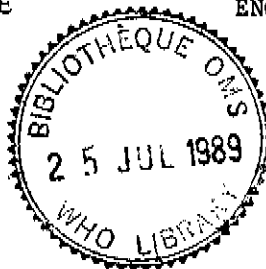




UNDP/WORLD BANK/WHO SPECIAL PROGRAMME FOR
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PRIORITIES FOR SOCIAL AND ECONOMIC RESEARCH
IN ONCHOCERCIASIS, MALARIA, METHODOLOGY AND HEALTH POLICY

REPORT OF THE FIFTH MEETING OF THE
SCIENTIFIC WORKING GROUP ON SOCIAL AND ECONOMIC RESEARCH

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1. INTRODUCTION

The fifth meeting of the Scientific Working Group (SWG) on Social and Economic Research (SER) of the UNDP/WORLD BANK/WHO Special Programme for Research and Training in Tropical Diseases (TDR) was held in Geneva from 17-19 October 1988.

The purpose of the meeting was to review the development of research priorities for SER, particularly in onchocerciasis, malaria, methodology and health policy.

Dr Tore Godal, Director of TDR, opened the meeting with a welcome address emphasizing the significance of social and economic research and underlining the challenges in the years ahead in terms of product development and testing, health education and integrated research. Immediate challenges to be addressed by SER included:

- (a) the problem of severe malaria in children and how to reach children with therapy to prevent mortality;
- (b) multidrug therapy for the treatment of leprosy and how to address the problem of low coverage of leprosy patients in some areas;
- (c) cost effectiveness studies to indicate health priorities at the country level;
- (d) the distribution of ivermectin to achieve at least the minimum coverage to prevent morbidity and mortality.

Dr Godal expressed his confidence in the relevance of social and economic research and in its ability to respond to these challenges.

Dr Vlassoff welcomed members and stated that the purpose of the SWG was to identify priority areas of research for the next few years. She introduced the new Chairman of the SWG and Steering Committee, Dr B. Singer.

2. SCIENTIFIC PRESENTATIONS: ABSTRACTS OF WORKING PAPERS AND CONTRIBUTORS' COMMENTS

2.1 The Role of Social and Economic Research in Onchocerciasis Control (Background Working Paper in Appendix)

- 2.1.1 "An Overview of the Epidemiological and Field Research Experiences which laid the basis for the present Ivermectin Control Strategy" by Dr E. M. Samba.

When the Onchocerciasis Control Programme (OCP) began in 1974 in the West African Savanna, there were no suitable drugs for the treatment of onchocerciasis, but interruption of transmission through vector control by larviciding seemed feasible. At that time, the prevalence of microfilariae (mfs) in skin snips in some villages was greater than 60%, the Community Microfilarial Load greater than 40 mfs, and blindness affected more than 5% of the population. At such extreme levels, onchocerciasis was an important public health problem which had direct demographic and economic consequences for the populations affected. By 1986 in the Central OCP area, the CMFL had dropped by more than 95% and the prevalence of ocular disease and blindness by 50%. Control operations were extended to the West and South East in order to eliminate the problem of reinvasion of infected flies.

Although vector control was extremely successful it involved weekly aerial spraying of larvicides over a vast area and was expensive. The

development of a new microfilaricidal drug, ivermectin, was therefore a welcome achievement, and in 1987 OCP commenced eight community trials of the drug. The trials addressed two main questions:

- (a) the risk of severe adverse effects following treatment with Ivermectin, and
- (b) the potential of Ivermectin mass treatment to control transmission either as an adjunct or as a replacement to larviciding.

Ivermectin has been found to be safe, and most side-effects are minimal. More adverse reactions were registered when communities were made aware that the drug might have unpleasant side-effects than when they were informed that side-effects would be minimal. An advantage of Ivermectin distribution was the involvement of national teams in distribution and monitoring which was impossible with larviciding. Whether distribution should continue to be centrally organized or integrated into Primary Health Care facilities will depend on local circumstances.

2.1.2 "Human Behaviour and Onchocerciasis in North Cameroon" by Frederic Paris

A multi-disciplinary study of a savanna onchocerciasis focus in North Cameroon, was undertaken from 1984-1987. A geographic approach to the study of man-vector contact was developed to explain significant variations in the endemicity of onchocerciasis among three ethnic groups exposed to the same Simulium damnosum breeding sites. The three ethnic groups inhabit a region of 1 000 square kilometres in the Bénoué River Basin. The Dowayo, an agricultural tribe, have an onchocerciasis prevalence in adults and children (15 years old) of 90% and 60% respectively; the Bata, farmers, and fishermen, of 50% and 20%, and the Fulanis, pastoralists, 10% and 2%.

Man-vector contact was lower in villages located far from breeding sites, but this advantage was modified by the presence of forest galleries. Some villages were exposed to blackflies from both near breeding sites and from forest galleries associated with additional breeding sites.

Man-vector contact was found to be reduced in compact villages with higher human population density. It has been observed, as well, in Burkino Faso, that when population density exceeds 50 persons per square kilometre, few villages have a high prevalence of blindness. Man density depended not only on village size, but on the mobility and distribution of individuals within a given area. Small production units working on scattered plots were likely to experience increased exposure to blackflies. Mobility has been monitored in the study area to establish the effects of movement on the level of endemicity over time.

Man-vector contact was found to be lowest among the Fulani for two reasons. Firstly, the Fulani make encampments in clearings at the highest point of the interfleuve to avoid tsétsé fly invasion of their cattle. Secondly, Simulium damnosum prefer feeding on cattle to humans. Thus, cattle herders near to breeding sites are protected from bites by this preference.

In future it should be possible to define a land occupancy model for each geographical region that would minimise the risk of transmission and which would be useful for planners in settlement areas where onchocerciasis has been brought under control.

COMMENTS BY DISCUSSANT PANEL

Dr C. Ginger

Ivermectin was used for veterinary purposes for many years before it was transferred for use in human onchocerciasis, in collaboration with the pharmaceutical company, Merck Sharpe & Dohme. Ivermectin is a microfilaricide, and treatment must be repeated - probably annually - until all adult worms have come to the end of their natural lifespan, approximately 15 years.

During the experimental period of clinical and community trials by the Onchocerciasis Control Programme (OCP) and Onchocerciasis Chemotherapy Project (OCT), ivermectin has been given under ideal conditions, namely:

1. Clinical trials have been conducted in a hospital situation, using lightly infected, otherwise healthy, young male patients.
2. OCP community trials have had the benefits of the existing OCP infrastructure.

However, in areas of Africa outside of the OCP area, and in Latin America, such an infrastructure does not exist and onchocerciasis control using ivermectin will be much more difficult.

Some restrictions on use of the drug have been made by the manufacturer, notably in pregnant women, postnatally during the first three months of lactation, and in children under 5 years of age. Although adverse reactions following ivermectin treatment are much less than with DEC (the drug used before ivermectin), a "Mazzotti reaction" (an allergic response to the killing of microfilariae) does occur which is proportional to the level of infection. Thus, on the first treatment, when high levels of microfilariae are present, reactions need to be medically supervised for about three days. This will probably not be required for subsequent treatments. Educational programmes will be needed to alert people to the long-term nature of the treatment and its possible adverse reactions. Distribution and management have been handled successfully in the OCP area but adequate organization and financing will be required outside the OCP area, and in the OCP area itself when the programme is terminated. This will be difficult to maintain when the disease has been reduced to the point where it is no longer perceived to be of public health importance.

A major question to be addressed to ivermectin distribution programmes is whether to treat all persons at risk (with no prior diagnosis), or to treat only persons infected. While the drug may be safe enough to justify treatment of all persons in hyperendemic areas, it may be more cost-effective to treat only infected patients in areas of lower endemicity. Surveillance would require the use of a simple field diagnostic method, e.g. skin snip, or clinical observation.

Dr C. P. Ramachandran

Although large-scale field trials have been conducted largely in the OCP area, TDR has funded a number of community trials in other areas. The effects of ivermectin have been monitored in selected areas in Africa and in Central America, and these trials have addressed particular questions of importance. For example, in Nigeria, the purpose of the study was to examine the effects of ivermectin on optic disease and skin lesions. In Liberia, prevalence rates are relatively low compared to other endemic areas and a six-monthly and two-yearly distribution of Ivermectin has been monitored for its effects on morbidity and level of transmission. In Guatemala a multiple dose treatment in conjunction with nodulectomy has been tried. The results of these studies

will be presented at a meeting to be held in Ougadougou in January 1989, and should indicate the potential problems which will need to be addressed in future Ivermectin distribution programmes.*

The Mectizan** Expert Committee (liason with WHO by Dr Davis and Dr Ranque) was created in 1988 to administer the Mectizan Donation Programme, through which Merck, Sharp & Dohme provide the drug free of charge to recognized/approved onchocerciasis control programmes. Donation of a drug to national governments, even when it is free, is not simple and requires many additional resources. Three approaches to distribution have been envisaged:

1. National Ministry of Health Control Programmes, or international health programmes like OCP.
2. Non-governmental organizations, such as organizations for the prevention of blindness.
3. Health clinics and general practitioners.

The associated costs of ivermectin distribution, in terms of establishing the prevalence of the disease, and the development of an infrastructure to deliver and monitor the effects of the drug are considerable.

Dr R. Le Berre

Member countries of the "Organisation de Coordination et de Coopération pour la Lutte contre les Grandes Endémies" met recently to discuss Ivermectin, particularly with reference to the current community studies in Cameroon. Its use will later be extended to those OCEAC countries not yet administering the drug. Countries differ with respect to vectors and in the distribution of savanna and forest onchocerciasis.

Ivermectin distribution should be primarily aimed at treating the individual, rather than in controlling the level of endemicity.

GENERAL DISCUSSION

The general discussion focused on:

1. Exclusion criteria for pregnant and lactating women.

Comments: Exclusions are based on toxicological studies in animals. The drug is highly lipid soluble and may be concentrated in breast milk. Ivermectin only exhibits toxicity in man when it enters the central nervous system. The human blood/brain barrier is normally intact at birth and the main danger is to premature babies following birth. In pregnancy little is known on the effects of Ivermectin on the developing human foetus. Teratogenicity has so far only been seen in rodents (club feet, cleft palate) using highly toxic doses.

Two animal populations (collie dogs and cattle) have been recognized to show extreme sensitivity to ivermectin, presumably based on a genetic defect which allows the drug to cross the blood/brain barrier. This raises the possibility that human groups may have similar genetic defects.

* It was pointed out that a double blind trial of ivermectin has also been conducted in Sierra Leone, which was neither TDR- or OCP-related.

** Mectizan is the trade name for ivermectin.

The fact that congenital defects are only poorly characterized in most developing countries raises the concern of how long-term adverse effects, such as birth defects, or tumour induction, will be recognized. Hopefully, ivermectin studies will be conducted in areas where some of these effects can be monitored, such as in Liberia, where the study population comes from a rubber plantation with its own hospital and retrospective records, and that studies will include details of the population before drug treatment which may reveal the occurrence of any subsequent adverse effects.

2. Effects of Treatment on Transmission

Comments: Ivermectin reduces the number of microfilariae in the skin and has dramatic effects on morbidity from disease in the individual. Blackflies feeding on infected persons who have only small numbers of microfilariae in the skin, however, may still be capable of producing significant numbers of infective larvae, and hence the reduction in transmission in the community may be less dramatic than the reduction of infection in the individual. It is also likely that high compliance rates will be required to substantially lower the community microfilarial load.

The view was also expressed that, although treatment of the individual is important, systematic distribution in the long term will be required to sustain these effects.

3. Effects of Migration on the Endemicity of Onchocerciasis

Comments: There is a need to understand patterns of human migration. In SW Africa there is a great deal of traditional migration through the area. In dry years there is increased movement south, but in wet years the movement is reversed. Migration covers different kinds of mobility and it is not known how these affect prevalence.

Resettlement of river valleys freed from onchocerciasis should be monitored for the re-establishment of foci of onchocerciasis transmission by infected immigrants.

4. Behavioural Responses to Ivermectin Treatment

To minimize non-compliance, it will be insufficient to describe attitudes to drug taking; an active effort will have to be made to find appropriate programmes to optimize compliance and to evaluate them. Education will form an important aspect of this, especially with regard to adverse reactions. The involvement of community health workers should be ensured, since they influence local opinion. As the epidemiology of the disease changes, so changes in attitudes and behaviour should be monitored.

5. Distribution of Ivermectin in the Primary Health Care System

If the drug is dispersed freely, it may be misused. Studies in the OCP and elsewhere may be able to define how frequently ivermectin should be administered. If there is a functional Primary Health Care system with well remunerated workers, distribution through health workers may be possible. But onchocerciasis is a chronic disease and community health workers involved in distribution have to be committed for a long period. Compliance is best when the disease is most severe. The longer the drug needs to be taken, the lower the rate of compliance. Community participation may mean either the community organizing itself for an alternative delivery system, or its direct participation in a vertical programme. In the long run, a macrofilarial drug will still be required, as it is not known for how long ivermectin will be provided free. Economic costs of different drug distribution systems need to be studied, but vector control in conjunction with ivermectin would be expensive.

2.2 Social Science Methodologies for Investigating Disease Epidemiology and Control

2.2.1 "Human Circulation and Malaria Risk" by Elias Sevilla Casas

A summary was presented of the conceptual and operational model developed by the Malaria Research Group of Cali to produce adequate data about human circulation and the related malaria risk. A distinction was made between risk and factors of movement, and risk and factors of infection following a given type of movement. The presentation concentrated on the second type of risk and factors, although comments were made concerning the need to put the 'malaria risk' as measured by epidemiologists within the cultural calculus of risk as measured by anthropologists.

The model combines the measurement of human presence in a determined 'place' (space time) and of the infectivity of such a place, as established by the biting and sporozoite rates of anophelines acting there, to predict risk of malaria. The outcome variable is malaria infection, diagnosed either immunologically, as a change in the level of antibodies, or as the days lost attributed to malaria disease in the followed-up individuals.

Examples were provided of the field instruments used and of the data analyzed by the model at an intermediate and a micro scale of measurement in a project carried out in the endemic area of the Central Pacific Coast of Colombia.

Finally there was a discussion of the problems associated with the measurement of the outcome variable in an endemic context where field conditions are harsh and parasitaemias low and mild, in spite of the continuous infection rate apparently occurring in the population. The paper concluded with comments on the necessity to promote a closer cooperation of biomedical and social scientific disciplines to deal adequately with human mobility as an important factor in malaria transmission.

2.2.2 "The Epidemiology of Malaria in Women in Madang, Papua New Guinea in relation to Language, Marriage Patterns and Mobility" by Loretta Brabin.

A study of 700 non-pregnant women of child-bearing age in 17 villages was conducted in Madang, Papua New Guinea, an area with year round transmission of malaria, in order to investigate small area variation in malarionetric indices, especially spleen rates.⁽¹⁾ Small area variation had been previously described in Papua New Guinea and Irian Jaya, and Metselaar⁽²⁾ noted that villagers in one coastal area of Irian Jaya had lower spleen rates than villagers from a few kilometres inland. He also observed that spleen rates in infants rose ahead of parasite rate and spleens were to a certain extent enlarged independently of malaria. These observations suggested that cultural factors which isolated one group from another, such as marriage patterns and language, might result in genetic differences which would be reflected in spleen rates.

1 L. Brabin, B. J. Brabin, H. J. v. der Kaay. High and low spleen rates distinguish two populations of women living under the same malaria endemic conditions in Madang, Papua New Guinea. Trans. Roy. Soc. Trop. Med. Hyg. 1988; 82, 671-676.

2 D. Metselaar. A pilot project of residual insecticide spraying in Netherlands New Guinea; contribution to the knowledge of holoendemic malaria. Ph.D. thesis University of Leiden, The Netherlands (1959).

The study was preceded by a census which showed that villages were not homogeneous units. In all villages non-traditional marriages were increasing and some coastal villages had permanent residents from inland villages who had moved to the coast to be close to schools and health facilities. It was evident that mobility was a factor which would have to be controlled for in the interpretation of the malarionometric data.

The analysis of parasite and spleen rates by village groups indicated that both language and inter-marriage were associated with spleen rates, but not consistently. The sample was then stratified by area of origin, irrespective of village of residence, to control for mobility. Five groups with different mobility patterns were distinguished. Three of these groups had significantly higher spleen rates, average enlarged spleen size and persistent splenomegaly, and it appeared that there were two distinct subpopulations of women who could be defined by spleen rate. Differences between the two subpopulations could not be related to mobility, but broadly corresponded to a difference in language group (Austronesian versus non-Austronesian). The implication of this study was that there are genetic differences in immune response to malaria in these two subpopulations who experience the same conditions of malaria endemicity⁽³⁾.

2.2.3 "Patient Treatment Compliance in the Multi-drug Therapy Era - Results from a Prospective Study in Bombay" by Atul Vadhver.

Since 1974 there have been numerous research reports on treatment non-compliance from major leprosy treatment centres. The incidence of non-compliance ranges between 6% to 75% in the published studies. A critical review of the existing literature on treatment compliance in leprosy reveals that the definitions between various studies and the research design and methodology utilized are diverse and unclear. There is also a clear absence of any explanatory or theoretical perspective. The main problems are:

1. Classification of compliance: failure to adhere to criteria laid down by WHO (1980).
2. Measurement of compliance: Usually either attendance rates or urine analysis. Few studies use more than one measurement, and several are principally concerned with the sensitivity of each measure.
3. Research design and methodology: Descriptive study design or a non-random sample; failure to characterize drop-outs before the sample is selected; failure to provide a rationale for the selection of variables for analysis or to analyze the data with suitable statistical tests.

Taking into account the past methodological and theoretical criticisms, a prospective study was designed and carried out over three years. The research was based in Bombay at two different projects, namely Bombay Leprosy Project and ALERT - India. Results from this detailed study show that irregularity and non-attendance is widespread (over 65%). This figure is unacceptable in the present M.D.T. era. Other studies reporting from different areas (mainly rural) show higher compliance rates. Factors which most affected compliance were acceptance of diagnosis, convenience of clinic time, family support and satisfaction with the treatment centre. (The variable "treatment regimen" is a confounding variable and is not appropriate as a best positive predictor of compliance). The results have practical significance at a personal, service and governmental level.

³ L. Brabin. Cultural factors and the epidemiology of malaria and viral infections in women. Ph.D. thesis, University of Leiden, The Netherlands (1988).

2.2.4 "Social Science and the Improvement of Tropical Disease Control" by Burton Singer.

Three conceptual and methodological innovations in the social sciences which may be useful in tropical disease control were outlined:

1. Anthropological (micro-approach) evidence

An important step to be undertaken before disease control can begin is the collection of baseline data by participant observation and in-depth interviews. In-depth interviews have been criticized as being subjective and variable in content, and there have been difficulties in developing a process to extract regularities from informal and written text in a relatively objective fashion. Recent advances in linguistics¹ and in automated text processing have led to the development of GATOR (The Generalized Automatic Text Organisation and Retrieval System)². This is a data base system designed specifically to provide computer-assisted support for the analysis of written and spoken text. GATOR permits rapid examination of the full range of material collected from hours of tape-recorded interviews on a given subject. It reduces the probability that a few "choice" interviews will be overused and reveals data on several variables that might otherwise remain hidden. GATOR requires researchers to read and code the relevant sections with appropriate key words. It is suited to researchers who want a high degree of cognitive control over the final product. A deep understanding of the organization of ideas with these texts requires, nonetheless, a linguistic theoretic base.

2. Grade of Membership Representations

Characterizing conjunctions of conditions associated with high prevalence of infection is an important aspect of defining "at risk" populations. This may be a complex procedure in conditions of social change, such as the increase in malaria in the Amazonian Region of Brazil, or of Chagas disease in Northwestern Argentina, where both diseases have increased dramatically due to migration. There are complex conjunctions of conditions consisting of the socio-economic characteristics of the human population, behavioural characteristics of vectors, and the ecology of the settlement areas. The Grade of Membership Representations is a methodological approach that was developed to characterize the health status of a community of the elderly, where single variables were inadequate to characterize the risk of illness. The methodology consists of constructing profiles on individuals, households, etc., such that many people have different profiles. In this way, a pool of candidate variables defines a high risk group. This methodology might be used for other diseases to define sub-populations for targeting interventions.

3. Programme Evaluation: Self-Selection and Performance-Based Ratings³

Randomized clinical trials to evaluate the efficacy of therapeutic treatment may not be suitable when:

1. voluntary self-selection into a treatment programme is a condition of entry;
2. it is unknown whether the decision criteria of volunteers is the same as non-volunteers;
3. the programme has several components;
4. a control group cannot be assembled.

1 Z. Harris. Language and Information, New York: Colombia University Press, 1987.

2 Giordano, J. Cole and H. Zuckermann "Text retrieval on a microcomputer": Perspectives in Computing, 8(1): 52-60, 1988.

3 B. Singer. "Self-selection and performance-based ratings: A case study on programme evaluation" in H. Wainer (ed) Drawing Inferences from Self-Selected Samples, New York: Springer-Verlag pp. 29-49, 1986.

This was the situation confronting evaluators of the Methadone Maintenance Treatment (MMT) programme for rehabilitation of chronic heroin addicts. Clinic success was likely to be attributable to the simultaneous occurrence of positive performance on several dimensions by clinic personnel, and proper administration of methadone. The comparison of what was defined subsequently as a successful programme with earlier versions (historical controls) seemed to be the only type of evaluation possible and led to the use of performance-based ratings, which also became part of continued monitoring. Such a methodology may be relevant in tropical disease control programmes where an acceptable control group is difficult to define.

The session was concluded by the Chairman who drew attention to the frequency that the "complexity" of disease control had been referred to. He reminded the meeting of two samples where simple solutions (although they entailed a great deal of hard work) had achieved prodigious results: the eradication of guinea worm in part of Pakistan, and of onchocerciasis from the Kodera Valley in Kenya.

2.3 Malaria Control in Socially Changing Environments: Introduction by Dr J. A. Najera.

Malaria resurgence has been concentrated in certain areas - notably India, China and Brazil, though most Brazilian cases can be traced to the Amazonian region. This latter area has become a focus of colonization and mining, attracting workers (generally non-immunes) from all over the country. Conditions of human settlement in labourers' camps are primitive, with overcrowded houses of poor construction sited near the irrigation canals from which there may be persistent seepage, providing plentiful breeding sites for mosquitoes. Labourers are often mobile and efforts to promote more stable communities have been unsuccessful.

Disappointment with results of control measures have led to an emphasis on the importance of social factors, and the need to improve the social environment of labour camps. The question arises: What are the factors that make for a successful control programme? Social science needs to provide insights as to why people live as they do and what factors make for the establishment of communities in which malaria control measures can be effected. A related issue is how to ensure that drugs can be provided in adequate quantities and at reasonable prices, while an official reporting system for early detection of epidemics depends on people's recognition and understanding of malaria symptoms. The population can contribute to surveillance and control if properly guided, and in some areas, with the assistance of technical and support systems, will be able to operate established control mechanisms.

Discussion

Comments on this presentation drew attention to predisposing factors to the malaria epidemic in Madagascar, particularly to economic difficulties which led to decreased spraying operations and a shortage of drugs. In this situation focal epidemics of malaria occurred. Although the situation was recognized to be serious, operations to contain the epidemics came too late. This illustrates that early warning systems can only be effective if attention is paid to the warnings. Nonetheless, while control of transmission may only be achieved in the long term, improvement of treatment at the local level can be facilitated if warnings are heeded.

2.3.1 "A Latin American Perspective on Integration of Malaria Control into National Health Care" by F. J. López-Antunano

The success of some vertical programmes in the eradication of disease led to their acceptance without due attention being paid to the socio-economic factors which would ensure their effectiveness and maintenance. The failure

to achieve eradication of such diseases as malaria, in the absence of a rural health services infrastructure, has been recognized by several World Health Assemblies since 1960, but there has been a reluctance in some countries to change the established operations. As a result, four kinds of malaria control programmes have emerged:

1. the vertical service as a specialized and semi-autonomous unit transposed from central government to the state or provincial level;
2. the control programme as part of the general health services in the face of the ineffectiveness of the specialized service;
3. the specialized services, as part of central administration, with ultimate control but collaborating with other public health bodies; and
4. decentralization of decision-making and the strengthening of regional and local health services.

Stratification is therefore still an important aspect of malaria control, although it has been recognized that many control activities could be integrated with primary health care. Pressure from WHO and the economic crisis stimulated a vigorous policy of structural change in countries like Mexico, Colombia, Brazil and Argentina. It is too early, however, to establish the impact of decentralization on their services, much less on the health of the population.

2.3.2 "A Brazilian Example of the Capacity of a Centralized Malaria Control Programme to Adapt to Locally Defined Epidemiological and Social Conditions" by W. D. Alecrim

The rise of malaria in the Amazon can be related to several factors: colonization, lack of efficacy of malaria control campaigns and malaria resistance.

The Brazilian malaria control programme, SUCAM, has as its specific objectives 1) to reduce the incidence of malaria in high transmission areas; 2) to interrupt transmission in low endemic areas; and 3) to prevent reestablishment following eradication. Its activities centre on house spraying with DDT, and detection and treatment of cases to reduce the reservoir of infection. In view of the rise in malaria, it has become a priority to conduct house-spraying in areas with the highest transmission, but overall, this has led to a reduction in the number of houses sprayed. The approach to malaria control, as the following list of control activities illustrates, has been uniquely bio-medical and has neglected the anthropological and cultural factors which contribute to the epidemiology of malaria.

The following specific control measures have been promoted:

1. Collective chemotherapy: 16 municipalities were administered chloroquine, fansidar and mefloquine. The number of infected persons decreased initially, but there was no significant improvement in the long run.
2. Microzoning: This system envisages dividing high transmission areas into smaller zones and then microzones of about 50 houses which are allocated to one health officer to develop control activities. Initial results have been encouraging.
3. Insecticide-impregnated jute curtains: Use of these curtains has led to a significant reduction in the number of cases of malaria observed.
4. New insecticides: Indoor spraying with lambda-cyhalothrin (a pyrethroid).

5. Insecticide-impregnated raffia curtains.
 6. Plasmodium falciparum monitoring plan to detect drug resistance: Initial results show high levels of resistance to chloroquine, amodiaquine and sulphadoxines and moderate resistance to quinine.
 7. Spatial sprayings: Trial programmes with use of PRO-FOG equipment using deltamethin and lambda-cyhalothrin. Despite these efforts, the coverage of treated houses failed to surpass 70% and P. falciparum infections represent more than half of the registered cases.
- 2.3.3 "Capacity of Centralized Malaria Control Programmes to Adapt to Locally Defined Epidemiological and Social Conditions: A Colombian Example"
by Elias Sevilla Casas

The trend towards deterioration of the malaria situation and its control has continued in Colombia during 1987 according to the Colombian Malaria Authorities (SEM). Besides particular factors that affect the situation in six major problem areas of the country, the SEM report identifies a lack of adequate development of the managerial and administrative structure of the programme as the major hindrance to the required change in the management of disease control.

The execution of the control programme is centered around wall-spraying and case detection and treatment. Performance is deficient and coverage low with poor results in terms of effective control. The execution of the programmes seems to be still carried out according to the philosophy of eradication, in spite of words about the process of control. Lack of flexibility for adapting to local and regional conditions is evident. A need for gradual but effective integration into the current leadership of the skills coming from various concerned disciplines is suggested, although there are complex social, psychological and political factors which impede this integration.

The inability of the system to accept change is seen mostly as a result of institutional inertia. It comes from the accruing of little obstructions of the staff at all levels. These obstructions emerge in some cases from bureaucratic inertia and in others from the existence of major or petty personal interests. The good intentions in favour of change that can be recognized in some SEM officers fade out when confronted with this subtle but effective social force. A suggestion was made for adequate study of this phenomenon, that can indicate how to initiate a process of institutional adaptation to the new requirements of disease control under changing conditions.

Discussion

It was noted that, in the days of malaria eradication, operations were conducted efficiently and effectively. The aim was to see a finished operation. Now that we are in the control process, there is no end in sight. There has been a marked fall-off in individual efficiency complicated by additional factors such as labour unions. Effective control will require the constant interest and encouragement of individuals.

- 2.3.4 "An In-depth Evaluation of the National Malaria Eradication Programme - A Case Study of Bihar and Haryana" by M. E. Khan and A.S. Dey

The present study was undertaken to carry out an in-depth evaluation of the National Malaria Eradication Programme in the states of Haryana and Bihar in four districts having a high incidence of malaria. All PHC staff involved in malaria work were interviewed for the study and a total of 1 200 households were interviewed. The major observations were:

1. Impact of Integration of Malaria with Other Health Programmes: Officials felt that the malaria programme had become a low priority since its integration with other health programmes. The performance of health workers was evaluated on the basis of their achievement in family planning activities and they were offered monetary incentives to promote family planning. Time spent on malaria work was only 7% of the total time of a worker in Bihar and 9% in Haryana and on average they were able to provide presumptive treatment to only 25% of the total estimated malaria or fever cases in Bihar and 51% in Haryana. Malaria eradication officers were unable to accomplish their targets and the same pressures were felt by PHC doctors. All programmes except family planning and, to an extent, immunization of children, are suffering seriously, especially malaria and public health.

2. Logistic Support: In Bihar, the malaria programme was functioning without a district malaria officer and many posts at the grass root level were vacant. The blood slide examination rate was very low and chemicals were in short supply or unavailable. The time lag between collection of blood smear and receipt of examination results was about 23 days and, for 17% of the cases the time lag was as high as 60 days. Frequent engagement of laboratory persons in other work without replacement also contributed to the delay. Workers faced resistance in obtaining blood smears from patients who were aware of the inefficiency. Compared to Bihar, the situation in Haryana was better.

3. Knowledge and Perception of Malaria: In both states all workers, particularly males, had a fairly good knowledge of the presumptive and curative treatment of malaria. Knowledge was better in Haryana than in Bihar. The study indicated a need for courses on malaria for health workers.

As regards perception and knowledge of the beneficiaries, 38% of the respondents in Bihar and 11% in Haryana did not know the causes of malaria, but 75% of them were aware of the symptoms of malaria. The majority also used at least one chemoprophylactic drug. Respondents knowledge of anti-malaria drugs was, however, poor.

4. Expenditure on Malaria Treatment: For every episode of malaria, the total expenditure approximated Rs.113 in Bihar and Rs.198 in Haryana which demonstrated that people were willing to spend money on treatment. Hence there is ample opportunity for PHCs/dispensaries to provide quality services by pricing their treatment. Alternatively, the government could consider introducing a health insurance scheme in selected areas on an experimental basis.

Discussion:

In the discussion following this paper it was noted that 60-70% of the population do not use PHC services but present at private facilities. This is relevant for point 4 above, on expenditure for treatment.

2.3.5 "The Malaria Control Programme in the Context of Primary Health Care: Issues and Prospects" by Elizabeth R. Ventura.

This paper described some of the problems encountered in the implementation of the Malaria Control Programme as an integrated service in Primary Health Care in the Philippines.¹ Although case finding, blood examination and treatment are integrated in the primary health care services at the barangay level (the smallest socio-political unit in the Philippines), there

¹ See also T. R. Lariosa, "Culture, environment and people's perceptions: considerations in malaria control in the Philippines: S. E. Asia J. Trop. Med. 2 Pub. Hlth, 17(3) 360-370 1986.

is still a vertical component (spraying), based on the rationale that spraying involves technical knowledge and skills which can best be administered through the Provincial Health Office. The problems encountered include operational and budgetary ones for the vertical component, lack of trained and motivated workers, and little understanding of community participation at the primary health care level.

Issues for social and economic research revolving around community health workers, community participation, and the health system were identified. The Barangay Health Worker (BHW) plays a crucial role and is often the only direct link between community and government. This role needs to be analyzed in the context of the dynamics of the BHW's activities, which in turn are imbedded in cultural, economic, political and socio-psychological factors. There is likewise a need to examine how the health system views the BHW. The way BHW's are treated within the health system should reflect the basic philosophy behind Primary Health Care. BHW's often have no training in malaria prevention and control. Increasing their knowledge and skills would increase their credibility and effectiveness in the community. Certainly, the interactions between the BHW, the community, and the health system present complex problems and there is a need for multidisciplinary analysis involving the individual, the community, the government bureaucracy and policy. The present combination of vertical and integrated approaches appears worthy of documentation and evaluation. The Directional Plan for 1988-1992 recognizes the need for mobilizing the community for prevention measures and case-finding, but discussions with malaria control programme staff show that they generally feel inadequate on this point. Processes of communications, decision-making, and resolution of conflicts may be looked into with the goal of increasing the effectiveness of the control programme.

The major contribution that social scientists could make to health education would be in content and process. The basic social and cultural data on beliefs, attitudes and values must somehow be integrated into the educational materials. One has to start at the level of one's audience and successively approximate a higher level of cognition and appreciation. This implies that the education campaign could be more sequential and long term, rather than a single exposure to complex and varied ideas.

Social scientists have the ability to conduct systems analysis and evaluation studies. In the collaboration between the two approaches, there can be a continuous feedback loop which would allow both sides a clearer perspective on the operational aspects of the control programme. The product would be a better coordinated, more efficient and socially relevant strategy as both groups learn from each other.

PRIORITIES FOR MALARIA RESEARCH

PANEL DISCUSSION

Professor Sir Ian McGregor

Dr McGregor reported on the SWG IMMAL/FIELDMAL Meeting in September 1988 to discuss the role of immunology in elucidating the epidemiology of malaria. There were 25 presentations at the meeting, constituting a very broad review of the epidemiologic uses of immunological tests and assessments in the study of malaria. Papers concerned:

1. The possible uses of malaria vaccines.
2. Diverse aspects of sporozoite immunity, asexual blocking stage immunity and immunity to sporogonic stages.

3. Tests of immunoresponsiveness and their relation to protection.
4. The dynamics of malaria transmission in relation to sporozoite density and inoculation magnitude.
5. The effects of serum concentrations of antimalarial drugs and ant sporozoite antibodies on sporozoite loads and infectivity of mosquitoes.
6. The use of immunological tools to categorize malaria endemicity.
7. The diagnosis and clinical grading of malaria.
8. The assessment of immunity and its consequences.

Meeting participants also divided into four working groups which reviewed past and current research on man's immune response to malaria and identified areas in which further studies were required.

The following four papers were considered to be of particular relevance for social scientists working in the field of malaria:

- (a) "Correlation between immune response to P. falciparum and protection, and their development in human populations" (B. M. Greenwood);
- (b) "Correlation between immune response to P. vivax and protection and their development in human populations" (D. Clyde);
- (c) "The diagnosis and grading of clinical malaria" (I. McGregor);
- (d) "Assessment of immunity (protection) against malaria (G. Brown).

Dr B. Doberstyn

Dr Doberstyn reported on the priorities of the CHEMAL component of the TDR programme, which include the development of new drugs (e.g. mefloquine, halofantrine); the improvement of old drugs (e.g. quinine, to which resistance has developed and which causes side effects), and the development of non-microscopic diagnostic tests such as DNA probes.

Areas of particular relevance to social science researchers include:

1. Identification of "risk" factors for severe malaria

A number of studies are currently looking at the epidemiology of severe malaria and investigating the genetic and biochemical markers which may be associated with immune susceptibility. Research on the social and demographic factors which dispose to severe malaria is also required -- for example, degree of risk of labour migrants and refugees. Predisposition may also be related to the lack of availability of drugs for particular social categories or individuals.

2. Drug distribution systems

There is a conflict in having ready access to drugs. On the one hand, it will reduce malaria mortality, but on the other, it will also foster drug resistance. The solution would seem to be some means for targetting drug distribution to people most in need. Another aspect of this is training and educating those who dispense drugs.

3. Ensuring provision of suitable sources of treatment (mobile health units, Aid Posts, etc) for different sectors of the population. For example, some services may be better suited to women and children, and others to men.

Dr R. Guidotti

Dr Guidotti commented on priorities for malaria research from the perspective of the Maternal and Child Health (MCH) Programme in WHO, and noted that the prevention of perinatal and maternal mortality, which was one of its main objectives, would benefit from research findings on malaria. MCH workers deal primarily with traditional birth attendants who often attend to women who do not attend PHC centres. One important question is whether traditional birth attendants should administer prophylaxis to pregnant women. The suitability of prophylaxis in pregnancy needed further study in different endemic conditions, as well as its efficacy when there is poor compliance, the effect of an irregular prophylactic regime on maternal morbidity, outcome of pregnancy and drug resistance, and cost.

Professor Somkid Kaewsonthi

Professor Somkid addressed the question of evaluating the costs of centralized and PHC programmes. The essential differences between centralized and PHC malaria programmes were summarized as follows:

Centralized: disease-specific, with planning, procedure and administration determined at governmental (national) level.

Primary Health Care: oriented to health problems at the community level, priority given to interventions which are effective, scientifically sound and affordable, responsive to felt needs and accessible to all.

To optimize operational efficiency, costs and performance must be considered and there is no information on the cost-effectiveness of PHC programmes. The most important task is to move to decentralization in the most rational and cost-effective way. The model for defining the short, medium and long-term objectives of costing such programmes has been described in detail elsewhere.¹

Social and economic research could contribute to a rational process of decentralization since three major groups of information are necessary to make informed decisions.

1. Social, economic, demographic and geographic information for each area.
2. Information related to the disease and its control measures (including, for example, household behaviour relating to transmission, behaviour of suppliers, patient behaviour in seeking care).
3. Information on costs and performance of control activities and field services.

GENERAL DISCUSSION

Discussion related primarily to the following issues:

1. The diagnosis of malaria morbidity

The question arose as to how well the perception of illness (self-reporting of fever or malaria, days lost to work due to malaria) corresponds to the level of malaria endemicity defined by parasitological indices. A

¹ S. Kaewsonthi Internal and External Costs of Malaria Surveillance in Thailand Chulalongkorn University. Thailand 1988.

behavioural response to malaria may not be a good indicator of infection. Only some people attending health clinics complaining of malaria are blood-slide-positive, and their presence in a health centre itself indicates their awareness of the importance of treatment (i.e. they are a selected group). Self-perception of illness also varies according to the level of malaria endemicity since acquired immunity modifies the severity of infection, and in hyper-endemic areas, most fevers are due to non-malaria infections. Seasonal changes are also important because, while prevalence and density of malaria infection may not vary greatly between wet and dry seasons, in the wet season there is a sharp increase of clinical malaria in susceptible. Clinical malaria is also related to parasite antigenic diversity since people need to experience different strains of the malaria parasite in order to achieve immunity. The prevalence of infection in any one area, therefore, implies an understanding of a number of factors, including parasitological and cultural parameters.

2. Factors related to malaria mortality

Attention was drawn to the need for a continuous review of risk factors for malaria mortality and how mortality can be prevented. Women and children are, for a variety of cultural and biological reasons, at high risk of malaria mortality. Factors that affect malaria mortality are:

- 1) antigenicity of parasite
- 2) dose of sporozoite inoculum (the more massive the dose, the more severe the infection)
- 3) virulence of parasite
- 4) past malaria experience of the individual
- 5) age
- 6) pregnancy
- 7) social factors

It may be difficult to look at one aspect without considering all aspects.

3. Importance of Interdisciplinary Research

Malaria control requires a multiplicity of skills. Conceptual and methodological skills represented by a number of disciplines should be put into practice. Training courses and research materials may need to be made available to develop this multidisciplinary approach.

4. How to make Primary Health Care more effective

Political will is required to control malaria in a primary health care setting, especially in areas where malaria can be largely attributed to the processes of colonization and economic development. This involves a commitment to providing and training health care workers and the development of control programmes which are responsive to local problems. The success of such programmes involves an understanding of how people respond to infection, their treatment-seeking behaviour, access to clinics for diagnosis, efficiency and attitudes of primary health care staff, and the benefits of attendance.

5. Malaria Control Measures within the Community

Communities can be encouraged to take responsibility for local control measures which include:

- a) drug delivery, either prophylaxis or the treatment of clinical episodes
- b) vector control, by a variety of methods such as drainage of swampy areas, larvivorous fish etc.
- c) personal protection, by use of bednets, insect repellents, insecticide-impregnated curtains, etc.
- d) cultural factors which reduce or increase the possibility of transmission. These include time/space variables, both daily and seasonal in relation to economic and recreational activities, housing design and the human to domestic animal ratio.

Community control programmes should be evaluated by parasitological, immunological, entomological and sociological indices.

2.4 Health Policy

2.4.1 "Overview of Health Policy and Planning Issues" by F. Golladay

I. The Theory of Public Policy

The terms "policy" and "plans" refer to instructions and guidelines that have been endorsed by formal institutions as the basis for future action. A policy or plan must be not only desirable but also implementable: it must advance the aims and purposes of the institution it serves, and must have authoritative backing.

The aims of policy analysis are to establish that a proposed course of action will (a) lead to desired ends, and (b) attract support. The feasibility of a policy may be evaluated by formulating a mathematical model which relates present circumstances to variables that can be manipulated. Models define (a) what can be done technically (b) the responses of clients and the public generally to alternative courses of action (c) the constraints imposed on a policy initiative by limited resources. Finally, a model predicts the outcome of manipulations of these variables.

There are three main classes of variables: (1) those that represent the activities that are in principle under the control of policy makers; (2) those that depict the outcomes of policy initiatives; and (3) those that portray the processes which translate policy into results. These variables are inter-related but the strength of the interrelationship varies, and separate empirical studies are usually required to ensure that a policy model accurately portrays a policy situation.

The implications of a policy initiative will be predicted accurately only so long as the major players continue to relate to each other as they did in the past. An alternative approach to influencing policy is to modify the relationship among the players, i.e. qualitative policies or institutional changes. The policy analyst then attempts to predict how the system will respond to such changes (e.g. decentralization, or community participation). Such policy initiatives are difficult to devise because they are assessed qualitatively.

These concepts lead to three broad categories of policies and plans:

- 1) The capital investment plan (e.g. the national development plan).
- 2) The formulation of specific systems and procedures, known as operational policies, which determine if high level goals are fulfilled.

- 3) "Strategic planning" by which an organization prepares itself for the reaction of competitors (game theory). The emphasis on strategic planning forces policy makers to mobilize support.

II Roles for Social Research

Firstly, social research clarifies the implications of policy initiative, e.g. how many more clients will comply with a prescribed treatment or support a programme if accessibility or effectiveness is improved by a defined amount. Secondly, it assesses the interests and responses to initiatives provoked by a new policy and how they might be influenced in order to advance the aims of the analyst's institution. Both of these roles demand a deep understanding of the workings of society and of political, professional and social institutions.

2.4.2 "Interaction Between Health and Economic Planning with Special Reference to Irrigation" by Mary Tiffen

Health benefits, particularly those deriving from an improved domestic water supply, better nutrition, and control of vector-borne diseases, can often be obtained in association with major infrastructural developments such as irrigation. However, this requires good intersectoral planning, good consultation with the users and local representative organizations, and good understanding of methods of planning by which benefits and expenditure relating to initial capital costs can be compared with benefits and expenditure on recurrent costs. The Internal Rate of Return, taken as an isolated figure, is often an inadequate criterion for the selection of a project design which is sustainable in terms of the resources available in a particular region.

The formal project cycle has been developed from the point of view of lending agencies. It gives very little emphasis to the long period after the Bank's role has finished, when the project should be so operated and maintained so that it continues to produce a stream of benefits for the users and the country as a whole.

In irrigation planning a crucial period comes shortly after identification, when the Terms of Reference are drawn up for the main feasibility studies. Countries with good mechanisms for planning at the regional or district level, through inter-sectoral meetings which include representatives both of different ministries and of local government sub-units, will have the advantage of seeing that the TOR take note of local conditions and interests, and include health aspects. This will help lead to a design which, for example, minimizes health risks and so reduces later expenditures on chemotherapy.

Health authorities will need to alert those responsible for the irrigation project both to the information already available within the country and to their institutional and financial needs during the implementation and operational periods. They will need to see that the institutional arrangements allow them to take an effective part in monitoring the health impact and in transmitting requests for necessary improvements to the authorities responsible for operation and maintenance.

Small-scale schemes are much less under government control, since they usually arise from the initiatives of individuals and groups. The Ministry of Health will have to see that village workers are aware of the new diseases that may occur, and that it has, starting from this base, a system for monitoring the spread of disease and identifying focal points for transmission. It will often be helpful if the Ministry of Health takes part in the in-service training of agricultural extension assistants and community development staff who are in direct contact with farmers.

General Discussion:1. How to quantify personal/household costs and benefits

How can these costs and benefits be measured and balanced against public costs when deciding on the relative merits of alternative plans? One approach is the "next best solution" to judge whether the health benefit would justify a more expensive option, but it is still difficult to express the costs and benefits quantitatively (cf. discussion above on "days lost to work" as a measurement of "personal costs").

2. Time required to conduct feasibility studies

Planning operations require rapid appraisal methods because developers will not wait on detailed reports.

3. Influencing donor agencies

Donors often prefer to implement a given plan and attach money for health services, rather than to prevent health damage by considering alternatives. A common policy among donors is desirable because competition for specific development projects may override health considerations. Donor agencies such as the World Bank are aware of the major problems but surmounting these problems will require systematic research. First, engineers can usually justify their operations in terms of health benefits and donor agencies will need to be presented with reasoned arguments of what the health issues are (i.e. facts, not emotion). Second, even in plans which incorporate health components there are enormous problems of inter-sectoral coordination which frustrate the objectives.

4. Collaboration with other units

The Panel of Experts on Environmental Management for Vector Control (PEEM/WHO) has been monitoring the adoption of economic, agriculturally compatible and socially acceptable approaches to development, including training and the development of problem-based learning materials. Similarly the Overseas Development Institute has initiated a series of networks representing a variety of disciplines to address this issue, and to disseminate existing knowledge. Future collaborative efforts with these bodies may be beneficial.

The SWG Meeting ended with a brief review by the Steering Committee Secretaries of the ongoing collaborative research between SER and the other component programmes of TDR. In the closing comments, participants were reminded of the recommendations of the External Review Committee and were asked to consider the new phase in the development of social and economic research as arising from, and as a next stage to, the large body of field research which has already been accomplished.

3. APPENDIX: NOTES ON APPROACHES TO IVERMECTIN DISTRIBUTION PROGRAMMES

1. Alternative approaches to vertical distribution

Following the first round, when vertical distribution was the most suitable form, distribution could be handled at village level, with twice-yearly distribution to follow up on non-attenders or people excluded in the first round. This would still be controlled delivery.

Alternatively, if considered safe, ivermectin could be made freely available to communities.

These issues need to be discussed in relation to the effects of different drug distribution strategies on the epidemiology of the disease, e.g. a dramatic decrease in the rate of transmission following planned distribution will affect all individuals, treated or not. Random distribution to treat symptoms of disease in individuals may be less effective in lowering transmission.

2. Monitoring of Compliance

In a controlled distribution programme, compliance and non-attendance should be optimized, and reasons for non-compliance followed up, particularly:

- (a) Refusals subsequent to severe reactions following treatment;
- (b) Increasing long-term drop out as disease becomes less severe;
- (c) Migrant groups: (i) transhumants, (ii) wage earners, (iii) resettlers;
- (d) Malnourished, low-weight children aged 5-11;
- (e) "Problem" villages or sub-groups where cooperation is poor due to local politics, or ethnic diversity.

3. Long-term Effects of Ivermectin on Women and Children and the role of Primary Health Care Facilities in Drug Distribution to these Population Groups

There will need to be long-term monitoring of pregnancy and delivery complication in women inadvertently treated when pregnant (women may conceal their pregnancies to receive treatment) and of congenital abnormalities in the offspring (e.g. cleft palate and club feet). There should also be monitoring of possible long-term improvements in the health status of women (and consequently offspring) as, for example, if improved iron status of women follows reduced infestation of intestinal parasites after treatment with ivermectin.

Distribution of ivermectin to women and children through primary health care facilities may be suitable. Long-term effects on children could also be monitored through schools. Cultural restrictions on women taking drugs should be ascertained.

4. Education Programmes

Education programmes will be needed to increase awareness that long-term treatment is required, and also to allay fears of people in currently vector-controlled areas, when uninfected black-flies reappear following cessation of aerial larvicide spraying programmes.

4. LIST OF WORKING PAPERS

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|----------------------------|---|
| ALECRIM, W.D. | A Brazilian example of the capacity of a centralized malaria control programme to adapt to locally defined epidemiological and social conditions. |
| BRABIN, L. | The epidemiology of malaria in women in Madang, Papua New Guinea, in relation to language, marriage patterns and mobility. |
| GOLLADAY, F. | Overview of health policy and planning issues. |
| KAESONTHI, S. | Comparative costs of centralized and decentralized control programmes. |
| KHAN, M. E. &
DEY, A.S. | An indepth evaluation of the National Malaria Eradication Programme - a case study of Bihar and Haryana. |

- LOPEZ-ANTUNANO F. J. A Latin American perspective on integration of malaria control into national health care.
- PARIS, F. Human behavioural onchocerciasis in North Cameroun.
- SAMBA, E. M. An overview of the epidemiological and field research experiences which laid the basis for the present ivermectin control strategy.
- SEVILLA CASAS E. Human circulation and malaria risk.
- SEVILLA CASAS E. Capacity of centralised malaria control programmes to adapt to locally defined epidemiological and social conditions: A Colombian example.
- SINGER, B. Social science and the improvement of tropical disease control.
- TILFEN, M. Interaction between health and economic planning with special reference to irrigation.
- VADHER, A. Patient treatment compliance in MDT era: results from a prospective study in Bombay.
- VENTURA, E. The malaria control programme in the context of primary health care.

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