INTEGRATION OF EXTERNAL QUALITY ASSESSMENT FOR MICROSCOPIC DIAGNOSIS OF MALARIA AND TUBERCULOSIS: FEASIBILITY IN KANO STATE, NIGERIA

Thesis submitted in accordance with the requirements of the University of Liverpool for the degree of Doctor in Philosophy

by

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DECLARATION

This thesis is the result of my own work. The material contained in the thesis has not been presented, nor is currently being presented, either wholly or in part for any other degree or other qualification.

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DEDICATION

I dedicate this work to

My Family

for their love and continuous support.

GLOSSARY OF TERMS

ACT	Artemisinin-based Combination Therapy
AFB	Acid Fast Bacilli
AKTH	Aminu Kano Teaching Hospital
APHL	Association of Public Health Laboratories
AMREF	African Medical and Research Foundation
BCC	Behavioural Change Communication
BCH	Bichi Laboratory
CDC	US Center for Disease Control and Prevention
CDP	Communication Diagnostics Programme
CIDA	Canadian International Development Agency
CSF	Cerebrospinal Fluid
DBT	Danbatta Laboratory
DC	Disease Control
DOTS	Directly Observed Treatment Short Courses
DFID	Department for International Development
ELISA	Enzyme-Linked Immunoabsorbent Assary
EQA	External Quality Assessment
EWG	Expert Working Group
FCT	Federal Capital Territory of Nigeria
FGN	Federal Government of Nigeria
FMOH	Federal Ministry of Health of Nigeria
FN	False Negative
FP	False Positive
GWZ	Gwarzo Laboratory
GZW	Gezawa Laboratory
HBP	Hasiya Bayero Paediatric Hospital
HFN	High False Negative
HFP	High False Positive
HIV	Human Immunodeficiency Virus
IEQAS	International External Quality Assessment Scheme
IDH	Infectious Diseases Hospital, Kano
IFP	International Ford Fellowship Programme
IHVN	Institute of Human Virology, Nigeria
IUATLD	International Union Against TB and Lung Diseases
KRY	Karaye Laboratory
KSHMB	Kano State Hospital Management Board
KUR	Kura Laboratory
LAPN	Labora tory Assessment Program Nigeria
LFP	Low False Positive
LGA'S	Local Government Associations
LPTP'S	Laboratory Proficiency Testing Programme

LQAS	Lot Quality Assurance Sampling
MAWSH	Muhammad abdullahi Wase Specialist Hospital
MDG	Millennium Development Goal
MDR	Multi Drug Resistance
MOH	Ministry of Health
MLSCN	Medical Laboratory Science Council of Nigeria
MMSH	Murtala Muhammad Specialist Hospital
NAA	Nucleic Acid Amplification
NAFDAC	National Food and Drug Administration Commission
NC	North Central
NE	North East
NHS	National Health Service
NMCP	National Malaria Control Programme
NMLP	National Medical Laboratory Policy
NLR	Netherland Leprosy Relief
NTBCP	National Tuberculosis Control Programme
NTBLCP	National Tuberculosis and Leprosy Control Programme
NW	North West
PATHS	Partnership for Transforming Health Systems
PCV	Packed Cells Volume
PEPFAR	President's Emergency Plan for AIDS Relief
PTB	Pulmonary Tuberculosis
PHC	Primary Health Care
PHCN	Power Holding Company of Nigeria
PV	Private Health Facility
QA	Quality Assessment
QC	Quality Control
QI	Quality Improvement
RA's	Research Assistants
RAN	Rano Laboratory
RBC	Red Blood Cell
RBM	Roll Back Malaria
RDT's	Rapid Diagnostic Tests
SE	South East
SML	Sumaila Laboratory
SOP	Standard Operating Procedures
SS	South South
SSA	Sub-Saharan Africa
SPSS	Statistical Package for Social Sciences
SW	South West
TER	Tertiary Health Facility
TB	Tuberculosis
TN	True Negative
TP	True Positive
UNICEF	The United Nations Children's Fund

UNDP	United Nations Development Programme
USAID	United States Agency for International Development
VCT	Voluntary Counselling Test
WDL	Wudil Laboratory
WHO	World Health Organization
ZN	Ziehl-Neelsen staining technique

TABLE OF CONTENTS

TABLE OF TABLES

TABLE OF FIGURES

ABSTRACT

Background: Tuberculosis (TB) and malaria are endemic and are major public health burdens in Nigeria. Sputum smear microscopy for AFB and malaria microscopy are important for laboratory diagnosis and management of TB and malaria respectively. The World Health Organization has recommended the integration of malaria microscopy Quality Assessment (QA) with that of other microscopically diagnosed diseases, but there is no published evidence about the feasibility of implementing this policy in a resource poor setting in sub-Saharan Africa.

Hypothesis: It is feasible to develop a model Quality Assessment (QA) system for malaria microscopy built on the existing TB microscopy QA system, in the context of the Nigerian health system.

Objectives: To assess the feasibility of linking malaria microscopy quality assessment into the existing AFB microscopy quality assessment system in Kano, Nigeria.

Materials and methods: Five TB microscopy centres were selected for implementing the integrated TB and malaria microscopy QA scheme in the state. A model system was designed based on the Lot Quality Assurance System for selecting and blinded rechecking of TB and malaria slides from these laboratories. Supervision and evaluation was conducted at 3 monthly intervals for 24 months.

Results: Microscopy tests made up 21% of the laboratory tests conducted in one year in Kano state. The proportion of malaria and AFB microscopy among the microscopy tests was 35.1% and 27.2% respectively. To implement the model the five laboratories selected for implementing TB and malaria microscopy quality assessments had at least one microscope and two microscopists covering both TB and malaria. Full integration of the QA for TB and malaria microscopy was achieved in two laboratories, and partial integration in two other laboratories. The system improved the quality of TB and malaria microscopy results, particularly specificity. The average specificity of TB microscopy from the five laboratories increased from 80% to 97.9% and for the two laboratories in which malaria microscopy QA was fully integrated it increased from 76.0% and 66.7% to 100%. The average specificity of malaria microscopy from the two laboratories increased from 77.8% to 80.0%. On average, the concordance rate of TB microscopy results increased from 81% at baseline to 91.0% at the final assessment. For malaria microscopy the concordance rate increased from 69.2% at the baseline, to 83.3% at the final assessment in one laboratory, but decreased from 100% to 83.3% in the other laboratory due to 16.7% false positive results. Increases in the concordant TB and

malaria microscopy results were positively associated with the ability of the laboratories to prepare and stain the TB and malaria slides. There was a decreased false positivity and false negativity rates of TB microscopy results in all the five laboratories.

Conclusions: It is feasible to integrate the QA system for TB and malaria microscopy and the assessment improved the quality of both services. However, a lot of advocacy is needed to engage all the relevant stakeholders and the integrated system needs testing out in different settings in order to be able to develop sound recommendations to guide the complex scaling up process.

CHAPTER 1

1.1 Introduction

This project aimed to design, implement and evaluate an integrated system for assessing and improving the quality of Acid Fast Bacilli (AFB) and malaria microscopy services in Kano state, Nigeria. Tuberculosis (TB) and malaria are endemic and are major public health burdens in Nigeria. Sputum smear microscopy for AFB and malaria microscopy are important for laboratory diagnosis and management of TB and malaria respectively (Mundy *et al*, 2002; WHO, 2006).

In response to the tuberculosis and malaria burdens, the Federal Government of Nigeria established the National Tuberculosis and Leprosy Control Programme (NTBLCP) and the National Malaria Control Programme (NMCP) as appropriate health intervention strategies for TB and malaria with specific objectives and goals towards achieving part of the Millennium Development Goals (MDG). The National Tuberculosis Control Programme has a system of Quality Assessment (QA) for TB microscopy which is currently implemented and managed by the Programme in collaboration with donor agencies. In contrast, the Malaria Control Programme has no system in place for the EQA of malaria microscopy in the country.

The WHO has recommended the integration of malaria microscopy QA with that of other microscopically diagnosed communicable diseases in order to enhance the accuracy of microscopic diagnosis of malaria especially in malaria endemic regions of the world (WHO, 2005a). However, the feasibility of the integration will depend on many factors, which can be determined through a situation analysis for scaling up the QA system. A review of the feasibility of linking disease control activities of malaria with other disease control activities such as elimination of lymphatic filariasis, onchocerciasis and schistosomiasis in low income countries, in order to accelerate

progress towards achieving the Roll Back Malaria (RBM) targets (Molyneux and Nantulya, 2004) concluded that linking the well funded malaria control programmes to other community directed health initiatives could greatly accelerate progress towards achieving the RBM targets. To our knowledge, the feasibility of integrating malaria microscopy Quality Assessment (QA) with that of other microscopically diagnosed communicable diseases has not been formally investigated. This project therefore aimed to design, implement and evaluate the feasibility of a model system for assessing and improving the quality of integrated AFB and malaria microscopy services in Kano state, Nigeria.

1.2 Background to the research project

High quality, effective laboratory services are essential for the diagnosis, management and control of tuberculosis and malaria diseases because accurate laboratory diagnosis plays a key role in the identification of the target population, risk stratification, implementation of targeted interventions, and tracking clinical outcomes.

Poor quality laboratory services lead to a poor clinical outcome, more hospital admissions and complications, and increase morbidity related to chronic illnesses (Emons, 2001). In developing countries especially those like Nigeria where patients pay for the laboratory tests, poor quality results also waste patients' scarce resources and those of the health service, and serve as sources of misleading public health information. Incorrect laboratory diagnosis of malaria, for example, leads to high rate of over-diagnosis and over-treatment of malaria (Amexo *et al*, 2004). Antimalarial treatment of many patients without malaria often leaves them untreated for the true cause of their illness. This results in prolonged and worsening illness, reduced productivity and school attendance, unnecessary purchase of drugs and toxicity, and economic opportunity costs of clinic visits (Barnish *et al,* 2004).

If the laboratory diagnosis of TB is unreliable, all other activities of the TB control programme will be affected. Microscopy errors are likely to result in failure to detect persons with infectious tuberculosis who will then continue to spread infection in the community. Left untreated, a person with infectious tuberculosis infects an average of 10-15 persons a year (Maher, 1999). Wrong TB microscopy results (false positive) may result in an unnecessary treatment for "non-cases". Errors in reading follow up sputum smears can also result in patients being placed on prolonged treatment, or re-treatment, or in treatment being discontinued prematurely.

Service quality in medical laboratories is influenced by a number of variables. They include the *pre-analytical* processes such as specimen collection, handling and storage, *analytical* procedures and *post-analytical* phases of the diagnostic process such as record keeping. In order to achieve the required quality in laboratory diagnosis, a national programme that supports, trains and monitors the testing performance of individual laboratories is required (APLH, 2002). A continuous system of quality assurance needs to be established within the programme comprising the internal quality control, participating in an external quality assessment schemes and the application of quality improvement measures (Paramasivan, 2003; Hertzberg *et al*, 2006).

One of the methods of QA involves sending samples on a regular basis to the participating clinical laboratories which they test as if they had come from patients. Results are returned to QA centres which provide a report that compares the participant's performance with that of all laboratories and/or groups of laboratories using the same test method(s). The results provide information on the quality of laboratory services provided in health facilities, and can be used as a regulatory tool for accreditation and registration purposes. In addition, the results can give an indication of specific laboratory activities that require remedial action. The QA exercise also provides a useful source of continuing education for the participants because the

materials used for the feedback can be stored and re-examined after the results are returned.

1.3 Justification of research question and objectives

The published laboratory QA schemes used in industrialized countries (Plebani, 2002) are not appropriate for laboratories in low-income countries because they are based on the assumption that the laboratory methods are generally automated and communication and transport systems are reliable. Developing countries need to have a broad and flexible approach to quality monitoring systems for laboratory services (Mundy *et al*, 2002). My project was designed with a significant degree of flexibility so that it would suit the local health system in Nigeria. The study aimed to produce a model quality assessment system together with a proposal for implementation in the health facilities within the state, and possible scale up across the country. The model will contribute to recommendations to state health administrators about the mechanisms and support systems necessary to provide sustainable high quality laboratory diagnosis of tuberculosis and malaria.

1.4 Hypothesis, aim and objectives of the project

The hypothesis of this project is that it is feasible to develop a model QA system for malaria microscopy from the existing AFB microscopy QA system, in the context of the Nigerian health system. Because of limited human resources and logistic support such as transport and communication, it may be beneficial to integrate QA process for malaria and TB microscopy. In an integrated system, activities such as monitoring visits, slide sampling and re-reading, and feedback mechanisms could be combined for malaria and TB microscopy.

This project aimed to design, implement and evaluate an integrated model system for quality assessing and improving TB and malaria microscopy services in Kano State, Nigeria.

1.5 Specific Objectives

1. To conduct a baseline assessment of medical laboratory service in Kano state to identify the laboratory administration, types of tests conducted and related workload, number, categories and distribution of laboratory personnel, state of basic equipment, safety issues, test procedures and methods of quality control and how these relate to TB and malaria microscopy in public health facilities in the state.

2. To compare the existing laboratory services in Kano with the recommendations of the national medical laboratory policy (FMOH, 2007) in order to identify the conformities and any deviations from the national policies and to identify the major constraints on the existing medical laboratory services for TB and malaria microscopy in Kano.

3. To design, implement and monitor quality assessment of TB microscopy followed by a systematic development and integration of malaria microscopy quality assessment into the TB microscopy quality assessment system.

4. To evaluate the impact of quality of TB microscopy and malaria microscopy services in the laboratories involved in the integrated system.

5. To assess the feasibility implementing of the proposed integrated system in the rest laboratories in Kano state and make recommendations about its sustainability at state level and national scaling up.

1.6 Project Design

A considerable degree of flexibility was made in the project design in order to accommodate inputs from the local stakeholders of laboratory services in Kano state. For instance the selection of project sites and the methodology of data collection were made in close consultation with laboratory staff and health administrators in Kano state. This was done in order to ensure that the project plan would be workable in Kano state health system. The project was conducted in three phases:

Phase 1: April 2005 – December 2005

- Consultation with officials of the Kano State ministry of health and senior laboratory scientists, modifications of project design, selection and modification of methods and instruments for data collection.
- Baseline assessment of laboratory services in public health facilities in Kano State.
- Selection of laboratories for project implementation in Kano State.
- Situation analysis of TB and malaria microscopy services in the selected laboratories.
- Determining the baseline qualities of TB and malaria microscopy in the selected laboratories.
- Development and piloting of a feedback mechanism on the quality of TB & malaria microscopy in the selected laboratories.
- Project review and finalization of QA design and project planning and modification of intervention strategies (September - December 2005).

Phase 2: January 2006 – March 2007

- Implementation and monitoring of the QA of TB microscopy using blinded re-checking technique in the selected laboratories (January 2006 – January 2007).

- Development and integration of malaria microscopy quality assessment into the existing TB microscopy quality assessment system (October 2006 to March 2007).

Phase 3: March 2007 – April 2007

- Project Evaluation: Evaluation of the impact of the implementation of the quality assessment system and the analyses of variables such as sputum smear / blood film preparation and staining that may be associated with the quality of TB and malaria microscopy.
- Comparison of the final assessments of results agreement, quality of smears / blood films, quality of staining, sensitivity and specificity were compared with the baseline results in order to identify the areas of improvement or otherwise.
- Evaluation of the success of the integration of TB and malaria QA system in the selected laboratories.

1.7 Thesis presentation

This thesis is presented in eight chapters. Chapter 1 presents an introduction to the research question, aim and objectives, outline of the project design and a brief description of the contents of each of the thesis chapters.

In Chapter 2, is a literature review which presents an overview of the disease burdens due to tuberculosis and malaria globally is presented. The importance, principles and methods of assessing the quality laboratory tests are discussed with a focus on tuberculosis and malaria. A review of external quality assessment (EQA) systems for TB and malaria in developed countries and in some African countries is presented. The feasibility of integrating the QA systems for TB and malaria under control programme condition is highlighted.

Chapter 3 provides the country context for the project and presents a brief background to Nigeria together with the description of the disease burden of TB and malaria in Nigeria. The Nigerian policies, strategies different levels of control and laboratory services in tuberculosis and malaria are discussed. A summary of the general situation of TB and malaria diagnostics in the context of Kano state is presented.

In chapter 4, a detailed method for conducting the baseline assessment medical laboratory service in Kano state is presented. Detailed accounts of the strategies in developing and implementing an EQA system for TB and malaria microscopy are presented. The methods of data collection, analysis, results presentation and project evaluation are described.

In chapter 5, results of the baseline assessment of laboratory capabilities in Kano state are presented and compared with the recommendations of the draft national medical laboratory policy to identify the conformities and any possible deviations from the national policies and the major constraints of the existing medical laboratory services in Kano. A summary of the situations for TB and malaria microscopy services in Kano state is presented.

In chapter 6, results of the quality assessment of TB and malaria microscopy services in five laboratories are presented. The process of the strengthening of the quality assessment system for TB microscopy and the development of TB – Malaria microscopy integrated QA system are presented. Evaluation of the results is presented as a comparison of the indices of quality assessment before the commencement of this project (baseline) and at the end of the project (final assessment) as well as the success and difficulties of integrating the TB and malaria QA scheme in the selected laboratories

Chapter 7 presents the discussion of findings of this project. The discussions are presented in three sections: baseline assessment of laboratory services in Kano; implementation and monitoring of quality assessment of TB microscopy using blinded re-checking technique in the selected laboratories and systematic development and integration of malaria microscopy quality assessment into the existing TB microscopy quality assessment system; evaluation of the impact of QA on quality of services in AFB and malaria microscopy in the selected laboratories.

Chapter 8 presents a review of the project according to the specific objectives of this study. The main findings under each of the five objectives are presented together with the achievements and difficulties encountered conclusions and recommendations on its implementation at the state level and possible national scaling up. Some suggestions for modifying the national laboratory policy are also given.

CHAPTER 2

LITERATURE REVIEW

2.0 DISEASE BURDEN, CONTROL STRATEGIES AND LABORATORY SERVICES FOR TUBERCULOSIS AND MALARIA

2.1 Introduction

Malaria, tuberculosis (TB) and HIV/AIDS are major public health burdens in low-income countries such as Nigeria. Although these diseases can be prevented, treated and controlled, they kill more than six million people every year (The Global Fund, 2004). It is an object of the MDGs to halt and begin to reverse the incidence of malaria, spread of HIV/AIDS and to promote tuberculosis case detection and cure under the Directly-Observed Treatment Short Courses policy (DOTS) (UNDP, 2006).

2.2 The burden of tuberculosis

Tuberculosis is a leading cause of disease and death globally, with approximately 2 billion people infected, causing 2 million deaths annually. TB is the seventh leading cause of death worldwide, second only to HIV/AIDS among infectious diseases (Keeler *et al*, 2007). Between 1990 and 1997, the number of new TB cases increased from 7.5 million to 8 million cases. Currently there are 8.4 million new cases of TB worldwide (Kim *et al,* 2007), 95% of which are in developing countries. In these regions, disease and death from TB occur mostly in the economically active segment of the population. The case numbers continue to rise in much of the sub-Saharan Africa, where HIV is endemic. In Eastern Europe there is an increasing burden of TB, which is associated with poor treatment outcomes due to multi drug resistance (MDR) (Keeler *et al*, 2007). The global burden of TB amounts to approximately $12 billion annually. Tuberculosis kills more women annually than all the causes of maternal mortality combined (Kim *et al*, 2007).

2.3 The burden of malaria

Malaria is one of the most serious health problems facing the world today (Carrington, 2001) and its burden is compounded by the resistance of malaria parasites to the first line antimalarial drugs (chloroquine, amodiaquine or sulfadoxine-pyrimethamine) and the introduction of newer drugs that are relatively more expensive and more toxic than the first line antimalarial drugs (Goodman et al, 2003). The World Health Organization estimated that over 300 million cases of malaria arise each year, with approximately two to three million deaths (Insight Health, 2006; Carrington, 2001). About 40% of the world's population living in the poorest countries is at risk of malaria infection (Amexo *et al*, 2004).

The malaria health burden is an important cause of morbidity and mortality as well as economic loss. Around 90% of the estimated 300 million new clinical cases of malaria per year occur in sub-Saharan Africa (SSA). In SSA, malaria is the single most important infectious disease in children, being responsible for the death of about 1 million children per year (25% of all childhood death) (Goodman et al, 2003). Africa bears the vast majority of the human and economic cost of malaria worldwide (BBC Focus on Africa, 2005). Annually malaria costs African countries between US$10 billion to US$12 billion in lost domestic product even though it could eradicated for a fraction of that amount (BBC, 2005). The economic growth in countries with a high level of malaria transmission is significantly lower than countries without malaria.

The severe form of malaria accounts for the majority of hospital admissions of young children in malaria endemic areas (Goodman *at al* 2003). The morbidity and mortality due to malaria (caused by *Plasmodium falciparum* infection) are associated with economic losses which have direct social and economic consequences. As a result of malaria, children spend days away from school and adults lose workdays (Goodman *at al* 2003).

2.4 Control strategies for TB and malaria

2.4.1 Tuberculosis control

In 1993, the WHO declared TB a global emergency, and prompted the Directly Observed Treatment with Short-course chemotherapy (DOTS) strategy for TB control. In DOTS strategy, health workers or volunteers form a close bond with their patients to help them successfully complete treatment (Kim *et al*, 2007). The DOTS strategy focuses on the passive case-finding of infectious pulmonary TB, which typically occurs when the patient presents with persistent cough (WHO, 2003a).

Without treatment, an estimated 70% of people with infectious TB will die. Although weak TB-control can decrease mortality, they have less impact on morbidity, as many people remain chronically ill. However, DOTS can rapidly reduce both mortality and morbidity from TB, often curing over 85% of patients. Since curing TB prevents the infection of others, it serves an important preventive function as well, breaking the chain of transmission (Kim *et al*, 2007). DOTS has five key elements (Keeler *et al*, 2007):

1. Government commitment to a sustained TB control activities.
2. Case detection by sputum smear microscopy among symptomatic patients self-reporting to health services.
3. Standardized treatment regimens lasting at 6-8 months for all confirmed sputum smear- positive cases, directly observed for the initial 2 months.
4. A regular, uninterrupted supply of all essential anti-TB drugs.
5. A standardized recording and reporting system that allows assessment of treatment results for each patient and of the TB control program overall.

2.4.2 Malaria control

The global community has committed itself to halving the morbidity and mortality from malaria worldwide by 2010 through the Roll Back Malaria (RBM) initiative (Goodman *et al*, 2003; Molyneux and Nantulya, 2004). RBM came as a result of the commitment

by the WHO in collaboration with UNICEF, UNDP and World Bank to initiate the project targeted at reducing the burden and mortality of malaria in African region by 50% by the year 2010. The African leaders resolve to initiate appropriate and sustainable action to strengthen the health system to ensure that by the year 2005:

- At least 60% of those suffering from malaria have prompt access to, and are able to correctly use, affordable and appropriate treatment within 24 hours of the symptom.
- At least 60% of those at risk of malaria, particularly children under five years of age and pregnant women benefit from the most suitable combination of personal and community protective measures such as ITN and other interventions which are accessible and affordable to prevent infection and suffering and
- At least 60% of all pregnant women, who are at risk of malaria, especially those in their first pregnancies, have access to chemoprophylaxis or presumptive intermittent treatment.

The current international strategies on malaria control focus on prompt access to treatment, presumptive treatment for pregnant women, and use of Insecticide Treated Nets (ITN). The international organizations recommended an effective and affordable treatment for all cases of malaria within 24 hours of onset of illness. Policies were made that recommend home treatment of all childhood fevers as malaria in malaria high-risk settings (Amexo *et al,* 2004).

2.5 Laboratory diagnosis of TB and malaria

2.5.1 Laboratory diagnosis of TB

The diagnosis of pulmonary tuberculosis is centred on the sputum smear microscopy of three stained sputum samples (WHO, 2003a). The sputum smear microscopy targets the most infectious cases (sputum smear positive) and is highly specific in most high-prevalence setting (Keeler *et al*, 2007). The availability and quality of sputum smear

microscopy in turn relies on the national programmes that support, train and monitor the testing performance of individual laboratories (APHL, 2002).

The WHO recommended that in the early phase of development of a laboratory service for TB in a high prevalence country the most economical and cost effective arrangement is as follows (WHO, 1998):

1. Establishment of ZN microscopy in small, multi-purpose public health laboratories. One microscopy centre per 100 000 population is usually sufficient to attain the target of 2 – 20 ZN smears per day.
2. Establishment of fluorescence microscopy at the regional laboratories where more than 100 smears are examined per day. One fluorescence microscopy centre per 500 000 to one million population is usually sufficient. However, this is much more strongly dictated by the daily case load than by the actual population covered.
3. Establishment of TB culture facilities at the regional or central level, to cover 500 000 to one million population.
4. Establishment of a central laboratory at the national or regional level, to cover 10 million or more population.

One advantage of sputum smear microscopy is that it is simple and yields timely results with a very high sensitivity of detection of tubercle bacilli transmitters. Sputum smear microscopy is also inexpensive to perform, very specific in high prevalence settings and detects the most infectious subset of patients (IUATLD, 2000). In low income and high tuberculosis prevalence countries, sputum smear microscopy is, and is likely to remain for the foreseeable future, the only cost-effective tool for diagnosing patients with infectious tuberculosis and to monitor their progress in treatment (IUATLD, 2000).

The limitations of sputum smear microscopy include its requirement for microscopes and the difficulty of maintaining them in poor settings. The results often have low sensitivity and under programme conditions, obtaining quality results requires the serious attention of trained and motivated laboratory staff (Keeler *et al*, 2007). This has resulted in a relatively very low case reporting of smear-positive TB cases. These problems limit both the extent and quality of its application and in turn its impact on TB control. Test sensitivity is also limited in many patients with ex-pulmonary TB (sputum smear negative) who have <10,000 AFB per ml of sputum, and are therefore missed by sputum smear microscopy (Keeler *et al,* 2007). Moreover, sputum smear microscopy requires the collection and laborious examination of many samples, and because of consequent delays many patients do not return for results (Squire *et al*, 2005).

Advances in the development of alternative diagnostic tools for tuberculosis have been reviewed (Perkins, 2000). The alternative diagnostic techniques that may have relevance for tuberculosis endemic countries include:

- Serological tests for detecting IgG or other immunoglobulin classes in dipstick or ELISA
- Tuberculin skin test to detect latent infection
- Radiometric liquid culture system
- Phage replication system that detects live mycobacteria in clinical samples or in young liquid cultures using phages that infect and replicate in mycobacterial cells as indicators
- Molecular detection of rifampicin resistance
- Nucleic acid amplification (NAA) assay

These diagnostic tests might have a significant impact on disease control by promoting rapid case detection, thereby reducing period of TB transmission (Perkins, 2000).

However, these tests offer limited benefits in the developing world, due to the constraints on their effectiveness and the infrastructure required (Keeler et al, 2007). Culture is the most sensitive method for detecting TB, but can take several weeks to yield results and demands advanced technical infrastructure that is not readily accessible in any countries (Cunningham *et al*, 2004).

Radiographic examination can detect some smear negative cases of TB. The radiographic appearance of mycobacteria is, however, not uniform and image interpretation is subject to observer error. This limits the sensitivity and specificity of X-rays in the field (Keeler *et al*, 2007). Sputum smear microscopy therefore remains the only cost-effective tool for diagnosing patients with infectious tuberculosis and is a pillar of the global strategy to control the disease.

2.5.2 Laboratory diagnosis of malaria

Microscopic examination of stained blood smears continues to be the method of choice—the gold standard—for confirming a clinical diagnosis of malaria and epidemiological studies (WHO, 2000a, 2004a). The WHO recommended that a laboratory test should be used to confirm the presence of parasites in most epidemiological situations. However, if this is not logistically possible for all suspected cases of malaria, laboratory diagnosis to confirm the presence of parasites is particularly desirable in all suspected cases of treatment failures and severe disease, as well as for diagnosing uncomplicated malaria during low transmission seasons (WHO, 2005a).

However, in sub-Saharan Africa, more than 80% of individuals with malaria self treat fevers with antimalarial drugs without seeking help from health sectors (Barnish *et al*, 2004). Cases of malaria in both adults and children are presented to health centres only when self treatment fails, and even then they do not receive a good quality diagnosis. Diagnosis of malaria at peripheral health centres, where there is lack of laboratory

facilities, is based solely on clinical features such as fever (Amexo *et al,* 2004). This approach is sensitive, but has very low specificity. As a result, malaria can be over-diagnosed considerably, while other febrile diseases are overlooked and not treated in a timely manner (WHO, 2005a).

Malaria microscopy, which is the gold standard for the diagnosis of malaria, is often not used and has an accuracy of only 70 – 75% in routine practice (Amexo *et al*, 2004). Without an effective quality assurance system for malaria microscopy, there is still no guarantee that all of the patients given antimalarials at the secondary and tertiary level of health care really had malaria.

Many Rapid Diagnostic Tests (RDTs) for malaria are currently available and are increasingly being used in the field. The principle of RDTs base on the identification of *P. falciparum* specific histidine-rich protein II (HRO2), parasite-specific lactose dehydrogenase (pLDH) or pan-specific aldolase (Rafael *et al*, 2007).

The potential advantages of RDTs include:

- In paediatric hospital, use of RDTs led to an improvement in case management, allowing rapid (within 20 minutes) diagnosis of malaria and better targeting of malaria treatment.
- RDTs can be used by first-line health workers at primary health care facilities
- The use of RDTs can be economically justified under specific conditions. The cost saving of malaria management with RDTs depends on a combination of factors such as the epidemiological pattern of malaria, the performance of the test and the recommended treatment regimens.

The potential disadvantages of RDTs include:

- Variable performance and degeneration at high storage temperature and high cost.
- RDTs that detect HRP2 antigen pose further problems as the antigen can remain in the blood for 3 weeks following successful treatment, hence confounding diagnosis when patients present with multiple fevers in a short time frame (Rafael *et al*, 2007).

Based on their higher sensitivity, greater stability and lower cost, HRP2-based tests are preferred for areas of stable malaria like Nigeria, where *P. falciparum* represents at least 90% of all malaria infections (WHO, 2004). A study on the detection threshold of three HRP2-based RDTs (Gon-Malaria, Accu-Stat Malaria and SD-Bioline) in Nigeria, suggests that the kits have good detection threshold and are suitable for use in *P. falciparum* malaria diagnosis in peripheral health facilities lacking trained microscopists. (Abubakar *et al,* 2004).

2.6 The need for quality assured laboratory diagnosis of TB and malaria

Timely and accurate diagnosis of both TB and malaria in patients and providing them with an appropriate treatment is essential for reducing disease burden and its related consequences as well as transmission in the community (Maher, 1999; Paramasivan, 2003). For diagnosis, the impact of errors in TB and malaria microscopy can be measured as the number of truly positive cases missed due to false-negative reading error as well as the number of truly negative 'non-cases' who were erroneously started on treatment due to a false-positive reading error. For treatment, the impact can be measured by examining the number of cases who received TB or malaria treatment due to false-positive reading error, or in TB treatment, the number of cases who are

inappropriately changed to continuation phase therapy or whose treatment is discontinued prematurely due to false-negative reading error (Nguyen, 1999).

The need and importance of accurate laboratory diagnosis of malaria have become acute with the spread of resistance of malaria parasites to the currently used antimalarial monotherapies (CQ, SP or amodiaquine) and the introduction of new more expensive ACT drug treatment. ACTs cost at least 10 times more than chloroquine, amodiaquine or sulfadoxine-pyriethamine. It is therefore more cost effective to improve the accuracy of malaria diagnosis so that these drugs are only used for confirmed cases of malaria (Amexo *et al*, 2004). Even where diagnostic test for malaria are not cost-saving, they could be considered cost effective if their use led to a significant improvement in case management (Goodman *et al*, 2003). Treating uncomplicated malaria with ACT without laboratory confirmation may have the following implications could result in the over-diagnosis of malaria and the irrational use of newer drug combinations for malaria (Amexo *et al*, 2004; Barnish *et al*, 2004)

The misdiagnosis and incorrect treatment for TB and malaria that may occur in the absence of laboratory tests or wrong results are wasteful in both time and resources, for patients who have to travel long distances for second or third visits, and when multiple drugs are prescribed by health workers who are unsure of a diagnosis. Poor quality laboratory tests therefore not only waste patients' scarce resources and those of the health service, but are also detrimental to the patient and a source of misleading public health information. It is therefore essential to establish, maintain and demonstrate the accuracy of TB and malaria diagnostic tests for all laboratories.

2.7 Methods of external quality assessment for TB and malaria microscopy

The published literature on the external quality assessment of sputum smear microscopy from different regions of the world including Africa is more extensive than the published literature on malaria microscopy EQA schemes. The approaches to EQA for TB and malaria microscopy are broadly categorized into three: 1) Panel testing, where centrally prepared smears / blood films with known results are sent out to laboratories of a network for external quality assessment. 2) Rechecking at a higher level, of routine examined smears / blood films from peripheral laboratories and 3) on-site evaluation or supervision of laboratory activities which is a complementary activity to each of the other two approaches.

2.7.1 Panel Testing

Panel testing is an EQA scheme where participating laboratories are sent samples at some defined intervals. The samples are tested the same as routine samples from patients. The test results are evaluated at the central EQA laboratory that is administering the EQA and returned to the participating laboratories with a report that compares the participant's performance with that of all the laboratories using the same test method(s).

Panel testing was applied in India in the quality assessment studies in eight state tuberculosis laboratories (Paramasivan *et al,* 2003). Coded panels of stained sputum smears with different grades of positivity, were sent from the central laboratory to the TB microscopy centres at 6-monthly intervals. The results were analyzed for agreement, as well as discordance. Panel testing was also use in the external quality assessment in the examination of blood films for malarial parasites within Ontario, Canada (Thomson *et al*, 2000). Samples consisted of blood films (Romanowsky stained and cover slipped) from cases submitted by participating laboratories. Survey results were reported with use of codes representing descriptive features and clinical deductions that would be

reported on clinical samples. Results were evaluated by Laboratory Proficiency Testing Programme (LPTP)'s scientific committees, and assessment of errors was based on clinical importance. Panel testing was also applied in developing an external quality assessment programmes for primary health in resource limited countries namely Tanzania, Kenya, Southern Sudan, Uganda and Somalia (Carter *et al*, 2002). Under a laboratory programme of the African Medical and Research Foundation (AMREF) external quality assessment scheme (EQAS), materials for parasitological, microbiological and haematological investigations were prepared from specimens obtained from patients. A total of 81 laboratories participated in the scheme from 1993 to 2000. Each participant was provided with their results together with the highest and lowest results of the other participating laboratories (anonymously) (Carter *et al*, 2002).

Advantages:

- Panel testing helps in evaluating the performance of individual laboratories.
- Provides an educational benefit of participation. For instance, it allows the development of recommendations and educational workshops to improve the standard of laboratory services. The materials used for the feedback can also be stored and re-examined after the results are returned.
- Provides valuable information for health administrators on the quality of services provided in health facilities, and can be used as a regulatory tool for accreditation and registration purposes. In addition, the results can give an indication of specific laboratory activities that require remedial action.
- Helps to monitor changes in performance between 2 assessment periods.

Disadvantages:

- This method is considered to be less efficient than rechecking because its results are not necessarily representative of routine performance and it is less motivating than blinded rechecking.

- Requirement for a reference laboratory capable of preparing the panel of slides and a mechanism for distributing the slide sets to peripheral laboratories without breakage or loss (mail, courier).
- Requirement for adequate funds for sending the slide set to intermediate and peripheral laboratories and returning slide sets to central laboratory for a review if necessary.

2.7.2 Blinded rechecking

Blinded rechecking is a process of rereading a sample of slides from a laboratory to assess whether that laboratory has an acceptable level of performance. This method requires a strong and consistent support from a national control programme for its implementation and sustenance. Blinded rechecking is the EQA method that provides evidence that a country has an effective TB microscopy laboratory network supporting DOTS and was recommended TB control programmes (APHL, 2002). However, blinded re-checking and panel testing were both shown to be viable measures of laboratory performance in TB microscopy DOTS (Martinez Guarneros *et al* 2002).

Blinded rechecking was used in the quality assessment of sputum microscopic examinations in southern Ethiopia. Routine slides collected from the TB peripheral laboratories were rechecked in the regional and the central laboratory to evaluate the level of agreement in reading of sputum smears (Shargie *et al*, 2005). In case of agreement between the peripheral and regional laboratory readings, the regional laboratory results were taken as final results. Slides with discordant readings were re-read at the central laboratory, and results from the central laboratory were considered as final results (Shargie *et al*, 2005).

Blinded rechecking was also used in the first broad quality assessment of sputum smear microscopy in peripheral health care facilities in Dar es Salaam, Tanzania (Basra *et al*,

2006). Slides randomly selected from the laboratory register were re-read by a second and third reader without sharing results, and discordance between these readers was resolved. Agreed results of reader two and three were regarded as a reference and were compared with those of a peripheral reader.

Two different approaches of implementing blinded rechecking EQA scheme were demonstrated in the studies from Ethiopia and Tanzania. While regional and central laboratories were used as the second and third readers in Ethiopia, two microscopists in the same laboratory were used for the same purpose in Tanzania. This demonstrates the flexibility of the blinded rechecking method and its applicability under different health settings.

In blinded rechecking schemes, feedback on the smearing and staining qualities together with the final AFB microscopy result at the reference laboratory were sent regularly to the peripheral laboratories for remedial actions.

Advantages

- It is the standard method for monitoring laboratory performance over a defined period of time and reflects the reality of routine performance.
- The method can be adopted by in both TB and malaria control Programmes .
- Suitable for the relatively low level of workload for the district laboratories
- Motivates improved daily performance as the technicians are expecting visits by the supervisors.
- Blinded re-checking was recommended as the most efficient procedure for making the first broad assessment of sputum smear microscopy services (Basra *et al*, 2006).

Disadvantages:

- The requirements for mobilization and complex logistic support

2.7.3 On-site supervision

On-site supervision involves on-site inspection of basic laboratory materials for TB and malaria microscopy services, quality control and other aspects that may have impact on the quality of the services such as the training need for microscopists. It is a complementary activity to panel testing and blinded rechecking procedures. On-site evaluation also involves a technical assessment of the quality of the material (sputum or saliva), of smearing (thickness and size), and of the staining.

The process involves the use of a standardized checklist to assess peripheral laboratories for tuberculosis diagnosis. A standardized checklist was used to assess and improve the supervision and performance of sputum smear microscopy in 48 TB diagnostic units in Ugandan Districts (Aziz and Bretzel, 2002).The situational analysis of the peripheral diagnostic units at the beginning and at the end of the study showed a marked improvement in laboratory performance in all aspects related to sputum smear microscopy. The systematic use of a standardized laboratory checklist was considered an important step forward in improving the performance of the peripheral laboratories in Uganda through on-the-spot correction of any identified shortcomings (Aziz and Bretzel, 2002).

The EQA schemes are applied widely in both developed and developing countries around the world with the same objectives but different approaches. The EQA schemes used in industrialized countries and published in the literature are not appropriate for rural laboratories in low-income countries because they are often based on assumptions that the methods are generally automated and communication and transport network are reliable. These systems are therefore too complex for a workforce in a weak health system (Bates and Maitland 2006) where laboratories face numerous constraints to providing quality services, including poor selection of techniques, difficulties in

equipment availability and maintenance, and shortages of supplies, staffing and supervision (Carter *et al*, 2002). Designing a quality assessment system by which the analytical system can be monitored and evaluated, therefore, remains a major challenge for most laboratories in low income countries with weak health systems. The need for devising workable methods with a broad and flexible approach for externally monitoring test results from laboratories have been highlighted (Mundy *et al*, 2002).

2.8 Feasibility of integrating TB and malaria microscopy quality assessment mechanisms

The WHO has recommended the integration of malaria microscopy Quality Assessment (QA) with that of other microscopically diagnosed communicable diseases in order to enhance the accuracy of microscopic diagnosis of malaria especially in malaria endemic regions of the world (WHO, 2005a). However, there is no published literature on a QA system that integrates malaria and tuberculosis microscopy. The feasibility of the integration will depend on many factors, which can be determined through a situation analysis for scaling up the QA system.

Tuberculosis and malaria share a common method of laboratory diagnosis by microscopy. It could therefore be feasible to share some activities of quality assessment for malaria and tuberculosis microscopy. There are particularly good examples of local quality-assurance systems designed to evaluate testing in tuberculosis control programs that could be expanded to include the malaria microscopy and further extended to other essential laboratory investigations, such as haemoglobin and transfusion- related tests (Bates and Maitland, 2006).

While the integration potentially has many advantages, it also could encounter many constraints such as:

- Integration must be proven to be necessary and cost-effective, leading to health and financial benefits.
- requirement for an integrated management system, trained QA staff who are capable of supervising and evaluating a multi-disease QA programmes for 2 or more diseases.
- Maintaining high standards across all disciplines and at all levels could be harder than in a system oriented toward a single disease.
- Confusion could be created over the standards required for different disciplines, especially between malaria and tuberculosis.

The capacity of a country to overcome these constraints will depend on the current objectives of the national disease control programmes, the infrastructure, the activities being carried out and the levels of funding of the respective programmes. The feasibility of integration should be determined as part of a situational analysis for scaling up QA (WHO, 2005a).

CHAPTER 3

THE NIGERIAN CONTEXT OF TUBERCULOSIS AND MALARIA CONTROL

3.1 Nigeria: Background information

Nigeria is a democratic Federal Republic consisting of the Federal, States and Local Governments levels of administration. Nigeria is the most populous country in Africa, and the tenth in the world. With a growth rate of 3.0%, Nigeria's population in 2005 was estimated to be about 134 million (FMOH, 2006b). The country has a diverse ethnic and cultural characteristics and variations in physical factors such as size, terrain and climate that could impinge on all aspects of social and economic life, including health.

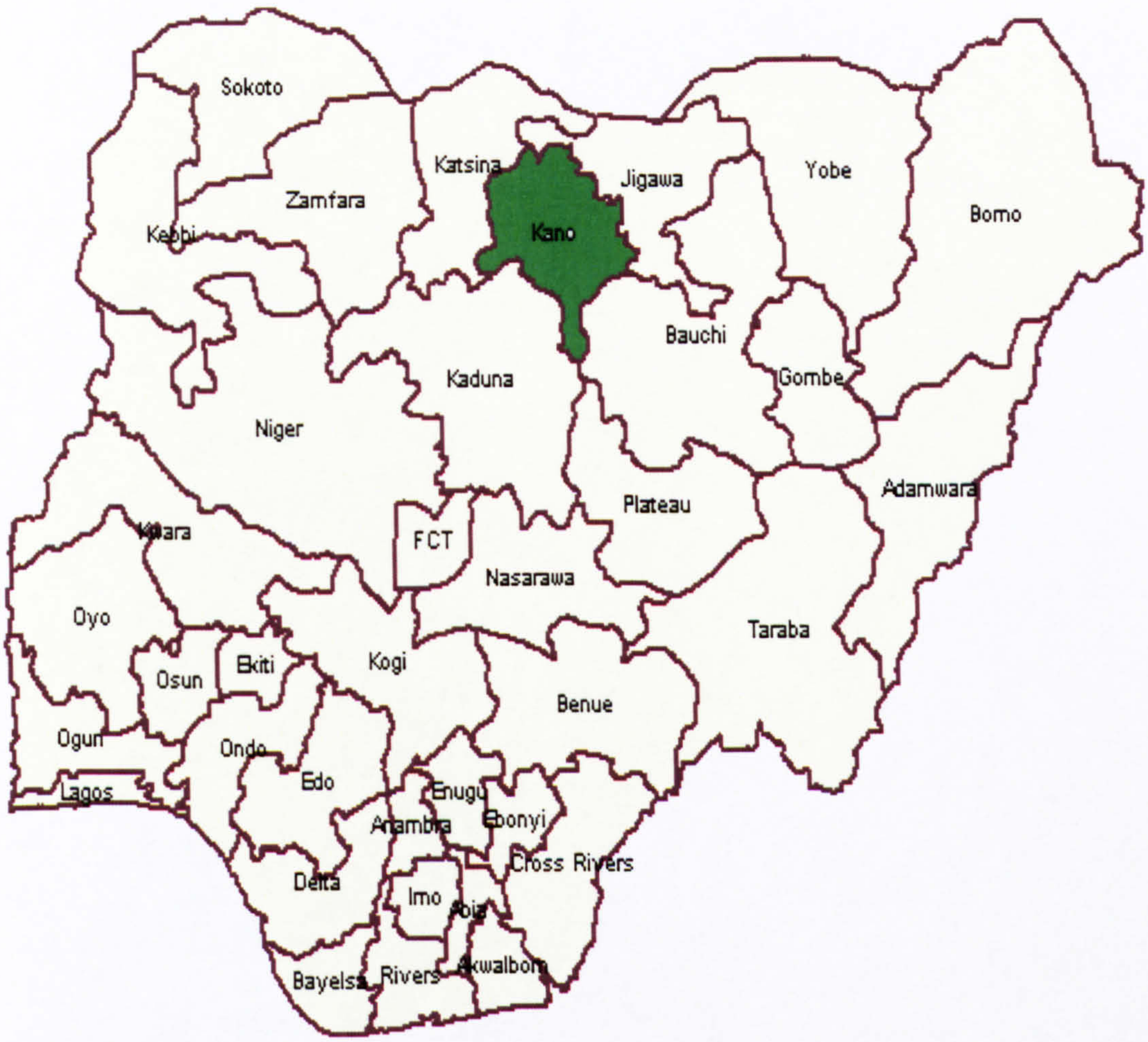


Figure 3.1: Map of the Federal Republic of Nigeria showing Kano State.
Source: Ministry of Health, Kano (2006)

There are 36 states and the Federal Capital Territory (FCT) in Nigeria (Figure 3.1). The states and the FCT are organized for political administration into 774 Local Government Areas. The states are further grouped into six geo-political zones—North East (NE), North West (NW), North Central (NC), South West (SW), South East (SE) and South South (SS). The zones differ from one another in size, population, ecological characteristics, language, culture, settlement patterns, economic opportunities and historical background.

The structure of Nigerian government reflects the administrative structure of the health system, disease control programmes and the laboratory systems in the country. The federal and state ministries of health are the highest administrative unit of health care delivery at the federal and state levels respectively. Primary health care, which is the basic unit of health care in the country, is administered at the local government level. The administrative and technical responsibilities including the laboratory services in control programmes for TB and malaria are defined according to the federal, state and local government structures in the country.

3.2 Kano State: Background information

Kano State is one of the 36 states of Nigeria, located in the northern part of the country (Figure 3.1). It has an estimated population of over 12 million people of which 75% live in the rural areas (K-SEED, 2005). The Kano state health care system is structured on the basis of the three-tier system of health care in Nigeria, namely: Primary Health Care, Secondary Health Care, and Tertiary Health Care (National Health Policy, 2004).

3.2.1 Health facilities in Kano state

In Kano state, there are 1062 health facilities comprising 5 specialist hospitals (including a teaching hospital), 29 General Hospitals (including cottage hospitals), 74 Health Centres / clinics, 99 Primary Health Centres, 528 health posts and 213 dispensaries. 49.7% of all public health facilities in the state are health posts (Table 3.1).

Table 3.1: Number and categories of health facilities in Kano state (2007)

	Hospitals			Clinics / Health Centres					Total
	TER / SPH	GEN / CT	PV	PB	PV	PHC	Health post	Dispensary	
Number	5	29	37	74	77	99	528	213	1062
%	0.5	2.7	3.5	7.0	7.3	9.3	49.7	20.1	100

Key: TER: Tertiary health facility SPH: Specialist hospitals

PV: Private health facility PB: Public health facility

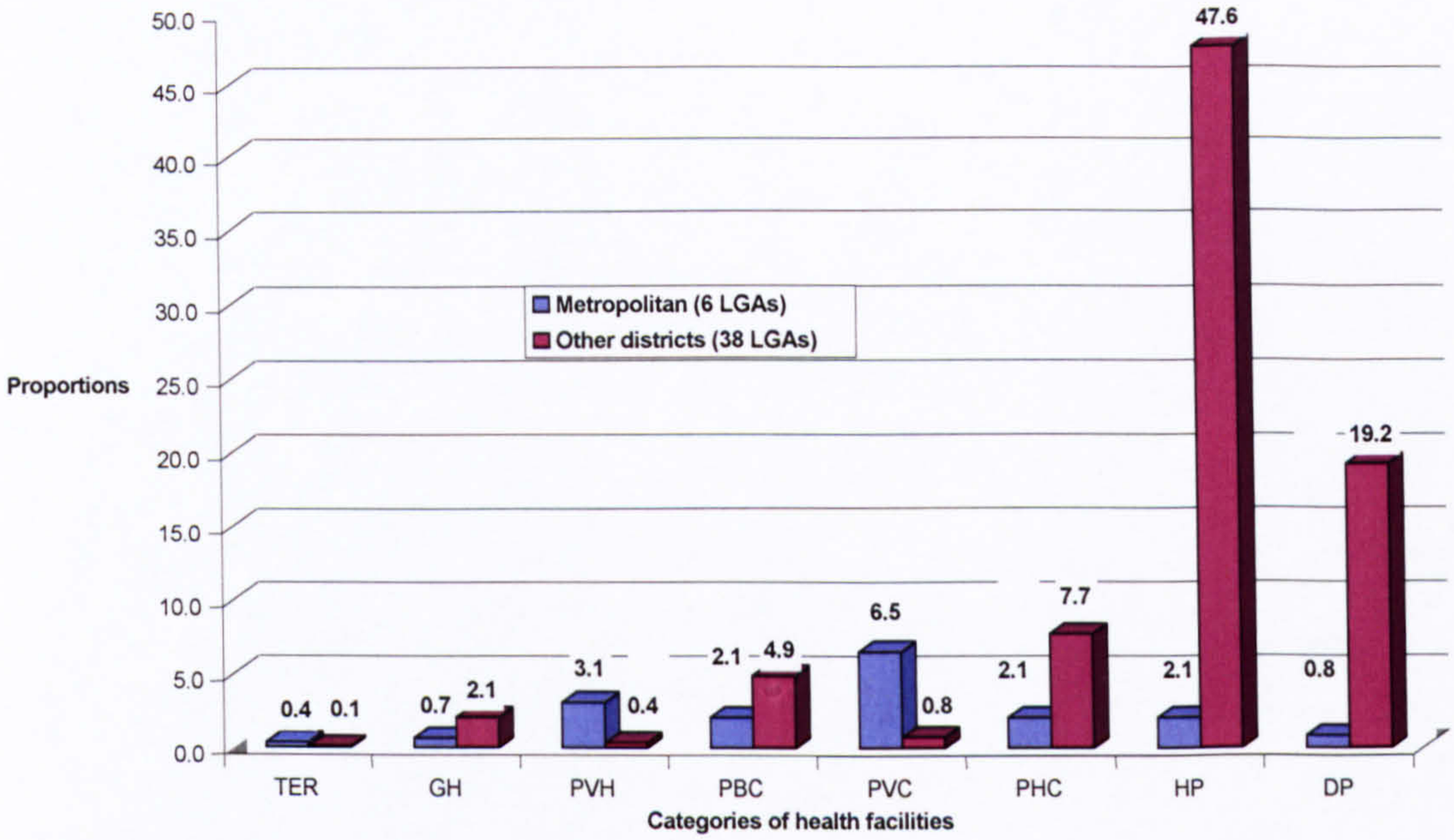
PHC: Primary Health Care

Source: Medical and health care department, Ministry of Health, Kano (2007)

The number of private hospitals exceeds that of the public general and specialist hospitals in the state. Private clinics have almost the same number with the public clinics.

The distribution of health facilities in Kano state shows relatively higher proportions of tertiary health facilities, private hospitals and private clinics in the metropolitan area of Kano state. Public hospitals, health clinics / centres, primary health centres, health posts and dispensaries have higher proportions outside Kano metropolitan area (Figure 3.2). Laboratory services are concentrated in the metropolitan area rather than elsewhere in Kano state. This is because, although recommended by the national policy, there are no laboratories in the public clinics, primary health centres, health posts and dispensaries, which are the major health facilities outside the metropolitan areas of Kano (Figure 3.2). Therefore the 75% of the population of Kano state who live in rural areas have less access to laboratory services.

Figure 3.2: Distribution of health facilities in Kano state (2007)



Key:

TER: Tertiary health facility SPE: Specialist hospitals HP: Health Post

PV: Private health facility PB: Public health facility DP: Dispensary

PHC: Primary Health Care PBC: Public Clinics

Source: Medical and health care department, Ministry of Health, Kano (2007)

Currently, the medical laboratory service unit is under the medical and health care services department within the Kano state health system. At the state hospitals management board, laboratory services are administered under the medical and health care department. At the zonal and hospital levels, the laboratory unit is administered along with other support units such as the radiology and physiotherapy units, under the medical department (Imam, 2007). There is no representation of laboratories in the management committees of the hospitals, health zones, hospital management board and the state ministry of health. Kano state government provides support for laboratory services in the public health facilities in the state. In the absence of a specific policy for

financing laboratory services, each of the 13 health zones finances laboratory services in health facilities within the zone.

3.3 Tuberculosis and Malaria burdens in Nigeria

Tuberculosis (TB) and malaria are endemic in Nigeria and amongst the most important public health burdens of the country.

3.3.1 The tuberculosis burden

Nigeria has the world's fourth largest tuberculosis burden, with nearly 374,000 estimated new cases annually. According to WHO (2006), 33,755 (or 57 percent) of the new TB cases in 2004 were pulmonary sputum smear-positive (SS+) cases. Total notified cases of all forms of TB increased from 46,473 in 2003 to 59,493 in 2004. At the end of 2005, 66,848 cases of TB had been notified, of which only 52 percent were SS+. Although still far short of the WHO target of 70 percent, the TB case detection rate increased from 15.3 percent in 2001 to 27 percent in 2005. While the treatment success rate had stabilized above 75 percent, it now stands at 59 percent. Both the case detection and treatment success rates were among the lowest of high-TB burden countries. It is estimated that in 2005 the TB case detection rate will be 27 percent and the treatment success rate will return to near 79 percent (USAID, 2006).

The public health burden posed by TB is becoming increasingly important as the country's HIV/AIDS epidemic unfolds. WHO estimates that 27 percent of Nigeria's TB patients are HIV-positive (USAID, 2006).

In Kano State, there were a total of 5,179 registered cases of tuberculosis at end of 2006, representing about 30% of estimated number of TB cases in the State. The state TB control program recorded a treatment success rate of 83% for new smear cases

registered in 2005. The trend of tuberculosis case findings in four years (2003 – 2006) is presented in Table 3.2.

Table 3.2: Four year comparison of TB case finding in Kano (2003 to 2006)

YEAR	New cases	Relapses	Failures	Return after default	Smear negatives	Extra PTB	TOTAL
2003	1180	0	7	1	1028	20	2236
2004	1395	11	35	7	2109	20	3577
2005	1484	54	7	29	2576	43	4193
2006	2306	99	43	79	2522	130	5179

Source: Kano State TB Control Program Annual Report Ministry of Health, Kano (2006)

There was an increase in the number of TB cases registered in Kano State since the commencement of DOTS implementation in the State in 2003. With the expansion DOTS to additional LGAs in the state, more patients were becoming aware of the programme and patronizing the services (Table 3.2).

3.3.2 The malaria burden

Malaria is endemic in Nigeria, and the population at highest risk includes children, pregnant women, and the non-immune persons (Carrington, 2001). There were 2,608,479 reported cases and 5,343 deaths due to malaria in Nigeria in 2003 (WHO, 2005). Forty three percent of the cases occur among children of under 5 years of age. The prevalence of malaria in Nigeria in 2003 was 21.03 per 1000 population (WHO, 2005). Malaria accounted for 60% of outpatient visits to health facilities in Nigeria and was responsible for 30% of childhood deaths, 25% of deaths in children under 1 year and 11% of maternal deaths (FMOH, 2005).

The financial loss due to malaria annually in Nigeria was estimated to be 123billion Naira (£492 million) annually in form of treatment cost, prevention, loss of work hours and other consequent losses (FMOH, 2005). Malaria contributes to both poverty and

underdevelopment for the nation, community, family and individuals because people spend large part of their yearly income on malaria treatment and prevention. Reducing malaria burden is therefore a cost effective way of promoting development and reducing poverty (FMOH, 2005b).

The malaria burden in Nigeria has been compounded further by the high level of resistance of malaria parasites to chloroquine and sulfadoxine-pyrimethamine (S-P). Results of a drug therapeutic efficacy trial conducted in the country showed a high level of resistance ranging from 23 – 96% to these drugs across the six geographical zones of Nigeria. The result indicated that chloroquine and Sulfadoxine-pyrimethamine are no longer effective in the treatment of malaria (FMOH, 2005a).

In Kano state, malaria was identified as one of the important immediate causes of mortality among children (K-SEEDS, 2005). According to the Kano state Infectious Disease Surveillance Report (IDSR), there were at least 264,481 reported cases of malaria from 44 LGA's in Kano State in the year 2003, with prevalence of 22 per 1000 population (MOH Kano, 2004). Although the prevalence is close to the national average, the figure may underestimate malaria in Kano because the state's health records are unreliable and inadequately organized. The available health data and statistics are generally estimates obtained through limited surveys, conducted by international organizations and through other health related surveys (MOH Kano, undated).

3.4 Role of the laboratory in TB and malaria control in Nigeria

In response to the tuberculosis and malaria burdens, the Federal Government of Nigeria established the National Tuberculosis and Leprosy Control Programme (NTBLCP) and the National Malaria Control Programme (NMCP) as appropriate health intervention strategies for TB and malaria. The TB and malaria control programmes in Nigeria are structured along the national, state and local government levels of administration.

3.4.1 Role of the laboratory in TB control in Nigeria

The central reference TB laboratory is hosted at the federal level of the TB control programme and collaborates with the administrative unit of the programme in the federal ministry of health. The functions of central laboratory are:

- Performing microscopy (both ZN and flourescence), mycobacterial culture, drug sensitivity testing and species identification.
- Rendering repair services for the laboratory equipment and controlling the reagents used in TB laboratories
- Updating of the methods and protocols for laboratory diagnosis of TB and review of guidelines on TB laboratory supervision
- Training of the laboratory staff, conducting quality assessment and proficiency testing exercise, surveillance of primary and acquired tuberculosis drug resistance and participate in epidemiological and operational research

The state level laboratories in TB control unit are integrated with the existing public laboratories in the secondary and tertiary hospitals located in the urban areas. The duties of these laboratories are to supervise peripheral laboratories PHC level and to serve as first level controller for reading of slides in the quality control exercise.

At the local government level of TB control programme, the peripheral laboratories are fully integrated with primary health care services located within the local government. The peripheral laboratories could be based at primary health care centre or district hospitals. The functions of these laboratories are:

- Collection of sputum specimens, sputum smear preparation, ZN staining and examination by direct light microscopy using standard operating procedures within the framework of national TB control programme.

- Prompt dispatch of results within 72 hours from the receipt of the specimen recording of results accurately in TB laboratory register.
- Cleaning (de-oiling) of examined slides with xylene and storing them serially in provided slides boxes as well as keeping the slide boxes away from direct sunlight.
- Making of quarterly request for reagents and other materials for use in the laboratory, cleaning of microscopes and control of reagents in the laboratory.
- Close collaboration with the local government TB supervisor and the state quality control officer for effective conduct of quality control and quality improvement for AFB microscopy.

An efficient AFB microscopy service that has the ability to detect 85% of pulmonary tuberculosis cases all within 72 hours is a significant epidemiological factor preventing transmission of tuberculosis (NTBLCP, 2004).

The National Tuberculosis Control Programme conducts a QA scheme for TB microscopy which is currently implemented and managed by the National Tuberculosis and Leprosy Control Programme (NTBLCP) in collaboration with donor agencies. The QA scheme for TB microscopy covers the whole process of sputum collection, smear preparation, smear staining, microscopy, recording and reporting. Data collection, data analysis, identification of problems and creative problem solving are key components of this process. QA also involves continued monitoring and identifying defects, followed by the remedial action to prevent recurrence of problems. The purpose of these quality checking processes is to identify laboratories where there may be serious problem in the sputum smear microscopy services, resulting in poor performance, not to identify individual slide errors or validate individual patient diagnosis (NTBLCP, 2004).

3.4.2 Role of the laboratory in malaria control in Nigeria

The national health policy highlighted the improvement of quality of diagnosis and treatment as well as the provision of functional laboratory facilities among the vital components of malaria management (National Health Policy, 2004). The national malaria treatment policy of Nigeria, as recommended by the WHO (WHO, 2000), indicated the need to confirm the diagnosis of malaria by laboratory test in the following cases (FMOH, 2005a):

- Uncomplicated malaria in low risk areas
- Treatment failure
- Suspected case of severe malaria

However, in contrast to the situation for TB, the national policy for malaria does not include any QA guidelines for malaria microscopy at any level of malaria control (FMOH, 2005a).

3.5 The basis of integrating TB and malaria microscopy QA schemes in Nigeria

In accordance with the national guideline, the Kano state TB control programme had a network of ten designated TB microscopy laboratories supporting the Directly Observed Treatment Short Courses (DOTS) and a quality assessment scheme for TB microscopy. In contrast, here is no network of malaria microscopy laboratories or quality assessment scheme for malaria microscopy at any level of health care in the state because in contrast to the situation for TB, the national policy for malaria does not include any QA guideline for microscopy (FMOH, 2005a).

The WHO has recommended the integration of malaria microscopy Quality Assessment (QA) with that of other microscopically diagnosed communicable diseases in order to enhance the accuracy of microscopic diagnosis of malaria especially in malaria endemic

regions of the world (WHO, 2005a).The NTBLCP and the national malaria treatment policy of Nigeria have recommended laboratory tests for TB and malaria at the PHC level in the country. Moreover, while the state levels of TB and malaria control are responsible for supervising the PHC level and conducting QA of peripheral laboratories, the national levels are responsible for the technical control, planning, budgeting, implementing and monitoring the QA scheme in both TB and malaria control programmes. This suggests that the integration of TB and malaria QA systems could have a potential added value because a single QA system with two components could simplify the administration, logistics of supply of reagents and equipment, reporting and evaluation of the performance of microscopy. It could also be less resource-intensive as QA for malaria could be combined with other QA system. For instance, integrating activities like supervision, sampling of slide, rechecking and feedback mechanisms, and the criteria for setting the acceptable level of performance of microscopists for TB and malaria microscopy. However, this innovative scheme requires a high degree of motivation and organization by the laboratory staff, as well as support from clinicians and regional or national healthcare managers (Bates and Maitland, 2006).

CHAPTER 4

METHODOLOGY

4.1 Baseline assessment of laboratory services in Kano state

The design of a QA system for TB and malaria microscopy requires a situation analysis and retrospective information on the infrastructure, workload and slide positivity rates for TB and malaria microscopy. The aim of conducting a baseline assessment was to document the current state of the medical laboratory service in Kano state in terms of management, types of tests conducted and related workload, number, categories and distribution of laboratory personnel, state of basic equipment, safety issues, test procedures and methods of quality control. The specific objectives were to:

- Compare the existing laboratory services in Kano with the recommendations of the national medical laboratory policy in order to identify the conformities and possible deviations from the national policies.
- Identify the major constraints of the existing medical laboratory practice in Kano.
- Document the situation of TB and malaria microscopy services in the state to guide planning and selection of laboratories for the implementation of this project.

4.1.1 Consultations and Ethical Issues

An approval for the project was granted by the Kano state ministry of health and conveyed in letters No. MOH/S/A/62/T.1/I/3 dated 14th September 2004, and MOH/S/A/62/T.1/I/7 of 19th April 2005. Consultations were also held with relevant officials of the ministry of health so that they could input to the objectives, activities and goals of this project. They were the Director, Primary Healthcare, Deputy Director,

Disease Control, state TB Control Officer, state Malaria Control Officer and some senior medical laboratory scientists including the state TB Quality Control Officer.

4.1.2 Research Assistants

Fifteen Research Assistants (RAs) were used for this project. The RAs were identified among the senior laboratory personnel in the state health service and were invited to participate in data collection. Their participation was based on their personal understanding and commitment to the objectives and the possible benefits of this project to Kano State health system. Through the project, transport, sustenance and meetings were financed token remunerations were given to the RAs as off duty allowances. The RAs were:

1. The state TB microscopy quality control officer in 2005 and the head of laboratory of Infectious Diseases Hospital (IDH), Kano.
2. The state TB microscopy quality control officer in 2006 and the head of epidemiology laboratory, Infectious Diseases Hospital (IDH), Kano.
3. A Chief Medical Laboratory Scientist, who was the former head of the laboratory services department Muhammad Abdullahi Wase Specialist Hospital.
4. 12 Heads of laboratory services units in the selected health facilities.

4.1.3 Development of instruments for the baseline assessment

A checklist (Appendix D1) was developed in order to obtain relevant information on laboratory practice. Items in the checklist were adopted from the Guidelines for Implementation and Monitoring Quality Systems for Medical Laboratories (WHO, 1998), External Quality Assessment for AFB Smear Microscopy Manual (ALPH, 2002) and checklists used in other African country (MOH Ghana, 2001). The checklist

consisted of eleven different sections intended to retrieve qualitative and quantitative, retrospective and prospective data.

The checklist was reviewed by three research assistants (1-3) and other the three senior laboratory personnel in the state ministry of health in order to identify possible omissions and ambiguities. Some relevant amendments were made based on their reviews.

A group of 10 senior and experienced laboratory personnel selected from IDH, MMSH, AKTH and MAWSH to collaborate in this project (Appendix D2). They were selected based on their long term experiences (5-10 years) in routine laboratory services involving TB and malaria microscopy. Some useful suggestions made by the collaborators were incorporated into the final project design.

4.1.4 Selection of laboratories for the baseline assessment

Records of the number of laboratories in these public health facilities within Kano were not available at the time of assessment. However, laboratory services are offered only in the secondary and tertiary levels of heath care and rarely in the primary health centres in the state (Bako, 2005). As it was not feasible to conduct the assessment on all the laboratories due to limited financial support and restricted time frame of the assessment, 1/3 of the estimated number of laboratories in the 34 (5 specialists and 29 general hospitals) (see Section 3.41) was taken as a sample.

Thirteen (13) laboratories were selected as a sample using a purposive sampling, which is a non-randomized sampling technique in which a specific population is identified and only its members are included in a survey (Kelly *et al*, 2003). The representative laboratories were from both tertiary and secondary health facilities located in the rural and urban areas of the state. Selection of the laboratories was made in consultation with

research assistants and the former coordinator of laboratory services of Kano the state and other senior officials of the state ministry of health. The thirteen selected laboratories comprised all ten designated DOTS microscopy centres in the state and three state specialist hospitals where TB microscopy was also carried out. They were the Murtala Muhammad Specialist hospital (MMSH), Muhammad Abdullahi Wase Specialist Hospital (MAWSH) and Hasiya Bayero Paediatric Hospital (HBP), The selected laboratories together with the health facilities within which they are located are shown in Table 4.1.

Table 4.1: Profiles of the health facilities included in the baseline assessment of medical laboratory services in Kano state (April 2005)

Levels of care	Laboratories	Locations (LGA)	Setting	Number of rooms within the laboratory	Estimated population***
Tertiary	MMSH	Kano Municipal	Urban District**	7	1,437,389
	MAWSH	Nassarawa	Urban District	5	1,437,389
Secondary	HBP	Gwale	Urban District	2	1,437,389
	IDH*	Fagge	Urban District	2	1,437,389
	WDL*	Wudil	Semi-urban	1	661,415
	GZW*	Gezawa	Semi-urban	1	435,266
	GWZ*	Gwarzo	Semi-urban	1	366,211
	DBT*	Danbatta	Semi-urban	1	346,268
	KUR*	Kura	Semi-urban	1	217948
	BCH*	Bichi	Semi-urban	1	202,237
	RAN*	Rano	Semi-urban	1	146,466
	SML*	Sumaila	Semi-urban	1	146,126
	KRY*	Karaye	Semi-urban	1	129,674

*Designated AFB microscopy centres.
** Urban Districts: Kano Municipal, Fagge, Tarauni, Gwale, Nassarawa, Dala
***Kano state projected population by local government areas (1999) available at www.kanoonline.com (accessed 27/6/07)

4.1.5 Methods of data collection for baseline assessment

A schedule of visits to the selected laboratories was prepared in consultation with the state TB quality control office, for a period of two months. Two visits were made to each of the selected laboratories for the assessment (Appendix D3). Visits for data collection were made together with the state TB quality control officer.

During the first introductory visit, the project objectives were explained to the hospital administrators and the laboratory staff in all the hospitals. The expected role to be played by the staff in the project was also explained to the laboratory staff. The proposed development and implementation of a quality assessment system of malaria microscopy was also highlighted. Various components of the checklist were explained to the officer in charge of the laboratory and clarifications were made on the question raised. Some of the safe and unsafe practices were observe and recorded during the visit.

During the second visit the numbers and types of tests conducted in the laboratories compiled by the laboratory staff were reviewed in order to identify and correct errors. Completed checklists were then retrieved from the laboratories.

i. General information: Documentation of information about laboratories comprising:

- Location of laboratory (Local Government Area)
- Number of health facilities served by the laboratory
- Number of rooms within the laboratory building (if applicable)

ii. Laboratory administration and financing: Information was obtained, from the officers in charge of the laboratories, on the administrative and financing authorities of each of the laboratories. Outlines of the administrative structure of the laboratories and respective staff responsibilities were also requested.

Data relating to financial management in the last year were requested from each laboratory. Heads of laboratories were requested to provide the main source(s) of financing, budget allocation to the laboratory, total expenditure, total turnover from patients' charges for tests, estimates of the total profits realized (if any), and the possible deficit incurred from services charges.

iii. Electricity and water supply: Prospective data on electricity and water supplies to each of the laboratories were obtained using a sheet to record the presence or absence of electricity and water to the laboratories during working hours of 8.00 am to 5.00 pm. Electricity and water supplies were monitored on separate score sheets by marking (√) to indicate the availability of electricity or water and (X) to indicate their absence within the working hours. Record of electricity and water supplies for a period of 2 weeks were requested from each of the selected laboratories.

iv. Safety inspection: A safety inspection form used previously for a baseline safety survey in the regional in-service training programme and establishment of nation-wide laboratory quality control system in Ghana (MOH Ghana, 2001) was adopted to assess the compliance of laboratories with some basic laboratory safety measures. The use of standard operating procedures (SOPs) and other safety indices such as the universal safety precautions, hand washing facilities (soap and water), written instructions personal protection, electrical and fire safety, waste disposal and first aid were inspected and recorded.

v. Basic laboratory equipment: The availability and conditions of some basic equipment required for district laboratories as depicted in Cheesbrough (1998) were assessed. Criteria for assessment were adopted from the guidelines for implementation and monitoring quality systems for medical laboratories (WHO, 1998). Equipment

assessed was microscope, refrigerator, water bath, weighing balance, incubator, autoclave and colorimeter. Information on the number, proper functioning and arrangements for maintenance were obtained with the assistance of the heads of laboratory units.

vi. Staffing: The number and qualifications of staff serving in the respective laboratories at the time of the assessment were recorded. Data on working hours, call duties and durations of annual leave and other forms of leave for the staff were also requested in the checklist.

vii. Workload: Retrospective data on the types and number of tests conducted in the last one year were retrieved from the laboratory registers by the heads of laboratories or heads of the respective units within laboratories that had separate sections. Where there was no record of the number of tests for the whole year, the average number of each test conducted per month was determined, from which projections were made to obtain the estimated number of tests for the year.

viii. Test selection, methods and quality control: Data on the method used for each of the available tests conducted in the selected laboratories were obtained. Information on the staff assigned to perform the test and method of assuring the quality of results (if any) was also obtained.

ix. Laboratory test requests: The systems of laboratory request were recorded using a form designed from the guidelines for implementation and monitoring of quality systems for medical laboratories (WHO, 1998). The system of making requests by clinicians for laboratory investigations were assessed based on the use of a standard designed request form, indication of patients' reference number, age and sex, clinical

diagnosis, relevance of specimen to requested tests and the clarity of information on the request form.

4.1.6 Determination of baseline quality of TB and malaria microscopy.

Five out of the 10 designated microscopy centres (IDH, WDL, GWZ, RAN and DBT) where TB microscopy slides were stored were selected for implementing the integrated TB and malaria microscopy QA scheme. The rest DOTS microscopy centres were not storing the examined TB slides. Examined TB slides were sampled from the five DOTS microscopy centres. Malaria slides were from only two of the five centres (IDH and WDL) where malaria slides were available during the assessment period.

4.2 Design and implementation of integrated quality assessment system for TB and malaria microscopy in Kano state.

It was recommended (APHL, 2002) that a quality assessment system for TB microscopy should be implemented in areas or regions where DOTS is well established. The first approach in developing an integrated QA system for TB and malaria microscopy was therefore to assist the state TB control programme establish and expand its TB microscopy QA system in accordance with the recommendations by the national TB control programme of Nigeria (NTBCP, 2004). In this project, therefore, the external quality assessment system for TB microscopy was started in the 5 centres that were storing examined slides and malaria microscopy QA was subsequently introduced in these centres.

4.2.1 Intervention strategies for setting up integrated QA system

Combining the TB and malaria quality assessment was a gradual process in which the feasibility depended on the success and progress made in establishing and strengthening the TB microscopy EQA system. The specific steps followed in the development and strengthening of TB microscopy quality assessment system in Kano were:

- Developing a modified external quality assessment system for the TB control programme.
- Piloting the modified method of data collection by conducting a baseline assessment of the quality of TB microscopy in DOTS laboratories in the state.
- Implementing the quality assessment system in the 5 microscopy centres.
- Performing the duties of the local government TB supervisors such as slide selection and training the supervisors on their role in the EQA activities.
- Organizing, along with the state TB microscopy quality control officer, schedules of visits to the selected centres for supervision, sampling, re-reading of slides and feedback for quality improvement.
- Compiling and analyze the results of EQA and writing an interim report at the end of each quarter and submission to the TB control officer.
- Providing transportation, feeding and stationary needs for the EQA activities in 2 quarters of 2005 and the four quarters of 2006.

Specific strategies for the development of malaria microscopy quality assessment system were to:

- Conduct a baseline study to determine the quality of malaria microscopy based on the Leishman stained thin blood films used in the laboratories.
- Train microscopists in the identify malaria parasites in both thin and thick blood films.
- Develop a mechanism of supply of materials required for malaria microscopy in the secondary and tertiary heath facilities.
- Advocacy to policy makers on the need for the development and support of a system for ensuring accurate laboratory diagnosis as the basis for treating malaria with new drug combinations (ACTs).

4.2.2 Selection of quality assessment procedures

Blinded re-checking was selected as the realistic procedure for the implementation of EQA for AFB microscopy for the following reasons:

1. It is the standard method for monitoring laboratory performance over a defined period of time and reflects reality of routine performance.
2. It is an ongoing and permanent process which could be expanded gradually after piloting.
3. The method is being adopted by the national TB control Programme of Nigeria and in malaria control programmes in Philippines (WHO, 2005a)
4. The heavy workload at the higher level (central QA laboratory) would match the distribution of laboratory staff in the state: senior laboratory scientists are concentrated in laboratories within urban Kano.
5. Suitable for the relatively low level of workload for the district laboratories
6. Motivates improved daily performance as the technicians are expecting visits by the supervisors.
7. Blinded re-checking was recommended as the most efficient procedure for making the first broad assessment of sputum smear microscopy services (Basra *et al*, 2006).

However, the process of blinded rechecking as described in the literature (APHL, 2002) does not suit the initial stage of implementation of the QA system for TB and malaria microscopy in Kano because of the following reasons:

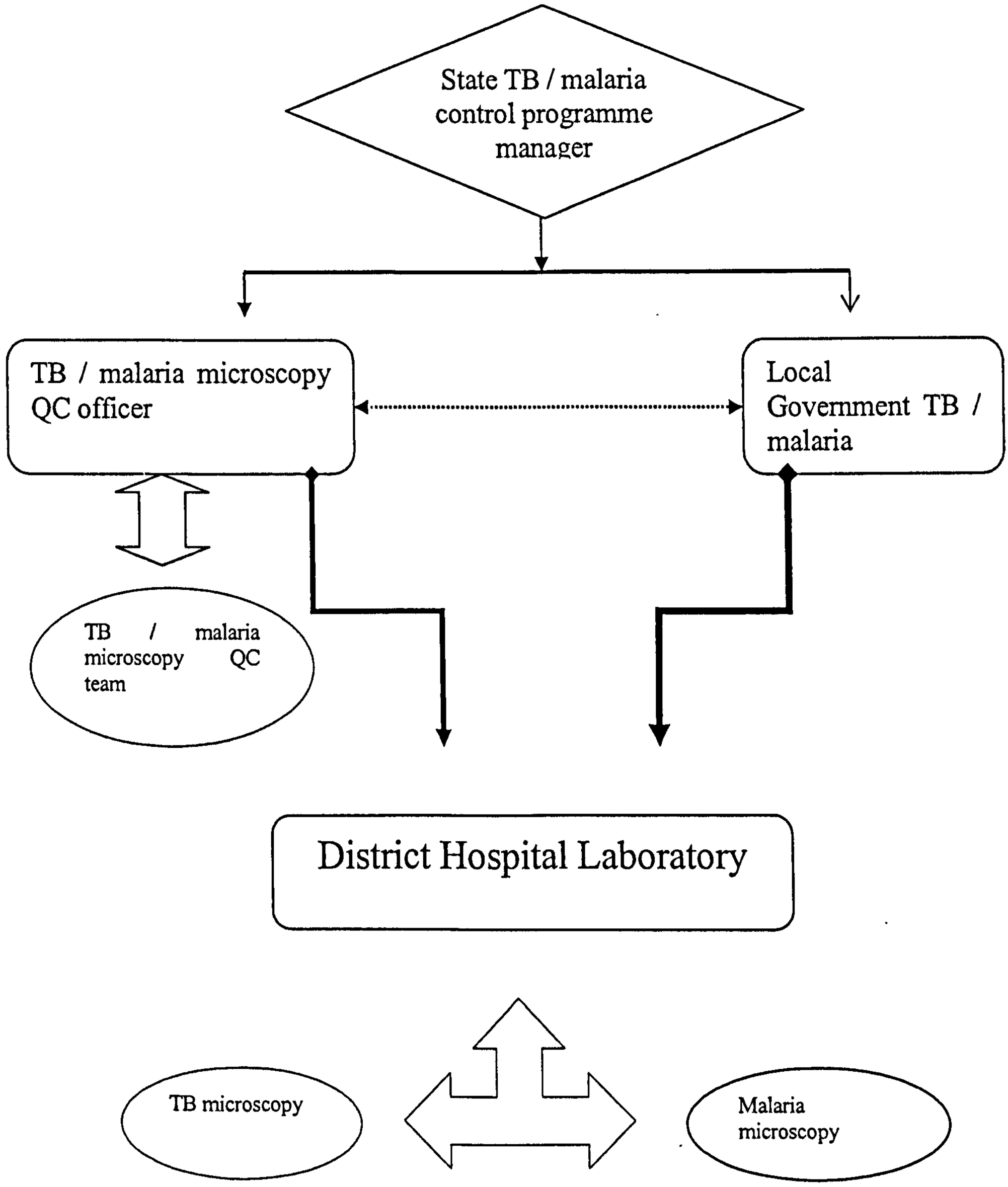
- There were only 5 designated TB microscopy centres at district levels, and these laboratories were at the same level of functioning as peripheral TB microscopy centres.
- There was no central laboratory at the state or zonal level that would serve as the second level re-checking centre.

For the purpose of this project, therefore, a modified system of blinded re-checking was designed. The blinded re-checking of slides sampled from the laboratories would be centralized in one laboratory where the first and the second re-reading would be conducted independently. The epidemiology laboratory situated at the IDH was made the laboratory for the re-checking activities because the state TB microscopy quality control officer was based in the laboratory and no other routine laboratory services were conducted in the laboratory. Also, a new microscope was available and preparation of reagents for ZN staining were performed centrally in this laboratory and distributed to other TB microscopy centres.

4.2.3 The structure and components of the integrated TB and malaria microscopy QA system

An outline of the proposed integrated EQA scheme for TB and malaria microscopy is shown in Figure 4.1.

Figure 4.1: The scheme for integrating TB and malaria microscopy quality assessment



4.2.3.1 Extending the role of TB microscopy supervisors to include malaria microscopy

The local government supervisors were staff of the medical and health department of the local government councils. One supervisor usually oversees the DOTS activities in one or two local government areas. The supervisors had a significant role in both maintaining a regular supply of reagents and materials for TB microscopy activities and the external quality assessment of TB microscopy by ensuring keeping of examined slides and performing the sampling of slides for EQA. They also collected TB slides for rechecking at the quality control laboratory in accordance with the guidelines of the TB control programme. They were trained on the integrated supervision and sampling of malaria slides for EQA. The state TB microscopy quality control officer was a senior trained microscopist with the relevant experience and competence to coordinate and supervise the quality assessment process.

4.2.3.2 Extending the role of TB microscopy quality control officers to include malaria microscopy

A group of 5 and experienced TB and malaria microscopists were selected from the tertiary and secondary health facilities. At lease four microscopists are required for the integrated re-reading of TB and malaria slides at every re-checking period. TB and malaria microscopy slides were collected by the TB supervisor and submitted to the state TB quality control officer at three month intervals for re-checking at a state secondary laboratory. The slides were re-checked independently by two of the five selected microscopists. TB and malaria microscopy checks were integrated by using a pair of microscopists from the pool of five experienced microscopists with skills in both malaria and TB microscopy. Re-checking was done by the two readers the same technique as used in the district laboratory to ensure that the technical characteristics of the method are comparable.

4.3 Method of sampling TB and malaria slides

4.3.1 Lot Quality Assurance Sampling (LQAS): The methods used for determining the number of slides to be sampled were based on the Lot Quality Assurance System (LQAS) (APHL, 2002). LQAS is a method to determine an optimum sample size which when applied properly, yields a statistically acceptable sample to assess quality of slides for TB microscopy. Protocols based on LQAS were also applied in determining the number of slides to be sampled for both TB and malaria microscopy for quality checking (Selvakumar *et al,* 2005; WHO, 2005a).

LQAS allows selection of a smaller number of random or consecutive slides sufficient to detect poor performance with a known degree of probability compared with the previous method of rechecking all positive slides and 10% of the total number of negative slides (APHL, 2002).

4.3.2 Parameters for determining the number of slides to be examined

a) Lot (N): Total number of negative slides prepared in a specified period of time (one month, one quarter, one year). In this project, number of negative slides in one year was considered. Number of negative slides in 2004 in the 5 selected DOTS laboratories was 2,464 (Table 4.3) while the number of negative malaria microscopy slides in 5 laboratories was 1,652 (Table 4.4).

b) Critical Value: A critical value is an upper threshold of the proportion of false negative among all the negatives beyond which intervention is deemed necessary. A critical value can be chosen from an estimate of historical (long term) false negativity rates, but in the early stages of an EQA programme, accurate data may not be available. However, the IUATLD guidelines recommended that when establishing a new quality control system, sampling should be designed to identify laboratories where the proportion of false negative slides (i.e. positive slides falsely classified as negative) is

likely to exceed a critical value of 5% (IUATLD, 1998). The critical value was therefore set at 5% in this project.

c) Acceptance Number 'd': The maximum number of false negative errors allowed in the sample after which the National Tuberculosis Programme can no longer be certain that the expected performance has been achieved. The value chosen for "d" has a direct impact on sample size. The larger the acceptance number, the larger the sample size required. In order to achieve the smallest, most efficient sample size, a value of d=0 is recommended. In this project, d=0 was therefore selected as the acceptance number for both TB and malaria microscopy.

d) Slide Positivity Rate: The proportion of positive smears among all slides in the laboratory from which the sample is to be taken. This number is estimated using the laboratory registers from the previous year. The number of slides to be examined was determined using the average positivity rate for the five selected laboratories since precision at the level of each laboratory may not be necessary or practical.

$$\text{SPR} = \frac{\text{Number of positive smears per year}}{\text{Total number of smears in 1 year}} \times 100$$

The average slide positivity rate for TB microscopy in the selected centres was 15% while that of malaria microscopy was 47.2%.

e) Sensitivity and Specificity: Sensitivity is the ability of the microscopist to detect AFB relative to the controller. Relative sensitivity for high positives (2+ to 3+) should be close to 95% but may be as low as 30 -50% for low positives (1-9 AFB / 100 fields). For new programmes a sensitivity of 75-80% is recommended in order to give smaller number of slides to be re-checked, which may help to make implementation of a rechecking programme more feasible. As the programme obtains additional resources,

and as overall performance is expected to improve, the sensitivity used to determine sample size should be increased to 80 or even 85%. Sensitivity was set at 80% for both TB and malaria microscopy.

Specificity is the ability of a microscopist to identify AFB correctly when present in the sputum smear. Specificity was set at 100% for both TB and malaria microscopy at a confidence interval of 95%.

4.3.3 Calculations of number of TB and malaria slides to be sampled for re-checking.

Table 4.2 Workloads and slide positivity rates for AFB microscopy in 5 laboratories in Kano (2004)

TB Centre	Number of slides	Number positive	Number negative	Slide positivity rate (%)
I D H	12,525	1,879	10646	15
Wudil	790	119	671	15
Gwarzo	349	49	300	14
Danbatta	508	56	452	11
Rano	320	70	250	22
Total	14,492	2173	12319	15

Average Slide Positivity Rate (2004) = 77 /5 = 15.4
Average workload (Negative slides) = 12,319 / 5= 2463.8
Round up to the nearest thousand =5000
Sensitivity = 80%
Specificity = 100%
Acceptance Number (d) = 0
Confidence Interval = 95%
Tabulated number of slides / year = 69
Slides to be sampled / quarter =69 / 4 = 17

Table 4.3 Workloads and slide positivity rates for malaria microscopy in 6 laboratories in Kano (2004)

Centre	Number of slides (2004)	Number positive	Number negative	Slide positivity rate (%)
I D H	1109	934	175	84.2
Wudil	2016	784	1232	38.9
MMSH	8700	4432	4268	51.0
MAWH	3251	761	2490	23.4
HBP	566	472	94	83.3
Total	15642	7383	8259	

Average Slide positivity Rate = 7383 / 15642 X 100 =47.2%
Average workload (negative slides) = 8259 / 5 =1651.8
Round up to the nearest thousand =1000
Sensitivity = 80%
Specificity = 100%
Acceptance Number (d) = 0
Confidence Interval = 95%
Tabulated number of slides / year = 33
Slides to be sampled / quarter = 33 / 4 = 8.25 Approximately 8

Table 4.4 Number of TB slides required for rechecking based on modified LQAS method

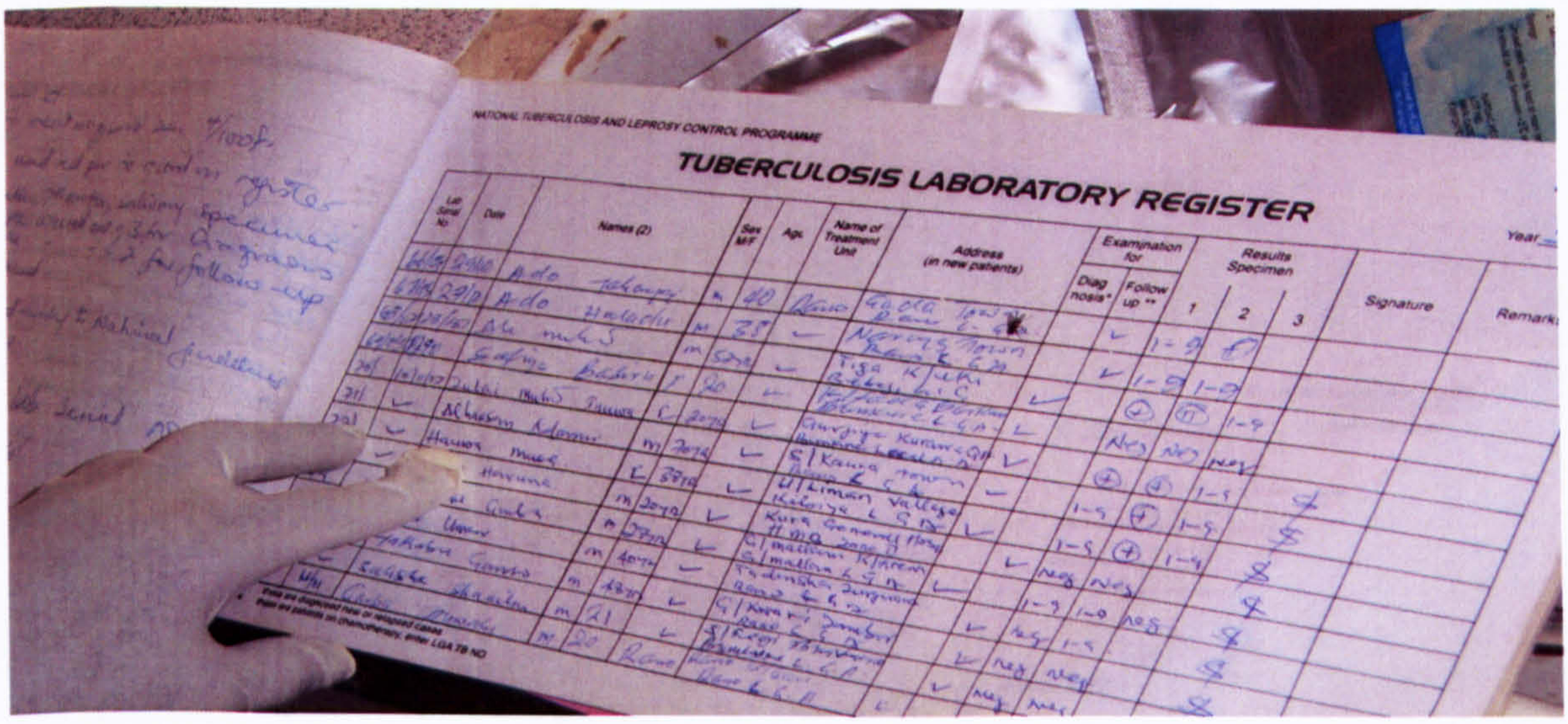
	Slide Positivity Rates					
Number of Negative Slides / Year*	**5%**	**10%**	**15%**	**20%**	**25%**	**30%**
200	107	72	54	43	36	30
500	154	89	62	48	39	31
1000	180	96	66	49	40	33
5000	208	103	69	50	40	33
50000	216	104	69	51	40	33

* Based on LQAS method applied to the negative slides with a sensitivity of 80 and specificity of 100%, Acceptance number d=0 and 95% Confidence Interval.
Source: External Quality Assessment for AFB Microscopy (APHL, 2002).

f) Selection of TB slides: The number of slides sampled at the end of each quarter in each of the laboratories was 17 slides. The average number of slides to be rechecked in district laboratories that processed approximately 5000 smears per year, with a

positivity rate of 15% is 69 slides per year (Table 4.4). This indicates that approximately 17 slides are to be collected during each quarterly visit. However, the state quality control officer suggested that the sample size should be fixed at 15 slides as recommended by the protocol of the NTBCP (NTBCP, 2004).

Figure 4.2 Selection of slides from the TB laboratory register using the LQAS method.



Sampling intervals were determined by dividing the total number of slides examined in the quarter by 15 and the resulting number (N) was the interval between each of the slides to be selected. If a laboratory examined a total of 330 slides, then every 22nd (330/15) slide was selected from the register to make up 15 slides for the rechecking exercise. The slide identification numbers and AFB microscopy results were entered into a QA form, together with the date and the name of the microscopy centre.

In order to eliminate selection bias, slides were selected using the laboratory register. In each of the centres I made the selection of slides to be examined from the register and recorded the results in a database (Figure 4.3). In this manner, the results were shielded (blinded) from the state quality control officer and the other 1st reader microscopist.

The selected slides were then collected from the entire set of slides. If a slide was missing, it was substituted by the one after it. When several slides were missing the selection was repeated from the register starting from a different point.

Figure 4.3 Sorting of selected slides from the lot of stored slides using the LQAS method.

g) Sample size of malaria slides

With an average slide positivity rate of 30% and aiming to detect performance at 80% sensitivity and 100% specificity for presence of parasites with a 95% confidence interval, 33 slides are required annually (Table 4.5). The number of slides required in each quarter is approximately 8 slides.

In this project, the average number of negative slides processed by the district laboratories was approximately 1000 per year, with a positivity rate of 47.2%. The number of slides required for a slide positivity rate of 47.2% is less than 8 slides per

quarter since the number of slides at a particular workload decreases with increase in the slide (Table 4.5).

Sampling intervals were determined by dividing the total number of slides examined in the quarter by 8 and the resulting number (N) was the interval between each of the slides to be selected. If a laboratory examined a total of 330 slides, then every 41st (330/8) slide was selected to make up 8 slides for the rechecking exercise. The slide identification numbers and malaria microscopy results were entered into a QA form, together with the date and the name of the microscopy centre.

4.4 Slides assessment criteria and rechecking protocols

4.4.1 Assessment of stained sputum smear slides and malaria blood films

Stained slides were assessed by the quality of sputum smear and ZN staining for TB microscopy according to the guidelines of the GLRA (GLRA, 2002). Malaria slides were assessed by the quality of blood film preparation and staining according to the description of Cheesbrough (1989) (Table 4.5).

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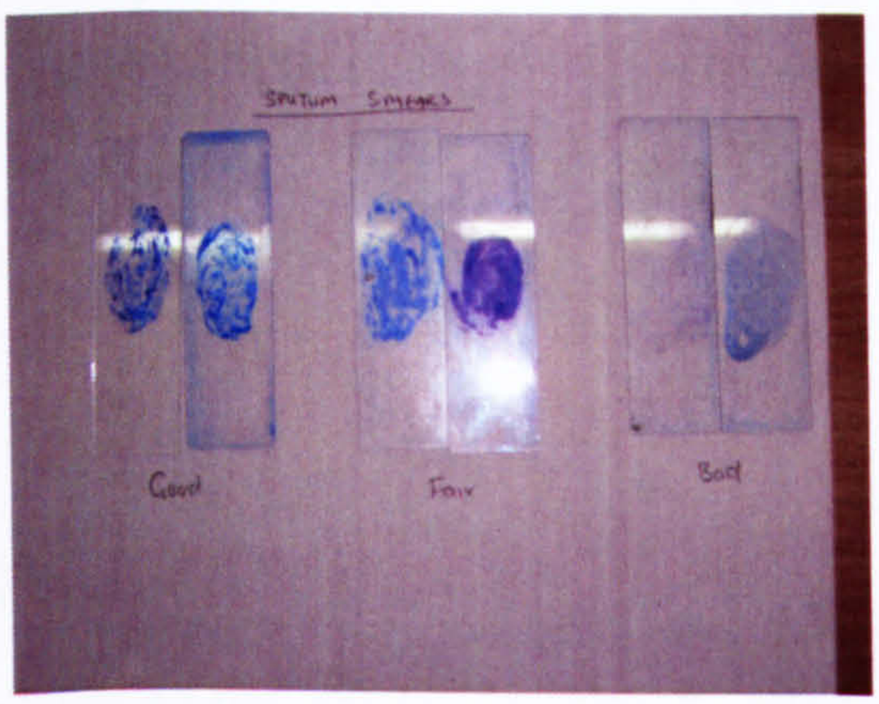
Table 4.5 Criteria for assessing the quality of TB and malaria slides

es	Quality of preparation and staining of sputum smear and blood films for TB and malaria microscopy	
	Sputum smear / staining	**Thin blood film / Leishman staining**
	Smear of approximately 1 x 2 cm, evenly distributed on the glass slide; thickness allows printed letters to be read through. Staining allows AFB and the background to be clearly distinguished as red against a bluish background.	**Gross appearance:** A thin film with distinct head, body and tail. **Microscopic appearance:** Demonstrates a monolayer of RBCs, and RBCs with normal and abnormal morphology. Staining allows the trophozoits, gametocytes and /or schizonts and the white blood cells to be clearly distinguished against the background.
	Smear is thick so that printed letter cannot be read through or unevenly distributed with a size more than 1x 2 cm. Staining: Due to over decolourization, AFB appears faint red colour or due to under decolourization remnants of carbol fuchsin or methylene blue appear on the background or unsmeared parts of the slide.	**Gross appearance:** Film with uneven tail, too thick, too wide or too long with uneven thickness. **Microscopic appearance:** Demonstrates a monolayer of RBCs, fixed RBCs and RBCs with abnormal morphology. Staining allows the trophozoits, gametocytes and /or schizonts malaria parasites and the white blood cells to be clearly distinguished against the background.
	Smear is made from saliva and was too thin with indefinite size or made too thick that printed letters cannot be read through. Stains sticks on the smear and difficult to spot fields with AFB or If smear was made from saliva and cannot pick up the stain.	**Gross appearance:** Film with ragged tail, too thick, too wide or too long with uneven thickness. **Microscopic appearance:** Distorted appearance of the RBCs, malaria parasite and the white cells. Difficult to spot fields with monolayer of cells and distorted appearance of the RBCs, malaria parasite and the white cells.

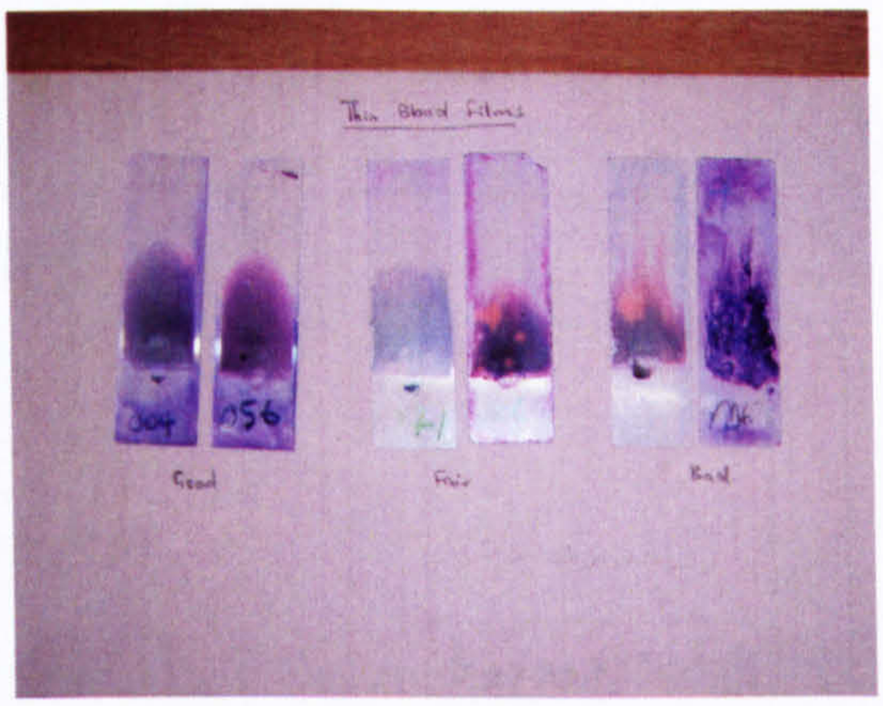
Sets of malaria slides and sputum smears which met the good, fair and bad criteria were used as control slides with which the sampled slides were assessed (Figure 4.4). A colour plate of the appearance of AFB in ZN stained sputum smear (WHO, 1998) was used as a reference for the microscopic appearance in TB microscopy (when necessary). Colour plates of the appearance of malaria parasites in Cheesbrough (1998) were used

as a reference to verify the microscopic appearance of malaria parasites observed (when necessary).

Figure 4.4: Control slides for assessing the quality of sputum smears and thin blood films.



(a) Control TB microscopy slides

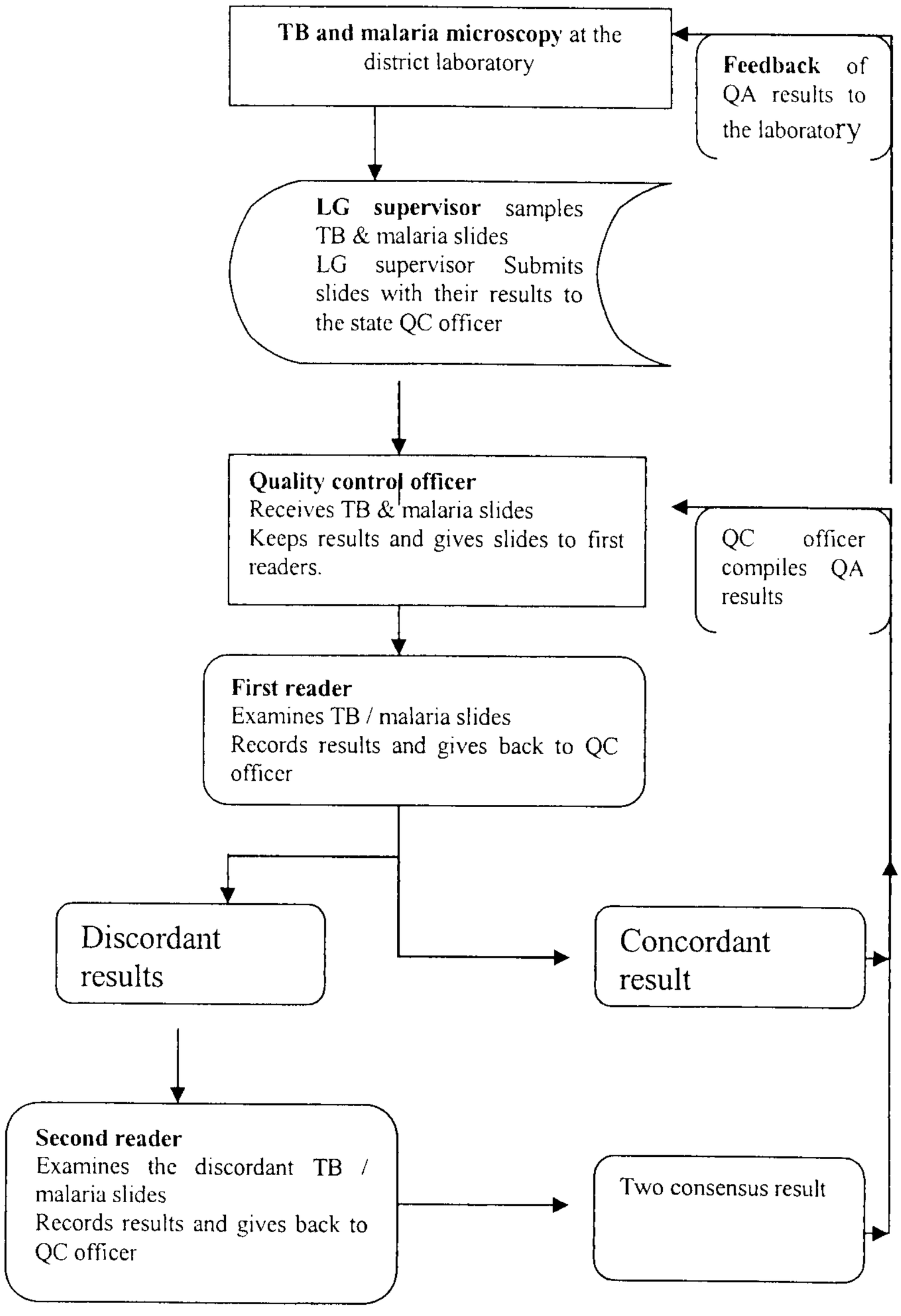


(b) Control malaria microscopy slides

4.4.2 Protocol for re-checking of TB and malaria slides

The first reader re-examined the sampled slides visually to assess the quality of smear and blood film preparation as good, fair or bad using pre-defined criteria (Table 4.5). 100 high power fields were examined for negative. Results from TB slides were graded using the standard grading table for TB microscopy (IUATLD, 2000). Results of malaria microscopy were recorded as positive *Plasmodium falciparum* trophozoites were present at < 10/field and >10/field or negative to indicate their absence (WHO, 2005a).

Figure 4.5: Integrated TB and malaria microscopy quality assessment scheme



The quality control officer collected the results of the first reader and compared them with the original results. If the original and first reader results agreed, the original result was accepted. Slides with discordant results were counter checked by the second reader without knowing the results of the first reader. The final result was taken as any two consensus results among the three readings (Figure 4.5).

Errors in reading TB and malaria microscopy slides were classified as:

- False positives (FP), when a negative sputum smear or blood film was misread positive
- False negatives (FN), when a positive sputum smear or blood film was misread as negative.

The assessment of quality of TB and malaria microscopy used were 1) the proportions of original microscopy results that were concordant, false positive or false negative, 2) the proportions of well prepared and / or stained sputum smear and blood films, 3) the sensitivity defined as the ability of microscopists to detect AFB or malaria parasite relative to the final results, and specificity defined as the ability of microscopists to identify AFB or malaria parasite correctly when present in a sputum smears or blood films. Trends in the changes of quality assessment and comparison of the baseline and final performance of each laboratory were evaluated.

The types of errors in TB microscopy were subdivided into major and minor errors. Major errors were:

(i) high false positives (HFP), when a negative smear was misread as 1+ to 3+ positive

(ii) high false negatives (HFN), when a 1+ to 3+ positive smear was misread as negative.

Minor errors were:

(i) low false positives (LFP), when a negative smear was misread as a low positive (1-9 AFB / 100 fields).

(ii) low false negatives (LFN), when a low positive smear (1-9 AFB / 100) fields was read as negative.

(iii) quantification error (QE), when there was a difference of one or more grades in quantifying AFB between the original reader and the controllers.

Results without any discrepancies were regarded as correct. The different categories of errors are presented in Table 4.6

Table 4.6 Classification of discordant results between the district laboratories and the first and second re-reading.

Result being rechecked	Result of re-checking				
	Negative	1-9 AFB / 100 f	1+	2+	3+
Negative	Agreement	LFN	HFN	HFN	HFN
1-9 AFB / 100 fields	LFP	Agreement	1+	QE	QE
1+	HFP	QE	Agreement	QE	QE
2+	HFP	QE	QE	Agreement	QE
3+	HFP	QE	QE	QE	Agreement

Source: Quality assurance for AFB smear microscopy (APHL, 2002)

4.4.3 Response on different types of errors

If there were no errors of any type the TB or malaria microscopy results are considered as target for the required performance at a sensitivity of 80%, specificity of 100% and 95% confidence interval.

Any major error (HFP or HFN) is unacceptable performance and triggers

- Evaluation of the causes of error.
- Corrective action.

Minor errors were reported back to the laboratory, but the laboratory performance is still considered acceptable unless they continue to appear in more significant numbers.

4.4.4 Feedback about quality of results to the Ministry of Health and participating laboratories

Feedback is a process of conveying the findings on the performance of laboratories after an external quality assessment exercise for correction and quality improvement. The primary purpose of a rechecking programme is to improve the overall quality of smear microscopy. Feedback on the findings of this project was made at 2 levels:

i. To the officials of the ministry of health

Following the analysis of the results of the re-checking at the end of each quarter, preliminary observations on the performance of each of the laboratories and the types of errors detected were compiled as an interim report and submitted to the TB control officer. This facilitated the identification of laboratories with excellent, good or poor performance and where immediate problem solving was most urgently needed. The interim reports consisted of the following components:

i Itinerary for the EQA visits

ii Brief account of AFB microscopy activities in each TB centre

iii Performance of each centre on the quality of AFB microscopy in terms of

- Smear preparation and staining qualities
- Proportions of true positive (TP), true negative (TN), high false positive (HFP), high false negative (HFN) and quantification error.
- Sensitivity, specificity, positive predictive value and negative predictive value.

iv Major technical and administrative problem(s) at each of the centres

v Suggestions for remedial action and service improvement.

A total of six interim reports were compiled and submitted at the end of the 2 quarters of 2005 and at the end of the four quarters of 2006.

No report submission of report was made to the malaria control unit because there was no laboratory component in the malaria control programme. However, the results of the rechecking of malaria slides were discussed with the state malaria control officer, the Directorate of primary health care and the Director of medical and health services in the state ministry of health. This was done in order to demonstrate the need for creating a sustainable system for quality checking of malaria microscopy in public laboratories in Kano.

The results of QA for both TB and malaria microscopy quality assessment were included in a progress report submitted to the commissioner of health in September 2006.

ii. To the laboratories

Findings were also used as feedback to the laboratories for remedial action during the next quality assessment visit. During the feedback sessions, the laboratory staff wer informed on their performance in terms of the quality of smear preparation, staining, agreement of their results with the finding of rechecking exercise, the errors found and their possible cause and suggestions on how to correct errors and improve the quality of their results (Figure 4.6a; Figure 4.6b).

Figure 4.6: Feedback of quality assessment results to the laboratories

Figure 4.6a: A feed back session at WDL

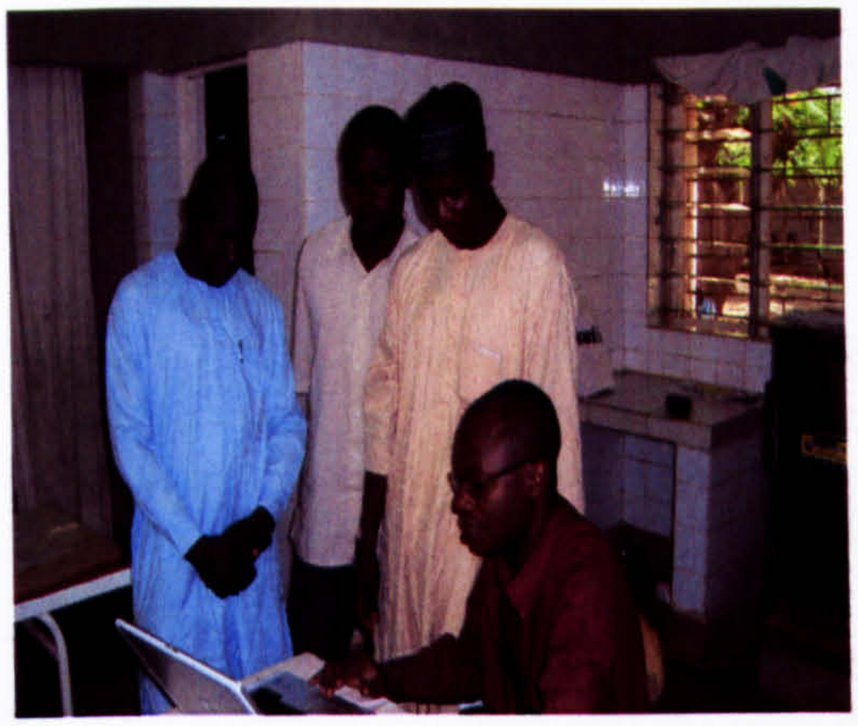


Figure 4.6b: A feedback session at GWZ

The feedback mechanisms developed and piloted in this project were:

1. Returning slides with discordant results to be repeated by the original microscopists and reviewing them with the state quality control officer and myself. This was used as an educational tool in order to give the microscopists a chance to show what they interpreted as AFB, or to be shown AFB they have missed.

2. Discussing the potential sources of error, including quality of stains and staining procedure, quality of microscopes, and administrative procedures that may contribute to reading errors with the laboratory personnel.

3. The results of the baseline assessment of malaria microscopy was discussed with the participants of the 1 day refresher training conducted for microscopists to demonstrate the degree of concordance and discordance of malaria microscopy results in relation to the final assessment result from different laboratories.

4. If numerous slides were missing, it may indicate that the microscopists may be destroying slides that were of poor quality, all slides are not being read, or technicians

may not understand the need to save slides for rechecking. The microscopists were made to understand that rechecking is not a method for validating individual patient's diagnosis, but rather of assessing overall laboratory performance, detecting unacceptable levels of errors so that corrective action can be taken, and providing continuous motivation for good performance.

5. If no obvious problem were detected the microscopists were commended and encouraged.

4.4.5 Remedial actions

Remedial action is the responsibility of the health managers. The input of this project to the remedial actions was the submission of interim reports identifying the technical and administrative problems and suggestions for their remedies. The project also provided training and 'back up' supplies.

a) On-site training for microscopists in the 5 sites on identification of AFB in sputum smears and mechanisms for internal quality control and external quality assessment.

b) Training of community tuberculosis control supervisors on their role in the supervision and sampling of examined AFB slides for the external quality assessment. A 1 day training was organized in collaboration with the state TB control programme organized training for the LGA TB supervisors with the following objectives:

- Sensitize the LGA TB supervisors on the meaning, principles and the importance of quality assurance of TB microscopy in DOTS services
- Expose them to the components, procedures as well as role of various personnel involved in the conduct of TB microscopy QA activities
- Promote proper coordination between the laboratory and the DOTS clinics in the TB patients care

- Familiarize them with their role in the conduct of TB microscopy QA and in the identification of problems and implementation of corrective measures for improving the quality of TB microscopy services

c) **A one-day refresher training workshop** on the identification of malaria parasites in Leishman stained thin blood film was conducted on Saturday 14th October 2006 for the microscopists in district hospitals of the 5 selected centres for this project. The workshop also introduces the participants to the principles of quality control of malaria microscopy. Consultation was held with the participants on the development of a model quality assurance system for malaria parasites microscopy and the feasibility study of conducting the external quality assessment of malaria parasite microscopy along with that of AFB microscopy in their respective laboratories.

d) Backup supply of some reagents and materials such as slide boxes to the centres in need.

4.5 Project Evaluation

The project was evaluated at the end of 24 months in terms of:

- Achievement in the scaling up and sustenance of the EQA system for TB microscopy in Kano state and the development of an integrated system for assessing the quality of TB and malaria microscopy.
- Impact of the implementation of the EQA strategies in terms of single time point difference at each assessment period using the quality of sputum smears / blood films and staining, agreement between results from the district laboratories and the first and second re-readings at the quality control unit, types of errors detected and the sensitivity and specificity.

- Result of the final assessments of results agreement, quality of smears / blood films, quality of staining, sensitivity and specificity were compared with the baseline results in order to identify the areas of improvement or otherwise
- The quality control culture in these laboratories was assessed by the availability of microscopists during supervisory visits and their ability to make available all the TB and malaria slides examined in their laboratories

4.5.1 Evaluation of integration

- Integration of TB and malaria microscopy QA was rated in individual laboratories by the number of times the evaluation exercise for TB and malaria were conducted in the laboratories.
- Full integration of TB and malaria QA in laboratories was defined as the three assessments for malaria microscopy that were conducted during the TB microscopy supervisory visits, partial integration was defined as at least one joint assessment and no integration was where malaria microscopy assessment was not conducted.

4.6 Data analysis and results presentation

Microsoft Excel (3003) and SPSS version 15 (2007) programs were used to analyze the quantitative data in terms of percentages of:

- Good, fair and bad categories of sputum smears and blood films
- Good, fair and bad categories of staining of sputum smears and blood films
- Concordance between results from the district laboratories and the re-reading of the first and second readers.
- Types of errors detected
- Evaluation of sensitivity and specificity of the district laboratory readings of TB and malaria slides relative to the first and second control readers

4.6.1 Statistical analyses

Statistical Package for Social Sciences (SPSS) 15.0 software was used to analyze the data to establish:

- The statistical significance of the trend of changes observed between the periods of assessment using the Chi square test of significance.
- Kappa statistics was used to determine the coefficient of agreement (Kappa) between results from the district laboratories and the first and second re-readings, using the Win Episcope version 2.0 programme.
- Correlation coefficients between the numbers of concordant results and the numbers of good, fair and bad sputum smears / blood films and staining were determined using the SPSS programme.

SPSS 15.0 software was used to determine the statistical significance of the changes observed between the periods of assessment using the Chi square test of significance. Kappa statistics was used to determine the coefficient of agreement (Kappa) between results from the district laboratories and the first and second re-readings, using the Win Episcope version 2.0 programme. Correlation coefficients between the numbers of concordant results and the numbers of good, fair and bad sputum smears and/or blood films and staining were determined using the SPSS programme.

CHAPTER 5

5.0 RESULTS OF THE BASELINE ASSESSMENT OF LABORATORY SERVICE IN KANO STATE

5.1 Laboratory structure and administration

Medical laboratories in Kano state were managed by laboratory scientists or experienced technicians and assistants. The administrative role of these officers was limited to the laboratory. They do not take part in the influential planning and budgeting committees at the hospital, health zones and the state ministry of health levels. Laboratories were represented on these committees by the medical department.

Laboratories in the tertiary heath facilities (MMSH and MASH) had separate units of blood banking, chemical pathology, haematology, microbiology, parasitology, and serology tests. The laboratories in secondary health facilities were multipurpose laboratories made of single or two rooms with separate work areas for different tests. They have less workload than the tertiary health facility laboratories.

The mode of financing laboratories was the revolving fund scheme. It was difficult to obtain records on financial management in 11/13 of the laboratories assessed because records were either not available or could not be accessed. (Table 5.1). The finance estimates suggest that both MAWSH and IDH laboratories generate profit from their services. However, a higher profit was generated from MAWSH laboratory (a tertiary health facility) than the IDH laboratory (a secondary health facility).

Table 5.1 Available laboratory financial data in Kano (2004)

Item	Amount per year (N)*	
	MAWSH	**IDH**
Budget allocation to the laboratory	300,000 (£1,250)	Not specified
Total expenditure	Not specified	142,290 (£592.88)
Turnover from patients' charges	1.5 million (£6,250)	300,000 (£1,250)
Estimated profit from patients' charges (if any)	300,000 (£1,250)	160,000 (£666.67)

* Exchange rate: £1 is equivalent to N240.00 (April, 2007)

5.2 Electricity supply: The main source of electricity supply to laboratories in Kano was the Power Holding Company of Nigeria (PHCN). There was a variation among laboratories on the duration of power supplies from the main source and from standby generators (Table 5.2). There were continuous power supplies to laboratories in the 2 (17%) tertiary health facilities. 10 (83.3%) of the laboratories had an intermittent inadequate electricity supply (Table 5.3). 6 (50%) had a standby generator to complement power supply from the main PHCN source. 5 (42%) laboratories that had no stand by generator relied solely on the main PHCN supplies.

Table 5.2: Electricity supply to medical laboratories in Kano (2005)

Laboratory	Hours of supply per day by PHCN
MMSH	Not recorded
MAWSH	Not recorded
HBP	4 hrs
IDH	4 hours on average (range 6 – 8)
WDL	< 2 hours
GZW	3hrs on average, range 0 – 5 hrs
GWZ	6hrs average, range 3-8 hrs
DBT	Not recorded
KUR	1.30 (0-6)
BCH	Not recorded
RAN	2 hrs on average, range 1-2 hrs
SML	Not recorded

Table 5.3: Durations of electricity supply to medical laboratories in Kano (2005)

Electricity Supply	Number of laboratories (n=12)
Continuous supply by PHCN	None
Intermittent supply by PHCN only	5 /12 (42%)
Continuous supply by PHCN & generator	2 /12 (17%)
Intermittent supply by PHCN & generator	10/12 (83%)

The current situation of electricity supply to laboratories in Kano was described by the laboratory staff as:

"It is very difficult to state the time when electric power supply is available, there is no specific time. All we know (is that) there is no stable power supply only some times that we do have light, but the days without light is much more than days spent with light" (Danbatta general hospital 2005)

"Electricity supply to the laboratory is inadequate. Sometimes there is low voltage electricity which is equivalent to none and cannot be used for any laboratory activity." (A laboratory staff in Gezawa general hospital April, 2005)

"Due to the problem and difficulties of these power supply in Kano and Bichi, most of works in the laboratory (that we could not perform) we send them to Kano. (Laboratory staff in Bichi general hospital April, 2005)

5.3 Water supply: The main source of piped water to 8/12 (67%) of the hospital laboratories assessed was the Kano State Water Board (KSWB). 4/12 (33.3%) had water supplies from boreholes. However, supplies by the main source were often irregular and not continuous. A continuous supply of piped water was available in the two tertiary health facilities and one secondary health facility 3/12 (23%). In MMSH and MAWSH, continuous piped water supply is achieved through bore holes constructed within the hospitals and an adequate electricity supply to pump the water to all parts of the hospitals. There were no water distillation, de-ionization or filtration facilities in any of the laboratories with continuous water supply. The majority 9/12 (76.9%) of the laboratories had taps and water sinks with no continuous water supply (Table 5.4).

Table 5.4: Water supplies to medical laboratories in Kano (2005)

Water Supply	Number of laboratories (n=12)
Continuous piped water supply	3 / 12(23%)
Intermittent piped water supply	9 /12 (77%)
De-ionizer available	0 (0%)
Water filter available	0 (0%)
Water distiller / deionizer	0(0%)

Continuous water supply in any laboratory depends on the ability of the management to maintain an alterative source of water supply, because supply from the main source was not continuous. The following comments were made by the laboratory staff concerning water supply to the laboratories:

"Bichi LGA is doing very well by supplying water all the time in the hospital and staff house as well" (Bichi general hospital April 2005).

"Water supply to the laboratory is from the hospital bore hole which is normally as early in the morning and it depends on the electricity supply. If there is electricity then there is water, no electricity, then no water" (Danbatta general hospital April 2005).

"There is poor water supply and the little daily water supply is inadequate. Borehole should be renovated or reconstructed". (Sumaila general hospital April 2005).

"... inadequate supply of water results in insufficient cleaning of laboratory" (Rano general hospital, 2005).

5.4 Laboratory safety

Assessment of safety was limited to the observable laboratory safety features during supervisory visits. The observable safety measures among the laboratories are presented in Table 5.5 with details in Appendix E1. At least 10 laboratories operated the following safety practices:

- The availability of hand washing facilities in all laboratories.
- Practice of hand washing before leaving the laboratory among staff.
- Use of disposable gloves when dealing with blood and blood products.

At least 10 laboratories demonstrated the following deficiencies in safety practices:

- Lack of written instruction for safe laboratory operation.
- Mouth pipetting.
- Access of non-laboratory staff to work areas.
- Food or and drinks in the laboratory premises.
- Lack of fire extinguisher or sand buckets.
- Lack of first aid kits.

Table 5.5 Safety measures observed in 10 laboratories in Kano (April 2005)

Safety measures	Observed (n=10)
Hand washing available in each laboratory room	10
Hand washing on leaving the laboratory	10
No mouth pipetting used for some tests	8
No food or drinks in the laboratory premises	6
Disposable gloves being worn	6
White coats being worn	5
Work area restricted to laboratory staff only	3
Fire extinguisher available	2
Written instructions for safe laboratory operations	0
Manual for equipment operation or maintenance	0
Planned programme of preventive maintenance for all electrical equipment	0
Safety hood available and being used	0
First aid kits available	0

5.5 Basic laboratory equipment: The assessment showed that MMSH and MAWSH had three functional microscopes each in their microbiology, parasitology and haematology units. Seven laboratories in secondary health facilities had one functional microscope each, while 2 laboratories had no microscope. 13 out of 22 (59%) microscopes all laboratories were functional. All (6/6) of the haematocrit centrifuges and 88% (15/17) of the desk top centrifuges were functional. Less than 50 % of incubators (31%), weighing balances (40%) and water baths (44%) were functional (Table 5.6). Overall, 62% of the equipment inspected was functional. The availability and condition of basic laboratory equipment is presented in Appendix D5.

Table 5.6 Assessment of basic equipment in laboratories in Kano (2005)

Equipment	Total Number	Number Functional (%)
Haematocrit centrifuge	6	6 (100)
Haematocrit reader	6	6 (100)
Centrifuge	17	15 (88)
Blood bank refrigerator	7	6 (86)
Autoclave	8	6 (75)
Laboratory refrigerator	26	17 (65)
Binocular microscope	22	13 (59)
Colorimeter / Spectrophotometer	12	6 (50)
Water bath	18	8 (44)
Weighing balance	15	6 (40)
Incubator	13	4 (31)
Total	150	93 (62)

Some of the staff in the laboratories assessed made the following remarks about the conditions of equipment in their laboratories:

"Most of the equipment are not functional and there is little or no arrangement for their repairs and maintenance. For some that are functional, there is no regular power supply to operate them" (A laboratory staff in Gezawa general hospital April 2005).

"Most of the equipment are obsolete and broken down. Those that are in good condition the maintenance and service of equipment is not easy to come by". (A laboratory staff in IDH Kano April 2005).

5.6 Staffing

There were high concentrations of laboratory staff in the tertiary health facilities. MMSH laboratory had the highest number of staff, having 60 (47%) staff, while MAWSH laboratory had 17 (12.5%) of the staff included in this assessment. The number of staff in the rest 11 laboratories ranged 1- 8 (Table 5.7). The major proportions of laboratory staff (32.8%) were laboratory assistants.

The number of staff per laboratory were 6 and 8 in IDH and HBP respectively (located in urban Kano), while in laboratories located in semi-urban areas, the number of staff ranged from 3- 6. KRY however had only one staff. There were 1 – 2 qualified medical laboratory scientists in 5 (38%) and none in 6 (46%) of the secondary health facilities. Laboratory assistants constitute the highest proportion (30.2%) of staff, while graduate scientists constituted 27 (21%) of the laboratory staff in Kano (Table 5.7).

Table 5.7: Distribution of different categories of laboratory staff in Kano (2005)

Centre	Lab. scientists	Graduate scientists	Technicians	Assistants	Attendants	Total
MMSH	19	12	10	15	4	**60**
MAWSH	2	8	0	6	1	**17**
HBP	0	2	2	4	0	**8**
IDH	2	0	1	2	1	**6**
WDL	2	1	1	0	1	**5**
GWZ	0	0	2	2	1	**5**
DBT	1	1	1	2	1	**5**
KUR	1	1	1	1	1	**5**
BCH	0	0	0	5	0	**5**
RAN	0	0	1	2	1	**4**
GZW	1	0	0	1	1	**3**
SML	0	2	0	1	0	**3**
KRY	0	0	0	1	0	**1**
Total (%)	**28 (21.9)**	**27 (21.1)**	**19 (14.8)**	**42 (32.8)**	**12 (9.4)**	**128**

5.7 Types and number of tests: Blood transfusion tests had the highest frequency among the types of tests carried out in the laboratories making up 29.5% of the total tests conducted in one year (Table 5.8). Blood transfusion tests comprise blood grouping (60%), cross matching (8.1%), HIV screening (18.5%), HBV screening (11.1%) and haemoglobin estimation (2.4%) Details of the categories and number of

individual tests conducted in the year 2004 in the selected laboratories are shown in Appendix E3.

Microscopy tests made up 21% of the number of tests conducted in one year. The proportions of malaria and AFB microscopy among the microscopy tests were 35.1% and 27.2% respectively (Table 5.9). The highest numbers of TB and malaria microscopy tests in Kano were conducted in IDH and MMSH laboratories respectively. TB and malaria microscopy were among the test procedures were performed by the scientists, technicians or assistants.

Table 5.8: Categories and number of tests conducted in laboratories in Kano (2004)

Category of tests	Total	Percentage
Blood transfusion	84832	29.5
Microscopy	59999	20.8
Haematology	56249	19.6
Chemical pathology	50096	17.4
Serology	25661	8.9
Culture	10949	3.8
Total	**287786**	**100**

Microscopy tests made up 21% of the number of tests conducted in one year. Malaria microscopy had the highest proportion of 35.1% followed by AFB microscopy (27.2%). Other types of microscopy services included urine microscopy (16.4%), stool microscopy (7.4%) and microscopic examination of swab specimens (13%). Microscopy of CSF, and other body fluids, fungal specimens and semen analysis make up 0.9% of the microscopy services conducted by the laboratories in the year 2004 (Table 5.9).

Table 5.9: Types and number of microscopy tests conducted 13 selected laboratories in Kano (2004)

Types of microscopy	Total	Percentage
Malaria Microscopy	21074	35.1
AFB Microscopy	16329	27.2
Urine Microscopy	9859	16.4
Stool Microscopy	4451	7.4
Swabs Microscopy	7790	13
CSF / Body Fluids Microscopy	233	0.4
Semen Analysis	227	0.4
Fungal Microscopy	36	0.1
Total	**59999**	**100**

The basic tests recommended in the primary health care level (NML Policy, 2006) were also conducted at the secondary and tertiary level laboratories. Greater proportions (58.1%) of these tests were conducted in tertiary level laboratories than in the secondary level laboratories (41.9%), with the exception of pregnancy tests (Table 5.10).

Table 5.10 Comparison of the number of basic laboratory tests conducted in the secondary and tertiary health facilities in Kano (2004)

	Secondary health facilities (n=10)	Tertiary health facilities (n=2)	
Tests	**Number of tests (%)**	**Number of tests (%)**	**Total**
Urine Microscopy	3756 (38.1%)	6103 (61.9%)	9859
Stool Microscopy	1343 (30.2%)	3107 (69.8%)	4450
Urinalysis	2750 (25.4%)	8057 (74.6%)	10807
Malaria microscopy	7448 (35.3%)	13626 (64.7%)	21074
Haemoglobin estimation	2028 (100%)	0 (0%)	2028
Pregnancy test	9537 (53.9%)	8166 (46.1%)	17703
HIV screening	7338 (46.8%)	8346 (53.2%)	15684
Total	**34200 (41.9%)**	**47405 (58.1%)**	**81605**

The following remarks were made by the laboratory staff in response to a section requesting their comments in workload in the checklist.

"The average number of tests per month for each of the tests listed will increase only when facilities for these tests were provided to the laboratory because most of these tests were referred (Sumaila general hospital April 2005)

"Most of the chemical pathology work is being referred to MMSH and AKTH because there is no supply of equipment for most of the tests being mentioned. (Danbatta general hospital April 2005)

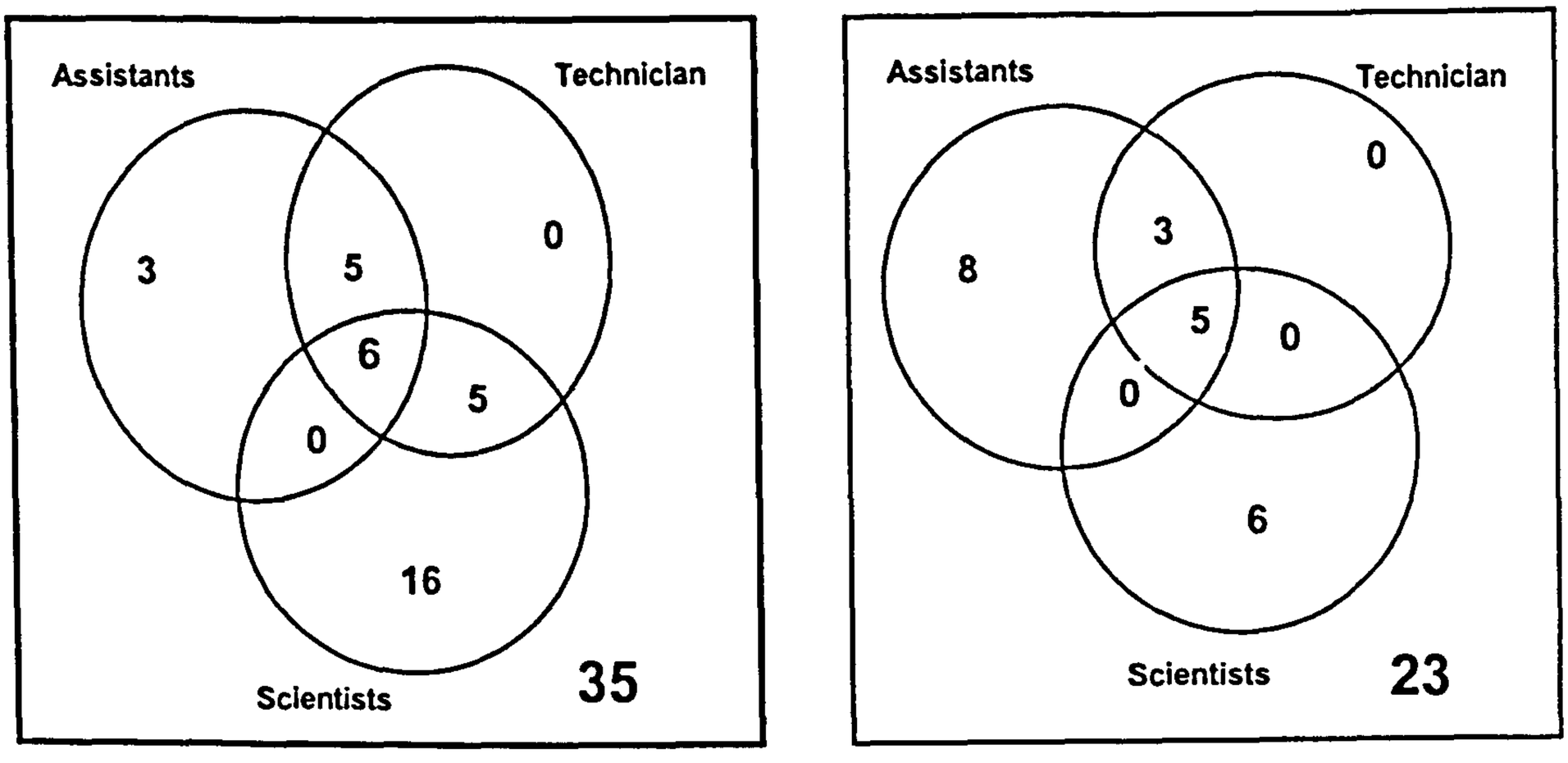
"Lack of most (of) these facilities (equipment), some of the tests will not be carried out. Mostly chemistry and microbiology we refer them to Kano" (Gezawa general hospital April 2005).

5. 8 Test selection and methods

A total of 36 different tests were conducted in the laboratories assessed. 35 of the tests were available at the tertiary health facilities, while 23 were conducted in the secondary health centres (Figure 5.1). The method used for each of the tests together with the staff (assistants, technicians and scientists) assigned to perform the test are presented in Appendix E4. Numbers in the sets (circles) represent the number of test procedures performed only by the staff category identified with the set, while numbers in the overlapping sets represent the number of test procedures shared among the different categories of staff in the laboratories.

The laboratory scientists performed more tests in the tertiary health facility laboratories (16/35) than in the secondary health facility laboratories (6/23). The tests performed by the laboratory scientists only were the microbiological cultures and some tests in chemical pathology such as urea and electrolyte / creatinine estimation, calcium and phosphate ions determination, CSF chemistry and the determination of protein in body fluids (Figure 5.1).

Figure 5.1: Number of different tests and staff conducting the tests in laboratories (2005)



The laboratory assistants performed more tests (8/23) in the secondary health facility laboratories, than in the tertiary health facilities (3/35). The tests performed by the laboratory assistants only comprised haemoglobin estimation (rapid method), stool microscopy, blood glucose test, pregnancy test, urinalysis, ESR, PCV and VDRL. Haemoglobin estimation using the Tallquist rapid detection technique was conducted in the secondary health facilities in semi-urban Kano.

The test procedures were performed by the scientists, technicians or assistants comprised blood grouping, cross-matching, HIV screening, TB microscopy, malaria microscopy and Widal test.

5.9 Methods of quality control

Responses by the head of laboratory units on the methods of internal quality control and external quality assessment of test results used in their respective laboratories are presented in Table 5.11.

Table 5.11: Methods of internal quality control and external quality assessment among 12 laboratories in Kano (2005)

Tests	Internal quality control methods
Pregnancy test, urinalysis, Widal test; Urine microscopy, culture and sensitivity	3 laboratories were repeating a test when in doubt of the result; Random sampling of analyzed samples to repeat the test
VDRL, HIV screening and HBV screening.	2 laboratories were following manufacturer's instructions and the use of kit's controls for each batch of the tests.
AFB microscopy and malaria parasites microscopy	5 laboratories were using preserved blood samples and slides with positive results to compare with the results of routine samples
Blood grouping and cross-matching	10 were using the cross-matching results as a control for blood grouping result of the same sample
Microbiolgical cultures	2 laboratories were sending samples to colleagues in other laboratory to repeat identification tests for bacteriological culture results.
	External quality assessment
HIV screening	3 laboratories participated the external quality assessment samples screened for HIV from voluntary counseling test (VCT) centres

The responses of some laboratory staff on the internal quality control and external quality assessments and the problems of associated with their practice in their respective laboratories were as follows:

"We have only quality control of our HIV tests for the voluntary counselling test (VCT) patient which takes place last year". (A scientist in Kura General Hospital Laboratory April 2005)

"The internal controls are mostly those included in the test kits, there is no specific guideline for QC for most tests carried out. Most problems encountered is that the revenue generating committee rarely allows for QC to be carried out using the test kits. Moreover, the number of tests per day sometimes hardly allows one to carry out control tests. Electricity is also not available to be keeping the control samples at the required storage temperature". (IDH laboratory April 2005)

"Quality control is only limited to the kits control and panel of sera kept within the laboratory for comparative test running ...cost constraints along with the attitude of the management which is not concerned with the quality of the results but revenue generated". (MMSH pathology laboratory April 2005).

5.10 Laboratory test requests

The use of standard laboratory forms was observed in 5/10 laboratories comprising 2 tertiary and 3 secondary health facilities. However, requests were still submitted to these laboratories occasionally on plain paper, prescription forms, headed note paper and X-ray forms. In 3/10 laboratories assessed, patient's cards were used to request laboratory tests, while results were reported on plain paper from the laboratory (Table 5.12).

Table 5.12: Assessment of request form completed by laboratory users in 10 laboratories in Kano (2005)

Feature of request form	Observed
Use of standard designed requisition form	5
Proper indication of patient's reference number	3
Proper indication of patient's age	6
Proper indication of patient's sex	10
Proper indication of clinical diagnosis	7
Relevance of specimens to requested tests	10
Clarity of information on the request form	7

There were indications of patients' sex (100%) and clinical diagnosis (70%) on the request forms assessed, while patients reference number were not indicated on most (70%) of the request forms (Table 5.12).

5.11 Situation analysis of TB and malaria microscopy in Kano (April, 2005)

In Kano state, multi-purpose laboratories located in district hospitals were used as designated TB microscopy centres. At the start of this project in April 2005, there were 8 TB microscopy centres among which only 5 had fully started TB microscopy and were storing the examined slides for external quality assessment. There were some internal quality control measures in the AFB microscopy centres which included preparing ZN staining reagents (carbol fuchsin, acid-alcohol and methylene blue) centrally at the TB control secretariat in IDH distributing to all the centres. New batch of staining solutions were tested by staining known, unstained, positive and negative smears by the quality control officer. Unstained smears were also provided to each of the microscopy centres and were being included in each batch of staining ever week. A minimum of one visit to each of the 5 centres in 2003 and 2004 was made for general supervision of microscopy activities, technical procedures, microscopes and supply of staining reagents and other materials.

However, the EQA scheme was not started because the appointed EQA officer was in charge of the IDH laboratories and was conducting other laboratory tests apart from TB microscopy, and had insufficient time for the quality assessment activities. There was lack of specific plans and adequate logistic support for transportation for the EQA activities. , the Local Government TB supervisors were also not involved in TB microscopy EQA activities. As such

- Selection and rechecking of TB slides from the microscopy centres had not begun.
- There was improper storage of slides or non storage of examined slides for rechecking in all the TB microscopy centres.
- Coordination between the laboratory and the DOTS clinics was inadequate.

There was no reference TB quality control laboratory. However, in the preparation for starting up the TB microscopy EQA, the TB control managers proposed laboratories in Gwarzo general hospital and IDH to be the 1st and 2nd readers respectively, for re-checking slides from the rest of the TB microscopy centres in the state (Mahmud, 2005). The state TB control programme proposed to adopt a slide sampling procedure of selecting 10 smear positive and 20 smear negative slides for rechecking between TB laboratories.

5.12 Situation analysis of malaria microscopy services in Kano (April 2005)

The national medical laboratory policy (FMOH, 2007) of Nigeria recommends that malaria microscopy services should be offered in the three-tiers of the health care system Nigeria. However, malaria microscopy was done only in the secondary and

tertiary levels of health care in most parts the country. At the primary health centres, malaria diagnosis was based solely on clinical signs and symptoms.

The results of our baseline assessment of medical laboratory services in Kano showed that:

- Malaria microscopy services were available in all the tertiary health facilities and 70% of the secondary health facilities in the state.
- Malaria microscopy constituted 35.1% of the microscopy tests conducted in one year in the tertiary and secondary health facilities.
- Leishman stained thin film examination was the technique use for malaria microscopy in all laboratories. Thick blood film using Giemsa staining technique was done in 8% (1/13) of the health facilities included in the assessment.
- RDTs were not used in any of the health facilities included in the assessment.

There was no refresher training of microscopists, no system for monitoring quality, and no infrastructure or financial support for malaria microscopy services in the state malaria control programme.

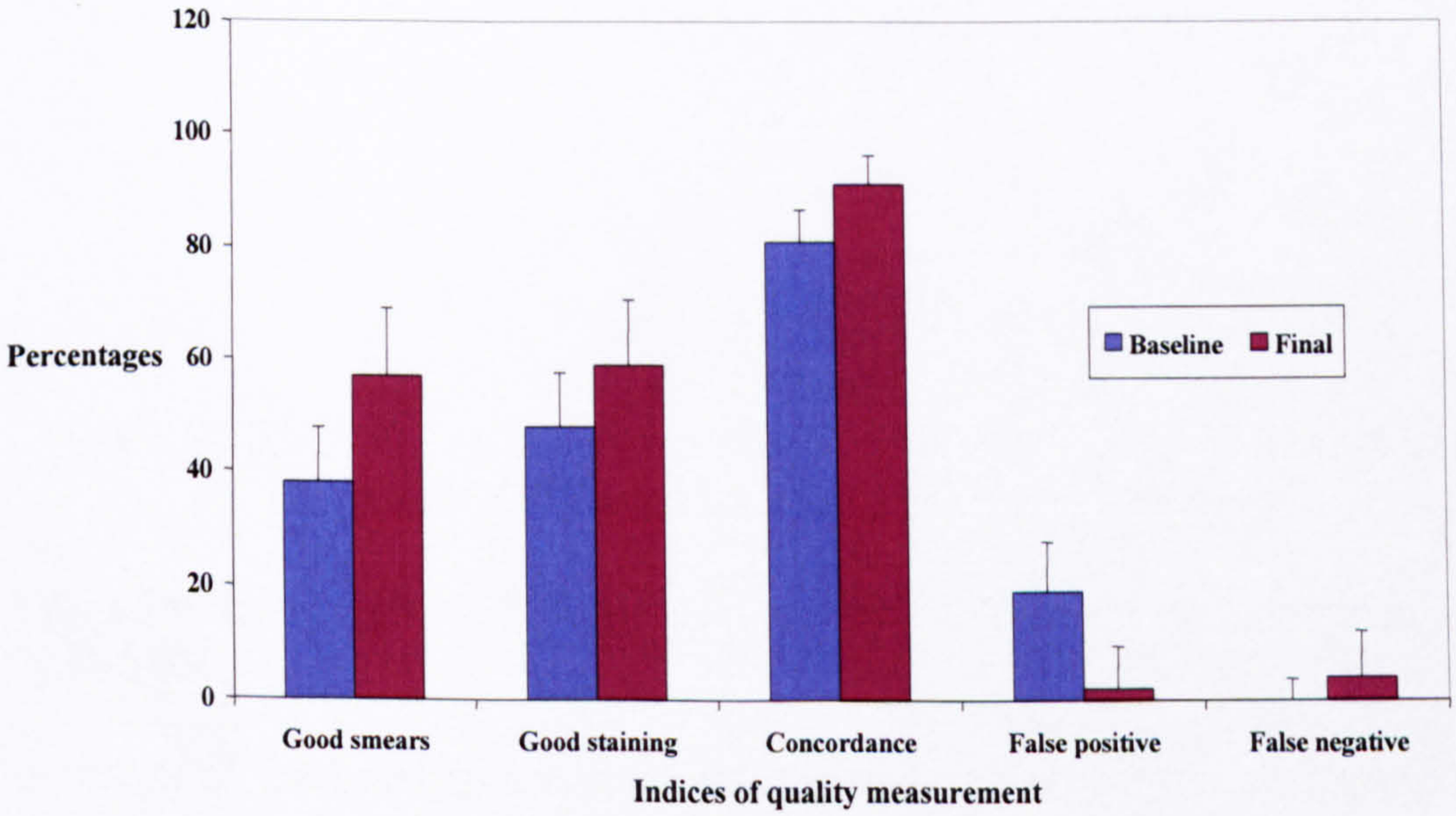
It is therefore essential to develop a system under the malaria control programme that would ensure accurate diagnosis of malaria as the basis for treatment with new antimalarial drug combinations and lower the cases of patients being treated for malaria for all cases of fever.

CHAPTER 6
6.0 RESULTS OF QUALITY ASSESSMENT OF TB AND MALARIA MICROSCOPY IN 5 LABORATORIES IN KANO.

6.1 Quality assessment of TB microscopy results from five laboratories in Kano (2005 – 2006)

The results of the baseline and final assessments of the qualities of sputum smears, staining, concordant results and the false positive and false negative results are compared in Figure 6.1.

Figure 6.1: Quality of TB microscopy from 5 laboratories in Kano before and after the project (2005-2006)



6.1.1 Quality of sputum smears

The proportion of good sputum smear preparation from all the laboratories had increased from 38% at the baseline to 57.1% at the final assessment (Figure 6.1). The trend of change in smear quality over time showed that smear quality decreased significantly between the baseline and assessment 5 after 18 months ($\chi^2 = 36.73$, $P < 0.001$) and then increased significantly between assessments 5 and 6 (21 months) from

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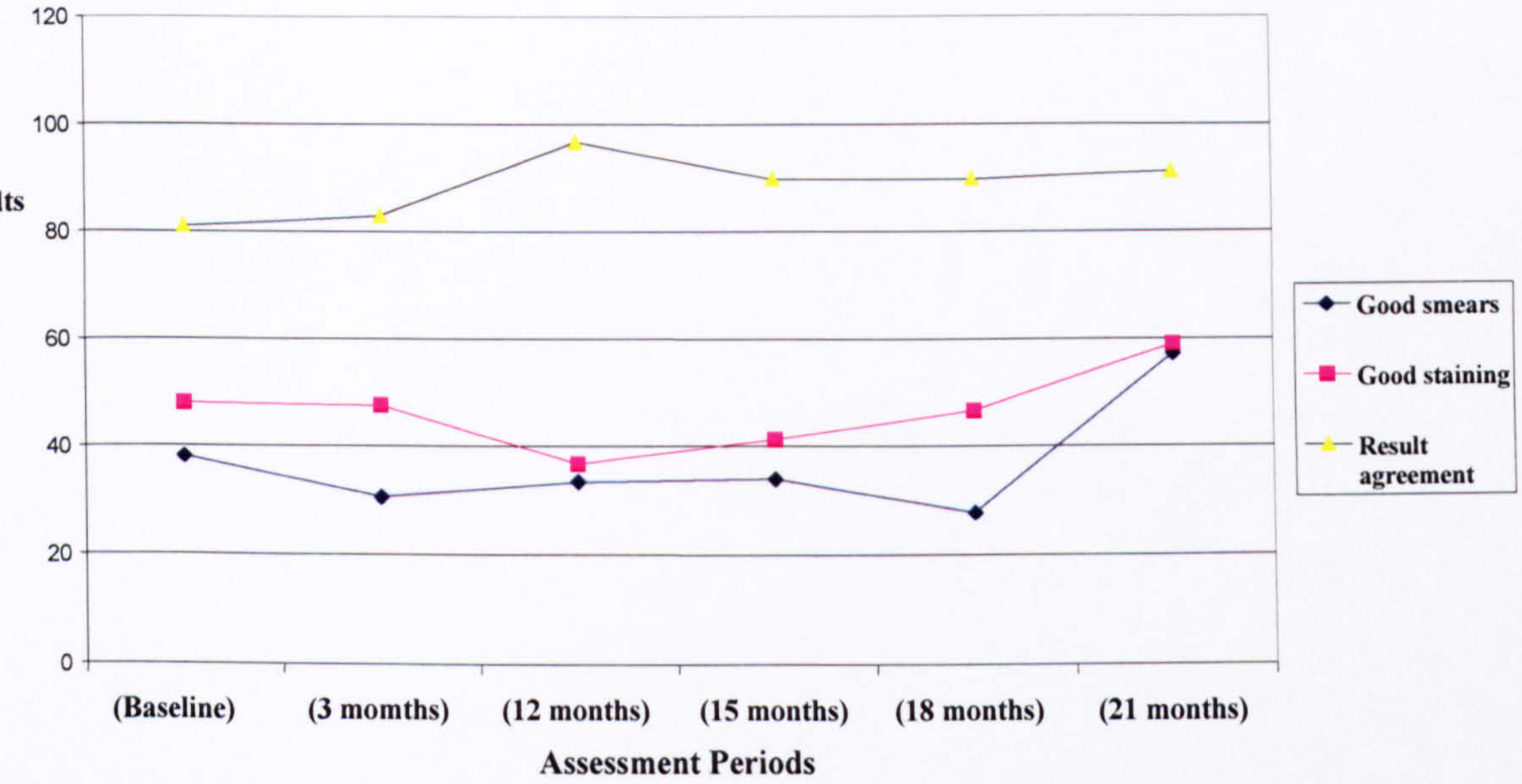
27.6% to 57.1% respectively (Figure 6.2). At the individual laboratories, there was a significant increase (χ^2 =18.55, P < 0.05) in the proportion of good sputum smears in WDL laboratory from 36.4% at the baseline to 73.3% at the final assessment (Appendix F.3).

Figure 6.2 Trends of changes in qualities of sputum smears, staining and concordance of tuberculosis microscopy results from 5 laboratories



6.1.2 Quality of staining

The proportion of good smear staining from all the laboratories had increased from 48% at the baseline to 58.9% at assessment time 6 after 21 months (Figure 6.2). The trend of change in staining quality over time showed a significant difference (χ^2 = 18.24, P < 0.05) in staining quality between the six assessments (Figure 6.2). At the individual laboratories, the proportion of good quality staining at WDL laboratory decreased gradually and significantly (χ^2 = 22.9, P < 0.05) between the baseline and assessment 5 after 18 months, returning to the baseline level at the final assessment (Appendix F.3). At DBT laboratory, the proportion of good staining was significantly higher at assessment 2 after 3 month than at any of the 4 periods for which data was available (Appendix F.6).

6.1.3 Quality of TB microscopy results

a. Concordant results

Concordant results, comprising the true positives and true negatives were defined as those results in agreement with the consensus result after re-reading of the first and second readers at the quality control unit. Although no statistically significant difference were observed between the concordance rates at different assessment periods, the concordance rates from all laboratories combined increased from 81.0% at the baseline to 91.1% at assessment period 6 after 21 months (Figure 6.2). The coefficient of agreement was relatively low (K = 0.353, range 0.203 – 0.502) at the baseline assessment indicating a high degree of agreement by chance, while the coefficient was relatively high (K = 0.792, range 0.533 – 1.245) at the assessment time 6 indicating a high degree of agreement beyond chance (Table 6.1).

The highest degree of agreement of 96.7% (K=0.889, 95% CI) between the readings at the laboratories and the first and second re-readers at the quality control unit was observed at assessment time 3 after 12 months (Table 6.1)

Table 6.1: Concordance of TB microscopy results from 5 laboratories in Kano with blinded re-checking result at the quality control unit (2005 – 2006)

	Concordant results (%)						
Assessment times	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
IDH (Kappa)	78.6% (0.404)	70% (0.918)	ND	58.7% (0.440)	92.3% (0.806)	86.7% (0.762)	**80% (0.685)**
WDL (Kappa)	72.7% (0.421)	100% (1.000)	100% (1.000)	13 (86.7%)	100% (1.000)	100% (1.000)	**94.2% (0.813)**
GWZ (Kappa)	95.5% (0.000)	93.3% (0.857)	93.3% (0.815)	100% (1.000)	86.7% (0.583)	100% (1.000)	**94.6% (0.817)**
RAN (Kappa)	58.3% (0.000)	53.3% (-0.125)	ND	86.7% (0.595)	ND	ND	**66.7% (0.026)**
DBT (Kappa)	96.3% (0.780)	100% (1.000)	ND	88.9% (0.000)	80.0% (0.286)	83.3% (0.400)	**91.0% (0.643)**
All Centres (Kappa)*	**81.0% (0.353)**	**82.9% (0.783)**	**96.7% (0.889)**	**89.7% (0.577)**	**89.7% (0.685)**	**91.1% (0.792)**	**87.5% (0.654)**

ND = No data available.
***Kappa coefficient at 95% level of confidence.**

Considering the overall performance as the proportions of concordant results from individual laboratories, GWZ and WDL had the highest proportions of concordant results (94.2% and 94.6%), while RAN had the lowest proportion. Results at the individual laboratories showed that 100% agreements (K=1.000) were achieved in 4/6 assessments at WDL laboratory and in 2/6 assessments at GWZ laboratory. This indicated a perfect agreement between results from these laboratories and the re-readings at the quality control unit.

At assessment 6, there were overall increase in the in the proportions of correct results from IDH, WDL and GWZ compared with that of the baseline (Figure 6.3). At DBT, the proportion of concordant results was 100% at assessment 2, but decreased to 83.3% at assessment time 6 (Figure 6.2). At RAN, data was available at only 3 assessment times (1, 2 and 4) shown in Appendix F5. There was also a marked increase in the

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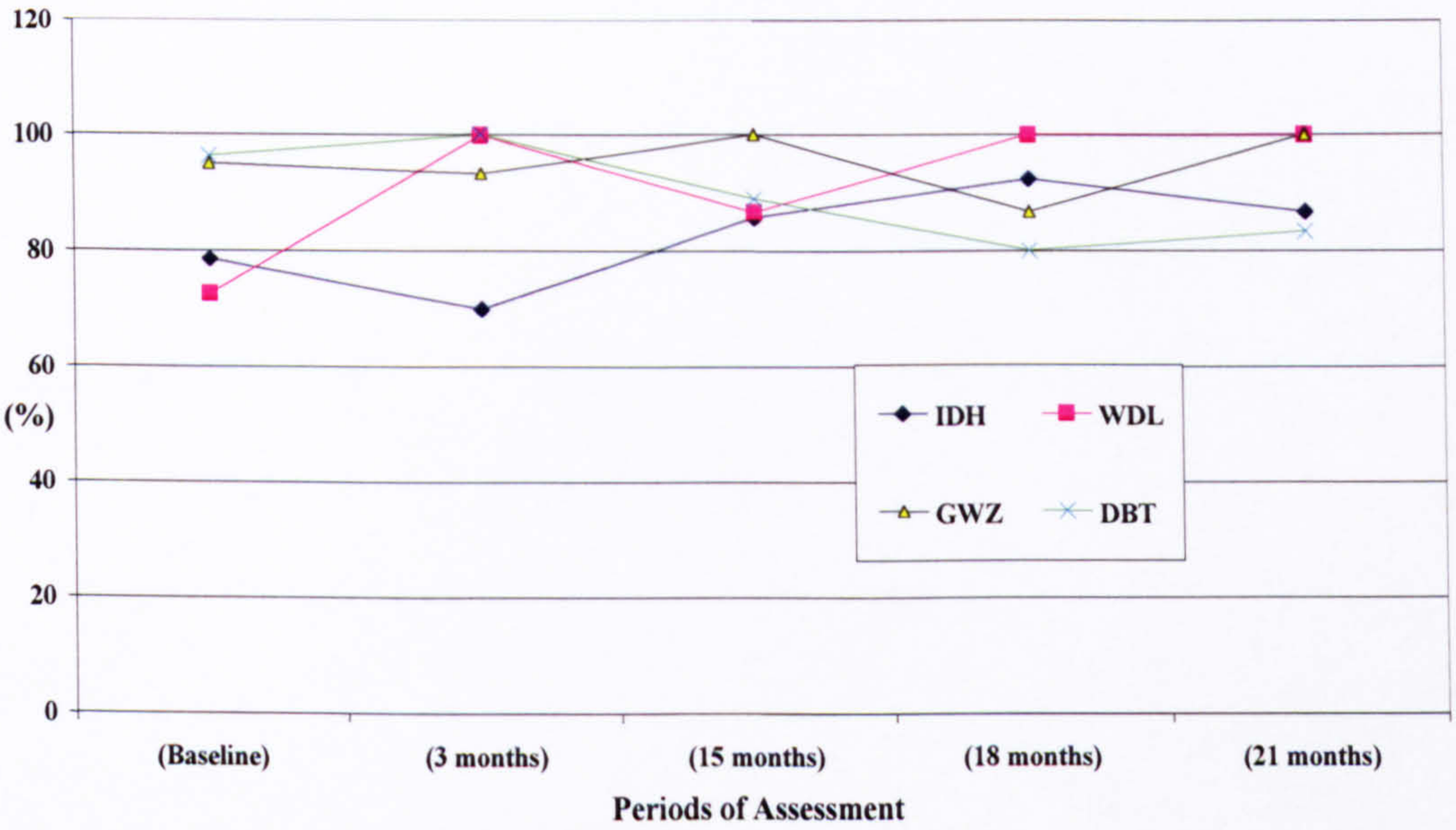
proportion of concordant results from RAN at assessment 3 compared with that at the other two assessment times for which data ware available.

Figure 6.3 Trends of proportions of correct TB microscopy results from 4 laboratories in Kano (2005 -2006)



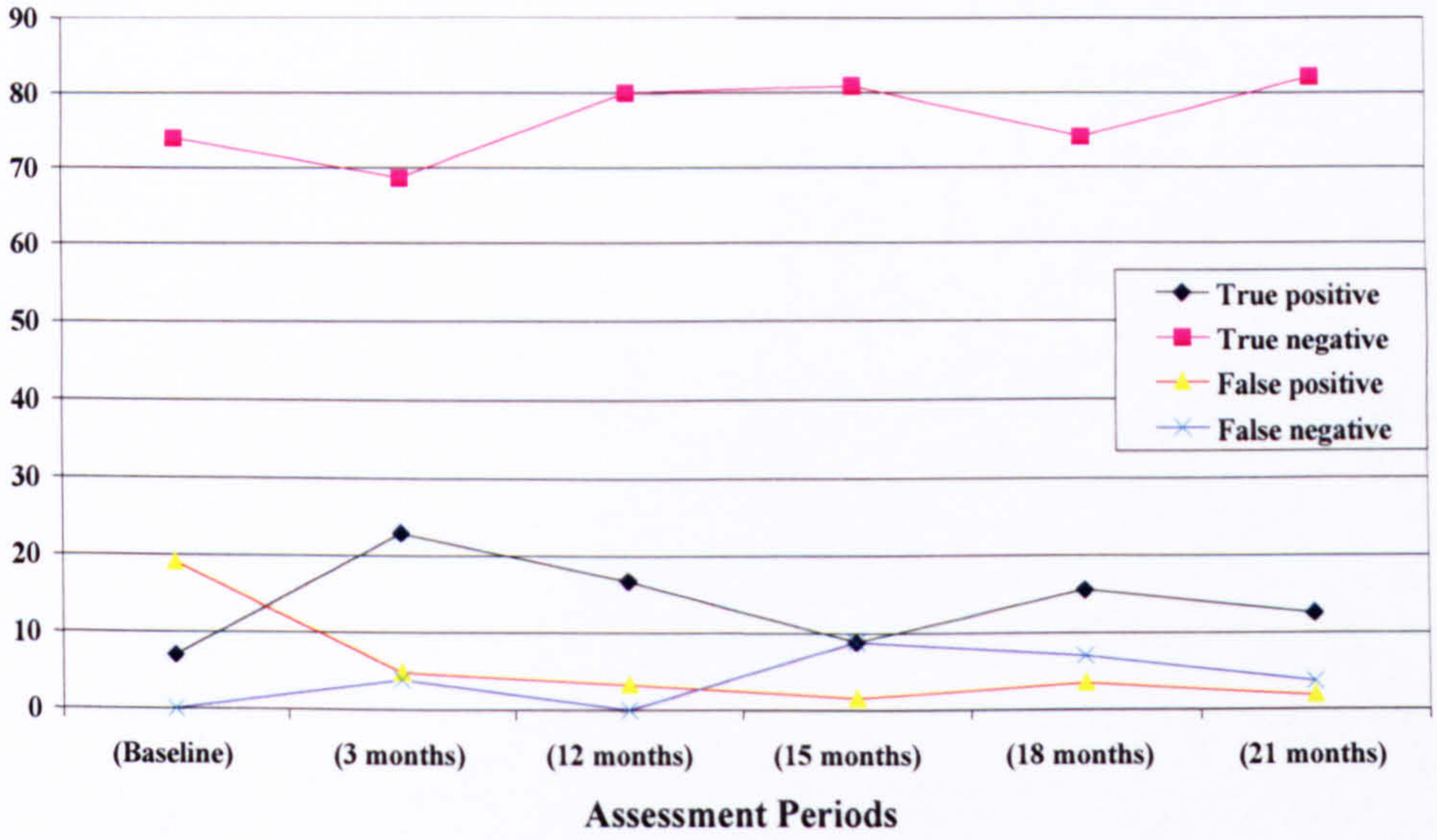
b. Discordant results

Discordant results, comprising the false positives and false negatives were defined as those results that were discordant with the consensus result after re-readings of the first and second readers at the quality control unit. Highly significant differences ($\chi^2 = 59.8$, $P < 0.001$) were observed in the proportions of different categories of TB microscopy results from the selected laboratories between the six assessments (Figure 12).

i. False positive results.

False positive results are defined as the results of negative sputum smears that were erroneously read as positive. The overall proportion of false positive reading from all the laboratories was 7.0% (Appendix F1). However, there was a decrease in the proportion of false positive results from 19% at the baseline to 1.8% at the 6th assessment after 21 months (Figure 6.4).

Figure 6.4 Trends of changes in the categories of TB microscopy results from 5 laboratories in Kano (2005 - 2006)



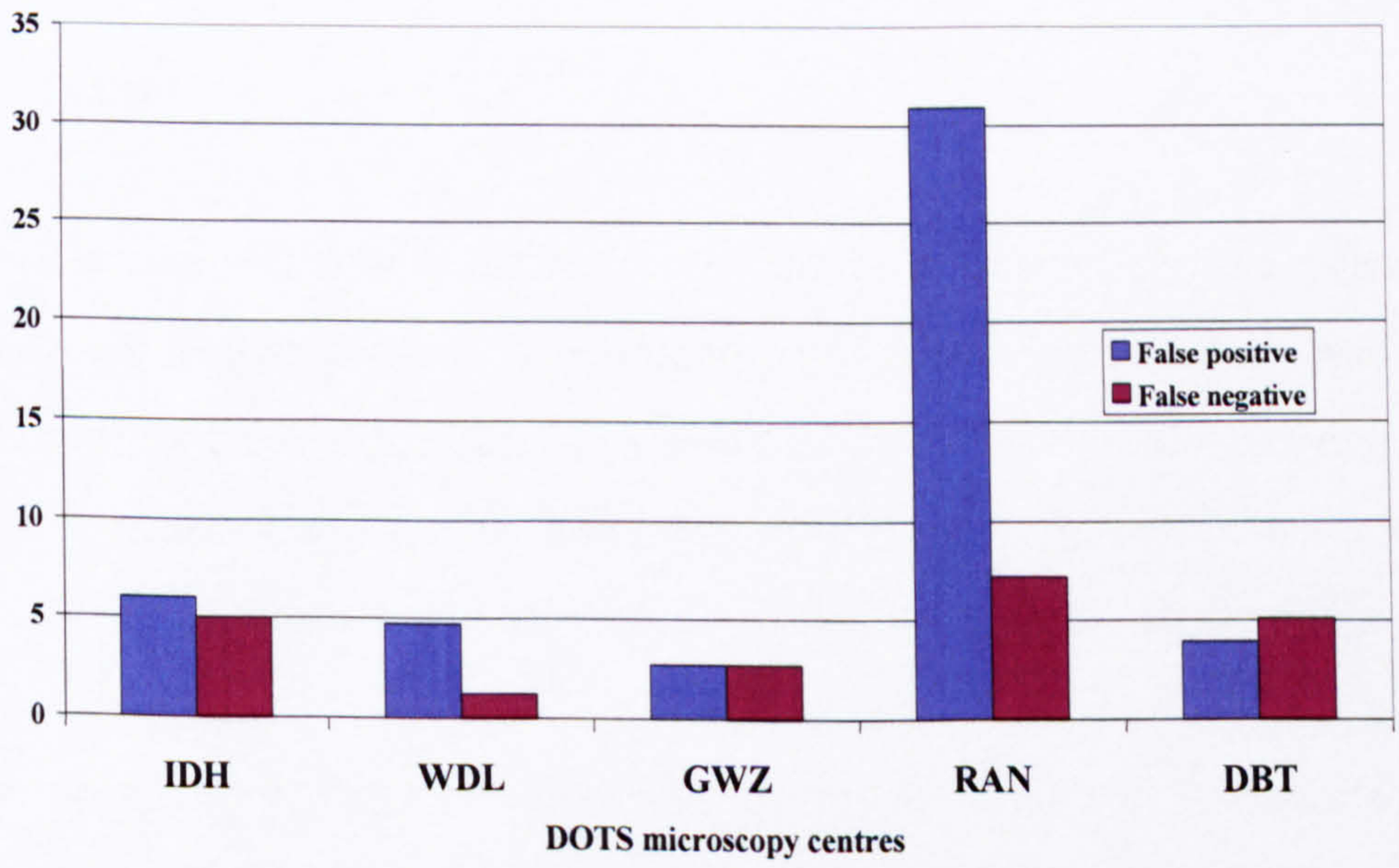
Considering results from individual laboratories, the proportion of false positive results at IDH laboratory decreased from 21.4% at the baseline to 0 % at the 6th assessment time, though this was not statistically significant (Appendix F2). At GWZ laboratory, there were highly significant differences ($\chi^2 = 35.54$, P =0.079) between the proportions of results at the six assessment periods. While at the baseline, there was a relatively high proportion of true negatives (95.5%), at assessment periods 2 and 3 there were relatively higher proportions of true positive results that at the rest of the assessment periods in GWZ laboratory (Appendix F4). At RAN laboratory, highly significant differences were observed between the three assessment periods for which data were available. The main component of this significance was the relatively higher proportion of false positive results (68.6%) at the baseline assessment that at the other two assessment periods (Appendix F5).

ii. False negative results

False negative results were defined as the results of positive sputum smears that were erroneously read as negative. The proportion of false negative results was observed to increase from 0.0% at the baseline assessment to 3.6% at the final assessment (Figure 6.4). The overall proportion of false negative readings from the 5 laboratories was 3.9% (Appendix F1), which was lower than the critical value of 5% set for this project.

False negative readings were observed to vary in individual laboratories. While the proportions of false negative readings in IDH and DBT were 5.0% each, the false negative readings in RAN was 7.2% (Figure 13). In WDL and GWZ, the proportions of false negative readings were 1.2% and 2.7% respectively (Figure 6.5).

Figure 6.5 Proportions of false positive and false negative TB microscopy readings from 5 laboratories in Kano (2005 - 2006)



6.1.4 Sensitivity and specificity

The sensitivity of TB microscopy readings from the selected laboratories was set at 80% at a confidence interval of 95%. The relative sensitivity of TB microscopy results

from the five microscopy laboratories was 100% at the baseline and at assessment period 3, and decreased to 77.8% at assessment period 6 (Table 6.2). The specificity was set at 100% at a confidence interval of 95%. The relative specificity of TB microscopy results from the five microscopy laboratories was 80% at the baseline and at assessment time 3, and increased to 97.9% at assessment time 6 (Table 6.2).

Table 6.2 Sensitivity (Sens) and specificity (Spec) of TB microscopy results from district laboratories relative to the first and second readers at the quality control unit in Kano (2005-2006)

Assessment periods		1	2	3	4	5	6	
Centres		0 month	3 months	12 months	15 months	18 months	21 months	Total
IDH	Sens (%)	100	88	-	33.3	75	66.7	77.2
	Spec (%)	76	100	-	100	100	100	92.3
WDL	Sens (%)	100	100	100	66.7	100	100	93.3
	Spec (%)	66.7	100	100	91.7	100	100	94.4
GWZ	Sens (%)	-	83.3	100	100	66.7	100	85
	Spec (%)	-	100	91.7	100	91.7	100	96.7
RAN	Sens (%)	-	-	-	50	-	-	40
	Spec (%)	-	-	-	100	-	-	64.9
DBT	Sens (%)	100	100	-	-	33.3	50	66.7
	Spec (%)	96	100	-	-	91.7	90	95.5
All Centres	Sens (%)	100	85.7	100	50	69.2	77.8	78.4
	Spec (%)	80	93.5	96	98.2	95.5	97.9	91.5

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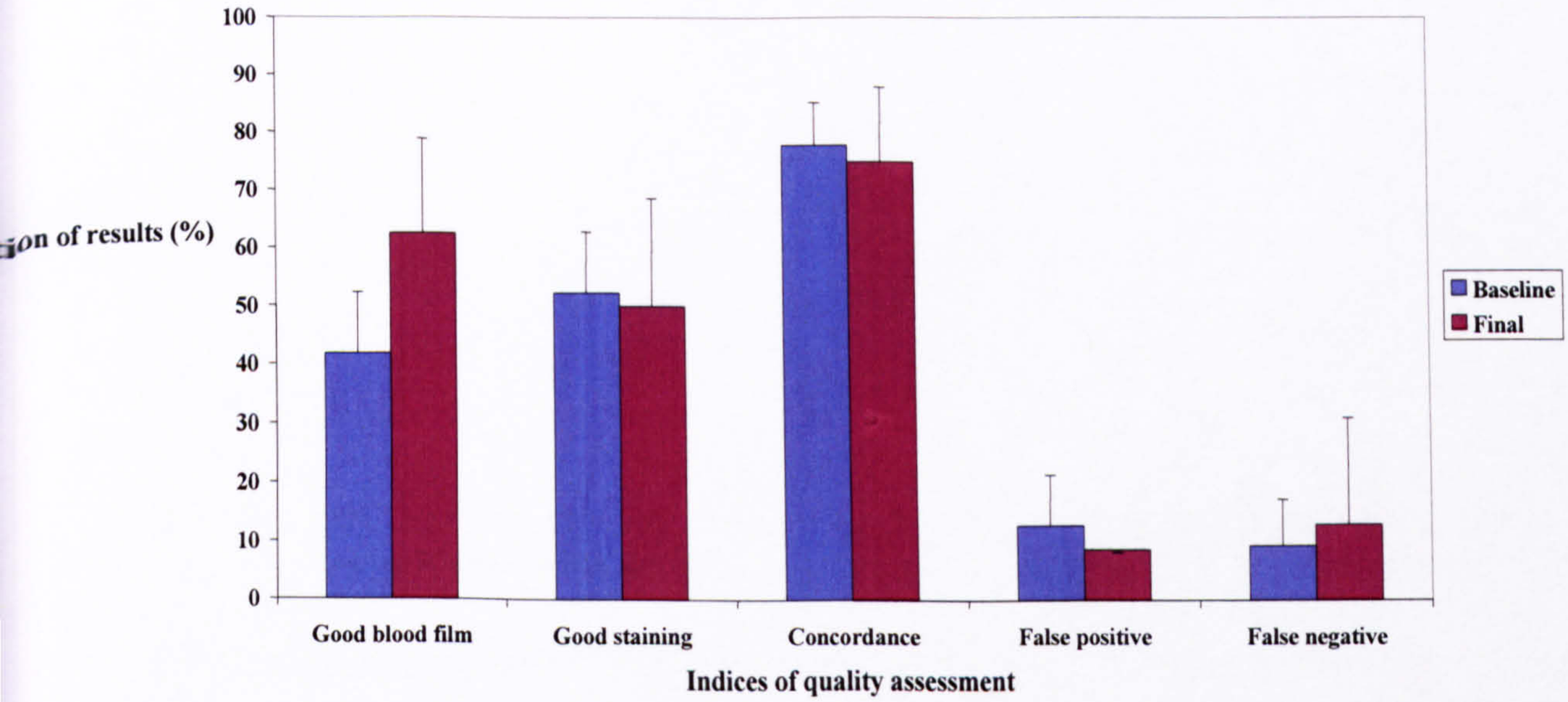
6.2 Quality assessment of malaria microscopy results from participating laboratories in Kano (2005 – 2007)

The results of the baseline and final assessments of the qualities of thin blood films, staining, correct results and the false positive and false negative results are compared in Figure 6.5.

Figure 6.6 Quality of malaria microscopy from selected laboratories in Kano before and after project implementation (2005 - 2007)

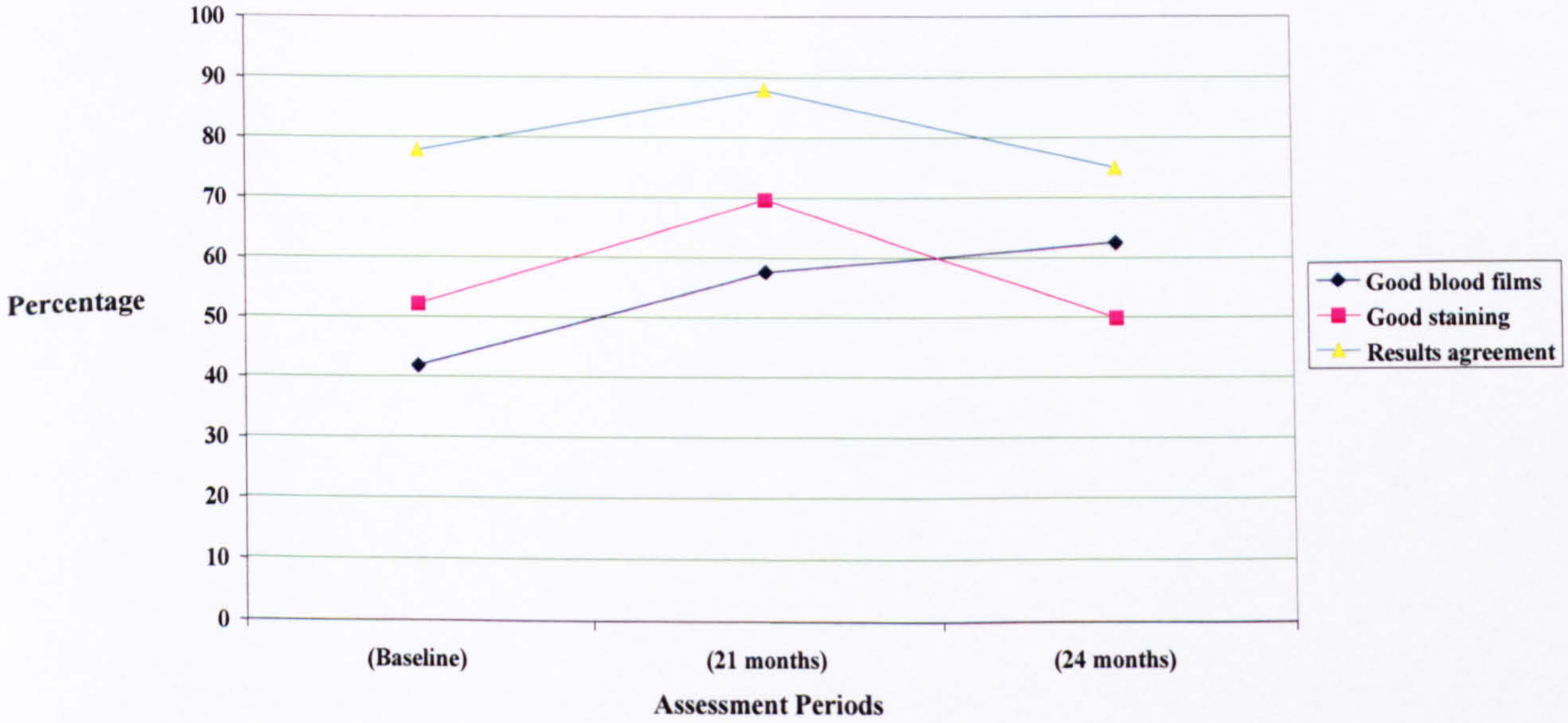


6.2.1 Quality of thin blood films.

The proportion of good thin blood film preparation from all the laboratories had increased from 41.9% at the baseline to 62.5% at the final assessment after 24 months (Figure 6.6). The proportion of good blood films increased from 41.9% at the baseline to 57.6% at the 2nd assessment after 21 months (Figure 6.10). The proportions of good thin blood films from individual laboratories increased in all the four laboratories at the final assessment when compared with the baseline (Appendix F14). However, the changes were not statistically significant.

There was a linear relationship between the proportions of concordant results and the quality of thin blood films. The correlation coefficient (r) between the concordant results good or fair thin blood films preparations were 0.908 and 0.791 respectively.

Figure 6.7 Trends of changes in the qualities of blood films, staining and malaria microscopy results from laboratories in Kano (2005 - 2007)



6.2.2 Quality of staining

The proportion of good blood film staining from all the laboratories had increased from 52.3% at the baseline to 69.7% at assessment period 2 after 21 months (Figure 6.6) and then decreased to 50% at the final assessment after 24 months. The trend of changes in staining quality over time did not show a statistically significant difference between the three periods of assessment. Considering the changes in staining quality at the individual laboratories, the proportion of good staining at IDH laboratory increased to 75% between the baseline and assessment 2 after 21 months, returning to 50% at the final assessment (Appendix F9). At WDL laboratory, the proportion of good staining decreased from 84.6% at the baseline to 66.7% at assessment 2 after 21 months, returning to the baseline level at the final assessment (Appendix F10).

Although, GWZ and DBT laboratories were not included in the baseline assessment, the proportions of good staining from both laboratories at assessment periods 2 and 3 were compared with the baseline. Good staining in GWZ at assessment 2 was 75% and decreased to 50% at assessment 3 (Appendix F11). At DBT the proportions of good staining at the 2 periods of assessment were both below the baseline (Appendix F12).

There was a linear relationship between concordant results and the quality of blood film staining. The correlation coefficient (P) between concordance and good or fair staining of blood film were 0.963 and 0.868 respectively.

6.2.3 Quality of malaria microscopy results

The accuracy of microscopy result was defined as the proportion of concordant results. The concordant results, comprising true positives and true negatives were defined as those results in agreement with the consensus result after re-reading of the first and second readers at the quality control unit. Although no statistically significant difference were observed between the proportion of concordant results at different assessment periods, the proportion of concordant results from all laboratories combined increased from 77.9% at the baseline to 87.9% at assessment period 2 after 21 months (Table 6.3). The coefficient of agreement at the baseline and assessment 2 were 0.551 and 0.756 respectively, indicating a good agreement beyond chance between results from the laboratories and that of the first and second quality control readers (Table 6.3). The proportion of concordant results decreased to 75% at assessment period 3 after 24 months with a coefficient of agreement of 0.563, indicating a moderate agreement between readings from the laboratory and the first and second quality control readers (Table 6.3).

Table 6.3: Concordance of malaria microscopy results from laboratories in Kano with blinded re-checking result (2005 – 2006)

Assessment periods	1	2	3	Total
Centres	**0 Month**	**21Month**	**24 Month**	**Total**
IDH (Kappa)	69.2% (0.435)	75% (0.500)	83.3% (0.667)	**73.9% (0.493)**
WDL (Kappa)	100% (1.000)	100% (1.000)	83.3% (0.667)	**96% (0.915)**
GWZ (Kappa)	NA	50% (0.000)	66.7% (0.250)	**60% (0.231)**
DBT (Kappa)	NA	75% (0.500)	66.7% (0.333)	**70% (0.400)**
All Centres (Kappa)*	**77.9% (0.551)**	**87.9% (0.756)**	**75% (0.563)**	**79.7% (0.602)**

NA = Not Assessed
***Kappa coefficient at 95% level of confidence.**

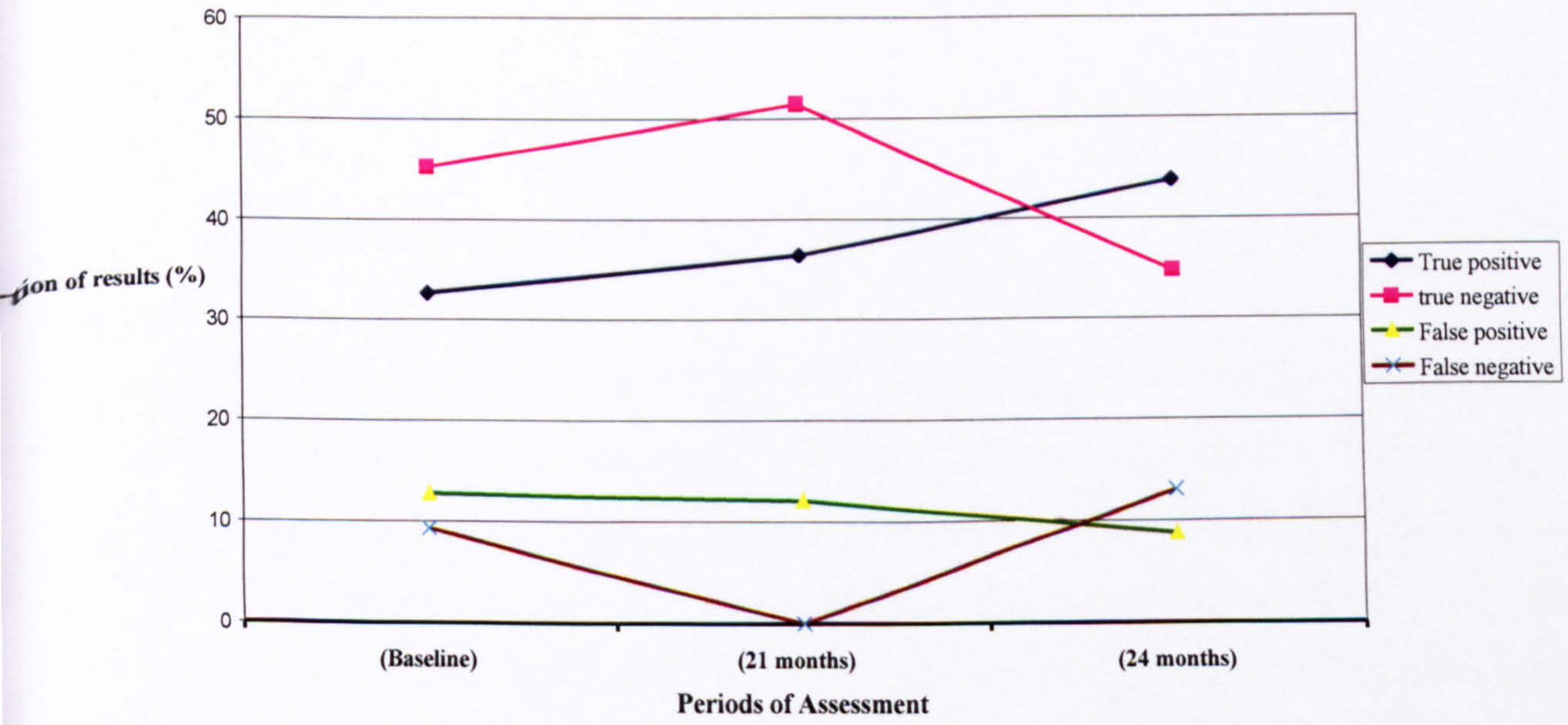
Considering the overall performance as the proportions of concordant results from individual laboratories, WDL had the highest proportions of concordant results of 96% (K = 0.915), while GWZ had the lowest proportion of 60% (K = 0.231). A degree of agreement of 100% (K=1.000) was achieved in 2/3 assessments at WDL laboratory. This indicated a perfect agreement between results from WDL laboratory and the readings of the 1st and 2nd quality control readers.

At assessment period 3, the proportions of concordant results from IDH and WDL were both 83.3% with a good degree of agreement (K = 0.667) between readings from these laboratories and that of the quality control readers (Table 6.10) the proportions of concordant results from GWZ and DBT at assessment 3 were both 66.7% with low coefficients of agreement of 0.250 and 0.3333 respectively (Table 6.3).

6.2.4 Discordant results of malaria microscopy

The discordant results, comprising the false positives and false negatives were defined as those results that were discordant with the consensus result after re-readings of the first and second readers at the quality control unit. There were no significant differences in the proportions of different categories of malaria microscopy results from the selected laboratories between the 3 assessment periods (Figure 6.7). However, there was a decrease in the proportion of false positive results from 12.8% at the baseline to 8.7% at assessment period 3 after 24 months (Figure 6.7).

Figure 6.8 Trends of malaria microscopy results from laboratories in Kano (2005 -2007)



Considering results from individual laboratories, the proportion of false positive results at IDH laboratory decreased from 30.8% at the baseline to 25 % at the 2nd assessment period and to 0.0% at the 3rd assessment period (Appendix F9). At WDL no false negative results were recorded at the three assessment periods. At GWZ and DBT

laboratories, there was a marked decrease in the proportions of false positive results between assessment periods 2 and 3 (Appendix F11 and F12).

6.2.5 Sensitivity and specificity of malaria microscopy readings

Sensitivity is defined as the ability of the microscopist to detect malaria parasite relative to the consensus result from the first and second readers, while specificity is the ability of a microscopist to identify malaria parasite correctly when present in the blood film. The relative sensitivity and specificity malaria microscopy results from the selected laboratories were both 78% at the baseline (Table 6.4). The relative sensitivity increased to 100% with a corresponding decrease in specificity at assessment period 2. At the third assessment period, the relative sensitivity decreased to 76.9% with a corresponding increase in specificity to 80% (Table 6.4).

Table 6.4 Sensitivity and specificity of malaria microscopy results from district laboratories relative to the first and second readers at the quality control unit in Kano (2005-2006).

Assessment periods		1	2	3	
Centres		0 month	21 months	24 months	Total
IDH	Sensitivity	100	100	75	88.9
	Specificity	55.6	66.7	100	64.2
WDL	Sensitivity	100	100	66.7	100
	Specificity	100	100	75	83.3
GWZ	Sensitivity	NA	-	75	75
	Specificity	NA	-	100	60
DBT	Sensitivity	NA	100	66.7	75
	Specificity	NA	100	66.7	66.7
All Centres	Sensitivity	77.8	100	76.9	88.5
	Specificity	78	69.2	80	67.7

NA = Not Assessed

Sensitivity and specificity of 100% was achieved at WDL laboratory at the baseline while it was achieved at assessment 2 both WDL and DBT (Table 6.4). There was an inverse relationship between sensitivity and specificity of malaria microscopy in all the laboratories at the 3 assessment times (Table 6.4).

6.3 Summary of key findings

1. Baseline assessment of TB and malaria laboratory services in Kano State (April 2005)

Microscopy tests made up 21% of the tests conducted in one year. The proportions of malaria and AFB microscopy among the microscopy tests were 35.1% and 27.2% respectively. The highest numbers of TB and malaria microscopy tests in Kano were conducted in IDH and MMSH laboratories respectively.

The five laboratories selected for implementing TB and malaria microscopy quality assessments had at least one microscope and two microscopists covering both TB and malaria. TB microscopy was concentrated at IDH, where 12,525 TB slides were examined in 2004, constituting more than 70% of all the TB microscopy slides examined in the same year. The number of TB slides examined in the other four laboratories ranged from 37 in BCH to 1800 in MMSH. The TB slide positivity rates in these laboratories ranged from 11% to 22%.

Malaria microscopy workload was highest in MMSH and MAWSH laboratories which examined 8,700 and 3251 malaria slides respectively in 2004. Malaria slides examined in MMSH constituted more than 40% of malaria slides examined in all the laboratories included in this assessment. The number of malaria slides examined in the other laboratories ranged from 205 in SML to 2,016 in WDL laboratories. The malaria slide positivity rates ranged from 23.4% to 84.2%.

2. Implementation of integrated TB and malaria microscopy QA scheme (2005-2007)

i. Integrating TB and malaria microscopy EQA scheme

The integrated TB-malaria QA scheme was fully or partially achieved in four of the five laboratories. Full integration of QA was achieved in two laboratories (IDH and WDL), where microscopists were able to make available all the TB and malaria slides examined in their laboratories during supervisory visits. Partial integration was achieved in two other laboratories (GWZ and DBT) where microscopists did not store malaria slides during the baseline assessment period.

ii. Assessment of the quality of TB and malaria microscopy results

TB slides were assessed on six occasions, while malaria slides were assessed on three occasions. Results of the baseline quality of TB microscopy from the five laboratories compared with results of the final assessment at 24 months showed that the concordance rate increased from 81.0% (K = 0.353) to 91.0% (K = 0.792). The concordance rate had a positive correlation with well made sputum smears (r = 0.539) and staining (r= 0.963) (Table 2). Concordance rate of malaria microscopy from IDH and WDL, where full integration was achieved, increased from 69.2% at the baseline (K =0.435), to 83.3% at the final assessment (K =0.667) in IDH and decreased from 100% to 83.3% in WDL. There was a similar positive correlation of concordant malaria microscopy results with well made blood films (r = 0.908) and good staining (r = 0.963).

The proportion of false positive TB microscopy readings from all five laboratories combined decreased significantly ($\chi^2 = 59.8$, $P < 0.001$) from 19.0% at the baseline to 1.8% at the final assessment. The false positivity rates of TB microscopy results

decreased in four of the laboratories. There was also a decrease in the false positivity rate of malaria microscopy in IDH from 30.8% at the baseline to 0% at the final assessment. The false negative rate increased from 0% at the baseline to 3.6% at the final assessment due to the appearance of false negative results from IDH and DBT laboratories at the final assessment.

There was an increase in the specificity of TB microscopy reading from all laboratories from 80% at the baseline to 97.9% at the final assessment while there was a corresponding decrease in sensitivity from 100% at the baseline to 77.8% at the final assessment. 100% specificity was achieved for TB microscopy results in four laboratories at the final assessment. A specificity of 100% for malaria microscopy was maintained in WDL throughout the study, while in IDH specificity of malaria microscopy results increased from 55.6% at baseline to 100% at the final assessment.

CHAPTER 7

DISCUSSION OF RESULTS

7.1 Baseline assessment of laboratory services in Kano state

In order to achieve the required quality in laboratory tests, a continuous system of Quality Assurance (QA) needs to be established. A baseline assessment of medical laboratory services in Kano was made in order to document the current state of medical laboratory service in Kano state focusing on the aspects that affect the quality of laboratory services particularly for TB and malaria.

7.1.1 Laboratory structure and administration

Quality of laboratory tests require a good management capability in coordinating administrative responsibilities such as budgeting, planning and decision making, as well as technical responsibilities such as organizing and conducting the internal quality control activities.

Laboratory departments in Kano state were headed by medical laboratory scientists, technicians or in some cases laboratory assistants with 5 – 10 years of experience in the service. The administrative role of these officers was limited to the laboratory management. There was no policy on laboratory management, defining the administrative role of laboratory managers at the three levels of health care in Nigeria. This study identified that in Kano state there was no central coordinating unit of laboratory services in the ministry of health and other management levels such as the zonal and hospital management teams. Laboratories are often represented by other health sectors. As a result, there were

- Scanty records of both the availability, capacity and the nature of services of public laboratories in the state.

- The records of laboratory data and its use in improving the accuracy of clinical diagnosis for patients' management and its use in public health uses such as investigating disease outbreak were also scanty.
- Difficulties in equipment availability and maintenance, and shortage of supplies in the majority of the public laboratories.
- The essential logistic support needed to underpin laboratory supervisory, training and quality monitoring activities such as transport and communications, is absent.
- There are also difficulties in maintaining production of standardized laboratory reagents, poor selection of techniques, and the absence of proper internal quality control and external quality assessment systems in the laboratories in both the tertiary and secondary health facilities.

7.1.2 Staffing of medical laboratories in Kano

Because of the lack of a policy defining the distribution of laboratory staff in the public health facilities at the state level, the distribution of laboratory staff indicated that there were relatively high concentrations of laboratory staff in the tertiary health facilities. The distribution and compositions of staff in individual laboratories were irrational and disproportionate because postings of staff to the laboratories are solely made by other health professionals with minimum informal consultations of laboratory personnel. This was identified as the main reason for lack of motivation of some laboratory staff and the migration of skilled laboratory personnel, especially those with higher academic qualifications from the public sector to higher-paying positions within the federal, private, research and non-governmental sectors.

The distribution of laboratory staff has created the following pattern in laboratory services in Kano state health sector:

- Absence of laboratory personnel and services at the primary health care levels

- Tests that are recommended at the PHC level laboratories were conducted either fully or partially at the secondary health facilities in the state and not at PHC level.
- Tertiary health facility laboratories conducted the recommended tests in the secondary health care laboratories.
- There was transfer of skilled personnel, especially those with qualifications up to or beyond a Masters degree, from the state public sector to higher-paying positions within the federal, private and research sectors. It had been reported that in many regions of sub-Saharan Africa, attrition of human capital is common and is frequently attributed to the emigration to better working conditions locally or internationally (Petti *et al*, 2006).

7.1.3 Types of tests conducted and related workload.

Blood transfusion tests had the highest frequency among the types of tests carried out in the laboratories making up 29.5% of the total tests conducted in one year. Blood transfusion tests comprise blood grouping (60%), cross matching (8.1%), HIV screening (18.5%), HBV screening (11.1%) and Haemoglobin estimation (2.4%). Haemoglobin estimation test is an important laboratory test that is used to detect anaemia, a contributing factor to about 50% of maternal mortality in northern Nigeria (Adamu *et al*, 2003). Haemoglobin estimation using the Tallquist rapid detection technique was conducted only in 4 of the secondary health facilities in semi-urban Kano. Talliquist method has been discredited by WHO and is not recommended for haemoglobin estimation in the district laboratories. Other laboratories indicated that they estimate haemoglobin concentration from the packed cells volume (PCV) results. This suggested that haemoglobin test was a neglected laboratory tests in at both the secondary and tertiary health facilities. It is therefore important that the availability and quality of haemoglobin test at all levels in Kano state health care should be assured. There is also a need for the government to provide quality laboratory services in

maternal and child care in the state in order to assist meet its health care targets.

Microscopy tests made up 21% of the number of tests conducted by the laboratories in one year. Malaria microscopy had the highest proportion of 35.1% followed by AFB microscopy (27.2%). Microscopy is an important test to detect malaria parasite, stool pathogens and some respiratory disease pathogens such as tubercle bacilli. Improving the quality of TB and malaria microscopy would however improve the microscopy skills for other microscopy tests such as urine and stool microscopy, examination of swab specimens, CSF and other body fluids, fungal specimens and semen analysis.

The laboratory workload of tertiary hospital laboratories in Kano had affected the performance of tests and quality of the results, because there is a direct relationship between workload, number of microscopists required and the quality of microscopy performed in laboratories. The relatively high workloads are a major contributor to poor performance in both TB and malaria microscopy. For instance and average of 61 TB slides read per day at the IDH laboratory exceeded the maximum number of TB smears examined per microscopist per day of 20 or less (WHO, 1998a). High false negative results have also associated with heavy workload due to under reading of microscopic fields (APHL, 2002). The average of 60 to 70 malaria slides read per day at the MMSH laboratory exceeded the 50 slides per 6-hour working days are recommended (when the slide positivity rate is 40%) (WHO, 2005a).

The distribution of laboratory staff had also affected the availability and types of tests the relative workload performed by the different categories of laboratory staff. For instance microbiological investigations such as culture and sensitivity tests and some serologic tests such as the determination of ASO titre are recommended tests in secondary health care laboratories according to the national medical laboratory policy. These tests were conducted only at the two tertiary hospital laboratories (MMSH and

laboratories (MMSH and MAWSH) and IDH that have qualified scientists to perform the tests. Pregnancy test, urinalysis, blood and urine glucose tests were the only chemical pathology tests performed in the secondary health facilities. The rest of chemical pathology tests recommended at the secondary level of health care were conducted only at the tertiary health facilities.

The sensitivity of a microscopist decreases when large numbers of samples are processed due to the time-consuming nature of the work. Visual fatigue will lead to deterioration of reading quality because microscopy is tedious and monotonous. Even highly competent microscopists cannot perform to their best if they do not have the time to correctly examine TB or malaria slides. This problem is compounded where microscopists have responsibilities for diagnosing other diseases.

7.1.4 Laboratory Safety

Laboratory safety refers to the provision of a safe working environment and infrastructure and the use of laboratory procedures that protect the health of practitioners, the community and the environment. It is a goal of the national medical laboratory policy to promote and sustain laboratory safety and safe laboratory practice among laboratory staff with a view to protecting the practitioners and the community.

Assessment of laboratory safety in this study was limited to only observable safety practices during supervision visits to the laboratories. The common safety practice observed in all the laboratories assessed were the practice of hand washing before leaving the laboratory among staff and the use of disposable gloves when dealing with blood and blood products.

The common unsafe practices observed in the laboratories during visits were the lack of written instruction for safe laboratory operation, mouth pipetting, accessing work areas

by non-laboratory staff, lack of fire extinguisher or sand buckets and the lack of lack of first aid kits in any of the laboratories. In addition, safety, sterilization and disinfection procedures were inadequately addressed in both the secondary and primary health facilities assessed. For example there were no specific guidelines on safety precautions, use of disinfectants and disposal of laboratory wastes in any of the laboratories assessed. The inadequacies of safety, sterilization and disinfection procedures, poor handling of all aspects of laboratory management, in rural health facilities have been reported previously (Carter *et al*, 2002)

7.1.5 Laboratory Equipment

Laboratories require basic equipment to be functioning properly in order to provide adequate services. This assessment showed that 62% of the basic laboratory equipment inspected was functional. 13 out of 22 (59%) microscopes all laboratories were functional. All (6/6) of the haematocrit centrifuges and 88% (14/17) of the desk top centrifuges were functional. Less than 50 % of incubators (31%), weighing balances (40%) and water baths (44%) were functional.

The lack of proper arrangement for repairs of faulty equipment in the laboratories has a direct effect on the type and number of tests conducted in the laboratories. An effective equipment management policy is therefore needed to guide selection, procurement, use and maintenance of equipment as part of the total quality management of laboratories. Petti *et al* (2006) noted that the existing infrastructure is not capable of supporting the routine use of laboratory tests and contributes to a failure to use the few existing laboratory resources (Petti *et al*, 2006). In Nigeria, the problems around laboratory equipment have been identified to be the result of the inadequate knowledge of equipment choice, unguided and uncoordinated purchase often lead to wrong acquisition coupled with the lack of spare parts render most procured equipment non functional (FMOH, 2007).

7.1.6 Electricity Supplies

Results of this study show that laboratories achieve continuous power supply only when alternative sources (such as the power generating plant or portable generators) were available. Electricity supply in any laboratory depends on the ability of the management to maintain an alterative source of electricity supply, because supply from the main source was always not continuous. The situation of electricity supply to laboratories in Kano indicated a reverse of what obtained about electricity supply to laboratories in Nigeria in the 1970s. In an assessment of medical laboratory services in western Nigeria, Esan and Adesina (1973) reported that:

"Electricity supply was available in all the 44 hospitals that responded: in 33 (75%), it is by the Nigerian Electricity and Power Authority (24 hours), in the remaining eleven (15%), the supply is by a private generator used for 3-6 hours daily (Esan and Adesina, 1973).

The current situation of electricity supply to laboratories in Kano has been described by a laboratory staff as:

"It is very difficult to state the time when electric power supply is available, there is no specific time. All we know (is that) there is no stable power supply only some times that we do have light, but the days without light is much more than days spent with light" (A laboratory staff in Danbatta general hospital 2005)

The lack of a continuous electricity supply often creates delays in conducting some basic tests such as microscopy, and may interfere with the accuracy of results and the efficiency of services provided by the laboratories (Cheesbrough, 1998). The lack

continuous electricity supplies in the majority (83%) of the laboratories included in this assessment affects the efficiency of the laboratories

The lack of continuous supply or alternative source of water storage facilities in the laboratories without continuous running water in Kano was a major problem that could interfere with performance and quality of the services and also has health and safety implications. It may create hazardous and potentially life threatening work condition for the laboratory staff. Written policy on laboratory services, guidelines on laboratory safety and quality control are not in place in the state health system.

7.1.7 Water supplies

Ideally laboratories should be supplied with continuous running water from piped water, well, bore hall or storage tanks. In areas where there are no pumping facilities, water could be placed in a large aspirator bottle with a tap (20-30 litre capacity) next to the sink. A continuous supply of piped water was available in 3 (23%) through bore holes constructed within the hospitals and adequate electricity supply to pump the water to all parts of the hospitals.

Unreliable water supply to laboratories also has health and safety implications. For instance insufficient water supply contributes to infection if there insufficient running water for hand washing, cleaning of work benches and glassware. This situation creates hazardous and potentially life threatening work condition for the laboratory staff. It also poses a serious threat to both the safety of personnel, good laboratory practice and the accuracy of the tests.

The lack of these alternative water storage facilities in the laboratories that had no continuous running water in Kano was a major problem that could interfere with performance and quality of the services. The absence of water distillers or de-ionizers in

any of the laboratories implies that the laboratories have no access to distilled water or de-ionized water which is essential for the preparation of laboratory reagents and rinsing of cleaned glassware (Cheesbrough, 1998). This made the quality of water used in these laboratories unreliable especially because the main alternative source of water is the bore hole. Bore hole water contains both positive ions (Calcium, Magnesium, Potassium and Sodium) and negative ions (Sulphate, Carbonate and Nitrate) which may interfere with certain reagents used in laboratory tests.

7.1.8 Quality control of laboratory tests

This study showed that there was no policy defining the conduct of internal quality control and external quality assessment of laboratory tests in Kano state. However, some practices of internal monitoring of the quality of results were identified in some laboratories.

One of the major constraints in establishing a quality assessment system in Kano state health facilities was that the laboratories were regarded more as a revenue generating sector than a service for generating quality results for improving the clinical diagnosis. There was often lack of confidence of the users of laboratory services because they are perceived by the physicians as unreliable and unhelpful, such that they remain underutilized and undervalued. On numerous occasions in Zambia, Uganda, and Ghana, clinical decision-making occurred in the absence of laboratory confirmation, even when tests were available. Even when tests are performed, there is evidence that clinicians may ignore results and proceed with treatment based on clinical judgment alone (Reyborn, Drakely *et al*; Petti *et al*, 2006).

7.2 Quality assessment of TB and malaria microscopy

The quality of microscopy results was shown to depend on the timely arrival of the specimen and adequate preparation and staining of smears (Mundy *et al*, 2002), because they are considered as independent variables that could affect the quality of smear results. Major errors in reading (high false positive and high false negative) are also considered to be gross errors indicating misclassification that changes the disease and management status of a patient (Paramasivan *et al*, 2003), and the main thrust of an EQA programme is to identify these errors. Quantification errors are errors of minor importance, as they do not influence case management, but can distinguish a good microscopist from a very good one (Paramasivan, 2003).

The indices of quality assessment considered in this study were 1) the sensitivity and specificity of laboratory results relative to the first and second control readers, 2) concordance between results from the laboratories and the first and second control readers, 3) adequately prepared and / or stained sputum smear and 4) false positive and false negative results. The study design does not allow the assessment of time between collection and arrival of specimen to the laboratory.

7.2.1 How reliable are TB microscopy results from DOTS centres in Kano state?

i. Sensitivity and specificity

An average sensitivity of 100% was achieved at the baseline assessment and after 12 months when no false negative results were observed. Sensitivity of 100% at individual laboratories was observed to be associated with the absence of false negative readings from the respective centres at the particular assessment period.

The average specificity of TB microscopy from the five laboratories increased from 80% to 97.9% and for the two laboratories undertaking malaria microscopy QA it increased from 76.0% and 66.7% to 100%. Specificity of 100% was achieved at individual laboratories when no false positive readings were observed from the respective centres at the particular assessment period.

Sensitivity and specificity, when selected based on reasonable expected overall performance of the laboratories, allows an EQA programme to focus corrective action on laboratories where performance is very poor. This is because a low relative sensitivity is associated with a high proportion of false negative results while a low specificity is associated with a high proportion of false positive results (APHL, 2002).

The relative sensitivity and specificity of TB microscopy readings achieved in this project were both lower than the expected sensitivity and specificity set for the project. This suggested that the rates of false positive readings of 1.8% and false negative readings of 3.9% resulted in achieving the overall sensitivity of sensitivity of 78.4% and specificity of 91.5%. The false positive and false negative values achieved in this project could be used as a basis for setting sensitivity and specificity values in determining sample size in future quality assessments for the state TB control programme. In a first broad quality assessment of TB microscopy in Tanzania, a sensitivity and specificity of 88.5% and 100% respectively were reported (Basra *et al*, 2006). In more established programmes sensitivity and specificity of 96.8% were reported in Ethiopia (Shargie *et al,* 2005), while in Argentina sensitivity and specificity of 91.3% and 98.9% respectively were reported (Kuszanierz *et al*, 2004).

ii. Concordance rate

The concordance rate for TB microscopy results increased from 81% during the first assessment period in April 2005 to 91.1% in the last assessment period in January 2007.

A concordance rate of 89.2% in reading of TB smears was also reported in a first broad assessment of sputum smear microscopy in Tanzania (Basra *et al*, 2006).

High concordance rates of at least 97% between readings from the peripheral laboratories and final readings of central laboratory were reported both in Ntcheu district of Malawi (Mundy *et al*, 2002), Argentina (Kusznierz *et al*, 2004) and southern Ethiopia (Shargie *et al*, 2005).

AFB smear microscopy is not a totally reproducible technique even under the best reading conditions. Even in studies performed with expert readers the reproducibility of readings ranged between 93% and 96% (Kusznierz *et al*, 2004). For this reason, a concordance rate of at least 97% was considered as satisfactory even if there is a low proportion of error (Shargie *et al*, 2005; Kusznierz *et al*, 2004). This indicated that the average concordance rate of 87.5% for the laboratories assessed was less than satisfactory, suggesting the need for an overall improvement if the performance of the laboratories collectively. However, a concordance rate of at least 93% was observed in 4/6 assessment periods at WDL laboratory and in 2/6 assessment periods at GWZ laboratory, suggesting that it was possible to achieve a satisfactory performance in individual laboratories when appropriate supervision, training and measures of quality control are put in place.

ii. Smear and staining quality

In this study, the overall quality of good smear preparations and good staining from the 5 laboratories were 36.2% and 47.2% respectively. There was an increase in the proportion of good smears from 38.0% at the start of this project to 57.1% at the end of the project. The proportions of good staining had also increased from 48.0% at the start of the project to 58.9% at the end of the project. Basra *et al,* (2006) reported a

proportion of well prepared smears of 86.2% and that of well stained smears of 81.2% in Tanzania.

There was a strong positive correlation between the proportions of concordant results and good or fair categories of sputum smears or staining (P = 0.539 - 0.776). The strong correlation between concordance and quality of sputum smears and staining suggested the dependence of quality of results on the quality of smears and staining. A relatively high rate of concordance was 98.2% was reported along with consistently good quality specimen, good smears and good staining in Malawi (Mundy *et al*, 2002). In Argentina an average concordance of 98.0% was reported with the proportion of 'good' smears was relatively lower (65.3%) than that of good stained smears (97.3%) (Kusznierz *et al*, 2004).

Thin smears (implying inadequate preparation) can induce false-negative results. However, 'deficient' staining or staining with slight defects influences the quality of the reading, as the frequency of disagreement is higher in such smears. It was found that 46% of the false-positive results were associated with defects in staining. False positivity can be due to fuchsin crystals in the smear that are confused with AFB by less experienced readers, and false-negative results can be related to weak decolorization that can hide bacilli or lead to confusion of other bacilli with AFB.

iii. Errors in reading

Identifying errors through rechecking is aimed at assessing the overall laboratory performance, detecting unacceptable levels of errors so that corrective action can be taken, and providing continuous motivation for good performance (APHL, 2002).

An upper threshold of the proportion of false negative (i.e positive sputum slides erroneously read as negative) beyond which intervention is deemed necessary is defined

as the critical value in a quality control system (APHL, 2002). Critical value can be chosen from an estimate of historical (long term) false negativity rates, but in the early stages of an EQA programme, accurate data may not be available. However, in this project, the critical value was set at 5% as recommended for a new quality assessment programme by the IUATLD (IUATLD, 1998).

In this study, the proportion of false negative results increased from 0.0% at the baseline assessment to 3.6% at the final assessment. The false negativity rate from the 5 laboratories was 3.9% can be considered as acceptable because it is lower than the critical value of 5% set for this project. This finding is comparable to finding in Ethiopia, where the proportion of false negative reading of 3.2% was also found to be below the critical value of 5% set by the national TB control programme (Shargie *et al*, 2005). Lower proportions of false negative results of 1.2% were observed in Argentina (Kusznierz *et al*, 2004) and 2.4% in Malawi (Mundy *et a*l, 2002).

However, false negative readings were observed to vary in individual laboratories included in this project. While the proportions of false negative readings in IDH and DBT were within the acceptable critical values of 5.0% each, the false negative readings of 7.2% in RAN exceeded the critical value. In WDL and GWZ, the proportions of false negative readings were 1.2% and 2.7% respectively were below the critical value. A wide variation of 3%–52% in the proportions of false negative results among 8 laboratories was reported in India (Paramasivan *et al*, 2003).

The false positivity rate of TB slides from all the laboratories was 7.0%. This finding is comparable to the 6.9% false positive results reported from Burundi (Buzingo et al, 2003). A lower proportion of false positive result of 3.2% was reported from Ethiopia (Shargie et al, 2005) and less than 2% was observed in Malawi (Mundy *et al*, 2002). In

this project, however, the proportion of false positive results was observed to significantly decrease from 19% at the start to 1.8% at the end of the project.

Considering results from individual laboratories, the proportion of false positive results ranged from 2.7% in GWZ laboratory to 30.9% in RAN laboratory. The documentation of 30.9% false positive results in RAN laboratory was a point of concern considering the number of cases under active treatment who could be continued on initial intensive therapy or might have their continuation phase therapy extended due to false-positive reading error (Nguyen *et al*, 1999).

Major errors in reading (high false positive and high false negative) are errors that may change the management of a patient (Paramasivan et al, 2003), and the main purpose of an EQA programme is to identify these errors. For case finding, the impact of errors in microscopy can be measured as the number of truly smear-positive cases missed due to false-negative reading error as well as the number of truly smear negative 'non-cases' who were erroneously started on treatment due to false-positive reading error (Nguyen *et al,* 1999). For treatment, the impact can be measured by examining the number of cases under active treatment who are continued on initial intensive therapy or have continuation phase therapy extended due to false-positive reading error, as well as the number of cases who are inappropriately changed to continuation phase therapy or whose treatment is discontinued prematurely due to false-negative reading error (Nguyen *et al*, 1999).

7.2.2 How reliable are malaria microscopy results in public laboratories in Kano?

i. Sensitivity and specificity

The relative sensitivity and specificity malaria microscopy results from the two laboratories that participated in the malaria QA exercises were both 78% at baseline. At

the final assessment, the relative sensitivity decreased to 76.9% with a corresponding increase in specificity to 80%.

The average specificity of malaria microscopy from the two laboratories increased from 77.8% to 80.0%. A specificity of 100% for malaria microscopy was maintained in WDL throughout the study, while in IDH specificity of malaria microscopy results increased from 55.6% at baseline to 100% at the final assessment. This is comparable to the malaria microscopy specificity of 93.5% - 98.3% observed in ten laboratories on the Thai-Myanmar border of Thailand (Hemme and Gay, 1998).

ii. Concordance rates

The concordance rate of malaria microscopy results from individual centres ranged from 60% at GWZ to 96% at WDL laboratories. It therefore suggested that although the performance at WDL laboratory was relatively better than that of the other 3 laboratories in which the assessment was conducted, there is a need for improvement in the overall performance of the laboratories.

In WDL laboratory, the presence of fresh graduate in haematology who had an adequate skill in malaria microscopy in thin blood film and a relatively higher frequency of malaria microscopy requests to the laboratory may have resulted in the better performance from the laboratory. A mean concordance rate of 86.2% was observed by Dini and Frean (2003) in a quality assessment of malaria microscopy in South Africa. Incorrect results of 13.8% were attributed to a lack of experience and a lower frequency of malaria specimens. In this study the majority of the incorrect results were from malaria non-endemic areas, which treat fewer malaria cases than the rest of South Africa (Dini and Frean, 2003).

ii. Smear and staining quality

In this study, the overall quality of good thin blood film preparations and good staining from the 4 laboratories were 49.0% and 55.9% respectively and were higher than the 41.9% good blood films and 52.3% good staining observed at the baseline assessment. The highest proportions of good blood film preparation of 72% and good staining of 80% were observed at WDL laboratory. The lowest proportions of 40% good blood films and 30 good staining were observed at DBT laboratory.

In this project, a strong positive correlation between the proportions of concordant results and good thin blood films preparation and staining was observed. These findings suggested the dependence of quality of results on the quality of blood film preparation and staining. The findings were contrary to that of Dini and Frean (2003) who reported no significant association between Giemsa stain quality and blood film interpretation. In their assessment of the quality of malaria microscopy in South Africa, most participant laboratories with incorrect blood film interpretation had acceptable Giemsa staining quality, indicating that there is less of a problem with staining technique than with microscopical interpretation of a blood film (Dini and Frean, 2003).

iii. Errors in reading malaria slides

In this study, the overall proportion of false negative malaria microscopy reading was 7.7% and was a little lower than the 9.3% observed at the baseline assessment. The proportion of false positive readings was 12.0% and was almost similar to the 12.8% observed at the baseline assessment. The false positive and false negative errors in reading yielded a sensitivity and specificity of 82.0% and 79.0% respectively, and were both lower than the sensitivity and specificity values of 78.0% each, observed at the baseline assessment. Although no statistically significant changes were established between the proportions of false positive and false negative readings at the baseline and

the overall results, findings indicated a high degree of errors in reading malaria microscopy slides among the laboratories assessed. The false negative rate of 7.7% yielding a specificity of 79% suggested that malaria was under diagnosed in these laboratories. In an assessment of internal quality control of the malaria microscopy in 10 laboratories on the Thai-Myanmar border of Thailand, where multidrug resistance to anti-malaria medications is a major problem, a sensitivity of 92.6 % - 96.6% and specificity of 93.5% - 98.3% was observed (Hemme and Gay, 1998). The study indicated the importance of a reliable quality control method for microscopy diagnosis of malaria in hyperendemic areas like Nigeria, where *Plasmodium falciparum* is the main species.

The project design and insufficiency of data does not allow an evaluation of the changes between the performances of individual laboratories at different periods of assessment. However, the lowest proportion of false positive (4%) and false negative readings (0.0%) was observed at WDL laboratory yielding a sensitivity and specificity of 100% and 83.3% respectively.

7.3 Integration of TB and malaria microscopy QA systems

In this project, a novel system of blinded re-checking TB and malaria slides was designed based on the Lot quality assurance system (LQAS). In this system, the blinded re-checking of slides sampled from the laboratories was centralized in one laboratory where the first and the second re-reading were done independently.

In the integrated system, activities such as monitoring visits, slide sampling and re-reading, and feedback mechanisms were combined for malaria and TB microscopy. The main contribution of this project to the laboratory system in Kano is the demonstration that an integrated TB and malaria microscopy EQA system is feasible.

The first phase of the development of this system was assisting the TB control programme to scale up and strengthen its TB microscopy external quality assessment (EQA) In the second phase, a model system for measuring and improving the quality of TB and malaria microscopy was developed based on the LQAS, blinded rechecking.

This project demonstrated that it was feasible to use the LQAS method for determining the number of TB and malaria slides to be examined in each laboratory as part of an integrated system. However, the numbers of slides selected needs to be adjusted depending on the workloads and slide positivity rates of malaria and TB microscopy.

7.3.1 Microscopists and the use of microscopes

In the integrated QA system, two trained microscopists were adequate for the integrated TB and malaria microscopy in a laboratory examining up to 500 slides each for TB and malaria per quarter (approximately 40 slides per week and 8 slides per 5 working days). The relatively high workloads are a major contributor to poor performance in both TB and malaria microscopy. For instance an average of 61 TB slides read per day at the IDH laboratory exceeded the recommended maximum number of TB smears to be examined per microscopist per day of 20 or less (WHO, 1998a). The average of 60 to 70 malaria slides read per day at the MMSH laboratory exceeded the recommended 50 slides per 6-hour working days (when the slide positivity rate is 40%) (WHO, 2005a).

One microscope was adequate for the integrated TB and malaria microscopy in a laboratory examining up to 500 slides each for TB and malaria per quarter. A laboratory that examines up to 3000 TB or malaria slides in a quarter requires 2 microscopes to adequately cope with the workload. The integration would optimize the use of microscopes and other equipment in laboratories with low work loads.

Having two microscopists in a district laboratory will facilitate the conduct of the internal quality control of the re-reading of sputum smears or blood films to ensure the accuracy of the results. Laboratories having only one microscopist for TB and malaria could pair up with another laboratory for the exchange and re-reading of sides at a reasonable and feasible interval (for instance every two weeks).

7.3.2 Local government supervisors

In this project the community tuberculosis control supervisors were trained on their role in the supervision and sampling of examined TB slides for the external quality assessment. A one day training was organized in collaboration with the state TB control programme in which the supervisors were introduced to the meaning, principles and the importance of quality assurance of TB microscopy in DOTS services and their role in coordinating between the laboratory and the DOTS clinics identifying problems and facilitating corrective measures.

This project demonstrated the feasibility of training the supervisors on the TB and malaria microscopy EQA activities both collectively in a workshop and individually during onsite evaluation. However, combining the supervision activities requires a high degree of commitment and motivation or it should be regarded as part of the supervisors' role and well supported by the state TB and malaria control programmes.

7.3.3 State TB microscopy quality control officer

The state TB microscopy quality control officer is normally based in the central quality control laboratory at the state or zonal level. One officer could also be adequate for coordinating EQA activities for TB and malaria if he is trained in both TB and malaria QA and is capable of coordinating, supervising and evaluating the QA scheme. The QA officer should also be able to identify and report problems that need immediate attention to the state TB control officer.

7.3.4 State level TB and malaria quality control laboratory

A team of four experienced microscopists were required for the integrated re-reading of TB and malaria slides. The scheme of re-reading of slides will depend on the skills of each of the personnel in either TB or malaria microscopy or both. In this project, two personnel with skill in TB microscopy served as the first and second readers for TB microscopy. Two other personnel with skills in malaria microscopy served as the first and second readers for malaria slides. A third independent reader was used in malaria slide re-reading if the discordance between the first and second reader could not be resolved.

An alternative scheme could also be followed in the re-checking process depending on the availability and skills of the quality control readers. If the four QA staff have skills each in both TB and malaria microscopy, a consensus result from the independent readings of the four staff could be taken as the correct result. If only two QA staff with skills in both TB and malaria microscopy are available, each of them could serve as a first or second reader to one another. This demonstrates the flexibility of this model and its applicability in variety of settings based on the available resources.

7.3.5 The values and challenges of integrated TB and malaria microscopy QA system

The value of integration is obvious because the DOTS programme relies on microscopy for case finding and monitoring of treatment for TB and with the introduction of new malaria treatment based on ACTs in Nigeria, it is cost effective to improve the accuracy of malaria diagnosis so that these drugs are only used for confirmed cases of malaria (Amexo *et al*, 2004). Even where diagnostic tests for malaria are not cost-saving, they could be considered cost effective if their use led to a significant improvement in case management (Goodman *et al*, 2003).

Furthermore, microscopes are essential equipment for laboratory services, offering diagnostic support for the clinical management of many diseases. This suggests that improvement in the skills of malaria and TB could aid in improving the skills of microscopic diagnosis of there diseases. For example, faecal specimens are examined for the presence of various protozoa cysts and helminth larvae and eggs. Urine specimens are usually examined to detect eggs of *Schistosoma haematobium*, and vaginal and urethral materials are examined for *Trichomonas vaginalis* (WHO, 2004).

Challenges:

i. The discipline of cleaning and arranging the slides in the slide box by the microscopists was one of the aspects that were difficult to improve because of three reasons:

- Heavy workload made the microscopist tired and unwilling to do the extra work of cleaning and arranging the slides.
- Lack of team work between the microscopists and often lack of confidence in the results of some positive slides resulted in several missing slides
- Lack of proper supervision

ii. Mobilizing the QA team during each of the assessment periods in the quality control laboratory was often difficult because the members of the team were stationed in different laboratories, and had primary responsibilities in their respective laboratories. This resulted in delays in the re-checking process, and advocated the need for establishing a central quality control laboratory with staff who have primary responsibility of quality control.

iii. The health managers perceived sustaining the integrated TB and malaria QA programme as additional burden to the health budget, while the TB programme managers perceive it as a potential threat to the smooth running of their QA system.

7.3.6 The need to expand QA system to a broad quality improvement programme.

The feasibility of implementing this model requires an integrated management system for both TB and malaria control programmes, in terms of administrative and technical responsibilities at both the state and federal levels. It also requires development of policy and its implementation. A laboratory central coordinating unit at the federal level would be helpful for the integration because it could be the initial basis for coordination between the TB and malaria control programmes.

Total Quality Management (TQM) involves the continuous improvement of laboratory results. The Quality management principles are associated with the organizational structures, responsibilities, procedures, processes, and resources. Continuous improvement of quality and its external assessment are therefore of high priority in order to guarantee a reliable, effective and cost-effective diagnostic service (Horvath *et al* 2003). One of the main constraints of laboratory services in Nigeria is that even when laboratory testing and services are available, physicians often perceive them as unreliable and unhelpful, such that they remain underutilized and undervalued. Even with improvements in the quality of TB and malaria microscopy, there is the need for consultations through seminars and workshops to discuss the quality and use of microscopy results with the laboratory personnel, clinicians and health managers.

Similar situations were reported in other sub-Saharan African countries (Petti *et al*, 2005) On numerous occasions in Zambia, Uganda, and Ghana, clinical decision-making were made in the absence of laboratory confirmation, even when tests were available. Conversely, when tests were performed, clinicians de-emphasized

seemingly contradictory laboratory results and elected to proceed with treatment based on clinical judgment alone (Petti *et al*, 2005).

There were major contributions to the laboratory services in Nigeria by the donor agencies such as the UK Department For International Development (DFID) funded Partnership for Transforming Health Systems (PATHS) and the US President's Emergency Plan for AIDS Relief (PEPFAR), through the Institute of Human Virology of Nigeria. The model of integrated EQA system for TB and malaria produced by this project could be considered in the implementation of new medical laboratory policy in Nigeria as a model that could be sustained locally or in collaboration with external support, rather than relying solely on the external support. One of the major advantages of this integrated system is that it is not dependent on external funding. Rather it needs strong management and organization using internal (ie within Nigeria) resources. One of the big risks though is that it depends on the TB programme being well functioning. It is recommended that this model be tested in other states of Nigeria in order to evaluate it applicability in different health settings in the country. Once the model is viable, it would guide to develop a policy for its incorporation under the new medical laboratory science policy.

CHAPTER 8

8.0 PROJECT OVERVIEW, CONCLUSION AND RECOMMENDATIONS

8.1. Objective 1: To conduct a baseline assessment of medical laboratory services in Kano state.

The baseline assessment of medical laboratory services conducted in 13 public hospital laboratories in Kano in 2005 showed that laboratory personnel and services were available only at the secondary and tertiary health care and not at the primary health care level. The laboratory scientists performed more tests in the tertiary health facility laboratories than in the secondary health facility laboratories compared to other cadres of laboratory staff, while the laboratory assistants performed more tests in the secondary health facility laboratories, than in the tertiary health facilities.

Blood transfusion tests were the most frequent tests carried out in the laboratories making up 29.5% of the total tests conducted in one year. Microscopy tests predominantly malaria (35.1%) and AFB microscopy (27.2%), made up 21% of the tests conducted by the laboratories in one year. TB and malaria microscopy were performed by all cadres of laboratory staff (i.e. scientists, technicians and laboratory assistants).

The Kano state health policy has been formulated in the context of the goals and philosophy of the National Health Policy of Nigeria, which lacks a clear definition of laboratory services in Kano state heath system. This has made laboratories one of the most neglected areas of health care provision in the state and affected both the administrative and technical aspects of laboratory activities in the state.

There was a lack of direct representation of laboratories on the policy making, influential planning and budgeting committees. Laboratory infrastructure and human resource management were determined solely by other health professionals with

minimum consultations with laboratory personnel. This has affected the modes of financing, staff distribution, types of tests conducted and quality control in the public laboratories.

Although laboratories were financed from the revolving fund scheme, there was no specific budget allocation to the laboratories (Ashir D, 2006). As such laboratories were often faced with problems of improper supply and lack of equipment maintenance. There was no specific pattern in the number and cadre of staff in the secondary and tertiary hospitals in the state. There were no rational training and retraining programme resulting in low morale of some of the laboratory staff and the migration of skilled personnel, especially those with higher academic qualifications from the state service to higher-paying positions within the federal, private, research and non-governmental sectors.

One of the major constraints to establishing a quality assessment system in the state laboratory facilities was that the laboratories were regarded by the health managers as a revenue generating unit rather than a service to produce quality results for improving clinical diagnosis. There was often lack of confidence of the users of laboratory services because they perceived the results to be unreliable and unhelpful, such that the laboratories were underutilized and undervalued.

Safety management, equipment maintenance and water and electricity supplies to the laboratories are other areas that need immediate attention. The problem of insufficient electricity and water supplies to the populace is persistent in Kano state and the situation is likely to remain for an unpredictable period of time. Some suggestions on how to overcome these problems are offered in the recommendations section.

8.2. Objective 2: To compare the existing laboratory services in Kano with the recommendations of the new national medical laboratory policy of Nigeria.

The medical laboratory system in Nigeria has undergone some major reforms in the past few years. The federal government of Nigeria has developed a new national medical laboratory policy (FMOH, 2007). An implementation committee for the national medical laboratory policy was inaugurated in October 2007 (Abubakar, 2008). The policy objective is to provide appropriate, efficient, safe and cost-effective laboratory services delivered by qualified staff at primary, secondary and tertiary health care levels to contribute towards achieving the millennium development goals (MDG). A target was set for providing all Nigerians with an appropriate, cost effective and high quality laboratory service as a functional component of a reliable national health care delivery system within five years.

The new national medical laboratory policy recommends urine microscopy, urinalysis, malaria microscopy, haemoglobin concentration measurement, stool microscopy, pregnancy test and HIV screening test at the primary health care centres. This study found that these tests were conducted either fully or partially at the secondary health facilities. The tertiary health facility laboratories conducted the recommended tests for the secondary health care laboratories, comprising the tests performed at the primary health centres and other advanced laboratory tests in haematology and blood transfusion services, chemical pathology and microbiology.

Some technical problems such as the improper selection of the types of tests conducted in the laboratories were also identified. For example the haemoglobin estimation, is an essential test for detecting anemia which contributes to about 50% of maternal mortality in northern Nigeria. However, proper techniques for haemoglobin estimation were not employed in either the secondary and tertiary health facilities in Kano. While a few district laboratories use the discredited Tallquist technique, the majority of the

laboratories estimate haemoglobin concentration from the packed cell volume (PCV) results.

The existing QA schemes for HIV testing and TB microscopy in the country rely mainly on external funding and there is no evidence that they are locally sustainable. Recent evidence suggests that the implementation of the new medical laboratory policy in Nigeria would assist in improving the quality of laboratory services in the country. It would also promote the establishment of QA schemes for laboratory services that could be sustained locally or in collaboration with external support, rather than relying solely on the external support.

8.3 Objective 3: To design, implement and monitor quality assessment of TB microscopy; develop and systematically integrate malaria microscopy quality assessment into the TB microscopy quality assessment system.

The WHO has recommended the integration of malaria microscopy QA with that of other microscopically diagnosed communicable diseases (WHO, 2005a), but there is no evidence about how this can be put into practice. There are no published data about the design and implementation of integrated TB-malaria QA systems.

In this project, a QA for malaria microscopy was developed from, and systematically integrated into, the existing QA system for TB microscopy. Full or partial implementation of the integrated TB-malaria QA was achieved in four of the five selected laboratories.

In this system, TB and malaria microscopy results recording, slide storage, monitoring visits to the laboratories, LQAS slide sampling, the process of rechecking by two experienced microscopists, results analyses and feedback mechanisms for communicating the performance of individual laboratories were combined for malaria

and TB microscopy. to the final results. The use of the same microscopists and microscopes and the provision of joint training and supervision for TB and malaria were feasible at the laboratory level. The system improved the quality of TB and malaria microscopy results, particularly specificity.

8.4. Objective 4: To evaluate the quality of TB microscopy and malaria microscopy services in the laboratories involved in the integrated system.

This study demonstrated the feasibility of assessing the quality of both TB and malaria microscopy in an integrated manner using a variety of indices of quality assessment.

The indices of quality assessment used in this project were 1) the proportions of microscopy results that were concordant or discordant (false positive and false negative) when examined by the first and second control readers. 2) Factors associated with the accuracy of results such as adequately prepared and / or stained sputum smear and blood films. 3) The sensitivity and specificity of laboratory readings relative to the readings of the first and second control readers. The study design did not allow the assessment of time between collection and arrival of specimen to the laboratory.

The integrated system improved the quality of TB and malaria microscopy results, particularly specificity. The average specificity of TB microscopy from the five laboratories increased from 80% to 97.9% and for the two laboratories undertaking malaria microscopy QA it increased from 76.0% and 66.7% to 100%. The average specificity of malaria microscopy from the two laboratories increased from 77.8% to 80.0%.

On average, the concordance rate of TB microscopy results increased from 81% at baseline to 91.0% at the final assessment. For malaria microscopy the concordance rate

increased from 69.2% at the baseline, to 83.3% at the final assessment in IDH, but decreased from 100% to 83.3% in WDL laboratory due to 16.7% false positive results. Increases in the concordant TB and malaria microscopy results were positively associated with the ability of the laboratories to prepare and stain sputum smears and blood films for TB and malaria microscopy respectively.

8.4.1 Summary of achievements and limitations of this project

- External Quality Assessment system based on slide rechecking process for the TB control programme started in 5 selected centres in March 2005 and follow up data were collected and analysed in 2 quarters of 2005 and 4 quarters of 2006.
- Slide rechecking process for malaria microscopy was integrated with TB rechecking process in October 2006. By the end of 2006, there was an overall improvement in the quality of TB microscopy results in the 5 selected centers from 81% concordance in March 2005 to 91.1%.
- Increase the proportions of true positive and true negative with corresponding decrease in false positive results
- Increase in case finding reflected by the increase in the number of smear positive cases in Kano state from 1,484 in 2005 to 2,306 in 2006. This was documented in the 2006 annual report of the state TB control programme
- The QA process was expanded to 10 more microscopy centres by the beginning of 2007.
- By April 2007, integrated TB-malaria QA system had been fully implemented in 1/5 centres with 100% sensitivity and specificity for the presence of AFB and malaria parasites on microscopy, partially implemented in 3/5 and not implemented in 1/5 of the selected laboratories.

This project generated interest in quality control among the laboratory staff in the study laboratories and provided a standardized approach and grading for measuring the competence and performance of laboratories, which facilitated the implementation of training, monitoring and evaluation. This study demonstrated the possibility of assessing the performance of laboratories in TB and malaria microscopy collectively and individually using the LQAS and blinded rechecking technique.

Limitations

- This project financed solely from my Ph D research grant provided by the International Ford Fellowship Programme (IFP). Activities and duration of the project were therefore planned within the limited funds and time frame of my Ph D programme. The project was not sustained beyond the period of data collection of my study.

- The required training and retraining of microscopists, supervisors and the QA team at regular intervals was not feasible due to limited funds available for the project activities.

- There was limited opportunity for remedial action for quality improvement in the laboratories and consultations with clinical staff.

- The quality assessment of malaria microscopy was based on Leishman stained thin blood films only because it was the only malaria test available in the study laboratories.

8.5. Objective 5: To assess the feasibility of the proposed integrated system and make recommendations about its sustainability at state level and national scaling up.

The feasibility of scaling up capacity of this integrated model in Nigeria depends on the goals and commitment of the TB and malaria control programmes.

In Nigeria, the objectives of both TB and malaria control programmes are to reduce the mortality and morbidity and disease burden due to TB and malaria. The tuberculosis and malaria control programmes share many features in common such as the structuring of the TB and malaria control programmes along the national, state and local government levels, and the microscopic technique used in the diagnosis of both diseases.

The feasibility of integrating the QA system in the two laboratories was characterized by good motivation and commitment of staff in both laboratories as well as clear understanding of the purpose of the quality assessment at the start of the project. Staff in the two laboratories where partial integration was achieved showed lack of motivation at the start of the project and appeared to perceive QA as a threat. Hence, microscopists in these laboratories did not make slides available for sampling during the baseline assessment.

Although the model worked well at peripheral laboratory level and the QA monitoring team, scaling up this integrated system to cover all laboratories in Kano State will be difficult. There are no guidelines in the national or state health policy for the development and implementation of a malaria microscopy EQA system, so there are no resources or commitment to establish malaria QA either as stand alone or integrated.

The feasibility of such integration therefore requires a policy for its development and implementation at the state level.

Implementing an integrated TB and malaria QA scheme at the control programme levels requires an integrated management system at both the federal and state levels for administrative and technical responsibilities. The TB control programme had mechanisms to supply reagents and materials to these laboratories, so there is a potential for incorporating materials needed for malaria microscopy into this existing system. A laboratory central coordinating unit at the federal level would be helpful because it could be the focus of coordination between the TB and malaria control programmes and other programmes that rely heavily on quality of laboratory services. One of the major advantages of this integrated system is that it is not dependent on external funding. Rather it needs strong management and organization using internal resources. One of the big risks is that it depends on a well functioning TB QA programme.

8.5.1 Responses from state and federal ministries of health officials to the outcomes of this project

i. State level

Discussions on the need and requirements for implementing the integrated QA for TB and malaria microscopy in Kano state were held in June / July 2006 with Dr Amiru Imam Yola (State Director of Medical and Healthcare Services), Dr Dayyabu Muhammad (Director of Primary Care), Dr Nasir Mahmud (Director TB programme), Baffa Muhammad Kademi (Director Malaria programme), the newly appointed Medical Director of IDH, Dr. Auwal Ibrahim Yola and Yunusa Aliyu (QA officer). A plan for implementing the system in 5 selected sites was submitted to the commissioner, Kano state ministry of health in September 2006 (Appendix C1).

In response to my submission, the commissioner instructed the Director of Medical and Healthcare Services to study the document and advise on how best the ministry could use my project outputs to inform policy. The Director has requested from me a more comprehensive submission on my project findings and recommendations which I will present after completing the thesis.

The DFID-funded PATHS project has implemented a programme of quality improvement and diagnostic outreach services to communities across several states including Kano. Information from my project has been used to inform the design of PATHS's programme and my model system formed the core on which PATHS built the state laboratory QA network.

ii. National Level

I was invited to present my project at the Community Diagnostics Programme (CDP) workshop in Kano held in March 2008 with participants from the Federal Ministry of Health and CDP state coordinators from Ekiti, Enugu, Jigawa, Kaduna and Kano (Appendix C2). CDP was launched by PATHS which involves five states in Nigeria to provide effective diagnostics at peripheral level in for poor communities who do not have access to diagnostic services for malaria, tuberculosis and anaemia. In response to discussions during the workshop about how to select the right number of slides for checking in the malaria microscopy QA process I gave a brief presentation to describe the evidence and principles underlying the systematic selection of a statistically meaningful number of slides. In response to a request from the participants at the workshop I will produce written guidelines about the systematic selection of a statistically meaningful number of slides for QA checking (Appendix C3).

Dr. Ali Onoja, the Head, Central Public Health Laboratory, Federal Ministry of Health, Nigeria and Coordinator and Secretary, Implementation Task Force, Nigeria National

Medical Laboratory Services Policy has requested a summary of my project findings so that this model can be incorporated into the national laboratory policy.

8.5.2 Partnership and funding factors

There have been major contributions to the laboratory services in Nigeria by the donor agencies. The UK Department For International Development (DFID) through the Partnership for Transforming Health Systems (PATHS) intends to strengthen the health systems in five states in Nigeria to deliver quality services to support achievement of the Millennium Development Goals (MDG). A Community Diagnostics Programme (CDP) was launched by PATHS which involves five states in Nigeria. The purpose of CDP is to provide effective diagnostics at peripheral level in for poor communities who do not have access to diagnostic services for malaria, tuberculosis and anaemia (CDP Report, 2007).

The US President's Emergency Plan for AIDS Relief (PEPFAR), through the Institute of Human Virology, Nigeria is implementing the AIDS Care and Treatment in Nigeria project. One of the objectives this project is to build the laboratory capacity within Nigeria's health care structure to support HIV diagnosis (IHVN, 2005). The Institute of Human Virology Nigeria established an EQA programme called the Laboratory Assessment Program Nigeria for the PEPFAR laboratories in Nigeria as a means of monitoring their proficiencies in HIV testing process. The US Centre for Disease Control and Prevention also provides technical support for the National HIV Sero-prevalence Sentinel Survey, including the quality control of HIV testing at both the state and central level is conducted in Nigeria annually aimed at providing information about the current HIV distribution in the country in order to sensitize all stake holders to take appropriate measures.

The existing QA schemes for HIV testing and TB microscopy in Nigeria rely mainly on external funding and there is no evidence that they are locally sustainable. The

involvement of donor agencies in responding to the HIV crisis have created a competition for human capital and financial investments due to the establishment of plural systems The model of integrated EQA system for TB and malaria produced by this project could be considered in the implementation of new medical laboratory policy in Nigeria as a model that could be sustained locally or in collaboration with external support, rather than relying solely on the external support. One of the major advantages of this integrated system is that it is not dependent on external funding. Rather it needs strong management and organization using internal (ie within Nigeria) resources.

8.6 Conclusions

This project demonstrated that it is feasible to integrate the EQA system for TB and malaria microscopy and the integration does improve the quality of both services. However, the integrated system needs testing out in different settings in order to be able to develop sound recommendations to guide the complex scaling up process.

8.7 Recommendations

8.7.1 State level

- The health managers, particularly the clinicians have a responsibility to support and advocate for their technical colleagues in the laboratory service, to ensure that they are involved in decisions affecting the laboratory at all levels, and to promote, facilitate, and demand high quality and responsive laboratory support for effective patient care.

- Review the distribution and supply of laboratory staff in Kano state health sector to comply with the international guidelines and about microscopy workload. In preparation for the implementation of the new medical laboratory services policy in Nigeria, there is the need to train more laboratory assistants

and train the existing assistants into technicians so that they could be able to manage laboratory services at the present 99 primary health care centres in the state.

- The existing tertiary / specialist, secondary and primary hospital laboratories in Kano state should be equipped to perform all the tests recommended at the respective levels by the national medical laboratory policy. The existing 5 tertiary / specialist hospital laboratories in the state should be fully equipped to perform all the tests recommended at the tertiary level by the national medical laboratory policy. This should be backed by the training of more pathologists and medical laboratory scientists to meet the demand of the recommendations in terms of staffing and the types of tests performed.

- Conduct a more comprehensive survey of laboratory safety in Kano state health institutions to assess what is required to create and sustain a safe working environment and promote the culture of safety among laboratory workers and the general public.

- All laboratories should be provided with a stand by electric generator and with adequate arrangements for its fuelling and repairs.

- Construction of boreholes in health facilities should be promoted and laboratories supplied with water storage tanks or large aspirator bottles with a tap (20-30 litre capacity) next to the sink. To ensure the reliability of reagents preparation, water distillers should also be provided.

- Mechanisms for the internal quality control should be set up for all the available tests performed in the laboratories. An EQA system for basic laboratory tests

should be developed and implemented in order to monitor the quality of these services at the state level.

8.7.2 National level

- The federal ministry of health in Nigeria should consider testing the integrated EQA system produced by this project in other states of Nigeria to determine its applicability in different settings. Once the model is viable, it would guide to develop a policy for its incorporation under the new medical laboratory science policy.

- Integration of TB and malaria EQ system should be incorporated into the national medical laboratory policy and implemented. The Medical Laboratory Science Council of Nigeria should be made the central laboratory coordinating unit for the integrated laboratory service in the country.
- The MLSCN should also regulate the importation, storage and marketing of medical laboratory reagents and diagnostic chemicals.

There is the need to modify the national medical laboratory policy to include:

- TB microscopy in the basic tests recommended at the primary health car laboratories

- Guidelines for on-the-job training of laboratory assistants and technicians by the qualified scientists at the state level as part of human resource development strategy
- Guidelines for the regulation of private medical laboratories to ensure that only trained, certified and licensed personnel render private laboratory services in the country.

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Appendix A: Abstract of Poster Presented at the 5th European Congress on Tropical Medicine and International Health held in Amsterdam, May 24, 2007 through May 28, 2007. The abstraci is published in the *European J. Trop. Med. & Intern. Health* Vol. 12 (Supplement 1) 195

Category: 8.7. Health systems research

Title: An integrated model system for improving the quality of malaria parasites microscopy and AFB microscopy in Kano State of Nigeria

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Text:

Objectives: Kano state in Nigeria has begun to establish a state-wide quality checking process for TB microscopy but does not have any system for quality checking malaria microscopy. We aim to test the feasibility of designing, implementing and evaluating an integrated model system for improving the quality of malaria parasites and Acid Fast Bacilli (AFB) microscopy in Kano State of Nigeria. A pilot study showed that while 92-97% of AFB microscopy results were correct, only 70 - 75% of malaria readings were correct.
Methods: Five district hospital laboratories in which both malaria parasites and AFB microscopy were conducted were selected for the project. A team of 5 quality assurance officers comprising the state AFB quality control officer and two quality control officers each for AFB and malaria parasite microscopy were recruited and trained to assist with project implementation at state level. Community tuberculosis control supervisors in the 5 selected centres were trained to incorporate supervision and sampling for quality checking of malaria slides into the existing TB system. A model system based on blinded re-checking of sampled malaria parasites and AFB slides with on-site training and supervision at 3 monthly intervals was instigated in March 2006.
Results: By January 2007 the model had been fully implemented in 1/5 centres with 100% sensitivity and specificity for the presence of AFB and malaria parasites on microscopy. The model had been partially implemented in 3/5 centres and not implemented in one centre. Implementation and evaluation is still ongoing but factors that promoted successful implementation included adequate support from the hospital administration, proper supervision and motivation from the microscopists.
Conclusion: It could be feasible to design, implement and expand an integrated model system for quality assessment of malaria parasites and AFB microscopy in a low-resource country.

Appendix B1: Letter of receipt of the manuscripts of an original article under peer review submitted to the Journal of Infections in Developing Countries (JIDC)

JIDC 53/08

Tuesday, 13 May, 2008 9:19 PM
From: "Salvatore Rubino" <rubino@uniss.it>
Add sender to Contacts
To: fsarkinfada@yahoo.co.uk
Cc: jw5@sanger.ac.uk

JOURNAL OF INFECTION IN DEVELOPING COUNTRIES

Original articles entitled: Impact of introducing integrated quality assessment for tuberculosis and malaria microscopy in Kano, Nigeria

Faruk Sarkinfada, Yunusa Aliyu, Charles Chavasse, Imelda Bates

Department of Medical Microbiology and Parasitology, Faculty of Medicine, Bayero University Kano, Nigeria, Kano State Tuberculosis and Leprosy control Programme, Ministry of Health Kano, Nigeria and Disease Control Strategy Group, Liverpool School of Tropical Medicine, UK

13 May 2008

MSJIDC53/08

Dear Dr Faruk Sarkinfada,

Thank you for submitting: Impact of introducing integrated quality assessment for tuberculosis and malaria microscopy in Kano, Nigeria

The assigned Editor for your manuscript is Dr. John Wain e-mail: jw5@sanger.ac.uk

In accordance with our Editorial policy, your manuscript will now be sent for peer review and will be assessed by two reviewers who are experts in the field. We will contact you when a decision has been reached.

In future correspondence regarding your manuscript, please refer to manuscript number JIDC 53/08

For information about the status of your manuscript please contact the editor in charge for your paper.

Thank you for your interest in the Journal of Infection in Developing Countries.

Sincerely yours

Salvatore Rubino

Appendix B2: Abstract of the manuscripts of an original article under peer review submitted to the Journal of Infections in Developing Countries (JIDC)

IMPACT OF INTRODUCING INTEGRATED QUALITY ASSESSMENT FOR TUBERCULOSIS AND MALARIA MICROSCOPY IN KANO, NIGERIA

Faruk Sarkinfada[1]*, Yunusa Aliyu[2], Charles Chavasse[3], Imelda Bates[3]
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Abstract

Background: The World Health Organization has recommended the integration of malaria microscopy Quality Assessment (QA) with that of other microscopically diagnosed diseases, but there is no evidence that it has been attempted. We assessed the feasibility of linking malaria microscopy into the existing TB microscopy QA system in Kano, Nigeria.

Materials and methods: Five TB microscopy centres were selected for implementing the integrated TB and malaria microscopy QA scheme in the state. A model system was designed for selecting and blinded rechecking of TB and malaria slides from these laboratories. Supervision and evaluation was conducted at 3 monthly intervals for 24 months.

Results: TB microscopy QA was strengthened in four laboratories. Full integration of the QA for TB and malaria microscopy was achieved in two laboratories, and partial integration in other two laboratories. The programme resulted in an increase in the specificity of both TB and malaria microscopy results. 100% specificity was achieved for TB microscopy results in four laboratories at the final assessment. There was an increased concordance rate and decreased false positivity and false negativity rates of TB microscopy results in all the five laboratories.

Conclusions: It is feasible to integrate the QA system for TB and malaria microscopy and the assessment improved the quality of both services. However, the integrated system needs testing out in different settings in order to be able to develop sound recommendations to guide the complex scaling up process.

Key words: Tuberculosis, Malaria, Microscopy, Quality, Kano

Appendix C1: An Outline of the Project Implementation Plan Submitted to Kano state Ministry of Health

Quality Assessment of Tuberculosis and Malaria Microscopy Services in Kano State

By

Faruk Sarkinfada

Liverpool School of Tropical Medicine, UK

Supervisor:

Dr. Imelda Bates

Head, disease Control Strategy Group, LSTM

Co-Supervisor:

Dr. Charles Chavasse

Head, Dagnall Teaching Laboratory, LSTM

September 2006

Background:

Medical laboratory science profession in Kano State of Nigeria has evolved gradually over a period of 4 decades. It has grown, over the years, in terms of personnel, training, services, and its role in support of patient and public health care in the state. Yet there is no effective system in place to guarantee that laboratories are producing high quality results.

In line with the Federal Ministry of Health's National Quality Assurance Programme, applicable to both public and private Medical Laboratories, the Ford Foundation International Fellowship Programme (IFP) has funded a Ph D project at the Liverpool School of Tropical Medicine (LSTM) on Quality Assurance of Essential Laboratory Services in Kano State.

Aim(s):

This study is expected to produce a model of quality assurance system and a proposal for its short term, medium and long term implementation in the health facilities within the state and in the country. The expected model will make part of recommendations to state health administrators about the mechanisms and support systems necessary to provide sustainable high quality laboratory services for diseases of major public health importance, particularly Malaria and Tuberculosis.

Research Progress

1st Phase: March – August 2005

First phase of the fieldwork for data collection, involves baseline assessment of medical laboratory services in Kano state, as well as piloting of quality assurance procedures for AFB and malaria parasite microscopy. This was conducted between March and August 2005. Up to 13 laboratories in public hospitals were involved in the survey. The result was used to design the model for implementing quality measuring and improvement systems for malaria and TB diagnosis. Consultations on the designed model were made with a wide range of stakeholders in Kano State health sector. Inputs and advice were also solicited from trusted colleagues and senior Ministry of Health officials. Through this process I was able to mobilize co-workers all levels in the state from the coordinating unit in the ministry, to district health providers and community workers.

This project has also been able to complement the TB state control programme to strengthen and expand its AFB microscopy External Quality Assessment (EQA) activities. A comprehensive report on the EQA for the 1st and 2nd Quarter of 2005 was submitted to the state TB control officer accordingly.

2nd Phase: January 2006 to November 2006

Major Aim:

To implement and evaluate an integrated Quality Assurance (QA) for Malaria Microscopy and AFB Microscopy in selected laboratories in Kano.

Objectives:

1. Selection and Profiling of eligible laboratories: structure, operations and role in patient management and disease control activities.

2. To ensure attainment of minimum requirements for the implementation of QA procedure in each of the selected laboratory.

3. Conduct training of the participating staff from selected laboratories on QA procedures

4. Implementation of integrated QA system for AFB and MP Microcopy in the selected laboratories

5. Evaluation of the impact of QA on quality of services in AFB and Malaria microscopy in the selected laboratories

6. Design sustainable model of QA scheme on essential laboratory services for implementation in the rest of the laboratories in the state for the support of diagnostic service for priority diseases.

QUALITY ASSURANCE OF MALARIA PARASITE MICROSCOPY

Design

Design and Implementation Plan was made in accordance with the provisions of the National Malaria Control Programme and in close consultation with the State Malaria control officer and collaborating medical laboratory scientists. Some Ideas were adopted from the External Quality Assessment for AFB Smear Microscopy text jointly produced jointly by the Association of Public Health Laboratories (APHL), CDC, IUATLD, KCNV, RIT and WHO (2002).

Selection of Project Sites:

6 laboratories are selected for the implementation of the Quality Assurance Project. They are laboratories in:

1. Infectious Disease Hospital (IDH) Kano
2. Gwarzo General Hospital
3. Wudil General Hospital
4. Danbatta General Hospital
5. Rano General Hospital

Controller Laboratories (1st and 2nd level)

Laboratories	1st controller	2nd controller
6 Selected Laboratories	IDH Main Lab	MMSH Laboratory

On-site Evaluation:

On-site evaluation of the selected laboratories will be conducted by the use of the standard 'On-site Comprehensive Checklist in collaboration with the State Malaria control programme. Results of the evaluation will be utilized to set a minimum requirement for the participation of the laboratory in the rechecking programme. Additional resources will be supplied where necessary to ensure continuity of services in order to meet the standards in all the selected laboratories.

Training:

Refresher training of the micriscopists and supervisors would be conducted in collaboration with the State Malaria control programme.

Rechecking Procedure

Sample Size Determination:

The procedure of sample size determination using Slide Positivity Rate (SPR) will be adopted. **Slide Positivity Rate** is the proportion of positive blood films among all slides in the laboratory from which the sample is to be taken. This number is estimated using the laboratory registers fro the previous year. Sample size will be determined using the average positivity rate for the six selected laboratories since precision at the level of each laboratory may not be necessary or practical.

$$\text{SPR} = \frac{\text{Number of positive smears per year}}{\text{Annual slide volume}} \times 100$$

Sensitivity (ability of the technician to detect malaria parasite relative to the controller) set at 85%.
Specificity (set at 100%) at a particular confidence interval (70%, 80%, 95%) will be determined using standard procedures outlined previously (APHL, 2002).

Reference tables are available for use to determine sample size based on a range of Lot sizes and positivity rates.

Slide Storage, Collection and Examination Protocols:

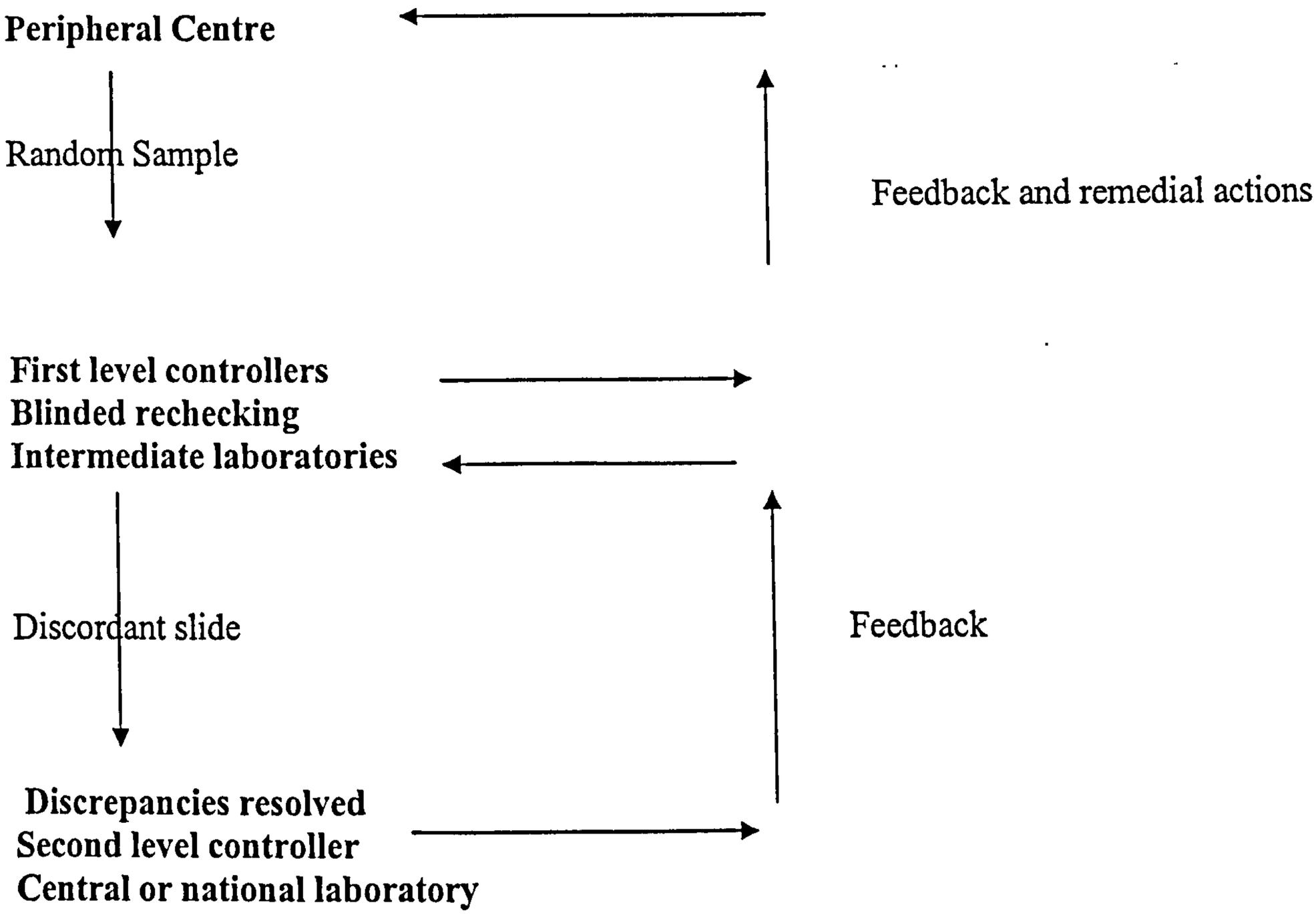
Storage of Slides:

1. Remove the oil by immersing the slides in xylene and allowing to dray. Do not rub slides with a cloth.
2. Store all slides from every malaria suspect in chronological order

Selection of slides by supervisor / QA officer

1. Slides for QA will be selected
a. During the On-site evaluation
b. After supplies of necessary resources at 3 month interval
c. After 6 months
d. After 9 months
e. After 12 months

Organization of Rechecking Process:



Final Analysis:

1. The QA Officer enters all the results in the appropriate columns
2. Results will be interpreted jointly by the QA Officer and EQA Project Manager
3. In case of agreement between the district and the 1st controller laboratory, the controller laboratory result is taken as final. For slides with discordant results that are re-examined by the QA team results from the team of microscopists is considered as final result.

Feedback:

The primary purpose of a rechecking programme is to improve the overall quality of malaria parasite microscopy, therefore regular and timely feedback to the selected laboratory is essential if any improvement in performance is expected. Annual reports should be sent to the regional health authority, district physician as well as the laboratory technicians. Although final analysis of the results and conclusions have to

await completion of rechecking of the whole (annual) sample, preliminary observations, feed-back and remedial action will often be possible at the end of each sampling period. This will indicate laboratories with good or poor performance where immediate problem solving is most urgently needed.

Appendix I: AFB Microscopy External Quality Assessment Result in Some TB Microscopy Centres in Kano (2005)

Centre	Slides Sampled	1st re-reading		2nd re-reading		Agreement	Discord
		Agreement	Discord	Agreement	Discord		
A	30	21	9	8	1	29	1
B	15	15	0	15	0	15	0
C	30	26	4	2	2	28	2
D	15	9	6	0	6	9	6
E	15	13	2	2	0	15	0
Total	105	84	21	27	9	96 (91%)	9 (9%)

Evaluation of Results (AFB Microscopy)

Centre	No. of Slides	TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
A	30	8	21	0	1	88.9	100	100	95.5
B	15	2	13	0	0	100	100	100	100
C	30	10	18	0	2	83.3	100	100	100
D	15	0	9	5	1	0	64.3	0	90
E	15	4	11	0	0	100	100	100	100
Total	105	24	27	5	4	85.7	93.5	96.6	94.7

Appendix II:Malaria Microscopy External Quality Assessment in Some District Hospitals in Kano (2005)

Centre	Slides Sampled	1st re-reading		2nd re-reading		Agreement	Discord
		Agreement	Discord	Agreement	Discord		
A	15	10	5	0	5	10	5
B	13	7	6	6	0	13	0
C	15	5	10	8	2	13	2
D	13	7	6	2	4	9	4
E	15	3	12	10	2	13	2
F	15	7	8	2	6	9	6
Total	86	39	47	28	19	67 (78%)	19 (22%)

Evaluation of Results (Malaria Microscopy):

Centre	No. of Slides	TP	TN	FP	FN	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)
A	15	6	4	0	5	54.5	100	100	44.9
B	13	4	9	0	0	100	100	100	100
C	15	5	8	0	2	71.4	100	100	80
D	13	4	5	4	0	100	55.6	50	100
E	15	3	10	1	1	75	90	75	90
F	15	6	3	6	0	100	33.3	50	100
Total	86	28	39	11	8	77.8	78	71.8	83

Appendix C2. List of participants, CDP workshop 3

Kano, March 2008

FEDERAL/NATIONAL

	Name	Position
1	Mr. Elton Oga	Dept. Hospital Services, FMOH, Abuja
2	Mr. Chukwuemeka Elom	NTBLCP, FMOH, Abuja
3	Mrs. Josephine Okon	Association of Medical Lab Scientists
4	Mrs. Maria Ollanji	Medical Lab Sc. Council of Nigeria
5	Dr. S.O. Banjo	Malaria Programme, FMOH, Abuja
6	Dr. Ali Onoja	Head, Central Public Health Lab, FMOH Yaba Lagos Coordinator and secretary, Implementation Task Force, Nigeria National Medical Laboratory Services Policy

KADUNA

	Name	Position
1	Mr. Chori Musa Idris **(Focal Person)***	AIMLS, Haj Gambo Sawaba Gen Hosp, Zaria
2	Mr. Emmanuel Kwasu Achi	BSc Biochemistry, (AIMLS) Yusuf Dan Tsoho GH, T/Wada, Kaduna South LGA.
3	Mr. Jonathan Zaki	MSc Microbiology, (AIMLS) BDSH, Kaduna
4	Mr. Banda Monday Jim	MSc Immunology, Gen Hosp Kafanchan

*musachori@yahoo.com

ENUGU

	Name	Position
1	Mr. Richard Eze* **(Focal Person)**	MLS, i/c, Agbani District Hospital, Agbani, Agbani DHB, Enugu State (public sector person)
2	Mr. Simon Ani	MLS, i/c, Udi District Hospital, Udi, Udi DHB, Enugu State (public sector person)
3	Rev Sr. Cecilia Chukwu	MLS, i/c, Annunciation Specialist Hospital, Emene, Enugu (private sector/faith-based person)
4	Mrs. Beatrice Ezeugwu	Absent on sick leave

*ezefrancisrich@yahoo.com

EKITI

	Name	Position
1	Mr. Oye Ariyo* **(Focal Person)**	Chief MLS, Disease Control Dept, MoH Ekiti State
2	Mr. Ojo Abiodun	SMLS, State Specialist Hospital Ado
3	Prince Adebayo Adesanmi	SMLS, State Specialist Hospital Ijero
4	Mr. Kolawole Olajide	SMLS, State Specialist Hospital Ikere

*ojobiyeye@yahoo.com

KANO

	Name	Position
1	Yunusa Aliyu* **(Focal Person)**	SMLS (QUALITY CONTROL)
2	Aminu Kurawa	ACML (SMJGH)
3	Kabiru Mohammed	MLS (WUDIL Gen Hosp)
4	Abdullahi Tanwa	ACMLS (MMSH)

*yunus_ma1@yahoo.co.uk

JIGAWA

	Name	Position
1	Lawan Sani Yakubu* **(Dep. Focal Person)**	PML Scientist Hadejia General Hospital
2	Ismaila Mohammed Jahun	SML Scientist Birnin Kudu General Hospital
3	Maryam Ekpenga	SML Scientist Kazaure General Hospital
4	Ibrahim Ado	PML Technician Birniwa Cottage Hospital

Appendix C3: CDP Workshop Report showing request for a guideline for systematic selection of a statistically meaningful number of slides by the participants from Federal Ministry of Health and 5 the state ministry of health.

PATHS

Nigeria Partnership for Transforming Health Systems

Report to PATHS National Programme Manager, Abuja

Support to the Community Diagnostics Programme

Dr Imelda Bates
Mr Russell Dacombe
Mr Bam Adeke

March 2008

Page 11

5. Selection of slides for malaria QA: Faruk Sarkinfada

Faruk is a senior biomedical scientist in Kano who has just completed his PhD on integration of TB and malaria QA systems. In response to discussions during the workshop about how to select the right number of slides for checking in the malaria microscopy QA process Faruk gave a brief presentation to describe the evidence and principles underlying the systematic selection of a statistically meaningful number of slides. He will produce a brief guide which will be disseminated to the participants.

Appendix D1: Checklist used for the baseline assessment

BASELINE ASSESSMENT OF MEDICAL LABORATORY SERVICES IN KANO STATE, NIGERIA.

Checklist

Background:

The quality of laboratory services is directly related to the excellence and uniformity of the information provided for medical care. It is of immense benefit to the users of such services in clinical management of patients and disease control, and to the less privileged individuals who live in areas where incidence and prevalence of these diseases are high. And because many clinical practice guidelines set well-defined standards using laboratory values, results of laboratory investigations are ideally suited to tie clinical interventions to evidence-based guidelines. Logically, successful treatment requires correct diagnosis based on the accuracy, reproducibility, and interpretability of investigations and examinations.

Medical laboratory Science profession in Kano State of Nigeria has evolved gradually over a period of 4 decades. It has grown, over the years, in terms of personnel, training, services, and support, roles in patient and public health care as well as management of the health care system in the state. Medical laboratories have long recognized the need for total quality management that incorporates the continuous improvement of all stages, such as the pre-analytical, analytical and post-analytical phases, of the diagnostic process, in addition to the traditional internal and external quality control of analytical procedures. Based on national and international experience, continuous improvement of quality and its external assessment are of high priority in order to guarantee reliable, effective and cost-effective diagnostic services. Quality assurance systems used in industrialized countries and published in the literature are not appropriate for rural laboratories in low-income countries such as Nigeria. They are based on assumptions that the methods are generally automated and communication and transport network are reliable. These systems are therefore too complex for a workforce in the Nigerian Health System.

The Disease Control Strategy Group of the Liverpool School of Tropical Medicine in collaboration with the Kano Sate Ministry of Health is set to conduct a baseline assessment of the medical laboratory services in Kano State, Nigeria. The aim of the survey is to provide background information for the development, implementation and evaluation of a sustainable quality assurance system in the essential laboratory services in selected sites of the study. Result is expected to contribute towards the effective use in patients' management, control of priority endemic diseases and the improvement of healthcare provision to the less privilege.

Faruk Sarkinfada

Ph D Student

INSTRUCTIONS:

This questionnaire consists of 11 sections A to K.

Sections A – D: Retrospective data; to be completed by the Head of Laboratory Units of the selected sites of the study.

Sections E - F: Continuous data; to be recorded by the collaborators in the respective laboratories over a period of six months

Sections G – K: Observational data; to be completed by the Principal Researcher with the assistance of the Head of laboratory Units.

SECTION A: GENERAL INFORMATION

1. Location of Laboratory (Local Government Area).....
2. Name of Hospital.....
3. Status of Laboratory (Public / Private).....
4. Name and position of collaborator.....
5. Date administered.....

6. Available Units within the Laboratory (if applicable)

Units	Yes	No
Blood Banking & Transfusion Services		
Chemical Pathology		
Haematologey		
Histipathology		
Microbiology		
Parasitology		
Serology		
Others (Specify)		

5. Number of Side / Ward Laboratories .....
6. Coverage: State the Hospitals / Clinics for which your laboratory provide services

.....

.....

7. Indicate the various sources of specimens and proportions to the laboratory

Source of specimens	Percentage
From within the hospital	
From other hospitals	
From private clinics	
From private laboratories	
Others	

8. State the estimated population served by your laboratory .....

SECTION B: ORGANIZATION

1. Parent Organization: Which is the Parent Organization for your Laboratory:
   - Federal Government
   - State Government
   - Local Government
   - Religious Body
   - Private
   - Community

2. Organogram: Give a brief outline of the organogram / administrative structure of your laboratory in relation to the parent organization.

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3. Describe the internal laboratory administrative structure indicating individuals' responsibilities.

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.....

4. Financial Management:

What is / are the main source(s) of financing your laboratory

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.....

What is / are the other source(s) of finance to your laboratory (if any)?

.....
.....
.....
.....

What are the following financial information for your laboratory for the last financial year (June 2003 to June 2004)

Item	Amount (=N=)
Budget allocation to the laboratory	
Total expenditure	
Turn over from patients' charges	
Profit from patients' charges (if any)	
Deficit incurred from patients' charges	

Do you have patient charge exemption policy for your services?

- Yes
- No

If yes, State your exemption regulations:

.....
.....
.....
.....
.....

SECTION C: STAFFING

1. Give the breakdown of the staff strength of your Laboratory:

Rank	Qualifications	Status (Permanent/ Temporary/ Contract)	Number	Training attended in the last 1 year	Normal Daily Working Hours	Call / shift duty Hours	Weekend service hours
Chief Med. Lab Scientist							
Assistant Chief Med. Lab. Scientist							
Principal Med Lab Scientist							
Med Lab Scientist I							
Med Lab Scientist II							
Senior Lab. Technician							
Junior Lab. Technician							
Senior Lab. Assistants							
Junior Lab Assistant							
Senior Lab Attendant							
Junior Lab Attendant							
Cleaners							
Messenger							
Security Officer							
Others							

What are the durations of your staff leaves?

Leave	Duration (Days)
Annual	
Sick	
Maternity	
Casual	
Study	
Accrued days off	
Others	

Comments:

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SECTION D: WORDKLOAD

In the table below, indicate the average number of tests per month for each of the listed tests.

MICROBIOLOGY

Microscopy	Number of tests in the last one year	Average Number of tests per month
Urine		
Acid-fast bacilli		
High Vaginal Swab		
Urethral Swab		
Wound swab		
Other Swabs		
Cerebro Spinal fluid		
Seminal fluid		
Aspirates		
Fungal		
Cultures		
Blood		
Urine		
Sputum		
Stool		
CSF / Aspirates		
Swabs / Fluids		
Fungal		

PARASITOLOGY

	Number of tests in the last one year	Average number of tests per months
Stool Microscopy		
Urine microscopy		
Urinalysis		
Malaria Parasite		

HAEMATOLOGY AND BLOOD TRANSFUSION SERVICES

	Number of tests in the last one year	Average number of tests per month
Hb Estimation		
Hb genotyping		
Blood Grouping		
Cross Matching		
Full Blood Count		
Malaria Parasite		
Erythrocytes Sedimentation Rate (ESR)		
Packed Cells Volume (PCV)		
Sickling Test		
Others		

CHEMICAL PATHOLOGY

	Number of tests in the last one year	Average number of tests per month
CSF Chemistry		
Fluid Protein		
Urinalysis		
Blood Glucose		
Liver Function Test (LFT)		
Pregnancy test		

SEROLOGY

	Number of tests in the last one year	Average number of tests per month
HIV screening		
HBV Surface Antigen		
Manteux Test		
Widal Test		
Anti-Streptolysin O titration		
VDRL		

Comments:

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E. ELECTRICAL SUPPLY TO LABORATORY:

Assessment of daily electrical supply to the laboratory during working period
(Mark Power on = √ Power off = X)

Day / Date	A.M						P.M				
	7	8	9	10	11	12	1	2	3	4	5

Comments (Problems and deficiencies):

.....

.....

.....

.....

.....

.....

Action required:

.....

.....

.....

F. WATER SUPPLY TO LABORATORY:

Assessment of daily water supply to the laboratory during working period
(Mark Power on = √ Power off = X)

Day / Date	A.M						P.M				
	7	8	9	10	11	12	1	2	3	4	5

Comments (Problems and deficiencies):

.....
.....
.....
.....
.....
.....

Action required:

.....
.....
.....
.....

SECTION G: SAFETY INSPECTION

Item	Yes	No	Comment
Design of premises			
Work area is large enough			
All equipments are on a stable surface			
Lighting is adequate			
Ventilation is adequate			
Laboratory is wholly or partially air-conditioned			
Dangerous chemicals are stored on floor level			
Poisons are kept locked up			
Only laboratory staff have access to the laboratory working area			
Standard operating procedures			
These are available in the laboratory			
The laminated SOPs are on display in an appropriate place			
Mouth pipetting is use for some tests			
Hand washing facilities (soap and water) are available in each lab room			
Written instructions are available in the laboratory for:			
Dealing with patients			
Handling samples			
Use of centrifuge			
Use of mechanical device			
Use of electrical equipments			
Decontamination procedures			
Spillage containment for infective materials			
Spillage containment for dangerous chemicals			
Waste disposal			
Pipetting instructions			
First aid			

Fire precautions			
Eye protection instructions			
Personal protection – did you observe any of the following?			
Eating and drinking in the laboratory			
Keeping foods and drinks in specimen refrigerator			
Licking of labels or envelop covers			
Jewellery being worn			
Disposable gloves being worn			
Disposable gloves being reused (excluding household rubber gloves used for decontamination, cleaning etc)			
New gloves being used for each patient during venesection			
White coats being worn			
Hand washing on leaving the laboratory			
Safety hood available and being used			
Universal safety precautions			
'Sharp' items are placed in puncture resistant containers			
All surfaces, glassware, pipettes etc are cleaned with disinfectant at the end of the day			
Toxic chemicals are supplied to the laboratory pre-diluted			
Electrical safety			
All electrical equipment complies with national or international safety standards			
There is planned programme of preventive maintenance for all electrical equipment			
Fire Hazards			
Fire extinguishers, buckets of sand etc, are easily available			
Flammable substances are clearly marked as FIRE RISK			
Bulk stocks of flammable substances are stored away from the laboratory			
Fire extinguishers are inspected regularly			
Waste disposal			
Sharps, containers are incinerated			
Other infectious materials are clearly marked, strong plastic bags			
Other infectious materials are autoclaved			
Other infectious materials are incinerated			
Other infectious material is buried			
A clear strategy available for chemical waste disposal			
All chemicals are disposed of down the sink			
First aid kit contains			

A card giving general first aid guidance			
Sterile adhesive dressings			
Sterile eye pads			
Triangular bandages			
Sterile wound coverings			
Safety pins			
Sterile water or saline			

SECTION H: BASIC EQUIPMENT

1. MICROSCOPES

	Yes	No
Is microscope available		
Number of microscope available		
Is the number of microscope sufficient		
Microscopes functioning properly		
Adequate light source present		
Arrangements for maintenance of microscopes		

2. REFRIGERATOR

	Yes	No
Is refrigerator available		
Number of refrigerators available		
Is the number of refrigerators sufficient		
Refrigerators functioning properly		
Adequate temperature regulator		
Adequate source of power for refrigerator		
Arrangements for maintenance of refrigerator		

3. WATER BATH

	Yes	No
Is water bath available		
Number of water bath available		
Is the number of water bath sufficient		
Water bath functioning properly		
Adequate temperature regulator available		
Adequate source of power for water bath		
Arrangements for maintenance of water bath		
Calibration inspected regularly		

4. WEIGHING BALANCE

	Yes	No
Mechanical balance available		
Number of Mechanical Balances		
Electrical Balance available		
Number of Electrical Balance		
Adequate number of weighing balance available		
Weighing balance functioning properly		
Regular source of power for electrical balance		
Arrangements for maintenance of refrigerator		
Calibration inspected regularly		

5. INCUBATOR

	Yes	No
Incubator available		
Number of incubators available		
Is the number of incubator sufficient		
Incubator functioning properly		
Regular source of power for incubator		
Arrangements for maintenance of incubator		
Calibration inspected regularly		

6. AUTOCLAVE

	Yes	No
Is Autoclave available		
Number of Autoclave available		
Is the number of Autoclave sufficient		
Autoclave functioning properly		
Adequate temperature regulator available		
Adequate source of power for Autoclave		
Arrangements for maintenance of Autoclave		
Calibration inspected regularly		

7. COLORIMETER

	Yes	No
Colorimeter available		
Number of colorimeter available		
Is the number of Colorimeter sufficient		
Colorimeter functioning properly		
Regular source of power for colorimeter		
Arrangements for maintenance of colorimeter		
Calibration inspected regularly		

Comments (Problems and deficiencies):

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Action required:

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SECTION I: OPERATIONS (To be filled with the assistance of Chief Laboratory Scientist / Head of Units)

In the table below, indicate the method(s) and how procedures and qualities of results are monitored for each of the tests listed.

MICROBIOLOGY

Microscopy	Method (s)	Who performs the test	Method of monitoring procedure assuring quality of results
Urine			
Acid-fast bacilli			
High Vaginal Swab			
Urethral Swab			
Wound Swabs			
Cerebro-Spinal fluid			
Seminal fluid			
Aspirates			
Other Fluids			
Mycology			
Cultures			

Urine			
Stool			
Sputum			
CSF / Aspirates			
Swabs / Fluids			
Fungal			

PARASITOLOGY

	Method (s)	Who performs the test	Method of monitoring procedure assuring quality of results
Stool Microscopy			
Urine microscopy			
Urinalysis			
Malaria Parasite			

HAEMATOLOGY AND BLOOD TRANSFUSION SERVICES

	Method (s)	Who performs the test	Method of monitoring procedure assuring quality of results
Hb Estimation			
Hb genotyping			
Blood Grouping			
Cross Matching			
Full Blood Count			
Malaria Parasite			
ESR			
PCV			

Sickling Test			
Others			

CHEMICAL PATHOLOGY

	Method (s)	Who performs the test	Method of monitoring procedure assuring quality of results
CSF Chemistry			
Fluid Protein			
Urinalysis			
Blood Glucose			
LFT			
Pregnancy test			

SEROLOGY

	Method (s)	Who performs the test	Method of monitoring procedure assuring quality of results
Anti-Streptolysin O			
HIV Screening			
HBV Surface Antigen			
Manteux Test			
Widal Test			
Others			
VDRL			

Comments:

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SECTION J: REQUESTS, REPORTS AND RECORDS

1. Quality of requisitions by clinicians for laboratory investigations:
(Y = Yes N = No):

	Y	N	Comment
Use of standard designed requisition form			
Proper indication of patients' reference Number			
Proper indication of patients' Age			
Proper indication of patients' sex			
Proper indication of clinical diagnosis			
Relevance of specimen to requested tests			
Clarity of information on the request form			

2. Ability of laboratory reports to provide the following information
(Y = Yes N = No):

	Y	N	Comment
Identity of the laboratory			
Date of Sampling			
Nature of Analyte (specimen)			
Units of measurements / reference intervals			
Indication of any observable characteristics that might affect the result			
Appropriate comment on interpretations			
Signature of Staff			
Despatch / Communication of Results			

3. Ability of recording system to provide the following information
(Y = Yes N = No):

	Y	N	Comment
Trace the request and individual results related to patients' specimen			
Records of Internal control and external quality assessment			
Record of equipment maintenance			
Records of Time period in which each reagent is prepared and its respective shelf life			

General comments:

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SECTION K: EXTERNAL QUALITY ASSESSMENT

Does your Laboratory participate in External Quality Assessment (EQA) and Inter-laboratory Comparison?

- Yes
- No

If yes, specify the tests involved;

Test	EQA	IC	Frequency

If no, state the reasons:

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Comments:

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Appendix D2: List of Collaborators / QA Team

Name	Address	Qualification	Skills
1. Saleh Idris T/ Wada	I D H Kano	M. Sc., FMLSCN	Clin. Chem Haem.
2. Al-Muktar Yahuza	I D H Kano	B. Sc., AMLSCN	Bact., Parasitolog
3. Abdurrazaq Hamza	MMSH Kano	M. Sc., AMLSCN	Bact., Immunol.
4. Ado Garba Abubakar	CDC, Kano	B. Sc., FMLSCN	Haem, Clin Chem
5. Ado Hamza	MAWH Kano	B. Sc., AMLSCN	Haem., Bact.
6. Hamisu U Takalmawa	AKTH, Kano	M. Sc., AMLSCN	Bacteriology
7. Jamilu Tijjani	I D H Kano	B. Sc., AMLSCN	Bacteriology.
8. Nasiru Magaji	AKTH	M. Sc., AMLSCN	Bacteriology
9. Auwal Ayagi	MMSH	Med Lab Tech	AFB Microscopy
10. Abdullahi Tanwa	MMSH	AMLSCN	Haematology

Appendix D3: Schedule of visits for the baseline assessment of medical laboratory services in Kano and the piloting of external quality assessment for AFB microscopy (April – June 2005)

Dates (Wed. / Fri.)#	Facility	Location (Local Government Area)
11 / 4 / 2005	Infectious Diseases Hospital (IDH)	Fagge* (Urban)
11 / 4 / 2005	Murtala Muhammad Specialist Hospital (MMSH)	Municipal (Urban)
13 / 4 / 2005	Muhammad Abdullahi Wase Specialist Hospital (MAWSP)	Nassarawa (Urban)
13 / 4/ 2005	Kano Central Prison Clinic	Municipal (Urban)
15 / 4 / 2005	General Hospital Wudil	Wudil*
20 / 4 / 2005	General Hospital Gwarzo	Gwarzo*
22 / 4 / 2005	General Hospital Danbatta	Danbatta*
27 / 4 / 2005	Comprehensive Health Centre Kura	Kura
29 / 4 / 2005	General Hospital Bichi	Bichi
4 / 5 / 2005	General Hospital Rano	Rano*
6 / 5 / 2005	General Hospital Wudil	Wudil (2nd visit)
11 / 5 / 2005	General Hospital Gezawa	Gezawa
13 / 5 / 2005	General Hospital Gwarzo	Gwarzo (2nd visit)
18 / 5 / 2005	General Hospital Sumaila	Sumaila
20 / 5 / 2005	General Hospital Danbatta	Danbatta (2nd visit)
25 / 5 / 2005	General Hospital Karaye	Karaye
27 / 5 /2005	General Hospital Kura	Kura (2nd visit)
1 / 6 / 2005	General Hospital Bichi	Bichi (2nd visit)
3 / 6 / 2005	General Hospital Rano	Rano (2nd visit)
8 / 6 / 2005	General Hospital Gezawa	Gezawa (2nd visit)
10 / 6 / 2005	General Hospital Sumaila	Sumaila (2nd visit)
15 / 6 / 2005	General Hospital Karaye	Karaye (2nd visit)

*AFB slides were sampled for External Quality Assessment

#Mondays, Tuesdays and Thursdays are dedicated for meetings the MOH officials, visits to laboratories within Kano Metropolis and other related project activities.

Appendix E1: Observable safety feature among 10 laboratories in Kano (April 2005)

Laboratory safety features	Laboratories										n =10	
	MMSH	MA WSP	IDH	KUR	BCH	GWZ	HBP	WDL	DBT	RAN	Total Yes	Total
Work Area restricted to Laboratory staff only	N	N	N	N	Y	N	Y	N	Y	N	3	7
Mouth Pipetting Used for some tests	Y*	N*	N	Y	Y	Y	Y	Y	Y	Y	8	2
Hand Washing facilities (soap and water) available in each lab room	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	0
Hand washing on leaving the laboratory	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10	0
Written instructions for safe laboratory operations	N	N	N	N	N	N	N	N	N	N	0	10
Manual for equipment operation or maintenance	N	N	N	N	N	N	N	N	N	N	0	10
Planned programme of preventive maintenance for all electrical equipments	N	Y	N	N	N	N	N	N	N	N	0	10
Personal Protection												
Foods and drinks in the laboratory premises	Y*	Y*	Y	Y	N	N	Y	Y	N	Y	6	4
Keeping food and drink in specimen refrigerator	Y*	N*	N	N	N	N	Y	Y	N	N	3	7
Disposable Gloves being worn	Y**	Y**	Y	N	Y	N	Y	N	Y	N	6	4
White coats being worn	Y**	Y**	Y	N	Y	N	N	N	Y	N	5	5
Safety hood available and being used	N*	N	N	N	N	N	N	N	N	N	0	10
Fire extinguisher available	Y*	N	N	N	N	N	N	N	N	Y	2	8
First Aid Kits Available	N	N	N	N	N	N	N	N	N	N	0	10

Key:
Y = Yes N = N *Observed in some units **Observed in some personnel

Appendix E2: Basic laboratory equipment

Equipment	Number available in Laboratories												
	MMSH	MAWSH	HBP	IDH	WDL	KUR	GWZ	DBT	GZW	KRY	SML	BCH	RAI
Binocular microscope	3	3	2	2	4 (2F)	1 (F)	1	2 (F)	1(F)	0	0	2 (F)	2 (1I
Laboratory Refrigerator	6	4	2 (F)	2	1	1	0	?4 (2F)	1 (F)	1	1 (F)	0	3 (F)
Blood Bank Refrigerator	1	1	0	0	1	0	1	1	0	0	0	1	1 (F)
Water Bath	7 (6F)	2	1	3 (F)	1	1	0	0	1 (F)	0	0	2	0
Weighing Balance	5 (4F)	4	0	2 (F)	2 (F)	1 (F)	0	0	0	0	0	0	1
Incubator	2	3	1	3 (F)	0	0	0	0	1 (F)	0	0	2 (F)	1
Autoclave	2	1	0	2 (1F)	1 (F)	1	0	0	0	0	0	1	0
Colorimeter / Spectrophotometer	2	1	2	1 (F)	3 (2F)	0	1 (F)	0	0	0	0	1 (F)	1 (F)
Centrifuge	4	3	1	1	1	1 (Mann)	1	1	2 (F)	0	0	1	1
Haematocrit Centrifuge	1	1	1	1	1	0	0	0	0	0	0	1	?
Haematocrit Reader	1	1	1	1	1	0	0	0	0	0	0	1	?

Appendix E3: Numbers of laboratory tests conducted in 13 hospital laboratories in Kano in 2004

Laboratory Services Provided in 2004	Number of tests												
	IDH	**DBT**	**WDL**	**RAN**	**BCH**	**GZW**	**KUR**	**SML**	**KRY**	**GWZ**	**HBP**	**MMH**	**MAWH**
BLOOD TRANSFUSION													
Haemoglobin estimation	-			321	349		740	618					
Blood grouping	25	3959	4500	900	769	1400	930	709	62	1830	158	34,200	1431
Crossmatching	-	1072	790	900	448		930	709	30		56	1368	537
HIV blood donors / patients	1725	2112	1200	990	448	502	1067	709	43	267	148	4800	1672
HBV blood donors /patients	-	1342	716	990	319	264	950				71	2880	1876
MICROSCOPY													
AFB Microscopy	12525	508	790	320	37					349		1800	80
Malaria microscopy	1,109	2350	2016	476	205	1448				953	566	8700	3251
Urine microscopy	149	83	1300	560	834	244	600	6		129	230	3600	2124
Stool microscopy	129	172	780	240	41	110					48	1037	1894
Swabs	-										10	6020	1760
CSF / Fluids	3		28								18	120	64
Semen analysis												120	107
Fungal	-											36	2
CULTURE													
Blood	-											35	-
Urine	149										264	1800	2124
Sputum	314											1800	180
Stool	100										194	360	1253
Swabs	30											360	1862
CSF / Fluids	3											60	64
Fungal	-											-	-
CHEMISTRY													

CSF chemistry	-											154	23
Fluids protein	-											146	48
Blood Glucose	78		260					112				8913	6184
Liver function test (LFT)	-											1553	460
Pregnancy test	72	1970	3900	660	357	798	900	154		798		6579	1515
Urinalysis	91	850	104	456	399	251	120	226	129	251	230	2602	5134
Urea & Electrolyte / createnin													
calcium and phosphate ions													
DIAGNOSTIC HAEMATOLOGY													
Full blood count	660		270	506	34						1,250	16368	4418
ESR	630		27	360	23	20	44				48	5040	376
Hb gynotype	-				19							3272	
PCV	700		5200	506	416	975				2,28	440	8100	6219
DIAGNOSTIC SEROLOGY													
VDRL – patients & antenatal screen	28											342	1699
Widal test	1,320	2350	3600	790	504	1442	805	183		660	1548	5760	4648
ASO titration													
Manteux test													

Appendix E4: Test methods and staff conducting the tests in laboratories (2005)

Laboratory Services Provided in 2004	Methods	Staff performing the test	
		S= Scientist, T=Technician, A=Assistant	
BLOOD TRANSFUSION		Tertiary	Secondary
1 Haemoglobin for transfusion assessment	Rapid Kits (Tellquest)	NA	A
2 Blood grouping	ABO & Rhesus – cell group only, slide test	A, T, S	A, T, S
3 Crossmatching	Saline crossmatching	A, T, S	A, T, S
4 HIV blood donors / patients	Particle agglutination screening or HIV-SPOT	A, T, S	A, T, S
5 HBV blood donors /patients	Screening test – agglutination	T, S	NA
MICROSCOPY			
6 AFB Microscopy	ZN stain – cold method	T, S	A, T, S
7 Malaria microscopy	Thin blood film preparation, Leishman stain	S	A, T, S
8 Urine microscopy	Wet preparation / deposit	A, T	A, T
9 Stool microscopy	Direct microscopy for ova, cysts, trophozoites	A, T	A
10 Swabs	Wet preparation / Gram stain	A, T	A, T
11 CSF / Fluids	Direct microscopy / Gram stain	T, S	NA
12 Fungal	KOH preparation	T, S	NA
13 Semen analysis	Direct microscopy	T, S	NA
CULTURE			
14 Blood	Enriched, differential & biochemical media – plating	S	NA
15 Urine	Enriched, differential & biochemical media – plating	S	S
16 Sputum	Enriched, differential & biochemical media – plating	S	S
17 Stool	Enriched, differential & biochemical media – plating	S	S
18 Swabs	Enriched, differential & biochemical media – plating	S	S
19 CSF / Fluids	Enriched, differential & biochemical media – plating	S	S
20 Fungal	SDA / Cornmeal agar	S	NA
CHEMISTRY			
21 CSF chemistry	Glucose / protein dipsticks & turbidometry	S	S
22 Fluids protein	Dipsticks / biuret reagent	A, T, S	NA
23 Blood Glucose	Dipsticks / glucose oxidase	A, T, S	A
24 Liver function test (LFT)	Dipsticks / Powell, H Valley	S	NA
25 Pregnancy test	Dipsticks	A	A
26 Urinalysis	Dipsticks	A	A
27 Urea & Electrolyte / createnin		S	NA
28 Calcium and phosphate ions		S	NA
DIAGNOSTIC HAEMATOLOGY			
29 Full blood count (total white cell count & differential)	Microscopic counting chamber, Leishman stain	S	NA
30 ESR	Westergren method	A, T	A
31 Hb gynotype	Electrophoresis	S	NA
32 PCV	Haematocrit	A	A
DIAGNOSTIC SEROLOGY			
33 VDRL – patients & antenatal screen	Rapid slide agglutination – carbon antigen	A, T	A
34 Widal test	Rapid slide agglutination	A, T, S	A, T
35 ASO titration	Titration	S	NA
36Manteux test	Tuberculin test	S	S

Appendix F1 Results of LQAS sampling and re-reading of TB microscopy slides from 5 laboratories in Kano (2005 – 2006)

	Proportion of results						
Parameters	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
Number of slides examined	100	105	30	68	58	56	**417**
Good smear preparations	38 (38.0%)	32 (30.5%)	10 (33.3%)	23 (33.8%)	16 (27.6%)	32 (57.1%)	**151 36.2%**
Good smear staining	48 (48.0%)	50 (47.6%)	11 (36.7%)	28 (41.2%)	27 (46.6%)	33 (58.9%)	**197 47.2%**
Concordance	81 (81.0%)	87 (82.9%)	29 (96.7%)	61 (89.7%)	52 (89.7%)	51 (91.1%)	**365 87.5%**
True positives	7 (7.0%)	24 (22.9%)	5 (16.7%)	6 (8.8%)	9 (15.5%)	7 (12.5%)	**58 13.9%**
True negatives	74 (74.0%)	72 (68.6%)	24 (80.0%)	55 (80.9%)	43 (74.1%)	46 (82.1%)	**314 75.3%**
High false positives	4 (4.0%)	2 (1.9%)	1 (3.3%)	0 (0.0%)	1 (1.7%)	1 (1.8%)	**9 2.2%**
Low false positives	15 (15.0%)	3 (2.9%)	0 (0.0%)	1 (1.5%)	1 (1.7%)	0 (0.0%)	**20 4.8%**
High false negatives	0 (0%)	1 (1.0%)	0 (0.0%)	0 (0.0%)	1 (1.7%)	0 (0.0%)	**2 0.5%**
Low false negatives	0 (0%)	3 (2.9%)	0 (0.0%)	6 (8.8%)	3 (5.2%)	2 (3.6%)	**14 3.4%**
Quantification errors	4	11	2	5	3	4	29
Sensitivity (%)	100	85.7	100	50	69.2	77.8	**78.4**
Specificity (%)	80	93.5	96	98.2	95.5	97.9	**91.5**

Appendix F2: Results of LQAS sampling and re-reading of TB microscopy slides from IDH laboratory, Kano (2005 – 2006)

Parameters	Proportion of results						
	0 month	3 months	12 months	15 months	18 months	21 months	Total
Number of slides examined	28	30	-	14	13	15	100
Good smear preparations	14 (50%)	10 (33.3%)	-	8 (57.1%)	5 (38.5%)	7 (46.7%)	44 (44.0%)
Good smear staining	19 (67.9%)	17 (56.7%)	-	8 (57.1%)	9 (69.2%)	6 (40%)	59 (59.0%)
Agreements	22 (78.6%)	21 (70%)	-	12 (85.7%)	12 92.3%)	13 (86.7%)	80 (80.0%)
True positives	3 (10.7%)	8 (26.7%)	-	1 (7.1%)	3 (23.1%)	2 (13.3%)	17 (17.0%)
True negatives	19 (67.9%)	21 (70%)	-	11 (78.6%)	9 69.2%)	12 (80%)	72 (72%)
High false positives	2 (7.1%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	2 (2.0%)
Low false positives	4 (14.3%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	4 (4.0%)
High false negatives	0 (0%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Low false negatives	0 (0%)	1 (3.3%)	-	2 (14.3%)	1 (7.7%)	1 (6.7%)	5 (5.0%)
Quantification errors	1	5	-	1	1	1	9
Sensitivity (%)	100	88	-	33.3	75	66.7	77.2
Specificity (%)	76	100	-	100	100	100	92.3

Appendix F3 Results of LQAS sampling and re-reading of TB microscopy slides from WDL laboratory, Kano (2005 – 2006)

	Proportion of results						
Parameters	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
Number of slides examined	11	15	15	15	15	15	86
Good smear preparations	4 (36.4%)	7 (46.7%)	5 (33.3%)	4 (26.7%)	4 (26.7%)	11 (73.3%)	35 (40.7%)
Good smear staining	8 (72.7)	11 (73.3%)	7 (46.7%)	4 (26.7%)	6 (40.0%)	12 (80.0%)	48 (55.8%)
Agreements	9 (81.8%)	15 (100%)	15 (100%)	13 (86.7%)	15 (100%)	14 (93.3%)	81 (94.2%)
True positives	2 (18.2%)	2 (13.3%)	2 (13.3%)	2 (13.3%)	3 (20.0%)	3 (20.0%)	14 (16.3%)
True negatives	6 (54.5%)	13 (86.7%)	13 (86.7%)	11 (73.3%)	12 (80.0%)	12 (80.0%)	67 (77.9%)
High false positives	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Low false positives	3 (27.3%)	0 (0%)	0 (0%)	1 (6.7%)	0	0 (0%)	4 (4.7%)
High false negatives	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Low false negatives	0 (0%)	0 (0%)	0 (0%)	1 (6.7%)	0 (0%)	0 (0%)	1 (1.2%)
Quantification errors	1	3	1	1	1	1	8
Sensitivity (%)	100	100	100	66.7	100	100	93.3
Specificity (%)	66.7	100	100	91.7	100	100	94.4

Appendix F4 Results of LQAS sampling and re-reading of TB microscopy slides from GWZ laboratory, Kano (2005 – 2006)

	Proportion of results						
Parameters	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
Number of slides examined	22	30	15	15	15	14	**111**
Good smear preparations	9 (40.9%)	8 (26.7%)	5 (33.3%)	6 (40.0%)	4 (26.7%)	9 (64.3%)	**41 (36.9%)**
Good smear staining	10 (45.5%)	8 (26.7%)	4 (26.7%)	7 (46.7%)	7 (46.7%)	10 (71.4%)	**46 (41.4%)**
Agreements	21 (95.5%)	28 (93.3%)	14 (93.3%)	15 (100%)	13 (86.7%)	14 (100%)	**105 (94.6%)**
True positives	0 (0%)	10 (33.3%)	3 (20.0%)	1 (6.7%)	2 (13.3%)	1 (7.1%)	**17 (15.3%)**
True negatives	21 (95.5%)	18 (60.0%	11 (73.3%)	14 (93.3%)	11 (73.3%)	13 (92.9%)	**88 (79.3%)**
High false positives	0 (0%)	0 (0%)	1 (6.7%)	0 (0%)	1 (6.7%)	0 (0%)	**2 (1.8%)**
Low false positives	1 (4.5%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**1 (0.9%)**
High false negatives	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (6.7%)	0 (0%)	**1 (0.9%)**
Low false negatives	0 (0%)	2 (6.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	**2 (1.8%)**
Quantification errors	0	1	1	1	1	1	5
Sensitivity (%)	-	83.3	100	100	66.7	100	**85**
Specificity (%)	-	100	91.7	100	91.7	100	**96.7**

Appendix F5: Results of LQAS sampling and re-reading of TB microscopy slides from RAN laboratory, Kano (2005 – 2006)

	Proportion of results						
Parameters	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
Number of slides examined	12	15	-	15	-	-	**42**
Good smear preparations	6 (50.0%)	2 (13.3%)	-	4 (26.7%)	-	-	**12 (28.6%)**
Good smear staining	5 (41.7%)	3 (20.0%)	-	6 (40.0%)	-	-	**14 (33.3%)**
Agreements	7 (58.3%)	8 (53.3%)	-	13 (86.7%)	-	-	**28 (66.7%)**
True positives	0 (0%)	0 (0%)	-	2 (13.3)	-	-	**2 (4.8%)**
True negatives	4 (33.3%)	9 (60.0%)	-	11 (73.3%)	-	-	**24 (57.1%)**
High false positives	1 (8.3%)	2 (13.3%)	-	0 (0%)	-	-	**3 (7.1%)**
Low false positives	7 (58.3%)	3 (20.0%)	-	0 (0%)	-	-	**10 (23.8%)**
High false negatives	0 (0%)	1 (6.7%)	-	0 (0%)	-	-	**1 (2.4%)**
Low false negatives	0 (0%)	0 (0%)	-	2 (13.3%)	-	-	**2 (4.8%)**
Quantification errors	0	0	-	2	-	-	**2**
Sensitivity (%)	-	-	-	50	-	-	**40**
Specificity (%)	-	-	-	100	-	-	**64.9**

Appendix F6 Results of LQAS sampling and re-reading of TB microscopy slides from DBT laboratory, Kano (2005 – 2006)

	Proportion of results						
Parameters	**0 month**	**3 months**	**12 months**	**15 months**	**18 months**	**21 months**	**Total**
Number of slides examined	27	15	-	9	15	12	78
Good smear preparations	5 (18.5%)	5 (33.3%)	-	1 (11.1%)	3 (20.0%)	5 (41.7%)	19 (24.4%)
Good smear staining	6 (22.2%)	11 (73.3%)	-	3 (33.3%)	5 (33.3%)	5 (41.7%)	30 (38.5%)
Agreements	26 (96.3%)	15 (100%)	-	8 (88.9%)	12 (80.0%)	10 (83.3%)	71 (91.0%)
True positives	2 (7.4%)	4 (26.7%)	-	0 (0%)	1 (6.7%)	1 (8.3%)	8 (10.3%)
True negatives	24 (88.9%)	11 (73.3%)	-	8 (88.9%)	11 (73.3%)	9 (75.0%)	63 (80.0%)
High false positives	1 (3.7%)	0 (0%)	-	0 (0%)	0 (0%)	1 (8.3%)	2 92.6%)
Low false positives	0 (0%)	0 (0%)	-	0 (0%)	1 (6.7%)	0 (0%)	1 (1.3%)
High false negatives	0 (0%)	0 (0%)	-	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Low false negatives	0 (0%)	0 (0%)	-	1 (11.1%)	2 (13.3%)	1 (8.3%)	4 (5.1%)
Quantification errors	2	2	-	0	0	1	5
Sensitivity (%)	100	100	-	-	33.3	50	66.7
Specificity (%)	96	100	-	-	91.7	90	95.5

Appendix F7: Overall results of LQAS sampling and re-reading of TB microscopy slides from 5 laboratories in Kano (2005 – 2006)

Parameters	IDH	WDL	GWZ	RAN	DBT	All Centres
Number of slides examined	100	86	111	42	78	417
Good smear preparations	44 (44.0%)	35 (40.7%)	41 (36.9%)	12 (28.6%)	19 (24.4%)	151 36.2%
Good smear staining	59 (59.0%)	48 (55.8%)	46 (41.4%)	14 (33.3%)	30 (38.5%)	197 47.2%
Concordance	80 (80.0%)	81 (94.2%)	105 (94.6%)	28 (66.7%)	71 (91.0%)	365 87.5%
True positives	17 (17.0%)	14 (16.3%)	17 (15.3%)	2 (4.8%)	8 (10.3%)	58 13.9%
True negatives	72 (72%)	67 (77.9%)	88 (79.3%)	24 (57.1%)	63 (80.0%)	314 75.3%
High false positives	2 (2.0%)	0 (0%)	2 (1.8%)	3 (7.1%)	2 (2.6%)	9 2.2%
Low false positives	4 (4.0%)	4 (4.7%)	1 (0.9%)	10 (23.8%)	1 (1.3%)	20 4.8%
High false negatives	0 (0%)	0 (0%)	1 (0.9%)	1 (2.4%)	0 (0%)	2 0.5%
Low false negatives	5 (5.0%)	1 (1.2%)	2 (1.8%)	2 (4.8%)	4 (5.1%)	14 3.4%
Quantification errors	9	8	5	2	5	29
Sensitivity (%)	77.2	93.3	85	40	66.7	78.4
Specificity (%)	92.3	94.4	96.7	64.9	95.5	91.5

Appendix F7a: Results of blinded re-reading of malaria microscopy slides from 4 laboratories in Kano (2005 – 2006)

Parameters	IDH	WDL	GWZ	DBT	Total
Number of slides examined	23	25	10	10	143
Good film preparations	11 (47.8%)	18 (72%)	6 (60%)	4 (40%)	70 (49.0%)
Good staining	15 (65.2%)	20 (80%)	6 (60%)	3 (30%)	80 (55.9%)
Concordance	17 (73.9%)	24 (96%)	6 (60%)	7 (70%)	114 (79.7%)
True positives	8 (34.8%)	9 (36%)	3 (30%)	3 (30%)	50 (35.2%)
True negatives	9 (39.1%)	13 (52%)	3 (30%)	4 (40%)	64 (45.1%)
False positives	5 (21.7%)	1 (4%)	3 (30%)	2 (20%)	17 (12.0%)
False negatives	1 (4.3%)	0 (0%)	1 (10%)	1 (10%)	17 (7.7%)
Sensitivity (%)	88.9	100	75	75	82.0
Specificity (%)	64.2	83.3	60	66.7	79.0

Appendix F8 Comparison of the baseline and final results of LQAS sampling and re-reading of TB microscopy slides from 5 laboratories in Kano (2005 – 2006)

Parameters	IDH		WDL		GWZ		RAN		DBT	
	Baseline	Final	Baseline	Final	Baseline	Final	Baseline	Final	Baseline	Final
Number of slides examined	28	15	11	15	22	14	12	15	27	12
Good smear preparations	14 (50%)	7 (46.7%)	*4 (36.4%)*[1]	*11 (73.3%)*[1]	9 (40.9%)	9 (64.3%)	6 (50.0%)	4 (26.7%)	5 (18.5%)	5 (41.7%)
Good smear staining	19 (67.9%)	6 (40%)	*8 (72.7)*[2]	*12 (80.0%)*[2]	10 (45.5%)	10 (71.4%)	5 (41.7%)	6 (40.0%)	*6 (22.2%)*[3]	*5 (41.7%)*[3]
Concordance	22 (78.6%)	13 (86.7%)	8 (72.7%)	14 (93.3%)	21 (95.5%)	14 (100%)	*4 (33.3%)*	*13 (86.7%)*	26 (96.3%)	10 (83.3%)
True positives	3 (10.7%)	2 (13.3%)	2 (18.2%)	3 (20.0%)	*0 (0%)*[4]	*1 (7.1%)*[4]	0 (0%)	2 (13.3)	2 (7.4%)	1 (8.3%)
True negatives	19 (67.9%)	12 (80%)	6 (54.5%)	12 (80.0%)	*21 (95.5%)*[5]	*13 (92.9%)*[5]	*4 (33.3%)*[6]	*11 (73.3%)*[6]	24 (88.9%)	9 (75.0%)
High false positives	2 (7.1%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	1 (8.3%)	0 (0%)	1 (3.7%)	1 (8.3%)
Low false positives	4 (14.3%)	0 (0%)	3 (27.3%)	0 (0%)	1 (4.5%)	0 (0%)	*7 (58.3%)*[7]	*0 (0%)*[7]	0 (0%)	0 (0%)
High false negatives	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Low false negatives	0 (0%)	1 (6.7%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)	2 (13.3%)	0 (0%)	1 (8.3%)
Quantification errors	1	1	1	1	0	1	0	2	2	1
Sensitivity (%)	100	66.7	100	100	-	100	-	50	100	50
Specificity (%)	76	100	66.7	100	-	100	-	100	96	90

Key: 1. χ^2=18.5, P = 0.05 2. χ^2= 22.8, P = 0.01 3. χ^2 = 21.7, P < 0.01 4. χ^2= 35.5, P < 0.05
5. χ^2= 35.5, P < 0.05 6. χ^2= 22.5, P < 0.01 7. χ^2= 22.5, P < 0.01

Appendix F9: Results of blinded re-reading of malaria microscopy slides from laboratories in Kano (2005 – 2006)

	Proportion of results			
Parameters	**0 month**	**21 months**	**24 months**	**Total**
Number of slides examined	86	33	24	**143**
Good film preparations	36 (41.9%)	19 (57.6%)	15 (62.5%)	**70 (49.0%)**
Good staining	45 (52.3%)	23 (69.7%)	12 (50%)	**80 (55.9%)**
Concordance	67 (77.9%)	29 (87.9%)	18 (75.0%)	**114 (79.7%)**
True positives	28 (32.6%)	12 (36.4%)	10 (43.5%)	**50 (35.2%)**
True negatives	39 (45.3%)	17 (51.5%)	8 (34.8%)	**64 (45.1%)**
False positives	11 (12.8%)	4 (12.1%)	2 (8.7%)	**17 (12.0%)**
False negatives	8 (9.3%)	0 (0.0%)	3 (13.0%)	**17 (7.7%)**
Sensitivity (%)	77.8	100	76.9	**82.0**
Specificity (%)	78.0	81.0	80.0	**79.0**

Appendix F10 Results of re-reading of malaria microscopy slides from IDH laboratory, Kano (2005 – 2006)

Parameters	0 month	21 months	24 months	Total
Number of slides examined	13	4	6	23
Good smear preparations	6 (46.2%)	2 (50%)	3 (50%)	11 (47.8%)
Good smear staining	9 (69.2%)	3 (75%)	3 (50%)	15 (65.2%)
Concordance	9 (69.2%)	3 (75%)	5 (83.3%)	17 (73.9%)
True positives	4 (30.8%)	1 (25%)	3 (50%)	8 (34.8%)
True negatives	5 (38.5%)	2 (50%)	2 (33.3%)	9 (39.1%)
False positives	4 (30.8)	1 (25%)	0 (0%)	5 (21.7%)
False negatives	0 (0%)	0 (0%)	1 (16.7%)	1 (4.3%)
Sensitivity (%)	100	100	75	88.9
Specificity (%)	55.6	66.7	100	64.2

Appendix F11 Results of sampling and re-reading of malaria microscopy slides from WDL laboratory, Kano (2005 – 2006)

Parameters	0 month	21 months	24 months	Total
Number of slides examined	13	6	6	25
Good smear preparations	8 (61.5%)	5 (83.3%)	5 (83.3%)	18 (72%)
Good smear staining	11 (84.6%)	4 66.7%)	5 (83.3%)	20 (80%)
Concordance	13 (100%)	6 (100)	5 (83.3%)	24 (96%)
True positives	4 (30.8%)	3 (50%)	2 (33.3%)	9 (36%)
True negatives	9 (69.2%)	3 (50%)	3 (50%)	13 (52%)
False positives	0 (0%)	0 (0%)	1 (16.7%)	1 (4%)
False negatives	0 (0%)	0 (0%)	0 (0%)	0 (0%)
Sensitivity (%)	100	100	66.7	100
Specificity (%)	100	100	75	83.3

Appendix F12 Results of sampling and re-reading of malaria microscopy slides from GWZ laboratory, Kano (2005 – 2006)

Parameters	0 month	21 months	24 months	Total
Number of slides examined	None	4	6	10
Good smear preparations	NA	2 (50%)	4 (66.7%)	6 (60%)
Good smear staining	NA	3 (75%)	3 (50%)	6 (60%)
Concordance	NA	2 (50%)	4 (66.7%)	6 (60%)
True positives	NA	0 (0%)	3 (50%)	3 (30%)
True negatives	NA	2 (50%0	1 (16.7%)	3 (30%)
False positives	NA	2 (50%)	1 (16.7%)	3 (30%)
False negatives	NA	0 (0%)	1 (16.7%)	1 (10%)
Sensitivity (%)	NA	-	75	75
Specificity (%)	NA	-	100	60

NA = Not Assessed

Appendix F13 Results of sampling and re-reading of malaria microscopy slides from DBT laboratory, Kano (2005 – 2006)

Parameters	0 month	21 months	24 months	Total
Number of slides examined	None	4	6	10
Good smear preparations	NA	1 (25%)	3 (50%)	4 (40%)
Good smear staining	NA	2 (50%)	1 (16.7%)	3 (30%)
Concordance	NA	3 (75%)	4 (66.7%)	7 (70%)
True positives	NA	1 (25%)	2 (33.3%)	3 (30%)
True negatives	NA	2 (50%)	2 (33.3%)	4 (40%)
False positives	NA	1 (25%)	1 (16.7%)	2 (20%)
False negatives	NA	0 (0%)	1 (16.7%)	1 (10%)
Sensitivity (%)	NA	100	66.7	75
Specificity (%)	NA	100	66.7	66.7

NA = Not Assessed

Appendix F14 Comparison of the baseline and final results of sampling and re-reading of malaria microscopy slides from 4 laboratories in Kano (2005 – 2006)

Parameters	IDH		WDL		GWZ		DBT	
	Baseline	Final	Baseline	Final	Baseline	Final	Baseline	Final
Number of slides examined	13	6	13	6	NA	6	NA	6
Good blood film Preparations	6 (46.2%)	3 (50%)	8 (61.5%)	5 (83.3%)	NA	4 (66.7%)	NA	3 (50%)
Good staining	9 (69.2%)	3 (50%)	11 (84.6%)	5 (83.3%)	NA	3 (50%)	NA	1 (16.7%)
Concordance	9 (69.2%)	5 (83.3%)	13 (100%)	5 (83.3%)	NA	4 (66.7%)	NA	4 (66.7%)
True positives	4 (30.8%)	3 (50%)	4 (30.8%)	2 (33.3%)	NA	3 (50%)	NA	2 (33.3%)
True negatives	5 (38.5%)	2 (33.3%)	9 (69.2%)	3 (50%)	NA	1 (16.7%)	NA	2 (33.3%)
False positives	4 (30.8)	0 (0%)	0 (0%)	1 (16.7%)	NA	1 (16.7%)	NA	1 (16.7%)
False negatives	0 (0%)	1 (16.7%)	0 (0%)	0 (0%)	NA	1 (16.7%)	NA	1 (16.7%)
Sensitivity (%)	100	75	100	66.7	NA	75	NA	66.7
Specificity (%)	55.6	100	100	75	NA	100	NA	66.7

NA = Not Assessed

Appendix F15 Comparison of the results of sampling and re-reading of malaria microscopy slides from 4 laboratories in Kano with the baseline (2005 – 2007)

Parameters	Baseline	IDH	WDL	GWZ	DBT
Number of slides examined	86	6	6	6	6
Good blood film preparations	36 (41.9%)	3 (50%)	5 (83.3%)	4 (66.7%)	3 (50%)
Good staining	45 (52.3%)	3 (50%)	5 (83.3%)	3 (50%)	1 (16.7%)
Concordance	67 (77.9%)	5 (83.3%)	5 (83.3%)	4 (66.7%)	4 (66.7%)
True positives	28 (32.6%)	3 (50%)	2 (33.3%)	3 (50%)	2 (33.3%)
True negatives	39 (45.3%)	2 (33.3%)	3 (50%)	1 (16.7%)	2 (33.3%)
False positives	11 (12.8%)	0 (0%)	1 (16.7%)	1 (16.7%)	1 (16.7%)
False negatives	8 (9.3%)	1 (16.7%)	0 (0%)	1 (16.7%)	1 (16.7%)
Sensitivity (%)	77.8	75	66.7	75	66.7
Specificity (%)	78	100	75	100	66.7

Appendix G1: Report of project supervisory visit to Faruk Sarkinfada,

Imelda Bates. Kano, Nigeria 19-21 June 2006

Faruk's is now halfway through his 3 year PhD project on '*design, implementation and evaluation of a model system for improving the quality of laboratory diagnosis of malaria and tuberculosis*' The purpose of this visit was to review progress against his project timeplan, to visit some of the field sites and meet his research team, to address any logistical or academic difficulties and to develop a framework for writing up his thesis.

Meetings and visits

Office space for our meetings was kindly provided in Kano by the PATHS (Partnership for Transforming Health Systems programme) with whom Faruk has forged links through his research. During the visit I met Dr Amiru Imam Yola (State Director of Medical and Healthcare Services), Dr Dayyabu Muhammad (Director of Primary Care), Dr Nasir Mahmud (Director TB programme), Baffa Muhammad Kademi (Director Malaria programme) and Yunusa Aliju (QA officer). Visits were made to hospitals which are part of the laboratory network involved in Faruk's project in urban Kano and Rano LGA.

Research progress

Faruk has managed his time well, despite many unforeseen difficulties. He has kept to his time plan and is on track for completing his PhD within three years. He has completed a pilot study and used the results to design the model for implementing quality measuring and improvement systems for malaria and TB tests. He has selected 5 hospital laboratories in Kano state to be involved in the project and has recruited a team of 5 quality assurance officers and 5 community TB supervisors who assist him with project implementation at state and hospital level respectively. Putting such teams together and maintaining their enthusiasm and motivation has been very challenging for Faruk but he has approached this in a very wise and thoughtful manner, soliciting help and advice from trusted colleagues and senior Ministry of Health officials. Through this process he has managed to engage key actors at all levels in the state from policy makers in headquarters, to district health providers and community workers.

Faruk has been rigorous in overseeing the quality of the data he has collected and now has information about baseline quality of malaria and TB tests in the 5 hospitals. He has provided some training for the laboratory staff and collected follow up data to see if there has been any improvement in quality as a result. He is in the process of analysing this follow up data. He has trained community TB supervisors and laboratory staff in the process of collecting samples for quality assurance and has trained his team of QA officers to provide blinded re-checking of the sampled slides. He has already shown that 92-97% of TB microscopy results are correct but only 75% of malaria readings are correct. He has provided training materials for laboratory staff to improve these tests and next month he will organise further training sessions training sessions to complement the three monthly site QA site visits. As part of his project, Faruk has identified some important deficiencies

in health and safety in the laboratories which he is also addressing through local interventions in the hospitals and education of the laboratory staff.

Faruk's next challenge will be to organise his writing up in a methodical and systematic way so as to demonstrate that he has clearly met his objectives. He has already produced a first draft of the introduction and literature review and we have discussed ways of sub-dividing this to make it more 'reader-friendly'. He is at a stage in the project where lots of data is becoming available and so he needs to develop a system for managing and analysing this data, and also for being selective about what to include and what to reject. If his current rate of progress is maintained he will complete his field work by February 2007. I would recommend that he comes to Liverpool to work on data analysis for 3-4 weeks later this year and again in February 2007 to finalise his thesis.

Personal and professional development

Through his project Faruk has proved himself to be conscientious, highly motivated and committed to improving the laboratory systems in Kano. He is an excellent team builder and organiser and has developed very sophisticated diplomatic skills which have enabled him to engage and work effectively with a wide range of stakeholders. The PATHS project is about to implement a programme of quality improvement and diagnostic outreach services to communities across several states including Kano. Information from Faruk's project has been used to inform the design of PATHS's programme and the system he has established will form the core on which PATHS will build the state laboratory QA network.

Faruk has not only become a highly respected adviser to the state ministry of health on laboratory matters, but he is also increasingly involved in federal level activities. These activities include reviewing national policy documents and acting as a resource person for laboratory quality assurance systems. He has the potential to be a national, and even international leader, in laboratory systems, if he is provided with the right opportunities and encouragement.

Dr Imelda Bates
Head of Disease Control strategy Group
Liverpool School of Tropical Medicine
Liverpool, UK
Project supervisor
22nd June 2006

Appendix G2: Experts' comments about this project

Hello Faruk,
In my opinion the work you did is one of the more difficult parts of an "improving quality project": to start and motivate people from the scratch ... Are you intended to continue and improve this project? May be we can find a way to support your training activities in malaria (and AFB).
Best regards,

Truus Derks
WHO Consultans on training and certification of microscopists
truusderks@hotmail.com
Amsterdam, Netherlands
June 5, 2007

Dear Faruk,

Well done you have completed all of the corrections we asked for and I think you have a thesis to be proud of. I have attached a letter stating that I recommend you for a PhD.

John Wain
Welcome Trust Sanger Institute
Hinxton, Cambs, UK
CB10 1SA
01223494828
Jw5@sanger.ac.uk
June 5, 2008

Appendix G3: Letter of confirmation of corrections requested by the thesis examiners

John Wain, (Team 100),
Welcome Trust Sanger Institute
Hinxton, Cambs, UK
CB10 1SA

06 June 2008

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Re: Corrections to PhD thesis by Faruk Sarkinfada

Title: INTEGRATION OF EXTERNAL QUALITY ASSESSMENT FOR MICROSCOPIC DIAGNOSIS OF MALARIA AND TUBERCULOSIS: FEASIBILITY IN KANO STATE, NIGERIA

Dear Faruk,

I have reread your thesis and confirm that you have competed all of the corrections requested by Vicki Doyle and myself. I now recommend you for the award of PhD.

Congratulations.

Yours sincerely

John Wain, Ph.D., F.R.C.Path.