







Report of Proceedings

Integrating Traditional South Asian
Medicine into Modern Health Care Systems

October 4-6, 2012 Jawaharlal Nehru University, New Delhi



Collaboratively organised by

Martin-Luther-Universität Halle-Wittenberg, Germany

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India Chapter-International Association for the Study of Traditional Asian Medicine

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REPORT OF PROCEEDINGS

International Workshop on "Integrating Traditional South Asian Medicine into Modern Health Care Systems"

October 4-6, 2012

Jawaharlal Nehru University (JNU) New Delhi – India

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Traditional medicine (TM) encompasses a broad and disparate spectrum of healing systems ranging from the codified and systematised forms of knowledge¹ to the non-codified traditional home remedies and folk practices². In recent times, different forms of TM are new relevance as health-seeking behaviour acquiring convincingly demonstrate that the general public seeks help from a range of health care knowledge systems because they realise that no single medical system has the best solutions for all modern health care needs. These are gaining increasing policy importance in public health care in all settings with the growing understanding of the limitations of a singular approach in addressing the needs of people. Moreover, TM retains a special significance in environments wherein modern medicine (MM) is not available, or is not cost-effective, or fails to deliver results. Though TM is being globally recognised within the formal health care systems and also being furthered by the WHO, this poses several challenges for modern health care systems because of the characteristic features of TM that are often at variance with the parameters of such modern systems. This scenario is further complicated by the innumerable forms of non-codified systems of LHTs that are not amenable to conventional methods of systematisation.

In the context of the recognition and resurgence of TM globally and concerted efforts at integrating it with existing modern health care systems, there are certain issues that particularly relate to Standards and Regulations of AYUSH and LHTs, which need to be critically understood and examined.

1. Among different stakeholder groups in the health sector in India, there is a strong realisation for developing mechanisms to ensure quality of services of AYUSH and LHTs. Moreover, research conducted by the National Health Systems Resource Centre (NHSRC) has indicated high utilisation of AYUSH services in the country wherever they have been provided with reasonable quality. However, little attention has been paid to these services from a health systems perspective in both the public and private sectors, in

¹ In India put together under the official acronym of AYUSH, i.e., Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Rigpa and Homeopathy.

² In official parlance it is often referred to as Local Health Traditions, i.e., LHTs.

- the context of local health traditions and folk practitioners, and in areas of integrative and inter-disciplinary research.
- 2. On the other hand, there is the German/EU systems' concern and need for standards and regulations to formally integrate Ayurveda and other Indian Systems of Medicine into their health care system. Presently, there is a negative formal response to Ayurveda and its medicines in several European countries, even while their practice outside the formal structures is increasing. Therefore, questions that need to be answered include: How can Ayurveda be defined, keeping its diversity, context specificity and holistic nature intact? What standards can be/have been developed to ensure quality of AYUSH services and products? What form of standardisation would be acceptable both to the modern systems of health care and the principles of Ayurveda?
- 3. An important need is to also give a rational basis to the existing pluralistic health-seeking practice of the lay people as people have developed their own system of making use of the various 'pathies' by experience and rule of thumb. These need to be validated and strengthened where positive, and corrected if irrational elements are found.

Therefore, the standards and regulations that are to be used for monitoring systems of traditional medicine must be such that these systems can be adopted and assimilated in modern health care systems, without losing their inherently rich diversity by way of getting homogenised and retaining their basic holistic epistemological principles. This appears to be a major challenge facing all the AYUSH systems and LHTs. Since the European and Indian contexts are very different, the answers to these questions may vary and be specific to their own contexts to some extent; yet in essence, a common future towards integrating all systems of medicine would have to be evolved. While most of these issues are well known and have been debated for long, they still remain unresolved and the need for more dialogue is urgent. More so, at a juncture when in the international community there is recognition of the need for restructuring health care systems and nationally efforts are on to design such restructuring in India, the contribution of AYUSH and LHTs will be crucial in this respect.

As individual countries strive to develop more organised medical systems along modern lines, the heterogeneities associated with TM pose ever greater challenges. These challenges are amplified as soon as national borders are crossed, ever more due to increasing globalisation.

Policies and legislation relating to public health and wellbeing are increasingly confronted by issues deriving from TM imported from other regions of the world, rooted in different cultures, societies and mindsets. Especially in environments with highly organised health care systems and legislation in effect this creates grave problems, not only for the host environment, but also – and maybe even more so – for TM itself, whose very legitimacy may thus be put on trial. It may also result in negative repercussions on its legitimacy in the society of origin itself, which would run counter to the avowed national and WHO aims of furthering TM in indigenous environments.

India and Sri Lanka are two of the few countries that officially inducted TM (and also homeopathy) into the formal health service system as early as the 1930s, not only as a conscious continuation of heredity and tradition, but also as a means of granting access to health care to sections of the population otherwise having only limited or no access. In India, an independent department of the Ministry of Health and Family Welfare deals with TM, implementing and overseeing various policies. India thus allows a good overview of the problems associated with this field. Some of the issues are as follows:

- Lack of clear, official and legally binding definitions of individual traditional medical systems, i.e., what exactly and unambiguously not only falls under a given label, but also what is excluded. This pertains to both synchronically and diachronically, and includes the issue of disparate and at times contradictory elements being united under individual categories.
- Standardisation and quality control, including in the preparation and certification of drugs and the manufacture and distribution of drugs based on parameters which are at variance with those required for the evaluation and certification of MM drugs.
- Teaching and training, including the issue of colleges organised on modern principles, with fixed (though not necessarily nationally standardised) curricula being on a par with traditional oral and/or individualised training methods.
- The relationship and dynamics between various forms of TM among themselves and also between TM and MM both as given and as a policy goal.
- The effects of general legal and policy measures, and standardisations on medical systems that are holistic and have complex variations which are based on contextual and individual

diversities with the resultant question of efficacy in the context of essentially alien parameters.

Given the geographical spread of the relevant TM systems, the above dilemmas pertain not only to individual South Asian countries, but transcend national boundaries of the region. At the individual national levels most issues remain unresolved and that supranational solutions are practically non-existent.

These problems are imported into European countries along with the respective TM systems. In contrast to South Asia, public health and wellbeing are highly regulated and legalised domains in European countries, particularly in connection with comprehensive and heavily legislated health insurance. Given the basic lack of formalisation in the region of origin in the monolithic mode of modern scientific systems, this is a major problem not only for the handling of South Asian TM, but also for its acceptance and valuation. The issue is further complicated by the fact that national policies in Europe too in this field vary. For instance, the use of Ayurvedic drugs as medicine is prohibited in Germany, but not in all European countries; however, the open flow of goods facilitates their import nevertheless.

These issues are extremely important for the development of health care systems the world over, but with their complexity, it was thought that the aim could not be to come up with solutions at this juncture. Rather, a catalogue of issues and their priority relating to South Asian TM in public health care that could be addressed nationally, regionally and globally needs to be drawn up. Thus, an expected outcome of the workshop was to bring forward recommendations to address these concerns. Though the workshop was focused on Ayurveda and LHTs, and not on all the seven systems of TM, it was assumed that notwithstanding the diversity within TM systems, the principles of integration worked out for any one such system should be able to inform the development of the others to a large extent. The experience of an Asian country outside South Asia, Korea, was also considered since it has attempted to position Traditional Korean Medicine globally, as well as within its health care system nationally. workshop organisers hoped that such interactions would form the basis for further future action ultimately leading to formulation and implementation of policies which address these issues satisfactorily on the national, regional and global level. Additionally, the impetus for this workshop came from a recognition of the need for practitioners of AYUSH, producers of AYUSH health care products, promoters and

regulators of AYUSH and LHTs, social science scholars and public health analysts to come together to engage with specific issues relating to standards and regulations of AYUSH and LHTs. Therefore, this workshop was an effort to bring an interdisciplinary group together to deliberate upon and develop concrete approaches and steps towards an integration of the traditional systems of medicine into modern health care systems. The immediate outcomes envisaged from this workshop are a report, a publication of the papers presented, and the establishment of a network dedicated to the issue of South Asian TM in the context of public health care.

Organised at the Jawaharlal Nehru University, New Delhi between 4th-6th October, 2012, by the Centre of Social Medicine and Community Health - JNU, Martin-Luther-Universität Halle-Wittenberg (Germany), Foundation for Revitalising Local Health Traditions (Bengaluru, India) and the India Chapter of International Association for the Study of Traditional Asian Medicine (IASTAM), the workshop was an attempt to create a space of dialogue between practitioners of Ayurveda, traditional folk health practitioners (THPs), public and private sector producers of Ayurvedic and herbal medicines, civil society activists who have worked with Ayurveda and THPs, officials of government agencies related to AYUSH, social scientists who have studied the issues of traditional medicine (TM), and public health scholars with experience in health systems development.

The key question sought to be answered through the deliberations was regarding the mode of operationalising integration of traditional codified and non-codified Indian systems of medicine into the health care system, and also simultaneously ensuring universal access to health care. In order to discuss the above theme and bring in a comparative perspective, this workshop brought together three diverse health system settings: Germany, South Korea and India. Some of the other relevant questions included: what lessons can we draw from the European and South Korean approaches to universal health care development and the role of TM within that? How does the hierarchical relationship between modern medicine, the codified TM systems and the non-codified TM influence the regulatory mechanisms and setting of standards? Occurring at a time when there is a strong public discourse on universal access to health care in India, and when policy makers are looking at ways to integrate TM into the mainstream health service system, the workshop organisers hope that the recommendations of the workshop will contribute to policy making discussions regarding TM in India.

The key themes that featured during the workshop are elaborated below.

 Legitimacy of Traditional Medicine: Lessons From Germany, India and Korea

Acceptance of traditional medicine as a legitimate way of understanding and treating ill-health in mainstream (i.e., biomedical)

health services settings is undoubtedly one of the most crucial concerns for the sector of traditional medicine and local health practices. While these issues were flagged off in the inaugural session, this was a recurrent theme in all the subsequent sessions through the conference. The first two sessions on the experience of traditional medicine in diverse settings of Germany and Korea presented important learnings vis-à-vis this theme: they demonstrated the uphill task that gaining legitimacy entails for traditional medicine, not just in terms of proving its scientific efficacy and validity, but also getting political acceptance as a legitimate knowledge system in its own right.

The European experience showed that 'efficacy' was not only a scientific category, but an overtly political one, fiercely guarded by the biomedical fraternity and pharmaceutical industry through exclusive definitions of 'science' and 'scientific', which by definition disqualified traditional medicine as 'unscientific'. Gaining efficacy would require establishing a scientific evidence base for traditional medicine, coupled with strong organizational efforts by traditional medical practitioners in order to achieve a truly democratic medical pluralism in our health care system.

The scenario in India reflects a marked lack of legitimacy accorded to traditional medicinal systems, as the colonial and the post-colonial state prioritized a techno-scientific epistemology, resulting in a progressive atrophy of traditional medicine. The Indian state accorded official recognition to systems of traditional medicine, thus establishing (at least at first glance) a plurality in health systems in India. Representatives of relevant departments in the Indian government (Dr. Prasanna Rao, Dr. Ramesh Babu and Shri D.C. Katoch) presented infrastructural arrangements, regulatory regimes, details education and research that the state policies are currently encouraging in the area of traditional medicine. However, as shown by Dr. Narendra Mehrotra and Prasanna Rao, in spite of official recognition of traditional medical systems and availability of basic infrastructure, the aforesaid bias has resulted in a ground reality of a profoundly undemocratic medical pluralism in India.

However, the experience of integrating traditional medicine in the health care system of South Korea offered some guiding principles for the Indian case. Korean traditional medicine was actively promoted by the Korean state in the post-Independence era, to assert a national identity distinct from its over-powering East Asian neighbours. This, coupled with active organization by traditional medical practitioners

and large-scale efforts to systematise Korean traditional medical literature and to modernise the practice and research of Korean traditional medicine has resulted in the latter gaining some formal recognition in Korean health care system vis-à-vis its biomedical counterpart, but the folk practice of herbal medicine by households had rapidly declined over the last two decades, atleast in the urban areas. The strategic use of the term 'Korean Medicine' without the appendage 'traditional' was educative for other countries.

A pertinent theme that was consistently discussed during the course of the conference was that of the audience towards whom efforts at gaining legitimacy were aimed. Thus the constant question: *legitimacy for whom?* Several discussants drew attention to the link and the dissonance between the need to gain legitimacy for traditional medicine in India via standardisation and regulation, and the increasing commercialisation of traditional medicine in the global wellness market. Discussants cautioned that attempts to standardise and regularise traditional medicine to gain legitimacy merely for the purpose of global export of traditional medicine was dangerous since it would not contribute towards strengthening of traditional medicine as a knowledge system. In his presentation, Mehrotra candidly critiqued the GOI's AYUSH policy, contending that the department was oriented more towards exporting AYUSH products and services rather than strengthening AYUSH sector in India per se.

These cases establish beyond doubt that legitimacy for traditional medicine (or its lack) is inextricably tied to the fundamentally asymmetrical relationship between biomedicine and traditional medicine in India as also elsewhere. The presentations underlined the need to frame all the subsequent discussions on standardisation, regulation, evidence base and monitoring within this context of an unequal power relationship between traditional medicine and biomedicine. Similarly, all the three cases demonstrate without doubt that the centrality of state policy in shaping the legitimacy accorded to traditional medicine cannot be under emphasised.

In addition was the issue of the wide diversity within TM in the Indian context, well detailed by Shri Janardan Pandey in the case of Ayurveda, and in the case of folk practice by Shri Hariramamurthi. The hierarchy between the codified systems of TM, the folk knowledge, and practice of TM designated as Local Health Traditions (LHT), was one of the issues running through all the discussions. Separate segments were devoted to the two so as to allow adequate space for the issues of LHT,

which are often quite different from those of the codified systems. The official agencies meant to strengthen the legitimacy and practice of TM largely related to the codified systems, not least because all the technical personnel employed there were graduates and specialists of the codified systems. It was therefore members of the Foundation for Revitalisation of Local Health Traditions (FRLHT) who made presentations on the status of LHT in India.

Dilemmas of Efficacy, Standardisation and Regulation

The question of legitimacy of AYUSH and LHTs in India is bound with requirements of regulation, standardisation and evidence base, as defined by the hegemonic biomedical regime. These requirements bring to the fore their own dilemmas: how to ensure the conservation of the unique epistemological features of systems of traditional medicine in the process of standardisation and building an evidence base? In the light of an asymmetrical relationship of power between biomedicine and traditional medicine, it is important to ensure that the essential features of the latter do not get erased or co-opted in the process of standardisation, regulation and integration. Dr. Harish Naraindas' presentation on education and research in Ayurveda underlined this caution: he demonstrated how integration for many contemporary Ayurvedic physicians translates as merely using an Ayurvedic pharmacopeia for biomedical nosological categories.

The difficult question of building an evidence base for systems of medicine which are not amenable to assessment by classic methods such as clinical trials and Evidence-Based Medicine (EBM) was articulated across the board by presenters from South Korea and India. Narendra Mehrotra brought up the stark dilemmas of standardising visà-vis Ayurveda and home remedies: establishing standards entails establishing a regulatory regime and the latter would be difficult to operationalize with regard to practices which are not institutionalized and highly diverse - such is the case with the marked variations in Ayurvedic practice across the country. Therefore, LHTs might suffer even a greater blow with standardisation: community practice and an informal mode that is at their core might be lost when LHTs are brought under a regulatory regime.

Notwithstanding these crucial dilemmas, the workshop showcased a wide range of methodologies aimed at establishing an evidence base/demonstrating efficacy of traditional medicine, which would legitimise this knowledge system and its health/well-being practices.

Presentations by Dr. Helen Lambert and Dr. Maarten Bode brought forth the contribution that social science methodologies can make to establishing evidence and clinical efficacy of traditional medicine. Implicit in the methodologies that they propounded (like People Reported Outcomes, ethnographic case studies and meaning response) was the equal importance accorded to the voice of the patients in evaluating the efficacy of health services that they were availing of. On similar lines, Shri Guy Attewell demonstrated how traditional medical practitioners use technology effectively in order to produce legitimacy for their practice. This is an important direction for future social science research in traditional medicine.

As regards the LHT sector, presentations by Smt. Bhanwar Dabhai, Prof. Debjani Roy and Dr. Padma Venkat were extremely significant, since they represented innovative attempts to acquire legitimacy and certification for LHTs and local health practitioners in their respective regions. These attempts could act as precursors to models of integrating LHTs in the health care system and also working issues around quality control and regulation. Importantly, in all these projects the standards of certification were derived largely from the contexts in which the practices existed, rather than depending upon an external, universal set of standards. In this regard, Shri K.N. Arjunan also made an important point: the proficiency of traditional practitioners acting as a quality control measure in producing certain medicines, as opposed to those products which are manufactured in bulk. These presentations were thus located at important crossroads: giving legitimacy to local knowledge, giving weight to people's perceptions in quality control and organizing a body of practitioners who are diverse and scattered.

The last stream of attempts was in the context of conventional research, aimed at devising scientific procedures designed to test the efficacy of traditional medicines for specific diagnoses and standardising them. Dr. Narendra Bhatt elaborated upon his model aimed at enabling clinical trials to test the efficacy and validation of Ayurvedic medicines. Ramesh Babu from Central Council for Research in Ayurvedic Sciences (CCRAS) also enumerated the list of biomedical diagnoses in which the Council was engaged for conducting research; he also specified that the Council was involved in standardising a host of Ayurvedic formulations.

Diversity Within Traditional Medicine

It was evident from the presentations during the workshop that the realm of traditional medicine cannot be understood as a monolith; the enormous diversity in its practices, principles and practitioners makes it imperative to conduct research on and document the sheer range of these practices. This point was reiterated by several speakers including P.M. Unnikrishnan, Padma Venkat, Hariramamurthi, Janardan Pandey and others. It would also be instructive to see how these practices have been differentially affected by state policies and NGO intervention. For instance, the question of *dais* seems to be doubly marginalized: while local health practices (LHPs) are being increasingly included in state conservation and public health programmes, Dr. Mira Sadgopal's presentation showed how the *dais* are in fact, being further pushed out of the zone of reproductive health.

Any policy intervention or attempts at integration would also have to be sensitive to the internal differentiation/hierarchies within traditional medicine in India, especially the divide between the codified and non-codified systems. Several speakers including Prof. Ritu Priya and Mira Sadgopal pointed out that if AYUSH systems were marginalised in the health services system in India, home remedies and local health practices were doubly marginalised within mainstream health systems as well as within AYUSH.

Integration: Efforts and Challenges

The last day of the workshop was explicitly aimed at exploring avenues for integrating traditional medicine systems with mainstream health care in all aspects: research, practice and service delivery. Presentations by Shri P. Ram Manohar and Dr. Tannaz Birdi highlighted the innovative research that their organisations had undertaken in introducing clinical trials in Ayurvedic research and testing clinical efficacy of plants used in local health traditions, respectively. That they were successful in doing so without violating the basic principles of TM was significant. Similarly, Dr. Ramesh Bijlani and Dr. Rama Jayasundar elaborated upon the conceptual and epistemological issues that integrative medicine would need to deal with in its attempts to synthesise biomedicine with traditional systems of medicine. Earlier, Padma Venkat had emphasised that any attempt at integrative research would entail the involvement of not just biomedical/traditional medical practitioners but also social scientists and public health experts, in order to conduct a truly trans-disciplinary research tradition.

These experiments and efforts were contributing to the emergence of a conceptual language that would be required to reconcile the systemic differences in biomedicine and traditional systems of medicine, as noted by the discussant Dr. Leena Abraham. This was crucial in the light of Dr. G.G. Gangadharan's contention that a review of past decades of research shows that it was conducted in a mutually exclusive way by both biomedical and traditional medical practitioners.

Presentations by Narendra Bhatt, Ravi Bapat and Ram Manohar showed the attempts at integrating biomedicine with Ayurvedic practice: they elaborated upon the use of Ayurvedic therapies, pharmacology and concepts in conjunction with biomedical services in health care.

While all these attempts at integration were crucial, linking these attempts to questions of public health and universal access to health care still remained a vital challenge, according to Ritu Priya. She contended that a structural change was required in the health care system in order to operationalize the ideal of integration, to achieve a truly democratic medical pluralism. Inclusion of traditional birth attendants, traditional practitioners and AYUSH service providers at the level of Primary Health Centres and Community Health Centres, promotion of home remedies, and incorporation of people's health-seeking choices in the institutional structure of health care service delivery were some of the key recommendations put forth by. Ritu Priya.

Concluding the Workshop

The workshop concluded with two drafts of recommendations and resolutions circulated by two of the participants. While endorsing the need for sincere dialogue between the two systems of medicine in the future, these recommendations reiterated that the principle of universal access to health care and empowering the community has to underpin any attempts at an integrated model of health care delivery system. The other set of resolutions primarily concerned the status of LHTs in the integration debate, emphasizing the need to strengthen this sector through policy, infrastructure, research and education initiatives.

October 4, 2012

9-10.00 am: Inaugural Session

Prof. S.K. Sopory, Vice-Chancellor, JNU: JNU Perspective on Inter-Disciplinarity and Integration

Introduction to the Workshop: Dialoguing Knowledge and Practice

- Prof. R.P. Das (Martin-Luther University, Germany)
- Dr. Narendra Bhatt (IASTAM India Chapter)
- Dr. Padma Venkat (I-IAIM, FRLHT)
- Prof. Ritu Priya (CSMCH, JNU)

Chair: Shri A.K. Ganeriwala, Joint Secretary, Dept. of AYUSH: Indian Policy Perspective on Integration of AYUSH & LHT into Modern Health Care Systems

10.30-1.30 pm

European Health Care Systems & their Regulatory Frameworks for Allopathy and other Medical Systems, with Particular Focus on Germany

Chair: K.R. Nayar (Professor, CSMCH, JNU)

Speakers

- Ananda Samir Chopra (Medical Director, Ayurveda-Klinik, Kassel) - Practicing Ayurveda in a German Hospital: Problems and Perspectives
- Gunnar Stollberg (Professor of Sociology, University of Bielefeld, Germany) Use of Traditional Asian Medicine in Germany and other EU Countries
- Reinhard Neubert (Professor of Pharmacy, University of Halle-Wittenberg, Germany) -Requirements of the Developments of Phytocosmetics and Phytopharmaceuticals in Germany
- Madhulika Banerjee (Associate Professor of Political Science, University of Delhi) - Official Approach of the European Union to Traditional South Asian Medicine

Discussants

- Harish Naraindas (Associate Professor, Centre for Study of Social Systems, JNU and Joint Appointments Professor, Faculty of Philosophy, South Asia Institute, Univ. of Heidelberg)
- Rajinder Sood (Deputy Secretary, Department of AYUSH)
- *Deepika Gunawant* (Former Head, Global Health, Dabur; presently, Medical Head, Integrative Medicine, Max Ventures)

2.30- 4.00 pm

The Korean Health Care System, Role of Traditional Medicine & its Regulatory Framework

Co-Chairs: Rama Baru (Professor, CSMCH, JNU) & Vyjayanti Raghavan (Associate Professor, Centre for Japanese, Korean and East Asian Studies, JNU)

Speakers

- Lee, Tae Hyung (PhD candidate, Department of Medical History, College of Korean Medicine, Kyung Hee University, Seoul, South Korea) The Medical Dispute between Korean and Western Medicine Examined through Medical Systematization in Korea
- Kang, YeonSeok (Assistant Professor, Department of Medical History, College of Korean Medicine, WonKwang University, Iksan, South Korea) - A Basic Study for the POST DongUiBoGam Project
- Kim, Dong Ryul (Masters Student, Department of Medical History) and Ahn SangWoo, (Adjunct Professor, College of Korean Medicine, Kyung Hee University, Seoul, South Korea)
 A Modern Application of "The Daily Records of Royal Secretariat of Chosun Dynasty" Medical Records

Discussant

 Narendra Bhatt (President, International Association for the Study of Traditional Asian Medicine - India Chapter)

4.30- 6.00 pm

The Indian Health Care System and the Diversity of Traditional Medicine in India

Chair: Mira Sadgopal (Principal Investigator – Jeeva Project)
Speakers

- Narendra Mehrotra (Retd. Scientist, CDRI & Founder Secretary, Jeevaniya Society) - The Overall Structure of the Health Care System in India & Regulation (with defining of AYUSH, Ayurveda and LHT)
- Janardan Pandey (Consultant, Morarji Desai National Institute of Yoga)- Structure and Variations within Ayurveda
- G. Hariramamurthi (Head, Centre for Local Health Traditions, Foundation for Revitalisation of Local Health Traditions (FRLHT) - Contemporary Structure of LHTs in India

Discussants

- Ramila Bisht (Associate Professor, CSMCH, JNU)
- Sandra Albert (Assistant Professor, Indian Institute of Public Health, Shillong, Meghalaya)
- Sanghmitra Acharya (Associate Professor, CSMCH, JNU)
- V. Sujatha (Associate Professor, CSSS, JNU)

October 5, 2012

9.00-11.00 am

The Approaches to Nature of 'Evidence' in Relation to Efficacy and Quality of Traditional Medicine

Chair: Imrana Qadeer (Retired Professor, CSMCH, JNU)

Speakers

- Helen Lambert (Reader in Medical Anthropology, School of Social & Community Medicine, University of Bristol, UK) 'Nature of Evidence for Health Systems Development'
- Maarten Bode(Adjunct Faculty, Department of Medical Anthropology and Sociology, University of Amsterdam) 'If

You Only Have a Hammer you Approach Everything as a Nail: Ayurveda and Medicine-Based Evidence'

- *P. Ram Manohar (Director & CSO, AVP, Coimbatore)* 'The Nature of Evidence in Ayurvedic Traditions'
- Padma Venkat (Director, FRLHT) A New Approach to Quality and Safety Research on LHT
- Narendra Bhatt (President, IASTAM India Chapter) A
 Structured Approach to Validation of Traditional Medicine

Discussants

- Harish Naraindas (Associate Professor, Centre for Study of Social Systems, JNU and Joint Appointments Professor, Faculty of Philosophy, South Asia Institute, Univ. Of Heidelberg)
- Rajib Dasgupta (Associate Professor, CSMCH, JNU)

11.30-1.30 pm

The Regulatory Mechanisms for Ayurveda in India: Research and Education

Chair: Ranjit Roy Chaudhury (National Professor of Pharmacology; Adviser - Department of Health and Family Welfare, Govt. of NCTD; Former Member, BoG – MCI)

Speakers

- Ramesh Babu (Director-General, Central Council for Research in Ayurvedic Sciences) Research in Ayurveda and & its Regulation
- Prasanna Rao (Member, Executive Committee, Central Council for Indian Medicine) - Regulation of AYUSH Professionals and Education
- Harish Naraindas(Associate Professor, CSSS, JNU and Joint Appointments Professor, Faculty of Philosophy, South Asia Institute, Univ. of Heidelberg) - Reframing the Pedagogy and Practice of Ayurveda: Lessons from the Past for the Present

Discussants

 Kishor Patwardhan (Assistant Professor in Kriya Sharir, Department of Kriya Sharir, Faculty of Ayurveda, IMS, BHU, Varanasi) • Leena Abraham (Associate Professor, Tata Institute of Social Sciences, Mumbai)

2.30-4.30 pm

The Regulatory Mechanisms for Ayurveda in India: Drugs and Practice

Chairperson: *Ranjit Roy Chaudhury* (National Professor of Pharmacology; Adviser Department of Health and Family Welfare, Govt. of NCTD; Former Member, BoG – MCI)

Speakers

- D.C. Katoch (Joint Advisor, Ayurveda, Dept of AYUSH) -Regulation of ASU Drugs
- A.P. Mahabharathi (General Manager, TAMPCOL) Regulation of Quality of Drug Production by TAMPCOL
- P. Madhavankutty Varier (Chief Superintendent, AH&RC, Arya Vaidya Sala, Kottakkal) - Traditional Forms of Self-Regulation for Quality and Safety of Services and Products in Ayurveda

Discussants

- *C. K. Katiyar* (Vice-President, Herbal Research Division, Dabur)
- Madhulika Banerjee (Associate Professor of Political Science, Univ. of Delhi)
- Ananda Samir Chopra (Medical Director, Ayurveda-Klinik, Kassel)

4.45- 6.30 pm

The Existing Standards and Regulatory Framework for Local Health Traditions (LHTs)

Chair: Shailaja Chandra (Former Secretary, Department of AYUSH, and Former Chief Secretary, Government of Delhi)

Speakers

- Bhanwar Dabhai (Founder, Rashtriya Guni Mission, Udaipur) Certification of Folk Practitioners by Panchayats
- Debjani Roy (Professor, Centre for Traditional Knowledge Systems, IGNOU) - The IGNOU Method for Certification of Traditional Folk Practitioners and Practices
- K.N. Arjunan (President, Folk Practitioners Association, TN) Regulation of Quality and Access of Raw Material by Folk Practitioners
- Mira Sadgopal (Principal Investigator, Jeeva Project) -Quality and Regulation of Traditional Birth Attendants
- P.M. Unnikrishnan (Research Coordinator, United Nations University-Institute of Advanced Studies) The International Experience of Regulation and Research with Traditional Folk Practitioners and Practices

Discussants

- Narendra Mehrotra (Retired Scientist, CDRI & Founder Secretary, Jeevaniya Society)
- Sunita Reddy (Assistant Professor, CSMCH, JNU)

October 6, 2012

Possibilities of Integration of Ayurveda and LHT into the Formal Health Care System (Integration in Basic and Clinical Research)

Chair: Nerges Furdoon Mistry (Trustee and Director, Foundation for Medical Research, Mumbai)

Speakers

- Ramesh Bijlani (Former Professor, Dept. of Physiology, AIIMS, New Delhi) - Synthesis of Medicine: Why, How & When
- Rama Jayasundar (Associate Professor, Dept. of Nuclear Magnetic Resonance, AIIMS) Systems Biology Approach of Ayurveda and Relevance in the Present Context

- P. Ram Manohar (Director & CSO, AVP Research Foundation, Coimbatore) Integrative Research Methodology: The Rheumatoid Arthritis Study
- Guy Attewell (Director, French Institute of Pondicherry) -Making Bodies of Evidence: X-rays, Fracture Reduction and Credibility Thresholds in a 'Bone-setting' Clinic in Hyderabad
- Tannaz Birdi [Deputy Director, Foundation for Medical Research (FMR), Mumbai] - Approach to Integrated Medicine at FMR

Discussants

- Rajni Kaul (Scientist E, Division of Basic Medical Sciences, ICMR)
- Dinesh Abrol (Senior Scientist, National Institute for Science, Technology and Development Studies)

11.30-1.30 pm

Integration in Practice and Health Service Delivery

Chair: Shailaja Chandra (Former Secretary, Dept. of AYUSH, and Former Chief Secretary, Government of Delhi)

Speakers

- G.G. Gangadharan (Director, Institute of Ayurveda and Integrative Medicine, FRLHT) The Approach of Integrative Medicine
- Ravi Bapat (Former Professor, Department of Surgery), and Supriya Bhalerao (KEM Hospital and College, Mumbai) -Integration of Ayurveda in Modern Surgical Practice
- Ritu Priya (Professor, CSMCH, JNU) Quality Improvement and Integration: AYUSH in Public Health from a Health Systems Perspective

Discussants

- Sunil Kaul (Member, The Action Northeast Trust The ANT; present Convenor, Medico Friends Circle)
- Krishna Soman (Associate Professor of Public Health, Institute of Development Studies, Kolkata)
- *Harilal M.S.* (Post-Doctorant, French Institute of Pondicherry)

2.30-5.00 pm

Round Table (Assigned persons to summarise points on specific issues over the three days.)

- The Consequences for Standards and Regulations of Ayurveda/AYUSH and LHTs if they had to conform to the European/German or Korean Health Care Model
- The Concerns about Standards and Regulations of Ayurveda/AYUSH & LHTs that need to be addressed in the Indian Context and Approaches to do so
- Steps Forward

Chair: Rahul P. Das (Professor, South Asian Studies, Martin-Luther University of Halle-Wittenberg, Germany)

5.00-5.30 pm

Valedictory: *Prof. Ranjit Roy Chaudhury* (National Professor of Pharmacology; Adviser - Department of Health and Family Welfare, Govt. of NCTD; Former Member, BoG – MCI)

5.30 pm

Vote of Thanks: *Sunita Reddy* (Assistant Professor, CSMCH, JNU)

Proceedings of the Workshop

The workshop was inaugurated by the Vice-Chancellor of JNU, Prof. S.K. Sopory. Himself a plant biologist, Sopory expounded on the importance of integration and inter-disciplinarity in research against the background of increasing specialization in the medical field. He highlighted the accessibility of traditional medicine and the trust that it inspires in local communities as valuable assets, which demand that due attention be given to the question of integration of traditional medicine within health care systems.

R.P. Das (Martin Luther University, Germany)

Prof. R.P. Das focused on the conceptual underpinnings of universal health care coverage. He cautioned that integrating diffuse systems of traditional medicine and biomedicine in a single system which aims to achieve universal coverage can be a challenge on account of conflicting perceptions of entitlements and questions of equitable apportioning of benefits of health services. Highlighting the inclusion of Korean and German context in the workshop, he suggested that the experience of this non-English speaking world in integrating diffuse systems of medicine would be more instructive for the Indian context, rather than seeking reference in the English speaking world of UK and USA, which have not fared so well in evolving an equitable and pluralistic health service delivery system.

Narendra Bhatt (IASTAM - India Chapter)

Dr. Narendra Bhatt, a practising Ayurvedic physician for several years, stressed the need for dialogue and communication between the two systems of medicine and questioned uncritical advocacy of regulation of traditional medicine, as a solution to the question of integration. According to Narendra Bhatt, engaging with the question of integration would require us to interrogate critically our categories of 'ancient vs. modern' and 'traditional vs. modern medicine'; it would require us to attribute a different meaning to science and objectivity itself. He expressed concern about the epidemiological relevance of chronic diseases like diabetes and hypertension in contemporary India and stressed the need for collaboration between systems of medicine to address these issues.

Padma Venkat (I-IAIM, FRLHT)

Dr. Padma Venkat highlighted the value of codified as well as non-codified systems of Indian medicine in the context of resource poor settings in rural India. She stressed the need to enhance our understanding of traditional medicinal systems, through systematic documentation, conservation and trans-disciplinary research, which would involve not just traditional and biomedical experts, but also social scientists and public health experts. Monitoring for safety and efficacy of traditional medicine needs to be conducted according to an indigenous framework instead of universal values of biomedicine, she said. She also elaborated upon the initiatives undertaken by her institution, in the context of research and conservation of traditional medicinal resources.

Ritu Priya (Centre for Social Medicine and Community Health, JNU)

Prof. Ritu Priya stressed in the beginning that the Centre for Social Medicine and Community Health sought to understand AYUSH and LHT sector through the lens of a public health approach and a health systems approach. She provided a historical overview of the process through which AYUSH and LHTs were systematically marginalized during the colonial regime as the colonial state withdrew patronage to all indigenous systems of knowledge and prioritized a technoscientific epistemology. This marginalization continued in post-Independence India as well, as the state policies reflected similar bias while designing health care delivery system in the country; the resultant focus on providing biomedical services further led to a decline in the quality of traditional medical services as well as the confidence of these systems. While the Indian state officially recognized Indian systems of medicine, this medical pluralism was fundamentally undemocratic, on account of the blatantly unequal priority given to the former, in terms of budgetary allocations, infrastructure and education. Recently there has been an interest in the revival of traditional medicine, as the limits to biomedicine are becoming evident globally.

Ritu Priya ended by emphasizing that we need to think about integration of traditional medicine in health care delivery at a systemic level; this entailed a dialogue between practitioners of both systems, which this workshop hopes to facilitate.

A.K. Ganeriwala (Joint Secretary, Dept. of AYUSH, Government of India)

Shri Ganeriwala emphasized that the state was committed to providing affordable and accessible health care to all. In this context, a public health system with a single medicine focus would be inadequate, he claimed. Users of health care delivery system should be able to choose from the existent multiple systems of medicine; it is with this perspective that the government of India extends support to AYUSH and LHTs, in terms of infrastructural support, drug manufacturing units, educational institutions and initiatives for research and documentation of traditional medicine. This support is reflected in National Health Policies of 1983 and 2002, both of which have stressed the need for meaningful integration of traditional medicine with modern health care delivery system: towards this end the government has also undertaken initiatives like co-location of AYUSH practitioners in Primary Health Care centres, utilization of existing AYUSH infrastructure in reproductive and ante-natal health care, making traditional medicinal literature accessible in contemporary formats and so on. Ganeriwala also stressed the added relevance of traditional medicine in the light of the fact that biomedicine does not provide solutions for the burden of chronic diseases which developing countries are now increasingly bearing.

The speakers in the inaugural session thus flagged off the major strands of discussion vis-à-vis traditional medicine and paved the way for further conversation to follow in the workshop. The session represented crucial challenges for the project of integration of traditional medicine with biomedical public health system: systemic issues, state support and policy requirements, the need for documentation and research on traditional medicine, the question of regulation and monitoring and the challenge of reconciling two fundamentally different epistemologies (traditional medicine and biomedicine). All the speakers reiterated the need for initiating dialogue and communication between practitioners of the two systems as well as taking an interdisciplinary approach in order to discuss what form and content integration would take as also grapple with the challenges that it posed.

Dialogue and Deliberations: Emerging Issues

In keeping with the themes highlighted in the background note as well as those flagged off by the organisers of the workshop in the inaugural

session, the topics that were deliberated upon by the participants with respect to each day were as follows:

<u>Day 1</u>

Asian TM in Three Diverse Contemporary Locations, which were:

- European health care systems and regulatory frameworks for Allopathy and other medical systems, with particular focus on Germany
- Korean health care system, role of TM within it and its regulatory framework
- Indian health care system and the diversity of TM in India

Day 2

Evidence, Standards and Regulations discussed in general and specific terms through the following:

- Approaches to nature of evidence in relation to efficacy and quality of TM
- Regulatory mechanisms for Ayurveda in India concerning research, education, drugs, and clinical practice
- Existing standards and regulatory framework for LHTs

<u>Day 3</u>

Possibilities of integration of Ayurveda and LHT into the Indian formal health care system in:

- Basic and clinical research
- Practice and health service delivery systems

Session-I

European Health Care Systems and Their Regulatory Frameworks for Allopathy and Other Medical Systems, with Particular Focus on Germany

Practicing Ayurveda in a German Hospital: Problems and Perspectives

Ananda Samir Chopra (Medical Director, Ayurveda-Klinik, Kassel)

Describing his own practice as an Ayurvedic physician in Ayurveda Klinik, Kassel, Germany, Dr. Ananda Samir Chopra specified that around 400-600 patients are being annually treated here for a range of conditions including spondylosis, depression, ailments of the knee and the backbone, cancer and stress related conditions, at times in conjunction with allopathic treatments.

After giving a brief overview of the Ayurvedic treatment regimen followed at the Klinik, Chopra elaborated upon some of the problems that Ayurvedic practice encounters in the German context. While knowledge about Ayurveda is woefully low amongst the biomedical practitioners in Germany, ironically Ayurveda has come to mean a wide of spectrum of services ranging from those offered in spas, resorts and barber shops.

In institutional terms, biomedicine continues to enjoy exclusive legitimacy in the German context. Importantly, this implies that Ayurvedic services are not covered by the insurance system in Germany, on account of their not being considered as 'adequate, purposeful and economical'. Chopra attributes this to several factors including the dominance of biomedicine and organisations representing biomedical practitioners in Germany. Consequently, users of these services have to pay out of their own pockets, thus making Ayurveda an expensive treatment and considered a 'luxury medicine'. Hinting at the possible disillusion with biomedical system in the German context, Chopra talked about a growing demand in Germany from patients for a system which has a conception of the human body different from the biomedical one.

Use of Traditional Asian Medicine in Germany and Other EU Countries

Gunnar Stollberg (Professor of Sociology, University of Bielefeld, Germany)

Prof. Gunnar Stollberg was unable to attend due to ill health and his paper was therefore presented by Prof. Rahul Das. It began with highlighting the stark contrast in the practice and visibility of acupuncture and Ayurveda in UK and Germany and proceeded to trace the comparative visibility and recognition of acupuncture through the conceptual framework of 'medical pluralism/political pluralism'.

In case of UK, acupuncture, as part of the Complementary and Alternative Medicine (CAM), was denied legitimacy and was labelled as 'inefficient' by British Medical Association in 1986; remarkably by 2000, the same professional body recommended formalisation of acupuncture education and its integration in the NHS. Though not yet professionalized like chiropractics and osteopathy, in UK today professional acupuncturist organizations comprise 12,000 practitioners, including 3,000 non-medical professionals. Stollberg attributed the success of acupuncture in gaining recognition to effective professional organization of acupuncturists and a process which he characterized as *politically-based pluralism*, i.e., the acceptance by legal and political establishments of multiple conceptions of health, disease and healing resulting in respect and regard for multiple ways of dealing with health and disease.

In case of Germany, the German Medical Association has moved from skepticism towards acupuncture to accepting Randomized Control Trials (RCTs) in order to understand the latter's efficacy. Acupuncture is now integrated into public health insurance system and the German Medical Acupuncturists' Association has about 30,000 members, though all of the acupuncturists here are professionally trained physicians. Stollberg contended that in the German case it was primarily on the basis of its proven *medical/scientific efficacy* (through RCTs) that acupuncture was granted legitimacy, thus making the German case a combination of medically and politically based pluralism. By suggesting that Ayurveda had to, '...do a lot of homework', Stollberg pointed towards the possible strategies that proponents of Ayurveda might have to adopt in order to gain legitimacy for their practice in these contexts.

Requirements of the Developments of Phytocosmetics and Phytopharmaceuticals in Germany Reinhard Neubert (Professor of Pharmacy, University of Halle-Wittenberg, Germany)

Prof. Reinhard Neubert's presentation examined the issues of standardisation, safety, toxicity and effectiveness - the major problems that phyto-products face in the German context. By definition, phytocosmetics and phytopharmaceuticals are prepared *only* from natural substances: combinations of extracts from plants, minerals and oil chains or their mixture. One of the crucial advantages of these products is their relatively mild nature and that they have a much lower extent of side effects. Though similar to traditional medicine in the German context, these products have to wage a struggle to gain acceptance in the landscape of medical pluralism in Germany.

Phytocosmetics and phytopharmaceuticals are broadly categorised into three types for purposes of regulation viz., cosmetics, medicinal products and drugs. The former two products are seen as having only physical effects, while drugs have pharmacological effects. All the three categories require standardisation for quality control and clinical trials for checking safety/toxicity and proving efficacy. However, conducting these procedures for cosmetics and medicinal products is relatively cheaper and hence more affordable for small and medium establishments. But in the context of products which are categorized as drugs, standardisation entails the preparation of analytical assays through gas chromatography which is a fairly expensive process and difficult for medium scale establishments to undertake for their products. While not discounting the importance of reliable methods of standardisation to collect data on safety and toxicity of phyto-products, this presentation also demonstrated how requirements of scientific efficacy (via their expensive procedures) effectively limit the entry of certain phyto-products as drugs or medicines.

Official Approach of the European Union to Traditional South Asian Medicine Madhulika Banerjee (Associate Professor of Political Science, University of Delhi)

Dr. Madhulika Banerjee presented an analysis of the Traditional Herbal Medicinal Plants Directive issued by the European Union in 2011, which is indicative of the official approach of the EU to Traditional South Asian Medicine. The directive has to be analyzed against the background of the increasing demand for Ayurvedic practices and services in Europe, which has been perceived as a threat to biomedical practitioners and products, thus generating stiff opposition to Ayurveda from the scientific community and pharmaceutical industry in Europe. Banerjee contended that this threat to biomedicine and its products is dealt through regulatory mechanisms that control the entry and legitimacy of Ayurveda in Europe, of which the EU directive is an instructive example.

She referred to the complicated definition of traditional medicine espoused by the directive which would result in the systematic exclusion of certain Ayurvedic products. Similarly, when the directive demands evidence regarding efficacy and scientific validity from Ayurvedic products and practices, efficacy and scientific validity itself is cast in Eurocentric, biomedical terms, thus making it impossible for Ayurvedic products to conform to them. For instance, a product, in order to be registered should demonstrate a history of prior long safe usage, i.e., for 30 years, but safe use only in a *European* country, practically making it impossible for any product to meet with this requirement.

Banerjee highlighted the politics of scientific validity by pointing out how regulatory mechanisms in Europe are not based on 'pristine' scientific principles, but in fact have evolved historically in tandem with the pharmaceutical industry and its requirements. The parameters of scientific validity then are set in accordance with a worldview which is closest to biomedicine, thus making it structurally impossible for other systems of medicine to conform to them easily.

This section summarizes the issues that emerge out of the above presentations as well as the ensuing discussion around these presentations. All the four papers establish unequivocally that Ayurvedic and other traditional systems of medicine have an increasing demand and popularity in the European context. In fact, according to Dr. Chopra, this increasing demand might be indicative of European users' felt need to access a system of medicine which has a more holistic conception of the body as compared to biomedicine.

However, gaining legitimacy and acceptance is an uphill task: practitioners of Ayurveda and other systems of traditional medicine have had to struggle hard in order to make a dent in the strongly guarded terrain of health system of Europe, dominated by biomedicine and its products.

It would be mistaken to consider this struggle for legitimacy as being fought only at the level of scientific validity and efficacy. All the presentations demonstrate implicitly and explicitly that 'efficacy' is not just a scientific category, but a fundamentally political one as well. Banerjee's paper shows how 'efficacy' in the context of European regulatory systems is cast exclusively in biomedical terms, thus denying the space for traditional medicinal systems to be evaluated in terms of their own epistemological logic. The resultant 'lack of efficacy' in traditional medicine is then used to effectively guard boundaries of biomedical practitioners, products and pharmaceutical industry. This boundary marking is manifested in many different forms, as seen in the above presentations: refusal to extend insurance coverage, insistence on expensive clinical trials for standardisation, definitions of traditional medicine that are exclusive and so on.

Thus the struggle for legitimacy and acceptance is not merely in terms of proving efficacy and scientific validity, but in political terms. Stollberg's paper is illustrative of the way in which the success of these battles for legitimacy is a function of the popularity of these practices, the extent of organisation of these practitioners in these countries which aids political articulation of their demands and their ability to prove efficacy and safety according to biomedical parameters. It thus shows how medical pluralism and political pluralism can combine to grant legitimacy to various systems of healing.

This also provides an instructive lens to view the place of traditional medicine in the Indian health care system, which can be characterized as 'an undemocratic pluralism' i.e., the existence of medical pluralism in the absence of political pluralism.

In order to arrive at the efficacy of traditional systems of medicine, there is a need to interpret and evaluate traditional systems of medicine on their own terms, requiring rigorous epistemological research in these respective fields. Similarly, it would be constructive to break down what constitutes 'efficacy' itself: what is the place of patients' perceptions in deciding the efficacy of a therapy? Would the perceived placebo effects be of relevance while deciding 'real' efficacy? What would be the implications of giving weight to patient perceptions of efficacy while formulating regulatory mechanisms and insurance coverage? These are some questions which are relevant while debating the position of traditional medicine vis-à-vis biomedical regimes in contemporary Europe.

Session-II The Korean Health Care System, Role of Traditional Medicine and its Regulatory Framework

The Dispute on the Modernization of Korean Medicine

Lee, Tae Hyung (PhD candidate, Department of Medical History, College of Korean Medicine, Kyung Hee University, South Korea)

This presentation highlighted the contentious issues between Korean traditional medicine and biomedicine, which is illustrative of the very fundamental epistemological differences between the two medical systems. The relationship between the two medical systems has a history dating back to the 1950s. After independence from Japanese colonialism, the Korean state legally made Korean traditional medicine as a part of conventional medical practice along with biomedicine. Since then there has been persistent criticism of Korean medicine regarding its modernity, sparking off several questions about scientific validity, systematization and standardization of Korean traditional medicine.

One of the most significant issues which characterize the relationship between the two systems of medicine is the question of systematization. Should the process of systematization of Korean traditional medicine proceed along its own intrinsic logic and principles, or should it be systematized according to the scientific principles which inform biomedicine? Korean traditional medicine does not subscribe to a scientific epistemological basis. However, Korean traditional medicine has its own foundational principles of yin/yang and the Five Phases theory of diagnosis and therapy: these principles are based upon experiences gained from clinical practices of Korean medicine over centuries; thus these principles are as much evidence-based as the principles of biomedicine.

The principles of Korean traditional medicine which rely upon experiential aspects related to the effects of treatment, as proof of its efficacy, do not pass the 'rational scientific' test, which demand an elaboration of causal mechanisms to prove efficacy. Some argue for the application of methods of Evidence-Based Medicine (EBM) to assess the clinical efficacy of traditional Korean medicine, since EBM advocates a focus on the actual effects of a medical intervention, rather than merely on causal mechanisms. But on the down side, EBM methodologies, which are based upon rigorous randomized controlled trials and systematic reviews present inherent limitations in assessing the diagnostic methods and the experiential aspect unique to Korean traditional medicine.

To deal with this quandary, Shri Lee proposed a reworking of scientific research methodologies, so as to accommodate the unique cosmology of medical systems other than biomedicine. He discussed a method which he termed as 'Historical Evidence-Based Medicine', which would entail formulating an EBM research methodology which would integrate principles of Korean traditional medicine. Similarly, efforts should be made to modernize Korean traditional medicine starting with a reassessment of classic traditional medical literature like the 'DongUiBoGam' and this could also serve as systematic reviews or meta-researches which could constitute meaningful evidence of clinical efficacy of this system.

In the end, Lee critiqued the policy of integrative medicine which professes to integrate Korean traditional medicine with the biomedical system; according to Lee, this policy, which neglects research methodologies and characteristics of Korean traditional medicine, ends up co-opting the latter, rather than integrating the two at par.

[2]

Current Status of Korean Medicine and Some Examples of Modernization of Traditional Medical Contents Kang, YeonSeok (Assistant Professor, Department of Medical History, College of Korean Medicine, WonKwang University, South Korea)

Dr. Kang began his presentation by elaborating upon the current status of traditional Korean medicine as an independent system of medicine: 21,000 doctors practice Korean medicine, with an addition of 800 to this workforce every year. Traditional Korean medicine has 12 private and public medical colleges dedicated to its teaching. Approximately 400 Korean medical doctors are employed in the National Health Care system, and traditional Korean medical treatments are included in insurance coverage since the 1980s. In 1994, the state established the Korea Institute of Oriental Medicine to encourage research on Korean medicine, with an annual budget of USD 40 million. The above figures attest to the extent of legitimization of Korean medicine, which enjoys an equal status vis-à-vis biomedicine and state recognition in Korea.

Kang charted the historical trajectory of state support for traditional Korean medicine, which was marginalized in the beginning of the 20th

century, when Japan colonized Korea, prohibiting traditional medical doctors from working in national hospitals. Till Korean independence in 1945, Korean Medicine was not included in the university education, thus leading to an increasing gap and hostility between biomedical doctors and practitioners of Korean traditional medicine. Though the Korean National Assembly reintegrated Korean medicine in the National Medical System in 1951, struggles to accord equal status to traditional Korean medicine continued till the late '90s in Korea, wherein numerous protests and demonstrations were held critiquing the lack of state support for Korean medicine.

Some areas of concern for Korean traditional medicine in contemporary question around the of standardization revolve internationalization of traditional Korean medicine. Similarly, there is considerable debate around the methods of research, education and treatment within practitioners of Korean medicine, in the context of coexistence of biomedicine and traditional medicine in Korea. In this regard, younger generations of practitioners are engaging with the question of methodology to integrate biomedicine with Korean medicine and the issue of subject and object of integration. There is also an increasing recognition that current methodologies like Evidence-based Medicine are inadequate to attest for the validation of Korean traditional medicine. At an international level, there exists a tension between traditional Chinese medicine and traditional Korean medicine as to which system adequately represents East Asian medicine in international arenas.

Kang elaborated upon a few examples of efforts directed at modernization of traditional Korean medical knowledge, including digitalisation and creation of databases featuring classic medical texts, research findings, medicinal plants database, and translation of rare Korean medical literature into modern Korean languages. Notably, DongUiBoGam, the 'Bible' of Korean traditional medicine, has been translated into English, on the 400th anniversary of its publication; DongUiBoGam has also been declared as a national heritage by UNESCO, thus demonstrating the increasing official recognition of this system in Korea. The World Traditional Medicine EXPO will be held in Korea in 2013 and will be a significant site for encouraging modernization of Korean traditional medicine.

Kang concluded by suggesting future directions for doctors of Korean traditional medicine, viz., the need to evolve a leadership to enable participation in global healthcare and the need to collaborate with experts of different systems of medicine.

A Modern Application of 'The Daily Records of Royal Secretariat of Chosun Dynasty' Medical Records

Kim, Dong Ryul (Masters Student, Department of Medical History, College of Korean Medicine, Kyung Hee University, Seoul, South Korea) & SangWoo, Ahn (Adjunct Professor, College of Korean Medicine, Kyung Hee University, Seoul, South Korea)

In this presentation, Shri Kim and Dr. Ahn highlighted the need of modernizing Korean traditional medicine and conducting research on Korean traditional medicine. Their project of analysing the records of the Royal Secretariat of Chosun dynasty from 17th century onwards constitutes an attempt to trace historically the practices within Korean traditional medicine.

The 'Daily Records' is a systematic chronicle about the king's daily official affairs which was documented uninterruptedly for 288 years from 1623 to 1910. It is the largest volume of the existing single records in the world and has also been given the status of 'Memory of the World Register' by UNESCO in 2001.

As an illustration, Kim and Ahn proceeded to elaborate upon a record from a day in 1673, which included the king's consultation with his healers; it showcases a process which could be considered equivalent to modern biomedical records. The treatment process was systematically recorded in a register, which proceeded from examination of the 'patient', recognising symptoms, diagnosis, reaching an agreement about treatment and finally executing the actual treatment.

The presenters also demonstrated samples of prescriptions, listing of symptoms, elaboration of physiology and pathology of the disease, prescription of diet regimen and guidelines for preparing a drug used in Korean traditional medicine.

Kim and Ahn ended their presentation with the suggestion that such historical analyses of Korean traditional medicine will be crucial in establishing a comprehensive database of this system, which can then be translated into application in modern clinical settings.

A striking feature of the practice and status of Korean traditional medicine is its extent and legitimacy in South Korea in contemporary time. This theme needs to be contrasted with the next section on Indian systems of medicine, which exhibit a stark marginalization in the realm of policy and infrastructure vis-à-vis biomedicine, which has received the chunk of state support. In fact, in the case of Korean traditional medicine it is instructive to trace its historical trajectory, which is marked by non-acceptance during the colonial rule of Japan, to its increasing official acceptance after Korean independence, to its current active *promotion* to assert a national identity distinct from its overpowering East Asian neighbours.

It is important to note, however, that even this encouraging state of affairs is underlined by a model of integration in which Korean traditional medicine is integrated in ways which are asymmetrical visa-vis biomedicine. This is evident from the main issues which were highlighted by the speakers specifically with regard to questions of standardization, scientific validity and clinical efficacy of Korean traditional medicine. The presentations also highlighted encouraging engagement with these questions as shown through the critiques of EBM methodologies and through attempts to reconceptualise these methodologies to fit the cosmology of Korean traditional medicine.

The creation of online databases, efforts at systematizing traditional knowledge, translation of ancient medical literature, etc., constitute attempts to recast the vast cache of traditional medical knowledge in a format which is accessible to and amenable to modern research. These attempts were commended greatly during the discussion that followed the presentations: some speakers contended that the Korean journey signified a model for Indian context, as the latter grapples with questions of systematizing and recognizing traditional knowledge inherent in Indian systems of knowledge.

Another commendable development was in the context of health insurance coverage extended to Korean traditional medicine, something which India has failed to achieve. According to Ahn, while the older generation of traditional medical practitioners were initially skeptical of bringing in their practices within the ambit of insurance coverage, this was eventually made possible by the persistent advocacy of the

younger generation of Korean traditional medical practitioners. Today Korean traditional medical treatments constitute about 4-5% of national insurance coverage.

Some of the other relevant questions raised during the ensuing discussion pertained to accessibility of Korean traditional medicine by the common people in historical times, nature of Korean traditional medicine's engagement with global markets, private actors in education of Korean traditional medicine, the status of non-formal practices in Korean traditional medicine and the contours of this system in North Korea.

Session-III The Indian Health Care System and the Diversity of Traditional Medicine in India

The Overall Structure of the Health Care System in India and Regulation (with defining of AYUSH, Ayurveda and Local Health Traditions)

Narendra Mehrotra (Retd. Scientist, CDRI & Founder Secretary, Jeevaniya Society, Lucknow; former Scientist – Central Drug Research Institute, Lucknow)

Dr. Narendra Mehrotra began by underlining the need to understand the worldview of any medical system, in order to initiate its regulation. There is also a need to know the lay of the land, i.e., the players involved in any health system to ensure its regulation. In the context of regulation of indigenous health systems, the 'players' would include organized knowledge systems of AYUSH, folk traditions and home remedies.

Mehrotra illustrated how the worldview of a medical system is relevant for its regulation, through the example of Ayurvedic worldview. In broad brushstrokes, Ayurveda conceptualizes human body as being integrated with the cosmos and defines health as a balance between body humors, processes of metabolism and excretion, and the wellbeing of senses, mind and the soul. Thus according to Ayurveda, health is constituted by an individual's physical and socio-economic wellbeing. By this logic, Mehrotra contended that achieving health of a population would make it mandatory to implement universal health coverage. Also, the Ayurvedic worldview dictates that the realms of education, health and judiciary should not be commercialized, which would have crucial implications for the way in which this system of medicine would be practiced and regulated.

Mehrotra outlined the major constituents of the indigenous health systems prevalent in India, viz., Ayurveda, Siddha, Yoga and Naturopathy, Sowa-Rigpa (Amchi), Local Health Traditions (covering a range of practitioners like bone-setters and traditional birth attendants), home remedies, Unani and Homeopathy. According to Mehrotra, for the sake of official record, Indian systems of medicine are equipped with all the infrastructural and policy support: like presence of hospitals, clinics, colleges, Research and Development institutions (for Ayurveda), research laboratories, institutionally trained and registered practitioners, and a centralized system of regulation of these systems, under the Central Council of Indian Medicines Act, passed in 1970.

In 2002, a separate policy for Indian systems of medicine, named as AYUSH was proposed, with provisions for a separate ministry; it was envisaged that eventually the AYUSH health care systems will be integrated with the national health care delivery systems. However, according to Mehrotra, the setting up of a separate ministry for AYUSH was not actually intended for promoting AYUSH systems per se, but for promotion of their export outside India and for their global recognition. Mehrotra contrasted this with the case of Korea and China, wherein the respective states strengthened their traditional medical systems internally before moving in the direction towards their globalization. This skewed priority has resulted in an abysmal state of affairs for AYUSH infrastructure, which has been neglected. At the same time, Mehrotra highlighted the wide coverage of AYUSH services, notwithstanding this neglect of infrastructural facilities and lack of institutional support.

The speaker then turned towards challenges facing AYUSH presently, of which a crucial issue was in the context of regulation of AYUSH systems. Despite the existence of two councils for regulation of AYUSH systems and 47 state boards for the same, there exist no standards for a large number of formulations used in Ayurvedic practice. Also, the question of regulating the realm of home remedies, wherein the knowledge base resides within communities, is a formidable one. A similar dilemma arises with regard to regulation and standardisation of single ingredient medicines in Ayurveda, which are sold as commodities, but consumed essentially as medicine.

He also highlighted the problems with curriculum design in AYUSH, wherein the flow of knowledge tended to be one way. In addition, AYUSH services are marred by restrictive remunerative practices. On the policy front, he reiterated the lack of policy and administrative support for these systems of medicine, which has resulted in an overall lack of confidence and leadership triggering an internal crisis within the AYUSH systems. These issues have been compounded by a further systemic erosion of the inherent strengths of these systems, caused by denigration of their resource base and of their educational infrastructure and their neglect in the mainstream healthcare. Mehrotra emphasised the necessity of bringing in the focus of AYUSH systems back to public health concerns, and an interaction between Ayurveda and biomedicine which is characterised by a dialogue, instead of top-down prescription.

Structure and Variations within Ayurveda Janardan Pandey (Consultant, Morarji Desai National Institute of Yoga)

In his presentation, Shri Janardan Pandey outlined the variations in traditions, governance and infrastructure in Ayurveda. He began by clarifying that variations in structure and practice of Ayurveda are manifested in myriad ways: differences in family traditions of practice, in 'guru-shishya' tradition, linguistic variations in interpretations, in institutional traditions, systems of governance and in commentators' view of original texts.

He highlighted 4 traditions of Ayurveda as elaborated by Prof. P.V. Sharma: Bangeeya, Kashi, Panchal and Dakshinapaty. Though, as Pandey clarified, several of these traditions in north India are fast disappearing, while it is largely the traditions practised in the South which are still surviving. While describing the process of creation of sub-traditions within a single Ayurvedic school, Pandey described the case of Ashtavaidyam tradition, native to Kerala. This tradition was exclusively practiced by Brahmins; but as the lower castes sought access to this knowledge, the latter blended their folk practices with the dominant Ayurvedic practice, thus giving rise to a new tradition of Ayurveda.

Variations in governance of Ayurveda are a consequence of the fact that health is a state subject while some issues are a part of the concurrent list, regulated by state governments thus resulting in difference in governance at state and central levels regarding technical directors, drug controllers, etc.

[3]

Contemporary Structure of LHTs in India G. Hariramamurthi (Head, Centre for Local Health Traditions, Foundation for Revitalisation of Local Health Traditions (FRLHT))

This presentation focused on the status of local health traditions (LHTs henceforth), which are distinct from the AYUSH systems. The latter are codified Indian systems of medicine, while LHTs refer to the non-

codified medical knowledge transmitted orally and which is practiced in non-institutionalized settings. Shri Hariramamurthi contended that while we lament the marginalization of codified Indian systems of medicine by biomedicine, the former in turn give no room to non-codified systems and practices. The framing argument of his presentation was the lack of policy support for LHTs in spite of the extremely high usage of these practices at the community level.

Elaborating upon the contours of LHTs in India, he specified that there are about 1 million practitioners of LHTs (traditional birth attendants, bone-setters, poison bite healers, herbal healers, etc.), apart from the several more millions who practice at the household level. LHTs are relevant for a large chunk of poor population in India for its advantages like providing access to knowledge and skills, medicinal plants, and indirect saving of household expenses for primary health care. LHTs also provide ecological and health security, while simultaneously providing livelihood options for the practitioners. A whopping 6,200 plant species constitute the resource base of LHTs, out of which almost 200 species are now threatened due to commercialization.

Hariramamurthi elaborated upon the problem areas in the context of LHTs: inadequate budget allocation, increasing privatization of existing health care services, erosion of traditional health care practices and knowledge, and shrinking of natural habitats which impact adversely the resource base of LHTs. These present a grim picture, when we consider that most of the poor in rural India depend largely upon LHTs in the absence of biomedical or Ayurvedic health care service.

He elaborated upon the efforts taken by his organization in order to conserve and promote LHTs, in a strategic partnership with community, state governments and NGOs, which involved developing a conservation network of plants in 18 states involving farmers, healers' associations and NGOs. Hariramamurthi emphasized the need to conserve resources, without which the knowledge base of LHTs will be rendered useless.

In the last section of the presentation, Hariramamurthi touched upon some broad policy-level prescriptions vis-à-vis LHTs. He stressed that in the light of inadequate financial and human resources for health care, LHTs constitute a 1 million strong community-supported health care practitioners who the poor can access and whose skills and knowledge base needs to be strengthened. Thus we need to deconstruct the belief that health care can only be provided by institutionally trained experts;

in fact Indian systems of medicine (AYUSH) and LHTs have the potential to play a much larger role in public health in India.

Similarly, there is a dire need to document the knowledge and practices prevalent in LHTs, especially since most of this knowledge is orally transmitted by now-aging healers. Lastly, he pointed out the futility in trying to evaluate the clinical efficacy of medicinal plants used in LHTs through clinical methods like RCTs (randomized controlled trials). Ayurvedic standards would be more appropriate in assessing the efficacy, according to Hariramamurthi. He ended by pointing out the need to critically re-examine the budget allocation of AYUSH and its implementation.

[4]

Summary of the Session

This session covered a wide range of themes relating to the structure, variations within and of contemporary status of traditional medicinal systems in India. It was evident from the presentations and the ensuing discussion that the current status of Indian systems of medicine and local health traditions is fundamentally linked to the state policies and their impact. From the presentations, it was clear that the scenario is bleak: historically one sees a consistently low level of priority given to Indian systems of medicine in terms of budgetary allocations, and policy and administrative support.

Thus as Mehrotra pointed out in his presentation, though Indian systems of medicine are equipped with the necessary infrastructure, the latter exists merely as lip service, since the systemic lack of support and marginalization has resulted in poor quality of the existing infrastructure and a lack of confidence and leadership within the realm of AYUSH. The rot has set in other ways as well, as manifested in erosion of traditional knowledge, erosion of the resource base/medicinal plants and so on.

From the presentations as well as the discussion, the acute neglect of Indian systems of medicine in mainstream health care system as also the lack of integration of the former in public health care in India was apparent. In recent times, the neoliberal policies of the Indian state have further added to the adverse policy effects on the Indian systems of medicine: for instance, Hariramamurthi pointed out the ill-effects of opening up the traditional systems of medicine to the vagaries of

commerce and market, and of privatisation of health care. Mehrotra also contended that the setting up of AYUSH department by the state was in fact geared more towards its export and globalization, rather than strengthening the systems per se.

The discussion raised the crucial question of integration of Indian systems of traditional medicine with mainstream health care services. The presentations earlier had pointed out to some efforts that have been made at the policy level in order to facilitate integration such as colocating AYUSH practitioners in PHCs, etc. However since the interaction between biomedicine and ISMs has always been characterized by a one way flow, rather than dialogue, these efforts seem suspect.

Is there a real change in attitude towards AYUSH, has it improved the status of AYUSH, has the power imbalance been addressed, these questions remain unanswered. Dr. V. Sujatha also questioned the concept of 'integrative medicine' which has found currency of late, which alludes to the efforts at combining allopathic medicine with other medicines from AYUSH: she contended that this was a genre created by pharmaceutical companies in order to co-opt local health traditions.

At a more generalized level this is an indicator of a politics of knowledge, which privileges biomedical system over other ways of perceiving health and managing ill-health. As Hariramamurthi emphasized, the issue of recognizing LHTs is in essence a questioning of the monopoly of institutionally trained biomedical experts in treating ill-health. In the discussion, Sandra Albert contended that knowledge needs to be recognized as residing within the community and not just within universities and institutions. She commended the efforts of Martin Luther Christian University in Meghalaya which recently gave honorary doctorates to persons who had made substantial contribution to LHTs.

Regulation of LHTs and AYUSH systems is the other contentious issue which raises crucial questions regarding the status and practice of traditional systems of medicine. Mehrotra brought up the stark dilemmas of standardising vis-à-vis Ayurveda and home remedies. Establishing standards would also entail establishing a regulatory regime; the latter would be difficult to operationalize with regard to practices which are not institutionalized or which are not easily amenable to assessment by classic methods of Evidence-Based Medicine.

V. Sujatha highlighted the paradox of regulation of Ayurvedic medicines: the state can allow hazardous things like GM crops and chemicals, but will raise objections about the use of Ayurvedic and traditional medicines in the name of safety. In this context, 'whose safety' is the relevant question to ask, taking us back to the point about the state merely wanting to export AYUSH, rather than to strengthen it. The linkage between attempts to regulate/standardise traditional medicines and commercial imperatives need to be closely studied in this regard.

In the context of LHTs also, regulation and standardisation brings forth difficult questions. Sandra Albert emphasized that community practice and an informal mode is at the core of LHTs and cautioned that some part of this essence might be lost when LHTs are brought under a regulatory regime.

All the presentations and the discussion indicated an urgent need to document the sheer range of traditional medical systems, both codified as well as non-codified. As Janardan Pandey and Hariramamurthi indicated, LHTs and Ayurveda have a wide range of traditions. The knowledgebase of oral traditions especially, run the risk of being lost due to lack of documentation. From a policy point of view, it is crucial to recognize that AYUSH systems and LHTs are not a monolith, but have several variations in their structure and practices.

Session-IV The Approaches to Nature of 'Evidence' in Relation to Efficacy and Quality of Traditional Medicine

Nature of Evidence for Health Systems Development

Helen Lambert (Reader in Medical Anthropology, School of Social & Community Medicine, University of Bristol, UK)

Dr. Helen Lambert contended that the dominant focus in terms of development of evidence base in India has been to test the efficacy of medicinal products along with a broad concern with legitimacy on the global stage. While the underlying objective of Evidence-Based Medicine (EBM) methodologies is to standardize the evidence of efficacy of various drug regimens to allow comparison between them, application of EBM methodologies to test the efficacy of Complementary and Alternative Medicine (CAM) is critiqued. This critique is based upon the fact that EBM methodologies like randomized control trials require the de-segregation of components that are actually combined in real world usage. Hence they do not really evaluate the effectiveness of the medicine/drug.

In order to illustrate the dilemma of producing standardized evidence across therapies which vary widely, she referred to her work with bone-setters in Rajasthan, who form a part of the local health tradition, excluded from the formal traditional medicine sector. The practitioners insist that a key component of their practice is the medicines that they use to reduce inflammation and they guard these recipes carefully since they are family secrets. But there is a lot of variation in the extent to which they regard the medicines as independently efficacious.

Lambert further clarified that in order to test their efficacy (speed and cost of treatment vis-à-vis allopathy) one would require to fill in forms of appraisal that preserve the integrity of this system on its own terms, what is termed as the 'Systems Approach'. Thus while considering the integration of traditional medicine in south Asia, there is a case for the production of this kind of evidence, about the comparison of effectiveness of real treatments in real health care settings, rather than a component efficacy or biological mechanism kind of study. Use of case studies and patient reported outcomes (PROs) could be possible directions for this, with substantial modifications in order to make it into a tool of appraisal. Lambert contended that the emphasis on outcomes of the treatment is actually helpful for building evidence of efficacy in the context of CAM.

It would also be important to see the pre-existing notions what constitute evidence within traditional systems themselves and how practitioners have understood evidence and operationalized notions of what constitutes fair test. She concluded by saying that we should worry less about epistemological incompatibility and methodological oppression and focus more on some of the original principles of EBM and traditional medicine, viz., accountability to patients and fair modes of evaluation.

[2]

If You Only Have a Hammer You Approach Everything as a Nail:
Ayurveda and
Medicine-Based Evidence
Maarten Bode (Adjunct Faculty, Department of Medical
Anthropology and Sociology, University of Amsterdam)

In this presentation, Dr. Maarten Bode attempted to re-interpret the placebo effect, termed as 'meaning response' in Anthropology, in order to provide evidence for Ayurveda. If we want to achieve integration with biomedicine without the erasure of Ayurveda, then it is necessary to develop evidence from the perspective of Ayurveda. Bode elaborated upon Ayurveda as a science and its underlying epistemology and contended that it is important not to lose Ayurvedic concepts in translation, while we do clincial research.

The Ayurvedic concept of the body is based on Indian classical philosophy and depicts it as having systematic associations between different spheres of life: somatic, ecological, spiritual and psychological. Ayurveda is characterized by synchronicity; thus disease from the Ayurvedic perspective is a conflation of different factors which present themselves at a certain point of time in the patient's body. This is different from allopathy, where disease is explained through layers of materiality, organ, cells and chrosomes.

The key perspectives on effectiveness of medical treatment include: empirical perspective, based upon experience; scientific perspective, which is based upon the evidence presented by certain ingredients of the medicines used, and 'meaning response', which is a symbolic perspective on effectiveness. Bode claimed that research shows that betwen 10 and 90 percent of effectiveness can be based upon the

'meaning response'. 'Meaning response' is defined as biologial consequences of a social, human and meaningful interaction.

Bode elaborated upon the contours of 'meaning response', saying that people express their diesase in a cognitive and a somatic way. To treat the illness aspect besides the disease aspect is crucial for effectiveness and it is in this context that ISMs like Ayurveda use metaphors generously, thus evoking a 'meaning response'. In a sense, according to Bode, 'meaning response' is a reinterpretation of the placebo effect.

Bode claimed that anthropologists can contribute to production of evidence on Ayurvedic medical treatments by working on case theories and by comparing and contrasting various treatments done in India by different physicians. Bode pointed towards the disciplines of clinical social science, ethnographic case studies, textual studies, and ethnopharmacology as helping to generate evidence for Ayurvedic treatments. He ended by emphasising that Ayurveda needs to consolidate its own research community and achieve a certain amount of convergence on concepts and methodologies within this system.

[3]

The Nature of Evidence in Ayurvedic Traditions *P. Ram Manohar (Director & CSO, AVP, Coimbatore)*

Shri Ram Manohar presented the Ayurvedic perspective on evidence as it has been documented and codified in classic Ayurvedic texts. According to him, Ayurveda projects itself as a knowledge system and not a belief system; hence it also gave legitimacy to internal and external skepticism and acknowledged the need to develop evidence to address this skepticism.

Ram Manohar elaborated upon various propositions within ancient Ayurvedic texts which indicate how the medical system conceptualized evidence. Thus Charaka Samhita differentiates between a 'chance effect' and a 'real effect': according to Charaka, if a physician cannot justify the outcome of his treatment with proper rationale and evidence, then it can be attributed to chance evidence. Besides this, there was also mention of self-limiting diseases and pharmacological and non-pharmacological modes of drug action, which helped to differentiate between placebo effect and drug effect. In a similar mode, Ayurveda claimed that there was difference

between coincidence, causation and correlation. All these indicate a concern with the efficacy of treatment in Ayurvedic texts.

According to Ram Manohar, Ayurveda was one of the earliest systems to characterize itself as a safe and efficacious medical system: thus *Shuddha prayoga* (a system which will cure one disease but not create a new disease in the body) was the gold standard of safety defined in Ayurveda. *Siddha prayoga* on the other hand, stresses the use of best practices within Ayurveda.

Similarly, the rule of thumb of Ayurveda about not using unknown substances worked as a regulatory guideline which controlled Ayurvedic practice. According to Ram Manohar, it was no wonder then that the history of the growth of Ayurvedic pharmacopeia shows that it took about 50-100 years for a new plant/substance to be included as a part of the pharmacopeia. He also specified that though there are no parallels of the clinical trials that we have today, individual plants had to be studied, combined, processed and applied correctly to make them safe. There was also mention of comparative efficacy between different formulations. Charaka differentiated between a genuine doctor and a quack, wherein the latter will be able to justify the rationale behind his treatment.

Lastly, Ram Manohar described the way in which evidence was presented in a documented form. For a text to be accepted as a valid body of knowledge, it had to comply with certain requirements: knowledge had to be generated out of observation, peer reviewed by reliable authorities and it had to fulfil the requirement of benefitting the larger society.

[4]

A New Approach to Quality and Safety Research on LHT Padma Venkat (Director, FRLHT)

What kind of evidence can we build to support the practices of medical systems which cater to a vast number of people who are untouched by biomedicine as well as Ayurveda? How can we standardize Local Health Traditions (LHTs) using parameters from another health system? Should we re-evaluate all the 8,000 formulations used in LHTs using biomedical parameters and would this process be affordable? These were some of the questions with which Dr. Padma Venkat started her presentation. According to her, Indian Systems of Medicine

hold two promises: they can provide home-grown, cost-effective solutions to ensure the health security of millions of rural households and second, they can make original contribution to the world of science, medicine and nutrition.

Presenting a critique of the current requirements of standardization, she claimed that the current parameters of standardization are not sensitive to the context from where the medicine/substance originates; this process does not reflect safety and efficacy, but at best can reflect identity and purity. She warned that in trying to standardize LHT medicines and Ayurvedic medicine we should be careful that it does not become unaffordable to the masses. The hegemony of Ayurveda is doing this to LHT today, where medicine is affordable it is available only to the rich elite.

She elaborated upon two modes to evolving parameters of safety and efficacy for LHTs, viz., centralized and decentralized. The former mode is essentially community-based and uses the community's awareness of substances (like plants, herbs and concoctions) as a quality, safety and efficacy control, since the level of familiarity can help create sustainable ways of quality checks for LHTs and home remedies.

She also elaborated upon an innovative de-centralized programme termed as 'rapid assessment of LHT'. This entails documenting LHTs in the presence of healers, community members and biomedical practitioners/pharmacologists, with inputs from all the groups. This is followed by compiling a list of all the herbs used in the community and its promotion through home herbal garden programmes. She described how her organization has promoted more than 200,000 home herbal gardens in India and used this method to bring out a list of healing substances for anaemia, malaria prophylaxis and drinking water. Some of the other methods in this section also included maintaining community knowledge registers, community pharmacy and informal outreach mechanisms.

The centralized approach involves more conventional scientific research and Padma Venkat went on to elaborate upon one of the processes: reverse pharmacognosy. This process entails identifying a drug by it appearance and its actions and then arriving at a relevant marker which can be used to control the quality of the traditional medicine prepared. For instance, she clarified that maturity of a particular tuber might be a crucial marker of quality control, in certain plants.

She concluded by reiterating that quality and safety of traditional medicine can be controlled through centralized as well as decentralized methods and the two need not be mutually exclusive. Research in ISM principles is at its infancy, and hence social scientists, public health experts and scientists need to collaborate closely; though in Indian context the three tend to work in their exclusive domains. According to Padma Venkat, R&D on LHTs needs to be more inclusive and more relevant to communities, receptive to alternative approaches, and to change perspectives if necessary, in order to come up with onground solutions.

[5]

A Structured Approach to Validation of Traditional Medicine Narendra Bhatt (President, IASTAM-India Chapter)

At the outset, Dr. Narendra Bhatt clarified that his current research was directed at exploring whether one can locate objectivity in Ayurvedic treatments, which can serve as the basis of validation of these treatments. In a review of research conducted on Ayurvedic treatments between 1982 and 2006, he found that out of a total of 142 papers, only 10 used Randomized Control Trials (RCTs) and only 2 used placebos. He said that this is an indicator as to how inconvenient and inconclusive it is to use RCTs for evaluating the efficacy of Ayurvedic treatments.

By providing illustrations of tests that he had conducted with specific Ayurvedic herbs in the context of particular ailments like leprosy and rheumatoid arthritis, he concluded that objectivity is not the paradigm of only one 'pathy'; it is possible to isolate objectively the clinical effects on a patient of any medical system, including that of Ayurveda.

He further clarified that clinical trials demand objectivity and to ensure this, the variables need to be reduced in any approach to treatment. Since Ayurveda demonstrates a vast data on clinical symptomatology, reducing the variables is a challenge, but not impossible, according to Narendra Bhatt. For starters, we need to minimize the objectives and end points of a research study and evolve very specific laboratory parameters if required in the study.

He then went ahead to elaborate upon a model he has worked upon, in order to establish objectivity in Ayurvedic treatments. The first phase of the EVA model constitutes of 'Evidence', though not in the

biomedical sense of the term; for Narendra Bhatt, it could be a simple observation about a particular therapy restricted to a particular objective. The basic objective of this phase is to document the substance being used and its attributes in terms of its clinical relevance.

Phase two, called 'Validation', the study tries to establish a relationship between the substance and its clinical outcome; this can be done through any kind of study: pharmacological, biological, toxicological and so on. This phase will vary according to the use that the substance is going to be used for, according to Narendra Bhatt. Once this is achieved, we can proceed to the last phase, wherein a wider number of clinical studies lead to the confirmed clinical use of the substance and its 'Acceptance' at the mass level.

Narendra Bhatt concluded by stressing that we have to use clinical trials in Ayurveda because clinical research is an essential part of the growth of any medical system. Also if we have to shift Ayurveda from a physician-based practice to an institutional based practice, then it is essential to establish these therapeutic linkages.

[6]

Summary of the Session

What strikes foremost through these presentations is that the issue of validation/clinical efficacy/evidence in traditional medicine is simultaneously a technical *and* a political issue. The presentations demonstrated a wide range of possibilities of establishing evidence for traditional medicine: through clinical route, as represented by Narendra Bhatt and Padma Venkat's presentations, which explored different models of testing the validity of and standardizing substances used in traditional medicine. Padma Venkat also pointed towards promising possibilities of a de-centralized, community-based approach towards the documentation of LHTs and of attempts to arrive at a standardized list, in collaboration with community, healers and biomedical personnel.

Presentations by Helen Lambert and Maarten Bode brought forth the contribution that social science methodologies can make to establishing evidence and clinical efficacy of traditional medicine. Implicit in the methodologies that they propounded (like People Reported Outcomes, ethnographic case studies and meaning response) was the equal importance accorded to the voice of the patients in evaluating the

efficacy of health services that they were availing of. Similarly, there was also an insistence on understanding how the local practitioners themselves understood notions of evidence and efficacy. In this sense, there was an argument made in favour of studying the 'emic view' or insider's view of what constitutes as efficacy and evidence in traditional medicine. This is an important direction of future social science research on traditional medicine.

But while the most efficacious ways of establishing evidence were debated in the presentations, some also raised the pertinent question of evidence for whom and towards what end? This has been a recurring theme hitherto in all the sessions: the question of legitimacy of traditional medicine vis-à-vis biomedicine is a highly contested *and* a political question, as was shown in the proceedings of day 1 itself; in this session those concerns were reiterated. As Bode cautioned the audience, one desires for integration of Ayurveda with biomedicine, *but without the erasure of the former in the process*. This question also resonated in the ensuing discussion. With specific reference to Ram Manohar's presentation, there was a discussion on whether it is pertinent to translate traditional texts in order to fit them into the terminology of biomedicine with the aim of building evidence.

On the other hand, some presenters did not think that building evidence essentially signified the hegemony of biomedicine. Padma Venkat emphasized that ISMs should not shy away from building evidence and that these systems should also recognize their limitations in devising new methods in order to build evidence.

There was also a concern with preserving the integrity of the medical system while devising a method of standardizing it. Lambert, Bode and Padma Venkat, all three speakers articulated this concern and emphasized that the concepts of traditional medical systems should not be 'lost in translation'.

The presentations also made it clear that modes of evaluating efficacy of and producing evidence might differ according to the different systems, primarily along the axis of codified versus non-codified systems of medicine. Thus, the presentations reminded the audience once again that traditional medicine is not a homogenous entity and that would largely influence the process of devising validation methods as well

Lastly, some presentations sounded a word of caution against the move to standardize traditional medicine: Padma Venkat warned against this saying that we should ensure that medicines (especially those used in LHTs) do not become unaffordable to poor people, once they are standardized. She critiqued that this trajectory seems to apply to Ayurvedic medicines which have been standardized. Similarly, Narendra Bhatt warned that the way we are proceeding with Ayurvedic products, plants and pharmaceutics in the name of standardization is going to create another set of problems in terms of adverse drug reactions.

Session-V Regulatory Mechanisms for Ayurveda in India: Research and Education

Research in Ayurveda and its Regulation Ramesh Babu (Director-General, Central Council for Research in Ayurvedic Sciences)

In this session, Dr. Ramesh Babu, Director-General, CCRAS, described the contemporary scenario of research in Ayurveda. He outlined some of the main challenges of conducting Ayurvedic research in the beginning, the main amongst them being: standardization and quality control of Ayurvedic drugs, a diverse range of concepts which cannot be brought under the modern scientific paradigm, and using clinical research designs and research protocols which are incompatible with the philosophy of Ayurveda.

Ayurvedic research began under the auspices of Indian Council of Ayurvedic Research, which was established in 1963, and till now about 600 Ayurvedic formulations have been standardized. The thrust areas for Ayurvedic research till now have included rheumatoid arthritis, diabetes, gastric ulcerations, liver disorders, stress, musculo-skeletal disorders and metabolic syndromes.

The three main government institutions which are involved in Ayurvedic research are Council of Scientific and Industrial Research (CSIR), Indian Council of Medical Research (ICMR), and Central Council for Research in Ayurvedic Sciences (CCRAS), which comes under AYUSH. Ramesh Babu went on to elaborate upon the Golden Triangle initiative between CCRAS, CSIR and ICMR for developing Ayurvedic medicines through to the stage of industrial production, and collaboration with BHU, AIIMS and BARC for research on cancer therapies.

He also mentioned that notwithstanding its poor infrastructure and low technical manpower, CCRAS has gotten many leads in areas like malaria, psoriasis, epilepsy, malnourishment and schizophrenia through clinical research. To date, CCRAS has obtained 29 patents in all and completed 17 multi-centric clinical trials.

Regulation of AYUSH Professionals and Education Prasanna Rao (Member, Executive Committee, Central Council for Indian Medicine)

Dr. Prasanna Rao, speaking on behalf of CCIM, presented the framework for regulation of Ayurveda education. He clarified that Ayurveda, Siddha and Unani (ASU) services and education is regulated by the Indian Medicine Central Council Act, 1970, including undergraduate, post-graduate and post-graduate diploma courses. He elaborated upon the objectives, curricula and the requirements of these various courses.

The Central Council has also brought forth a minimum standards requirement regulation with the aim to exert some control on the institutions which taught Ayurveda. This regulation recommends minimum standards of infrastructure, teaching and training facilities in these institutions. Presently, there are 252 Ayurveda undergraduate colleges and 90 post-graduate colleges; 41 Unani undergraduate colleges; 9 Siddha undergraduate colleges; and 185 Homeopathy colleges. He acknowledged the poor quality in a large number of colleges and espoused the proposal to shut them down.

While there exist about 420,000 practitioners of ASU presently, Prasanna Rao expressed frustration that this large and important pool of human resource is not utilized in health programmes and health care services in India.

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Reframing the Pedagogy and Practice of Ayurveda: Lessons From the Past for the Present

Harish Naraindas (Associate Professor, CSSS, JNU and Visiting Professor, Faculty of Philosophy, South Asia Institute, Univ. of Heidelberg)

Dr. Harish Naraindas' paper addressed what he termed as, 'a seeming oxymoron': the term 'the modern doctor of traditional medicine'. Naraindas contended that all the students of Indian Systems of Medicine are faced with dual epistemological universes in their education as they are exposed to biomedicine and the respective

traditional systems that they study. This admixture of two different conceptual universes is termed by Naraindas as 'epistemic mangling'. He uses a case study of an Ayurvedic physician practicing in a metropolis in India, in order to show how this *epistemic mangling* is translated into clinical and pharmaceutical practice. This process is fundamentally asymmetrical according toNaraindas: in straddling the two cognitive systems of biomedicine and Ayurveda, it is usually the biomedical categories of disease causation (nosology) that are underwritten by an Ayurvedic therapeutic language, but never the reverse.

He illustrated this process through the case study, in which an Ayurvedic physician conducts his first examination of a patient in order to rule out or confirm an *Allopathic* diagnosis. He then proceeds to treat the patient with Ayurvedic medicine, merely replacing the Allopathic de-worming tablet with Ayurvedic medicine. This according to Naraindas was reflective of a larger process of transformation of Ayurveda, wherein Ayurvedic practitioners, exposed to both biomedicine and Ayurvedic systems, end up using an Ayurvedic pharmacopeia to address a biomedical nosology. This kind of Ayurvedic research/practice does not further the cause of Ayurvedic system in essence.

Comparing the interaction between Ayurveda and biomedicine to the process of creolization, Naraindas contends that the consequence of this asymmetrical interaction is the transformation and simplification of an Ayurvedic protocol to address a biomedical nosological category.

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Summary of the Session

This session was illustrative of the challenges that Ayurvedic research and education face in contemporary India. Prasanna Rao, speaking on behalf of CCIM, outlined the structure and regulation of Ayurveda (and ASU on the whole) education in India. Discussant Kishor Patwardhan shared the experience of consultations by CCIM for revamping the Ayurveda curriculum where several recommendations were discussed, and yet these were not incorporated in the final draft. Instead, several existing standards had been diluted. Ms. Shailaja Chandra said that there is a need to decide what kind of practitioner should be considered eligible to create an appropriate curriculum – should they practice only Ayurveda, or Ayurveda and Allopathy, or Allopathy alone? It was

pointed out that there were efforts to revive the *Guru-Shishya Parampara*, for instance, at the Rashtriya Ayurveda Vidyapeeth.

Naraindas' paper showed the fundamental asymmetry between Ayurveda and biomedicine, which is reflected not just in education for ASU students, but also carries on in clinical and pharmaceutical practice. His contention that the transformation and simplification of Ayurvedic system into a mere 'cookie jar' for practitioners to dip into to treat disorders derived from biomedical nosology finds some resonance in Dr. Ramesh Babu's presentation. Ramesh Babu's presentation highlighted hitherto state-sponsored Ayurvedic clinical research which examined the effectiveness of Ayurvedic pharmacopeia for biomedical diagnoses.

Session-VI Regulatory Mechanisms for Ayurveda in India: Drugs and Practice

Regulation of ASU Drugs D.C. Katoch (Joint Advisor, Ayurveda, Dept. of AYUSH)

The Department of AYUSH, set up in 1995, comes under the Ministry of Health and Family Welfare and is responsible for the regulation of Indian Systems of Medicine in India. The network of AYUSH is quite dense in India with more than 7,000 registered AYUSH practitioners, out of which 70% are institutionally qualified. Similarly at the moment, there exist 8,900 licensed drug manufacturing units for AYUSH.

According to Shri D.C. Katoch, in the context of India, in spite of the state policy support for AYUSH systems, the integration attempted between AYUSH and biomedicine is only at the physical level and not at a functional level. Thus there now exist AYUSH facilities in Primary Health Centres (PHCs), Community Health Centres (CHCs), etc., where doctors of different medical systems offer the patients a choice of treatments, but there is no real functional integration between these systems, in treatment of the patient.

Katoch then went on to elaborate upon the provisions of the Drugs and Cosmetics Act, 1940, which incorporated a separate chapter on regulation of Ayurveda, Siddha and Unani medicine (ASU henceforth) in 1983. Two distinct categories of ASU drugs - classical or generic and patent and proprietary, are legally defined to specify that the ASU medicines and their ingredients have to be essentially from the authoritative books listed in Schedule-I of the Drugs Act. The Central Government is empowered to make and amend the regulatory provisions but the enforcement of law is in the hands of State Governments, for which dedicated Licensing Authorities or Drug Controllers are appointed for ASU drugs.

For policy and technical matters of ASU drugs, the Central Government is advised by an interdisciplinary body of experts called Ayurveda-Siddha-Unani Drugs Technical Advisory Board (ASUDTAB) and for enforcement issues a Drugs Consultative Committee chaired by the Drug Controller General is provided to facilitate decisions for uniform implementation of legal provisions across the country. It is mandatory for ASU drug industry to follow Good Manufacturing Practices (GMP) and pharmacopeial standards of drugs. Drugs not complying with the legal requirements are defined as

adulterated, misbranded or spurious and the defaulters are liable to penal actions.

The Central Government has the powers to ban any drug in public interest and objectionable advertisements in terms of false or exaggerated claims of cure for certain under the Drugs & Magic Remedies (Prevention of Objectionable Advertisements) Act, 1954. In spite of retail sale of ASU drugs being free, all commercial products in the market have to be licensed and the onus of quality lies with the drug manufacturer.

In order to control the quality of ASU drugs, the central government has proposed setting up a central drug controlling body of AYUSH systems, titled the 'Pharmacopoeia Commission for Indian Medicine'. Currently there exist tenure-based pharmacopeia committees, for the duration of three years. These committees are constituted by a panel of interdisciplinary experts including experts from the fields of photochemistry, geochemistry, pharma sciences, medicinal plants, etc.

The process of formulating regulations is complex, following its trajectory from stake holders, to AYUSH, to Drug Technical Advisory Board, pharmacopeia committees, before drafting rules. Comments of stakeholders are again sought on the draft rules and only after the latter's response is the notification finalized and becomes a legal statute. Complex and systematic process of framing the regulations: issues are raised by the state regulatory body or the stake holders: the issues are taken up by the Drugs Consultative Committee or AYUSH, then brought to the Drug Technical Advisory Board, then referred to pharmacopeia committees and draft rules are made and notification is given to the stakeholders in the gazette of India, commenting on that draft and then the notification is finalized and it becomes a rule, consent of Law Ministry is taken.

The central government, through state medicinal plant boards, has supported the cultivation of medicinal plants in more than one lakh hectares of land across the country in order to ensure a sustained supply of quality raw material. Since three years AYUSH has also started an accreditation programme: one which gives AYUSH Standard Mark for domestic market, and AYUSH Premium Mark for the international market.

Regulation of Quality of Drug Production by TAMPCOL A.P. Mahabharathi (General Manager, TAMPCOL)

Shri A.P. Mahabharathi addressed the issue of regulation of quality of drug production by elaborating upon its implementation in Tamil Nadu Medicinal Plant Farms and Herbal Medicine Corporation Limited, popularly known as TAMPCOL. TAMPCOL was set up in 1983 and is a Tamil Nadu government undertaking. Its objectives include cultivation of medicinal herbs and production of ASU products, which are supplied to a variety of state agencies, including General Hospitals, Primary Health Centres, NRHM wings and government medical colleges. TAMPCOL has established one drug manufacturing unit, which is a Good Manufacturing Practices (GMP) certified unit and now has the license to manufacture 197 ASU products.

Mahabharathi proceeded to describe in detail the ways in which TAMPCOL complies with the provisions and requirements of the Drugs and Cosmetics Act, in terms of standard operative procedures, condition of premises, procurement of raw material through a tender process, employment of professional experts, codifying raw drugs and testing them for quality control, regulation in production process, analysis of finished products, etc.

Some of the challenges faced by TAMPCOL concerned procurement of raw material, often due to non-availability of or substandard quality of raw materials. He mentioned that Right to Information (RTI) applications which seek clarifications are a challenge, because at times it is not possible to give all the exact details. But TAMPCOL products are much more affordable as compared to allopathy medicines and that they supplied around 60% of the state government's drug requirements, claimed Mahabharathi.

Traditional Forms of Self-Regulation for Quality and Safety of Services and Products in Ayurveda

P. Madhavankutty Varier (Chief Superintendent, AH&RC, Arya Vaidya Sala, Kottakkal)

Shri Madhavankutty Varier started with the historical context of Ayurveda, wherein Ayurveda was essentially a physician centered activity; the practice of Ayurveda was controlled primarily through self-imposed regulation by the practitioners, i.e., the regulation agreed upon by the medical fraternity in the best interest of the patients' health. Ancient Ayurvedic texts focus on two kinds of regulations, related to therapeutic preparations and those related to clinical services.

Ayurvedic physicians had to comply with a range of requirements related to the process of making formulations and medicines. This included ensuring that the raw material is free of contamination, processing of certain herbs and materials, preparation of formulations in appropriate vessels (depending upon the raw material to be processed), controlling the heat applied, etc. There was also a requirement to elaborate upon the characteristics of the final product. Varier contended that this requirement could be seen as a preliminary form of standardization, both in terms of physical profile and the organic properties of the product.

Similar guidelines applied to clinical procedures as well. Guidelines were provided not just about informed consent of the patients, but also on who should be considered as a patient. A specific modus operandi is insisted for each procedure, especially in the *panchakarma* procedures. There are specific directions in the event of complications during the procedures. The older texts also mention the charges to be levied for professional health services.

Varier concluded that these guidelines could be seen as parallel to the modern medical regulatory mechanisms.

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Summary of the Session

While Ramesh Babu's presentation laid out the regulatory regime of the state for ASU drugs in terms of structure and production, A.P. Mahabharathi demonstrated how this regulatory regime plays out in the manufacturing unit of TAMPCOL in Tamil Nadu. Varier examined Ayurvedic texts in order to show how provisions in these texts functioned as self-regulatory mechanisms for the Ayurvedic physicians in historical times, in areas of preparation of medicines as well as provision of health services.

Dr. C.K. Katiyar of Dabur said that the Bio-diversity Act and Patents Act had impacted production of Ayurvedic medicines such that no investment was happening any longer. Madhulika Banerjee pointed out that the Ayurvedic nosology was either completely ignored or completely restricted to it by two opposing streams of Ayurvedic practice. In production of medicines, even those who attempt textual practice, such as Kottakkal, have had to 'contemporise' Ayurveda, i.e., to adapt to contemporary conditions.

Ananda Samir Chopra appreciated the challenging task in India of putting regulation on an existing practice, in contrast to the German and European situation where pharmacopeia and regulatory processes were easier to put in place for a newly entering practice. Narendra Bhatt commented that the Department of AYUSH was not doing its homework, for instance, there was no data or survey of the Ayurvedic drugs being sold in the country. Mehrotra spoke of the need for lowering GMP for smaller production units. He pointed out that the internal standardization methods of Ayurveda were not used in the Pharmacopeia Council that depended on modern pharmaceutical paradigms rather than those internal to the knowledge system. Padma Venkat too spoke of the need to work with engineers to create appropriate production technologies while keeping the principles intact. Mira Sadgopal and Bhanwar Dabhai critiqued AYUSH for its disproportionate focus on Ayurveda at the cost of folk healers and LHTs.

Session-VII The Existing Standards and Regulatory Framework for Local Health Traditions (LHTs)

Certification of Folk Practitioners by *Panchayats* Bhanwar Dabhai (Founder, Rashtriya Guni Mission, Udaipur)

At the outset, Smt. Bhanwar Dabhai elaborated upon the objectives of her organization: to conserve and protect traditional health practices so as to enable affordable and efficient health services to the population. Rashtriya Guni Mission (RMG) has been functioning in 9 states of India since 13 years, organizing training camps and workshops for about 1,200 Gunis (healers) in the respective communities. She defined Gunis, as local healers and herbal specialists who have accurate knowledge of the flora and fauna of their respective regions and who heal through their herbal repertoire. Most of the Gunis gain their expertise in herbs and medicinal qualities through an inter-generational oral tradition, she said. She was also of the opinion that Gunis do not discriminate on the basis of caste or religion in providing their healing services and that serving the people is their main motivation, as against commercial reasons.

She then proceeded to elaborate the process through which her organization certifies local healers as Gunis. They first try to zero in on the local healers in a village through the village *sarpanch*, or *aanganwadi* worker and then call a village meeting (*gram sabha*). In this meeting it is the people of the community/village who testify for the healing capacity and quality of the healer in question. It is the people of the community themselves who are then asked to submit an application on behalf of the healer to certify him from the village *Panchayat* as a Guni. Once the *Panchayat* certifies them, the healer is accepted as a member of RGM.

The Gunis' medicines are then evaluated by Ayurvedic and botanical experts on behalf of RGM. During health camps organized by RGM, the organization's experts document the medicines prescribed by the respective Guni, so as to follow up on the efficacy of the medicine. Only after follow-up with the patient, is the Guni certified by RGM.

She also elaborated upon the training that Gunis are required to go through, organized by RGM. This includes familiarizing Gunis with basic traditional healing practices and with the process of preparing medicines and exchange of information and expertise about herbs between the healers, Ayurvedic experts and botanists, which occurs on the field (i.e., through organized trips to local forests).

The IGNOU Method for Certification of Traditional Folk Practitioners and Practices Debjani Roy (Professor, Centre for Traditional Knowledge Systems, IGNOU)

Prof. Debjani Roy of IGNOU explained the concept of accreditation and certification of prior learning (ACPL) of the traditional health practitioners (THPs) developed by IGNOU with technical support from FRLHT and QCI, and financial assistance from the Department of AYUSH. As part of the pilot project of this certification, 236 THPs have been certified for the minimum standard of competency for the management of specific ailments.

Dr. Roy explained in brief the concept of ACPL, which is used in a variety of settings across the world today. This form of certification requires that the standards of quality are developed by those in the domain in which the standards are supposed to be applied and competency to be tested. The larger objective of this project is to promote self-regulation of all traditional health workers while ensuring safety and efficacy of TLHPs (Teaching and Learning for Health Professionals) by a third party, voluntary, transparent mechanism.

She also explained the structure of this scheme, spread across 8 states in the country and functioning through district accreditation committees, evaluation committees and nodal institutions who help identify the local healers. The eligibility criteria for healers are defined in terms of age and experience in healing and residence in local areas.

The process is a multi-stage one, proceeding from multiple stake-holder meetings, rapid village surveys, pilot survey, in which they also utilise the data available with local healers' association, if there are registered associations in the local areas. Once the healers are certified, their certification is valid for 5 years.

Regulation of Quality and Access of Raw Material by Folk Practitioners K.N. Arjunan (President, Folk Practitioners Association, TN)

Shri K.N. Arjunan is himself a practicing healer, belonging to the 47th generation of a Siddha healing lineage. He is also the President of the Folk Practitioners' Association in Tamil Nadu. In the beginning of his presentation he touched briefly upon some concepts from Siddha medicine, like concepts of anatomy, longevity of life, etc. He emphasized that their services were accessed by the poor, on account of unaffordable biomedical services and made a case for being included in the mainstream public health strategy. He critiqued the state health policy, saying that the policy has made it harder for the poor to access quality health services, while at the same time enabling a small, elite group of people to access them.

Regarding the question of access of folk practitioners to raw material, he pointed out that the government rules do not allow poor traditional healers to have easy legal access to even a small portion of raw material from their nearby forests; but these same rules facilitate the transport of huge amounts of raw material from their forests to meet the needs of urban people and also for exporting medicines.

He asserted that while traditional quality standards might not appear very scientific to an outsider to the system, the local healers have accurate, innate knowledge about the material they use, and their own practices, which is passed on through generations and is integrated into the healers' everyday context. He illustrated this through the example of turmeric. To be efficacious it is necessary that turmeric is harvested at night. But, he questioned, how can we be sure that the factory-produced medicine ensures that they use turmeric harvested at night only? On the other hand, he clarified that as a healer he cannot use turmeric that has not been harvested in the night. Hence, in a way, his innate knowledge ensures an internally established quality control system, one which need not necessarily be there in factory-produced drugs and medicines.

Quality and Regulation of Traditional Birth Attendants Mira Sadgopal (Principal Investigator, Jeeva Project)

Dr. Mira Sadgopal began by pointing out that midwifery as a profession has been severely under-rated in India. Even though there are about 500,000 *dais* practicing in rural areas today, their services are completely invisibilised. Lack of evidence of their care and services is cited as the main reason to exclude dais from any national health initiative. Mira Sadgopal stressed that the objectives of Jeeva project were precisely to gather evidence for *dais* work and consider it as a knowledge system from a public health perspective.

Dais largely hail from lower castes across India and learn their craft through oral tradition and hands-on experience by apprenticeship with a senior dai. They have an ethic of commitment to the birthing woman and her family and their services are accessed through the caste-based feudal system of exchange of services (Jajmani) in north India. She emphasized that dais belong to a rare skilled tradition which is imparted through women. Also, a lot of their practices bear stark resemblance to those mentioned in Ayurvedic texts.

She mentioned that the marginalization of *dais* began since the colonial period and continued through ambivalent government policies in post-Independence era, leading to a severe degradation of *dais*' skills and status. Structural factors like discrimination based upon their low caste status, poverty and low self-esteem has further deteriorated their skills. The state discourse never links *dais* with health services system; as a result they are not included in NRHM and the government has lost out on an opportunity to capitalize on their enormous experience.

Mira Sadgopal emphasized that one needs to take a political stance for revival of *dais*' skills. It was crucial to organize *dais* along with a strengthened evidence base. There is a need to involve senior *dais* to develop standards and pass on their knowledge to younger practitioners, this way the regulation can start from below, instead of a top-heavy approach.

Research is needed to explore the sub-strata within this group; i.e., who are the practitioners, who are birth attendants, who provide post-partum care, etc. She pointed out that there is an urgent need to break the epistemological gap between biomedical notions of hygiene, quality

and safety, and local understanding of cleanliness and purity (like the earth is considered to be clean in most local contexts, placenta is considered to be sacred and not toxic waste).

Lastly, she emphasized that the link between *dais'* practice and Ayurveda needs to be strengthened, in order to get legitimacy for the former. Ayurvedic physicians should be willing to help *dais* to evolve guidelines to have self-regulation.

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The International Experience of Regulation and Research with Traditional Folk Practitioners and Practices P.M. Unnikrishnan (Research Coordinator, United Nations University-Institute of Advanced Studies)

Dr. Unnikrishnan started by pointing out that most international conventions and global policy positions on traditional knowledge and traditional medicine ignore traditional healers and their concerns. This is despite the fact that in many parts of the developing world (including India) the doctor-patient ratio is much less than the local healer-patient ratio. It is now accepted that cultural cognition of local health practices is much better for those seeking health services, there is social legitimacy for these healers in their respective communities and that local health practices are easily accessible and cost effective. Local health practitioners thus have a clear public health role - as health care givers, counsellors, health educators, and also as priests, ritual specialists and diviners in their respective communities.

Touching upon the examples of bone-setters in South India and traditional birth attendants, Unnikrishnan outlined some of the major challenges in this area: lack of regulation, inadequate government support and reducing community support due to over-medicalization of health care. Similarly, in many countries the role of local healers is recognized as merely an interim role, till the health system is well-developed, i.e., till the latter becomes bio-medicalized. There are also issues of top-down approaches, one-way flow of knowledge, cultural insensitivity and healers' subordination, in the context of approaches towards integration of local healers in health care systems.

Some of the outstanding needs of this sector today concern the preservation and transmission of local healers' traditions, their skill assessment and livelihood support for healers. Unnikrishnan highlighted that we need more research on the extent of local practitioners, their socio-economic conditions, lineage, outreach, training, social legitimacy and quality of care. Research also needs to explore how to maintain the autonomy of local healers and create an inter-generational transfer of knowledge system.

While in recent times local healers are being included in conservation and public programmes, he stressed that there is still a long way to go till the latter can become public health models. Not only do we need to have more rigorous data on successful models of integration, but we also need to have a system of organizational support for traditional healers, where they can interact with mainstream better.

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Summary of the Session

This session covered a vast range of issues, which resonated with several themes discussed during the earlier sessions. A crucial point that came forth with regard to LHTs was their location vis-à-vis the communities in which they were practiced and accessed. It is clear that LHTs are entrenched in the cultural and social context of local communities, thus making their cultural cognition far easier than biomedical categories. Apart from their cost-effectiveness, the above feature makes LHTs and local healers physically *and* culturally accessible to the local populations. This characteristic came across strongly in all the presentations.

Presentations by Bhanwar Dabhai and Debjani Roy were extremely significant, since they represented recent attempts to acquire legitimacy and certification for LHTs and local health practices, which is a welcome move. These attempts might be precursors to models of integrating LHTs in the health care system and also working issues around quality control and regulation. It is important to note that in both the projects the standards of certification were derived more or less from the contexts in which the practices existed, rather than depending upon an external, universal set of standards.

In that sense, these presentations were located at important crossroads: giving legitimacy to local knowledge, giving weight to people's perceptions

in quality control and organizing a body of practitioners who are diverse and scattered. One question raised in this context was regarding the impact on other kinds of local healers: Dr. Lambert wondered what effect this drive of certification will have on local healers termed as *jhaad-phoonk waalas* and *nabhi-bithand waala* (these categories could also be perceived as quacks).

Which brings us to another striking feature of the presentations: the enormous diversity within the practices understood as LHTs. As Unnikrishnan pointed out, there is an urgent need to conduct research on the sheer range of these practices. It would be also instructive to see how these practices have been differentially affected by state policies and NGO intervention. For instance, the question of *dais* seems to be doubly marginalized: thus while LHPs are being increasingly included in state conservation and public health programmes, Mira Sadgopal's presentation showed how the *dais* are in fact, being further pushed out of the zone of reproductive health.

Arjunan's presentation was also extremely important: it represented a traditional healer's first-hand view point on issues of quality control and state policy. His presentation made an argument against external regulation of traditional practices by highlighting how quality control is internalized in these systems because of their inter-generational transmission and the healers' acute knowledge of their craft.

Session-VIII
Possibilities of Integration of Ayurveda and LHT into
the Formal Health Care System
(Integration in Basic and Clinical Research)

Synthesis of Medicine: Why, How & When Ramesh Bijlani (Former Professor, Dept. of Physiology, AIIMS, New Delhi)

According to Dr. Ramesh Bijlani, medicine needs a synthesis that would incorporate the best of modern scientific medicine and traditional systems of medicine. This process needs a critical but unbiased and sympathetic look at the fragments that we wish to synthesize. The first step in the synthesis is to understand the basic principles, and the underlying philosophy of each system that we wish to incorporate in the synthesis. This will require not only studying the systems, but also getting rid of several misconceptions and prejudices that abound about each system. For example, Ayurveda has a coherent underlying philosophy, although it cannot be understood easily in terms of modern science. Without this understanding of Ayurveda, either we would reluctantly accept a few of its drug formulations, or even reject it altogether because its formulations have not yet gone through the mill of randomized controlled trials.

Ramesh Bijlani stressed that appropriate synthesis of different systems of medicine has immense potential for promoting positive health, preventing disease, and making healthcare less expensive, more effective and culturally acceptable. He concluded by saying that the first step towards a synthesis should be making some bold and radical changes in our policies in the areas of medical education, research and healthcare.

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Systems Biology Approach of Ayurveda and Relevance in the Present Context Rama Jayasundar (Associate Professor, Dept. of Nuclear Magnetic Resonance, AIIMS)

In her presentation, Dr. Rama Jayasundar contrasted biomedicine and Ayurveda as distinct systems with disparate underlying philosophies. She pointed out that systems biology attempts to understand the relationship between the whole and its parts, assuming that at each level of organization, the body can be reduced to smaller components. This is a fundamentally structural view of the body in which

interactions between cellular components are assumed to give rise to behaviours of systems.

On the other hand, she elaborated upon the Ayurvedic perspective, which is predominantly functional in nature. Thus Ayurveda understands the psycho-physiological functions of the body through three main properties, viz., movement (*vata*), metabolism (*pitta*) and growth and support (*kapha*). Health is defined as a state of balance between these three aspects and it is the imbalance between these constituents that results in disease.

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Integrative Research Methodology: The Rheumatoid Arthritis Study P. Ram Manohar (Director & CSO, AVP Research Foundation, Coimbatore)

Shri Ram Manohar began his presentation by clarifying that in earlier scientific research on Ayurveda, single plants, single formulations or single interventions of Ayurveda were studied in experimental conditions out of context of the complex decision-making system used by physicians in clinical practice, thus simplifying Ayurvedic principles. The resultant 'lack' of scientific evidence thus posed hurdles in the scientific community acceding legitimacy to the efficacy of Ayurvedic therapeutics. He then proceeded to describe a study on Rheumatoid Arthritis, which was conducted in collaboration with NIH and University of Washington at Seattle. This study constitutes a landmark in evolving a research methodology, which can reconcile the demands of a scientific evidence base with the holistic principles of Ayurveda.

It is crucial to note that it was the external biomedical institutions which approached the AVP for evidence testing and the study began on the premise that Ayurvedic physicians did not adhere to the former's diagnostic categories and hence did not necessarily view this as a treatment of 'rheumatoid arthritis'. In designing the research study, the Ayurvedic practitioners insisted that their treatments not be interfered with and that they should be allowed to modify the drugs and therapies in course of the treatment in line with Ayurveda's individual treatment modalities.

According to Ram Manohar, this study demonstrated that rigorous clinical trials can be designed without compromising the holistic and individualised approach of Ayurvedic treatment. This study introduced for the first time placebos for classical dosage forms of Ayurveda and maintained a double blind, randomized, placebo controlled study design even as it allowed the use of multiple formulations and individualisation of therapy.

He contended that this is the only study that has reported an ACR 70 response to Ayurvedic treatment with a clinically significant improvement in DAS28 score. This study seems to have fulfilled the dual goal of satisfying the Ayurvedic community as well as modern scientists. The outcomes of the study found their way as research papers in prestigious journals like Annals of Rheumatic Diseases and Journal of Clinical Rheumatology. The outcomes of the study were also presented at the Annual Scientific Meeting of the American College of Rheumatology.

In the end, Ram Manohar said that it was a spirit of dialogue between scientific and Ayurveda fraternities and respect for each other's tradition and practice that ensured the success of this unique research design and could point to directions in which future research could proceed.

[4]

Making Bodies of Evidence: X-rays, Fracture Reduction and Credibility Thresholds in a 'Bone-setting' Clinic in Hyderabad Guy Attewell (Director, French Institute of Pondicherry)

Shri Guy Attewell presented a case study of bone-setters in Hyderabad to show how the bone-setters themselves are agents in producing evidence for their practice and also in their attempts at integration. In the first part of his presentation he described a tremendously popular bone-setter's practice on the outskirts of Hyderabad, which demonstrated all the markers of a modern medical practice: X-ray facility on-site, in-patient department, referral system and traffic of patients from urban areas. Similarly he described the case of bone-setters in Hyderabad city who used rigorous documentation of their cases, maintenance of records, photos, videos and testimonies of orthopaedic surgeons in the city in order to legitimize their practices

and as an attempt to present 'outcome-based evidence' of their therapies.

Attewell thus demonstrated how haptic skills find new ways of being measured through technology, through which they can be compared, scrutinized and measured. He contended that these case studies show that local health traditions themselves are stratified and heterogeneous.

[5]

Approach to Integrated Medicine at FMR Tannaz Birdi (Deputy Director, Foundation for Medical Research (FMR), Mumbai)

Dr. Tannaz Birdi shared the FMR methodology being developed using spectrometry for calibrating the efficacy of medicinal plants as to develop standards for community practice. FMR conducted research on using medicinal plants from local health traditions in order to prepare single dose formulations for diseases relevant from public health point of view, viz., tuberculosis and diarrhoea. Would the formulations be intended as self-help, home remedy medicines, or would they be merely a stopgap arrangement till biomedical interventions were available? These were the relevant questions with which the research began.

FMR shortlisted the plants through a collaborative effort involving botanists, Ayurvedic experts, traditional healing experts and local people; short listing was done based upon frequency of quotes, ancient texts and literature evidence. The procedure involved pre-clinical testing and laboratory assays, wherein the efficacy amongst plants was compared, appropriate cultivation methods were decided upon, standardization was extracted and effect of storage and toxicity was tested. The speaker cautioned that choice of assays is important with reference to confirming the efficacy of a plant.

Tannaz Birdi explained that a combination of crude extracts is far more effective than isolated active principles; but standardizing the multiple compounds is a challenge for plant research. She specified that FMR is currently conducting research on a plant extract which works on a range of anti-diarrheal pathogens, bypassing the need for differential diagnoses in the field, which is important in resource-poor settings.

FMR has also identified pepper as an anti-tuberculosis drug extract, and is in the process of standardizing these extracts.

[6]

Summary of the Session

As the discussant of this session Leena Abraham noted, the presentations in this session represented efforts towards integrating biomedicine and traditional systems of medicine at all levels: theoretical, epistemological, methodological and practical. She highlighted some of the key issues that come to the fore, while attempting integration. For instance, how do we make these discussions and attempts at integration relevant to the question of public health and universal healthcare? How can these conversations contribute to the achievement of democratic pluralism? Abraham noted that these experiments and efforts were contributing to the emergence of a conceptual language that would be required to reconcile the systemic differences in biomedicine and traditional systems of medicine.

Dr. Dinesh Abrol also lauded these efforts at integration undertaken at the level of research. He pointed out that this was commendable given the fact that even within allopathy there is hardly any collaboration between basic and clinical research. He pointed out that the Health Research Policy put out by the Department of Health Research did not mention Traditional Medicine at all. The Sectoral Innovation Council on Health had attempted to initiate a dialogue but it did not happen since the focus was on modern science.

In the context of various research projects elaborated upon in the presentations, V. Sujatha from JNU cautioned that it is important to elide dichotomy between the mind and the body: this is a fundamentally biomedical perspective, and it is important to avoid forcing this dichotomy on Ayurvedic concepts while designing and conducting research. She forcefully argued that a false categorization of Rationalism vs. Holism was inadvertently being created through superficial comparisons of biomedicine and Ayurveda. She critiqued use of the term 'Integrative Medicine' since it is largely being used by the mainstream globally to privilege biomedicine over traditional medicine, not bringing them together on an equal footing.

Session-IX
Possibilities of Integration of Ayurveda and LHT into
the Formal Health Care System
(Integration in Practice and Health Service Delivery)

The Approach of Integrative Medicine G.G. Gangadharan (Director, Institute of Ayurveda and Integrative Medicine, FRLHT)

According to Dr. G.G. Gangadharan, integrative medical practice could be understood as the creation of safety, efficacy and evidence of Ayurvedic medicine by extensively using conventional diagnostic mechanisms. The intention behind this venture is not to devalue Ayurvedic methods but to create a dialogue between the two systems and develop evidence in a form, which is understandable to the majority of medical fraternity. He added that his institute was also in the process of developing bio-markers for Ayurvedic concepts like dosha, aama, etc., working on the basic premise of the holistic system approach: which encompasses all the conditions which will affect the body, mind and spirit in terms of diet, medicines and lifestyle changes.

According to Gangadharan, a review of the last several decades of research shows that this research has happened without any mutual interaction between practitioners of two systems. Thus the challenge for integrative medicine is to initiate a dialogue between practitioners of various systems of medicine, with mutual respect and understanding. To achieve this he proposed conception, promotion and support to clinical research projects which involved professionals from multiple systems of medicine. He further elaborated upon integrative medicine as being developed at IAIM, where Ayurveda was the main form of practice with modern diagnostics being brought in, as also elements of modern physiotherapy and ophthalmology.

[2]

Integration of Ayurveda in Modern Surgical Practice Ravi Bapat (Former Professor, Department of Surgery), and Supriya Bhalerao (KEM Hospital and College, Mumbai)

Presenting the jointly authored paper, Dr. Supriya Bhalerao contended that the USP of modern medicine is its ability to demonstrate the cause-effect relationship for a disease; according to her if the line between experimental validation and observational evidence can disappear then Ayurveda can gain legitimacy. She proceeded to elaborate upon the

practice of integrating Ayurveda in biomedical practice in two research centres, located at the interface of tertiary medical care.

She described integrative practice in three areas, viz., use of Ayurvedic medicines in treating allopathic diagnoses, use of Ayurvedic therapies and last, use of Ayurvedic concepts in clinical research. In the context of use of Ayurvedic medicine she gave several illustrations including the use of *rasayan* plants effectively for treating obstructive jaundice, cancer, healing wounds, diabetic neuropathy and tuberculosis.

Similarly, she also elaborated upon the use of Ayurvedic therapeutic procedures to treat paediatric patients of fistula, varicose veins and obesity. Finally, she contended that Ayurvedic concepts can be integrated with biomedical practice as well: e.g., recently efforts have been made towards developing biomedical markers for the Ayurvedic concept of 'prakriti'. She elaborated upon research which attempts to test the response of persons with different prakriti to allopathic treatments. There are even referrals from biomedical doctors to test patients' prakriti, so that the former can adjust their treatment according to the prakriti of the patient.

[3]

Quality Improvement and Integration: AYUSH in Public Health from a Health Systems Perspective Ritu Priya (Professor, CSMCH, JNU)

Prof. Ritu Priya contended that the neglect of AYUSH and LHTs in the health care service system in India is a function of health care planning in post-Independence India. Not only was the process of health care planning top-down, but it also embraced uncritically biomedical technology as the model for development of health care services, at the cost of AYUSH systems and LHTs. She said that in order to achieve people-centred health care and a genuinely democratic medical pluralism, planning needs to introduce structural changes in the health care system.

She pointed out the flaws in the existent health service structure, viz., lack of infrastructure for outreach of AYUSH services, inferior quality of education, inequality in allocation of budgets for AYUSH and biomedicine, and an overall lack of vision in integrating AYUSH with primary health care services. Health care needs to be redefined from

signifying hi-tech tertiary care to rational secondary and tertiary care as a necessary component of care given at PHC and CHC level, according to Ritu Priya. She also emphasized that people's empowerment is entirely absent from the current public health discourse and there is a need to insert this aspect in future planning.

She proposed details of a structure of health care delivery system, which embodied a public and community centred structure. This proposed structure was based upon an NHRC study conducted across 18 states, which indicated that wherever health services were of reasonable quality and there was no constraint on access, patients exercised a rational choice between allopathic therapies and therapies from Ayurveda or Siddha. The survey showed that almost 20-90% of the households surveyed used LHTs for a variety of ailments. Notably, 70% of the biomedical doctors interviewed in the survey agreed that traditional medicines had therapeutic value and 55% were ready for cross-referral: these findings are crucial from a policy point of view.

According to Ritu Priya, the new proposed structure thus aims to promote home remedies actively, since the latter have been systematically delegitimized over the last few decades. She added that apart from *Aanganwadi* workers and village health and sanitation committee, local health practitioners and traditional birth attendants (TBAs) should also be a part of the committee at the village level which is responsible for local health care. Some of the other recommendations included: appointment of an AYUSH doctor to lead the team at the level of community health care to promote local health practices, cultivation of herbal gardens in the premises of PHC, appointment of a social worker to the team, who would be responsible for intersectoral co-ordination and for ensuring access of marginalized sections of the village to health care services.

In conclusion, Ritu Priya reiterated that it is crucial to incorporate people's choices (of accessing AYUSH services) in the institutional structure of health care service delivery: this would amount to legitimizing people's knowledge. Encouraging appropriate research, appropriate utilization of AYUSH resources and an open dialogue between systems of medicine would eventually pave the way for a democratic pluralism. She, however, cautioned that achievement of democratic pluralism remains a question in the context of increasing commercialization and commoditization of health care in contemporary India.

The first two presentations in this session demonstrated the attempts to integrate Ayurvedic practice with biomedical diagnostics. In the last session, Ritu Priya elaborated upon the relevance of integrative medicine from the point of view of public health and universal access to health care. Thus, while Gangadharan and Supriya Bhalerao's presentations represented attempts to integrate the two systems in health care practice and research, the last presentation brings up the issue of institutionalising this attempt at integration in the state health care delivery system, in order to achieve universal access to health care.

These presentations demonstrate that integration of traditional and biomedicine has to be achieved at multiple levels: research, practice, institutional structure and policy. Only then will we be able to achieve the ideal of 'democratic pluralism' which Ritu Priya elaborated upon in her presentation.

List of Participants

Sl. No.	Name	Designation	Institutional Affiliation
1.	A.K. Ganeriwala	Joint Secretary	Dept of AYUSH
2.	A.M. Khan	HoD, Department of Social Sciences	NIHFW
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5.	Ananda Samir Chopra	Medical Director	Ayurveda-Klinik, Kassel
6.	Anil Kumar	Statistical Assistant	CSMCH, JNU
7.	Anuradha Jain	Senior Consultant	NHSRC
8.	Anuradha Singh	Scientist	NISTADS
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25.	Helen Lambert	Reader in Medical Anthropology	School of Social & Community Medicine, University of Bristol, UK
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