THE UNIVERSITY OF HEALTH AND ALLIED SCIENCES - SCHOOL OF PUBLIC HEALTH RESEARCH CENTRE

EXPERIENCES

1976-2018

(Nick Opoku)



(Tamale 1976-1987)

Following discussions between a visiting WHO team, the Ministry of Health and Tamale hospital staff in Ghana in 1976 it was agreed that:

Tamale hospital could host an Onchocerciasis Chemotherapy Research Centre (OCRC), provided essential equipment and consumables are provided.

An agreement between the MOH and WHO would ensure the viability of the Centre was then signed in 1976

The MOH provided infrastructure and seconded clinical and laboratory staff to centre and the WHO was main funder of the activities of the centre

Dr Awadzi was to set up and direct the activities of the Centre



OBJECTIVES

- 1. Primary The development of safe drugs that are effective against the adult worms of *Onchocerca volvulus* and suitable for control
- 2. Investigate any queries or questions related to the control of onchocerciasis
- 3. Act as a resource centre for scientists from local and foreign institutions
- 4. Provide support for other hospitals and institutions



(Tamale 1976-1987)

Metrifonate was suggested as the drug of choice for the first trials and initial studies with Metrifonate started in April 1977.

Successful vector control by OCP resulted by 1986 in

- the interruption of transmission
- an increase in the proportion of dead adult worms
- absence of young worms in untreated persons.
- In 1978 was agreed to relocate the OCRC to Hohoe in the Volta Region in the Eastern part of Ghana



MERGER OF OCRC WITH UNIVERSITY OF HEALTH AND ALLIED SCIENCES

Following WHO/TDR strategic shift co-inciding with end of moxidectin Phase 3 study in 2012 funding of the centre by WHO/TDR also ended in 2012.

The centre then was absorbed into the newly School of Public Health of University of Health and Allied Sciences

UNIVERSITY OF HEALTH AND ALLIED SCIENCES SCHOOL OF PUBLIC RESEARCH CENTRE (UHAS SPHRC) IN 2014

A Census of Activities

The OCRC started operations when diethylcarbamazine (DEC) was the reference microfilaricide and suramin the reference macrofilaricide.

Activities undertaken can be classified as follows:



A Census of Activities

1. Improvement in the use of established drugs

Diethylcarbamazine (DEC)

Dose finding studies and the generation of a dose-response curve

Evolution of a treatment regimen for DEC

Pharmacokinetics of radio-labelled DEC

Manipulation of the kinetics of DEC using sodium bicarbonate

Suramin

Evolution of an alternate low dose treatment regimen Pharmacokinetics of radio-labelled suramin



A Census of Activities

2. Supporting activities

Evolution of a standard method for the determination of mf densities in skin snips

Quantification of the systemic clinical reaction to microfilaricides

Quantification of ocular reactions to microfilaricides

Monitoring adult worm death by ultrasonography after suramin treatment

A Census of Activities

3. Assessment of Candidate anti-filarial drugs

Single agents

Metrifonate

Furazolidone, Nitrofurantoin

Desmethylmisonidazole

Mebendazole, Mebendazole-citrate

Flubendazole, Albendazole

Levamisole

Ivermectin

Amocarzine

Moxidectin



A Census of Activities

3. Assessment of Candidate antifilarial drugs

Combination therapy

Nitrofurantoin+DEC

Furazolidone+DEC

Levamisole+mebendazole

Levamisole+mebendazole-citrate

Levamisole+flubendazole

Levamisole+albendazole

Ivermectin+albendazole

Ivermectin+amocarzine

Ivermectin+levamisole



A Census of Activities

5. Others

The immunopathogenesis of the Mazzotti reaction to DEC, ivermectin

The ocular immunopatholgy of onchocerciasis

Evaluation of ready to use DEC patch for the diagnosis of onchocerciasis

Investigation of persistent microfiladermias despite multiple treatments with ivermectin



Institution	Field of activity
The Onchocerciasis Control Project in West Africa	Setup of centre
UNICEF/UNDP/World Bank /WHO (TDR),	Clinical trials drugs for onchocerciasis
Neglected Diseases Programme (NTDs) of the	Supervision of initial ivermectin mass
Ghana Health Service	distributions; Provision of ivermectin and albendazole
University of Ibadan, Ibadan, Oyo State, Nigeria	Clinical trials drugs for onchocerciasis
University of Nigeria, Enugu, Nigeria	Suramin pharmacokinetics
Centre for Tropical Clinical Pharmacology and Therapeutic, University of Ghana Medical School Ghana	DEC pharmacokinetics
Seth GS Medical College and KEM Hospital Acharya Donde Marg. Parel Mumbai . India	Amocarzine pharmacokinetics

Institution	Field of activity
Noguchi Memorial Institute for Medical Research (NMIMR) University of Ghana, Ghana	The entomology of suboptimal response to ivermectin
Unit of Molecular Biology, Multi Disease Survellance Centre (MDSC/BIOMOL), Ouagadougou, Burkina Faso	Evaluation of DEC patch for the diagnosis of onchocerciasis
The Liverpool School of Tropical Medicine, Pembroke Place Liverpool L3 5qa UK	Initial supervision of clinical trials Purchase of equipment and reagents software development for data analysis
The Department of Pharmacology & Therapeutics, University of Liverpool	Pharmacology of onchocercal drugs
National Institutes of Health, 9000 Rockville Pike Bethesda, Maryland 20892 USA	Immunopathogenesis of Mazzotti reaction immunopathology of ocular onchocerciasis

Institution	Field of activity
The Bernhard-Nocht-Institute for Tropical Medical, Germany	Cellular pathology-processing and reading of onchocercal nodule In-vitro drug assays against adult O. Volvulus.
McGill University Institute of Parasitology, Canada	Provision of onchocercomata and parasite material for a study of genetic markers of ivermectin resistance
The University of Alabama at Birmingham, 477 Boshell Building Birmingham, AL 35294-0012 USA	Immunopathogenesis of onchocersiasis
University of Tubingen, Geschwister- Scholl-platz, 72074 Tubingen, Germany	Examination of onchocercal nodules after collagenase digestion
Malaria Vaccine Research and Capacity Building Project in Ghana	Provision of Laboratory Support



Institution	Field of activity
DOLF Consortium	Ivermectin + Albendazole and Ivermectin + DEC + Albendazole efficacy against onchocerciasis studies
Medicines Development for Global Health	Moxidectin Registration



PROTOCOL SUBMISSION

 Clinical trial protocol needs approval from Institutional and or National Review Boards and The Ghana FDA and it usually takes over 3 months to get approvals

 Have pre-submission of the protocol meeting with the Ghana FDA.

• Submit protocol in parallel to the IRBs and Ghana FDA



RECRUITMENT

- The recruitment of patients from the out patients departments hospital yielded a heterogenous group with differing epidemiological backgrounds.
- It was essential that patients be recruited from villages in the endemic area.
- It is essential to involve chiefs and elders of communities recruitment and briefed in detail as to the aims of the project and the investigative procedures that needed to be performed
- Visits at intervals to acquaint the chiefs and elders of progress or to discuss mutual problems.



It is essential to involve National NTD programmes

LOGISTICS

- The supplies of water, electricity and fuel are erratic in our settings.
- It is difficult to keep to a planned time table if you don't have control water electricity and fuel supplies.
- Ensure you have standby ready to use generator/s for backup electricity.
- Protect essential equipment with power stabilisers (UPS)
- Store Fuel and water reservoirs
- It is better to contract this out catering and not rely on hospital catering services

STAFF RETENTION

- Clinical staff (nurses and Laboratory technician) are temporarily seconded/recruited on the trials from the hospital to support the trials.
- Conducting Clinical trials is usually NOT the primary function of most of the staff of the Institution/Hospital
- These are usually trained on the trials but when they become experience and useful and there are no immediate trials they leave or get transferred
- Ophthalmologist & Optometrist



ARCHIVING

- If the trial is successful the drug may need to be registered
- Registration inspection requires proper documentation filing and archiving of study documents.
- Start proper filing and archiving of all documents of the study from the study
- Budget for archiving



SPHRC (HOHOE)

Infrastructure

- Current infrastructure includes:
- 2 clinical studies wards
- 12 bed Capacity ward located at the School of Public Health premise
- 20 bed Capacity ward located inside the Hohoe Municipal Hospital
- Dedicated Laboratory Complex
- Ophthalmology Unit
- Minor Surgical Theatre
- A Pharmacy room
- 2 Standby Generators



Infrastructure





SPHRC (HOHOE)

EQUIPMENTS

- Current equipment includes:
- LABORATORY
 - 2 Selectra Pro M Clinical Chemistry Analysers
 - 1 Sysmex Haematology Analyser
 - 2 Refrigerated Centrifuges
 - 1 minus 80 °C Freezer & 2 minus 20 °C Freezers
 - 2 Inverted Microscopes & 2 Ordinary Microscopes
 - 1 Safety Hood



SPHRC (HOHOE)

EQUIPMENTS

- Current equipment includes:
- OPHTHALMOLOGY
 - 2 Slit Lamps
 - 1 Frequency Doubling Technology (FDT) perimeter
 - 1 Retinal photography equipment
 - 1Optical Coherence Tomography (OCT)



ONGOING STUDY

Safety and efficacy of triple drug therapy Ivermectin + DEC + Albendazole (IDA) for individuals with ocular onchocerciasis

(DOLF)

210-300 subjects



THANK YOU

