



^a Roadmap for Research



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Apollo Hospitals

Educational and Research Foundation

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PREFACE

The Apollo Hospitals Group is today recognized as the “Architect of Healthcare” in India. Its history of accomplishments, unique ability in resource management and able deployment of technology and knowledge to the service of mankind, justifies its recognition in the Healthcare Industry within and outside the country. The Apollo Hospitals Group has continuously redefined excellence and levels of expertise, and this ceaseless pursuit has positioned the Group as the benchmark for quality healthcare in India. The Apollo Hospitals Group, which began as a 150-bed super speciality hospital in Chennai in the year 1983, today owns and manages 40 locations with a capacity of 8000 beds, in India, Sri Lanka and Bangladesh. Apollo is now a seamless, integrated healthcare delivery system, encompassing primary, secondary and tertiary care, health information technology, manpower sourcing and placement, medical business process outsourcing, hospital consultancy, pharmacy retailing, telemedicine and third party insurance. Apollo Hospitals has an ongoing collaboration with the renowned Johns Hopkins Medicine International of USA for research, particularly in the fields of Cardiology, Oncology, Neurology and Orthopedics. As the Apollo Group stands on the threshold of its third decade, the Group has built up resources that continue to create and augment value for its patients. The Group has been in the forefront of many a technology upgradation in the country and has been largely instrumental in putting India firmly on the International Healthcare map.

In the year 2005, The Apollo Hospitals Group instituted awards for 'Excellence in Healthcare' to honor the contribution of Indian and NRI physicians, whose work has contributed significantly in the alleviation of human suffering.

Apollo Hospitals Educational and Research Foundation (AHERF) was set up to undertake, promote and assist in scientific and medical research programs, having a bearing on the health, scientific, social, economic and industrial needs of India. Further, it is charged with a mission to undertake and promote fundamental, basic, translational and clinical research in all medical disciplines.

In accordance with its mission, AHERF has embarked on an ambitious project of education and research. This project will tap into the rich resource pool within the Group and harness this expertise for clinical and biomedical research. The Apollo Group is ideally suited to provide synergies in the complex field of research with its vast source of world-class doctors, a large and varied patient pool and comprehensive infrastructure in terms of equipment and support staff. AHERF aims to contribute significantly to

strengthening the country's research base and providing a knowledge bank from which other research studies can develop.

An area of keen focus for AHERF is the traditional medicine systems of the country such as Ayurveda and Unani. These systems have withstood the test of time and have many adherents. It will be AHERF's endeavour to bring modern scientific methods of research and enumeration into these traditional practices and also help establish standards of medicines, drugs and processes. The aim of this area of focus is to convert traditional medicine systems from 'alternative' into 'mainstream' medicine.

The Apollo Hospital Group is recognized for its DNB programme for post-graduate studies and AHERF intends to attract into its research initiatives, the best scientific brains with country. AHERF will nurture such research talent, both in-house and in collaboration with other researchers. The Group regularly conducts Continuing Medical Education programmes to keep senior and junior doctors abreast of the latest technical innovations. Consultants are encouraged to present research papers at national and international fora. With its reputation as a Center of Excellence, Apollo Group considers it imperative to be a leader in research, particularly in cutting edge areas like stem cell research, molecular diagnostics, genomics, pharmacogenetics, etc. This will help not only to deliver better clinical care within the Group but, more importantly, to establish the scientific credentials of the country.

Finally, on behalf of the Apollo Group, I would like to thank Prof Ranjit Roy Chaudhury and all members of the Apollo Task Force for Research, who despite their hectic schedules, attended and contributed to valuable deliberations over numerous meetings of the Task Force. Without their commitment, this road map would not have been possible.

Dr Anupam Sibal
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INTRODUCTION

This Road Map for Research by the Apollo Hospitals Educational and Research Foundation (AHERF) has been prepared as an instrument that would fulfill the vision of the management. It endeavours to strengthen and expand the research being carried out in the Apollo Group of Hospitals. It provides options to the AHERF, and to scientists and clinical researchers for carrying out quality, cutting-edge research keeping in mind the healthcare priorities of the country as well as the strengths of the Apollo Group of Hospitals. Developing a strong research programme would further reinforce the excellent existing standards of clinical care and state-of-the-art diagnostic facilities.

Any outstanding international medical centre needs to have a well-orchestrated audit of functioning activities at the highest level of clinical care, research and training. This is the aim of the Apollo Hospitals and this document provides the backdrop against which greatly enhanced activity in research will take place in the coming years.

The Task Force set up to prepare the Road Map had as its members the topmost researchers in the country. Keeping the standards of excellence of the Apollo Group of Hospitals in mind, members felt research should be carried out in areas described as 'cutting-edge' technology. Some of these areas have been identified in the first section and include stem cell research, research in molecular diagnostics, clinical proteomics and genomics, and pharmacogenetics. Research in these areas should be carried out in collaboration with institutes that have established facilities and expertise, but where researchers keenly feel the lack of access to clinical material.

The strength of the Apollo Group of Hospitals lies in its competent clinicians and clinical researchers, availability of a large number and variety of patients, state-of-the-art diagnostic, surgical and therapeutic technology, and an excellent medical records system. The Task Force was of the opinion that these strengths should be built upon. With some augmentation of resources, the Apollo Group of Hospitals could become a role model for and the leader in all clinical research in the region. Clinical trials' research would be one such area. There is an endeavour to make India an international centre for clinical trials, but not at the cost of ethics, transparency and equity. Besides the scientific value of carrying out such trials in India, there is a financial aspect to this as well. The clinical trials market in India will grow from Rs 225 crore in 2004 to Rs 1100 crore by the end of 2006, and is expected to grow at an even higher rate from 2006 to 2010. By that time, the Indian

pharmaceutical market would be valued at US\$ 1.2 billion according to the McKinsey report.

There is an urgent need for scientifically planned conduct of clinical research of some of our traditional medicines and herbal remedies. Research in traditional medicine has thus been included in the Road Map. These should be carried out with scientific rigour but without sacrificing the basic concepts of Ayurveda or the Unani system of medicine. The Apollo Group of Hospitals, working together with experts in traditional medicine, could take a leadership role in this area, particularly for diseases such as arthritis, bronchial asthma, hepatitis and diabetes. The use of traditional medicines is increasing in the West and it is estimated that in 2015 the market will be worth around a trillion US dollars.

Epidemiology forms the third key area identified by the Task Force. The Task Force is well aware that there are no epidemiological data on the prevalence of non-communicable and other diseases. This has created major problems for national planners in the health field. Baseline data could be collected by the Apollo Group of Hospitals located in different parts of India. This section also includes studies on the use of telemedicine — an area in which the Apollo Group has already taken innovative strides.

Research can only be carried out by trained investigators. A plan has been developed and outlined in the section on Developing Human Resources, which would ensure that qualified, trained human resources are available; more will be trained not only for the Apollo Group of Hospitals but nationwide. This programme would work closely with the Educational Programme already under way at the Apollo Hospitals. The McKinsey Report has calculated that India would need 50,000 trained professionals by 2010 if it is to benefit from this surge of international interest in carrying out clinical trials.

In the last section, the Task Force has dealt with some aspects of resource mobilization. Possible sources of international and national funding have also been indicated in the context of individual programmes.

It is hoped that the Road Map would prove useful to the AHERF in the years ahead. The Task Force is deeply appreciative of having been given this unique opportunity and expresses its gratitude to the management of Apollo Hospitals – Dr Prathap C. Reddy, Ms Shobana Kamineni (Vice Chairperson, Research Wing, AHERF) and Dr Anupam Sibal – for bringing the Task Force together.

Professor Ranjit Roy Chaudhury
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RESEARCH IN CUTTING-EDGE TECHNOLOGY

1.1 Stem cell research

Most cells in the human body are committed to fulfilling a single function in an organ such as the skin or heart. A unique set of cells are not so specialized. These cells – stem cells – retain their ability to differentiate into many or all cell types of the body and play a crucial role in repairing organs and body tissues throughout life. Stem cells have the potential to be used for the treatment of many incurable conditions. They can also be used as alternate therapeutic strategies for conditions that are difficult to treat and cure.

Embryonic as well as adult stem cells can be employed for clinical use. Although embryonic stem cells have considerable plasticity, there are several ethical and religious issues connected with their use. Adult stem cells also possess a good degree of plasticity and thus have potential for therapeutic use. The list of adult tissues reported to contain stem cells is growing and includes the bone marrow, peripheral blood, blood vessels, skeletal muscles, epithelium of the skin and digestive system, cornea, dental pulp of the tooth, retina, liver and pancreas. These can differentiate into three major types of brain cells (neurons, oligodendrocytes, astrocytes), skeletal muscle cells, cardiac muscle cells and liver cells. Stem cells from the bone marrow (stroma) can differentiate into cardiac muscle cells, fat, bone and cartilage, and stem cells from the brain can differentiate into blood and skeletal muscle cells.

An adult stem cell should be capable of self-renewal during the lifetime of the organ. Ideally, adult stem cells should be clonogenic and able to give rise to fully differentiated cells with mature phenotypes that are fully integrated into tissues and can perform the functions required of that tissue. The clinical application of haematopoietic stem cells has aroused great interest. These cells could be isolated or obtained from peripheral blood, umbilical cord blood and bone marrow.

Apollo Hospitals should set up a repository ('stem cell bank') of adult stem cells, especially

haematopoietic stem cells. These can be obtained from different sources such as the bone marrow or umbilical cord following birth. They can be collected from various hospitals (umbilical cord blood/peripheral blood/bone marrow) and from healthy donors (peripheral blood, bone marrow). Utmost care should be taken while collecting stem cells. Ethical practices should be kept in mind and the requirements and regulations of the government adhered to by following the guidelines of the Indian Council of Medical Research (ICMR) and Department of Biotechnology (DBT). All 'donors' need to undergo the following: (i) screening for infectious agents, (ii) pedigree assessment, and (iii) molecular genetic testing. Stem cells that have been isolated need to be characterized in terms of the morphology of cell surface markers, biochemical markers, gene expression and karyotype analysis. Collected cells that have been characterized can be cryopreserved for a long period; such cells are suitable for clinical use after the appropriate renewal procedure. After adequate clinical trials, the cells from the repository can eventually be used for the treatment of patients with incurable conditions.

For a start, studies could be carried out in clinical conditions such as cardiac disorders and diabetes, as well as in the areas of orthopaedics and oncology. The repository could be used for patients from Apollo Hospitals and later act as a 'service unit' for the supply of such cells to treat patients in hospitals other than those of the Apollo Group.

Short-term goal

This would be the development of a repository of well-characterized adult stem cells.

Long-term goals

1. To use these cells for therapeutic purposes, depending on the availability of appropriate infrastructure and the interest of doctors at the Apollo Hospital
2. To act as a 'service unit' for the provision of characterized cells to other hospitals

Institutes/centres/organizations for networking and collaboration

1. All India Institute of Medical Sciences (AIIMS), New Delhi
2. Post Graduate Institute of Medical Education and Research (PGIMER), Chandigarh
3. Christian Medical College (CMC), Vellore
4. LV Prasad Eye Institute, Hyderabad
5. National Centre for Cell Science, Bangalore

6. Centre for Cellular and Molecular Biology (CCMB), Hyderabad

Potential sources for funding

- Department of Biotechnology (DBT)
- Organizations in the private sector

1.2 Research in molecular diagnostics

Specific molecular tools could be set up for the diagnosis of ongoing infections, such as malaria, tuberculosis, hepatitis, cancer and lifestyle-related disorders. In addition, diagnostics to establish the aetiology of infertility, inborn errors of metabolism and mental retardation could also be developed. The objective should be to provide a specific diagnosis in the shortest possible time. The same facility could be used to provide predictive genetic diagnoses for lifestyle-related disorders. To achieve these aims, expertise in already proven and well-established technologies may be developed initially at one of the Apollo Group of Hospitals. Simultaneously, attempts should be made to develop simpler tests that can be used by the clinician at the bedside for certain infectious agents, thereby taking the diagnostic tools from the laboratory to the bedside of the patient. Such assays (one-step) may be based on lateral flow technology using colloidal gold or nanoparticles. In addition, polymerase chain reaction (PCR)-based assays for various infections and genetic abnormalities may also be established for the better care of inpatients and for the definitive diagnosis of outpatients. These studies could be carried out in collaboration with the DBT, AIIMS, Department of Biochemistry, Delhi University, Institute of Genomics and Integrative Biology (IGIB), Delhi University and the Dr B.R. Ambedkar Centre for Biomedical Research, New Delhi.

Short-term goal

To set up these molecular tools

Long-term goal

To use genetic markers to predict disease patterns

Potential sources of funding

- Department of Science and Technology (DST)
- Department of Biotechnology (DBT)
- The pharmaceutical Industry

1.3 Clinical proteomics and genomics

Clinical genomics and proteomics are other areas in which research should be initiated. Clinical genomics can be used to identify new genes that are switched on or off in response to a drug. Novel genes that are up-regulated or down-regulated in various cancers can be identified by micro-array or differential display reverse transcriptase PCR (DDRT-PCR). Protein profiling by two-dimensional SDS-PAGE gels can help in the identification and characterization of novel proteins that are present only in cancerous tissue. The proteomic approach can also be used to identify particular proteins expressed during the early stages of infections. These could form the basis for the development of new diagnostic assays and lead to the identification of new targets for drugs.

Short-term goal

The short-term goal is to build a repository of serum and saliva samples from patients coming for routine check-ups to Apollo. This programme could be a part of the ongoing Indian genome variation data collection project (IGVdb) of the Council of Scientific and Industrial Research (CSIR). The CSIR is building a database by screening various populations within India for polymorphism in a large selection of genes implicated in different complex diseases. Apollo can collaborate in carrying out polymorphism analysis in specific gene-related diseases.

Long-term goal

The long-term goal would be to develop a state-of-the-art research facility at the Apollo Group of Hospitals. This facility would not only perform highly sophisticated and sensitive assays in-house for better patient care but also provide novel therapeutic regimens that are not available in other hospitals. It should develop competence in undertaking basic and clinical research on topics of interest.

Collaborating centres

This programme could be carried out in collaboration with the National Institute of Immunology (NII) and the IGVdb of the CSIR.

Potential sources of funding

- Department of Biotechnology (DBT)
- Indian Council of Medical Research (ICMR)

1.4 Research in pharmacogenetics and the use of drugs

The incidence of a disease and its response to therapy is determined by the genetic profile of a population, the religious group and race. The same drug could therefore be curative in certain individuals, partially curative or ineffective in others and induce adverse drug reactions in some.

Recent advances in molecular genetics and genome sequencing have fuelled considerable interest in research in pharmacogenetics. New technologies permit rapid screening for specific polymorphisms as well as sequencing of target genes such as those coding for enzymes, ion channels and receptors involved in drug response. The focus, therefore, is on identifying specific genes and gene products associated with various diseases, and identifying genes and allelic variants of genes that affect the response to drugs. This mapping will identify specific genes implicated in diseases such as diabetes, cancer and arthritis. Thus, determining genetic variations that affect the efficacy of drugs in current use will have immense clinical application. This would enable clinicians to avoid empirical treatment and opt for targeted drug therapy.

Short-term goals

1. To determine individual patient genotypes and single nuclear polymorphisms (SNPs) in metabolic and degenerative disorders, and infectious diseases.
2. To monitor the response of current drugs or drug combinations in the situations mentioned earlier.

Long-term goals

1. To understand the mechanism of action of certain drugs
2. To identify the genetic factors that determine response to drugs
3. To develop guidelines for 'personalized' therapy
4. To identify new drug targets and develop new drugs

These studies could be carried out in collaboration with organizations such as the Dr B.R. Ambedkar Centre for Biomedical Research, New Delhi, CCMB, Hyderabad and IGIB, Delhi.

Potential sources of funding

- The pharmaceutical industry

- Private organizations such as the Sir Dorabji Tata Trust
- National Institutes of Health, Bethesda, USA
- World Health Organization (WHO)

1.5 Development of leads for new drugs

New drug development is a time-consuming and cost-intensive process involving multidisciplinary teams. The average cost of development of a new drug was over US\$ 1 billion in 2005 and the time taken was 10–12 years. The use of CombiChem has neither reduced the cost of nor the time required for drug development. The critical step in drug development is the discovery of lead molecules which may yield new drugs. Natural products and their derivatives have frequently generated leads. Currently, about 60% of drugs are either natural products or derivatives of natural products.

Another area which has gained importance is the discovery of new uses for known drugs. For this, patient treatment records have to be scanned and adverse drug reactions identified; these may throw up leads for a new use of an established drug.

Short-term goals

1. Computerize all treatment schedules disease-wise
2. Scan all adverse drug reactions (ADRs) drug-wise

Long-term goals

1. To identify possible new uses of known drugs by observing the side-effects
2. To develop the known drug for its new use by conducting clinical trials
3. To patent the new use of a known drug

Collaborating centres

- Central Drugs Research Institute (CDRI), Lucknow
- Indian Institute of Chemical Technology (IICT), Hyderabad
- Selected pharmaceutical houses

Potential sources of funding

- The pharmaceutical industry

1.6 Technology development

Technology development is taking place worldwide and much of it is being done by scientists of Indian origin. Apollo could take a lead in developing new devices which would benefit the entire human race, besides having commercial advantages. These devices would be cheaper for Indians and would enhance competence within the country. An important aspect would be the clinical evaluation of newly developed devices.

Some projects which could be undertaken are:

1. Development of metal stents such as cardiac, biliary and enteric stents
2. Prosthesis and implants for the knee, hip and spine
3. Development of wireless monitors and probes. Most monitoring devices have wires attached to them which restrict mobility
4. Development of computers for the paralysed. This project is ongoing with DST.

Short-term goal

Apollo could take up a project in collaboration with the Bioengineering department of the Indian Institute of Technology (IIT) to develop metallic stents and implants within two years of the onset of research.

Long-term goal

Apollo could collaborate with the Electronics/Bioengineering department of the IITs to develop wireless monitors and probes. The convenience of these would be welcome and make commercial sense in the long run.

Potential sources of funding

- Ministry of Science and Technology, Government of India
- The pharmaceutical industry

CLINICAL RESEARCH INCLUDING TRADITIONAL MEDICINE

2.1 Clinical trials

Apollo Hospitals has considerable experience in the ethical conduct of global multicentric clinical drug trials, mainly those in Phase III and some in Phase II and Phase IV (post-marketing).

The strengths of the Apollo Group are a dedicated Clinical Trials Unit and Site Management Organization (Spectra Clinical Research Centre merged into Apollo Hospitals Educational and Research Foundation [AHERF], a non-profit organization). This has competent, dedicated and well-qualified staff, state-of-the-art technology in diagnostics, qualified investigators, a large patient pool with diverse diseases and an Independent Ethics Committee functioning as per the ethical guidelines for biomedical research on human subjects issued by the ICMR and International Conference on Harmonization–Good Clinical Practices (ICH-GCP).

Short-term goals

1. Short-term courses could be developed to train clinical research coordinators and other personnel in the research methodology of clinical trials and GCP.
2. Courses could also be conducted on ethics in research for members of Ethics Committees from other hospitals.
3. Clinical research could be expanded to cover additional areas such as devices, interventions and diagnostics.

Long-term goals

1. The Clinical Trials Unit would be further strengthened and clinical trials conducted not only for pharmaceutical companies but also for government organizations, which would have access to the expertise and high-quality diagnostics available at the Apollo Hospitals.
2. The AHERF could develop clinical research-related documents such as study protocols, informed consent forms (ICFs) and case report forms (CRFs).

3. The existing site management services could be extended all over India to hospitals other than those of the Apollo Group.
4. The AHERF could conduct post-marketing surveillance and pharmacovigilance (Phase IV) studies in collaboration with contract research organizations (CROs).

Institutes/Centres/Organizations where networking and collaborative research could be carried out

In partnership with the ICMR, a centre of excellence would be developed for research and training in clinical trials, clinical research and clinical pharmacology. Apollo would work with reputed pharmaceutical houses and other government organizations such as the DBT, DST and CCMB.

Potential sources of funding

- The pharmaceutical industry
- World Health Organization (WHO)
- European Community
- Indian Council of Medical Research (ICMR)
- Kennedy Foundation, USA

2.2 Studies on the costs of treatment and diagnostics

The National Commission on Macroeconomics and Health has reported that the private sector attends to 65%–75% of cases of cerebrovascular accident (CVA), acute myocardial infarction (AMI) and fractures, and over 50% of cases of hypertension, diabetes and psychiatric illnesses. Nearly 57% of major surgeries and 37% of minor surgeries are performed by the private sector. This provides ample opportunity for undertaking research in assessing the costs of treatment and providing information on cost-effective treatment modalities and alternatives.

The private sector handles a large proportion of diagnostic procedures, especially for chronic diseases. For example, 74% of coronary angiographies are done in the private sector, and almost 50% of haematological and urine investigations. The costs to the patient, hospital and society are important determinants of a cost-effective strategy to facilitate policy-making by the government and other sectors, and help the patient in making informed choices. The Apollo Excellence Clinic Model, which provides information on clinical pathways for various illnesses, has already been developed.

The majority (80%) of full-time allopathic specialists and superspecialists in areas such as dentistry, cardiology, ophthalmology, orthopaedics and urology are in the private sector.

The large database from urban settings, outreach into smaller towns, excellent data management systems and an outstanding infrastructure provide a good platform for building research activities.

Short-term goals

1. *Quality of care assessment:* Apollo's network of tertiary care hospitals, as well as access to secondary and primary care infrastructure and facilities, provide a unique platform for assessing the quality of care in these settings. The multiple disciplines under Apollo's umbrella can provide excellent material for assessment of care practices, whether linked to surgery, physician performance or patient satisfaction. Research in this area will facilitate improvement in service delivery, quality of patient care and long-term outcome of health delivery.
2. *Health economics:* A cost-benefit analysis of health systems can be carried out. Initially, a baseline assessment is done followed by a post-assessment after introducing changes such as the rational use of drugs.
3. *Diagnostic algorithms:* The cost-benefit and cost-effectiveness of the use of sophisticated equipment can be compared with existing or less sophisticated equipment or tests. Some tests or diagnostics are not available in public-funded institutions, and Apollo can provide important cost-benefit analyses on the use of such tests/diagnostics by beneficiaries such as the government, corporate sector or insurance companies.

Long-term goals

Performance of the healthcare system: A trim, efficient manpower structure, with objective measures for evaluation of work performance in the private sector (Apollo) offers wide scope for evaluating the performance of the healthcare system. Research into departmental needs and functioning, and projections of future needs, especially those linked to technological developments, can be assessed.

Institutes where collaborative research could be carried out

While Apollo Hospitals and their network will form the research base, collaboration will be needed with some institutions to build research plans and parameters for evaluation. The Indian Institute of Health Management Research (IIHMR), Jaipur; IIT, Delhi; Indian Institute

of Management (IIM), Ahmedabad; Institute of Economic Growth, Delhi University; Departments of Community Medicine and Departments of Statistics from select medical institutions could be included in the network.

Potential sources of funding

- World Bank
- World Health Organization (WHO)
- European Community

2.3 Research in traditional medicines

A large number of Indians opt for traditional systems of medicine. Ayurveda, Unani, Homeopathy, Siddha and Yoga are some of the systems practiced throughout the country.

Drugs from herbal sources and other natural substances including heavy metals are often employed in such preparations. Traditional medicines mainly constitute herbal products, and are exported to various developed and developing countries as health foods and food additives.

The efficacy and safety of these drugs is often based on anecdotal accounts. Very few reports of scientifically conducted clinical trials are available. At present, it would be unwise to either accept or reject claims of the effectiveness and safety of these remedies. It is absolutely essential to carry out well-planned, randomized double-blind trials of these preparations while respecting the concepts of Ayurvedic or Unani medicine. These studies would need to be carried out in accordance with the scientific methodology of clinical trials.

Areas for research

Initially, clinical trials should be carried out in areas such as arthritis, bronchial asthma, diabetes and HIV/AIDS. At a later stage, clinical trials could be carried out for psoriasis, parasitic infestations and stroke.

Short-term goals

1. To strengthen the centre for Ayurvedic medicine at the Apollo Hospitals, Chennai and to establish such centres at other Apollo Hospitals in India.
2. To carry out clinical trials of one or two selected traditional medicines/ medicinal plants in the first two years.
3. To organize training courses for clinical trials in traditional medicine.

Long-term goal

To establish an international centre for clinical research and clinical trials in traditional medicine for South-East Asia.

Collaborating centres

Collaborating organizations could include the Central Council for Research in Ayurveda and Siddha (CCRAS), New Delhi; IIHMR, Jaipur; Arya Vaidyasala, Kottakkal; and the ICMR, New Delhi. Studies could also be carried out on the products of pharmaceutical houses active in the area of research in traditional medicine such as Dabur, Himalayan Drug Company and Zandu Pharmaceuticals. International support could be obtained from organizations that have expressed keen interest in supporting clinical trials in traditional medicine such as the National Institute of Alternative and Complementary Medicines, the Samueli Foundation and the Bill and Melinda Gates Foundation. Both technical and financial support could be available from these organizations. To conform to the Indian law, such clinical trials should be carried out under the joint supervision of qualified Indian Ayurvedic/Unani physicians.

Potential sources of funding

- Sir Dorabji Tata Trust
- Department of AYUSH, Government of India
- Council of Scientific and Industrial Research (CSIR)
- Samueli Foundation
- Bill and Melinda Gates Foundation
- Center for Complementary and Alternative Medicine, National Institutes of Health, Bethesda

2.4 Clinical research in areas identified by clinicians

From time to time, clinicians of various specialties come across new problems. Many problems could also be anticipated by laboratory scientists. These ideas should be followed through by carrying out initial exploratory research studies. Such research could result in interesting findings. A mechanism should be developed by which clinicians and laboratory personnel can be supported to pursue such research ideas.

Potential sources of funding

These would depend on the area of research.

EPIDEMIOLOGICAL RESEARCH

3.1 Prevalence of non-communicable diseases

The projected alarming rise in India of conditions such as coronary heart disease and diabetes underscores the importance of studying the prevalence of non-communicable diseases. The National Commission on Macroeconomics and Health (2005) has emphasized the need for such studies as these data do not exist.

These data would be collected at surveillance sites which would be set up close to the Apollo Hospitals. One surveillance site would be established for approximately 200,000 population (two administrative blocks).

The demographic profile of such a population would be as follows:

Below 5 years	30,000
0 – 15 years	80,000
15 – 20 years	100,000
Above 50 years	20,000

A field office with systems for monitoring and recording events and data management would be established. There would be a dedicated team with a team leader at each surveillance site.

Short-term goals

To generate data on the prevalence and incidence of non-communicable diseases in various age groups. Collaborative studies could be carried out with national bodies such as the Confederation of Indian Industry (CII), Federation of Indian Chambers of Commerce and Industry (FICCI) and Associated Chambers of Commerce and Industry of India (ASSOCHAM). Support could also be obtained from these national bodies and international agencies.

Long-term goals

Based on the information collected, intervention strategies would be developed to improve the healthcare of the community. Apollo could carry out this study with the International Clinical Epidemiology Network (INCLLEN) as its major partner.

Potential sources of funding

- Indian Council of Medical Research (ICMR)
- Ministry of Health and Family Welfare, Government of India
- World Health Organization (WHO)
- United States Agency for International Development (USAID)
- The pharmaceutical industry

3.2 Baseline data from different parts of India

Executives of Apollo Hospitals across the country have the facility to collect data on baseline health status. This information should be in a uniform and structured format. The wide geographical reach of the Apollo Group of Hospitals would be an advantage for this enterprise.

Short-term goals

Once this information has been collated and analysed, it would provide useful information on the upper middle class of the population, despite the biases of hospital data collected from self-referred subjects on the prevalence of different morbidities in this segment.

This segment of the population could be followed up in a longitudinal manner for the incidence of various morbidities/non-communicable disorders and associated risk factors.

Long-term goals

The information derived from these individuals on the potential risks could form the basis for intervention programmes initiated by the Apollo Hospitals.

Apollo can assemble or build cohorts of the employees of corporate houses. Subsequently, Apollo could initiate intervention programmes for the prevention of common non-communicable disorders among corporate employees.

Institutes/centres/organizations for networking and collaborative research

Linkages could be established with various corporate groups and insurance providers. Apollo can approach existing network of such studies.

Potential sources of funding

- Indian Council of Medical Research (ICMR)
- Council of Scientific and Industrial Research (CSIR)
- Confederation of Indian Industry (CII)
- Federation of Indian Chambers of Commerce and Industry (FICCI)
- World Health Organization (WHO)
- International Labour Organization (ILO)
- United Nations Children's Fund (UNICEF)
- Ministry of Human Resource Development (Department of Women and Child Development), Government of India

3.3 Collection of baseline health and morbidity data in schoolchildren

Apollo could adopt schools in cities, both upper class and middle to lower class, and offer periodic, structured check-ups as a service programme. This activity could start after calculating the sample size required.

Short-term goal

Information about childhood morbidities, especially non-communicable diseases, could be collected from all Apollo Hospitals. Besides increasing Apollo's client base, this would be a social service.

Long-term goal

Interventions could be designed and executed after studying the information generated during the initial phase of data collection.

Potential sources of funding

- Health and education departments of state governments
- United Nations International Children's Emergency Fund (UNICEF)
- World Health Organization (WHO)

3.4 Establishment of registries

The high-quality facilities available at the network of Apollo Hospitals would be very useful in

establishing registries, such as those for cancer in Hyderabad and Bilaspur. Collaboration with organizations such as the ICMR would help in creating registries, as none exist. National and regional data collected by Apollo could be linked to existing registry networks, particularly those coordinated by the ICMR.

Short-term goal

To ensure that the work-up of patients and the diagnosis of disease are in conformity with existing registries. This would enhance quality assurance. Initially, the programme should focus on malignancies.

Implementation

The team would consist of a pathologist and an oncologist supported by research staff that would be needed for data collection, data storage and processing. A formal agreement should be made with the ICMR for the establishment of these registries so that the data could be used for national programmes.

Long-term goal

Human leukocyte antigen (HLA) typing and similar registries could be started and linked with existing registries.

Potential sources of funding

The ICMR would be a likely source. Depending on the type of registry, other donors could be approached.

3.5 Health economics

In India, there is a paucity of high-quality validated data on the cost of different interventions. The National Commission on Macroeconomics and Health (2005) has stated that 'we were unable to find any studies or research which provided evidence demonstrating the efficacy of specific interventions under a programme in Indian conditions and among different population groups'. In addition, current research in the private sector falls short in providing financial and policy implications for the government on how best to contract the private sector.

Initiation of a series of studies based on the economics of health interventions is planned. One such area could be the introduction of a programme of rational use of medicines; the economic benefits of such a programme could be worked out after linking the results to the change in

morbidity and mortality brought about after introduction of the programme. Another area could be the economic consequences of the alarming rise in diabetes in India and the identification of cost-effective measures to combat this problem.

The effect of various modalities of health insurance on the healthcare delivery system, both in the corporate and the government sector, would be another important area for research.

Short-term goal

To develop expertise in carrying out health economics-related research at the Apollo Hospitals.

Long-term goal

To carry out such studies at the Apollo Group of Hospitals and at other satellite centres so that information from both the urban and the rural areas can be obtained.

Potential sources of funding

- World Bank
- Asian Development Bank (ADB)
- World Health Organization (WHO)
- Insurance companies

3.6 Research on the use of telemedicine

Telemedicine can be used for the diagnosis and treatment of diseases in areas where healthcare facilities are limited. Research on the use of telemedicine should focus on the following:

1. To determine the present health scenario in rural Tamil Nadu with reference to the availability of healthcare (in a sample of 10–15 villages)
2. To determine the present scenario in rural Tamil Nadu with reference to the availability of information and communication technology (in a sample of 10–15 villages)
3. To utilize a simple, indigenously fabricated, cost-effective, need-based telemedicine system (ReMeDi™) in existing wireless internet kiosks in rural areas to provide better healthcare to the villages.

Methodology

1. A major pilot project covering about 30 villages (100,000 individuals) would be carried

- out initially in Tamil Nadu.
2. Full details should be obtained about the prevalence of various diseases and how the population avails of healthcare at present — details of distance travelled, time taken, cost, non-availability of specialists, etc.
 3. A prototype should be tested of a low-cost telemedicine equipment now being clinically validated (low bandwidth webcam/wireless transmission of pulse/BP/heart sounds/ECG/EMR facility) using existing wireless internet kiosks and multipurpose kiosk operators.
 4. To evaluate in detail the difference that such a rural telemedicine network makes to the healthcare of villagers.

Short-term goal

To fine-tune a system by which trained villagers will use low-cost telemedicine equipment from internet kiosks to contact specialists in tertiary care urban hospitals for provision of healthcare to the remotest villages

Long-term goal

To extrapolate the lessons learnt in this pilot project to a larger study and eventually design a system by which rural telemedicine could be used nationally to provide healthcare to rural India. This will include diagnostic services, pharmacy services, etc.

Organizations where collaborative research would be carried out

1. Neurosynaptic Communications of the Tenet Group of the Indian Institute of Technology, Chennai (*see* www.neurosynaptic.com)
2. Chiraag section of En Logue Ltd (*see* www.n-logue.in)

Potential sources of funding

- The Planning Commission
- Department of Information Technology, Ministry of Information
- Indian Council of Medical Research
- Department of Science and Technology
- CSIR

DEVELOPING HUMAN RESOURCES

The following considerations have been kept in mind while devising the strategy for developing human resources:

1. The Apollo Group of Hospitals has competent clinical investigators carrying out research. However, constraints on the time available to them is an issue that needs to be addressed.
2. Many institutions and research centres in India are equipped with cutting-edge technology as well as trained scientists who carry out excellent laboratory research. However, they lack access to clinical material.
3. The excellent diagnostic and investigation facilities at the Apollo Group of Hospitals generate daily a large amount of data. These data are presently not being used for research.

The following steps are recommended to ensure that research could be initiated in the various areas outlined in this document.

1. Creation of a core group to coordinate research

It is proposed that a team of three members be constituted as the Research Coordinating Group. This Group would initiate, coordinate, monitor and evaluate the research programme, provide help to investigators at the Apollo Hospitals in developing projects, and mobilize resources for the research. The team should consist of a Director of Research who will take overall charge of the research programme, and two Associate Directors. One Associate Director would be in charge of all the training programmes while the second would look after the research projects, networking, collaborative research and resource mobilization.

2. Creation of Apollo Fellowships for Research

Around 6–8 carefully selected investigators should be awarded three-year fellowships to work full time on projects selected for research support as a follow up of this Task Force Report. These scientists should be given reasonable financial support to work for up to

three years at the Apollo Hospitals with clinicians who are the Principal Investigators of the projects. These fellows could also work towards a Master's degree in specialty areas recognized by a University. Selected fellows should be established investigators and bring with them their expertise and experience.

3. Creation of Apollo Adjunct Research Associates

It is envisaged that several of the research projects would be carried out in collaboration with institutes and centres where sophisticated laboratory procedures required for research are already in place. Thus, there would be no need to establish similar facilities at the Apollo Hospitals. Scientists from these institutes collaborating with Apollo investigators could be given the designation of Apollo Adjunct Research Associates. Being recognized by Apollo would be a mark of distinction for these scientists. They would get recognition in the form of papers published and receive further training and exposure to the areas of research being undertaken by Apollo. Apollo Adjunct Research Associates could be paid a modest honorarium in consultation with their parent institute

4. Bringing consultants for short periods to Apollo to develop specific areas and train staff

These carefully selected experts would be brought in from different centres in India or, if necessary, from abroad to set up specific technology as needed and train local staff.

5. Sending Apollo staff for training

If needed, Apollo staff should be sent for specific training to centres in India or abroad.

6. Secondment for research

Staff members of Apollo with a track record of research should be encouraged. They should be willing to reduce the time spent on clinical work to 25% and carry out research in selected areas for 75% of their time. This will improve the quality of research at the Apollo Hospitals. The management may consider ways to compensate them for their loss of earnings from clinical work.

7. Workshops, seminars and training courses

These already form an important part of the activities of the Apollo Group of Hospitals. These activities will be strengthened, especially in priority areas of the Apollo Research

programme. For example, in the field of clinical trials, the Apollo Clinical Trials training programme could become an annual international event for clinical researchers from all over South-East Asia, the Middle East and Far East. Special programmes on clinical trials of traditional and herbal medicines would also be of great interest to scientists in Europe, the UK and the USA. Emphasis on training in this field could clearly result in Apollo Hospitals emerging as a global leader in the area of clinical trials research. In addition, special programmes in clinical trials methodology would be held for clinicians at the Apollo Hospitals. The area of clinical trials is merely an example; many more areas could be explored in the same way.

Potential sources of funding

- Wellcome Foundation
- Fogarty Foundation
- Indian Council of Medical Research (ICMR)
- Departments of Health and Family Welfare and AYUSH, Government of India

RESOURCE MOBILIZATION

In recent years, resources available for research have increased several-fold. This is due in part to the rise in budgets of national research-supporting organizations such as the ICMR and Department of Biotechnology (DBT), as well as support from external sources such as the World Bank, the European Community and the Bill and Melinda Gates Foundation. It would appear that any well-planned programme of research could, in theory, be able to obtain research support.

Another positive trend is that resources and support for research from national and international sources are now being offered largely to private sector research organizations and non-governmental organizations. The earlier reticence to support research in the private sector is no longer there.

The corporate sector has realized that corporate social responsibility demands that funds be allocated from their budgets for research. In addition to organizations supporting research unilaterally, as was being done to some degree in the past, today organizations such as the CII and FICCI also support research activities.

In view of this changed climate, it should not be difficult to obtain research support for the different programmes envisaged. Funding could be obtained from outside Apollo but some initial seed money from the AHERF would be needed.

A few issues need to be kept in mind. Donors, particularly international donors, have already identified their priority areas of research. A 'donor profile' has to be prepared and kept up to date to help researchers. Not only do donors have their own areas of interest (e.g. the Bill and Melinda Gates Foundation are interested in supporting research on HIV/AIDS and malaria), but several large donors have also identified geographical areas where they would provide support. The Department for International Development (DFID), UK would, for example, provide support for projects in Himachal Pradesh while the German aid agency, GTZ would provide support for research in West Bengal. The request for research support has thus to be tailored, not only according to the need of the

researcher but also according to the profile of the donor.

Another possible source of funding for research would be from international agencies such as the World Bank, the National Institutes of Health, Bethesda, the European Community and the Wellcome Foundation, who advertise regularly asking researchers and organizations to apply for grants in specific areas that these organizations have already identified. These grants are open to Indian organizations and Indian researchers, and the selection of grantees is fair and transparent. The conditions of the grant, however, have to be met.

These donors would prefer to support research projects carried out by a group of institutions or where at least two institutes are working together as a consortium. That is why this report has identified potential partners where possible. For example, a joint proposal by the AHERF and the NII for research on clinical proteomics would have much more success in obtaining a grant than if only one organization was to apply.

Finally, the proposals submitted must be of good scientific quality. These should be carefully reviewed by the topmost experts in the field. A joint programme would then need to be developed and submitted to the appropriate organization, which would already have been identified by the investigator or the coordinating unit of the AHERF.

One prerequisite for obtaining grants from government agencies is recognition of the AHERF as a research organization by the Department of Scientific and Industrial Research (DSIR).

Long-term support could also be obtained from pharmaceutical houses interested in developing quality facilities and identifying investigators for continued clinical evaluation of their drugs. This could form a mutually beneficial partnership.

THE WAY FORWARD

The Road Map needs to be widely disseminated to all clinicians and researchers at all the Apollo Hospitals. Only a few of the proposals outlined in the document would be implemented in the first phase.

As early as possible, the core team of three would need to be in position. Doctors who would like to be chief investigators in any of these areas would need to be identified. The chief investigator would then, with the help of the research coordinator, identify a research partner outside the Apollo Hospitals, if necessary. Most of the proposals in the areas of cutting-edge technology and epidemiology would probably need collaborative research. The chief investigator would then, with the Director of Research, approach the institute concerned and work out a Memorandum of Understanding. This would be followed by the writing up of a proposal for financial support of the research to be undertaken. The potential organization which would be asked for support should also be identified before the research proposal is written and discussed with a representative of that organization.

Once the proposal for support has been written it should be discussed in-house, particularly with other units of the Apollo Hospitals which would be participating in the study. The proposal should then be submitted to the Institutional Ethics Committee for approval. If the proposal is for a drug trial, it should also be submitted to the Drugs Controller General of India. The pharmaceutical house or institute sponsoring or collaborating in the trial could also take on this responsibility.

A donor profile would have to be prepared along the lines described earlier. To obtain resources from agencies and donors supporting biomedical research, one person in the coordinating unit would need to have a dialogue with these agencies and get to know their priorities. Such agencies are also on the look out for institutes and centres where the research they are interested in could be carried out. A special effort would need to be made to develop

relationships with agencies in the corporate sector willing to support research as part of their corporate civil responsibility. Very often, they do not know how to identify centres where support should be given.

Training programmes that are already ongoing in the Apollo Hospitals should be expanded to include areas identified in the report. In due course, some of these could become international training programmes. One such programme that would be of interest to donors and also benefit Apollo researchers and India would be 'Leadership for health'. The Coordinating Group would need to be pro-active and link up the training programmes at Apollo with University courses and programmes. In the important field of public health, much innovative activity is likely to take place in the future. The Apollo Hospitals Research Programme should definitely be a part of this programme.

The way ahead is challenging, exciting and full of potential. The approach needs to be pragmatic and innovative. It should be kept in mind, however, that whatever is done as part of this research programme at Apollo should be of the highest quality. This should become the hallmark of research at Apollo, and would set the standards for research not only for corporate hospitals in India but also for national institutes and medical colleges throughout the country. There is every reason for this to be achieved.

APPENDIX – SOME AGENCIES SUPPORTING RESEARCH

1.0 National organizations

Government

- Ministry of Health and Family Welfare
- Ministry of Science and Technology
- Indian Council of Medical Research
- Council of Scientific and Industrial Research
- Department of AYUSH
- Ministry of Environment and Forests

Non-government

- Sir Dorabji Tata Trust
- Confederation of Indian Industry
- Federation of the Indian Chambers of Commerce and Industry
- PHD Chamber of Commerce
- Pharmaceutical houses

2.0 International organizations

UN agencies

- World Health Organization
- UNICEF
- UNAIDS
- Global Fund for HIV/AIDS, TB and Malaria
- European Community

Government agencies

- National Institutes of Health, USA
- Center for Applied and Complementary Medicine, USA
- Fogarty Foundation, USA
- DFID, UK
- GTZ, Germany
- Save the Children Fund

- Canadian International Development Agency (CIDA)
- Swedish International Development Agency (SIDA)
- Netherlands Development Agency

Private agencies/foundations

- Rockefeller Foundation
- OXFAM
- Ford Foundation
- Population Council
- Bill and Melinda Gates Foundation
- Wellcome Foundation
- International Clinical Epidemiology Network (INCLIN)
- Sasakawa Foundation

APPENDIX – ABBREVIATIONS

ADB	Asian Development Bank
ADR	Adverse drug reaction
AHERF	Apollo Hospitals Educational and Research Foundation
AIIMS	All India Institute of Medical Sciences
AMI	Acute myocardial infarctions
ASSOCHAM	Associated Chambers of Commerce and Industry of India
CCMB	Centre for Cellular and Molecular Biology
CCRAS	Central Council for Research in Ayurveda and Siddha
CDRI	Central Drugs Research Institute
CIDA	Canadian International Development Agency
CII	Confederation of Indian Industry
CMC	Christian Medical College
CRO	Contract research organization
CSIR	Council of Scientific and Industrial Research
CVA	Cerebrovascular accident
DBT	Department of Biotechnology
DFID	Department for International Development, UK
DST	Department of Science and Technology
FICCI	Federation of Indian Chambers of Commerce and Industry
GTZ	German aid agency
HLA	Human leukocyte antigen
ICF	Informed consent form

ICH-GCP	International Conference on Harmonization–Good Clinical Practices
ICMR	Indian Council of Medical Research
IGIB	Institute of Genomics and Integrative Biology
IGVdb	Indian genome variation data collection project
IICT	Indian Institute of Chemical Technology
IIHMR	Indian Institute of Health Management Research, Jaipur
IIM	Indian Institute of Management
IIT	Indian Institute of Technology
ILO	International Labour Organization
INCLIN	International Clinical Epidemiology Network
NII	National Institute of Immunology
OPD	Outpatient department
PGIMER	Postgraduate Institute of Medical Education and Research
SIDA	Swedish International Development Agency
SNP	Single nuclear polymorphism
UNICEF	United Nations International Children's Emergency Fund
USAID	United States Agency for International Development
WHO	World Health Organization

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