

INDIAN SOCIETY FOR LEGAL AFFAIRS

न हि ज्ञानेन सदृशम् पवित्रम् इह विद्यते

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To
Dr. Harsh Vardhan
Hon'ble Minister of Health and Family Welfare
Government of India

&

Dr. Ravi Shankar Prasad Hon'ble Minister of Communications, Electronics & Information Technology and Law & Justice Government of India

Sub: Rationing of Scarce Medical Resources during CoVID-19 outbreak

Dear Sir,

- I. This is in reference to the absence of regulations or guidelines for allocation of scarce medical resources, during a public health emergency. CoVID-19 has compelled India and other countries to shore up their response in preventing the spread of the outbreak. Through various preparedness and mitigation measures, India has displayed a strong sense of responsibility and commitment towards saving the lives of millions of Indians.
- II. However, there is one issue that should be urgently addressed by Government of India pertaining to rationing of scarce medical care infrastructure. Evidence emerging from several countries shows that health care infrastructure required to deal with the pandemic exceeds the available resources. For instance, due to shortage of ventilators and intensive care units, doctors in Italy have been forced to make some heart wrenching decisions on who lives and who dies. Known as triage, these evaluations bear numerous ethical and legal considerations and many jurisdictions have already published guidelines to help doctors and hospitals in allocating scarce medical resources in the midst of a pandemic.
- III. Many countries, including the UK, Italy, US, have already published guidelines to help doctors and hospitals in allocating scarce medical resources in the midst of a pandemic. These guidelines ensure the most efficient and humane

- redistribution of resources among patients while eliminating individualist and personal preferences of hospitals in making critical triage evaluations.
- IV. In India, there are no official rules or regulations to deal with a situation of public health emergency where hospitals and doctors have clear and precise instructions to deal with a situation where triage decisions have to be made.
- V. The Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002 promulgated by the Medical Council of India provide no guidance to hospitals and doctors on the subject. Chapter 2 of the Regulations, dealing with the duties of a physician, is patient centric focus of clinical health in ordinary circumstances. These regulations do not deal with public health emergencies where health care professionals will have to prioritize community health over individual health.
- VI. It is, therefore, extremely urgent and necessary that Board of Governors under the Medical Council of India Act 1956 makes appropriate regulations laying down comprehensive regulations dealing with the ethical duties of hospitals and doctors during a public health emergency where swift life saving interventions are necessary for reducing both mortality and morbidity.
- VII. Based on the recent global best practices, there are few broad considerations that should be borne in mind in making these regulations:
- Maximization of Scarce Resources: In any public health care emergency, 1) the central focus should be on most efficient utilization of scarce resources. A severe respiratory illness such as COVID-19 can require ventilator or ECMO support for critically ill patients in an intensive care unit, with ongoing monitoring by respiratory technicians and critical-care nurses. An unexpected rise in the number of infected patients in need of critical care might occupy available resources in a very short span of time. In these circumstances, where paucity and shortage in resources is likely, it is essential to prioritize limited resources that should aim both at saving the most lives and at maximizing improvements in individuals' post-treatment length of life. Saving more lives and more years of life is a consensus value across expert reports. Therefore, patients with greater life expectancy should be given more preference in allocation of scarce medical resources. This approach has been endorsed by the Advisory Committee to the Director of the Centre of Disease Control which recommends that principle of sickest first for critical care may

¹ Ethical Framework for Health Care Institutions Responding to Novel Coronavirus SARS-CoV-2 (COVID-19): Guidelines for Institutional Ethics Services Responding to COVID-19, available at https://snlg.iss.it/wp-content/uploads/2020/03/AA-Hastings-Center-Covid-Framework-2020.pdf.

² Zucker H, Adler K, Berens D, et al., *Ventilator allocation guidelines*. Albany: New York State Department of Health Task Force on Life and the Law, November 2015 available at https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf.

not apply during a pandemic because it might ultimately lead to utilization of resources by those who are too sick to survive.³

However, in making these assessments, the future quality of life (*emphasis supplied*) of the patient should be an incidental objective that should assume relevance only when choosing between two patients with the same prognosis. Further, in case of a tie, ethicists recommend using a lottery system instead of a first-come-first-serve approach that might disadvantage those who fell sick later in time, or do not have immediate access to dedicated hospitals for CoVID-19. A lottery-based framework is more ideal as it would eliminate structural inequalities faced by patients on account of race, religion, language and financial status. In this respect the World Health Organisation has stated that *equity demands special attention should be given to individuals and groups that are the most vulnerable to discrimination, stigmatization, or isolation.*⁴

It would be highly recommended that consent forms signed by patients admitted into ICU or in need of a ventilator incorporate the possibility of removal from the ICU or withdrawal of ventilator at the time of admission. This would prevent doctors and healthcare professionals from wanton litigations relating to professional liability and criminal negligence.

- 2) Alternative medical support: Patients who do not respond to ventilator support or ICU treatment over time may have these treatments withdrawn. This implies that the patient has abysmally low chances of surviving even with continued access to critical care. In such a scenario, patients who do not meet the conditions required for receiving ventilator support or ICU treatment will be administered palliative care i.e. pain control and comfort measures. The same standard should also apply to patients who are eligible for ventilator support or ICU treatment but cannot be so provided due to shortage of resources.
- 3) Establishment of expert committees of triage officers: Medical Ethicists have been advocating that tough choice of allocating of resources to a patient in the times of a pandemic should be taken away from the frontline clinicians. The type of triage required in these times of resource scarcity is challenging

³ Ethical Considerations for Decision Making Regarding Allocation of Mechanical Ventilators during a severe pandemic or other public health emergency, Centers for Disease Control and Prevention, USA, Page 9. Available at https://www.cdc.gov/od/science/integrity/phethics/docs/Vent Document Final Version.pdf

⁴ WHO, Guidance For Managing Ethical Issues In Infectious Disease Outbreaks, available at https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

⁵ New York State Task Force on Life & the Law New York State Department of Health, *Ventilator Allocation Guidelines* available at https://www.health.ny.gov/regulations/task_force/reports_publications/docs/ventilator_guidelines.pdf

both clinically and psychologically. Making decisions about whom to treat can exact an acute and lifelong emotional toll on clinicians. Thus, to the extent possible, the interpretation of allocation principles should not be entrusted to clinicians who have pre-existing professional relationships that create an ethical obligation to advocate for the interests of specific patients. Senior specialized physicians who have prior experience and training in triage should make these choices. The triage committee shall help in applying guidelines; assist in rationing decisions, and even in the outright implementation of choices—relieving the individual front-line clinicians of that burden.

- 4) Duty to Safeguard frontline doctors and health care professionals: Healthcare professionals, doctors, nurses and medical students are exposed to an advanced risk of getting infected from CoVID-19. Therefore, priority in extending clinical interventions PPE, testing, ICU Beds and ventilators should be given to these groups. Failure to do so is bound to bring the system under colossal strain as more infected and sick healthcare professionals means lesser patients in need of critical care either infected by CoVID-19 or not being attended. This might severely dampen the efforts in controlling the outbreak. A study published in the Harvard Business Review⁹ explained how Veneto's multi-pronged response that laid special emphasis on protection of healthcare professionals produced better and positive outcomes in dealing with the pandemic.
- 5) Equitable Distribution between CoVID-19 and non-CoVID-19 patients: Resources should be allocated equitably between CoVID-19 and non-CoVID-19 patients. Another aspect that should be borne in mind is that even with overwhelmed resources, prompt attention should be given to vulnerable groups not infected by CoVID-19. Mostly these groups would include, heart and cancer patients, pregnant ladies and other people suffering from life-challenging ailments.

Legal Considerations

VIII. The most challenging legal issue faced in treating patients during a pandemic is the modified standard of care applicable during public health care emergencies. Internal policies and guidelines framed by hospitals and

⁶ Critical Care During a Pandemic, *Final report of the Ontario Health Plan for an Influenza Pandemic (OHPIP) Working group on Adult Care Admission, Discharge and Triage Criteria*, available at https://www.cidrap.umn.edu/sites/default/files/public/php/21/21 report.pdf

⁷ Guidance for managing ethical issues in infectious disease outbreaks, World Health Organisation, available at https://apps.who.int/iris/bitstream/handle/10665/250580/9789241549837-eng.pdf?sequence=1&isAllowed=y

⁸ Ezekiel J. Emanuel, M.D., Ph.D., Govind Persad, J.D., Ross Upshur, M.D, et all, 'Fair Allocation of Scarce Medical Resources in the Time of Covid-19, The New England Journal of Medicine, available at https://www.nejm.org/doi/full/10.1056/NEJMsb2005114#

⁹ Gary P. Pisano, Raffaella Sadun and Michele Zanini, *Lessons from Italy's Response to Coronavirus* available at https://hbr.org/2020/03/lessons-from-italys-response-to-coronavirus

clinicians may not be sufficient to shield them against potential lawsuits. Furthermore, there is no guarantee that such policies would be enforceable legally and afford protection to doctors and health car professionals for actions taken by them. With existent laws not adequate in responding to the various consequences the health care system and infrastructure may have to confront, it is in the best interest, that the Government of India or the Board of Governors constituted under the MCI Act frame suitable regulations.

Way Forward for India

- IX. India has emerged as key stakeholder in fighting the pandemic. International organizations and countries alike, have praised the response of the Indian Government in unison for its efforts in pushing back the deadly virus. Having regulations as suggested in this representation will only improve India's preparedness in the global fight against CoVID-19.
- X. In that spirit, we urge the Hon'ble Minister to recommend the Board of Governors to frame regulations under the MCI Act as soon as possible.

For further information, the representation has been copied to:

- 1) Ld. Secretary, Ministry of Health and Family Welfare, Government of India
- 2) Ld. Secretary (Justice), Ministry of Law and Justice, Government of India
- 3) Ld. Law Secretary, Department of Legal Affairs, Ministry of Law and Justice, Government of India
- 4) Ld. Joint Secretary, Ministry of Health and Family Welfare, Government of India
- 5) Ld. Nodal Officer, Department of Justice, Ministry of Law and Justice, Government of India

Sarthak Raizada

For and on behalf of

Indian Society for Legal Affairs

Sarthak Raizada President ISLA Nikunj Agarwal Executive President ISLA Rishabh Malhotra Joint Secretary ISLA

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