

The pilot adopted a daily treatment regimen lasting a total of 8 months. In the initial two-month directly observed intensive phase patients were receiving rifampicin, isoniazid, pyrazinamide and ethambutol. In the unsupervised 6-month continuation phase patients received isoniazid and ethambutol. A novel aspect of the pilot was the use of 3-drug fixed dose combination tablets of rifampicin, isoniazid and pyrazinamide in the intensive phase. This was the first time this combination had been used in Nigeria. No implementers experienced interruptions in supplies of anti-TB drugs largely due to the organised supervisory activities of the National Tuberculosis and Leprosy Officer (STBLCO). Local infrastructure and facilities were used for storage of drugs, but the stores at both State and LGA level are in a poor state of repair and lack adequate air-conditioning and lighting. At the start of the pilot the STBLCO took responsibility for drug distribution, but as the pilot has matured the LGA Store Officers have begun to take up this responsibility.

#### Key Points for Policy and Practice

- Three-drug fixed-dose combination tablets can be used effectively and safely in Nigeria. This is useful information as Nigeria will now be moving to 4-drug fixed-dose combination tablets procured through the Global Drug Facility of the Stop-TB Partnership.
- The general drug procurement, storage, and distribution system needs considerable strengthening and maintenance if it is to be used for the TB drugs required in expanding TB activities.
- Although drugs were delivered free of charge, patients on treatment still faced barriers to continuation with therapy which included the need to travel daily for direct supervision of tablet ingestion and to travel daily for the follow-up sputum smear microscopy needed to document outcomes amongst smear positives.

#### Government and Stakeholder Commitment

A considerable investment of time and negotiation was required to secure political and financial commitment from all levels to complement the investments being made by the DFID-funded projects and to maximise the chances of ultimate sustainability. The broad mix of stakeholders and the operation of the pilot through existing health structures at all three levels of government has contributed towards an emerging sense of shared ownership and responsibility for TB control in Benue State. This has sustained the pilot activities despite repeated strikes by different health work cadres because of irregular payment of salaries and through civil unrest. As the pilot has progressed the relative involvement of the different stakeholders has changed so that more and more responsibility has shifted to the local stakeholders. As the pilot funding ends, the responsibilities will change further and there will be an increased role for the State and Local Government.

#### Key Points for Policy and Practice

- The State TB & Leprosy Control Officer and his/her team will need strengthening in terms of support staff and office infrastructure in order to act as the focal management point for expanding TB control activities through multiple stakeholders.
- Future expansion of TB control activities should include HIV control programme and service delivery stakeholders as partners with explicit responsibilities outlined in planning and implementation.
- It is important that there is adequate investment in time and negotiation for sustained political and financial commitment from the State Ministry of Health.
- Careful planning of the sequence of implementation for expansion of DOTS is needed. For example, if training of staff precedes important activities such as infrastructure review and rehabilitation by too long a period of time, then staff are not able to implement their newly acquired skills soon enough after training.

#### Major Achievements

- Quality managed smear microscopy network established. At baseline only 51% of smears were reported correctly. By July 2002, 97% of new patients had their smear status reported correctly and all laboratories manage a fast turn-around of results.
- Good case detection rate - pilot detected 479 of the target 560 smear positive cases in first 16 months. This is equivalent to an overall detection rate of 51% and on track to reach the target of 60% by the end of the pilot.
- Good cure rate - in first 16 months 284/368 (77%) of smear positives converted at 2 months. Final outcome data only available from patients enrolled in the first 7 months show 125/181 (69%) cured.
- Strong sense of commitment from staff at all levels despite industrial action and irregular payment of salaries and allowances.

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# briefingpaper

## THE BENUE TB CONTROL PILOT

### *A Public-Private Initiative Integrated with Primary Health Care*



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## BENUE TB CONTROL PILOT

### Background

Globally, TB is the largest cause of premature deaths due to a single pathogen. TB-related mortality and morbidity have been increasing steadily in Nigeria as a whole. The situation has been critical in Benue State where contributing factors include lack of funding and drugs, poor case management, high community HIV prevalence and poverty. HIV-related illnesses, particularly TB, account for over 30% of in-patients in Benue State. The DOTS strategy is widely regarded as the most cost-effective TB control strategy and is advocated internationally by the World Health Organisation and the STOP-TB Partnership. There are five elements of the strategy and this briefing paper reports the experiences of the Benue TB Pilot under each of these elements:

- Diagnosis using direct smear microscopy.
- Observation of therapy.
- Therapeutic monitoring.
- Short course chemotherapy.
- Government and stakeholder commitment.

### TB Control Pilot

Prior to the pilot project, TB control activities were largely uncoordinated and inconsistent with the National Guidelines as contained in the National Tuberculosis and Leprosy Control Program Revised Workers' Manual (1999).

- Smear microscopy only available in two of the 4 LGAs (in secondary level hospitals – 1 mission, 1 state).
- No smear microscopy in Primary Health Care.
- No TB treatment at PHC level.
- Drugs available on fee basis only in some institutions; no supervision; no outcome data.

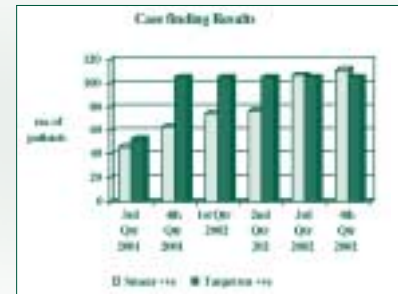
The relatively high costs (both direct and indirect) to the individual of accessing diagnosis, paying for drugs and completing treatment were significant barriers, resulting in delays in starting treatment and/or failure to complete treatment.

In response to the expressed needs of primary stakeholders, the State Ministry of Health (SMOH), assisted by DFID through the Benue Health Fund (BHF) and the LATH STD/HIV Management Project developed a proposal for a DOTS pilot tuberculosis control project in 1999. Four LGAs in which the two DFID-funded projects were active were chosen for the pilot. The strategy adopted involves the decentralisation of TB case management from hospital-based diagnosis and treatment to integration within the Primary Health Care (PHC) system while adhering to the principles of international best practice. The emphasis is on diagnosis and treatment on an outpatient basis. It also involves developing partnerships with private medical practitioners, and mission-supported health facilities. This is in line with the integration strategy of the National TB and Leprosy Control Programme (NTBLCP) and aims to improve quality of care at PHC level, enhancing equity of access in the process.

### Diagnosis

In the overall DOTS strategy, sputum smear microscopy is emphasised as the main diagnostic and screening

tool for TB patients because it provides the most specific way of identifying those cases posing a significant infectious risk to others. Therefore treatment is targeted mainly towards smear positive cases. The Pilot has succeeded in implementing a diagnostic system based around a smear microscopy service with built-in quality management. Four smear microscopy centres (one in each of the LGAs chosen for the pilot) were supported. Laboratory practice was standardised through intensive on-site training and through production of, and diligent adherence to, standard operating procedures. Prior to the pilot, symptomatic patients were identified by PHC staff and referred to the nearest microscopy centre. Numbers of TB suspects submitting sputa through the pilot microscopy centres increased throughout the life of the pilot. 16 months after implementation the pilot had detected 479 smear positive cases (out of a target of 560). An additional 337 smear negative patients were diagnosed and started on treatment. This is a remarkable achievement against a backdrop of civil unrest and strikes in the State and in the light of the late start of one of the LGAs.



### Key Points for Policy and Practice

- Guidelines for diagnosis and referral along a "pathway to care" should be carefully developed before TB control activities are implemented. This must take place in a consultation exercise with all stakeholders.
- Training of all stakeholders around these guidelines is essential.
- The Benue Pilot guidelines and training modules can serve as templates for guideline development and training as PHC-based DOTS services are extended to further LGAs in Benue and to other States in Nigeria.
- Quality-managed smear microscopy services, incorporating quality control and quality assessment components, can be established even in the absence of linkage to a State TB Reference Laboratory. It is extremely important not to underestimate the level of investment required in this area.
- Linkage to a regional Reference Laboratory is recommended as a key component in sustaining quality over the longer term.
- Patients experience problems with the payment of user-fees for lab services and other consultations in the pathway to diagnosis. User-fees are particularly difficult for the poorer patients – the very group that TB services should serve best.
- Health Promotion and Health Education strategies for TB control and to improve case-finding are best developed after a functioning service has been established, by which time the reputation of the service is already spreading.

## BENUE TB CONTROL PILOT

### Observation, Adherence and Clinical Care

Observation of each dose of treatment, especially in the intensive first two months of therapy, is advocated strongly in international circles as the most reliable way of ensuring adherence. The TB pilot has been successfully integrated into the Primary Health Care (PHC) system. PHC staff have a strong sense of ownership of TB control activities and organise their work well in accordance with the Pilot guidelines. They report an increase in their general clinical work load which is attributed to an improved image of the PHC in the community. In addition their morale as health providers has been improved as a result of witnessing cure of TB cases – a phenomenon that some PHC staff did not think possible. Swallowing of all doses of TB therapy in the intensive phase is directly supervised on a daily basis in the PHC centres. This is in accordance with the Pilot guidelines but is causing some difficulties for some patients – particularly those who have to travel considerable distances. Although well placed to provide holistic clinical care, the PHC centres do not at present apply general clinical principles in caring for TB patients; for example, HIV-related complications are not being sought or treated. This is partly because of a lack of knowledge and training and partly because the PHC system itself is weak as a result of years of partial use and inconsistent funding.

### Key Points for Policy and Practice

- Integration of TB control activities into the PHC system is possible and represents a significant step forward in providing accessible services in the community for HIV-infected individuals who develop TB. This progress should be built on to more explicitly address the needs of HIV-infected patients by including guidelines for recognition and care for HIV-related conditions other than TB (including opportunistic infections). This, in turn, can be linked to voluntary testing and counselling services.
- The pilot provides useful lessons about the extent of health system strengthening required to make drugs available throughout the PHC system and will be particularly relevant for distribution, monitoring and evaluation of anti-retroviral treatment.
- As DOTS expansion proceeds, different options for ensuring concordance with therapy will need to be explored.

### Therapeutic Monitoring

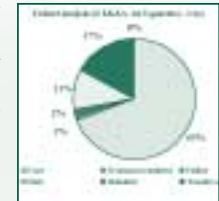
Routine, built-in monitoring of the results of treatment and case finding is emphasised as the only way of objectively documenting the effectiveness of TB control. Additional data was collected in the Pilot on:

1. numbers of patients being referred from PHC's and numbers screened in the microscopy centres
2. outcomes amongst smear negatives

The first of these was intended to provide quantitative indicators of access – especially for poorer patients – and the second was intended to provide a proxy indicator of outcomes for HIV infected patients with TB as these tend to be over-represented in the smear negative group. Data recording for these indicators was patchy and of poor quality because PHC staff did not see the usefulness of these data for the pilot.

Nonetheless these indicators are important and mechanisms to ensure quality data collection of this kind must be sought in plans for expansion of TB control activities.

With modern short course chemotherapy and little prevailing drug resistance among circulating TB infections it should be possible to demonstrate cure in 85% of TB patients treated, provided none of these patients also have underlying HIV infection. At the start of the Pilot it was known that many patients defaulted from chaotic TB treatment regimens making it likely that some of the circulating TB infections were drug resistant. It was also clear that a significant, but undetermined, proportion of TB cases were HIV co-infected. Therefore the pilot set a target of curing 70% of the smear positive cases under treatment and documenting treatment completion in 60% of the smear negatives under treatment. Primary Health Care supervisors (rather than designated TB & Leprosy Supervisors) were trained to monitor both the TB case finding activities and cure rates and to collect the data for compilation and reporting by the State TB and Leprosy Control Officer on a quarterly basis. Final outcomes have been analysed on the first 181 smear positive cases treated during the first three quarters of the pilot (at this time only 3 LGAs were enrolling patients). An overall cure rate of 69% was documented.



### Key Points for Policy and Practice

- Supervision by PHC supervisors rather than designated TB supervisors has taken place and the routine TB monitoring data has been reliable. The need for written and verbal feedback to the PHC staff needs to be re-emphasised.
- PHC staff and supervisors were able to focus on the technical aspects of data collection required to demonstrate effectiveness of the programme, but not on data collection to document access issues. These important issues should be taken up during DOTS expansion through the development of an Operational Research capacity.
- A committed and hard-working State TB & Leprosy Control Officer has been crucial in overall supervision and motivation of all the different stakeholders in the pilot.

### Short Course Chemotherapy

This element of the international strategy is used to emphasise the importance of the use of recognised multi-drug regimens of proven efficacy. Other important factors included here are:

- Assurance of the quality of drugs from procurement through to administration to the patient.
- Delivery of drugs without financial costs to patients.
- Assurance of an uninterrupted supply.
- Delivery in accordance with an internationally recognised regimen.