

A case for an integrative model of healthcare pivoted around Ayurveda to meet the healthcare challenges of 21st century

Final Paper for the Master of Management degree – IMHL

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Dedication

Dedicated to the fond memory of Bhargavi Amma,

My beloved mother,

Who passed away on 02.12.2013, even as I wrote this manuscript.

She was a dedicated student of Indian Knowledge systems, especially Ayurveda and

Vedic astrology and had internalized their essence.

To me, she was more than a loving mother; she was a friend, philosopher and

guiding light, who will be missed till my last breath...

Key words

Ayurveda

Healthcare

Integrative Medicine

CAM

Healthcare model

Non-Communicable Diseases



List of Abbreviations

NCD	: Non Communicable Disease
DM	: Diabetes mellitus
CAM	: Complementary and Alternative Medicine
IM	: Integrative Medicine
RCT	: Randomised Controlled Trials
WHO	: World Health Organization
LAMIC	: Low and Middle Income Countries
TCM	: Traditional Chinese Medicine
AYUSH	: Ayurveda, Yoga, Unani, Siddha and Homeopathy
CVD	: Cardio-Vascular Disease
COPD	: Chronic Obstructive Pulmonary Disease
DALY	: Disability Adjusted Life Year
INR	: Indian National Rupee
GDP	: Gross Domestic Product
PEN	: Package of Essential Non-communicable
USD	: US Dollar
NCCAM	: National Centre for Complementary and Alternative Medicine
TM	: Traditional Medicine
ISM&H	: Indian Systems of Medicine & Homoeopathy
TOS	: Therapeutic Outcome Studies
R&D	: Research and Development

Prologue – the case

‘The intuitive mind is a sacred gift and the rational mind is a faithful servant. We have created a society that honors the servant and has forgotten the gift.’

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— Albert Einstein

The great seers of Ayurveda too considered an intuitive mind as an indispensable pre-requisite to appreciate the depths of its theoretical foundations. The *Vedas* believed in the concept of one global family (*Vasudhaiva Kutumbakam*)^a, which presupposes the absence of boundaries for knowledge systems like Ayurveda. Knowledge, as contained in *Vedas*, is as relevant to a software programmer sitting in front of his laptop in Silicon Valley as it is to a farmer ploughing his field in a remote Indian village. This paper is borne out of the conviction that Ayurveda can play a positive role in an inter-disciplinary collaboration for an effective model of healthcare with universal application and relevance.

The present work recognizes the rising global demand for alternatives to mainstream medical system owing to its inability to satisfactorily address all the current healthcare needs. It is making the case for one such alternative model of IM that has Ayurveda in the pivot and combines other systems like yoga, physiotherapy and certain elements of Allopathy, to be investigated as a feasible model of IM specifically in the context of India. It is intended to kick start an informed debate on the argument: An approach that combines the clinical strength and wisdom of Ayurveda with Allopathy may be better than Allopathy in isolation for treating chronic diseases in India.

Currently, the need for such an approach is not widely recognized and consequently no studies (on an impactful scale) on these lines are being contemplated within the

^a The original verse is contained in the classical Indian *Vedic* text called Mahopanishad VI.71-73 and means that the whole world is one single family.



sector. This paper is meant to initiate a debate on the need for such an approach amongst important stakeholders of healthcare. This work also argues for the need to generate evidence through outcome-based rigorous documentation of the existing clinical practice of Ayurveda, as opposed to reducing it to fit it into existing clinical research paradigm of Allopathy that ascribes a disproportionate importance to Randomised Controlled Trials (RCTs).

This work may be relevant to health policy makers, open-minded allopathic doctors, votaries of CAM and notably to the Ayurveda community (0.7 million Ayurveda practitioners) in India. This work would have served its purpose if it is able to widen the horizon of my fellow Ayurveda practitioners in their interactions with other systems of medicine, especially Allopathy and also nudge a few open minded allopathic doctors and votaries of CAM to think of Ayurveda beyond the boundaries of it being merely an inventory of herbal formulations that can be prospected to be appended to the conventional system of medicine and help them appreciate the depth of its unique philosophies of health and disease.

Once fully evolved, through focused research, this model of healthcare may be relevant as a model to be studied globally, but would certainly require to be customized to suit the needs and collective sensibilities of the ecosystem where it is sought to be implemented.

Introduction

The 21st century is witnessing a global upheaval of unprecedented proportions in current healthcare models as they struggle to deal with the explosive increase in non-communicable diseases (NCDs), primarily cardiovascular disease, cancer, diabetes, chronic respiratory conditions and mental illnesses. The World Health Organization (WHO) estimates that, non-communicable diseases account for 59% of 56.5 million deaths globally and contributes to 45.9% of the global burden of disease.¹ 80% of the burden of NCDs is borne by low and middle income countries (LAMIC), where premature death (under 60 years) due to NCDs (41%) is three times the proportion in high income countries.²

Recognizing the magnitude of this problem, the General Assembly of the United Nations met on a health-related issue for the second time in its history in 2011 - (the first was in 2001 on HIV/AIDS) to develop a global strategy for the prevention and control of NCDs. The political declaration noted the 'critical importance of... strengthening healthcare for people with non-communicable diseases by developing evidence-based norms, standards and guidelines for cost-effective interventions and *by reorienting health systems to respond to the need for effective management of diseases of a chronic nature.*' (Italics added). The scope of this resolution is sweeping, encompassing all levels of society and requires a fundamental rethinking of concepts of health and disease. This resolution begs the question of whether the currently dominant Western system of medicine, hereafter referred to as 'conventional medicine' or 'Allopathy' in isolation is capable of meeting this challenge in its current form, particularly in the case of the developing world where access and affordability of healthcare are of critical concern. The successes of molecular biomedicine and prevailing drug development strategies have promoted a reductionist search for pathogenic mechanisms at the single molecule/receptor level, which may be inappropriate for NCDs which are being increasingly understood as 'life-style' disorders. A fundamental rethinking of concepts of health and disease



may be necessary as NCDs are being increasingly understood in terms of behavioral risk factors such as alcohol abuse, smoking, lack of physical activity and unhealthy diets negatively impacting metabolic functions necessary to maintain the stability of the internal environment of the body, or homeostasis.^{3,4} Conventional medicine also suffers from being expensive and difficult to access due to the need for sophisticated infrastructure lacking in developing countries.

Ayurveda, by virtue of its whole-system approach that uses a judicious combination of lifestyle modifications, dietary changes, detox therapies as well as pharmacological disease management to restore normalcy of biological mechanisms is in a unique position to address the challenge of non-communicable diseases. Ayurveda is gaining increasing acceptance world-wide, along with other hitherto disregarded systems of health and medicine including Yoga, Homeopathy, Traditional Chinese Medicine (TCM), Acupuncture, etc., (referred to collectively as CAM), evidenced by their inclusion in medical college curricula and establishment of IM centers. Alternative systems of medicine are alive and thriving in India, with the Department of Ayurveda, Yoga, Unani, Siddha and Homeopathy (AYUSH), Government of India, dedicated to promoting “AYUSH systems as the preferred systems of living and practice for attaining a healthy India.”⁵

This paper will explore the hypothesis that a model of IM that uses Ayurveda as a foundation, incorporating aspects of conventional medicine along with physiotherapy and yoga when warranted, would be optimal for dealing with chronic conditions, particularly in the context of India. The management of DM, a disease with considerable health, social and economic implications, will be used as a narrative model to elucidate the integrative approach that is being proposed. DM is well suited to an integrative approach, as it affects nearly all systems of the body, resulting in neurological, psychiatric, renal, visual and cardiovascular complications, despite being defined narrowly as a disorder of insulin metabolism reflected by high blood sugar levels. The conventional strategy of managing a multisystem disorder



by referring patients to multiple specialists greatly complicates care and increases costs. Pharmacological management is the first line of treatment, but drugs for complications such as depression may worsen control of blood sugar.⁶ Furthermore, excessive reliance on pharmacology-based intervention may result in ignoring lifestyle modifications, leading to poor treatment outcomes. Alternative treatments are generally not covered by healthcare systems and insurance plans, leading to high out-of-pocket costs. This paper, in the first section, will discuss the impact of non-communicable diseases globally and in India, followed by their management by conventional medicine in the second section, with a focus on DM in order to identify challenges that warrant a new model for management. The third section will discuss the global surge towards alternatives in medicine and the fourth will talk about Ayurveda. The fifth and last section will discuss on a model of IM pivoted on Ayurveda that is relevant for India to suggest ways to move forward.

In the Indian context, it makes sense to promote such an integrative model pivoted on Ayurveda because India has over five millennia of experience with medical knowledge systems like Ayurveda and Yoga. There is a wealth of knowledge including advanced theories of individual health and disease, sophisticated principles of drug design and delivery, a vast repository of knowledge about drugs and their effect on human systems, as we are now beginning to understand. In this model, Ayurveda's sophistication in both theory and clinical practice is a major advantage and the chief motivation, not the mere fact of it being Indian or that it is widely patronized and accepted by a very large section of the society in this part of the World.

Nevertheless, in other parts of the world, other models of IM may evolve into different dimensions of healthcare. Ayurveda may be the pivot in most of India, Nepal and in many parts of South East Asia. However Siddha may be the appropriate pivot for IM in Tamil Nadu and certain pockets in South East Asia,

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while TCM may play that role in China. Each model may prove relevant and essential to provide healthcare in its respective area.

Although the term 'IM' was initially coined to promote multi-disciplinary practice where modern medicine together with one or more of the complementary systems would be available under the same roof, the model being discussed as 'IM' in this paper is different. The model being discussed in this paper is contextual and it will have Ayurveda at its pivot; it will be complemented suitably by Yoga, which has the same philosophical roots, theoretical foundations and practical nuances, Physiotherapy is included whenever it is relevant and it will have a limited role for Allopathic medical system in diagnostics and critical care.

1. Section 1: Global Healthcare scenario

1.1. Global epidemic of NCDs

Non-communicable disease is an umbrella term encompassing a number of disorders of non-infectious etiology, including cardiovascular disease (CVD), cancers, diabetes, chronic obstructive pulmonary disease (COPD), asthma, neuropsychiatric conditions (e.g., mental diseases, epilepsy, dementia), congenital conditions, skin and musculoskeletal conditions (e.g., arthritis), eye conditions, skin diseases, diseases of the digestive system (e.g., peptic ulcer) and genitourinary conditions (prostate diseases, nephritis). Of these, cardiovascular disease, chronic respiratory conditions, diabetes and cancer are considered the big four, as they are closely related conditions that share common and preventable risk factors and are amongst the top ten leading causes of mortality and morbidity worldwide. Mortality due to these conditions has outstripped other causes, including communicable, maternal, perinatal and nutritional diseases. According to the WHO estimates, of the 57 million deaths occurring globally in 2008, 36 million or 63% were due to NCDs.⁷ Of these, 80% or 29 million occurred in low and middle-income countries. In the current decade (2010-2020), deaths due to NCDs are projected to increase globally by 15%, with the greatest increase in the South East Asian Region estimated at 10.4 million by 2020. Part of the increase is due to longer survival: as populations' age, deaths due to NCDs alone are projected at 52 million in 2030.

However, there is a recent and disturbing trend in LAMIC of 41% of deaths due to NCDs occurring under the age of 60 years (three times the number of early deaths compared to high income countries) ⁸ although NCDs are a cause of death generally over 60 years.⁹ This has grave implications, suggesting either variations in etiology, or the lack of early interventions shown to prolong life in developing countries, or a combination of both factors.

Mortality estimates do not convey the entire picture. Some non-communicable diseases, such as diabetes may have lower mortality than cancer (3.4 million vs. 7.6 million in 2008)¹⁰ but contribute significantly to disease burden due to disability and socio-economic impact. This concept is captured by the Disability Adjusted Life Year (DALY) parameter, which combines years of life lost due to premature mortality and years of life spent in ill-health ¹¹ However, DALYs may not be the ideal tool for certain age-related non-communicable diseases, as the age weighting assumes that a year of life increases in value until the age of 22 and then decreases, thus giving greater weight to the death of a child compared to the death of an older person. NCDs, particularly cardiovascular disease, account for nearly half the disease burden in low-and middle income countries, compared to nearly 80% of the burden in high income countries. Estimates for the future are mixed. While the overall global burden of disease¹² is projected to decrease by 11% by 2030 from 1.53 billion DALYs in 2004 to 1.36 billion DALYs in 2030 despite a population increase of 25%, most of this is due to the control of non-infectious diseases: the contribution of NCDs is expected to rise to 69%.¹³ Developing countries will still have to deal with the 'double burden of disease', where communicable causes of premature death and disability co-exist alongside growing burdens from non-communicable causes.

Risk factors common to most non-communicable diseases include unhealthy diet, tobacco consumption, lack of physical activity and alcohol abuse, indicating a common underlying theme of maladaptive and unhealthy lifestyle choices.^{14,15} Tobacco use accounts for 71% of lung cancer, 42% of chronic respiratory disease and 10% of cardiovascular disease, with the highest incidence amongst men in lower middle income countries such as India. Alcohol abuse accounts for 3.8% of deaths overall, with more than half resulting from cancers, cardiovascular disease and liver cirrhosis. Insufficient physical activity is associated with 20-30% increased risk of mortality overall. Insufficient consumption of fruits and vegetables has been estimated to cause nearly 2.8% of deaths worldwide. These factors are postulated to



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result in four metabolic changes which are not only associated with non-communicable diseases, but which directly contribute to mortality: raised blood pressure (13% of global deaths), overweight/obesity (5% of global deaths), hyperglycemia (6% of global deaths) and hyperlipidemia (4.5% of global deaths).

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NCDs have a devastating economic impact, affecting global and national economies, healthcare systems, families and individuals. This is often disastrous in developing countries, where catastrophic medical spending (more than 40% of household income after basic needs have been met)¹⁶ and loss of billions of dollars of national income due to reduced productivity deliver a double blow to development. Lack of access to healthcare and lack of awareness in developing countries result in delayed diagnosis of the disease, where extensive and expensive hospital care is required for severe complications. Direct out-of-pocket costs have been estimated to result in financial catastrophe for 150 million people globally, while another 100 million are forced below the poverty line, of which 90% live in low income countries.¹⁷ A vicious cycle then ensues, as poverty and lack of education are becoming highly significant risk factors for non-communicable diseases, once considered diseases of affluence.¹⁸

1.2.NCDs – The Indian scenario

In India, NCDs accounted for 62% of total disease burden in 2004, of which cardiovascular disease accounted for 12.7 %, cancer for 3.5 %, respiratory diseases for 4.6 % and diabetes for 1.1 %.¹⁹ Estimates of mortality obtained in 2008 indicate that total deaths due to NCDs were 2.96 million in men and 2.2 million in women, with premature deaths at 38% in men and 32% in women. Age-standardized death rates per 100,000 were greatest for cardiovascular diseases and diabetes combined at 386.3 for men and 283 for women, followed by chronic respiratory diseases at 178.4 for men and 125.5 for women and cancers at 78.8 for men, 71.8 for women. Risk factors were more balanced across sexes, with increased blood pressure being the most common at 32%, followed by increased blood cholesterol (27.1%), increased blood glucose (10%) and overweight/obesity (12.9%). Smoking was skewed predominantly towards men (25.1% vs. 2%), while physical inactivity was more common in women (17.3% vs. 10.8%). Future projections indicate that by 2030, cardiovascular diseases are expected to be the main cause of death (36%), characterized by earlier occurrence, higher case fatality rates, and disease onset at lower risk factor thresholds compared to developed countries.²⁰ The prevalence of diabetes is expected to increase by 5–15 % in urban populations, 4–6 % in semi-urban populations, and 2–5 % in rural populations. The prevalence of hypertension is expected to increase by 80%, from 118.2 million in 2000 to 213.5 million by 2025.

The most recent figures for India are limited to urban families requiring hospitalization, but are still alarming. Out-of-pocket spending for non-communicable diseases was INR 396 billion in 2004 (US\$ 6.9 billion at current exchange rates), with an increase of 32 to 47% from 1995-1996,²¹ Hospital stays increased drastically from 1995-1996 to 2004, with 278% for diabetes, followed by injuries (172%), asthma (164%) heart disease (127%), hypertension (126%) and cancer (103%). Hospital stays were distributed equally between private and public sectors.



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About 45% of out-of-pocket costs were for medicines, diagnostic tests and medical appliances.²² Nearly 40% of total costs were financed by borrowing or by sale of assets.^{23,24} Cancer had the greatest financial impact, with 170% odds of catastrophic spending and 133% odds of falling below the poverty line compared to communicable diseases. Other studies have shown that tobacco and alcohol use significantly increase the risk of borrowing and asset sale to pay for hospitalization by 16%,²⁵ while diabetes care can cost up to one-third of the income of low-income families. Estimates of the effect at national level are significantly varying. Annual income loss due to illness and caregiving was estimated by one study to be US\$ 23 billion for 2004 from all non-communicable diseases²⁶, while another estimated a US\$ 9 billion for 2005 from heart disease, stroke and diabetes.²⁷ Projections for the future are grim: the WHO has estimated a loss of \$ 237 billion, or 1.5% of GDP over the period of 2005-2015 due to non-communicable diseases.^{28,b} Indeed, it has been estimated that each 10% rise in NCDs is associated with 0.5% lower rate of economic development.²⁹

^b An international dollar has the same purchasing power as the US dollar in the United States and is used to translate and compare costs across countries using the US dollar as a common reference point

2. Section 2: Management of NCDs

2.1.Challenges in managing NCDs

A three-pronged strategy has been developed by the WHO for facing the challenge of non-communicable diseases: information, prevention and healthcare.³⁰ First, developing national and international programs to systematically map the epidemiology of disease and identify social, economic, political and behavioral determinants to guide policy and decision making. Second, preventive efforts focused at the four main modifiable risk factors for disease: alcohol, tobacco, diet and exercise, while at the same time providing access to healthy lifestyle choices. Third, developing evidence-based norms, standards and guidelines for cost-effective interventions and equipping health systems for effective management. Prevention is ideal for developing countries, as appropriate care and access to essential technologies and medicines is often compromised. Many health-care interventions are cost-effective in early stages compared to the extensive and expensive care that is required when detection and treatment are delayed.

The principal shortcoming of national and international strategies is that despite the emphasis on the need for lifestyle modifications in preventing NCDs, there is very little advice on what those modifications should be beyond general recommendations. In contrast, advice on pharmacological intervention is extensive and based on rigorous evaluation obtained from RCT. One example is the 'Package of Essential Non-communicable Disease Interventions (WHO PEN)' developed by the WHO for primary care in low-resource settings.³¹ Although PEN is promoted as a prioritized list, it consists mainly of a list of drugs and diagnostic tools.

2.2. The example of Diabetes mellitus

DM is an excellent test case for discussing integrative approaches to the management of non-communicable disorders. Although DM is associated with the least mortality amongst non-communicable diseases, it contributes significantly to disease burden by increasing the risk of cardiovascular disease – the biggest killer of the big four. Global prevalence diabetes in 2011 was estimated at 366 million, projected to increase to 552 million by 2030.³² Estimated global expenditure due to diabetes was USD 465 billion dollars, amounting to 11% of total healthcare expenditures in adults (20-79 years). Prevalence of diabetes in India was estimated at 62.4 million, with 77.2 million at extremely high risk of progressing to diabetes.³³

Although discussed primarily as a condition of increased blood sugar (hyperglycemia), resulting from reduced insulin production or increased body resistance to insulin, diabetes is a multisystem disorder with cardiovascular, neurological, psychiatric, renal and visual complications. Diabetes shares risk factors with all other NCDs – alcohol, tobacco, diet and lifestyle. Furthermore, diabetes can increase the risk of other non-communicable disorders such as cardiovascular disease and stroke, with greater concomitant morbidity and mortality.³⁴ The conventional strategy of managing a multisystem disorder by referring patients to multiple specialists greatly complicates care and increases costs. Pharmacological management is the first line of treatment, but drugs for complications such as depression may worsen control of blood sugar.³⁵ Furthermore, reliance on pharmacology may result in ignoring lifestyle modifications, leading to poor treatment outcomes. Alternative treatments are generally not covered by healthcare systems and insurance plans, leading to high out-of-pocket costs.³⁶

There is increasing evidence to support a multifactorial approach to diabetes management.^{37,38,39} Standard regimens of oral anti-glycemic (sugar-lowering) drugs work initially, but have poor long-term efficacy with poor treatment adherence.⁴⁰

One response to this issue is to recommend more aggressive pharmacological management, with insulin and drug poly-therapy even in the early stages of the disease.⁴¹ However, a survey of 13 countries in Asia, Europe, Australia and the United States revealed that poor psychological wellbeing may be one of the biggest factors in lack of treatment efficacy, regardless of culture, education or socioeconomic status.⁴² Diabetic care providers reported lack of confidence in their ability to diagnose and manage psychological issues. Page | 19

The importance of diet may have unique implications for India. There is increasing evidence that the etiology and pathogenesis of diabetes may be different in South East Asians, with the description of the “Asian Indian Phenotype”, characterized by increased body fat, lower muscle mass and a possible genetic susceptibility to early diabetes (10-15 years earlier than Caucasians) and premature cardiovascular disease.⁴³ Such a phenotype has increased vulnerability to dietary changes associated with increasing urbanization and industrialization, including excess consumption of calories, increasing meat intake, saturated fats, trans fatty acids, simple sugars, and salt, with low intake of fiber, monounsaturated fatty acids, and n-3 polyunsaturated fatty acids. There has been a progressive reduction in the consumption of pulses, legumes and high-fiber carbohydrates, which tends to increase blood sugar levels.⁴⁴ This dietary pattern, coupled with sedentary behaviors promotes obesity, diabetes and cardiovascular disease in both urban and rural areas.

The importance of diet, lifestyle and psychological issues, with the need to consider genetic factors that may be unique to India suggest that any integrative model of medicine should be based on a whole-system approach. The following section will demonstrate that Ayurveda may hold great relevance in mitigating the devastating effect of non-communicable disorders in India and globally.

3. Section 3: Complementary and Alternative Medicine (CAM)

3.1. Global surge towards alternative medicine

Complementary, alternative and IMs are terms being increasingly used in the current scenario of medical pluralism. CAM has been defined largely in relation to conventional biomedicine, depending on whether the practice complements or replaces conventional medicine. The commonly accepted definition states that CAM is a '...a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period. CAM includes all such practices and ideas self-defined by their users as preventing or treating illness or promoting health and well-being.'⁴⁵ Boundaries within CAM and between the CAM domain and that of the dominant system are not always sharp or fixed.⁴⁶ The dominant health system of course refers to the conventional Western medical model as it is practiced today. Ironically, the very same definition may be used for Western medicine in Indonesia, China, Japan and Vietnam, where the so-called 'traditional medicine' is used by the majority of the population.⁴⁷ It is also interesting to note that osteopathy, which holds that all diseases can be explained as disorders of the musculoskeletal system and therefore cured by joint manipulation, is considered conventional medicine in the U.S., despite its radical deviance from the principles of biomedicine. In contrast, homeopathy and naturopathy, which also evolved in the West, are given greater professional recognition in the U.K. and in Europe than in the United States.⁴⁸

CAM practices are generally grouped into those administered by practitioners, including herbal medicine, acupuncture, homeopathy, Traditional Chinese Medicine (TCM), chiropractic, naturopathy, osteopathy, Ayurvedic medicine, and massage therapy and self-administered therapy: homeopathy products, herbal supplements, TCM products, naturopathic products, and nutritional products.⁴⁹ The diversity of

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philosophies and methodologies of various systems resist classification and it is highly likely that the very definition of what is conventional, complementary or alternative is susceptible to change.^{50,51,52}

3.2. The CAM and IM movements

The 1990s were a landmark decade in the rise of CAM in the west, it was estimated that in the United States visits to CAM providers greatly outnumbered visits to primary care physicians (425 million vs. 388 million), with equivalent out-of-pocket, or non-insured costs (\$10.3 billion vs. \$12.8 billion) in 1990.^{53,54,55} Alternative therapies were most commonly used for chronic conditions, including back problems, anxiety, depression, and headaches. The enactment of the Dietary Supplement and Health Education Act (DSHEA) in 1994 to regulate the use of herbal preparations as food supplements and establishment of the office of Alternate Medicine by the National Institutes of Health, which evolved into the National Centre for Complementary and Alternative Medicine (NCCAM), indicate the growing recognition that conventional medicine alone was insufficient to deal with the healthcare needs of the public. NCCAM's third strategic plan (2011-2015) acknowledges that 'the boundaries between CAM and conventional medicine (also called Western or allopathic medicine) are not absolute.' A WHO survey in 2002 of the prevalence of CAM use revealed up to 80% use in Africa for primary health needs and was fully integrated into the health system in China (95% of hospitals), Japan (72% of physicians), India (2,860 hospitals), Thailand and Vietnam. In the west, CAM was not fully integrated into the healthcare system, but was used by 29-42% in the United States, 49% in Australia and 75% had used CAM at least once in France.

IM is a new concept where the modern biomedical system is trying to integrate aspects of traditional systems in areas of its weakness. In most of these models the integration was only appropriation or misappropriation of certain elements of traditional medicines without going into its philosophy. Indeed it has been argued that IM is "...not the changing of conventional medicine but the taming of CAM".^{56,57} One example of truly IM is the work of Dr. Dean Ornish to apply the practice of



yoga and dietary changes according to Ayurveda to reversal of conventionally diagnosed cardiovascular disease without drugs or surgery, which had a profound impact on conventional medicine.⁵⁸ There has been a shift in medical practice towards treatments that are evidence-based regardless of medical tradition, despite increasing resentment and campaigns against integrating CAM with conventional medicine.⁵⁹ There is therefore a growing need to revitalize and promote Ayurveda and such other Traditional Medicine (TM) systems for their contemporary relevance with the spirit of a dispassionate scientific enquiry. It is however important to recognize that Ayurveda is not merely meant to be used as an inventory for prospecting new molecules or extracts, but it is also to be explored for its sophisticated theory of homeostasis and bio-regulation.

Alternative systems of medicine are alive and doing well in India, with 785,185 registered practitioners, 3277 hospitals, 495 undergraduate and 106 post-graduate institutions, 8644 drug manufacturing units, 24,289 dispensaries in 2010, all regulated and promoted by the Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) of the Ministry of Health and Family Welfare, Government of India.⁶⁰ Indeed, the vision of AYUSH is to “position AYUSH systems as the preferred systems of living and practice for attaining a healthy India”.⁶¹ However, government investment in AYUSH is minimal, at only 2.86% of the entire budget allocation for Health in 2013-14 (INR 1,069 crores out of INR 37,300 crores)^c. Even though a 35% tax rebate on branded Ayurvedic, Unani, Siddha and Homeopathic medicines has been proposed⁶² but even this is yet to be implemented. Thought leaders in Ayurveda and health sciences infer that the sector is in crisis and facing formidable challenges.^{63,64,65} The inference is based on the unimpressive performance of the sector on all fronts – education, research, clinical practice, industry and regulation. Reasons for the crisis are complex, including proximate causes such as the attitudes of entrenched administrators, educators, scientists,

^c 1 crore = 10 million

practitioners, industry, and above all lack of strategic vision and political will at the government level; at a deeper and more invisible level is the cultural and epistemological divide between globally dominant western sciences and the still marginalized Indian knowledge systems.^d It appears that we are yet to outgrow the colonial legacy of decrying Indian sciences. Page | 24

^d This is evident from that fact that starting from 7th Five year Plan till the current Five year plan, each time the Government of India has allocated roughly 3% of the National Health Budget to all alternate systems combined. This is clearly pointing to the fact that these systems have been on starvation diet when it comes to research and developmental funding for the past many decades and would require investment of unprecedented magnitude for a sustained period to recover from its stunted growth trajectory and become self-reliant.

4. Section 4: Ayurveda – a brief introduction

4.1. Ayurveda in the Indian healthcare scenario

Historically, Ayurveda has been a holistic, inclusive, progressive and continuously evolving knowledge system with universal attributes. The logic, theoretical foundations and epistemology of Ayurveda are based on the six *darśanas*, mainly the *Sāṅkhya* and *Nyaya-Vaisesika* systems of natural philosophy. An integrative holistic approach to healthcare and cure has been a distinct facet of Ayurveda practice.⁶⁶ On the other hand, critical care and advanced invasive treatments are great contributions of modern medicine to healthcare, while for curative care, its approach has been reductionist, which many biomedical scientists believe, does not probe the root of the disease.⁶⁷ A careful scrutiny of the classical writings of Ayurveda will enable us to appreciate the rational and scientific development of medical knowledge in India. It will help us know the reason why genuine practitioners of Ayurveda who have relied entirely on classical medicines invariably claim to have got clinical outcomes that were predicted of them, ages ago.

Nevertheless, one cannot undermine the need for clinical evidence in a form discernible to the conventional scientific community when it is evident that no single system can claim to offer a complete cure. In this age of globalization of information where people have access to the entire body of medical literature at the click of a button, they can be expected to judge for themselves the good in every system and resort to them as they deem suitable. Just as critical care and invasive procedures of contemporary medicine are evidently helpful, Ayurveda can make two major contributions in the current healthcare scenario. One is in the management of chronic ailments (like Diabetes, Bronchitis, Stress etc.), and second one in home based remedy for primary healthcare.

It has been a long recognized need that India should take up the initiative of developing a healthcare model pivoted on Ayurveda by integrating traditional and

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modern systems.^e As a first step it should attempt to look for commonalities in the various traditional practices like Ayurveda, Siddha, folk medicines etc. and then invest in rigorous clinical documentation of their clinical outcomes in an integrative framework that is made available in a form that can be accessed and understood by any modern scientist. Page | 26

While medical pluralism may be the future direction and indeed the new form of healthcare, the shift from singular knowledge systems to new plural systems cannot happen without very serious and long term investment in research, followed by comprehensive educational programs.^{68,69}

India can be a world leader in this new field of 'Integrative Health Sciences and Technology' because we have over the last century or so assimilated and achieved a reasonable degree of competence in bio-medical and life sciences and we possess an incredibly rich medical heritage of our own. Revitalization of the TM sector is essential for this leadership role.⁷⁰

^e The Chopra Committee, a committee appointed the government of India to advise on its healthcare strategy as early as in 1948, had recommended a blueprint that gave Ayurveda an equal role in rural and urban health services.

4.2. Inherent strengths of Ayurveda

Clinical management in Ayurveda is characterised by multiplicity of the interventions. There is a very strong case to believe that this approach may lend itself excellently in the management of diseases that are by nature chronic and multifactorial. The multiple facets of Ayurvedic management of health and disease are:

1. Customised intervention that varies according to individual constitutional framework (*prakriti*)⁷¹ and the stage & phase of disease.
2. Multi-component intervention involving drug, diet, lifestyle, *panchakarma* (detox) and yoga.⁷²
3. A systemic cleansing of body (*shodhana chikitsa*)⁷³ using techniques of Panchakarma that is unique to Ayurveda
4. A treatment approach⁷⁴ that has homeostasis or restoration of balance as its end point. In this approach, stress is laid on two things:
 - a. **Apunarbhavatva:** Achieving a stable state of homeostasis that does not relapse to the prior diseased stage (non-recurring).
 - b. **Yonyamanyamudeerayet:**⁷⁵ Achieving homeostasis without causing any disturbance to any other systems (without side-effects).

The Ayurvedic logic behind the action of drug is constructed based upon the five inherent characteristic of a drug, viz. *Rasa* (Taste), *Guna* (Quality), *Veerya* (potency), *Vipaka* (nature of its metabolite) and an action of particular drug that is not attributable to the first four characteristic or is in contrast/antagonistic to them is said to be due to a supra-logical phenomenon and given the name *Prabhava*⁷⁶ (a supra-logical action). (E.g. Honey is sweet in nature but does not increase *kapha* or *medha* (fat) (sweet substances are expected to increase *kapha* or *medha* (fat)). These five characteristics together are known in Ayurveda as *Dravya Panchaka*.⁷⁷ This understanding contributes to the complexity of the variables that are in play in

Ayurvedic management warranting a radically different method of evaluation that is sensitive to these variables.

A multi-faceted approach is always a better proposition in NCDs, as it naturally lends itself to tackle the multi-layered etio-pathology of chronic diseases. Nevertheless, to ascertain the efficacy of a drug/procedure, the reductionist approach is definitely called for, but it has relevance only in well-defined specific conditions. A critical scrutiny of the classical texts of Ayurveda is necessary to understand and appreciate that Ayurveda has had an integrative approach traditionally.⁷⁸ It is also to be understood that Ayurveda has the distinct characteristics of a knowledge system like a well-defined epistemology and ontology, a logical and rational approach to defining health and diseases and its management; considering it merely as another form of herbal medicine is to do a monumental disservice to the progress of medical science as a whole.

Ayurveda defines every disease on the basis of a very seemingly simple, yet sophisticated theory of bio-regulation involving three functional units called as *Dosha (Vata, Pitta and Kapha)*. It postulates a unified theory of health and disease using the matrix of these three bio-regulatory entities and provides an exhaustive framework to understand the effect of a host of factors like diet, lifestyle, herbs, environment, diurnal changes, seasons, metals and minerals etc. on these bio-regulatory entities. The gap however lies in the translation of these theories to experimental findings that will make sense to the modern scientific community, but that in no way diminishes the immense contemporary value of this knowledge system.

An illustration of the logical approach in Ayurveda is the threefold management strategy explained in Ayurveda. They are as follows:

- 1 **Hetu-viparita or Hetu-viparitarthakari:**⁷⁹ This is an approach that involves an intervention that is designed to tackle the cause of the disease rather than the

specific type of imbalance of homeostasis or *dosha*. Such interventions would be individual specific and cannot be generalised. To illustrate the point, *Hareetaki* (*Terminalia Chebula*) is a drug used for many conditions, one of which is constipation, but it is specifically contra-indicated in certain people and in certain conditions (E.g. An exhausted and physically drained person, a person who has lost a lot of fluids, a very lean person, pregnant women, children etc.). This implies that if one were to undertake a clinical trial to study the action of *Hareetaki* (*Terminalia Chebula*) in constipation then it should be a trial for only individuals for whom it is indicated and not for constipation in general.

- 2 **Vyadhi-viparita or Vyadhi-viparitarthakari:**⁸⁰ This is an approach that involves an intervention that is designed to tackle a specific disease entity irrespective of the nature of imbalances of homeostatis or dosha. These are interventions that are disease specific. For example, the plant *Patha* (*Cissampelos Pareira*) is advised as a drug of choice in diarrhoea. It could be used in all kinds of diarrhoea, except in a condition called *amatisara*⁸¹
- 3 **Ubhaya-viaparita or Ubhaya- viparitarthakari:**⁸² This is an approach that involves a strategy that is designed to tackle the disease as well as its cause, the imbalance in homeostatis or dosha. For example the herbal formulation, *Dashamoola Kwatha* (a decoction made from the roots of ten medicinal plants) is advised in *vataja shotha* (a specific kind of inflammation). *Dashamoola* acts on both, the specific type of imbalance (*vata dosha*) which is the cause of the disease, as well as, on the inflammation (*shotha*) which is the actual manifestation of the disease.

Therefore, we can clearly note that Ayurveda has inherently followed a logical and rational approach to healthcare and the most authentic text books of Ayurveda have at all times advocated an evidence-based approach to clinical practice. While it is true that there is indeed a dearth of published research and documentation in a form acceptable to scientific community, but that does not logically translate to the

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absence of a rational and scientific knowledge system in Ayurveda. *Absence of evidence is not evidence of absence* of a scientific knowledge system in Ayurveda. In order to further appreciate the rationality of Ayurveda, it may be worthwhile to get introduced to how Ayurveda functions in the real world and for that we take a case in point of DM and elaborate how it is understood and managed in Ayurveda. Page | 30

4.3. Relevance of Ayurveda in the management of NCDs

At the outset, it is essential to understand that IM is a means not an end; it is a way of thinking and doing, more an approach to healthcare management rather than a well-developed protocol of intervention. As things stand today, it is probably at a nascent stage of its evolution as far as the model involving Ayurveda is concerned and one would have to confess that there is still a long way to go before we have a definitive framework to practice such a model.

When we take DM as an example, the approach of the two systems involved, in this case Allopathy and Ayurveda are diagonally opposite. To be more specific, Allopathy perceives DM as a condition in which a hormone (insulin) is either not secreted sufficiently to convert the glucose to glycogen or the cells develop resistance to insulin. This understanding is reductionist in nature and the management strategy also is simply either to provide insulin externally or enable the cells to increase its production or give chemical agents to alter the receptibility of cells to facilitate exchange of glycogen and glucose. Whereas Ayurveda, like other holistic systems, views this as an imbalance in the internal milieu of the body due to various external and internal, immediate and remote etiological factors that bring about systemic changes in the body leading to blockage of channels that carry bio-regulatory signals, energy and nutrition, impairment of conversion of tissue materials and it proposes that certain body types are predisposed to such changes. Ayurveda divides all human beings to seven body types, the treatment starts from understanding these body types, analysing the imbalance and correcting this imbalance depending on its onset, progression and chronicity.

Here there is a paradigm shift in understanding; one stream of knowledge understands from a reductionist view point of a cell or molecule while the other system is viewing from the holistic perspective of internal and external environments. If one is able to clean up the micro-channels, improve the tissue



metabolism through correction of diet, lifestyle modification, detox etc. then the end point of bringing the serum sugar levels to normal limits is achievable, and at the same time, even without correcting this internal environment if one supplements the deficient bio-molecule (insulin) externally, the same end point can be achieved, both are acceptable and plausible. This plausibility is an important factor in gauging the efficacy of systems like Ayurveda. Page | 32

The above context does not imply that there is no meeting point, simply that to find it will be a challenge. All the integrative approaches have started from a simplistic method of putting two systems together without understanding each other, for instance, taking DM as an example, Ayurveda does not perceive insulin as a factor in diabetes at all, on the other hand a structural unit in the body which is a factor of all tissue elements and principle of cohesiveness is the basic factor involved in the disease development. Ayurveda strives to bring this back that dynamic equilibrium which was prevailing before the onset of the disease.

IM, to achieve its goal has to pass through a journey of summative medicine, in which two systems are put into practice for different purposes to achieve a common goal. For e.g. in insulin dependent DM, insulin cannot be stopped at once, but a systematic procedure of purification and rejuvenation of body cells through a classical approach of Ayurveda can initiate bodily changes that can allow a gradual tapering in the dose of insulin and bring down or in many cases stop the use of insulin over a period of time. In certain cases of diabetic management where the peripheral nerve systems are affected, the Ayurvedic approach can correct the systems, change the milieu and offer significant relief to the patient.

In certain conditions like Diabetic Retinopathy, protective measures in Ayurveda can help reduce the severity of the diseases or delay the progression. Here the principle of dryness versus unctuousness, a basic principle in Ayurveda, something that is difficult to comprehend in terms of the reductionist framework, is utilised in clinical

practice. Both neuropathy and retinopathy result from an increase in the dryness of the body and the treatment is strategized to counter this dryness through interventions that promote external and internal unctuousness.

An integrative model based on culturally sensitive Ayurveda incorporating useful elements from yoga (which, at a subtle level, is an extension of Ayurveda), region-specific folk practices and a few diagnostic, prognostic & supportive elements of biomedicine should be, we believe, practical and relevant in the Indian context. It is being experimented at our centre with some degree of measurable clinical effectiveness and is found to be both feasible and possible.

This model can be extrapolated with various degrees of addition and deletion from other systems in many of the chronic diseases. Ayurveda by definition is a science of wellbeing and looks at health from a level of macro-micro interaction. It is important that the internal environment be in tune with its external milieu. In IM, one is not trying to mix two systems. Rather one is trying to use two different systems to meet the goal of well-being. That's the reason why it is probably pertinent to note that IM is an evolving concept and a continuous process as against the old notion of integrated medicine, where one system dominates and takes elements of other systems to suit its need many a time disintegrating them and distort their effect.

Three stages of life; a) Regeneration and growth, b) Sustenance and balance and c) Degeneration and decay are important factors in managing health and healing diseases. These three stages differ in different body types, so an integrative model based on Ayurveda will have a comprehensive understanding of the human body. A person who is practicing this model will be able to understand the limitations and scope in order to be able to fill the gaps appropriately from other systems, which can bring in sudden change in the body that goes against the nature but may be necessary in certain conditions. For that change to be sustained, natural system has to be brought into action; these dynamics are the crux of integrative approach, that's



why it is important to note that it is an evolving science rather than a fully defined system. Integrative model has only a place when two systems of different paradigm have to come together for a common goal otherwise there is no need for integrative approach.

Contrary to popular perception in the developed world of Ayurveda being a mystical science, it has a very logical and pragmatic approach to defining health and disease. Every disease (Diabetes included) is demystified in Ayurveda into stages of pathological progression and clinical findings that mark each stage have been listed. It is possible to map many of these clinical findings to current understanding of the disease and thereby to its biochemical correlates. However, we must bear in mind is that Ayurveda relies purely on a systemic understanding of human system and bases its management strategies on careful clinical observations that may or may not correlate entirely with the current non-clinical marker of the disease.

The management strategy is distinctly described in Ayurveda for every stage of the disease pathogenesis which does not begin at the stage of full blown disease but at the stage of causation itself. A trained Ayurveda physician would therefore be able to give very practical interventions that may be extremely relevant in primary, secondary and tertiary prevention of DM.

This is the distinct advantage that Ayurveda brings to the table, which is, to be able to provide clinically useful advice individualized to a subject for effective primary prevention and for positive health that can be customized to suit every stage of progression in the etio-pathology of a disease.

The second distinct advantage that Ayurveda extends is that of cultural relevance in the context of the Indian Subcontinent. Cultural relevance is vital in the effective communication of a public health message and also for the acceptance of a public health intervention. Several illustrations can be cited for bolstering the importance of cultural relevance of public health interventions and one of the most glaring

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examples would be the National Nutritional Anemia Prophylaxis Program in our country. Despite 40 years of prevention, Iron Deficiency Anemia is endemic in India: 79.2% in children aged 6-35 months, 57.9% in pregnant women, 56.2% in women of child-bearing age (15-49 yrs.) and 24.3% in adult men. ^{83,84,85} One of the critical impediments in the effective implementation of the program has been the poor compliance of the population to the intervention which basically involved consuming pills that they were not culturally used to consuming (it produced a characteristic iron taste in the mouth, caused constipation and gastric irritation). By contrast, Ayurveda is deeply embedded in national awareness of the country in terms of household, family and community practices for everyday nutritional and home-based solutions to health problems. It can easily be called the natural choice of people living in this part of the world and that itself is its unique and most remarkable asset.

5. Section 5 Ayurveda and Integrative Medicine

5.1. Need for medical communities to work together

The answer to the question whether a course correction is required in the current healthcare delivery strategy of India will be a resounding yes, because critical health indices of the country pertaining to maternal mortality, infant mortality and malnourishment are comparable to Sub-Saharan Africa.⁸⁶ Clearly there is something amiss fundamentally in our system where a sustained spending on public health through conventional means (the cure-centric approach of mainstream medicine) has not produced the desired results and our rank in terms of health indices did not improve much compared to other developing countries.⁸⁷

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The planning commission of India, the apex planning body of the nation, that guides and determines the allocation of resources in the country, for the first time adopted a consultation from interested stake holders via the Commission's web-site to finalize the 12th five year plan (for the period 2012-2017). Based on an intensive consultative process within the Commission, "Twelve Strategy Challenges" were identified to initiate these consultations. The "strategy challenges" refer to a few core areas that require new approaches to produce the desired results.⁸⁸ The strategy challenge in healthcare was identified as follows:

'India's health indicators are not improving as fast as other socio-economic indicators. Good healthcare is perceived to be either unavailable or unaffordable. How can we improve healthcare conditions, both curative and preventive, especially relating to women and children?'⁸⁹

Therefore it is evident that we need to re-strategize. But, the questions that beg to be answered are: What course correction is warranted to usher in a discernible and sustainable positive change in the situation? Whether Ayurveda has a role to play in it?

The National Health Policy of India (2002) notes that ‘Global experience has shown that the quality of public health services, as reflected in the attainment of improved public health indices, is closely linked to the quantum and quality of investment through public funding in the primary health sector. The table below gives statistics which clearly show that standards of health are more a function of the accurate targeting of expenditure on the decentralized primary sector (as observed in China and Sri Lanka), than a function of the aggregate health expenditure.’⁹⁰ Page | 37

Table 1: Public Health spending in select Countries

	<i>Population with income of less than one dollar per day</i>	<i>IMR /1000</i>	<i>Health expenditure to GDP</i>	<i>Public expenditure on health to total health expenditure</i>
India	44.2 %	70	5.2%	17.3%
China	18.5 %	31	2.7%	24.9%
Sri Lanka	6.6 %	16	3.0%	45.4%
UK	-	6	5.8%	96.9%
USA	-	7	13.7%	44.1%

The policy also noted that ‘Under the overarching umbrella of the national health frame work, the alternative systems of Medicine – Ayurveda, Unani, Siddha and Homoeopathy – have a substantial role. Because of inherent advantages, such as diversity, modest cost, low level of technological input and the growing popularity of natural plant-based products, these systems are attractive, particularly in the under-served, remote and tribal areas.’⁹¹

It is estimated that nearly 600,000 allopathic medical doctors are available for over 1.2 billion Indians indicating a physician to population ratio of over 1:2000, which is not even half way mark into the ideal ratio recommended by WHO (One physician



to serve a population of 1000).⁹² About 75% of health infrastructure, medical manpower and other health resources are concentrated in urban areas where 27% of the population lives.⁹³

What is lost in this statistic and which is extremely disappointing to any open minded, inclusive healthcare practitioner is the fact that India also has over 700,000 licensed, registered practitioners from the AYUSH (acronym for Ayurveda, Yoga, Unani, Siddha and Homoeopathy) systems of medicine, whose presence was not sufficiently factored into the healthcare delivery plan of the state till recently. Fortunately many of these practitioners work in rural areas where conventional health services are either unavailable or poorly available and the travails of insufficient healthcare delivery are more acutely experienced. Having not leveraged the presence of this alternative health resource has proven to be ill-advised given that affordability and accessibility has been identified as critical issues plaguing the healthcare sector in India in general and rural areas in particular.⁹⁴

It is in this backdrop that we should read the basic objective of the National Policy on Indian Systems of Medicine & Homoeopathy (2002), inter alia, the 'integration of ISM&H in healthcare delivery system and National Programs and ensure optimal use of the vast infrastructure of hospitals, dispensaries and physicians.'⁹⁵

Today, there is sufficient awareness in the country that healthcare systems need to come out of the narrow idea of health and disease as merely bio-chemical phenomena and understand the complex interplay of biology, behaviour, socioeconomic and environmental factors that shape health.⁹⁶

This makes it imperative for the Ayurveda and allopathic medical communities in India to join hands to give the nation at least a reasonable chance of effectively addressing its current healthcare challenges.

5.2. Research methodologies agnostic to scientific paradigm

It is known that developing a credible model of IM is a multi-disciplinary and complex task that calls for new capacity building and extensive applied and clinical research.⁹⁷ The complexity of the task increases manifold when the disciplines involved have evolved from completely different knowledge paradigms such as Ayurveda and Allopathy, as one would have to be careful not to compromise or distort the core values and basic principles of either knowledge systems while undertaking such multi-disciplinary research. Nevertheless, one has to find common ground as research is imperative for progress and that warrants the need to identify and evolve suitable methodologies that are agnostic to the scientific paradigm.

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Randomised Controlled Trials (RCTs) are considered the Gold Standard in clinical evidence.⁹⁸ The ascendancy to RCTs in conventional medicine is owing to the fact that it enables you to assess whether the intervention itself, as opposed to other factors, caused the observed outcomes. It has a perceived ability to minimise bias – specifically what is known in clinical research parlance as Type 1 error – and also to maximise the power of a study. In simpler terms, fewer Type 1 errors lessen the chances of releasing a bad drug into the market and a greater power for the study implies an increased chance of discovering a good drug.

However, the case of Ayurveda is unique in that it is a legitimately practised medical system in India with a documented history of use among a very vast majority of population dating back to thousands of years and the questions of Type 1 error and power in the conventional sense do not apply to it.

The principles that characterise good research are ethics, transparency and scientific unbiasedness.⁹⁹ If we were to apply only this criterion without getting fixated with RCTs then it is possible to identify numerous ways and means to do good research involving Ayurveda. Today, there is persuasive evidence that suggest that ‘Well-matched’ comparison-group designs may be a good alternative when an RCT is not

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feasible.¹⁰⁰ Other options that are worth considering are pragmatic trial designs that look at therapies as ‘black boxes’ or trials where the rator of the outcome variable is a third party blinded from the intervention helps reduce bias and greatly improve the validity of the results.

5.3. Towards a mutually acceptable scientific basis for cooperation

In 2010, the department of AYUSH of the Government of India had commissioned a report on the status of Indian medicine (Ayurveda, Unani and Siddha Systems) by Dr. Shailaja Chandra, the former secretary to the Government of India for the department. The focus was on the benefits that the public has received and it was additionally required to indicate the gaps that needed to be filled when the 12th five-year (2012-2017) plan for the nation was formulated.¹⁰¹

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The report – which was prepared after extensive consultation with experts from both Ayurveda and Allopathy representing multiple stakeholders in the healthcare sector – provides some definite directions to move forward. It documents a chorus of opinion from renowned scientists that point to the need for a change in track when it comes to collaborative research involving Ayurveda. The major suggestions that will help formulate a scientific basis for mutual cooperation is listed below:

- Generating evidence of quality, safety and efficacy of Ayurveda interventions through rigorous Therapeutic Outcome Studies (TOS)
- Designing clinical studies that have novel inclusion and exclusion criteria, controls efficacy and safety standards and end points relevant to Ayurveda
- Undertaking observational studies that rigorously document and study Ayurveda in real life clinical settings in all the diverse ways that it is practiced
- To come up with data that address basic concerns regarding safety and efficacy of Ayurveda interventions in the form that they are being offered to the public today

These suggestions re-affirm the need to evolve new guidelines where due weightage is given to empirical evidence based on the basic principles of Ayurveda without compromising on parameters of safety and efficacy. Use of effective and safe Ayurvedic treatments become more important, particularly in chronic conditions

like Rheumatoid Arthritis, where long-term support by single chemical drugs of choice can lead to life-threatening damage to vital organs.¹⁰²

To summarize the strategy for a mutually acceptable scientific basis for cooperation, I would like to quote from the status report, the suggestion given by Dr. T Ramasami, a well-known scientist and formerly secretary to the Government of India for the Department of Science and Technology, on how future clinical research should be undertaken. He provides a simple roadmap for the future that is in tune with what has been discussed thus far and carries conviction. The report confirms that this approach has been corroborated by several experts engaged in traditional medicine research.

‘In my opinion, the grammars of Alternative and Modern Medicine do not match. Both forms of medicine are valuable in their own ways but the R&D tools of modern medicine may not seem to fit the needs of traditional medicine. Modern medicine is based on reductionism and understanding of the chemical biology of diseases and statistical assessment of drug responses on live systems. Animal models and clinical trials on human subjects form the basis of drug discovery. It employs the tools and grammar of discovery science and learning from closed systems and laboratory observations. Traditional medicine employs the tools of integrative biology and empirical observations of healthcare outcomes on human subjects (made over centuries) and uses the concept of personalized medicine. These concepts do not lend themselves to application of animal models. While sophisticated analytical techniques could be gainfully employed, it seems rather difficult to subject the traditional medical formulations to clinical pharmacological studies employed for modern medicine without introducing ambiguities. Ayurveda and Siddha treat man as a part of an ecosystem while modern medicine tries to rely on drug host responses at molecular and system biological levels. If man is a part of an ecosystem, inspiration for solutions to human health related problems could in principle be sourced from the plants of the same ecosphere. The question is whether such forms



of medicine could be globalized or not. We need to retrofit the two systems built on widely different grammar. Traditional medicine is based on empirical observations collected over long periods of time. Modern medicine is structured with the rigor of laboratory findings under controlled conditions. Traditional medicine relies on the principle of connecting a grid of causes with a grid of effects while modern science is built on the structure of a single cause coupled with a single effect. Therefore, new paradigms are required to leverage the mutual benefits of modern and traditional medicines to benefit each other. As a scientist trained with the tools of rigor and an analytical approach but as someone bearing faith in the value of traditional medicine, I would like to propose a new approach for revalidation of formulations from traditional medicine using modern tools, without sacrificing the merit of traditional practice. I may like to propose the following.

Let us select and identify 100 patients treated through traditional medicine for say arthritis. The treatment protocol might have employed different formulations based on genotype of patients. This is no issue. Based on the history of treatment, we classify our targeted patients based on their "*Prakritis*" or genotypes. We then analyze their body fluids using the analytical tools of modern science rather rigorously and search for evidence of biomarkers. For example, in the case of arthritis some proteins and their degradation products could be traced. If there are any statistically significant trends and correlations between health and disease status of the 100 patients treated only by through traditional medicine are compared to those treated using modern medicine, we could derive a more suitable revalidation system for traditional medicine using modern analytical tools. Subjecting traditional medicine to animal models as employed by modern systems may not be appropriate for revalidation. Extrapolation from mouse to man in traditional medicine is not feasible. We need to study effects on men and men only.

We could equally well retrofit my concept to diseases other than arthritis as well. DST is mounting a coordinated research project on "*Ayurvedic Biology*". We need to

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work at the cross borders of science enrolling human beings as unit of observation rather than molecules, cells and animals.’¹⁰³

In India, where the practice of Ayurveda is legal and widespread, it is very important that we invest in evidence generation through clinical documentation of that practice rather than allow it to languish in the fringes of conventional scientific deliberations. Therefore, future research efforts should focus on robust documentation of Ayurveda practice and understanding the mode-of-action of its various interventions to harness its potential to help provide an affordable and safe healthcare system.¹⁰⁴

Summary and Conclusion

In this paper we have presented a case for the plausibility of developing an alternative model of IM that has Ayurveda in the pivot integrated with other systems like yoga, physiotherapy and elements of Allopathy as a feasible model specifically in the context of India. First, we examined the impact of non-communicable diseases globally and in India, followed by their management by conventional medicine in the second section, with a focus on DM. Our case was strengthened as we examined the challenges faced in the management of NCDs using current methods in the next section. Subsequently we connected the global surge towards alternatives in medicine and the scene of Ayurveda in India. Our case was further bolstered by the fact that policy makers of the country have recognized the need to leverage the reach and acceptance of Ayurveda and factor them in the healthcare delivery strategy. Lastly, we examined the need for Allopathic and Ayurveda physicians to come together within a new framework of mutually acceptable scientific basis for cooperation and pointed to some possible ways to move forward in that direction.

The conclusions that we seek to articulate are as follows:

1. Ayurvedic texts exhorts its proponents to be open to new information even if it comes from unfamiliar sources and it is in its inherent nature to constantly update its knowledge system.
2. In the light of persuasive evidence to suggest to the contrary, evaluating every Ayurveda intervention only in terms of RCTs is not warranted, rather newer outcome based approaches is desirable.
3. Ayurveda interventions need to be evaluated for safety and efficacy on parameters that are valid and acceptable to conventional scientific wisdom if it has to lend itself to IM.

4. Ayurvedic and allopathic physicians need to jointly evolve a new integrative framework for the management of NCDs that will combine the best of both approaches.
5. While doing so, there is a need to approach Ayurveda – vast and intricate as it is – with a healthy dispassionate curiosity sans prejudices and indifferent attitudes that the word ‘traditional’ has inadvertently come to evoke. Page | 46
6. A critical mass of outstanding researchers will gradually emerge as a natural outcome of such an inter-disciplinary dialogue, who are able to appreciate and acknowledge the conceptual resources derived from Ayurveda as a critical source of advancement of current medical science.

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Appendix 1:

Glossary of key Sanskrit terms

1	<i>Agni</i>	Digestive capacity/Metabolic capacity
2	<i>Ama</i>	A state of incomplete transformation of the ingested food. It is claimed in Ayurveda to be a toxic by-product generated due to improper or incomplete digestion
3	<i>Apachita dhātu</i>	Immature tissue element
4	<i>Asamhataśarīra</i> (<i>śaithilya</i>)	Slack built
5	<i>Darśanas</i>	Systems of Indian philosophy
6	<i>Dashamoola</i>	A set of roots of 10 specific medicinal plants
7	<i>Dhatu</i>	Basic tissue elements of the body (seven in number)
8	<i>Dhatukshaya</i>	Degeneration of body tissues
9	<i>Dhatvagnimāndya</i>	Improper metabolism of tissue
10	<i>Dosha</i>	Functional unit of the body or 3 energies that govern the body namely vata, pitta, and kapha
11	<i>Dravya Panchaka</i>	Set of five pharmacological constructs in Ayurveda claimed to be determining the action of a drug
12	<i>Guna</i>	Quality of a drug
13	<i>Guru, Snigdha, Amla, Lavanaahara</i>	Food which are having qualities of heaviness (heavy to digest) unctuousness, sour and salty
14	<i>Kapha/Kaphadosha</i>	<i>Kapha</i> is the body fluid principle which relates to mucus, lubrication, nourishment and the carrier of nutrients.
15	<i>Kashaya</i>	Medicated decoction made by boiling of water with the herbs in a prescribed proportion.
16	<i>Kledavridhi</i>	Increase in moisture content
17	<i>Madhumeha</i>	A type of <i>prameha</i> that can be co-related with diabetes mellitus
18	<i>Madhura rasa</i>	Sweet taste
19	<i>Mala</i>	Impurity/ waste product of the body
20	<i>Mamsadhatu</i>	Muscle tissue
21	<i>medha</i>	Fat tissue
22	<i>Nyaya-Vaishesika</i>	Two among the six streams of systems of Indian philosophy that has informed and influenced Ayurveda
23	<i>panchakarma</i>	Fivefold purificatory measures in Ayurveda
24	<i>Panduvarna</i>	Paleness/ palor
25	<i>Pitta/Pittadosha</i>	One of the three functional entities of the body. It is the principle of transformation energy and governs heat and metabolism in the body, is concerned with the digestive, enzymatic, and endocrine systems,

26	<i>Prabhava</i>	Trait of an herb responsible for a special or peculiar action of a drug not explicable by its pharmacological property.
27	<i>Prabhūtamūtratā</i>	Poly urea / increased micturition
28	<i>Prakriti</i>	Prakriti refers to Ayurvedic profile or unique psychosomatic temperament of an individual, encompassing his or her physical, functional and behavioural characteristics.
29	<i>Prameha</i>	Disease having main symptom as excessive urination
30	<i>Rasa</i>	Taste of a drug
31	<i>Rukshaguna</i>	Dryness
32	<i>Sāmkhya</i>	One of the six philosophical streams in India
33	<i>Samshodhana</i>	Purification of the body
34	<i>Shodhanachikitsa</i>	Purificatory treatment
35	<i>Shotha</i>	edema / swelling
36	<i>Siddha</i>	One of the Indian systems of medicines native to Southern part of India especially in Tamil Nadu State and southern tip of Kerala State.
37	<i>VasudhaivaKutumbakam</i>	Phrase that means that the whole world is one single family."vasudhā", the earth; "ēva" = indeed is; and "kutumbakam", family;) which says animals, birds, plants, trees and other organisms in the ecosystem have atma they are part of our family
38	<i>Vata/Vatadosha</i>	One among three functional entity which is considered as driving force for all the movements in the body
40	<i>Veerya</i>	Potency - strength of the drug
41	<i>Vipaka</i>	Outcome of digestion/ metabolism

Appendix 2:

I-AIM HEALTHCARE CENTRE'S INTEGRATIVE APPROACH TO MANAGEMENT OF DIABETES MELLITUS (*MADHUMEHA*)

Disease and its Bio-medical correlation

Madhumeha is one of the types of *Vataja Prameha*. It is characterized by a change in the physical as well as chemical composition of urine. Precisely, the urine assumes the nature of honey (Glycosuria). DM, often simply referred to as diabetes, is a referred to a group of metabolic diseases in which a person has high blood sugar, either because the body does not produce enough insulin, or because cells do not respond to the insulin that is produced. This high blood sugar produces the classical symptoms of polyuria (frequent urination), polydipsia (increased thirst) and polyphagia (increased hunger).

Aetiology

As per Ayurveda

Ayurveda classifies causative factors responsible for *Madhumeha* into those leading to increase in vata or those that result in dhatukshaya. Such causative factors produce a specific etiopathogenesis where in the dhatus are brought to the bladder and excreted out through the urine giving rise to *Madhumeha*. Some of the factors that may lead to these are Intake of excessive Guru, Snigdha, Amla, Lavana aahara, intake of excess amount of food, freshly harvested cereals and wines, excessive sleep, sedentary lifestyle, lack of mental and physical exercise and avoidance of a seasonal Samshodhana karma aggravates Pitta, Kapha, Meda and Mamsa dhatu. It is quite interesting to note that whilst these are mainly Santarpana Hetus (i.e. factors caused as a result of over-nutrition), they still produce the disease *Madhumeha* in which mainly apatarpana (under nutrition) of body occurs.

As per Bio-medicine

The cause of diabetes depends on the type of Diabetes. Type II diabetes is primarily due to lifestyle factors and genetics. Type I diabetes is partly inherited and then triggered by certain infections.



EXECUTIVE MEDICAL HISTORY

Signs and symptoms

The following are the symptoms of diabetes, which may develop rapidly (weeks or months) in type 1 diabetes while in type 2 diabetes they usually develop much more slowly and may be subtle or absent: Page | IV

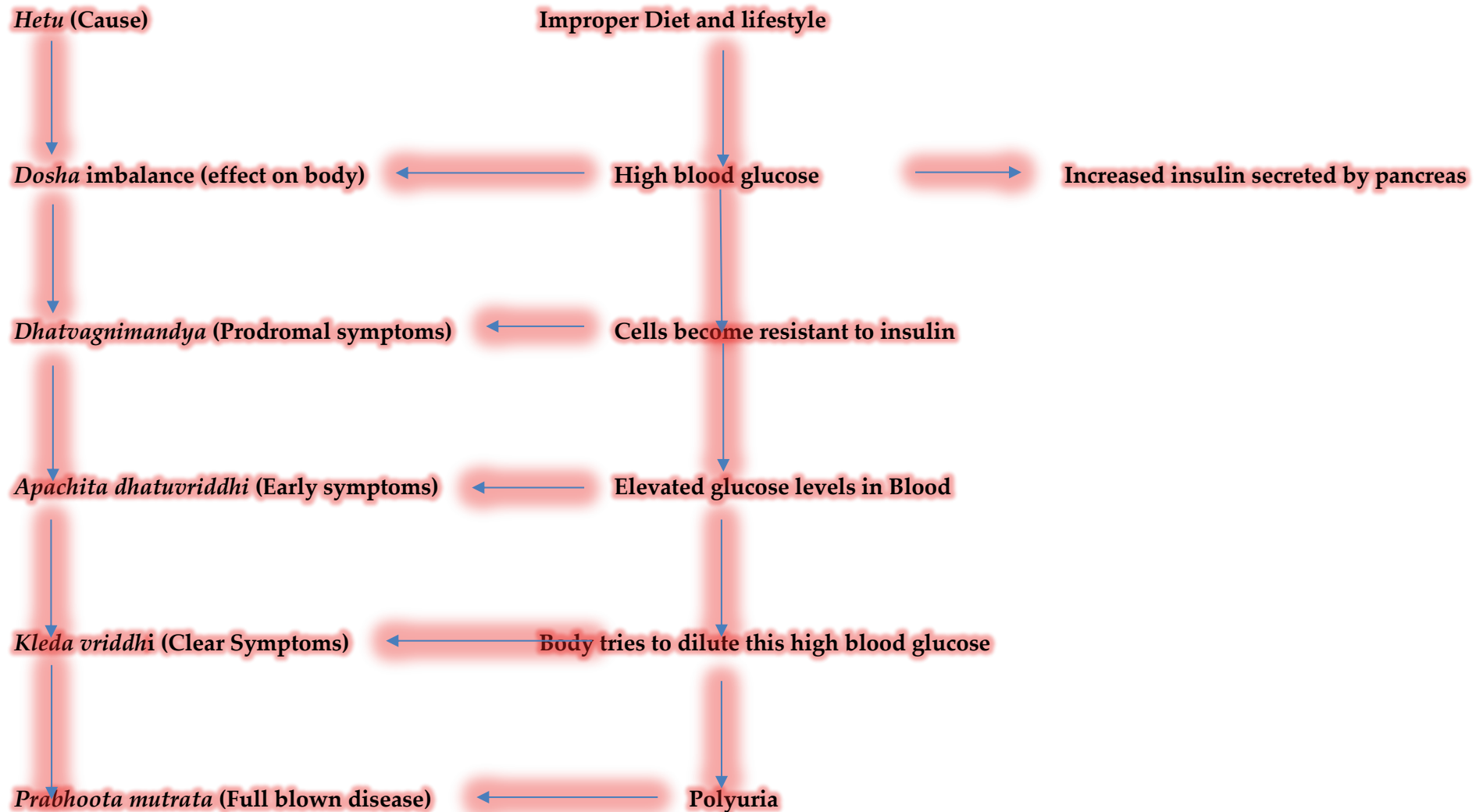
- Polyuria (frequent urination)
- Polydypsia (increased thirst) and
- Polyphagia (increased hunger).

Ayurveda defines that Madhumehi passes urine having Kashaya and Madhura rasa, Pandu varna and Ruksha guna. The urine of Madhumehi resembles honey and typically such subjects prefer standing to walking, sitting to standing, lying down to sitting and sleeping to lying down.

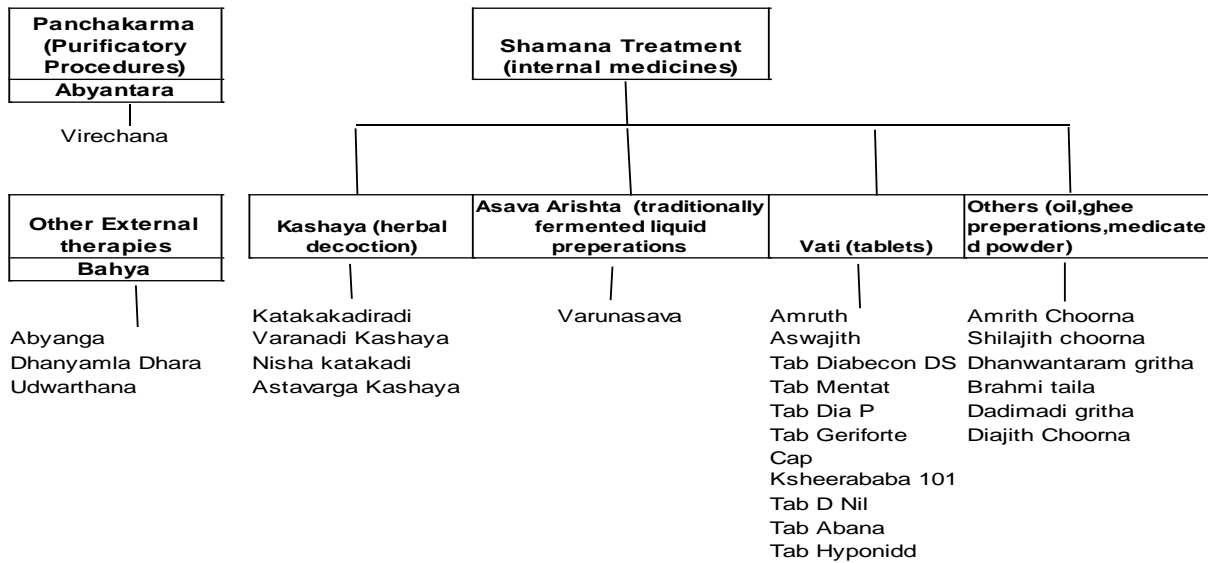


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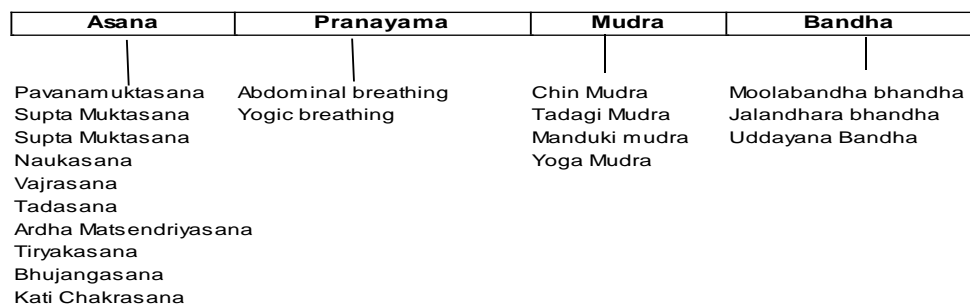
Illustration 1: Ayurvedic understanding of Diabetes mapped to biomedical understanding of the same:



DM (*Madhumeha*) – Integrative Management Strategy



Yoga Management



Physiotherapy Management

Exercises

-Aerobic exercises
-Resistance exercises

Eg
Biceps Curls
Triceps Curls
Hamstring curls

Knee extension exercises
Abdominal curls

Table 1: Herbs in Ayurveda with known hypo-glycemic activity:

<i>Guḍūci</i>	:	Tinospora cordifolia		<i>Udumbara</i>	:	Ficus Glomerata
<i>Puṣkaramūla</i>	:	Inula racemosa		<i>Jambu</i>	:	Eugenia Jambolana
<i>Bījasāra</i>	:	Pterocarpus marsupium		<i>Apāmārga</i>	:	Achyranthes Aspera
<i>Patraka</i>	:	Cinnamomum tamala		<i>Patha</i>	:	Cissampelos Pareria
<i>Karavellaka</i>	:	Momordica charantia		<i>Guḍmār</i>	:	Gymnema Sylvestre
<i>Palāṇḍu</i>	:	Allium cepa		<i>Māmejjak</i>	:	Enicostemma Littorale
<i>Laśuna</i>	:	Allium sativum		<i>Saptaraṅgi</i>	:	Caesaria Ecculentum
<i>Vyjayanti</i>	:	Clerodendron Phlomidis		<i>Aśwattha</i>	:	Ficus Religiosa
<i>Dāruharidra</i>	:	Berberis Aristata		<i>Bimbi</i>	:	Coccinia Indra
<i>Niṣpāva (Gowar)</i>	:	Cyamopsis Tetragonoloba		<i>Ponkoraṅṅi</i>	:	Salacia Prenoides

Table 2: Diet and lifestyle advises in Ayurveda for DM:

Diet		
Items	Pathya (Advised-wholesome)	Apathya (Avoidable-unwholesome)
Cereals	Purānaśāli-old rice/Oriza sativa, ṣaṣṭikaśāli-Orizanivara, Yava –Barley/Chenopodium album Godhūma –Wheat/Triticumaestivum, śyāmaka-Canalgrass/Cymbopogon schoenanthus, Kodrava-Kodo millet/Paspalums Scrobiculatum, Bājara-indian millet	New cereals
Pulses	Mudga - Green gram/Phaseolusaureus, Caṇaka - chicken pea/Cicerarietinum, Kulattha-horse gram/Vigna unguiculata, Niṣpāva -Lablab purpureos, Tūr dāl-Pigeon pea/Pisum sativum, Math-tepariy bean/Phaseolusa conitifolius	Pavata
Vegetables and leaves	Tiktaśākas like- Medhika-fenugreek/Trigonellafoenum, Nimba – Nīm/AzadirachtaIndica, Karavella –Bitter gourd/ Momordica charantia, Paṭola –Snake gourd/Trichosanthes Anguina, Rasona – Garlic/Allium sativum Gudūci leaves-Tinospora /Tinospora cordifolia Kadaḷisār, Flower of coconut palm, śigru – Drumstick/Moringaolifera, Cabbage-Brassica oleracea, Kūṣmāṇḍa-Ash gourd/Benin casahispida, Kamala kāṇḍa-Nelumbonucifera	
Fruits	Jambu-Syzygiumcumini, Tālaphala- Borassus	

	<p>flabellifer Kharjūra - Phoenix sylvestris Kṛṣṇakadaḷī-over ripe banana/ Musa paradisiaca Raw fruit of Tiṇḍuka-Diospyros embryopteris, Kalinda –Watermelon/Citrullus vulgaris, Udumbara-Craddock/Ficus racemosa</p>	
Oils	<p>Neem oil-azadiracta indica, Íngudi oil –Balanitesa egyptiaca, Bhallaṭaka oil-Semicarpus anacardium Atasi oil –Linum usitassimum, Mustard oil- Brassica nigra Danti oil-Baliospermum montanum.</p>	Til oil- Sesamum orientale
Milk and milk products	Camel milk, butter from goat milk, buttermilk from cow and buffalo milk	Curd, ghee
Sugars, honey etc.	Kṣaudramadhu, Cchatramadhu, Dalamadhu Old jaggery	Juice of tender sugarcane- Saccharum officinarum, sugarcane juice obtained by machine, New jaggery
Spices	Jātiphala –Nutmeg/Myristica fragrans, Celery – Apium Gaveolens, Betel nut- Areca catechu	Chillies, Garlic
Fish, Meat etc.	Animals in dry region like- Hariṇa –Deer flesh śaśaka –Rabbit, Birds like Kapota-Pigeon, Peacock, Sparrow	Meat of animals in region where water is abundant and fish.
Salts and kṣāra	Bidalavana-Rock salt, Kṣāras-alkalis like Yavakṣāra, Sarjakṣāra	
Tubers	Varāhikāṇḍa-Taccaintegrifolia	
Taste of food	Kaṭu, Tikta, Kaṣaya/Pungent, Bitter, Astringent	Madhura, Amla, Lavana/Sweet, Sour, Salty
Food preparations and drinks	Soup of Pomegranate-punicagranatum and Āmalaka-Emblicaofficinalis, PañcāmṛtaYuśa, Nimbapañcāṅga, Yavaka, Mantha, prepared from roasted yava, Kulatthayuśa, Lāja, cold food, plenty of liquid food, old wine	New wine, Alcohol, starchy foods Hot foods
Miscellaneous	Sheep urine	
Lifestyle		
Items	Pathya (Advised-wholesome)	Apathya (Avoidable-unwholesome)
NA	Purgatives, fasting, emetics, Massage with powder of agaru (Aquelloria ageloccha) and candana (Santalum album), Physical Exercise	Smoking, induction of sweating, bloodletting, sleep during day, suppression of urge of micturition.



Appendix 3:

AYURVEDA BASED CHECKLIST FOR EARLY DETECTION OF DIABETES MELLITUS *

<p>Asamhata Shareera (Shaithilya) Lambanam</p> <p>Abdominal Girth, Arm circumference in supine and standing positions Abdominal muscle strength</p>
<p>Dhatu Asarata Lakshana</p>
<p>Kapha Chaya Aalasya (Lethargy) Gaurava (Heavyness) Shwaitya (Panndutva / Pallor) Ati Nidraa (Excessive sleep) Shlathangatva (Looseness of the body) Shwaasa (Breathlessness) Agnisaada (Dhaatvagni)</p>
<p>Kapha Prakopa Upalepa (increased coating over tongue, eyes, external auditory canal) Gaurava (Heavyness) Ati Nidra (Excessive sleep) Swaadu aasyataa (Sweet taste in the mouth) Tandra (Lethargy)</p>
<p>Maamsa Vriddhi Keela (Corn/polyp/skin tag) Alajee (skin rash) Tvak Shyamatva (Acanthosis) Kha Mala Vriddhi (Increased ear wax production)</p> <p>Mid arm, mid-thigh, mid-calf circumference</p>
<p>Meda Vriddhi Skin Fold thickness Waist Hip ratio Neck circumference Tender Fat Visceral fat Shotha (Inflammation) Sveda Vriddhi (Increased perspiration)</p>
<p>Medovaha Srotas Dushti Ashtauninditeeya Sthoola Krishna (Meda Dhatu Sthana) Hrasva Deerga (Anguli Parimana) Aloma Atiloma (body hair) Ati Gaura Ati Krishna</p>

Prameha poorvaroopa (Prodromal symptoms)

Swedaadhikya
Shareer Durgandha
Shareer shithilatha
Desire for Shayya sukha, aasya sukha, swapna sukha
Ghana Angata
Netra, Jihwa, Karna Mala Vriddhi
Coating on teeth and Gums (Spongy gums, bleeding gums)
Kesha, Nakha ati vridhi (increase of nails and hair growth)
Sheeta priyatwam (desired to have cold things)
Shushkasyata [dryness of gala (throat) & talu (pallet)]
Mukh Madhurya [sweet taste in mouth]
Kara Pada Daha [burning palms and soles]
Pipeelika akranta mootra [attraction of ants to urine]
Snigdha (Oily), Pichchhila (Stickiness), Guru gatra
Shukla mootrata (Pale urine)
Tandra (Lethargy)
Pipasa (Thirst)
Durgandha shwasa (bad breath)
Jatila kesha (Entangling of hair)
Mala Aadhikya (increased coating or secretions)
Sneha sweda sareera

Kleda Dushti

Vrana Ati Sraava
Delayed healing of wounds
Boils
Skin Manifestations
Rhinorrhoea (Naassasrava)
Leucorrhoea

Mootra Lakshana

Prabhoota Mootrata
Avila Mootrata
Mootra Lakshana as per 20 Prameha types

Diet

As per classical texts of Ayurveda

Lifestyle

As per classical texts of Ayurveda

Sagarbhavastha Itihasa (H/O intrauterine life)

History of daytime sleep, excess sweet, fatty diet by mother during pregnancy
Birth weight
Mahasrotas
Document preventive factors (diet, lifestyle...)

* This checklist was developed during the consultative workshop on High Impact Projects (HIP) conceived and hosted by Dr. Bhushan Patwardhan at IHST, Bangalore.
