

Møtedato: 25. april 2024

Vår ref.:Saksbehandler:Dato:2024/553-1Finnsson18.4.2024

Styresak 57–2024 Internasjonal helse - prosjekt *Helse Nord Tuberculosis Initiative* (HNTI)

Forslag til vedtak

Styret i Helse Nord RHF inviteres til å fatte følgende vedtak:

- 1. Styret i Helse Nord RHF tar informasjonen om Helse Nord RHFs tuberkuloseprosjekt i Malawi til orientering.
- 2. Styret bevilger 2 mill. norske kroner årlig (ekskl. årlig lønns- og prisjustering) til HNTI for årene 2025 og 2026 for at fire PhD-kandidater som ble kraftig forsinket i sitt arbeid på grunn av Covid 19-pandemien skal kunne fullføre sine doktorgrader (PhD-er).

Bodø, 18. april 2024

Marit Lind administrerende direktør

Org.nr: MVA 883 658 752

Formål

I denne saken orienteres styret i Helse Nord RHF om status for Helse Nord RHFs tuberkuloseprosjekt i Malawi, som har finansiering ut 2024. På grunn av Covid 19-pandemien ble prosjektene til fire PhD-kandidater kraftig forsinket. De vil ikke kunne fullføre sine prosjekter innen utgangen av 2024. Det er behov for totalt 4 mill. norske kroner (i 2025 og 2026) for at disse fire PhD-gradene skal kunne fullføres.

Sammenheng med strategi og grunnleggende verdier

Dette prosjektet oppfyller Helse Nords verdier *kvalitet, trygghet* og *respekt* ved at fire leger kan fullføre sine PhD-grader og derved bidra til å styrke kompetansen innen forskning, undervisning og veiledning og til økt kvalitet i pasientbehandlingen. Prosjektet har etablert et godt lagspill i Malawi og over landegrenser. Det er viktig at planlagt arbeid gjennomføres tross forsinkelser i arbeidet på grunn av Covid 19-pandemien.

Bakgrunn/historikk

Helse Nord RHFs tuberkuloseprosjekt (Helse Nord Tuberculosis Initiative, HNTI) i Malawi har pågått siden 2010/2011. Fra starten var prosjektet finansiert av ADs midler til disposisjon. Senere har styret i Helse Nord RHF bevilget 5 mill. kroner pr år til prosjektet, først for perioden 2018-2020 og videreført med samme årlige beløp for perioden 2021-2024.

Prosjektet er tidligere omtalt i *styresak 60-2017 Internasjonal helse-prosjekt* (styremøte 23. mai 2017) og i *styresak 142-2019 Internasjonal helse -prosjekt Helse Nord Tuberculosis Initiative (HNTI), budsjett 2021-2024* (styremøte 18. desember 2019). Prosjektet omtales også på Helse Nord RHFs nettside¹.

Overordnet visjon ved starten av prosjektet var å støtte et tverrfaglig forskningssamarbeid innen tuberkulose (TB) og HIV ved College of Medicine (COM), Blantyre, Malawi.² Langsiktig mål for prosjektet var å bygge lokal forskningskapasitet som er bærekraftig, av ypperste kvalitet, og som bidrar til lokal og internasjonal tuberkulosekontrollpolitikk- og praksis. Viktige mål var å etablere diagnostikk av høy kvalitet med kort svartid og å øke kompetansen innen vitenskap hos personell med lokal tilknytning. Det var ønskelig å etablere, vedlikeholde og videreutvikle fagmiljøet lokalt.

Leder av prosjektet de første årene var en engelsk professor (Liz Corbett) med kunnskap om og erfaring fra arbeid med tuberkulose og HIV i flere land i det sørlige Afrika. Hun har vært engasjert av WHO i flere overordnede utvalg innen disse fagområdene. Hennes mål er at resultater av forskningen skal være til nytte for befolkningen lokalt og også bygge og utvikle kompetanse om forskning og drift hos lokalt personell som kan videreføre arbeid av høy kvalitet. Corbett er professor ved University of Cambridge, England. Hun er fortsatt tilknyttet HNTI, bl. a. som medlem av styringsgruppen.

¹ https://www.helse-nord.no/helse-nords-tuberkuloseprosjekt-i-malawi/

² COM ble i 2021 slått sammen med Kamuzu College of Nursing til Kamuzu University of Health Sciences (KUHeS). HN RHF viderefører samarbeidet med det samme fagmiljøet, nå i KUHeS.

Planer

Prosjektet var i starten konsentrert om tuberkulose og HIV. Det var stor oppmerksomhet om å etablere selvtesting for HIV og oppsøkende virksomhet for å identifisere tuberkulosetilfeller for å kunne starte behandling og forhindre videre spredning av begge sykdommer. Prosjektet er etter hvert utvidet til også å omfatte studier innen andre infeksjonssykdommer. Det skal nå søkes Kamuzu University of Health Sciences (KUHeS) om å få etablere et senter der for klinisk forskning innen infeksjonssykdommer i Malawi. *Concept for the Centre for Infectious disease Clinical Research in Malawi* (vedlegg 1) gir en god beskrivelse av hvordan arbeid som har vært gjennomført under Helse Nord RHFs tuberkuloseinitiativ er et godt grunnlag for en overgang til og videreføring av arbeidet i et nytt forskningssenter.

Resultater

HNTI har ved sin basisfinansiering vært sentralt i etableringen av en infrastruktur for virksomheten/prosjektet. Mange organisasjoner finansierer enkeltprosjekter, men er ikke alltid like opptatt av å etablere og styrke kunnskap, kompetanse og infrastruktur lokalt. HNTI har et bredt samarbeid med andre organisasjoner som arbeider i Blantyre, Malawi. Samarbeidet med det nasjonale tuberkulosekontrollprogrammet (NTP) i Malawi og med MLW³ er sentralt.

Ved starten av HNTI var det essensielt å etablere tuberkulosediagnostikk av høy kvalitet. Tuberkuloselaboratoriet ved COM ble oppgradert og laboratorieutstyr for diagnostikk av høy kvalitet ble anskaffet og tatt i bruk. Sammen med MLW har HNTI finansiert etablering av et P3 laboratorium ved COM. P3 laboratorium er en forutsetning for å kunne arbeide med høyrisiko smittestoffer, bl. a. for å kunne arbeide med nærmere karakterisering av tuberkulosebakterier og å kunne gjøre resistensbestemmelse av dem. HNTI har også oppgradert forskningslaboratorier og undervisningslaboratorier for studenter til god standard. Moderne apparatur for diagnostikk og mikroskoper for studentundervisning er kommet på plass.

HNTI finansierte utdanningen av den andre spesialisten i klinisk mikrobiologi i Malawi. Hun fullførte utdanningen i Sør-Afrika som planlagt, og var sentral i å etablere mikrobiologisk diagnostikk av høy kvalitet ved Queens Hospital i Blantyre. Denne diagnostikken er sentral ved behandling og forskning bl. a. knyttet til infeksjoner hos gravide og fødende. På grunn av familieforhold har denne spesialisten dessverre flyttet fra Malawi til Canada. Hun arbeider som mikrobiolog der.

Malawis første spesialist i klinisk mikrobiologi var sentral ved starten av HNTI. Etter flere år i administrativt arbeid for andre organisasjoner (bl. a. CDC), har han nå returnert til HNTI med verdifull lederkompetanse og internasjonal erfaring. Han arbeider nå innen klinisk mikrobiologi og underviser som lektor ved KUHeS. En sentral leder i HNTI og dekan ved KUHeS er i år utnevnt til professor ved KUHeS.

Undervisning og veiledning på alle nivåer har vært og er sentrale aktiviteter i HNTI – fra skolering og videreutdanning av personell i laboratoriediagnostikk til generelle universitetskurs på bachelor-, mastergrad- og PhD-nivå som gjennomføres regelmessig for kandidater fra ulike fagområder.

³ Malawi-Liverpool-Wellcome-Trust Clinical Research Programme,

Forskningen har resultert i tallrike publikasjoner i velrennomerte tidsskrifter. Erfaring fra flere av forskningsprosjektene er tatt inn som anbefalinger i nasjonale retningslinjer og i retningslinjer fra WHO vedrørende tuberkulose og HIV.

Hittil har åtte kandidater gjennomført sine PhD-er i regi av og under veiledning fra HNTI, seks av dem fullfinansiert av HNTI og to i hovedsak finansiert av HNTI. Vedlagt er en oversikt over gjennomførte PhD-er, og hva kandidatene nå gjør (vedlegg 2). Alle kandidatene har gjennomført det meste av PhD-arbeidet i Malawi. De fleste av dem arbeider fortsatt i Malawi og flere av dem er fortsatt knyttet til HNTI, bl. a. som veiledere for nye PhD-kandidater. De bidrar til økt kompetanse og kapasitet til undervisning og veiledning ved universitetet lokalt. Vedlagt er også en oversikt over 14 kandidater som har fullført sine mastergrader under HNTI (vedlegg 3).

Dokumentet *Research Outcome and Impact Framework for the Helse Nord Tuberculosis Initiative* (vedlegg 4) viser i tabell en oversikt/oppsummering av gjennomførte aktiviteter i perioden 2012-2023, resultater av prosjekter og en vurdering av prosjektenes betydning på kort og lang sikt. Det er også omtale av aktivitetene i Newsletter ISSUE 03/January 2024 (vedlegg 5).

Aktiviteten er bred, fra studier av sosiale og samfunnsfaktorers betydning for å la seg teste og behandle for tuberkulose og HIV, og hvordan nå ut til ulike deler av befolkningen med testing og behandling, til politisk påvirkning for å kunne gjennomføre storskalaintervensjoner for å påvise og behandle sykdom. Storskalaintervensjon for aktivt å påvise TB og finne folk med ubehandlet TB i samfunnet, økte påvisning av TB i samfunnet med 32%. Ansvarlig for aktuelle studier var PhD-kandidater og postdokkandidater ved HNTI. Det er en signifikant nedgang i TB sykdomsbyrde i Malawi, 80% reduksjon i prevalensen av TB i Blantyre City i løpet av perioden 2011-2019. Ved revisjon av WHO-retningslinjer er det tatt inn nye anbefalinger om aktiv oppsøkende virksomhet for å påvise TB. Antall nye HIV-tilfeller i Malawi er sterkt redusert i perioden 2000-2021. HNTI har gjennom forskingsprosjekter deltatt i arbeidet med å utvikle strategier for selvtesting av HIV. Selvtesting for HIV er nå blitt en del av nasjonal praksis for selvtesting i Malawi og inngår også i retningslinjer fra WHO.

Det gjøres klinisk evaluering av ulike typer ny diagnostikk, genetiske analyser av tuberkulosebakterien, randomiserte kliniske studier med tanke på å kunne forkorte behandlingen av tuberkulose, digitale verktøy for å minne om medisinering ved behandling av HIV-infeksjon. Det er gjennomført et større forskningsprosjekt knyttet til antibiotikaresistens ved behandling av tuberkulose. Det er etablert plattformer for sekvensering og bioinformatikk i forbindelse med kolera-epidemien i Malawi og det er utviklet diagnostisk evaluering som ble brukt i epidemisk respons under Covid 19-pandemien.

Forskning på kvinnehelse er økt i omfang i HNTI- med nye tema som ikke var omtalt i *styresak 142-2019.* En av de aktuelle PhD-kandidatene har som prosjekt å få på plass testing for HPV (humant papilloma virus) ved at kvinner selv tar prøve for testing. HPV forårsaker livmorhalskreft og Malawi er av de land i verden som har høyest forekomst og høyest dødelighet av denne kreftformen.

En jordmor disputerte i februar 2024 om bruk av misoprostol i håndtering av inkomplett abort (misoprostol - medikament som får livmoren til å trekke seg sammen f eks ved ikke fullstendig abort). Hennes stipendiat er fullfinansiert av HNTI. Det er også gjennomført en PhD knyttet til miljøgifter i graviditet. Denne graden er i hovedsak finansiert av HNTI. Et av de pågående PhD-prosjekter er knyttet til testing og behandling av HIV og schistosomiasis. Schistosomiasis er endemisk i Malawi og skyldes en ferskvannsparasitt. Fiskere i Lake Malawi er utsatt for smitte av denne parasitten, og det aktuelle PhD – prosjektet retter seg mot denne delen av befolkningen.

En fellesnevner for de ulike aktiviteter knyttet til forskning og intervensjoner er at de alle er relatert til sykdommer som forekommer hyppig i Malawi, og er viktige å få under kontroll. Sykdommer som nærmest er tabubelagte alminneliggjøres. Befolkningen kommer til testing og behandling og det bidrar til redusert sykelighet og bedret folkehelse. Publiserte resultater sprer kunnskap og praksis til andre land. Dette er spesielt nyttig hvor det er stor sykdomsbyrde.

Covid 19-pandemien - konsekvenser for PhD-kandidatene

Malawi var hardt rammet av Covid 19-pandemien, og pandemien påvirket i stor grad progresjonen for planlagt arbeid i HNTI-regi i perioden 2021-2022. På grunn av nedstengning og restriksjoner måtte alt feltarbeid innstilles og datainnsamling til kliniske studier ble kraftig forsinket. Da samfunnet ble reåpnet i 2022 hadde de aktuelle PhD-kandidatene gjenstående arbeider fra tidligere studier. En av dem skulle lede fullføringen av en større studie av diagnostisk nøyaktighet ved tuberkulose hos barn. HNTI-personalet bidro sentralt i arbeidet mot Covid 19 i Malawi. De ga informasjon om sykdomskontroll tidlig under pandemien, laboratoriepersonellet var i førstelinje. En av våre tidligere PhD-kandidater var også eksepsjonell i å bistå helsedepartementet med «public health -respons». Titus Divala shares his experience of communicating COVID messages to the masses – Malawi Liverpool Wellcome Programme (mlw.mw). Han tok pause i sitt gradsarbeid for å delta aktivt i «Covid-arbeidet». En av dagens PhD-kandidater og en veileder ledet studier som evaluerte nye Covid 19-selvtest-sett. En annen av dagens kandidater var involvert i pasientarbeid og drev aktivt arbeid med folkeopplysning for å bedre vaksineopptak.

De fire kandidatene som nå skal gjennomføre sine PhD-prosjekter er alle leger. De er alle registrert og tatt opp ved samarbeidende universiteter i Europa for å være knyttet opp mot spesialkompetanse og veiledning derfra. De har også lokale veiledere ved KUHeS. Kandidatene og deres prosjekter er omtalt i Newsletter ISSUE 03/January 2024. Se også oversikt over kandidatene som nå holder på med sine PhD-er (vedlegg 6).

Administrerende direktørs vurdering

Administrerende direktør vurderer at HNTI har gjennomført planlagt aktivitet og overoppfylt prosjektets opprinnelige mål innenfor de budsjetterte økonomiske rammer som Helse Nord RHF har tildelt. Det er utviklet svært god kompetanse innen forskning og diagnostikk og det gjennomføres prosjekter knyttet til flere sentrale helseutfordringer i Malawi. Prosjektet samarbeider med flere internasjonale organisasjoner og har bidratt til å utvikle et godt fag- og forskningsmiljø knyttet til flere infeksjonssykdommer av sentral betydning i Malawi.

Det er opparbeidet et bredt kompetansemiljø. Fagfolkene som er utdannet arbeider i hovedsak fortsatt i Malawi, og har ikke flyttet til vestlige land for videre karrierer der.

Covid 19 -pandemien rammet hardt i Malawi. Fire nye PhD-kandidater i HNTI fikk to års forsinkelse i sine PhD-prosjekter. De er nå alle registrert ved samarbeidende universiteter, er vel i gang med sine studier og har god progresjon i arbeidet. Administrerende direktør anbefaler at styret i Helse Nord RHF bevilger 2 mill. norske kroner årlig (ekskl. årlig lønns- og prisjustering) til HNTI for årene 2025 og 2026 (totalt 4 mill. kroner) for at fire PhD-kandidater som ble kraftig forsinket på grunn av Covid 19-pandemien skal kunne fullføre sine doktorgrader (PhD-er).

Vedlegg:

- 1. Concept for the Centre for Infectious disease Clinical Research in Malawi
- 2. Past PhD training update (2012 to 2024)
- 3. MSc candidates completed
- 4. Research Outcome and Impact Framework for the Helse Nord Tuberculosis Initiative 2012 to 2023
- 5. Newsletter Issue 03, January 2024
- 6. Current PhD candidates (2019 to 2026)

Concept for the Centre for Infectious disease Clinical Research in Malawi

1. Background

The Chichiri Centre for Infectious Disease Research (CCIDR) is being established as a Centre of excellence in clinical, laboratory and epidemiological infectious diseases research and training in the Kamuzu University of Health Sciences. The CCIDR emerges from strategic investments by the Helse Nord RHF in Malawi and represents an amalgamation of thriving research groups under the Pathology department conducting research on various pathogens and diseases. The centre is also a sustainability, growth and institutionalization plan of the Helse Nord Tuberculosis Initiative (HNTI), the research investment plan between 2010 and 2024.

Vision

A Centre of excellence in clinical, laboratory and epidemiological infectious diseases research and training in Africa.

Mission

To conduct multi-disciplinary research in infectious disease that is sustainable, internationally excellent and makes direct contribution to local and international policies and practice for improved health of people in Africa.

Organogram

To ensure the seamless functioning of the Centre and to maintain the highest standards of excellence, a well-structured organogram has been established.

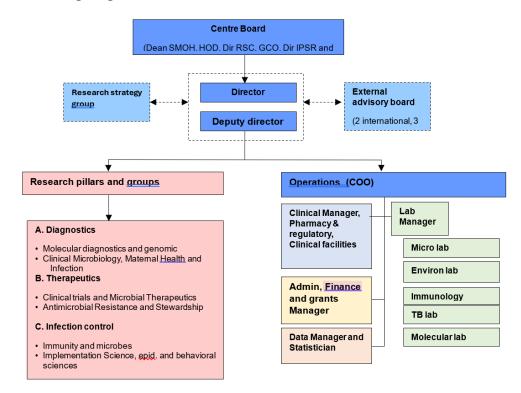


Figure 1: Centre Organogram

The leadership is provided by the centre board, research strategy group, external advisory board, the director and deputy director -Fig 1. The research strategy group, in general, is responsible for making centre strategies and meets at intervals to access the progress of the entire research centre. The current membership list of the

research strategy group consists of: The Representative of Pathology Department; The Representative of the MLW; and invited attendees which may include; RSC Director; NTNU representative and centre fellows. The external advisory board is comprised of 2 internal and 3 local members. It provides wise counsel regarding myriad issues that the research center faces.

The Administration team, the Chief Operations Officer (COO) is responsible for overseeing the administration, accounts, operations, data management, laboratories (TB, Immunology, Microbiology, Molecular, Environmental) and Clinical Trial Facilities (pharmacy and field Facilities). However, the laboratory manager is responsible for day-to-day operations of all laboratories.

2. Programmatic areas and research groups

The centre's research areas cover all aspects of *diagnosis, treatment and control of infectious diseases*. The current plan is to fund groups rather than individual fellowships. A research group is a science-driven group of staff, coming together to promote research in a specific area. A group has a lead, a pipeline of trainees (Pre-MSc, MSc & PhD) and research staff (research assistants, field workers, nurses etc), and supporting research funding. Research group in the centre will be required to generate competitive concepts that will be used to win grants, have at-least 1 active study at any one point and prepare at least 3 manuscripts for publication per year. They will also be required to maintain and forge new meaningful collaborations (i.e. a collaboration that leads to generation of new funding, capacity development, leading of work-packages/publications, supervision of students, increasing centre visibility & research support).

Diagnostics

Molecular Diagnostics and Genomics Group

This group uses molecular and genomics techniques to gather evidence on the genetic diversity, epidemiology, and transmission dynamics of pathogens prevalent in Malawi as well as those that are emerging. Specifically, our work focuses on characterizing pathogen genetic changes, understanding disease transmission patterns including reservoirs, and risk factors for infection, and studying host-microbe interactions at the molecular level to better understand pathogenesis, immune evasion, and susceptibility to infectious diseases. Our work also includes studying the molecular mechanisms underlying the emergence of antimicrobial resistance, tracking the spread of drug-resistant pathogens, and developing highly sensitive point-of-care molecular assays for the rapid detection and monitoring of infectious disease outbreaks.

• Clinical, Microbiology, Maternal Health and Infection Group

This group focuses on application of epidemiology and clinical microbiology to ensure a high level of clinical care for pregnant and non-pregnant women, as well as other adult and paediatric populations. The group is especially working on addressing infectious sexual reproductive health issues through direct preventative and therapeutic interventions targeted at key sexually transmitted infections, including HPV, chlamydia, and gonorrhea, among other sexually transmitted diseases. The HPV work in turn begins to address the issue of HPV-related cancers, with particular emphasis on cervical cancer. Key bodies of work include describing the epidemiology of HPV and cervical cancer in the region, implementing novel high sensitivity screen-and-treat approaches for identifying precancerous cervical abnormalities, and the interventions to facilitate the countrywide scale up of cervical cancer screening and HPV vaccination.

The group provides Clinical Microbiology services including diagnostic and antimicrobial therapy to specified wards, including Obstetrics and Gynaecology wards, with the aim of generating an antibiogram repository that would benefit the development of empiric therapeutic options for the wards.

Therapeutics

• Microbial therapeutics and clinical trials

This is a clinical research group with the aim to advance the evaluation of new medical interventions. The area of focus is the evaluation of new treatment options for infectious diseases. Current portfolio involves the evaluation of new tuberculosis (TB) drug regimens for shortening duration of treatment to 3 or 4 months through the conduct of novel phase 2 and phase 3 clinical trial designs. We also host a number of various clinical trials focusing on 1) timing of antiretroviral therapy relative to TB diagnosis in people living with HIV; 2) assessing the utility of digital adherence tools in improving care of people living with HIV; and 3 evaluations of clinical impacts of novel diagnostics for infectious diseases.

We aim to grow our research facilities through construction of clinical trial rooms and pharmacy. The research group has excellent personnel and expertise in dealing with regulatory and ethical issues enabling us to collaborate with various international teams in the conduct of clinical trials on diagnostics, therapeutics, devices and vaccines.

• Antimicrobial Resistance and Stewardship Group

The Antimicrobial Resistance and Stewardship (ARAS) Group focuses primarily on defining the burden of antimicrobial resistance by studying the epidemiological patterns of bacterial pathogens and also related socioeconomic factors in affected communities and institutions. This is then combined with deliberate and targeted communication and dissemination initiatives to inform antimicrobial stewardship programs and interventions across the one-health spectrum.

Our research interests and approaches include: 1) Using molecular and microbiology techniques to identify pathogens and their related antimicrobial resistance (AMR) profiles. We have access to the Kamuzu University of Health Sciences (KUHeS) Microbiology and Molecular Laboratories, and also the University's core sequencing facility. 2) Exploring multiple environments including hospitals, animal farms, waste management plants and households to pinpoint the drivers of AMR. Ongoing work in this area includes sampling from large and small scale commercial poultry farms and characterization of effluent from waste-water treatments plants in Blantyre and Zomba, for extended spectrum beta-lactamase producing organisms. 3) Gathering data on the costs of AMR to families and healthcare facilities to build a case for continued investment in programs aimed at mitigating the burden of AMR. 4) Using vaccines to stop the spread of antimicrobial resistance. 5) Implementation research that cuts across multiple sectors to develop and roll out antimicrobial stewardship (AMS) programs and assess their cost-effectiveness and also impact of the AMS programs on infection rates. 6) Community engagement and involvement to describe antimicrobial usage practices and understanding the gaps and opportunities for education and awareness on AMR.

Infection Control

Microbes, Immunity & Vaccines Group

The Microbes, Immunity and Vaccines (MIV) research group overarching goal is to generate deeper knowledge on natural immune responses to microbes and performance of candidate and licence vaccines for use in low-

and medium-income countries. The groups use natural and vaccine human-cohorts from endemic settings to study immune responses using blood and gut biopsy specimens. The research group studies immune responses to diverse microbes of public health importance including *Plasmodium falciparum*, *Salmonella* Typhi, *Salmonella* Typhimurium, SARS-CoV-2 and HIV. MIV group uses a well-resourced Kamuzu University of Health Sciences (KUHeS) Immunology laboratory, under the Department of Pathology. Advanced immunological techniques are employed for the study of immune responses including tissue culture, multi-colour flow cytometry, systems serology, serum killing assays, bead-based cell sorting and multiplexing bead assays readout by imaging or fluorescence. MIV group hosts KUHeS and other Universities undergraduate, and post-graduate trainees.

Broad objective for the research group include: 1) To determine the mechanism of protective immunity or susceptibility using natural cohorts to inform development strategies of immunological interventions e.g. vaccines. 2) To evaluate the immunogenicity of candidate and licenced vaccines in-order to inform administration strategies. 3) To potentiate functional antibody and cellular immune responses against microbes. 4) To develop immunological tools for evaluation of correlates of protection. 5) To determine immunological biomarkers for infectious disease diagnosis and disease progression.

Implementation Science and Epidemiology Group

This group focuses on the intersection of implementation science and epidemiology. Thus, it plays a critical role in advancing evidence-based public health practice. Building on an extensive background work on HIV self-testing and TB research, our future work will focus on identifying novel approaches for delivering public health interventions to maximize health benefits in diverse populations. We will expand our focus to include neglected tropical infectious diseases beyond HIV and TB.

This group also offers modern statistical and epidemiological methods built upon high quality surveillance and survey data to understand disease burden. It offers tailored strategies as well as strong partnerships with communities and policymakers to facilitate the adoption and integration of evidence-based interventions into diverse settings.

3. Research platforms

The following are the Core Facilities that will uphold the centre; Admin, Accounts & Operations, Data Management, Laboratories (TB, Immunology, Microbiology, Molecular, Environmental) and Clinical Trial Facilities: Pharmacy, Field Facilities. We propose a new clinical research facility to allow for procedures such as PK sampling and other advanced infectious disease research procedure (Figure 2). We will also buy two vehicles to facilitate research work.



Figure 2: Proposed clinical research facility (estimated cost \$250,000)

4. Training

Training is a core component of the centre. In the new programme we propose to train one postdoc and one PhD candidate per group. In a consolidated manner we will also deliver first group of clinical trainees in specialty areas of pathology including microbiology, histopathology and hematology.

5. International outlook

The centre has a lot of international collaborations strengthened at group level. On a corporate level two international scientific advisors will be invited to make sure the centre is in touch with contemporary issues in global health. The centre will also strengthen student exchange programs particularly for Norwergian students.

6. Centre budget and sustainability

A grant total of **USD 4,128,315** is required **over 5 years** to deliver centre aims (See attached budget). Continued Helse Nord RHF funding would be important to support core Centre functions as well as protected research time for senior researchers and investments in new cutting-edge research areas. Within each group, researchers will write grants and compete for funding to support research specific to their group and to maintain research staff. Each group hosted in the centre will contribute to ongoing capacity building initiatives identified as important in the long-term survival of the centre. The research centre will link to existing structures in the University and be subject to auditing and financial management procedures of the University.

Centre of Infectious Diseases Research (2025 to 2029) – Budget Summary

Centre of infectious Diseases Nes	Year 1	Year 2	Year3	Year4	Year5	Total Budget
A. Personal costs						
Centre staff	228,942.00	251,836.00	277,020.00	304,722.00	335,194.00	1,397,714.00
B. Research support and postgraduate training						
Postdoc bridging funds		54,000.00	54,000.00			108,000.00
Postdoc stipend	60,000.00	60,000.00	60,000.00	60,000.00		240,000.00
Ph.D. Fellows stipend	86,400.00	86,400.00	86,400.00	86,400.00		345,600.00
Start up costs- Postdocs	54,000.00		54,000.00			108,000.00
Research costs Ph.D. For Ph.D fellows	120,000.00	60,000.00	60,000.00			240,000.00
Mmed training	97,000.00	97,000.00	124,000.00	181,000.00		499,000.00
C. Capital equipment, Materials, supplies and running costs				T		
Office Supplies and equipment	19,000.00	19,000.00	19,000.00	19,000.00	19,000.00	95,000.00
Procurement of centre vehicles, maintanance and rentals	367,700.00	30,500.00	30,500.00	30,500.00	30,500.00	489,700.00
Centre visibility	8,000.00	4,500.00	4,500.00	4,500.00	4,500.00	26,000.00
Services	10,000.00	5,000.00	4,000.00	4,000.00	4,000.00	27,000.00
D. Meetings, networking and travel						
Local meetings (within Malawi)	20,000.00	20,000.00	20,000.00	20,000.00	20,000.00	100,000.00
International meetings (Outside Malawi)	17,000.00	15,000.00	15,000.00	15,000.00	15,000.00	77,000.00
						-
COM Overheads (10%)	108,804	70,324	80,842	72,512	42,819	375,301
Total	1,196,846	773,560	889,262	797,634	471,013	4,128,315

Past PhD training update (2012 to 2024)

Folio			Date of PhD		Ongoing roles at HNTI
#	Name	PhD Thesis Title	Completion	Current position	
1	Kruger Kaswaswa	Providing sustainable household contact tracing and screening for Tuberculosis Patients and Families: a Cluster-randomised trial in Blantyre, Malawi (PACTS trial- ISRCTN 81659509)	January 2018	Research, Engagement & Innovation Officer, Australian Redcross	No ongoing roles at HNTI
2	Moses Kumwenda	Partnership dynamics and care seeking trajectories among couples after HIV self-testing in Malawi	March 2018	Senior Research Fellow, University of Southampton. Career Development Fellow, KUHeS - HNTI	Supporting qualitative research of current PhD candidates and prospective group leader in new centre
3	Marriott Nliwasa	HIV and tuberculosis prevalence and risk of mortality in adults with symptoms of tuberculosis in the era of scale-up of antiretroviral therapy	June 2019	Senior Research Scientist, KUHeS - Helse Nord Tuberculosis Initiative	Research programme lead at HNTI, PhD supervision and prospective research group leader in new centre
4	Victor Ndhlovu	Understanding molecular mechanisms underlying Mycobacterium tuberculosis persistence	November 2018	Head of Department, Biomedical Sciences at KUHeS	No ongoing roles at HNTI
5	Titus Divala	Accuracy and Consequences of using Trial- ofantibiotics for TB diagnosis (ACT-TB Study)	March 2021	Research Lead, Epidemics and Epidemiology	PhD supervision of current HNTI candidates
6	Augustine Choko	Investigating interventions to increase uptake of HIV testing and linkage to care or prevention for male partners of pregnant women in antenatal clinics in Blantyre, Malawi	November 2018	Senior Lecturer, Liverpool Sch of Trop Medicine and Interim Group Head for Public Health at MLW	PhD supervision and prospective research group leader in new centre

Folio #	Name	PhD Thesis Title	Date of PhD Completion	Current position	
7	Mphatso Mwapasa	Environmental and dietary exposure to persistent toxic substances (PTS) and trace elements in pregnancy and birth outcomes.	January 2024	Part time basis at HNTI	Will be offered a position at MUST (Malawi University of Science and Technology) Will be an important contribution to academic competence building in Malawi
8	Bertha Chakame	The Use of Misoprostol in the Management of Incomplete Abortion in Selected Health Facilities in Malawi.	February 2024	Senior Lecturer at KUHeS	Will be offered a position at MUST (Malawi University of Science and Technology) Will be an important contribution to academic competence building in Malawi

MSc candidates completed

Name Research title		Degree	University	Year of completion	
Aaron Mdolo	Comparison of TB treatment outcomes between patients with sputum culture positive or negative	MSc Epidemiology	LSHTM, UK	2014	
Dr Mphatso Mwapasa	Efficacy of insecticide impregnated clothes on reducing malaria incidence among prisoners at Chichiri Central Prison in Blantyre, Malawi: A Cluster Randomised Control Trial	MSc Clinical Trials	LSHTM, UK	2017	
Dr Tamiwe Tomoka Breast Cancer receptors profile in women in Subsaharan Africa: A Systematic review and meta-analysis		MSc Epidemiology	LSHTM, UK	2019	
Dr Lerato Mambulu	Clinical outcomes of patients with suspected meningitis in Blantyre, Malawi	MMed Internal Medicine	KUHES, Malawi	2019	
Dr Martin Kamponda	Use of Xpert MTB/RIF Ultra and Focused Assessment with Sonography for diagnosis of Extra-pulmonary tuberculosis	MMed Internal Medicine	KUHES, Malawi	2019	
Edson Mwinjiwa	Use of Xpert MTB/RIF for diagnosis of Tuberculous Meningitis	Master of Public Health	KUHES, Malawi	2019	
Dr Madalo Thindwa	The impact of Xpert MTB/RIF Ultra assay for diagnosing tuberculosis in ambulant HIV positive patients in Blantyre, Malawi: An analysis of a randomized controlled trial	MSc Epidemiology	LSHTM, UK	2020	
Gabriel Ndhlovu	Efficiency of the Centralized Tuberculosis Drug Susceptibility Testing System in Selected Districts of Malawi: 2019	MS HS Antimicrobial stewardship	KUHES, Malawi	2020	
Dr Robina Semphere	Evaluating clinical features leading to end-point tuberculosis case definition in a paediatric cohort in five high burden tuberculosis countries	MSc Epidemiology	LSHTM, UK	2021	
Dr Hussein Twabi	Prevalence of third trimester urinary tract infection and its association with adverse delivery outcomes among pregnant women at Queen Elizabeth Central Hospital in Blantyre, Malawi; a cross-sectional study	MSc Epidemiology	LSHTM, UK	2022	
Mable Kisyombe	Factors associated with deaths among paediatric tuberculosis patients in Blantyre, Malawi	MSc Epidemiology	KUHES, Malawi	2022	
Dalitso Kalua	Experimental Evolution of Pseudomonas aeruginosa to Piperacillin-Tazobactam Resistance	MSc Tropical Biology	UoL, UK	2022	

Tionge	The prevalence of multi-drug resistant	MS HS	KUHES,	2022
Sikwese	tuberculosis disease in clinical isolates in	Antimicrobial	Malawi	
	Blantyre and Lilongwe, Malawi	stewardship		
Alice	Molecular investigation of the aetiology of	MS HS	KUHES,	2022
Mnyanga	tuberculosis-like clinical syndromes in adults	Antimicrobial	Malawi	
	presenting for primary health care at Limbe and	stewardship		
	Ndirande health centres in Blantyre, Malawi			

Research Outcome and impact Framework for the Helse Nord Tuberculosis Initiative 2012 to 2023

#	Outputs	Intermediate outcomes	Long form outcomes	Impact
#	Outputs (Research is conducted generating evidence which is packaged and promoted)	(New research and evidence fills knowledge gaps, improves understanding and drives development of new interventions)	Long-term outcomes (New solutions and policies are implemented based on supporting research evidence)	Impact (The disproportionate impact and risk of infectious diseases is minimized in the most affected communities)
Α	Social and behavioral sciences			
A1	Understanding social and behavioral factors that influence the decision to test and seek appropriate treatment for tuberculosis and HIV among the elderly, young people, men (influences of masculinity), sex workers and cohabiting couples (gender and relation dynamics) in Malawi (HNTI PhD and senior fellowship, collaborative research – Dr Moses Kumwenda) (1) (2) (3)	 Research provided better insights and understanding of the barriers to HIV and tuberculosis testing and treatment in key populations. Research highlights the importance of stigma, lack of appropriate coping mechanisms, inaccurate risk perception and lack of information in affecting testing and treatment. Men's access to tuberculosis testing is affected by existing precarious socioeconomic conditions; gendered social norms; and general constraints in the health system. Development of information and communication tools to facilitate HIV treatment Engagement with policy makers and other researchers, collaborations with implementers: PSI, Pakachere, Civil Society 	Findings incorporated in the Malawi National HIV-self-testing policy, and World Health organization's guidelines	High coverage of HIV self- testing in key populations such as elderly, young people, men, sex workers and cohabiting couples.
A2	HIV transmission is becoming concentrated in selected populations in Malawi. Innovative and effective ways of reaching such populations are required (Research underway) (HNTI PhD Fellowship, Dr Madalo Thindwa)	Understanding whether use of social networks is an effective way of improving HIV-self testing coverage and uptake of antiretroviral therapy	Expected long-term impacts : potential for multiple applications in health	Expected impact : improved HIV care in key populations

# B	Outputs (Research is conducted generating evidence which is packaged and promoted) Community interventions for tuberculosis	Intermediate outcomes (New research and evidence fills knowledge gaps, improves understanding and drives development of new interventions)	Long-term outcomes (New solutions and policies are implemented based on supporting research evidence)	Impact (The disproportionate impact and risk of infectious diseases is minimized in the most affected communities)
B1	Conducted a large-scale evaluation of community-based tuberculosis active case finding (ACF) using two strategies (mobile teams and door-to-door) to find people with untreated tuberculosis in the community. (Malawi Tuberculosis Group) (4)	Community-based ACF intervention resulted in increased detection of tuberculosis disease in the community diagnosis by 32% by contribution of tuberculosis patients directly detected through mobile teams and door-to-door mechanisms but also by improving passive case finding in the target communities	Informed WHO guideline revision 2021, now recommend ACF for general population Malawi National Tuberculosis and Leprosy Elimination Programme secured funding to implement community-based ACF	Significant reduction in tuberculosis disease burden in Malawi, demonstrated 80% reduction in tuberculosis prevalence in Blantyre City 2011-2019
B2	Research conducted to assess innovative interventions to improve screening and diagnosis of tuberculosis in the community. A cluster-randomised trial conducted to evaluate the impact of a patient-delivered household contact tuberculosis screening and diagnosis (HNTI PhD, Dr Kruger Kaswaswa) (5)	The research enhanced our understanding of impact of tuberculosis screening in household contacts; screening provided an alternative means of diagnosis of adult tuberculosis and increased initiation of preventive treatment in under-five children	Expected outcome: Implementation of patient-delivered contact tracing and tuberculosis screening by the National Tuberculosis and Leprosy Elimination Programme	Expected impact: Timely diagnosis of adult-tuberculosis and decline in childhood tuberculosis disease.

#	Outputs (Research is conducted generating evidence which is packaged and promoted)	Intermediate outcomes (New research and evidence fills knowledge gaps, improves understanding and drives development of new interventions)	Long-term outcomes (New solutions and policies are implemented based on supporting research evidence)	Impact (The disproportionate impact and risk of infectious diseases is minimized in the most affected communities)
C C1	Randomized-controlled trials conducted to show impacts of computer-aided chest x-ray (CAD-CXR) to improve tuberculosis diagnosis in general health facility attendees as well as HIV positive individuals. (HNTI Postdoctoral fellowship, Dr Marriott Nliwasa and Malawi Tuberculosis Group) (6) (7)	Clinical trials showed CAD-CXR improves TB diagnosis among primary care attendees and HIV positive individuals Stimulated national interest in computeraided diagnosis of tuberculosis disease in Malawi.	Research informed the World Health Organisation's Policy on tuberculosis screening & diagnosis as well as research strategies of the Foundation For Innovative New Diagnostics (FIND), leading to inclusion of artificial intelligence (AI)-based diagnosis of tuberculosis for the first time. Malawi National Tuberculosis and Leprosy Elimination Programme and other Implementation Partners scaling-up use of CADCXR in Malawi	Timely diagnosis of tuberculosis disease in key groups
C2	A randomized controlled trial conducted to assess use of urine LAM for diagnosis of tuberculosis disease in hospitalised adults living with HIV (Malawi Tuberculosis Group)	Clinical trial showed improved tuberculosis diagnosis among People Living with HIV compared to standard of care Research enabled collaborations with other research groups working on novel urine LAM assays	Urine LAM recommended for TB diagnosis among hospitalised people living with HIV National scale-up of use of urine LAM being conducted by the Ministry of Health in Malawi and International Partners	Increased diagnosis of tuberculosis in people living with HIV
СЗ	On-going research on novel assays for diagnosis of tuberculosis disease Research to assess novel panel of host transcriptional markers that are able to distinguish latent and active tuberculosis disease in adults Prospective diagnostic accuracy study evaluating several candidate tests for tuberculosis in children including tests on blood, urine and stool. (HNTI PhD Ritah Nakiboneka, HNTI PhD Dr Robina Semphere)	Expected outcome; inclusion of host-response markers analysis in clinical decision making. Capacity for diagnostic evaluation used in epidemic response (Covid-19) and extended to include newer technologies such as CRISPR	Expected outcome: Research informs national and international guidance. Better characterisation of tuberculosis patients including differences in host-response markers	Expected impact: Improved diagnosis of tuberculosis disease and stratified tuberculosis care approaches
C4	Ongoing research to understand the implementation and scale up of human papillomavirus (HPV) testing using self-sampling techniques and point-of-care diagnostics for the screening of cervical cancer in Malawi (HNTI PhD, Dr Hussein Twabi)	Expected outcomes: improved algorithms for screening for cervical cancer in women. Better understanding of factors motivating women to take up HPV self-sampling	Expected outcome; scale-up of innovative ways of increasing access to cervical cancer screening, Impact on national guidelines	Expected impact: prevention of cervical cancer in at-risk women

#	Outputs	Intermediate outcomes	Long-term outcomes	Impact
#	(Research is conducted generating evidence	(New research and evidence fills knowledge	(New solutions and policies are	(The disproportionate impact and risk
				of infectious diseases is minimized in
	which is packaged and promoted)	gaps, improves understanding and drives	implemented based on supporting	
_		development of new interventions)	research evidence)	the most affected communities)
D	Genomic analysis of microbes of public			
	health importance in Malawi			
D1	Research conducted to understand lineages of mycobacterium tuberculosis prevailing in Malawi and characterization of epigenetic mechanisms influencing phenotypes of <i>M. tuberculosis</i> -related to treatment response. (8) (9) (HNTI PhD, Dr Victor Ndhlovu)	Research helped us understand that Lineages 1 to 4 were predominant lineages in Malawi, 16% and 72% respectively. In addition, discovered information that an epigenetic mechanism of methylation could influence persistence of some <i>M. tuberculosis</i> thereby affecting treatment. Establishment of platforms for sequencing and bio-informatic analysis. Conducted microbe sequencing as part of epidemic response to the 2022-23 Cholera epidemic in Malawi, with linked epidemiological research (10). Collaboration to groups conducting	Application to understanding of transmission of tuberculosis in communities. Applications to understanding in differences in tuberculosis treatment response.	Implementation of interventions to interrupt transmission. Better/ individualized treatment options
		sequencing.		
E	Research in novel treatments for infectious diseases	ooquonomy.		
E1	Randomized controlled clinical trials in Malawi with the aim to shorten the treatment of tuberculosis disease from 6 months to 3 months by optimizing doses of current agents.	Improving quality of clinical trials conducted in Malawi. Investments in laboratory infrastructure Stimulating therapeutic trials in Malawi including regulatory processes.	Improve profile of HNTI among sites able to conduct such quality trials along with leading African countries like Kenya, Tanzania, Uganda and South Africa.	Expected impact: Shortened tuberculosis treatment will impact people's lives as an estimated 18,000 suffer from tuberculosis annually in Malawi alone.
	Digital health			
E2	Ongoing randomized control trial to assess impact of digital adherence tool to improve adherence to HIV treatment among young people.	Demonstration of effectiveness of the digital adherence tool	Changes in national policies about options for dealing with adolescents not adhering to their HIV treatment.	Scale-up of application of intervention in Malawi
	(HNTI PhD, Dr Takondwa Msosa)			
	Research to design and improve the ePAL (electronic participant locator) (Malawi Tuberculosis Group)	Improved accuracy and functionality of the ePAL Electronic system	Wider applications of ePAL, such as tuberculosis spatial modelling.	Adoption of ePAL by MoH initially by the tuberculosis programme and then other departments or programmes to inform geographical spread of various health problems.
	(Malawi Tuberculosis Group)			







Continued collaboration between Helse-Nord RHF and KUHeS

A successful steering group meeting was held on 24 to 30 June 2023. The meeting included site visits to MUST and Thyolo DHO.

The Malawi leadership updated the Norwegian partners on the progress of the training pipeline, upcoming research, and other capacity building initiatives.



PhD Cohort 2023: meet the

candidates doing the PhDs

Maternal health segment:

Overview of the research

Research outcome and impact

teams in the frontlines

framework for HNTI

infections in women

Candidates present their PhD projects to partners

The HNTI PhD programme is now well underway with five candidates fully registered



Researchers engage with communities in Blantyre

The HNTI is working with communities in Blantyre to understand their health needs



Dedicated staff interact with participants at QECH

We celebrate the efforts of our frontline staff who work directly with the patients and community

2022 AND 2023



DEMONSTRATING THE LINE PROBE ASSAY a game changer in the arena of TB DST

The Helse Nord Tuberculosis Initiative is a collaborative programme between the Helse Nord RHF and the Kamuzu University of Health Sciences. The HNTI's work encompasses a wide spectrum of research areas, including evaluating new diagnostic tests for infectious diseases, community interventions, medical anthropology, molecular epidemiology and clinical trials of medical devices and therapeutics. This work is supported by a robust training programme consisting of MScs, PhDs and Postdocs and Senior Researchers.

From 2022 to 2023, there has been growth in the training programme. Over 15 MSc candidates and 4 PhD candidates have completed training and a current cohort of 5 PhD candidates is underway and conducting their research studies. The training provided by the HNTI is of the highest quality as we aim to build internationally excellent research leaders.

Over the last year, there has been consolidation of the gains in our diversified research portifolio. The HNTI continues to conduct high quality clinical research studies incorporating advanced analytical/statistical methods. Collectively the group and affiliates have over 85 publications since 2012.

Good administrative and financial systems are necessary for good conduct of clinical research. In 2022, the administrative team at HNTI has been strengthened with new trainings and new staff appointed. There is also more integration with the administrative systems of the University and we continue to advance our goal to gain recognition as a centre of excellence in infectious diseases remove their through the continue to advance our goal to gain recognition as a centre of excellence in infectious diseases remove their through their resity.

25. april 2024 - innkalling og saksdokumenter

REFLECTIONS

PROGRESS ON CLINICAL TRIALS

The HNTI has an excellent track record of conducting clinical trials in Malawi. Currently we are conducting trials that evaluate efficacy of shortened treatment of tuberculosis disease by optimizing doses of current agents. Additional trials aim to address key gaps in the arena of HIV care.

MATERNAL HEALTH RESEARCH

Planned work on maternal health has commenced. The main areas of focus are improved screening for cervical cancer in women. We also continue the provision of microbiology service to the Department of Obstetrics and Gynacology at the Queen Elizabeth Central Hospital.

COLLABORATIONS AND ENGAGEMENTS

Maintaining meaningful engagement and collaborations remains a key strategy of the HNTI. The HNTI has increased its efforts to engage with the communities that we conduct our research in. This has been achieved through meetings with lay members of the community as well as routine health workers.

The HNTI has strengthened its local collaborations with the MLW and the NTLEP. We have established new regionals collaborations with centres in Tanzania, Mozambique and Gabon. Our key oversees scientific collaborations are with the NTNU, the LSHTM, University of Amsterdam and the University of Liverpool.

ENGAGING WITH THOSE WHO MATTER

feedback meeting with the community



OUR PHD FELLOWS

MOULDING UPCOMING SCIENTISTS, RESEARCHERS, AND SCIENTIFIC LEADERS



The training programme at HNTI includes fellows at junior and senior levels. Since its inception, the HNTI has graduated six PhD candidates.

Currently, there are four PhD candidates namely Dr Robina Semphere, Dr Madalo Mukoka, Dr Hussein Twabi, and Dr Takondwa Msosa. The HNTI also supported Ritah Nakiboneka from Uganda as she conducted her research work in Malawi.

The training programme is part of the growth strategy of HNTI. The research topics of the various candidates are diverse in nature. This allows the group to grow in different directions of impact.

The training programme allows HNTI to advance the quality of its research. We believe that the current trainees will advance and move on to become independent researchers managing research studies within a centre.

The aim of the HNTI is to build research scientists in Africa who demonstrate excellent research and leadership skills.













Madalo Mukoka is a medical doctor, epidemiologist and PhD student with the London School of Hygiene and Tropical Medicine.

Her PhD focuses on designing delivery models optimized through social networks for HIV for fishermen in Mangochi. The PhD will aim to provide delivery models for such HIV services to the fishermen in their communities. The proposed start for data collection is February 2024.

Madalo is being supervised by Prof Katherine Fielding, Dr Alison Price and Dr Augustine Choko, with periodic input from social network specialist, Dr Guy Harling.









"Clustered Regularly Interspaced Short Palindromic Repeats technology offers hope for TB Diagnostics"

Robina is a medical doctor, epidemiologist and a PhD student at the Unviersity of Glasgow, under the tutelage of Dr Marriott Nliwasa, Prof Peter MacPherson and Dr Titus Divala.

Robina's PhD aims to shed light on the obstacles to healthcare access, patient retention, and treatment success in Malawi. By understanding these challenges, she hopes to pave the way for tailored diagnostic interventions that enhance care and treatment outcomes, offering hope to those affected by TB in Malawi.

She is currently in her first year and is scheduled to complete the PhD in 3 years.







Takondwa Msosa is a medical doctor and public health scientist by profession. He is a doctoral candidate at the University of Amsterdam, through funding from the European and Developing Countries Clinical Trials Partnership (EDCTP).

His PhD aims to investigate the effect of real time medication monitoring on adherence to ART and viral load suppression in young people living with HIV in Malawi.

Currently, his main study has been recruiting participants since September 2023 and it is expected that the study will be completed in June 2025, in line with the planned completion date for the PhD.

Styremøte i Helse Nord RHF 25. april 2024 - innkalling og saksdokumenter









"It is disheartening to see the high number of mortality and morbidity from cervical cancer in Malawi when the cancer is so preventable"

Hussein Twabi is a medical doctor and epidemiologist by profession. He is a doctoral candidate with the University of Liverpool under the supervision of Dr Maria Lisa Odland, Prof David Lissauer and Dr Chisomo Msefula.

His PhD is focused on understanding the implementation and scale up of human papillomavirus testing using self-sampling techniques and near point-of-care diagnostics for the screening of cervical cancer in Malawi.

He is currently halfway through the recruitment of participants in his main study for the PhD and is on target to complete by 2025.

COVID-19 self-testing work: Madalo Mukoka

Madalo Mukoka presenting her research work on Covid-19 self-testing at the 30th Conference on Retroviruses and Opportunistic Infections (CROI) in Seattle, USA.



Ritah presenting at the Union in France

Ritah is a joint PhD candidate of HNTI and University of St Andrews. She is undertaking her PhD studies investigating host response biomarkers for diagnosis of TB disease.



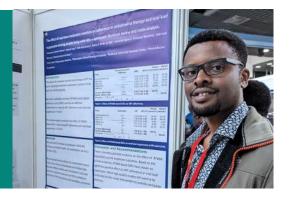
Maternal infections and sepsis: **Hussein Twabi**

Hussein presented his research on improving microbiological diagnosis of infections in maternal health in France and won the best oral talk at the KUHeS RDC in Malawi



Adolescents and HIV: Takondwa Msosa

Takondwa presented his systematic review on digital adherence tools for improving adherence to ART in adolescents at the EDCTP Forum in France and at the CPHIA in Zambia



Adults and HIV: Robina Semphere

Robina Semphere coordinates the SADAPT Trial which aims to understand timing of ART initiation following concurrent TB diagnosis and treatment in people living with HIV.



CLINICAL RESEARCH METHODS

Advancing postgraduate research skills through theoretical and practical learning processes in research methodology

Clinical Research Method is a postgraduate course aimed at equipping research students with critical skills to conduct research. The course covers Quantitative, Biomedical and Professional support modules. The course also covers hands-on experience with advanced analytical softwares required to conduct effective research.

Capacity building is at the heart of HNTI's main objectives and one activity under this initiative is offering trainings. The last Clinical Research Methods training occurred in September 2021.



Course contents:

- 1. Research questions and grant writing
- 2. Scientific writing and publishing
- 3. Computational analysis skills
- 4. Strategies of data analysis
- 5. Measures of disease and effect
- 6. Principles of clinical trials & meta analysis
- 7. Generalized linear models
- 8. Survival analysis and cox regression
- 9. Analysis of correlated/clustered data
- 10. Model building techniques
- 11. Reproducible analysis using R
- 12. Big data and machine learning
- 13. Spatial data handling and analysis
- 14. Mathematical modelling

Upcoming Clinical Research Methods

The Advanced Short Course in Postgraduate Research Methods course will be taught by researchers and academics working at KUHeS, MLW and other research and academic institutes in Malawi. The course will be conducted in **Quarter 1 of 2024**. It is designed for postgraduate students and researchers in fields such as Epidemiology, Demography, Biology, Statistics, Public Health, Computational Mathematics as well as junior faculty. The course will focus mostly on developing hands-on advanced data driven skills in R statistical software as well as scientific writing and publishing.

Leading experts in the fields of complex study designs, statistics, mathematical modelling and epidemiology will lead the development and the delivery of the course.

The course is structured in 2 and a half-hour sessions (1 hour theory and 1 and a half hour practical). Reproducible research will be at the centre of the course with R as the preferred software.



RESEARCH IN FOCUS

The HNTI is focused on conducting epidemiological, clinical and laboratory research that has impact on people's lives. Researchers at HNTI are working in diverse areas of research viz: social and behavioral sciences, community-based interventions, evaluation of accuracy and impact of diagnostics, applied genomics, digital health, and therapeutics research. To enhance international excellence each area of research establishes collaborations. Research outputs are measured in number of publications in each research area as well as capacity for training. The core funding from Helse Nord RHF has stimulated the set-up of these research areas, but researchers are required to write grants to other funders support the expanding research portfolio.

DIAGNOSTIC EVALUATION



Leverages advances in biotechnology where new tests for infectious diseases are developed. Work assesses the value of new tests on patient outcomes.

COMMUNITY INTERVENTIONS



Aimed at enhancing access to diagnostic and treatment options for infectious diseases. Interventions ensure direct impact on a population-level.

SOCIAL AND BEHAVIOURAL SCIENCES



Focuses on understanding behavioral factors affecting mental health, access to diagnosis and treatment of infectious diseases in vulnerable groups.

APPLIED GENOMICS



Researchers at HNTI conduct genomic analyses of various infectious diseases. This is enabled by improvements in sequencing capacity in-country.

RESEARCH IN FOCUS

THERAPEUTICS RESEARCH



The work here involves conducting clinical trials to assess new treatments.

The issue of emergence of drug-resistant microbes is also of concern.

DIGITAL HEALTH



Advancements in digital technologies has helped researchers to think innovatively on how to use these powerful tools to improve people's lives.

MATERNAL HEALTH



Upcoming work focussed on addressing key issues related to maternal morbidity, mortality and equitable access to health services.

CHILDREN AND ADOLESCENTS



Researchers at HNTI design and conduct studies to eliminate key disease conditions afflicting paediatric and young adult cohorts.

HNTI has a long story of successes in research and capacity building of research scientists in Malawi, showcasing a number of high impact publications and contribution towards national, regional, and global policy and practice.



TB DRUG TRIALS

MALAWI RESEARCH GROUP RANDOMIZES FIRST PATIENTS INTO TUBERCULOSIS THERAPEUTIC TRIALS

The HNTI is now conducting cutting-edge clinical research. Drs Marriott Nliwasa, Hussein Twabi and Madalo Mukoka-Thindwa are leading two randomized controlled clinical trials in Malawi that aim to shorten the treatment of tuberculosis disease from 6 months to 3 months by optimizing doses of current agents. These high-quality clinical trials are enabled by investments by the Helse Nord RHF in our laboratory infrastructure. This work puts our centre among sites able to conduct such quality trials along with leading African countries like Kenya, Tanzania, Uganda and South Africa. The trials are co-funded by the EDCTP and the HNTI. The platform is set and the HNTI is now able to investigate clinical impacts of therapeutics of various infections.



A phase 2B/C, open label trial to evaluate three treatment regimens with optimised antibiotic agents in adults with new pulmonary tuberculosis, with the primary aim of shortening treatment duration from 6 months to 3 months.

A pragmatic trial, phase 3 trial of optimized dose of rifampicin and moxifloxacin for the treatment of drug susceptible pulmonary tuberculosis, with the aim of shortening TB therapy to 4 months as opposed to the standard 6 months.



TB DRUG TRIALS



"Long treatment duration means that the patient is exposed to these drugs for a long time and as all drugs, they do have side effects and it might be uncomfortable for them.

Additionally, you have to support the patient throughout the entire six months of treatment, meaning that there is a higher cost on the health care systems as well as per-patient costs.

The regimens that we're testing have newer molecules within them, meaning that they can be more efficacious in reducing the bacterial load and killing the bacteria than our standard treatment.

Hopefully, we will thus see less relapse cases, less resistance and more completion and cure rates than we have been seeing before. The more people we cure the more we reduce the burden of disease and also reduce the risk of transmission within the community, thus feeding towards the elimination of TB agenda"

KUHES SEEKS TO ESTABLISH SHORTER DURATION TB TREATMENT REGIMENS

Scientists at Kamuzu University of Health Sciences (KUHeS) say the institution will soon begin two drug trials which seek to establish shorter Tuberculosis treatment regimens so as to lessen patients' burden of being on Tuberculosis treatment for six months and over.

During a two-day TB Research Network Dissemination Conference held from 24th October to 25th October, 2023 in Blantyre, it was disclosed that in Malawi, estimated TB incidences have declined from over 200 cases per 100,000 population in 2019 to around 115 cases per 100,000 this year.

These shorter duration regimens will enhance treatment adherence by the patients as they would be required to be on medication for a shorter period thus reducing the burden of pill taking and also financial burdens due to inability to work, frequent follow up visits and occurrence of relapse cases.

Dr Hussein Twabi who is Medical Doctor and Infectious Disease Epidemiologist and a Research Fellow at Helse-Nord Tuberculosis Initiative (HNTI), a project at KUHeS, told Malawi24 that some people find the six-month treatment so daunting.

Dr Twabi said some TB patients may not adhere to the full six-month treatment which may end up not getting the optimal treatment effect in the end, resulting in either the TB not being treated adequately or developing resistant bacteria which also result in a complication in terms of management and the direction thereof.

The Infectious Disease Scientist then indicated that KUHeS will soon begin two drug trials which are being supported by the Pan-African Consortium for the Evaluation of Antituberculosis Antibiotics with funding from European and Developing Countries Clinical Trials Partnership (EDCTP).



HNTI RESEARCH OUTCOME AND IMPACT FRAMEWORK 2012 TO 2023

Social and Behavioural Sciences

Eutputs

among the elderly, young people, anfluence the decision to test and men, sex workers and cohabiting seek treatment for TB and HIV Juderstanding factors that couples in Malawi.

concentrated in selected populations in Malawi. Innovative and effective ways of reaching such populations HIV transmission is becoming are required.

Intermediate outcomes

testing and treatment in key populations. Insights on the barriers to HIV and TB Development of tools to facilitate HIV Engagement with stakeholders. Understanding whether use of social netantiretroviral therapy

Longterm outcomes

Impact

Findings incorporated in the Malawi National HIV-self-testing policy, and World Health organization's guidelines.

self-testing in key popula-

tions such as elderly,

High coverage of HIV

young people, men, sex

workers and cohabiting

Improved HIV care in key populations.

Potential for multiple applications in HIV-self testing coverage and uptake of works is an effective way of improving

Community Interventions for Tuberculosis

Outputs

teams and door-to-door approaches Conducted a large-scale evaluation to find people with untreated TB in of community-based tuberculosis active case finding using mobile

the impact of a household contact TB TB in the community and to evaluate improve screening and diagnosis of Research to assess interventions to

screening and diagnosis.

Longterm outcomes Intermediate outcomes

ACF intervention resulted in increased detection of tuberculosis disease in the comteams and door-to-door mechanisms and munity directly detected through mobile also by improving passive case finding in the target communities

Screening provided an alternative means creased initiation of preventive treatment of diagnosis of adult tuberculosis and inin under-five children.

Informed WHO guideline revision 2021, now recommend ACF for general population.

Malawi National Tuberculosis and Leprosy Elimination Programme secured funding to implement community-based ACF

contact tracing and TB screening by the Implementation of patient-delivered National Tuberculosis and Leprosy Elimination Programme (NTLEP).

Significant reduction in TB disease burden in Malawi, demonstrated 80% reduc-Blantyre City 2011-2019. tion in TB prevalence in

Impact

adult-tuberculosis and decline in childhood tuber-Timely diagnosis of culosis disease

Clinical Evaluation of Novel Diagnostics

Outputs	Intermediate outcomes	Longi
and and omized-controlled trials conjugated and omized-controlled trials configurated to show impacts of computations and chest x-ray (CAD-CXR) to a semillar and health facility attendees as being as HIV positive individuals.	Clinical trials showed CAD-CXR improves TB diagnosis in primary care and HIV positive individuals Stimulated national interest in CAD for TB disease in Malawi.	Inform diagno diagno NTLEF scaling
by A search to understand the post implementation and scale up of HPV mesting using self-sampling and point-of-care diagnostics for the	Improved algorithms for screening for cervical cancer in women. Better understanding of factors motivating women to take up HPV self-sampling	Scale- access Impac

r.	Informed WHO Policy on TB screening &	diagnosis as well as research strategies of	FIND, leading to inclusion of Al-based	diagnostics of tuberculosis.	NTLEP and other Implementation Partners	scaling-up use of CADCXR in Malawi.
l	Inforr	diagn	FIND	diagn	NTE	scalin

Time diagnosis of TB in

Impact

term outcomes

key groups.

-up of innovative ways of increasing ss to cervical cancer screening, ct on national guidelines.

cancer in at-risk women Prevention of cervical

Digital Health

screening of cervical cancer in Malawi

Impact	
Longterm outcomes	
Intermediate outcomes	
rtputs	

Demonstration of effectiveness of the digital adherence tool. Ongoing randomized control trial to assess impact of digital adherence tool to improve adherence to HIV treatment among young people.

Research to design and improve the ePAL (electronic participant locator).

Wider applications of ePAL, such as tuberculosis spatial modelling. Improved accuracy and functionality of

the ePAL Electronic system

Scale-up of application of intervention in Malawi.

options for dealing with adolescents not

adhering to their HIV treatment.

Changes to national policies about

Adoption of ePAL by MoH departments to inform gegramme and then other initially by the TB proographical spread of nealth conditions.

Framework for the evaluation of outputs for select bodies of work undertaken by the HNTI in collaboration with relevant stakeholders.



GHRG-GI STUDY

NIHR GLOBAL HEALTH RESEARCH GROUP ON GASTROINTESTINAL INFECTIONS



Launch of GHRG-GI study at the Malawi-Liverpool Wellcome Trust in Blantyre, Malawi

Diarrhoeal diseases are responsible for over 500,000 deaths annually in children under five years of age, with the highest mortality rates occurring in sub-Saharan Africa. Diarrhoeal diseases thrive in populations with high rates of malnutrition, poor sanitary conditions and reduced access to healthcare.

Vaccines are a critical public health tool to reduce the burden of diarrhoeal diseases, but applied health research is required to enable equitable population benefit. The roll-out of vaccines such as rotavirus, cholera and typhoid has reduced diarrhoeal illness and deaths in African children, but in some populations vaccination does not work well, and vaccination is received late or not at all. Vaccines against other enteric infections are also needed.

The GHRG-GI will apply world-leading, multidisciplinary GI infection and vaccine research to build capacity and improve health outcomes from childhood diarrhoea in Eastern and Southern Africa. Areas of work include disease burden estimation, assessment of impact and cost-effectiveness of interventions and policy engagement. The GHRG GI annual meeting was held in Nairobi, Kenya in 2023, brought together collaborators from Kenya, Malawi and Ethiopia.

The GHRG-GI will make a major contribution to reducing gastrointestinal infections in sub-Saharan Africa



DR MOSES KUMWENDA

HNTI SENIOR RESEARCH FELLOW

Depression and anxiety prevent youth from productivity and innovation and from reaching their full educational and social potential.

This is critical in African countries, where 60% of the population are aged under 25. Depression and anxiety are key risk factors for self-harm and for suicide, which is the third leading cause of death in this age group.

There is increasing knowledge about ways to help youth deal with thoughts, behaviour and emotions commonly seen in depression and anxiety. These Africa Youth In Mind Project aims to improve access to mental health services by young people in Malawi, Ghana and Zimbabwe. The project is a collaboration with researchers from UK and Zimbabwe.

NIHR Global Health Research Group on Interventions for Youth with **Depression and Anxiety Disorders in African Countries**

This body of work aims to understand ways of improving the well-being of young people on the continent. He has a strong academic background and research experience. As part of the African Youth in Mind Project, this research endeavours to shed light on the unique challenges and opportunities that African youth face in the realm of mental health. Through a combination of empirical research, data analysis, and interdisciplinary collaboration, Dr Mushonga strives to contribute valuable insights to the development of effective mental health policies and interventions tailored to the African context.

Dr Rufaro Mushonga is a dedicated researcher working with the African Youth in Mind Project, addressing mental health among the youth in Sub-Saharan Africa.

DR RUFARO MUSHONGA **POSTDOCTORAL FELLOW**



SUSPECT-SEPSIS GROUP

Scientists join hands to deal with infections affecting women









Infections are a leading cause of death among women during pregnancy and delivery, as well as after delivery. Seeing the need to deal with the problem, research scientists and doctors from KUHeS, the Queen Elizabeth Central Hospital, MLW, NTNU and other partners collaborated and introduced a service to better diagnose and manage the infections.

The programme was supported by the HNTI and the Pathology Department in KUHeS. As part of the project activities, doctors from the hospital were able to send blood, urine and other samples to laboratories at KUHeS for detailed testing. These samples and their results were analysed and interpreted by specialist clinical microbiologists. The microbiologists also provided advice on the appropriate treatment options.

The project proved to be useful in the improvement of patient care. Patients were provided with appropriate diagnoses and antibiotics for their conditions. In some cases, recommendations were made to change the medications received by the patients. Part of the reason for this is the presence of drug resistant microbes. Since, current medications are not always effective, choice of antibiotics must be arrived at after appropriate testing.

The group of scientists working on the project intend to continue with the work, expanding collaborations with other partners with similar interest. The aim is to improve health and wellbeing of more women in Malawi.



IN THE FRONTLINES

BEHIND EVERY RESEARCH PAPER IS A DEDICATED TEAM

In the realm of scientific discovery, the invaluable contributions of research staff on the frontlines remain an unsung cornerstone. These dedicated individuals, often working tirelessly behind the scenes, play a pivotal role in the advancement of knowledge and the betterment of society.



COVID-19 STUDY

Staff on the COVID-19 self-testing study prepare tools in preparation for receiving partipants at QECH



care-HPV STUDY

Chikumbutso screening a potential participant for the care-HPV study on cervical cancer screening in Thyolo.



REMIND-AYA STUDY

Custodianship of research records is a key task of research assistants as demonstrated by Edred



PANACEA STEP IIC TRIAL

Expert research nurses train primary care facility health workers on the recruitment criteria for the drug trials



OPTIRIMOX TB TRIAL

Trials coordinator, Tionge Sikwese, meticulously reviewing supporting documentation for the drug trials



SADAPT STUDY

Dr Robina Semphere discusses participant eligibility for the SADAPT Study with her study nurse



Community Advisory Board (CAB)

A CAB is set-up as a committee facilitating engagement between health researchers and the community. CABs ensure that research conducted is responsive to the needs of the society



Community Meeting 1: Engagement with CBOs

The meeting brought together volunteers of various community-based organizations in Blantyre. During the meeting members of the community were informed about research and shared their priority health needs.



Community Meeting 2: Health Worker Feedback

The HNTI conducted a TB seminar with the aim of orientating health workers on TB research. This meeting was held at QECH. Participants included clinicians, nurses and laboratory technicians.



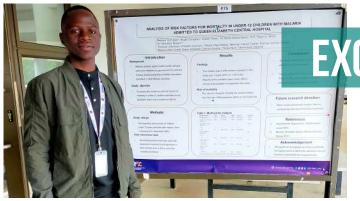
Community Meeting 3: Adolescents and Young People

Youth in society have specific needs. Through an engagement meeting, members of HNTI get to understand how best to involve youth in ongoing research.



STUDENT SUPPORT

Ongoing efforts to develop a strong research backing in undergraduate and postgraduate students



EXCELLENT MENTORSHIP

An undergraduate student presenting his work at the 2023 KUHeS Research Dissemination Conference after fruitful mentorship from Dr Takondwa Msosa

EXCHANGE PROGRAMME

Dr Madalo Mukoka showcasing the COVID-19 study to exchange students from the Norwegian University of Science and Technology who were supervised by Dr Hussein Twabi



HOLISTIC APPROACH

Exchange students from Norway interact with the project teams at a refreshing team building retreat in Thyolo, under the supervision of Dr Hussein Twabi



The project endeavours to create future research scientists and leaders through the continued support of undergraduate and postgraduate Malawian students

- inn<mark>kalling og saksdokumenter</mark>



CUTTING EDGE SCIENCE

Students of all levels have the opportunity to gain experience in advanced scientific and statistical technologies such as R for statistical analysis.



On 4th May 2021, a new university, the Kamuzu University of Health Sciences (KUHeS) started operations in Malawi following the notice of its commencement by the Ministry of Education.

The (semi) new university emerged from the amalgamation of two (former) constituent colleges of the University of Malawi (UNIMA), i.e. the Kamuzu College of Nursing (KCN) and the College of Medicine (CoM).

Kamuzu University of **Health Sciences Private Bag 1** Lilongwe @KUHeS_mw ur@kuhes.ac.mw https://www.kuhes.ac.mw/ Tel: 01 751 622 Fax: 01 756 424

> #enrollwithus #partnerwithKUHeS #futuretogether #bigger&better

KAMUZU UNIVERSITY

OF HEALTH SCIENCES

Kamuzu University of Health Sciences (KUHeS) is a comprehensive health and allied sciences higher learning institution established with the primary function of training health workers under one roof in order to promote inter-profession collaboration, team building and team work from early days of training.

The future is better with all health professionals (Nurses, Doctors, Midwives. Pharmacists, Lab scientists, Research Scientist etc.) working together, starting from early years of training.





The KUHeS Council appointed Prof. Macpherson Mallewa and Mr. Stuart Potiphar Chirambo as Vice Chancellor and **University Registrar** respectively.

THE FUTURE IS BETTER

Promoting interprofessional education.

#BIGGER&BETTER

Styremøte i Helse Nord RHF 25. april 2024 - innkalling og saksdokumenter



JANUARY 2024 ISSUE

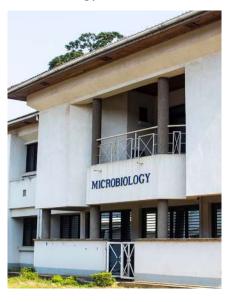


The Pathology Department is not only providing training but also high quality laboratory based research as well as service provision to hospitals in the vicinity of the University.

DEPARTMENTAL NEWS

Updates from Pathology Department

The Department of Pathology sits under the School of Medicine and Oral Health. The department is headed by Dr Tonney Nyirenda, who oversees the academic and administrative functions of the departmental units. These units include anatomical pathology, microbiology, parasitology, immunology and research units including the HNTI.





The Pathology department offers trainings in PhDs, MSc and supports undergraduate programmes. The department also intends to start trainings in Master of Medicine Pathology disciplines. The flagship fully online Masters in Health Sciences in Antimicrobial Stewardship which is hosted in the department has now seen a number of cohorts graduate. The program is designed to improve key infection related health statistics in Malawi and other countries in the SADC region by conducting research and generating evidence on the nature and extent of antimicrobial resistance with a view to designing context specific interventions for its containment.

The department would also like to share news of the on-going renovations especially the Microbiology building which will see improvements in the working environment for staff and also expansion and reorganization of laboratory spaces. The Department is also embarking on expanding its capacity to conduct specialized laboratory tests such as whole genome sequencing for various microbes.

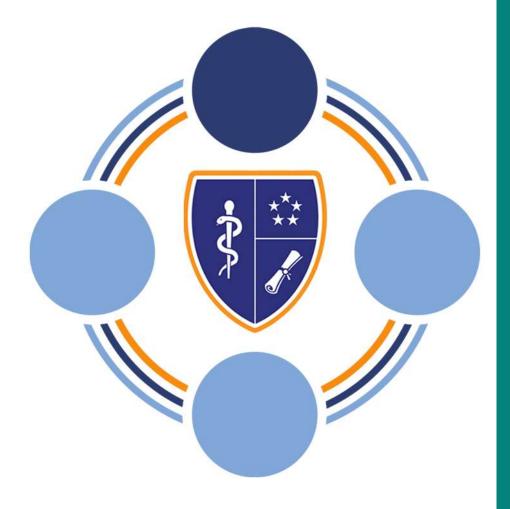
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scientific research that drives *policy* and *practice*

The Helse Nord Tuberculosis Initiative is a product of the

KAMUZU UNIVERSITY

Styremøte i Helse Fold RALTH SCIENCES 25. april 2024 - innkalling og saksdokumenter

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Current PhD candidates (2019 to 2026)

Candidate	PhD Topic	Supervisory team	Registration	Current stage	Progress on publications
			status		
Ritah	Clinical evaluation of host	Dr Chisomo Msefula	In year 4 at University of	Writing PhD thesis	One manuscript draft
Nakiboneka	transcriptional markers for tuberculosis	(Malawi), Dr Wilber	St Andrews and Kamuzu	expected defense in	available, multiple
	diagnosis and treatment response	Sabiiti (UK), Dr	University, registered a	June 2024	international conference
	monitoring in Blantyre, Malawi	Marriott Nliwasa	St Andrews on 27 Sept		presentations done
		(Malawi)	2020 and KUHeS 20 July		
			2021		
Takondwa	The effectiveness of a customised	Dr Marriott Nliwasa	Registered at University	Currently conducting	Two publications done,
Msosa	digital adherence tool on virological	(Malawi), Dr Marion	of Amsterdam on	data collection,	one manuscript in
	outcomes in adolescents and young	Sumari (Tanzania),	18 August 2022	expected to	preparation, multiple
	people living with HIV in Blantyre,	Prof Tobias Rinke de		complete by Dec	international conference
	Malawi	Wit (Netherlands)		2025	presentations done
Madalo	Using social network approaches to	Dr Augustine Choko	Registered with London	Currently conducting	One manuscript draft
Thindwa	optimize efficient delivery of Public	(Malawi), Prof	School of Hygiene and	data collection,	available
	Health interventions: Application to HIV	Katherine Fielding	Tropical Medicine on	expected to	
	and schistosomiasis services via the	(London), Prof Guy		complete by June	
	FISH cluster randomized trial in Malawi	Harling (London)	09 January 2023	2026	
Hussein Twabi	Novel screening and management of	Maria Lisa Odland	Registered with	Currently conducting	Two manuscript drafts
	cervical precancerous lesions in Malawi	(Liverpool, UK),	University of Liverpool	data collection,	available, multiple
		Chisomo Msefula	on	expected to	international conference
		(Malawi)	30 May 2023	complete by June	presentations done
				2026	
Robina	Investigating the value of novel rapid	Dr Marriott Nliwasa	Registered with	Currently conducting	Two manuscript drafts
Semphere	and ultra-sensitive diagnostic	(Malawi), Dr Peter	University of Glasgow	data collection,	available
	tests for tuberculosis in adults and	MacPherson	on	expected to	
	children	(Liverpool), Dr Titus	01-June-2023	complete by Dec	
		Divala (UK)		2026	