



Clinical Medicine, Research and Primary Health Care – An Overview and Introduction to the Symposium

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Abstract – *Clinical medicine is an art based on science. It is exemplified by its intrinsic ability to heal, i.e. to prevent disease whenever possible and, if required, to effect a cure or to restore to health. Clinical research is most appropriately described as controlled clinical medicine. It entails clinical experimentation and the collection and analysis of data generated at the bedside of patients. Primary health care is essentially a combination of clinical medicine and clinical research aimed at promoting health, preventing disease and treating the sick. This may seem simple but, in reality, various extraneous factors influence clinical medicine, clinical research and primary health care. And, at the end of the various interactions, the patient who should be the most important person in the equation, often does not get optimal benefit and, at times, is adversely affected.*

The problems and the inequalities in health care, particularly in the developing countries, are legendary. The concept of primary health care based on equity and justice is a distant illusion for the vast majority in the developing countries. There can be little doubt that these countries, including India, face gigantic problems. Almost a billion or more people around the world are trapped in the vicious cycle of poverty, malnutrition, disease and despair. The stated goal of the World Health Organisation of 'Health for All by the year 2000' seems more like an unfulfilled dream as we embark upon the last decade of this century. Even the more limited objective of 'Health Care for All by the Year 2000' is most unlikely to be attained by the year 2000. This bleak scenario and related facts will be briefly discussed in this overview and introduction to the Symposium on "The Role of Clinical Research in Health Care Delivery in the Developing Countries".

INTRODUCTION

Countries of the Third World (now an obsolete term in view of the galloping changes in Russia and Eastern Europe), are generally classified as

the less developed or developing nations based on their technological and industrial developmental status and, inevitably, have widely differing health care status. Nevertheless, they have a commonality to the extent that many of their endemic problems

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are related to poverty, malnutrition, inadequate public health facilities and low purchasing power. There can be little doubt that these countries, including India, have a gigantic problem to resolve if the stated objective of the World Health Organisation of 'Health for All by 2000 A.D.' is to be achieved. The 'silent emergency' of infection and malnutrition kills almost 300,000 children worldwide every week, of which India's contribution is a staggering 20 per cent. It is just as unacceptable for so many millions of children to die every year of needless malnutrition and infection as it is for them to die in sudden droughts or famine. Even during the African crisis of 1985-86, more children died in the Indian subcontinent than in 46 nations of Africa put together - a staggering fact, to say the least. An analysis by the World Health Organisation in 1981 showed that one billion people were trapped in the vicious cycle of poverty, malnutrition, disease and despair. Here again, India's contribution to this depressing statistic is regrettably significant.

THE DEVELOPING WORLD

The problems of ill-health in the Developing World can only be solved by a judicious blend of various possible approaches to improve living conditions and standards of people, prophylactic measures such as universal immunization programmes, and curative intervention through use of appropriate therapeutic agents. The availability of medicines for endemic diseases prevalent in these countries to meet their qualitative and quantitative needs and the prospects of discovery, development and distribution of these drugs are also matters of both relevance and urgency. The inequalities in health care in India are legendary. Hospital-based and cure-oriented approaches towards medical services have largely benefited the upper crust of society, especially in urban India. These approaches have been at the cost of comprehensive health care services to the entire population. One does not need much expertise or imagination to conclude that radical changes are required in the quality and the extent of health care delivery available to the Indian masses in the final decade of the 20th century. And yet, after seven successive five-year plans when the budgets allocated for health care averaged two per cent or less of the gross national product (GNP), there seems little likelihood of additional funding in the foreseeable future. For instance, health, although universally recognised as an integral part of general socioeconomic development, does not appear anywhere in the 'thrust areas' of the Indian

Government, as published in early 1990 (see Appendix I).

Given that better health status for all citizens is a desirable outcome, planning is the foundation for action to achieve that outcome. In the health sector, most developing countries are characterised by:

- Poor health status of the population, as evidenced by high infant mortality rates and low life expectations at birth,
- Large inequalities in health status within the population, with women and children, the rural poor and underprivileged, the economically and politically weaker urban dwellers being especially vulnerable,
- Poor government investment in health, and
- Theoretical commitment of governments to free health care being poorly maintained in actual practice.

THE INDIAN SCENE

From the Indian experience, it has become clear over the tragically long period of four decades that the definition of desirable health goals within a time-frame and the identifiable strategies with which it is technically feasible to achieve the desired outcomes are not enough when attempts to set into motion the organisational mechanisms to mobilise the resources available, translate the strategies into reality at the grass roots level, and establish reliable processes for evaluation and midcourse corrections when necessary, are bogged down by a multitude of reasons and blot the landscape. The Government of India dedicated itself to the elimination of poverty, ignorance and ill health in 1950. An appraisal of the health situation of the country four decades later reveals a mixed scenario of success and failure. Life expectancy has increased consequent to the slow but steady decline in overall mortality. Some communicable diseases like small pox and plague have been eliminated, while others like cholera contained. The prevalence of immunizable diseases has registered a decline in recent years. Nevertheless, the overall morbidity pattern remains largely unchanged. Diarrhoeal disorders (amoebiasis and other causes), acute respiratory infections, malaria, tuberculosis, typhoid and viral hepatitis continue to take a heavy toll of the lives of our people. The problem of nutrition is not significantly alleviated. Adding to the burden of ill-health due to the aforesaid causes, is the emergence of new life-style diseases like coronary artery disease, hypertension, etc. Critical examination of the reasons for failure suggests that many of the programmes

and policies envisaged and implemented by successive Governments were probably ill-conceived and improperly executed. The social, cultural and environmental determinants of health were neither perceived nor incorporated into the strategies of control.

A critical assessment of the evolution of medical care in India clearly suggests that the inheritance of the allopathic system of medicine was unavoidable in independent India. The traditional systems were too fragmented and disorganised. A strong, educational edifice had already been built for western scientific medicine. The dramatic contribution of this type of medicine in saving human lives had just been highlighted by the advent of the antibiotic era. The country could, therefore, ill-afford to engage in debates on which system of health care to adopt. The role of modern medical care in meeting the health needs of the rural masses was well defined by expert committees such as the Bhore Committee (1943) and the National Health Planning Committee (1948). The inability of modern health care to deliver the goods in modern India was not due to the inappropriateness or irrelevance of allopathic medicine based on scientific principles. The practice of this type of medicine had its limitations because of the absence of a suitable and simultaneous developmental approach to provide basic inputs like education, safe drinking water, environmental sanitation, access to food and decent shelter for the rural and urban poor. The concomitant and seemingly unstoppable explosion in population in independent India compounded an already bleak scenario. In contrast, subsequent events showed that in parts of the country where overall development percolated to the grass roots level, as in Kerala and Lakshadweep, the pace of health development and care was encouraging.

While practically all the developing and developed countries have explicitly or implicitly adopted the World Health Organisation's Declaration of Health For All By 2000 A.D. (Alma Ata Declaration), the planned policies and modalities of implementation differ from country to country. India has adopted the approach of setting up Primary Health Centres under its own National Health Policies and various Five Year Plans within the overall control of the Ministry of Health and Family Welfare of the Central Government. Drugs (or medicines as I prefer to call them) constitute a significant component of health care.

Clinical Pharmacology

The regulations governing the approval of medicines on both sides of the Atlantic have become stricter by the day since the 1960s in the aftermath of the

thalidomide tragedy, particularly in the United States and the EEC countries where substantial evidence of both safety and efficacy of each medicine for each listed indication is now mandatory. Proponents of this system argue that the medicines available today are safer and more clearly effective for their specified indications. Critics argue that the system is too complex, discourages the development of new medications and delays the introduction of new therapeutic agents, thus indirectly causing harm to the public. The truth, as always, is reflected in a balanced, sober, intermediate position.

The Drug Regulatory Authorities in many developing countries, including India, have adopted regulations which are closely similar to those of the USA and the EEC countries without recognising the undeniable fact that the technical and clinical expertise and infrastructure do not exist in the country concerned for a meaningful implementation of the regulations. Thus, very often, the regulations remain on the statute book and various interpretations of them come into play, not necessarily ensuring that safety and efficacy are demonstrated as they should be, for the benefit of the indigenous population. It should be obvious to those who formulate policies that models for the developing countries must be tailored to the needs and real-life situations in the countries. Creation of these new approaches is both a challenge and an opportunity for these countries to take up, thus exploring the enormous potential to improve health worldwide.

In this regard, India has evolved policies which are similar in content to those of the affluent, developed countries. However, these policies often remain unimplemented because of the ever-increasing number of pharmaceutical manufacturing units across the country and the inadequate staff of the various State Drug Regulatory Authorities as well as the Central Drug Regulatory Authority to cope with the work entailed in strict monitoring. Thus, policies exist on paper but are unimplementable. Consequently, the real control of both pre-clinical and clinical aspects of the development of medicines, has been slow to evolve. The attention to critical issues such as Good Manufacturing Practice (GMP), Quality Assurance (QA), Good Clinical Practice (GCP) has been woefully inadequate. The implications of this for the consumer have received scant attention. Accountability is more often than not a theoretical concept rather than a mandatory requirement. The virtual absence of any regulations concerning the manufacture, quality, therapeutic claims and distribution of indigenous or herbal medicines is scandalous.

The role of well-equipped Clinical Pharmacology Units with properly trained staff in the generation of meaningful and relevant data from bioavailability and pharmacokinetic studies has so far been given less

importance than clinical trial data often emerging from busy clinical units where attention to fundamental requirements of controlled clinical trials is inadequate.

Millions of people in developing countries still have no access to life-saving drugs. Others such as Indians, although deluged with thousands of formulations under a bewildering choice of brand names, may also not have access to some life-saving drugs. Polypharmacy, for which the medical profession is responsible, and aggressive promotion of dubious drugs for which the responsibility must be laid at the doorstep of the pharmaceutical industry, are regrettably rampant in the developing countries. The vast majority of drugs continue to be available 'over the counter'. Irrational drugs and drug combinations continue to be available long after they have been withdrawn or banned in the developed countries. India looms large in the tragic realm of these facts not only because of its sheer size and population (estimated at being approximately 830 million at the time of writing) but also due to a lack of implementation of and a callous disregard for, regulations.

Biomedical Devices

The state of affairs concerning biomedical devices is not much better. The single most important factor which has slowed progress almost to a trickle at times is low perceived demand. But, in addition, the problems extend far beyond this fact. The reluctance of financing institutions to fund what they perceive to be high-risk low-return projects, the current apparent low local demand for biomedical devices, the unrestricted import and unfair competition from foreign products, the hesitancy of Indian consumers to use devices made in India, the absence of control of Indian 'look-alike' products and, last but not least, the scant attention – if any – paid to the critical and crucial concept of Good Manufacturing Practice (GMP) are but a few of the unfortunate facts which hamper good biomedical device production in this country. Here again, the ultimate loser is the Indian consumer.

Technology Transfer

The considerable international activity in technology transfer across national and continental boundaries of the past four decades has also affected the developing countries in many ways. Although numerous international and philanthropic agencies have supported the transfer of technology from the developed to the developing countries, there have been notable failures to blot the scenario of successful projects and the horizon of technological advance. The lessons

learnt from these experiences emphasize the need to be cognizant of a variety of socio-economic, geo-political and historical/cultural factors, in addition to the basic technical aspects that are necessary for successful technology transfer.

Medical Education

The common denominator in all aspects of Health Care is the doctor who should play a role both in the health strategies of the short-term where visible elements aimed at symptoms are critical and of the long-term where supportive elements aimed at causes are equally paramount. These strategies of the short and long-term are not mutually exclusive but complementary. Thus, the education of the doctor attains considerable importance. The need to change the undergraduate curriculum has long been recognised in many developing countries, including the Indian medical establishment. But this need has seldom led to constructive action. It is perhaps overdue to abandon the old British model with its ivory tower approach (now out of vogue even in Britain) in favour of less inflexible methods of teaching and a more practically oriented course to give the students a better appreciation of the prevalent diseases and health care problems in the community along with a realistic idea of how these may best be managed with limited resources.

Increases in student numbers without a concomitant increase of facilities or staff is a problem for many state-run medical schools. The clinical staff have vast service commitments as many hospitals are overflowing with patients. Systems which allow full-time staff in most state hospitals to leave the hospital earlier than they should to do private practice do not suggest that teaching students is seen as a priority. The medical student survives, gets corrupted by wrong methods and values, occasionally learns and leaves ill-equipped in various ways to be released on the unsuspecting population. The system often, though not always, accepts racehorses and turns out asses. In certain other instances, admissions to medical schools are based solely on the ability to pay capitation fees of not inconsiderable amounts with little, if any, attention paid to academic credentials, aptitude and motivation. In these institutions, more often than not, the quality of the input is the same as that of the output. Furthermore, the medical curriculum continues to rely on medical and surgical crises almost all of the time and not on Primary Care. Particularly in developing countries, many of the patients are caught up in the vicious cycle of poverty, malnutrition, disease and despair. The importance of being compassionate is paramount but is seldom taught.

William Osler, at the turn of the century wrote: 'Clinical medicine is a science of uncertainty and an art of probability. The most mature expression of the clinician's skill is the ability to make consistently good decisions when faced with uncertainty'. 'The task of medicine is to promote health, to prevent disease, and to treat the sick . . . These are not only medical functions but highly social functions', wrote H. E. Sigerist in 1943. The question that we need to ask ourselves is whether the young medical graduates churned out by many of the medical schools in India and the rest of the developing world will measure up to the task of Osler's definition of clinical medicine and Sigerist's simple but succinct definition of the task that faces all doctors. Clinical research, at the end of the day, is nothing more and nothing less than the controlled practice of clinical medicine. It does not necessarily require high technology or sophisticated gadgetry. It is merely medical research combined with professional care. Its essential components are: Sound knowledge of clinical medicine, self-confidence, enthusiasm, compassion for others, respect for truth, honesty, moral values and quality, resilience, hope and courage.

CONCLUSION

Tony Smith, in an editorial on 'Poverty and Health in the 1990s' of a recent number of the *British Medical Journal* (August 18-25, 1990), wrote: "In every country of the world, the rich are healthier than the poor. What it comes down to, in the end is that the poor are likely to remain unhealthy so long as they remain poor; conversely, the way to improve their health is to improve their economic state . . . eliminate poverty and health improves; everyone acknowledges this as the truth for the inhabitants of the slums and the shanty towns of the developing and some of the less developed countries. What recent research in social medicine has shown is that health continues to improve progressively as people get wealthier. If we care about the health of the poor we need to abolish their poverty".

The concepts of good clinical medicine, clinical research and primary health care are synonymous. They should be based on equity, acceptability, self determination and social justice. They should reflect the spirit of the 'Health for All' commitment introduced at Alma-Ata in 1978 and re-affirmed at Riga 10 years later. But the reality is that in many developing countries and in many areas of India, clinical medicine, clinical research and primary health care today are as they were in developed countries in the 18th and 19th centuries. The failure of this

triumvirate of interdependent entities can be justifiably attributed in these countries to one or more of the following reasons: a fragmented approach to health sector development, a lack of broad-based support for a viable national programme, obsolete organisational training, inadequate management support and on-the-job education, failure to develop a planning capability and to involve the local community in national and regional health care programmes and, last but not least, a failure to increase significantly the resources to enhance health care.

These and other related subjects formed the theme of a symposium on 'The Role of Clinical Research in Health Care Delivery in Developing Countries' attended by experts from India and abroad and a multidisciplinary audience at Madras in February 1990. The deliberations at the Symposium comprise this issue of *Current Science*. The Symposium was held under the aegis of the Menon Foundation, a neutral, non-profit, apolitical organisation.

APPENDIX I

THRUST AREAS OF NF GOVERNMENT*

- Long-term fiscal policy, Bills on right to work, and to information, Panchayat Raj, poll reforms and media autonomy.
- Fifty per cent of investments to be in rural and farm sectors.
- Priority to land reforms.
- New export-import policy to be announced on April 1, 1990.
- National security council, inter-State councils and high level judicial panel to be set up.
- New programmes for urban poor and welfare of women and tribals.
- Network of warehouses for farm products.
- Long-term policy on sugar mills licensing on March 31, 1990.

RECOMMENDED READING

1. Alma-Ata 1978. *Primary Health Care: Report of the International Conference on Primary Health Care, Alma-Ata, USSR, 6-12 September 1978*. Geneva: World Health Organisation, 1978.
2. Bang A, Patel A J (eds). *Health Care: Which Way To Go*. New Delhi: Medico Friend Circle, 1986.
3. Black D, Morris J N, Smith C, Townsend P. *Inequalities in Health: The Black Report*. Harmondsworth: Penguin, 1982 (First published by the DHSS, London, 1980).
4. Evans J R, Hall K L, Warford J. Shattuck Lecture - Health Care in the Developing World: Problems of Scarcity and

* *Financial Express*, January 2, 1990.

- Choice *The New England Journal of Medicine* 1981, 305(19) 1117-27
- 5 Javarao K A, Patel A J *Under The Lens: Health and Medicine* New Delhi: Medico Friend Circle, 1986
- 6 Sen Gupta A (ed) *Drug Industry and The Indian People*. New Delhi: Delhi Science Forum, 1986
7. Sigrist H E *Civilization and Disease*. Chicago: University of Chicago Press Phoenix Edition 1962. 241 (First published by Cornell University Press, 1943)
- 8 Smith R A Primary Health Care - Rhetoric or Reality? *World Health Forum* 1982, 3(1): 30-37
- 9 Smith T Poverty and Health in the 1990s *British Medical Journal* 1990, 301: 349-50.
- 10 World Health Organisation. *Global Strategy for Health for All by 2000 AD* Geneva 1981, 19

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The Menon Foundation

Established in the early 1980s, *The Menon Foundation* is a registered, non-profit organisation actively devoted to the educational, medical and social upliftment of society in keeping with their motto -



Many projects in rural health and development have been helped and sustained by the Foundation which has also assisted projects for handicapped children, and worked closely with organisations dedicated to the upliftment of the underprivileged. The Foundation also provides the funds for a major annual research award in medicine channelled through the ICMR, scholarships for meritorious students and help for the genuinely needy individual.

The Foundation has embarked upon a new and challenging phase in the 1990s. It organised the first of a series of symposia on 'The Role of Clinical Research in Health Care Delivery in Developing Countries' at Madras between February 22 and 25, 1990. The symposium which was a success, served as the Foundation's statement of intent to be a forum to discuss matters of importance in the Developing Countries.

This issue of *Current Science* records the proceedings of the symposium.

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HIV Virus in American University Students

The number of students enrolled at universities and other institutions of higher education in the United States of America is estimated to be approximately 13 million. Adolescents and young adults comprise the majority of this student population. This group often tends to experiment with sex in a country where society is tolerant. A recent survey conducted by the Centres for Disease Control in collaboration with the American Health Association to estimate the prevalence of Human Immunodeficiency Virus (HIV) among the aforesaid student population confirmed its presence on American university campuses. However, the rate of incidence (positive samples for antibodies to HIV) was 0.2 per cent, significantly lower than the rate of seroprevalence in the general population (0.4 per cent) which is the equivalent of one million people in the United States infected with HIV, and even more so than that of segments of the populations at risk (drug addicts, homosexuals). Nineteen universities were surveyed and 16,863 specimens were examined. The samples were tested for HIV antibodies by enzyme-linked immunosorbent assay and Western blot analysis. All but two of the infected students were men.

Excerpted from Gayle H D, Keeling R P, Garcia-Tunon M, *et al.* Prevalence of the human immuno-deficiency virus among university students. *The New England Journal of Medicine* 1990; 323: 1528-41.