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सत्यमेव जयते

DRAFT

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GOVERNMENT OF INDIA

REPORT OF TASK FORCE

ON

EVIDENCE-BASED TRADITIONAL
MEDICINE FOR HEALTH CARE IN INDIA



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Executive Summary

India has a pluralistic healthcare system where conventional medicine and traditional medical systems contribute to healthcare. The practitioners of each system work parallelly in clinical practice and institutions of public health. The efforts of the Government of India and initiatives of various stakeholders of TM have resulted in an increased interest in TM research, education and practices. However, the need to harness the potential of TM for improving India's health indicators is being increasingly recognized, also owing to the pitfalls of dependency on a single system of medicine. The National Academy of Medical Sciences (NAMS) formed a Task Force (TF) titled 'Evidence-based Traditional Medicine for Health Care in India' comprising expert scientists and practitioners in biomedicine and TM. The members of the task force had several rounds of discussions and recommended measures to bridge the evidence-to-action gap for TM. The TF recommends policies for optimal integration of TM with modern medicine and research priorities considering the Indian healthcare scenario. The need for a transdisciplinary approach in education and research on TM knowledgebase has been highlighted.

While existing evidence has to be implemented in health policies and programs, more focus on evidence generation in TM is needed. The TF suggests potential areas for work that will leverage existing research. Iron deficiency anaemia, filariasis management, infant growth and development, and mental health and well-being could be considered priority areas where the application of TM evidence can be evaluated in programs aiming to overcome the limitations with a current focus solely on modern medicine.

The TF advocates commissioning an expert group in research methods to develop an appropriate methodology for evidence generation sensitive to TM epistemology and demonstrate its application for select conditions of national priority. The National Academy of Medical Sciences with support from the Ministry of Ayush and the Ministry of Health and Family Welfare, Government of India, may continue work on this task.

Background

The National Academy of Medical Sciences (NAMS) in a meeting on April 2022 decided to constitute a task force on Evidence-based Traditional Medicine for Health Care in India.

A Task Force (TF) with experts in Biomedicine and Traditional medicine engaged in research and practice was formed under the chairmanship of Prof Bhushan Patwardhan. The following terms of reference were provided to the TF. This document is a report of the TF's work during the six weeks duration in October and November 2022.

1. To identify the need for "Evidence-based traditional medicine for health care".
2. To identify the deficiencies which need to be addressed.
3. To make recommendations based on the gaps concerning national needs and current policies in the field of Evidence-based traditional medicine for health care.

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Chapter 1: Introduction

India has a distinct pluralistic health system with the modern or allopathic system practised and legitimised as also several traditional medicine systems. Traditional medicine (TM) is the sum total of the knowledge, skill and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness. (WHO,2019). In India two separate Ministries govern the health system- the Ministry of Health and Family Welfare (MoHFW) governs the contemporary modern system while the Ministry of AYUSH governs the TM systems that include viz, Ayurveda, Yoga, Siddha, Unani and Sowa-Rigpa. In this chapter, we present in brief the milestones in the history of medicine systems in India and the existing gaps where TM may have a relatively effective role in health.

TM use in the Indian health system – attempts at integration

The Bhore Committee (1946) that laid the foundation of the health system for independent India did not pay enough attention to TM systems resulting in the marginalisation of Indian systems of medicine (ISM) and thus monopolizing western biomedicine. However, several nationalist scholars including Sir Ram Nath Chopra (1948), and KN Udupa (1958) highlighted the need for evidence-based integration. Several policies by the Government since 2002 have encouraged the revitalization of LHTs and emphasized the need for integration and strengthening of Traditional Medicine in India. The major policies comprise the National Policy on Indian Systems of Medicine and Homeopathy 2002 which acknowledged the long neglect of traditional systems of medicine and mentioned the revitalization of folk medicine for the first time. Subsequently in 2005, the National Rural Health Mission suggested mainstreaming AYUSH and revitalizing local health traditions as part of strengthening primary health care. Further National Health Policy (NHP) 2017 also emphasised prevention through lifestyle advocacy, and health care delivery through integration, colocation, and medical pluralism. The policy interventions lead to recognition of the role and potential of AYUSH systems/TMs in achieving national health targets and their mainstreaming and integration into the national health system. The 12th Five Year Plan (2012-2017) followed by NHP 2017, National Education Policy (NEP)-2020 and the latest National Digital Health Mission (2020) have strongly advocated the need for harnessing the potential of AYUSH systems by its integration in the mainstream healthcare.

However, true integrative health care has remained elusive in the context of medical education, health research, health services and administration. Thus, there is a need to further this vision with more attention to the emerging evidence from TM systems in the larger interest of people.

The term 'integration' is perceived differently in different parts of the world based on local culture, practices and priorities. India needs to define integration and create its model based on her own cultural strengths and ground-level requirements. Mere co-location, bridge courses or cross-pathway practice may be a very limited view of integration. For effective integration, India requires to transform from a pathy-based reductionist approach to person-centred holistic health care (Lele

& Patwardhan, 2020). The scientific basis and vision for rational integration of the traditional medicine system are made explicit by some of the landmark publications (Patwardhan et al 2015).

Gaps in medical systems and health care in India from a medicine systems perspective

Although allopathy (modern medicine) remains dominant globally, the role of traditional, complementary and integrative (TCI) medicine can no longer be ignored. The World Health Organization (WHO) formally recognizes the role of TCI as an important component of integrated health services to meet Sustainable Development Goals. Shanghai Declaration 2016 considers the growing importance and value of traditional medicine, which could contribute to improved health outcomes, including those in the SDGs. The WHO Traditional Medicine Strategy 2014-2023 sets out the course for TCI to foster its appropriate integration, regulation, and supervision as a vibrant and expanding part of health care. It aims at harnessing the potential contribution of TCI to health, wellness, and people-centered health care and also to promote its safe and effective use through the regulation of products, practices, and practitioners. In this report, we are using the term TM representing Traditional, Complementary and Integrative (TM/TCI) medicine in line with the WHO's recommendations and emerging global consensus in this context.

According to the Global Centre for Traditional Medicine, World Health Organization, about 40% of existing pharmaceutical drugs have originated from traditional medicine (Chaturvedi et al., 2023). The rising use of traditional and complementary medicine by people is known to stem from patient dissatisfaction with modern medicine, the success of complementary medicine in chronic conditions which have not responded well to modern medicine treatment and patients' desire for holistic care. The world overall is becoming more eager to find other satisfying modes of treatment and care than western models of health care. The global indicators in the field of Medicine evolved through the ages have demonstrated a gross shift from medical care towards health care, covering preventive, promotive and rehabilitative aspects besides therapeutic management and cure. This has gained attention to the integration of different healthsystems to complement and supplement the unmet need.

Modern medicine, though useful in acute diseases and injuries, is not as effective for treating chronic diseases or for health enhancement. In the majority of the cases with autoimmune disorders, skin conditions and lifestyle disorders, modern medicine has very few substantive offers and even the expensive drugs and surgical procedures that are promoted for these conditions are not effective in actually correcting them. The four primary determinants of health are nutrition, lifestyle, environment and genetic composition. If any of these components is compromised it may lead to ill health and may require medical care. The current focus of health systems seems to be on pharmacological interventions based on laboratory diagnostics, symptomatic cures and prescription of drugs. In the currently dominant modern medicine's drug and surgery approach to health, the role of diet, lifestyle and exercise, the prime factors of daily living are neglected or ignored. The therapeutic value of foods, herbs and natural treatment methods from massage to meditation are often forgotten. The organic basis of health and well-being is obscured by the very complexity of diagnostic and treatment measures. Necessary attention to clinical acumen, physiological interventions, nutrition, diet, lifestyle and behavioural interventions based on body-mind synergy is missing.

There is a possibility to fill these gaps by putting the best of modern and TM systems together for comprehensive holistic treatment cum care. The WHO Global Action Plan for the Prevention and Control of Non-communicable Diseases 2013-2020 is recommended for recognizing, promoting and integrating traditional knowledge, and cultural heritage and integrating Traditional Medicine in the Prevention and Control of Non-Communicable Diseases (NCDs).

Apart from NCDs, the role of TM systems in combating certain infectious diseases has been studied and offers encouraging results, especially in conditions where biomedicine has limitations such as Systemic Lupus Erythematosus, Rheumatoid Arthritis, Interstitial Lung Disease to mention a few. Also, the potential of complementing TM to improve beneficial effects, reduce side effects of biomedicine or improve adherence is being increasingly realised. This is often through studies and practices by individual practitioners or institutions, however, a clear recommendation for formal adoption into routine practice is rare. For example, filariasis is a neglected tropical disease prevalent in many parts of India and patients undertaking usual allopathy treatment as prescribed in the national program often are left with difficult sequelae that biomedicine has no cure for. A successful example of integrating filariasis treatment with traditional medicine is offered by the work at the Institute of Integrative Dermatology, Kasargod (Narhari et al 2011, Aggithaya et al 2013, Narhari et al 2013) but remains an institutional speciality and expertise. During the recent COVID-19 pandemic, the use of TM to prevent or control early-stage COVID-19 has been popular and documented by multiple studies. Ayush drugs such as AYUSH 64 (Chopra et al., 2023), Kabasura Kudineer (Srivastava et al., 2021), and Anu Tail (Rizvi et al., 2021) were found to be effective and safer adjuvants to standard care in COVID-19 treatment (details in chapter 2). A first of its kind integrative protocol for the management of COVID-19, including biomedicine and TM, was released by the MoHFW. The more such potential exists and needs to be explored for the benefit of the people and health system at large.

Chapter 2:

TM in Indian Health Care System – Status and Potential

The significant efforts and investments over time have ensured the preservation and development of TM in India resulting in it being presently widely available in private and public hospitals in India. 2018, there are 4035 government hospitals and 27951 dispensaries to provide medical care facilities under AYUSH. As of March 2020, the AYUSH component was included in 31 State Programme Implementation Plans, AYUSH facilities were available at 497 District Hospitals, 2757 Community Health Centres and 7779 Primary Health Centres across the country. Nearly twelve thousand AYUSH practitioners were in contractual positions under the *Rashtriya Bal Swasthya Karyakram* and other programmes.

TM at the family level in India

A nationally representative survey documenting the usage of various medical systems in India reported home to be the main source of Indian TMs (Srinivasan & Sugumar, 2014). However, in the current context of the health system in India, the family or household level is not considered adequately – the infrastructure includes the clinics and hospitals but not the household and community and the drugs and supplies considered are only from the pharmaceutical preparations but not those from plants and other local resources used by people (Mathpati et al 2022). In the context of the COVID-19 pandemic, the relevance of the family or household tier has been more apparent and is proposed as the fourth tier of the health system (Mathpati et al 2022). The concept of the fourth tier is people's self-reliance in health wherein people's capacity for self-care and their responsibility to the health system and its values is respected. Traditional knowledge of health practices is gaining increasing attention in behavioural medicine as lifestyle diseases are on the rise.

TM use for specific health conditions

Patients often use multiple systems of medicine simultaneously, especially in cases where biomedicine has limitations. For example, over one-third of cancer patients presenting to oncologists in a hospital in Kerala reported using TM (Sarada et al 2021). The popularity of TM use in paediatric oncology cases has received due consideration from the International Society of Paediatric Oncology (Ladas et al 2017).

Ayush in COVID-19

The extensive use of Ayurveda and Yoga by the people in India during the COVID-19 pandemic is a recent example. The Ministry of Ayush developed and launched Ayush Sanjivani mobile application to generate data on the acceptance, and usage of Ayush advocacies among the population and its impact on the prevention of COVID-19. The findings of a cross-sectional analysis of the collected data highlighted that a good proportion of the representative population has utilized Ayush measures across different regions of the country, during the COVID-19 pandemic and have considerable benefits in terms of general well-being and reduced incidence of

COVID-19. The National Repository on Ayush COVID-19 available on the AYUSH research portal of the Ministry of AYUSH provides details of over 125 COVID-19-related Ayush studies including pre-clinical, epidemiological studies, clinical trials and scientific publications (<https://ayushportal.nic.in/Covid.aspx>). The Ministry of AYUSH's Inter-disciplinary Ayush R&D Task Force consisting of scientists, pulmonologists, epidemiologists, and pharmacologists from premier organizations and research institutions formulated guidelines for Ayush clinical and observational studies in COVID-19 covering various aspects of trial protocols (Ministry of AYUSH 2020). This is an important example worth emulating (Kotecha, 2021).

Policy context for TM in India

National Health Policy 2017 (NHP2017) has reiterated mainstreaming of AYUSH through co-location with modern medical practice, offering it to "persons who choose" to use these systems of medicine. The policy recommends yoga be used more widely for health promotion in schools and workplaces. Continuing from previous policies, the NHP 2017 repeats the need to standardize and validate Ayurvedic medicines and establish a robust and effective quality control mechanism for AYUSH drugs. It mentioned the need to develop infrastructural facilities for teaching institutions, and capacity building for education and research. Similar to the recommendations of earlier committees, the NHP2017 advocated convergence at the Community Health Worker level, with Accredited Social Health Activists (ASHA) and the Village Health Sanitation and Nutrition Committees as the point for initiating convergence and mainstreaming of AYUSH into the public health system. The utilization of T&CM practitioners at the Health and Wellness centres under the Pradhan Mantri Jan Arogya Yojana (Ayushman Bharat) programme, represents one more step towards inclusion of T&CM practitioners in the national health system, albeit with little apparent parity with the status or remuneration being provided to doctors of modern medicine.

Regulatory environment for TM in India

Appropriate legislation has been developed to regulate T&CM in India, which includes the Indian Medicines Central Council Act of 1970, the Homeopathy Central Council Act of 1973 and the Drugs and Cosmetics Act of 1940 (amended in 2009). The Indian systems of medicine i.e. Ayurveda, Unani, Siddha and Sowa-Rigpa were regulated by the Indian Medicine Central Council Act, of 1970 earlier. Very recently, the National Commission for Indian system of Medicine (NCISM) Act, 2020 repealed the Indian Medicine Central Council Act, 1970 for regulating the medical education system and practice of Ayurveda, Unani, Siddha, and Sowa-Rigpa and their adoption of the latest medical research.

Legislations have been put in to protect the intellectual property rights of knowledge holders. T&CM practice is licensed at certificate, graduate and post-graduate levels and includes completion of compulsory rotating internship. A separate essential drug list for Ayurveda and Unani medicines has been developed. Herbal medicines which are used in Ayurvedic, Unani and Siddha treatment are included under Schedule E of the Drugs and Cosmetics Rules are available on prescription from licensed pharmacies, or from licensed practitioners in case of non-

prescription medications. GMP regulations guide the manufacturing of herbal drugs. Manufacturing units are granted licenses requiring 3-yearly renewal. GMP manufacturing has to be based on existing pharmacopoeias and monographs and involves routine inspection of facilities and testing of final products at designated government laboratories for analysis.

Financial resources for TM systems

The allocation for TM systems is comprised of that of the Ministry of AYUSH. After the separate Ministry was formed, the allocation has been considerably increased to Rs 3050 Crore in 2023. However, this remains a meagre sum when compared to Rs 89,155 Crore for Ministry of Health & Family Welfare. The scope of Department of Health Research needs to be extended to bring transdisciplinary health-related research to bring better synergy and resource optimization.

Status of TM research in India

Research on TM in India is on the rise, more steeply in the recent decade as indicated by the Scopus database that shows a peak in the number of publications in the TM field, especially Ayurveda and Yoga. Notably, nearly half of the published works on Ayurveda are from pharmacology and medicine fields drawing attention to the need to bring focus on the strengths of TM systems in prevention, promotion and wellness rather than only treatment

India has several institutes conducting Yoga related research. such as *Swami Vivekananda Yoga Anusandhana Samsthana (SVYASA)*- Bangalore, National Institute of Mental Health and Neurosciences, (NIMHANS), All India Institute of Medical Sciences (AIIMS), Somaiya University (Mumbai), Visva-Bharati, and Santiniketan. (Chapple) The increase in studies on Yoga in India is steered by dedicated funding for Yoga research mainly by the Ministry of AYUSH and contributions from the Quality Council of India (QCI). The Indian Government has been keen on promoting the integration of Yoga intervention into the current healthcare system.

The recent establishment of integrative medicine departments at key national institutions such as AIIMS and NIMHANS is expected to steer research and evidence-based integration of TM in practice. Research in the recent two decades into the fundamentals of some of the TM systems has provided new insights into understanding the relevance of these systems in current times of stagnation with some of the approaches in modern medicine. For instance, the initiative of Ayurvedic biology has led to several studies into the restoration of physiological functions for treatment and improved well-being (Joshi K et al 2022). Pioneering works under the Ayurved biology program such as the work on the concepts of Prakruti and its association with the gut and oral microbiome have provided impetus for translation of Prakruti principles for personalised approaches to health (Shalini TV et 2021). Ayurgenomics has emerged as a promising research area offering newer insights into the genotypic-phenotypic classification and genetic basis of the Ayurveda concept of Prakriti (Ghodke Y et al 2011),(Patwardhan and Bodeker, 2008). Ayurgenomics research involving whole system clinical trial (Joshi et al., 2017) and whole exome sequencing has indicated potential to bring innovation by integrating a unique phenotyping approach for the identification of predictive markers and their translation for predictive personalized medicine (Abbas et al., 2022)(; Wallace RK 2020).

The potential of TM contributions to the Indian health system

A majority of the Indian population lives an unhealthy lifestyle and is exposed to the risk factors associated with NCDs. Middle-income countries with limited health professionals tend to have a higher prevalence of NCDs, which are not diagnosed at pre- or early disease stages, which places a heavy burden on health systems. The National Health Mission emphasised involving AYUSH personnel to address the shortage of human resources in the available health care system (Gopichandran V, 2012). Shortage of health care professionals can be solved by both, providing more human resources and promoting preventive health care and healthy lifestyle that can reduce disease prevalence and hence the need for trained medical personnel. (Eton DT, 2017). By promoting healthy lifestyles and reducing risk factors common to several diseases, TM systems can potentially reduce the burden on healthcare systems (Sharma RA, 2008).

Globally nearly 41 million people succumb to the burden of NCDs amounting to 74% of deaths (WHO, 2022). Prevalence of the NCDs in India is on the rise while the burden from infectious and neglected tropical diseases (NTDs) persists. Mental health issues are a growing concern and pose distinct challenges, especially because of the very limited success of modern medicine in this area.

The critical strategy for reducing the rising burden of NCDs is adequate prevention and better management. The key components of management include screening, detection, and treatment. Besides individual behaviour and lifestyle modifications, several other factors like economic, social, and political approaches also act as critical factors of NCDs (Yang, 2018; Krieger, 2001; Budreviciute, 2020). For most of the NCDs, the available biomedical treatment is limited and also expensive which contributes to the increased economic burden (Peter R 2019). Hence prevention of NCDs is emphasised.

As a traditional form of exercise, yoga benefits the human body by encouraging physiological and psychological well-being, as well as preventing the development of NCDs. Yoga practice is recommended by the Global Action Plan on Physical Activity (WHO, 2019). Yoga is a mind-body practice, that includes both physical and mental exercise which promotes physical and psychological well-being. Yoga is not only cost-effective but also a feasible form of exercise for individuals of all age groups and it has the potential to reduce the risk factors which are responsible for the development of NCDs such as obesity, impaired glucose metabolism, psychological imbalance, high cholesterol level and blood pressure.

The practice of yoga alters the mind's capacity to facilitate systemic function across multiple organ systems, thus affecting the different systematic axis of the body including hypothalamic–pituitary–adrenal axis (HPA-axis), the cardiac axis (Mohan M, 1986), psycho-neuro-immune axis, ghrelin axis (Yu AP, 2018) and normalization of biomarkers of neuro-immune axis not only at the molecular level but at the genetic level also (Gautam S, 2020).

The above evidence support promotion of Yoga for a healthy lifestyle and NCD prevention. The relevance of Yoga as a powerful preventive intervention in NCDs through neural, endocrine, immunological, cellular, epigenetic and genetic mechanisms is increasingly recognized and understood by modern science approaches. (Basu Ray I 2021). A National Programme for Control of Cancer, diabetes, cardiovascular disease and stroke was undertaken

during 2016-17 followed 3044 participants for six months. The intervention studies included basic lifestyle modifications, yoga practice and simple Ayurvedic drugs. The results of this huge programme are encouraging and demonstrate the role of TM systems in the control of NCDs (Sharma et al.2019). It would therefore be prudent for India to invest more in these measures to tackle the rising burden of NCDs.

Studies at several departments at AIIMS, Delhi including cardiology, anaesthesiology, pulmonary medicine, neurology and genetics have strongly highlighted the need for integrative medicine as the future path of the Indian health system. Works at other institutes of repute such as the Institute of Liver and Biliary Sciences have shown the potential of utilising the TM concepts of lifestyle modifications in understanding and treatment of metabolic and liver diseases (Eslam et al 2022, Sarin SK et al 2019). The Yoga-CaRe trial that tested the effectiveness of Yoga-based cardiac rehabilitation programmes in India and the UK has provided evidence for Yoga-based options to conventional care (Prabhakaran D, et al 2020). A landscape review of Yoga research studies in the year 2020 highlights the rising works on yoga research in a range of conditions and restoration of physiological functions for health (Dutta A et al 2022). Similarly, NIMHANS has provided a body of evidence on the effectiveness of Yoga in the prevention and treatment of mental illnesses and for mental well-being and importantly the lessons for adopting an Integrative Health Care model (Bhargav et al 2022).

TM interventions that have the potential to improve overall health and prevent the incidence of NCDs including mental health problems deserve serious consideration by the Indian health system. Identifying TM interventions that are to be relatively better than conventional care or improve outcomes when used in combination with conventional care and exploring the best utilisation of these in routine health care should be done on priority.

Chapter 3:

Challenges to Improve TM Use in Indian Health System

India has a pluralistic healthcare system. There is a co-existence of conventional medicine with traditional medical systems, which are regulated under the umbrella framework of Ayush. However, there is minimal interaction between the two medical systems, with practitioners of each system working independently in practice and clinical decision-making.

Unlike western countries, traditional medical practitioners are licensed to practice in India and can offer the full range of interventions to the general public.

Conventional medicine and Ayush practitioners are educated separately within the health system. This state of affairs nurtures avoidance patterns in which an integrative approach is not encouraged because of conceptual conflict rooted in distrust between the two systems (Lim et al 2017).

In contrast, in Western countries, the Integrative Medicine movement emerged intending to integrate evidence-based complementary and alternative medicine into mainstream medical practice (Gannota et al 2018). However, CAM practitioners themselves have limited legal sanctions to practice.

The TM systems in India are very distinct and complex. The practitioners of these systems work in silos without engaging in cross-talk and exploring possibilities of integration. As a result, the TM system is itself fragmented and its full potential is not being harnessed to address public health care needs. The worldwide integrative medicine movement is focused on integrating evidence-based CAM practices into the mainstream rather than integrating whole CAM systems with conventional medicine.

In India, we face the challenge of integrating multiple legitimized whole traditional medical systems with conventional medicine. It is much more difficult to generate "scientific evidence" for the entire medical system than for selected practices. Limited integration of TM with mainstream health care delivery systems creates big gaps in the optimal utilisation of its strengths. Students of conventional medicine do not get adequate knowledge about TM systems as it is missing in the curriculum (Patwardhan K, 2013). On the other hand, students of TM systems have significant exposure to conventional medicine during their training. The disproportionate inclusion of conventional medical topics in the TM curriculum hinders the development of the core competence of students in respective TM systems.

This leads to the unhealthy trend of cross-system practice resulting in TM physicians practising conventional medicine. There is an emerging trend amongst conventional medicine practitioners to prescribe herbal supplements and other OTC TM products without sufficient

training and knowledge of these systems (Math et al 2013).

Adequate evidence from well-conducted studies is not yet available regarding TM interventions to develop integrative treatment protocols that will facilitate making informed choices for optimal health care. Inadequate data on herb-drug interactions poses a major challenge in when it is administered as an add-on therapy (Borse et al, 2019). This also creates challenges for ethical clearance to evaluate the safety and efficacy of add-on TM treatments in clinical integrating TM treatments with a standard of care at the point of care, especially TM treatments are often complex and multimodal. It is difficult to generate a complete phytochemical profile of the multi-herbal formulations and understand the complex synergism of the constituents. It is also difficult to study complex TM treatments using conventional pre-clinical as well as clinical study designs. Reductionist methods are commonly used for the evaluation of TM treatments and formulations. As a result, evidence backing the real-world practices of TM systems is scarce, even as piecemeal evidence is being built on fragmented elements of TM treatments and formulations. There is a need to balance evidence-based medicine and evidence-informed healthcare (Chaturvedi et al 2021.)

The materia medica /pharmacopoeia and food inventory of TM systems like Ayurveda need updating to include articles widely used today. Understanding the properties of new foods and drugs from the TM epistemological framework is lacking. This limits the development of TM-based health advisories that takes into consideration prevalent dietary practices and usage of botanicals. TM treatments are personalised and there is also heterogeneity in the protocols being followed by various practitioners even within one TM system. Research to report outcomes of real-world practice in TM systems is non-existent. This makes it difficult to recommend specific treatment protocols for public health interventions in priority areas. In the prevailing situation, integration is patient-driven, and the use of TM in the healthcare system is not optimal as it is not knowledge-driven. As a result, while the pluralistic healthcare system in India gives freedom for both practitioners to practice and people to choose different treatment modalities, it is impossible to make informed decisions regarding the appropriate use of conventional medicine and Ayush systems.

Challenges in implementation studies for TM use in the Indian health system

Below is a list of the long-standing challenges in the implementation of TM for disease prevention and cure. (Srinivasan P, 1995)

Academic limitations

Research and development in the field: Research in the field of Traditional medicine has remained neglected until recently. Small sample numbers, inconsistent or varied outcomes, and poor research methods are some of the key factors that make studies regarded as defective and insufficient. Other issues include weak controls, inconsistent descriptions of the treatment or product, low statistical power (perhaps due to small sample sizes), and a lack of comparisons with other therapies, a placebo, or both (Nahin et al,2001). Folk traditions and wisdom of traditional medicine are handed over from generation to generation in India and are termed as

'people's health culture with the scarcity of documentation and patents in the field of traditional medicine. Attaining patents with modified and improved TM components requires the promotion of and investments in research, currently inadequate.

Technology to preserve the research data: While there is an increasing trend with the use of TM worldwide, still the research in this field is inadequate with serious difficulties in data acquisition and preservation. The research data generated is not safeguarded and preserved in a way that it can be retrieved and reproduced. This poses challenges to retrieving, sharing and future use.

Protocols and SOPs: Despite the rising research and acceptance of the field of TM, certain studies are reporting adverse health effects of TM, this may be due to the variable quality, efficacy and contents of herbal products as a class of medicinal products. In this regard development of SOPs for carrying out research studies based on TM, less attended to thus far is a limitation to evidence generation. (Ali et al 2015).

Funding: There is a limited higher education support system in traditional medicines such as PhD and Post Docs. Limited opportunities for higher education focused on TM limits young scholars from taking up TM topics thus limiting the evidence generation and career progression with works focused on TM.

Publication avenues- For the wide acceptance of research, publication in high-impact journals is paramount, but a limited number of high-impact journals consider publishing research data on TM not only due to limitations in the research data but also due to the lack of approval for TM research.

Administrative Limitations

Administrative bodies: There are fewer administrative policies specially made for traditional medicines. In Medical institutions, it is often difficult to obtain ethical approvals for conducting TM research as the committee members are not experts in TM and do not feel equipped to take decisions on TM projects.

Development and enforcement of policy and regulations: In TM, there is a wide range of products, techniques, and practitioners. Some provide health benefits, while others come with risks or are solely motivated by business interests. Government should choose where to concentrate its efforts given its limited resources to give consumers the greatest and safest type of healthcare while meeting the requirement to protect consumer choice and it must be supervised within their jurisdiction. In TM systems that are referred to as codified medical systems, policymaking, and standardization are arguably the most challenging issues for instance, some courses might place more emphasis on the physical parts of the healing system than others, which might place more emphasis on the mental and spiritual aspects. For this to be done correctly, it would be necessary to have policies and particular nodal agencies to control and offer guidance. The WHO recommends that to implement TM in any country's healthcare system formulation and implementation of national policies and laws as per the country's situation are needed (WHO 2004).

Awareness among the medical practitioners about TM: Providers in the conventional healthcare system are less informed of TM and the research upcoming in the field. This creates

barriers to innovative works in TM to generate more evidence.

Quality: Implementation and functioning of Inter-University centres are required to generate enthusiasm and data out of collaborative research between various Institutions through student exchange and Inter-University projects.

Collaboration: The anticipated unification of the nation's Traditional Health and Modern Medical systems suffers poor implementation and clearly defined procedures.

Integration between Western medicine and Traditional Medicine: A significant barrier to the incorporation of TM into mainstream medical practices is the absence of pharmacological and clinical data on the bulk TM items (Fong et al 2002).

Integration of TM into National and Primary Healthcare: The traditional medicine research is focused on 'testing interventions' rather than taking the learning forward and building a 'program' based on respective interventions. Hence the research output does not make advancement into either practice or policies. Amongst the TM systems in India, Ayurveda has been studied most (~8000 papers in PubMed) however this has hardly resulted in the generation of practice guidelines or even public health programs and the same may be the case for other TM systems.

The research on traditional medicine intervention must be followed further in health policy and systems research. Implementation of an intervention is more than management and now being considered a science. It focuses on the application of research in a real-world setting (McNulty et al 2019). Implementation research is defined as the "scientific study of the use of strategies to adopt and integrate evidence-based health interventions into clinical and community settings to improve patient outcomes and benefit population health."

There is an urgent need for implementation studies on traditional medicine for assessing its value for the betterment of public health systems (Chaturvedi and Patwardhan 2016). This needs consideration of the following steps:

1. Prioritizing the evidence-based interventions for implementation in community settings
2. Study of acceptance and utilization of TM interventions by the community or public health systems
3. Assessment of effectiveness by studying Patient Reported Outcome Measures (PROMS) in diverse settings
4. Development of health systems based on the learning from the implementation studies
5. Transforming the data for evidence-based policy decisions and utilizing the learning from primary research

Appropriate clinical protocols for TM system

Research on Traditional Medicine should consider its foundations and epistemology. Most of the studies focus on interventions ignoring the concepts of TM (Shankar, 2018). This approach leads to a fragmented view of TM and may get a false negative or partial understanding of the scenario. As most TM therapies are focused on health, they are customised and include a

'package' rather than a 'product'. The following challenges need to be addressed for the development of clinical protocols that explore TM concepts or interventions:

- TM practices of the real world are reduced to convenience-driven methods
- Lack of cross-talk between researchers making TM 'monodisciplinary'
- Over-emphasis of TM terminologies and practice approaches restrict widespread applications of important concepts
- Ignorance about multi-disciplinary research restricts understanding of TM
- Replicating protocols used in modern medicine limits the value of TM
- Insufficient validated measures for disease diagnosis and outcome assessment
- The holistic nature of therapeutics is converted into a reductionist approach suitable to conventional research
- Ontological differences posing knowledge gaps between modern and traditional medicines
- No systematic efforts for bridging the communication gaps
- Short-term goals and utilitarian approach of researchers that ignore TM foundations
- A superficial review of research proposals making less imaginative and non-productive research process

Comparative efficacy studies for TM treatments

Traditional Medicine based practices or interventions can be used for reasons. Expected benefits of TM may include health promotion, disease prevention, treatment as stand alone therapy, adjuvant care with mainstream medicine, prevention of complications, improve the safety of the primary intervention, rehabilitation, palliation, and many other goals in the management of health and diseases. The value of TM needs systematic assessment and sound evidence for its intended benefits (Patwardhan and Mashelkar 2009). However, the research methods should be based on the expected benefits. The research should be much more than a randomized controlled study and focus on real-world usage of TM.

Comparative Effectiveness Research (CER) follows evidence generation and synthesis for assessing the benefits and harms of two or more methods for prevention, management, or monitoring a clinical situation and improving the delivery of care in a real-world scenario. The CER helps all the stakeholders to make informed decisions for the improvement of health care (Dang 2016).

Generally, randomized controlled trials with tight protocols improve the internal validity of the study and are considered the best for regulatory requirements. The stringent protocols may limit the applications of findings in real-world settings, hence reducing the external validity or ability to generalize the findings. In such situations, pragmatic studies, observational studies, synthesis of available literature and careful analysis of prevalent practices may be useful to address the limitations of RCTs or such explanatory trials. The most important factor that differentiates TM and modern medicine is the history of safe use. Hence TM may follow Reverse Pharmacology (RP) approach, where knowledge about respective TM therapy can be borrowed from clinical

practice and further can be tested in systematic studies, including explanatory trials or mechanistic studies (Raut et al, 2015). RP utilizes epistemology sensitive approach and involves a collage of study methods for various levels of biological organization. It embraces study designs from omics to health system research for evidence generation for safety and efficacy.

The role of clinical practitioners is central to this process (Vaidya R, 2011).

In the context of TM research, the principles and important considerations of CER can be useful.

1. Review and synthesis of current medical literature with risks of bias and methodological lacunae
2. Identification of needs of clinical practice and related gaps in current literature
3. Generate new scientific data following methods suitable to research questions

Transcending disciplinary boundaries for health goals

The National Health Policy 2017 aims at mainstreaming Ayush and making it available at all levels for effective Universal Health Coverage. The policy also recommends mainstreaming with effective collaboration and cooperation with different health systems. The cross-talk will strengthen efforts for validation, evidence, and research and generate a common pool of knowledge. To achieve this goal, several opportunities should be created to facilitate the cross-talk between TM practitioners and those from modern medicine. Registration of new clinical trials during the COVID-19 pandemic suggests increasing collaborations between institutions of modern medicines and the Ayush sector.

Chapter 4:

Recommendations for Optimal TM Use in Indian Health System

Bridging the evidence to action gap for TM

The specific measures to improve the utilisation of evidence from TM into practice are as follows:

1. Build health information systems that are integrated nationally for specific diseases
2. Plan evidence synthesis (meta-analysis, systematic and narrative reviews) and make the data available to clinicians and policymakers
3. Develop modules for creating public awareness about health interventions and preventive measures
4. Identify research priorities based on research gaps that would be helpful for funding agencies for the allocation of research support
5. Undertake efficiency-oriented clinical trials and foster clinical translation
6. Subsequently, plan implementation of interventions that have proven efficiency
7. Provide implementation grants to support the practice and health delivery models in individual states
8. Develop and implement objective TM indicators that are aimed to identify TM-specific inputs to assess the level of progression, facilitators and barriers to a predefined objective of the outcome of health delivery.

Policies for optimal TM integration in India

The goals of policies aimed to achieve TM integration should be:

1. Set up a mechanism in national regulatory bodies to bridge the gap between conventional medicine and TM
2. Introduce the evidence on TM research in modern medicine curricula
3. Improved inclusion of TM interventions for health finance mechanisms in India including government schemes and private medical insurance.
4. Inclusion of TM interventions in health delivery mechanisms and targeted programs at national and sub-national levels for specified health conditions, its prevention and to promote well-being, aimed at maximising the health delivery to all of the population. This should be guided by the ethos of the UN's promise of "leave no one behind" which is the soul of its central, transformative promise of the 2030 Agenda for Sustainable Development.
5. Inclusion of evidence-based, safe, and effective TM interventions which have proven advantage of efficiency in clinical/ financial / or patient-reported wellness outcomes, in specific clinical conditions in the area of NCDs and NTDs.

6. Skilling and utilisation of TM human resources to deliver TM services, in specific clinical areas, by their pro-active inclusion in health system building blocks at appropriate levels.

Research for improved TM use in the Indian health system

1. Research into methods for optimal TM integration: More research focused on the various models globally to inform strategies for the integration of TM in mainstream health care is recommended. Higher education institutes, engaged not only in medicine but also in social science and policy research should be promoted to undertake such research on priority.
2. Development of epistemology-sensitive protocols: Increased investments into researching TM systems and keeping to the principles and philosophies of these systems are essential.
3. Limitations of contemporary research training and approaches for TM research being recognised, it is recommended to promote research into developing epistemology-sensitive approaches and protocols for TM research.
4. Comparative efficacy studies for TM interventions: Integration of TM evidence into health care and national programs needs to be informed by comparative effectiveness studies. Promoting comparative effectiveness research is hence recommended.

Promoting the exchange of TM knowledge

The inclusion of specific and level-appropriate skill development programs for the Ayush health workforce is recommended. These can be mandatory and program-specific.

The following programs could be undertaken for improving transdisciplinary research:

1. Education and Research

- Inclusion of introduction to TM/TCI in syllabi of modern medicine.
- The recent initiative of the National Medical Commission to include Yoga in the MBBS curriculum is an important step in this direction.
- Emphasis the role of TM/TCI systems especially in the management of NCDs, lifestyle, behaviour modification and nutrition.
- Students internships in cross disciplinary institutions should be encouraged
- Transdisciplinary research project grants for faculty and PG students to support collaborations research on TM/TCI
- Providing opportunities for teachers from TM and modern medicine colleges for mutual exposure through faculty exchange programs Include TM/TCI-based "best practices for healthy living" within the school syllabus and curricula, spread across classes 1 to 9, for children in an appropriate manner.

2. Clinical Practice

- CME programs on TM/TCI especially for Family Medicine/General Practitioners and allopathic clinicians

- Development of specialized credit courses for TM/TCI interventions
- Training medical practitioners on selected interventions (e.g. Ksharsutra, Massage, Meditation, Yoga therapies)
- Offer TM/TCI courses to modern medical graduates which shall provide them with the opportunity to practice the systems under a regulated environment in select foreign countries

3. Public Health

- Mainstreaming evidence-based Ayush systems by including them in national programs
- Identification of local health practices and studies on their acceptance and effects
- Studies on TM-based culturally conducive care for local health priorities
- Awareness of health practices concerning locally available resources
- Make accessible Ayurveda and Yoga based self-health care tools that are language and context-specific, within the broad agenda of well-being.

Strategic collaborations with the World Health Organization's Global Centre for Traditional Medicine (WHO GCTM) and other national/global organizations should be explored to bring effective integration in the best interest of people.

Chapter 5:

The Way Forward

Agreeably, more evidence needs to be generated for appropriate TM use, it is important to utilise existing evidence from TM systems in health policy and practice in India. While recognising that the current scenario of more scope for evidence generation is a result of underinvestment in research in TM for several past decades and more research needs to be promoted, it would be appropriate to also focus on promoting the uptake of the existing evidence. Developing clinical practice guidelines integrating the existing evidence derived from TM systems is an important measure towards this.

The integrative protocol for COVID-19 released by the Ministry of Health offers a distinct example in this regard. More such protocols for real-world applications are required.

The way forward to appropriate utilisation of TM evidence for the Indian health system lies in systematic scrutiny and wider application of the existing evidence while promoting more and improved research in TM systems.

In the recent few years, India has witnessed significant developments in the direction to promote TM system contributions to health care. Notable among these is the formation of the Integrative Health System Committee by the NITI Aayog. The Committee provided a white paper to the Indian government on the integrative health system. The Lancet Citizens Commission to Reimagine India's Health System is sensitive to the need to address AYUSH-related challenges for a better health system in India. The establishment of the WHO GCTM in Jamnagar in India is an important milestone in promoting TM/TCI use for a healthier world. These initiatives serve as good examples of concrete actions for evidence from the TM system for population health in India.

This TF has attempted to scrutinise the existing evidence on Ayurveda interventions for iron deficiency anaemia. The subgroup comprising TM and modern medicine practitioners worked collectively on this task to scrutinise evidence on the management of iron deficiency anaemia and answer if that can address the failures with current management and improve outcomes. The details are provided in the supplementary material and suggest the potential for better management of anaemia using Ayurveda interventions in terms of clinical outcomes, adherence and costs. (Annexure 2).

Hence this TF is of the opinion that the way forward to appropriately utilise evidence from TM/TCI for health care in India can be made through small concerted efforts aiming at demonstrating the use of TM/TCI evidence for national health needs in the current health system.

In this regard we suggest the following for immediate tangible outcomes:

- Identify up to four priority areas to undertake this activity. The criteria for this choice could be
 - i. areas that are persistent challenges to national health where biomedical approaches have had limited success
 - iii. where national programs based on biomedicine have resulted in limited public health impact
 - iv. where interventions from TM are available and are relatively simpler and backed by the experience of clinical use by TM practitioners.
 - v. Exemplar guidelines for the management of selected clinical conditions based on evidence from TM

The TF suggests initial potential areas of iron deficiency anaemia, filariasis management, infant growth and development and mental health and wellbeing.

- Develop the methodology to demonstrate and evaluate the implementation of TM/TCI interventions in the above-identified areas. The following steps are recommended:
 - i. Expert group formation: Identify a pool of expert TM/TCI practitioners to lead this initiative in coordination with the designated task force subgroup. It would be best to handpick experts based on clinical experience in the selected conditions.
 - ii. Draft implementation plan: Develop an implementation plan and note for the initiative for review and suggestions from TF members and invited experts.
 - iii. Workshops for technical finalisation: Finalise the implementation plan in two-day long workshops for each of the topics selected. The experts at the workshop would systematically scrutinise the available evidence and clinical experience and arrive at a choice of interventions for chosen conditions and the related technical details.
 - iv. Implementation: Each of the identified interventions could be implemented systematically through chosen centres such as government hospitals and health centres. Implementation spread out through twenty outlets in five states of India could be considered to generate an adequate variation for learning. It would be best to design these implementation studies and identify a nodal agency to execute these systematically through protocol development, approvals, process documentation, data collection and analysis, monitoring and evaluation and reporting. An 18-24-month duration with biannual reviews and mid-course corrections is suggested. The Ministry of Ayush and the Ministry of Health and Family Welfare, Government of India, may allocate the required financial resources for this work.
- Advocate the uptake of the lessons from the above implementation exercise into the health system at different levels including policy, practice and research.
- Revisit the procedures and the strategies for the above activities and provide recommendations to inform future activities in this direction.

For longer-term impact and addressing the root cause of limited and appropriate TM/TCI evidence, we recommend Commissioning an expert group in research methods to develop the appropriate methodology for evidence generation sensitive to TM/TCI epistemology and demonstrate the application of its select conditions of national priority.

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Annexure 2: Ayurveda for Iron-Deficient Anaemia – Is enough evidence available?

Introduction

Iron-deficient anaemia (IDA) is the most prevalent micronutrient deficiency in India and affects 1.5 billion people globally. IDA is a multi-factorial disorder. Pregnant women, school-going children and the geriatric population suffer from IDA often. Half of our pregnant women and children are anaemic. Table 1 below is the WHO (2011) Hb levels chart for diagnosing anaemia.

IDA adversely affects cognitive performance, behaviour and growth in children of all ages.

Age groups	No Anaemia	Mild	Moderate	Severe
Children 6–59 months of age	≥11	10–10.9	7–9.9	<7
Children 5–11 years of age	≥11.5	11–11.4	8–10.9	<8
Children 12–14 years of age	≥12	11–11.9	8–10.9	<8
Non-pregnant women (15 years of age and above)	≥12	11–11.9	8–10.9	<8
Pregnant women	≥11	10–10.9	7–9.9	<7
Men	≥13	11–12.9	8–10.9	<8

Source: Haemoglobin concentration for the diagnosis of anaemia and assessment of severity. WHO

The immune system and physical capacity get reduced and thus make prone children to infections and stunted physical appearance. IDA is a consequence of either increased iron demand/loss and/or decreased intake. Iron requirements are highest for pregnant women>infants>adolescent girls>adolescent boys>women>children>men (Welfare, 2013). Pregnant women are the highest-risk IDA population. Repeated pregnancies for less than 3 years and due to excessive blood loss, they become anaemic. In females having regular & normal menstrual history IDA was more common as the amount of iron required to replace the loss is not fulfilled adequately. The vegetarian diet is also a factor because the iron supplied is mainly non-haem iron and its bioavailability is only about 1-10%. Habituation to tea i.e. tannins in tea can cause iron absorption to drop by 60% (7).

Fig. 1 below depicts the global problem of anaemia in preschool children

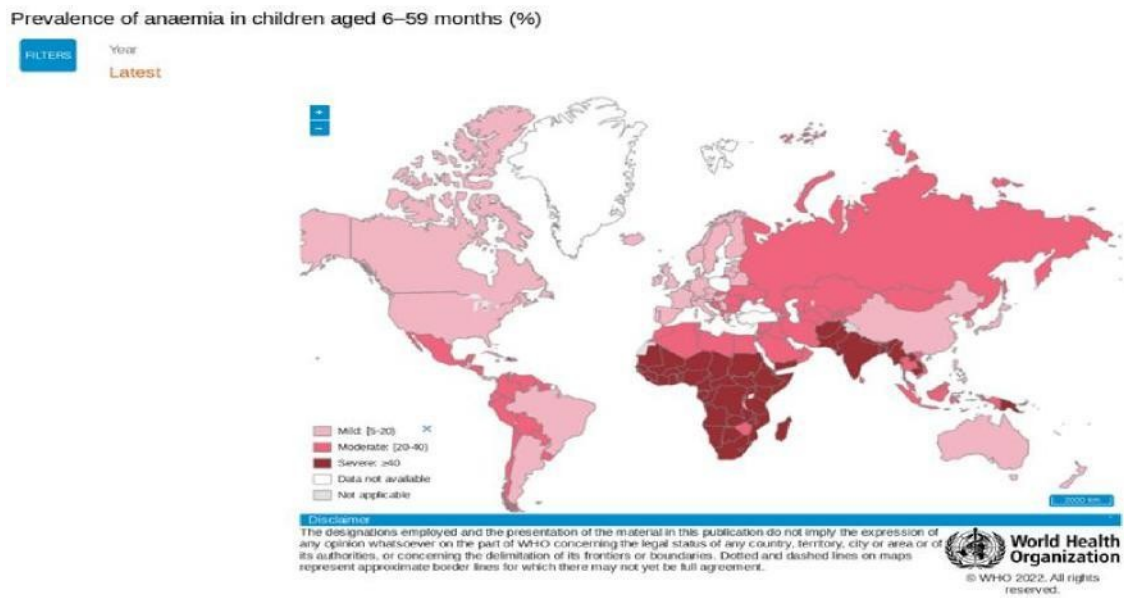


Fig. 2 below depicts the global problem of anaemia in women (15-49 years)

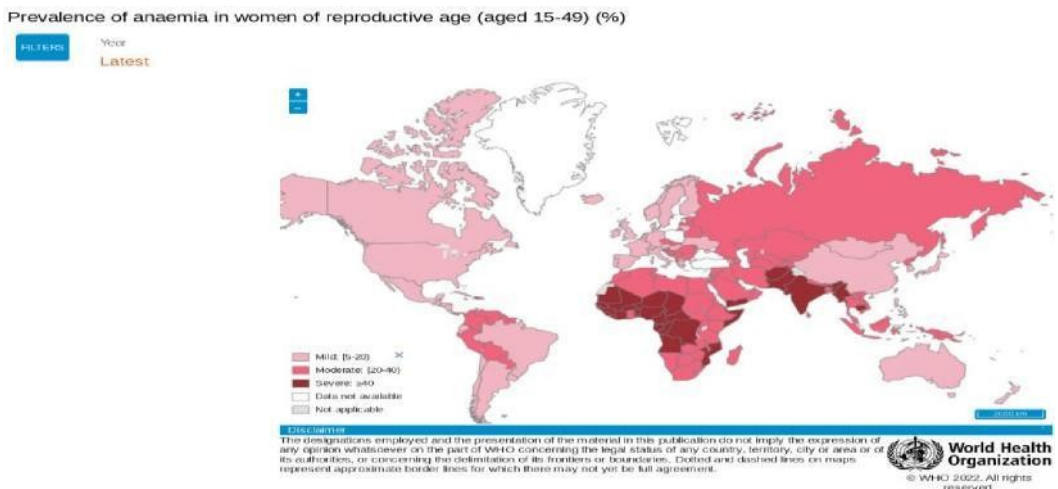


Table 2: Shows prevalence of anaemia among different age groups in India (NFHS-5; 2019-21)

Indicators	Urban (%)	Rural (%)
Children age 6-59 months who are anaemic (<11.0 g/dl)	64.2	68.3
Non-pregnant women age 15-49 years who are anaemic (<12.0 g/dl)	54.1	58.7
Pregnant women age 15-49 years who are anaemic (<12.0 g/dl)	45.7	54.3
All women age 15-49 years who aranaemic	53.8	58.5
All women age 15-19 years who aranaemic	56.5	60.2
Men age 15-49 years who are anaemic (<13.0 g/dl)	20.4	27.4
Men age 15-19 years who are anaemic (<13.0 g/dl)	25.0	33.9

Ayurveda for IDA management

Ayurveda is an ancient Indian traditional medicine system. In ayurvedic terminology, anaemia is known as *pandu* which means paleness. *Pandurog* mentioned in ayurvedic classics is similar to IDA. Ayurveda gives importance to the physical appearance of the patient, and symptoms and has been used to treat thousands of patients for centuries. In modern times, ayurveda doctors consider blood reports along with the traditional practice of *nadi* examination, physical appearances and symptoms. We did a literature search for ayurvedic preparations and comparative studies in Pubmed and Google Scholar and prepared Table 3.

Table 3 below summarizes the studies conducted on humans using ayurvedic intervention suffering from mild to moderate anaemia.

Punarnava Mandura

Study	Study Design (n)	Inclusion criteria	Ayurvedic Preparation	Results	Authors' Conclusion
(Ambika, 2013)	Pre-Post (50)	Children aged 10 to 14	Punarnavadi Mandura 500 mg BD and dadimadiGhritha 10 ml B.D with lukew arm water for 84 days (3 lunar months)	Statistically significant response in haemoglobin and other haematological investigation	Intervention Effective in management of Pandu roga (IDA)
(Khan delwalet al., 2015)	Pre-Post (24)	Pregnant women, belonging to the age group of 18 to 40	Group A (n = 15): 2 tablets of PunarnavaMandura (500 mg each) thrice a day; with one cup of buttermilk; Group B (n = 9) 2 tablets of	Statistically significant (P < 0.05) difference was noted in Hb%, MCV, MCH, and MCHC. It shows that Group A is	PunarnavaMandura is comparatively better in Garbhini Pandu

Study	Study Design (n)	Inclusion criteria	Ayurvedic Preparation	Results	Authors' Conclusion
		years with 6 g% to 10 g% of hemoglobin	Dhatri Lauha (500 mg each) thrice a day; with one cup of lukewarm water (administered for 90 days)	better than Group B	
(Pandya & Dave, 2014)	Pre-post single group (50)	Patients having Hb% below the normal range (in men: 7–13 g/dl and in female: 7–12 g/dl; age group 50 and 80 years)	Patients were given 2 tablets (250 mg each) of Punarnava Mandura twice a day after lunch and dinner with the Anupana of 100 ml of Takra (freshly prepared butter milk) for the duration of 90 days.	Statistically insignificant were found in hematological parameters that is, Hb%, Total blood cell (RBC), MCV, MCH, MCHC, PCV, ESR, platelet count and in serum iron Study follow up was for 1 month	Punarnava Mandura is a unique poly herbo mineral formulation which may work as a Panduhara and Rasayana in the patients of geriatric anaemia and can counteract most of the pathological manifestations related to Pandu Roga in old age (geriatric anaemia).

(No study reported any of the adverse events.)

Dhatrilauha

Study	Study Design (n)	Inclusion criteria	Ayurvedic Preparation	Results	Authors' Conclusion
(Srikanth, 2010)	Open-label multicentric trial (458)	Age between 15 to 60 years; Hb level 6 to 10 gm/dl.	Dhatri Lauha 500 mg BD for forty five days with warm water.	Significant effect ($p < 0.05$) in improving the hb; serum iron and stored iron (serum ferritin) were increased	The Dhatri Lauha is safe and significantly increases the Hb, serum Iron and Ferritin in subjects with Iron Deficiency Anaemia.

Study	Study Design (n)	Inclusion criteria	Ayurvedic Preparation	Results	Authors' Conclusion
(Daya Shankar, 2014)	randomized, non-blinded and placebo controlled (30)	18-70 years age; hb concentration <12 gm/dl in men and <11 gm/dl in women were included.	Dhatrilouha and Novayaslouha in dose of 250 mg respectively BD for 30 consecutive days	After the 30 days of treatment it was found significant (p<0.05) response	The two Ayurvedic preparations are effective, well tolerated and clinically safe for correction of iron deficiency anaemia. The results need to be ascertained a larger scale in multi-centre study.
(Ruparaj et al., 2013)*	Parallel random (26)	(No full-text access)	Pandughni Vati 2 tablets of 250mg tds and Group B (n10) Dhatri Lauha Vati 1 tablet of 250mg tds.	Group A The result observed in dyspnoea (60%) and palpitation (53.33%) were highly significant statistically (<0.001). Daurbalya (33.33%), fatigue (40%), anorexia (28.57%) and Pindikodvestana (55.55%) were decreased significantly statistically (<0.05) whereas in pallor (24%) it was not significant. In (56.25%). The results in fatigue (61.54%), palpitation (55.55%), anorexia (42.85%)	On comparing the effect of therapy study was finding better percentage improvement in group B consistently in most of subjective and objective parameters. So it can be said that Dhatri Lauha Vati has somewhat better results, proving it better to Pandughni Vati.
(No study reported any of the adverse events. Follow up: NI. * Full text was not accessible.)					

Navayasa Lauha

Study	Study design (n)	Inclusion criteria	Ayurveda preparation	Results	Conclusion
(Daya Shankar, 2014)	randomized, non-blinded and placebo controlled (30)	18-70 years age; hb concentration <12 gm/dl in men or <11 gm/dl in women were included.	Dhatrilouha and Novayaslouha in dose of 250 mg respectively BD for 30 consecutive days	After the 30 days of treatment it was found significant (p<0.05) response	The two Ayurvedic preparations are effective, well tolerated and clinically safe for correction of iron deficiency anemia. The results needs to be ascertained a larger scale in multi-centre study.
(Mahavir Kho, 2013)	Parallel group clinical study (60)	18-35 years age pregnant women; hb concentration 8-10 gm/dl	Group A – DhatriLauha (250)mg T.I.D. in the form of vati, after food for 90 days with ghee / honey. Group B – NavayasaLauha (250) mg – T.I.D. in the form of vati food for 90 days with honey/water	Dhatri&navayas aLauha provided significant result on Hb gm% ,RBC,MCV,PC V serum iron percent transferrin saturation and TIBC	DhatriLauha showed significant result in anemia in pregnancy (Garbhini Pandu)

(No study reported any of the adverse events. Follow up: NI)

Saptamrit Lauha

Study	Study Design	Inclusion criteria	Ayurvedic Preparation	Results	Authors' Conclusion
(Hiremath & Kulkarni, 2021)	Open-label prospective trial (43)	Age between 12 to 16 years; Hb level 8 to 11 gm /dl.	Albendazole 400 mg before initiating the trial medication. Saptamritlohavati (500 mg) after food with water twice daily for a period of 60 days. Children in the control group received Dhatrilohavati (500 mg) in a similar way	Saptamritloha is effective in improving the clinical features and hematological parameters significantly and the results were comparable with the standard control. The mean improvement in hemoglobin(Hb) was 1.17 g% in the trial group during the course of treatment (P < 0.001)	Saptamritloha is effective in the management of Panduroga in children.

(No study reported any of the adverse events. The study had 1 month follow up.)

Current scenario

Oral iron supplementation is a cheap, safe, and effective means of increasing haemoglobin levels and restoring iron stores to prevent and correct iron deficiency. Many preparations are available, varying widely in dosage, formulation (quick or prolonged release), and chemical state (ferrous or ferric form). For the treatment of iron deficiency anaemia, current guidelines recommend the dose of 60 to 120 mg of elemental iron of ferrous sulphate per day for a minimum duration of 3 months in adolescents and adults, including pregnant women.

However gastrointestinal side-effects are seen in nearly 22% patients and associated with ferrous sulfate oral supplementation (Tolkien et al., 2015). Prominent adverse effects are nausea, vomiting, abdominal cramps and discomfort with diarrhoea or constipation. Bioavailability of these meds is about 20%. Ferrous ascorbate has high bioavailability from 30-40% up to 67%, but concerns about its safety and cost are there (Chowdhury, 2021). Many studies conducted using ayurvedic preparations to address mild to moderate anaemia bear promise. Side effects reported are minimal and efficacy of these drugs is equivalent or even better than the ferrous preparations used to treat anemia, probably attributed to improved compliance.

Modern medicine prescribes forms of iron like ferrous sulphate and fumarate but they have side effects. Prominent adverse effects are nausea, vomiting, abdominal cramps and discomfort with diarrhoea or constipation. Furthermore, they are not cost-effective. Many studies conducted using ayurvedic preparations to address mild to moderate anaemia bear promise.

Discussion

Punarnava mandura is composed of triphala, trikatu, chitraka, vidanga, and pippalimula. Unlike modern medicine side-effects, the components of punarnavamandura are appetizer and carminative (Pandya & Dave, 2014). Dadimadighrita and Punarnava mandura are prescribed in pandurog management. Mandura which is chemically Fe_2O_3 increases serum ferritin while punarnava decreases gastric irritation produced by Mandura. PunarnavadiMandura is preferably taken with buttermilk which is having low pH and contains lactic acid. Iron absorption is aided by decreased pH. Furthermore, iron may combine with lactic acid to form ferrous lactate before absorption which is used by modern allopathic medicine for the management of IDA. *Dhatrilauhavati* contains *Lauha Bhasma*, which is an iron supplement and leads to proper metabolism and *Dhatuposhana*.

Ayurveda experts and allied scientists have worked extensively on various possible formulations and the efficacy of ayurvedic drugs mentioned in the classical texts. However, the trials suffer from bias and poor reporting. There is a lack of pharmacodynamics and pharmacokinetics studies which can determine the mechanism of action of ayurvedic drugs. The clinical trial methodology is also rarely followed. Up to now, only one multi-centric clinical trial was conducted with an enrolment of 458 patients. The study was conducted in 11 peripheral research institutes of Central Council for Research in Ayurveda and Siddha and Mahatama Gandhi Institute of Medical Sciences, Wardha to evaluate the safety and efficacy of *dhatrilauhain* the IDA management. The trial has shown promising results (Srikanth, 2010). It was observed that the prevalence of anaemia was significantly higher in females than males, which is due to the higher requirement of iron in reproductive age group and pregnancy. Out of 400 patients of anaemia which completed the study, maximum patients (57.2%) were illiterate and under matriculate. It may be due to lack of awareness of nutritious diet in less educated and lower socio-economic group. It may be due to inadequate availability and capacity of the resources for taking nutritious diet. Few cases reported adverse reactions like burning sensation and nausea. Overall clinical improvement was significantly seen in 77.25% and feeling of well-being was observed in 79.75% patients at the end of the study. The therapy provided significant effect ($p < 0.05$) in improving the hemoglobin percentage.

Pharmacoeconomics of Ayurveda and Allopathy Drugs

Table 3: Ayurveda Drugs and price

Sl. No	Ayurveda Medicine	Dosage form and Strength	Per day Cost (INR)
1	PunarnvaMandoor	500 mg (Twice a day)	2.8
2	NavayasaLauha	500 mg BD (Twice a day)	2.8
3	Saptamrit	500 mg BD (Twice a day)	1.9

Table 4: Allopathic medicines for iron deficiency anaemia treatment with price

Sl. No	Allopathic Medicine	Dosage form and Strength	Per day Cost (INR)
1	Film-coated	Each film coated tablet contains Ferrous Ascorbate eq. To elemental Iron 100mg Adenosylcobalamin 15mcg Zinc Sulphate monohydrate eq. to elemental Zinc 22.5mg Folic Acid 1.5mg. (Once a day)	3.79
3	Film-coated	Each film coated tablet contains: Folic Acid IP 5mg, Methylcobalamin IP 1500mcg Pyridoxine Hydrochloride IP 20mg. 10 Tablet). (Once a day)	3.87
3	Ferrous Sulphate manufactured by facmed pharma	28 Tablet. (Once a day).	6.6

As per the above tables (Table 3 & Table 4), Ayurveda drugs show less price compared to Allopathy medicines. The price (INR) difference is 0.9 rs, 1.07 rs, and 4.7 rs, respectively.

Guidelines & recommendations

Although, Ayurvedic drugs are well tolerated and hold promise in managing IDA without side effects; and subsequent phase III/IV clinical trials should be conducted to prove efficacy and long-term safety. The Ministry of AYUSH has advised the use of TrikatuChurna/ GuduchiChurna/ DhanyakaChurna/ ShunthiChurna/ JeerakChurna, Dhatri Lauha/ PunarnavadiMandura/ DadimadiGhrita / AnnabhedhiChenduram/ Saptamritlauha / MandoorVataka / Navayaslauha / Drakshavleh / Dadimavleha / Dhātrīavaleha for the management of mild to moderate anaemia under the supervision of Ayurvedic Medical Officer (Advisory, n.d.).

National Institute of Ayurveda suggests use of *punarnavamandura* for anemic children 125-250mg BD and adolescent girl/pregnant women 250-500mg BD; *drakshadiavaleha* for anemic children 3-5g BD and adolescent girl/pregnant women 5-10gm.

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Annexure 3: Oil massage for infant health

Research Question- Is there enough evidence to recommend oil massage in full term infants in home settings?

Introduction

Newborn, infant and child health is a high priority area for sustainable development. Mortality indicators are improving globally. Neonatal mortality is on the decline with the world's neonatal mortality rate (NMR) falling from 37 deaths per 1000 live births in 1990 to 18 per 1000 live births in 2018 (1). In India, NMR is still higher compared to many parts of the world. Skin interventions have been implemented to reduce neonatal mortality, demonstrating the role of skin-care practices in neonatal innate immunity (2).

Massaging the newborn and infant is a popular traditional practice in India and most of Asia. Literature suggests the need to study and adapt interventions that are culturally acceptable, including community-based interventions. Infant care practices tend to be region- and culture-specific and influence child health outcomes. Cultural practices are sometimes beneficial and sometimes harmful, and for some there exists no clear evidence of benefit or harm. Evidence-based of the prevailing childcare practices and their effects is hence important to inform practice and public programs.

The World Health Organization's guidelines on 'Maternal and newborn care for a positive postnatal experience' (3) recommend gentle whole body massage for term, healthy new-borns for its possible benefits to growth and development. Massage as much as it has therapeutic value, it is also a common cultural routine newborn care practice across many countries. The massage techniques, the steps involved, tactile-kinaesthetic stimulation, massage with or without any topical lubricant, variety of oils used, etc. may have ethno-cultural and eco-geographical variations. But, essentially, the practice of massage as newborn infant care is universally prevalent.

Massage in infants, with and without oils, has been researched and several benefits have been reported. These include improved anthropometric parameters such as weight gain velocity and length (4). A meta-analysis of infant oil massage found it to be effective at promoting physical growth and had limited risk of adverse skin reactions (5). A majority of reports on effects of topical applications to infant skin, termed as 'emollient therapy,' are from hospitalized babies that are born premature and require intensive care (6).

Infant massage therapy studies have predominantly focused on preterm infants with low or very low birth weight with primary objective of weight gain, and the underlying mechanisms for massage leading to weight gain. Clinical studies have proven that the topical application of oil is effective in

- (a) enhancing the skin barrier function, reducing infections and saving the lives of newborns (Darmstadt et al., 2004; Darmstadt et al., 2005);
- (b) promoting somatic growth because the fatty acids in the oil provide nutrition supplementation (Fernandez, Krishnamoorthy, Patil, Mondkar, & Swar, 2005; Soriano et al., 2000); and (
- c) reducing TEWL (transepidermal water loss), which leads to improved thermoregulation with a reduced incidence of hypothermia (Darmstadt et al., 2005; Kulkarni, Kaushik)

The practice of oil massage has also gained favor in the neonatal intensive care units of developed countries (7, 8) However, these studies primarily focus on preterm or low birth weight infants and not necessarily healthy full term infants. This leads to limitations in generalization of the results. There are variations in types of massage, pressure applied during massage, topical emollient or oils used for massage, hospital or home settings, clinical or physiological outcomes of massage, etc.

The Tradition of Oil massage in India:

Infant massage with emollients is a common practice culturally followed across India. In a survey conducted in Indian states of Maharashtra and Madhya Pradesh involving 1497 infants, it was observed that infant massage was highly prevalent practice with 93.8% of the mothers massaging the baby at least once a day [95%CI: 92.4,94.9] (4). It was further observed that 97% of the respondents (mothers, family/caregivers) used Oil as the preferred substance to massage the baby. In a survey conducted among women in Nepal about traditional practice, it was observed that 89.5% of women gave oil massage (9).

The practice of massage with oil resembles with *Abhyanga* procedure prescribed in Ayurveda classics. In Indian sub-continent, infant massage is generally practiced with topical oil application.

Benefits of Oil massage:

जलसिक्तस्य वर्धन्ते यथा मूलेऽङ्कुरास्तरोः ।

तथा धातुविवृद्धिर्हि स्नेहसिक्तस्य जायते ॥

- सु.चि. २४/३२

Ayurveda classics have suggested that regular oil massage immensely helps to promote growth and development of body tissues analogous to how regularly watering a plant promotes its growth.

Research studies have shown that the oil applied during infant massage enhances the skin barrier function and thermoregulation, reduces trans-epidermal water loss and neonatal infections, and improves skin integrity, neurodevelopment, and mother-infant bond (10). Research on health benefits of emollient therapy in healthy, full term infants is scarce.

With this background, a systematic review was undertaken to answer if oil massage to full

term infants can be recommended as a routine practice for infant health.

To determine the current state of knowledge about infant massage, a systematic literature review was performed according to the PRISMA guidelines.

Literature review for relevant studies was performed on the PUBMED database and the studies that fulfilled the inclusion criteria were selected. The studies published from 2000 to 2022 were included for recent research on infant oil massage.

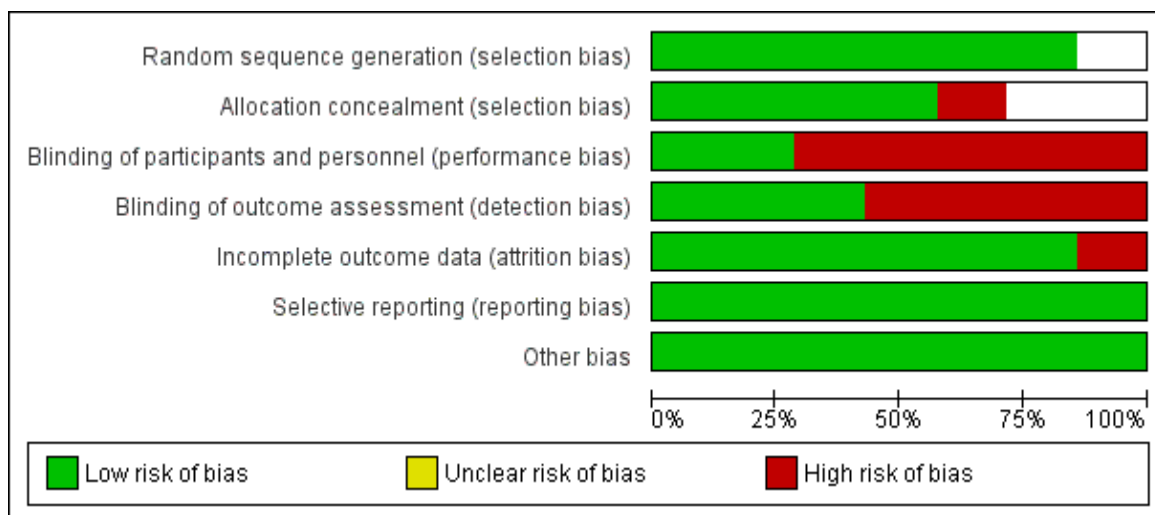
PICO for the review was as follows:

- Population: healthy, full term infants from 0–12 months; preterm infants when intervention was oil massage
- Intervention: infant massage (with and without Oil) administered by parents or professionals
- Control group: blank or care as usual or other intervention
- Outcome: weight gain, length gain, No adverse effect
- Study type: randomized controlled trial (RCT), clinical controlled trial (CCT)

A total of 1372 articles were retrieved. The search used a combination of keywords related to Healthy infant (normal infant, term baby), intervention (infant massage, oil massage), and outcome measures (weight gain, infant growth, adverse effects). The studies identified for inclusion were narrowed down to full text articles written in English.

Preterm infants with low birth weight or very low birth weight were excluded, to allow generalization of the findings for the community at large. Studies related to oil massage administered as intervention were included if they included medically stable preterm infants. Clinical studies and RCTs were included. Massage Therapy with topical emollients, topical oils, lubricants were also screened to have a comparative overview. Studies (RCTs) that mention Massage technique, Duration, Frequency were included. Seven studies met the inclusion criteria of this systematic review. The characteristics of included studies are presented in Table 1. Figure 1 below presents the assessment of quality of included studies (GRADE).

Assessment for Risk of Bias:



	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Agarwal KN, 2000	+		-	-	+	+	+
Arora J, 2005	+	+	-	-	+	+	+
Fallah R, 2013	+	+	+	+	+	+	+
Kumar V, 2013	+	+	-	-	+	+	+
Sankaranarayanan K, 2005	+	+	-	-	-	+	+
Solanki K, 2005	+		+	+	+	+	+
Summers A, 2019		-	-	+	+	+	+

Figure 1: Quality of included studies- GRADE assessment

Table 1: Characteristics of included studies:

Selected Study and year	Level of evidence	Study design	Population	No. of subjects	Age of infants when intervention administered	Intervention	Frequency	Control	Duration of intervention (days)	Major Outcomes in Massage Group
Agarwal 2000 (11) ⁱ	High	RCT	Full term Birth weight : more than 3 kg	125	Started at 6 weeks of age, till next weeks of age	Herbal oil massage Sesame oil massage Mustard oil massage mineral oil massage	10 min Once a day Similar Swedish massage	Blank	28	Oil massage improves weight gain, length gain, mid arm mid leg circumference , blood velocity and blood flow. Sesame oil appears to be better than other groups.
Summers et al 2019	High	Cluster RCT	Full Term, Preterm	995	Not mentioned	Sunflower seed oil, Mustard Oil	Not mentioned Routine massage practice	Mustard Oil Standard practice	28	Oil type may contribute to differences in skin integrity when neonates are massaged regularly. The more rapid acid mantle development observed for SSO may be protective for neonates in lower resource settings
Solanki 2005 (12)	Moderate	RCT	Stable neonates three subsets viz., (a) gestational age	118	Hemodynamically stable after 3rd day of birth	Safflower oil massage Coconut oil massage	10 min/ session, 4 times per day Trained massager	Only massage	5	Topically massaged oil is absorbed significantly in neonates. Types of oil used can alter the lipid profile of the baby and may help in

			<34 weeks, (b) gestational age 34-37 weeks, (c) gestational age >37 weeks.							absorption of nutrients Oil application may be considered for reversal of essential fatty acid deficiency in neonates No Adverse reaction
Sankaranarayan 2005 (13)	Moderate	RCT	Full term , Preterm Term births weighing more than 2500 grams	192	from day 2 of life	Coconut oil massage Mineral oil massage	4 Times per day Oil massage was given by a trained person from day 2 of life till discharge, and thereafter by the mother until 31 days of age,	Only massage	31	Coconut oil massage has beneficial effects on the weight gain in preterm neonates compared to mineral oil massage No significant Neurobehavioral benefits No Adverse reaction
Arora 2005 (14)	Moderate	RCT	Medically stable Preterm (Neonates with birth weight <1500 grams, gestation < 37 weeks)	62	Within 10 days of birth	Sunflower oil massage	10 Minutes/session 4 times per day.	Without Oil, No massage	28	Weight gain in the oil massage group (365.8 + 165.2g) was higher compared to the only massage group (290.0 + 150.2g) and no massage group (285.0 + 170.4g). Since Oil massage is a culturally

										accepted practice, it should be encouraged as part of early neonatal intervention in very low birth weight infant care both in hospitals and at home
Fallah 2013 (15)	High	RCT	Medically Stable Preterm Gestational age:33–37 weeks, Birth weight of 1500–1999 g,	54	Within ten Days of birth	Sunflower oil massage	3 times per day Mother	Only massage	14	In the oil massage group, mean weight at ages 1 month (mean ± SD: 2339 ± 135 vs. 2201 ± 93 g, P = 0.04) and 2 months (mean ± SD: 3301 ± 237 vs. 3005 ± 305 g, P = 0.005) was significantly greater than that of the body massage group
Kumar 2013 (16)	High	Cluster RCT	Healthy neonates	n=26,587 13,478 live-born infants 13,109 infa	applying sunflower seed oil at the first application during the first 6 h after birth, within 7 days of birth	Cold-pressed Sunflower Seed oil massage	3-times per day using gentle massage with washed hands.	Standard practice of mustard oil, or other prevalent community practice of massage	28	Weight (g) Weight gain (g) Length (cm) Head circumference (cm)

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Based on the above review findings the following guidelines for oil massage of full-term infants is developed.

The prescribed guidelines are intended for healthy, full-term infants who are medically stable, completed 34 week gestation and weight above 1.8 kg. The guidelines are specifically to recommend an evidence-based, simple, practical approach to the traditional practice of oil massage in hospital or home settings.

1. Review question: What age is appropriate to start oil massage to infants?

Recommendation:
 The oil massage can be started after 3rd day of birth once the medical fitness is well established. Medical fitness can be stated as :

1. Apgar score >7 at 1 and 5 minutes with no resuscitation required at birth.
2. Medically stable with no requirement of drugs (other than mineral and vitamin supplements or any interventions/ procedures).

Rationale:

From the selected studies for review, in the cluster randomized trial by Kumar et al, a total of 26,587 infants were followed up from birth (day 1) to 28 completed days. The intervention oil (sunflower seed oil) and the standard care with Mustard oil massage were administered during the first 6 hours after birth, without any serious adverse effects. This asserts the fact that oil massage can be safely administered within six hours of birth.

Authors Arora et al and Fallah et al have prescribed their oil interventions within 10 days of birth, where age at enrolment for was mean 117.4 hours, with SD of 55.7. Shankar Narayan et al have safely demonstrated the administration of oil massage from day 2 onwards, whereas Solanki et al have administered the oil massage after confirming the hemodynamic stability after day 3 onwards. The age at inclusion for Safflower oil massage was Mean 1.54 days with SD (0.7), whereas Coconut oil massage was Mean 1.53 days with SD (0.7) days.

In a cross-sectional study in states of Maharashtra and Madhya Pradesh, Chaturvedi et al have observed that massage was mostly initiated in the first week of life (82%) in India.

Ayurveda Recommendation:

In newborn care regimen, described as '*Jaat-matraParicharya*', it has been recommended to sprinkle *Bala Tail* (Sesame oil based herbal oil preparation) immediately after the birth once vitality of the neonate is established upon delivery.

.ⁱⁱ The rationale is, Ayurveda considers the process of birth as an arduous effort for the baby, and a process which aggravates the *Vaatdosha*. Hence the application of oil is recommended as a soothing practice to neutralize the aggravated *Vatadosha*.

Points to consider:

- **Training:** In the studies where oil massage was administered within 10 days of birth, the massage was given by a trained worker till discharge, thereafter the mother was taught the technique of oil massage. New mothers may be apprehensive in handling the baby and not confident in administering the oil massage. Hence, training of mothers/ parents/ family is necessary.
- **Handling the baby:** The massager needs to be very careful in handling the baby during and after the massage to avoid slippage of baby due to oiliness.

2. Review question: Which oil is safe for infant massage?

Recommendation:

Coconut oil, Sunflower seed oil and Sesame oil are safe and beneficial for infant oil massage. Mineral oil, Mustard oil, Olive oil are not recommended for infant massage.

Sesame oil:

Agarwal, *et al.* observed that full term infants at 6 weeks massaged with sesame oil showed a significant increase in length, midarm and midleg circumferences compared to infants receiving herbal oil, mustard oil, or mineral oil for massage daily for 4 weeks. They demonstrated that oil massage in infancy improves growth and post-massage sleep. However, these effects were prominently observed in infants massaged with Sesame oil.

In the group with sesame oil massage increase in length, midarm and midleg circumferences by 1.0, 0.9 and 0.7 cm, respectively was significant ($P < 0.05$, <0.01 & < 0.05). The femoral artery blood velocity, diameter and flow improved significantly by 12.6 cm/sec, 0.6 cm and 3.55 cm³/sec respectively in the group with sesame oil massage as compared to the control group. Massage improved the post massage sleep, the maximum being 1.62 h in the sesame oil group ($P < 0.0001$).

Ayurveda Recommendation:

सर्वेषां तैलजातानां तिलतैलं विशिष्यते ।

बलार्थं स्नेहने च

- च.सू. १३/१२

Tiltaila (Sesame oil is considered the preferred oil for massage as it is considered the best especially for growth and oleation for neutralizing the aggravated Vatadosha)

Coconut Oil:

Coconut oil is especially rich in medium chain triglycerides (MCT), which are known to have different absorptive mechanisms from the gut and are said to be easily metabolised in the body. Shankarnarayan et al studied to compare the effect of massage with coconut oil versus mineral oil and placebo on growth velocity and neuro-behavior in well term and preterm babies. Coconut oil massage resulted in significantly greater weight gain velocity as compared to mineral oil and placebo in the preterm babies group; and in the term baby group, as compared to the placebo. Weight gain velocity over the first 31 days was higher in the coconut oil group as compared to the placebo group ($p = 0.02$).

Sunflower seed oil:

In the studies included for the review, 4 studies are related to oil massage with sunflower oil. (Summers et al, Arora et al, Fallah et al, Kumar et al). The community-based cluster randomized controlled trial by Summers et al included 995 neonates assigned to full body massage with sunflower seed oil (SSO, intervention) or mustard seed oil (MO, standard practice) for 28 days to evaluate topical emollient therapy with oil massage. The emollient therapy involved consistent repetitive, daily, high frequency oil exposure with vigorous massages each day. The effect of type of oil on skin integrity was assessed on the parameters of skin condition (erythema, rash, dryness), skin surface pH, stratum corneum (SC) cohesion/protein concentration, and trans-epidermal water loss (TEWL).

The use of Sunflower seed oil increased the rate of skin pH reduction during week one of life, suggesting a faster acid mantle development. An acidic environment is required for lipid metabolism, bilayer structure formation, desquamation, bacterial homeostasis, skin colonization, and inhibition of pathogenic bacteria. The more rapid acid mantle development observed for Sunflower seed oil may be protective for neonates in lower resource settings.

Solanki et al have demonstrated transcutaneous absorption of massaged oil in newborns where the essential fatty acid (EFA) rich - safflower oil and (ii) saturated fat rich coconut oil, were studied on fatty acid profiles of massaged babies. Considering the fact that topically massaged oils can be absorbed transcutaneously and that infant massage is a daily followed practice for longer duration, caution is advised for the purity of oil.

Oils to avoid:

Mineral oil should be avoided. Olive oil is not recommended for baby massage because of its high oleic acid content (18). This can make the baby's skin more dry. Regular use of Mustard oil for infant massage is a common practice in many parts of the world. However, recent studies have suggested that mustard oil might have toxic effects on the epidermal barrier (19).

3. Review question:

What is appropriate duration and frequency of oil massage to infants?

Recommendation:

The healthy term infant can be given gentle oil massage for 10 to 15 minutes per massage session, for minimum once to maximum three times a day, depending on the temperature and humidity of the settings and geographic region.

Rationale:

In the studies included in this systematic review, five studies had a duration of each massage session was 10 to 15 minutes and frequency was 3 to 4 times per day.

However, all these studies were related to a total duration of not more than 5 days to 31 days. To recommend oil massage as a routine standard care of practice for longer duration throughout infancy, seasonal variations (temperature, humidity), availability of resources (family support, oil consumption) and convenience to baby and the mother (caregiver) must be considered.

In the RCT by Agarwal et al, the oil massage given once a day for 10 minutes for a duration of weeks showed improved weight gain and increased post-massage sleep after oil massage. This demonstrates that oil massage, if administered correctly, even for a frequency of once a day, can be beneficial for infant.

The majority data on infant oil massage focusses on weight gain as clinical outcome of massage intervention in Preterm neonates. Here, Oil massage is prescribed more as therapeutic intervention at hospital settings than a standard safe routine practice at home settings. Thus there is a need to attune the duration and frequency of Oil massage as standard care of practice at home settings for healthy term infants.

In an extensive cross-sectional study (n=1497) by Chaturvedi et al to evaluate the perceptions and prevalence of oil massage practices in India, where oil massage is widely viewed as a traditional practice. It was common to massage the baby once daily (77%), before bathing (77%), and after feeding (57%).

Ayurveda Recommendation: -

अथ जातान्नपानेभ्यो मारुतघ्नैः सुगंधिभिः ।

यथर्तुं संस्पर्शसुखैस्तैलैः अभ्यगमाचरेत् ॥

- अ.सं.सू. ३

Acharya Vagbhat has described that the oil massage should be administered after the consumed food/ liquids have been digested well. The oil massage should be given with soothing pressure and pleasant mild oils suitable according to the season.

तत्र प्रकृतिसात्म्यतुदेशदोषविकारवित् ।

तैलं घृतं वा मतिमान् युज्यादभ्यंगसेकयोः ॥

- सु.चि. २४/३४

Acharya Sushrut has described further that the selection of lubricant (oil/ ghee) formassage should be according to Prakriti, compatibility (non-allergic), season, aggravated Dosha and type of disorder.

- Frequency of oil massage:

अभ्यङ्गोद्वर्तनं स्नानं प्रत्यहं च समाचरेत् ॥

- अ.सं.उ. १/४९

Ayurveda recommends that oil massage should be administered daily.

- Duration of Oil massage:

Acharya Dalhana, the celebrated commentator of the Sushruta Samhita, and the author of 'NibandhaSangraha' is one of the ancient luminaries of the Indian system of medicine of the 12th Century A.D. It is very interesting to note that Acharya Dalhana has propounded the effect of duration of oil massage on various body tissues from hair roots to Asthi (bones).
अभ्यंगोऽत्र सकल शरीर कर्णादिगत स्नेहस्य शिरामुखादिगत स्नेहस्य

शिरामुखादिभिः । शरीरसंतर्पण काल केचिदत्र पठन्ति -

रोमांतेष्वनु देहस्य स्थित्वा मात्र शतत्रयम् ।

ततः प्रविशति स्नेहोश्चतुर्भिर्गच्छति त्वचम् ॥

रक्तं गच्छति मात्राणां शतैः पंचभिरेव तु ।

षडभिर्मांसं प्रपद्येत मेदः सप्तभिरेव च ॥

शतैरष्टाभिरस्थीनि मज्जानं नवभिर्ब्रजेत् ।

तत्रस्थान शमयेत् रोगान् वातपित्तकफात्मकम् ॥

- डल्हण

Dalhana, the celebrated commentator of the Sushruta Samhita, and the author of 'NibandhaSangraha' is one of the ancient luminaries of the Indian system of medicine. Acharya Dalhana has described that oil when massaged takes 300 matra (95 seconds) to cross hair roots. Total 400 Matra (133 seconds) to reach the Twacha (skin), Total 500 matra (160 second) to reach the Rakta, 600 Matra (190 sec) to reach the Mansa, 700 Matra (228 sec) to reach Meda, 800 matra (240 sec) reach Asthi, 900 Matra (285 sec) to reach majja and then it will alleviate the diseases of that place.

For practical application, it can be considered that oil massage for each body part should be administered at least for 4 minutes for the oil to reach the Asthidhatu (bone tissue), if bone nourishment is intended.

4. Review question: What are the appropriate techniques/procedure for oil massage to infants?

Recommendation:

- The infant oil massage should be started from supine (face-up) position of the baby. The massage should include tactile as well as kinesthetic stimulation with mild to moderate pressure. Massage should involve the entire body starting from head, neck, trunk and extremities (procedure described below).
- Mothers or caregivers who will administer the oil massage to infants need to be guided to follow appropriate method.

Rationale:

Methods of massage:

Of the seven studies, all the studies followed different steps/ methods of oil massage. One study followed the method given by Mathai et al (Sankarnarayan et al), one study followed method given by Field et al (Fallah et al), Two studies did not clearly mention the method/ steps followed (Summers et al and Solanki et al). One study referred to Swedish method of massage (Agarwal et al 2001) and has given sequence of massaging the body parts starting from legs and feet. The study did not mention supine or prone position. The Kumar et al study mentioned gentle massage with washed hands of the caregiver, with no description of steps of massage. Arora et al developed their standardized massage method starting with shoulders, neck and waist in prone position, with 20 gentle massage strokes.

Who should give massage?

In three studies Massage was administered by the mother (Agarwal et al, Fallah et al, Summers et al), in one community settings study by family member (Kumar et al) and in three studies by trained investigators or massagers (Solanki et al, Arora et al, Shankarnarayan et al). In the studies where mothers administered the massage throughout the intervention period or after discharge at home, training was given to mothers to give massage to babies and adherence was assessed at pre-determined intervals by investigators.

Pressure during massage:

Two studies (Agarwal et al and Solanki et al) have not mentioned the pressure for oil massage. Two studies (Arora et al and Kumar et al) have mentioned gentle pressure or gentle strokes, as the inclusion criteria also involves preterm and very low birth weight babies. Authors Fallah et al have mentioned the massage pressure should be so as to only produce a slight indentation in neonatal skin during massage. Summers et al have not intervened upon the prevalent community practice which involves daily, repetitive, consistent, high frequency application of vigorous massages.

Field et al have advised that for specific clinical outcomes of weight gain in medically stable preterm infants, moderate pressure is shown to be better than light pressure massage.

For practical recommendations, the following methods have been referred:

1. Mathai et al (commonly followed in most of the massage therapy research in Indian context) (21)
2. Field et al (commonly followed in most of the massage therapy research)(22)
3. Chaturvedi et al (Most recent Expert consensus, with reference to oil massage in Indian context) (23)

In both the techniques demonstrated by Mathai et al and Field et al the massage is a combination of tactile and kinesthetic stimulation. Tactile stimulation implies gentle stroking, whereas kinesthetic stimulation implies flexion and extension movements are performed at major joints viz. ankle, knee, elbow and shoulder. The Field's technique Massage is given in 15 minute sessions starting with 5 minutes of tactile stimulation followed by 5 minutes of and ending again with 5 min of tactile stimulation. In Mathai technique the procedure was divided into 2 phases of tactile stimulation: first phase, the baby is placed prone and 12 strokes of 5 sec each is provided starting from head, neck, shoulder to buttocks; second phase the baby is

placed supine 12 strokes of 5 sec each was given starting from face, cheeks, chest, abdomen, upper limb, lower limb, palms and soles. Third phase consists of kinesthetic stimulation in which alternate flexion and extension movements are performed at major joints: ankle, knee, elbow and shoulder. The massage can be interrupted for a few minutes when the baby passes stool/urine or cries excessively. Pre-requisites for massage:

In a comprehensive review by Indian pediatricians Kulkarni et al (24), the authors have given practical instructions suitable for Indian context, which are as follows:

- A conducive environment needs to be established before initiation of massage.
- A room with soft light, warm temperature, and low noise levels is ideal.
- Massage should be given between the feeds and ideally 45 min to 1 hour after a feed to avoid regurgitation or vomiting of the feed.
- Massage should involve the entire body starting from head, neck, trunk and extremities. A firm stroke with flat of fingers is used during massage therapy.

These above steps or methods are relevant to massage in general, and not oil massage. There are no fixed guidelines available for infant oil massage. A well- designed expert consensus study by Chaturvedi et alⁱⁱⁱ has elaborately prescribed guidelines relevant to infant oil massage at home setting, which can be referred to recommend steps of oil massage at community settings in India

Recommended procedure for infant Oil massage*:

*(Based on recommendations by Chaturvedi et al)

1. Massage should always be performed unidirectionally from proximal to distal end and centrifugally, do not massage in reverse direction. Massage should be performed in this sequence: chest, abdomen, shoulders, upper limbs, lower limbs, head and face, neck, back, and buttocks.
 - i) Chest- Begin with gentle movements from centre towards the sides of the chest – starting from midline, upwards, outwards, downwards and back to the initial point. The nipples of the infant should not be squeezed, there can be secretions coming from infant nipples, this is normal and does not require anything to be done.
 - ii) Abdomen- The abdomen should be massaged more gently with palms making circular movements around the umbilicus in a clockwise manner. In the early days of life when the umbilical cord stump is yet not fallen, spare that area from massage until it falls.
 - iii) Shoulders – Massage both shoulders simultaneously with strokes beginning from midline in the outward direction passing gently down the shoulders. Make sure the neck does not get twisted. Perform about five circular movements with fingers at each shoulder joint.
 - iv) Limbs- the direction of strokes should be downwards. Massage each upper and lower extremity separately beginning from shoulder to wrist for upper extremity

and hip to ankle for lower extremity. Massage each palm and sole with circular movements. Hold the ball of the toes (the bulky part on the sole that is under the toes) gently pressed for a few seconds. Massage the elbows, knees and ankles with circular movements.

- v) Head and face- Massage the scalp with clockwise circular movements beginning from the centre and expanding towards the periphery. Apply oil to the scalp and hair, do not apply extra oil on the hollow portion on the scalp that is the unclosed anterior fontanelle. Massage the forehead beginning from the midline in outward direction simultaneously with fingers of both hands. For cheeks use circular movements from sides of the nose downwards and outwards and back to the initiating points. Please ensure the oil does not enter into the infants' eyes or nose.
 - vi) After completing the sequence with the infant lying on the back (face up), gently place the infant in the prone position (face down/lying on the tummy) and repeat the body massage as above. Make sure the nose of the infant is placed properly and not obstructed.
 - vii) Back of Neck and shoulders – Neck massage should be done very gently with the thumbs in upward direction. Massage both shoulders simultaneously with strokes beginning from midline in the outward direction passing gently down the shoulders. Make sure the neck does not get twisted.
 - viii) Massage the back up to buttocks with relatively firm and long strokes.
 - ix) Massage the buttocks using both hands simultaneously with palms using circular movements.
 - x) Massage the back of the head beginning with circular movements beginning at the centre in clockwise manner.
2. After completing the massage in prone position, gently place the infant in supine position for movements of the extremities. For this perform passive flexion and extension movements of the large joints for about two seconds each – shoulders, elbows, hips, knees and ankles. These movements should be very gentle and short duration. Perform light exercise as below:
- i) In supine position, both upper extremities of the infant should be crossed over chest alternatively, with light pressure.
 - ii) In supine position, both legs should be folded at hip joint, over abdomen, not in cross position. This procedure expels abdominal gas through anus.

3. If the infant passes urine or stool during the massage, stop temporarily and can restart after cleaning and handwashing.
4. A massage session should be completed in 10 to 15 minutes; longer sessions are not recommended.
5. After completing the massage, the infant routine can be continued as usual. If the infant is to be bathed after oil massage, do not use cold water for bath. It is not recommended to instil oil in infant's ear or nose during massage.

5. Review question: What are the general cautions to be followed during oil massage to infants?

Recommended cautions:

1. Check fitness of baby, whether the baby is normal or not sick before starting oil massage
2. Generally, massage can be given to a baby appearing warm as usual, taking feeds and passing stools as usual, having no fever, no vomiting, no cold or no obvious breathing problems.
3. Avoid oil massage immediately after feeding.
4. Massage should ideally be given in the morning hours of the day, before bath as a routine.
5. If massage is to be repeated, the time before putting the baby to sleep at night is good choice.
6. Before selection of preferred oil for massage (sesame oil, coconut oil, sunflower seed oil, or any other which is considered safe for baby, a patch test is recommended to test for any possible reactions or allergies.
7. Prepare the place for massage by laying a clean and smooth piece of cotton cloth/sheet on a flat and slightly hard surface, such as a wooden surface topped with few cotton sheets layers. Do not use silky or slippery clothes. If a plastic sheet is being used, it should not be in direct touch with the infant skin.
8. Ideally the mother is considered the best person to perform infant massage as this helps both mother and the baby who is most comforted by mother's touch.
9. Ideally the same person should perform the massage routinely so that the infant is habituated to the touch from this person. Family members/parents performing the massage is useful to help develop bonding with the infant.
10. Hygiene, gentleness and feeling of security are important considerations in choosing a person to perform infant massage.
11. The caregiver performing the massage should wash their hands with soap and water and dry with a clean towel. Ensure the hands are not too cold before touching the infant, rubbing palms against each other helps warm the hands.
12. Avoid vigorous massage as it may harm the neonatal skin and muscles.
13. Avoid over-stretching of the limbs and joints.

14. Observe for Signs of baby enjoying massage e.g. happy vocal sounds like cooing, easy breathing pattern, bright eyed look, ability to focus and take in surroundings comfortably and enjoying stretching, sucking, clasping own hands or feet. Infants may sleep after massage.
15. Reddening of the skin or infant crying during the massage are signs that the technique or oil used is not appropriate.
16. Ideally, the caregiver should be trained in giving oil massage to the baby.
17. Check fitness of baby, whether the baby is normal or not sick before starting oil massage
18. Generally, massage can be given to a baby appearing warm as usual, taking feeds and passing stools as usual, having no fever, no vomiting, no cold or no obvious breathing problems.
19. Avoid oil massage immediately after feeding.
20. Massage should ideally be given in the morning hours of the day, before bath as a routine.
21. If massage is to be repeated, the time before putting the baby to sleep at night is good choice.
22. Before selection of preferred oil for massage (sesame oil, coconut oil, sunflower seed oil, or any other which is considered safe for baby, a patch test is recommended to test for any possible reactions or allergies.
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32. Ideally, the caregiver should be trained in giving oil massage to the baby.

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