institute has gone through another year of research success.

All of our researchers are driven not only by the desire to advance science, but also by the real, positive impact their research can have on improving the health and lives of patients. NIMR scientists have contributed extensively to knowledge and evidence generation through one hundred and eight (108) peer-reviewed publications in various areas of health to include HIV, Malaria, TB, One Health, NTD and others. During the reported period, the institute coordinatied the 7th East African Health and Scientific Conference in March 2019 where the United Republic of Tanzania was the host. The event was attended by over 700 delegates from East African nations and beyond. In 2019, NIMR hosted the NIH Fogarty Director who visited Tanzania to strengthen collaboration for health research motivated by the opportunities and strengths seen in the country.

NIMR through its regulatory arm received three hundred and sixty-seven (367) applications that have been processed through the National Health Research Ethics Committee this year. This is a slight increase from the previous year 2017/18 which continues to show the increase of conduct of health research in Tanzania.

I am pleased to announce the appointment of new NIMR coordinating and Centre Directors. These are Dr Paul Kazyoba, Dr Ndekya Oriyo, Dr Nyanda Ntinginya, Dr. Safari Kinung'hi and Prof John Lusingu. I also have the pleasure to introduce our new Chief Accountant CPA Daniel Ngari. I welcome them in joining us to raise NIMR to greater heights.

NIMR will celebrate forty years in operation in the year 2020. We look forward to showcasing our achievements over the past 40 years.

I thank all our partners and collaborators whom have walked with us through the phases of getting NIMR to where it is today. We look forward to continuing working with you all to have an even greater impact in the year to come.

Prof Yunus D. Mgaya
Director General

TABLE OF CONTENTS

1.0 ABOUT THE NATIONAL INSTITUTE FOR MEDICAL RESEARCH

The National Institute for Medical Research (NIMR) is a parastatal institution established by the Act of Parliament in October 1979 with the following mandate:

i) To carry out and promote the carrying out of health research, including traditional medical practices designed to alleviate disease among the people of Tanzania;

ii) To carry out, and promote the carrying out of, medical research into various aspects of local traditional medical practices for the purpose of facilitating the development and application of herbal medicine;

iii) In co-operation with the Government or any other person or body of persons, to promote, or provide facilities for, the training of local personnel for carrying out scientific research into medical problems;

iv) To monitor, control and co-ordinate medical research carried out within Tanzania, or elsewhere, on behalf of or for the benefit of the Government of Tanzania, and to evaluate the findings of that research;

v) To establish a system of the registration of, and to register, the findings of medical research carried out within Tanzania, and promote the practical application of those findings for the purposes of improving or advancing the health and general welfare of the people of Tanzania;

vi) To establish and operate systems of documentation and dissemination of information on any aspect of the medical research carried out by or on behalf of the institute;

vii) Carry out, and promote the carrying out of, research and investigation into the causes and the ways of controlling and preventing the occurrence in Tanzania of particular diseases or a category of them.

viii) In co-operation with the Government or any person or body of persons, carry out and promote the carrying out of, basic, applied and operational research designated to provide effective measures for the control of diseases endemic in Tanzania

Vision: *To be an institution of excellence for advancement of health research and development in Tanzania and beyond.*

Mission: *To conduct, coordinate, regulate and promote scientifically and ethically sound, high quality health research and deliver evidence-based information that is responsive to the needs of human wellbeing.*

1.1 COMPOSITION OF THE NIMR COUNCIL

S/N	NAME	POSITION	QUALIFICATIONS
1.	Dr. Deodatus Mtasiwa	Chairperson	PhD in Internal Medicine
2.	Prof. Yunus D. Mgaya	Secretary / NIMR Director General	PhD in Marine Biology
3.	Prof. Projestine S. Muganyizi	Member	PhD in Obstetrics & Gynaecology
4.	Dr. Mayasa Salum Ally	Member	PhD in Pharmacy
5.	Dr. Khadija Innocensia Malima	Member	PhD in Epidemiology
6.	Mr. Richard Lange Mkumbo	Member	MSc in Health Economics & Planning
7.	Dr. Godfrey M. Mubyazi	Member	PhD in Health Economics
8.	Dr. Leonard Subi	Member	Doctor of Medicine & Master of Public Health

1.2 INSTITUTION MANAGEMENT

	Name	Position
1.	Prof Yunus D. Mgaya	Director General
2.	Dr Paul E. Kazyoba	Director, Research Coordination & Promotion
3.	Dr Ndekya M. Oriyo	Director, Research Information Technology & Communication
4.	CPA Obedi S. Ole-Kaondo	Director, Finance, Human Resource & Planning
5.	Dr William Kisinza	Director, Amani Research Centre
6.	Prof John P. Lusingu	Director, Tanga Research Centre
7.	Dr Safari Kinung'hi	Director, Mwanza Research Centre
8.	Prof Sayoki G. Mfinanga	Director, Muhimbili Research Centre
9.	Dr Nyanda E. Ntinginya	Director, Mbeya Research Centre
10.	Ms Bupe L. Ndelwa	Human Resource Manager
11.	CPA Daniel Ngari	Chief Accountant
12.	Mr John Msangi	Ag Chief Internal Auditor

2.0 FINANCIAL MANAGEMENT AND RESOURCE MOBILIZATION

Financial Performance for the Year

NIMR is committed to the highest levels of fiscal responsibility and accountability in the delivery of the Organization functions. Every resource entrusted to us are properly utilized and accounted for advancement of high-quality health research and innovations.

Presented below are extract statements from NIMR's audited Financial Statements for the financial year 2018/2019, which have been prepared in accordance with International Public Sector Accounting Standards (IPSAS) and in compliance with Public Audit Act No. 11 of 2008.

The Auditors have expressed Unqualified Opinion, on the financial statements. In his Opinion the National Institute for Medical Research procurement transactions and processes have generally complied with the Public Procurement Act No 7 of 2011 (As amended in 2016) and its underlying Regulations of 2013 (As amended in 2016).

During the current year (2018/2019),the Institute recorded a surplus of TZS 102.1 million compared to a surplus of TZS 1.1 Billion recorded in 2017/2018. The reduction in surplus for the current year was contributed by the decrease in revenue earned which amounted to TZS 19.1 Billion compared to TZS 19.7 Billion earned in 2017/2018. Expenses incurred during the current year amounted to TZS 19.0 Billion compared to TZS 18.7 Billion incurred in 2017/2018.

2.1 REPORT OF THE CONTROLLER AND AUDITOR GENERAL

INDEPENDENT REPORT OF THE CONTROLLER AND AUDITOR GENERAL

Chairperson,
Governing Council,
National Institute for Medical Research,
P.O. Box 9653,
DAR ES SALAAM

REPORT OF THE CONTROLLER AND AUDITOR GENERAL ON THE FINANCIAL STATEMENTS OF NATIONAL INSTITUTE FOR MEDICAL RESEARCH FOR THE YEAR ENDED 30TH JUNE, 2019

Unqualified Opinion

I have audited the financial statements of the National Institute for Medical Research which comprise the Statement of Financial Position as at 30th June, 2019 and the Statement of Financial Performance, Cash Flow Statement, Statement of Changes in Net Assets/Equity, and the Statement of Comparison of Budget and Actual Amounts for the year then ended, and notes to the financial statements, including a summary of significant accounting policies.

In my opinion, the accompanying financial statements present fairly, in all material respects, the financial position of National Institute for Medical Research as at 30th June, 2019, and its financial performance and its cash flows for the year then ended in accordance with International Public Sector Accounting Standards (IPSAS) Accrual basis.

Basis of Opinion:

I conducted the audit in accordance with International Standards on Supreme Audit Institutions (ISSAI). My responsibility under those standards are further described in the auditor's responsibilities for the audit of the financial statements section of my report. I am independent of the National Institute for Medical Research in accordance with the International Ethics Standards Board of Professional Accountants (IESB code) together together with the National Board of Accountants and Auditors (NBAA) Code of Ethics, and I have fulfilled my other ethical responsibilities in accordance with these requirements.

I believe that the audit evidence I have obtained is sufficient and appropriate to provide a basis for my opinion.

Other Information

Management is responsible for other information. The other information comprises the Governing Council's Report and Declaration by the Head of Finance but does not include the Financial Statements and my audit report thereon.

My opinion on the financial statements does not cover the other information and I do not express any form of assurance conclusion thereon. In connection with my audit of the financial statements, my responsibility is to read the other information and, in doing so, consider whether the other information is materially inconstent with the financial statements or my knowledge obtained in the audit, or otherwise appears to be materially misstated.

If, based on the work I have performed on the other information that there is a material misstatement of this other information; I am required to report that fact. I have nothing to report in this regard.

Key Audit Matters

Key audit matters are those matters that, in my professional judgement, were of most significance in my audit of the financial statements of the current period. These matters were addressed in the context of my audit of the financial statements as a whole, and in forming my opinion thereon, and I do not provide a separate opinion on these matters. I have determined that there are no key audit matters to communicate in my report.

Responsibility of Management and Those Charged with Governance for Financial Statements

Management is responsible for the preparation and fair presentation of the financial statements in accordance with the International Public Sector Accounting Standards (IPSAS), and for such internal control as management determines is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, management is responsible for assessing the Institute's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless management either intends to liquidate the Institute or cease its operations, or has no realistic alternative but to do so.

Those charged with governance are responsible for overseeing the Institute's financial reporting process.

Auditor's Responsibilities for the Audit of the Financial Statements

My objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an audit report that includes my opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISSAI will always detect a material missstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in aggregate, they could reasonably be expected to influence the economic decicions of users taken on the basis of these financial statements.

In addition, Sect. 10 (2) of the Public Audit Act No. 11 of 2008 requires me to satisfy myself that, the accounts have been prepared in accordance with the appropriate accounting standards.

Further, Sect. 48 (3) of the Public Procurement Act No. 7 of 2011 (as amended in 2016) requires me to state in my annual audit report whether or not the audited entity has complied with the provisions of the law and its Regulations.

Report on Other Legal and Regulatory Requirements

Compliance with the Public Procurement Act, 2011 (as amended in 2016)

In view of my responsibility on the procurement legislation, and taking into consideration the procurement transactions and processes I reviewed as part of this audit, I state that National Institute for Medical Research procurement transactions and processes have generally complied with the Public Procurement Act No 7 of 2011 (as amended in 2016) and its underlying Regulations of 2013 (as amended in 2016).

Charles E. Kichere
CONTROLLER AND AUDITOR GENERAL

National Audit Office,
Dodoma, Tanzania

09th March, 2020

2.2 FINANCIAL STATEMENTS

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

STATEMENT OF FINANCIAL POSITION AS AT 30TH JUNE, 2019

	NOTES	30.06.2019 TZS	30.06.2018 TZS
ASSETS			
Current Assets			
Cash and cash equivalents	2	15,039,202,696	14,497,979,174
Receivables, deposits & prepayments	3	2,115,258,993	2,573,546,480
Inventories	4	84,587,565	82,310,053
		17,239,049,254	**17,153,835,707**
Non-current assets			
Productive livestock	5	4,191,000	5,491,000
Intangible Assets	6	18,891,905	-
Property, plant and equipment	7	43,028,159,342	14,692,334,686
		43,051,242,247	**14,697,825,686**
TOTAL ASSETS		**60,290,291,501**	**31,851,661,393**
Liabilities			
Current Liabilities			
Payable and Accrued charge	8	1,970,165,848	2,496,210,686
Total Current Liabilities		**1,970,165,848**	**2,496,210,686**
Non- Current Liabilities			
Research and development grants	9	12,341,664,407	12,021,253,959
Capital Grants	10	1,672,556,082	1,384,556,466
Total Non- Current Liabilities		**14,014,220,489**	**13,405,810,425**
TOTAL LIABILITIES		**15,984,386,337**	**15,902,021,111**
NET ASSETS		**44,305,905,164**	**15,949,640,282**
EQUITY AND LIABILITIES			
Capital and Reserves			
Tax Payers' Fund	11	42,604,142,272	14,337,782,272
Accumulated Surplus/(Deficit)		1,701,762,892	1,611,858,010
TOTAL EQUITY		**44,305,905,164**	**15,949,640,282**

NOTES 1 TO 20 FORM PART OF THESE FINANCIAL STATEMENTS

CHAIRMAN

DATE: FEBRUARY 28TH, 2020

COUNCIL MEMBER

DATE: 28th February 2020

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

STATEMENT OF FINANCIAL PERFORMANCE FOR THE YEAR ENDED 30TH JUNE, 2019

	NOTES	2018/2019 TZS	2017/2018 TZS
REVENUE			
Revenue from Non-Exchange Transaction	12	9,191,161,241	9,988,634,100
Revenue from Exchange Transaction	13	9,790,522,604	9,312,068,588
Amortization of capital grants	10	143,041,766	440,217,859
TOTAL REVENUE		**19,124,725,611**	**19,740,920,547**
EXPENSES			
Staff salaries and allowances	14	14,019,567,630	13,968,579,441
Administrative expenses	15	2,932,937,718	3,165,896,158
Repairs and maintenance	16	324,563,832	294,540,025
Other expenses	17	761,024,002	295,588,322
Consultancy activities expenses	18	201,033,806	216,356,894
Audit Fees		62,720,000	79,152,363
Depreciation		720,782,630	653,081,655
TOTAL EXPENSES		**19,022,629,618**	**18,673,194,858**
Surplus/(Deficit) for the year		**102,095,993**	**1,067,725,689**

NOTES 1 TO 20 FORM PART OF THESE FINANCIAL STATEMENTS

CHAIRMAN

DATE: FEBRUARY 25TH, 2020

COUNCIL MEMBER

DATE: 28TH February 2020

NATIONAL INSTITUTE FOR MEDICAL RESEARCH

STATEMENT OF CHANGES IN EQUITY FOR THE YEAR ENDED 30TH JUNE, 2019

Particulars	Tax Payer Fund	Accumulated Surplus/(Deficit)	Total
	TZS	TZS	TZS
Balance as at 30th June, 2017	**14,337,782,272**	**1,569,999,251**	**15,907,781,523**
Changes in Equity for the FY 2017/2018:			
Capital Fund	-	-	-
Prior Year Adjustments	-	(1,025,866,930)	**(1,025,866,930)**
Surplus/(Deficit) for the Year	-	1,067,725,689	**1,067,725,689**
Balance as at 30th June, 2018	**14,337,782,272**	**1,611,858,010**	**15,949,640,282**
Balance as at 1st July 2018	**14,337,782,272**	**1,611,858,010**	**15,949,640,282**
Changes in Equity for the FY 2018/2019:			
Capital Fund	28,266,360,000	-	**28,266,360,000**
Prior Year Adjustments	-	(12,191,111)	**(12,191,111)**
Surplus/(Deficit) for the Year	-	102,095,993	**102,095,993**
Balance as at 30th June, 2019	**42,604,142,272**	**1,701,762,892**	**44,305,905,164**

NOTES 1 TO 20 FORM PART OF THESE FINANCIAL STATEMENTS

CHAIRMAN

DATE: FEBRUARY 28TH, 2020

COUNCIL MEMBER

DATE: 28TH February 2020

3.0 HUMAN RESOURCE

3.1 STAFF APPOINTMENTS

During the year, the Governing Council pursuant to the provisions of section 3.9 of the NIMR Staff Regulations and section 8 (1) (2) Part III on power and operations of the NIMR Act, approved appointment of five Directors following their successful performance during internal recruitment interviews conducted by the Institute for the respective positions. These include:

1. Dr. Paul Erasto Kazyoba - Director of Research Coordination and Promotion
2. Dr. Ndekya Maria Oriyo - Director of Research Information Technology and Communication
3. Dr. Safari Methusela Kinung'hi - Centre Director for NIMR Mwanza
4. Dr. Nyanda Elias Ntinginya - Centre Director for NIMR Mbeya
5. Prof. John Peter Lusingu – Centre Director for NIMR Tanga

3.2 STAFF RECRUITMENT

To fill human resource gaps and enhancing institutional performance, Management approved transfer request of employees from other Government Institutions whereby seven (7) employees joined the Institute – these include Human Resource Officers (2), Senior Assistant Accountant (1), Assistant Accountant (2), Research Assistant (1) and Principal Public Relations Officer (1). Management also relocated staff within the Institute. Through transfers and relocations, the Institute maximised utilisation of human resource and eliminating idle workforce. The Institute was also joined by twelve (12) new recruits as follows: Researchers (4), Drivers (2), Laboratory Technologists (3), Data Entry Clerk (1), Accounts Clerk (1) and Human Resource Officer (1).

3.3 STAFF PROMOTION, RECATEGORIZATION AND CONFIRMATION

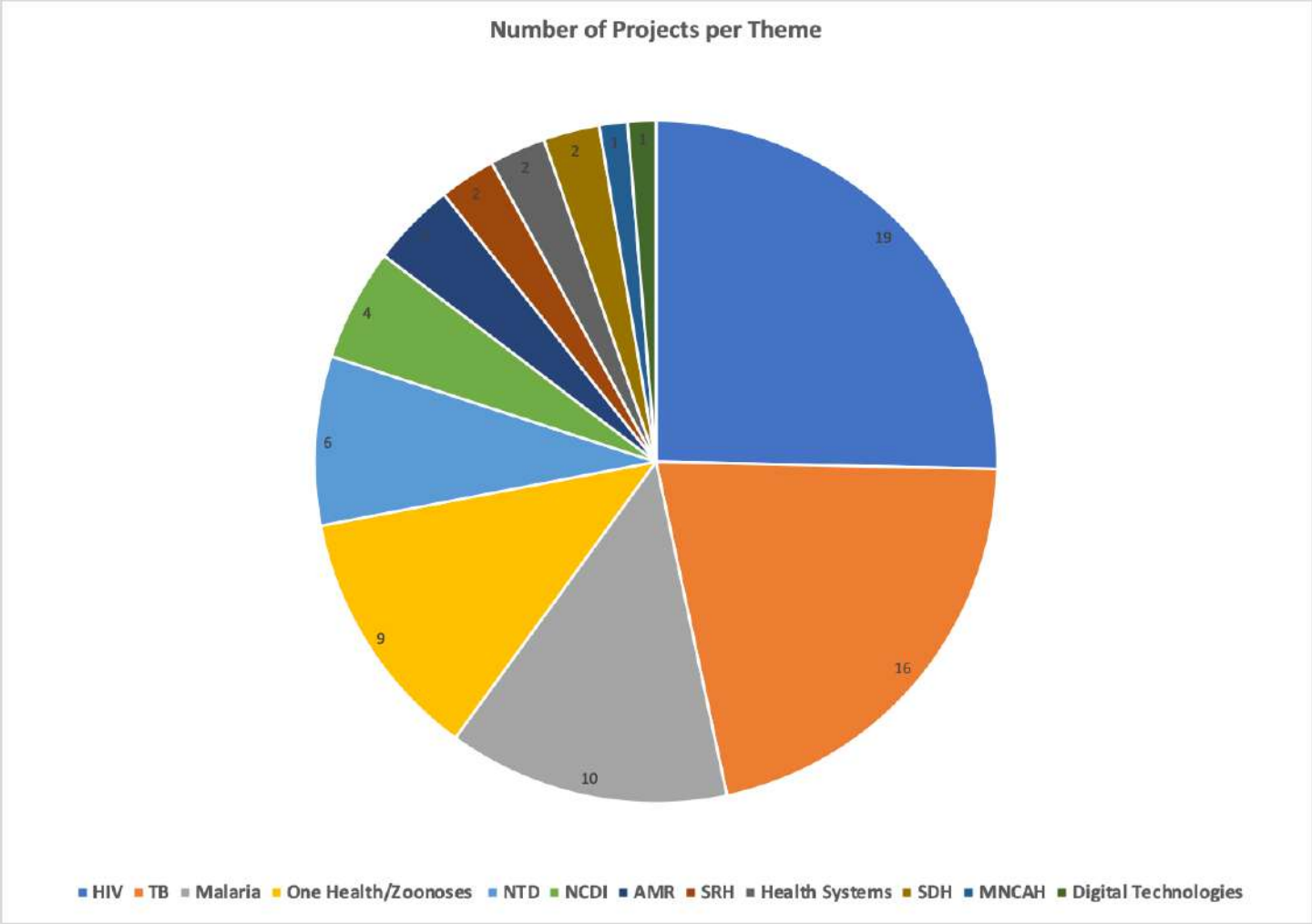
A total of twenty-five (25) employees were approved by the Governing Council for promotion subject to UTUMISHI approval, while thirteen (13) staff were approved for re-categorization subject to UTUMISHI approval. During the same year a total of ten (10) employees were approved for confirmation following successful completion of their probationary period.

4.0 HEALTH RESEARCH REGULATION

The Medical Research Coordinating Committee (MRCC) is the national health research coordinating body that ensures all health research follows country's ethics requirements. The MRCC has delegated functions of registering, ethical review, approving and monitoring of research to the National Health Research Ethics Review Sub-Committee (NatHREC), which is hosted at NIMR Headquarters. NatHREC is responsible for overseeing all issues pertaining to health research data and material transfers. NatHREC has delegated functions for ethical clearance to zonal ethics committees including the Mbeya and Mwanza Zonal Health Research and Ethics Committees. During the period, NatHRECreceived a total of three hundred and sixty-seven (367) proposals for ethical approval.

Permission to publish is a condition of ethical clearance to monitor ethical clearance adherence and research output. One hundred and eleven (111) manuscripts were granted permission to publish during the reporting period.

5.0 HEALTH RESEARCH CARRIED OUT



Key: NTD- Neglected Tropical Diseases; NCDI- Non-communicable diseases and injury; AMR-Antimicrobial resistance; SRH – Sexual and Reproductive Health; SDH – Social Determinants for Health; MNCAH – Maternal, neonatal, child and adolescent health

5.1 HUMAN IMMUNODEFICIENCY VIRUS (HIV)

Tackling the Structural Drivers of the HIV Epidemic (STRIVE) -NIMR Mwanza

Gerry Mshana, Joyce Wamoyi, John Changalucha, Saidi Kapiga, Lori Heise, Janet Seeley, Charlotte Watts

Undertake rigorous research into what works to tackle the structural determinants of HIV and maximize learning from interventions that have effectively influenced policy. STRIVE works on four, interlocking structural drivers: (1) *Gender roles and inequalities* that are culturally and institutionally reinforced and structure men's and women's sexual behaviour, economic opportunities, power and vulnerability to violence, and that undermine their efforts to avoid HIV; (2) *Stigmatisation, discrimination and criminalisation* that prevents people from HIV testing and hinders the efforts of marginalized or disempowered groups such as sex workers to avoid HIV and/or access services; (3) *Poor livelihood opportunities* and the associated population movements, which help shape patterns of sexual mixing, deplete hope, self-efficacy and trust, which can foster risky behaviour, and hinder HIV prevention and treatment efforts; and (4) *Unrestricted alcohol availability and drinking norms* that influence HIV risk and exacerbate sexual risk-taking and gender-based violence. The STRIVE team in Tanzania has worked with the Ministry of Health, Community Development, Gender, Elderly and Children (MoHCDGEC) to address issues of alcohol use in national policies. Specifically, the team has provided input in various drafts of the revised National Health Policy (of 2018) to highlight how alcohol use contributes to the disease burden in the country and how it should be addressed in the policy.

Monitoring access to HIV services in Kisesa ward, Tanzania through real time record linkage (Mesh study) – NIMR Mwanza

Mark Urassa, Christopher Rentsch, Richard Machemba, George Reiner, Basia Zaba

The main aim is to measure the determinants of successful (and unsuccessful) utilization and navigation of HIV services in Kisesa ward at a population level so that modifiable mediators of service uptake may be effectively targeted by interventions to improve engagement in HIV care. Real-time record linkage is the extension of the probabilistic record linkage that involves a brief interview with consented individuals to ultimately obtain a true match between health facility and community cohort data. As there are no identifiers that uniquely link health facility records to the community data in Kisesa, personal identifying attributes that are common to both datasets (e.g. name, sex, date of birth, residence information) have to be used to match records. Similar to probabilistic methods, this personal information is input into a software application that automatically calculates matching weights and returns likely matches to the data clerk/interviewer. Then, through the brief interview, the data clerk can search through the returned potential matches and ask the consented individual in "real-time" some further questions, such as other household member names, in order to locate the true match. Once a true match is located, the data clerk saves the match in the software application window, which outputs the unique numerical DSS identifier along with the respective clinic identifier (e.g. HTC, ANC, CTC) directly into an encrypted database, and the entered data gets automatically erased from the software application's fields. This means that the personal information will only be visible to the specially trained data entry personnel (data entry clerks and data managers supervising them) at the time the data are entered.

Diabetes and associated complications in HIV patients (CICADA study) - NIMR Mwanza

George PrayGod, Nyagosya Range, John Changalucha, Henrik Friis, Daniel Faurholt-Jepsen, Mette Olsen, Suzanne Filteau. Rikke Krogh-Madsen, Jerome Kamwela, Harleen Grewal, Naomi Oxberry, Kidola Jeremiah, and Kaushik Ramaiya

The emerging data from high-income countries suggest that HIV and ART may increase the risk of Diabetes Mellitus (DM). However, there is limited data on these links in SSA; lack of these data prevents efforts to improve DM care in HIV programmes in SSA. The study aims to study the link between HIV, ART and other risk factors on pre-DM and DM and associated complications and explore if these links are explained by inflammation, dyslipidaemia, and excessive adiposity in HIV patients. Recruit participants from two existing HIV cohorts recruited between 2006-2011, and recruit new smaller HIV cohort, all with a total of 640 HIV+, 1035 HIV-, and 670 HIV+ on ART participants to study these associations and explore if such associations are explained by chronic inflammation, dyslipidaemia, and ART-associated changes in body composition. At baseline and end of one and two years, data on pre-DM and DM and risk factors and complications will be collected. Blood samples are collected for glucose testing, assessment of inflammatory markers and kidney functions. In addition, body composition is measured using anthropometry and bioelectrical impedance analyser. Data collected at beginning of the two existing cohorts as well as in the two years

follow-up will be used to address study objectives. Multiple regression analysis models will be used to control for multiple confounding. Data generated on the links between HIV and ART and DM in SSA will be used by the Ministry of Health to optimize prevention and clinical care of DM in HIV patients. The project has both human and infrastructure capacity building. To strengthen human research capacity, two PhD students have been enrolled.

Translating Research into Practice (TRIP): Evaluating and Speeding up the adoption of an evidenced based innovative REMSTART package to reduce mortality in advanced stage HIV patients starting antiretroviral therapy in Tanzania - NIMR Muhimbili

Sayoki Godfrey Mfinanga, Sokoine Lesikari Kivuyo, Bernard Ngowi, Godfather Kimaro, Amos Kahwa, Esther Ngadaya, Angela Ramathani, Janneth Mghamba, Tom Harrison, Sile Malloy, Angela Loyse

The previously conducted REMSTART trial showed that Cryptococcal Antigen (CrAg) Screening and pre-emptive treatment with fluconazole combined with a short period of home support for 4 weeks reduces mortality by about 30% among advanced HIV patients presenting for antiretroviral therapy. In this translational study, the TRIP intervention will involve 1) Cryptococcal meningitis screening using CrAg test plus pre-emptive treatment with fluconazole and 2) weekly mobile telephone messaging as a home support for one month followed by monthly telephone consultations for next 3 months. The aim is to assess the cost-effectiveness and feasibility of large-scale implementation of TRIP package to reduce mortality in advanced HIV/AIDS patients starting on ARV in routine health system in urban and rural settings. Such large-scale implementation and evaluation are essential before national scale-up can be considered. The principle objective is to determine feasibility of scaling up the TRIP intervention in routine health system. The design will involve sequential implementation of the intervention in a staggering manner involving 16 urban and 8 rural health facilities from Dar es Salaam and Morogoro rural district, respectively. Our primary endpoint will be all-cause mortality. Secondary endpoints will include adherence, costs of the strategies and patient retention on ART. The implementation involves packaging activities into four work packages. 1) Project management; 2) Translation, dissemination and adaptation of REMSTART package; 3) Implementation and evaluation; and 4) Networking and Capacity building.

Integrating the diagnosis and management of HIV-associated central nervous system (CNS) infections into routine health services in low- and middle-income countries (LMICs) {Driving Reduced AIDS-associated Meningo-encephalitis Mortality (DREAMM)} - NIMR Muhimbili

Angela Loyse, S Mfinanga, Sokoine Laskari, G Kimaro, E Ngadaya, Janneth Mmgamba, Angela Ramadhani, C Kouanfack, C Kanyama, Tom Harrison, Shabbar Jaffari

This is an implementation study with evaluation done using a before-after design done in 3 phases: 1) Audit; 2) Training and 3) Algorithm implementation. The study population is 450 HIV-infected patients admitted with symptoms and/or signs of meningo-encephalitis such as tuberculosis, Cryptococcal, Toxoplasmosis and bacterial meningitis. It is conducted in 3 geographically distinct sites in Sub-Saharan Africa: 1) Central Africa-Hôpital Central Yaoundé, Cameroon; 2) East Africa-Amana Hospital, Dar Es Salaam, Tanzania; 3) Southern Africa- Kamuzu Central Hospital, Malawi. Intervention will include implementation of point of care tests within a diagnostic and treatment algorithm together with support and additional training of laboratory and clinical staff to reduce all-cause mortality in patients with meningo-encephalitis at 2 and 10 weeks.

RV 262 Study (HIV Vaccine Trial) – NIMR Mbeya

Leonard Maboko and Marco Missanga

This study evaluates the safety and tolerability of PENNVAX™-G DNA (env & gag) administered by IM Biojector® 2000 or IM CELLECTRA® electroporation followed by IM MVA-CMDR (HIV-1 CM235 env/ CM240 gag/pol) boost in healthy HIV-uninfected adult participants. The primary objective is to evaluate the safety and tolerability of the proposed vaccine regimen. Methods: This Phase I Study is a randomized, placebo controlled, double-blinded, with respect to study products, and is conducted at sites in Kenya, Tanzania and Uganda. The Kenya and Tanzania sites will each enrol twenty participants and Uganda will enrol a total of forty participants. Participants will be randomized 4:1 to receive PENNVAX™- G DNA at a dose of 4 mg or placebo administered using either the Biojector® 2000 needleless device or the CELLECTRA® IM EP device. The MVA-CMDR (HIV-1 CM235 env/ CM240 gag/pol) boost will be administered by IM injection at $1x10^8$ pfu on days 84 and 168.

HVTN 703/HPTN081 (HIV Vaccine Trial) – NIMR Mbeya

Lucas Maganga and Emmanuel Kapesa

A phase 2b study to evaluate the safety and efficacy of VRC01 broadly neutralizing monoclonal antibody in reducing acquisition of HIV-1 infection. Effective biomedical interventions are needed to reduce the acquisition of HIV. The global HIV-1 epidemic continues and while many countries have made progress toward levelling HIV prevalence over the last few years, micro-epidemics of infection continue to occur in nearly all regions, even in countries possessing the full toolkit of proven prevention approaches. The Vaccine Research Center (VRC), NIAID, NIH has developed VRC01, a broadly neutralizing human mAb that targets the HIV-1 CD4 binding site. This mAb was originally discovered in a participant infected with HIV-1 for more than 15 years who maintained viral control without use of antiretroviral therapy (ART). VRC01 has the capacity to neutralize a broad range of HIV-1 strains in vitro and has conferred protection against simian-human immunodeficiency virus (SHIV) challenges in nonhuman primate (NHP) studies. It has an acceptable safety profile, as seen in previous phase 1 studies. Primary objectives are to evaluate the safety and tolerability of VRC01 mAb administered through IV infusion in each of 2 cohorts and to determine if the VRC01 mAb prevents HIV-1 infection and to estimate the level of efficacy in each of 2 cohorts. Design: The study is a multicentre, randomized, controlled, double-blind conducted in North and South America, and Southern Africa. Participants: 1500 HIV uninfected women volunteers aged 18 to 50 years at risk of HIV-1 infection from southern Africa; 2:1 active: control allocation total 1000 VRC01 mAb, 500 control.

RV 217: HIV-1 Prevalence, Incidence, Retention, Host Genetic and Viral Diversity in High Risk Cohorts in East Africa and Thailand" RV 217 Study (Cohort Study) - NIMR Mbeya

Lucas Maganga, Joseph Hidda, Leonard Maboko, Frowin Nichombe, Inge Kroidl, Arne Kroidl and Michael Hoelscher

This study measures the epidemiology of HIV in a cohort drawn from high-risk populations in these countries and also characterizes behavioural and other risk factors associated with HIV-1 infection, and augment HIV-1 prevention and education programs, human resources, and laboratory infrastructure to support future vaccine trials. The study is divided into two parts, a pilot study to access feasibility (A) and the full study (part B). About 500 participants will be enrolled in the study (200 for part A and 300 for part B). Only after establishing feasibility of the proposed design in part A would enrolment open fully in part B. The study itself, as conducted in both Parts A and B, incorporates two phases (I, II). Very frequent surveillance as proposed in the study has not been conducted in the HIV field. It is possible that participants will either be unavailable this frequently or unwilling to participate, therefore a pilot study is proposed to ensure that protocol procedures are going to be successful in meeting the audacious goals of the study. Primary Objectives: (1) Define the risk behaviour, prevalence and incidence of HIV infection and retention of a high-risk cohort of adults in Thailand, Uganda, Kenya and Tanzania and (2) Obtain approximately 150 acute HIV infections (AHI) with at least 30% captured within Fiebig stages I and II to support the full characterization of host responses and viral dynamics. Methods: The main study activity, or phase I, is the observational cohort or surveillance activity which will last for 15 months.

RV 329 D (The AFRICOS study) - NIMR Mbeya

Emmanuel Bahemana, Lucas Maganga

AFRICOS is an open-ended prospective cohort study, enrolling 3000 HIV infected adults and 600 HIV uninfected adults at MHRP PEPFAR-associated clinical sites in Kenya, Tanzania, Uganda and Nigeria. The study will follow participants every six months and will collect social, demographic, clinical and laboratory data as well as blood and sputum samples for storage in the AFRICOS Repository. The Primary objective is to longitudinally assess the impact of clinical practices, biological factors and socio-behavioural issues on HIV infection and disease progression in an African context. These areas include social and behavioural domain; medical-HIV prevention and management (programmatic); Medical-HIV management (subject); medical-opportunistic infections and other morbidities; Human papillomavirus and other STIs; viral Hepatitis; Malaria; Stools pathogens (prevalence of helminth and bacterial stool pathogens and their impact on HIV disease outcomes); test characteristics for rapid diagnostic tools for co-infections (including Hepatitis B, Hepatitis C, malaria, and tuberculosis) as they apply to the PEPFAR setting, Medical-Maternal-child transmission management; medical-Prevention of horizontal HIV infection and medical-host genetics and pathogenesis.

RV 398 (HIV Therapeutic Trial) - NIMR Mbeya

Joel Mwakisisile, Joseph Hiddah, Lucas Maganga, Arne Kroidl, Michael Hoelscher, Leonard Maboko, Nyanda Elias Ntinginya, and Revocatus Kunambi

Long-term use of antiretroviral therapy (ART) in HIV-positive persons may be challenged by the need for high-level lifelong adherence to a daily regimen, development of drug resistance and cross-resistance, short and long-term toxicities, and cost. Even with complete and durable viral suppression, standard antiretroviral therapies do not fully restore health, as some degree of immunodeficiency and/or chronic immune activation and inflammation persists. Furthermore, the large and growing global population of HIV infected individuals and the costs of ART present a significant challenge for providing treatment to those in need, particularly through public health systems where resources are already constrained. There is, therefore, a growing interest and need for the development of curative approaches for HIV that include treatment strategies that confer durable virologic control with less frequent dosing or even sustained remission in the absence of ART. The Vaccine Research Center (VRC)/NIAID, Division of AIDS (DAIDS)/NIAID, and MHRP are collaborating to evaluate the clinical uses of VRC01 in these acutely diagnosed populations. This broadly neutralizing human mAb is thus far demonstrated to be safe and well tolerated in initial Phase 1 studies. It has also been demonstrated to decrease viremia in a rhesus macaque model. The current study aims to determine the safety and impact of mAb therapy on AHI in humans. It will evaluate the effect of VRC01, with and without ART, on viremia and the establishment of an HIV-1 reservoir during early acute infection. Primary Objectives are (1) Safety of VRC01 in acutely HIV-infected viremic individuals and (2) Impact of VRC01 on plasma viremia in each mAb arm compared to the ART plus placebo control at day 7 (+/- 1 day). Methods: This is a placebo-controlled study of the safety and impact of broadly neutralizing monoclonal antibody therapy with VRC01 on viremia in acute HIV infection, alone or in combination with antiretroviral therapy (ART). Twenty-four subjects will be enrolled during early acute HIV infection, as defined by two positive nucleic acid amplification tests (NAATs) for HIV-1 RNA within 21 days of a prior negative NAAT (as determined during their participation in RV 217). They will be randomized to three groups: ART initiation and single placebo infusion, ART initiation and single infusion 40mg/kg VRC01 and Single infusion 40mg/kg VRC01ART initiation.

HVTN 120 - NIMR Mbeya

Wiston William, Faith Mlagalila and Emmanuel Kapesa

HVTN 120 will compare the HVTN100/HVTN702 regimen (without a boost at Month 12) with two corresponding regimens containing the $AS01_B$ adjuvant, one at the same protein dose (100 mcg), and the other at a lower protein dose (20 mcg). As such, HVTN 120 will generate supporting safety and immunological data regarding protein dose and adjuvant type in context of the HVTN 702 regimen. Systematic evaluations of well-characterized adjuvant/immunogen formulations, such as proposed in HVTN 120, will aid in developing an HIV vaccine that can elicit and drive effective and durable functional immune responses against HIV. With that, results can help guide the way forward in the development of an efficacious preventative HIV vaccine regimen. Once the optimal dose and adjuvant have been determined, further trials, in a sequential manner, can be used to improve upon the current regimen. Primary objectives (1) to evaluate the safety and tolerability of ALVAC-HIV and bivalent gp120 protein/MF59 or bivalent gp120 protein/$AS01_B$; (2) to compare HIV-specific CD4+ T-cell response rates at the month 6.5 timepoint (2 weeks after the fourth vaccination) of ALVAC-HIV and bivalent gp120 protein/MF59 to each of the bivalent gp120 protein/$AS01_B$ vaccine regimens and (3) to compare HIV-specific Env-gp120 binding antibody response magnitudes at the month 12 timepoint (6 months after the fourth vaccination) of ALVAC-HIV and bivalent gp120 protein/MF59 to each of the bivalent gp120 protein/AS01B vaccine regimens. Design: The study is a multicentre, randomized, controlled, double-blind.

bNAb Study – NIMR Mbeya

Wiston William, Lucas Maganga and Janeth Stephen

In natural HIV disease, a small fraction (1-2%) of infected individuals develops exceptionally high titres of HIV-1 neutralizing serum activity. Antibodies isolated from these individuals have been shown to be highly active against a broad range of different HIV strains and are therefore called broadly neutralizing antibodies (bNAbs). These antibodies are in fact able to prevent (s)HIV infection in animal models and therefore of great interest for the development of an HIV vaccine. Information of neutralizing antibodies in patients from Africa is still scarce and would be of great value in the development of adapted HIV vaccine strategies in these regions. In this study we therefore aim to study African HIV-infected individuals, who have developed neutralizing antibodies using highly specialized laboratory

methodologies. Primary Objective: The primary objective of this study is to identify HIV-infected patients which exhibit exceptional HIV-1 neutralizing activity (so called elite neutralizer) and to perform in those patients in depth characterization. Methods: Observational cohort study in HIV-infected, preferentially ART-naïve patients from various health facilities involved in HIV Voluntary Counselling and Testing (VCT) and HIV Care and Treatment (CTC) within Mbeya Region. The study will screen a total of 500 participants for identification of broad neutralizing HIV-1 antibodies (a single visit) and those identified as elite neutralizers will undergo a second visit which is expected to take place in maximum 6 months after the screening visit. The recruitment duration is expected to be 18 months.

TWENDE – NIMR Mbeya

Nyanda Ntinginya and Leonard Maboko

The East African 'TWENDE' project an abbreviation of "Tuberculosis Working to Empower the Nations Diagnostic Effort" is funded by the European Union through the European & Developing Countries Clinical Trials Partnership (EDCTP). The word 'TWENDE' is a Swahili word that means "Let's go" and indeed encourages one another within and beyond the consortium to move forward and in this case against TB. This project aims to understand and overcome the barriers to the implementation of WHO endorsed TB diagnostics in the three East African Countries that forms part of the 22 global TB High Burden Countries. Partner research institutions in E. Africa involved in the TWENDE project includes; Makerere University Kampala (Uganda), CPAR Uganda, Kenya Medical Research Institute, NIMR-Mbeya Medical Research (NIMR-MMRC), Mbeya and Kilimanjaro Clinical Research Institute (KCRI), Moshi, University of St. Andrews together with the East African Health Research Commission (EAHRC) of the East African Community. The project further seeks to dialogue and enlighten policy makers and implementers on their stake in ensuring availability of good diagnostic services as well as uptake of new innovation for public benefit.

Validation of rapid tests for the serological diagnosis of HIV in 9 to 24 months old children - NIMR Tanga

Samwel Gesase, John PA Lusingu, Edwin Liheluka, Mercy Grace Chiduo

Main objective: To evaluate the performance of three rapid tests for detection of HIV infection in children 9-24 months of age. Other specific objectives include (1) to evaluate the sensitivity and specificity of the rapid serological test HIV-1/2 Bio- Manguinhos screening in children 9-24 months, taking as reference molecular testing; (2) To evaluate the sensitivity and specificity of the rapid Oral Fluid test HIV- 1/2 Bio- Manguinhos screening in children 9-24 months, taking as reference molecular testing; (3) To evaluate the sensitivity and specificity of the rapid imunoblot test HIV- 1/2 Bio-Manguinhos in children 9-24 months, taking as reference molecular testing and; (4) Evaluate variations in accuracy of rapid tests according to clinical features of mothers and children: Prenatal treatment of the mother; early treatment of the child etc.

A randomized placebo-controlled double-blind phase II trial to determine the effects of metformin versus placebo on glycaemia in HIV-infected persons with pre-diabetes in Tanzania – NIMR Muhimbili

Sayoki Mfinanga et al.

Metformin is the recommended first line drug for persons with diabetes and HIV-infection in the UK, Africa and elsewhere. Metformin has also been evaluated in persons with HIV infection on ART who have lipodystrophy and metabolic syndrome. Based on the evidence, we believe that metformin is safe for use in HIV-infected persons on ART who have pre-diabetes. Our purpose is to conduct a phase II trial and generate the data needed to design a phase III trial. Eligible patients (for the phase II trial) will be HIV-positive adults on ART and confirmed to be pre-diabetic using the Oral Glucose Tolerance Test (OGTT), with no contraindication to being randomized to either the metformin or the control group and who are able to attend the study clinic. The trial will be done at Hindu Mandal Hospital, and at Amana Hospital. Eligible patients will be randomised 1:1 to the intervention or control group: Intervention: Metformin hydrochloride 2000 mg per patient per day. Control: Matching Placebo. All patients will continue to take their ART. The primary outcome measure is glycaemia at 12 months as ascertained by the oral glucose tolerance test. Recruitment is estimated to be complete within a 90-day period. Participants will be followed up for a duration of 12 months after recruitment (baseline, 2 weeks, 1 month, 3 months, 6 months, 9 months and 12 months).

Role of Environmental Enteropathy on HIV Associated Diabetes Mellitus (REEHAD) – NIMR Mwanza

George PrayGod, Kidola Jeremiah, Henrik Friis, Daniel Faurholt-Jepsen, Rikke Krogh-Madsen, Suzanne Filteau

Objective: This is a mechanistic study aiming at determining the role of environmental and HIV-associated enteropathy on evolution of diabetes among HIV patients.

PrEPVacc Registration Cohort – NIMR Mbeya

Doreen Pamba, Elizabeth Ntapara and Lucas Maganga

The PrEPVacc Registration Cohort "Development of an HIV negative Registration cohort for future participation in an HIV vaccine study" aims to prepare a population of HIV negative individuals who are at risk of acquiring HIV for possible participation in the PrEPVacc HIV preventative vaccine study, expected to start in 2019.The study measures the epidemiology of HIV in a cohort drawn from high-risk populations in four countries i.e. Tanzania, Uganda, South Africa and Mozambique. In Tanzania, the focus is on recruiting 200 females considered to be at high risk for HIV.

Objectives: To identify, recruit, and follow-up a cohort of HIV-negative volunteers at high risk of HIV infection in preparation for the PrEPVacc trial; To estimate incidence of HIV infection in the study volunteers;To ascertain knowledge, perceptions, uptake of and adherence to PrEP (where it is available); To develop and refine key messages about HIV vaccines and PrEP as well as tools for conveying these messages and; To educate participants about, PrEP, HIV vaccine research in general and the PrEPVacc trial in particular. *Methods:* The study comprises of long (6 monthly) and short (3 monthly) visits for a period of 36 months per each participant and a minimum of 12 months. In short visits, participants will be counseled and tested for HIV and assessed of their risk for pregnancy. In long visits, participants will be counseled and tested for both HIV and pregnancy.

Risk for HIV Infection through Nematodes (RHINO) Study – NIMR Mbeya

Inge Kroidl, Mkunde Chachage and Lucas Maganga

The study "Risk for HIV Infection through Nematodes (RHINO)" plans to evaluate changes in the immune system of individuals infected with Wuchereria bancrofti. Previous studies from our group (EMINI study) have revealed an increased susceptibility for HIV among W. bancrofti infected individuals and the RHINO study plans to decipher the underlying reasons the observed phenomenon will be addressed. This is a cross sectional study requiring only one additional blood draw. Additionally, selected female participants will be addressed to participate in an activity of comparing mucosal and systemic immune profiles. Participants will be enrolled from Mbeya, Lindi and Pwani. Study Objectives: To describe the impact of 10 years of mass drug administration on W. bancrofti prevalence; To describe immune profiles of individuals infected with *W. bancrofti* associated with enhanced susceptibility to HIV; To describe helminth-associated factors, which enhance or hinder HIV susceptibility in vitro; To compare early cellular events in endemic normal and W. bancrofti infected cohorts following HIV infection in vitro; To determine the immune profile of cells in the human female reproductive tract; and To determine the influence of *W. bancrofti* infection on the T cell responses to HIV.

Improving Evaluation Capacity within the Government of Tanzania under the President's Emergency Plan for AIDS Relief – NIMR Headquarters

Ndekya M. Oriyo, Jonathan M. Mshana, Grades Stanley, Evord Kimario and Eric Mutemi

Since 2004, PEPFAR Tanzania has been working closely with the Tanzanian Government and other donors to respond to the HIV epidemic. The Government of Tanzania (GoT) is implementing a range of programs for the prevention, care and treatment of people living with HIV/AIDS with the support of PEPFAR. Relevant research findings and dissemination enable formulation of policies that are evidence-based specific to Tanzania, contributing to improvement in the provision of HIV/AIDS-related services. The National Institute for Medical Research (NIMR) plays a pivotal role in strengthening health systems activities, specifically, in facilitating the implementation of health interventions, operational research, policy analysis, public health leadership and practice improvement that impact on health in Tanzania. The project main objectives are: Strengthen the current medical and public health research capacity within the Government of Tanzania; Facilitate coordinated outbreak responses with FELTP in partnership with MOHCDGEC through strengthened collaboration; Ensure NHLQATC is adequately supported to execute its main functions.

5.2 TUBERCULOSIS

Partially Randomized Trial to Evaluate the Efficacy, Safety and Tolerability of a 4-month Treatment of Bedaquiline plus Pretomanid plus Moxifloxacin plus Pyrazinamide (BPaMZ) Compared to a 6-month Treatment of HRZE/HR (Control) in Adult Participants with Drug-Sensitive Smear-Positive Pulmonary Tuberculosis (DS-TB) and a 6-month Treatment of BPaMZ in Adult Participants with Drug Resistant, Smear-Positive Pulmonary Tuberculosis (DR-TB). Protocol name: SimpliciTB – NIMR Mbeya

Nyanda Elias Ntinginya, Christina Manyama, Issa Sabi, Elimina Siyame, Ombeni Chimbe, Joseph Hidda, George PrayGod and Kidola Jeremiah

The current TB treatment regimens and treatments for drug-sensitive TB are decades old. The available treatments have a lengthy duration of treatment, involve multi-drug therapy, and require large commitments of resources and infrastructure. High rates of noncompliance are common, which often results in increased mortality and chronic, infectious, drug-resistant cases. The present TB epidemic and the challenge of current treatment options demonstrate the clear need for effective novel TB drugs and drug regimens that are safe for drug sensitive and drug resistant TB disease and that are well-tolerated and will shorten the current treatment duration for patients. New combination regimens are desperately needed for two reasons: to shorten treatment to a duration more easily manageable by patients and public health services, and to provide more efficacious, safer and better tolerated, affordable treatments for the growing number of patients suffering from multidrug-resistant and extensively drug-resistant tuberculosis.The objective of this trial is to evaluate the efficacy, safety and tolerability at 8 weeks, 52 weeks and 104 Weeks post the start of the following treatment regimens in participants with BPaMZ given for 17 Weeks or Standard HRZE/HR treatment given for 26 weeks (Drug Sensitive TB) or BPaMZ given for 26 Weeks (Drug Resistant TB).

Improving Tuberculosis case detection and diagnosis among children in Tanzania - NIMR Muhimbili

Esther Ngadaya, Godfather Kimaro, Sayoki Mfinanga, Johnson Lyimo, Erica Sandi and Ramadhani Shemtandulo

This study aims to determine the performance of stool Xpert among TB suspects. The study populations are all TB suspects with emphasis on children receiving services in selected facilities in Arusha, Kilimanjaro, Pwani, Dar es Salaam, Mtwara and Morogoro. If all turns positive, we can revolutionise the diagnosis of TB in children in Tanzania by using stool instead of sputum samples which is hard to get among children.

Factors associated with low enrolment to treatment among patients with Multi Drug Resistant Tuberculosis in Tanzania - NIMR Muhimbili

Esther Ngadaya, Godfather Kimaro, Sayoki Mfinanga Isack Lekule, Erica Sandi, Ramadhani Shemtandulo, Alexander William, Riziki Kisonga, Hassan Mbega, Richard Kinyaha, Athumani Mohammed

This study is conducted in all districts in the country with MDR-TB patients who are not yet enrolled into care. The main objective is to determine the number and factors associated with low enrolment to treatment among patients with MDR-TB in Tanzania. We reviewed all MDR TB patients registered in the GeneXpert alert system from the Central Tuberculosis Reference Laboratory (CTRL) during the years 2013 – 2015 and compared with those who were/have received MDR TB care at Kibong'oto to get those who were not enrolled into treatment. We also interviewed respective regional TB & Leprosy Coordinator and District TB & Leprosy Coordinator.

Improved diagnosis of extra-pulmonary tuberculosis among adults and children: Implementation of a rapid, robust, sensitive and specific immunochemistry-based assay in the routine tuberculosis control programme settings (IRRSSIA study) - NIMR Muhimbili

Sayoki G Mfinanga, Esther Ngadaya, Yakobo Lema, Amosi R Mwakigonja, William J Muller, Msafiri Ladislaus Marijani, Tehmina Mustaf

Extra-pulmonary TB accounts for approximately 14-40 % of all TB infections, and the diagnosis has always been a challenge. The routinely used diagnostic tests have low sensitivity due to the paucibacillary nature of the disease. We have developed a method based on immunochemistry to detect the secreted mycobacterial antigen MPT64 from various biological fluids, aspirates and tissues. It aims to improve the diagnosis and increase the case detection of extrapulmonary TB in adults, children and HIV-TB coinfected by introducing the assay in the selected tertiary care hospitals in high TB (Tanzania, Pakistan and India) and high-low (Norway) human immunodeficiency virus (HIV) burden countries using a routine TB control programme.

Translation research into policy and practice: Scaling up evidence based multiple focus integrated intensified TB screening to end TB (EXIT-TB) in the East African region – NIMR Muhimbili

Esther Ngadaya, Godfather Kimaro, Amosi Kahwa, Getnet Ali, Maowia Mukhtar, Mbazi Senkoro, Sokoine Kivuyo, Marywinnie Nanyaro, Janneth Mghamba, Barbara Castelnuovo, Bruce Kirenga, Blandina Theophil Mmbaga, Steve Wandiga, Johnson John, Sara Moses, Elizabeth Shayo, Sven Gudmund Hinderaker, Alimuddin Zumla, Jaffar Shabbar & Sayoki Godfrey Mfinanga

The aim is to accelerate the translation of research into policy and practice through implementation of Evidence Based Multiple Focus Integrated Intensified TB Screening package (EXIT-TB). The EXIT TB package will involves: i) Screening all patients for TB who passively report cough at the out patients department (OPD) and reproductive and child health (RCH) clinics ii) actively screening of all children with a contact with TB, iii) Testing for TB irrespective of TB symptoms among all patients with advanced HIV/AIDS diseases (*CD4* < 200 cells/mm3 and/or WHO stage 3 or 4 and iv) actively screen for TB among diabetic patients. We believe that EXIT-TB package will increase TB case detection, reduce treatment delay, increase number of TB patients including women and children put into TB care, and thus reduce TB transmission and mortality in the East Africa (EA) region. The study will be implemented in Tanzania (Lead country), Kenya, Uganda, Ethiopia and Sudan.

The Tuberculosis Xpert in Tanzania - Local perspectives on a global technology roll-out – NIMR Muhimbili

In 2010 the World Health Organization officially endorsed the GeneXpert assay Xpert MTB/RIF (Cepheid, Sunnyvale, California) for detection of Mycobacterium Tuberculosis, and subsequently the world has experienced something close to a revolution in the field of TB-diagnostics. The United Republic of Tanzania is regarded as one of 22 global high-burden TB-countries, and currently a large national scale-up of the GeneXpert technology is underway. Although a massive body of research exists on the assay both internationally and specifically for Tanzania, there are significant gaps in the literature, especially related to impact. This project is of an anthropological nature and intends to contribute to addressing this gap in Tanzania from a social scientific perspective. Hence, we are looking beyond the strictly clinical impacts of GeneXpert, and rather address socio-medical and socio-political structures being affected by- and affecting the technology. Methodologies employed are qualitative, and entail participant observation, semi-structured interviews and text analysis.

A Phase 2 Open-Label Partially Randomized Trial to Evaluate the Efficacy, Safety and Tolerability of combinations of bedaquiline, moxifloxacin, PA-824 and pyrazinamide during 8 weeks of treatment in Adult Subjects with Newly Diagnosed Drug-Sensitive or Multi Drug-Resistant, Smear-Positive Pulmonary Tuberculosis. Acronym: NC005 Study (TB Drug Trial) - NIMR Mbeya

Christina Manyama, Chacha Mangu, Wiston William, Anke Kohlenberg, Leonard Maboko

Although some progress has been made in recent years in controlling TB globally, TB has remained a problem in the developing countries of Africa, Asia and South America. The 6 months duration of treatment plus side effects, result in poor compliance which is particularly likely to occur after the second month of treatment. As a result of poor treatment compliance, drug resistance is becoming more common and fears of an epidemic with virtually untreatable strains of TB – extensively drug resistant TB (XDR-TB) - are growing. The current study NC-005, is an 8 week trial designed to further the investigation into the combination of some of these new agents, namely bedaquiline, PA-824 and pyrazinamide (J-Pa-Z) in DS-TB and bedaquiline, moxifloxacin, PA-824 and pyrazinamide (J-M-Pa-Z) in MDR-TB. This study follows study NC-003 which demonstrated that bedaquiline, PA-824 and pyrazinamide have good 14 day early bactericidal activity. The primary objective of this study is to evaluate the bactericidal activity, safety, and tolerability of J-Pa-Z in drug-sensitive TB and J-M-Pa-Z in MDR TB. Design and Scope: This is a phase 2, multi-centre, open label, partially randomized clinical trial in four parallel treatment groups. Subjects with Drug-Sensitive (DS) TB will be randomized to receive either J (loading dose/t.i.w)PaZ; or J(200mg)PaZ;or HRZE. Subjects with Multi Drug-Resistant (MDR) TB will receive J(200mg) MPaZ. Participants will be recruited from Tanzania, South Africa and Uganda with appropriate sites recruiting Drug-sensitive TB (DS-TB) and/or Multi Drug-resistant TB (MDR-TB).

Pathogenesis and risk factors of long-term sequelae of pulmonary TB defining individual outcomes and public health impact. "TB Sequel" - NIMR Mbeya

Nyanda Elias Ntinginya, Issa Sabi and Elimina Siyame

TB Sequel is a multi-country multisite cohort study describing the evolution of pulmonary TB symptoms and functional lung impairment during and after TB treatment. Additionally, the study aims to assess immunological, microbiological and social economic factors affecting pulmonary TB outcomes. Recruitment will be conducted at the African sites

including NIMR Mbeya site, MRC Unit the Gambia, National Institute for Research in Mozambique and at the University of Witwatersrand in Johannesburg South Africa. In each site 400 participants will be recruited making overall total 1600 of participants.

EIRMMA-TBT– NIMR Mbeya

Bariki Mtafya; Nyanda Elias Ntinginya, Issa Sabi, Yahya Msuya, Stephen Gillespie and Wilber Sabiiti

Current TB treatment monitoring options which relies on detection of Mtb from sputum specimens are not sufficient and has many drawbacks. Unlike, HIV where host markers (CD4 count) and pathogen markers (viral load) are used to monitor the progress of patient on anti-retroviral therapy (ART), host markers for monitoring the success of TB treatment are not yet validated despite some of the recent progress. For effective TB treatment monitoring, fast, sensitive and specific tests which can measure Mtb in real time are needed. The molecular bacterial load assay (MBLA) which measures the decline of Mtb 16SrRNA during treatment has recently been developed. The performance of MBLA is better than culture-based methods for patients on standard TB therapy. Additional benefits of MBLA includes not being affected by sample contaminants, reproducible and adaptable in resource poor settings of the tropic where there is high prevalence of TB. The main objective is to evaluate the feasibility of MBLA for monitoring TB treatment response in routine programme settings and its capability to detect dormant state of M. tuberculosis. Design and Scope: This is an observational cohort study. Pulmonary TB patients will be enrolled at the time of TB diagnosis and prospectively followed for six months after treatment initiation in line with the National TB and Leprosy control guidelines (NTLP). Treatment and sample collection will be performed in the respective health facility by the trained Direct Observed Treatment Short course nurses (DOTS). All clinical assessments and sample collections for mycobacteriological treatment response assessment will be performed according to the pre-defined schedule of event and NTLP treatment monitoring schedules.

Reach4Kids (R4K) Africa: Evaluating novel diagnostics and enabling preventive measures for childhood tuberculosis in Sub Saharan Africa – NIMR Mbeya

Issa Sabi and Nyanda Elias Ntinginya

Reach4Kids Africa is a multi-country multisite childhood TB diagnostic study aiming at addressing two important bottle necks for TB control in children, namely lack of diagnostics and lack of roll out of IPT to those most in need. Children below 15 years of age and who have TB symptoms will be prospectively recruited. into the study. The study will establish a repository of samples for testing performance of existing diagnostics and to validate novel assays in order to develop reliable diagnostic tools for childhood tuberculosis. The study will be conducted in four sites in Africa including Tanzania, Gambia, Mali and Nigeria. In each site 200 participants (children) will be recruited making overall total 800 of participants.

develop reliable diagnostic tools for childhood tuberculosis. The study will be conducted in four sites in Africa including Tanzania, Gambia, Mali and Nigeria. In each site 200 participants (children) will be recruited making overall total 800 of participants.

Evaluation of under-reporting of tuberculosis cases in health care facilities in Tanzania – NIMR Muhimbili

Andrew M Kilale, Charles Makasi, Melkizedeck Majaha, Emmanuel Nkiligi, Webhale Ntagazwa, Nyagosya Range, Bernard Ngowi, and Beatrice Mutayoba

Tuberculosis (TB) now ranks alongside human immunodeficiency virus (HIV) as a leading cause of death worldwide. Global targets for reducing the burden of disease caused by TB were set for 2015. The target set within the United Nations Millennium Development Goals (MDGs) is that the number of new cases of TB arising each year should be falling by 2015. The recent WHO modeled estimates in 2015 show that the prevalence of TB all forms in Tanzania is 528 per 100,000 with an incidence of 327 per 100,000 and case detection rates determined at 36%. In 2015, Tanzania notified a total of 62,180 cases of all forms of TB, and WHO Global TB report of 2015 estimated that Tanzania is missing approximately 108,429 TB cases of all forms each year. This is a cross sectional study which aims to determine the extent of TB under-reporting in high TB burden in Tanzania. The assessment was conducted in in 10 randomly selected regions of Dar es Salaam, Lindi, Mwanza, Mara, Mbeya, Rukwa, Arusha, Tanga, Morogoro and Tabora.

Improving TB case detection in a rural population by linkage to a HIV Test and Treat Programme in Tanzania -NIMR Muhimbili

Godfrey Sayoki Mfinanga, Godfather D. Kimaro, Matteo Capuzzo and Sabine Hermans

This project is a 2-year project which will incorporate TB case finding into a funded HIV test & treat programme in Shinyanga, Tanzania. It will be jointly implemented by NIMR – Muhimbili Medical Research Center, Amsterdam Institute for Global Health and Development (AIGHD), and Doctors with Africa CUAMM, aiming to increase case notifications by 36%. The project is expected to provide evidence for its impact and feasibility for rollout with Tanzania's recently adopted test & treat policy. In addition, operational research embedded in the project will offer insights into improving performance of such a screening strategy. The project commenced July 2018. After all the necessary pre-field logistics had been in place include: signing of subcontract, hiring of the coordinator, field staff and laboratory scientist have been employed and procurement of all important supplies and equipment, the field activities started in July, 2018 in which our project team joined the HIV test and treat team for the community based screening. A total of 3450 of individuals who showed for HIV test were verbally screened for TB symptoms during and a total of 59 presumptive TB patients were identified for further evaluation.

A survey of prevalence and factors associated with transmission of tuberculosis among primary and secondary school children in North and Eastern Costal Regions – NIMR Muhimbili

Manase Chilengwa, Godfather Kimaro, Erica Sandi, Amani Wilfred, Johnson Mshiu, Godfrey S Mfiananga, Ndereria Swai and Esther Ngadaya

The study aims to determine the prevalence and factors associated with transmission of Tuberculosis among primary and secondary school children in North and Eastern Region. From these regions we will select a total of 18 (9 secondary and 9 primary) schools will be included in the study. Ten of these schools will be selected from Dar es Salaam. Kilimanjaro, Pwani and Morogoro regions will each contribute four schools in this study. Decision for including more schools from Dar es Salaam was purposefully reached because of the fact that Dar es Salaam contributes more than 25% of the TB patients recorded in the country. Two separate lists – one for secondary schools and one for primary schools will be prepared for Kilimanjaro, Morogoro and Pwani regions and for each of five districts of Dar es Salaam. The study population targets school children in primary and secondary schools in the selected region which are Kilimanjaro, Dar es Salaam, Mororgoro, and Pwani.

Improving tuberculosis case detection and linkage to care among elderly population through mhealth assisted enhanced contact tracing in Tanzania – NIMR Muhimbili

Esther Ngadaya, Godfather Kimaro, Nicholous Mnywambwa, Rose Marwa, Marrywine Nanyaro, Coline Mahende, Frank Eric, Erica Sandi, Sara Moses, Joseph Kaduma, Felix Christopher, Amani Wilfred, Erick Mgina, Zenais Kiwale and Sayoki Mfinanga

This study aims at investigating the effectiveness and feasibility of mHealth assisted self TB screening and linkage to TB care through CHWs in increasing TB case notification among the elderly population in specified rural and urban areas in Tanzania. The duration of the study will be six months. This study will recruit elderly TB contact aged 45 years and above from an index TB case residing in regions mentioned below. We conducted interviews with all elderly contacts with an index TB case who meets our inclusion criteria. Qualified research assistants and community healthcare workers received training to conduct interviews. The proposed evaluation area for this project were the catchment area of the selected facilities according to the NTLP. For the purposes of this study, the TB notifications in this area were defined by the notifications in all selected facilities namely Ndanda, Kibong'oto, Sumbawanga and Musoma hospitals as intervention hospitals, and Bagamoyo hospital, Levolosi, Mbeya Medical Centre hospital and Nyamagana hospital in Mwanza as control sites.

Rapid and Accurate Diagnosis of Paediatric (RaPaed) TB - An AIDA (Assessment of Innovative Diagnostics and Algorithms for Early and Sensitive Detection of Acute TB) platform study (RaPaed-AIDA-TB) – NIMR Mbeya

Nyanda Elias Ntinginya, Issa Sabi, Christina Manyama, Elimina Siyame, Ombeni Chimbe and Joseph Hidda

Most current TB tests and sampling strategies are geared towards adult TB. Obtaining adequate samples for those tests from children is difficult, time- and resource-consuming, and often requires hospitalization. Moreover, paediatric samples, especially from the mentioned vulnerable groups, have small volumes and low bacterial burdens. This is a tragedy, considering that timely treatment in children leads to good outcomes, even in the case of drug resistance. New testing strategies are desperately required – these need to have improved sensitivity, but at the same time be much more feasible than current tests; so need to work well on samples which are easy to obtain from children - one important barrier to widespread testing is the current technically challenging and time-consuming sampling of sputum or gastric aspirate which often requires hospitalization. Study design and Objectives: This study is designed as a single-gate, multi-diagnostic study in the target population of children ≤14 years suspected of having TB. Therefore, only symptomatic children will be enrolled and both standard of care and experimental diagnostics will

be performed. NIH-convened consensus panel recommendations on case definitions and design of paediatric TB diagnostic studies will be followed. The study will compare several novel TB test candidates to the reference standard of combined microbiological and clinical disease confirmation or exclusion. Study population: It is aimed to recruit approximately 200 children with suspicion of active TB, of which a minimum of 50 cases should be microbiologically confirmed.

A Phase 2, Double-blind, Randomized, Placebo-Controlled Study to Evaluate the Safety and Efficacy of H56:IC31 in Reducing the rate of TB Disease Recurrence in HIV Negative Adults Successfully Treated for Drug-Susceptible Pulmonary Tuberculosis (POR TB) – NIMR Mbeya

Issa Sabi, Nyanda Elias Ntinginya, Elimina Siyame, Christina Manyama, Ombeni Chimbe, Joseph Hidda, Julieth Lalashowi and Beatrice Ngaraguza

There is growing bacterial resistance to available drugs, which means the disease is becoming more difficult to treat. There were an estimated 480,000 cases of multi-drug resistant (MDR-) TB in 2015. The current tools for controlling TB are clearly insufficient, and without new efficacious TB vaccines, the 2035 World Health Organization's End TB strategic goals of a reduction of TB deaths and cases of TB disease will not be met, nor will the target within the UN Sustainable Development Goals of ending TB by 2030 (UN General Assembly, 2014). Recurrence of TB disease following successful treatment is a significant issue with rates of recurrence varying between 2% and 8% (Gillespie SH et al, 2014; Friedrich SO et al, 2013; Merle CS et al, 2014) as a result of relapse. The availability of an efficacious TB vaccine preventing recurrence will be a significant advance in the control of TB disease. Primary objectives: To evaluate the following in HIV-negative participants who have completed at least 5 months (22 weeks) treatment for drug-susceptible pulmonary TB and who test negative for acid fast bacilli (AFB) on sputum smear microscopy prior to vaccination (participants unable to produce sputum, and considered asymptomatic by the investigator, may be considered negative): Efficacy of H56:IC31 compared to placebo in reducing the rate of recurrent TB disease (relapse or reinfection). Study population: HIV negative adults of 18 to 60 years of age diagnosed with drug-susceptible pulmonary tuberculosis are planned to be included after completion of at least 5 months (22 weeks) of treatment and tested acid-fast bacilli (AFB) negative.

5.3 MALARIA

Efficacy of artemether-lumefantrine and Dihydroartemisinin-piperaquine and the effects of human gene polymorphism in the drug metabolizing enzymes on treatment outcome among patients with uncomplicated falciparum malaria in Tanzania – NIMR Tanga

Celine Mandara, Reginald Kavishe, Samuel Gesase, Janneth Mghamba, Esther Ngadaya, Peter Mmbuji, Sigsbert Mkude, Renata Mandike, Ritha Njau, Ally Mohamed, Martha Lemnge and Deus Ishengoma

Following changes of malaria treatment guidelines in Tanzania in 2006, Artemether/Lumefantrine (AL) was the only artemisinin combination therapy (ACT) that was introduced for treatment of uncomplicated falciparum malaria. However, alternative drugs such as dihydroartemisinin-piperaquine (DP) are urgently required to ensure effective case management. This study was conducted in two districts with different malaria transmission intensity to assess the efficacy and safety of AL and DP for treatment of uncomplicated falciparum malaria. It will also assess different pharmacogenomic markers, which might be associated with treatment outcome among patients treated with ACTs. The broad aim of this study was to determine the genetic polymorphism within drug metabolizing enzymes which affect treatment outcome among patients with uncomplicated falciparum malaria treated with either artemether/lumefantrine (AL) or dihydroartemisinin-piperaquine (DP). Methodology: This was an open-label, randomized; non-inferiority trial that recruited children aged six months to 10 years with uncomplicated falciparum malaria at two sites of Muheza Designated District Hospital and Ujiji Health Centre in Tanga and Kigoma regions, respectively. Enrolled children were treated under direct observation of a study nurse with standard doses of either AL or DP; and were followed-up for 28 (extended to 42) and 42 (63) days for AL and DP, respectively. Parasite and fever clearance were monitored in the first 72 hours post treatment. The primary outcome was parasitological cure on days 28 (extended to 42) for AL, and day 42 (extended to 63) for DP. Secondary outcomes included parasite clearance in the first 72hours post treatment and recovery of haemoglobin (Hb) levels during follow-up. Genome-wide association (GWAs) analysis will be used to assess different single nucleotide polymorphism (SNPs), located in the genes involved in the metabolism of artemisinins and partner drugs. Candidate gene approach will be used and SNPs in selected genes, including the cytochrome (CPY) genes families, acetyl transferases, glutathione transferases and glucuronosyltransferase (UDP-glucuronyl transferase) will be analysed.

Assessing the Intrinsic and extrinsic drivers and IPTp with dihydroartemisinin-piperaquine and azithromycin for malaria, sexually transmitted and reproductive tract infections in pregnancy in high sulphadoxine-pyrimethamine resistance areas in Kenya, Malawi, and Tanzania: an international multi-centre 3-arm placebo-controlled trial (IMPROVE Study) - NIMR Tanga

John P. A. Lusingu, Franklin Mosha, Daniel T. R. Minja, Christentze Schmiegelow, Samwel Gesase, Omari Abdul & George Mtove

Overall objective: To determine if IPTp with Dihydroartemisinin-Piperaquine (DP), either alone or combined with azithromycin (AZ), is safe and superior to IPTp with SP for reducing adverse pregnancy outcomes due to malaria and sexually Transmitted infections (STIs)/Reproductive tract Infections (RTIs). Methodology: An international, multi-centre, 3-arm, parallel, partially placebo-controlled, individually randomised, phase-3, superiority trial involving 4,680 (1,560 per arm) pregnant women in approximately 10 sites in areas of high malaria transmission and high SP resistance in western Kenya, northern-eastern Tanzania and southern Malawi. HIV-negative pregnant women (all gravidae) attending for antenatal care (ANC) between 16- and 28-weeks' gestation inclusive, assessed by ultrasound dating, will be eligible. Women will be seen monthly until delivery. Mothers and infants will be followed for 6 to 8 weeks post-partum. A sub-group of women will also be followed up 6 months postpartum from some selected sites.

Malaria Research and Capacity building for field trials in Tanzania. Acronym: MaReCa – NIMR Tanga

John P. A. Lusingu, Daniel Minja, Samwel Gesase, Edwin Liheluka, Anangisye Malabeja, Theresia Mtui, Christian Wang, Ali Salanti, Thomas Lavstsen, Morten Nielsen

Overall objective: 1. To document burden of malaria in the study area over years 2. To develop and characterize efficacious malaria vaccine for children and pregnant women 3. To build malaria research capacity at masters and PhD levels 4. To establish and maintain mentorship programme 5. To sustain clinical research and clinical trials in Korogwe Research Station, Tanga Centre. Methodology: These studies are ongoing at the Korogwe District Hospital (KDH), the NIMR Korogwe Research Laboratory, Magu District Hospital and two villages within Korogwe District namely, Mkokola (lowland) and Kwamasimba (highland). The paediatric study recruits children aged less than five years of age, admitted at the paediatric ward of KDH with the intention to treat (ITT) for malaria whereas the PCD of febrile malaria episodes through CORPs is done to individuals of all ages in the two study villages of Mkokola and Kwamasimba. For the paediatric hospital study, plasma and red blood cells were separated and stored. Red blood cells infected with P. falciparum were cultured and assessed for their ability to bind to various human receptors including endothelial protein C receptor (EPCR) and CD36. The *P. falciparum* malaria parasite proteins are implicated in the pathogenesis of various clinical syndromes of falciparum malaria and EPCR in particular has been shown to be a candidate receptor where *P. falciparum* strains causing cerebral malaria (CM) bind. The CORPs study involves collection of finger prick blood for preparation of thick and thin blood smears and rapid diagnostic tests (mRDTs) of malaria. Community malariometric cross-sectional surveys are conducted on annual basis during peak transmissions whereby finger prick blood is collected for malaria diagnosis using mRDTs and microscopy. Filter paper blood and plasma samples are also collected for subsequent molecular and immunological analyses.

Effectiveness and safety of intermittent preventive treatment for malaria using either dihydroartemisinin-piperaquine or artesunate-amodiaquine in reducing malaria related morbidities and improving cognitive ability in school-aged children in Tanzania (IN-SMART-School STUDY) – NIMR Tanga

Dr. Geofrey Makenga, Dr. Daniel T. Minja, Dr. George Mtove, Dr. Vito Baraka, Filbert Francis, Swabra Nakato, Rashid Madebe, Edwin Liheluka, Dr. Samwel Gesase, Prof. John P. A. Lusingu, Prof. Jean-Pierre Van Geertruyden.

Primary objective: The primary objective is to assess the longitudinal impact of a four monthly IPTsc with DP, ASAQ on both anaemia and clinical malaria incidence in school-aged children living in high endemic areas. A phase IIIb, randomized, open label, controlled trial will enrol school children aged 5-15 years, who will receive either DP or ASAQ or control (no drug), using a "balanced block design" with the "standard of care" arm as reference.

Effectiveness of different types of bi-treated long lasting insecticidal nets and deployment strategy for control of malaria transmitted by prethyroid resistant vectors (PAMVERC) – NIMR Amani

Natacha Protopopoff, Alphaxard Manjurano, Jacklin Mosha, Frank Mosha, Mark Rowland, Immo Kleinshmidt, Catherine Pitt, Manisha Kulkami, Monica Taljaard

Main objective: To evaluate the efficacy of 3 bi-treated LN as compared to standard LN across the lifespan of the LNs (3 years) on malaria infection prevalence in children from 6 months to 14 years in an area of Western Tanzania where the main malaria vectors are resistant to pyrethroid insecticide [Malaria infection prevalence will be lower in the interventions arms with bi-treated LN than in the control arm]. Methodology: The Study compares bi-treated LN to the standard LN. By measure the prevalence of malaria infection in children aged 6 months to 14 years at 12 and 24 months using Rapid diagnostic test , haematocrit, Digital ear thermometer for all children , Temperature and history of fever , CDC light trap, Standard CSP-ELISA to estimate the EIR, confirmation of positive samples with a second ELISA using a heating technique, PCR and Screening for CYp6 genes using Microarrays.

Detection and monitoring of insecticide resistance to malaria vectors in Tanzania – NIMR Amani

William Kisinza, Bilal Kabula, Victor Mwingira and Patrick Tungu

The insecticide resistance monitoring is being carried out annually to detect possible resistance at earlier stage in order to initiate effective management strategies. Therefore, this project aimed at conducting a nationwide surveillance across the 22 sentinel districts to establish vector susceptibility levels and intensity of resistance of malaria vectors to insecticides from the four major chemical classes. The objective of this study was to detect mosquito resistance to insecticide and to determine the intensity of resistance in selected sites. The WHO standard method was used to detect knockdown and mortality in the wild female *Anopheles* mosquitoes reared from larvae collected in sentinel districts. Molecular diagnostic methods were employed to identify species of resistant mosquito and detect their mechanisms of resistance. Field mosquito collection and on-site insecticidal testing was successful completed. Resistant mosquitoes were identified morphologically and their resistance level quantified. Molecular technique was used to substantiate complex species and identify resistance mechanisms. As part of capacity building for vector control, the project trained 50 scientists and technologists from councils and government institutions on detection and monitoring of insecticide resistance in mosquitoes.

The National Malaria Vector Entomology Surveillance (MVES) – NIMR Amani

William Kisinza, Bilal Kabula and Patrick Tungu

Successful malaria control programmes depend on a good knowledge of the species and its abundance and distribution, and levels and dynamics of insecticide resistance in the local mosquito population, followed by continuous resistance monitoring in order to detect resistance to insecticides. This is a longitudinal National Malaria Vector Entomological Surveillance (MVES) in 62 selected district councils (sites).

To detect mosquito resistance to insecticide and to determine the intensity of resistance in selected sites. Adult mosquitoes are collected from three houses in each of the selected sentinel site for three consecutive days using Centre for Disease Control (CDC) light traps. Collected mosquitoes are sorted, identified, appropriately preserved and sent to the central laboratory of NIMR Amani centre for further analysis. The field mosquito collection is going on in all 62 selected district councils. Mosquito samples collected are regularly sent to our centre for laboratory analysis. More than 12,000 mosquitoes have been received and analysed for species identification and sporozoite rate.

The Genome-based diagnostics for mapping, monitoring and management of insecticide resistance in major African malaria vectors – NIMR Amani

William Kisinza and Bilal Kabula

Malaria is a leading cause of disease and death especially in sub Saharan Africa (SSA). Malaria is transmitted by the female Anopheles mosquito, through mosquito bites. The methods used for control of the mosquitoes make use of chemical insecticides of which there are only 4 classes approved for use in malaria control. There has been a rise in insecticide resistance where mosquitoes fail to survive when exposed to insecticides. Knowledge of emerging resistance through the detection of DNA markers of resistance would assist malaria control programs plan their vector control activities better and more effectively. The study makes use of techniques that are able to scan through the whole genetic makeup of the mosquitoes to identify possible resistance markers. Once the markers are identified, maps will be created showing where the markers are and their frequencies. The objective of this project was to identify

new markers of insecticide resistance for use by control programs. The study makes use of techniques that are able to scan through the whole genetic makeup of the mosquitoes to identify possible resistance markers. Once the markers are identified, maps will be created showing where the markers are and their frequencies. Phenotyping and genotyping of mosquitoes is currently underway in the field and laboratory respectively. Additional sampling is also going on in the field.

The effect of malaria and/or sexually transmitted infections/reproductive tract infections (STIs/RTIs) during pregnancy on foetal growth, pregnancy outcome and post-natal growth trajectories – NIMR Tanga

Prof John Lusingu, Daniel Minja and George Mtove

Malaria in pregnancy (MIP), sexually transmitted infections (STIs) and reproductive tract infections (RTIs) are associated with adverse pregnancy outcomes like foetal growth retardation, abortion, and stillbirth. Intermittent preventive treatment during pregnancy using Sulfadoxine Pyrimethamine (IPTp-SP) is used for controlling MIP, but the intended therapeutic potential of IPTp-SP is threatened by parasite resistance to SP. An effective and safe regimen to replace SP for IPTp is warranted. Current evidence suggests that Dihydroartemisinin Piperaquine (DP) alone or in combination with Azithromycin (AZ) may reduce the detrimental pregnancy outcome related to MIP and STIs/RTIs.

The main objective of this study was to compare the safety and efficacy of IPTp regimens of SP only (control), DP only and DP plus AZ among 4,680 pregnant women in Tanzania, Malawi and Kenya. The women will be followed until 6 weeks post-delivery. Gestational age will be estimated using ultrasound and testing for malaria done repeatedly during pregnancy.

Phase III evaluation of a window double screen trap for capturing mosquitoes and to demonstrate that the traps reduce malaria transmission when combined with pyrethroid treated long lasting insecticidal net in NE Tanzania – NIMR Amani

William Kisinza and Victor Mwingira

The 3D mosquito screen is a double screen setup, made of a screen with 3D geometric structures, parallel to a commercial mosquito screen creating a trap between the two screens. When placed on a window, the screen creates window double screen traps that not only prevent mosquitoes from entering houses but also trap mosquito exiting from the house. Mosquitoes can penetrate the 3D screens from one side (towards the space between the two window screens creating the trap) but not from the other (the way back to the outside of the trap).

The Phase III studies aim to determine whether our product has enough protection ability to communities and durability in real-life field conditions. To compare the performance of LLINs only (control) against LLINs plus 3D screen traps in preventing malaria and diminishing haemoglobin levels. The cohorts will be followed until 12 months post-installation. Mosquito density, parasite rates, haemoglobin levels and immunity will be investigated longitudinally for 12 months.

5.4 MATERNAL, NEWBORN AND CHILD HEALTH

Operational research study for implementation of an intervention to prevent complications of unwanted pregnancies (The Harm Reduction) in selected health facilities in Ilala Municipal Council, Dar es Salaam Tanzania – NIMR Muhimbili

Amos Kahwa, Isihaka Mwandalima, Coline Mahende, Godfather Kimaro, Esther Ngadaya, Erick Mgina, Sylvia Haule, Naku Makoko and Sayoki Mfinanga.

This study aims to conduct an operational research for implementation of 'the Harm Reduction' in selected two health facilities, Tabata A and Tabata NBC in Ilala Municipal Council, Dar es Salaam Tanzania. The study involves both quantitative (KAP questionnaires, data extraction) and qualitative data (interviews) collection to address; Health facilities staff´s knowledge and perceptions of the available services related to unintended pregnancies before (pre) and after (post) the implementation of the harm reduction model. Acceptability of the Harm Reduction model (initial visit and follow-up services, including post-abortion family planning counselling) to women (of reproductive age, 15 – 49 years) facing unwanted pregnancies who receive services in study facilities. The role of community mobilizers in

facilitating access to relevant health services, including comprehensive post-abortion care (CPAC) family planning services, in the Tanzanian context.

5.5 SEXUAL AND REPRODUCTIVE HEALTH

Case-control study to identify risk factors associated with Human Papilloma Virus (HPV) associated lesions within the female reproductive tract (2H STUDY) - NIMR Mbeya

Christof Geldmacher, Ruby D. Mcharo and Arne Kroidl

Cervical carcinoma is the most frequent cancer in African women and the risk of developing cervical carcinoma and pre-malignant HPV lesions is ~8-fold elevated in HIV+ females despite Antiretroviral therapy. The 2H study began as a case control study, in 2013. Currently, the study has a longitudinal component, following up yearly on all women who were enrolled as cases and controls, to answer further objectives. This study investigates risk factors associated with high-grade squamous intraepithelial lesion (HSIL) or squamous cell carcinoma (SCC) within the reproductive tract of HIV+ and HIV- Tanzanian women and identify High Risk (HR) HPVs that most frequently cause such disease in HIV+ and HIV- women. The study focuses on HPV and HIV related factors, particularly on infecting HPV genotype(s) and immune system related factors, such as CD4 T cell count, antiretroviral therapy (ART) status and HIV induced dysfunction of HPV-specific adaptive immunity. In addition, socio-economic factors, such as sexual behaviour, age and smoking will be studied. This study involves different clinical and biomedical disciplines. The main objective is the identification of frequent high-risk Human Papilloma Virus types (HR HPV) associated with high risk of High grade Squamous Intraepithelial Lesions (HSIL) or Squamous Cell Carcinoma (SCC) in HIV positive and negative women. The study will also serve to establish clinical research infrastructure for cervical carcinoma clinical studies and HPV vaccine trials.

Cash transfers for adolescent girls and young women to reduce sexual risk in Tanzania: A qualitative and behavioural economics assessment of participants in the Sauti program – NIMR Mwanza

Joyce Wamoyi, Audrey Pettifor, Susan Maman, Peter Balvanz

The HIV epidemic in Eastern and Southern Africa is characterized by a high incidence and prevalence of HIV infection among adolescent girls and young women (AGYW). AGYW aged 15-24 years in this region have HIV infection rates three times higher than that of young men of the same age group. Sexual behavior, in particular mixing patterns (trans-generational sex) whereby adolescent girls and young women have sexual relationships with older male partners who are more likely to be infected with HIV and/or other sexually transmitted infections (STIs), is part of the explanation. Inter-generational sex may be due to a mix of negative economic and social factors faced by AGYW. These factors include lack of education opportunities, limited livelihood options, gender inequality and negative gender norms, and poverty. The preliminary phase of behavioural economics research in this study, called Immersion, aimed to explore and develop an understanding of the local context, goals and experiences of AGYW. Immersion research also aimed to inform development of EthnoLab, a later behavioural economics method which used a game format to elicit contextual factors, mental models, and emotions that drive decisions and behaviours of AGYW. The qualitative portion of the study aims to understand the ways through which cash transfers to AGYW may influence their sexual behaviours and dynamics with partners, and to explore male partners' understanding of AGYW's involvement in the cash transfer program, and their perceptions of the program's impact on their relationships.

5.6 NON-COMMUNICABLE DISEASES AND INJURIES

Magnitude, awareness and prevention of non-communicable diseases among employees of the financial institution in Tanzania - NIMR Muhimbili

Esther Ngadaya, Godfather Kimaro, Ayoub Mgimbwa, Sayoki Mfinanga Erica Sandi, Ramadhani Shemtandulo and Monica Shayo.

This study aims to investigate the magnitude and awareness of NCDs among employees of the financial institution in Tanzania as a proxy to understand the burden of NCD's and NCD's risk factors among workforce in Tanzania. The study will then develop, introduce and test a mobile NCD screening, control and prevention model at financial institution. The study will also establish willingness to pay for the mobile NCD screening and prevention model. The study was conducted for two years in Kilimanjaro, Arusha, Dar es Salaam and Morogoro. Capacity building included procurement of NCD screening and follow up facilities for NIMR Muhimbili that could be used even with another projects. The study empowered the work force from financial institutions to be able to prevent and control NCD's. In addition, the study developed NCD prevention model than can be used among the workforce in the country.

A Randomized, Double-Blind, Parallel-Group, Multicenter, Phase III Study to Evaluate the Effect of Ticagrelor versus Placebo in Reducing the Rate of Vaso-Occlusive Crises in Pediatric Patients with Sickle Cell Disease [HESTIA3] – NIMR Tanga

John P.Lusingu, Bruno P Mmbando, Mercy G. Chiduo, Vito Baraka, Misago D. Seth, Rashid A. Madebe, Geofrey Makenga and Mohammed S. Abdallah

Primary Objective: To compare the effect of ticagrelor vs placebo for the reduction of Vaso-Occlusive Crises (VOCs) this is the composite of painful crisis and/or Acute Chest Syndrome (ACS), in paediatric patients with sickle cell diseases (SCD). This is an international, multicentre, double blind, randomised, parallel group, placeblo controlled phase III study. Sickle cell patients with the between the age of 2 to 18 years with two or more recorded VOCs within 1 year will be screened for recruitment.

Integration of HIV and NCD in the health service delivery in Tanzania and Uganda – NIMR Muhimbili

Sayoki Mfinanga, Sokoine Kivuyo, Elizabeth H Shayo et al

The project aims at integrating the services for HIV, hypertension and diabetes in one stop centre. The project is in its initial stages of integration. Main objective: Strengthen management of chronic conditions through integrated approach. The project comprises of formative phase to generate baseline information, interventions development, implementation and evaluation.

NIHR Global Health Research Group on the prevention and management of HIV-infection and non-communicable diseases – NIMR Muhimbili

Sayoki Mfinanga et al.

HIV, diabetes and hypertension are major determinants of the massive and rising burden of communicable and non-communicable diseases in Africa and provision of accessible effective care for these conditions is probably Africa's biggest health challenge.The group will build a programme of research to define integrated approaches for the prevention and management in HIV, diabetes and hypertension that are suitable for the local context of limited health staff and resources and the challenges that patients face in accessing care. The studies will be designed to provide reliable data on both the benefits and potential challenges of integration so that we can choose which research areas to prioritize. The data will be used to design the subsequent large-scale research studies and also to develop the research skills of staff including in study design, statistical analysis, paper and proposal writing among research staff. Data and estimated potential cost-effectiveness of different approaches will be modelled. The vision is that future studies will be large-scale comparative studies evaluating different approaches of prevention and management for major chronic conditions.

5.7 ONE HEALTH AND ZOONOSES

Potential of non-human primates as a reservoir for human yaws- NIMR Muhimbili

Knauf, Sascha, Roos, Christian, Kazwala, Rudovick R, Keyyu, Julius D, Lejora, Inyasi AV, Esther Ngadaya, Clara Lubinza, Mfinanga, Sayoki GM and Liu Hsi

This is the second phase of the project. The project combines basic research in the field of Treponema infection with capacity building and early-career research training at the African location. The overall objective is comparison of

human and NHP Treponema isolates from Africa, especially in areas that are known as hotspots for Treponema infection in both humans and NHPs. The recent description of a *T. pallidum* strain which causes genital ulceration in baboons though it is genetically most closely related to non-venereal human strains, in combination with reports that indicate the zoonotic potential of West African simian strains, provides evidence that NHPs may serve as a natural reservoir for *T. pallidum* as well as potentially representing a missing link that can shed light on this bacterium's evolution. In the previous phase of this study we found that in all genome analysed simian strains, including 6 new West and 2 more East African NHP strains could be TPE strains signifying the possibility of all other NHP strains to have equal zoonotic potential and thus should be considered in yaws eradication. However, this question will be definitively answered when available data on simian infections are compared to data from humans found in areas with characterized simian infection. A minimum of 400 participants are required.

Evaluation of an antibody detecting point-of-care test for the diagnosis of *Taenia solium taeniasis* and (neuro) cysticercosis in communities and primary care settings of highly endemic, resource-poor areas in Tanzania and Zambia, including training of/and technology transfer to the Regional Reference Laboratory and health centres. Acronym "SOLID" - NIMR Muhimbili

GS Mfinanga, Ngowi BJ

Taenia solium taeniasis/cysticercosis (T/CC) is a neglected zoonotic parasitic disease complex with significant economic and public health impacts. Neurocysticercosis (NCC) is estimated to be responsible for 30% of cases of acquired epilepsy in endemic areas. Currently, there are no cheap, easy to apply, sensitive and specific diagnostic tools available for the detection of this parasite. The main objective of this study is to contribute to the implementation of a rapid, cheap and simple POC test for the detection of *T. solium* taeniasis and (neuro) cysticercosis in two resource-poor, highly endemic areas in sub-Saharan Africa. It also aims to improve the *T. solium* disease recognition, diagnostic and clinical case management capacities of these countries as well as their capacity to conduct diagnostic and clinical studies. The proposed project will therefore field validate the POC test, which simultaneously detects *T. solium* taeniasis and (neuro) cysticercosis, in Tanzania and Zambia, both at the community and primary health facility levels. WHO has identified the development of POC tests for *T. solium* T/(N) CC as a top priority and confirms its endorsement and implementation if successfully validated. Commercialization of the test will be facilitated once successfully validated.

Epidemiology, clinical, immunology and neuroradiological characteristics of *Taenia solium* cysticercosis in people with and without HIV/AIDS in Southern Highlands of Tanzania Mbeya and Iringa – NIMR Muhimbili

Ngowi BJ, Kilale AM, Mfinanga GSM

Taenia solium cysticercosis/taeniosis (TSCT) represents an emerging, neglected and potentially eradicable infectious disease in many countries of sub-Saharan Africa with huge impact on human and animal health as well as community livelihood in endemic areas. The study aim is to advance knowledge on the epidemiology and clinical characteristics of TSCT/neurocysticercosis (NCC) and its involved pathomechanisms. Research plan: 1) Large scale community-based and hospital-based studies to identify symptomatic patients with NCC and calculate the prevalence 2) A diagnostic reference laboratory for TSCT will be established and quality control as well as knowledge transfer will be performed through a TSCT reference laboratory 3) The immune response to TSCT in immunocompetent and immunocompromised hosts will be evaluated against the clinical and radiological presentation of NCC, 4) Preventative strategies will be explored through community-based studies testing the effect of different public health intervention programmes on the prevalence of porcine cysticercosis and human taeniosis.

Genetic determinants for the transmission of Cryptosporidium spp. among humans and animals in Africa and antimicrobial resistance – NIMR Tanga

John P. A. Lusingu, Samwel G. Gesase, Joyce R. Mbwana, Daniel Eibach, Denise Dekker, Juergen May

Objectives: 1. To obtain information on transmission routes of Cryptosporidium species between human –human – animal in children below five years; 2. To establish cryptosporidium consortium in Sub-Saharan Africa countries through training and career planning to African junior scientists and built a network on cryptosporidiosis research within SSA 3. Also, to identify associations of bacterial pathogens and their subtypes with diarrhoea among children less than five years old 4. To study antimicrobial resistance.

Methodology: Study site was the Outpatient Department (OPD) Korogwe District Hospital. Patients with history of diarrhoea who met inclusion criteria were asked to provide stool samples. Prior to performing laboratory investigations, specimen was divided into two parts; for detecting Cryptosporidium infections and bacterial-associated diarrhoea. Crypto study; first checked the presence of Cryptosporidium parasite in the stool using Crypto Rapid Diagnostic Test (CerTest BIOTEC®). Then, genomic DNA was extracted using commercial PowerSoil® Kit, Qiagen. For the detection of Cryptosporidium spp, quantification PCR (qPCR) was performed in a Real- time PCR (Lightcycler480) at NIMR Korogwe laboratory. All patient who were positive, additional stool specimen were also collected from household member, friends and animals so as to study the transmission route of Cryptosporidium. In order to illustrate Cryptosporidium transmission pathways, RFLP- PCR and gp60 subtyping techniques were employed to identify the genotypes and subtypes of Cryptosporidium respectively. The analysis of whole Genome Sequencing will later be carried out.

Prevalence of zoonotic bacterial infections: A cross-sectional study in Korogwe District, Tanga Region, North-Eastern Tanzania. Short Title: Zoonosis Study – NIMR Tanga.

Daniel T.R. Minja, Juergen May, Omari Abdul, Samwel Gesase, John P.A. Lusingu, Joyce R. Mbwana, Joseph W. Kaseka, Peter Sothmann, Cassandra Aldrich and Daniel Eibach.

Overall objective: To determine the burden of zoonotic bacterial infections in febrile in- and outpatients in Korogwe District, Tanga Region, north-eastern Tanzania. Methodology: This is an observational health care based cross-sectional survey intertwined with longitudinal follow up, involving 500 patients of all age groups presenting to the Inpatient and Outpatient Department of KDH or in satellite dispensaries within the Korogwe demographic surveillance system (DSS) area with fever or a reported history of fever within the last 48 hours. Blood samples and skin swab will be collected at recruitment, day 7 post recruitment (from PCR positive patients), and on day 28 (for convalescent samples). Collected specimens will be used for screening of zoonotic bacterial infections by molecular and serological techniques. bacterial infections amongst individuals with febrile illnesses.

Emerging viruses in Africa: Molecular identification and characterization of rodent-, shrew-, and bat-borne Hantaviruses and assessment of their public health potential. Hanta Study (Hantavirus study) – NIMR Mbeya

Chacha David Mangu, Lwitiho Sudi, Nyanda Elias Ntinginya, Detlev Kruger, Ariane Dux, Sabrina WeiB, Fabian Leendertz and Sébastien Calvignac

Hantaviruses, family *Bunyaviridae*, cause two life-threatening human zoonoses; haemorrhagic fever with renal syndrome (HFRS) and hantavirus cardiopulmonary syndrome (HCPS), with case fatality rates of up to 50% Hantaviruses are spread by aerosolized excreta of small mammals (i.e. Rodents-, Shrews- and Bats). The general objective of this study is to determine the presence of Hantaviruses and other zoonotic viruses, such as arena- and coronaviruses, in small mammals, particularly bats; and to analyse the geographical distribution of these animal reservoirs according to ecological and climatic characteristics. The animal sampling will be extended into the biomes that are so far under-represented. Methodology: This study involves a cross section survey expected to be conducted in between April 2017 and April 2018. Within this cross section we expect to collect samples i.e. blood, urine, organ necropsies (lung, spleen, liver, kidney and Intestine) for the purpose of stated objectives and further extend the fight against febrile illness.

Genetic adaptation of non-typhoid Salmonella within human and animal reservoirs in sub-Sahara Africa (SASSA STUDY). – NIMR Tanga

John P.Lusingu, Samwel M. Gesase, Daniel T. Minja , Omari A. Msemo, Edwin A. Liheluka, Joseph W. Kaseka, Joyce R. Mbwana, Daniel Eibach, Denise Dekker, Juergen May

The aim of the study is (i) to determine the frequency of NTS from animal and human sources; (ii) to detect differences in the genomes of the collected Salmonella isolates using whole genome sequencing; (iii) to detect host genetic susceptibility to invasive Salmonella disease; (iv) to determine socio-economic consequences of iNTS and enteric NTS infections (eNTS); and (v) to strengthen the scientific network within the African- and African-German partners and support professional career development of African scientists including North-South and South-South exchange of personnel. The study is being carried out in Tanga Municipal.

RV456 (Ebola Vaccine Trial) - NIMR Mbeya

Nyanda Elias Ntinginya AND Jimson Mgaya

A Randomized, Observer-blind, Placebo-controlled, Two-part, Phase 2 Study to Evaluate the Safety, Tolerability and Immunogenicity of Two Prime-boost Regimens of the Candidate Prophylactic Vaccines for Ebola Ad26.ZEBOV and MVA-BN-Filo. Primary objective 1: To assess the safety and tolerability of different vaccination schedules of Ad26.ZEBOV and MVA-BN-Filo administered intramuscularly (IM) as heterologous prime-boost regimens in healthy adults and in HIV-infected adults, with Ad26.ZEBOV prime and MVA-BN-Filo boost vaccination on Days 1 and 29, respectively and MVA-BN-Filo prime and Ad26.ZEBOV boost vaccination on Days 1 and 15, respectively. Primary objective 2: To assess the immune responses to the EBOV GP (as measured by [enzyme-linked immunosorbent assay] ELISA antibody titer) of different vaccination schedules of Ad26.ZEBOV and MVA-BN-Filo administered IM as heterologous prime-boost regimens in healthy adults and in HIV-infected adults, with Ad26.ZEBOV prime and MVA-BN-Filo boost vaccination on Days 1 and 29, respectively and MVA-BN-Filo prime and Ad26.ZEBOV boost vaccination on Days 1 and 15, respectively. This is a randomized, observer-blind, placebo-controlled, parallel-group, multicenter, 2-part, Phase 2 study to evaluate the safety, tolerability and immunogenicity of different vaccination regimens using Ad26.ZEBOV at a dose of 5x1010 viral particles (vp) and MVA-BN-Filo at a dose of 1x108 infectious units (Inf U, nominal titer), administered IM.

Mosquito-borne emerging and re-emerging diseases: trends, surveillance and risk modelling – NIMR Tabora

Leonard E.G. Mboera, Mark Rweyemamu, Gerald Misinzo, Esron Karimuribo, Susan Rumisha and Calvin Sindato

The proposed project aims at adding value to the existing surveillance systems for human and animal infectious diseases in developing capability in the disease detection and early warning systems based on new concepts and technologies. The main objective is to build the regional and national capacities to cope with and build resilience to infectious disease epidemics. The specific objectives are: To strengthen national capacities for early detection, identification and response to emerging and re-emerging mosquito-borne arbovirus diseases; To strengthen the national capacities in mathematical/statistical modelling and computational skills in epidemic-prone diseases; To strengthen systems for data collection, analysis, interpretation and information dissemination for animal and human diseases in the region; and To enhance the utilisation of routine disease surveillance, climate and research data to improve the community, national and regional capacity to timely respond to infectious disease epidemics.

5.8 NEGLECTED TROPICAL DISEASES

Impact of Mass Drug Administration for control of *Schistosoma mansoni* infections in Mwanza Region, Tanzania: Understanding factors associated with sustained high prevalence in some areas despite repeated high treatment coverage (SCORE HOT SPOT) project – NIMR Mwanza

Safari Kinung'hi, Dan Colley, Joseph Mwanga, Teckla Angelo, Justina Mosha, Jane Maganga and Carl Campbell

Overall objective: To examine whether villages which do not show substantial decreases in the prevalence of schistosomiasis despite repeated, high coverage mass drug administration (persistent hot-spot villages) differ from villages which show substantial decrease in prevalence across various factors (declining prevalence villages) and evaluate the impact of an enhanced mass drug administration intervention in persistent hot-spot villages.

Infectiology (*Wolbachia* Genetics of hydrocoele & lymphoedema) – NIMR Tanga

WH Makunde, HJ Mshana, V Baraka, SX Ngowi, K Pfarr, A Hoerauf, & G Misinzo

Sub-study: Epidemiological status of Bancroftian filariasis in the endemic communities during the era of elimination in north-eastern Tanzania. Overall objective: To assess current clinical disease and infection status of bancroftian filariasis during the MDA in endemic communities north-eastern Tanzania. Methodology: Microfilaria (Mff) were detected using counting chamber technique while filarial antigens were detected using rapid test immunochromatographic card test (Binax NOW®, Scarborough, Inc., USA). For clinical disease, physical examination was carried out to detect lymphoedema (LE) of the lower and upper extremities and scrotal swellings.

Retinoids profile in onchocerciasis skin disease-associated morbidity: A cross-sectional field study in endemic areas in southern Tanzania. -NIMR Tanga

WH Makunde, AR Mawson, S Rubinchk G Komba , A Kubweja, SX ,Filbert F, Ngowi& JC, ZX N Savael Meade.

Sub-study 1: Assessment of clinical, parasitological and serological status after 14 years of CDTI in six communities of Ruvuma. Overall objective: To assess current clinical disease levels and infection status of OSD and serological (IgG4 specific antibodies to recombinant filarial antigen-Ov16). Methodology: Microfilaria (Mff) were detected using counting skin snipping from iliac crest right and left, after cleaning the area with antiseptic then drying. Similarly, filarial antigens were detected using rapid test SD Bioline IgG4 test to detect exposure to the parasite (onchocerca volvulus). Clinically, physical examination was carried out to detect acute and chronic skin conditions (APODs & CPOD, DMP, ATP LOD, HG& lymphoedema). Sub-study 2: Assessment of clinical, parasitological and serological status after 14 years of CDTI in six communities of Ruvuma. Overall objective: To assess current clinical disease levels and infection status of OSD and serological (IgG4 specific antibodies to recombinant filarial antigen-Ov16). Methodology: Microfilaria (Mff) were detected using counting skin snipping from iliac crest right and left, after cleaning the area with antiseptic then drying. Similarly, filarial antigens were detected using rapid test SD Bioline IgG4 test to detect exposure to the parasite (onchocerca volvulus). Clinically, physical examination was carried out to detect acute and chronic skin conditions (APODs & CPOD, DMP, ATP LOD, HG& lymphoedema).

An epidemiological assessment of prevalence and incidence of epilepsy and its relation to onchocerciasis control measures using ivermectin in the endemic area of Mahenge, Ulanga district, Tanzania – NIMR Tanga

Bruno P Mmbando, RobertColebunders, William Matuja, Williams Makunde, Helena Greter, Mohamed Mnacho

The main objective of this study is to identify the effect of long-term onchocerciasis control measures on the prevalence and incidence of OAE in selected villages in the Mahenge area of the Ulanga district in Tanzania. This study is designed as cross-sectional, population-based survey. A two-stage approach will be applied for case identification within the villages. The door-to-door approach was used to identify epilepsy cases. All inhabitants of the involved villages were eligible for participation and were included in the questionnaire screening survey. Suspected cases of all forms of epilepsy identified during the household screening survey were invited for clinical examination by a neurologist. For all suspected OAE cases and children 6-10 years, their serological status of Ov16 antigen was determined using onchocerciasis rapid diagnostic test (RDT).

Multi-disciplinary approach to control onchocerciasis-associated epilepsy in the Mahenge area in Morogoro region, Tanzania – NIMR Tanga

Bruno P Mmbando, Robert Colebunders, William Matuja, Williams Makunde, Mohamed Mnacho, Dan Bwana, Akili Kalinga, Oscar Kaitaba, Vito Baraka

Overall objectives: 1. Increase the multi-disciplinary research capacity concerning oncho and epilepsy/NS in Tanzania. 2. Reduce rates of onchocerciasis and epilepsy/NS in the Mahenge area. Methodology: An epilepsy/NS surveillance system will be set up to identify and follow-up persons with epilepsy. Trained Community health workers (CHWs) based in the study villages will be used. Focus groups discussion, in-depth interviews and questionnaires will be used as main means of data collections. Advocacy and awareness programmes will be implemented through meetings, training sessions and by radio broadcastings. Electronic data capturing system using ODK will mainly be used in this project.

LeDoxy Study: Doxycycline 200mg/d vs. 100mg/d for 6 weeks to improve filarial lymphedema - a multinational, double-blind, randomized, placebo-controlled trial – NIMR Headquarters

Upendo Mwingira, Abdallah Ngenya, John Ogondiek, Ndekya Oriyo, Ruth Laizer et al.

The previously demonstrated effect of doxycycline in reversing or stopping the progression of lymphedema of patients with stage 1-3, irrespective of their filarial infections being active or not, provides an opportunity to include the drug as a new tool in LF morbidity management programs. However, before recommendations can be made regarding the frequency of its usage or alternate dosing patterns the findings of the two RCTs should be replicated in other settings. This multi-national trial is designed to show efficacy of a lower dosage of doxycycline (100 mg instead of 200 mg) and to confirm the findings of the lone study that in patients with stages 1-3 lymphedema [3] irrespective of active LF infection (group A), as well as in people with higher grades of lymphedema (stage 4-6, group B). Primary Objectives: Group A (LE stage 1-3): - to confirm the efficacy of a 6-week course of daily doxycycline 200mg on lack of

progression of filarial LEv- to reduce the dosage of doxycycline from 200mg/d to 100mg/d for 6 weeks for the treatment of filarial LE. Group B (LE stage 4-6): - to show efficacy of a 6-week course of daily doxycycline 200mg on lack of progression of filarial LE.

5.9 ANTIMICROBIAL RESISTANCE

Rational use of Antibiotics to lower the risk for REsistance (RARE STUDY) – NIMR Tanga

Vito Baraka, Geofrey Makenga, Daniel T. Minja, Filbert Francis, Rashid Madebe.

Broad objective. To explore how antibiotic resistant genes can be mobilized in patient populations during treatment with antibiotics, affecting the microbiota, the selection for resistance in the normal flora, and the spread of resistance through bacteriophages. Goal: To provide evidence for recommendations on strategies for rational use of antibiotics aimed at decreasing the risk for antibiotic resistance. Clinical relevance: Since the collateral damage of commonly employed treatments for common infections will be determined our results will help to give strength to recommendations on the treatments of these and other infections.

Antibiotic resistance pattern of bacterial isolates from clinical specimens in selected hospitals, Tanzania – NIMR Muhimbili

Godfather Kimaro, Coline Mahende, Haron Alex, Esther Ngadaya, Nicodem Bernado Mgina, Sayoki Mfinanga, Erica Sandi and Ramadhani Shemtandulo.

This study aims to assess the pattern of bacteria causing infections and their *in-vitro* antibiotic resistance pattern from various clinical specimens in selected hospitals of Tanzania. This will be a prospective laboratory-based study involving clinical specimens collected from both outpatients and inpatients in four selected regional hospitals of Kigoma, Mara, Rukwa and Mtwara. All clinical specimens will be assessed for pathogenic bacteria using standard microbiological methods. The study will be conducted for 3 years.

Policy analysis of the drivers of antimicrobial resistance within Tanzania's one-health care systems – NIMR Headquarters

Mecky Matee, Taane Clark, Helena Legido-Quigley, Stephen Mshana, Henry Magwisha, Leonard Mboera, Sharadhuli Kimera, Ndekya Oriyo, Gasto Frumence, Mark Rweyemamu

The causes and impacts of AMR are multi-factorial, and inter-disciplinary approaches are needed. The project aims to uncover the drivers of AMR within Tanzania's health system using a "One Health" research approach.

The overall expected outcome will be a cost effective, evidence base for policy recommendations, which are relevant in human and animal health systems in Tanzania. By engaging with key policy actors in Tanzania, we will contribute evidence to inform strategies for implementation of the National AMR Action Plan, which could serve as a model for other LMIC countries. Further, the project aims to build capacity for AMR investigations in Tanzania.

Main objective: To attain a holistic understanding of AMR in Tanzania. The project objective will be achieved through 1) conducting a needs assessment to identify the gaps that currently exist in the areas of surveillance, access to and stewardship of antimicrobials at all levels of the human and animal health systems; 2) reviewing existing policies, programmes and structures that address antimicrobial use (AMU) and AMR in humans and animals; 3) conducting a stakeholder analysis of the AMR environment to examine the motivations, social constructs, contextual drivers and power relations of policy actors that influence behaviours and decision-making processes in developing policies for AMR, specifically in relation to the appropriate AMU; 4) Based on the policy analysis and needs assessment and stakeholder analysis, identify and prioritise potential interventions in the healthcare and veterinary sectors that can be tested by applying appropriate epidemiological designs and by incorporating suitable evaluation methods to measure their impact; and 5) developing strategies and tools for working with policy makers to effectively implement policies for responsible AMU in human and pig populations.

5.10 DIGITAL TECHNOLOGIES

mHealth-assisted conditional cash transfer to improve timeliness of vaccinations study – NIMR Muhimbili

Godfrey S. Mfinanga, Esther Ngadaya, Joy Noel Baumgartner, Ayubu Masasi Happy Suvomita Ghosh,Jan Ostermann and Lavanya Vasudevan.

Feasibility of mHealth-assisted conditional cash transfers to improve the timeliness of vaccinations in Tanzania (Mobile Health Technology and Outcomes in Low- and Middle-Income Countries)" has been funded by DUKE and NIH. The aim

of the study is to develop, implement and test mHealth-assisted approach in Tanzania to increase the uptake of timely childhood vaccinations through the use of conditional cash transfers and phone-based reminders to clients. Cross sectional study conducted in selected health facilities and communities in Mtwara and Kilimanjaro regions for two years from 2016 to 2018. The study has two components – 1) formative research comprising of interviews with health providers and focus group discussions with parents of young children to identify supply and demand-side barriers to vaccinations respectively, and 2) an acceptability and efficacy evaluation of the mHealth-supported multi-tiered CCT program for improving vaccination coverage and timeliness at 6, 10 and 14 weeks and involving longitudinal follow up of children for up to 6 months of age.

5.11 HEALTH SYSTEMS

Molecular and epidemiological determinants of persistence cholera outbreak in Tanzania – NIMR Muhimbili

Ngadaya E, Kimaro G, Nicholaus Mnyambwa, Abade Ahmed Erica Sandi, Rose Marwa, Kijakazi Mashoto, Mfinanga GS

This is the one-year project conducted throughout the country where there was cholera epidemics with the aiming at characterizing biological, epidemiological and environmental drivers for the persisted cholera transmission in the country. Policy implication: If the results turn up to be promising we will be able to predict future epidemics and hence prepared and prevent its occurrence.

International Multidisciplinary Program me to Address Lung Health and TB in Africa (IMPALA): Protocol for an Integrated Health Systems Approach for Improving Health Care Services for Chronic Lung Diseases in Sudan and Tanzania – NIMR Mbeya

Nyanda Ntinginya, Elizabeth Shayo, Stella Mpagama and Beatrice Mutayoba

Chronic lung diseases (CLDs) major global health challenge and Low-Income Countries have the highest burden. However, they are not prioritized by health systems actors and communities in LMICs. While there is a better system for TB, majority with chronic cough not followed through. Around 90% of patients investigated for chronic cough do not have TB and these are potential cases for CLD. Generate evidence on the requirements and process for developing context appropriate integrated lung health services in Sudan and Tanzania from health systems and community perspectives. The project comprises of formative phase to generate baseline information, interventions development, implementation and evaluation. The study site in Tanzania is Chamwino district in Dodoma region.

5.12 SOCIAL DETERMINANTS OF HEALTH

Difficult Decisions: Rural livelihoods, children's work and parental investment in education in north-western Tanzania – NIMR Mwanza

Mark Urassa, Jim Todd, Sophie Hedges, David Lawson, Rebecca Sear

Objectives: To collect data to investigate trade-offs between children's education and work activities in Kisesa and Welamasonga villages. The study involved household surveys in 400 households (200 per village). The household survey included a household roster, a socioeconomic module collecting information about household livelihood and assets, a food security module, and an education attitudes module. For each child in the household aged between 7 and 19, a survey was also completed with information about their parents, siblings, and education. Then each child was interviewed about their work activities, and their time allocation during the previous day.

Preventing Violence against Children in Schools (PVACS): Protocol for a cluster randomized controlled trial of the EmpaTeach behavioural intervention in Nyarugusu Refugee Camp – NIMR Headquarters

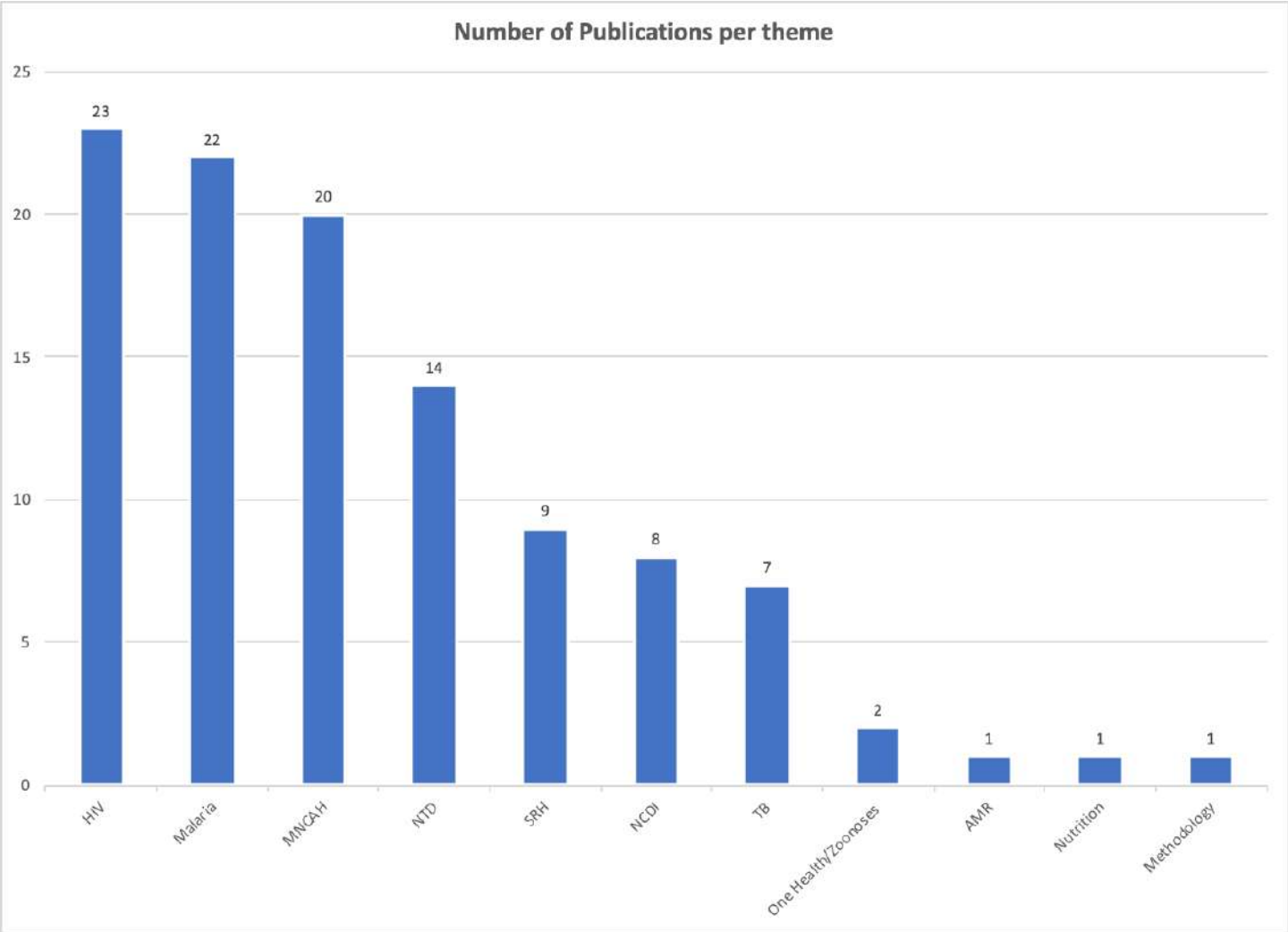
Elizabeth Shayo, Vivien Barogo, Karen Devris et al

This project is being implemented in Nyarugusu Camp by London School of Hygiene and Tropical Medicine (LSHTM) and IPA where NIMR is the local partner. As a local Principal Investigator, Elizabeth Shayo and Vivien Barongo are monitoring the collection of baseline data, mid-line and end-line, and its implementation. Preventing violence in schools through innovative behavioural change approaches. It includes baseline, intervention, monitoring and evaluation. Midline data started in May 2019 under the guidance of NIMR and is on-going (with support from IRC that had no budget item for NIMR to travel to the site). We have now received funding from MRC which allows the NIMR team to travel to Nyarugusu to physically asses and continue with midterm assessment.

6.0 DISSEMINATION AND UTILIZATION OF RESEARCH FINDINGS

6.1 NIMR PUBLICATIONS

NIMR scientists and collaborators published one hundred and eight (108) manuscripts in peer-reviewed journals *(Appendix 1)*.



Key: NTD – Neglected Tropical Diseases; NCDI – Non-communicable diseases and injury; AMR-Antimicrobial resistance; SRH – Sexual and Reproductive Health; SDH – Social Determinants for Health; MNCAH – Maternal, neonatal, child and adolescent health

6.2 THE 7TH EAST AFRICAN HEALTH AND SCIENTIFIC CONFERENCE

The 7th East African Health and Scientific Conference was held from 27-29 March 2019 at the Julius Nyerere International Convention Centre. It was jointly organised by the Ministry of Health, Community Development, Gender, Elderly and Children Tanzania Mainland, The Ministry of Health and Social Welfare Zanzibar and The Ministry of Foreign Affairs and East African Cooperation. The National Institute for Medical Research (NIMR) was the conference Secretariat. The National Steering Committee and seven subcommittees led the preparations.

The main theme of the conference was *"Technology for health systems transformation and attainment of the UN-Sustainable Development Goals"* and the Keynote speech was on "Invest in Digital Health to catalyze East Africa attain the UN-Sustainable Development Goals". The 7th EAHSC comprised of various sessions including conference opening; keynote speeches; plenary presentations; parallel session presentations; interactive digital poster presentations and symposia. In addition to the conference scientific sessions, an international health exhibition was held during the conference, where research institutions, health care facilities, medical /health academic institutions, medical and pharmaceutical industries, Ministries, EAHRC Secretariat, Civil Society organizations, Non-Governmental Organizations, International organizations, UN agencies showcased their products and activities. The conference was attended by 720 participants. The working language of the conference was English. The opening ceremony was officiated by Her Excellency Samia Suluhu Hassan, the Vice President of the United Republic of Tanzania and the closing ceremony was officiated by the Minister of Foreign Affairs and East African Cooperation, Hon. Prof Palamagamba Kabudi.

Opening Ceremony 7th EAHSC

Closing Ceremony 7th EAHSC

Chairman of the 7th EAHSC Prof Eligius Lyamuya

The conference had 193 oral and poster presentations. There were 5 Symposia organized by partner states and other institutions on day 3. There were 22 exhibitors from 5 partner states, the EAC Secretariat and the EAHRC.

The conference had nine (9) recommendations from the proceedings for EAC implementation. The conference recommends that the EAC should:

1. Expedite development and application of innovative approaches (such as the cross-border health unit model) to cross border health, disease outbreak, preparedness and response in border areas while adding values to the national health system.
2. Promote establishment of national bio banks and data repositories among the partner states and develop a regional policy for guiding the use and security of the repositories.
3. Partner states should participate in development, evaluation and formalization of emerging technologies intended for promoting digital health.
4. Harmonise regional IP policies to guide development and uptake of digital health technologies.
5. Strengthen the platform for digital inclusion where communities have full access to information on surveillance and disease management.
6. Fast track the adoption and implementation of Evidence Based Surveillance and enhance mechanisms of sharing information and best practice.
7. Enhance coordination and collaboration between East African countries and international Institutions involved in diseases control including the African CDC.
8. Promote the involvement of frontline healthcare workers in the design of digital health tools to ensure readiness, for easy adoption, decreasing cost, and increased sustainability.
9. Develop and adopt innovative Regional Public Private Partnership (PPP) policies and models specific to digital health Technologies.

6.3 HEALTH RESEARCH SYMPOSIUM FOR NIH-FUNDED PROJECTS

Signing of the letter of intent NIH, NIMR and COSTECH at NIMR Headquarters

NIMR facilitated the convening of a Health Research Symposium for NIH funded projects in Tanzania on 31st January 2019. Dr. Rogers Glass the NIH Fogarty Director and Ms Stacy Wallick NIH Project Officer attended.
The main aim of Dr Glass's visit was to officially launch an agreement between NIH, NIMR and COSTECH for Complementary Fellowship Awards that will benefit NIH-funded investigators and enhance biomedical and behavioural research and training cooperation between Tanzania and the United States. A Letter of Intent for Complementary fellowship awards between NIH, COSTECH and NIMR was signed. This agreement is aimed at the desire to enhance biomedical and behavioral research and training cooperation between Tanzania and the United States; and recognizing the importance of supporting collaborative research, personnel exchanges, and fostering the next generation of biomedical investigators in the pursuit of common scientific and public health goals. The half-day health research symposium was attended by 42 with 12 presentations in the areas of HIV, Malaria, Diabetes, Cardiovascular Disease, Cancer, Mental Health, Sickle Cell Disease, Injuries, Reproductive & Child Health, Human

Resource for Health, Health Education and Health Research. Prof Charles Mgone the Vice Chancellor of Hubert Kairuki Memorial University chaired the symposium

Group photo of NIH symposium participants at NIMR Headquarters

7.0 APPENDICES

7.1 APPENDIX 1: LIST OF NIMR PUBLICATIONS

1. Mtafya B, Sabiiti W, Sabi I, John J, Sichone E, Ntinginya NE, Gillespie SH. Molecular Bacterial Load Assay Concurs with Culture on NaOH-Induced Loss of Mycobacterium tuberculosis Viability. J Clin Microbiol. 2019 Jun 25;57(7):e01992-18. doi: 10.1128/JCM.01992-18. PMID: 31018981; PMCID: PMC6595441.

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7.2 APPENDIX 2: INTERNAL AND EXTERNAL COLLABORATORS

1. Aeras Africa
2. Bernhard-Nocht Institute of Tropical Medicine (BNITM), Germany
3. Centers for Disease Control and Prevention (CDC), USA
4. Centre for International Health, Norway
5. Chung-Ang University, Republic of South Korea
6. East African Community
7. Georgetown University, USA
8. German Federal Ministry of Education and Research (BMBF)
9. Global Alliance for TB Drug Development (TB Alliance)
10. Henry Jackson Foundation (HJF), USA
11. Ifakara Health Institute (IHI)
12. Imperial College London, UK
13. International Centre for Insect Physiology and Ecology (ICIPE), Kenya
14. Kilimanjaro Christian Medical University College (KCMUCo)
15. Kilimanjaro Clinical Research Institute (KCRI)
16. Korean Advanced Institute for Science and Technology (KAIST), Republic of South Korea
17. Liverpool School of Tropical Medicine, UK
18. LMU Munich, Germany
19. London School of Hygiene and Tropical Medicine, UK
20. Makerere University, Uganda
21. Muhimbili University of Health and Allied Sciences (MUHAS)
22. National AIDS Control Programme
23. National Malaria Control Programme
24. Neglected Tropical Diseases Control Programme
25. Nelson Mandela African Institute of Science and Technology (NM-AIST)
26. RTI International
27. Sokoine University of Agriculture (SUA)
28. Statens Serum Institut (SSI), Sweden
29. The European and Developing Countries Clinical Trials Partnership (EDCTP)
30. The Global Fund to Fight AIDS, Tuberculosis and Malaria
31. Uganda Virus Research Institute (UVRI)
32. UNICEF
33. United Nations Population Fund (UNFPA)
34. University College London, UK
35. University of Antwerp, Institute of Tropical Medicine, Belgium
36. University of Bonn, Germany
37. University of Cambridge, UK
38. University of Copenhagen /CMP, Denmark
39. University of Dodoma (UDOM)
40. University of Edinburgh, Scotland (UK)
41. University of Notre Dame
42. University of St Andrews, UK
43. US Military HIV Research Programme, USA
44. USAID
45. World Health Organization