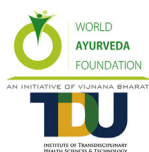




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Discussion Kernel

How do we dynamically evolve AYUSH COVID-19 guidelines in real-time to further empower people and *Vaidyas*?

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ABSTRACT

The crisis of the second wave of COVID-19 in India is anticipated to peak over the next few weeks, stressing the healthcare system further. India has the unique strength of AYUSH with access to safe traditional medications, certain scientifically validated interventions, a highly skilled resource pool of nationwide vaidyas who are willing to engage with its leadership. The excellent foundations laid for COVID-19 response by AYUSH can be further developed to empower people and the vaidyas. The current guidelines are based on classical references, biological plausibility and scientific studies done in a conventional mode. It is now an opportune time to document clinical observations, identify symptom specific interventions and engage with mainstream management to evolve Integrative Ayurveda guidelines for COVID-19 management. This article discusses the premise and the details of the next steps. There is a hope that a conducive environment created by AYUSH will alter the landscape of Integrative Medicine and health in India, inspiring global health practices.

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As the second wave in India recedes, the Government is bracing itself for the third wave. The current healthcare crisis was precipitated and aggravated by many factors – regulatory, disaster management, community behavioral practices, and people's uninformed and fear-driven health-seeking. In this setting, the activation of centralized healthcare delivery machinery from India's traditional medicine systems viz., Ayurveda, Yoga and Naturopathy, Unani, Siddha, and Homeopathy (AYUSH) has been unprecedented and historical [1]. As the systems have rapidly evolved to tackle the second wave and prevent the third wave, responsive national public and practitioner guidelines can continue to make a major impact.

AYUSH in India has done a good job in making informed recommendations from a 'disease perspective'.

1. Investigating the role of AYUSH-64, showing its safety and efficacy in mild-to-moderate management of COVID-19 [2].
2. The rigorous scientific investigation of the role of *Withania somnifera* (Ashwagandha) for COVID-19 is exemplary, and has been summarized in a recent review article [3].

3. Structuring the protocol for COVID -19 management for people's use [4].
4. Collecting traditional references for Ayurvedic physicians to consider in various stages of the disease [5]. These suggestions have been based on classical references, biological plausibility, and ongoing clinical studies.
5. The AYUSH Sanjivani app is also a progressive tool impacting point-of-care by current guidelines.

It is now time to accommodate signals from the patient-context and *Vaidya* perspective in the COVID-19 guidelines. It will be a game-changer if we can generate feedback loops from these signals for informed public health integration and refined clinical decision-making support. As next steps towards this, I have identified some important and feasible starting points to consider; first for the general public, and second for the practitioners.

1. Empowering people further by additions and refinements to protocol for people's use [4]

1.1. Suggested additions

1. Summaries from published case reports can be contextualized for usage in mild, moderate or severe conditions [6–8].

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2. Home remedies for specific clinical symptom-management at home can have more traditional Ayurvedic nuances like *dosha avastha*.
3. Recommendations of easily accessible – classical formulations for symptom management which can be bought over-the-counter.
4. Informed statements of herb–drug interactions on high-risk scenarios occurring due to co-administration with conventional medicine. For example, should we have recommendations to reduce garlic with aspirin consumption, or eliminate licorice if there are any specific corticosteroids prescribed? These can be based on pharmacodynamic and pharmacokinetic understanding. There can be caution statements for these herbs as people self-administer these often.
5. Opinion if AYUSH-64 and paracetamol can be taken together? Classical Ayurveda recommends to not take anti-pyretics prematurely. There is enough field experience where *Vaidyas* have successfully managed COVID cases despite no anti-pyretics and used it judiciously as the protective response intended by the body. Can we educate the people about this?

1.2. Suggested refinements

1. Replacing the Sanskrit and Latin names of vegetables with photographs.
2. Priority status for all the suggestions is crucial because not everyone can do everything. The exhaustive lists are daunting for people dealing with the disease.
3. *Mahasudarshana ghanvati* has been successfully used by *Vaidyas* all over India for a long time as a first-line in fevers. It can be safely given at home for the mild-moderate COVID-19 management. While AYUSH-64 has been studied for the same purpose, yet its availability does not seem to be as widespread as *Mahasudarshana ghanvati*. It can be highlighted as an accessible alternative to AYUSH-64 as there is also an overlap of some medicinal plants in both.

2. Empowering *Vaidyas*

Vaidyas are also unsung frontline health-workers who are functioning without much systemic support to implement all the protocols. They are changing life trajectories, one person at a time and doing their best amid multiple responsibilities, often single-handedly. They are also the most unique strength of India's healthcare. As the modern world attempts to outsource health to marketable products and technology, these *Vaidyas* offer an informed, supportive voice to the patients and people. Supporting *Vaidyas* and developing their potential will allow India to continue to be a leader in Integrative Health in the times to come.

There are three aspects to consider to empower *Vaidyas* – enhance their clinical effectiveness, identify and plug therapeutic gaps, provide skilled support for critical management with *rasaushadhies* and other plant-based formulations.

2.1. Enhancing clinical effectiveness

Currently, the COVID-19 guidelines for Ayurvedic practitioners [2] are derived from Ayurvedic *samprapti vighatana* based on disease manifestations that occurred in 2020. While this is a great start, it does not necessarily reflect the on-ground symptomatology and disease course especially in the second wave. The immediate need is to inform *Vaidyas* of clinical signals and success from other *Vaidyas*.

- a. **Acknowledging and supporting clinical signal generation:** Some clinical observations occurring in the practices of *Vaidyas* can potentially change the course of lives. For example, a published case report had shown that the sublingual application of *apamarga kshara* increased SpO₂ [8]. Is this effect real and replicable? How do we support *Vaidyas* making such observations real-time? There are many Ayurvedic clinical softwares available and developed in the last decade. These can be quickly assessed without bias to identify the best available candidate to further fortify the observations. Can we create systems and have trained interns acting as virtual assistants supporting the *Vaidyas*?
- b. **Further assessment and development of clinical signals:** While the finer aspects can evolve and develop with time, an immediate commitment can be made for an AYUSH – led space for the new world. There can be a webinar series of *Vaidyas* who seem to have a good experience with COVID-19 management by now. This would be presented to an expert panel which in turn can filter information to the public with a gradation for the 'levels of clinical experience'. This can be developed akin to levels of clinical evidence [9]. It can be a foundation to design further studies with most clinical beneficial leads. Observational therapeutics is one of the approaches that can be adopted to identify signals from the noise [10]. The *Vaidyas* can be rewarded with a promise of public acknowledgement, or royalty or IPR benefits depending on the stage the lead would develop into.
- c. **Planning clinical studies for signals with high 'level of experience':** There are many Ayurveda institutions with COVID patients in their fever clinic and isolation. Research protocols which take into consideration Ayurvedic parameters can be developed for those leads. A fortified signal can then be implemented in nationwide multicentric trials with a large sample size. The robust outcomes can be incorporated in the guidelines, and capacity building can be done for implementation. Mechanisms for field data can be in place upfront to make this a continuous loop with enhanced and diversified applications (Fig. 1).

From a classical Ayurveda standpoint, a fine-tuned classification of *lakshana-samprapti* (like cough being segregated as *kaphaja* or *vaataja*) in a language understandable by the public is important. Traditional *Vaidyas* use this regularly in their practice and it must reflect in the guidelines so its rational for a *Vaidya* to make his/her clinical decisions. The documentation of outcomes must reflect this nuanced nomenclature.

2.2. Identification of therapeutic gaps from mainstream management

Co-morbid conditions are an inadvertent reality to navigate at the clinics. Let us take the example of diabetes. AYUSH guidelines currently suggest Ayurvedic known anti-diabetics for supportive management. However, the intention is not to treat diabetes as much as to safely navigate it while resolving COVID-19. The guidelines must reflect that using modern understanding of diabetes and nature of herbs and foods.

A clinical problem that was reported as a signal in the first few days of May 2021 was the incidence of mucormycosis [11] in uncontrolled diabetics who needed to take steroids during COVID-19 infection. In such cases, what should be the Ayurvedic formulation, nutrition, and herb advice? These are the therapeutic gaps we can quickly help address systematically with expert teams of diabetologists, nutritionists and *Vaidyas*.

Preparation of a list of such therapeutic gaps by clinical observations is the need of the hour. Asking the conventional medicine doctors of their clinical management challenges can help in

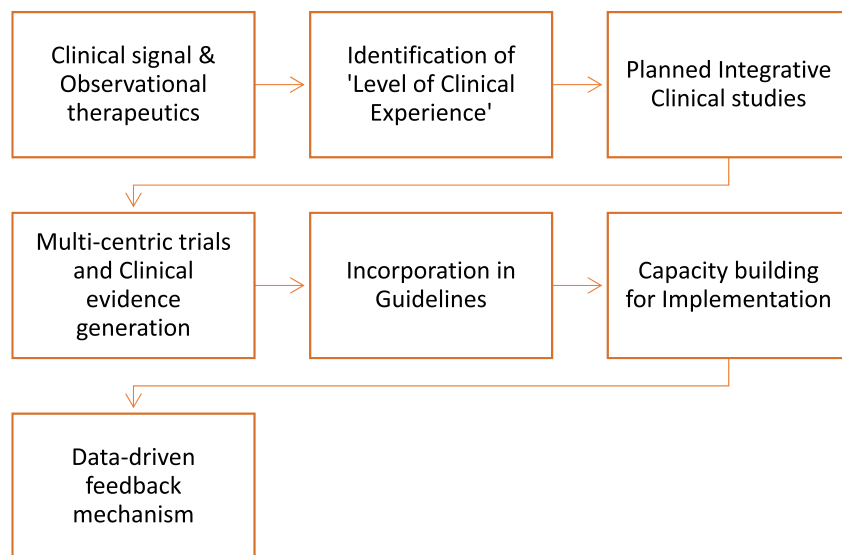


Fig. 1. Process of clinical signal to large-scale implementation for COVID-19 (and other medical conditions).

fostering connection and support to that community working tirelessly.

Meanwhile, conventional medicine has platforms like UptoDate for evidence-based clinical-decision with the latest studies about the disease manifestations and consequences, treatment avenues with safety, pathological hypothesis and even patient education resources. Can we create this for integrative Ayurveda management for one disease – COVID-19? This will need new thought processes for data collection and statistical interpretation, whose premise exists even in the mainstream conversation on statistics [12], and publications in J-AIM by Somik Raha [13]. I have had consistent discussions on 'Ayurvedic statistics' with Dr. Ashok Vaidya, a leading clinical pharmacologist committed to Ayurveda research for five decades. Dr. Mohan Kale has also made foundational contributions in this field and a brainstorming meeting for evidence methods in clinical Ayurveda is an urgent need of the hour. I have also summarized some of these in a talk on 'New directions for Ayurveda Research: Vision 2030' delivered last Oct 2020 for Council for Ayurveda Research, United States.

2.3. Role of *rasaushadhis* (Herbo-mineral preparations)

Rasaushadhis are designed for effectiveness, especially in dire circumstances. While they are full of controversies due to heavy metal toxicities, they also have demonstrated significant clinical effectiveness. Not all *rasaushadhis* have the heavy metals – lead, arsenic and mercury. They can be formulated with minerals like *abhraka* (mica), *tankana* (borax), *makshika* (ferrous sulphate) and safer metals like *vanga* (tin), *suvarna* (gold), and *tamra* (copper). Can these be studied to improve the clinical outcomes in moderate and severe disease states? Simple questions can be asked to design clinical studies and run outcome trials in unison all over the nation, for these and also herbal preparations. Strategic templates to assess these outcomes can be quickly designed and disseminated with the use of the technology in our strengthened infrastructure. We can quickly get excellent initial data for the well-chosen formulations in this manner. Recommendations for AYUSH-accredited companies to source these from and information on how to monitor response will be tremendously

useful. Implementation can be guided with the help-lines setup by AYUSH.

An objectively prepared guide of these with dosing, duration, and clear short-term use case scenario needs to be developed. Stratification of evidence levels – as peer experience, case report, clinical outcome studies, and formal clinical trials can be used to inform the public and health professionals.

3. In conclusion

AYUSH has risen to the challenge of COVID-19 commendably in the past year, against many odds to effectively inform the public, control the mushrooming of products with tall claims and embark upon a true integration at least within the Ayurveda, Yoga, Siddha systems. It is now time to enhance the internal offerings, and externally integrate with the mainstream – medicine and nutritional professions through people-centric, contextual solutions beginning with public health and education [14].

Learning how to work respectfully with mainstream practitioners for patient benefit is an important attitude and skill we need to hone for the future. Reasonability, humility, and mutual respect on both sides of the conversation will change the landscape of India's future health. Historically, there has never been a more opportune time to break walls, look within, hold hands, be vulnerable and strong together to face the future.

Our response can be the foundation for AYUSH to guide not just India but also the world in the future. As Ayurveda rises as a profession in the Western world, it looks to India for guidance. We have the opportunity to change the future as we can rise as 'humanity-united' to respond to the second and potentially a third wave of COVID-19 and beyond

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Conflict of interest

None.

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