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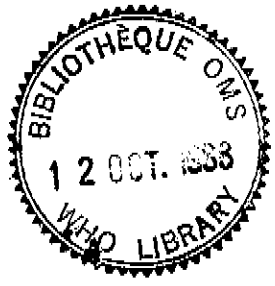

THE NATIONAL TUBERCULOSIS/LEPROSY PROGRAMME IN TANZANIA[1]

by

K. Styblo, Research Director, International Union against Tuberculosis and Lung Disease

[1] Based on the working paper presented at the Consultation on tuberculosis control as an integral part of Primary Health Care, Geneva, 22-26 September 1986 (document TRI/TB.PHC/86.12).

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1. Short history

In the mid-1970s, the Government of the United Republic of Tanzania identified tuberculosis and leprosy as important public health problems. The Government then requested the International Union against Tuberculosis (IUAT) to advise on a national tuberculosis programme and to coordinate outside assistance for the joint programme. The IUAT first organized, with the Government and international tuberculosis and leprosy experts, a National Panel and Workshop on these two diseases in Arusha in 1977. Its purpose was to elaborate a draft of the National Tuberculosis/Leprosy Programme (NTLP). The health authorities decided to establish a combined programme for tuberculosis and leprosy which would cover the whole country from the very beginning.

This paper will deal only with the tuberculosis part of the NTLP.

2. The National Tuberculosis/Leprosy Programme

The first draft of the tuberculosis part of the NTLP was elaborated in 1977; the final Guide and Manual, defining the programme for both tuberculosis and leprosy, were issued in 1981. Although the NTLP formally started in mid-1977, the tuberculosis part was implemented only in October 1978, when an agreement was signed between the Swiss Government and the IUAT about financial support to the programme.

The programme is based on the principles laid down in the 9th Report of the WHO Expert Committee on Tuberculosis:

- case-finding is carried out among tuberculosis suspects who seek medical advice at the general health service (hospitals, health centres, dispensaries), predominantly by means of microscopy examination of sputum;
- adequate chemotherapy - predominantly on an out-patient basis - is given to detected cases of tuberculosis, particularly to those smear-positive on entry; chemotherapy is applied by the general staff of hospitals, health centres and dispensaries;
- mass BCG-vaccination of newborn or young children is part of the Expanded Programme on Immunization.

Although the NTLP falls within the general health service, it needs managerial and supervisory staff dealing solely with the two diseases. At present, this staff is found at 3 levels of the NTLP:

(i) at the Ministry of Health level, with a Tuberculosis/Leprosy Control Unit (TLCU) consisting of 3 medical officers and a supply officer;

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(ii) at the regional level, where the Regional Tuberculosis/Leprosy Coordinator (RTLC), a full-time medical officer, is responsible for the implementation of the NTLP in his region; and

(iii) at the district level, where the District Tuberculosis/Leprosy Coordinator (DTLC), a medical assistant or rural medical aid, is employed full-time to supervise case-finding and chemotherapy in the health units of the district.

3. Bacteriological service

Bacteriology is one of the keystones of a tuberculosis programme in any developing country. It is vital not only for case-detection and diagnosis of tuberculosis but also for follow-up of chemotherapy. In most developing countries bacteriological services are inadequate, both in regard to the availability of skilled staff working in general laboratories, and to the lack of adequate equipment and deficiences in supply of laboratory reagents.

With the help of the British Medical Research Council's Unit for Laboratory Studies on Tuberculosis, the Ministry of Health Central Tuberculosis Laboratory was equipped to cope with the increased number of culture and sensitivity tests, supervised by an experienced technologist from this unit.

Moreover, Great Britain supplied new microscopes in the early 1980s for all laboratories in hospitals, health centres and some dispensaries.

With additional help from the Swiss Government, zonal culture laboratories were established in Moshi and Mwanza.

In cooperation with the TLCU, the staff of the Central Tuberculosis Laboratory organizes a series of refresher courses for Regional Laboratory Technicians (RLTs), and participates in refresher courses for District Laboratory Technicians (DLTs) organized by RLTs. It has also developed a quality control system for microscopy.

4. Supply

The IUAT is responsible for procuring antituberculosis drugs, laboratory reagents, laboratory equipment, sputum containers and spare parts for laboratory equipment in the NTLP which are not readily available in Tanzania.

An effectual supply system was developed for the tuberculosis part of the NTLP during the first 2 years of its existence and has been maintained ever since. No major shortcomings were observed from 1981 up to now, particularly in regard to supply of antituberculosis drugs.

Items required for the NTLP (antituberculosis drugs, laboratory reagents, sputum containers, tuberculin, etc.) are monitored by the TLCU and reported to the IUAT Secretariat twice a year. The IUAT Secretariat orders the items, at low preferential prices, and the goods are delivered to the TLCU. Regional Tuberculosis/Leprosy Coordinators (RTLCs) report on a standard form twice a year to the TLCU on the stock of drugs and reagents available in their regions and their requirements.

5. Recording and reporting

Recording and reporting aim at improving and facilitating both the quality of work and the collection of quantitative data on the amount of work performed and results obtained, thus enabling the programme to be evaluated.

Evaluation of the programme concerns 2 aspects:

(i) evaluation of the control measures applied in the programme. The 2 most important parts are case-finding and treatment;

(ii) evaluation of the programme's impact on the overall tuberculosis situation. This is best measured by the trend in the risk of tuberculosis infection.

6. Supervision

Regular and systematic supervision is of extreme importance at all levels of the programme. Its aims are: (i) to assess the implementation; (ii) to identify problems and factors interfering with the implementation and to try and solve such problems on the spot; (iii) to encourage and teach staff; and (iv) to assess the background data on evaluation of the programme. Prerequisites to adequate supervision are, inter alia, appropriate knowledge and attitude, and transport facilities.

Supervision within the programme is carried out at 3 levels: by the staff of the TLCU, RTCs and DTLCs.

7. Results

It can be said that the programme in Tanzania is one of the few long-term effective tuberculosis programmes existing in poor developing countries. It is firmly backed by the Government, is run by able officers, has reasonable managerial teams at the regional and district levels, smoothly run laboratory services, uninterrupted supply of antituberculosis drugs and laboratory reagents, supporting transport facilities and a relatively well-developed infrastructure of the general health service. The IUAT consultant has been visiting the country regularly twice a year (16 times to date), on several occasions accompanied by a second consultant either from Switzerland or the IUAT. The cooperation with leprosy colleagues is stimulating and fruitful, and the combination of the two programmes mutually beneficial.

7.1 Case-finding

In Tanzania, there are no tuberculosis or chest clinics. Most of the tuberculous patients are diagnosed in out-patient departments of general hospitals. X-ray facilities are either not available or cannot be used for case-finding of tuberculosis owing to financial and technical constraints. Thus mainly patients with smear-positive tuberculosis are being diagnosed; cases positive by culture only or culture-negative cases are discovered in large hospitals only.

One of the first priorities was to collect reliable data on the number and type of cases of tuberculosis diagnosed in Tanzania. The figures reported were based on district tuberculosis registers. The results of case-finding of tuberculosis cases (all forms) reported in Tanzania during the period 1979-1985 are shown in Table 1. This table suggests that approximately 12,000 cases (all forms) were diagnosed annually during the period under study, and that of them about 7,500 were new smear-positive cases and some further 500 were relapse smear-positive cases.

Table 1: Tuberculosis cases reported in Tanzania from 1979 to 1985

Year	Tuberculosis cases (all forms)	Of them smear-positive*		
		New cases N	New cases Rate/100,000	Relapse cases N
1979	10 751	7 019	39	282
1980	11 483	7 391	41	512
1981	12 123	7 083	38	694
1982	11 748	6 383	33	593
1983	11 782	6 680	34	411
1984	12 089	7 523	37	474
1985	14 292	8 265	38	591
Total	84 268	50 344	37	3 557

*The remaining are smear-negative pulmonary or extra-pulmonary cases.

The number of reported smear-positive cases of pulmonary tuberculosis fluctuated between 6,383 in 1982 and 8,265 in 1985, and the rates varied from 33 per 100,000 in 1982 to 41 per 100,000 in 1980. However, the rates might have been influenced to a certain extent by deficiencies in the recording and reporting of case-finding, which had been noticed during the first years of the Programme. Recording has been considerably improved in recent years, particularly by including bacteriological examination on entry in all patients enrolled on short-course chemotherapy.

7.2 Results of chemotherapy

7.2.1 Standard chemotherapy of newly diagnosed bacillary cases

The basic regimen for newly diagnosed tuberculosis is isoniazid and thioacetazone in combined tablets for 12 months, supplemented with streptomycin for the first 2 months of chemotherapy. Initially the programme depended, to a large extent, on entirely ambulatory treatment (Bull. Int. Un. Tub., 52, 1977). In-patient treatment was indicated at the beginning of the programme only for severely ill patients and for those patients who lived too far away from a health unit to attend for daily streptomycin. It soon became obvious, however, that many patients on ambulatory treatment were not receiving the full supplement of streptomycin injections during the initial phase (which is by far the most important period of the treatment), because of failure to visit health units daily. It was therefore decided to admit as many patients as possible for the initial intensive phase of 2 months. From 1980 onwards the great majority of cases were admitted to hospital for the initial intensive phase. In 1982, a total of 7,268 patients were admitted to hospital. All of them, except 156 patients in Tanga, were on standard chemotherapy.

Chemotherapy progress was followed up by sputum examination 6, 9 and 12 months after the start of its application. A patient was declared "cured" when at least two negative smear results were obtained at an interval of 3 months or more. The results of treatment were reported quarterly per district for smear-positive cases of pulmonary tuberculosis registered 15-18 months earlier. Table 2 shows the reported results for 1979-1984.

The proportion of "cured" and "treatment completed" cases improved from 44% in 1979 to 55% in 1980 and was 53% and 52% respectively in 1981 and 1982.

An improvement in the cure rate was observed in 1983 (43% "cured" and 15% "treatment completed"); this was due to substantially improved results achieved in 799 new smear-positive patients enrolled on short-course chemotherapy in 1983. A further increase in the cure rate was observed in 1984 when 2,727 new smear-positive patients were enrolled on short-course chemotherapy: 49% "cured" and 18% "treatment completed".

Table 2. Results of treatment with standard chemotherapy (1979-1982) and with standard and short-course chemotherapy (from 1983 onwards) for smear-positive cases of pulmonary tuberculosis registered 15-18 months earlier

Year of registration	Number assessed	Results* in percentages					
		Cured	Treatment completed	Transferred out	Defaulted	Still on treatment	Died
1979	5 418	31	13	10	23	18	5
1980	5 867	39	16	13	15	10	7
1981	5 527	39	14	12	18	10	7
1982	5 498	37	15	15	14	13	6
		Standard and short-course chemotherapy					
1983	5 825	43	15	10	15	10	7
1984	7 172	49	18	7	14	5**	7

*Results:
- "Cured" - see text above;
- "Treatment completed" - chemotherapy of 12 months completed, no clinical signs of tuberculosis but no smear results;
- "Transferred out" - patients who have been transferred to the jurisdiction of another district;
- "Defaulted" - patients who have not attended for 2 or more consecutive months;
- "Still on treatment" - usually because the patient was smear-positive and continued chemotherapy (standard or retreatment); **from 1984 onwards "Positive";
- "Died" - patients known to have died from any case whatsoever.

Chemotherapy results with the standard regimen, after 4 years of programme implementation, were judged too low considering the efforts made and the cost of the programme. A substantial improvement in treatment results could not be expected with the standard regimen, in spite of improvement in drug supplies, supervision of patients, etc. This is because removal of material problems will not automatically result in considerable improvement of the patient's compliance. A disadvantage of standard chemotherapy is that after 60 doses of streptomycin and Thiazina around 50% of patients remain sputum-positive. If they abscond from treatment or are irregular they become in many instances chronic excretors of tubercle bacilli. Inadequate chemotherapy, while not curing the patient, prolongs his life, so that chronic cases increase the number of sources of infection in the community and contribute to perpetuate the transmission of infection.

There is no doubt that the patient complies best when he is seriously ill. The short-term compliance of the patient, lasting often only a few weeks, must be exploited by giving him a very potent chemotherapy which is able to kill the vast majority of tubercle bacilli in his body as quickly as possible.

For this and various other reasons it was decided in 1982 to explore the efficacy of short-course chemotherapy under field conditions.

7.2.2 Short-course chemotherapy of newly diagnosed smear-positive cases

The short-course regimen for new smear-positive cases comprises an initial intensive phase of 4 drugs (isoniazid, rifampicin, pyrazinamide and streptomycin) given daily under strict supervision, mostly in a general hospital, and a continuation phase with daily Thiazina (isoniazid and thioacetazone) for a further 6 months on an ambulatory, self-administered basis. When thioacetazone cannot be used because of severe side-effects, isoniazid alone instead of Thiazina is given in the continuation phase, provided that the patient is smear-negative at 2 months. This regimen has a cure rate close to 100% in controlled clinical trials.

The regimen was introduced as a pilot study in the Tanga region in April 1982. A 77% cure rate was achieved in 146 consecutive patients enrolled during 1982. These results were very encouraging and short-course chemotherapy has been extended to other regions since that time.

It was decided that in the study phase the bacteriological evaluation would consist of the following:

- on entry, direct smear examination at the local laboratory. A specimen would also be sent to the central tuberculosis laboratory for culture; this would prevent the inclusion of "false positive" patients in the study.
- culture of a sputum specimen at the end of the initial intensive phase to compare the bacteriological quiescence rates in the study with the rate achieved in controlled clinical trials.
- direct smear-examination at 5 and 8 months after the start of treatment at the peripheral laboratory. At 8 months, a specimen would also be sent to the central tuberculosis laboratory for smear and culture examinations.

In February 1986 microscopy and culture examinations at 2 months in new smear-positive cases (but not in retreatment cases) were discontinued.

By June 1986, short-course chemotherapy was expanded to all 20 regions of Tanzania. Table 3 shows that the results of short-course chemotherapy at 8 months under routine conditions continue to be satisfactory: 75% were negative, 3% were positive, 6% died, 12% absconded and 3% were transferred to another district.

Table 3. Preliminary results of short-course chemotherapy at 8 months in 5,674 new smear-positive cases enrolled before July 1, 1985

Cases	N	%
Enrolled	5 674	
False positive	231	4
Evaluated	5 443	100
Negative	4 078	75
Positive	189	3
Died	315	6
Absconded	675	12
Transferred out	186	3
Total	5 443	100

If those who died are excluded from the analysis, the success rate is 80% (Table 4).

Table 4. Results of short-course chemotherapy at 8 months in 5,230 patients who were alive 8 months after the start of chemotherapy, Tanzania, 1982-1985

Patients	N	%
Negative	4 078	80
Positive	189	4
Absconded	675	13
Transferred out	186	4
Total	5 128	100

If one takes into consideration that sputum conversion is likely to have occurred in the "transferred out" and "absconded" groups, the cure rate might be close to 90%.

Table 5 shows the preliminary results at 5 months in 2,481 patients enrolled during the second half of 1985 (figures for the region of Kilimanjaro and 2 districts of Morogoro are not included). Of the 2,481 cases, 63 (3%) were false positive. Sputum conversion at 5 months was achieved in 76% of the remaining 2,418 patients. Nine per cent (9%) of patients had no information on smear-examination at 5 months by the end of June 1986.

Table 5. Results of short-course chemotherapy at 5 months in 2,481 patients with smear-positive tuberculosis enrolled during the second half of 1985

Patients	N	%
Enrolled	2 481*	
False positive	63	3
Evaluated	2 418	100
Negative	1 839	76
Positive	28	1
Smear-examination not (yet) done	214	9
Died	130	5
Absconded	145	6
Transferred out	62	3
Total	2 418	100

*excluding the Kilimanjaro region and 2 districts of the Morogoro region

7.2.3 Short course chemotherapy of smear-positive cases on the retreatment regimen

Short-course chemotherapy in retreatment cases only started in 1984. The results in the first 531 cases enrolled in 1984 (273 cases) and the first half of 1985 (258 cases) are shown in Table 6.

Table 6 shows that the results at 8 months in the first 531 smear-positive cases (relapse and failure cases) are satisfactory. Of the 531 patients 22 (4%) were "false positive". Of the remaining 509 patients 387 (76%) were negative on bacteriological examination, 22 (4%) were positive, 21 (4%) died, 67 (13%) absconded and 12 (2%) were transferred to another region. A high proportion of retreatment cases were resistant to isoniazid on entry, and some of them were also resistant to streptomycin.

Table 6. Results of short-course chemotherapy at 8 months in 531 smear-positive cases on the retreatment regimen enrolled during 1984 and the first half of 1985

Patients	N	%
Enrolled	531	
False positive	22	4
Evaluated	509	100
Negative	387	76
Positive	22	4
Died	21	4
Absconded	67	13
Transferred out	12	2
Total	509	100

It can be concluded that the success rate achieved in Tanzania by a relatively cheap short-course chemotherapy regimen under routine conditions (about US$23 for rifampicin and pyrazinamide given for 2 months, in addition to the US$17 per patient for the standard chemotherapy) fully justifies the introduction of the above short-course chemotherapy regimen for treatment of new smear-positive cases on a large scale, in Tanzania.

It is evident that the first aim of the programme, namely to alleviate human suffering, is being achieved.

7.3 Improvement of the epidemiological situation

Although alleviation of human suffering is the primary aim of any tuberculosis programme, an additional very important aspect of it is to markedly improve the epidemiological situation of tuberculosis in the country. This is what ensures that the disease no longer becomes a public health problem. The impact on the epidemiological situation can be measured by the trend in the risk of tuberculous infection in the community. The risk of infection is measured through tuberculin testing of a representative sample of children.

In Tanzania, the National Tuberculin Survey was launched in 1983 with a large sample of schoolchildren selected at random and tested in 60 out of 100 districts, the aim being to establish the risk of tuberculous infection within 5 years. The survey will be repeated in the same schools from 1988 to 1992. This will enable the measurement of the trend in the risk of infection achieved by the present programme of passive case-finding of tuberculous cases and short-course chemotherapy of smear-positive patients.

Results of the National Tuberculin Survey are available for two-fifths of the sample of schoolchildren (more than 27,000 children), i.e. the children tested in 1983 and 1984. They show that the current annual risk of tuberculous infection in Tanzania lies below 1.5% and may be only 1.2% or so. This corresponds to the average annual risk of tuberculous infection in Europe in the mid-1950s. There was a definite, albeit slight, decrease in the risk of infection of 1 to 2% annually between 1957 and 1984. The decrease may be higher than 2% in the last few years. A better estimate of the current risk of tuberculous infection will be made in 1987 when the first round of the National Tuberculin Survey is completed.

8. Predictable evolution of the tuberculosis situation in Tanzania in the 1990s

We hope that with the current case-detection rate of smear-positive cases (more than 60%) and the results of short-course chemotherapy (around 90%) an annual decrease in the risk of infection by approximately 4 to 5% will be achieved. This would correspond to the decrease in the risk of tuberculous infection (and primary disease) which existed in developed countries in the pre-chemotherapy era. With an annual decrease of 4 to 5% in the risk of infection, the number of persons infected and diseased persons would decrease by 50% in about 14 to 17 years.

With the present risk of tuberculous infection at about 1.2 to 1.3%, the risk would have halved itself by the year 2000, i.e. tuberculosis would cease to be a major public health problem.

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