

7 December 2020

Statement¹ of Council for International Organizations of Medical Sciences (CIOMS) International Expert Working Group XI:

**Patient contribution to the development and safe use of medicines
during the Covid-19 pandemic²**

The threat of another infectious disease pandemic has loomed over the world since the 1918 influenza pandemic caused by the H1N1 influenza A virus ("Spanish flu"). The brief and limited outbreaks related to coronavirusesⁱ, SARS and MERS, were preludes to the future, which has now arrived with a novel coronavirus that has impacted every country in the world.

This new pandemic coronavirus, designated as SARS-CoV-2 ("COVID-19"), has catapulted the issue of the patient voice in healthcare and healthcare policy to the front of the global agenda. In this context, we are all patients or potential patients, which includes all members of the public, healthcare professionals, patients with pre-existing conditions and so forth, and we will use the term "Patient" to designate this. The world population has been affected with varying government-required risk mitigation measures including social distancing, national, regional and local "lockdown" quarantinesⁱⁱⁱ, and the wearing of masks along with diligent handwashing. Clearly, not all of these measures are possible in every country due to a lack of resources and healthcare infrastructure, and it will surely be Patients who will suffer the most as a result. This issue must be dealt with responsibly on the local level by all countries and Patients cooperating with and supporting overwhelmed healthcare systems and aiding the planned implementation of mitigation measures. **If not, pockets of SARS-CoV-2 will remain in these regions with continuous suffering of their populations^{iv}. This is critical as we still do not fully understand the clinical, pathological and epidemiological attributes of SARS-CoV-2; the longer it stays embedded and circulating, the possibility of mutation into a deadlier virus remains along with further waves of epidemics.^v**

Unanswered questions surrounding prevention and treatment for SARS-CoV-2, including the urgency of vaccines, hygiene, clinical trials, "emergency use authorizations", compassionate use, testing and convalescent plasma, have arisen and the world has moved beyond general issues to another crucial one: the role of the Patient voice in partnering with scientists and governments. The Patient voice can help answer the crucial questions resulting from the evolving clinical and epidemiological behaviour of a potentially devastating virus through informed and active participation in the scientific and medical quest for solutions. This is not "a nice to have" but rather a requirement in view of this pandemic.

Communication that is jointly developed with Patient partners, and which is timely, reliable and factual, must be disseminated in plain language. Patients are already organizing in such a way as to exchange experiences regarding signs and symptoms of SARS-CoV-2, and on the consequences to their health due to the lockdown and the interruption of planned care,^{vi} and as such, a clearer clinical picture of the infection is potentially developing. This is an opportunity for researchers (who are also Patients!) to apply methodologies to the exchange of information.

Our armamentarium of medical weapons to fight SARS-CoV-2 (swifter and more accurate testing, re-purposed existing therapeutics and experimental medicines, expedited vaccine development) have received the most attention. But within the context of a pandemic, the active participation of the general global population is needed to help "flatten the curve."^{vii} The pandemic has resulted in an evolution of healthcare rhetoric. In general, from a healthcare policy perspective, some have been discussing "the patient voice" in a passive manner. An important lesson from this ongoing pandemic is that we must now shift to a more comprehensive understanding of "Patient actions" and how these can be incorporated into the search for solutions in defeating this virus. Patients wish to participate in research on the physio-pathology of the disease

¹ Disclaimer. The views and opinions expressed in the statement above are the consolidated views of the participants of the CIOMS Working Group and should not be attributed to any individual expert in those or any organization with which these individuals are employed or affiliated.

² CIOMS Working Group WG XI: Patient involvement in the development and safe use of medicines. For more information about the Working Group and its members, please visit: <https://cioms.ch/working-groups/working-group-xi-patient-involvement/>

and in clinical trials testing experimental treatments within scientific protocols.^{viii} Outside such protocols, all Patients could potentially contribute with their data collected in medical records and/or databases.

As with any ecosystem, the component parts of global healthcare systems are not necessarily equal, but they are requirements for success^{ix}. The Patient voice must be recognized and be integral to the scientific march in defeating this virus. **This requires that all ethical, patient consent, scientific and public health processes that were in place prior to the pandemic, must involve Patients and adhere to robust methodologies and responsible peer review in order to avoid decisions that could bring about dangerous public health consequences.** This requirement will maximize the safest route forward until effective and safe therapies are identified and implemented, which will be an enormous endeavor in view of the billions of people affected.

The struggle against SARS-CoV-2 is truly a battle in which we are all called upon to unite to find global solutions. As Patients, we are all affected and we can have a powerful and active voice. We will learn from this pandemic, and we will apply these lessons and thereby be better prepared for the next pandemic that emerges from whatever infectious agent.

The CIOMS WG XI, focusing on patient involvement in the development and safe use of medicines, has been working diligently with patient organisations, academia, pharmaceutical industry, and health authorities to help address the questions raised in this Statement and other issues. The CIOMS WG XI report is expected to be published in 2021.

ⁱ Kilbourne ED; Influenza Pandemics of the 20th Century; Emerging Infectious Diseases • www.cdc.gov/eid • Vol. 12, No. 1, January 2006

ⁱⁱ De Witt, E. et al: SARS and MERS: recent insights into emerging coronaviruses; NATURE REVIEWS | MICROBIOLOGY; VOLUME 14 | AUGUST 2016 | 523-534

ⁱⁱⁱ Czeisler, M. et al; Public Attitudes, Behaviors, and Beliefs Related to COVID-19, Stay-at-Home Orders, Nonessential Business Closures, and Public Health Guidance — United States, New York City, and Los Angeles, May 5–12, 2020; MMWR / June 12, 2020 / Vol. 69

^{iv} United Nations Department of Economic and Social Affairs; COVID-19 and the least developed countries; Policy Brief No. 66; May 2020

^v Yuiki, K. et al: COVID-19 pathophysiology: A review; Clinical Immunology 215 (2020) 10842

^{vi} <https://patientsafetymovement.org/helpful-coronavirus-covid-19-resources/>; <https://www.ema.europa.eu/en/partners-networks/patients-consumers/eligible-patients-consumers-organisations>

^{vii} <http://info.primarycare.hms.harvard.edu/blog/flattening-the-curve>

<https://healthblog.uofmhealth.org/wellness-prevention/flattening-curve-for-covid-19-what-does-it-mean-and-how-can-you-help>
<https://science.sciencemag.org/content/sci/early/2020/03/30/science.abb6936.full.pdf>

^{viii} <https://covid19studies.org/>

^{ix} https://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php