As we are gripped in the midst of the crisis, the COVID 19 pandemic has emerged as a major threat to the public health. This pandemic’s onslaught on the health systems has raised multifaceted and unprecedented ethical challenges in terms of saving human lives, at the same time, addressing the desperate need for interventions of various kinds to reduce morbidity and mortality. With the absence of any specific treatment or vaccine available, and potentially little known illness pattern caused by coronavirus, has created quite a panic among public and posed a daunting task for physicians, health-care providers, policy makers, and the government to contain the pandemic.

According to the Clinical Trial Registry of India, around 300 clinical studies are being conducted on COVID 19 with 39 among them being randomized control trials. About three quarters of them involve alternative or complimentary medicine. Others, majorly being observational studies, case series or case reports involving Ayurveda, Unani, and Siddha. What concerns the most is the ethics involved in conducting such researches, types of trials being conducted, specialized research techniques being used, and implications of such researches once it reaches the public domain, where it is met with such hue and cry, less subject to analysis, much to the jubilation of social media and press conferences, which is just not scientific.

Right now, there is a hunt for a “Drug.” A drug which is safe with proven benefits, free from unfavorable side effects and applicable in real world setting. A rationale needs to be observed which meets the criteria of “hierarchy of evidence.” At the bottom of which lies our ideas, opinions, beliefs, idiosyncrasies, our own biases which we carry in our clinical practices, quote or unquote some interesting cases, in form of case reports and case series. Then, the retrospective (case–control) and prospective (cohort) studies and the apex lies the randomized control trials. The descriptive studies cannot be relied on due to the absence of any comparison group in which the relationship between intervention and outcome does not stand clinically meaningful. Hence, RCT design only, can provide a clear, robust evidence about any intervention/ drug with its potential risk or benefits, where it specifies the endpoints, sample size, reduces bias by randomization, and double blinding.

While RCT holds the key in terms of therapeutic trials, where the patients are the subjects primarily while in case of vaccine trials, ethical concerns are raised a bit more as it involves healthy population and predominantly the vulnerable strata, that is, children, elderly (as in the current pandemic).

In a pursuit to develop vaccine against COVID 19 at the earliest, many pharmaceutical companies have flocked for market captivity. Over a dozen clinical trials are going on across the globe, with governments of various countries investing in vaccine trials, the whole issue has become somewhat politicized. However, little heed has been paid in noticing the obstacles, otherwise might face, in developing the COVID 19 vaccine. Certain factors need to be explored, which may go unaddressed in this mad rush for developing the vaccine. As this pathogen holds a lot of public health importance, so animal models are unlikely to be included. An array of vaccines is under clinical trials, which aims to expose the body to an antigen that will not cause the disease but will provoke immune response that can block the virus if the person becomes infected. Following the vaccine trials, biggest concern is unpredictability of long-term sequelae or persistent infection. The spectrum of diseases related to COVID 19 has not been deciphered, whether the infection will take similar course or adopt any different route. An attenuated version of COVID 19 is still not as much controlled, to be considered harmless. Dose specifications in terms of viral load required for successful challenge is unpredictable, and so is the illness pattern which is not only confined to lungs, but can cause much wider damage to various organs such as kidneys, liver, heart, and brain. Much added lack of discernment is linked to its various genomes and multiple strains rendering the virus unstable and subject to mutation; hence, the sensitivity of the treatment is deeply affected. On the other hand, where people are volunteering themselves for trials, the consent process requires high level of comprehension and seeks trial transparency, and not mere sacrifice in terms of serving the humanity, which may face a severe backlash if something goes wrong. The issue treads on fine line of intentional human harm and is deeply concerned with erosion of trust among people.
Another disheartening issue that has come forth us is the hurdle that comes in the way of affordable access to proven treatment. In such a catastrophic time, where the unsurely looms over treatment measures, the drug which is of said advantages over the disease is available at exorbitant prices, making it impossible for the poor and destitute. Following post-trial access, drugs which are made patented by the pharmaceutical companies, at the same time, gain emergency approval in the pandemic control. With potentially no government policies to regulate prices and no revoking over the patents results in skyrocketing of the drug prices in such testing times of the pandemic.

The need of the hour is the equitable access of treatment and vaccine to the community, while encouraging community engagement for support at levels of implementation and execution. Furthermore, the policies of the government need to be framed in such a manner which ensures more transparency on researches being conducted and data availability of trials on public domain. The purpose is not to simply launch a vaccine but to instill faith in the efficacy of the vaccine in long run. Furthermore, the affordability of drugs, needs to be prioritized which are lifesaving and gained emergency approval by placing cap on the prices of drugs irrespective of their patented status, through TRIPS flexibility and Doha Declaration. A channelized outlook can only clear the cluttered perceptions which are prevailing in the face of global emergencies in order to address the demands of our research infrastructure.

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