**Title: Public Health Ethics: AYUSH, Modern medicine and COVID-19 Pandemic**

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**Declarations:**

* The submission is not under consideration for publication in any other journal.
* We declare that we have no competing interests, financial or otherwise. We also declare the appointment of Dr Bhushan Patwardhan as the Chairman of the Interdisciplinary AYUSH Research and Development Task Force appointed by the Ministry of AYUSH. This is a non renumerative honorary position for national cause.
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**Abstract:**

The COVID-19 pandemic has posed several challenges to the Indian health care system. Here, we examine the situation in India considering the moral and ethical imperatives of decision making for public health. Currently, in the absence of proven therapies, empirical evidence is being used for treatment of COVID-19 disease. We find a dual standard of practice. Currently, only modern medicine (MM) therapies are used on empirical basis, however, the same principle is not considered for the use of AYUSH systems. Appropriate use of evidence is required. In the ethics context and in the interest of larger public good we suggest inclusion of simple and safe measures from AYUSH systems in the integrative protocols for prophylaxis and treatment of COVID-19.

**Public Health Ethics: AYUSH, Modern Medicine and COVID-19 Pandemic**

**Sarika Chaturvedi, Nandini Kumar, Girish Tillu, Sharad Deshpande and Bhushan Patwardhan**

The COVID-19 pandemic has compelled governments and medical fraternity to make hard choices for its prevention, control and management. The urgent need for decision making regarding treatment confronted with limited information available makes it difficult to balance common good with individual freedom and the need to contain its spread against economic losses. These choices ought to be guided by both, scientific knowledge and ethical considerations. In the wake of the Severe Acute Respiratory Syndrome (SARS), Middle East Respiratory Syndrome (MERS) and other epidemics, several agencies such as World Health Organisation (WHO)(1), Nuffield Council of Bioethics (2), European Commission(3), Human Health Services, USA(4) and United States Food and Drug Administration (5)have developed guidance for response in global health emergencies. Few independent frameworks to foster ethical decision making in times of crisis have also been developed (6). The WHO guidance on ethical considerations in developing a public health response to pandemic influenza recommends that policy makers should develop a process for setting priorities and promoting equitable access**(**7**).** It is also expected that ‘duty bearers’ should ensure that their decisions are transparent, fair, help in reducing suffering and treat all people as morally equals. Notably, WHO guidance mentions that the public is entitled to timely and accurate information on availability of drugs for prophylaxis, treatment, and other measures. Here, we examine the COVID-19 situation in India in the light of this international guidance.

The COVID-19 has posed several challenges to the Indian health care system. The number of cases and deaths is rising continuously, currently involving more than half of the 714 districts in the country(8). The world’s biggest lockdown happened in India first for 21 days, which has now been extended further to last 40 days in total. The necessity of the lockdown to ensure compliance to social distancing is resulting in huge economic loss and socio behavioural effects which may unravel in the near future. The resource poor health care system in India with persistent shortages of personnel and equipment, may not sustain for an emergency response required for management of COVID-19. The strategy and pattern of response in Western countries may not be feasible in India. Hence, effective prevention, early control and less resource intensive management are most essential for the Indian situation.

Current therapy for COVID-19 involves only symptomatic treatment, supportive care and prevention of complications, however, no specific drug or targeted intervention is available yet. The repurposed experimental drugs being recommended include hydroxychloroquine (HCQ), remdesivir, lopinavir/ritonavir, in combination with or without Interferon β 1a (WHO’s Solidarity trial)(9), experimental vaccine, convalescent plasma, manipulated cells and sometimes high dose steroids. These drugs except HCQ and steroids are very costly or involve complicated procedures of production and all of these could cause serious adverse events. Therefore, the best cost-effective strategy would be primary prevention by reducing exposure to the pathogen, controlling spread, arresting progress and enhancing individual immunity.

HCQ for COVID-19 prophylaxis is under investigation globally. The Indian Council of Medical Research (ICMR) has recommended its use in high-risk individuals including asymptomatic frontline health workers and asymptomatic household contacts of laboratory confirmed individuals (10)**.** In India, the prevention and treatment of COVID-19 has largely been restricted to modern medicine (MM) / biomedicine (BM) whereas, China has successfully integrated Traditional Chinese Medicine (TCM) in mainstream health care (11). Historically, India has followed a pluralistic system where the choice to select suitable treatment remains with the patients. Indian recognised traditional systems, namely, Ayurveda, Yoga and Naturopathy, Unani, Siddha, Sowa Rigpa and Homeopathy (AYUSH) are regulated by an independent Ministry. Each of these systems has its own education policy, standards for professional qualifications, registry of practitioners and research council.

Indian policy makers, since independence, have emphasized integrative approach involving traditional and modern medicine in preventive and curative services while the 2017 National Health Policy mentions mainstreaming AYUSH (12-14). Globally, integrative approaches for health are getting increasingly acceptable (15). However, in the context of COVID-19 epidemic in India, a freedom of choice is denied and patients are offered only MM treatment (16). Few exceptions are emerging such as States of Kerala, Goa and Gujarat that have boldly adopted integrative approach with reports of much higher success at prevention and control of COVID-19. The neglect of integrative approach is not merely pronounced, but is also contradictory to the nation's policy and to its pluralistic cultural foundation. AYUSH treatments have been kept out of the options available to COVID-19 patients. Besides, AYUSH human resource in public services have been deprived of opportunities to include these interventions and they are almost compelled to follow only MM-based guidelines. As yet there is no proven standard of care established for prophylaxis or treatment in MM for the new disease COVID-19. The current allopathic drugs are used solely on empirical basis. However, the same principle is not considered for the application of AYUSH systems. This dual standard of practice raises ethical considerations in advancing one particular therapy over the other and therefore deserves to be examined and revised.

Ayurveda recommends local and systemic prophylaxis measures for respiratory diseases that may be beneficial in COVID-19 prevention. These include medicated water, mouth rinse and gargle, steam inhalation, nasal oil application and use of Rasayana as immune strengthening therapy. Reasonably good empirical evidence is available for these measures. Also, there are some age-old traditional practices in popular use. Our argument for the inclusion of these as public health measures for COVID-19 prophylaxis has garnered international attention(17). Respecting person’s autonomy is an ethical principle giving freedom to a person to voluntarily choose a treatment. The person’s preference should be respected by giving the relevant details about available evidence from the prevalent systems of medicine. Depriving any person to choose among available alternatives is unethical. Use of non-pharmacological approaches such as psycho-neuro-immunity for COVID-19 prophylaxis that includes diet, sleep and immunity boosting is gaining attention (18). Similar approaches are well described in Ayurveda, Yoga, Unani, Siddha and Sowa Rigpa systems. However, despite supportive evidence of practice in India, these measures are not integrated with prophylaxis and management of COVID-19. The AYUSH Ministry has released its independent advisory to people for selfcare measures, which has received enthusiastic response from people (19).

The Ayurvedic Rasayanas are known for immuno modulation and rejuvenation properties, which are important in COVID-19 management. Several *in vitro*, animal and clinical studies have demonstrated the immunomodulatory effects of the Rasayana drugs such as Ashwagandha (*Withania somnifera*), Guduchi (*Tinospora cordifoloia*), Amalaki (*Emblica officinale*) among many others (20,21). We believe there is enough evidence of immunomodulation property of Ayurvedic Rasayana especially Ashwagandha and Guduchi and therefore, they are strong candidates for use in COVID-19 prophylaxis and management. Few classical formulations such as Sudarshanghanavati are used as safer symptomatic measures for conditions such as coryza and fever. Despite such empirical evidence, these interventions have not been considered for clinical use. From a moral standpoint, the dangers of not attending to evidence are no less significant than ethical issues in its application.

The National Taskforce on COVID-19 constituted by the Indian Council of Medical Research (ICMR) has recommended a protocol for use of HCQ as prophylaxis of for protection of high-risk individuals against COVID-19. The Drug Controller General of India has approved this protocol for restricted use under emergency situation (22). It is important to note that the decision to use HCQ in COVID-19 patients lacks any proof of concept and pharmacokinetic study in the same context. This means that there is no sufficient evidence to recommend HCQ for COVID-19 prophylaxis. Interestingly, in a well-controlled study in rheumatoid arthritis, clinical efficacy of HCQ was found to be equivalent to Ashwagandha formulation (23). Another study has reported that Chloroquine was no better than analgesic in the treatment of Chikungunya (24). Several recent articles in scientific journals have raised questions regarding use of HCQ as prophylaxis in COVID-19(25). Moreover, ICMR guidelines do not prescribe anything regarding what is to be done by the high-risk individuals after the prescribed 7-week treatment. It will be scientifically incorrect to assume that they will be protected beyond this period. It will also be ethically incorrect to leave them to their own fate after this period in the light of re-infection reported in a patient in India.

The omission of using AYUSH modalities is possibly due to the deep-rooted neglect of Indian systems of medicine(26) which in the current pandemic may result in huge societal costs. While there is a moral obligation to use scare resources for the largest good, we are currently witnessing a clear ignorance or avoidance to recognize empirical evidence of Ayurveda Rasayana and other AYUSH measures. This neglect is not in favour of people nor science and is not ethical.

Tying ethical analysis with empirical evidence is important for policy decisions. Norman Daniels, in his framework for priority setting argues that decision making process of policy makers should be accountable for the reasonableness of their decisions which are expected to be fair and transparent(27). Procedural conditions to guarantee fair decisions recommended in public health ethics include transparency (*publicity condition*), reasonable explanation (*relevance condition*), and openness for revision (*revision and appeals condition*) in addition to adherence to regulation (*regulative condition*). On this premise, the decision not to include evidence from Indian AYUSH systems in the search for solutions and management of COVID-19 seems unreasonable and unfair.

In proposing a framework for decision making in public health, Tannahill proposes that while there is a ‘moral imperative’ for evidence-based medicine, an ‘ethical imperative’ for public health with implications for accountability is to use available evidence ‘appropriately to inform judgements’(28). However, it appears that with the dominance of the MM/BM, the search for effectiveness evidence is skewed towards interventions relating only to MM/BM. Appropriate use of available evidence calls for breaking silos of medical systems and making decisions in the spirit of public health gains. Agreeably, every medical system should strictly adhere to principles of quality, safety, science and ethics.

The Ministry of AYUSH is making serious efforts to promote a culture of collaboration without losing basic principles of respective systems. The establishment of Interdisciplinary AYUSH Research and Development Taskforce on COVID-19 is a positive step in this direction. Appropriate exploration of AYUSH systems of medicine for solutions to COVID-19 is needed as failure at this juncture is bound to cost society and science dearly. Opportunity to undo the unfair decisions and to open doors to evidence from AYUSH systems is not yet lost. Actively promoting the Ayurveda drugs and Yoga interventions showing empirical evidence might benefit more with minimal potential for harm. Agreeably, more research is needed to confirm this, however, in exceptional situation of COVID-19, use of these safer options need to be adopted. There is sufficient rationale, pre-clinical data, and evidence of safety from long-time clinical use for common indications. This can justify urgent need for systematic clinical research in patients with COVID-19. While intensive care should be left to super specialists from MM, AYUSH doctors should have access to mild to moderate cases of COVID-19 patients. AYUSH doctors should be allowed to work with allopathic doctors under a national level integrative protocol for effective management of COVID-19. The clinical use should either be as per the Monitored Emergency Use of Unregistered Interventions (MEURI) framework by the WHO or should be based on strong ethical ground (29).

Adhering to scientific standards, integrating simple and safe measures from AYUSH systems in the protocols for prophylaxis and treatment of early stages of COVID-19 is reasonable and fair in the interest of larger public good. Urgent action for such integration would be justified.

**References:**

1. World Health Organization. Guidance For Managing Ethical Issues In Infectious Disease Outbreaks; 2016
2. Nuffield Council on Bioethics. Research in global health emergencies: Ethical issues. Nuffield Council on Bioethics; 2020.
3. European Union. Guidance on the Management of Clinical Trials during the COVID-19 (Coronavirus) pandemic; March 2020.
4. Human Health Services. OHRP Guidance on COVID-19. April 2020
5. United States Food and Drug Administration. The State of US Public Health Bio-preparedness: Responding to Biological Attacks, Pandemics an demerging Infectious Disease Outbreaks. USFDA Available at https://www.fda.gov/news-events/congressional-testimony/state-us-public-health-biopreparedness-responding-biological-attacks-pandemics-and-emerging Accessed 21 April 2020
6. Thompson AK, Faith K, Gibson JL, Upshur RE. Pandemic influenza preparedness: an ethical framework to guide decision-making. BMC medical ethics. 2006 Dec;7(1):12.
7. World Health Organization. Ethical considerations in developing a public health response to pandemic influenza. Geneva: World Health Organization; 2007.
8. Ministry of Health and Family Welfare, Government of India, New Delhi.COVID-19 India Updates Available at https://www.mohfw.gov.in/ Accessed 21 April 2020
9. World Health Organisation. WHO SOLIDARITY Clinical trial for COVID 19 treatments. Available at https://www.who.int/solidarity-clinical-trial-for-covid-19-treatments Accessed 21 April 2020
10. Indian Council of Medical Research. Recommedation for empiric use of Hydroxychloroquin for prophylaxis of SARS-Cov 2 infection. phx https://icmr.nic.in/sites/default/files/upload\_documents/HCQ\_Recommendation\_22March\_final\_MM\_V2.pdf Accessed 21 April 2020
11. National Health Commission of the People’s Republic of China. Guideline on diagnosis and treatment of COVID-19 (Trial 6th edition). [http://en.nhc.gov.cn/2020-03/29/c\_78468.htm](about:blank)
12. Ministry of Health and Family Welfare. National Health Policy 1993.New Delhi: Government of India;1993.
13. Ministry of Health and Family Welfare. National Health Policy 2002.New Delhi: Government of India;2002.
14. Ministry of Health and Family Welfare. National Health Policy 2017.New Delhi: Government of India;2017.
15. Patwardhan B, Mutalik G, Tillu G. Integrative approaches for health: Biomedical research, Ayurveda and Yoga. Academic Press; 2015.
16. Ministry of Health and Family Welfare. Government of India. New Delhi. Guidelines on Clinical Management of COVID-19. Available at https://www.mohfw.gov.in/pdf/GuidelinesonClinicalManagementofCOVID1912020.pdf Accessed 21 April 2020
17. Tillu G, Chaturvedi S, Chopra A, Patwardhan B. Public Health Approach of Ayurveda and Yoga for COVID-19 prophylaxis. Journal Alternative and Complementary Medicine. https://doi.org/10.1089/acm.2020.0129
18. Kim SW, Su KP. Using psychoneuroimmunity against COVID-19. Brain, Behaviour and Immunity. https://doi.org/10.1016/j.bbi.2020.03.025
19. Ministry of AYUSH. Ayurveda’s immunity boosting measures for self care during COVID19 crisis.Available at [https://www.mohfw.gov.in/pdf/ImmunityBoostingAYUSHAdvisory.pdf](about:blank) Accessed 22 April 2020
20. Balasubramani SP, Venkatasubramanian P, Kukkupuni SK, Patwardhan B. Plant-based Rasayana drugs from Ayurveda. Chin J Integr Med. 2011;17(2):88-94.
21. Agarwal R, Diwanay S, Patki P, et al. Studies on immunomodulatory activity of *Withania somnifera* (Ashwagandha) extracts in experimental immune inflammation. J. Ethnopharmacol.1999;67: 27–35.
22. Ministry of Health and Family Welfare. Government of India.New Delhi.Advisory on the use of hydroxychloroquine as prophylaxis for SARS Cov2 infection. Available at [https://www.mohfw.gov.in/pdf/AdvisoryontheuseofHydroxychloroquinasprophylaxisforSARSCoV2infection.pdf.](about:blank)  Accessed 22 April2020.
23. Chopra A, Saluja M, Tillu G, et al. Comparable efﬁcacy of standardized Ayurveda formulation and hydroxychloroquine sulfate (HCQS) in the treatment of rheumatoid arthritis (RA): a randomized investigator-blind controlled study. Clin Rheumatol 2012;31:259–269.
24. Chopra A, Saluja M, Venugopalan A. Effectiveness of chloroquine and inflammatory cytokine response in patients with early persistent musculoskeletal pain and arthritis following chikungunya virus infection. Arthritis & Rheumatology. 2014 Feb;66(2):319-26.
25. Rathi S, Ish P, Kalantri A, Kalantri S. Hydroxychloroquine prophylaxis for COVID-19 contacts in India. The Lancet Infectious Diseases. 2020 Apr 17. [https://doi.org/10.1016/S1473-3099(20)30313-3](about:blank)
26. Bodeker G, Kronenberg F. A public health agenda for traditional, complementary, and alternative medicine. American journal of public health. 2002;92(10):1582-91.
27. Daniel N. Accountability for reasonableness. BMJ 2000,321:1300-1301.
28. Tannahill A. Beyond evidence—to ethics: a decision-making framework for health promotion, public health and health improvement. Health Promotion International. 2008:23(4):380-90.
29. World Health Organisation. Notes for the record: Consultation on Monitored Emergency Use of Unregistered and Investigational Interventions for Ebola Virus Disease (EVD)". World Health Organization. 17 May 2018. Accessed 21 April 2020.