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EDITORIAL

Breaking all the rules, at lightning speed

Watching the world come together to fight the coronavirus has been an eye opener. This is the first time in living memory, at least for those born after World War II and after many colonies achieved independence, that a single issue has bothered so much of the world. The Spanish flu, a century ago, is believed to have killed between 17 and 50 million people, and those figures tell us the scale of what may happen this time, too.

India's Ministry of Health and Family Welfare reports that so far about 3500 Covid-19 deaths have taken place in the country, and the Johns Hopkins Coronavirus Research Centre reports that the world-wide figure is almost 340,000. To place these figures in perspective, let us look at some of the other leading causes of death around the world. The World Health Organization (WHO) and other sources report that malaria, tuberculosis and HIV today collectively kill over 2.5 million people per year. And in 2009 it was reported that this figure was almost five million. So, even in recent memory, many tens of millions have died from these three diseases alone. Viral hepatitis kills about 1.3 million per year and road accidents about 1.5 million. Globally, around nine million die of starvation and related illnesses. So, this short list accounts for almost 15 million people dying each year. In parallel with a billboard in New York that lists the number of avoidable coronavirus fatalities in the United States, we need a similar billboard for the millions of deaths each year that could have been prevented, had the world made a concerted effort to avert them.

To return to the coronavirus, what are the kinds of steps that the world is taking to combat it? There is general agreement that a vaccine would be one of the best solutions. The Bill and Melinda Gates Foundation will spend billions of US dollars to support the building of factories for multiple vaccines that have not yet been approved, and which may never be approved. It is doing this knowing full well that much of this money will be wasted, but the goal of getting the vaccines to billions of people as fast as possible means that the factories have to be built before the vaccine is trialled or approved. The Serum Institute, in Pune, has already started manufacturing a vaccine that has only proved itself on animals thus

far. In the US, Anthony Fauci, the highly respected, long standing director of the National Institute of Allergy and Infectious Diseases, is promising a vaccine in 12–18 months. However, the National Geographic informs that in the case of mumps, it took four years from the collection of virus samples to the approval of a vaccine, and this has been the fastest ever approval. Further, vaccines for respiratory diseases have not been very successful, and may take decades, as it did for Respiratory Syncytial Virus (Polack, F. P. and Karron, R. A., *Pediatr Infect. Dis. J.*, 2004, 23(1 Suppl.), S65–S73). Also, no vaccine has been developed for Severe Acute Respiratory Syndrome (SARS), also caused by a coronavirus, which ran amok in East and South-East Asia in 2003. The US Department of Health and Human Services has now announced 'Operation Warp Speed', involving the government, the military and the pharma industry, that aims to have 100 million doses of vaccine ready by the end of 2020, that is within the next seven months.

Other unusual steps being taken to attack the virus are visible in actions big and small. The CEOs of about a dozen large pharma companies have been meeting multiple times a week to talk Covid-19, and the Gates Foundation has announced that the companies have expressed willingness to share compound libraries. A group of the largest tech firms in the world have signed an Open Covid Pledge, committing to the temporary free use of hundreds of thousands of patents (<https://opencovid-pledge.org/>). In one case this extends to patent applications that will be filed over the next three years. At the moment, Gilead's drug, remdesivir, appears to be the most promising against the coronavirus. It is widely reported that the company has signed an agreement for the transfer of technology to manufacture it, to Cipla, Hetero and Jubilant Life Sciences and is planning to do so with several other Indian companies as well. For the moment, these are royalty-free agreements. In mid-February, it was reported that over 120 clinical trials targetting the virus were planned, targetting a mind-boggling 40,000 participants (<https://www.statnews.com>), and in mid-May, the WHO's International Clinical Trial Registry Platform tells us that this number has ballooned to over

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2000 trials. Presumably, all clearances are being obtained in record time. And whereas a trial often fails due to inadequate enrolment, the *Financial Times* reported that a trial for a drug against the virus, being run at the University of Oxford, is the fastest recruiting trial in history. In a parallel situation in the US, the President of Rochester Clinical Research has stated that over 500 potential trial participants have been in touch to contribute to the company's vaccine development efforts (<https://13wham.com>), again a record for the company. The Government of India has issued a notification on applications for drugs, vaccines and so on to deal with the virus. This notice mentions the possibility of data requirements for different kinds of studies being waived, deferred, or abbreviated. It also uses the terms 'expedited review', 'accelerated approval' and 'priority for review and approval' for applications to import, manufacture, market or repurpose a drug or vaccine. The Indian Council for Medical Research has, apparently for the first time, permitted online meetings of ethics committees, and has also allowed participants to send their consent to be part of a trial by email or other digital means (<https://www.hindustantimes.com>). About 3500 scientists of the Council of Scientific and Industrial Research are involved in attacking this virus, from making masks to devising drugs. And publications, ranging from *The Lancet* to *The New York Times*, are making their corona content free.

The virus came to global attention in January 2020, and the WHO declared it a pandemic on 11 March. I am writing these lines in May. So, all these developments have taken place in less than six months. Warp speed, indeed!

As briefly recounted above, there is cooperation, across national boundaries and across the boundaries of public and private institutions. All of this has happened in the past in some measure, but there is an unprecedented intensification for this virus. In several ways, we are approaching the absolute optimum kind of effort one could imagine. Is this the beginning of a new way of doing things? Will any of this last beyond the pandemic? One of the few examples of experiences during the pandemic-related lockdown that, we are told, will be sustained in future, is as follows. Companies had already found that their employees are more productive working from home, and well-known Indian and foreign companies have announced that after this recent experience, they will soon move a large fraction – up to 100% in some cases – of their employees to work in this mode. This is an enormous jump from the current low levels of staff working from home, and amounts to a paradigm shift in work habits. To be noted, though, this does align with business

interests, since among other things, the company cuts back expenditure on space, and employees are saved the expenditure of time and money on a commute.

WHO is pushing for everything that will help tackle the virus to become available to every person in need, around the world. This goes against the 'business as usual' framework, and as a law professor writing in the highly respected www.statnews.com stated 'the call for global solidarity must actually trump commercial prerogatives, nationalism, and demagogic egos'. Fences that silo institutions, states or nations, have come down. Whereas the optimist would hope that some of these fences would stay down forever, the more cynical would note the use of the word 'temporary' in some of the corporate announcements. The even more cynical would imagine that the corporate world sees a business opportunity arising from others having temporary use of their patents, for instance.

As stated above, this coronavirus is by no means the only large challenge the world faces. So, what is it that causes such urgency? Yes, it is highly infectious, and has a higher mortality rate than many other extant viruses. But are there not other – unstated – angles? Hasn't this virus created a more level playing field in terms of you and I, the middle class, being as vulnerable as a poorer person? Also, is it that the rich, who can usually buy solutions to most of their problems, find that this one will not be solved by individual action? Does it really require that kind of a threat to mobilize everyone? I mean no disrespect to all the admirable efforts focused on ameliorating or preventing the worst possible effects of the pandemic. However, in general, it is amazing how the world has paid so little attention to so many other major killers. And to see the current pulling together, and bending and breaking of rules in such a short time frame, shows us what is possible should we choose to make such a dedicated effort.

We need a socio-economic system with different incentive structures. We also need more humanity and empathy. Perhaps it would lead to a permanent alteration of major rules, and a change in how we prioritize what challenges to tackle. The world could become a better place, for all of us, at all times.

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