COVID-19-specific clinical research using traditional medicine: lessons from traditional Chinese medicine for India's AYUSH systems

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Challenges of COVID-19

The global pandemic due to the novel coronavirus (SARS-CoV-2) leading to coronavirus disease 2019 (COVID-19) originated in China and was reported to the World Health Organization (WHO) on 3 January 2020 (refs 1, 2). The WHO declared this SARS-CoV-2 as a Public Health Emergency of International Concern (PHEIC) on 30 January 2020, and subsequently, as a pandemic on 11 March 2020, as it affected more than 100 countries[3]. In view of the significant morbidity and mortality associated with this pandemic, many research activities are ongoing globally to explore possible therapeutic regimens or prophylactic agents. Further, the scientific community has started repurposing existing drugs for SARS-CoV-2 (ref. 4). Also, options available from the whole group of traditional/complementary and alternative medicine are being explored worldwide. While leading the world with the battle against the virus, the People's Republic of China (PRC) also leads in the search for potential traditional medical systems through traditional Chinese medicine (TCM)[5].

After China, the Indian subcontinent has a rich heritage of traditional medicine. The Indian traditional medical systems are collectively referred to as AYUSH (as an acronym earlier it meant the medical systems of Ayurveda, Yoga, Naturopathy, Unani, Siddha and Sowa-Rigpa, and Homoeopathy). These systems are well-recognized and well-supported by the Government of India (GoI) through various plans and policies. The systems are governed by a Ministry of AYUSH, GoI[6]. During the pandemic due to the lack of any therapeutic or prophylactic modalities, India turned towards the AYUSH systems. In the past individually the AYUSH systems have reported to have contributed to outbreak conditions. For COVID-19, the Ministry of AYUSH, GoI, released several advisories/guidelines[7]. However, the research potential remains untapped.

Given the complexity of crisis and paucity of related research from AYUSH at this stage, we reviewed TCM's COVID-19 specific reactions and responses available from public domains (Government websites, medical research databases and media) to draw relevant lessons for India.

TCM response to COVID-19

Building on its long-historical tradition, the engagement of TCM for COVID-19 response was from the very beginning of the pandemic (Table 1). The Government of China initially developed a framework to combine the TCM and Western medicine to jointly respond to the pandemic[8]. The TCM physicians observed the clinical signs and symptoms, and its progression. Based on traditional principles, the TCM experts developed guidelines to treat the patients. The TCM treatment plan included multiple herbal prescriptions targeting fever, heavy coughing, loss of appetite, nausea, vomiting, diarrhoea, shortness of breath and tiredness[9].

A specific chapter detailing TCM treatment during a patient's medical observation, clinical treatment and recovery has been included in the latest version of the COVID-19 diagnosis and treatment scheme released by the National Health Commission of PRC. TCM contributed in improving a patient's physical condition and immune function, whereas bio modern medicine concentrated on the respiratory and circulatory life-saving assistance. This fetched good results in managing COVID-19 patients. Mild symptoms showed obvious improvement after TCM treatment, and for critical patients, TCM decreased their lung exudation, stabilized blood oxygen saturation and reduced respiratory support and antibiotic use. Wuhan's coronavirus control headquarters ordered integrated treatment of TCM and Western medicine,

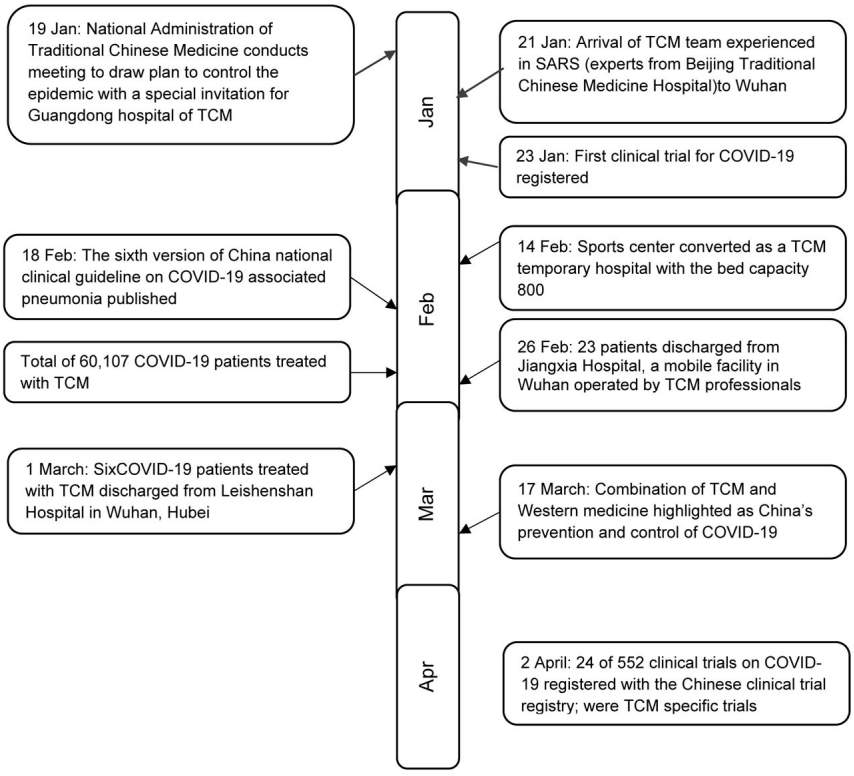

Table 1. Timeline of Traditional Chinese Medicine activities during COVID-19.

especially among non-critical patients, and observation of the curative effects of TCM at designated hospitals. TCM offered individualized treatment to the patients at different stages of the disease. More than 2220 TCM professionals from across the country were deputed to Wuhan to combat the epidemic. TCM was used in the treatment regimen of nearly 95% of the admitted patients. Among those discharged, over 90% underwent integrated treatment of TCM and Western medicine[10].

Apart from clinical care services to COVID-19 patients, government institutions, physicians and scientists initiated scientific research amidst the epidemic. The first clinical trial for COVID-19 was registered on 23 January 2020. In fact, one-third of the registered clinical trials on COVID-19 in the registry were that of TCM. As of 2 April 2020, 552 clinical trials were registered in the Chinese registry on COVID-19. Among them, 24 trials were registered under TCM[11].

In 2003, TCM played an important role in treating patients during the severe acute respiratory syndrome (SARS) outbreak[12]. Of the total SARS cases in the world, 58% were from the Chinese mainland. China extensively involved TCM during SARS. Building on such experience, PRC could engage TCM and formulate a plan in the immediate aftermath of the COVID-19 pandemic. In fact, historically, TCM has played a significant role in the control of communicable diseases in China. In 2016, PRC accorded equal status to TCM on par with Western medicine. This was in terms of ideological, legal, academic and practical applications. TCM has been included in the Chinese National Health Policy 2030 (ref. 13). China has successfully integrated TCM in the modern hospitals. Efforts were made to improve the system of administration related to TCM, increased financial input, formulation of specific policies, laws and regulations suited to the unique features of TCM, promotion of coordinated development of TCM and Western medicine. A platform was set up for TCM and Western medicine to complement each other[13].

In the COVID-19 context, amidst efforts to contain the pandemic, TCM has steered scientific research with rigour. Almost 30% of the clinical trials registered during January–March 2020 in the Chinese clinical trial registry were under standalone TCM interventions for COVID-19. Another 15% of the clinical trials were registered with TCM and Western medicine as integrative treatment for COVID-19 (ref. 11). The dividend sharing of TCM in registering clinical trials was high. The spirit of taking TCM to the scientific platform by conducting trials is a good lesson to all the countries with a rich heritage of traditional medical systems as a part of their healthcare. Sixteen national clinical research bases have been set up as part of the clinical research system for preventing and treating infectious diseases and chronic non-infectious diseases with TCM.

TCM has distinctive training schemes for professionals. Training has been designed as multi-dimensional education comprising integrative medicine, community health, conservation of traditional pharmacological skills and master apprenticeship[13].

Lessons for the AYUSH sector in India

Overall, the national status of AYUSH is increasingly becoming prominent, but not treated on par with that of Western medicine. The National Health Policy accords such status; however; ground-level realities are far from satisfactory. TCM status in PRC is something worth emulating in India.

The Indian policy recognizes medical pluralism and supports 'integration' of medical systems. However, in terms of practical implementation, except for 'co-location' in public sector facilities, 'integration' is yet to be fully realized[14]. Similar to TCM, AYUSH has been striving to achieve functional integration for a long time. Integrative medicine, as proposed in the policy documents, will help in appropriately distributing resources and addressing priority health conditions meaningfully.

In the context of research, AYUSH research has been limited to few clinical entities. The quality and quantity of such studies are insufficient[15]. India's AYUSH infrastructure for research and education has been well conceived and well supported. However, research output has to be commensurate with such investment. Interdisciplinary approach is the key for empowering AYUSH research. Collaborating with national-level medical, science and technology bodies is crucial towards achieving the same.

Initiatives such as the International Yoga Day highlighted the role of AYUSH in non-communicable diseases/ lifestyle disorders[16]. The COVID-19 pandemic has brought the focus back on AYUSH. As such the capacity of AYUSH in public health response has been limited and not fully explored, except in some settings. GoI has issued a number of advisories for the same. The Indian Prime Minister has called for evidence-based research in AYUSH for COVID-19. GoI has established 'interdisciplinary AYUSH Research and Development Task Force' towards COVID-19 response and to take the research forward[17]. We learn that more than 1000 research proposals on AYUSH interventions have been submitted in response to a call by this Task Force. TCM has shown the way right from SARS to COVID-19 in addressing public health challenges posed by any pandemic. It is time to convert the threat into an opportunity to collaborate and undertake interdisciplinary research with scientific rigour. Taking up AYUSH research in progressive way is the only option to take it to the international scientific community.

In the context of outbreak response, it is imperative that AYUSH professionals need clinical and public health-specific orientation and training around outbreak conditions. In fact, the Ministry of AYUSH, GoI has trained more than 3000 health professionals for COVID-19 surveillance and response. Taking clue from PRC's framework and early engagement of TCM is a model for AYUSH systems. AYUSH should aim to empower their professionals by incorporating integrative medicine, public health and professional development in their curriculum.

Beyond the current situation, these are ways and means to increase the contribution of AYUSH by making sure integration works, research delivers and public benefits at large. Such efforts can bring AYUSH closer to reality and thus create opportunities at times of public health emergency such as the current pandemic and therefore sustain during 'peaceful' times as well.

Finally, undertaking any interdisciplinary AYUSH research will be translated into good clinical practice as a positive outcome. AYUSH research outcomes will not only provide solution to the current COVID-19 problem, but also create an opportunity for managing any

potential outbreaks in the future. Even though, it is considered difficult to address the pandemic with AYUSH interventions at present, the efforts taken are worth in gaining knowledge. As the conduct of integrative clinical trials with AYUSH intervention is still uncertain, the Ministry of AYUSH, GoI has to make efforts to contribute in the management of COVID-19 through thoroughly scrutinized research proposals received by it.

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Connecting the unconnected: the way forward for public health to reach the unreached tribal communities in India

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India is home to more than 10.43 crore Scheduled Tribe (ST) people accounting for 8.6% of the country's total population. Among the 705 STs, 75 groups are categorized as particularly vulnerable tribal groups. The Government of India has a number of programmes and schemes for holistic development of the tribes. In spite of this, tribal health continues to be a major concern. Invariably, in every tribe there are traditional healer(s) who provide primary healthcare and also a medium to connect man with nature and the divine. However, till date there are no policies to recognize and acknowledge the services being provided by these healers for the community at large. This note envisages to draw attention to this critical policy gap which, if filled, could help in achieving universal health coverage for all, especially in tribal areas.

India is home to more than 104 million tribal people who comprise 705 different ethnic groups classified as Scheduled Tribes (STs) according to Article 342 of the Constitution of India[1]. The tribal population is in fact not a homogenous group[2]. Recent studies have shown that as a group STs fare much worse compared to non-STs in the country with respect to health outcome indicators[3]. The Government of India introduced affirmative provisions for the overall socio-economic development of this marginalized section of the society about seven decades ago soon after the independence. Even so, the concept of Tribal Sub Plan (TSP) was introduced about five decades ago to ensure that there is no dearth of funds for the holistic development of the tribes. In spite of all these efforts, tribal health remains a major concern even now.

Studies from across the globe, and not just in India, have shown that tribal groups have their own unique ways of defining health and disease, and also dealing with health issues[4]. Almost all these communities have traditional healers who provide the connect between man, and nature and the divine. There is no formal system of learning these practices and all these healers are carrying forward the traditional knowledge gathered over generations of habitation close to nature. Most importantly, it has been seen that the tribal people in India approach this traditional medicine man first when facing health issues[5], irrespective of their education level. However, when we evaluate the connect between traditional healers and the public health system, we find that it simply does not exist. In a country with such a huge tribal population, the public health system has so far failed to acknowledge the presence of this age-old system of healing which is still in vogue, especially in areas inhabited by these ethnic groups. The need of the hour is to integrate the traditional healers, known as *Gunia*, *Guni* or *Bhumka* in Baiga, Bhil and Bharia tribes