1 Introduction to the Karonga DSS Site (Karonga Continuous Registration System, CRS)

The Karonga programme began in 1978 with support from the British Leprosy Relief Association (LEPRA), as a population laboratory for evaluation of tools developed by the IMMLEP (Immunology of Leprosy) component of the WHO/TDR programme (the first skin and serological tests for M. leprae infection and an M. leprae antigen-based vaccine). It was designed initially as a large cohort study for risk factors of leprosy infection and disease, covering the entire district of Karonga (the population was selected because it had the highest burden of leprosy in that part of Africa). It assumed responsibility for tuberculosis diagnosis and treatment in the district in 1984, became the largest vaccine trial ever carried out in Africa in 1986 (comparing one versus two doses of BCG versus a combined BCG plus killed M. leprae vaccine, against both leprosy and tuberculosis) and began studies of HIV in 1987 (since which date an effort has been made to HIV test all leprosy and tuberculosis cases, and appropriate controls). The combined epidemiological and vaccine trial activities became known as the Karonga Prevention Study (KPS), by which name the project is still known. The trial codes were broken in 1995, revealing that BCG had provided appreciable protection against leprosy (50 % one dose; 75 % two doses) but none against tuberculosis.1 The trial results raised a variety of scientific questions, which, in combination with a unique sample archive and body of knowledge about the population, led to two Wellcome Trust supported programmes, first from 01/09/96 to 31/08/01 and the second (current) from 01/09/01 to 31/08/05. Throughout its history the programme has been linked closely to the London School of Hygiene & Tropical Medicine, for overall scientific direction, data management support, technical laboratory support, supplies and communication.

2 Physical Geography of the Karonga CRS

Karonga District is a rural area in northern Malawi, bordered by Lake Malawi on the east, the Songwe floodplain and river on the north (the boundary with Tanzania) and the Central African plateau and Nyika escarpment on the west and south. The terrain is varied, with a flat coastal plain along the lake, rising to hills and the plateau (c. 2600 m) to the west. The climate is appreciably wetter in the north than in the south of the District, which is reflected in differences in vegetation, agriculture and disease patterns (more leprosy, filariasis and schistosomiasis in the north). The people are of Bantu origin and include several language groups, predominantly Tumbuka in the south and Nkhonde in the northern part of the District. The population has more than doubled during the period of the project, from approximately 110,000 in 1980 and approaching 250,000 today.

The district was without effective road access until 1981. There is now good road access both to the south (Mzuzu, the capital of Malawi’s northern region, is 2.5 hours away) and to the north (Mbeya in Tanzania, c. 3 hours). Lilongwe, Malawi’s capital and site of the nearest international airport, is 592 km and 6.5 hours away by road.

The project’s headquarters are located near Chilumba, a port-village on the lake in the southern part of Karonga District. Most staff are based there, though some are based in Karonga Boma and in Kaporo, in the north.

The area of the Karonga CRS is located in the south of the district near the project headquarters in Chilumba between latitudes 10.38° and 10.50°S and longitudes 34.08° and 34.27°E and covers an area of approx. 150 km². The CRS area is unambiguously defined by the lake-shore in the east and the Nyika National Park boundary in the west, the north and the south delineation follow village boundaries. The CRS population is predominantly rural and the economy is based upon subsistence agriculture and fish from the lake. In these rural areas homesteads are scattered, however the area includes 2 peri-urban settlements, a truck stop and trading centre on the Trans-African Highway (M1) and the port-village of Chilumba where the settlement structure is dense. Approximately 5,000 population live in these peri-urban centres.
3 Karonga CRS data collection and processing

The baseline census for the Karonga CRS was started in 08/2002, and the demographic surveillance system was started in 10/2002. As of 11/2003 approx. 20,000 of the target population size of 35,000 are under demographic surveillance. Integrated into the census survey is a system of ‘census-tickets’ that is designed to facilitate the re-identification of known individuals seen in the census and also serves to update the KPS database. ‘Tickets’ and the accompanying set of booking registers are produced as an electronic report querying the database for all individuals whose last known residence is in the targeted village. The tickets of individuals who have died or left are used to record the year of death or the year of departure and the new residence.

Basic socio-economic and demographic data and data needed to define the household identity are collected on one general household form per household. Demographic and basic health data are recorded on one census form per individual. Whenever available, health documents are used to record vaccination histories for all children under 5 and to supplement information on birth dates. The survival status and residence information is recorded for the parents of all individuals.

The baseline census includes active case detection for TB (cough survey & on the spot sputum collection in suspicious cases) and a BCG-scar survey (identification and measurement of BCG scars) to link to previous work.

Mapping: The GPS co-ordinates of all households are hand recorded by the booking team during the initial census and thereafter by the interviewers for every new household registered in the CRS. Village and cluster boundaries are tracked electronically by GPS using the village headman or a delegate as a guide. A selection of roads, tracks and footpaths as well as rivers and shoreline are also recorded in the field to be used as reference points for maps. The data recorded are transferred into ArcView for editing and hardcopy maps are produced that display all main landmarks and the cluster boundaries. The maps allow the field workers to allocate new households to the correct cluster and facilitate the retrieval of existing households during demographic surveillance.

The Karonga CRS uses a key informant (KI) system for monthly vital registration and annual registration of migration. KIs are recruited in consultation with the village headman (whenever possible traditional village advisors ‘ndunas’ are selected) and grouped into reporting groups (approx. 10 KIs per reporting group). Each reporting group is trained in a formal and standardised training session after the baseline survey in the area has been completed. KIs are responsible for a geographically defined cluster comprising on average 35 households (190 individuals) and are issued with a household register that is produced from the CRS database. There is a monthly reporting session for each reporting group where the KIs meet with the CRS supervisor to report all vital events. Births are followed up by the CRS supervisor within 2 days of the report when he fills a special birth registration form. Deaths are followed up by a medical assistant at an appropriate time allowing for a 2 week mourning period. VAs are done for all deaths. The monthly follow up of all vital events triggers a complete observation of the respective household and any migrations found in the household are registered opportunistically at that time. Movements within the CRS are concluded without delay by filling the departure form at the departure household and an arrival form at the arrival household which is visited in all cases. After 11 months, a special training session is organised to prepare the reporting group for the complete registration of all migrations that have occurred since the baseline survey or the previous annual update session (AUS). In the month before the AUS, the KIs are requested to visit every household in their cluster and record any changes systematically in their household register. At the AUS, the CRS supervisor takes the reports of new households and movements; households with vital events or in-migrations are visited and the events are registered by filling the appropriate forms. Households with only departures are not visited but dealt with at the AUS by using the KIs to fill the departure forms.

All forms are returned to the data office where they are checked and processed by 3 trained coders and double entered by 2 data entry clerks. The design of the CRS data management system has proven a significant challenge since it was desired to link tightly to the project’s existing database. The KPS database originates from 2 whole population surveys of the district that were conducted in the 1980s and has been continuously maintained for 24 years. It stores the identifiers of 260,000 individuals (approximately 60% of
the population alive in the district today) whose residence and survival status has been updated opportunistically in the context of various studies conducted since the first surveys. Each individual has had on average 2.3 study contacts since the start of the project in 1979 and the project staff has developed exceptional skills and dedication to correctly identify individuals by matching information collected in the field with the details held on the database. The CRS data management system has an Access front-end and links to its private Access database and to the pre-existing non-relational FoxPro database.

A series of batch checks is run for each reporting group before their monthly reporting session and all errors or inconsistencies that cannot be corrected by the coders are returned to the field staff.

4 Karonga CRS Basic Output

The actual demographic surveillance in the first reporting group started in 10/2002 and demographic indicators of the Karonga CRS will be available once the baseline census is completed and all reporting groups have accomplished 12 months surveillance. Besides the basic demographic indicators, the Karonga CRS will provide data on cause specific mortality (obtained by VA) for all age-groups and migration data for individuals on the level of the social group and for whole households on the level of the geographical cluster.

Priority Research Areas

The current multidisciplinary research programme at KPS concentrates on three broad project areas: immunological studies comparing T cell memory and responses to BCG between infants and adults, and between Malawi and the UK; expanded epidemiological studies of tuberculosis; and the initiation of a demographic surveillance system with emphasis on HIV-related studies. The demographic surveillance system at KPS was designed to measure the impact of the HIV epidemic in Karonga District. The Karonga CRS was tailored to maximise the overlap with a population based HIV cohort study (Family Health Study) that was conducted during the previous research programme. In preparation for operational research into the modes of delivery of PMTCT the CRS area was also designed to match the catchment area of 2 ANC clinics in the south of the district. We are hoping to contribute to the assessment of the practicalities and the impact of large-scale introduction of HAART in a rural setting.

As in the previous programmes the project continues to be interested in vaccine related research and data on vaccination histories are routinely collected from all children under 5 seen in the census.

5 Capacity for Conducting Clinical Trials

Although clinical trials are not part of our current work, KPS has significant experience in conducting a TB vaccine trial in collaboration with a 2nd study site in Zambia and the National TB Control Programme, Malawi. The TB vaccine trial became the largest vaccine trial ever carried out in Africa in 1986 (comparing one versus two doses of BCG versus a combined BCG plus killed M. leprae vaccine, against both leprosy and tuberculosis, see publication list).

Potential future clinical trials at KPS would have to be designed considering the very basic standard of the district health system and may require considerable investment into clinical facilities.

6 Description of Clinical Facilities

The government clinical facilities in Karonga District are basic even by Malawian standards and KPS does not have any clinical facility of its own. However, the project used to have staff based at all hospitals and health centres in the district during the leprosy and TB vaccine trials. In the current studies staff are maintained in the district hospital and 3 other rural health facilities including Chilumba Rural Hospital (CRH) close to the project headquarters. There are currently 4 clinicians working at KPS (see staff list), 2 of which are carrying out regular clinical responsibilities in the infant study and in TB case ascertainment. The project currently employs the only radiographer and x-ray technician in the district who is based at the district hospital and splits his time between study work and routine clinical services. 12 project paramedical staff
dedicate part of their time to see referrals for skin conditions and leprosy suspects. From the census camp, KPS runs a weekly skin / TB case-finding clinic for self-referrals and patients met in the baseline census. KPS maintains close co-operation with the National TB Control Programme.

7 Laboratory Facilities at KPS

All specimens (~30 per day) are brought to the central laboratory reception area for electronic registration. This involves computer-entry of identification and test details from the field specimen form, computer assignment of lab numbers and then separation for their destination laboratory.

The free-standing Category 3 laboratory suite was purpose-built with Wellcome Trust support, commissioned in 2000 and operates to high safety standards comparable with the UK. It is used for mycobacteriology and for other high-risk samples. It is air conditioned, has two Class 1 safety cabinets, one centrifuge, 3 incubators, 5 refrigerators, 1 -70oC freezer, fluorescence microscope, sink (for slide staining) and a hand basin. The majority of the workload consists of smear (Auramine screen confirmed by ZN) and culture (Lowenstein Jensen) of M. tuberculosis (mainly sputa, 3000 per annum), fungal microscopy (KOH method), malaria films (Field’s stain, primarily for staff) and slit skin smears for leprosy (ZN).

There is an air conditioned tissue culture room within the Category 3 laboratory with one Class 2 safety cabinet and CO2 incubator, for whole blood assays of high risk samples (HIV positives, tuberculosis cases and contacts).

There is also a sterilising room with two bench-top autoclaves and wash-up facilities. All Category 3 waste is autoclaved and then burnt.

A separate Category 2 laboratory building accommodates laboratories, offices (laboratory manager’s and immunologist’s) and the computer server room.

The immunology laboratory is used for serum separation, serology (HIV by Edgware particle agglutination and Vironostika Uniform II for blood, GACEELISA for saliva; syphilis by RPR and TPPA; HSV2 by Kalon IgG ELISA) and DNA extraction (Nucleon). It contains an ELISA reader, 2 centrifuges, 2 freezers, networked computer and bench top autoclave. An attached tissue culture suite with Class 2 cabinet and CO2 incubator is used for whole blood and T cell assays of low risk specimens.

There is a air-conditioned flow cytometry room containing a 4-colour flow cytometer (FACSCalibur) for T cell immunology studies and CD4 counts.

A dedicated parasitology laboratory is used for stool (Kato-Katz and Parasept) and urine (formalised sedimentation) samples. The project has –20 and –70 freezer facilities.

8 List of Scientists

8.1 Dedicated to DSS

PI: Basia Zaba, LSHTM, UK

Karonga CRS field leader: Andreas Jahn, clinical epidemiologist, KPS Malawi

Data-management: Keith Branson, Jacky Saul, programmers, LSHTM, UK

Project Statistician: Sian Floyd, LSHTM, UK

Field Staff: 8 trained full time interviewers (baseline census, mapping, continuous demographic surveillance)

1 medical assistant to conduct all verbal autopsies

Office Staff: 2,5 trained coders, 2 trained data-entry clerks
8.2 Other KPS Projects

PI’s: Prof Paul Fine, LSHTM, Prof Hazel Dockrell, LSHTM, UK
Field director: Amelia Crampin, clinical epidemiologist, KPS, Malawi
Scientific Staff: Anne Ben-Smith, immunologist, KPS, Malawi
Frank Mwaungulu, assistant field director, medical officer, KPS, Malawi
Hazzie Mvula, paediatrician, clinical officer, KPS, Malawi
Other Malawi based staff: 2 senior technical support staff, 3 administrative staff, 15 data office staff, 20 paramedic, 5 laboratory technicians, 32 technical & ancillary staff

9 Catalogue of completed and ongoing projects

9.1 Completed Research Projects

Pre-Wellcome Trust Period: see introduction and publication list

This programme centred around four project areas: genetics of leprosy and tuberculosis; immune responses to BCG vaccine in Malawi (with comparative studies in the UK, funded by WHO and LEPRA); tuberculosis epidemiology; and HIV epidemiology

9.2 Ongoing Research Projects

SECOND WELLCOME TRUST PROGRAMME (01 Sept 2001– 31 Aug 2005):
The second (current) programme concentrates upon three broad project areas: the initiation of a demographic surveillance system with emphasis on HIV-related studies, immunological studies comparing T cell memory and responses to BCG between infants and adults, and between Malawi and the UK; and expanded epidemiological studies of tuberculosis.

9.3 Projects that have directly influenced national health policy

The ability of co-trimoxazole to reduce mortality in HIV-positive tuberculosis has been an important issue in Africa since the initial report from Cote d’Ivoire in 1999. Because of that report, controlled trials of the intervention in South Africa and Malawi were stopped as unethical, despite a lingering concern that the intervention might not be as effective in Eastern and Southern Africa as in West Africa, because of differences in opportunistic pathogens and drug sensitivity patterns. An opportunity to test the intervention arose in Karonga because of the availability of appropriate historical controls with known HIV status. The proposal was supported by DFID and the work carried out in collaboration with the National Tuberculosis Control Programme. A parallel study was carried out at the same time in Thyolo District, in southern Malawi, though without historical HIV data.

During the year 2000, all consenting HIV-positive registered TB patients in Karonga were offered co-trimoxazole prophylaxis. Co-trimoxazole was started as soon as the HIV-positive test result was known, at a dose of 960mg daily. It was administered with the anti-tuberculosis drugs under direct supervision for those hospitalised in the wards (during the intensive phase of treatment) and was given unsupervised to those taking continuation phase treatment in the community. The drug was given for the duration of one year to all study patients. For those on continuation phase, monthly supplies of the drugs were given together with their monthly supplies of TB drugs. Patients were followed up for 18 months.
Case fatality rates were unchanged between the 2 years in HIV-negative patients (suggesting the historical controls were appropriate), but fell in HIV-positive patients from 43% to 24%. The improved survival became apparent after the first two months and was maintained beyond the end of treatment. It was most marked in patients with smear positive TB and others with confirmed TB diagnoses.

Findings in Thyolo district were consistent with this. These results were presented to the National Tuberculosis Control Programme in 2002, leading to a change in national policy, recommending voluntary counselling and testing, followed by co-trimoxazole prophylaxis for all HIV positive tuberculosis patients. This policy is now being introduced in a phased manner throughout the country, with Karonga among the first districts to implement it.

10 Publications

I JOURNAL ARTICLES


32. Pharoah PDP, Pönnighaus JM, Lucas SB. Two cases of cutaneous leishmaniasis in Malawi. Transactions of the Royal Society of Tropical Medicine and Hygiene 1993; 87: 668-670.


45. Sterne JAC, Fine PEM, Pönnighaus JM, Sibanda F, Munthali M. Does bacille Calmette-Guérin scar size have implications for protection against tuberculosis or leprosy. Tubercle and Lung Disease 1996; 77: 117-123.


95. Weir RE, Black GF, Dockrell HM, Floyd S, Fine PEM, Chaguluka SD, Stenson S, King E, Nazareth B, Warndorff DK, Ngwira B, Crampin AC, Mwaungulu L, Sichali L, Jarman E, Donovan L, Blackwell JM. Mycobacterial PPDs stimulate innate immunity: Malawians show enhanced TNFα, IL-1β and IL-10 responses compared to UK adolescents (Submitted).


II LETTERS


III ABSTRACTS


16. Lucas SB, Fine PEM, Job CK, Meyers WM, Pönnighaus JM, Sterne JAC. Observer variation in the histological diagnosis of leprosy. How important is it? J Pathol 1993; 169: (supplement); 126A


35. Crampin AC, Floyd S, Glynn JR, Mwinuka V, Malema SS, Ngwira B, Fine PEM. The role of household and other contacts for tuberculosis risk in Karonga District, Malawi. 27th Tuberculosis Surveillance Research Unit meeting Munchenwiler, Switzerland, April 5-7 2001.


40. Fine PEM. Tuberculosis epidemiology and environmental influences. Abstracts of the 149th ordinary meeting of the Society for General Microbiology University of East Anglia, 10-13 September 2001. P.3-4


IV OTHER PUBLISHED REPORTS TO WHICH LEP / KPS HAS CONTRIBUTED DATA


## 11 Human Resources

### Management

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<thead>
<tr>
<th>Position</th>
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<tr>
<td>Field Director</td>
<td>Dr M Crampin</td>
</tr>
<tr>
<td>Assistant Field Director</td>
<td>Dr F Mwaungulu</td>
</tr>
<tr>
<td>General Manager</td>
<td>Mr R Hartzenberg</td>
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<tr>
<td>Administrator</td>
<td>Mr S Banda</td>
</tr>
<tr>
<td>Senior Immunologist</td>
<td>Dr A Ben Smith</td>
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<tr>
<td>Laboratory Manager</td>
<td>Mr R Dacombe</td>
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<tr>
<td>Medical Epidemiologist</td>
<td>Dr A Jahn</td>
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<tr>
<td>Paediatrician/Chief Officer</td>
<td>Dr H Mvula</td>
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### Senior positions

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<tr>
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<tbody>
<tr>
<td>Administrative Assistant</td>
<td>Mr LED Mponda</td>
</tr>
<tr>
<td>Administrative Assistant Officer</td>
<td>Ms S Chirwa</td>
</tr>
<tr>
<td>Project Secretary</td>
<td>Ms JC Mwafulirwa</td>
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<tr>
<td>Data Manager/Programmer</td>
<td>Mr S Kileta</td>
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<tr>
<td>Data office administrator</td>
<td>Mr A Nyondo</td>
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<tr>
<td>Senior Laboratory Technician</td>
<td>Mr S Chaguluka</td>
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<tr>
<td>Senior Interviewer</td>
<td>Mr SS Malema</td>
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<tr>
<td>Senior Interviewer</td>
<td>Mr VK Mwinuka</td>
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<tr>
<td>Senior LCA/Paramedic</td>
<td>Mr GK Msiska</td>
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### Technical staff

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<tr>
<td>Laboratory Technician</td>
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<td>Mr KJM Makamoe</td>
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<td>Laboratory Technician</td>
<td>Mr A Mwanyimbo</td>
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<td>Laboratory Technician</td>
<td>Mr R Ndhlovu</td>
</tr>
<tr>
<td>Laboratory Attendant</td>
<td>Ms M Thindwa</td>
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<tr>
<td>Laboratory Attendant</td>
<td>Ms J Mthunhil</td>
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### Senior positions

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<tr>
<td>Stores Keeper</td>
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<tr>
<td>Mechanic</td>
<td>Mr KG Msiska</td>
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<tr>
<td>Electrician</td>
<td>Mr CT Nyirenda</td>
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### Ancillary staff

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<tr>
<td>Messenger</td>
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<td>Messenger</td>
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<td>Camp Attendant</td>
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<td>Camp Attendant</td>
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<td>Labourer</td>
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<tr>
<td>Watchman</td>
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### Clinical staff

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<tr>
<td>Radiographer</td>
<td>Mr S Mpfande</td>
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<tr>
<td>Research Nurse</td>
<td>Ms C Chisambo</td>
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<td>Ms L Phiri</td>
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<td>Ms JT Mwaungulu</td>
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<td>Medical Assistant</td>
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### Other field staff

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<td>Ms B Kishombe</td>
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<td>Mr B Mangongo</td>
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<td>Mr G Chiona</td>
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<td>Interviewer</td>
<td>Mr E Mwanyiyehele</td>
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### Based Elsewhere

- Mol biologist (CPHL): Dr G McCormack
- Geneticist (Oxford): Dr J Fitness
- Geneticist (Oxford): Dr R Siddiqui

### Based at LSHTM:

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<thead>
<tr>
<th>Position</th>
<th>Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Investigators</td>
<td>Prof P Fine</td>
</tr>
<tr>
<td>Investigators</td>
<td>Prof H Dockrell</td>
</tr>
<tr>
<td>Investigators</td>
<td>Ms B Zaba</td>
</tr>
<tr>
<td>Immunologist</td>
<td>Dr R Weir</td>
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<tr>
<td>Immunologist</td>
<td>Dr P Gorak-Stolinska</td>
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<tr>
<td>Epidemiologist</td>
<td>Dr J Glynn</td>
</tr>
<tr>
<td>Laboratory Technician</td>
<td>Ms Maeve Lalor</td>
</tr>
<tr>
<td>Statistician</td>
<td>Ms S Floyd</td>
</tr>
</tbody>
</table>

### (1st WT Programme)

- Field Director: Dr D Warmendorff
- Ass't Field Director: Dr B Ngwira
- Immunologist: Dr G Black

### Based at LSHTM:
2 of our Malawian senior staff are funded to complete an MSc in Epidemiology at LSHTM during the current research programme, KPS is committed to continue to support local staff to assume leadership positions in research and is hoping to extend the allocation of resources for training programmes in the future.