



# Patient Contribution to the Development and Safe Use of Medicines During the Covid-19 Pandemic

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## Abstract

COVID-19 has catapulted the issue of the patient voice in healthcare and healthcare policy to the front of the global agenda. The world population has been affected with varying government-required risk mitigation measures including social distancing, national, regional and local “lock down” quarantines, 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. 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.

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”).<sup>1</sup> The brief and limited outbreaks related to coronaviruses,<sup>2</sup> 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” quarantines,<sup>3</sup> 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.<sup>4</sup> 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,

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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/>.

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<sup>1</sup> Kilbourne ED; Influenza Pandemics of the 20th Century; Emerging Infectious Diseases • [www.cdc.gov/eid](http://www.cdc.gov/eid) • Vol. 12, No. 1, January 2006.

<sup>2</sup> De Witt, E. et al.: SARS and MERS: recent insights into emerging coronaviruses; NATURE REVIEWS MICROBIOLOGY; VOLUME 14 | AUGUST 2016 | 523–534.

<sup>3</sup> 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.

<sup>4</sup> United Nations Department of Economic and Social Affairs; COVID-19 and the least developed countries; Policy Brief No. 66; May 2020.

the possibility of mutation into a deadlier virus remains along with further waves of epidemics.<sup>5</sup>

The traditional role of the patient voice in drug development has been to share the human component of disease. To date, this has largely meant the sharing of personal, emotional anecdotes. These highly charged stories certainly help to make the drug development process more three-dimensional. But does ‘playing the victim card’ result in ‘meaningful engagement’? Anecdotes have impact, but is it impact of the right kind, of the most powerful nature? No. The plural of “anecdote” is not “data.” Regulatory actions are, and must always be, data-based. Patient passion is important but it must be combined with a more dispassionate, scientific understanding of regulatory paradigms. The 21st century patient voice can and must evolve into a tool used to impact regulatory decision making from both the heart and the head.

Urgent issues surrounding prevention and treatment for SARS-CoV-2, including new therapeutics, vaccines, hygiene, clinical trials, “emergency use authorizations”, compassionate use (expanded access), testing, convalescent plasma, have moved beyond the traditional realms of medical, scientific and economic questions to another crucial one: the role of the patient voice in partnering with scientists and governments. The patient voice can help inform many of crucial questions resulting from the evolving clinical and epidemiological behaviour of a potentially devastating virus through the active participation in the scientific, medical and societal quest for solutions. This is not “a nice to have” but rather a requirement in view of this pandemic.

## Communications

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,<sup>6</sup> 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. There is important information and context to be communicated through the experiences and perspectives of both patients and caregivers.

<sup>5</sup> Yuiki, K. et al: COVID-19 pathophysiology: A review; *Clinical Immunology* 215 (2020) 10842.

<sup>6</sup> <https://patientsafetymovement.org/helpful-coronavirus-covid-19-resources/>; <https://www.ema.europa.eu/en/partners-networks/patients-consumers/eligible-patients-consumers-organisations>.

## The Development of Medical Technologies

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.”<sup>7</sup> 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 and in clinical trials testing experimental treatments within scientific protocols.<sup>8</sup> Outside such protocols, all patients could potentially contribute with their data collected in medical records and/or databases.

## Patient-Informed Best Practices

As with any ecosystem, the component parts of global healthcare systems are not necessarily equal, but they are requirements for success<sup>9</sup>. 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. Similarly, the patient voice can (indeed must) be a potent tool in driving broader acceptance and use of the wearing of masks, social distancing and enhanced personal hygiene. There is also the opportunity to better understand the health consequences caused (directly and indirectly) from the patient experience of lock-downs and the ensuing economic hardships. These messages, coming from all directions (national and local authorities, medical professionals and patient-peers) will drive bet-practice compliance and maximize the safest route forward until effective and safe therapies are identified and implemented, which will

<sup>7</sup> <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>.

<sup>8</sup> <https://covid19studies.org/>.

<sup>9</sup> [https://www.pnhp.org/single\\_payer\\_resources/health\\_care\\_systems\\_four\\_basic\\_models.php](https://www.pnhp.org/single_payer_resources/health_care_systems_four_basic_models.php).

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.

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