

Editorial: Tuberculosis control: did the programme fail or did we fail the programme?

Introduction

Under pressure of the increasing numbers of tuberculosis (TB) cases in the world, TB control has once again become a major challenge. As such it is the subject of intensive scientific activity, as evidenced by the numerous studies and publications that have been devoted to it over the last few years. *The Lancet* recently published two documents which summarize present concerns: the minutes of the conference organized in Washington DC by *The Lancet*, in September 1995: 'The challenge of tuberculosis: statements on global control and prevention' (Enarson *et al.* 1995) and an article which proposes substantial modifications of activities in the standard tuberculosis control programme (De Cock & Wilkinson 1995). From the most recent literature, two major challenges may be identified (Reichman & Hershfield 1993; Porter & McAdam 1994; De Cock & Wilkinson 1995; Enarson *et al.* 1995): On the one hand there is a call for the development of new diagnostic techniques, especially procedures that are faster and more sensitive than smears or cultures and techniques that would improve or facilitate the diagnosis of smear-negative TB; and a call for new treatments that are effective against multidrug-resistant TB and/or that would shorten length of treatment. On the other hand, the scientific community also acknowledges the importance of some operational aspects of TB, such as problems of drugs delivery and financing, and patient compliance to treatment (Reichman & Hershfield 1993; Porter & McAdam 1994; De Cock & Wilkinson 1995; Enarson *et al.* 1995). This last point is considered a top priority, and WHO is currently promoting DOT (Daily Observed Therapy) as a new strategy to be implemented by each TB control programme (Enarson *et al.* 1995).

However, other aspects linked to the organization and the functioning of health services, or linked to the perception of the illness by both health personnel and patients, are underestimated. In his presidential address, given at the 21st Andhra Pradesh TB and Chest Diseases Conference held in July 1994 in India, Dr Ranga Rao

proposed a critical self-evaluation of the state TB control programme which started more than three decades ago (Rao 1994). This physician, who has been working as a TB officer for more than 25 years, identified 17 major weaknesses of the TB control programme. His very impressive list begins with:

'We failed in implementing the programme in the health districts.

We failed in providing the services of all the trained medical and paramedical key personnel continuously in some districts, due to frequent transfers or otherwise.

We failed in improving the laboratory services in the primary health centres.

We failed in seeking administrative support of the competent authorities to run the programme ... etc.'

What is striking about this presidential address given by a TB specialist to the members of a tuberculosis association, is that most of the 17 weaknesses identified are related to human or organizational failures and some to lack of political will, but none are directly attributed to a technical problem.

Whether in industrialised or in low-resource countries, our experience points in the same direction: we failed in implementing TB control programmes mainly for operational reasons (human and/or organizational failures linked to the overall functioning of health systems), not because of a problem of diagnostic tools or drug resistance. These operational reasons are due to specific challenges arising from the integration of a TB control programme into general health services and from the quality of the overall functioning of the health services.

An operational model for the analysis of TB control programmes

Piot (1967), who at that time was attached to WHO's TB programme, put forward a model enabling a

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comprehensive assessment of all the different technical and operational aspects of a TB control programme. We propose a simplified version of this model focusing on the problems raised by the integration of the TB programme into the general health services.

The model, which is conceptually simple, is based on the passive detection strategy of smear-positive TB cases. It starts from a description of the different steps individuals in the community go through between becoming ill with active TB and getting cured by the TB control programme under consideration. The main steps – the number of which may vary according to the characteristics of the control programme – are summarized below:

- Step 1: Motivation: Patients suffering from symptoms related to TB contact a health care delivery point.
- Step 2: Selection: The health professional suspects TB and requests a sputum examination (smear).
- Step 3: Examination: The sputum test is correctly carried out on the patients thus selected.
- Step 4: Sensitivity: The smear is positive if the patient has bacilli in the sputum.
- Step 5: Prescription: The newly identified case of TB receives the correct treatment prescription.
- Step 6: Treatment: The TB patient obtains the prescribed treatment.
- Step 7: Regularity: The TB patient takes his treatment regularly as prescribed.
- Step 8: Effectiveness: The patient is cured with a certain probability if treatment is taken as prescribed.

In ideal circumstances, all new cases of TB consult without delay, are suspected of suffering of TB and are diagnosed promptly and accurately, receive a correct treatment prescription, obtain the prescribed treatment and take the full treatment regimen regularly to finally be cured. This would lead to a 100% prompt cure rate of new TB cases in the population and to a decrease in the transmission of TB. Of course, real life is different.

At each step problems and difficulties arise: a suspect individual is not identified, there is no reagent to carry out the sputum smear, a positive sputum is missed by the laboratory technician, drugs are out of stock, the patient does not present at the health centre regularly, and so on ... The probability that a patient does proceed from one step to the next is a measure of the performance of different TB control activities.

Some steps are essentially technical (sensitivity of diagnostic test, theoretical effectiveness of treatment) and depend on the choice made at the central level by the TB programme officers. Their probabilities are theoretically independent of circumstances. Other steps' probabilities are quite variable from one situation to another because they depend in the first place on the quality and performance of the health services where TB control activities are integrated. These so called 'operational steps' depend on the operational quality of the health services such as they are and include: motivation, selection, examination, prescription, treatment and regularity. To illustrate the importance of the problems encountered in the field and the need of a global approach, we briefly discuss two of these operational steps, examination and regularity.

Examination is often the weakest link in the chain of steps that should lead to the cure of TB patients. Many types of problems are encountered in practice. First there is the case of the doctor who failed to properly explain the importance of this examination, and the patient who thus is not inclined to queue up again at the laboratory, especially if he needs to come back two more times in order to complete the required series of three sputum examinations and one more time to hear the result (the whole process often takes more than a week, several days at best (Aluoch *et al.* 1984). Secondly, the laboratory technician does not adequately instruct the patient on how to produce sputum or does not allow him the necessary time; the collected specimen is saliva instead of bronchial secretions. We have seen this situation over and over again. Thirdly, the sputum collection may be correct, but the smear not correctly prepared: old slides are used (one of the sources of false positives), the sputum is badly spread out, reagents are either past the expiry date or out of stock, procedure is not followed, the staining is done badly.

Lastly, an adequate sputum sample is correctly prepared, but microscopic examination by the laboratory technician is not reliable due to

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incompetence or lack of professional attitude. Another explanation – our own experience in Latin America – has to do with integration of TB programs. In their willingness to detect as soon as possible all new TB cases, TB officers tend to push health professionals to identify more and more suspect patients (the sometimes observed ‘rule’ that 1% of the new patients at the OPD or curative clinic have to be selected for sputum examination). As a consequence, too many ‘suspects’ may be referred to the laboratory, the workload becomes too high, the health officer tends to select fewer suspected patients and/or the laboratory technician does not respect the prescribed duration of reading the slide and the result is a false negative. This is an example where maximization could be counterproductive.

The reliability of this step (quality of sputum production and collection, quality of smear preparation, quality of microscopic examination) thus appears to be crucial, all the more so since it depends entirely on factors within the health services, and especially since high quality (in other words, a probability value close to 1.0) is technically and organizationally feasible. As a matter of fact, operational research has shown that decentralization of this step, and the reading of slides by auxiliary personnel with only 6 weeks’ training (Toman 1979) and even less (2 weeks in one author’s field experience – PM), could be done without any noticeable loss of quality, but requires regular supervision. None of these problems are identified or discussed in recent literature. Knowing the present state of dilapidation of many health services, regular surveillance of the technical quality of this step is absolutely necessary in order to avoid too many false positives as well as false negatives.

Regularity or long-term compliance among TB patients under treatment varies from one programme to another. As for Step 1, *Motivation*, this is highly influenced by geographical accessibility, indirect costs, quality of relationship between health professionals and patients (Nagpaul *et al.* 1970), state of health of the patient, defaulter retrieval procedures implemented by the health services (Rao 1994), capacity of the service to solve social problems, family problems and various other kinds of problems that patients encounter (Anastasio 1995). What is certain is that ensuring a TB patient’s treatment regularity is difficult. In fact, we know very little in this field; we do know many of the factors that are associated with irregularity, but very

little research has been done to evaluate interventions with a view to improve regularity. For certain authors, admission of patients in the hospital would guarantee better regularity, whereas it has been demonstrated that in a functional health district the health centres can ensure better regularity than can be obtained by admission in the hospital (Kasongo Project Team 1981). In Korea, experimental research showed a significant increase of patients’ regularity from 65% to 79% when central level supervision was organized in order to help district health professionals to solve their operational problems (Jin *et al.* 1993).

Direct Observed Therapy (DOT) is very fashionable at the moment and sometimes presented as a panacea (WHO 1995). This strategy guarantees of course a high level of regularity, but also has a number of disadvantages. It is costly in terms of human resources and difficult to implement in sparsely populated regions. The DOT strategy also presents another major problem: the underlying assumption is that the patient is incapable of understanding the importance of what he or she is being asked to do: regular treatment for a sufficiently long time. However, our experience does not support this; if health professionals take the necessary time to explain clearly what is at stake, and if they are able to ensure an empathic follow-up of the patient, the majority of TB patients *can* be regular (Kasongo Project Team 1981; Grange & Festenstein 1993; Jin *et al.* 1993; Anastasio 1995).

Conclusion

The use of an operational model like the one we have proposed allows us to identify the problems that may arise at different steps and can be used as a tool for dialogue between specialists in charge of TB control and public health professionals. This model also allows us to improve the identification of research priorities, especially in the field of operations research.

Of course, technical research on diagnostic tools (to decrease the dependency on qualitative factors such as staining, reading) and on treatment (to decrease the dependency on regularity) may help control some of the operational difficulties. However, new techniques will more often simply displace the problem: if a one-day TB treatment will solve the compliance failure, this operational problem still remains a challenge with the present ‘short course’ therapy.

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To be effective, tuberculosis control needs to be conceived in a comprehensive way, be it before or in the HIV era. The different steps of a TB programme are closely linked, and concentrating all resources on one step, while neglecting the others, will not lead to perceptible improvement. We will neither reduce human suffering nor decrease TB transmission by curing a few patients more with a novel treatment that is even better than the existing ones if, at the same time, the majority of new patients are not identified in a timely way. By the same token, the transmission of TB will not be reduced if we concentrate all resources on the DOT strategy while failing to ensure correct selection and examination of suspect cases, leading to false negatives who continue to contaminate their environment.

There are no miracle solutions in TB control. We feel that present approaches and research priorities are too narrowly focused on technical aspects while ignoring those that have to do with the overall functioning of health services and integrating the TB programme into the general health services. Furthermore, problems related to the perception of TB by both health personnel and patients are underestimated. The different elements of an entire programme need to be improved together. An operational model like the one we propose will help us to reach this comprehensive approach.

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