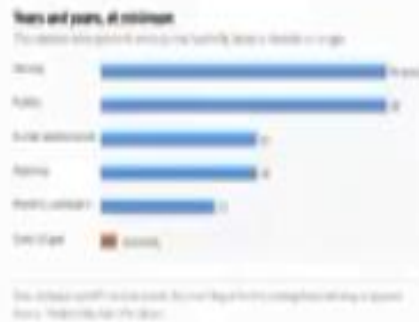
A world map with a dark grey background. Numerous red dots of varying sizes are scattered across the map, representing COVID-19 cases. The dots are most densely packed in North America, Europe, and parts of Asia. The map is labeled with continents and oceans in a light grey font. The text 'Regulatory Framework for COVID-19 Vaccine in Pakistan' is overlaid in the center in a large, white, sans-serif font.

# Regulatory Framework for COVID-19 Vaccine in Pakistan

Sarfaraz K. Niazi, Ph.D., University of Illinois, University of Houston, HEJ Karachi University, NUST, Islamabad; Aga Khan University (Past)

First Consultative Meeting, 14 September 2020, Islamabad



AJMC | [www.ajmc.com](https://www.ajmc.com)

THE FUTURE OF VALUE-BASED CARE

### Biosimilarity: A Novel Approach to Develop Therapies and Vaccines for COVID-19

September 8, 2020  
September 8, 2020

ICMRA

GUIDANCE DOCUMENT

## Development and Licensure of Vaccines to Prevent COVID-19

Guidance for Industry

JUNE 2020

- As new biological drugs (351a) requires full dossier; 50% primary end point
  - Secondary endpoint novel testing accepted by FDA: Niazi
- FDA has issued final guidance: everyone follows it; do not create your own
- ICMRA consortium has 29 medicines' agencies; the WHO as an observer.
  - **Pakistan not participating?** Information for public and professionals.
- Several novel vaccine types, never approved by FDA, take longer
  - Takes decades to develop a vaccine; fastest was H1N1 nine months
- Top candidate testing halted in US due to adverse events (AstraZeneca)
  - Likely triggering pending MS; can bring other autoimmune diseases
- Emergency use authorization is not qualified for vaccines: developers signed off not to ask for even faster approval

Continue to adhere to high scientific and ethical standards regarding the conduct of clinical trials and the rigor of manufacturing processes.

Only subject for approval in emergency use authorization after demonstrating safety and efficacy through a Phase 3 clinical study that is designed and conducted to meet requirements of expert regulatory authorities such as the FDA.

Work to ensure a sufficient supply and range of vaccine options, including those suitable for global access.

We believe this path will help ensure public confidence in the rigorous scientific and regulatory process by which COVID-19 vaccines are evaluated and may ultimately be approved.



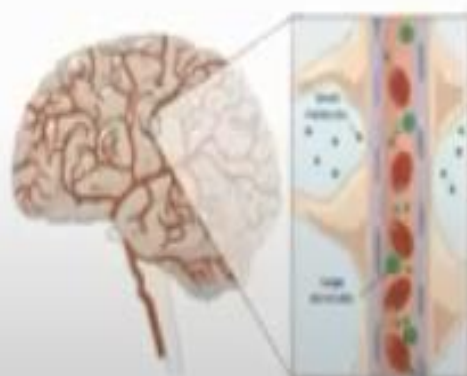
# The New York Times

## Covid-19 Vaccine May Not Be the Ultimate Panacea

Sarfraz K. Niazi, Ph.D., Adjunct Professor, University of Illinois, Chicago, Illinois

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...Our body has a robust protective system—the blood-brain barrier—that keeps many chemicals including the antibodies produced in response to a vaccine out. COVID-19 enters the brain directly leaving the possibility that even those who are vaccinated may end up with infected brains and die. While the world is betting on a vaccine to end the pandemic, the optimism evaporates with this new finding. At-risk here is the fear that with a vaccine in hand, we will stop efforts to contain the spread that may result in a rebound of a different kind, for which we will not have a solution. My advice is that we should look forward to a safe and effective vaccine but do not see this as the ultimate panacea....



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bioRxiv is receiving many pre-prints concerning SARS-CoV-2. A reminder that these are preliminary reports that have not been peer-reviewed and may contain errors. For more information see <https://www.biorxiv.org/help/faq>.

New Results

0 Comments (0)

### Neuroinvasion of SARS-CoV-2 in human and mouse brain

Erin Song, Ca Zhang, Benjamin Isattone, Alice Lu-Culligan, Alba Vives Prada, Sophia Simatone, Professor Lu, Qin-Hu Wu, Fei-Li Li, Yile Dai, Clara Sargent-Buck, Tali Youmans, Guilan Wang, Christopher Conradi, Janna Hattis, Evelyn Ng, John Wheaton, Pia Madel, Adigun, Estelle Larsson, Benjamin Ferrer, Neil G. Ravindra, David Van Dijk, Shrikant Mane, Murat Gunel, Aaron Ring, Syed A. Jaffer Kazem, Kai Zhang, Craig B. Wilen, Tomas L. Harvath, Isabella Pio, Seythone Hek, Jean-Louis Thomas, Angelika Lavin, Shelli F. Farhadian, Arata Huzman, Daniela Soffran, Nicolas Renier, Kapil Bilgicer, Akiba Inasaki

doi: <https://doi.org/10.1101/2020.06.21.169946>

This article is a preprint and has not been certified by peer review [what does this mean?]

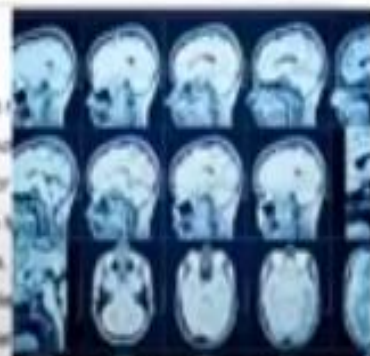
Abstract

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0 Reviews (0)



SARS-CoV-2 with antibodies or by administering cerebrospinal fluid from a SARS-CoV-2 patient. Second, using mice overexpressing human ACE2, we demonstrate *in vivo* that SARS-CoV-2 neuroinvasion, but not respiratory infection, is associated with mortality. Finally, in brain autopsy from patients who died of COVID-19, we detect SARS-CoV-2 in the cortical neurons, and note pathologic features associated with infection with minimal immune cell infiltrates. These results provide evidence for the neuroinvasive capacity of SARS-CoV-2, and an unexpected consequence of direct infection of neurons by SARS-CoV-2.

## Pakistan Regulatory Strategy

### *From Asia to Africa, China Promotes Its Vaccines to Win Friends*

With pledges of a coronavirus vaccine, China is on a charm offensive to repair strained diplomatic ties and bolster engagement with other countries.

- No facility capable of production in Pakistan; several in India even the for novel vaccines. Sad.
- No EUA coming in developed countries; do not allow in Pakistan
- Use outside experts to review safety data, as does the FDA.
- No evaluation for approved vaccines: Automatic registration, No bureaucratic filing requirements
- Partner with companies manufacturing approved vaccines; direct supply unlikely
- SinoVac attenuated virus is a likely option; widely exploited politically. Be careful—they may not deliver
- Do not allow testing in Pakistan without an IND—do not depend on your evaluation of safety
- There will be many more pandemics, develop domestic manufacturing—easier now with genetic vaccines