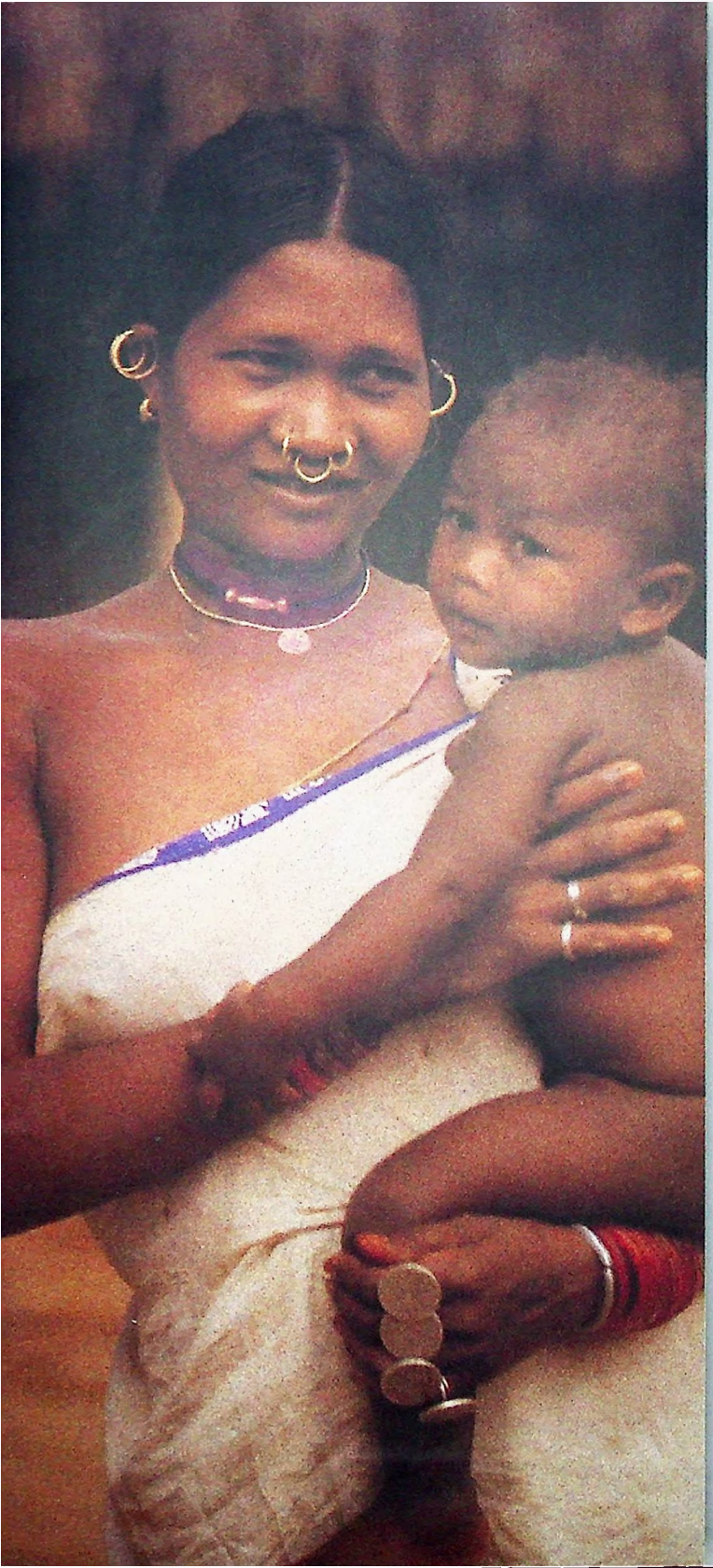

HEALTH

SIR DORABJI TATA TRUST

PROMOTING HEALTH AND DEVELOPMENT IN INDIA

V RAMALINGASWAMI
RANJIT ROY CHAUDHURY

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Preface

Sir Dorabji Tata Trust, since its establishment in 1932, is guided by a deep sense of commitment towards the country – with a vision for national progress. In 1999, the Trust commissioned a series of strategy papers to scholars and experts whose mandate was to review the critical needs of the development sector in India and discern the role a sensitive philanthropic organisation could play. The process of producing these discussion papers was guided by a spirit of exploration and identification of what is best to give to the country in the fields of social development. The areas identified were management of natural resources, livelihoods, education, health and social development initiatives. The last paper included a number of sectors such as civil society initiatives, human rights, family welfare, the physically/mentally challenged, art and culture and disaster relief. The overarching questions that each discussion paper was expected to explore were:

- *How are perceptions/concepts in philanthropy changing? What is the perspective for the future?*
- *What, according to the academic and grass-roots perspective, are the needs in the different fields? And what could be the new fields of endeavour that could be explored?*
- *How does one choose an area of focus from the vast range of possibilities within each field?*
- *Within the chosen focus, what are the alternative approaches and what is the expected impact of these approaches? Which type of initiatives should be selected for major support and which should be given token assistance?*

A strategic direction for grant making was to be proposed in specific sectors. The experts were also to offer an opinion on how to respond to thematic issues in urban, rural or tribal areas; and suggest measures to incorporate equity and gender concerns.

The Trust is happy to present some of these papers to a wider audience. Each of the sectors is vast and although newer concerns will always emerge – because of the changing development context – the papers offer valuable insights and a perspective for the future.

The strategy paper for the health sector was first commissioned to Professor V Ramalingaswami. He presented a draft in 1999, under three broad sections. Unfortunately, Professor Ramalingaswami passed away before the paper could be finalised and after an interval Professor Ranjit Roy Chaudhury was approached to assist with the task of finalising the strategy paper on health. His contribution substantially complements and brings up to date the first draft of Professor Ramalingaswami.

Though the two papers were written separately, they have been integrated into one – co-authored by two eminent health experts in the country. The bringing together of the two papers has necessitated certain editorial changes.

We gratefully acknowledge the authors and the contributions of all who have assisted and enriched the final publication of the strategy papers; in particular, Dr Janki Andharia who put the two papers together during her tenure at the Trust.

Sir Dorabji Tata Trust
Mumbai, 2003.

PROMOTING HEALTH AND DEVELOPMENT IN INDIA

I. INTRODUCTION

The status of health is an important indicator reflecting social development and the quality of human life. Further, health care is one of the most basic human rights, vital for preservation and promotion of health (Article 25 of the universal declaration of human rights).

As a result of poor public health facilities compounded by inadequate allocation, less than 20 per cent of the population seeking out-patient department services and less than 45 per cent of the people who seek indoor treatment avail of the services of public health facilities (National Health Policy – 2002). Consequently, people are forced to go to private sector health providers where accountability systems are weak or non-existent.

The regional disparities and the rural-urban divide in health care outcomes continue and much remains to be done in the sector, which from the state perspective, is resource starved. Health care in a mixed economy is viewed from two perspectives: Firstly as an industry within the domain of the private sector. Secondly as a service within the domain of the government or the public sector. The meager government spending is concentrated on secondary and tertiary sector hospitals in urban areas and rural areas remain largely ignored in the country. A sensitive grant maker must keep the larger context of financial allocation to this sector in mind as well as keep track of developments in the delivery systems of health care and its structuring, which are continuously being reviewed and experimented upon by a variety of civil society organisations.

Public participation, increasing democratisation, the growing awareness of governance and civil society, the breathtaking advances in science and technology and pressures to ensure respect of human rights are important features of a rapidly-changing world scene. This paper on health is part of an overall strategy encompassing many areas.

Several status papers and policy documents brought out in the last two years have been taken into consideration when framing a strategy in 2003.

Some of these documents are:

- The National Health Policy of the country issued by the Ministry of Health and Family Welfare – 2001.

- The National Population Policy issued by the Population Commission of India – 2000.

- The policy of the Indian Systems of Medicine in draft form issued by the Ministry of Health and Family Welfare – 2001.

- The Pharmaceutical Policy issued by the Ministry of Chemicals and Fertilisers – 2002.

- The Tenth Five Year Plan document of the Planning Commission – 2001.

- A document prepared and released by the Indian Council of Medical Research (ICMR) titled *Priorities in Health Systems Research and Biomedical Research and Development* and the document *Changing the Indian Health System* prepared by the Indian Council for Research on International Economic Relations (ICRIER).

- The report of Jeffrey Sachs and the Commission set up by the World Health Organisation, in 2002. This is a valuable document focusing on the need for more resources in the field of health in developing countries. Following the publication of the Sachs Report, the National Commission on Macroeconomics and Health was established by the government of India in October 2003.

One of the authors (Professor Roy Chaudhury), has been closely involved in identifying priorities and in the preparation of each of these documents. This experience has been put into the writing of this paper.

The paper is presented under six broad sections. The first is an Introduction followed by a brief presentation of the changing scenario. Principles of the proposed strategy are described in section III. Constraints in the optimal use of research carried out in the country are presented in section IV. Programme priorities are discussed in section V under several subsections including a range of diseases and issues of significance such as medical ethics and leadership development in the health sector. The paper ends with a few concluding observations.

II. THE CHANGING SCENARIO

Overview

There is a need to periodically review the changing socio-economic and cultural scene in India, the developments taking place in science and technology and examine what promise they hold for health and well-being. The impact of economic liberalisation and globalisation on equity and access, especially on marginalised people; the effects of the forces of 'modernisation' and ill-conceived developmental activities on environmental degradation; the changes in lifestyle, diet and behaviour; and the speed of travel and increasing urbanisation are some of the factors that impinge upon human health and are worthy of attention. In this section, the problems relating to health arising out of the unprecedented changes taking place in society are highlighted. This is in line with the spirit of a 'new social contract for science'. The integration of natural sciences, social sciences and the humanities is necessary to cope with environmental degradation, social problems, overpopulation, continuing poverty and inequity.

Demographic Transition

India is in the process of passing through a demographic and health transition, as a consequence of an increase in life expectancy and the aging of the population. While some infectious diseases have been brought under control (such as polio, guinea worm disease and leprosy), several existing diseases have shown a resurgence such as malaria, tuberculosis (TB), dengue haemorrhagic fever and kalaazar. New and deadly infections such as HIV/AIDS have emerged. As the infant and under-five child mortality rate come down, more and more people are living longer and the incidence of non-communicable diseases such as heart disease, high blood pressure and cancer have increased. In fact, Asia, including India, is passing through a hidden epidemic of cardiovascular diseases.

Cancer has increased in prevalence as the population ages. Certain types of cancers are particularly common to India, such as oral cancer

and its relationship to tobacco chewing – an area that the Tata Memorial Hospital (TMH) has been addressing over the years.

To sponsor research on factors that promote healthy aging is a worthy pursuit. It can be related to diet, nutrition, physical activity, infectious diseases and susceptibility to cancers. A proactive approach to efforts that promote healthy living in the aging population is recommended. Problems in mental health and behavioural disturbances could rise in the future. The focus should be on community mental health and community psychiatry. The National Institute of Mental Health and Neuro-Surgery (NIMHANS), Bangalore, has done pioneering work in this area. In the area of 'disability and rehabilitation', the focus should be on low-cost indigenous technology/devices for the physically handicapped. Leprosy will continue to need attention for some more time till the backlog of leprosy-cured patients with deformities can be rehabilitated.

The Human Genome Project

The Human Genome Project has recently been completed with many participating institutions around the world. It provides a wealth of opportunities to design new approaches to the study of the role of genetic factors in diseases. India has considerable strengths in genomic research and the Indian Institute of Science (IISc) in Bangalore has played a leading role. The establishment at the IISc of the Centre for Research in Tropical Diseases, the Tata Institute of Fundamental Research (TIFR) and other government institutes could play a critical role in the development, evaluation and clinical application of advances in genomics. These developments deserve special attention so that they may look for strategic opportunities to pioneer improved policies and the practice of genetic science and the ethical aspects thereof.

Surveillance of Diseases

Installing a national surveillance system for diseases to provide early warning of impending disease outbreaks and advanced preparedness can safeguard the future health of humankind. There is no area more critical for ensuring the future health of the nation. Although the government has accepted the report on a national surveillance and response system prepared by a group of scientists following the 'plague' outbreak in 1994, a catalytic role can be played by a sensitive grant maker in pioneering the development of such a system in a phased manner on a pilot basis, developing modules for replication. The Kerala Initiative is currently in the offing and projects such as this could be considered for support.

Health Implications of Large-scale Developmental Activities

Well-intentioned, large-scale developmental activities such as dams and irrigation systems, buildings, roads and railways, often leave behind an environment conducive to proliferation of disease-carrying vectors unless they are foreseen and acted upon for prevention. As a consequence, outbreaks of vector-borne diseases have taken place in the country. Malaria is an example. The study of ecological disturbances induced by developmental activity can be undertaken by sponsoring pilot projects.

III. PRINCIPLES OF THE STRATEGY

A strategic approach to grant making in the health sector may follow a few broad principles, which are presented in this section.

Build Selectively on the Investments and Successes of the Past

In the first place, the idea must be timely and fulfil a deeply-felt need. Then a leader with a vision

must be identified to implement the idea. A team that works in harmony towards the stated goals must be established. Mid-course corrections, flexibility and sustainability must be ensured. A philanthropic organisation has a critical role to play in planting the seeds of new and innovative institutions. The Centre for Research in Tropical Diseases established in conjunction with the IISc in Bangalore is an example.

Adjust to Contemporary Challenges and Changing Needs: A New Paradigm in Research

Any future strategy must make adjustments to contemporary challenges and changing needs. The new paradigm of development research should reflect the following elements:

Focus and Connectivity: Should a philanthropic organisation disperse its relatively limited resources to support diverse, small-scale, unrelated activities or should it focus on a few development-oriented activities? Focusing is the desired goal and connectivity of areas such as health, nutrition, population and environment should be recognised in its programme selection (see Pattern of Grants below). Compartmentalism must replace integration and synergy for maximum impact.

Monitoring and Evaluation: End-stage evaluation and feeding the results to policy channels, often neglected, are of crucial importance. In most projects impact analysis is generally weak including in the public-supported national research agencies. Research advances best with interdisciplinary and inter-sectoral approaches. Social and behavioural sciences must increasingly interact with biomedical and health sciences to facilitate application of research results for human betterment. Monitoring and evaluation must be an integral part of all projects supported by a grant.

Community Involvement: In field projects the community must be actively involved at all stages including the early stage of goal-setting right through to the concluding stages. Participatory research is essential for maximising the outcome of research and its sustainability. An informed public opinion in matters of health and disease facilitates the application of research results. Enhancing public understanding of science and community participation in planning, execution and evaluation of projects are key to sustainability.

Pattern of Grants

One approach to grant making is to follow a dual policy of providing medium-sized grants to a few selected institutions, while the majority of grants should be small scale, responding to acutely-felt societal needs over a wide field. An alternative might be to introduce a different approach in a phased manner, not all of a sudden. This would involve setting goals and priorities, and increasing the size and duration of the grants to the selected priorities to demonstrate an impact; and gradually reducing the number of small grants but not abolishing them altogether. A philanthropic organisation should be able to respond to small but acute needs over a wide front. Such small grants should not be construed as 'promotional' charity. A formula of 90:10 or 80:20 might be suggested for the relative sizes of the two types of grants.

Human Capacity Building

Grants for training in new skills and concepts in India and abroad may be a continuing feature and contribute in no small measure to the pool of knowledge, skills and research capacity in India. Compared to the government and bilateral agencies, this may be small but it is critical. Training must be according to institutional needs and is most

valuable at this time when there is a declining interest and fall in the number of fellowships and scholarships available for training abroad under government auspices. Especially in areas of cutting-edge science, there is a continuing need for relatively short-term training for those mid-career scientists working in frontier areas.

Role of Philanthropy

There are some unique features of trusts, foundations and philanthropies, which are highly relevant to nation-building. These are: flexibility, innovativeness, risk-taking and demonstrative action to serve as advance action for large-scale replication. Scientific endeavour today, is characterised by 'big science', vast inputs and infrastructure for which government funds are being increasingly devoted to. Nevertheless, there is a critical role that philanthropies with relatively small resources can play.

It may be remembered that it was a small grant from the Rockefeller Foundation that enabled Florey and Chain to consummate the original discovery of Fleming and led to one of the great discoveries of modern science with great human benefit, viz. penicillin.

Partnership with other Research Agencies

Co-funding and partnerships with national and international research agencies are avenues, which could be explored. After a choice is made of a worthwhile project to be funded, it might be of tactical advantage to a grant-making organisation to enlist other research agencies in the country to provide additional resources. This is one way of leveraging funds for advancing research in areas, which a philanthropic organisation considers important.

IV. CONSTRAINTS IN THE USE OF RESEARCH

Funds available for research in the health sector are meager and even the results of this limited research have not been utilised effectively. A few of the factors preventing the country's progress in the field of health – particularly relevant to research in the country– are described in this section

The Balance between Individual Research Interests and National Priorities

One area of concern is that an individual research worker, a research group or even a research institute is not easily able to strike a balance between individual or group research interests on the one hand and national priorities on the other. Despite the fact that national planners in the Planning Commission and other programme managers have repeatedly brought out priority areas of research and work, it is not very often that research workers look at these priorities or fashion their research within the framework of the priorities.

Yet, the research interest of an individual should not be crushed. As Smt Indira Gandhi once said (to the Scientific Advisory Board of the Council of Scientific and Industrial Research [CSIR] at one of the board meetings), "Let the dreamer dream." However, it would be more pertinent to national interest and resources would be more effectively spent, if the researcher could dream within the parameters of national priorities. Otherwise, we have the unfortunate situation of research areas being at one spot and the actual research needs of the nation being somewhere else.

Resources could be earmarked for work in the priority areas. National awards could be

given for work in the areas of research needs. However, these are marginal mechanisms – the real challenge is to change the mindset of the individual researcher in a way that encourages him or her to work in the priority areas.

The Utilisation of the Results of Research and Pilot Projects in National Health Programmes

This remains an area of weakness in research endeavours in the country. So often the researcher and his or her team spend 10 years or so on a research project, obtain what he/she believes are results that should be introduced into a national programme like nutrition, leprosy or TB, only to be told by the national programme managers that the results are not what are needed! Further, he/she is told – in no uncertain terms – that there is no way that these results could be used. This has happened many times and in important areas. Thus, it is necessary to take national programme persons into confidence, even while planning a research programme. However, this is easier said than done. Nowadays, researchers and research institutes usually invite representatives of the line ministries to their meetings. Very often, particularly if the meeting is held in New Delhi, ministry officials disappear after lunch to the safe and secure environment of Nirman Bhavan. This is an issue, which needs to be tackled.

Concerted efforts need to be made to ensure that national health programmes adequately use the relevant research, which is being carried out within the country.

Challenges in Collaborative Efforts

The third issue is of collaborative research or networking. The common perception regarding the Indian scientist if he/she could be so profiled, is that he or she is excellent when carrying out research in isolation or with his or her team. Today, however, several things, which need to be done, cannot be completely carried out by one group of scientists, such as in the field of drugs development. There is an absolute necessity for teamwork with other scientists and to network with other groups of scientists. And here the Indian scientist has been found wanting. Time and again, collaborative ventures have failed, and not because of science, but because of ego clashes, a sense of insecurity and a feeling of competitiveness. These constraints need to be overcome if we are to carry out good quality research in the frontier areas.

Challenges in the Development of Leadership and a Succession Policy

The need for development of leadership and for creating a transparent succession policy cannot be overemphasised, and yet this has hardly ever been done. How many times have we not seen an outstanding centre of research under a dynamic charismatic leader wither away into mediocrity or worse after the leader retires or goes into a high bureaucratic position or is whisked away to the comfortable environs of the United Nations or the World Health Organisation (WHO)? This has happened because there has been no succession policy.

An Experiment

One innovative experiment carried out by the Department of Family Welfare was to create a research group in reproductive and child health within the ministry, but consisting entirely of outside experts. Some funds, which were earlier used by the ICMR were earmarked for research recommended by this committee. This has worked very satisfactorily and all projects supported are those marked for support in the ICMR document *Guidelines for Research Support in Reproductive and Child Health Research*. In fact, now the ICMR itself recommends three-four projects to the committee, which are funded, when approved, by this mechanism.

The leader has a right to go on to better things, but he or she also has the responsibility to create his/her successors. A lot of resources – financial, technical and human – are lost when there is no continuity in the work being carried out and in the quality of the work being done.

V. PROGRAMME PRIORITIES

Within the context of the strategic principles, the changes in the scenario and the constraints in the optimum use of research set out above, this section deals with programme priorities. The canvas is vast and the choices are difficult. No listing of priorities can ever be considered as complete or final. This section is, therefore, indicative and not exhaustive. The areas of high priority are given below and in each area some examples are given for the type of project that could be considered for support.

Tuberculosis

The scourge of tuberculosis looms over India which has the largest number of TB patients in any one country and accounts for one-third of TB patients all over the world. About 2.2 million persons are added each year to the existing load of 15 million active cases. TB is the leading cause of death among women in the reproductive age group of 25-44 years. It is expected that the number of TB cases will shoot up in the presence of HIV infection. There are some estimates, which suggest that deaths due to TB, if TB is not controlled, can go up to four million in the next decade. In addition, the number of multiple drug-resistant TB patients has gone up largely due to irresponsible prescribing of anti-TB drugs. The cost of treating a multi-drug-resistant case of TB is 250 times more than what it costs to treat a patient who is not resistant to the standard anti-TB drugs – rifampicin, isonicotinic acid hydrazide, pyrazinamide and ethambutol. In addition, the drugs used in multi-drug-resistant cases like kanamycin, ethionamide, ofloxacin and cycloserine are toxic drugs. Today, being inflicted with multi-drug-resistant TB is like having a death sentence.

The irony of this entire scenario is that many of the path breaking discoveries leading to the directly observed treatment shortcourse (DOTS) management of TB, which is what the WHO has advocated all over the world, were first identified in India.

DOTS treatment, which cures 90 per cent of TB patients while they remain at home – the domiciliary concept – was first demonstrated in Bangalore. The value of carrying out sputum examination instead of using x-rays was demonstrated in India. The efficacy of intermittent treatment with anti-TB drugs,

The DOTS Programme

India is committed to the DOTS programme, which entails that individuals with TB are allocated all the medicines and drugs needed for its full treatment. These are directly given to the patient at the DOTS centre by a health care worker or some other responsible person. This total 'package' ensures that, as far as possible, the patient takes all the anti-TB drugs needed for a cure and that lack of drugs will not be a factor in receiving an incomplete course which could lead to drug resistance.

The five elements which together form this anti-TB package are:

- Government commitment.
- Diagnosis primarily by microscopy.
- A regular supply of good quality anti-TB drugs.
- The direct observation of the patient taking the drugs.
- A system of surveillance and monitoring. Four drugs are given for two months followed by two drugs for four months for patients who have not been treated previously for TB. If the drugs are taken regularly, the cure rate is 90 per cent.

again was demonstrated in India. And yet, we have not been able to sucessfully meet the onslaught of this dreaded and insidious disease. Indeed, a director general of the World Health Organisation has said, "The whole world has benefited from the fruits of Indian research – the whole world, except India."

Studies are needed to find out why doctors have not been prescribing the anti-TB drugs as they ought to, since this is well known and why the patients do not complete the course as they are supposed to – even when the drugs are available. In Mumbai alone, 35 different regimens of anti-TB drugs are being prescribed by doctors. Multi-drug resistance is largely a man-made entity. Intervention measures can only be taken into consideration when we know why there has been a failure in India of applying and using a proven technology outside the government TB programme.

Unfortunately, patients are prescribed a variety of drug regimens, some of which are inappropriate, including only a single drug or two drugs. Private practitioners practising in low-income areas of India are largely ignorant about modern advances in the diagnosis and treatment of TB. It has been shown that about 33 per cent of urban patients and 36 per cent of rural patients had not been diagnosed as TB patients even four weeks after they had approached a practitioner. These irrational practices, including administration of wrong drugs, perhaps at wrong doses and wrong combinations, contribute to the rise of multi-drug-resistant tuberculosis in India. When one takes into account the fact that about 80 per cent of all qualified doctors, 75 per cent of all dispensaries, 60 per cent of hospitals and 75 per cent of the country's health expenditure are in the private sector one realises that a DOTS programme only in a government centre can never be adequate. Private practitioners need to be closely involved in the programme and provide free drugs for the treatment of their patients with TB. This programme has just begun but private practitioners, even though they are equipped with medicines, would naturally like to be reimbursed for the time they have spent on their patients. This will have to be worked out as the patient should not have to pay as he or she would not have to do so if he or she went to a government DOTS centre. Organisations such as the Indian Medical Association would necessarily have to get closely involved in the programme and include the treatment of TB repeatedly in their programmes of continuing medical education.

Studies should also be carried out whether, in addition to the DOTS programme, in an effort to reach all TB patients we should not complement it with a self administered therapy (SAT) programme, in which the individual obtains all the treatment medication initially and takes them individually without supervision.

TB and HIV

The Revised National TB Control Programme (RNTCP) and the DOTS programme were initiated in India in 1993. By 2001, the DOTS coverage was 40 per cent – enabling about 450 million people to have access to DOTS. It is unfortunate that the advent of HIV and AIDS threatens to wipe out to a great extent the gains accrued so far.

It is estimated that there are about four million HIV-infested people in India and half of these are also infected with mycobacterium tuberculosis. Active tuberculosis will probably develop in seven per cent of these cases every year, producing 1,40,000 cases of tuberculosis each year, only from reactivation of a dormant focus of infection. This represents an approximate 10 per cent increase in cases even at the current low rate of HIV infection. TB is the commonest cause of HIV-related death. TB also has an adverse effect on HIV. There are studies, which indicate that transcriptional activity of HIV-1 is enhanced in patients with the two diseases, which might accelerate the natural progression of HIV infection.

A challenge for the future is to see how, in India, the TB programme and the AIDS programme can work together more closely. For many years those involved primarily in tackling TB and those involved primarily in tackling HIV/AIDS have largely pursued separate courses. The TB programmes have mainly concentrated on making sure that all TB patients have access to the basic essentials of TB control, while the HIV programmes have formulated their own strategies. There is a growing recognition today that there must be much a greater collaboration between the two. Such an enhanced endeavour will yield benefits for more effective use of medicines, the supply system, training and surveillance.

Studies have shown that prescriptions by general practitioners are extremely irrational in Maharashtra and West Bengal. A grant maker in the health sector could consider organising a dialogue, in these states, in an attempt to bring these two health programmes closer and also to bring government programmes closer to private practitioners.

HIV/AIDS

The National Health Policy document of the government of India – 2002 states in paragraph 1.5, "A new and extremely virulent communicable disease – HIV/AIDS – has emerged on the health scene since the declaration of the National Health Policy – 1983. Since there is no existing cure or vaccine for this infection, the disease constitutes a serious threat not merely to public health but to the economic development of the country." Surprisingly the only other references to HIV/AIDS are in Box IV of the document where it has been stated that the goal of the national programme is to achieve zero level growth of HIV/AIDS by the year 2007 and a passing reference in paragraph 4.3.1 that vertical programmes like HIV/AIDS would need to be continued till moderate levels of prevalence have been reached.

HIV/AIDS was first detected in India in the early 1980s. The disease has had a major impact in the states of Maharashtra, Tamil Nadu, Pondicherry and Manipur. According to the figures released by the WHO in December 2002, India had 12,239 reported cases of AIDS while HIV infection was present in 3,860,000 persons. The infection rate was 380 per 100,000 of the population.

In spite of the projection of goals enunciated in the National Health Policy there is no sign of abatement in the new cases of HIV/AIDS. HIV infections are no longer confined to high-risk behaviour groups such as commercial sex workers and transport workers, but have spread to all corners of the country. It is no longer present only in urban areas. Indeed, because of this emphasis, the National AIDS Control Organisation (NACO) has been criticised as it has confined its activities to sex workers and truck drivers in addition to setting up a country-wide network of sentinel centres.

The NACO statistics reveal that unprotected sexual intercourse accounts for nearly 83 per cent of the total HIV/AIDS cases. In Manipur and Nagaland, the predominant route for HIV transmission is the sharing of needles by intravenous drug users accounting for about four per cent. Transmission through blood and blood products account for another four per cent, while nearly two per cent of AIDS cases were due to prenatal infection – from an infected mother to the child during pregnancy. It would be wise to consider these figures as only a fraction of the HIV/AIDS morbidity in the country. The relationship between TB and AIDS has been discussed in the tuberculosis section. Some authorities state that nearly two-thirds of the opportunistic infections among AIDS patients is TB, which could lead sometimes to a dual epidemic of both TB and AIDS.

The HIV vaccine and the pricing of drugs: The extensive research being carried out globally and in India has not led to any vaccine being on the anvil. Some vaccines developed in research laboratories have gone on to clinical evaluation but have not demonstrated any beneficial effect. No such development for public health use can be foreseen in the next five years.

On the other hand, there has been a remarkable fall in the prices of drugs for the treatment of HIV and AIDS. And there are more drugs available today than before. The National Health Policy document statement that, "there is no existing cure or vaccine", needs to be modified. There are medicines today to treat patients with AIDS. It is up to us to use these medicines wisely – to determine which category of patients should be given the drugs, when these drugs should be given, how these drugs should be distributed and what doses of which drugs should be given.

Unfortunately, although the Indian pharmaceutical industry has played a leading role in bringing down the prices of antiretroviral drugs worldwide, no thought at all – till recently– was given to the use of anti-HIV drugs for our patients. The only policy decision that was being implemented in pilot studies was that a pregnant mother and her newborn should be treated with antiretroviral drugs so that 80 per cent of infants born from HIV-positive women would be free of HIV.

After considerable struggle, the Indian government has recently announced (in November 2003) that antiretroviral drugs would be made available free in the country's health programme to certain segments of HIV carriers. Pharmaceutical companies have agreed to lower the prices of these drugs as well.

The conclusion of the committee of the ICRIER on the current AIDS scenario in India in September 2001 was, "The response in India to the HIV/AIDS epidemic has been generally slow, often inadequate, and highly uneven. The epidemic, however, is at an early stage, and this provides both central and state governments with the opportunity to stabilise it over the next decade at no more than three per cent of the adult population."

A philanthropic organisation can take a careful look at the steps outlined to determine where to support work in spite of several national and international organisations like the World Bank, UNAIDS, the WHO and the Department for International Development, UK (DFID) supporting AIDS programmes in India. These steps are:

The Pricing of Drugs for the Treatment of AIDS

It would be interesting to look at what has been happening in the pharmaceutical sector in the last two years. Early in 2001, an Indian firm CIPLA made a dramatic offer, to price a three-drug combination for AIDS treatment at $350 for a year's supply to the organisation Medicines Sans Frontiers for free distribution for the AIDS programme in Africa. This price was as little as one-thirtieth to one-fortieth of the price of drugs available in the Western markets. Leading Western drug companies recently negotiated discount deals with Senegal, Uganda and Rwanda, which brought the cost down by 90 per cent. However, the price of the Cipla drug combination was still cheaper. Subsequently, the pharmaceutical house of Glaxo wrote to the drug distributor in Ghana and to Cipla stating that the sale of the generic version of its drug Combivir was illegal as they were violating company patents. As a result, the Indian company stopped selling its low-cost version of the combination. Other pharmaceutical houses have now brought down the prices of antiretroviral drugs to a fraction of what it cost before. The cost of treating HIV/AIDS patients would come to about Rs15,000 a month. Twelve antiretroviral drugs have been included in the WHO List of Essential Drugs.

- The development of a reliable database drawing from different kinds of surveys and surveillance systems and the mapping out of high-risk or core transmitter groups.

- The need for stronger political commitment.

- The involvement of the private health sector.

- The development of HIV/AIDS awareness and education programmes.

- The development of support services for those with AIDS.

- The recognition that HIV/AIDS is more than a health problem, affecting – as it does – every facet of human life.

Of these options, it is felt that developing awareness and education programmes along with a research base could be considered by a grant maker. It is the study of human sexual behaviour that will provide answers to questions such as why the use of condoms is so low in India. Whether there is a vaccine or not, it is here that a philanthropic organisation can make an effective contribution by bringing social and behavioural scientists in our country together to work in a given area and demonstrate how such a change, viz. behavioural change towards safe sex, can be brought about.

In view of the unexpected availability of anti-HIV drugs in the country at cheap prices, a philanthropic organisation could be the catalyst to organise meetings of clinicians, clinical pharmacologists, pharmacologists, toxicologists, health economics specialists, public health specialists and representatives of the pharmaceutical industry. The group could focus on issues like:

- The appropriate stage at which drugs should be used.

- The optional combination, dosage and regimen of administration.

- The distribution systems to be established.

- The training of doctors in the use of these drugs.

- The financial implications of providing antiretroviral drugs to some categories of HIV/AIDS patients and carriers.

A grant maker would advance the endeavour towards containing this dreaded disease if it supports such meetings. They could perhaps be organised by the Sir Dorabji Tata Institute of Tropical Medicine at Bangalore as part of its ongoing programme.

Malaria

The National Health Policy – 2000 has shown the epidemiological shift in the number of malaria cases over the years. There were 75 million cases in 1951, 2.7 million cases in 1981 and 2.2 million cases in 2000. What these figures do not say, of course, is that soon after India's malaria eradication programme commenced, the number of cases had been brought down to a record low figure of 0.1 million cases before it started rising again. The reasons for the short-lived success story of the 1960s are many and it may be useful to take a quick look at some of these factors.

The anti-malarial teams were disbanded and shifted to carry out work in the field of family planning. The use of DDT for spraying was curtailed as it was found to be toxic. Drug resistance started appearing. The states did not provide the assistance that they were supposed to under the pattern of assistance. And finally, vigilance for picking up new malaria cases was replaced by a misplaced sense of euphoric complacency that malaria was on its way out. In fact, when the Ciba

Research Centre started functioning at Goregaon, Mumbai in 1962, meetings were held to determine those areas where new medicines would be needed so that research programmes could be initiated by this centre in those areas. Professor Roy Chaudhury – one of the co-authors of this paper – was privileged to participate in those discussions. When the subject of malaria and the development of anti-malarial drugs was discussed, it was agreed by all the scientists that there was no need for activity in the field of malaria as it was nearly out. It is ironical that 40 years later, this paper suggests the need for better anti-malarial drugs and possible support for this activity in cases of chloroquine-resistant falciparum malaria.

After reaching the record low of 0.1 million cases, malaria resurfaced and the number of cases in 1976 were reported at 6.4 million. A modified plan of operation was launched in 1977 to contain the disease. The three objectives of the plan of operation were to prevent deaths, reduce morbidity and consolidate the gains. The number of malaria cases was brought down to about 2.14 million cases annually in 1984 and it has remained at about that level. Further decrease in the number of cases could have been achieved, but again there were constraining factors such as parasite resistance to conventional insecticides and anti-malarial drugs in high endemic areas and environmental changes caused by development activities which included rapid unplanned urbanisation and irrigation projects.

It should also be remembered that there are wide differences in the disease prevalence between different states in the country. This needs to be kept in mind if a grant maker considers supporting appropriate intervention in this field. Ten states in India account for 93 per cent of the total disease burden. The states in the list include Orissa, Bihar, Madhya Pradesh, West Bengal, Gujarat, Assam, Mizoram, Andhra Pradesh, Rajasthan and UP. Orissa, Madhya Pradesh, Rajasthan, Bihar and Maharashtra account for over 80 per cent of the total caseload. Madhya Pradesh and Orissa account for 50 per cent of the mortality cases.

The current programme involves a special strategy being implemented under the National Anti Malaria Programme (NAMP) in 28 towns, 318 districts, 10 per cent of the primary health centres and about 24,844 villages. These are all in the high endemic range. A total population of about 200 million would be covered by NAMP. In the high endemic areas, 100 per cent central assistance is provided under the World Bank-assisted Malaria Control Project. Funds have been provided for the provision of synthetic pyrethroids, impregnated bed nets, rapid diagnostic tests, artemisinin injections, vehicles, microscopes and also for advocacy and social mobilisation campaigns.

It is in this scenario that a philanthropic organisation needs to consider where its inputs could make a difference. An increasing cause of considerable concern is the growing number of malaria cases caused by plasmodium falciparum, the strain of malaria which is much more dangerous than the normally occurring plasmodium vivax. This type of infection causes death and is commonly referred to as 'cerebral malaria'. Particularly worrying is the fact that these cases are sometimes resistant to the common anti-malarial chloroquine. The number of chloroquine-resistant plasmodium falciparum cases has also increased and the number of deaths due to malaria has also increased.

The mainstay of the treatment of chloroquine-resistant falciparum malaria is quinine, but this is a toxic drug and quinine has to be administered in an injectable form. The

only ray of hope in recent years for treatment of this entity has been the discovery of artemisinin from herbal sources. This is, today, the only powerful non-toxic drug, which can cure chloroquine-resistant falciparum malaria. The three compounds artemisinin, artesunate and arteether were isolated around the year 1972 from the *quinghao-su* plant, Artemesia annua by Chinese scientists.

Fortunately cases of resistance to the artemisinin compounds are, up till now, few. However, with increasing use of this drug there is every possibility that resistance may develop. In that case we would be left with no drug. It was for this reason that artemisinin was not released for use for a few years although the drug was available. When deaths from chloroquine-resistant falciparum infection increased in different parts of the country, there was every reason to make it available. Even then, it was made absolutely clear that it was released only for hospital use.

It is important to find and develop at least one, if not two, other drugs for use in falciparum malaria. This could be a drug from our plant sources and from Ayurveda or the Unani system of medicine. It could also be a synthetic compound. It is suggested that initiating a research project, multi-centred to discover an anti-falciparum drug could be considered by a philanthropic organisation. It would be a focused study to prepare for the day when resistance develops to artemisinin. This would also fit in with the recommendations of the ICMR document *Priorities in Health Systems Research and Biomedical Research and Development – 2001*. They have stated that one of the priority activities would be to "screen and develop new anti-malarial, especially herbal-based products". This is a very broad mandate. The area being suggested for a grant maker is more focused. It could be "to develop an anti-malarial drug for chloroquine-resistant plasmodium falciparum infection from plants". This is an important niche that has not been specifically filled by any donor or national agency. The possibility of a vaccine for malaria has not been fulfilled and laboratory research, primate efficacy and clinical evaluation would take many years before such a vaccine, ever if discovered, could be made available to the public.

Reproductive Health

Problems and issues relating to maternal and child health and family planning are major concerns in the country in the field of reproductive health. In fact, the two cannot be separated. All the studies carried out till now suggest that population stabilisation could be achieved within a reasonable time frame if firstly, there could be an improvement in the quality of care provided at the primary health care and referral levels and secondly, if a wide range of contraceptive technologies could be made easily available throughout the country. There are 20 per cent of women of reproductive age in the country who

Vital Statistics

The National Family Health Survey – 1998-1999 reported that the total fertility rate for India was 2.8 per woman. The crude birth is around 26.1 with an annual population growth rate of 1.7. The contraceptive prevalence among married women of reproductive age (15-49) is 48.2. The extent of unsafe abortions is not known but the WHO publication, *Health Situation in the South East Asia Region (1998-2000)* carries a statement which says, "In India during 1990-1994, 11-14 per cent of maternal deaths in rural India were due to unsafe abortions." Further, 60 per cent of all abortion deaths in 1994 were of young women in the 15-24 year age group. The infant mortality rate (IMR) is around 67.6 per 1000 live births. The IMR is high when the mother's age is below 20 years, then declines in the 20-29 age group and rises in the 40-49 age group. Maternal mortality is around 440 maternal deaths per 100,000 live births.

would like to use contraceptives but who do not have easy access to these and are therefore, not using them. These two interventions, together with other measures, such as enhanced literacy and empowerment of women, would go a long way in stabilising our population. In addition, additional problems are unsafe abortions, high maternal morbidity and mortality, high infant mortality including perinatal and neonatal mortality and sexually-transmitted infections.

It is in this scenario that a foundation needs to think where the greatest needs are. Giving high priority to women's issues, such as reproductive health and the high level of maternal mortality is important.

Improvement in quality of care: One of the main focus areas of the national programme, in its endeavour to reduce the maternal mortality rate and enhance care of the newborn, is to increase the number of institutional births. At present, this is very low. To carry out this programme successfully and to increase the quality of care at the primary health care level, the government needs to enlist the cooperation and involvement of non-governmental organisations (NGOs) and practitioners of obstetrics and gynaecology in the private sector. Unless all these players act in concert and in partnership, the results will not be satisfactory. At the moment, though the government has been collaborating with NGOs to some extent, much more needs to be done. For example, there is no point in turning over the running of primary health centres to NGOs because they do not have experience in this. The requisite training needs to be given first. It is not necessary to confine this collaboration to NGOs only in the health field. NGOs with a good track record in other fields could be entrusted with this responsibility after some training.

It is proposed that a pilot project be initiated to see whether in six-eight districts this approach of partnership in the delivery of health services is successful. In addition to the private sector, industry in the area could be asked to participate in this effort. Already the Population Foundation of India has initiated highly innovative projects in reproductive health with active collaboration from the Tata Group and Ranbaxy. Setting up, at one or two centres, a model training programme for doctors from the NGO sector and for the private sector should be considered. Training would need to be provided in each of the following areas: family planning, maternal and child health, safe abortion techniques, sexually-transmitted diseases and infertility.

Providing easily accessible contraceptive methods – reducing the 'unmet need': The National Family Health Survey (1998-1999) states that about 40 million women in the country have an unmet need for contraception. If all these women (who have said that they would want to space or limit their births) could have access to family planning methods, then the current contraceptive prevalence rate of 48 per cent would rise to 64 per cent and this one step alone would begin, according to demographers, to lower the total fertility rate to replacement levels. The awareness appears to be there as also the desire to use contraceptives, but easy access to a wide range of contraceptive methods is not prevalent. The National Commission on Population set up a working group to look specifically at this aspect and to suggest strategies to address the unmet need of contraception.

The Commission recommended that a "basket of services" should be made available and that greater emphasis should be placed on increasing the choices among reversible contraceptive methods. New methods, such as the monthly injectable contraceptive for women and emergency contraception with RU-486 or leavonorgestrel should be made available with proper counselling after the safety, efficacy

and acceptability have been studied among Indian women in different parts of India. There are several new methods in the offing, including one or two technologies for males, complementing the only methods available to men today – which are vasectomies and condoms.

The problem appears to be in reaching these contraceptives to the potential users throughout the country. The Commission suggested that lessons could be taken from the Delhi model for the selection, procurement and distribution of drugs including measures to ensure quality control. It was felt that this model should be introduced in a few states. Availability of contraceptives and other medicines could be markedly improved by means of pooled procurement of a selected list of essential drugs and an efficient system of distribution.

It was felt that it was essential to reach out supplies and services everywhere, quickly and regularly. It may be necessary, once again, to reach out to the private sector and the corporate sector to learn how the products of the pharmaceutical houses and other commodities reach the far corners of the country. A suggestion now being tossed around in national policy making bodies is the possibility of actually entrusting the distribution of contraceptives and pharmaceuticals to the corporate sector. Other organisations should also be encouraged to join this programme. The Gram Panchayats could play an important role after being exposed to the issues and the challenges in the prevailing situation. Finally, selected staff from the 150 or more medical colleges scattered throughout the country could involve themselves much more in the reproductive health services of the country. This is being done in cities through the Federation of Obstetrics and Gynaecology, but more involvement could come in terms of systems research and in monitoring the programme at different levels.

Finally, research in the area of contraceptive technology needs to be supported because no country, other than China, is carrying out research in this vital area. Thus, no answers are forthcoming from the West. The government, perhaps, has not realised the tremendous cost in terms of human resources, materials and time needed to discover a new contraceptive or any new drug. The quantum of such long-term support is never available. One such area, particularly relevant to this country, is the development of a herbal contraceptive from our rich heritage of traditional medicine and medicinal plants. It is sad to note that this country which was in the forefront of international contraceptive research in the 1960s and 1970s, today has very few centres interested in this work. The centres at New Delhi, Chandigarh, Lucknow, Hyderabad, Jaipur, Ludhiana, Mumbai, Chennai, Varanasi and Bangalore – to mention a few – were at the front line of contraceptive research. Is it worthwhile to think of a resurgence in this sphere and is it something, which a sensitive philanthropic organisation could consider?

Diabetes

Diabetes mellitus has emerged as a major health threat, both globally and in India. There were, according to the World Health Organisation, 135 million diabetics in the world in 1995. The figure is expected to grow to 300 million by the year 2025. India, because of its number, has the largest diabetic population found in any country and equally alarming is the increase in the number. The percentage of population affected by diabetes is the second highest in India out of all the countries in the South-East Asia region of the WHO. Only Sri Lanka appears to have a higher percentage. In the 1970s, the prevalence of diabetes amongst

urban Indians was at 2.1 per cent. Today, it is 12.1 per cent. In addition, there is a very large number of Indians who are not yet diabetics, but who have an impaired glucose tolerance and many of these will suffer from diabetes in the future. There were 19.4 million individuals affected with diabetes in 1995. It is projected that by 2025 that figure will be at 57.6 million.

Why has there been such an increase in diabetes in Indians? It is difficult to pinpoint to one reason, more likely, it is a combination of several factors. A change in lifestyles – a more sedentary life with lack of exercise could be one reason. A change in diet with more intake of junk food and a diet of high-calorie fat would add to the risk factors of a person with irregular exercise. Increased longevity and a familial genetic background are also reasons, which need to be considered.

The effects of diabetes are on many organs. Diabetic patients are 25 times more likely to develop blindness, 17 times more likely to develop kidney disease and twice likely to suffer myocardial infarction or suffer a stroke than a person without diabetes. The disease, unless controlled at an early stage, affects the kidneys, the eyes, the coronary vessels and the nerves.

A national programme for the prevention and control of diabetes mellitus is needed and the government is in the process of developing such a strategy. The preventive strategy would be to provide information to the public about diabetes stressing the need for exercise and a balanced diet. The other major component of the strategy would be early diagnosis and prompt treatment. While diabetes is not yet a major health threat, the population needs to be informed more about this disease so that people can alter their lifestyle and food habits and avoid the disease. What is encouraging is that interventions of this type do lead to beneficial effects and some of the changes regress. This too, has to be made clear.

It is a pity that the National Health Policy statement does not give adequate importance to diabetes. It has been mentioned just once in paragraph 1.6, which says, "The period after the announcement of the National Health Plan – 83 has also seen an increase in mortality through lifestyle diseases – diabetes, cancer and cardiovascular diseases." While issues concerning cancer and cardiovascular diseases have been in the forefront, diabetes has not. Support by a grant maker in the vital area of creating awareness about diabetes through NGOs or providing support to some selected organisations would bring rich dividends in the years to come. No national organisation or group has taken up diabetes as its priority area of support.

The occasional disappearance in the market of insulin and the difference in prices of the different types of insulin are also areas, which have to be looked at. Finally, the Indian Systems of Medicine have several plants, which are used to treat diabetes both from Ayurveda and the Unani system of medicine. Some of these should be scientifically evaluated. The ICMR, after working on a plant called *viyjayasar* (Pterocarpus marsupium) for the last 12 years, has brought research to a stage when all the work can be handed over to a pharmaceutical concern for marketing. It has been a long and hard journey from the Madhya Pradesh jungles where it is found and from traditional medicine – supported by references in ancient Ayurvedic texts – to it becoming a drug. However, it could perhaps, help many people in India who need a mild anti-diabetic drug and particularly those who cannot afford to buy more expensive medicines.

Cardiovascular Diseases

The hidden epidemic of cardiovascular diseases in India and its accompaniments – stroke, hypertension and cancer – require intervention at the biological end as well as at the social end including lifestyle changes. There are immense opportunities here for highly relevant research to be undertaken within the various communities in India with different lifestyles, food habits and customs. As an example of an area, which could be funded to make a difference, is the study of the effects of yoga, meditation and other natural methods on the prevalence and control of coronary artery disease and hypertension. There are exciting opportunities in this regard to finding alternative ways of dealing with the new wave of non-communicable diseases.

The Delhi Model

The Delhi Model was first established in public sector teaching hospitals, smaller hospitals and health centres of the Delhi government. Its success was recognised and components of the programme are being implemented by the WHO and DSPRUD in 14 states. The programme, however, has been implemented, by and large, only in government or corporate hospitals. The challenge for the future is to initiate programmes in the rational use of medicines in the private sector and also to inform and educate the public so that they take the drugs prescribed properly and do not ask for unnecessary drugs.

The Delhi programme has been continuously assessed by the WHO review committees who are very positive about its success. The beneficial effects of the programme are:

- The medicines are procured at 30-35 per cent less than the prices paid for by other government agencies.
- The availability of medicines to the patients has increased remarkably and 90 per cent of the prescribed drugs are provided free to the patients.
- The quality of the medicines is good and the fear of substandard drugs being supplied has disappeared.
- The quality of prescribing, according to the WHO criteria, is very good.

Rational Use of Medicines

The rational use of medicines is a programme, which cuts across all other programmes and can be used in every sphere of therapeutic and prophylactic medicine. The WHO-supported programme, implemented in India by the Delhi Society for the Promotion of Rational Use of Drugs (DSPRUD) has demonstrated unequivocally that, without any additional expenditure, 90 per cent of the medicines being prescribed in Delhi government hospitals are actually provided free to the patients. These drugs are of good quality. Earlier only about 30 per cent of the drugs were available in the hospitals.

The basis of the concept of the rational use of medicines is that 90 per cent of diseases and symptoms of diseases can be treated by about 300 medicines. This is known as the List of Essential Drugs. Other components of the programme, which can only come into place after an Essential List of Drugs is in place are:

- A pooled procurement of medicines.
- A quantification of the medicines needed.
- A transparent two envelope system of procurement of medicines and effective distribution of medicines.
- The establishment of a system of quality assurance to ensure that the drugs are of good quality.
- Rational prescribing.
- Providing objective information to the doctors and to the public.

Side by side, the programme would need to have continuous monitoring and evaluation using quantitative indicators and run training programmes for all categories of persons dealing with medicines. Publications such as *Standard Treatment Guidelines* and *Formularies* and mechanisms such as drugs and therapeutic committees would be effective tools for this programme.

However, all the above achievements in the public sector fade into relative insignificance when one realises that the use of medicines in the public sector is only about 15 per cent of the drugs in use. It is in the private sector that an effective programme needs to be set up so that the public and patients do not unnecessarily pay more for medicines that they do not need or pay for more expensive medicines when a cheaper, equally effective medicine is available. This is not ethical, not economical and not good therapeutics. Perhaps, a philanthropic organisation could consider supporting a dialogue to discuss how this type of programme could be introduced in a few selected hospitals in the private sector.

It is heartening to note that while five years ago the rational use of drugs would not have found a mention in any policy document, today no policy document fails to mention its importance. The National Health Policy – 2002 states clearly in paragraph 4.11, "This policy emphasises the need for basing treatment regimens in both the public and private domain, on a limited number of essential drugs of a generic nature. This is a prerequisite for cost-effective public health care." The policy document very unusually actually mentions the need for preparing standard treatment guidelines in paragraph 4.16. "NHP – 2002 envisages the co-option of the non-governmental practitioners in the national disease control programmes so as to ensure that standard treatment protocols are followed in their day to day practice."

The Population Policy prepared by the Population Commission has dealt in depth with the issue of the rational use of drugs particularly emphasising the procurement and distribution of medicines and contraceptives and the need for the medicines to be of good quality. Similar recommendations have been made by the Planning Commission in the Tenth Five Year Plan, the ICMR in its 2001 policy document *Priorities in Health Systems Research and Biomedical Research and Development* and by the ICRIER (2001).

Food, Nutrition, Environment and Disease

Food security, nutritional security and health security are an interconnected chain. Food-associated infections are rampant and have not received much attention in the country. Appropriate projects for support in this area would be those that improve the skills of our laboratory scientists to detect food-associated infections and intoxication by prompt and reliable laboratory investigations to provide inputs for an appropriate health policy. The recent tragedy of epidemic dropsy in Delhi due to contamination of edible oil with Argemone mexicana should teach the nation a number of lessons in this area.

Environment and Disease: This area offers opportunities for research and application for the benefit of the human population in India. Again, the area is very vast and there are a number of agencies that are already working in this field. However, there are problems of acute concern to the public in which a philanthropic organisation can make a difference while working with other research agencies. Examples where a grant maker could be particularly effective are the problems of excess arsenic and fluoride in drinking water. These are well-known problems, but a recent shocking experience of the unfolding of the tragic sequelae of excess

fluoride in drinking water in parts of Rajasthan must open one's eyes to the need for developing simple and appropriate technology to bring down the levels of arsenic and fluoride in drinking water to permissible limits.

There is room for improved technologies to be developed but equally important is to install in communities, simple and acceptable technology that could be maintained by the communities themselves with technical support from skilled workers in the area. Pollution of environmental waters with toxic chemicals either as industrial effluents or as run off of insecticides into the waterways are again problems of vast dimension in need of practical measures of prevention and control. Modern methods of measuring atmospheric pollution need to be spread widely within the country so that the burden of pollution on humans in different cities could be quantified objectively and appropriate methods should be introduced for the reduction of these hazards. A sensitive philanthropic organisation could be receptive to projects that are submitted by competent institutions and organisations to delve into some of these aspects of environment, health and diseases.

For example, a grant maker could work closely with the Centre for Science and Environment (CSE) to identify priority areas in the field of environmental health. A sensitive philanthropic organisation could also avail of the expertise of organisations like the National Environmental Engineering Research Institute (NEERI) at Nagpur and the Council of Scientific and Industrial Research laboratories in identifying areas that could be supported in this field.

Traditional Medicine

No background paper on India's health system can be complete without recognising the fact that without the support of traditional medicine practices and the Indian Systems of Medicine such as Ayurveda, the Unani system, Sidha and Naturopathy, our health care structure could not function and would have collapsed, particularly in rural areas. The challenge for the future, as delineated in the National Policy on Indian Systems of Medicine and Homeopathy (2002), is to see how this system could be integrated more into the national health system, how harmonisation between the systems could occur, how a scientific base could be brought into the use of these systems and how more research could be undertaken to discover new medicines from the incomparable rich heritage we have been bestowed with – both within the treasure house of knowledge of these systems and the rich biodiversity that is still available to us.

The Indian government policy statement and the ICRIER report (2001) state that the true potential of these systems of medicine is still largely unrealised, despite the creation of a large and well dispersed infrastructure. It appears that even in the last 50 years the effect of centuries of neglect of systems such as Ayurveda has not been counteracted. Practitioners of these systems of medicine appear to have lost confidence in themselves and in the systems. The constantly recurring question as to whether the scientific methodology particularly in assessing the safety and efficacy of medicinal plants and traditional medicines has any relevance or is appropriate, has still not been resolved.

Collection of authentic plants, standardisation of the products and quality assurance are other areas which need attention. Even in research, in spite of scores of laboratories carrying out research on medicinal plants and despite there being hundreds of theses written by postgraduate students on medicinal plants, only one plant has found its way into the armamentarium of modern or allopathic medicine. This is *gum guggal* (Comnifera mukul) for reducing cholesterol

levels in patients with a high level of cholesterol. It is hoped that very soon *vijayasar* (Pterocarpus marsupium) will be the second plant. There is a need to take a good look at the way we have approached research on traditional medicines. This may then identify the factors why there has been so little progress in the discovery of drugs from our herbal sources. Recently, pharmaceutical houses have begun working on these plants to bring them out, not as drugs, but as herbal supplements.

Other issues, again unresolved, relate to the integration of the different systems – at least at the primary health care level. Whether undergraduate medical students in allopathy should be exposed to the concept and practice of the other systems of medicine and vice versa has often been discussed, but no clear-cut consensus has emerged.

Exports of medicinal plants from India to other countries are only a fraction of what percentage they could be at and far below the export earnings of our neighbour, China. Even in the area of conservation of plants identified for their medicinal value we have a long way to go. Even *gum guggal* is hardly available. The following quotation from the ICRIER report sums up the situation: "There was some recognition of the Indian Systems of Medicine (ISM) after independence, but very little was done by way of follow up. An institutional framework was indeed established to standardise education and drugs and to promote research, but inadequate attention by policy makers and insufficient financial support made these initiatives largely ineffective. ISM continued to be developed as a parallel stream with no attempt to synthesise or integrate the systems with modern medicine and assign them a role in public health." This last fact has also been brought out in the ISM policy document. The statement made says, "Although the government set up an independent department in 1995 to give focus to these issues, the ISM has not been able to play a significant role in health care delivery services for want of their legitimate involvement in public health programmes."

Studies in alternative medicine for discovering molecules in plants not known to science yet and extracting active principles by scientific research could be supported by a philanthropic organisation. Dr Dahanukar, an eminent researcher in traditional medicine, has said, that in addition to therapeutic substances, Ayurveda subscribes to the art of living healthy. Educating people on the usage of home remedies has a great role to play in self care. There is need to support valid documentation of folklore medicine. A panel of experts could be convened and the entire area could be carefully explored. In the vast area of traditional medicine, a philanthropic organisation could profitably focus on maternal health.

Following these observations one could identify two major areas where vital inputs and intervention programmes could be looked at by a grant giver. The first would be to support an all-round investigation of a traditional remedy or medicinal plant and help in its development as a new product. This would involve the collection of the material, pharmacognostic studies, toxicology, standardisation and clinical evaluation. Except for the ICMR, no other organisation has been willing to support such studies, not even the pharmaceutical houses who have chosen the easier route of making a combination of several plants and putting them on the market as a herbal health food.

The other area is to encourage and provide support for a field study to see whether the Indian System of Medicines could indeed be used in the health services in one or two districts. A successful model would go a long way towards the government initiating more pilot studies. The districts would have to be chosen carefully with

support from the local Panchayat actively elicited, support from the state and central governments would have to be obtained and the support of a team of public health specialists and Ayurvedic physicians would be needed. Special legal exemptions would have to be obtained for Ayurvedic physicians to use allopathic drugs and for allopathic physicians to prescribe Ayurvedic medicines. This should not be a problem as this would be considered a research project, besides the medicines could be prescribed jointly which would cover the legal provisions. It would be a difficult, but worthwhile study. Other interventions of a piecemeal nature are continuing, but have not lead to substantial progress in the right direction.

The area of traditional medicine needs a background paper of its own, but we have presented some of the issues and suggest two possible areas of support worthy of consideration by a funding organisation.

Drugs Discovery

It has often been said that after information technology, India's next success story could be in the area of pharmaceutical drugs development. The reasons for this belief are:

- The availability of a competent pool of scientists capable of discovering drugs.

- The abundance of leads for new drugs from the biodiversity present in India.

- The success story of the pharmaceutical industry in copying drugs allowed up till now.

- The successful export of drugs in the last decade.

The government also wishes to encourage drugs discovery in India. After 2005 when the provisions of TRIPS come into operation, our scientists may not be able to synthesise a drug discovered elsewhere by a different route of extraction or purification and claim its patent. In order to encourage and help the Indian pharmaceutical sector to carry out research, the Pharmaceutical Research and Development Committee has been set up. This Committee will help those pharmaceutical houses that qualify to become a research and development intensive company. Help would also be provided to them through another body, which has been set up – the Pharmaceutical Research and Development Support Fund. The Pharmaceutical Policy document of the government of India has suggested the following conditions for a pharmaceutical house to qualify as a research and development intensive company.

- It should invest at least five per cent of its turnover per annum in research and development (R & D).

- It should invest at least Rs 10 crore per annum in innovative research including drugs development.

- It must employ at least 100 research scientists in R & D in India.

- It should have been granted at least 10 patents for research done in India.

- It should own and operate manufacturing facilities in India.

The programme has been slow in getting off the ground and the takers have been few, but it is still too early to comment on the success or lack of success of this programme.

However, one has to be realistic and there are several serious constraints which would make it a difficult, if not an almost impossible task to convert a Rs 5 billion industry to a Rs 25

billion industry by 2020 – as is hoped and envisaged. Listed below are some of the constraints:

(1) The regulatory system for new drugs in India is not in keeping with the new role of Indian scientists discovering new molecules and trying to make them into drugs. The mechanisms of the regulatory body are slow and cumbersome. Several committees have suggested a major expansion of the capabilities and strengths of the office of the Drugs Controller General of India. There have been repeated calls for setting up a National Drug Agency. This agency would have expertise in the different disciplines related to the assessment of new drug submission. It would have its own laboratories with an adequate number of scientists. It would also have an expanded hand of pharmaceutical/ drug inspectors to look at the market and keep a watch out for sub-standard drugs. Unfortunately, in spite of the many recommendations, this body has not been set up although some marginal and some cosmetic changes have been made. The head of the organisation is no more the Drugs Controller of India, but the Drugs Controller General of India.

(2) There are very few centres in this country capable of carrying out reliable acute and subacute preclinical toxicology studies in India. This is a major obstacle. As a result, some pharmaceuticals have the toxicology carried out in countries outside India, an essential prerequisite for drugs development. Several times the toxicology of compounds developed in India is carried out in the Czech Republic and Poland. This is undesirable, as the quality of work at these laboratories cannot be verified.

Another unfortunate consequence is that several leading pharmaceuticals carry out studies on a potentially new compound in India and then, instead of carrying out further toxicological studies and clinical trials in India, the company sells the molecule to a pharmaceutical house outside India who would then arrange for these tests to be carried out. This is undesirable as drugs which could have been discovered and developed in India, may now be developed outside the country. In the long run this would have an effect on the pricing of the drug.

(3) There are very few centres where good, controlled clinical trials are carried out. The quality of most centres carrying out clinical trials of medicines is very poor.

(4) There are probably not more than one or two centres where reliable phase I studies can be carried out in this vast country.

(5) There is a great paucity of toxicologists and trained clinical pharmacologists to take compounds to the development stage. The only centre in India, which provides training and a super-specialist degree in clinical pharmacology is the Postgraduate Institute of Medical Education and Research, Chandigarh.

These are very serious drawbacks and it is clear that drugs discovery cannot be successful in India unless these constraints are removed.

The ICMR has started the development of a network of toxicology and clinical pharmacology centres at their existing centres by expanding the centres and adding to their strength. However, this will take time and would be functional in about three to five years time. The clinical pharmacology centres are being developed at the KEM Hospital, Mumbai, the Nair Hospital, Mumbai, the Tuberculosis Research Centre, Chennai and the Nizam Institute of Medical Sciences, Hyderabad. Toxicology centres are being established at the National Institute of Nutrition, Hyderabad, the National Institute

for Reproductive and Child Health Research, Mumbai and at the Central Drug Research Institute, Lucknow.

In this endeavour to take India into a different mode and pace of functioning, a philanthropic organisation would do a great service to the country if it could consider support for training people in all aspects of clinical pharmacology and toxicology relating to drugs development. Just as the International Clinical Epidemiology Network (INCLEN) has, for the last 10 years taken up the cause of training clinical epidemiologists from all over the world, some organisation is required at this time to provide strength and support for the training of toxicologists and clinical pharmacologists at different centres in India. The pharmaceutical industry needs to partner the other players in this endeavour, as eventually they would benefit as a result of good clinical trials being carried out in India. There is also a precedent here. In the United States of America, the pharmaceutical house Merck, Sharpe and Dohme took up this challenge. Together with the Rockefeller Foundation, Merck Sharpe and Dohme provided fellowships to investigators from different parts of the world but mainly to American doctors at American centres for training in clinical pharmacology. This has helped make the USA a leading centre of clinical pharmacology in the world.

Medical Ethics

There is a great need to teach medical ethics in the undergraduate medical curriculum as there has been a growing loss of credibility in the public about the medical profession. The increasing number of complaints (for example, to the Delhi Medical Council) against doctors for medical negligence, the many cases against doctors in the consumer courts and the criminal courts show that many doctors have not followed the precepts of being a member of a noble profession. As a result, one hears and reads of instances where doctors have been beaten up, clinics have been smashed and doctors have been taken into police custody and kept in jail. These were things one could not imagine 20 years ago.

There is also a growing feeling in many persons that they are not being dealt with fairly by the doctors. The perception is that unnecessary diagnostic tests have to be carried out and that these tests have to be carried out at a specific laboratory or x-ray clinic or Catscan centre, which would then give the doctor a part of the income from carrying out these tests – the practice commonly described as fee-splitting. The patient is often not certain why he or she has been asked to stay longer in a nursing home. Is it because he/she needs to do so or is it because the doctor is using this as an instrument to enhance the income of the hospital and his or her own intake? The patient is uncertain why he/she has to purchase expensive medicines. Does he/she really need them? Or is there a nexus between the pharmaceutical houses and the doctors to enhance the sale of a particular medicine and thereby accrue profit to the pharmaceutical house? The pharmaceutical house, in turn, provides the doctors who prescribe their drugs or who are likely prospects to prescribe their medicines with computers and expensive gifts, with free trips for him or her and the family in the garb of attending meetings to places like Goa and Singapore and other benefits like supporting his or her research work. This unfortunate, unethical conduct by doctors has been commented upon not only in the lay press, but also in professional journals.

Fresh medical graduates do not even necessarily know what constitutes ethical or unethical conduct and when they may end up being taken to court. In a recent case, we were told by medical doctors and the owner of a nursing home that they were not aware that it was unethical to send out printed circulars to

general practitioners in the neighborhood saying that if they sent patients to this nursing home, they would be paid 25 per cent of the fees as referral charges.

There are several other basic, ethical values which doctors sometimes violate. One increasingly common practice is to refuse to take into a hospital an emergency case such as an accident victim who is not in a position to pay. The ethical code of the doctor and the legal position is quite clear on this point. Providing information to the patient regarding treatment and illness is something that should be done if the patient wants the information. Yet, this is a very common complaint against doctors at smaller nursing homes.

There is, therefore, an urgent need in teaching medical ethics to the younger generation of would-be doctors. At this stage, their minds are fresh and if these concepts are ingrained in their thinking at such a time, it will stay with them throughout their lives. The medical colleges do not teach this and the state councils rarely even have a code of conduct.

It is proposed that in view of this great gap and since no organisation has made any attempt to close the gap, a funding agency could consider taking the initiative in introducing courses at a few selected medical colleges on medical ethics. The course curriculum would need to be prepared, tested in pilot studies and then implemented and its long-term effect studied. There would be organisations willing to provide technical help and there would be medical colleges willing to undertake this experiment. However, some resources are needed as well as imaginative leadership. Besides this, a round-table discussion could also be organised each year on the different aspects of medical ethics and the proceedings could be published and widely disseminated as a series.

The need for this type of activity has been recognised in the government's National Health Policy – 2000. Paragraph 4.2.1 states,"NHP-2002 envisages that in order to ensure that the common patient is not subjected to irrational or profit-driven medical regimen, a contemporary code of ethics is to be notified and rigorously implemented by the Medical Council of India."

Very closely linked to medical ethics in medical practice is ethical conduct of research. Here too, there is a need to teach young doctors what is considered unacceptable, unethical and illegal research. In the past few years, we have seen several cases of clinical trials with new drugs and a combination of drugs developed outside this country on patients in this country without any approval of either the Drugs Controller General of India or the ICMR. On questioning, in one case a leading doctor stated that he was not aware that such approval was necessary. These unethical conduct of trials are being held at both private and government medical centres. In another case, an investigator began clinical trials on a new anti-HIV vaccine developed outside the country without the approval of any organisation from within the country. A hospital in the city collaborated in the trial. Suddenly, one morning it was found that the chief investigator and his team had vanished leaving all their patients in the middle of the trial.

There are very clear guidelines and rules about sending out tissue samples and blood specimen outside the country for collaborative research. These rules are very fair, clear and transparent. Yet investigators do not follow these rules and only when something controversial breaks out, is there an outcry. In a recent case, the Indian investigator justified the sending out of samples by saying in an international scientific journal that she was not aware of these rules.

Finally, there are cases of fraud in research where results are reported when the research has not even been carried out or where the number of patients or animals participating in the research has been increased even though those numbers did not exist.

It is proposed that a sensitive philanthropic organisation could take a careful look at ethics in medical research and consider taking an initiative in this important area.

Leadership Development in Health

There is a need for the development of leadership in health. Over the years, leadership in health has deteriorated to a great extent and there are various reasons for this. Some of them are:

- The mediocrity of teachers in medical colleges in India.

- An equally depressing lack of leadership qualities in the health managers of the public health services at the centre and state level.

- The increasing role of the bureaucracy and non-medical persons in decision-making in health matters.

- The erosion of the autonomy of our leading institutions.

- The marginalisation of those few who have had the courage to go against the establishment.

- Political interference, particularly in top-level appointments and the management of our health services by persons of modest attainment who have reached these positions of power because of their political links or other reasons – and having reached these positions, have not functioned effectively.

This conveys the message that hard work and dedication go unrewarded, while persons with 'other' qualifications can get ahead. This indeed, is one of the main reasons for our doctors immigrating to the USA, Canada, Australia and the UK – believing that they would get a better and fairer deal in those countries.

Fortunately, there are still – even in this depressing scenario – a few outstanding leaders in health in the country, doctors with vision, dedication and charisma. It would be an opportunity lost if an effort was not made to make use of these dwindling numbers to create a new wave of emerging leaders in the health field. No organised programme that targets the development of leaders in the field of health has been initiated so far on a national scale – unlike programmes in leadership development in fields such as management sciences and information technology.

The INCLEN has recently, with support from the Rockefeller Foundation initiated a well-planned international programme for the development of leadership in health. This programme is being developed in India as well and this country's experience would be looked at carefully by the rest of the world.

Amongst other things, two workshops have been held titled, 'Managing Your Programme/ Project More Effectively' and 'Preparing The Next Generation Of Leaders'. Future workshops will deal with subjects such as time management, team and coalition building, conflict resolution, communication, e – conferencing and strategic planning. Modules have already been prepared in each of these areas with examples from health.

A new activity within this programme will be the Mentorship Programme in India. Potential leaders between the ages of 30-40 have been identified and will be classified as 'mentees'.

Criteria are being developed for the selection of the mentors – established leaders who have much to contribute. The mentor and the mentee would then be linked together in the hope that the mentee would gain qualities of leadership by having a 'hands-on' experience with a leader in the field.

It is suggested that a philanthropic organisation could take a look at the need for leadership development in health in this country. With its financial resources as well as its capacity to bring leaders from the corporate sector and the public sector into a programme of leadership development, a funding organisation could certainly make a difference.

VI. CONCLUSION

A background paper like this can perforce deal with certain areas and not deal with others. No paper on the health status in India can avoid giving major emphasis on the three diseases – tuberculosis, malaria and HIV/AIDS. This is also a global priority and a $ two billion trust has been formed called the Global Programme on TB, HIV and Malaria. A major contribution has been made by the Bill and Melinda Gates Foundation. The challenge is to use the funds in the most cost-effective way. Reproductive health is another area of concern in India and has been dealt with at some length. Diabetes is a totally new field, which has been added on because of its potential to grow at epidemic-like proportions and also because it has not received the attention or priority it deserves, either from the government and donor agencies or from NGOs.

While identifying areas of discussion, one factor taken into account is the need for support in this area of work. More specifically, we have earmarked the possibility that there could be a niche where support from philanthropy could make a big difference – a catalytic support leading to a substantial impact in a neglected, but vital area. Thus, suggestions for such support have been made throughout the paper. Areas, which are important, but have been well funded such as cancer have not been included.

Traditional medicine is a subject that deserves a background paper of its own. A few areas of possible interest have been brought out in this background paper. It is hoped that this will help to stimulate thinking about how best we can use this unique heritage of biodiversity and knowledge.

Drugs development and the rational use of drugs are discussed at length in this paper – the first subject has been tackled because the implications of drugs development need to be appreciated. Why the country has not been successful in this in the past and why it will not be successful in the future unless major steps are taken are important questions to raise. The rational use of drugs deals with equity, ethics, good therapeutics and management. It has been included because it cuts across all sectors. Finally, no organisation has looked at important concerns such as medical ethics and leadership in health and it was felt worthwhile to bring these to the fore for the attention of a philanthropic organisation.

In conclusion, a few observations about primary health care and the development of a surveillance response system would be in order. 'Health for All' was a concept propounded by the WHO in 1978, at Alma Ata. This was to be achieved through primary health care, which is a combination of preventive and promotive approaches to health as well as with treatment of endemic disorders in close collaboration with the communities themselves. There is an urgent need to rejuvenate the primary health care system in the country and to realise its full benefits. Any efforts by investigators to develop

appropriate models of primary health care deserve support. Very little attention has been paid to this important area by existing research agencies in the country. The integration of nutrition effectively into the primary health care system is also appropriate for a grant maker to encourage. Nutrition lies at the interface between agriculture, health and social sciences.

A tactical approach by a grant maker that would make a difference is to develop a protocol at the primary health centre level – through a pilot project which would give information to mothers on weaning foods and on health-promoting activities during the weaning period. An independent evaluation of the ongoing government nutrition programme such as the Integrated Child Development Scheme (ICDS) can make a valuable contribution. Carefully designed proposals on home remedies for maternal health/childcare could be supported financially with great benefit.

The emphasis in grant giving could shift to the development of a surveillance/response system at a national level. Being a method for disease control through the laboratory system, it would be the warning, which would activate the public health system to take action and control epidemics. The government of Kerala has taken the initiative and is developing a state level surveillance system. Dr Jacob John, is a pioneer in surveillance systems, and has made a proposal for developing such a system in Kerala. This can act as the forerunner for a nationwide system.

In applying science and technology for future health care, the focus should be on areas where community participation is part of the process. After evaluation, valuable knowledge from the research studies should be made into policy.

Lastly, a grant maker needs to be selective and identify people in the front line in areas of interest and solicit proposals from known individuals or institutions. The interventions need to be guided by the principles of availability, accessibility, responsive to the principle of equity, gender sensitivity, cost-effectiveness and sustainability.

Abbreviations

AIDS	:	Acquired Immuno Deficiency Syndrome
CSE	:	Centre for Science and Environment
CSIR	:	Council of Scientific and Industrial Research
DFID	:	Department for International Development, UK
DOTS	:	Directly observed treatment shortcourse
DSPRUD	:	Delhi Society for the Promotion of Rational Use of Drugs
HIV	:	Human Immuno Deficiency Virus
ICDS	:	Integrated Child Development Scheme
ICMR	:	Indian Council of Medical Research
ICRIER	:	Indian Council for Research on International Economic Relations
IISc	:	Indian Institute of Science
IMR	:	Infant mortality rate
INCLEN	:	International Clinical Epidemiology Network
ISM	:	Indian Systems of Medicine
KEM	:	King Edward Memorial Hospital
NACO	:	National AIDS Control Organisation
NAMP	:	National Anti Malaria Programme
NEERI	:	National Environmental Engineering Research Institute
NGO	:	Non-governmental organisation
NHP	:	National Health Policy
NIMHANS	:	National Institute of Mental Health and Neuro-Surgery
R & D	:	Research and development
RNTCP	:	Revised National TB Control Programme
SAT	:	Self administered therapy
TB	:	Tuberculosis
TIFR	:	Tata Institute of Fundamental Research
TMH	:	Tata Memorial Hospital
TRIPS	:	Trade Related Intellectual Property Rights System
WHO	:	World Health Organisation

Ranjit Roy Chaudhury

Professor Ranjit Roy Chaudhury is one of the leading clinical pharmacologists of the country. He has been head of the department of pharmocology, dean and director at the Postgraduate Institute of Medical Education and Research, Chandigarh from 1964 till 1981. He has also worked with the World Health Organisation in Geneva, Bangkok, Alexandria and Myanmar.

Professor Roy Chaudhury is currently an emeritus scientist at the National Institute of Immunology, New Delhi; the president of the Delhi Medical Council; and the president of the Delhi Society for the Promotion of Rational Use of Drugs. Since its inception, he has held the UNESCO Chair in the rational use of drugs at Chulalongkorn University, Bangkok and is the chairman of the International Clinical Epidemiology Network.

Professor Roy Chaudhury has written several books including three volumes of International Experience in the Rational Use of Drugs, Some Aspects of Toxicology, Herbal Medicine for Human Health, HIV/AIDS and Traditional Medicine *and* Enhancing Access of Medicines to the Undeserved. *He has also received many awards. Some of these are the Dr B C Roy Award, the Amrut Mody Award, the S S Bhatnagar Award, the Chulalongkorn Plaque and the Unitwin Award from UNESCO. In 1998, he received the prestigious Padma Shri in recognition for his contribution to the field of medicine.*

Sir Dorabji Tata Trust

Sir Dorabji Tata Trust is a philanthropic organisation established in 1932 by Sir Dorab Tata, son of Jamsetji Tata with a vision for the advancement of the country. Jamsetji was a man sensitive to the development needs of the nation and followed a philosophy of 'constructive philanthropy'. The Trust has pioneered institutions such as the Tata Institute of Fundamental Research, Tata Institute of Social Sciences, Tata Memorial Centre and the National Centre for the Performing Arts – the first of their kind in the country.

During the last decade, the Trust has also set up the Sir Dorabji Tata Trust Centre for Research in Tropical Diseases at the Indian Institute of Science, Bangalore, the JRD Tata Ecotechnology Centre at Chennai and the National Institute of Advanced Studies at Bangalore.

The work initiated by the Trust bears contemporary relevance as it continues to support innovative enterprises for development of the people of India. Thoughtful and committed work pioneered by voluntary organisations is supported in various fields of development. Need-based educational and medical grants are given to individuals. The Trust endeavours to uphold the vision of its founding trustees – that of nation building and of providing humanitarian assistance to improve the quality of life of the people of India.