

Evidence Based Traditional Medicine: For Whom and to What End?

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Abstract

Like any form of knowledge traditional medicine (TRM) is constantly asserted, debated, reformulated and rearticulated. Scientific evidence is increasingly becoming a challenge for the integration of traditional medicine (TRM) in health care. At the same time even proof for the effectiveness of the well-established medicines of India and China is meager. One of the reasons for this state of affairs is that the project of Evidence Based Medicine (EBM) and its epitome the Randomized Controlled Trial (RCT) are biomedically centred and therefore tied up with power relations. Whole Systems Research and a participatory approach to medical effectiveness are suggested as methodologies for (im-)proving the quality of TRM. After all, seen from the perspective of patients and their social network the effectiveness of medical treatments is a local and private phenomenon. Traditional medicines and treatments are actively used for generations. Their evaluation therefore need not begin in state of the art research laboratories but can be initiated from the clinical side. To provide health security to people with limited financial means we need innovative and transdisciplinary perspectives on medical efficacy. For our critical discussion on the worth of TRM India and Ayurveda provide the context.

Key words

Evidence Based Medicine, Traditional Medicine, Ayurveda, India, World Health Organization, placebo, efficacy, in situ effectiveness, Whole Systems

Research, revitalization, accreditation, participatory approach

1. Introduction

In the view of at least some commenters, the rise of alternative medicine is a quest for a more compassionate, personalized, and comprehensive health care. The trend is almost certainly also fuelled by a growing faith in so-called natural products as intrinsically good and safe, which is not at all a valid assumption. This faith is easy to exploit commercially. It is less easy to exploit when traditional medicine is in the hands of properly trained, experienced, and licensed practitioners performing an ancient, culturally respected, and useful art of compassionate care and healing (Margaret Chan, Director General of WHO, WHO World Congress on Traditional Medicine, Beijing 2008).

In our times of Evidence Based Medicine (EBM) it is reasonable to ask Traditional Medicine (TRM) to prove its worth. However, we lack established research methodologies that accommodate locally bounded disease categories, aetiologies and therapeutics. We better also realize that scientific validation of treatment efficacy by itself does not guarantee treatment effectiveness for individual patients and local communities especially not for those who have to survive on a few dollars a day. Apart from economic constraints, social and cultural factors determine if treatment is sought at all and if treatment regimens are followed properly. In developing countries services and medicines are often not available, not affordable, or due to local perspectives on the body and its ailments, may not always make sense. Even well researched therapies fail when health care providers do not diagnose properly due to extremely short consultation time and lack of respect for patients and what they have to say. According to the World Health Organization (WHO) sixty to eighty per cent of people in developing countries depend on TRM for their health security. This makes it necessary to provide TRM of good quality.

This essay wants to suggest realistic ways of determining both efficacy and effectiveness of TRM treatments.¹ Though our focus is on patients in areas euphemistically known as resource poor, some of our arguments and suggestions

¹In the article we treat 'efficacy' and 'effectiveness' as reserved terms. The former denotation refers to outcomes of research sanctioned by the international biomedical and pharmacological research community while the latter implies the worth of treatments on the ground, i.e. for patients who make use of them.

are also of relevance to CAM therapies frequented by middle class urbanites from the North and the South. Local perspectives on the value of medical treatments can complement and therefore improve the quality of TRM in its popular, folk and semi-professional forms. Determining the efficacy and effectiveness of TRM treatments and medicines cannot be left in the hands of pharmaceutical companies, national and international bodies, and university departments alone. Stakeholders such as traditional experts, patients and households can contribute to the evidence base of TRM.

We start with discussing the constraints of the current project of EBM from the perspective of TRM. Then we examine the WHO's contribution to the validation of TRM. In the two sections that follow we suggest Whole Systems Research and a stakeholders approach as means for testing and improving the quality of TRM. Ayurveda as the largest form of Traditional Indian Medicine (TIM) provides the context for our discussion on the worth of TRM. We have chosen Ayurveda because both authors are acquainted with Ayurveda though from different perspectives and points of departure. Before we start our discussion of the contribution of the WHO to measure and improve TRM we critically examine the project of EBM from the perspective of TRM.

2. The limits and rhetorics of Evidence Based Medicine

The efficacy of TRM has been a recurring theme in the work of medical anthropologists over the last forty years (see for example Kleinman and Sung, 1979; Young, 1982; Van der Geest, 1988; Anderson, 1991; Waldram, 2000; Barnes, 2005; Lambert, 2006; Adams, 2010-2011). These authors argue that medical evidence and medical effectiveness are deeply embedded in social relations. When it comes to clinical practice factors like the natural course of disease trajectories, the body's capacity to cure itself, the health benefactions that come with care and attention, the easing of anxieties through diagnosis and treatment, the expectation of relief, the power of the human imagination, and the will and trust of both patient and practitioner at times substantially add to disease management and cure. Empirical research shows that human bodies react to meaning (see for example Kaptchuk, 1999, 2000; Moerman, 2002; Ritenbaugh & Nichter 2009). This meaning response – positively labelled 'the placebo effect' (lit. I shall/will please) and negatively 'the nocebo effect' – plays an important role in medical encounters. However, RCTs (Randomized Controlled Trials) – the epitome of EBM – are designed to filter out biological responses to meaning. In RCTs patients and medical practitioners are blinded, because their preferences, affinities and commitments are not allowed to influ-

ence outcomes. Clinicians however know that positive expectations can enhance recovery and can help patients to accept and live with their ailments. Many medical treatments need active and accommodating patients. Compliance with treatment regimens in its turn asks for trust and commitment. These all are important ingredients – some might even say they are indispensable – of successful medical treatment. Optimism and observance can evoke the body's self-healing capacity and enhance 'spontaneous recovery'. The logic behind RCTs does away with the meaning response and therefore favours:

(...) biomedical's mechanic perspective on the body. The body as a machine robbed from its meaning giving capacity. The dismissal of the placebo is an intentional act and part of biomedicine's quest to identify those aspects of human experience over which it can claim authority and therefore assert control (Waldram 2000, 32).

Though Waldram's qualification of 'intentional' can be critiqued, RCT rhetorics and the project of EBM too easily become a threat to the integrity of TRM and its critical evaluation. From a methodological perspective RCTs are strong in reliability in the sense of replicability of research outcomes but weak in validity, which makes it difficult to generalize research findings to diseases as they manifest themselves in day to day life.² The prestige and structural power of modern biology and biomedicine make it hard to acknowledge alternative medical rationalities. The RCT as ultimate signifier of valid medical evidence has led to the dissection of TRM treatment approaches into researchable components, the use of biomedical parameters to measure outcomes, and to a focus on materia medica at the expense of non-material treatment aspects (see for example Fønnebø et al., 2007). This denies the fact that medical systems have their own way of defining, explaining and treating somatic and behavioural dysfunctions. They all represent different realities in health, disease and healing.

When discussing the effectiveness of medicine it is paramount to distinguish between theory and practice. All medical systems suffer from '(...) a fundamental contradiction: its practice deals with the individual while its theory grasps universals only' (Bates, 1995). Medical theories formulate general laws about diseases while in clinical practice health care providers treat individual patients. This is true for TRM and biomedicine alike. Another objection against

²Obviously, reliability and validity are related like communicating vessels. Reliability is high when experimental conditions are strictly controlled; validity is high when the experiment makes room for the idiosyncrasies of daily life.

the contemporary state of affairs in the production of medical evidence is more specific to TRM. Conventional research on medical efficacy is very costly. Before a medical substance gets registered with the American FDA usually hundred millions of dollars have been invested in research. This kind of money simply is not available for research in TRM.³ A methodological monoculture and lack of research funds at least partly explain why scientific proof for the efficacy of TRM is scarce. Not surprisingly, a recent review of reviews article published in the *Journal of Alternative and Complementary Medicine (JACM)* – a magazine established in the 1990s with the objective to provide TRM with a research base – concludes that there is “(...) an overall lack of evidence of efficacy and research support” for Traditional Chinese Medicine (Xue et al. 2010, p.310). This conclusion is revealing. Not only because it comes from a magazine that supports TRM but also because it concerns Traditional Chinese Medicine (TCM), the best researched medical tradition. A study that compares the scientific status of TCM with Ayurveda shows that for Indian medicine the situation is even worse (Patwardhan et al., 2005). It therefore does not come as a surprise that peer reviewed biomedical and pharmacological journals do not provide evidence for the efficacy of chyawanprash, Ayurveda’s best-selling medicine (Bode, 2009). Lack of modern scientific evidence for the efficacy of Ayurvedic medicines and treatments has also been noted in the case of leukoderma (vitiligo), rheumatoid arthritis, osteoarthritis and diabetes mellitus, all diseases for which Ayurvedic physicians are often consulted (see Elder, 2004; Park & Ernst, 2005; Narahari et al., 2010; Vijitha De Silva et al., 2011).

The concept of EBM is also problematic in another way. It simply is too obvious. Nobody will object to the idea that patients are entitled to treatments that have proved to be effective. Seen from this perspective the notion of EBM is sheer rhetorics and therefore easy to manipulate (see Goldenberg, 2006). EBM is foremost an ideal, not a reality. It is common knowledge among scientists and practitioners that not more than twenty per cent of medical treatments performed in state of the art biomedical hospitals are evidence based. Moreover the majority of the world population does not get the best possible medical treatment. Due to lack of medicines, qualified personnel and diagnostic facilities the poor are often palmed off with surrogate medicine (for India see Langford, 2003; Pinto, 2004). Another observation is that the logic of the market largely determines the focus of medical research projects and even its outcomes (Abraham, 1995; Fisher, 2009). Not the invalidating character of a disease is the most important criterion for investments in research, but a treat-

³The yearly budget of the Indian department of TRM (AYUSH) is approximately two hundred million US\$.

ment's potential profitability. The diseases of the poor therefore do not get the attention they need. However, make no mistake. TRM certainly is not beyond commerce. Empirical research reveals that the commodification of TRM and the commoditisation of its materia medica are common global phenomena (see for example Janes, 2002; Van Hollen, 2005; Bode, 2008; Kim, 2009; Sujatha, 2011).

In the rest of this essay we first critique the efforts done to advance TRM by those in power. It often seems that bureaucrats of international and national bodies for the promotion and improvement of TRM mainly offer lip-service. As a case in point we evaluate the attempts of the World Health Organization in this respect. Secondly, we challenge TRM researchers to make use of methodologies and perspectives of the Whole Systems Research movement which has become more articulated over the last decade. Thirdly, we plead for a stakeholders approach to sift the wheat from the chaff. As an example we put forward the Rapid Assessment-Local Health Traditions (RA-LHT) developed and improved over the last fifteen years by the Foundation for the Revitalisation of Local Health Traditions (FRLHT), an NGO in Bangalore.

3. The World Health Organization (WHO) and TRM: mostly lip-service

More than three decades after the declaration of Alma Ata – till today the declaration is referred to as a mantra – in which TRM was hailed as a means to improve the quality of public health services in the South, integrated public health of good quality is a wish not a reality (for India see Priya & Shweta, 2010; Chandra, 2011). As a biomedically-grounded organization with high ranking officials coming from countries with indigenous scholarly medical systems like China and India, the WHO signals ambiguity. For example, the WHO document 'General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine' states that TRM disease management – apart from physical and psychological aetiologies – also deals with spiritual, cultural and environmental dimensions of health. According to the WHO,

Holism is a key element of all systems of traditional medicine. Therefore, when reviewing the literature on traditional medicine (both herbal medicines and traditional procedure-based therapies), the theories and concepts of the individual practice of traditional medicine, as well as the cultural background of those involved, must be taken into account (WHO, 2000).

Is this a case of lip service to the notion of holistic medicine? After all, the

WHO usually signals biomedical logic and endorses the research methodology of modern pharmacology. Primordial elements (*pañcabhūtas*), digestive fire (*agni*), undigested material (*āma*) and energy (*ojas, chi*) are not accepted scientific categories. The medical and pharmacological logics of TRM differ from biomedicine. But almost four decades after Alma Ata the WHO has not come up with accepted protocols for conducting research on the efficacy of TRM treatments and how to integrate these practices in Primary Health Care (Ahn et al., 2010; Payyappallimana, 2010). A recent analysis of WHO policies shows that these:

(...) fall short of adequately addressing a comprehensive list of concerns related to traditional medicine such as safety, efficacy, quality, access, rational use, inadequate understanding of socio-cultural context of their practice and usage, sustainable use of natural resources and inequity in transactions at various levels. A major gap has been insufficient documentation and studies of existing models of integration and their impact on respective health systems. Such documentation should further strengthen better practice-policy linkages (Payyappallimana, 2011: 6).

Documentation such as surveys is a first step in evaluating the worth of TRM. Without documentation we do not know what really happens on the ground. This can lead to all kinds of misrepresentations of TRM. TRM easily gets stereotyped. Is TRM always holistic and community oriented? Are its treatments always multi-component, individualized and non-reductionist? The answer is negative as many empirical studies tell us (see for example Van Hollen, 2005; Bode, 2006). Evidently, TRM is a container concept mainly defined by what it is not. 'Biomedicine and the rest' reminds us of another crude dichotomy 'the West and the rest'. Though it might be easy to draw a sharp line between biomedicine on the one hand and herbalists and shamanistic practices on the other, but when it comes to the institutionalised medical traditions of India and China such a demarcation becomes rather difficult. In these institutionalized and standardized medical traditions biomedical diagnostics and disease categories have made strong inroads, both in practice and training. The same can be said about the manufacturing and marketing practices of Indian and Chinese manufacturers of traditional patent medicines (for India see Bode, 2008; Banerjee, 2009). Also traditional herbalists and orthopaeds are not always holistic and spiritual in their practices (Unnikrishnan et al., 2010).

Whereas traditional use was considered by the WHO to give legitimacy to TRM this is changing rapidly due to the growing standing of evidence based medicine (EBM). Nevertheless, historical trajectories, variations in forms of

TRM, national and regional specific patterns of use, and policy differences condition the kind of evidence required. For instance in regions such as Japan, USA and parts of the European Union, sanctioned TRM mainly consists of single herbs or formulas with a very limited number of chiefly herbal ingredients for which scientific monographs have been produced and submitted to the authorities. Whereas in countries like India and China clinical practice is centred on multidrug formulations and procedure based treatments. Due to these differences countries address the issue of evidence in their own way and only broadly adhere to international guidelines. For instance the SEARO region holds the position that when a traditional medical substance is part of a long-standing medical practice within a local community, toxicity and efficacy studies are not needed unless the substance is marketed outside the community of its origin. At the same time the WHO is of the opinion that, "The quantity and quality of the safety and efficacy data on traditional medicine are far from sufficient to meet the criteria needed to support its use worldwide" (WHO, 2002). This indicates that at least in developing nations there is a separation between the 'community context' and the 'market context'. In the South it therefore makes sense to distinguish between a public health approach to TRM and a market and medical product based approach. It is doubtful if in an overly globalizing world the implementation of such a two stream policy is tenable.

At the same time we see that history and culture determine the representations, perceptions and utilization patterns of TRM. As an example we examine the case of Kerala state in India which has over a century's experience in institutionalizing TRM systems such as Ayurveda and has today an accomplished integrative model. In Kerala today pharmacopoeia and treatment approaches evolved and documented by local physicians in the 17th or 18th century, are widely followed. The formal education system of Ayurveda is modelled on this and there are around seven hundred fifty indigenous pharmaceutical industries making around five hundred traditional Keralean formulations (Harilal, 2009). Many of them are dispensed by approximately ten thousand officially licensed Ayurvedic physicians who are well integrated into the health system through public and private hospitals, clinics and pharmacies. These traditional medicine practitioners are supported by a host of paramedical staff, pharmacists, nurses and therapists who apply elaborate treatment procedures. Albeit some challenges, Ayurveda continues to thrive as a mainstream approach in the health system of this South Indian state. Ayurvedic practices and products are sanctioned by the authorities and are considered to be effective by the public and the authorities alike. The integration of Ayurveda and biomedicine in the state is seen as one of the reasons for relatively good health outcomes in Kerala. Keralean medicines and treatment regimens are exported to other Indian states

and on a more modest scale also to Europe and America. However there are hardly any research based clinical data on any of the drug formulations and treatment procedures which are used in Kerala apart from experiential data of practitioners. Nowadays these data are at the most considered as raw materials for the production of scientific data on Keralean Ayurveda. The modern pharmacological and medical imperative for standardisation contradicts the idea current in TRM that local materia medica and regional medical techniques are to be preferred. Familiarity with medical substances and techniques back up informed usage and explain the popularity of Ayurvedic medicines and treatment procedures. What does it actually mean when for example the WHO says that additional evidence is required for these widely accepted and utilized practices? Are only those Ayurvedic practices and medicines legitimate when efficacy studies have appeared in peer reviewed medical journals which are mainly biomedically orientated and published in the West? Or is the production of scientific evidence only needed when aspects of Keralean Ayurveda gets exported? In a highly competitive global health market where lies the balance between historical, cultural and modern pharmacological evidence to support safety and efficacy of traditional medicines and procedures?

Though the WHO guidelines testify off a broad and inclusive perspective on TRM this has hardly prompted actions of policy makers and the biomedical research community on the pressing issues of medical integration and medical evidence. This has blocked the development of well-reasoned and well researched perspectives on how to integrate TRM and biomedicine without violating the paradigmatic and social logics of the former. It therefore comes to no surprise that the research guidelines published by the WHO in 2000 have not been updated and enlarged by increasingly sophisticated methodological and theoretical guidelines and discussions. Guidelines for research and integration only make sense when they are implemented and adapted accordingly as is the case in biomedicine with the CONSORT guidelines for conducting, documenting and reporting clinical trials (Moher et al., 2001). Is this too much to ask of an international organization like the WHO which again and again has emphasised that TRM is a health reserve billions cannot do without? As it stands now the WHO guidelines for TRM seem to be mainly a formal exercise possibly inspired by a wish for political correctness. Policy makers and researchers need to develop a perspective on how EBM can be made into a tool for advancing the traditional medical sector and how its medical practices, procedures and substances can be integrated with biomedically grounded health services. In this process there must be ample room for local realities of an economic, cultural and historical nature. These policy makers should inform themselves on standing approaches on how to deploy EBM to TRM without

throwing away the baby with the bath water, i.e. without ignoring the paradigmatic and social logics of TRM. In the remainder of this article we discuss two complementary ways of doing this.

4. Whole Systems Research

We need clinical, physiological, psychological and biochemical parameters that make sense within the logics of TRM. After all TRM knowledge systems have unique pharmacological and medical perspectives. Their logics are mainly synthetic and phenomenological. In this sense they differ from the analytical and reductionist perspective of modern science and biomedicine. Though Randomized Controlled Trials (RCT) have the highest status in biomedical research observational studies, factorial designs, and preference trials, seem to be better alternatives for improving and testing TRM treatments (Verhoef et al., 2005; Van der Greef, 2011). Observational studies, for example, are more suitable for the evaluation of TRM. They are cheaper, have higher external validity, and are better equipped to accommodate the medical logics and therapeutic goals of TRM. Alternatives to RCTs are also better placed to accommodate TRM's inclusion and exclusion criteria for patients such as their somato-psychic constitution. Some other alternatives to the RCT design are the retrospective treatment-outcome survey (RTO), the comparison of prognosis and outcome study (CPO) – an 'outcome method' in which biomedical physicians monitor traditional treatments – and the dose escalating prospective study (PDE) which looks at the way experimental subjects respond to traditional single and compound drugs (Graz et al., 2007). TRM treatments often consist of multiple elements such as edible medicines, behavioural guidelines and spiritual practices. Traditional medicines are not the magic bullets antibiotics were in the first decades after their wide distribution. Somato-psychic characteristics and symptoms understood in traditional medical parlance determine which patients are most likely to benefit from a treatment. Treatment objectives also differ. TRM does not have the specific and machine objectified goals of biomedicine such as diminishing cholesterol or elevating the number of red blood cells. Balancing functional systems, cleaning channels, optimizing digestion and reinforcing tissue building are the treatment objectives of the traditional medicines of India and China. TRM also differs from conventional biomedicine in what it considers to be amendable for treatment. Ayurveda, for example, postulates six stages in the progression of disease (*sat kriya kala*). This reflects a different understanding of pathology, aetiology and nosology. Here pathological processes are laced on a continuum leading to increased severity and chronicity. Prodro-

mal symptoms are recognized as early manifestations of a disease and treating patients at an early stage of disease development is considered most effective. Many of these prodromes cannot be objectified by biomedical techniques.

The complexities involved in measuring the safety and efficacy of TRM plant, mineral, metal and animal based drugs must not be underestimated. There are many local variations in names given to medical ingredients and similar compound medicines come under different names. Other challenges are linked up with the logics of traditional pharmacologies in which plant names often indicate their effects. Traditional pharmacologies are often anthropocentric (for Ayurveda see Zimmermann, 1995). Factors such as time and place of ingredient collection, processing methods, and the way a formula is deployed in clinical practice are directly related to the effectiveness of medications. Progress is mostly assessed through clinical signs and symptoms as they show themselves in interaction with other biological parameters such as somatopsychological constitution (*prakriti*), digestive power (*agni*), disease resistance (*bala*), and habituation (*satmya*) to food items, regimens and climates. Visual, tactile and clinical interrogations measure how individual patients react to treatment regimes. Outcomes determine the direction of further treatment. In the non-linear logic of Ayurveda and other forms of TRM diseases are linked to faulting feedback systems which in their turn undermine somatic, sensory, emotional and cognitive functions. Ayurvedic nosology and aetiology testify of a whole system approach and a multi-causality framework. Therefore, one to one correspondences between Ayurvedic and biomedical physiological and pathological entities are highly unlikely. There is growing evidence for the compatibility of modern pharmacological research into genotypes as the basis for developing individualized pharmaceuticals and the logic of individual responses to medicines and treatments of Ayurveda and TCM (Patwardhan & Bodeker, 2008; Van der Greef, 2011; Ghodke et al., 2011). New developments in modern pharmacology undermine RCT concepts such as ‘average patient’ and ‘uniform treatment’ (Liu et al., 2011). It seems that modern developments like system biology and the strife for personalized medicine narrow the gap between biomedicine and Asian scholarly medicines. However, modern pharmacological research is expensive and therefore unaffordable for the traditional medical sector as a whole. A bottom-up approach to quality improvement is a welcome addition to the top-down approach of modern pharmacology and pharmacognosy. In the last section we discuss such a evaluation method that starts from current traditional medical practices, their providers and patients.⁴

⁴Because of the huge interests involved we also need to be sceptical towards medical evidence. After all, the manufacturing of medical evidence has be-

5. Bottom-up research on effectiveness: a stake holders approach

Many people in the South depend upon TRM for their health. Empirical studies show that local providers of TRM are consulted because of positive outcome perceptions. The continued use of TRM has been observed in places where biomedicine is available and is therefore not due to lack of access to modern health care alone (Diallo et al., 2006; Mathez-Stiefel, Vandebroek, Rist, 2012). At least for forms of TRM rooted in local cultures the top-down approach used for testing newly designed biomedical drugs is unrealistic and unpractical. The costs are simply too high and such a top-down approach ignores the empirical knowledge on effectiveness and safety that exists among TRM practitioners and the communities in which they practice. From a local perspective it also does not make much sense to compare the efficacy and safety of TRM drugs against modern pharmaceuticals when the latter are not affordable or available. What we need are in-vivo research methodologies based on perceptive assessments of local health needs and with a keen eye for local empowerment in health issues. TRM has no established research community in the modern sense of the term. However, it would be wrong to assume that therefore evidence for the effectiveness of medicines and treatments does not exist. Such knowledge is transmitted orally from generation to generation and in countries with long standing codified traditions like India and China we find documentation on medical practices and their effects in abundance. Scholarly and oral medical traditions partly overlap though the latter can be less complex in terms of philosophy, medical concepts, and treatment strategies. In the Indian state of Kerala, for example, there exists a rich medical literature in Malayalam, the language of the state (Payyappallimana, 2011). The codification of empirical medical knowledge of local Keralean communities has always been an integral part of Kerala's scholarly medical knowledge (Pannikar, 1994; for Tamil Nadu see Sujatha, 2007). Some scholarly Ayurvedic practitioners possess comprehensive treatment and outcome records extending over more than a century (see Yamashita & Ram Manohar, 2007-08, 2009, 2010, 2011, 2012). Traditional medical knowledge is far from stagnant and is constantly revised and improved (see Sujatha, 2011; Payyappallimana, 2011; Bode, 2012). The systematic documentations of contemporary practitioners and their predecessors can be a first step in the creation of modern medical evidence. To this end stakeholders must create a TRM data base that holds information on diagnostic procedures, disease categories, etiologies and treatments, etc. This also opens the possibility of correlating traditional medical knowledge with biomedical

come an industry by itself (see for example Fischer, 2009).

and pharmacological insights, which might give us a better grip on the validity of traditional disease categories, diagnostic procedures and disease management practices.

To prevent further erosion of folk medicine Indian NGO's and government agencies collaborate since the 1990s with local healers and their communities on projects with the objective to strengthen the bond between codified and oral health traditions (Torri & Laplante, 2009). Improving the medical skills of folk practitioners and boosting their self-esteem and local prestige must lead to the revitalization of local health practices. One way of doing this is the Rapid Assessment Local Health Traditions (RA-LHT), a research methodology which complements assessment with medical training and was introduced in the 1990s by the Foundation for the Revitalization of Local Health Traditions, a NGO from South India. More recently this methodology has been introduced to African and other Asian countries. The experiences with this methodology so far show that RA-LHT is a useful alternative and a precursor to more formal scientific studies on efficacy and effectiveness.⁵ The research process moves from comprehensive documentation via comparing oral knowledge with existing biomedical and codified traditional medical knowledge to a participatory assessment at the community level based on a social learning approach. To make scientific evidence on safety and efficacy of a particular prescription practice locally available the social learning phase of RA-LHT starts with a literature survey. This facilitates the community level assessment phase in which community members, folk healers, scholarly traditional practitioners, biomedical physicians, botanists and field workers, participate. The aim is to come up with systematized TRM practices. A core element in this process is the documentation of experiences of communities with particular medical practices and assessing their quality with the help of evidence from outside sources. The RA-LHT methodology also helps in identifying key community priority health needs and offers a rapid and cost effective approach for determining medical practices that are effective and relevant for local community health. In the last decade networks of traditional healers and other TRM related knowledge carriers such as botanists have been established across India with the objective to share knowledge and experience.

The participatory research methodology RA-LHT is also used to document, evaluate and improve the local handling of regional health priorities. For example in the malaria endemic regions of Orissa and the North Eastern

⁵One of the authors (UP) has worked with this methodology for over a decade and was also part of the team which introduced RA-LHT outside of the Indian subcontinent.

Indian states this methodology has been applied to identify and assess local specific substances for malaria prophylaxis. In a documentation and rapid assessment workshop in Orissa sixteen prophylactic substances were selected and consequently assessed for their malaria preventive activity. Semi-structured interviews were conducted with promising local healers to collect dense information on their malaria related practices. Then these local practices were compared with data on malaria prevention and treatment from codified Ayurveda, phytochemistry and pharmacology. Existing literature was also consulted to determine the safety of the local medicines used for malaria prevention. Multiple stakeholders such as local community members, healers, Ayurvedic physicians, pharmacologists, and ethnobotanists participated in this assessment workshop. It revealed that there is documented evidence on two of the substances locally applied for malaria prevention. Cohort clinical studies are the next step in testing the effectiveness and safety of local preventive and curative treatments. From this case it can be concluded that the RA-LHT methodology advances the systematic documentation of local knowledge and experience in the treatment and management of diseases that are of public health concern of which malaria is just one example.

A recent initiative of the Institute of Ayurveda and Integrative Medicine (I-AIM) together with the Indira Gandhi National Open University (IGNOU) promotes a unique program for assessing and accrediting the knowledge and skills of folk practitioners. This accreditation project also offers clinical training. It is expected that training and accreditation will eventually boost the skills, the prestige and the morale of local healers. Critical revitalization of TRM is an ongoing process. We need constant documentation and evaluation of clinical outcomes, regular community assessments of TRM services and practitioners, and continued support for networks of healers (Payyappallimana & Hariramamurthi, 2012). This bottom-up accreditation and improvement process will eventually sift the wheat from the chaff and lead to the standardization of medical practices and substances up to a certain extent.

6. Conclusion

Medical effectiveness as a 'floating signifier' is contingent upon social, ontological – valid categories and their relations – and epistemological – means for constructing valid knowledge – contexts (Adams et al., 2005). Medical effectiveness is also bounded by individual illness trajectories, objectified disease taxonomies (nosologies) and disease explanations expressed in the words and grammar of a specific medical system (aetiologies). Biomedicine's social

hegemony, the commodification of medical evidence and the huge research investments needed, evoke questions such as ‘what counts as evidence?’ and ‘which parties benefit from the current state of affairs in which RCTs are on top of the evidence hierarchy?’. At the same time it is important to realize that, though there are multiple rationalities in medicine, curing and healing, not everything goes in medical treatment. Fortunately modern science has much more to offer than RCTs for testing the worth of treatments. The fact that medical evidence is socially and ontologically contingent makes it mandatory to critically evaluate the suitability of research models and the validity of research findings. This is all the more necessary because of the huge costs and the vested interests involved in the project of EBM. It now costs one billion US\$ to bring a new FDA-approved drug on the market and the logic of modern biology frames what a drug or a treatment is expected to do in terms of what are considered to be valid mechanisms of action. Both factors work against TRM though it seems very likely that TRM offers valuable services to people in developing countries who are financially poor. It is also important to note that for patients and their families the effectiveness of medical treatments is foremost a local and private phenomenon. The search for good medicine therefore needs an active stand from local communities and socially concerned researchers. It cannot be left solely in the hands of biomedically oriented scientists who tend to ignore social-cultural and economic determinants of health. As a valuable means to sift the wheat from the chaff this essay suggests linking a bottom-up stakeholders approach to the emerging academic field of Whole Systems Research.

TRM does not vanish because sceptics have no faith in it. Millions of people in Asia, Africa and South America depend upon it for their health and wellbeing. We therefore better try to improve upon existing treatments and abolish those that are harmful. One way of doing this is looking at the clinical end of the research spectrum. We need in-vivo research on the worth of TRM practices, materials and notions. This research must be combined with in-vitro laboratory research together with more rigid clinical trials. Trustworthy medical evidence demands triangulation from different sources such as the experiences of patients, practitioners, user communities, clinical scientists, botanists, pharmacologists and social scientists. Drawing from the words of the Director General of the WHO it can be said that for the relatively affluent interest in TRM is the result of the wish for benevolent, individualized and holistic health care, but for others TRM is first resort and often the only available healthcare option. We better take the challenge to provide proper evidence seriously.

References

- Abraham, J. *Science, Politics and the Pharmaceutical Industry*. London: UCL Press, 1995.
- Adams, Vincanne. (2002) Randomized Controlled Crime: Postcolonial Sciences in Alternative Medicine Research. *Social Studies of Science* 32, 659-690.
- Adams, Vincanne et al. (2005) The challenge of cross-cultural clinical trials research: case report from the Tibetan autonomous region, People's Republic of China. *Medical Anthropology Quarterly* 19(3): 267-289.
- Adams, Vincanne. (2010-2011) Encounters with Efficacy. *Asian Medicine: Tradition and Modernity* 6, 1-21.
- Ahn, Andrew C. et al. (2010) Applying principles from Complex Systems to Studying the efficacy of CAM therapies. *The Journal of Alternative and Complementary Medicine*, 16(9), 1015-1022.
- Anderson, Robert. (1991) The efficacy of ethnomedicine: Research methods in trouble. *Medical Anthropology* 13, 1-17.
- Banerjee, Madhulika. (2009) *Power, knowledge, medicine: Ayurvedic pharmaceuticals at home and in the world*. Hyderabad: Orient Blackswan.
- Barnes, Linda L. (2005) American Acupuncture and Efficacy: Meanings and Their Points of Insertion. *Medical Anthropology Quarterly* 19(3), 239-266.
- Bates, Don. (1995) Scholarly Ways of Knowing: An Introduction. In Don Bates (ed.), *Knowledge and the Scholarly Medical Tradition*. Cambridge: Cambridge University Press, pp. 1-22.
- Bode, Maarten. (2006) Taking Traditional Knowledge to the Market: The Commoditization of Ayurvedic and Unani Medicine. *Anthropology & Medicine* 13(3), 225-236.
- Bode, Maarten. (2008) *Taking Traditional Knowledge to the Market: The Modern Image of the Ayurvedic and Unani Industry*. New Perspectives in South Asian History 21. New Delhi: Orient Blackswan.
- Bode, Maarten. (2009) Ayurvedic Pharmaceutical Products: Government Policy, Marketing Rhetorics, and Rational Use. In Karen Eggleston (Ed.), *Pharmaceuticals in Asia-Pacific: Manufacturers, Prescribing Cultures, and Policy* (pp. 251-265). Palo Alto: APARC, Stanford University.
- Bode, Maarten. (2012) Ayurveda in the 21st Century: Logic, Practice, and Ethics. In Leena Abraham and V. Sujatha (eds), *Indigenous Medicine, State and Society: Medical Pluralism in Contemporary India*. New Delhi: Orient Blackswan, pp. 59-76.
- Chan, Margaret. (2008) *Address at the World Congress on Traditional Medicine, Beijing 2008*. <http://www.who.int/dg/speeches/>.
- Chandra, Shailaja. (2011) *Status of Indian Medicine and Folk Healing*. Department of AYUSH, Ministry of Health and Family Welfare, Government of India, New Delhi.

- De Silva, Vijitha et al. (2011) Evidence for the efficacy of complementary and alternative medicines in the management of osteoarthritis: a systematic review. *Rheumatology* 50(5), 911-920.
- Diallo, D. et al. (2006) Malaria treatment in remote areas of Mali: use of modern and traditional medicines, patient outcome. *Transactions of the Royal Society of Tropical Medicine and Hygiene* 100, 515–520.
- Elder, C. (2004) Ayurveda for diabetes mellitus: a review of the biomedical literature. *Alternative Therapy, Health and Medicine* 10(1), 44-50
- Fisher, Jill A. (2009) *Medical Research for Hire: The Political Economy of Pharmaceutical Clinical Trials*. New Brunswick, NJ: Rutgers University Press.
- Fønnebø et al. (2007) Researching complementary and alternative treatments – the gatekeepers are not at home. *BMC Medical Research Methodology* 7(7).
- Fritts et al. (2008) Traditional Indian Medicine and homeopathy for HIV/AIDS: a review of the literature. *Aids Research and Therapy* 5, p. 25
- Ghodke, Y, & Kalpana Joshi, Bhushan Patwardhan. (2011) Traditional Medicine to Modern Pharmacogenomics: Ayurveda *Prakriti* Type and CYP2C19 Gene Polymorphism Associated with the Metabolic Variability. *Evidence-Based Complementary and Alternative Medicine* (eCAM), Article ID 249528.
- Goldenberg, Maya J. (2006) On Evidence and Evidence-Based Medicine: Lessons from the Philosophy of Science. *Social Science and Medicine* 62(11), Special Issue: Social Science Perspectives on Evidence-Based Health Care, 2621-2632.
- Graz, Bertrand & Elaine Elisabetsky, Jacques Falquet. (2007) Beyond the myth of expensive clinical study: Assessment of traditional medicines. *Journal of Ethnopharmacology* 113(3), pp. 382–386.
- Harilal, M.S. (2009) Commercialising Traditional Medicine: Ayurvedic manufacturing in Kerala. *Economic and Political Weekly* 44(16), pp. 44-51.
- Janes, Graig R. (2002) Buddhism, Science, and Market: the Globalisation of Tibetan Medicine. *Anthropology & Medicine* 9(3), 267-289.
- Kaptchuk, Ted. (1998) Powerful Placebo: The dark side of the Randomised Controlled Trial. *Lancet* 351(9117), 1722-1725.
- Kaptchuk, Ted. (2000) The double-blind, randomized, placebo-controlled trial: Gold standard or golden calf? *Journal of Clinical Epidemiology* 54, 541–549.
- Kim, Jongyoung. (2009) Transcultural medicine: a multi-sited ethnography on the scientific-industrial networking of Korean Medicine. *Medical Anthropology* 28(1), 31-64.
- Kleinman, Arthur & Liliang Sung. (1979) Why do indigenous practitioners successfully heal? *Social Science & Medicine* 13B, 7-26.
- Lambert, Helen. (2006) Accounting for EBM: Notions of Evidence in Medicine, Special Issue Social Science Perspectives on Evidence-Based Health Care. *Social Science & Medicine* 62(11), 2633-2645.

- Lambert, Helen. (2012) Medical pluralism and medical marginality: Bone doctors and the selective legitimation of therapeutic expertise in India. *Social Science & Medicine* 74, 1029-1036.
- Langford, Jane. (2003) Traces of folk medicine in Jaunpur. *Cultural Anthropology* 18(3), 271-303.
- Liu, J.P. et al. (2005) Herbal medicines for treating HIV infection and AIDS. *The Cochrane Database of Systematic Reviews* Issue 5, Art. No. CD003937.
- Liu, L & Elaine Lai-Han Leung, Xiaoying Tian. (2011) The clinical trial barriers. *Nature* Vol 480, Issue 7378, S100.
- Mathez-Stiefel, S., I. Vandenbroek & S. Rist. (2012) Can Andean medicine coexist with biomedical healthcare? A comparison of two rural communities in Peru and Bolivia. *Journal of Ethnobiology and Ethnomedicine* 8:26.
- Moerman, Daniel E. (2002) *Meaning, Medicine and the "Placebo Effect"*. Cambridge: University Press.
- Moher D. & K.F. Schulz, D.G. Altman. (2001) The Consort Statement: Revised Recommendations for Improving the Quality of Reports of Parallel Group Randomized Trials. *BMC Medical Research Methodology* 1(2).
- Narahari, Saravu R., & M.G. Aggithaya, K.R. Suraj. (2010) Conducting literature searches on Ayurveda in PubMed, Indian, and Other Databases. *The Journal of Alternative and Complementary Medicine* 16(11), 1225-1237.
- Panikkar, K.N. (1994) Indigenous Medicine and Cultural Hegemony: A Study of the Revitalisation Movement in Keralam. *Arya Vaidyan* 7(4), 212-223.
- Park J. & Edzard Ernst. (2005) Ayurvedic medicine for rheumatoid arthritis: a systematic review. *Seminars in Arthritis and Rheumatism* 34(5), 705-713.
- Patwardhan, Bhushan & Dnyaneshwar Warude, P. Pushpangadan and Narendra Bhatt. (2005) Ayurveda and Traditional Chinese Medicine: A Comparative Overview, *Evidence-Based Complementary and Alternative Medicine* 2(4), 465-473.
- Patwardhan, Bhushan & Gerard Bodeker. (2008) Ayurvedic Genomics: Establishing a Genetic Basis for Mind-Body Typologies. *The Journal of Alternative and Complementary Medicine* 14(5), 571-576.
- Patwardhan, Bhushan & Ashok Vaidya. (2009) Ayurveda: scientific research and publications. *Current Science* 97(8), 1117-1121.
- Patwardhan, Bhushan et al. (2011) Vaidya-scientists: catalysing Ayurveda renaissance. *Current Science* 100(4), 476-483.
- Payyappallimana, U. (2010) Role of Traditional Medicine in Primary Health Care: An Overview of Perspectives and Challenges, *Yokohama Journal of Social Sciences*, Vol. 14 No. 6, 57-77.
- Payyappallimana, U. (2011) Traditional Medicine in Health System Development: A Case Study of Kerala State, India, *Yokohama Journal of Social Sciences*, Vol.15, No.3, 77-101.

- Payyappallimana, U. (2011) *Role of traditional medical systems in health system development: Case studies from Kerala state, India and Japan*, Doctoral thesis (unpublished).
- Payyappallimana, Unnikrishnan and G. Hariramamurthi. (2012) Local health practitioners in India: Resilience, Revitalisation and Reintegration. In Leena Abraham and V. Sujatha (eds.), *Indigenous Medicine, State and Society: Medical Pluralism in Contemporary India*. New Delhi: Orient Blackswan, pp. 279-304.
- Pinto, Sarah. (2004) Development without Institutions: Ersatz Medicine and the Politics of Everyday Life in Rural North India. *Cultural Anthropology* 19(3), 337-364.
- Priya, Ritu & A.S. Shweta. (2010) *Status and Role of AYUSH and Local Health Traditions under the National Rural Health Mission*. National Health Systems Resource Centre, National Rural Health Mission, Ministry of Health and Family Welfare, Government of India, New Delhi.
- Priya, Ritu. (2012) AYUSH and public healthy: Democratic pluralism and the quality of health services. In Leena Abraham and V. Sujatha (Eds.), *Indigenous Medicine, State and Society: Medical Pluralism in Contemporary India*. New Delhi: Orient Blackswan, pp. 103-129.
- Sujatha, V. (2007) Pluralism in Indian medicine: medical lore as a genre of medical knowledge. *Contributions to Indian Sociology* 41(2), 169-202.
- Sujatha, V. (2011) Innovation within and between traditions: Dilemma of Traditional Medicine in Contemporary India. *Science, Technology & Society* 16(2), 191-213.
- Thompson, J.J., C. Ritenbaugh & M. Nichter. (2009) Reconsidering the Placebo Response from a broad anthropological perspective. *Culture, Medicine and Psychiatry* 33, 112-152.
- Torri, M. C., & Laplante, J. (2009) Enhancing innovation between scientific and indigenous knowledge: pioneer NGOs in India. *Journal of Ethnobiology and Ethnomedicine*, 5, 29.
- Unnikrishnan, P.M., L. Kumar & D. Shankar. (2010) Traditional Orthopaedic Practitioners' Place in Contemporary Health. In K. Sheikh, & A. George (Eds.), *Health providers in India: On the frontlines of change*. New Delhi: Routledge, pp.182-199.
- Van der Geest, S. (1988) Pharmaceutical Anthropology: Perspectives for Research and Application. In: S. van der Geest & S. R. Whyte (Eds.), *The Context of Medicines in Developing Countries. Studies in Pharmaceutical Anthropology*. Dordrecht: Kluwer Academic Publishers, pp. 329-66.
- Van der Geest, S., J.D. Speckman & P.F. Streefland. (1990) Primary health care from a multi-level perspective: Towards a research agenda. *Social Science & Medicine* 30(9), 1025-1034.
- Van der Greef, Jan. (2011) Perspective: All Systems Go. *Nature* 480(7378), S87.
- Van Hollen, Cecilia. (2005) Nationalism, Transnationalism, and the Politics of "Traditional" Indian Medicine for HIV/AIDS'. In Joseph S. Alter (Ed.), *Asian Medicine and Globalization*. Pennsylvania: University of Pennsylvania Press, 88 -106.

- Verhoef, Marja J., et al. (2005) Complementary and alternative medicine whole systems research: Beyond identification of inadequacies of the RCT. *Complementary Therapies in Medicine* 13(3), 206-212.
- Waldram, James B. (2000) The Efficacy of Traditional Medicine: Current Theoretical and Methodological Issues, *Medical Anthropology Quarterly* 14(4), 603-625.
- WHO. (2000) *General Guidelines for Methodologies on Research and Evaluation of Traditional Medicine*. Geneva: World Health Organization.
- WHO. (2002) *WHO Traditional Medicine Strategy 2002-2005*. Geneva: World Health Organization.
- Xue et al. (2010) Traditional Chinese Medicine: An Update on Clinical Evidence. *The Journal of Alternative and Complementary Medicine* 16(3), 301-312.
- Yamashita, Tsutomu & P. Ram Manohar. (2007-08, 2009, 2010, 2011, 2012) Memoirs of Vaidyas. The Lives and Practices of Traditional Medical Doctors in Kerala, India, Part 1-6. *eJournal of Indian Medicine* Vol 1 pp. 43-60, pp. 141-163; Vol 2 pp. 25-50; Vol 3 pp. 23-51; Vol 4 pp. 11-33; Vol 5 pp. 1-23.
- Young, Allan. (1982) The anthropologies of illness and sickness. *Annual Review of Anthropology* 11, 257-285.
- Zimmermann, Francis. (1995) The Scholar, Wise man, and Universals: Three Aspects of Ayurvedic Medicine. In Don Bates (Ed.), *Knowledge and the Scholarly Medical Tradition*, Cambridge: Cambridge University Press, pp. 297-319.