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Edition 60- Lessons from COVID-19 - Building a more resilient response for the next pandemic - Health System and Drug Development perspectives - HPHR Journal

By Preet Kukreja, Kinshuk Saxena, Snigdha Santra

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Abstract

This paper evaluates the challenges faced by the healthcare systems and the drug-development industry in responding to the COVID-19 pandemic. We explore the role of key stakeholders and different healthcare models that can help ensure a robust pandemic response. In drug-development, we scrutinize the challenges linked with COVID-19 antivirals, vaccines, and antibodies and explore the potential of repurposing existing therapeutics through the use of advanced technologies while predicting clinical trial outcomes. We consider the intricacies of manufacturing, regulatory, and funding factors in vaccine preparedness. We conclude by exploring the future of pandemic preparedness, highlighting rapid innovation, and the potential for accelerated drug discovery as powerful tools in addressing the next pandemic.

Challenges faced during the COVID-19 pandemic

Health System Challenges

The health system response faced challenges in terms of shortage of skilled workers, particularly at the community level. The relevance of community health workers (CHWs) in public health emergencies, particularly in overcoming staff shortages, was highlighted by the COVID-19 pandemic. We learned that effective Community Health Worker Utilization is key to crisis response because they help with contact tracing, community engagement, health education, and the delivery of vital medical treatments. In order to give CHWs the knowledge and abilities they need to respond to public health emergencies, comprehensive training programs should be devised. Infection control, effective communication, data collecting, and cultural competency should be part of the training.[1] CHWs should work closely with medical professionals, public health organizations, and community-based groups. The efficient coordination, collaborative decisionmaking, and streamlined service delivery are made possible by this integration. [2]

Another crippling factor in the healthcare system response during the pandemic was a severe lack of healthcare professionals, including doctors and nurses. CHWs can come to the rescue here as well – assisting in non-clinical tasks like contact tracing, community surveillance, and health education, which lessens the workload on healthcare professionals and frees them up to concentrate on providing vital medical care. CHWs are frequently integrated into communities, allowing them to administer crucial healthcare services, monitor patients, and make sure preventive measures are followed. This localized strategy lessens the burden on healthcare facilities and addresses healthcare inequities.

In order to solve workforce shortages and improve the healthcare system's response to public health emergencies, community health workers must be used effectively. Building infrastructure and maximizing the potential of CHWs can be done successfully by following the example of the New York State Public Health Corps. We can successfully address labor shortages and enhance overall crisis response by enhancing CHW training, integrating them into healthcare teams, and utilizing their community involvement skills. The role of CHWs should be prioritized in future preparedness efforts, and mechanisms should be put in place to maximize their contributions to the public health disaster response.

Drug Development Challenges

The development of effective therapeutics for COVID-19 faced significant challenges, including the difficulty of rapidly identifying the right drug candidate, navigating complex regulatory landscapes, adapting to emerging viral variants, and coordinating efforts among diverse stakeholders in the drug development process. These hurdles underscore the complexity of responding swiftly to a pandemic and highlight the need for improved strategies and collaborations in the pharmaceutical and life sciences sectors.

The urgent need for effective therapeutics to combat the SARS-CoV-2 virus posed a significant challenge, primarily due to the difficulty in identifying the right drug candidate. The initial response was uncoordinated, akin to throwing darts at a moving target in the hope that something would stick. Several drug combinations, including remdesivir, hydroxychloroquine, and their combinations with other antiretrovirals such as tocilizumab and lopinavir/ritonavir, as well as some steroids, were initially tried. However, none of these approaches yielded compelling results, underscoring the complexity of rapidly identifying the right drug candidate from a vast pool of potential candidates [3, 4]

Regulatory approval, crucial for ensuring the safety and efficacy of new treatments, can significantly impact drug development timelines, especially for biological products like vaccines and gene therapies. This impact is heightened during emergencies like pandemics, where swift action is required but often hindered by the complexity of product development and extended review periods. Making sure new medical products are high-quality and consistent is complicated. Companies have to follow strict rules called Good Manufacturing Practices and Chemistry, Manufacturing, and Controls. These are important for safety. But each country has slightly different rules. When there's a pandemic, companies want to release products quickly in multiple countries at the same time. But with different rules everywhere, it takes longer to get approvals. Before COVID-19, companies and regulators were trying to streamline things to speed up development of high-quality products. But during the pandemic, the lack of agreement internationally on how to accelerate the process while ensuring quality made it hard to get products out swiftly worldwide. [5]

Outbreaks of more infectious variants, such as Omicron, continue to diminish the utility of available vaccines and drugs. Thus, the effectiveness of vaccines and drugs against the most current variants is a primary consideration in the continual analyses of clinical data that supports updated regulatory decisions.[6]

Drug discovery and development is characterized by highly complex, time-consuming, expensive (yet profitable), often unsuccessful, multidisciplinary processes carried out by a myriad of local, national, and international public and private organizations. These players may have divergent interests, leading to delays in formulating a coherent strategy for quickly initiating and progressing drug development.[7]

Social Justice Challenges

The COVID-19 pandemic magnified existing health disparities and highlighted significant social justice challenges. Racial and ethnic minority groups faced higher rates of infection, hospitalization, and death compared to non-Hispanic Whites [8]. Contributing factors included occupational exposures, multigenerational housing, and discrimination in [9]. Incarcerated populations experienced outbreaks due to overcrowding and inadequate healthcare [10]. Homeless individuals lacked access to testing, treatment, and shelter options [11]. Restrictive policies also impacted undocumented immigrant communities' willingness to seek care [12]. Overall, the pandemic response failed to adequately protect marginalized groups, revealing the need for greater health equity and social justice focus during public health emergencies.

Strategies to prepare for the next pandemic

Healthcare System Strategies

To analyze the quantitative data, descriptive statistics were performed to provide a summary of the data. The AREA survey was completed by 12 out of 14 (86%) FM core residency faculty prior to the intervention and 8 (66.7%) faculty after the intervention (see table 3). Prior to the intervention, the majority of faculty demonstrated engagement in the areas of awareness and reflection/empowerment while lower engagement levels were seen in action. After the intervention, faculty engagement levels slightly increased in the areas of awareness and action and slightly decreased in reflection/empowerment.

Healthcare System Strategies

Planning, coordination, training, and infrastructure development are all necessary components of a well-prepared healthcare system in order to efficiently respond to public health emergencies and safeguard the general populace's health and wellbeing. To improve and learn from prior experiences, it is crucial to examine previous public health events, carry out post-event evaluations, and update emergency response plans. [-13]

Proactive Workforce Planning

It is important to have detailed emergency response plans at the national, regional, and local levels. Roles, duties, and coordination mechanisms for various healthcare providers, public health organizations, and other stakeholders should be explicitly outlined in these plans.[14] An effective response requires cooperation and collaborations between emergency management organizations, public health organizations, and hospital institutions. These networks enable resource sharing, information exchange, and cooperative training exercises, improving readiness and response capacities.[14]

During the pandemic, the New York State Department of Health (NYSDOH) Public Health Corps stood out as an exceptional project for building infrastructure and utilizing CHWs' skills. The NYS Public Health Corps recruited people from a variety of backgrounds and gave them thorough training to improve their abilities and expertise in public health emergency response. As a result, they were prepared to assist communities in need. CHWs from the NYS Public Health Corps were crucial in interacting with locals, distributing correct information, and addressing the unique healthcare requirements of underserved groups. Their culturally sensitive strategy enhanced health literacy, encouraged community engagement, and created trust· In order to address the public health workforce shortfall and improve readiness, the NYSDOH also created the Public Health Corps Fellowship Program. This program offers training and job placement opportunities in a variety of organizations in an effort to develop a qualified workforce of public health professionals. Individuals can support preparedness efforts and assist in preventing potential worker shortages during public health emergencies by taking part in the NYSDOH fellowship program.[15]

Leverage Non-Traditional Funding Resources

Organizations and governmental bodies frequently offer emergency funding to help with response efforts during public health catastrophes. These grants are typically intended to support infrastructure development, community engagement initiatives, healthcare service reforms, and research studies.[16] Regular updates on funding opportunities from credible institutions like the CDC, WHO, and regional government agencies devoted to emergency response are necessary to stay abreast of the emergency funds that are currently available. New York City Department of Health and Mental Hygiene (NYC DOHMH) has been instrumental in providing the emergency funding opportunity during COVID-19 pandemic and Mpox public health emergency. They also incorporated the contracted community health workers as a part of the emergency grants to aid the overly burdened healthcare organizations during COVID-19 pandemic. This enables the healthcare organizations to provide free COVID-19 vaccination along with the screening services in the community. Due to their strategic and timely response, COVID-19 vaccination rates have improved in the city significantly.

Drug Development Strategies

Rapid Drug Candidate Identification

Technological advancements and data science have the potential to significantly expedite the drug identification process, particularly in the context of a pandemic. Utilizing techniques such as artificial intelligence (AI) and machine learning (ML), large datasets can be analyzed to swiftly identify potential drug candidates. Furthermore, maintaining a virus-specific database of potential drug candidates can enhance the speed of response when a new pandemic arises.

Promising studies show that AI computer models can successfully predict which drug candidates will work well. Remarkably, these simulations have been 91% accurate, showing their potential to rapidly identify effective vaccine candidates for future pandemics. [17]

Additionally, recent advances in molecular dynamics (MD) simulations can predict how well drug molecules will bind to their targets, which is key for drug design. A deep learning model called Dynaformer built on MD data has demonstrated cutting-edge abilities to score and rank drug candidates' potential. [18] This provides a more precise, efficient way to identify the best candidates, further boosting AI and machine learning for drug discovery. Another example is the COVID Moonshot project, which used distributed computing to run simulations prioritizing which candidates to test in the lab. [19]

Overall, these AI and modeling approaches can greatly speed up and enhance how top drug candidates are identified during pandemics.

These data-driven, efficient, and predictive approaches can significantly streamline the assessment of new drugs' potential success in clinical trials, thereby enhancing the overall response to a pandemic.

Robust Regulatory Strategy

Innovative regulatory strategies can be employed to further enhance the regulatory response in future pandemics. Advances in technology and data science, such as artificial intelligence and machine learning, can be leveraged to analyze large datasets, including RWD, and identify potential drug candidates more quickly.[20] Additionally, maintaining a database of potential drug candidates for various types of viruses can expedite the process when a new pandemic occurs.

The COVID-19 pandemic underscored the critical role of collaboration among various healthcare stakeholders in addressing a global health crisis. Pharmaceutical corporations have been identified as the leading players in the fight against the pandemic due to significant involvement and cooperation with governments, society, and businesses, both at the national and international levels. [21] The first aspect of this collaboration is data sharing. The rapid exchange of information, such as genomic data of the virus and clinical data of patients, can expedite the understanding of the disease and the development of effective treatments.[22] For instance, the sharing of real-world data during the COVID-19 pandemic played a crucial role in the rapid development and approval of vaccines.[23] The collaboration between Israeli authorities and Pfizer/BioNTech is a prime example of how data sharing can accelerate vaccine response. The Israel Ministry of Health, Pfizer Inc., and BioNTech SE announced real-world evidence demonstrating dramatically lower incidence rates of COVID-19 disease in individuals fully vaccinated with the Pfizer-BioNTech COVID-19 Vaccine (BNT162b2). This was possible due to the comprehensive real-world data gathered by the Israel Ministry of Health, which showed that unvaccinated individuals were 44 times more likely to develop symptomatic COVID-19 and 29 times more likely to die from COVID-19. This data was crucial in demonstrating the effectiveness of the vaccine and has been of global importance to other countries as vaccination campaigns continue worldwide. The data collected was also significant as it was gathered when the more transmissible B.1.1.7 variant of SARS-CoV-2 was the dominant strain in the country, providing real-world evidence of the effectiveness of BNT162b2 for prevention of COVID-19 infections, hospitalizations, and deaths due to variant B.1.1.7 25 In the future, establishing a global data sharing platform can facilitate the rapid exchange of information during a pandemic.[24]

The second aspect is joint research efforts. Collaborative research can pool resources and expertise to accelerate the development of treatments. For example, the drive to tackle COVID-19 has led to innovations that could speed up cancer drug discovery.[25]

To summarize, the development of flexible, modular pandemic preparedness plans, technology access pools based on non-exclusive global licensing agreements, and WHO-supported vaccine technology transfer hubs can facilitate the rapid development and manufacturing of vaccines.[26] These strategies, combined with continued collaboration and innovation, can help ensure a more effective and efficient response to future pandemics.

Social justice strategies

Social justice is an important consideration when strengthening pandemic preparedness through health system improvements and drug development. Historically marginalized groups encounter unique challenges that must be addressed [27, 28, 29]. For the homeless, tailored outreach, mobile clinics, and shelter collaborations can facilitate healthcare access [27]. Incarcerated populations need customized infection control and care continuity due to overcrowding [28]. Inclusive clinical trials are necessary to account for differences in drug reactions across racial/ethnic/sexual minorities [29]. Age-appropriate formulations may benefit foster youth given their distinct needs [30]. Developing treatments for prevalent conditions in jails and prisons could aid incarcerated groups [31]. Obtaining informed consent in an understandable, culturally competent manner is critical for homeless and incarcerated participants [32]. Autonomy and guardianship arrangements must be respected for foster children [33]. Building trust and ensuring equitable access are essential for minorities [34].

Overall, focusing on marginalized communities will lead to more ethical, equitable pandemic preparedness through health systems and drug development. Tailored care, inclusive trials, and addressing unique needs can promote social justice.

Disclosure Statement

The authors have no relevant financial disclosures or conflicts of interest.

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About the Authors

Preet Kukreja, MBA, MHA

Preet Kukreja, MBA, MHA is the director of Population Health Initiatives at St. John's Episcopal Hospital and an expert in public health with extensive experience in project and grant-implementation, evaluation and sustainability. She serves as a co-chair of the Program Committee at Healthcare Innovation and Lean Network of New York that brings together Lean and innovation practitioners in healthcare facilities across the state. She also serves as a Judge for the SIIA CODiE Awards, American Best in Business Awards, Globee Leadership Awards and Golden Bridge Awards that honors top companies, products and people as leaders in innovation and excellence. She has also served as an abstract reviewer for the American Public Health Association (APHA) 2023 Annual Meeting & Expo. She is also a certified emergency response team member with New York City Office of Emergency Management which not only prepared her for any emergency situation but also equipped her with the ability to assist the community in times of crisis.

She has been instrumental in implementation of the public health programs and grants to address pandemic-COVID-19, public health emergencies-Mpox and health needs of the communities – Cancer, Obesity, Hypertension, Diabetes, Substance Use and HIV among others. Preet was instrumental in building partnerships with the NYC Department of Health and Mental Hygiene, churches, schools, community-based organizations, and congregations to address the health disparities prevalent in the Far Rockaway community. During the pandemic, she has secured grants through NYC DOHMH which led to expansion of access to care and improved COVID-19 vaccination rate in the community. She is passionate about serving underserved, medically marginalized and vulnerable communities through implementation of programs in addressing health disparities such as medical transportation, improving access to care, providing preventative screenings and point of care testing, health education, nutritional counseling, health-related resources, and improving vaccination rates. She has received acknowledgement and a certificate from NYC DOHMH for playing a prominent role in advancing health equity and preventing COVID-19 in NYC through Public Health Corps.

Her work has been recognized by the NYC Department of Health and Mental Hygiene through the acknowledgement of her role in advancing health equity and preventing COVID-19 in NYC through the Public Health Corps. She has been recognized as one of the Top 25 Emerging Leaders by Modern Healthcare for significant contributions to the culture of innovation and transformation in the field of healthcare. She is also a winner of the Boston Congress of Public Health – Health Innovator to Watch Award 2023 for health and healthcare innovation in the traditional public health field. She is also a winner of Stevie Award 2023 for Achievement in Management – Health Products & Services category. She has also been awarded with the International Achiever's Award for her outstanding achievements and contributions towards nation building. She has been recognized as the Alum of the Month (May) by Hofstra University for making outstanding contributions in the field of public health. Her programs have received notable recognition such as the Food Security Program, which received membership spotlight on the Healthcare Association of NYS (HANYS) platform and the Mobile Health Outreach Program, which was nominated for a Community Health Improvement Award through HANYS.

Preet has received her MBA in India, Masters in Health Administration from Hofstra University and is currently pursuing Master's in Public Health from CUNY School of Public Health. She is a Lean green belt and six sigma white belt certified. She hold certification in DOHMH led training in HIV, HEP-C, STI, PEP, PREP & Other Biomedical Interventions, Best Practices in PEP & PrEP Education & Counseling, HIV Stigma, LGBTQIA+ Primer, HIV Rapid Testing, Linkage to Medical Care, Undetectable=Untransmittable and & Hepatitis
C Patient Navigation. She is a member of the New York Academy of Medicine, Healthcare Association of New York State, American College of Health Executives, Healthcare leader of New York, American Public Health Association, and New York State Public Health Association.

She can be reached via email at preetkukreja@gmail.com. You can also find her on LinkedIn at www.linkedin.com/in/preetkukreja.

Kinshuk Saxena, MBA

Kinshuk Saxena, a distinguished expert in the life sciences and healthcare sector, currently holds a pivotal role as part of the Internal Strategy group at Novartis. Throughout his illustrious career, Kinshuk has demonstrated unparalleled expertise in strategy development and execution across a spectrum of pharmaceutical and medical technology organizations. Prior to his tenure at Novartis, Kinshuk led transformative initiatives, advised executive leadership teams, and drove digital transformations in his roles at Strategy& and IQVIA Consulting.

In his current position at Novartis, Kinshuk steers key strategic initiatives and transformations, working closely with the Executive Leadership Team. His leadership has been instrumental in developing business case briefs, designing and delivering operating models, spearheading oncology operating model transformation, and leading the Intellectual Property and Strategic Transactions (IPST) and Budgeting workstreams.

Before Novartis, as an Engagement Manager at Strategy&, Kinshuk led the development of a "Reimagine Primary Care" strategy as part of a digital transformation effort. His work at IQVIA Consulting involved leading international project teams on a wide range of assignments, including market analytics, due-diligence, portfolio optimization, launch strategy, market access, patient journeys, clinical development transformation, and regulatory strategy.

Kinshuk holds an MBA from Rutgers Business School, where he was a two-time winner of the Biopharmaceutical Case Competition. He also holds a Doctorate of Pharmacy from Manipal University. Earlier in his career, Kinshuk formulated regulatory strategies, managing the submission and approval of Phase 2/3 oncology products while laying the groundwork for breakthrough therapy designation. He was recognized by the CEO for his work in the development and commercialization of an orthopedic medical device.

A dynamic speaker and thought leader, Kinshuk is frequently invited to speak at multiple life science conferences. His contributions extend beyond his professional roles, as he actively engages in podcasting on life-science and healthcare topics. When he's not shaping the future of healthcare, Kinshuk enjoys spending quality time outdoors with his family.

Snigdha Santra, MPH

As the Director and Head of Business Insights and Strategy at Chugai Pharmaceuticals, **Snigdha Santra** leads with a clear purpose: to bring unique, patient centric clinical insights into early drug development and strengthen partnerships in the drug development continuum, ultimately aiming to have a transformational impact on human health.

Over the course of her diverse career spanning more than a decade, Snigdha has held several senior positions across a variety of markets and disciplines, from leading payer analytics at Wunderman Health to multiple commercial leadership roles at Novartis Pharmaceuticals. Her experience working with international teams and managing cross-functional collaborations has enriched her understanding of the global healthcare landscape, further fueling her commitment to ensure equitable access to medicines.

At Chugai Pharmaceuticals, Snigdha has led insights generation for early-stage products in rare diseases. She has fostered a culture of innovation, courage, and excellence within her team, driving them to become more science-driven and research-oriented. This focus on innovation has led to the start of multiple patient centered engagements within the organization.

One of Snigdha's most notable achievements is her work with patient advisory groups in rare diseases and diseases with high unmet need. Her dedication and relentless efforts have led to the development of resources to support patient education – an accomplishment that echoes the company's commitment to improving patient outcomes.

In addition to her role at Chugai, Snigdha also upholds her commitment to social responsibility. As a former Lead Health Columnist for Impakter, an online magazine, she contributed to global health discussions that help shape the discourse in her field.

Snigdha holds a Master's in Public Health with a focus on Health Policy and Management from Columbia University, New York and a Master of Clinical Pharmacy from Manipal University, India. In recognition of her leadership and contributions to the field, she has received several awards including Most Valuable Player at Wunderman Health and the Chugai Awards for Product Lifecycle Innovation from 2019-2022.

In her various roles, Snigdha remains a member of the global healthcare community, dedicated to improving patient outcomes and advocating for equitable access to medicines. Her leadership and commitment to innovation continue to inspire her colleagues and others in her field.