VACCINEINSIGHTS

COVID-19: HOW IS THE PANDEMIC CHANGING THE VACCINES SPACE?

SPOTLIGHT

A new chapter for the COVID-19 pandemic – and for the vaccines space

Charlotte Barker & Fred Cassels

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FOREWORD

Vaccine Insights 2022; 1(1), 107–110

DOI: 10.18609/vac.2022.017

Welcome to the inaugural issue of *Vaccine Insights*, and our Spotlight exploring how the COVID-19 pandemic has changed – and is still changing – the vaccine field.

Contributors to this Spotlight represent some of the world's leading authorities on COVID-19. Along with an army of government, industry, academic and non-profit scientists, they have worked tirelessly from the moment a novel coronavirus was identified in Wuhan in December 2019. SARS-CoV-2 was sequenced within weeks, clinical trials of vaccine candidates began three months later, and the first COVID-19 vaccines were licensed for use just 11 months after the viral genome was published.

In large part due to those vaccines, we are moving into a new phase of the pandemic. At this unique moment in the pandemic – and in history – we feel that the time is right to take stock, consider lessons learned, and look ahead to what will be needed to counter new COVID-19 variants and future pandemic viruses. In this issue, we ask leading experts in all areas of vaccine development, manufacture, and delivery to share their thoughts in a series of articles and interviews.

Nick Jackson (Clover Biopharmaceuticals, formerly Coalition for Epidemic Preparedness Innovations, CEPI) sets the scene with an overview of how the vaccines space has been changed by the pandemic to date – from the meteoric rise of mRNA vaccines to an influx of new companies into the industry, with the technology platform 'toolbox' having grown considerably in the process.

Anthony Fauci (NIH) has been at the heart of the COVID-19 response in the US – in an interview, he lays out the key lessons governments and funders must heed if they are to protect the public from future pandemic threats. He introduces several threads that run throughout the issue, including the need for sustained investment in pandemic preparedness and vaccine research, the importance of developing strategies to tackle mis/disinformation, and the increasing focus on broadly protective vaccines.

After an mRNA vaccine made history by becoming the first approved vaccine for COVID-19, there has been great excitement about the potential of this platform technology – we sat down with RNA pioneer Drew Weissman (University of Pennsylvania) to get his thoughts on the past, present, and future of RNA vaccines.

A recurring theme from our contributors was the role of regulators in accelerating vaccine approvals – in our Expert Roundtable video and transcript, we bring together Peter Marks (FDA), Marco Cavaleri (EMA), Carla Vinals (Moderna), and Adam Hacker (CEPI) to discuss how regulators adjusted and adapted to pandemic conditions, and what that means for vaccine developers going forward.

Analytical development is one area where vaccine developers can avoid regulatory delays – Anna Särnefält and Ingrid Kromann (CEPI) urge developers to start early and think ahead in assay development.

An area that is garnering attention from regulators, researchers, and developers alike is correlates of protection (CoPs). Peter Gilbert (Fred Hutchinson), Stanley Plotkin (University of Pennsylvania), and Peter Dull (Bill and Melinda Gates Foundation) are three of the world's leading experts on CoPs for vaccines and they join us for an Expert Roundtable to discuss the nuances around the use of CoPs and, importantly, how CoPs can be used for regulatory decision-making.

Of course, the story – and the challenges – didn't end with the regulatory approval of COVID-19 vaccines. Tracing the journey from approvals to 'shots in arms,' Michael Angelastro and Robert Johnson (Biomedical Advanced Research and Development Authority, BARDA) describe the US government's approach to supply chain management, while Darin Zehrung (PATH) discusses the unique challenges of delivering pandemic vaccines in lower- and middle-income countries (LMICs). mRNA vaccines, in particular, have challenging ultra-low temperature storage and transport requirements. In the next phase of the pandemic, cheaper and more easily stored vaccines are likely to gain importance, says

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Biological E's Vikram Paradkar, in an article describing the development of the company's $2/dose adjuvanted protein subunit vaccine, CORBEVAX™.

COVID-19 vaccination rates remain low in many LMICs, and Jerome Kim (International Vaccine Institute) and Maria Elena Bottazzi (Baylor College of Medicine) offer six key lessons to achieve more equitable vaccine delivery in future pandemics. Emily Adhikari (University of Texas Southwestern Medical Center) et al highlight another group underserved in this pandemic – pregnant and lactating women – and call for more inclusive clinical trials.

The impact of COVID-19 goes beyond the morbidity and mortality of acute disease. With millions worldwide suffering ongoing respiratory and neurological symptoms, Peter Hotez (Baylor College of Medicine) and members of the Lancet COVID-19 Commission ask whether vaccination should be considered as a preventative or therapeutic option for 'long-COVID.'

Next, we turn our attention to future threats. We appear to be moving toward endemicity, but new variants can still pose fresh challenges, and the prevalence of coronaviruses in key zoonotic reservoirs (most notably bats, with many introductions of bat-related viruses into humans annually) means that a new human coronavirus pandemic is inevitable. After decades of studying coronaviruses, Ralph Baric (University of North Carolina) believes our best hope for the future lies in developing multiple lines of defense, including development of broadly protective vaccine strategies. It's a sentiment echoed by zoonotic disease expert Linfa Wang (Duke-NUS Medical School), who cautions that development of broadly protective coronavirus vaccines will be a stepwise process, but whose lab is developing a promising pan-sarbecovirus vaccine.

The deadliest pandemic since the 1918 pandemic influenza, COVID-19 has touched all our lives. But will the world remember the hard-won lessons our contributors have shared, including the importance of long-term investment into pandemic preparedness and vaccine development? Will changes to the vaccine industry wrought by the pandemic last? As Philip Dormitzer (GSK) points out, interest in – and funding for – vaccines has historically been cyclical. But after the series of epidemics and pandemics the world has seen in recent decades, we cannot afford to let the current momentum diminish.

We believe that the vaccines space is entering an exciting new chapter. *Vaccine Insights* will continue the story, with upcoming Spotlights offering insights into vaccine formulation and administration, preclinical and clinical research, what's next for RNA vaccines, and the future of vaccine manufacturing. We hope you'll join us!

BIOGRAPHIES

Charlotte Barker, Editor, *Vaccine Insights*

Charlotte Barker is an experienced writer and editor with a passion for communicating the latest scientific advances. As Editor of *Vaccine Insights*, she works with a variety of stakeholders to generate timely, accessible content for readers engaged in vaccines development and manufacture around the world. Charlotte has worked in scientific and medical publishing for 17 years, most recently as Associate Content Director at Texere Publishing, maintaining high editorial standards and a unique voice across publications covering analytical chemistry, translational science, and pharmaceutical manufacturing. She began her career at Future Science Group, where she managed Medline-indexed journals including *Regenerative Medicine* and *Bioanalysis*.

Fred Cassels, Global Head for Enteric and Diarrheal Diseases, Center for Vaccine Innovation and Access, PATH

Fred Cassels is Global Head for Enteric and Diarrheal Diseases (EDD) at the Center for Vaccine Innovation and Access at PATH. Projects within the EDD group encompass vaccine discovery, proof of concept, process development, cGMP manufacture, Phase 1–4 clinical trials, licensure,

and introduction – all for the benefit of low- and middle-income countries. Previously, Fred was Chief of the Enteric and Hepatic Diseases Branch, Division of Microbiology and Infectious Diseases (DMID), NIAID. While at DMID, Fred also served as the SARS and Influenza Vaccines program officer.

AUTHORSHIP & CONFLICT OF INTEREST

Contributions: *All named authors take responsibility for the integrity of the work as a whole, and have given their approval for this version to be published.*

Acknowledgements: *None.*

Disclosure and potential conflicts of interest: *The authors declare that they have no conflicts of interest.*

Funding declaration: *The authors received no financial support for the research, authorship and/or publication of this article.*

ARTICLE & COPYRIGHT INFORMATION

Article source: *Invited.*

Submitted: *May 27 2022; Revised manuscript received: May 30 2022;* ***Publication date:*** *Jun 9 2022.*

DOI: 10.18609/vac.2022.017